# Appendix A

# Cal/EPA Risk Assessment Procedures by Mandate ("Program Summary Sheets")

| Chemical Risk | Mandate | Sheet Number |
|---|---|---|
| From Air Emissions | Air Toxics "Hot Spots" Program, AB2588,<br>*Health and Safety Code Section 44300 - 44384* | A-1 |
| | Toxic Air Contaminants Program, AB1807,<br>*Health and Safety Code Section 39650-39671* | A-2 |
| | Criteria Air Pollutant Program,<br>*Health and Safety Code Sections 425 and 39606* | A-3 |
| | Toxic Permitting Program<br>*Health and Safety Code Sections 39666, 42300, and 44300; and*<br>*Federal Clean Air Act Section 112(g)* | A-4 |
| From Discharges to Water | California Inland Surface Waters Plan,<br>*California Water Code Sections 13170*, and<br>California Enclosed Bays and Estuaries Plan,<br>*California Water Code Sections 13170 and 13391* | A-5 |
| | California Ocean Plan,<br>*California Water Code Sections 13170 and 13170.2* | A-6 |
| | Bay Protection and Toxic Cleanup Program,<br>*California Water Code Sections 13390 et seq.* | A-7 |
| | California Safe Drinking Water Act of 1989<br>*Health and Safety Code Section 4023* | A-8 |
| | Fish Evaluation<br>*Fish and Game Code 217.6 and 7715*<br>*Health and Safety Code Sections 205 and 207* | A-9 |
| From Waste Sites | Site Mitigation Program, CERCLA/SARA,<br>*Health and Safety Code Sections 25201, 25351, 25355, 25358* | A-10 |
| | Solid Waste Disposal and Codisposal Site Cleanup, AB2136<br>*Public Resources Code, Section 48021* | A-11 |
| | Multiple Programs Covered by the Regional Water Boards Addressing Threats to Water Resources (e.g., underground tanks, DOE and DOD sites; also described in sheet 10)<br>*California Water Code Section 13304 (Cleanup & Abatement)*<br>*Health & Safety Code, Division 20, Chapter 6.7 (UTs)* | A-12 |

| Chemical Risk | Mandate | Sheet Number |
|---|---|---|
| From Hazardous Substances | Hazardous Waste Management Program, RCRA<br>*Health and Safety Code Sections 25101, 25150, 25159, 25200 and 25246* | A-13 |
| | Toxic Substances Spills<br>*Health and Safety Code Sections Div. 20 Chapter 6.5* | A-14 |
| | Rail Accidents, SB48 (Chapter 776, Statutes of 1991)<br>*Health and Safety Code Section 59019* | A-15 |
| From Pesticide Use | Dietary Risk Assessment, AB2161,<br>*Food and Agricultural Code Section 13134* | A-16 |
| | General Authority to Regulate Pesticides,<br>Birth Defect Prevention Act, SB950<br>*Food and Agricultural Code Sections 11501, 12824, 12825, 12890, 13121 through 13133* | A-17 |
| | Pesticide Illness Surveillance Program<br>*Health and Safety Code Section 2950*<br>*Food and Agricultural Code Chapter 2, Article 10.5 Sections 12980 and 12982* | A-18 |
| | Tolerance Assessment, AB2848<br>*Health and Safety Code Section 26205* | A-19 |
| | Risk Assessment for Dietary and Pesticide Related Hazards<br>*Health and Safety Code Section 205* | A-20 |
| From Carcinogens and Reproductive Toxicants | Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)<br>*Health and Safety Code Section 25249.5 (et seq.)* | A-21 |

Acronyms used in the document are listed below:

| Acronym | Full Name |
|---|---|
| **Organization** | |
| ARB | Air Resources Board, Cal/EPA |
| APCD | Air Pollution Control District |
| AQMD | Air Quality Management District |
| Cal/EPA | California Environmental Protection Agency |
| CAPCOA | California Air Pollution Control Officers Association |
| CDFG | California Department of Fish and Game, Resources Agency |
| CDHS | California Department of Health Services, Health and Welfare Agency |
| CIWMB | California Integrated Waste Management Board, Cal/EPA |
| DOD | United States Department of Defense |
| DOE | United States Department of Energy |
| DPR | Department of Pesticide Regulation, Cal/EPA |
| DTSC | Department of Toxic Substances Control, Cal/EPA |
| IARC | International Agency for Research on Cancer, World Health Organization |
| NAS | National Academy of Sciences |
| OEHHA | Office of Environmental Health Hazard Assessment, Cal/EPA |
| OSHA | United States Occupational Safety and Health Administration |
| RWQCB | Regional Water Quality Control Board, Cal/EPA |
| SCWG | Standards and Criteria Work Group, Cal/EPA Intra-agency group |
| SWRCB | State Water Resources Control Board, Cal/EPA |
| USDA | United States Department of Agriculture |
| US EPA | United States Environmental Protection Agency |
| **Technical or Regulatory Terms** | |
| CERCLA | Comprehensive Environmental Response, Compensation and Liability Act |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| HEAST | Health Effects Assessment Summary Table |
| IRIS | Integrated Risk Information System |
| LOAEL | Lowest Observed Adverse Effect Level |
| MCL | Maximum Contaminant Level |
| MCLG | Maximum Contaminant Level Goal |
| NOAEL | No Observed Adverse Effect Level |
| NPDWR | National Primary Drinking Water Regulation |
| PEA | Preliminary Endangerment Assessment |
| PRG | Preliminary Remediation Goal |
| SARA | Superfund Amendments and Reauthorization Act |
| TLV | Threshold Limit Value |
| UTs | Underground Tanks |

**Chemical Hazard:** **Chemical Risk From Air Emissions**
**Mandate:** **Air Toxics "Hot Spots" Program, AB2588,**
***Health and Safety Code Section 44300 - 44384***
**Departments Involved:** **ARB and OEHHA**

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Risk Assessment Type: Site specific. Evaluate health hazards associated with air emissions from stationary point sources. (Guidelines for preparing emission inventories were developed by ARB and guidelines for risk assessment were developed by CAPCOA, ARB, and OEHHA)

Assessment Procedure:

Hazard Identification. Chemicals subject to the Act identified by statute and the list is maintained by ARB.
Dose-response Evaluation. Use nonthreshold, linear extrapolation model for carcinogens in the absence of adequate data indicating an alternative approach is needed. For noncarcinogens either use (1) NOAEL or LOAEL and uncertainty factors, or (2) benchmark dose method. Done by OEHHA.
Exposure Assessment. Based on self-reporting air toxics emission inventories and air dispersion models such as the Industrial Source Complex model. Review by local AQMD. Chemical doses through inhalation and other indirect exposure routes are calculated using exposure equations and input parameters. Review by OEHHA.
Risk Characterization. Both individual excess cancer risk at appropriate locations and the maximum individual offsite cancer risk are calculated. Population excess cancer burden and zone of impact are also used in characterizing health risk. Hazard index approach is used to estimate the potential for acute and chronic noncancer health effects. Quantitative expressions of uncertainty are optional. Review by OEHHA.

Risk Objective: To identify facilities posing a significant risk to the public from air emissions. Significant risk is determined at the local level by air districts but is usually a cancer risk of $10^{-5}$ or greater and a hazard index greater than 1.

Risk Management: Local air pollution control districts may require public notification and risk reduction audits and plans from significant risk facilities.

Example(s) of Standard Procedures: Risk assessments for >700 facilities

Exception(s): A few submitted assessments also presented stochastic models as an appendix

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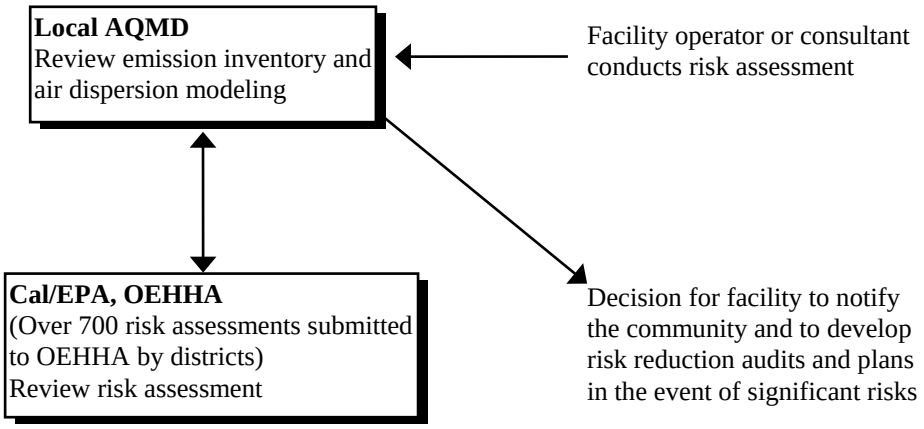
Cooperation among Cal/EPA and other regulatory and scientific bodies:



**Appendix A** **Report of the Risk Assessment Advisory Committee**

**Mandate:** **Toxic Air Contaminants Program, AB1807**
***Health and Safety Code Section 39650 - 39671***

**Departments Involved:** **ARB, DPR, and OEHHA**

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Risk Assessment Type: Chemical specific. Evaluate health hazards associated with airborne chemicals.

Assessment Procedure:

Hazard Identification. Based on IARC and other established lists. For pesticides, FIFRA required health effects studies and open literature search. Done by ARB, OEHHA and DPR.

Dose-response Evaluation. Use nonthreshold, linear extrapolation model for carcinogens in the absence of adequate data indicating an alternative approach is needed. For noncarcinogens either use (1) NOAEL or LOAEL and uncertainty factors, or (2) benchmark dose method. Done by OEHHA and DPR.

Exposure Assessment. Use ARB monitoring results to estimate ambient air concentration in California. Use existing emission inventory for stationary sources and mobile sources. Use indoor air data from ARB-sponsored research. Use fate data to determine persistence. Done by ARB and DPR. When data permit, distributional analysis of exposure is also used. Done by ARB and DPR.

Risk Characterization. Chemical dose through inhalation is calculated assuming standard body weight and inhalation rate. Based on a number of selected bioassay results, a range of risk estimates associated with exposure to ambient concentration may be provided. Uncertainty is addressed qualitatively and quantitatively. Done by OEHHA and DPR.

Risk Objective: To identify toxic air contaminants which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health.

Risk Management: ARB decides whether or not to list a chemical as a toxic air contaminant. DPR decides for pesticides. Once a chemical is listed, ARB, DPR and local air quality management districts explore ways to control and reduce emission of the chemical.

Example(s) of Standard Procedures: Inorganic arsenic (ARB, 1990), benzo(a)pyrene (ARB, 1994), formaldehyde (ARB, 1991), ethylene dibromide (ARB, 1985), ethyl parathion (DPR, 1992), and nickel (ARB, 1991).

Exception(s): Air dispersion modeling for ethylene oxide (ARB, 1987), adduct information used in extrapolating from high to low dose for 1,3-butadiene (ARB, 1992), cell-proliferation model for formaldehyde (ARB, 1992) and physiologically based pharmacokinetic model was used for chloroform, methylene chloride, perchloroethylene, and vinyl chloride (ARB, 1990, 1989, 1991, and 1990).

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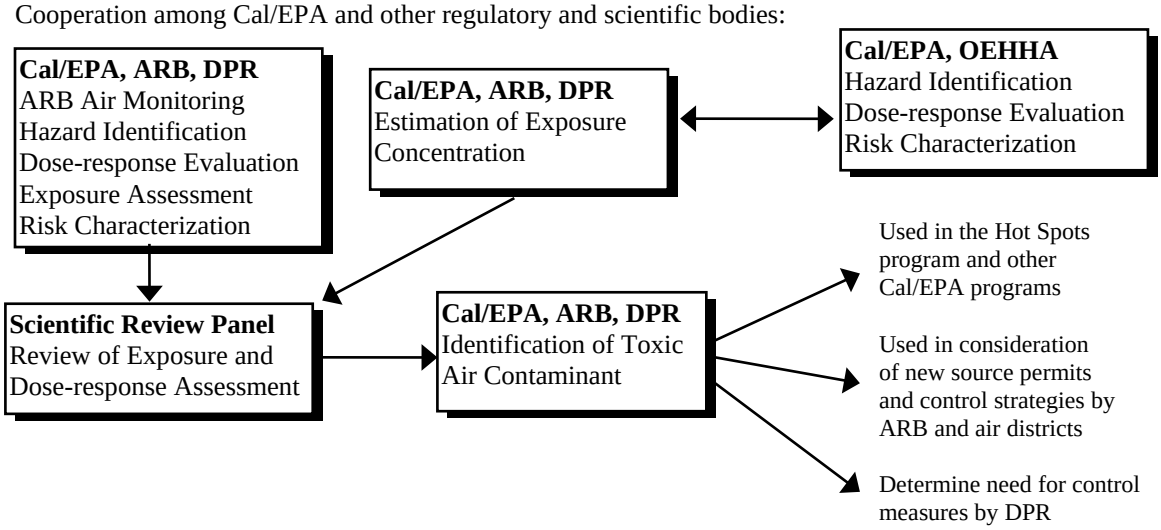
Cooperation among Cal/EPA and other regulatory and scientific bodies:




**Chemical Hazard:** **Chemical Risk From Air Emissions**

**Mandate:** **Criteria Air Pollutant Program,**
***Health and Safety Code Section 425 and 39606***

**Departments Involved:** **ARB and OEHHA**

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Risk Assessment Type: Chemical specific. Identify health hazards and evaluate dose response relationship associated with airborne criteria contaminants (e.g., $SO_x$ and $NO_x$).

Assessment Procedure:

Hazard Identification. Based on review of the literature, primarily epidemiology and controlled human exposure studies. Done by ARB and OEHHA.

Dose-response Evaluation. Only noncarcinogens are treated through this program. Usually dose-response is evaluated in controlled exposure studies, with the objective of identifying a NOAEL or LOAEL.

Exposure Assessment. Done by ARB and local AQMDs, based on monitoring data.

Risk Characterization. Specification of ambient level at which no health effects are expected to occur.

Risk Objective: Adoption of state ambient air quality standards by the ARB.

Risk Management: Done by ARB and local districts through control strategies.

Example(s) of Standard Procedures: Nitrogen dioxide and sulfur dioxide (OEHHA, 1992 and 1994; ARB, 1992 and 1994)

Exception(s): None

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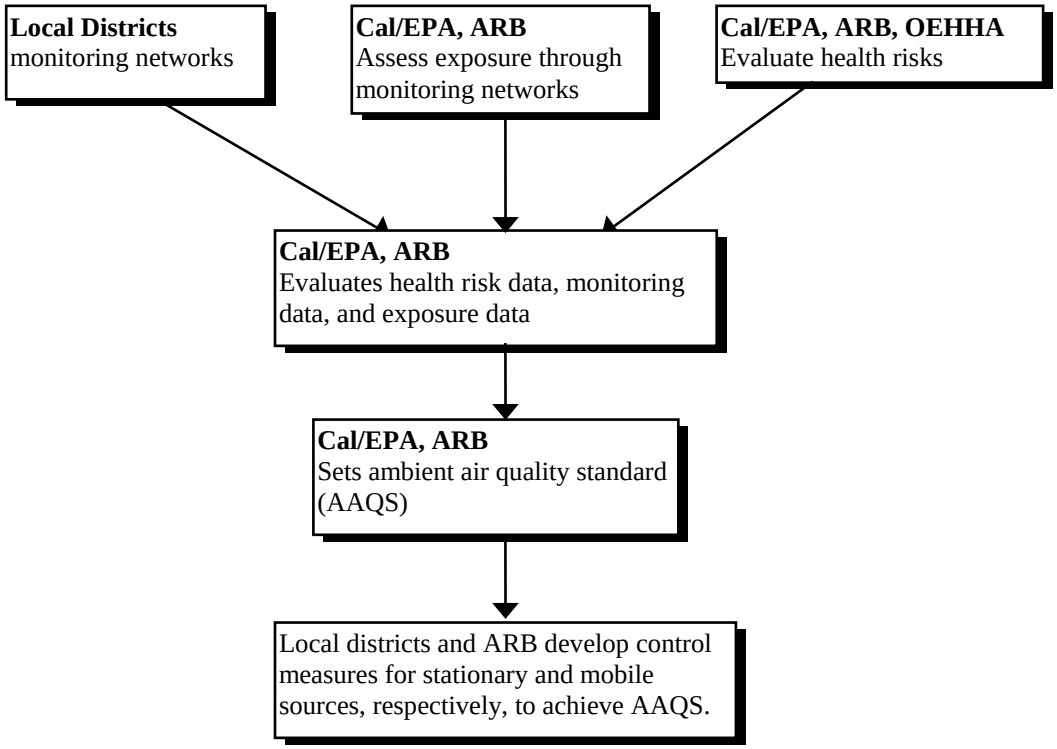
Cooperation among Cal/EPA and other regulatory and scientific bodies:



**Chemical Hazard:** **Chemical Risk From Air Emissions**
**Mandate:** **Toxic Permitting Program**
***Health and Safety Code Sections 39666, 42300, and 44300; and Federal Clean Air Act Section 112(g)***
**Departments Involved:** **Local APCD or AQMD (primary); ARB (consultant-basis); OEHHA and US EPA [Section 112(g)]**

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Risk Assessment Type: Site-specific. It is applicable to new and modified sources that manufacture, formulate, use, or release toxic air contaminants.

Assessment Procedure:

District's rules or policies require permits for new and modified sources emitting toxic air contaminants. These rules or policies require significant new and modified sources to install the best available control technology (T-BACT) and to evaluate the risk remaining after installing T-BACT. Currently, 17 of the 34 districts have toxic New Source Review rules or policies. Districts issue permits only if the source can meet the specified risk limits. The source may evaluate risk per the CAPCOA Risk Assessment Guidelines or guidance generated by the district. The CAPCOA Risk Assessment Guidelines were prepared in consultation with the ARB and the OEHHA. OEHHA is revising these guidelines to provide more information in the risk assessments about the uncertainty of the analysis and the variability of the data.

Risk Objective: To protect public health by managing potential cancer and noncancer health risks from new or modified sources of toxic air contaminants.

Risk Management: See Table 1.

**Table 1: ARB Risk Management Guidelines: Suggested Risk Levels in Permitting Process**

| Adverse Health Impact Measure | | Guidance for Permit Decision | |
|---|---|---|---|
| **Cancer Risk** | **Noncancer Risk -- Total Hazard Index** | **Action** | **Requirements** |
| < 1 per million | 0.2 to 1 | Approve | None |
| 1 to 10 per million | 0.2 to 1 | Approve | T-BACT[a] required |
| 10 to 100 per million | 5 to 10 | Case-by-case approval | T-BACT, other controls, special findings |
| > 100 per million | > 10 | Denial | |

[a] T-BACT: Best Available Control Technology for Toxics

Example(s) of Standard Procedures: South Coast Air Quality Management District Rule 1401, Monterey Bay Unified Air Pollution Control District Rule 1003, and the ARB Risk Management Guidelines

Exception(s): None

**Chemical Hazard:** **Chemical Risk From Discharges to Water**
**Mandate:** **California Inland Surface Waters Plan,**
***California Water Code Sections 13170***
**California Enclosed Bays and Estuaries Plan,**
***California Water Code Sections 13170 and 13391***
**Departments Involved:** **SWRCB and OEHHA**

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Risk Assessment Type: Chemical specific: Develop health-based water quality objectives that are used by Regional Boards in issuing discharge permits. [Note: Both the Inland Surface Waters Plan and the Bays and Estuaries Plan are under development. The current schedule calls for the plans to be adopted in 1997.]

Assessment Procedure:

Hazard Identification. Use monitoring data to identify specific agents of potential concern. Rely on US EPA and OEHHA to characterize the human health hazards of specific water contaminants.

Dose-response Evaluation. Generally use cancer potency factor or reference dose. SCWG (primary source), US EPA (secondary source). Values are reviewed to determine if they need to be updated based on new information. Done by OEHHA.

Exposure Assessment. Currently, the SWRCB staff are involved in a task force process created to provide recommendations on key issues in the development of both plans, including appropriate fish consumption rate and dilution factors. Tissue levels in aquatic organisms can be used as a surrogate for concentration of chemical in receiving waters. Direct monitoring data may also be collected. Dilution and other factors may be used to estimate receiving water concentration resulting from a particular concentration in the effluent.

Risk Characterization. 1) Water quality objectives take into account the results from hazard identification, dose-response evaluation and exposure assessment. 2) In considering whether to permit a facility, the established water quality objective will be compared to the expected concentration of a contaminant in the receiving water. Mitigating factors such as dilution factor and discharge condition are considered in evaluating the expected concentration in receiving water.

Risk Objective: To identify concentrations of US EPA priority pollutants that are potentially harmful to human health, as well as to freshwater and estuarine aquatic life.

Risk Management: When SWRCB adopts water quality objectives for the two plans, the Regional Boards will implement water quality objectives by developing waste discharge requirements for all discharges into surface waters, bays and estuaries. The Regional Boards take enforcement actions against discharges that exceed water quality objectives placed in the waste discharge permits.

Reference(s)/Example(s): Quality Criteria for Water “Gold Book” (US EPA, 1986)

Exception(s): Site specific exceptions allowed in discharge permits if it can be demonstrated that beneficial uses are not impaired.

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**Chemical Hazard:** **Chemical Risk From Discharges to Water**
**Mandate:** **California Ocean Plan,**
***California Water Code Sections 13170 and 13170.2***
**Departments Involved:** **SWRCB and OEHHA**

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Risk Assessment Type: Chemical specific. Develop health-based water quality objectives that are used by Regional Boards in issuing discharge permits.

Assessment Procedure:

Hazard Identification. Field monitoring is conducted (sediment, water column, biota) at stations located in vicinity of ocean discharge to identify potential hazards. Rely on US EPA and OEHHA to characterize the human health hazards of specific water contaminants.

Dose-response Evaluation. Generally use cancer potency factor or reference dose. SCWG (primary source), US EPA (secondary source). Values are reviewed to determine if they need to be updated based on new information. Done by OEHHA.

Exposure Assessment. 1) Tissue levels in aquatic organisms can be used as a surrogate for concentration of chemical in receiving waters. Direct monitoring data may also be collected. Dilution and other factors may be used to estimate receiving water concentration resulting from a particular concentration in the effluent. 2) When consumption of contaminated organism is a concern, fish and shellfish consumption rate is assumed to be 23 g/day as recommended by CDHS/OEHHA.

Risk Characterization. 1) Water quality objectives take into account the results from hazard identification, dose-response evaluation and exposure assessment. 2) In considering whether to permit a facility, the established water quality objective will be compared to the expected concentration of a contaminant in the receiving water. Mitigating factors such as dilution factor and discharge condition are considered in evaluating the expected concentration in receiving water.

Risk Objective: To identify concentrations of toxic substances, including US EPA priority pollutants, that are potentially harmful to human health as well as to marine aquatic life.

Risk Management: RWQCBs and publicly owned treatment works staff work together to control discharge of contaminants. RWQCBs also work with local government agencies to implement and enforce SWRCB's Nonpoint Source and Stormwater management plans.

Example(s) of Standard Procedures: Chlorobenzene (SWRCB, 1990), benzene (SWRCB, 1990), PCBs (SWRCB, 1990).

Exception(s): Site specific exception allowed in discharge permits if it can be demonstrated that (1) protection of Ocean Waters for beneficial uses is not compromised and (2) the public interest is served.

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**Chemical Hazard:** **Chemical Risk From Discharges to Water**
**Mandate:** **Bay Protection and Toxic Cleanup Program**
***California Water Code Sections 13390 et seq.***
**Departments Involved:** **SWRCB, OEHHA and CDFG**

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Risk Assessment Type: Chemical specific. Develop health-based sediment quality objectives.

Assessment Procedure:

Hazard Identification. Pore water and sediment toxicity bioassays are conducted by CDFG, using standard protocols to identify toxic hot spots in enclosed bays and estuaries. Rely on OEHHA and US EPA in identifying human health hazards for specific agents.

Dose-response Evaluation. Generally use cancer potency factor or reference dose. SCWG (primary source), US EPA (secondary source). Values are reviewed to determine if they need to be updated based on new information. Done by OEHHA.

Exposure Assessment. Human exposure to contaminated sediments is determined indirectly through fish and other seafood consumption. Fish and other sea food are analyzed for toxic chemicals.

Risk Characterization. 1) Adverse human health impacts from consuming contaminated wildlife are evaluated using standard procedures. Sediments which exhibit toxicity in aquatic bioassays are analyzed for chemical constituents. 2) A benthic community analysis at the site is also conducted in some cases to assess potential toxicity to aquatic life.

Risk Objective: To prevent toxic hot spot buildup, as well as identify existing hot spots and develop appropriate cleanup plans.

Risk Management: Toxic hot spots will be referred to the Regional Boards for cleanup activity. Fish consumption advisories are issued by OEHHA.

Example(s) of Standard Procedures: Programs in development.

Exception(s): Research on the development of health-based sediment quality objectives is on hold due to funding shortfall.

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**Chemical Hazard:** **Chemical Risk From Discharges to Water**
**Mandate:** **California Safe Drinking Water Act of 1989**
***Health and Safety Code 4023***
**Departments Involved:** **OEHHA, CDHS, RWQCBs, and SWRCB**

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Risk Assessment Type: Chemical specific. Develop safe levels or Recommended Public Health Goals (RPHGs) used in setting primary drinking water standards (MCLs).

Assessment Procedure:

Hazard Identification. Based on designation of authoritative bodies in priority: SCWG, OEHHA Proposition 65, US EPA, IARC, or develops own approach. Done by OEHHA.

Dose-response Evaluation. Generally use cancer potency factor or reference dose. SCWG (primary source), US EPA (secondary source). Values are reviewed to determine if they need to be updated based on new information. Done by OEHHA.

Exposure Assessment. All relevant exposure routes and sources are considered, e.g., inhalation of volatile chemicals during showering. Standard exposure equations and input parameters are used in estimating potential health effects. Typical use of 2 l/day of water consumption, but can be higher for volatiles. Default relative source contribution is 20% for drinking water.

Risk Characterization. Several chemicals mandated for control under Federal Safe Drinking Water Act or earlier state law.

Risk Objective: No significant risk. Recommended Public Health Goals for carcinogens usually $10^{-6}$ lifetime risk. For noncarcinogens, a safety margin of 100 if the data are based on long-term studies or 1000 if the data are based on short-term studies.

Risk Management: Engineers in CDHS Division of Drinking Water and Environmental Management evaluate economic and technical feasibility of RPHGs. CDHS responsible for monitoring and enforcement. RWQCBs and SWRCB use the MCLs as water quality objectives for the municipal and domestic uses of water bodies (surface and ground water).

Example(s) of Standard Procedures:

Exception(s): DBCP state standard was repealed. Emergency adoption of Federal standard.

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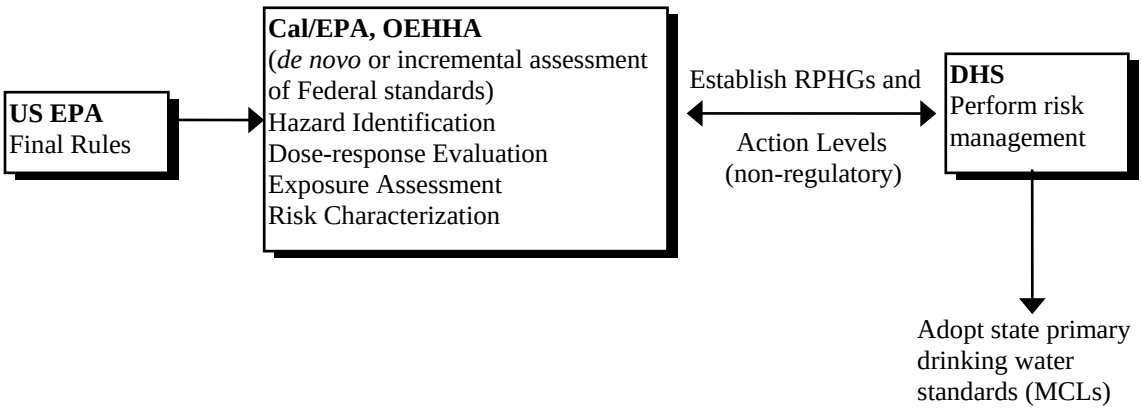
Cooperation among Cal/EPA and other regulatory and scientific bodies:



**Chemical Hazard:** **Chemical Risk From Discharges to Water**
**Mandate:** **Fish Evaluation**
***Fish and Game Code Sections 217.6 and 7715***
***Health and Safety Code Sections 205 and 207***
**Departments Involved:** **OEHHA and SWRCB**

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Risk Assessment Type: Chemical or site specific. Evaluate potential health hazard associated with local sport fish consumption. Make recommendations regarding restriction of commercial fishing based on evaluation of potential human health hazard.

Assessment Procedure:

Hazard Identification. Based on designation of authoritative bodies in priority: SCWG, OEHHA Proposition 65, US EPA, IARC, or develops own approach. Done by OEHHA.

Dose-response Evaluation. Generally use cancer potency factor or reference dose. SCWG (primary source), US EPA (secondary source). Values are reviewed to determine if they need to be updated based on new information. Done by OEHHA.

Exposure Assessment. Chemical concentrations in fish are measured (fish sampling and analyses are usually by other departments) and used in exposure assessment. An average seafood consumption rate of 23 grams per day is generally used as a default (this value is currently under review and may change). Done by OEHHA. SWRCB may request OEHHA to develop fish advisories based on data from its monitoring programs.

Risk Characterization. Excess lifetime cancer risk to sport fishers from consumption of sport fish from California waterbodies is evaluated. Noncarcinogens are evaluated by comparing the estimated daily dose with the reference dose. Based on the concentrations of chemicals found in fish, corresponding safe fish consumption rates for fish are recommended. Done by OEHHA.

Risk Objective: To provide health advisories to warn against unlimited consumption of contaminated sport fish.

Risk Management: Issue health advisories on sport fish which are provided as news releases to the media, public and local environmental health programs, and published in the CDFG's California Sportfish Regulation booklet. Make recommendations to CDFG for commercial fishing area closure.

Example(s) of Standard Procedures: A Study of Chemical Contamination of Marine Fish From Southern California. II. Comprehensive Study.

Exception(s):

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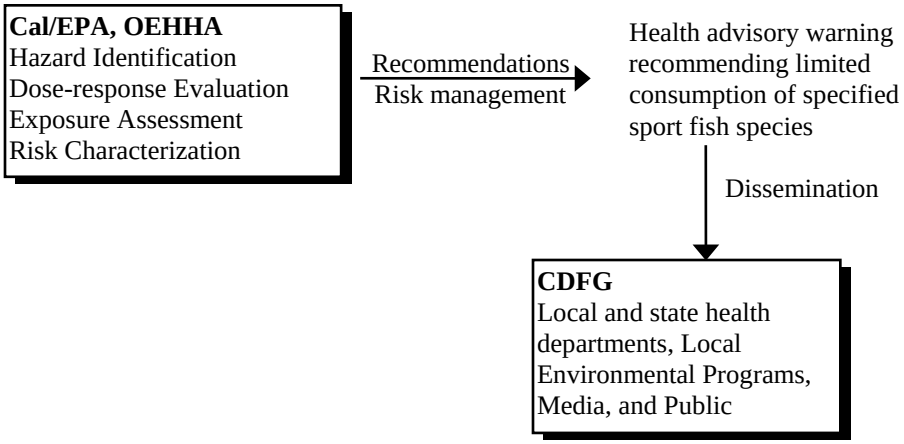
Cooperation among Cal/EPA and other regulatory and scientific bodies:



**Chemical Hazard:** **Chemical Risk From Waste Sites**
**Mandate:** **Site Mitigation Program, CERCLA/SARA**
**Departments Involved:** **DTSC, ARB, OEHHA and RWQCBs**

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Risk Assessment Type: Site specific. See Table 2 for a description of the various risk assessment activities under CERCLA/SARA and specific Health and Safety Code references.

Assessment Procedure:

Hazard Identification. Toxicity based on designation by Cal/EPA (OEHHA, DPR), US EPA, use of chemical surrogates, or review of the scientific literature (in descending hierarchical order).

Dose-response evaluation. Rely on Cal/EPA, US EPA IRIS, US EPA HEAST, or approach as described in Risk Assessment Guidance for Superfund (in descending hierarchical order).

Exposure assessment. Concentrations in exposure media are based on levels measured in environmental media and/or resulting from fate and transport modeling. Multi-medium and multi-pathway exposures are considered. Exposure equations and input parameters are the same as those in US EPA guidelines. EPA input parameters are a combination of upper-bound and midrange assumptions to get a "reasonable maximum exposure".

Risk Characterization. Total excess lifetime cancer risk is estimated by summing risk from different chemicals, environmental media, and exposure pathways. Hazard index approach is used to estimate noncancer health effects. Uncertainty is usually addressed qualitatively. Risk characterized by two concentration levels - the arithmetic mean and the 95% upper confidence level of the arithmetic mean. More recent risk assessments address uncertainty quantitatively using Monte Carlo procedures.

Risk Objective: Identify sites that require further action (PEA); quantify human health and ecological risk posed by a non-mitigated site (baseline risk); estimate risk reduction resulting from remedial alternatives; estimate risk resulting from remedial activities.

Risk Management: Use the nine evaluation criteria as listed in the National Contingency Plan to choose remedy for the site. Criteria include (in general order of importance): overall protection of human health and the environment, compliance with applicable requirements, long-term and short-term effectiveness, reduction in toxicity, mobility and volume, implementability, cost, and acceptability. Thresholds are lifetime individual cancer risk levels of $10^{-6}$ to $10^{-4}$ and hazard index below unity.

Example(s) of Standard Procedures: See Table 2.

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Cooperation among Cal/EPA and other regulatory and scientific bodies: ARB - review air dispersion models at the request of the DTSC; OEHHA - obtain toxicity criteria information; RWQCB - review fate and transport modeling if there is potential for ground water impact.

**Table 2: Risk Assessment Activities at Different CERCLA/SARA Hazardous Substance Release Sites**

| Type of site | Types of site specific risk assessments[a] | Assessor | Examples of standard procedures |
|---|---|---|---|
| Orphan (abandoned site without responsible party)<br>H&SC 25355; 25355.5<br>*No. of sites: ~3* | Usually a screening assessment, with calculated clean-up goals for designated land use. | DTSC performs | Alark Hard Chrome, Riverside (presence of hexavalent chromium in groundwater) |
| State superfund sites<br>H&SC 25351.5; 25358.3<br>*No. of sites: ~400 to 800* | Screening; baseline, assuming no clean-up and residential use; risk reduction resulting from remediation; risks associated with clean-up activities | Responsible party performs and DTSC reviews or DTSC contractor performs with DTSC oversight | Neville Chemical Company, Santa Fe Springs; Chatham Brothers Barrel Yard, Escondido (quantitative uncertainty analysis) |
| US EPA superfund sites<br>H&SC 25351.5; 25358.3<br>*No. of sites: ~90* | Baseline, assuming no clean-up and residential use; risk reduction resulting from remediation; risks associated with clean-up activities | Responsible party or US EPA contractor performs and US EPA and DTSC review | Lawrence Livermore National Laboratory (baseline assessment); former Firestone Facility, Salinas (risk-based clean-up of groundwater); Thompson-Hayward Agriculture and Nutrition, Fresno (risk assessment after clean-up) |
| Closing military bases<br>*No. of sites: ~26* | Screening; baseline, assuming no clean-up and residential use; risk reduction resulting from remediation; risks associated with clean-up activities | US Department of Defense performs and US EPA and DTSC review | Fort Ord (risk calculated from specific land-use); Hunter's Point (background level determination); Sacramento Army Depot (multiple sources - regional risk); Presidio of San Francisco (multiple land uses including parks, freeways) |
| Open military bases<br>*No. of sites: ~27* | Screening; baseline, assuming no clean-up and generic use associated with continued operation; risk reduction resulting from remediation; risks associated with clean-up activities | US Department of Defense performs and DTSC reviews | Vandenberg Air Force Base (multiple sources of contamination; 18 preliminary assessments, large area); Point Mugo Naval Air Weapons Station (pesticides, environmental effects) |
| Miscellaneous sites in other regulatory jurisdictions<br>*No. of sites: ~15* | Screening; baseline, assuming no clean-up of contamination and, usually, residential use; calculation of health-based clean-up goals | Responsible party performs and DTSC reviews at the request of the regulatory agency | Rockwell International - Rocketdyne Division Facility, Canoga Park (proposed re-development of land); Governor's LA Redevelopment Agency (Westside Children's Center)(screening risk assessment) |
| Request from responsible parties (voluntary clean-up; fee for service)<br>H&SC 25201.9<br>*No. of sites: ~5* | Baseline, assuming no clean-up of contamination and, usually, residential use; calculation of health-based clean-up goals | Responsible party performs and DTSC reviews as per terms of agreement | Alhambra Town Gas Site (assessment of cleanup goals); San Pedro Town Gas Site (base-line risk assessment) |

[a] Risk assessments must conform to US EPA (1989) *Risk Assessment Guidance for Superfund*

**Chemical Hazard:** **Chemical Risk From Waste Sites**
**Mandate:** **Solid Waste Disposal & Codisposal Site Cleanup, AB2136**
***Public Resources Code, Section 48021***
**Departments Involved:** **CIWMB**

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Risk Assessment Type: Site specific. Evaluate present and future public health and safety or environmental risk associated with solid waste disposal.

Assessment Procedure:

1. Closed, illegal and/or abandoned site identified
2. Hazard(s) associated with the site identified
3. Sites are evaluated through the Site Investigation Process (SIP)(CIWMB, 1993). SIP is the first of a mathematical risk-model ranking system.
4. Site may be further evaluated through the Solid Waste Ranking System (SWRS)(CIWMB, 1995) for prioritization of site clean-up funding. SWRS determines the magnitude of threat a site poses to the local environment and population receptors.
5. Funding made available and sites cleaned up.

Risk Objective: Ensure that public health and safety and the environment are adequately protected. Clean-up values are not used as the majority of site clean-ups result in the removal of all waste.

Risk Management: Economic and technical feasibility is evaluated for all site clean-up. Public hearings are provided for public comment.

Example(s) of Standard Procedures: Essie Haywood Illegal Site, Tulare County; Igo/Ono Site, Shasta County.

Exception(s): Not applicable

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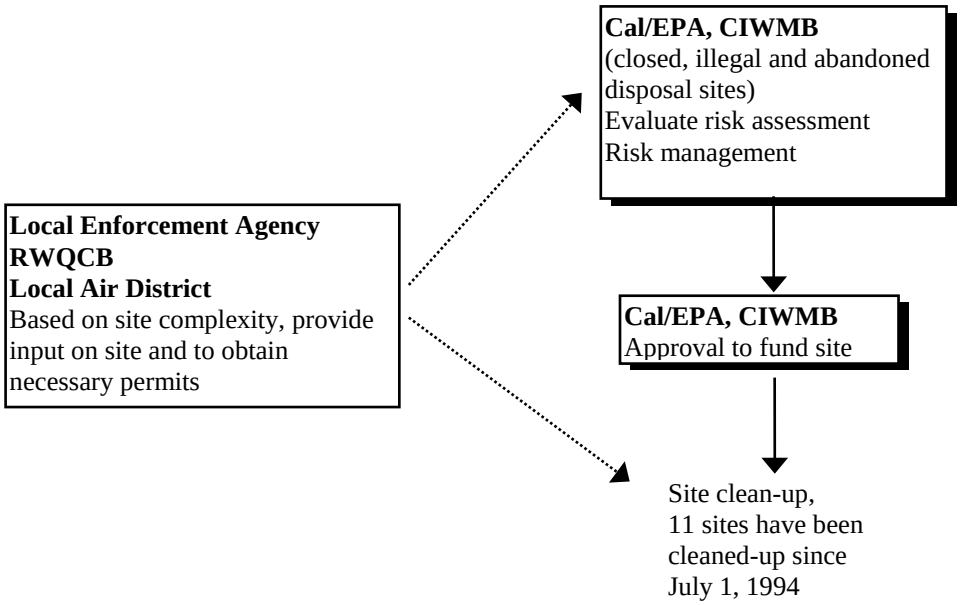
Cooperation among Cal/EPA and other regulatory and scientific bodies:



**Chemical Hazard:** **Chemical Risk From Waste Sites**
**Mandate:** **Multiple Programs by the Regional Water Boards Addressing Threats to Water Resources (Also described on Sheet 10)**
***California Water Code Sections 13304 (Cleanup & Abatement)***
***Health and Safety Code, Division 20, Chapter 6.7 (UTs)***
**Departments Involved:** **SWRCB & RWQCBs (plus local oversight agencies for UTs), supported by OEHHA, DTSC, and local health agencies**

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Risk Assessment Type: Site specific. Evaluate human health and environmental hazards (including threats and impacts to water resources) associated with surface water or groundwater pollution or with discharges of waste which threaten to cause pollution or nuisance.
**Note**: Due to the committee's focus, only human health-related assessment information is discussed below.

Assessment Procedure:
Hazard Identification. SWRCB and RWQCBs rely on applicable water quality standards (beneficial use designations + water quality objectives), supported by health-protective criteria developed primarily by CDHS, US EPA, OEHHA, and NAS to determine impacts to municipal and domestic supply and other beneficial uses of water resources that may involve human exposure. Multimedia human health risk assessments are deferred to OEHHA, DTSC, or local health agency.
Dose-response Evaluation. SWRCB and RWQCBs rely on applicable water quality standards (beneficial use designations + water quality objectives), supported by health-protective criteria developed primarily by CDHS (MCLs, action levels), US EPA (MCLs, MCLGs, IRIS, health advisories, National Ambient Water Quality Criteria), OEHHA (Cancer Potency Factors, Proposition 65 No-Significant Risk Levels), and National Academy of Sciences (Suggested No Adverse Response Levels, cancer risk estimates) to determine impacts to municipal and domestic supply and other beneficial uses of water resources that may involve human exposure (e.g., via crop uptake). Multimedia human health risk assessments are deferred to OEHHA, DTSC, or local health agency.
Exposure Assessment. Based on monitoring data on water quality, soil contaminants and waste constituents, often supported by transport modeling. Multimedia human health risk assessments are deferred to OEHHA, DTSC, or local health agency.
Risk Characterization. Estimate risk of degradation of the quality of water resources. Estimate risk of pollution, i.e., non-compliance with water quality standards that are applicable to the impacted or threatened water resources. Generally qualitative treatment of uncertainty analysis. In the absence of scientifically valid data to the contrary, theoretical risks from chemicals are considered additive across all media of exposure, and additive for all chemicals having similar toxicological effects or having carcinogenic effects. Multimedia human health risk assessments are deferred to OEHHA, DTSC, or local health agency.

Risk Objective: Eliminate water pollution (noncompliance with water quality objectives) or nuisance and the threat of pollution or nuisance. Minimize the degree of water quality degradation, consistent with the maximum benefit to the people of California. No excessive exposure to sensitive biological receptors. No detrimental physiological responses in humans.

Risk Management: Corrective action measures to meet risk objectives are negotiated between waste discharger (responsible party) and Regional Water Board staff. Enforcement orders are adopted by the Regional Water Board in a public hearing or are issued by the Executive Officer. Staff decisions may be appealed to the Regional Water Board, whose decisions may be appealed to the State Water Board for review. Decisions of the Water Boards are to ensure reasonable protection of existing and future beneficial uses of water and must consider economic factors and technologic constraints.

Example(s) of Standard Procedures: Aerojet (Sacramento), Occidental Chemical (Lathrop), and Sacramento Army Depot.

Exception(s): Some cases have DTSC or local agency lead oversight with RWQCB/SWRCB support on water quality issues. CERCLA cases may also involve US EPA.

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Cooperation among Cal/EPA and other regulatory and scientific bodies: Risks to water resources are the primary authority of the SWRCB/RWQCBs. Multimedia human health risk assessments are deferred to OEHHA, DTSC, or local health agency. Site assessment information is shared between Cal/EPA agencies involved in a particular case. The more limiting of these risk objectives normally determines the risk management decisions and the extent of corrective action at each site.

**Chemical Hazard:** **Chemical Risks From Hazardous Substances**
**Mandate:** **Hazardous Waste Management Program (RCRA)**
**Departments Involved:** **DTSC**

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### 1. Permitting facilities that treat, store and/or dispose of hazardous wastes to operate (~20 facilities). Health and Safety Code Section 25150 and 25159.5

Risk Assessment Type: Site specific. Evaluate health hazards associated with treatment, storage, and disposal of hazardous wastes. Risk assessments are not required by RCRA but are used to support California Environmental Quality Act (CEQA) provisions requiring protection of human health and the environment. Submitted risk assessments must conform to US EPA Risk Assessment Guidance for Superfund (EPA RAGS).

Assessment Procedure:

Hazard Identification. Chemicals of concern are identified from review of waste manifests received by the facility, by assuming the presence of specific chemicals based on the process, and/or by assuming the chemicals of concern will be identical to similar facilities (surrogate facilities). Potential toxic effects based on designation by Cal/EPA (OEHHA, DPR), US EPA, or review of the scientific literature (in descending hierarchical order).
Dose-response evaluation. Rely on Cal/EPA, US EPA IRIS, US EPA HEAST, or approach as described in Risk Assessment Guidance for Superfund (in descending hierarchical order).
Exposure assessment. Maximum waste volumes are assumed from throughput capacity of the facility. Although multi-medium and multi-pathway exposures are considered, inhalation is usually the only relevant exposure route. Sources must be identified, emissions rates calculated for each source, dispersion modeling performed, and the potentially exposed population area identified. Exposure equations and input parameters are the same as those in US EPA guidelines. Input parameters are a combination of upper-bound and midrange assumptions to estimate a "reasonable maximum exposure".
Risk Characterization. Total excess lifetime cancer risk is estimated by summing risk from different chemicals, environmental media, and exposure pathways. Hazard index approach is used to estimate noncancer health effects. Uncertainty is addressed qualitatively. Risk characterized by two concentration levels - the arithmetic mean and the 95% upper confidence level of the arithmetic mean. Consequences of worst case accident scenarios are evaluated for adequacy of prevention measures and emergency response capabilities.

Risk Objective: Provide a human health and ecological assessment of routine facility emissions to ensure that the facility will operate in a manner fully protective of public health and the environment. Acceptable risk ranges from $10^{-6}$ to $10^{-4}$.

Risk Management: Risk assessment is one of the criteria for approving permit applications and may be used as a basis for setting permit conditions. Other regulatory standards have been used instead of risk assessment.

Example(s) of Standard Procedures: Safety Kleen, Salida

Exception(s): None

### 2. Corrective action at facilities that treat, store and dispose of hazardous wastes (~5 facilities). Health and Safety Code Section 25200.10

Risk Assessment Type: Site specific. Evaluate health hazards associated with treatment, storage, and/or disposal of hazardous wastes. Risk assessments are not required by RCRA, but submitted risk assessments must conform to US EPA Risk Assessment Guidance for Superfund (US EPA, 1989). Risk assessment performed by responsible party or by the DTSC.

Assessment Procedure:

Hazard Identification. Toxicity based on designation by Cal/EPA (OEHHA, DPR), US EPA, or review of the scientific literature (in descending hierarchical order).

Dose-response evaluation. Rely on Cal/EPA, US EPA IRIS, US EPA HEAST, or approach as described in Risk Assessment Guidance for Superfund (in descending hierarchical order).
Exposure assessment. Chemicals of concern are identified based on site characterization studies of the facility. Concentrations in exposure media are based on levels measured in environmental media and/or resulting from fate and transport modeling. Multi-medium and multi-pathway exposures are considered. Exposure equations and input parameters are the same as those in US EPA guidelines. Input parameters are a combination of upper-bound and midrange assumptions to get a "reasonable maximum exposure".
Risk Characterization. Total excess lifetime cancer risk is estimated by summing risk from different chemicals and media. Hazard index approach is used to estimate noncancer health effects.

Risk Objective: Set facility-specific risk-based clean-up goals for chemicals released to the environment as a result of facility operations. Use goals to analyze effectiveness of any corrective or cleanup measures.

Risk Management: Clean-up standards are used to select the remedy.

Example(s) of Standard Procedures: Certainteed Corporation, Chowchilla CA (CalTOX model may be used in the near future by the DTSC as a screening level risk assessment tool).

Exception(s): None

Cooperation among Cal/EPA and other regulatory and scientific bodies: OEHHA has responsibility for reviewing risk assessments for incinerators and some large landfills with DTSC/OSA overseeing the review and interacting with risk managers.

### 3. Closure of facilities that treat, store and/or dispose of hazardous wastes (~10 facilities) Health and Safety Code Section 25246

Risk Assessment Type: Site specific. Evaluate health hazards associated with any remaining contamination at a closing facility that treated, stored, and/or disposed of hazardous wastes. Risk assessment methods must conform to US EPA Risk Assessment Guidance for Superfund (EPA RAGS) and are used to calculate health-based closure levels. Risk assessments performed by responsible party and reviewed by the DTSC.

Assessment Procedure:
Hazard Identification. Toxicity based on designation by Cal/EPA (OEHHA, DPR), US EPA, or review of the scientific literature.
Dose-response evaluation. Rely on Cal/EPA, US EPA IRIS, US EPA HEAST, or approach as described in Risk Assessment Guidance for Superfund.
Exposure assessment. Chemicals of concern are identified based on review of wastes handled by the facility and site characterization studies. Potential future uses of the site are evaluated. Exposure equations and input parameters are the same as those in US EPA guidelines.
Risk Characterization. Total excess lifetime cancer risk is estimated by summing risk from different chemicals, environmental media and exposure pathways. Hazard index approach is used to estimate noncancer health effects. Uncertainty is usually addressed qualitatively.

Risk Objective: Risk assessment methods used to develop health-based facility-specific closure levels.

Risk Management: Facility-specific levels are used to determine the necessity for clean-up or control of environmental media at facility prior to closure.

Example(s) of Standard Procedures: Solar Turbine (Renzi).

Exception(s): None

Cooperation among Cal/EPA and other regulatory and scientific bodies: None usually necessary.

### 4. Identification and classification of wastes as hazardous. Health and Safety Code Sections 25101 and 25159

Risk Assessment Type: 1) Chemical specific: Classify waste as hazardous based on toxicity, ignitability, corrosivity, and reactivity. 2) Site or process specific: Evaluate requests for reclassification of a specific waste as non-hazardous.

Assessment Procedure for Classifying Wastes as Hazardous:

Assessment of toxicity of a waste is based on the following characteristics of regulated constituents: leachability to ground water, total concentration, acute toxicity, and if the constituent is listed as a carcinogen in hazardous waste classification regulation. a) Leachability is measured using the Waste Extraction Test (WET). If the result for a chemical is higher than the Soluble Threshold Limit Concentration (STLC), the waste is identified as hazardous. STLCs are derived from drinking water standards multiplied by a 100-fold attenuation factor. For substances without a drinking water standard, STLCs are based on aquatic toxicity and a 50-fold attenuation factor. b) Total concentration of a constituent (total threshold limit concentration, TTLC) is based on the established STLC and an uncertainty factor. Constituents present at levels higher than the TTLC are identified as hazardous. c) Constituents present at levels higher than thresholds established from $LD_{50}$ or $LC_{50}$ information are considered hazardous wastes because of their acute toxicity. d) Carcinogens recognized by the OSHA are considered hazardous wastes if present over a threshold percentage (of the waste).

Assessment Procedure for Reclassifying Specific Wastes:

Hazard Identification. Toxicity based on designation by Cal/EPA (OEHHA, DPR), US EPA, use of chemical surrogates, or review of the scientific literature (in descending hierarchical order).

Dose-response Evaluation. Rely on Cal/EPA, US EPA IRIS, US EPA HEAST, or approach as described in Risk Assessment Guidance for Superfund.

Exposure assessment. Identify potentially exposed populations including children, workers, and adjacent residences to landfills or other disposal site types. Exposure equations and input parameters are the same as those in US EPA guidelines.

Risk Characterization. Total excess lifetime cancer risk is estimated by summing risk from different chemicals and media. Hazard index approach is used to estimate noncancer health effects. Uncertainty is usually addressed qualitatively.

Risk Objective: For reclassifying specific wastes, determine if waste presents a hazard to specified receptors under particular conditions. For noncarcinogens, hazard indices above 1 are indicative of hazard. To date, risk assessments have not been performed for wastes presumed to pose carcinogenic hazard. In such cases, the risks falling below $10^{-6}$ would be considered insignificant, in the range $10^{-6}$ to $10^{-4}$ possibly significant, and above $10^{-4}$ significant.

Risk Management: 1) Place in regulation a list of threshold values for specific chemicals for classifying wastes as hazardous. 2) Determine if the waste should be reclassified as nonhazardous under specific conditions pertaining to the generation of that waste.

Example(s) of standard procedures: 1) Chemical specific - see Handbook for the Analysis and Classification of Wastes (Cal/EPA, 1994). 2) Site-specific - a leather finisher has applied for reclassification of their wastes as not hazardous due to binding in matrix. DTSC is using risk assessment methods to determine whether the application can be granted. If 100% bioavailability is assumed, the risk will be excessive, and the application will be denied. The applicant will conduct a bioavailability study to determine what value should be used for this term.

Exception(s): None

Cooperation among Cal/EPA and other regulatory and scientific bodies: None normally needed in the realm of risk assessment. Consultation on policy and notification from time to time.

**Chemical Hazard:** **Chemical Risks from Hazardous Substances**
**Mandate:** **Toxic Substances Spills**
***Emergency Response, Health and Safety Code 25354 Railroad Accident Prevention and Immediate Deployment (RAPID), Public Utility Code Section 7718 Standardized Emergency Management System, Government Code 8607***
**Departments Involved: DTSC, OEHHA, CDHS, DPR, ARB, SWRCB, local air districts and water boards**

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Risk Assessment Type: Incident-specific, dynamic, qualitative or semi-quantitative. Evaluation of chemical spill emergencies with substantial uncertainties. Risk assessments performed by any participating appropriate agency.

Assessment Procedure:

Hazard Identification. Carrier or facility identifies the chemicals involved. Potential short-term and long-term toxic effects from high-level acute exposures may be poorly characterized.

Dose-response Evaluation. Acute health impacts are primary concern, but reliable data is unavailable for many chemicals. Usually rely on TLVs or Immediately Dangerous to Life and Health (IDLH) values.

Exposure Assessment. Concentrations in air and water are based on modeling in the early stages after an incident with variable duration of the release (hours to days) complicating evaluation. Later, on-site monitoring may be done. Relevant fate processes, persistence and dispersion of chemicals are determined; multi-medium and multi-pathway exposures are considered.

Risk Characterization. Identify potential toxic effects, affected populations, and exposure duration. If appropriate, rank chemical hazards on the basis of their relative toxicity.

Risk Objective: Identify chemicals involved and their toxic effects; identify toxicity criteria and applicability to population affected; identify potential toxic interactions between chemicals; assist risk managers in deciding whether to shelter in place or evacuate exposed populations.

Risk Management: Priorities, in order, are protection of public health, the environment, and property. Emergency response often requires swift evaluation of risk in order to make risk management decisions.

Example(s) of Standard Procedures: No standardized procedure but follows general risk assessment procedures.

Exception(s): Cantara (metam sodium spill); General Chemical, Richmond (sulfuric acid release).

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Cooperation among Cal/EPA and other regulatory and scientific bodies: DTSC, OEHHA and CDHS working on delineating areas of expertise, points of contact, roles and responsibilities during chemical emergencies. Goal is to maximize expertise of each participating agency and take advantage of overlapping regulatory authority.

**Chemical Hazard:** **Chemical Risks from Hazardous Substances**
**Mandate:** **Rail Accidents, SB48 (Chapter 766, Statutes of 1991)**
***Health and Safety Code Section 59019***
**Departments Involved:** **OEHHA**

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Risk Assessment Type: Chemical specific. Identify commodities that pose a potential threat to the public, property and the environment when transported by rail.

Assessment Procedure:

Hazard Identification. Identification of hazardous commodities that are of concern due to their lethality, irritant properties, carcinogenicity, reproductive or developmental toxicant, neurotoxicity, or other adverse health effects are based upon definitions adopted from the US Department of Transportation's hazardous material transportation regulations, or draft definitions developed by OEHHA. Identification of a hazardous commodity as a carcinogen, or as a reproductive or developmental toxicant is not done *de novo*, but is instead based upon the designation of the material as such under Proposition 65.

[Note: (a) Commodities are also listed based upon other hazardous properties besides toxicity, e.g., flammability, explosiveness, corrosiveness, tendency to generate hazardous decomposition products, etc.; (b) The initial OEHHA Railroad Hazardous Commodities List (1192) was compiled by incorporating the US Department of Transportation's Hazardous Materials Table and Organic Peroxides Table, and the California Department of Industrial Relations' Director's List of Hazardous Substances; no chemical-specific hazard evaluations were conducted at the time.]

Dose-response Evaluation. Not applicable
Exposure Assessment. Not applicable
Risk Characterization. Not applicable

Risk Objective: Prevention or reduction of potential impacts to the public, property and the environment from an uncontrolled release of a hazardous commodity.

Risk Management: California statute specifies that the OEHHA list will be used by the Public Utilities Commission to promulgate regulations for transporting listed commodities to reduce potential railroad hazards.

Example(s) of Standard Procedures: All of the chemicals proposed for addition to the initial list.

Exception(s): Not applicable. Only materials that satisfy hazard definitions are listed. The definitions include hazards other than toxicity to humans.

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Cooperation among Cal/EPA and other regulatory and scientific bodies:

* Additions to the 1992 Railroad Hazardous Commodities List are proposed; the list will be updated following a public workshop and comment period.

**Chemical Hazard:** **Chemical Risk From Pesticide Use**
**Mandate:** **Dietary Risk Assessment, AB2161**
***Food and Agricultural Code Section 13134***
**Departments Involved:** **DPR and OEHHA**

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Risk Assessment Type: Chemical specific. Evaluate general population's dietary exposure to pesticides. Where appropriate, this dietary evaluation is conducted as part of the evaluation of the overall exposure to a pesticide. There are approximately 350 pesticide active ingredients and 2,200 products registered in California for use on food commodities.

Assessment Procedure:

Hazard Identification. Health effects studies (primarily FIFRA required) are evaluated using FIFRA guidelines.

Dose-response Evaluation. To calculate potency for carcinogenic effects, nonthreshold, linear extrapolation models are used, in the absence of adequate data indicating an alternative approach is appropriate. For noncarcinogenic effects, a NOAEL or benchmark dose and uncertainty factor approach is used.

Exposure Assessment. Pesticide residue concentrations in agricultural commodities are characterized based primarily upon residue measurements, field trial studies, and/or food tolerances. Food consumption is estimated based upon modeling programs (Technical Assessment Systems) and USDA National Food Consumption Survey data.

Risk Characterization. Risk for nonthreshold oncogenic effects is calculated using the product of the potency and exposure dosage. For nononcogenic effects, a margin of safety approach is used to characterize the risk. The margin of safety is calculated as the ratio of the NOAEL to the expected human exposure.

Risk Objective: To determine if pesticide use represents a dietary risk that is deleterious to the health of humans. For non-threshold carcinogens, risks greater than $10^{-6}$ to $10^{-5}$ are generally considered to be significant. For threshold effects, margins of safety greater than 100 are generally considered to be protective if based on animal studies (10 if based on effects in humans).

Risk Management: If the pesticide use represents a dietary risk that is deleterious, DPR shall take action to modify the use of the pesticide or the tolerance as necessary to protect public health. Such action may include decreased use, elimination of use on certain crops, cancellation, or suspension.

Example(s) of Standard Procedures: Chlorpyrifos (DPR, 1992), Abamectin-Avert (DPR, 1993), Mevinphos (DPR, 1994), Fenoxyprop-ethyl (DPR, 1994). See also: A Joint Review of Existing Federal and State Pesticide Registration and Food Safety Programs (DPR, 1994).

Exception(s): Not applicable

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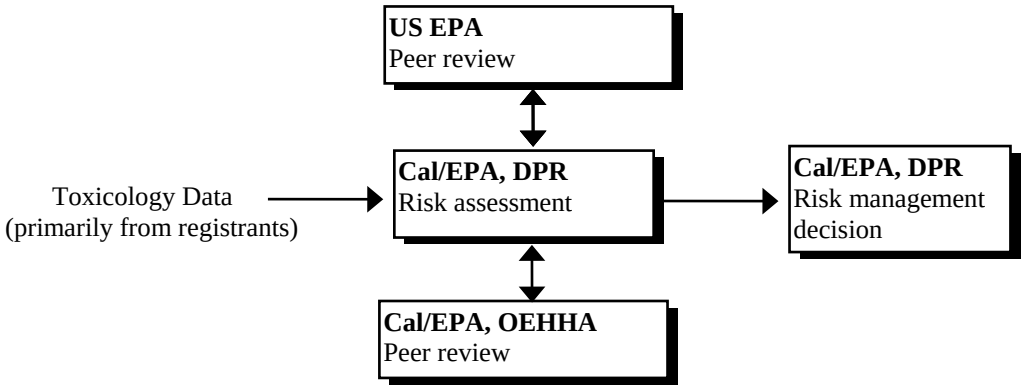
Cooperation among Cal/EPA and other regulatory and scientific bodies:



**Chemical Hazard:** **Chemical Risk From Pesticide Use**
**Mandate:** **General Authority to Regulate Pesticides,**
**Birth Defect Prevention Act, SB950**
***Food and Agricultural Code Sections 11501, 12824, 12825, 12890, 13121 through 13133***
**Departments Involved:** **DPR, OEHHA, RWQCBs, and SWRCB**

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Risk Assessment Type: Chemical specific. Evaluate general population and occupational exposure to pesticides. There are approximately 770 pesticide active ingredients and 10,000 pesticide products registered in California.

Assessment Procedure:

Hazard Identification. Health effects studies (primarily FIFRA required) are evaluated using FIFRA guidelines.

Dose-response Evaluation. To calculate potency for carcinogenic effects, nonthreshold, linear extrapolation models are used, in the absence of adequate data indicating that an alternative approach is appropriate. For noncarcinogenic effects, a NOAEL or benchmark dose and uncertainty factor approach is used.

Exposure Assessment. Dietary, occupational, and residential exposure are evaluated. All relevant routes of exposure are considered. Dietary exposure is evaluated using pesticide residue concentrations and food consumption data (see program summary sheet on dietary risk assessment). Occupational and residential exposures are estimated based upon exposure monitoring and biomonitoring data. If these data are unavailable, surrogate exposure data from similar compounds and use scenarios are used. Done by DPR in consultation with OEHHA.

Risk Characterization. Risk for nonthreshold oncogenic effects is calculated as the product of the potency and exposure dosage. For nononcogenic effects, a margin of safety approach is used to characterize the risk. The margin of safety is calculated as the ratio of the NOAEL to the expected human exposure.

Risk Objective: To characterize the risk of adverse health effects and to determine if this risk is significant. For non-threshold carcinogens, risks greater than $10^{-6}$ to $10^{-5}$ are generally considered to be significant. For threshold effects, margins of safety greater than 100 are generally considered to be protective if based on animal studies (10 if based on effects in humans).

Risk Management: If the risk is significant, mitigation action is taken to reduce the exposure to levels that do not present a significant risk. Such action may include decreased use, altered use practices, increase use of protective equipment, cancellation, or suspension. Under the terms of a Management Agency Agreement (MAA), when the RWQCBs or SWRCB find pesticides in the waters of the state, the findings are referred to DPR. Appropriate follow-up action is taken by DPR and the boards based on guidance provided in the MAA.

Example(s) of Standard Procedures: Mevinphos (DPR, 1994), Abamectin-Avert (DPR, 1993), Fenoxyprop-ethyl (DPR, 1994), Cyromazine (DPR, 1993).

Exception(s): 1,3-Dichloropropene-Telone (1994)

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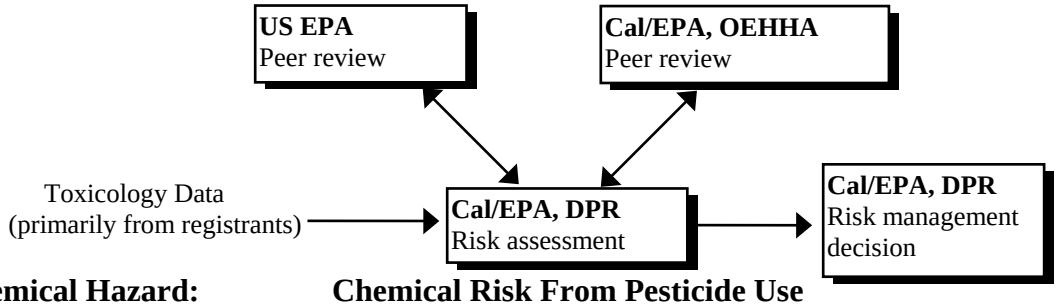
Cooperation among Cal/EPA and other regulatory and scientific bodies:



**Mandate:** **Pesticide Illness Surveillance Program,**
***Health and Safety Code Section 2950***
***Food and Agricultural Code Chapter 2,***
***Article 10.5, Section 12980 to 12982***

**Departments Involved:** **DPR and OEHHA**

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Risk Assessment Type: Chemical specific. Evaluate health hazards associated with pesticide usage.

Assessment Procedure:

Hazard Identification. County Agricultural Commissioners investigate all reported cases of human illnesses suspected of being derived from pesticide exposure. Investigation reports are submitted on forms produced by DPR, which evaluate, classify, record, analyze and summarize the findings. OEHHA produces the Pesticide Illness Report form on which suspect cases are reported, receives notification of episodes that appear to meet certain criteria of severity, and investigates selected episodes as appropriate.
Dose-response Evaluation. Review published literature.
Exposure Assessment. Analyze samples of body fluids, clothing, ambient air, foliage and surface contacted as available.
Risk Characterization. Risk relative to other pesticides and exposure conditions is evaluated by comparing case reports to reported usage and employment levels. Uncertainty is addressed qualitatively. Done by DPR.

Risk Objective: Any documentable harm to human health caused by pesticide exposure raises concern.

Risk Management: DPR considers surveillance results in making registration decisions and establishing the terms and conditions of legal pesticide use. OEHHA, with input from DPR and county health officers, provides training to physicians and health care professionals on the requirements of physicians' illness reporting, and the recognition and management of organophosphates and n-methyl carbamate pesticide poisonings. OEHHA also provides oversight of the medical supervision of agricultural pesticide applicators and produces the document "Guidelines for Physicians" for medical supervisors of workers.

Example(s) of Standard Procedures: Pesticide Illness Surveillance Program Summary Report (DPR, 1994), Risk Factors for Cholinesterase and Non-Cholinesterase Effects of Exposure to Organophosphate Insecticides in California Agricultural Workers 1982-1990 (DPR, 1994); Guidelines for Physicians (OEHHA, 1996).

Exception(s): Not applicable

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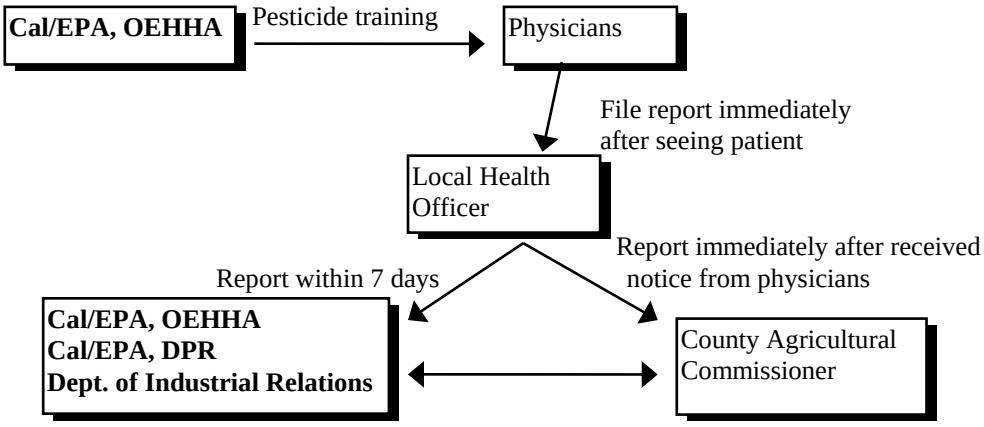
Cooperation among Cal/EPA and other regulatory and scientific bodies:



**Chemical Hazard:** **Chemical Risk From Pesticide Use**
**Mandate:** **Tolerance Assessment, AB2848**
***Health and Safety Code Section 26205***
**Departments Involved:** **OEHHA and DPR**

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Risk Assessment Type: Chemical specific. May develop pesticide tolerances for processed food.

Assessment Procedure:

Hazard Identification. Based on designation of authoritative bodies in priority: SCWG, OEHHA Proposition 65, US EPA, IARC, or develops own approach. Done by OEHHA.
Dose-response Evaluation. Generally use cancer potency factor or reference dose. SCWG (primary source), US EPA (secondary source). Values are reviewed to determine if they need to be updated based on new information. Done by OEHHA.
Exposure Assessment. Use Technical Assessment Systems software or USDA food consumption survey data to estimate food consumption. Use pesticide concentration data at existing tolerance level, and residue level from monitoring or field trials. Done by OEHHA.
Risk Characterization. Determine if existing tolerances are adequately protective of public health.

Risk Objective: Ensure that public health and safety and the environment are adequately protected.

Risk Management: Establish health protective tolerance levels

Example(s) of Standard Procedures: Documents prepared on a case by case basis as appropriate.

Exception(s):

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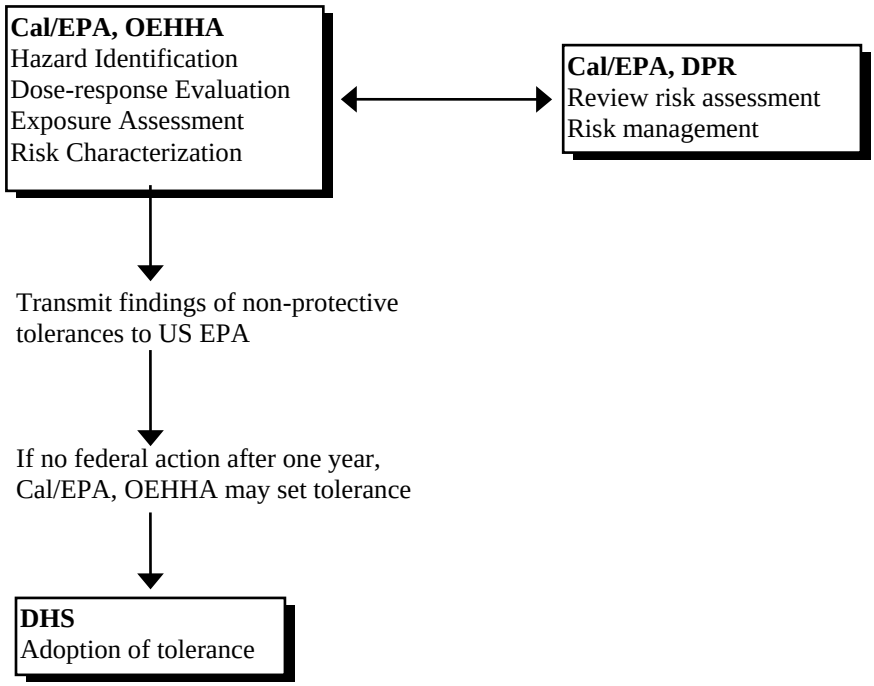
Cooperation among Cal/EPA and other regulatory and scientific bodies:



**Chemical Hazard:** **Chemical Risk From Pesticide Use**
**Mandate:** **Risk Assessment for Dietary and Pesticide Related Hazards**
***Health and Safety Code Section 205***
**Departments Involved:** **OEHHA (DPR, only if Pesticide Related)**

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Risk Assessment Type: Chemical or site specific. Evaluate health hazards of accidental or intentional release of pesticides or other chemicals in various media.

Assessment Procedure:

Hazard Identification. Based on designation of authoritative bodies in priority: SCWG, OEHHA Proposition 65, US EPA, IARC, or develops own approach. Done by OEHHA.

Dose-response Evaluation. Generally use cancer potency factor or reference dose. SCWG (primary source), US EPA (secondary source). Values are reviewed to determine if they need to be updated based on new information. Done by OEHHA.

Exposure Assessment. Exposure concentrations are derived from food residue, or environmental monitoring data when available and supplemented by modeling. Consider all relevant exposure pathways. Site-specific information is used in the assessment.

Risk Characterization. Estimate risk to public. Both cancer and noncancer health risk are evaluated.

Risk Objective: Ensure safety for community residents (if chemical spill) or consumers (food, consumer products).

Risk Management: Consideration of restricted use and other actions (for pesticides); recall (food, consumer products); evacuation of area (if toxic spill).

Example(s) of Standard Procedures: Malathion-Bait (CDHS, 1991), Metam Spill in the Upper Sacramento River (OEHHA, 1992), daminozide in apples (OEHHA as part of CDHS, 1987), and lead in ceramic ware (in preparation, 1996).

Exception(s):

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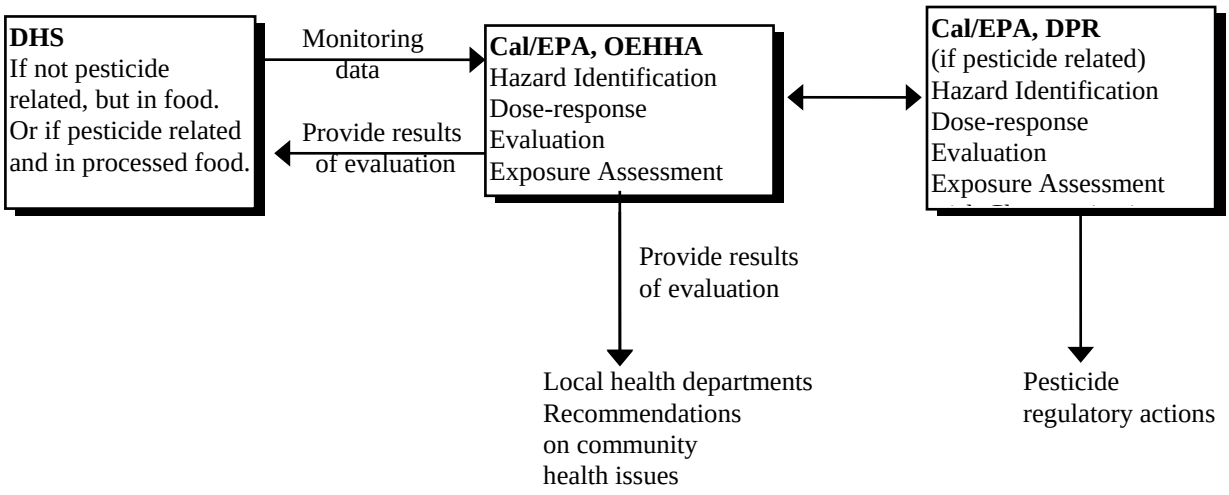
Cooperation among Cal/EPA and other regulatory and scientific bodies:



**Chemical Hazard:** **Carcinogens and Reproductive Toxicants**
**Mandate:** **Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)**
***Health and Safety Code Section 25249.5 (et seq.)***
**Departments Involved:** **OEHHA, DPR, and SWRCB**

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Risk Assessment Type: Chemical and situation specific. Warning the public and prohibiting discharges for case of significant exposures to carcinogens and reproductive toxicants.

Assessment Procedure:

Hazard Identification. Three mechanisms: 1) Agents identified by the state's qualified experts (Two Science Advisory Board committees)(OEHHA and DPR author hazard identification documents.); 2) agents identified by Proposition 65 authoritative bodies (International Agency for Research on Cancer, National Institute for Occupational Safety and Health, National Toxicology Program, US Environmental Protection Agency, US Food and Drug Administration) following guidelines given in Title 22 CCR Section 12306 (OEHHA implements); 3) agents required to be labeled as causing cancer or reproductive toxicity by a state or federal agency (Title 22 CCR Section 12902) (OEHHA implements).

Dose-response Evaluation. In the absence of data indicating it is scientifically more appropriate to do otherwise, cancer potency derived using standard methodology (Title 22 CCR Section 12703). For carcinogens, No Significant Risk Level (NSRL) estimated for a risk of 1 in 100,000 based on cancer potency. For developmental and reproductive toxicants, no observed effect level (NOEL) taken from the literature, and, as required by the Proposition 65 initiative, divided by 1000 to establish the "Specific Regulatory Levels" (SRL)(Title 22, Section 12805). When available and appropriate, values from existing regulatory programs are used.

Exposure Assessment. Chemical exposure can be calculated by standard procedures using exposure factors specified in Title 22 CCR Sections 12703 and 12721. Carried out by responsible parties, interested citizens, or in certain cases by DPR or OEHHA.

Risk Characterization. Evaluate whether exposure estimate exceeds NSRL or MADL, and thus whether significant risks may be experienced. Carried out by responsible parties, interested citizens, or the Attorney General's Office.

Risk Objective: For carcinogens, significant risk is defined in the implementing regulations as one excess case of cancer in an exposed population of 100,000. For developmental and reproductive toxicants, exposures at 1000 times NOEL trigger the warning requirement and discharge prohibition.

Risk Management: No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual. Responsible parties who fail to comply may be subject to civil penalties. SWRCB developed the "sources of drinking water policies" in response to Proposition 65.

Example(s) of Standard Procedures: Cancer NSRLs: 222 promulgated; 63 additional proposed. Approximately 400 carcinogens and 150 listings under reproductive toxicity are listed under Proposition 65.

Exception(s): aflatoxin (cancer potency); physiologically based pharmacokinetic modeling for several agents; oral exposure to several metals and metallic compounds.

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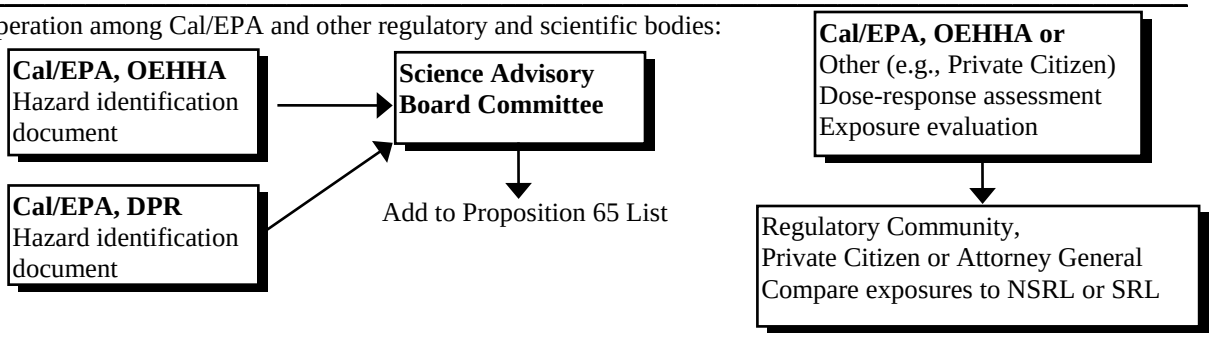
Cooperation among Cal/EPA and other regulatory and scientific bodies:



# Appendix C

# An Overview of Exposure Assessment Methodology and Practice of Cal/EPA and US EPA

## Introduction

This document compares exposure assessment procedures used or recommended by the California Environmental Protection Agency (Cal/EPA) with those developed by the US Environmental Protection Agency (US EPA) and the National Research Council (NRC). Since the majority of promulgated exposure assessment guidelines are related to the regulation of hazardous waste, a large portion of this document is devoted to that area. Assessment of chemical-specific exposure (e.g., to waterborne contaminants and pesticides in the environment) is also included. As an overview, this document does not provide in-depth treatment on many topics related to exposure assessment. In the following sections, relevant exposure assessment documents are referenced as sources of more detailed information.

Before comparing the exposure assessment practices of Cal/EPA, US EPA and NRC, it may be useful to review risk assessment activities performed by various departments and sections of Cal/EPA. A compendium document "Cal/EPA Risk Assessment Procedures by Mandate" provides an overview of risk assessment activities in Cal/EPA. It is located in the Appendix A of this report.

For ease of discussion, we have chosen to classify risk assessment activities in this document along two lines, those that are site- or facility-specific (Section 1) and those that are chemical-specific (Section 2). Risk assessments conducted under the requirements of Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA amended in 1986 by the Superfund Amendments and Reauthorization Act) and California Air Toxics "Hot Spots" program are site or facility specific risk assessments. They are used by the Department of Toxic Substances Control (DTSC) and Office of Environmental Health Hazard Assessment (OEHHA) to evaluate potential health and environmental impacts associated with chemical releases from manufacturing facilities, hazardous waste treatment, storage and disposal facilities or hazardous waste sites. Exposure assessment procedures recommended or used by these programs are discussed in Section 1.

Section 2 includes exposure assessment procedures used in chemical-specific risk assessments. This grouping includes all risk assessments not classified as site or facility specific risk assessments. These are generally not targeted towards a particular site or facility, but are used to evaluate potential hazards associated with the usage of a chemical or to ensure the exposure of the public is within acceptable limits. For example, chemical-specific risk assessments are used by the Air Resources Board (ARB), the Department of Pesticide Regulation (DPR) and the State Water Resources Control Board (SWRCB) to control air pollution, regulate pesticide usage and develop water standards, respectively.

Under the Safe Drinking Water and Toxic Enforcement Act of 1986 (or Proposition 65), exposure assessments and toxicity evaluations are used by the Reproductive and Cancer Hazard Assessment Section of OEHHA to identify chemicals that have the potential to cause reproductive defects or cancer. The exposure assessment method used by Proposition 65 is described in the California Code of Regulations Title 22, Section 12721.

The activity of California Integrated Waste Management Board (CIWMB) is not covered in this document. CIWMB risk assessments are used to evaluate the potential health threat of a waste site to the surrounding communities. Because the purpose of the evaluation is to prioritize waste sites using both quantitative sampling results and qualitative observations, it is difficult to compare this procedure to those recommended by other programs.

Some exposure assessments by OEHHA are conducted on a case-by-case basis and, thus, can not be generalized. In these assessments, different procedures are employed dependent on the chemical, medium, site characteristics and purpose of the study. Examples of such exposure assessments include a study of fish consumption (OEHHA, 1992), and the aerial spraying of malathion (for control of medflies) in Los Angeles (CDHS, 1991).

## 1.0 Exposure Assessment in Site- and Facility-Specific Risk Assessments

Site-specific risk assessments are used to evaluate potential health impacts associated with chemical releases from manufacturing facilities or hazardous waste sites. "Science and Judgment in Risk Assessment" (NRC, 1994) strongly advocates a tiered approach in conducting site-specific risk assessments. A similar approach is recommended by Cal/EPA in the Air Toxics "Hot Spots" program (CAPCOA, 1993) and the Preliminary Endangerment Assessment (DTSC, 1994) program. It is suggested that a site-specific risk assessment can be carried out at two levels, screening and detailed. In a screening evaluation, relatively simple models, conservative assumptions and default parameters are used to calculate an upper-bound risk estimate associated with a chemical release. No detailed evaluation is warranted if the estimate is below a reference level. On the other hand, if the screening risk estimate is above the reference level, then a more detailed evaluation should be performed. The purpose of this approach is to optimize the use of resources and perform a detailed risk assessment only when it is warranted.

Likewise, US EPA endorses a tiered approach in evaluating toxic chemical releases. In "Guideline on Air Quality Models" (US EPA, 1986a) and "Superfund Exposure Assessment Manual" (US EPA, 1988), US EPA recommends that screening level contaminant release and fate and transport models should first be used. An assessor should contemplate the use of more advanced models only if the screening risk estimate is above the level of concern.

A related technique used by US EPA Region IX is the development of Preliminary Remediation Goals (PRGs). They are concentrations of contaminants in environmental media that are considered by US EPA Region IX to be "safe" for humans. US EPA Region IX has issued a set of PRGs (US EPA, 1995) that can be used as screening tools for human health evaluation of hazardous waste sites. A full scale health effects investigation is required only when the maximum contaminant concentration detected at a site is above the PRG. It should be noted that this terminology and intent is inconsistent with US EPA's Risk Assessment Guideline under Superfund Part B and other draft policies on soil screening levels. Cal/EPA DTSC does not endorse this generic "cleanup" value approach. Cal/EPA DTSC instead endorses US EPA's Risk Assessment Guideline under Superfund Part B approach that allows for a site-specific approach to screening.

Guidelines and recommendations provided by Cal/EPA and US EPA on how to carry out screening and detailed exposure evaluations are discussed and compared in the following sections. For ease of discussion, they are grouped under identification of exposed populations and exposure pathways (Section 1.1), estimation of exposure point concentrations (Section 1.2), and estimation of contaminant intakes (Section 1.3).

## 1.1 Identification of Exposed Populations and Exposure Pathways

This section describes the guidelines recommended by Cal/EPA and US EPA for identifying exposed populations and exposure pathways. Different approaches are used in screening and detailed evaluations.

### 1.1.1 Screening evaluation

In a screening exposure assessment, a residential exposure scenario is often used as the default scenario. It is because the assumptions in this scenario generally result in the highest potential exposure and health risk. For this reason, Cal/EPA in the Preliminary Endangerment Assessment (PEA) (DTSC, 1994) and in the Air Toxics "Hot Spots" program (CAPCOA, 1993) recommends the use of on-site residents or the closest off-site residents as the potential human receptors. Generally, in site-specific risk assessments, adults are the subject of evaluation. However, in the PEA, Cal/EPA also requires the exposure of a child to non-carcinogens to be evaluated as this assumption would result in the greatest estimated exposure. [It should be noted that under US EPA Resources Conservation and Recovery Act of 1976 (RCRA) closure of a hazardous waste treatment, storage and disposal unit a similarly constructed exposure scenario is employed.]

Exposure pathways that are assumed to be complete under the residential exposure scenario and require quantitative evaluation by the PEA and the Air Toxics "Hot Spots" programs are shown in Table 1. Direct exposure pathways such as inhalation of airborne chemicals and particulates, ingestion of soil, and dermal contact of soil are considered by both programs. Exposure to contaminants in water pathway is considered by PEA only. However, ingestion of contaminants through mother's milk by infants is only considered in the Air Toxics "Hot Spots" program. For comparison purpose, exposure pathways considered by US EPA Region IX in the development of PRGs are also included in Table 1.

### 1.1.2 Detailed evaluation

In a detailed exposure assessment, identification of exposed populations and complete exposure pathways are dependent upon a number of site-specific factors, such as the nature of the release, characteristics of the site, characteristics the surrounding community and physical and chemical properties of the chemicals released.

Several criteria have been used by Cal/EPA and US EPA in identifying current and future exposed populations:

- populations that have the greatest potential for exposure
- populations that are representative of a geographic area
- sensitive sub-populations

## Table 1. Default exposure pathways evaluated in screening risk assessments

| Hazardous Waste Site | | Air Pollutant |
|---|---|---|
| **Preliminary Remediation Goals (US EPA, Region IX)(1)** | **Preliminary Endangerment Assessment (OSA, DTSC, Cal/EPA)(2)** | **Air Toxics "Hot Spots" program (ATES, OEHHA, Cal/EPA)(3)** |
| Inhalation of airborne vapors including volatile organic compounds from soil and from using household water<br>Inhalation of airborne particulates | Inhalation of airborne vapors including volatile organic compounds from soil and from using household water<br>Inhalation of airborne particulates | Inhalation of airborne vapor and particulates |
| Ingestion of soil | Incidental ingestion of soil | Ingestion of soil |
| Dermal contact with soil | Dermal contact with soil | Dermal contact with soil |
| NC | Dermal contact with surface water and ground water (e.g., showering) | NC |
| Ingestion of surface water and ground water | Ingestion of surface water and ground water | NC |
| NC | NC | Ingestion of mother's milk by infants |
| NC | If food chain contamination is suspected or is plausible, then this screening level evaluation should not be used | If a facility emits any of the substances listed in **Table 2**, other pathways, such as ingestion of crop, meat, eggs, dairy products, fish, and water, may also be included |

NC = not considered

(1) US EPA, Region IX (1994). Region IX Preliminary Remediation Goals (PRGs). September 1995.

(2) DTSC, Cal/EPA (1994). Preliminary Endangerment Assessment Guidance Manual. January 1994.

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

**Table 2. Substances to be Evaluated for Non-inhalation Exposures**
(The list of chemicals is taken from Table III-5 of the CAPCOA Risk Assessment Guidelines for the Air Toxics "Hot Spots" Program, October, 1993)

| Metal | Organic Compound |
|---|---|
| Arsenic | Chlorobenzene |
| Beryllium | Chlorinated dibenzo-p-dioxins |
| Cadmium | (as 2,3,7,8-equivalents) |
| Chromium (hexavalent) | Chlorinated dibenzofurans |
| Lead | (as 2,3,7,8-equivalents) |
| Mercury | 2-Chlorophenol |
| | p-Dichlorobenzene |
| | Hexachlorobenzene |
| | Hexachlorocyclohexanes |
| | Nitrosamines: |
| | N-Nitrosodiethylamine |
| | N-Nitrosodimethylamine |
| | p-Nitrosodiphenylamine |
| | N-Nitrosodi-n-butylamine |
| | N-Nitrosodi-n-propylamine |
| | N-Nitrosomethylethylamine |
| | N-Nitrosomorpholine |
| | N-Nitrosopiperidine |
| | N-Nitrosopyrrolidine |
| | PAH (Polycyclic aromatic hydrocarbons) including, but not limited to: |
| | Benz[a]anthracene |
| | Benzo[b]fluoranthene |
| | Benzo[k]fluoranthene |
| | Benzo[a]pyrene |
| | Dibenz[a,h]anthracene |
| | Indeno[1,2,3-cd]pyrene |
| | Naphthalene |
| | Polychlorinated biphenyls (PCBs) |
| | Pentachlorophenol |
| | 2,4,6-Trichlorophenol |
| | 2,4,5-Trichlorophenol |

Sensitive sub-populations are those people at increased risk from chemical exposure due to increased sensitivity or behavior patterns; they may include for example: young children, chronically ill individuals and persons who consume unusually large amounts of locally caught fish or locally grown produce. It is recommended by both agencies that local census data and information from local public health officials be used for the identification of exposed population locations.

Both Cal/EPA and US EPA recommend the use of site-specific information for identifying complete exposure pathways in a detailed exposure assessment. According to US EPA (1989), an exposure pathway is considered to be complete when all of the following elements exist:

- a source and mechanism of chemical release,
- a retention or transport medium,
- a point of potential human contact with the contaminated medium, and
- an exposure route at the contact point.

The same approach is used by Cal/EPA for identifying complete exposure pathways. Table 3 lists the potential exposure pathways recommended by Cal/EPA and US EPA to be considered in the evaluation of hazardous waste sites. As shown in the first two columns, basically the same set of exposure routes is recommended by the two agencies. However, there are some differences: inhalation of airborne vapor from contaminated tap water and ingestion of mother's milk by infants are only considered by DTSC while incidental ingestion of and dermal contact with sediment are only considered by US EPA.

In addition, DTSC (1992) has also developed an algorithm to help risk assessors in identifying pathways which can be excluded from an exposure evaluation. The approach outlined by DTSC was developed to supplement and/or clarify the approach described by US EPA (1988, 1989a, 1989b). The method combines a generic intake model and conservative input parameters with contaminant-specific information to estimate the potential chemical intake per unit concentration associated with every plausible pathway. Then the pathway with the largest potential chemical intake per unit concentration for each medium is identified. Other pathways are included if they are likely to increase significantly the exposure estimated for a medium.

As shown in Table 4, multimedia exposure to air pollutants and hazardous waste incinerator emissions is considered by Cal/EPA. This approach is consistent with the recommendations of NRC (1994), which recognizes the importance of "indirect" pathways for some classes of air pollutants such as lipophilic compounds and heavy metals. By contrast, US EPA generally does not include non-inhalation exposure in the evaluation of air pollutants under the Clean Air Act and may underestimate exposure and risk.

**Table 3. Exposure pathways recommended to be considered in detailed risk assessments**

| **Hazardous Waste Site** | | **Air Pollutant** | | **Hazardous Waste Incinerator** |
|---|---|---|---|---|
| **Hazardous Waste Sites and CalTOX programs OSA, DTSC, Cal/EPA (1) and (2)** | **CERCLA Office of Emergency and Remedial Response, US EPA (3)** | **Air Toxics "Hot Spots" program ATES, OEHHA, Cal/EPA (4)** | **Clean Air Act Air Quality Planning and Standards, US EPA** | **Permitting of Hazardous Waste Incinerators HWTS, OEHHA, Cal/EPA (5)** |
| Inhalation of airborne vapors including volatile organic compounds from soil and contaminated tap water; inhalation of airborne particulates | Inhalation of chemical vapors and particulates, indoors and outdoors | Inhalation of airborne vapor and particulates | Inhalation of airborne vapor and particulates | Inhalation of chemical vapors and particulates, indoors and outdoors |
| Incidental ingestion of soil/dust | Incidental ingestion of soil/dust | Ingestion of soil | NC | Incidental ingestion of soil/dust |
| Dermal contact with soil | Dermal contact with soil | Dermal contact with soil | NC | Dermal contact with soil |
| Ingestion of mother's milk | NC | Ingestion of mother's milk | NC | Ingestion of mother's milk |
| Ingestion of fruits, vegetables and grains | Ingestion of vegetables | Ingestion of root crops, leafy crops, and vine crops | NC | Ingestion of fruits, vegetables and grains |
| Ingestion of meat, milk, eggs, fish and sea food | Ingestion of meat and game, dairy products, eggs, fish and shellfish | Ingestion of meat (poultry, cattle, goats, pigs and sheep), milk, eggs and fish | NC | Ingestion of meat, milk, eggs and fish |
| Ingestion of tap water, and surface water during swimming or other water recreation | Ingestion of surface water and ground water | Ingestion of surface water | NC | Ingestion of water |
| Dermal contact with surface water while swimming and contaminated water in baths and showers | Dermal contact with surface water and ground water | NC | NC | NC |
| NC | Incidental ingestion of and dermal contact with sediment | NC | NC | NC |

NC = not considered

Table 3 footnotes:

(1) DTSC, Cal/EPA (1992). Supplemental Guidance for Human Health Multimedia Risk Assessments of Hazardous Waste Sites and Permitted Facilities. Office of Scientific Affairs, Department of Toxic Substances Control, California Environmental Protection Agency, Sacramento, California.

(2) DTSC, Cal/EPA (1993). CalTOX - A Multimedia Total Exposure Model for Hazardous-Waste Sites. The Office of Scientific Affairs, Department of Toxic Substances Control, California Environmental Protection Agency, Sacramento, California.

(3) US EPA (1989). Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part A). Interim Final. EPA 540/1-89/002.

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

(5) OEHHA, Cal/EPA (1994). Format for Health Risk Assessments for Hazardous Waste Incinerators. Hazardous Waste Toxicology Section, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Sacramento, California.

**Table 4. Inter-media transfer routes recommended by Cal/EPA and US EPA to be considered in site-specific risk assessments**

| | Hazardous Waste Site | | | Air Pollutant |
|---|---|---|---|---|
| **Inter-media Transfer Route** | **Hazardous Waste Program, DTSC, Cal/EPA (1)** | **CalTOX Program, DTSC, Cal/EPA (2)** | **Hazardous Waste Program (CERCLA), US EPA (3)*** | **Air Toxics "Hot Spots" Program, ATES, OEHHA, Cal/EPA (4)** |
| Wet and dry deposition of particle-bound chemicals from air to surface soil and surface water | NC | x | x | x |
| Wet and dry deposition of particle-bound chemicals from air to plants (grass, vegetables, and fruits) | x | x | x | x |
| Partition of chemical vapors from air to plants (grass, vegetables, and fruits) | x | x | NC | NC |
| Uptake of chemicals from soil to plant through the root system | x | x | x | x |
| Transport of particle-bound chemicals from soil to plant surface through rainsplash | NC | x | NC | NC |
| Transfer of chemicals from grass to milk and beef through grass and hay ingestion | x | x | x | x |
| Transfer of chemicals from soil to milk and beef through soil ingestion | x | x | x | x |
| Transfer of chemicals from air to milk and beef through inhalation | x | x | x | x |
| Transfer of chemicals from water to milk and beef through water ingestion | x | x | x | x |
| Transfer of chemicals from water to fish through absorption | x | x | x | x |
| Transfer of chemicals from water to plant through irrigation | x | x | NC | NC |
| Transfer of chemicals from mother to infant through breast milk | x | x | NC | x |
| Degradation and transformation in the environment | NC | x | NC | x |

NC = not considered

Table 4 footnotes:

* No inter-media transfer model is explicitly recommended in the US EPA guidance document; however, several models in the literature similar to that recommended by CAPCOA (1993) are suggested as possible substitutions for monitoring data.

(1) DTSC, Cal/EPA (1992). Supplemental Guidance for Human Health Multimedia Risk Assessments of Hazardous Waste Sites and Permitted Facilities.

(2) DTSC, Cal/EPA (1993). CalTOX - A Multimedia Total Exposure Model for Hazardous-Waste Sites. The Office of Scientific Affairs, Department of Toxic Substances Control, California Environmental Protection Agency, Sacramento, California.

(3) US EPA (1989). Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part A). Interim Final. EPA 540/1-89/002.

(4) CAPCOA (1993). Air Toxics “Hot Spots” Program. Revised 1992 Risk Assessment Guidelines. Toxics Committee of the California Air Pollution Control Officers Association (CAPCOA).

## 1.2 Estimation of Exposure Point Concentrations

This section compares the recommendations made by Cal/EPA and US EPA for determining exposure point concentrations. Exposure point concentration is defined as the concentration of a chemical in an environmental medium (e.g., air, water, soil, and food) with which a human receptor may come into contact.

Exposure point concentrations are calculated differently in screening and detailed risk assessments. The highest determined contaminant concentration is often used as the exposure point concentration in screening evaluations. For instance, in the Air Toxics "Hot Spots" program, it is recommended that the air concentration predicted by air dispersion modeling for the maximum exposed individual receptor (MEI) is to be used in the screening evaluation (CAPCOA, 1993). Similarly, in the "Preliminary Endangerment Assessment Guidance Manual", it is suggested that the highest concentration of each contaminant in soil be used in estimating the potential health hazard (DTSC, 1994). Likewise, US EPA Region IX in its PRG document (US EPA, 1995) also suggests that either the maximum or upper 95 percent upper confidence limit on the arithmetic mean of the site contaminant concentrations be used in the screening process.

In a detailed exposure assessment, the exposure point concentration is dependent on the location of the human receptor being modeled or measured and whether the receptor is considered to be a reasonable maximally exposed individual (RME) or an average exposed individual (AEI). Comparable guidelines are issued by Cal/EPA and US EPA on how to calculate exposure point concentrations. When an evaluation is conducted for a RME, the 90 percent (DTSC, 1992) or 95 percent (US EPA, 1989b) upper confidence limit on the arithmetic mean (or geometric mean, if the values are log-normally distributed) of the contaminant concentration can be used to represent the exposure point concentration. If there is a high degree of variability in contaminant concentrations, the upper confidence limit on the average concentration could be above the maximum detected or modeled value. In such a situation, Cal/EPA and US EPA both recommend the maximum contaminant concentration be used to represent the exposure point concentration. The concept of RME is most often used in hazardous waste site risk assessments (DTSC, 1992; US EPA, 1989b).

When an evaluation is conducted for an AEI, the arithmetic mean of the contaminant concentration can be used to represent the exposure point concentration. This approach is used in the evaluation of hazardous waste site and CalTOX (DTSC, 1992 and DTSC, 1993a). A refined assessment under the Air Toxics "Hot Spots" program includes the determination of the potential health impact at the offsite point of maximum impact, the maximum exposed individual worker (MEIW), and the maximum exposed individual receptor (MEIR)(CAPCOA, 1993).

As discussed in Section 1.1 (Tables 1 and 3), when a released contaminant persists in the environment or bioaccumulates, it is sometimes necessary to evaluate the potential health impact through indirect pathways (e.g., food chain contamination). In the following section, inter-media transfer models recommended by regulatory agencies that can be used

to estimate exposure point concentrations of food and other indirectly impacted environmental media are discussed.

### 1.2.1 Inter-media Transfer Models

Inter-media transfer models can be used to predict the distribution of a chemical in the environment. Table 4 shows the inter-media transfer routes that are recommended for consideration by Cal/EPA and US EPA. A few more transfer routes are listed by Cal/EPA than US EPA.

Two types of inter-media transfer model are used by Cal/EPA, a steady-state model and a fugacity model. In a steady-state model, the system is assumed to be made up of many compartments such as air, soil, and vegetation. Contaminant concentration in each of the compartments is assumed to be uniform but contaminant concentrations in two compartments need not be the same. Inter-media transfer models recommended by Cal/EPA in the Air Toxics "Hot Spots" Program (CAPCOA, 1993) and the hazardous waste program (DTSC, 1992) are steady-state partitioning models. Due to the large uncertainty that often associate with inter-media transfer modeling, US EPA does not explicitly recommend any model in the "Risk Assessment Guidance for Superfund" (US EPA, 1989b), instead it recommends that the appropriate medium should be sampled to estimate exposure concentrations. However, when monitoring data are not available, US EPA suggests one of the steady-state models in the open literature may be used for inter-media transfer modeling.

As the name implies, an important characteristic of steady-state models is that contaminant concentrations in various compartments are assumed to be constant with time. Hence, they are suitable for situations in which contaminants are released over a long period of time (e.g., several months to several year) at a more or less uniform rate. Steady-state models may overestimate exposure point concentrations when the release is sporadic or when contaminant concentrations decrease with time. These models may underestimate short-term exposures because exposure is averaged over time.

A fugacity model is the other type of inter-media transfer model used by Cal/EPA. In a fugacity model, the system is also assumed to be made up of many compartments; but unlike the steady-state model, contaminant concentration in a compartment may vary with time. The CalTOX model developed by DTSC (1993a) is composed of two parts, the multimedia transport and transformation model and the human exposure model. The multimedia transport and transformation model is a fugacity model and is used to model the distribution of contaminants among air, plants, soil, surface water, and sediments. The human exposure model of CalTOX is a steady-state model and is used to model the transfer of contaminants from the environment to food products, like milk, meat, eggs, and fish.

Another important feature of the CalTOX model is that in its design sensitivity and uncertainty analyses are incorporated directly into the model operation. Unlike other models recommended by Cal/EPA and US EPA, instead of point estimates, parameter values suggested for use in CalTOX are described in terms of mean values and a coefficient of variation (DTSC, 1993b). When CalTOX is used together with Monte Carlo simulation, the result it produces is described in terms of a confidence interval rather than a single value.

Cal/EPA uses two different types inter-media transfer models: the one described in CalTOX (DTSC, 1993a) and the one used in the Air Toxics "Hot Spots" Program (CAPCOA, 1993). Because these models are structurally different, they are not amenable for comparison on a side-by-side basis. In addition, the needs for each program differ considerably. Contaminants in hazardous waste sites are more amenable to monitoring the contaminated medium than are those subject to the Air Toxics "Hot Spots" program, and some of the chemicals of concern (e.g., metals) in the Air Toxics "Hot Spots" program are not modeled well by the fugacity model in CalTOX.

### 1.3. Estimation of Contaminant Intakes

Contaminant intake is defined as the amount of chemical that crosses a boundary from the environment to the human (e.g., absorption through lung, gut, or skin). In exposure modeling, the potential impact of every exposure route is estimated by an intake equation. Intake equations used by Cal/EPA and US EPA are similar and have the general formula shown below:

$$I = (C \times CR \times EF \times ED) / (BW \times AT)$$

Where:

I = intake of a chemical via an exposure route (e.g., inhalation, ingestion, and dermal contact), mg/kg/day

C = exposure point concentration of a chemical in an environmental or food medium (e.g., air, tap water, food, soil), $mg/m^3$, mg/l, or mg/kg

CR = contact rate; the amount of contaminated medium contacted per unit time or event, $m^3$/day, l/day, g/day

EF = exposure frequency, days/year

ED = exposure duration, years

BW = average body weight over the exposure period, kg

AT = averaging time; period over which exposure is averaged, days

For dermal exposure, an additional parameter, dermal absorption factor, is generally used to convert intake dose, I, into absorbed dose. This factor has no unit and is always less than or equal to one as it is used to reflect the desorption of a chemical from soil adhered to the skin surface and the absorption of the chemical across the skin and into the blood stream.

Some intake equations recommended by US EPA can be found in the "Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual" (US EPA, 1989b). Although pathway-specific intake equations used by Cal/EPA and US EPA are similar, human receptors and exposure durations that need to be modeled in different programs are not the same. Table 5 compares some of the characteristics of human exposure models recommended by Cal/EPA and US EPA. Table 6 compares the default contact factors recommended by the two agencies.

**Table 5. Comparison of intake models recommended by Cal/EPA and US EPA**
(References for Table 5 are listed in Page C-26)

| | Hazardous Waste Site | | | Air Pollutant | |
|---|---|---|---|---|---|
| **Exposure Model** | **Hazardous Waste Program, DTSC, Cal/EPA (1)** | **Hazardous Waste Program, CalTOX DTSC, Cal/EPA (2)(6)** | **CERCLA, Office of Emergency and Remedial Response, US EPA (3)** | **Air Toxics "Hot Spots" program (4) and Emission Permitting OEHHA, Cal/EPA** | **Clean Air Act, Air Quality Planning and Standards, US EPA** |
| **Intake Factors, Exposure Frequencies and Durations** | Refer to Table 6 | Refer to Table 6 | Refer to Table 6 | Refer to Table 6 | Refer to Table 6 |
| **Length of Exposure Modeled** | Chronic, subchronic and acute exposures | Chronic exposures | Chronic, subchronic and acute exposures | Chronic and acute exposures | Chronic exposures |
| **Human Receptors and Activities Modeled** | Adults, children and infants. Childhood exposures are considered for noncarcinogens | Adults and infants Childhood exposures are considered for noncarcinogens | Adults and children. Childhood exposures are considered for noncarcinogens | Adults and infants | Adults |
| | Residential and off-site worker exposures are considered. | Residential and off-site worker exposures are considered. | Residential and off-site worker exposures are considered in baseline health risk assessments | Residential and off-site worker exposures are considered | Residential exposure |
| **Intake Equations** | Input parameters are point estimates of average and RME | Input parameters are probability density functions | Input parameters are point estimates of average and 90-95th percentile (RME) | Input parameters are high end estimates | Input parameters are point estimates |
| | Fractional intake is considered in soil and food ingestion pathways | Fractional intake is considered in all exposure pathways | Fractional intake is considered in soil and food ingestion pathways | Fractional intake is considered in food ingestion pathways | Not applicable |
| | Default values of body surface area and body weight are "matched" | Correlation of contact rate and body weight is assumed | Default values of body surface area and body weight are "matched" | Default values of body surface area and body weight are "matched" | Default values of body surface area and body weight are "matched" |

**Table 6A. Comparison of contact factors recommended by Ca/EPA and US EPA**

**Residential Exposure Scenario (Adult)** (References for Table 6A are listed in Page C-26)

| | | **Hazardous Waste Site** | | | **Air Pollutant** | |
|---|---|---|---|---|---|---|
| **Exposure Pathway** | **Exposure Parameter** | **Hazardous Waste Program, DTSC, Cal/EPA (1)** | **Hazardous Waste Program, CalTOX DTSC, Cal/EPA (2) (6)** | **CERCLA, Office of Emergency and Remedial Response, US EPA** | **Air Toxics "Hot Spots" program (4) and Emission Permitting OEHHA, Cal/EPA** | **Clean Air Act, Air Quality Planning and Standards, US EPA** |
| **Inhalation exposure** | Inhalation rate ($m^3$/day) | 20 | 24 (a) | 20 (reasonable upper-bound for housewives, household workers and retired people) (3, 7) | 20 | 20 |
| | Exposure frequency (days/year) | 350 | NA* | 350 (7) | 365 | 365 |
| **Soil dermal contact** | Surface area of exposed skin ($cm^2$/day) | 5800 (RME)<br>5000 (average) | 5112 (b) | For outdoor activities: 5000 (typical), 5800 (reasonable worst case) (8) | 4656 | NA |
| | Soil loading on skin ($mg/cm^2$) | 1 | 0.5 [CV=0.4] | Whole body: average = 0.2 mg/cm2/day, RME = 1 mg/cm2/day | 0.5 | NA |
| | Fraction of soil from contaminated source | Site specific ? | NA* | 1 | 1 | NA |
| | Exposure frequency (days/year) | 100 | 137 events/year [CV= 0.6] | Pathway-specific (3)<br>350 (7) | 365 | NA |
| | Dermal absorption | Chemical specific (see Table 7) | Chemical specific (provided in the CalTOX) | Chemical specific (see Table 7) | Chemical specific (see Table 7) | NA |

* 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.

## Table 6A (continued). Comparison of contact factors recommended by Ca/EPA and US EPA

### Residential Exposure Scenario (Adult)

| | | Hazardous Waste Site | | | Air Pollutant | |
|---|---|---|---|---|---|---|
| **Exposure Pathway** | **Exposure Parameter** | **Hazardous Waste Program, DTSC, Cal/EPA (1)** | **Hazardous Waste Program, CalTOX DTSC, Cal/EPA (2) (6)** | **CERCLA, Office of Emergency and Remedial Response, US EPA** | **Air Toxics "Hot Spots" program (4) and Emission Permitting OEHHA, Cal/EPA** | **Clean Air Act, Air Quality Planning and Standards, US EPA** |
| **Soil ingestion** | Soil ingestion rate (mg/day) | 100 (age groups > 6 years old), 200 (for child between 1-6) | 10 (c) | 100 (age groups > 6 years old) (3, 7), 200 (for child between 1-6) | 110 (lifetime average) | NA |
| | Fraction ingested from contaminated source | Site specific | NA* | Pathway-specific value | 1 | NA |
| | Exposure frequency (days/year) | 350 | 137 events/year [CV=0.6] | Site specific (3)<br>350 (7) | 365 | NA |
| **Water ingestion** | Drinking water ingestion rate (l/day) | 2 | 1.4 (d) | 2 (90th percentile)<br>1.4 (average) (3) | 2 (lifetime average) | NA |
| | Exposure frequency (days/year) | 350 | NA* | 350 (7) | 365 | NA |
| **Vegetable ingestion** | Vegetable ingestion rate (kg/day) (wet weight ) | Fruit : 0.042<br>Vegetable : 0.08 | Fruits and vegetables: 0.3 (e)<br>Grain: 0.2 (f) | Fruit: 0.14<br>Vegetable: 0.2 (5) | Root crop, 0.05<br>Vine crop, 0.25<br>Leafy crop, 0.01 | NA |
| | Exposure frequency (days/year) | 350 | NA* | NA | 365 | NA |
| | Fraction ingested from contaminated source | Site specific, or 30-40% (7) | Fruits and vegetables: 0.24 [CV=0.7]<br>Grains: 0.12 [CV=0.7] | Fruit: 20% (typical) and 30% (reasonable worst case)<br>Vegetable: 25% (typical) and 40% (reasonable worst case) (5) | Site specific | NA |

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.

**Table 6A (continued). Comparison of contact factors recommended by Ca/EPA and US EPA**

**Residential Exposure Scenario (Adult)**

| | | Hazardous Waste Site | | | Air Pollutant | |
|---|---|---|---|---|---|---|
| **Exposure Pathway** | **Exposure Parameter** | **Hazardous Waste Program, DTSC, Cal/EPA (1)** | **Hazardous Waste Program, CalTOX DTSC, Cal/EPA (2) (6)** | **CERCLA, Office of Emergency and Remedial Response, US EPA** | **Air Toxics "Hot Spots" program (4) and Emission Permitting OEHHA, Cal/EPA** | **Clean Air Act, Air Quality Planning and Standards, US EPA** |
| **Milk ingestion** | Milk ingestion rate (kg/day) | NA | Milk and dairy: 0.26 (g) | Dairy products: 0.4 (5)<br>0.3 (7) | 0.3 | NA |
| | Exposure frequency (days/year) | 350 | NA* | 350 | 365 | NA |
| | Fraction ingested from contaminated source | NA | 0.4 [CV=0.7] | 0.4 (typical)<br>0.75 (reasonable worst case) (5) | Site specific | NA |
| **Meat ingestion** | Meat ingestion rate (kg/day) (wet weight ) | NA | Meat: 0.18 (h) | Beef: 0.1 (5) | 0.1 | NA |
| | Exposure frequency (days/year) | 350 | NA* | 350 | 365 | NA |
| | Fraction ingested from contaminated source | NA | 0.44 [CV=0.5] | 0.44 (typical)<br>0.75 (reasonable worst case) (5) | Site specific | NA |
| **Fish ingestion** | Fish ingestion rate (kg/day) (wet weight ) | 0.054 (recreational) | 0.02 (i) | 0.0065 (average for general population) (5);<br>0.054 (recreational);<br>0.132 (95th percentile for subsistence fishing) (7) | 0.024 | NA |
| | Exposure frequency (days/year) | 350 | NA* | 360 (7) | 365 | NA |
| | Fraction ingested from contaminated source | Site specific | 0.7 [CV=0.3] | Pathway-specific value | Site specific | NA |

* 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.

## Table 6A (continued). Comparison of contact factors recommended by Ca/EPA and US EPA

### Residential Exposure Scenario (Adult)

| | | Hazardous Waste Site | | | Air Pollutant | |
|---|---|---|---|---|---|---|
| **Exposure Pathway** | **Exposure Parameter** | **Hazardous Waste Program, DTSC, Cal/EPA (1)** | **Hazardous Waste Program, CalTOX DTSC, Cal/EPA (2) (6)** | **CERCLA, Office of Emergency and Remedial Response, US EPA** | **Air Toxics "Hot Spots" program (4) and Emission Permitting, OEHHA, Cal/EPA** | **Clean Air Act, Air Quality Planning and Standards, US EPA** |
| **Showering** | Inhalation exposure ($m^3$/hr) | NA | 1.33 m3/hr [CV=0.3] | 0.6 -showering (all age groups) (3) | NA | NA |
| | Skin surface area exposed ($cm^2$) | 23000 (upper bound, whole-body value) | 17040 (j) | Function of body weight | NA | NA |
| | Exposure time (hr/day) | 0.25 | 0.27 [CV=0.6] | 0.2 (90th percentile) 0.12 (50th percentile) (3) | NA | NA |
| | Exposure frequency (days/year) | 350 | NA* | 350 (7) | NA | NA |
| **Water ingestion during swimming** | Water ingestion rate | NA | 50 ml/day (k) | 50 (ml/hour) (3) | NA | NA |
| | Exposure time (hr/day) | NA | 0.5 [CV=0.5] | 2.6 (national average for swimming) (3) | NA | NA |
| | Exposure frequency (day/year) | NA | 15 [CV=4] | 7 (national average for swimming) (3) | NA | NA |
| **Dermal contact with chemicals in water during swimming** | Skin surface area available for contact ($cm^2$) | NA | 17040 (j) | 18200 (3) | NA | NA |
| | Exposure time (hr/day) | NA | 0.5 [CV=0.5] | 2.6 (national average for swimming) (3) | NA | NA |
| | Exposure frequency (day/year) | NA | 15 [CV=4] | 7 (national average for swimming) (3) | NA | NA |

* 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.

**Table 6A (continued). Comparison of contact factors recommended by Ca/EPA and US EPA**

**Residential Exposure Scenario (Adult)**

| | | Hazardous Waste Site | | | Air Pollutant | |
|---|---|---|---|---|---|---|
| **Exposure Pathway** | **Exposure Parameter** | **Hazardous Waste Program, DTSC, Cal/EPA (1)** | **Hazardous Waste Program, CalTOX, DTSC, Cal/EPA (2) (6)** | **CERCLA, Office of Emergency and Remedial Response, US EPA (3)** | **Air Toxics "Hot Spots" program (4) and Emission Permitting, OEHHA, Cal/EPA** | **Clean Air Act, Air Quality Planning and Standards, US EPA** |
| **General** | Body weight (kg) | 70 | 71 [CV=0.2] (adult, 16-70 years)<br>62 [CV=0.2] (child and adult combined) | 70 (average adult)<br>15 (1-6 years old) | 70 (average)<br>6.5 (infant) | 70 |
| | Exposure duration (year) | 30 (6 years as child and 24 years as adult) | 30 [CV=1] | 30 (90th percentile at one residence) (7)<br>9 years (50th percentile at one residence) | Chronic exposure: 70 years;<br>acute exposure: 1 hr | 70 |
| | Averaging time for Noncarcinogens (year) | 30 | 30 | 30 | Chronic exposure: 70 years;<br>acute exposure: 1 hr | 70 |
| | Averaging time for Carcinogens (year) | 70 | 70 | 70 | 70 | 70 |

Table 6A footnotes:

NA = Not available

Note: 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.

(a) 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 and 16 hr /day of active breathing and 8 hr/day of resting breathing

(b) 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

(c) 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

(d) Based on an average water ingestion rate of 0.02 l/kg-day [CV=0.2] and an average body weight of 71 kg

(e) Based on an average fruits and vegetables ingestion rate of 0.0042 kg/kg-day [CV=0.2] and an average body weight of 71 kg

(f) Based on an average grain ingestion rate of 0.0028 kg/kg-day [CV=0.2] and an average body weight of 71 kg

(g) 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

(h) Based on an average meat ingestion rate of 0.0026 kg/kg-day [CV=0.2] and an average body weight of 71 kg

(i) Based on an average fish ingestion rate of 0.00028 kg/kg-day [CV=0.3] and an average body weight of 71 kg

(j) 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

(k) Based on an average ingestion rate of 0.0007 l/kg-day [CV=1] and an average body weight of 71 kg

**Table 6B. Comparison of contact factors recommended by Ca/EPA and US EPA**

**Industrial/Commercial Exposure Scenario.** (References for Table 6B are listed in Page C-26)

| | | Hazardous Waste Site | | | Air Pollutant | |
|---|---|---|---|---|---|---|
| **Exposure Pathway** | **Exposure Parameter** | **Hazardous Waste Program, DTSC, Cal/EPA (1)** | **Hazardous Waste Program, CalTOX, DTSC, Cal/EPA (2) (6)** | **CERCLA, Office of Emergency and Remedial Response, US EPA** | **Air Toxics "Hot Spots" program (4) and Emission Permitting, OEHHA, Cal/EPA** | **Clean Air Act, Air Quality Planning and Standards, US EPA** |
| **Inhalation** | Inhalation rate ($m^3$/day) | 20 | NA | 20 $m^3$/8 hr-workday (7) | 20 $m^3$/8 hr-workday | NA |
| **Drinking water ingestion** | Drinking water ingestion rate (l/day) | 1 | NA | 1 (7) | NA | NA |
| **Ingestion of soil and dust** | Soil ingestion rate (mg/day) | 50 | NA | 50 (7) | NA | NA |
| **General** | Exposure frequency (days/year) | 250 | NA | 250 (7) | 260 | NA |
| | Exposure duration (years) | 25 | NA | 25 (7) | 46 | NA |

NA = Not available

## Table 6C. Comparison of contact factors recommended by Ca/EPA and US EPA

**Residential Exposure Scenario (Child)** (References for Table 6C are listed in Page C-26)

| | | Hazardous Waste Sites | | |
|---|---|---|---|---|
| **Exposure Pathway** | **Exposure Parameter** | **Hazardous Waste Program, DTSC, Cal/EPA (1)** | **Hazardous Waste Program, CalTOX, DTSC, Cal/EPA (2) (6)** | **CERCLA, Office of Emergency and Remedial Response, US EPA** |
| **Soil ingestion** | Soil ingestion rate (mg/day) | 200 (1 through 6 years old) | 64 (0-15 years) (l) | 200 (1 through 6 years old) (3) |
| | Fraction ingested from contaminated source | Site specific | Site specific | Pathway-specific value |
| | Exposure frequency (days/year) | 350 | NA* | 365 (3) |
| **Soil dermal contact** | Surface area of exposed skin ($cm^2$/day) | 2000 (1 to 6 years) | 2784 (0-15 years) (m) | NA |
| | Soil loading on skin ($mg/cm^2$) | 0.2 to 1 (average to RME) (8) | 0.5 [CV=0.4] | 0.2 to 1 (average to RME) (8) |
| | Fraction of soil from contaminated source | Site specific | NA* | Site specific |
| | Exposure frequency (days/year) | 350 | 137 [CV=0.6] | 350 |
| **Mother's milk ingestion** | Breast-milk ingestion rate (kg/day) | NA | 0.8 (n) | NA |
| | Frequency of exposure (days/year) | NA | 365 | NA |
| | Breast-feeding period (year) | NA | 1 | NA |
| **General** | Body weight of a child (kg) | 15 | 29 [CV=0.24] (child, 0-15 years) | 15 (1 through 6 years old, 50th percentile) (7) |
| | Body weight of an infant (kg) | NA | 7.2 [CV=0.3] (0-1 year) | NA |

* 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.

Table 6C footnotes:

NA = Not available

Note: 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.

(l) 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

(m) 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

(n) Based on an average breast-milk ingestion rate of 0.11 kg/kg-day [0.2] and an average body weight of 7.2 kg

## References for Tables 5, 6A, 6B, and 6C

(1) DTSC, Cal/EPA (1992). Supplemental Guidance for Human Health Multimedia Risk Assessments of Hazardous Waste Sites and Permitted Facilities. State of California Environmental Protection Agency, Department of Toxic Substances Control.

(2) DTSC, Cal/EPA (1993). CalTOX. A Multimedia Total Exposure Model for Hazardous-Waste Sites. Technical Reports. The Office of Scientific Affairs Department of Toxic Substances Control, California Environmental Protection Agency, Sacramento CA.

(3) US EPA (1989). Risk Assessment Guidance for Superfund Volume 1. Human Health Evaluation Manual (Part A). Interim Final. Office of Emergency and Remedial Response, Washington DC. EPA 540/1-89/002.

(4) CAPCOA (1993). Air Toxics "Hot Spots" Program. Toxics Committee of the California Air Pollution Control Officers Association (CAPCOA), Air Toxicology and Epidemiology Section Office of Environmental Health Hazard Assessment and the Toxic Air Contaminant Identification Branch Air Resources Board.

(5) US EPA (1989). Exposure Factors Handbook. United States Environmental Protection Agency, Office of Health and Environmental Assessment, Washington DC. EPA/600/8-89/043.

(6) DTSC, Cal/EPA (1993). Parameter Values and Ranges for CalTOX (Draft). The Office of Scientific Affairs Department of Toxic Substances Control, California Environmental Protection Agency, Sacramento CA.

(7) US EPA (1991). Human Health Evaluation Manual, Supplemental Guidance: "Standard Default Exposure Factors". Office of Emergency and Remedial Response and Office of Waste Programs Enforcement, United States Environmental Protection Agency, Washington DC.

(8) US EPA (1992). "Dermal Exposure Assessment: Principles and Applications." ORD, Washington, DC.

## Table 7. Dermal Absorption Values for Inorganic and Organic Chemicals

| | Hazardous Waste Site | | Air Pollutant |
|---|---|---|---|
| **Chemical** | **Hazardous Waste Program, DTSC, Cal/EPA (1)** | **Hazardous Waste Sites (CERCLA), US EPA Region IX** | **Air Toxics "Hot Spots" program (4) and Emission Permitting, OEHHA, Cal/EPA** |
| Inorganics (default values) | NA | 1% (2) | NA |
| Organics (default values) | 10% | 10% (2) | 10% |
| TCDD | 3% | 3% (2), 0.1 - 3% (3) | 2% |
| PCDDs and PCDFs | 3% | 3% (3) | 2% |
| Tetrachlorobiphenyl (TCB) | NA | 0.6 - 6% (3) | |
| PCBs and Aroclors | 15% | 6% (2 and 3) | 15% |
| Cadmium | 0.1% | 1% (2), 0.1 - 1% (3) | 0.2% |
| Arsenic | 3% | 3% (2) | 0.1% |
| Hexavalent chromium | 0% | NA | 1% |
| Other metals and complexed cyanides | 1% | NA | 0.1% |
| Free cyanide | 10% | NA | NA |
| Chlorinated insecticides | 5% | NA | NA |
| Polynuclear aromatic hydrocarbons | 15% | NA | 3% |
| Organophosphates | 25% | NA | NA |
| Pentachlorophenol | 25% | 25% (2) | 10% |

NA = not available

(1) DTSC, Cal/EPA (1994). Preliminary Endangerment Assessment, Guidance Manual.

(2) US EPA (1995). Region IX Preliminary Remediation Goals.

(3) US EPA (1992). Dermal Exposure Assessment: Principles and Applications. Office of Research and Development, United States Environmental Protection Agency, Washington DC. EPA/600/8-91/011B.

(4) CAPCOA (1993). Air Toxics "Hot Spots" Program. Toxics Committee of the California Air Pollution Control Officers Association (CAPCOA), Air Toxicology and Epidemiology Section Office of Environmental Health Hazard Assessment and the Toxic Air Contaminant Identification Branch Air Resources Board. (Values are for absorption from soil matrix, not solutions).

# 2.0 Exposure Assessment in Chemical-Specific Risk Assessments

## 2.1 Exposure Assessment Associated with Pesticide Usage (DPR, Cal/EPA)

Chemical-specific risk assessments are used by the DPR to evaluate health hazards that may be associated with pesticide usage, and to establish use procedures that are protective of human health. Exposure assessments are an integral portion of these risk assessments. DPR evaluates occupational exposures (application, harvesting, etc.), dietary exposures, exposures from use around the home, and other general population exposures (e.g., ambient air). There are fundamental differences between the dietary exposure scenarios and the other exposure scenarios, in both the data bases and exposure characteristics, and thus will be discussed separately. Assessment of dietary exposure is described in Section 2.1.1 and evaluation of occupational and residential exposure to pesticides is described in Section 2.1.2.

### 2.1.1 Evaluation of Dietary Exposure to Pesticides

In carrying out the mandates of AB 2161 (sometimes referred to as the Food Safety Act), DPR conducts a stand-alone assessment of dietary exposure to pesticide residues. In other comprehensive evaluations conducted by DPR, dietary exposure is combined with exposures from other sources to give an estimate of the total exposure to a specific pesticide. DPR evaluates the safety of pesticide residues in fresh produce and processed foods in the total diet, and examines the established tolerance levels. Because of the diversity in food consumption patterns in a population, DPR routinely evaluates the exposure of population subgroups based upon age, sex, race-ethnicity, and seasons (when applicable). DPR is in the process of attempting to harmonize its dietary exposure assessment procedures with those of US EPA.

Attached in this section is a brief overview of dietary exposure assessment at DPR that was prepared for harmonization discussions with the US EPA. Also attached are Tables 8, 9, and 10 that compare dietary exposure procedures at DPR with those of US EPA.

A more detailed description of the procedures used at DPR and US EPA to evaluate dietary exposure to pesticides can be found in “A Joint Review of Federal and State Pesticide Registration and Food Safety Programs: A Report to the California Legislature by the Pesticide Exposure to Children Committee” (DPR, 1994). The document also discusses the differences between the procedures used by the two agencies, and the reasons for these differences.

2.1.1.1 General Information

(A) Residue Data

Sources of Data: Include DPR and federal (FDA, USDA) regulatory monitoring programs, field residue trials, and registrant submitted survey studies. Some of the criteria for the choice of data are:

1) quality of data
2) representativeness (e.g., sample size, label-approved pesticide use)
3) the detection limits when no residue is detected in the majority of samples

General Assumptions: Although the residue levels at the time of sampling may not represent the levels at the time and/or in the form of consumption, data for making these adjustments are generally not available. Unless sufficient data exist, the following variables are not routinely accounted for:

1) change in residue level over time
2) residue reduction of non-systemic pesticides through washing/peeling
3) residue reduction in processing/food preparation (e.g., cooking)

Concentration Factor: Default concentration factors provided by the Technical Assessment Systems (TAS) are applied when food processing would result in concentrating/dehydrating. After applying the factor, the residue level at or below the relevant tolerance (i.e., for raw agricultural commodities or processed foods) is used.

(B) Consumption Data

Database used is from USDA's 1987-88 National Food Consumption Survey (NFCS) as compiled by TAS (1992).

(C) Exposures

The exposures of various population subgroups are analyzed for a specific pesticide. The subgrouping can be based on age, gender, and ethnicity (e.g., nursing and non-nursing infants, 1-6 yrs, 7-12 yrs, pregnant/nursing and non-nursing females above 13 yrs, male 13-19 yrs, male and female above 20 yrs, Hispanic, non-Hispanic. whites, non-Hispanic. blacks, non-Hispanic. others). Seasonal exposures can also be evaluated if data are sufficient for doing so.

(D) Computer Programs

TAS (1992) Exposure-4® and Exposure-1® are used in estimating the acute and chronic exposures, respectively. Data input consists of a single residue value for each of the commodities/food forms included in the analysis. Exposure-4® provides a distribution of exposures based on the consumption distribution of consumption-days (days the surveyed population/subgroup consumes at least one of the commodities included in the analysis). Exposure-1® provides the exposures based on the consumption of all surveyed population/subgroup (including both the non-consumption- and consumption-days).

2.1.1.2 Anticipated Residue Analysis - Acute Exposures

Residue levels: The default assumption is that all commodities for which a tolerance has been established can contain a level of residue. Depending on the availability of data, one of the following three assumptions is made when selecting the level of residue:

1) the highest detected level at or below the tolerance or, when statistically defensible, the 95th upper confidence limit
2) the tolerance when no residue data are available
3) the minimum detection limit (MDL) or minimum quantification limit (LOQ) when no residues are detected.

Exposures

The 95th percentile of the consumption-day exposure level for each population subgroup is generally taken as default upper bound of exposures for the calculation of margins of safety (MOSs). A MOS is the quotient of the NOEL and the exposure.

2.1.1.3 Anticipated Residue Analysis - Chronic Exposures

Residue levels: The default assumption is that all commodities for which a tolerance has been established can contain a level of residue equivalent to the average of all samples at or below the tolerance from a selected monitoring program. The samples with no residue detected are assumed to have residue at half of the MDL or LOQ. When no monitoring data are available, the residue is assumed to be at the tolerance.

Exposures

The average exposures of all surveyed population/subgroup are used for calculating the MOSs. The time-weighted lifetime exposure for estimating the oncogenic risk is calculated based on the age-specific exposures amortized over a lifetime.

2.1.1.4 Tolerance Assessment

The current DPR approach to evaluating the health protectiveness of tolerances is through the assessment of acute exposures to an individual commodity at the tolerance level. The 95th percentile of the consumption-day exposure level for each population subgroup is taken as default upper bound of exposures for the calculation of MOSs.

The risk of acute exposures to all label-approved commodities at their respective tolerances in a single setting/day is not evaluated because the occurrence is highly improbable. This is supported by the pattern of residue data shown in the many years of monitoring.

The risk of chronic exposures to either a single or all label-allowed commodities is also not evaluated because consuming commodities daily at tolerances for a lifetime of 70 years is highly improbable.

**Table 8. Dietary Exposure Assessment - General Aspects Comparison of US EPA and DPR, Cal/EPA**

| | US EPA | DPR |
|---|---|---|
| Assessment Approach | Tier Approach<br>Tier 1: Tolerance<br>Tier 2-4: residue adjustment | Anticipated Residue<br>& Tolerance Assessment |
| Computer Program | DRES | TAS |
| Exposure Estimation | Residue: Point estimate<br>Consumption: Distribution | Residue: Point estimate<br>Consumption: Distribution |
| Population Subgroup | Age/Gender (10)<br>Ethnic background (4)<br>Seasons (4)<br>US Geographic locations (4) | Age/Gender (10)<br>Ethnic background (4)<br>Seasons (4)<br>Western US (1) |
| Exposure Level[1] | Acute: 95-99th percentile<br>Chronic: average | Acute: 95 percentile<br>Chronic: average |
| Consumption Data | NFCS 1977-78 | NFCS 1987-88 |
| Routes of Exposures | Dietary | Dietary & other routes |
| Future Directions | 1) Exposure Assessment:<br>Monte Carlo analysis (DRES II)<br><br>2) Consumption data:<br>--- | <br>Monte Carlo analysis (TAS)<br><br><br>Include CSFII (via TAS) |

NFCS: National Food Consumption Survey by USDA
DRES: Dietary Risk Evaluation System
TAS: Technical Assessment Systems, Inc.
CSFII: Continuing Surveys of Food Intake of Individuals, by USDA; 1989-1992 available.
[1]The exposure level from each population subgroup used for the calculation of the margin of safety (MOS).

**Table 9. Anticipated Residue Analysis Comparison of US EPA and DPR, Cal/EPA**

| | US EPA | DPR |
|---|---|---|
| Exposure Assessment | Part of the Tier Approach | Stand-alone assessment |
| Exposure Scenarios | Acute and Chronic | Acute, Subchronic/Seasonal Chronic |
| Number of Commodities | Multiple | Multiple |
| Residue Database | Monitoring data (MD),<br>Marketplace Survey (MS),<br>Field Studies (FS),<br>Tolerance (T) | Monitoring data (MD),<br>Marketplace Survey (MS),<br>Field Studies (FS),<br>Tolerance (T) |
| Residue Level (acute) | T or high end of FS<br>Ave for mixed commodities<br>---<br>--- | High end of MD, MS, FS<br>---<br>MDL for non-detect<br>T for surrogate |
| Residue Level (chronic) | T, ave FS or high end of MD,MS<br>1/2 MDL for non-detect | Ave. of MD, MS or FS<br>1/2 MDL for non-detect |
| Residue Level (onco-genicity) | Average residue | Same as above |
| Residue Adjustment | 1) Processing<br>- Concentrating<br>- Reduction<br>2) % of Crop Treatment<br>- Acute: adjusted after 1st Tier<br>- Chronic: adjusted<br><br>3) "Single Serving Size" data<br>- Pending availability | <br>- Concentrating<br>---[1/]<br><br>- Acute: not adjustment<br>- Chronic: some adjustment<br><br><br>- Pending availability |

MDL: Minimum Detection Limit
[1]Adjustment for residue reduction under consideration pending data availability

**Table 10. Tolerance Evaluation Comparison of US EPA and DPR, Cal/EPA**

| | US EPA | DPR |
|---|---|---|
| Exposure Assessment | Part of the Tier Approach | Stand-alone assessment |
| Exposure Scenarios | Acute and Chronic (TMRC) | Acute |
| Number of Commodities | Multiple | Single |
| Residue Adjustment | 1) Processing | |
| | - Concentrating | - Concentrating |
| | - Reduction | --- |
| | 2) % of Crop Treatment | --- |
| | 3) Reduction in time[1] | --- |

[1]Adjustment made for declining residue level in time or during movement in commerce

2.1.2 Evaluation of Occupational and Residential Exposure to Pesticides

Cal/EPA, DPR conducts most of the pesticide exposure assessments for the State of California. Guidance for the production of pesticide exposure assessments for DPR is detailed in the document entitled "Guidance for the Preparation of Human Pesticide Exposure Assessment Documents" (DPR, 1993). The basis for producing exposure monitoring data and for conducting pesticide exposure assessment as practiced by US EPA Office of Pesticide Programs is summarized in three basic documents. Exposure assessment methods for handlers of pesticides (mixer/loader/applicator) is detailed in the document entitled "Pesticide Assessment Guidelines Subdivision U: Applicator Exposure Monitoring" (US EPA, 1986b). Exposure to pesticide residues on surfaces and in air following application are summarized in the document entitled "Pesticide Assessment Guidelines Subdivision K, Exposure: Reentry Protection" (US EPA, 1984). Because exposure to most pesticides occurs predominately via the dermal route, the US EPA "Pesticide Assessment Guidelines Subdivision F, Series 85-3 Dermal Absorption of Pesticides" are very important.

Two specific examples of DPR's exposure assessments are referenced which demonstrate the types of data and default assumptions used. Because of its volatile nature, 1,3-Dichloropropene produces exposure to both applicators and residents off-site. Its volatility also produces exposure almost exclusively via the inhalation route. Documents are appended by authors Powell and Sanborn that estimate exposure for residents and applicators, respectively. The document on the synthetic pyrethroid, fenpropathrin, is an example of exposure estimated for pesticide handlers with a minimal amount of pesticide specific data.

2.1.2.1 Default Factors in Pesticide Exposure Assessment

Enumerated in Table 11 are the point-by-point comparisons between US EPA's Occupational and Residential Exposure Branch (OREB) and Cal/EPA's Department of Pesticide Regulation (DPR) Worker Health and Safety Branch in regard to exposure assessment default assumptions that have been used over the last few years. It is difficult to characterize US EPA's position because it is rapidly evolving. The defaults ascribed to US EPA were taken from several documents including exposure assessments for fenamiphos, hydrogen cyanamide, and Subdivision U (referenced above). Cal/EPA, DPR's position on defaults and its rationale are available (DPR, 1993). Cal/EPA, DPR and US EPA, OREB are actively involved in ongoing harmonization discussions as summarized in the poster entitled "Harmonization of Issues Involving Pesticide Exposure Assessment in North America" (Ross, 1995), and US EPA appears to be moving toward using values closer to DPR's. Because several of the physiologic parameters have already been adopted by the US EPA's Office of Health and Environmental Assessment from the Exposure Factors Handbook (US EPA, 1989a), it is likely that OREB will come into conformance with DPR on these values. OREB is actively researching the basis for protection provided by engineering controls and personal protective equipment starting with work clothing, and indicate their preliminary findings are similar to those of

Cal/EPA. The defaults listed in Table 11 are only a portion of those in use. Default values for children's body weight, surface and inhalation rates are truncated to conserve space. The relatively high inhalation rate normalized to body weight dictates that children must be accounted for in residential exposure scenarios when a significant portion of the exposure is via inhalation. Similarly, the relatively high surface area to body weight ratios for infants necessitates estimating their exposure for surface residues of pesticides.

**Table 11. Default Exposure Factors Used by US EPA and Cal/EPA, DPR**

| FACTOR | | US EPA | DPR |
|---|---|---|---|
| Work Clothing Protection | | 50% | 90% |
| Full Body Chemical Resistant Protection | | 50% | 95% |
| Chemical Resistant Gloves Protection | | ? | 90% |
| Closed Mixing/Loading System Protection | | 50% | 95% |
| Closed Cab Protection | | 50% | 90% |
| Closed Filtered Air Cab (positive pressure) Protection | | ? | 98% |
| Full Face Respirator With Cartridges (Approved by NIOSH and/or MSHA) | | ? | 98% |
| Half Face Respirator With Cartridges (Approved by NIOSH and/or MSHA) | | ? | 90% |
| Water Soluble Bag Protection | | ? | 95% |
| | | | |
| Life Expectancy | | 70 yr | 75 yr |
| Years Worked per Lifetime | | 35 yr | 40 yr |
| Hours Worked per Day | | 8 hr | 8 hr |
| | | | |
| Breathing Rate (Rest) (L/min) | Adult Male | 7.4 | 12 |
| | Adult Female | 4.5 | 6 |
| | 6 yr old Male | ? | 6.7 |
| (Light Activ.) | Adult Male | 29 | 14 |
| | Adult Female | 16 | 8 |
| | 6 yr old Male | ? | 13.3 |
| | 1 yr old Male | ? | 4.2 |
| (Heavy) | Adult Male | 60 | 80 |
| | Adult Female | 25 | 48 |
| | 6 yr old Male | ? | 33 |
| | | | |
| Body Weight (kg) | Adult Male | 70 | 75.9 |
| | Adult Female | 54.8 | 61.5 |
| | 6 yr old Male | ? | 21.9 |
| | 1 yr old Male | ? | 10.5 |
| | | | |
| Body Surface Areas | Adult Male | 21,110 $cm^2$ | 19,400 $cm^2$ |
| | Adult Female | 21,110 $cm^2$ ? | 16,900$cm^2$ |
| | 6 yr old Male | ? | 8,660 $cm^2$ |
| | 1 yr old Male | ? | 3,925 $cm^2$ |
| Dermal Absorption Absent Data | | 100% | 100% |
| Respiratory Uptake Absent Data | | 100% | 50% |

## 2.2 Exposure Assessment Associated with the Setting of Water Standards

### 2.2.1 Exposure Considerations in Calculating Drinking Water Levels for Chemical Contaminants

Calculations of concentrations of chemical contaminants in drinking water associated with cancer risks of $10^{-4}$ to $10^{-6}$, or negligible risk for non-carcinogens, must take into account the toxicity of the chemical itself, as well as the potential exposure of individuals using the water. Tap water is used directly as drinking water, for preparing foods and beverages, and for bathing or showering.

The OEHHA of Cal/EPA uses the following equations for calculating negligible risk levels of chemical contaminants in drinking water.

For non-carcinogens:

$$c = \frac{\text{NOAEL x RSC}}{\text{UF x l/day}} = \text{mg/L}$$

For carcinogens:

$$c = \frac{\text{BW x } 10^{-6} \text{ x RSC}}{q_1^* \text{ x l/day}} = \text{mg/L}$$

where:

| | | |
|---|---|---|
| c | = | concentration associated with negligible risk |
| NOAEL | = | no observed adverse effect level |
| RSC | = | relative source contribution |
| UF | = | uncertainty factor |
| l/day | = | liters per day of water consumed |
| BW | = | body weight |
| $q_1$* | = | upper 95% confidence limit on the cancer potency slope |
| mg/L | = | milligrams of contaminant per liter of drinking water |

There are two factors in these equations which make up the consideration of exposure. The Relative Source Contribution (RSC) is a factor which is based on an estimate of the contribution of drinking water relative to other sources of exposure to the chemical contaminant. The other sources are food, air, etc. Often food is the most significant source of exposure in addition to drinking water exposure. The RSC default used by both Cal/EPA and the US EPA is 20%. This is based on the assumption that drinking water makes up 20% of the exposure to the chemical. The other 80% comes from the diet and other sources. In those cases where OEHHA has data on which to base a more precise estimate of the value for the RSC, OEHHA uses the available information to estimate an RSC other than the default. When this is done the RSC may assume a value anywhere from 10% to 100%. The US EPA restricts RSC values to the 20% to 80% range in performing their calculations of negligible risk drinking water levels.

US EPA uses RSC only in calculations for non-carcinogens. Cal/EPA uses RSC for some carcinogens, for example arsenic.

The other exposure factor in the equation is the water intake in l/day. This factor represents the amount of drinking water which an individual consumes as drinking water, as well as mixed with beverages and used in cooking. The adult default for this factor is 2 l/day. For children, 1 l/day is used.

For some chemicals dermal absorption may contribute significantly to exposure. Inhalation of volatile materials released from tap water may also contribute. If a review of the exposure information reveals this to be the case, then an estimate is made of the contribution of the various routes of exposure, and the equivalent amount of exposure is added to the water intake in liter equivalents per day (leq/day). For example, if it were estimated bathing and/or showering could add an exposure equivalent to drinking 2 l/day, then the total would be 4 leq/day to account for both drinking and bathing/showering. For this chemical 4 leq/day would be used in the equation to calculate the negligible risk level in drinking water. With the apparent exception of radon, US EPA considers only ingestion of drinking water in calculating negligible risk levels for chemical contaminants. In this way the California method which considers the inhalation and dermal absorption routes of exposure is more health protective than the US EPA method which considers only ingestion.

Table 12 compares the default values and ranges used by OEHHA, Cal/EPA and US EPA in calculating drinking water levels for chemical contaminants. Table 13 gives some examples of RSC and leq/day values used by OEHHA, Cal/EPA in calculating drinking water levels for chemical contaminants.

**Table 12. Comparison of OEHHA, Cal/EPA and US EPA methods for calculating drinking water levels based on adult exposures**

| | ***OEHHA, Cal/ EPA Method*** | | ***US EPA Method*** | |
|---|---|---|---|---|
| | **RSC** | **leq/day** | **RSC** | **leq/day** |
| default value | 20% | 2 | 20%* | 2 |
| range | 10% to 100% | 2 or greater | 20% to 80% | 2 |

* US EPA uses RSC only for non-carcinogens. Cal/EPA uses RSC for some carcinogens, for example arsenic.

**Table 13. RSC and leq/day values used by OEHHA, Cal/EPA in calculating drinking water levels**

| **Chemical Contaminant** | **RSC** | **leq/day** |
|---|---|---|
| Aluminum | 17% | 2 |
| Arsenic | 20% | 2 |
| Copper | 100% | 1 (child exposure) |
| Trichloroethylene (TCE) | 100% | 7 |
| Uranium | 50% | 2 |

2.2.2 Exposure Considerations in Determining Water Quality Objectives for Protection of Human Health (SWRCB, Cal/EPA)

Under the Ocean Plan, the SWRCB evaluates potential health hazards associated with the consumption of contaminated fish and shellfish. Similar to the approach used by US EPA, SWRCB determines criteria for human health based on two types of biological endpoints:

1) carcinogenicity
2) systemic toxicity, which is defined as all adverse effects other than cancer.

US EPA uses the following formula to calculate water quality criteria for carcinogens:

$$C = \frac{70 \times 10^{-6}}{q^{1*}[WI + (0.0065)(BCF)]}$$

Where: C = water quality objective (mg/l)
WI = average human water intake (l/day)
(this factor is typically assumed to be 2 l/day; it is not used when calculating water quality objectives for saline waters
$q^{1*}$ = cancer potency factor (kg-day/mg)
BCF = bioconcentration factor (l/kg)

In this equation, 70 represents the weight of a standard person in kg and 0.0065 is an estimate of the average daily consumption (in kg/day) of fresh water fish and estuarine fish and shellfish on a per capita basis. $10^{-6}$ represents a risk level of 1 excess cancer per 1,000,000 persons (however, US EPA will accept cancer risk policies from the States in the range of $10^{-5}$ to $10^{-7}$). All of the BCF values were obtained from EPA Region VIII CWA 304(a) Criteria Chart Indicating Published Criteria and Updated Human Health Values, current for the triennium 1994-1996. Since US EPA Region IX has not developed a similar criteria chart for BCF values, Region IX staff recommended use of the EPA Region VIII criteria chart.

In developing the 1990 Ocean Plan, the SWRCB used the equation shown above for calculation of water quality objectives for carcinogens, but used 0.023 kg/day as an estimate of average total daily seafood consumption. This estimate of daily fish consumption is based on rationale developed by the California Department of Health Services (CDHS) and submitted to the SWRCB during the previous triennial review. CDHS reviewed literature published between 1971 and 1989 which reported average daily fish/shellfish consumption rates within the range of 23 to 40 g/day for consumers. CDHS concluded that average fish and shellfish consumption rate was at least 23 grams per day and recommended this value to be used for the development of Ocean Plan.

US EPA uses the following formula to calculate water quality criteria for noncarcinogens:

$$C = \frac{70 \times RfD}{WI + [(0.0065)(BCF)]}$$

Where: C = water quality objective (mg/l)
WI = average human water intake (l/day)
(this factor is typically assumed to be 2 l/day; it is not used when calculating water quality objectives for saline waters
RfD = reference dose (mg/kg-day)
BCF = bioconcentration factor (l/kg)

70 represents the weight of a standard person in kg and 0.0065 is an estimate of the average daily seafood consumption (in kg/day). The SWRCB uses this same US EPA equation for calculation of water quality objectives for noncarcinogens, but substitutes 0.023 kg/day as an estimate of daily seafood consumption.

For more detailed information about the Ocean Plan, please refer to the "Draft Functional Equivalent Document, Amendment of the Water Quality Control Plan for Ocean Waters of California".

## 2.3 Toxic Air Contaminant Identification and Control Program (ARB, Cal/EPA)

The California Toxic Air Contaminant Program was designed for the risk assessment and risk management of toxic air contaminants. This program is required by a California law which took effect in 1984 (AB 1807, Tanner, Chapter 1047, Statutes of 1983, Health and Safety Code sections 39650-39674). It created a comprehensive program administered by the ARB to address the adverse public health impacts caused by exposure to toxic substances emitted into the ambient air. Under Health and Safety Code section 39660 (f), the ARB evaluates the potential for human exposure to the substance in California. This includes evaluating emissions from many types of sources, the uses of substances, near source ambient, statewide ambient and indoor concentrations, and atmospheric persistence and fate.

The ARB Monitoring and Laboratory Division (MLD) has comprehensive programs for ambient monitoring of toxic compounds, criteria pollutants, hydrocarbons, acid deposition, and meteorology. The toxics monitoring program supports the California's Toxic Air Contaminant Program and the monitoring network consists of 22 stations located throughout the state (See Table 14) and 3 in Mexico. The toxic compounds that MLD currently monitors and the sampling schedules are listed in Table 15.

To estimate the population exposure in the ambient air to a toxic compound, an average population-weighted statewide ambient concentration is calculated. If ambient measurements of a substance are available from the ARB's toxic monitoring network the ARB uses that data and latest population census data to estimate the population-weighted statewide annual average concentrations. To estimate a population-weighted statewide average ambient concentration, the Technical Support Division (TSD) of the ARB interpolates mean annual concentrations derived from the monitoring stations to census tract centroids for the most populous areas of California. For other areas, the annual mean concentrations for all of the monitoring stations in a given area are averaged, and the entire population of each monitored area is assumed to be exposed to this average concentration.

To estimate the population exposure in the ambient air to a toxic compound when no ambient measurements are available, TSD models the emissions of the substance from all known sources within a certain area. One tool for this is air dispersion modeling with a US EPA approved model such as the Industrial Source Complex model (ISC 3). This model uses emission rates, meteorological data, and source characteristics to predict a one-hour maximum or an annual average ambient concentration. The results of this analysis provide an approximation of what the ambient concentrations a population would be exposed to if ambient monitoring had been conducted. For estimating the near source ambient concentration, TSD also uses the ISC 3 model which can predict average 1-hour and annual near source concentrations. Ambient measurements for near source exposure may be available due to regulations requiring monitoring for that substance. For example, some facilities that emit lead into the air are monitored to make sure that

the ambient levels do not exceed the federal and state ambient air quality standards for lead.

Sophisticated exposure assessment tools have not been available to fully incorporate indoor and personal exposure information into the exposure assessments. In recognition that people spend an average of 85 percent of their time indoors and that time accounts for a major portion of exposure, the ARB funded the development of a population exposure model, called the California Population Indoor Exposure Model (CPIEM), to facilitate improved population exposure estimates. The CPIEM is nearing completion and is currently undergoing internal ARB review. It combines activity pattern data and breathing data from studies of California adults and children with pollutant concentration data from various microenvironments (such as inside residences, public buildings, and vehicles, and outdoors) to estimate distributions of both population exposure and inhaled dose. The CPIEM can provide population exposure and inhaled dose distributions for specific microenvironments, for total indoor exposure and inhaled dose, and for total (indoor and outdoor) exposure and inhaled dose. The model is currently being used to refine estimates of population exposure to diesel exhaust, and is likely to be used to develop more refined, quantitative indoor and total exposure estimates for most toxic pollutants addressed by the ARB in the future.

The ARB's exposure assessments for identifying substances as toxic air contaminants provide information on the California population exposure to the statewide and near source ambient concentrations to a certain toxic substance. These exposure assessments also include information on emissions estimates, uses, and atmospheric fate from the most recent studies and literature available. The exposure assessments for the following substances are available upon request: acetaldehyde, asbestos, benzene, benzo[a]pyrene, 1,3-butadiene, cadmium, carbon tetrachloride, chlorinated dioxins/furans, chloroform, diesel exhaust (draft), ethylene dibromide, ethylene dichloride, formaldehyde, ethylene oxide, hexavalent chromium, inorganic arsenic, inorganic lead (draft), methylene chloride, trichloroethylene, vinyl chloride, nickel, and perchloroethylene.

**Table 14. ARB Toxics Monitoring Network: Monitoring Stations**

| LOCATION | OPERATING AGENCY |
|---|---|
| Bakersfield | ARB |
| Burbank | South Coast Air Quality Management District |
| Calexico | ARB |
| Chico | ARB |
| Chula Vista | San Diego County Air Pollution Control District |
| Roseville | ARB |
| Concord | Bay Area Air Quality Management District |
| El Cajon | San Diego County Air Pollution Control District |
| Fremont | Bay Area Air Quality Management District |
| Fresno | ARB |
| Los Angeles | South Coast Air Quality Management District |
| Long Beach | South Coast Air Quality Management District |
| Modesto (2)* | ARB |
| Richmond | Bay Area Air Quality Management District |
| Rubidoux | South Coast Air Quality Management District |
| San Francisco | Bay Area Air Quality Management District |
| San Jose | Bay Area Air Quality Management District |
| Santa Barbara | Santa Barbara County Air Pollution Control District |
| Simi Valley | Ventura County Air Pollution Control District |
| Stockton | ARB |
| Upland | South Coast Air Quality Management District |

* There is one monitoring station at each location, with the exception of Modesto which has two.

**Table 15. ARB Toxics Monitoring Network: Compounds and Sampling Schedule**

| TOXIC COMPOUND | SAMPLING SCHEDULE |
|---|---|
| VOCs: | Every 12 days for 24 hours |
| Benzene | |
| 1,3-Butadiene | |
| Chlorobenzene | |
| Ethylene Dibromide | |
| m-, o-, and p-Dichlorobenzene | |
| Methylene Chloride | |
| Ethenylbenzene (styrene, vinylbenzene) | |
| Ethylbenzene | |
| Perchloroethylene | |
| Carbon Tetrachloride | |
| Toluene | |
| Chloroform | |
| Methyl Chloroform | |
| Trichloroethylene | |
| m-, o-, p-Xylene | |
| Carbonyls: | Every 12 days for 24 hours. |
| Acetaldehyde | |
| Formaldehyde | |
| Methyl Ethyl Ketone | |
| Polycyclic Aromatic Hydrocarbons (PAHs): | Twice a month for 24 hours |
| Benzo[a]pyrene | |
| Benzo[b]fluoranthene | |
| Benzo[k]fluoranthene | |
| Dibenz[a,h]anthracene | |
| Benzo[g,h,i]perylene | |
| Indeno[1,2,3-cd]pyrene | |
| Toxic Metals: | Every 12 days for 24 hours |
| Arsenic | (Every 6 days in Kern County) |
| Cadmium | (Every 6 days in Kern County) |
| Chromium | |
| Hexavalent Chromium | |
| Lead | |
| Manganese | |
| Nickel | |

(Source: Air Resources Board. October 13, 1995. "Ambient Monitoring Activities". Memorandum from Bill Loscutoff, Chief, Monitoring and Laboratory Division to Monitoring and Laboratory Division Staff. Sacramento, CA.)

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# CAppendix D

# An Overview of Fate and Transport Models Commonly Used in Analyses Developed or Reviewed by Cal/EPA

## Introduction

Fate and transport models are used by the California Environmental Protection Agency (Cal/EPA) and the regulated community to predict contaminant concentrations in environmental media, supplement monitoring data, and design control or remedial actions. With a few exceptions, Cal/EPA does not develop fate and transport models but may recommend a list of models that are widely used by the modeling community and supported by the U.S. Environmental Protection Agency (US EPA). The purpose of this document is to provide an overview of the models commonly used in analyses developed or reviewed by the agency.

There is considerable flexibility within Cal/EPA regulatory programs for selection and use of air or ground water models to address specific situations and regulatory program needs. In general Cal/EPA gives the responsible party or consultant the responsibility of model selection. As long as the proposed model fulfills a set of criteria and is expected to give reliable results, it is deemed acceptable for the regulatory purpose. To help the regulated community, Cal/EPA has published documents such as "Ground Water Modeling for Hydrogeologic Characterization - Guidance Manual for Ground Water Investigations" (Cal/EPA, 1994) to assist risk assessors in the selection and application of ground water models. Similarly, the State Water Resources Control Board (SWRCB) is in the process of developing a general method for evaluating ground water model applications to provide guidance to the Regional Water Quality Control Boards (RWQCBs).

The fate and transport models used or reviewed by Cal/EPA can be categorized into three types: air models, ground water models, and inter-media transfer models. Brief descriptions of these models and their applications are provided in Tables 1, 2, 3, and 4~~3, respectively~~.

## Air Models

The Air Resources Board (ARB) and Department of Toxic Substances Control (DTSC) use air dispersion models for evaluating health impacts associated with emissions from, for example, industrial stacks, incinerators, and hazardous waste sites.

The Department of Pesticide Regulation (DPR) uses air dispersion models to supplement pesticide monitoring and regulate pesticide applications. Four air models commonly used by Cal/EPA are listed in Table 1; they are: SCREEN; Industrial Source Complex Model (ISC); Complex Terrain Dispersion Model Plus Algorithms for Unstable Situations (CTDMPLUS); and Fugitive Dust Model (FDM). With the exception of FDM, the other three models are also recommended by US EPA for modeling the movement of airborne contaminants. In addition to these four models, ARB also uses the Urban Airshed model to estimate the formation of photochemical ozone and the SARMAP (SJVAQS/AUSPEX Regional Model Adaptation Project) to evaluate regional air quality.

## Ground Water Models

Table 2 describes some of the ground water models that are commonly used in assessments submitted to DTSC and SWRCB for review. These models are used to evaluate health and environmental impacts associated with landfills, leaking underground storage tanks and hazardous waste sites. Under the ~~In~~ regulatory programs of DTSC, RWQCBs, and SWRCB, ground water modeling is most often used for one or more of the following purposes: (a) to demonstrate ground water contamination is not likely, (b) to determine the timeframe when off-site wells will be impacted, or (c) to evaluate remedial pump and treatment systems. Vadose zone models, such as VLEACH, are often used by consultants to demonstrate that contaminants in soil will not move and impact the ground water. In addition to modeling, DTSC and RWQCBs generally also require soil contaminant solubility analysis and installation of monitoring wells to confirm that ground water, as a natural resource and as a human exposure medium, is not likely to be impacted. Ground water transport models, such as RESSQ and MODFLOW, are often used to predict the timeframe until public or private water supply wells are affected by contaminants in soil or ground water. This information plays an important role in determining the urgency of remedial action at each site. Ground water models, such as FLOWPATH, are also used to demonstrate that the well spacing and pumping rate is sufficient to intercept any migration of contaminants past a given point. In this way, ground water models are used by consultants and regulators to identify potential problems with the remedial design and protect the ground water resource.

For purposes of predicting potential health risks from using or consuming ground water at the site, risk calculations in the baseline risk assessment are primarily based on ground water monitoring data. The standard practice of assessing potential risks associated with a drinking water well (often hypothetical) is to assume that the well is located in the plume of contamination. This is the usual practice for California Superfund sites since most of the ground water within the state has been designated as actual or potential drinking water sources. There are exceptions, however, where human health risk assessments are based on ~~sophisticated~~ ground water modeling results. For example, chemical movement from soil to ground water was modeled at March Air Force Base (OU2) using VLEACH and MixCell, and the modeled ground water concentrations were used in a human health risk assessment.~~This level of ground water modeling effort~~

~~is not common and is usually found at large hazardous waste sites.~~ It is likely that more ground water modeling will be conducted at other military facilities and waste sites in the future, and the ground water modeling results will be used in the risk assessments.

~~The ground water models listed in Table 2 are divided into three groups: (a) release models, (b) flow models, and (c) flow and contaminant fate and transport models. Release models, such as VLEACH and SESOIL, are used to predict the movement of contaminants from the soil column into the ground water. Flow models are used by hydrogeologists for the prediction of direction and flow rate of ground water. FLOWPATH and MODFLOW are two numerical models commonly encountered by Cal/EPA. Flow and contaminant fate and transport models are similar to flow models, but they also consider transport and transformation processes including absorption, chemical reaction, dispersion, and biodegradation. BIOPLUME II, MT3D, and AT123D are three examples. Table 3 summarizes some of the characteristics of these models.~~

## Inter-Media Transfer Models

Table 4 describes procedures developed by Cal/EPA to predict inter-media transfer of environmental contaminants.

CalTOX is a fugacity model developed by DTSC for evaluating the time dependent movement of contaminants in various environmental media. The model~~It~~ is designed to be used for stochastic analyses but can also be used deterministically. The model algorithm has gone through extensive external reviews, and the model capability and reliability have been evaluated through a number of validation studies. A brief development history and implementation schedule of CalTOX is included in Attachment D-1.

To implement the Air Toxics "Hot Spots" Program, CAPCOA and OEHHA have developed a series of inter-media transfer equations for estimating indirect exposure to airborne contaminants. Risk assessors within and outside the state government use these equations for estimating health hazards associated with an emission source. Finally, the Solid Waste Ranking System (SWRS) is a ranking model developed by the California Integrated Waste Management Board (CIWMB) to rank closed solid waste disposal sites and prioritize their clean-ups.

## Other Models

Cal/EPA generally does not use surface water models for regulatory purposes. However, there are a number of projects that monitor the impact of environmental pollutants to surface water. ~~Some of the findings of these projects are included under Tab 4 of the briefing book.~~ Not included in this document are other screening level fate and transport models commonly used in CERCLA and RCRA programs. Most of these models can be found~~are described~~ in the Superfund Exposure Manual (US EPA, 1988)~~and are provided under various tabs of the briefing book.~~

~~Committee members who want more information on any of the models or procedures mentioned in this document or the briefing book can contact Dr. David Ting at (510) 540-2084.~~

**Table 1. Air models commonly used in analyses developed or reviewed by Cal/EPA**

| Model Name | Model Type and Description | Application | Cal/EPA Program/Department |
|---|---|---|---|
| SCREEN | SCREEN is a simple Gaussian plume model suitable for screening purposes. It can be used to estimate 1-hour maximum ground-level concentrations and the distance to the maximum effects of building downwash on the maximum concentrations, concentrations due to inversion break-up and shoreline fumigation, and determining plume risk for flare releases. Adjustment factors can be used to estimate longer term average concentrations based on the maximum 1-hour values. | The model is used to model stack, simple area and simple volume sources. It is often used to quickly determine if either (1) the source clearly poses no air quality problem or (2) the potential for an air quality problem exists. | Air Toxics "Hot Spots" Program (ARB, OEHHA) |
| Industrial Source Complex Model (ISC) | ISC is a steady-state Gaussian plume model which can be used to assess pollutant concentrations from a wide variety of sources associated with an industrial source complex. The model can account for the following: settling and dry deposition of particles; downwash; area, line and volume sources; plume rise as a function of downwind distance; separation of point sources; and limited terrain adjustment. It operates in both long-term (ISCLT) and short-term (ISCST) modes. | ISCST is used by DPR to evaluate environmental impact from area and point sources. For example, it is used to estimate flux rates using back calculation procedures, to understand and normalize off-site air concentration monitoring results, to determine buffer zone for pesticide application, and to set conditions for aeration of building.<br><br>ISCST and ISCLT are used to estimate contaminant concentration at off-site locations due to facility emissions.<br><br>ISCLT is used to estimate contaminant concentration at off-site locations due to hazardous waste sites | Environmental Monitoring and Pest Management Branch (DPR)<br><br>Air Toxics "Hot Spots" Program (ARB, OEHHA) and Toxic Air Contaminant Program (ARB)<br><br>CERCLA and RCRA (DTSC) |

**Table 1. Air models commonly used in analyses developed or reviewed by Cal/EPA (continued)**

| Model Name | Model Type and Description | Application | Cal/EPA Program/Department |
|---|---|---|---|
| Complex Terrain Dispersion Model Plus Algorithms for Unstable Situations (CTDMPLUS) | CTDMPLUS is a refined point source Gaussian air quality model for use in all stability conditions for complex terrain applications. It requires more detailed meteorological data and terrain information than SCREEN and ISC. | The model is used for evaluating contaminant concentration at off-site locations due to a point source. | Air Toxics "Hot Spots" Program (ARB, OEHHA) and Toxic Air Contaminant Program (ARB)<br><br>CERCLA and RCRA (DTSC) |
| Urban Airshed Model with Carbon Bond IV Chemistry (UAM/CB-IV) | UAM/CB-IV is an urban scale, three dimensional, grid type numerical simulation model. The model incorporates a condensed photochemical kinetics mechanism for urban atmospheres. | The UAM/CB-IV is used by local air districts and ARB for computing ozone ($O_3$) concentrations using short-term, episodic conditions lasting one or two days resulting from emissions of oxides of nitrogen ($NO_x$), volatile organic compounds (VOC), and carbon monoxide (CO). | Local air districts and ARB for California Clean Air Act planning purposes |
| SARMAP | The SARMAP modeling system consists of the SARMAP Meteorological Model (SMM), the SARMAP Air Quality Model (SAQM), and the SARMAP Emissions Inventory Model (SEIM). The SMM is a non-hydrostatic three-dimensional model to predict the wind components, temperature, mixing ratio, pressure perturbation, ground temperature, mixing depth, cloud cover, precipitation, and vertical diffusivity of heat and momentum. The SAQM is a three dimensional regional-scale non-hydrostatic model capable of simulating transport, dry deposition, and chemical transformation. The SEIM emissions model is designed to accept time and space-varying meteorological input with the capability of modifying and adjusting emission rates and emission projections. | Same as above but designed for the San Joaquin Valley | Same as above but designed for the San Joaquin Valley |

**Table 1. Air models commonly used in analyses developed or reviewed by Cal/EPA (continued)**

| Model Name | Model Type and Description | Application | Cal/EPA Program/Department |
|---|---|---|---|
| Fugitive Dust Model (FDM) | It is an air quality model specifically designed for computing concentration and deposition impacts from fugitive dust sources. The model is based on the well-known Gaussian Plume formulation for computing concentrations, but it has been specifically adapted to incorporate an improved gradient-transfer deposition algorithm. | FDM is used to estimate concentration of airborne soil particles at off-site locations as a result of either human activities or the action of wind. | CERCLA and RCRA (DTSC) |

**Table 2. Ground water models commonly used in analyses developed or reviewed by Cal/EPA**

| Model Name | Model Type and Description | Application | Cal/EPA Program/Department |
|---|---|---|---|
| VLEACH | One-dimensional finite-difference vadose zone organic contaminant fate and transport model. | Vadose zone fate and transport simulation which requires consideration of only one-dimension. | SWRCB and RWQCBs |
| SESOIL | Finite difference soil compartment model for hydrologic, sediment and pollutant fate. | Soil compartment simulations, especially for risk assessment. Commonly used to provide concentration values for saturated zone models (especially AT123D). The SWRCB's LUFT Manual, which may be revised, currently has criteria based on SESOIL. | SWRCB and RWQCBs<br><br>Hazardous waste programs (DTSC) |
| HELP | One-dimensional analytical water budget model. | Estimation of water in- and out- flow by leachate formation in landfills and waste piles to make decisions regarding design and siting. Commonly used to provide input for fate and transport models (especially MULTIMED). | SWRCB and RWQCBs<br><br>Hazardous waste programs (DTSC) |

**Table 2. Ground water models commonly used in analyses developed or reviewed by Cal/EPA (continued)**

| Model Name | Model Type and Description | Application | Cal/EPA Program/Department |
|---|---|---|---|
| MULTIMED | Multimedia exposure assessment model which simulates contaminant transport and transformation by analytical and semi-analytical approach. | Multimedia environmental risk assessment, screening level contaminant fate and transport calculations. | SWRCB and RWQCBs |
| FLOWPATH | Two-dimensional, single aquifer flow model. | Delineation of flow and hydraulic head distribution within a single aquifer under steady-state and transient conditions. Usually used for well-head and capture zone delineations. | SWRCB and RWQCBs |
| BIOPLUME II | Two-dimensional single aquifer finite-difference flow and contaminant fate and transport model by plume delineation. | Delineation of hydrocarbon plumes released into saturated zone. | SWRCB and RWQCBs |
| RESSQ | Two-dimensional, semi-analytical contaminant transport model | Delineation of contaminant fronts in a homogeneous, isotropic confined aquifer. | CERCLA and RCRA (DTSC) |
| MODFLOW | Three-dimensional multiaquifer flow model. | Delineation of flow and hydraulic head distribution within aquifers in three-dimensions and steady-state and transient conditions. Usually used to provide input to three-dimensional contaminant fate and transport modeling (especially MT3D, see below). | SWRCB and RWQCBs<br><br>CERCLA and RCRA (DTSC) |

**Table 2. Ground water models commonly used in analyses developed or reviewed by Cal/EPA (continued)**

| Model Name | Model Type and Description | Application | Cal/EPA Program/Department |
|---|---|---|---|
| MT3D | Three-dimensional multiaquifer finite-difference contaminant fate and transport model. | Three-dimensional contaminant fate and transport delineation within complex saturated zone systems. | SWRCB and RWQCBs |
| AT123D | Three-dimensional analytical flow and contaminant fate and transport model. | Three-dimensional contaminant fate and transport for uniform conditions. Usually used for risk assessment (especially in combination with SESOIL described above). The SWRCB's LUFT Manual, which may be revised, currently has criteria based on AT123D. | SWRCB and RWQCBs CERCLA and RCRA (DTSC) |

**Table 3. Capabilities and limitations of some commonly used mathematical models**

| MODELS | PROCESS | | | DIMENSION | | | MEDIA | | | | | MATHEMATICAL APPROACHES | | | | | SYSTEM VARIABILITY | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | GROUND WATER | | | | | | NUMERICAL | | | | | | |
| | | | | | | | | POROUS | | FRACTURED | | | | | | | | | | |
| | FLOW | TRANSPORT | TRANSFORMATION | ONE-D | TWO-D | THREE-D | SURFACE WATER | VADOSE ZONE | SATURATED ZONE | VADOSE ZONE | SATURATED ZONE | ANALYTICAL | SEMI-ANALYTICAL | FINITE DIFFERENCE | INTEGRATED FINITE DIFFERENCE | FINITE ELEMENT | HOMOGENOUS | HETEROGENOUS | ISOTROPIC | ANISOTROPIC |
| **MODFLOW** | ■ | | | | | ■ | | | ■ | | | | | ■ | | | | ■ | | ■ |
| **FLOWPATH** | ■ | | | | ■ | | | | ■ | | | | | ■ | | | | ■ | | ■ |
| **DELTA** | ■ | | | | ■ | | ■ | | ■ | | | | | ■ | | | | ■ | ■ | |
| **MULTIMED** | | ■ | ■ | ■ | | ■ | | ■ | ■ | | | ■ | ■ | | | | ■ | | ■ | |
| **AT123D** | | ■ | | ■ | ■ | ■ | | | ■ | | | ■ | | | | | ■ | | ■ | |
| **BIO1D** | | ■ | ■ | ■ | | | | | | | | | | | | | | | | |
| **BIOPLUME II** | | ■ | ■ | | ■ | | | | ■ | | | | | ■ | | | ■ | | ■ | |
| **MT3D** | | ■ | ■ | | ■ | | | | ■ | | | | | ■ | | | | ■ | | ■ |
| **VLEACH** | | ■ | | ■ | | | | ■ | | | | | | ■ | | | ■ | | ■ | |
| **SESOIL** | | ■ | ■ | ■ | | ■ | | ■ | | | | | | ■ | | | | ■ | | ■ |
| **FTRANS** | | ■ | ■ | | ■ | | | | ■ | | ■ | | | | | ■ | | ■ | | ■ |
| **TOUGH** | | ■ | | | | ■ | | ■ | | ■ | | | | | ■ | | | ■ | | ■ |

**Table 4. Inter-media transfer models developed by Cal/EPA**

| Model Name | Model Type and Description | Application | Cal/EPA Program/Department |
|---|---|---|---|
| CalTOX | CalTOX is a fugacity model and can be used to evaluate the partition of environmental contaminants among various media. | CalTOX can be used to evaluate health hazards associated with hazardous waste sites and facilities that handle or store hazardous materials. | DTSC |
| CAPCOA guidelines | The set of inter-media transfer equations can be used for estimating transfer of airborne contaminants to soil, surface water, and food products. | These equations are used to evaluate indirect health impact of air emissions from point sources. | Air Toxics "Hot Spots" Program of ARB, OEHHA, and local air districts |
| Solid Waste Ranking System (SWRS) | The SWRS is a ranking model rather than a fate-transport model. The methodology of the SWRS is based upon EPA's Hazardous Ranking System which is used in prioritizing Superfund Sites. Once discovered, each site is ranked for possible clean-up action to ensure that public health and safety and the environment are protected. The SWRS is an Excel-based program. Assumptions in using the SWRS are that the user has access to data on site conditions (geology, meteorology, waste conditions, surrounding land-use, etc.) | The SWRS ranks site specific conditions using three primary factors: (1) identify sites with the greatest need for corrective action; (2) assist local governments in investigation and inspection of sites requiring remediation; (3) determine applicable closure or remediation requirements.<br>Due to limited resources in collecting health data for a site, the model does not try to establish direct links between the site and health problems associated with surrounding conditions, i.e., it does not try to correlate specific illness or disease with constituents at a site. In terms of establishing a site score based on actual impacts to public health, the model is not rigorous. | The SWRS is used by CIWMB staff in the Permitting and Enforcement Division. |

# Attachment D-1

# Risk Assessment and CalTOX in DTSC

A number of issues were raised with regard to CalTOX at the Risk Assessment Advisory Committee meeting held February 8th at Stanford University. Time constraints did not permit all of the issues to be adequately addressed by DTSC staff. Therefore, the following questions and responses were drafted.

**Why does DTSC use risk assessment?**

The legislative mandate requires DTSC to protect human health and the environment. Federal regulations under the National Contingency Plan are also used by DTSC. They require decisions about sites with contaminated soil to balance nine considerations. One of the nine criteria is the effect of a decision on human health and the environment. Risk assessment is the means by which US EPA and DTSC obtain information on human health and the environment.

**How is a DTSC risk assessment conducted?**

In 1989, US EPA published the "Human Health Evaluation Manual" (HHEM) which is part of the Risk Assessment Guidance for Superfund (RAGS) series. HHEM clearly defines how risk is related to total daily dose (toxicity assessment) and describes the mathematical intake equations for computing daily doses from exposures to contaminated soil, water, air, and food. These intake equations address three potential routes of exposure: inhalation, ingestion, and dermal contact. DTSC has adopted HHEM and used this approach since its publication.

**Who prepares risk assessment documents?**

In general, the regulated party provides a risk assessment document with supporting calculations to the DTSC regional project officers of the Site Mitigation and Hazardous Waste Management Programs. Generally, environmental consulting firms are hired to prepare these documents. The risk assessments are usually reviewed by risk assessment scientists within the DTSC Office of Scientific Affairs (OSA). OSA staff prepare written comments to the regional project officers, the project officers communicate the issues they feel to be important to the responsible parties, and the environmental consultants modify the risk assessment documents or provide responses to the DTSC comments. There may be multiple rounds of review and revision before a document is approved by DTSC.

**Limitations of HHEM guidance**

The HHEM does not address the relationship of the chemical concentration in the contaminated soil with the concentration in the air, water, food, and soil to which a person may be exposed. US EPA has not clearly articulated a multimedia approach to chemical rate and transport. Instead US EPA provides an array of disconnected models from which risk assessors may choose. Furthermore, the HHEM is based on upper-bound point estimates for input parameters values. This deterministic procedure based on "reasonable maximal exposure" is not likely to underestimate risks, but will certainly overestimate risks for a portion of the population. In addition, use of a single point estimate of risk implies a degree of precision not reflective of the uncertainties in a risk assessment. A probabilistic approach to risk assessment is clearly more consistent to the objective of presenting a more realistic estimate of the range of the actual health risks to the population of concern.

**What is CalTOX?**

CalTOX is a risk assessment model that mathematically relates the concentration of a chemical in the soil to the theoretical dose a person may receive. CalTOX extends the intake equations and toxicity assessment methodology found in HHEM. CalTOX adds a multimedia compartment model for predicting time-dependent concentrations in exposure soil, air, water, and food based on an initial site-specific soil concentration. Furthermore, CalTOX is designed to be used stochastically. It can be used to estimate the range or distribution of risk for a given soil concentration. Alternatively, it can be used to compute a range of health-based target soil concentrations, given an acceptable risk. CalTOX is implemented on an EXCEL spreadsheet with a series of macros which makes it easy to compute risk or health-based target soil concentration estimates.

**How will CalTOX be used?**

CalTOX risk information will be used by DTSC risk managers in exactly the same fashion risk information from HHEM risk assessments is used. CalTOX has intentionally adopted intake equations and toxicity assessment identical to HHEM, so as to ensure consistency with the current regulatory process. CalTOX would mesh with the three tiers described in the Risk Based Corrective Action (RBCA) as described in the American Society for Testing and Materials standard ES-38-94, 1994. CalTOX will be used to replace the Preliminary Endangerment Assessment as a screening process. The screening process will be based on parameter input distributions which characterize the uncertainty and variability of those values throughout the State of California. These are "default" or non-site specific input distributions would be equivalent to the RBCA Tier 1. In RBCA Tier 2, these site-specific parameter distributions could be substituted for the default input distributions. If CalTOX is shown to be inappropriate or data is obtained to support the use of a more sophisticated model, than an alternative or Tier 3 model could be used instead of CalTOX.

**Advantages of CalTOX**

CalTOX presents a more accurate evaluation of human health risks from hazardous waste sites and permitted facilities because it incorporates an appropriate fate and transport model and stochastic risk assessment process. Due to its spreadsheet implementation, it is faster and easier to obtain risk information on a site than current procedures. This could reduce the time and cost associated with providing risk assessment information to the DTSC decision maker. In addition, it will provide a conceptual site model which can be used to assist in site investigation. This should help focus the issues for a given site, and lead to more cost-effective site characterization.

**Will CalTOX be required?**

Unless the CalTOX model is promulgated into regulation in the process laid out in the Administrative Procedures Act, DTSC cannot require its use. DTSC prefers to keep science based processes out of regulation because scientific knowledge is constantly changing. The regulations change at a much slower rate than science and tends to retain processes long after their scientific basis has changed. Rather than promulgate CalTOX into regulation, DTSC would like to open CalTOX to continued scrutiny and ask scientists from academia, government, and industry to help improve the scientific integrity of the model. Ideally, all parties would agree that the risks estimated by CalTOX are the most accurate that can be computed at any given point in time. Therefore, CalTOX would be used not because it is required, but because it is recognized as a reasonable approach to characterizing the risk including the uncertainty associated with a facility or site.

**Who has funded CalTOX's development?**

Initially DTSC funds were used exclusively. Over the past three years, DTSC has experienced financial difficulties. US EPA has provided the bulk of funding during this period. We anticipate the need to find funding through multiple sources in the future if CalTOX is to maintain a state-of-the-art approach to risk assessment.

**US EPA and CalTOX**

US EPA has provided funding for CalTOX development. The US EPA Science Advisory Board published the following excerpt:

"The State of California model (CalTOX, 1993), which is in the Beta-test stage is potentially the most advanced of all of the models reviewed with respect to exposure, although the transport components are simplified for ease of handling. Intake equations are the same as those used by the EPA, with two modifications. First, there is a multimedia total exposure model. Second, it is used stochastically (instead of a single risk level, a Monte Carlo derived distribution of risk is presented). CalTOX contains fugacity based multimedia fate and transport equations." (US EPA SAB Report (1995): Human Exposure Assessment. EPA-SAB-IAQC-95-005.)

**How has CalTOX been developed to date?**

Dr. Tom McKone of the University of California was hired to extend the HHEM intake equations. He developed a multimedia model based on information in the peer-reviewed literature. The result, CalTOX, was described in technical reports which were submitted for peer review to thirteen recognized academic authorities in the various field on which CalTOX draws in the Fall of 1992. The comments of these reviewers were evaluated and summarized. The technical reports were modified and responses were written for each comment. The second draft of the reports and comments, as well as the responses, were sent to scientists throughout the Cal/EPA for comment in the Winter of 1993. The Cal/EPA comments were treated in a manner identical to the academic reviewers. Finally, the third draft was made available to the general public in the Summer of 1993. The comments from the general public were treated as the previous comments. The draft final of this document was published in December of 1993. The term "draft" appears because we see CalTOX changing as new scientific information becomes available and is incorporated into the draft final as appendices.

The mathematical equations of CalTOX were written into an EXCEL spreadsheet. This spreadsheet was provided to a number of beta-testers in the Spring of 1994. These beta testers included environmental consulting firms representing industry or with ties to environmental groups.

**How is CalTOX available?**

A modified version of the beta spreadsheet (version 1.5) has been available since September 1994 from the National Technical Information Service. CalTOX version 1.5 costs $250 and the NTIS phone number is (703) 487-4650. The order numbers are PB-95500146 for IBM computers and PB-95500153 for Macintosh computers. Users must have a computer running Microsoft EXCEL 4.0 or higher. An add-in program to EXCEL for stochastic applications is required to run CalTOX probablistically. CalTOX was written to interface with Crystal Ball of Decisioneering, Inc. Decisioneering can be reached at (800)289-2291.

**Current Status**

CalTOX is currently ready for use. However, the Risk Assessment Advisory Committee convened under SB1082 is reviewing all risk assessment processes used by the Cal/EPA. Therefore, DTSC has delayed implementing CalTOX until the findings of the committee have been published to ensure that the use of CalTOX is consistent with the committee's findings and recommendations.

CalTOX currently has a number of limitations. These limitations are stated in the technical reports and the users manual. The limitations include exclusion of metals, high concentrations of chemicals, and off-site receptors.

**Future Changes**

Efforts are currently underway to obtain data on the uptake of chemicals by garden vegetables. This may result in modifications to these controversial models. In addition, a modification is being worked on to eliminate the "low concentration" requirement. Finally, some dispersion models are being developed to address off-site receptors. If funding can be obtained, DTSC would like to address the issue of inorganic chemicals.

**Training**

DTSC is offering a course on CalTOX through the UC Davis extension program in March of 1996. Enrollment information can be obtained by calling (800) 752-0881 and the section number is 953K140.

**Policy Considerations**

The regulated public has indicated concern about the implementation of CalTOX. CalTOX can easily be substituted for current risk assessments because it is based on the HHEM. CalTOX makes it easy to compute risks for several food pathways that appear in the HHEM but are currently often ignored because the computed risks are very uncertain. CalTOX also mathematically computes transfer of chemical from soil to groundwater. Humans exposure to groundwater is then modeled. The groundwater pathway is often not included in current pathways due to uncertainties in vadose transport models. For some chemicals, the food or the groundwater pathway can dominate the exposure and that leads to much higher estimated exposure doses than assessments that exclude these pathways.

In contrast to most regulatory transport models, CalTOX conserves mass. This would lead CalTOX to estimate lower estimates for exposure than infinite source models. CalTOX also models chemical transformation (degradation). For many chemicals, CalTOX risk estimates are very sensitive to these transformation rate constants. CalTOX will lead to lower estimates of risk when compared to models that do not account for source depletion or degradation for some chemicals.

Our objective with CalTOX is to improve the quality of the risk information used by decision makers. To achieve this goal, it is going to take time for risk assessment scientists within academia, DTSC, regulated parties and the public to work together to forge policies and identify areas in need of change in the model. Because of the wide range of sites regulated by DTSC and the novel changes CalTOX introduces, it would be unwise to formulate policy in a vacuum. DTSC had envisioned that regulated parties would have volunteered to work with the Department in implementing CalTOX on their sites and to develop appropriate policy and improve the model. That invitation was extended in the Fall of 1994. This did not lead to any volunteered sites.

**Implementation Schedule**

After the findings of the Risk Assessment Advisory Committee have been finalized, CalTOX can be used by scientists within the Office of Scientific Affairs to compare with the results of the standard HHEM risk assessments submitted for review. This will be a screening process to identify those CalTOX chemical-specific risks that are significantly less those reported in the submitted risk assessment. Those chemicals that differ significantly will become the focus of the review. The objective of the review will be to determine the reason for the difference. Identified differences and preliminary reasons will be written and presented to the authors of the risk assessment for their analysis and comments. When differences are due to alternative mathematical algorithms, then risk assessment authors must provide scientific information identifying the reason(s) they believe their algorithms to be superior to those used in CalTOX. Differences, reasons and comments will be summarized in a fashion similar to that in Part IV of the technical reports. These summaries will be posted on the CalTOX BBS in the CalTOX Policy Conference (identifying the chemical, site conditions and models but not the site, responsible party or environmental consulting firm). The CalTOX BBS phone number is (916) 323-3353.

The BBS will permit users to leave messages in the CalTOX Policy Conference. They may include specific comments on the posted summaries, other problems with the spreadsheet, or general comments. The objective of this BBS will be to maintain an open, public, documented log of issues relevant to the development of policy for the implementation of CalTOX. It will require one year to compare the use of CalTOX with current methods to cover the wide variety of chemicals, sites and exposures regulated by our Department. At the end of that year, the BBS log will serve as the basis for formulation of a clearly articulated policy detailing the implementation of CalTOX. The policy will be made available to the public for review and comment. As with the technical reports, the comments on the policy document will be summarized and responses will be written. In addition, workshops will be held to maximize input from all stakeholders.

# RAppendix E

# Risk Assessment Issues Raised by an Inter-Departmental Work Group of Cal/EPA

The Standards/Criteria Work Group, an inter-departmental work group of the California Environmental Protection Agency (Cal/EPA) risk assessment staff, identified a series of issues related to risk assessment which were presented to the Risk Assessment Advisory Committee (Committee) for consideration at each of its topic-specific meetings.

These issues are of concern to the staff members of the working group and do not represent an official position or policy of Cal/EPA. At the first meeting, the Committee requested that the Standards/Criteria Work Group prioritize these issues and indicate the reason for bringing an issue to the attention of the Committee. The following responds to that request. The issues are provided in order of the following topics:

- hazard identification
- dose-response assessment
- exposure assessment 1: human intake parameters, inter-media transfers and exposure monitoring
- exposure assessment 2: contaminant fate and transport
- variability, uncertainty and risk characterization

## Hazard Identification

### 1. Defining adverse effects

Concerns around this issue stem from experience in trying to assess the risks associated with certain chemicals in which our understanding of the health effects is not clear. For example, in some cases an effect might be considered merely a perturbation of a cellularly- or systemically-regulated process or an adaptive response (e.g., cholinesterase inhibition and phytoestrogen responses). Similar difficulties arise in determining the significance of biomarkers of effect. Should criteria be developed to help define when such responses are to be treated as adverse?

### 2. Criteria for determining whether an animal response is relevant to a human response

Although the issues for this topic are multifaceted, the work group was primarily concerned with the proper application of mechanistic data in determining the relevance of responses observed experimentally. How much information on the mechanism of toxicity is needed to establish when an animal response is relevant to a human response? Can criteria or guidance be developed for evaluating mechanistic data in this regard?

**3. Should genotoxicity data, structure-activity relationships, pharmacokinetic data or similar evidence be use to classify a chemical as a carcinogen in the absence of bioassay or epidemiological evidence?**

The work group's primary concern about this issue is the process by which assessors would prioritize or rank these types of data in "weight-of-evidence" determinations. In the past, ancillary data have been used only as supportive evidence and in general has not been used in the absence of bioassay or epidemiological data for weight-of-evidence carcinogen identification. Exceptions include benzidene dyes, TCDD and related compounds.

**4. Should Cal/EPA adopt US EPA or IARC system for carcinogen classification?**

Cal/EPA's current criteria for classifying carcinogens are outlined in the 1985 carcinogen guidelines written by California Department of Health Services. Over the past 5 years, Cal/EPA has been working on revising those guidelines. An inter-departmental work group was established to address this issue and drafted guidance to be used. The guidance parallels the recent International Agency for Research on Cancer (IARC) classification scheme. One frequent question in the discussions was "Why not adopt US Environmental Protection Agency (US EPA) or IARC system for carcinogen classification?" A major issue was the need for more guidance in the use of ancillary data.

The following are other issues related to the topic of this meeting that were identified as important by the Cal/EPA Standards/Criteria Work Group:

- Criteria for evaluating the quality of epidemiological studies and how to weigh human studies of varying quality and strength.
- Criteria for evaluating conflicting studies
- Methods for evaluating the validity of data from an animal bioassay

## Dose-Response Assessment

**1. Issues of interspecies extrapolation**

The current default approach used to scale cancer potency from animals to humans is based on allometric scaling. Cal/EPA and US EPA assume that dose is equivalent for animals of different body size when expressed in units of amount per surface area, or, alternatively, amount per body weight to the three-fourths power. US EPA and the Department of Pesticide Regulation (DPR) have recently adopted the 3/4-power scaling; Office of Environmental Health Hazard Assessment (OEHHA) employs surface area scaling (i.e., 2/3-power scaling). An inter-departmental work group established for the revision of the cancer guidelines reviewed the available scientific

evidence on this subject, and noted the difficulty in distinguishing between the two alternatives on scientific grounds. The group developed alternative options to the use of a single allometric scaling relationship, such as the use of a distribution of scaling factors, but did not adopt any particular one. An issue that was extensively discussed entails the degree to which the scaling addresses pharmacokinetic differences, and additional pharmacodynamic differences and uncertainties. For non-cancer endpoints, similar issues arise regarding the scientific support for the application of the uncertainty factor of 10 to account for species differences. Regarding the application of physiologically-based pharmacokinetic (PBPK) modeling for species extrapolation, in many cases insufficient data exists to reduce the uncertainty in output below that implied by the current defaults.

**2. Appropriate use and implementation of the benchmark dose, as an alternative to the 'no observed adverse effect level'**

The use of the benchmark dose (BMD) as an alternative approach for developing a reference dose for non-cancer endpoints was addressed by an inter-departmental work group of Cal/EPA staff, the Cal/EPA Benchmark Dose Working Group. Under the BMD approach, a dose-response model is fit to experimental data and a dose level associated with a pre-selected response (e.g., 5% incidence), or a lower bound value, is estimated. This estimate is 'the benchmark dose' and replaces the No-Observed-(Adverse)-Effect Level [NO(A)EL] in derivations of acceptable human exposure levels; uncertainty and adjustment factors are applied as is done in estimating the reference dose from a NOAEL. Issues identified by the BMD Working Group include: 1) applicability/appropriateness of the BMD approach; 2) omission of higher dosages to improve model fit; 3) selection of response level (e.g., 5%, 10%); 4) use of uncertainty factors; 5) choice of mathematical models (e.g., Multistage, Weibull, lognormal probit, least squares/straight line), criteria for selection and/or elimination of certain models, and use of a single default model vs. multiple models; 6) additivity to background exposures or otherwise (i.e., the assumption regarding whether the dose adds to a background exposure operating by the same biological mechanism versus an entirely independent exposure); 7) maximum likelihood estimate vs. lower-bound estimate; 8) choice of toxicity endpoint among available comparable studies (e.g., for the same chemical, shapes in dose response curves differ according to endpoints and exposure patterns); 9) competing risks and progression of severity (e.g., fetal anomaly versus fetal death); and 10) conversion of continuous data to quantal data. Additional issues for consideration in methodology development include adjustments for exposure duration (see also Issue #3 below) and route.

**3. Averaging procedures to adjust for discontinuous exposures, including methodologies to account for length of exposure, age at the time of exposure, and other exposure regimen considerations**

The timing of exposure in relation to age and the rate of exposure can have profound effects on toxicity. However, procedures for routine use by US EPA and Cal/EPA to address the issue of discontinuous exposures are not available. For acute as well as chronic effects, there are limited data on which to base the development of such

methods. Typically, for cancer endpoints, both Cal/EPA and US EPA use a default approach of averaging the total amount of intake over a lifetime. When other methods and data are available, they may be used in place of the default approach if appropriate. In several potency calculations from experiments with discontinuous dosing, a Doll-Armitage correction has been applied (e.g., vinyl chloride). For non-cancer endpoints, some form of averaging is always employed (e.g., concentration over eight hours produces the same effect as concentration averaged over a 24-hour period). Should particular approaches be adopted agency-wide? How should they differ for the various endpoints? Additionally, short-term human exposures to carcinogens pose a particularly difficult challenge to the risk assessor. How should one evaluate risks to relatively high carcinogen exposures over short periods of time? In assessing acute impacts, repeated intermittent acute (as opposed to subchronic) exposures are often treated as if they each occur independent of one another, and not to the same individual, and combined impacts may not be considered. Is this manner of assessing such exposures adequate?

**4. Uncertainty/adjustment factor procedures for computing Reference Doses (RfDs) and Reference Concentrations (RfCs), Reference Exposure Levels (RELs), and assessing the Margin of Safety (MOE)**

A variety of concerns have been raised over the use of uncertainty and adjustment factors in non-cancer risk assessments. Adjustment/uncertainty factors for inter-species extrapolations, inter-individual variability, incomplete study length and others are often multiplied, resulting in overall multipliers exceeding, in some cases, 1000. To what extent should the final multiplier be bounded? Alternatively, in some cases, the default factor used may be insufficient to account for variation in human susceptibility. What is the extent of scientific evidence required to move from the default factor? How does data quality come into play in making such an assessment? What considerations should be given to evaluating the adequacy of the calculated MOE? Finally, various Cal/EPA programs have expressed results of these analyses differently, with some programs using uncertainty and adjustment factors to establish RfDs, RfCs, and RELs, and others using the margin of safety approach.

**5. Criteria for selecting of non-default approaches for high-to-low dose extrapolation**

Cal/EPA assumes the absence of a threshold and uses the linearized multistage procedure as the default method for estimating cancer potency. Part of the current standard procedure involves adjusting for dose differences in pharmacokinetics, if adequately supported by data. The selection of alternative dose-response models based on assumptions regarding mechanism of action has been difficult because of our limited understanding of carcinogenic mechanism in most cases. What should the extent of scientific evidence be for rejecting the default, non-threshold hypothesis and accepting the hypothesis that the dose-response curve has a threshold? How should one address the issue of background exposures in deciding whether or not a threshold model is appropriate? Can specific, general criteria be developed to guide decisions regarding the

rejection of the non-threshold hypothesis? In some cases, where the threshold hypothesis may have strong support, the alternative choices to the default include modeling of cell dynamics, and the more simplistic NOAEL/adjustment-uncertainty factor approach. In addition, where the non-threshold hypothesis has considerable support, there may be a large body of scientific data suggesting that an alternative model to the linearized multistage may be more appropriate. What factors should be considered in choosing among the alternatives to the linearized multistage procedure? Related concerns arise with route-to-route extrapolations.

## Exposure Assessment 1: Human Intake Parameters, Inter-media Transfers and Exposure Monitoring

### 1. Default Exposure Parameter Values

The primary concern relates to the validity of using default exposure parameters in estimating exposure of the general population. In regards to the default for body weight, Cal/EPA uses the 70 kg as the average body weight for adults. This value is comparable to the mean value of 71.8 kg for adult men and women ages 18 to 75 years, but it does not include an important segment of the population, namely adolescents or children. An age-weighted lifetime average default value that includes adolescents and children would be closer to 62 kg. Thus, use of the 70 kg default may underestimate the risk for the population as a whole.

Two other important default parameter values are inhalation rate and water ingestion rate. The most widely used default adult inhalation rate is 20 $m^3$/day, which has been characterized by US EPA as a "reasonably conservative" (OSWER), "upper percentile" (Exposure Factor Handbook, US EPA, 1995) value. An age-weighted lifetime "reasonably conservative" inhalation rate would likely be less. Although not directly comparable to the "conservative" value, an age-weighted lifetime average inhalation rate of 12.4 $m^3$/day can be calculated from US EPA's Draft Exposure Factors Handbook (1995). Another widely used default exposure value is the upper bound water ingestion rate for adults of 2.0 L/day, with an average of 1.4 L/day. The corresponding age-weighted lifetime values would be 1.8 and 1.2 L/day, respectively. Thus, in these cases, use of the standard defaults may over-estimate exposure or dose to the "average" person but may still under-estimate exposure or dose to certain segments of the populations, e.g., athletes. A related issue is when should average and high-end exposure parameters be used in lifetime and short-term exposures?

Another concern regarding the representativeness of default exposure values is whether or not they should be scaled concordantly. For example, body surface area would scale with body weight. However, inhalation, water ingestion, food intake, or incidental soil ingestion may not change linearly as a function of body weight as they are also dependent on activity level and behavioral pattern.

There is also a concern as to what extent that a default exposure value represents a given population. US EPA and Cal/EPA typically address this issue by using 90 to 95th percentile exposure parameter values in the numerator and 50th percentile values in the denominator of the intake equations used to calculate average daily dose. This choice of defaults tend to overestimate the dose to the "average" person, but may underestimate the dose for certain segments of the population.

**2. Sensitive Subpopulations**

In order to be more inclusive in estimates of risk to an exposed population and to provide "bounding" estimates of risk, "sensitive" subpopulations are often evaluated. Sensitive subpopulations are those with readily identifiable physiological characteristics or activity patterns that would result in a greater dose from a given exposure than most individuals in the general population. US EPA and Cal/EPA currently evaluate risks to the following subpopulations: breast-fed infants (0 to 12 months), children (1 to 6 years), subsistence fishermen, recreational fishermen, subsistence farmers, and workers in an industrial/commercial setting. US Food and Drug Administration and Cal/EPA also evaluate risks to non-nursing infants, older children (7 to 12 years) and women (pregnant or nursing). Are these categories sufficiently inclusive to provide adequate bounding estimates on risks from chemical exposures?

**3. Exposure Scenarios**

Exposure "scenarios" generally follow classifications based on land use. For example, US EPA has defined 4 basic land-use scenarios: residential, commercial/industrial, agricultural, and recreational. Each of these scenarios would have associated exposure pathways that contribute to average daily dose (ADD). For example, the residential scenario would include: dermal exposure to contaminated soil, ingestion of potable water, incidental ingestion of soil and house dust, inhalation of contaminated air, and consumption of home grown produce. Are these exposure scenarios adequate in evaluating potential health hazards? What are the circumstances where they are not applicable?

Exposure through each pathway can be calculated using exposure parameters that would ultimately yield three estimates of risk: worst-case "bounding estimates" (maximum exposed individual, or MEI), 90 to 95th percentile "upper-end" estimates (reasonable maximum exposure, or RME), and 50th percentile estimates or "central tendency" estimates (average exposed individual, or AEI). Expressing exposures (ultimately risks) over this range is one way to provide an indication of the uncertainty. A more sophisticated alternative is to develop a stochastic risk assessment based on probability density functions (PDFs) for each of the exposure parameters. Default values for the PDFs (e.g., mean and standard deviation) for most of the exposure parameters have yet to be developed. Risk assessors in Cal/EPA have also expressed concern regarding criteria (or lack thereof) for summing "point" estimates of exposure across multiple pathways and the additional uncertainty this may introduce. For example, how

many RME pathways can be summed and the final result still represent an RME? Also, when should chemical exposures from natural background levels (e.g., in soil), anthropogenic "background" levels (e.g., pollution in an air basin) or unrelated sources (e.g., nearby industries or freeways) be included in an exposure assessment?

**4. Exposure Models and Algorithms**

The work group is concerned that most exposure algorithms used to estimate intake and exposure have not been sufficiently validated. There are inadequate field data available to validate these algorithms. Many exposure assessment algorithms rely on receptor (humans, animals, and plants) exposure concentrations that are modeled from distant point or area sources. Most of these models have not been validated under real-world conditions, but rely on basic principles of physics, chemistry, and assumptions about local meteorology and hydrology. What are the most important considerations or steps in going from environmental media concentrations to exposure media concentrations that affect human exposure and dose?

In addition to the uncertainty associated with the exposure algorithms, inputs to the algorithm have themselves different degrees of variability and uncertainty. For example, parameters such as, exposure frequency, exposure duration, and averaging time included in exposure algorithms are often policy-based point values, but in reality each of them can be represented by a range and may vary depending on a number of factors. For instance, exposure frequency for outdoor activities can very much be a function of climate; thus, the frequency of some outdoor activities is less during inclement weather. Also, exposure duration is often related to length of time living at one residence or the time required for a remedial action or cleanup. Cal/EPA risk assessors are concerned over the use of default point estimates on the characterization of uncertainty and variability in risk estimates.

## Exposure Assessment 2: Contaminant Fate and Transport

### 1. Deposition Modeling and Plume Depletion

In many environmental programs air dispersion models are used to predict off-site air concentrations. At the screening level and in the absence of site-specific information, assumptions are often made on emission characteristics such as particle size and density. For example, 0.2 and 0.5 cm/sec are often used for controlled and uncontrolled (no air pollution control devices) sources, respectively. Depending on the actual size of the emitted particles, these assumptions may lead to an under- or over-estimate of the impacted area and concentration of particles deposited onto the ground.

Also of concern is that most screening level air dispersion models do not consider plume source depletion. For example, of the commonly used air dispersion models, only ISC3 contains a routine to address depletion of particles in a plume. Are there cost-effective ways to semiquantitatively address the bias and uncertainty (e.g., a simple engineering "rule of thumb")?

### 2. Validation of Models and Algorithms

Exposure assessors are concerned about the accuracy of fate and transport models. Many models rely on theoretical constructs from chemistry, physics, and meteorology but do not account for local conditions (e.g., local topography and meteorology), nor in some cases certain chemical specific factors (e.g., biological and chemical half-life). It is critical to use models that are properly calibrated and validated for a given situation. However, given the limited time and resources, it is not clear to what degree a model should be calibrated before it is considered acceptable? Model validation is expensive and in a climate of diminishing resources, can the Committee suggest cost-effective approaches to model validation?

### 3. Criteria for Selecting Models

For assessments developed by or submitted to Cal/EPA, there is considerable flexibility in the selection of air and ground water models. Cal/EPA staff reviewing exposure assessments generally use a set of guidelines and criteria to determine if the proposed model is able to address specific situations and regulatory program needs. Model selection guidelines and criteria developed by Cal/EPA and US EPA are provided in Tabs 5 and 6 of the briefing book (i.e., background materials provided to the Committee for the meeting). Is this guidance sufficient in terms of model selection? Are there additional criteria that should be considered in selecting the most appropriate model for a given set of release and environmental conditions?

### 4. Propagation of Uncertainty When Models are Linked

Exposure assessors are concerned about propagation of uncertainty through the practice of linking models. For example, soil gas emission rates are often modeled based on laws of diffusion (e.g., Farmer's model). The modeled emission rates are then used in dispersion models (simple box model or Gaussian model) to predict downwind air concentrations of a chemical. There may be differences in the assumptions used in each model, and each model has its own degree of uncertainty. What are the steps an assessor can take to ensure that it is appropriate to link two models together? What is the best way to address compounding uncertainties in this regard?

## Variability, Uncertainty and Risk Characterization

### 1. How to communicate uncertainty, variability, and assumptions made, to the public or to the risk manager

Without proper communication, risk assessments can be misunderstood and misused. For toxic substances, the risk manager must decide control or mitigation levels which provide adequate protection of public health. The questions become "What is a safe level? Or, is the risk negligible?" In order to make this decision, the risk manager needs to understand the risk assessment, the assumptions made, and the uncertainties associated with the assessment result. The challenge to the risk assessor is to communicate the technical information to a risk manager who may not have a background in toxicology. The risk manager may then balance the risk estimate and its associated uncertainties with the costs, benefits and economic impact of control. Likewise, the public needs to be made aware of what a risk assessment is, the information considered and how the results were derived. The numbers generated through the risk assessment process are estimates only, usually conservatively-derived, and several types of uncertainty may be involved. Important information is often lacking and assumptions must be made in the absence of such information. The concepts of "acceptable risk" and "safe level" need to be explained in non-technical terminology so they can be understood by the general public. How can the complexities of risk assessment methodology and the results of the assessment be more clearly communicated to the risk manager and to the public?

### 2. Criteria for estimating total risk from multiple contaminants

Multiple-chemical exposure is a critical issue in risk assessment, yet one that historically has not been completely addressed by regulatory agencies. A common question asked at most public meetings about toxic substances is "have we taken into account all the chemicals in the mixture and how they might interact?" The exposure scenario may involve a single exposure source with multiple chemicals or multiple sources with either single or multiple chemicals. Given the large number of possible combinations of chemicals, it is very difficult to accurately characterize exposure and health effects. With multiple chemical exposure, there undoubtedly is interaction (i.e.,

synergism and antagonism) among the different chemicals. When there is some knowledge of the mechanism of action, concentration, and dose-response relationship of chemicals in the mixture, modeling may be used to shed light on the plausible overall health impact of the mixture. However, detailed toxicological information for such exercises is generally available only for a small number of mixtures. Given the technical difficulties in evaluating the risks of mixtures, how should their risks be characterized?

**3. Use of probability distributions versus point estimates (mean, reasonable maximum, or maximum)**

This issue is important to most regulatory decisions based on risk. No risk situation is understood with complete certainty, and variability in exposure and human susceptibility are characteristic of most risk situations. Traditionally, regulatory agencies have dealt with uncertainty and variability by erring on the side of overestimating risk in selecting some parameter values and assuming average or median values for others. Information on human variability which may be available have typically not been explicitly incorporated into risk assessments, and selected parameter values may not account for the wide range of response that can occur in a population. One proposed way of conveying information about the uncertainty and variability is to report to the risk manager probability distributions instead of point estimates. Questions for the Committee to consider on this issue include: To what extent can or should uncertainty and variability be quantified and expressed in terms of probability distributions? Should the level of quantification vary with the type of decision and the extent of data available? Under what situations are point estimates and ranges of risk estimates more appropriate quantitative expressions than probability distributions? How should inter-individual variability be described in distributional presentations? Since this activity is very resource intensive, how can the costs of analysis and data gathering be weighed against the potential value of the information in deciding whether or not to represent risk as a probability distribution?

**4. How to apply quantitative uncertainty analysis to risk assessments**

Risk assessors want to use methodology that is scientifically sound and defensible. Quantitative uncertainty analysis may allow risk assessors to better characterize uncertainty in risk estimates. The use of defaults can result in either overestimates or underestimates of risk. Quantitative uncertainty analysis may allow scientists to analyze uncertainties and better utilize available scientific information on a case-specific basis. However, uncertainty analysis can be complicated and resource intensive, and analytically difficult in cases of limited data. It may not be equally useful for all types of decisions. Are there criteria for deciding when quantitative uncertainty analysis is desirable? For which types of decisions is quantitative uncertainty analysis recommended? Are there instances where qualitative descriptions of uncertainty may be preferred?

# RAppendix F

# Meeting Format and Agendas

This section describes the process by which the Risk Assessment Advisory Committee (Committee) formulated the agendas for their meetings. Copies of the agendas from the Committee's nine meetings and one workshop are included.

**General framework for meetings as determined by the Committee**

Early in the process, the Chair and Vice Chair of the Committee suggested a basic template for the meetings which resembled an academic "site visit", where the Committee would meet with California Environmental Protection Agency (Cal/EPA) risk assessors to learn how risk assessments are actually performed by the different departments in order to make recommendations for improving these practices. During the first day of each meeting, the Committee members would hear presentations on the risk assessment activities of the US Environmental Protection Agency (US EPA) and the National Academy of Sciences (NAS), and each of the boards and departments within Cal/EPA. The Committee would discuss with the presenters and the audience how these risk assessment activities could be improved through the use of current scientific information or through consistency of application across departments of Cal/EPA. The Committee would also assess the appropriateness of differences between the risk assessment practices of Cal/EPA and those of US EPA, NAS and other similar bodies. Committee members would reconvene on the second day to deliberate on their draft findings and make recommendations to improve the scientific basis and consistency of risk assessment at Cal/EPA.

At the first topic-specific meeting, the Committee facilitated its efforts by discussing important issues in the context of three basic questions related to the risk assessment practices of Cal/EPA. These were:

1. Is Cal/EPA consistent with US EPA?
2. Are Cal/EPA Boards and Departments internally consistent?
3. Are Cal/EPA risk assessments based on sound scientific knowledge, methods and practices?

This general set of questions was, for the most part, utilized by subsequent expert Committees at the other topic-specific meetings.

The Committee acknowledged its charge to compare Cal/EPA risk assessment practices to those of NAS, but noted that NAS does not routinely practice nor has it adopted procedures for risk assessment. However, because the NAS provides information on state-of-the-art risk assessment practice, the Committee decided to use recommendations from various NAS reports as an indication of the good science or

"state-of-the-art", and in that manner respond to the SB 1082 mandate. A report frequently referred to by the Committee for this purpose was *Science and Judgment in Risk Assessment* (NAS, 1994).

**Development of the meeting agendas**

For topic-specific meetings, agendas were set by the expert Committee members designated for that topic (see list of members located inside the front cover of the report). The Core Committee set the agendas for the Cross-Cutting Issues meeting and the two final meetings to discuss the draft Committee report.

The Committee members had a number of sources of information available in selecting topics and issues for discussion at the meetings. These included issues identified by the Committee and the public at the Case-Studies Workshop, issues identified by an inter-departmental working group of Cal/EPA staff, issues identified by the public prior to the review process, personal knowledge of the field, and review of technical material provided to the Committee prior to the meeting.

Workshop: Case Studies in Risk Assessment

The Committee felt it needed a mechanism to help identify important issues in risk assessment in order to facilitate the planning of the agendas for future meetings so that it could spend its limited time on the most critical topics. To accomplish this, the Committee convened a workshop in September 11-12, 1995, near the beginning of the review process, where they investigated case studies of risk assessments either conducted by Cal/EPA or by responsible parties who submitted them to a regulatory agency for evaluation.

OEHHA, on behalf of the Committee, requested submission of case studies from Cal/EPA staff and the public. The request called for examples to illustrate a variety of risk assessment approaches, including the state-of-the-art that should be emulated, typical or non-standard approaches, and outdated methodologies. In all, 29 cases were suggested for the Committee's review, 15 of which were received from the public, and 14 from Cal/EPA Boards and Departments. From these, the Committee chose to study the following at the workshop:

- Exposure assessment of PCBs at two hazardous waste sites (a RCRA site in Southern California and a CERCLA site in Southern California)
- Modeling migration of chlorinated solvents in groundwater to indoor air (at a hazardous waste site in Sunnyvale)
- Risk assessment and issuance of air permits (using as an example the South Coast Air Quality Management District)
- Risk assessment of a pesticide, Telone II
- Development of a health-based standard for toluene in drinking water

A briefing book of background materials was prepared and made available before the meeting. The materials included case descriptions, documents sent with each case submission, and for the chemical-specific cases of Telone II and toluene, similar risk assessments developed by US EPA and NAS were provided, if available. Each case was presented by a representative of the group submitting the case to the Committee for review. A panel of other parties with an interest in the case was made available to provide comments or further explanation and to answer Committee questions. Panel participants included staff of Cal/EPA Boards and Departments and of the California Department of Health Services, US EPA staff, private consultants, and industry representatives. The presentation of each case was followed by extensive Committee discussion and public comment. The last half-day of the meeting was reserved for Committee discussion of issues, and recommendations regarding those most important for discussion at the future meetings. The agenda for the workshop is included in this appendix (page F-13).

The Committee discussion during the final session of the workshop focused on issues for the two subsequent meetings on hazard identification (October 18 and 19, 1995) and dose-response (November 15 and 16, 1995), and on issues which were common to all the topic-specific meetings. Issues for which there was general Committee consensus, as well as general and specific comments, were noted on flip charts by scribes. In addition, for each case presented, "survey sheets" were provided to all Committee members and other workshop attendees, who were invited to write down issues stemming from that case and related to the future meeting-topic areas. Finally, generic issues were raised related to the characterization of variability, uncertainty, and risk, the topic of the previous Committee meeting. It was agreed that these concerns would be passed on to the risk characterization experts on the Committee, for their consideration during the drafting of their report on the topic.

Issues identified by an inter-departmental working group of Cal/EPA staff

The Standards/Criteria Work Group, an inter-departmental work group of Cal/EPA risk assessment staff, identified a series of issues related to risk assessment which were presented to the Committee for consideration at each of its topic-specific meetings. Prior to each Committee meeting, the Cal/EPA working group would discuss issues that it felt were important for the Committee to consider in its review. It prioritized these issues and provided explanatory text describing why each issue was considered important. The issues and their explanations are provided in Appendix E of this report.

Issues identified by the public prior to the Committee review process

Additional issues considered by the Committee included responses from interested parties to a public request made by OEHHA (via the California Regulatory Notice Register and the trade press), prior to the establishment of the Committee. The period for this initial phase for public input ended January 1, 1995. Suggestions received from the public from this process were provided to the Committee members for consideration as they formulated their review.

Technical, briefing materials

Background materials (i.e., briefing books prepared by OEHHA) were given to the Committee members prior to the meetings. The briefing books contained Cal/EPA and US EPA risk assessment guidance related to the topic of the meeting, examples of Cal/EPA and US EPA risk assessments, and other relevant material (suggested by both Cal/EPA staff and the Committee members). Also included in these materials were documents developed by Cal/EPA in response to Committee requests. In some instances, Committee members requested that additional issues be added to the agenda upon reviewing these materials; and conversely, additional materials were provided related to issues that Committee members wanted to discuss at the meeting.

**Committee attendance at the meetings and workshop**

The Committee members who attended each meeting are listed below:

Meeting 1. Science and Consistency in Risk Assessment (June 1995)

| Core members | Expert members | Members for other topics |
|---|---|---|
| James Seiber (Chair) | Hoda Anton-Culver | Gerald Last |
| Robert Spear (Vice-Chair) | Richard Clark | Thomas Mack |
| Herschel Griffin | Alison Cullen | Fumio Matsumura |
| Judith MacGregor | Clay Frederick | Paul Price |
| John Moore | Andre Journel | William Walker |
| | Charles Lapin | |

Meeting 2. Variability, Uncertainty and Risk Characterization (August 1995)

| Core members | Expert members[1] | Members for other topics |
|---|---|---|
| James Seiber (Chair) | Adam Finkel | Steven Brown |
| Robert Spear (Vice-Chair) | William Walker | Richard Clark |
| Herschel Griffin | James Wilson | Charles Lapin |
| Judith MacGregor | | Andre Journel |
| John Moore | | William Nazaroff |
| | | Christopher Portier |
| | | Paul Price |

[1] Committee member Thomas Burke, an identified expert in risk characterization, was unable to attend and submitted his comments on the topic to the Committee before the meeting.

Workshop. Cases Studies in Risk Assessment (September 1995)

| Core members | Expert members | Members for other topics |
|---|---|---|
| James Seiber (Chair) | Steven Brown | William Nazaroff |
| Robert Spear (Vice-Chair) | Richard Clark | Christopher Portier |
| Herschel Griffin | Alison Cullen | Paul Price |
| Judith MacGregor | Clay Frederick | Akula Venkatram |
| John Moore | Charles Lapin | William Walker |
| | Jerold Last | James Wilson |

Meeting 3. Hazard Identification (October 1995)

| Core members | Expert members | Members for other topics |
|---|---|---|
| James Seiber (Chair) | Andrew Hendrickx | Richard Clark |
| Robert Spear (Vice-Chair) | Charles Lapin | Jerold Last |
| Herschel Griffin | Thomas Mack | Paul Price |
| Judith MacGregor | Ronald Melnick | |
| John Moore | John Peters | |
| | Richard Thomas | |

Meeting 4. Dose-Response Assessment (November 1995)

| Core members | Expert members[2] | Members for other topics |
|---|---|---|
| James Seiber (Chair) | Richard Clark | Hoda Anton-Culver |
| Robert Spear (Vice-Chair) | Kenny Crump | Charles Lapin |
| Herschel Griffin | Clay Frederick | Paul Price |
| Judith MacGregor | Jerold Last | Richard Thomas |
| John Moore | | James Wilson |

Meeting 5. Exposure Assessment 1. Human Intake Parameters, Inter-Media Transfers and Exposure Monitoring (December 1995)

| Core members | Expert members | Members for other topics |
|---|---|---|
| James Seiber (Chair) | Gladys Block | Steven Brown |
| Robert Spear (Vice-Chair) | Alison Cullen | Richard Clark |
| Herschel Griffin | Howard Maibach | Charles Lapin |
| Judith MacGregor | Fumio Matsumura | Richard Thomas |
| John Moore | William Nazaroff | |
| | Wayne Ott | |
| | Paul Price | |

[2] Committee member Christopher Portier, an identified expert in dose-response assessment, was unable to attend the meeting due to the federal government shutdown and submitted his comments on the topic after the meeting.

## Meeting 6. Cross-Cutting Issues (January 1996)

| Core members[3] | Members for other topics | Members for other topics |
|---|---|---|
| James Seiber (Chair) | Steven Brown | Christopher Portier |
| Robert Spear (Vice-Chair) | Clay Frederick | Paul Price |
| Herschel Griffin | Gerald Last | Richard Thomas |
| Judith MacGregor | Charles Lapin | James Wilson |
| John Moore | Thomas Mack | |

## Meeting 7. Exposure Assessment 2. Contaminant Fate and Transport (February 1996)

| Core members | Expert members [4] | Members for other topics |
|---|---|---|
| James Seiber (Chair) | Steven Brown | Richard Clark |
| Robert Spear (Vice-Chair) | Steven Gorelick | Charles Lapin |
| Herschel Griffin | Andre Journel | Paul Price |
| Judith MacGregor | William Nazaroff | Richard Thomas |
| John Moore | Kent Udell | |
| | Akula Venkatram | |

## Meeting 8. Synthesis (April 1996)

| Core members[3] | Members for other topics | Members for other topics |
|---|---|---|
| James Seiber (Chair) | Steven Brown | Ronald Melnick |
| Robert Spear (Vice-Chair) | Richard Clark | William Nazaroff |
| Herschel Griffin | Adam Finkel | Paul Price |
| Judith MacGregor | Gerald Last | Richard Thomas |
| John Moore | Charles Lapin | Akula Venkatram |
| | Thomas Mack | James Wilson |
| | Fumio Matsamura | |

## Meeting 9. Committee Working Session (May 1996)

| Core members[3] | Members for other topics |
|---|---|
| James Seiber (Chair) | Gerald Last |
| Robert Spear (Vice-Chair) | Charles Lapin |
| Judith MacGregor | William Nazaroff |
| John Moore | Christopher Portier |
| | Paul Price |

[3] This meeting was organized by the Core members.
[4] Committee member William Yeh, identified expert in contaminant fate and transport, was unable to attend and provided comments after the meeting.

**Office of Environmental Health Hazard Assessment**
**California Environmental Protection Agency**

# MEETING AGENDA

## SCIENCE AND CONSISTENCY IN RISK ASSESSMENT IN CAL/EPA PROGRAMS

*California Environmental Protection Agency*
*Office of Environmental Health Hazard Assessment*
*15 th and 16 th of June, 1995*
*Air Resources Board, Lower Level Hearing Room, 2020 L Street, Sacramento CA*

The Office of Environmental Health Hazard Assessment has convened a Risk Assessment Advisory Committee (RAAC) to review and make recommendations for improving risk assessment practices of California Environmental Protection Agency (Cal/EPA). The RAAC will use this meeting to help it identify program areas and risk assessment activities that need to be reviewed in detail in later meetings. The review process is being undertaken to ensure that Cal/EPA risk assessment practices (1) are based on sound scientific knowledge, methods and practices and (2) are consistent internally and with US Environmental Protection Agency (US EPA) and National Academy of Sciences (NAS), to the extent appropriate (Health and Safety Code Section 57004; SB1082).

### Day 1. Review Cal/EPA Risk Assessment Activities and Receive Public Input

**8:30 AM** Welcome and Oath of Office
*James W. Stratton, Interim Director, Office of Environmental Health Hazard Assessment, Cal/EPA*

Introduction of the Committee Members
*James N. Seiber, Chair, Risk Assessment Advisory Committee*

Committee Charge and Overview of Cal/EPA
*Jack J. Pandol, Undersecretary, California Environmental Protection Agency*

Development of Risk Assessment Practices at the National Academy of Sciences
*Richard D. Thomas, Director, International Center for the Environment and Health*

Human Health Risk Assessment at US EPA
*Jim Cogliano, Chief, Cancer Statistics and Epidemiology, National Center for Environmental Assessment, US EPA*

Scientific Issues in Human Health Risk Assessment Identified by Cal/EPA Standards/Criteria Work Group
*David M. Siegel, Chair, Standards/Criteria Work Group, Cal/EPA*

**10:20 AM** **BREAK**

**10:40 AM** An Overview of Risk Assessment Activities of Cal/EPA
*Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, Cal/EPA*

Presentations on Risk Assessment Activities by Cal/EPA Boards and Departments:

*Office of Environmental Health Hazard Assessment (OEHHA)*
*Department of Toxic Substances Control (DTSC)*
*Department of Pesticide Regulation (DPR)*
*Air Resources Board (ARB)*
*California Integrated Waste Management Board (IWMB)*
*State Water Resources Control Board (SWRCB)*

(Each Cal/EPA Board or Department will give a 10 minute presentation on their mandates and their risk assessment practices.)

Committee Discussion with Cal/EPA and Outside Presenters

(The committee will ask questions about the risk assessments practices in each program and the consistency of those practices with those of US EPA and NAS.)

**12:30 PM** **LUNCH**

**1:30 PM** Committee Discussion with Cal/EPA and Outside Presenters (continuation)

**2:30 PM** **BREAK**

**2:50 PM** Public Comment

(Verbal comments should be concise and may be limited to 5 minutes or less per speaker by the committee chair, depending on the number wishing to speak. Speakers will indicate their interest in speaking by filling out public comment cards which will be available at the front door.)

Committee Discussion with Meeting Participants, Including the Public

**5:00 PM** **ADJOURNMENT OF DAY 1**

## Day 2. Committee Discussion and Planning Session

**8:30 AM** Welcome
*Richard A. Becker, Deputy Director of Scientific Affairs, Office of Environmental Health Hazard Assessment, Cal/EPA*

**8:40 AM** Committee Discussion and Action: Future Meeting Topics and Other Committee Issues

Public Comment

Committee Discussion and Action

**12:30 PM** **ADJOURNMENT**

# SB1082 IMPLEMENTATION: SECOND MEETING OF THE RISK ASSESSMENT ADVISORY COMMITTEE (RAAC)

## VARIABILITY, UNCERTAINTY AND RISK CHARACTERIZATION

*August 10 and 11, 1995*
*Laurel Heights Campus, University of California at San Francisco*
*3333 California Street, San Francisco, California*

This is the second in a series of meetings of the Risk Assessment Advisory Committee of the Science Advisory Board of the Cal/EPA Office of Environmental Health Hazard Assessment. The committee's review is being undertaken to ensure that Cal/EPA risk assessments (1) are based on sound scientific knowledge, methods and practices and (2) are consistent with the US Environmental Protection Agency and the National Academy of Sciences, to the extent appropriate, pursuant to Health and Safety Code Section 57004 (SB1082).

## DAY 1. Characterization of Risks and Analysis of Variability and Uncertainty

Meeting Chair: *Robert C. Spear, Vice-Chair of the Risk Assessment Advisory Committee (RAAC)*

8:30 a.m. Welcome and Oath of Office by New Committee Members
*James W. Stratton, Interim Director, Office of Environmental Health Hazard Assessment (OEHHA)*

8:40 a.m. Expectations for the Meeting
*Robert C. Spear, Professor, University of California, Berkeley, and Vice-Chair of the RAAC*

## Session 1: Variability, Uncertainty and Risk Characterization

8:50 a.m. Risk Characterization Policy of the US Environmental Protection Agency
*James P. Kariya, Co-chair, Risk Characterization Implementation Team, US EPA*

9:05 am Risk Characterization and the National Academy of Sciences
*RAAC participants in National Academy of Sciences Committee on Risk Assessment of Hazardous Air Pollutants, Adam M. Finkel and James N. Seiber, and the Committee on Risk Characterization, James D. Wilson.*

9:20 a.m. Variability, Uncertainty and Risk Characterization at Cal/EPA (Panel Presentations)

Overview, *Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Section, OEHHA*

Air Resources Board
*Genevieve A. Shiroma, Chief, Air Quality Measures Branch*
California Integrated Waste Management Board
*Diane J. Kihara, Senior Industrial Hygienist, Permitting and Enforcement Division*
Department of Pesticide Regulation
*Keith D. Pfeifer, Senior Toxicologist, Medical Toxicology Branch*
Department of Toxic Substances Control
*Jeffery J. Wong, Science Advisor, Office of Scientific Affairs*

Office of Environmental Health Hazard Assessment
*Richard A. Becker, Deputy Director for Scientific Affairs*
State Water Resources Control Board and the Regional Water Quality Control Board
*James Cornelius, Principle Engineer, Regulatory Programs Branch, State Water Resources Control Board, Division of Clean Water Program*

(**Break taken at 10:00 a.m.)**

10:45 am Public Comment

(Verbal comments should be concise and may be limited by the meeting Chair, depending on the number of individuals wishing to speak. We ask that commentors indicate their interest in speaking by filling out the public comment cards available at the front door.)

11:10 a.m. Committee Questions and Discussion

11:30 a.m. **Lunch**

## Session 2: Examples of Variability, Uncertainty and Risk Characterization Practices at Cal/EPA

12:30 p.m. **Conduct and Use of Risk Characterization in the Assessment of Hazardous Waste Sites**
Panel Coordinator: *Richard A. Becker, Deputy Director for Scientific Affairs, OEHHA*

Variability and uncertainty analyses in risk assessment of waste sites
*Thomas E. McKone, Senior Staff Scientist, Lawrence Livermore National Laboratory*
Risk characterization and hazardous waste sites
*Jeffery J. Wong, Science Advisor, Office of Scientific Affairs, Department of Toxic Substances Control*
Consistency of Cal/EPA and US EPA characterization
*Gerald Hiatt, Senior Toxicologist, Technical Support Section, Federal Facilities Clean-up Office, Hazardous Materials Management, Region 9, Superfund Programs, US EPA*
Practical application of risk characterization in site clean-up strategies
*Barbara Cook, Chief, Site Mitigation Branch, Department of Toxic Substances Control*
Application of risk characterization in site clean-up strategies
*James Cornelius, Principle Engineer, Regulatory Programs Branch, State Water Resources Control Board, Division of Clean Water Program*

1:00 p.m. Public comment

Committee (Questions of Clarification)

1:30 p.m. **Break**

1:45 p.m. **Conduct and Use of Risk Characterization in the Assessment of Airborne Contaminants**
Panel Coordinator: *George V. Alexeeff, Chief, Air Toxicology and Epidemiology Section, OEHHA*

Variability, uncertainty and risk characterization of toxicological effects
*Melanie A. Marty, Senior Toxicologist, Air Toxicology and Epidemiology Section, OEHHA*
Variability, uncertainty and risk characterization of airborne pesticides
*Keith D. Pfeifer, Senior Toxicologist, Health Assessment Section, Medical Toxicology Branch, Department of Pesticide Regulation*
Variability and uncertainty analyses in exposure assessment
*Anthony Servin, Associate Air Resources Engineer, Air Resources Board*
Application of risk characterization in air pollutant control strategies
*Robert D. Fletcher, Chief, Emissions Assessment Branch, Air Resources Board*
Application of risk characterization in air permitting
*Patricia A. Holmes, Toxicologist, Permit Services Division, Bay Area Air Quality Management District*

2:15 p.m. Public comment

Committee (Questions of Clarification)

2:45 p.m. **Conduct and Use of Risk Characterization for Accidental Chemical Releases**
Panel Coordinator, *David M. Siegel, Hazardous Waste Toxicology Section, OEHHA*

Risk characterization for accidental chemical releases
*Rupali Das, Public Health Medical Officer, Air Toxicology and Epidemiology Section, OEHHA*
Uncertainty in exposure assessment of accidental chemical releases
*Mark Cameron (tentative), Department of Toxic Substances Control*
Needs and uses of risk characterization information by the Incident Commander
*Karl E. Palmer, Chief, Emergency Response Unit, Department of Toxic Substances Control*
Perspective and Needs of the County Health Officer
*Richard J. Lee, Senior Industrial Hygienist, San Francisco Department of Public Health*

3:05 p.m. Public Comment

Committee (Questions of Clarification)

**(Break taken at 3:15 p.m.)**

## Session 3. Committee Deliberation

3:45 p.m. Public Comment

4:00 p.m. Committee Discussion

5:00 p.m. **Adjournment**

## DAY 2. Committee Discussion and Development of Recommendations

Meeting Chair: *Robert C. Spear, Vice-Chair of the RAAC*

| | |
|---|---|
| 9:00 a.m. | Welcome, *Richard A. Becker, Deputy Director for Scientific Affairs, OEHHA* |
| 9:05 am | Discussion and Formulation of Recommendations |
| 10:20 a.m. | Public Comment |
| 10:30 a.m. | **Break** |
| 10:45 p.m. | Discussion and Formulation of Recommendations (continued) |
| 12:00 a.m. | **Lunch Break** |
| 1:00 p.m. | Public Comment |
| 1:20 p.m. | Discussion and Formulation of Recommendations (continued) |
| 1:40 p.m. | **Break** |
| 2:00 p.m. | Planning of Workshop on Case-studies in Risk Assessment |
| 2:50 p.m. | Public Comment |
| 3:00 p.m. | **Meeting Adjournment** |

# SB1082 IMPLEMENTATION: WORKSHOP OF THE RISK ASSESSMENT ADVISORY COMMITTEE

## RISK ASSESSMENT CASE STUDIES

*September 11 and 12, 1995*
*Buehler Alumni Center, University of California, Davis*

This workshop, convened by the Risk Assessment Advisory Committee (RAAC) of the Science Advisory Board of the Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA), will review risk assessments that illustrate approaches, methodologies and practices of Cal/EPA. The committee's review is being undertaken to ensure that Cal/EPA risk assessments (1) are based on sound scientific knowledge, methods and practices and (2) are consistent with the US Environmental Protection Agency and the National Academy of Sciences, to the extent appropriate, pursuant to Health and Safety Code Section 57004 (SB1082).

## DAY 1. Site-specific Risk Assessments

Meeting Chair: *James N. Seiber, Chair of RAAC*

8:30 a.m. Welcome
*James W. Stratton, Interim Director, OEHHA, Cal/EPA*

8:40 a.m. Format and Expectations for the Workshop
*James N. Seiber, Chair of RAAC*

9:00 a.m. Case Study : Exposure Assessment of Polychlorinated biphenyls (PCBs) at Hazardous Waste Sites

RCRA Site in Southern California
*Mark C. Maritato, Senior Health Scientist, ChemRisk*

CERCLA site, Chatham Brothers Barrel Yard
*Steve M. DiZio, Staff Toxicologist, Office of Scientific Affairs, DTSC, Cal/EPA*

Comments from the Public and State Staff, Committee Questions and Discussion

**(Break taken at 10:00 a.m.)**

11:30 a.m. **LUNCH**

1:00 p.m. Case Study : Modeling of Migration of Chlorinated Solvents in Groundwater to Indoor Air

*William W. Nazaroff, Associate Professor, Department of Civil Engineering, University of California, Berkeley*

Comments from the Public and State Staff, Committee Questions and Discussion

2:45 p.m **BREAK**

3:00 p.m. Case Study : Risk Assessment and Issuance of Air Permits

*Mark D. Saperstein, Health and Safety Department, ARCO*

Comments from the Public and State Staff, Committee Questions and Discussion

Committee Deliberation

**Adjournment**

## DAY 2. Chemical-specific Risk Assessments

8:30 a.m. Welcome
*Richard A. Becker, Deputy Director for Scientific Affairs, OEHHA, Cal/EPA*

8:40 a.m. Case Study : Risk Assessment of a Pesticide, Telone II (1,3-Dichloropropene)

*Nu-may R. Reed, Staff Toxicologist, Department of Pesticide Regulation, Cal/EPA*
*Sally Powell, Senior Environmental Research Scientist, Department of Pesticide Regulation, Cal/EPA*
*Bruce R. Johnson, Senior Environmental Research Scientist, Department of Pesticide Regulation, Cal/EPA*

Comments from the Public and State Staff, Committee Questions and Discussion

10:25 am **BREAK**

10:40 a.m. Case Study : Development of a Health-based Standard for Toluene in Drinking Water

*Joseph Brown, Staff Toxicologist, Pesticide and Environmental Toxicology Section, OEHHA, Cal/EPA*

Comments from the Public and State Staff, Committee Questions and Discussion

12:15 a.m. **LUNCH**

1:45 p.m. Committee Discussion and Formulation of Recommendations

3:15 p.m. **BREAK**

3:30 p.m. Committee Discussion and Formulation of Recommendations (continued)

5:00 p.m. **Meeting Adjournment**

## SB1082 IMPLEMENTATION: THIRD MEETING OF THE RISK ASSESSMENT ADVISORY COMMITTEE

# HAZARD IDENTIFICATION

*October 18-19, 1995*
*Press Room, Morgan Center, University of California, Los Angeles*

This is the third in a series of meetings of the Risk Assessment Advisory Committee (RAAC) of the Science Advisory Board of the Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA), pursuant to Health and Safety Code Section 57004 (SB1082). The committee is reviewing Cal/EPA risk assessments to ensure that they (1) are based on sound scientific knowledge, methods and practices and (2) are consistent with the US Environmental Protection Agency and the National Academy of Sciences, to the extent appropriate.

## DAY 1.

Meeting Chair: *Robert C. Spear, Vice-Chair of the RAAC*

8:30 a.m. Welcome and Oath of Office by New Committee Members
*James W. Stratton, Interim Director, OEHHA*

Expectations for the Meeting
*Robert C. Spear, Professor, University of California, Berkeley, and Vice-Chair of the RAAC*

8:45 a.m. **Hazard Identification Policies and Practices**

Hazard Identification at the US Environmental Protection Agency (US EPA)
*James Cogliano, Chief, Quantitative Risk Methods Group, National Center for EnvironmentalAssessment, US EPA*

Hazard Identification and the National Academy of Sciences (NAS)
*Richard Thomas, Director, International Center for the Environment and Health and former project director of NAS risk assessment programs*

Hazard Identification at Cal/EPA
*Richard A. Becker, Deputy Director for Scientific Affairs, OEHHA*

Committee Questions and Discussion and Public Comment

9:45 a.m. **BREAK**

10:00 a.m. **Issue 1: Defining Adverse Effects**

Overview of the issue

- evaluating adverse acute and subchronic effects
- generic descriptors of disease
- biomarkers of effect (e.g., cholinesterase inhibition) or exposure
- identifying adverse effect versus inconsequential perturbations of homeostasis

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

11:00 a.m. **Issue 2: The Predictivity of Human Response from an Animal Response**

Overview of the issue

- site concordance between animals and humans
- use of animal data versus human data
- use of mechanistic data
- confirmation of findings

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

12:00 a.m. **LUNCH**

1:15 p.m. **Issue 3: The Use of Mechanistic and Other Relevant Data in Identifying Chemical Hazards**

Overview of the issue

- quality of evidence relating the mechanism to the outcome; possibility of multiple mechanisms; competing explanations
- criteria for evaluation of potential hazards not adequately studied in animal bioassays or epidemiological studies
- hazard identification for structurally-related chemicals within given classes
- modification of default approaches (upgrading or downgrading classifications)

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

2:30 p.m. **BREAK**

2:45 p.m. **Issue 4: The Regulatory Process of Hazard Identification**

Overview of the issue

- the legislative and statutory mandates that impact hazard identification in California
- commonality of approaches of Cal/EPA, US EPA, IARC and others
- criteria for selection and evaluation of potential hazards, including classification schemes
- adoption of findings of authoritative bodies
- natural versus anthropogenic materials
- classifying evidence in categories versus alternate approaches

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

4:00 p.m. Conclusion of Day 1 Discussion of Issues.
(Optional: break-out room discussion of RAAC expert members on hazard identification. The public is welcome to attend.)

5:00 p.m. **Adjournment for the day**

**DAY 2.**

8:30 a.m. **Issue 5: Sensitive Populations**

Overview of the issue

- hypersensitivity
- how to define sensitive populations
- biomarkers of susceptibility
- population-specific hazard identification
- sensitivity in timing and age of exposure (especially in reproductive and developmental toxicity)

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

9:15 a.m. **Issue 6: Chemical Mixtures, Impurities, and Concomitant Exposures**

Overview of the issue

- confounders
- interaction
- data needs
- default approaches
- modeling approaches (e.g., use of structure activity, modeling interaction)

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

10:00 a.m. **BREAK**

10:15 a.m. **Committee Discussion and Formulation of Recommendations**

Committee Discussion of Findings and Formulation of Recommendations

Public Comment

11:45 a.m. **LUNCH**

1:00 p.m. Committee Discussion of Findings and Formulation of Recommendations (continued)

Public Comment

3:00 p.m. **Meeting Adjournment**

**Office of Environmental Health Hazard Assessment**
**California Environmental Protection Agency**

## SB1082 IMPLEMENTATION: FOURTH MEETING OF THE RISK ASSESSMENT ADVISORY COMMITTEE

# DOSE-RESPONSE ASSESSMENT

*November 15-16, 1995*
*Garden Room, Clark Kerr Campus, University of California, Berkeley*

This is the fourth in a series of meetings of the Risk Assessment Advisory Committee (RAAC) of the Science Advisory Board of the Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA), pursuant to Health and Safety Code Section 57004 (SB1082). The committee is reviewing Cal/EPA risk assessments to ensure that they (1) are based on sound scientific knowledge, methods and practices and (2) are consistent with the US Environmental Protection Agency (US EPA) and the National Academy of Sciences (NAS), to the extent appropriate.

## DAY 1.

Meeting Chair: *Robert C. Spear, Vice-Chair of the RAAC*

8:30 a.m. Welcome and Oath of Office by New Committee Members
*James W. Stratton, Interim Director, OEHHA*

Expectations for the Meeting
*Robert C. Spear, Professor, University of California, Berkeley, and Vice-Chair of the RAAC*

8:45 a.m. **Overview of Policies and Practices at Cal/EPA, US EPA and NAS**

Dose-response assessment at the US EPA
*James Cogliano, Chief, Quantitative Risk Methods Group, National Center for Environmental Assessment, US EPA*

Dose-response assessment and NAS
*Richard Thomas, Director, International Center for the Environment and Health and former project director of NAS risk assessment programs*

Dose-response assessment at Cal/EPA
*Richard A. Becker, Deputy Director for Scientific Affairs, OEHHA*

Committee Questions and Discussion and Public Comment

9:45 a.m. **BREAK**

10:15 a.m. **Dose-Response Assessment for Acute Exposures**

Overview, Cal/EPA Policies and Practices

*George Alexeeff, Chief, Air Toxicology and Epidemiology Section, OEHHA*

*Michael Lipsett, Physician Epidemiologist, Air Toxicology and Epidemiology Section, OEHHA*

Issues for discussion include

- Extrapolation
  - -- dose averaging, dose-rate response, and study duration adjustments
  - -- use of uncertainty/adjustment factors
  - -- sensitive subpopulations: age and other susceptibility considerations
- Weighing human versus animal data in study selection
- Approaches for deriving guidance levels
  - -- benchmark dose versus NOAEL/LOAEL
  - -- considerations of endpoint severity
- Comparison of Cal/EPA acute exposure guidance levels to those of other institutions

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

12:00 a.m. **LUNCH**

1:00 p.m. **Non-Cancer Dose-Response Assessment for Subchronic and Chronic Exposures**

Overview, Cal/EPA Policies and Practices

*Keith Pfeifer, Senior Toxicologist, Health Assessment Section, Department of Pesticide Regulation*

Issues for discussion include

- Extrapolation
  - -- dose averaging, dose-rate response, and study duration adjustments
  - -- use of uncertainty/adjustment factors
  - -- sensitive subpopulations: age and other susceptibility considerations
- Weighing human versus animal data in study selection
- Approaches for deriving guidance levels
  - -- benchmark dose versus NOAEL/LOAEL
  - -- considerations of endpoint severity
- Comparison of Cal/EPA guidance levels to those of other institutions

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

**(Break taken at 2:30 p.m.)**

3:15 p.m. **Dose-Response Assessment for Carcinogens**

Overview, Cal/EPA Practice of Dose-response Assessment for Cancer Endpoints
*Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Section, OEHHA*

Issues for discussion include

- Extrapolation
  - -- time: dose averaging, dose-rate response, and study duration adjustments
  - -- inter- species and route
  - -- high-to-low dose
  - -- sensitive subpopulations: age and other susceptibility considerations
- Weighing human versus animal data in study selection
- Approaches for deriving cancer potency values
  - -- standard procedures
  - -- "expedited" assessment
  - -- alternatives to the standard procedure
- Comparison of Cal/EPA cancer potency values to those of other institutions

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

**(Break taken at 4:00 p.m.)**

5:30 p.m. **Adjournment for the day**

## DAY 2.

8:30 a.m. Continuation of discussions on Day 1 (Optional)

9:30 a.m. **Committee Discussion and Formulation of Recommendations**

Committee Discussion of Findings and Formulation of Recommendations

Public Comment

**(Break taken at 10:00 a.m.)**

11:45 a.m. **LUNCH**

1:00 p.m. Committee Discussion of Findings and Formulation of Recommendations (continued)

Public Comment

**(Break taken at 2:30 p.m.)**

4:00 p.m. **Meeting Adjournment**

**Office of Environmental Health Hazard Assessment**
**California Environmental Protection Agency**

## SB1082 IMPLEMENTATION: FIFTH MEETING OF THE RISK ASSESSMENT ADVISORY COMMITTEE

# EXPOSURE ASSESSMENT 1. HUMAN INTAKE PARAMETERS, INTER-MEDIA TRANSFERS AND EXPOSURE MONITORING

*December 14-15, 1995*
*Garden Room, Clark Kerr Campus, University of California, Berkeley*

This is the fifth in a series of meetings of the Risk Assessment Advisory Committee (RAAC) of the Science Advisory Board of the Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA), pursuant to Health and Safety Code Section 57004 (SB1082). The committee is reviewing Cal/EPA risk assessments to ensure that they (1) are based on sound scientific knowledge, methods and practices and (2) are consistent with the US Environmental Protection Agency (US EPA) and the National Academy of Sciences (NAS), to the extent appropriate. This is the first of two meetings of the Committee on exposure assessment. The second meeting, tentatively scheduled for February 1996, will address issues related to fate and transport of contaminants in the environment.

## DAY 1.

Meeting Chair: *Robert C. Spear, Vice-Chair of the RAAC*

8:30 a.m. Welcome and Oath of Office by New Committee Members
*James W. Stratton, Interim Director, OEHHA*

Expectations for the Meeting
*Robert C. Spear, Professor, University of California, Berkeley, and Vice-Chair of the RAAC*

8:45 a.m. **Overview of Policies and Practices at Cal/EPA, US EPA and NAS**

Exposure assessment at the US EPA
*Michael A. Callahan, Director, National Center for Environmental Assessment, US EPA, Washington, D.C.*

The NRC Report on Assessing Human Exposures to Airborne Pollutants: Principles and Recommendations
*Joan M. Daisey, Head, Indoor Environment Program, Lawrence Berkeley Laboratory*

Exposure assessment at Cal/EPA
*Richard A. Becker, Deputy Director for Scientific Affairs, OEHHA, Cal/EPA*

Committee Questions and Discussion and Public Comment

9:45 a.m. **BREAK**

10:00 a.m. **Physiological Characteristics and Intake Parameters**

This session covers dermal exposure factors (e.g., skin surface area, absorption efficiency), drinking water ingestion and inhalation (e.g., ventilation rate) exposure factors.

Overview, Cal/EPA Policies and Practices

*Melanie A. Marty, Senior Toxicologist, Air Toxicology and Epidemiology Section, OEHHA, Cal/EPA*

*Robert Howd, Staff Toxicologist, Pesticide and Environmental Toxicology Section, OEHHA, Cal/EPA*

Issues for discussion include

- use of defaults versus population/site-specific data (or extrapolation from other sites or populations)
- uncertainty, variability and covariance
- model validation and testing of assumptions

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

11:40 p.m. **LUNCH**

12:40 p.m. Total Human Exposure Methodology: an Overview of the Science

*Wayne R. Ott, Senior Environmental Engineer, National Exposure Research Laboratory, US EPA and Visiting Scientist, Statistics Department, Stanford University*

1:00 p.m. **Human Activity Patterns, Behavioral and Dietary Characteristics**

This session covers human activity pattern data, food ingestion patterns, breast feeding rates, duration of residential tenure, soil ingestion, and other topics.

Overview, Cal/EPA Policies and Practices

*John H. Ross, Senior Toxicologist, Worker Health and Safety Branch, Department of Pesticide Regulation, Cal/EPA*

*William A. Vance, Senior Toxicologist, Hazardous Waste Toxicology Section, OEHHA, Cal/EPA*

Issues for discussion include

- selection of data set
  - -- defaults versus situation-specific data (or extrapolation from other sites or populations)
  - -- identification and best use of all available data (e.g., statewide probability survey data)
- projections of future land use and behavior, including population mobility
- use of human activity pattern exposure models
- uncertainty and variability
- model validation and testing of assumptions
- exposure scenario
  - -- extreme versus average (individuals, scenarios)
  - -- future projections (how far into the future?)

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

2:40 p.m. **BREAK**

2:55 p.m. **Contact Medium Concentration**

Overview, Cal/EPA Policies and Practices

*Thomas E. McKone, School of Public Health, UC Berkeley and Lawrence Livermore Laboratory*

*Peggy L. Jenkins, Senior Air Pollution Specialist, Indoor Exposure Assessment Section, Air Resources Board, Cal/EPA*

Issues for discussion include:

- modeling of inter-media transfers
  - -- food chain (e.g., meat, fish, and breast milk)
  - -- indirect exposure to VOCs in tap water
- monitoring (food, air, water, soil)
  - -- personal versus area sampling
  - -- characterizing the level and extent of contamination
  - -- representative probability sampling
  - -- Total Exposure Assessment Methodology approach
- extrapolation
  - -- short term to long term and vice versa
  - -- spatial differences
  - -- between population groups, including age groups
- model validation and testing of assumptions
- uncertainty and variability

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

4:35 p.m. **BREAK**

4:50 p.m. **Cross-Cutting Issues in Exposure Assessment**

Overview, Cal/EPA Policies and Practices

*Jeffrey J. Wong, Science Advisor, Office of Scientific Affairs, Department of Toxic Substances Control, Cal/EPA*

Issues for discussion include

- monitoring
  - -- air (ambient, indoor, personal)
  - -- use of biomarkers
  - -- respondent selection and response rate
- source apportionment of exposures / prioritization of exposure pathways
- coordination of exposure metric with dose-response structure
- modeling
  - -- model selection and validation
  - -- introducing new science and new models

- assessing and quantifying uncertainty and variability
  - -- point estimates versus distributions; deterministic versus stochastic assessment
  - -- coordination of treatment of variability and uncertainty in exposure assessment with that of dose-response assessment
  - -- covariance structure
- model validation and testing of assumptions

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

6:00 p.m. **Adjournment for the day**

## DAY 2.

8:30 a.m. **Cross-Cutting Issues in Exposure Assessment (Continued)**

Cal/EPA and US EPA Panel Comment, Committee Questions, and Public Comment

9:45 a.m. **Break**

10:00 a.m. **Committee Discussion and Formulation of Recommendations**

Committee Discussion of Findings and Formulation of Recommendations

Public Comment

11:30 p.m. **LUNCH**

12:30 p.m. Committee Discussion of Findings and Formulation of Recommendations (continued)

Public Comment

2:00 p.m. **Meeting Adjournment**

## SB1082 IMPLEMENTATION: SIXTH MEETING OF THE RISK ASSESSMENT ADVISORY COMMITTEE

# CROSS-CUTTING ISSUES

*January 24-25, 1996*
*Lincoln Plaza, Room 1160, 400 P Street, Sacramento, California*

This is the sixth in a series of meetings of the Risk Assessment Advisory Committee (RAAC) of the Science Advisory Board of the Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA), pursuant to Health and Safety Code Section 57004 (SB1082). The committee is reviewing Cal/EPA risk assessments to ensure that they (1) are based on sound scientific knowledge, methods and practices and (2) are consistent with the US Environmental Protection Agency (US EPA) and the National Academy of Sciences (NAS), to the extent appropriate. At this meeting, the Committee will review and make recommendations regarding issues that affect multiple components of Cal/EPA's risk assessment practices.

## DAY 1

8:30 a.m. Welcome and expectations for the meeting
*James N. Seiber, Chair, Risk Assessment Advisory Committee*

Keynote remarks
*Carol Henry, Associate Deputy Assistant Secretary, Office of Environmental Management, U.S. Department of Energy*

9:00 a.m. **Session 1. Incorporation of New Science in Risk Assessment**
Introduction of Issues
*John A. Moore, Core Member, Risk Assessment Advisory Committee*

- Mechanisms for bringing in new science to risk assessment
  - -- Dealing with consistency requirements
  - -- Propagating scientific concepts and information through the Agency
- Tiered approaches to risk assessment
- Consideration of recommendations from the National Academy of Sciences (NAS) and other science advisory boards
- Data needs
  - -- When should new data be solicited or required from external sources? What should incentives be for generating new data?
  - -- Data quality, filling data gaps and ensuring consistent databases of monitoring results, exposures, and chemical properties
- Evaluation of risks to susceptible and highly exposed populations
- Characterization of scientific debate and uncertainty

Committee and Panel Discussion
Staff and Public Comment

10:30 a.m. **BREAK**

10:45 a.m. **Session 2. Consistency and Harmonization**

Introduction of Issues

*Robert Spear, Vice Chair, Risk Assessment Advisory Committee*

- Promoting consistency among Cal/EPA, US EPA, NAS and other relevant organizations
  - -- Process for deviating when appropriate
  - -- Documenting the reasons for deviating
- Consistency among Cal/EPA boards and departments
  - -- Ensuring, as appropriate, uniformity in safety factors, defaults, potency factors, RfDs and other risk assessment methods and models.
  - -- Ensuring, as appropriate, a consistent database of monitoring results, exposures, chemical properties, etc.
  - -- Role of Cal/EPA's Standards/Criteria Work Group

Committee and Panel Discussion
Staff and Public Comment

12:30 p.m. **LUNCH**

1:30 p.m. **Session 3. Peer Review of Cal/EPA Risk Assessments**

Introduction of Issues

*Judith A. MacGregor, Core Member, Risk Assessment Advisory Committee*

- Role of peer review in Cal/EPA risk assessment activities
  - -- Existing science advisory committees (OEHHA-Science Advisory Board committees, ARB-Scientific Review Panel, OEHHA-Air Quality Advisory Committee)
  - -- Are there other risk assessment activities for which peer review should be incorporated or expanded?
- Involving stakeholders (e.g., regulated community, environmental groups, US EPA) on a continuing basis

Committee and Panel Discussion
Staff and Public Comment

3:15 p.m. **BREAK**

3:30 p.m. **Session 4. Guidelines**

Introduction of Issues

*Herschel E. Griffin, Core Member, Risk Assessment Advisory Committee*

- Updating, promulgating or using existing guidelines for risk assessment in general and for the various steps of risk assessment
- Linking severity of endpoints with the use of defaults, such as uncertainty factors
- Involving stakeholders (e.g., regulated community, environmental groups, US EPA) in guidelines development
- Present and future role of Standards/Criteria Work Group in guideline development and implementation

Committee and Panel Discussion
Staff and Public Comment

5:15 p.m. **Adjournment for the day**

## DAY 2

8:30 a.m. **Session 5. Resources and Organization**

Introduction of Issues

*James N. Seiber, Chair, Risk Assessment Advisory Committee*

- Allocation and sufficiency of resources
- Scientific expertise within Cal/EPA boards and departments
  -- Does Cal/EPA have the necessary expertise (e.g., epidemiologists, environmental modelers, etc.)?
- Are there programs within Cal/EPA that currently do not use risk assessment but could benefitfrom its use?
- Improving interaction between risk assessors and risk managers
- How to couple risk assessment and risk communication, especially in communicating uncertainty and differences in assessments by Cal/EPA and US EPA.
- Simplifying the process (e.g., computer programs, flow charts, etc.) for risk managers and stakeholders (e.g., the regulated community and community groups)
- Increasing flexibility in risk management decisions (e.g., as in the cases of small exceedances or decrements)
- Data bases and their management. What improvements are needed (if any) in the collection, storage, and retrieval of such data as monitoring results, toxicity data, exposure levels collected by or provided to Cal/EPA?

Committee and Panel Discussion
Staff and Public Comment

10:15 a.m. **BREAK**

10:30 a.m. **Committee Discussion and Formulation of Recommendations**

Committee Discussion of Findings and Formulation of Recommendations

Public Comment

11:30 a.m. **LUNCH**

12:30 p.m. **Committee Discussion and Formulation of Recommendations (continued)**

Committee Discussion of Findings and Formulation of Recommendations

Public Comment
Discussion of committee business and planning for future meetings

2:00 p.m. **Meeting adjournment**

## SB1082 IMPLEMENTATION: SEVENTH MEETING OF THE RISK ASSESSMENT ADVISORY COMMITTEE

# CONTAMINANT FATE AND TRANSPORT

*February 7-8, 1996*
*Oak Lounge West, Tresidder Memorial Union, Stanford University, Palo Alto, California*

This is the seventh in a series of meetings of the Risk Assessment Advisory Committee (Committee) of the Science Advisory Board of the Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA), pursuant to Health and Safety Code Section 57004 (SB1082). The Committee is reviewing Cal/EPA risk assessments to ensure that they (1) are based on sound scientific knowledge, methods and practices and (2) are consistent with the US Environmental Protection Agency (US EPA) and the National Academy of Sciences (NAS), to the extent appropriate. This meeting is the second of two on exposure assessment. The first meeting, held December 14-15, 1995, discussed topics such as human intake parameters, inter-media transfers and exposure monitoring. At this meeting the Committee will review and make recommendations on methods and practices by which Cal/EPA evaluates the fate and transport of contaminants in the environment.

## DAY 1

Meeting Chair*: James N. Seiber, Chair, Risk Assessment Advisory Committee*

8:30 a.m. Welcome and Oath of Office
*James W. Stratton, Interim Director, OEHHA*

Expectations for the Meeting
*James N. Seiber, Chair, Risk Assessment Advisory Committee*

## Session 1. Fate and Transport of Contaminants in Groundwater and Surface Water

8:50 a.m. **Overview, Cal/EPA Policies and Practices on Modeling of Contaminants in Groundwater**
*Ike Lukas, Associate Engineering Geologist, State Water Resources Control Board, Cal/EPA*
*John Woodling, Senior Hydrologist, Site Mitigation Branch, Department of Toxic Substances Control, Cal/EPA on contract to the U.S. Army Corps of Engineers*

**Issues for Discussion Include**

- Migration of contaminants from soil to groundwater and surface water
- Tiered approach to groundwater modeling
- Acceptance of new modeling techniques and methods
- Use and integration of information (e.g., conductivity, pumping data, head pressure, etc.) in groundwater modeling
- Evaluation of heterogeneity of the medium
- Uncertainty in transport parameters
- Uncertainty and variability in modeling results
- Model validation, data availability
- Coupling of groundwater models to intermedia transfer and risk models
- Appropriateness of a model for a given task
- Reliability of the models

- Use of point estimates versus distributions for input parameters
- Use of ground and surface water models in exposure and risk assessments

9:25 a.m. Committee and Panel Discussion
Staff and Public Comment

10:15 a.m. **BREAK**

10:30 a.m. Committee and Panel Discussion (Continued)
Staff and Public Comment (Continued)

12:00 p.m. **LUNCH**

1 p.m. . **Overview, Cal/EPA Policies and Practices on Modeling of Contaminants in Vadose Zone**
*Victor J. Izzo, Associate Engineering Geologist, Regional Water Quality Control Board, Central Valley Region, Cal/EPA*

1:15 p.m. Committee and Panel Discussion
Staff and Public Comment

## Session 2. Fate and Transport of Contaminants in Air

2:00 p.m. **Overview, Cal/EPA Policies and Practices**
*Anthony Servin, Associate Air Resources Engineer, Air Resources Board, Cal/EPA*

**Issues for Discussion Include**
- Emission characterization, e.g., emission inventory, AP-42, etc.
- Tiered approach to air dispersion modeling
- Criteria and flexibility in selecting air dispersion models, e.g., Gaussian plume, urban air shed and trajectory models
- Ways to ensure proper application of air dispersion models
- Source apportionment, fingerprint concentrations at receptor sites
- Extent of conservatism built into some models
- Uncertainty and variability in and reliability of modeling results
- Model validation
- Use of air models in exposure and risk assessments

2:30 p.m. **BREAK**

2:45 p.m. Committee and Panel Discussion
Staff and Public Comment

4:15 p.m. **BREAK**

4:30 p.m. Committee and Panel Discussion (Continued)
Staff and Public Comment (Continued)

5:30 p.m. **Adjournment for the Day**

**DAY 2.**

## Session 3. Inter-media Transfer of Contaminants and Other Issues in Fate and Transport Modeling

8:30 a.m. **Overview, Cal/EPA Policies and Practices**

*Ned Butler, Staff Toxicologist, Office of Scientific Affairs, Department of Toxic Substances Control, Cal/EPA*

**Issues for Discussion Include**

- Intermedia transfers (e.g., deposition of airborne particles onto the surface water, ground, and agricultural products)
- Indoor exposure to water and air contaminants
- Model validation
- Degree to which inter-media transfers (alternate pathways) are considered
- Urban runoff
- Exchange of chemicals between sediment/soil, air and water
- Conservation of mass in inter-media transfers
- Use of inter-media transfer models or fate and transport models (e.g., CalTOX) in exposure and risk assessments

8:45 a.m. Committee and Panel Discussion
Staff and Public Comment

10:00 a.m. **BREAK**

10:15 a.m. Committee Discussion of Findings and Formulation of Recommendations
Public Comment

11:30 a.m. **LUNCH**

12:30 p.m. Committee Discussion of Findings and Formulation of Recommendations (Continued)
Public Comment (Continued)

1:45 p.m. **BREAK**

2:00 p.m. Committee Discussion of Findings and Recommendations of Previous Meetings
Public Comment

3:30 p.m. **Meeting Adjournment**

**Office of Environmental Health Hazard Assessment**
**California Environmental Protection Agency**

## SB1082 IMPLEMENTATION: EIGHTH MEETING OF THE RISK ASSESSMENT ADVISORY COMMITTEE

# SYNTHESIS

*April 10-11, 1996*
*Lincoln Plaza, Room 1160, 400 P Street, Sacramento, California*

This is the eighth in a series of meetings of the Risk Assessment Advisory Committee (RAAC) of the Science Advisory Board of the Cal/EPA Office of Environmental Health Hazard Assessment, pursuant to Health and Safety Code Section 57004 (SB1082). The committee is reviewing Cal/EPA risk assessments to ensure that they (1) are based on sound scientific knowledge, methods and practices and (2) are consistent with the US Environmental Protection Agency (US EPA) and the National Academy of Sciences (NAS), to the extent appropriate. At this meeting, the Committee will review and revise their draft report on the Cal/EPA's risk assessment practices.

## DAY 1

8:30 a.m. **Welcome and opening remarks**
*James W. Stratton, Interim Director, Office of Environmental Health Hazard Assessment*

**Expectations for the meeting**
*James N. Seiber, Chair, RAAC*

9:00 a.m. **Chapter 2, Variability, Uncertainty and Risk Characterization**
Summary of findings and recommendations
*James D. Wilson, Expert Lead, RAAC*

Committee discussion and public comment

10:15 am **BREAK**

10:30 a.m. **Chapter 3, Hazard Identification**
Summary of findings and recommendations
*Thomas M. Mack, Expert Lead, RAAC*

Committee discussion and public comment

11:45 am **LUNCH**

1:15 p.m. **Chapter 4, Dose-response Assessment**
Summary of findings and recommendations
*Jerold A. Last, Expert Lead, RAAC*

Committee discussion and public comment

2:30 p.m. **BREAK**

2:45 p.m. **Chapter 5, Exposure Assessment 1**

Summary of findings and recommendations

*William W. Nazaroff, Expert Lead, RAAC*

Committee discussion and public comment

4:00 p.m. **BREAK**

4:15 p.m. **Chapter 6, Exposure Assessment 2**

Summary of findings and recommendations

*William W. Nazaroff, Expert Lead, RAAC*

Committee discussion and public comment

5:30 p.m. **Adjournment for the day**

## DAY 2

8:30 a.m. **Welcome**

*James W. Stratton, Interim Director, Office of Environmental Health Hazard Assessment*

8:35 am **Briefing on President's Commission on Risk Assessment and Risk Management**

*Gil S. Omenn, Chair, Commission on Risk Assessment and Risk Management (by teleconference)*

9:05 am **Chapter 7, Cross-Cutting Issues**

Presentation of findings and recommendations

*John A. Moore, Core Committee Member, RAAC*
*Robert C. Spear, Vice Chair, RAAC*
*Judith A. MacGregor, Core Committee Member, RAAC*
*Herschel E. Griffin, Core Committee Member, RAAC*
*James N. Seiber, Chair , RAAC*

Committee discussion and public comment

10:30 a.m. **BREAK**

10:45 a.m. **Discussion on the Executive Summary, Introduction, and other issues of the RAAC report**

Summary of findings and recommendations

*James N. Seiber and Robert C. Spear, Chair and Vice Chair, RAAC*

Committee discussion and public comment

11:45 a.m. **LUNCH**

12:45 p.m. Continue discussion; public comment

2:00 p.m. **Meeting adjournment**

**SB1082 IMPLEMENTATION: NINTH MEETING OF THE RISK ASSESSMENT ADVISORY COMMITTEE**

# COMMITTEE WORKING SESSION

*May 10, 1996*
*University Club, University of California, Davis*

This is the ninth in a series of meetings of the Risk Assessment Advisory Committee (RAAC) of the Science Advisory Board of the Cal/EPA Office of Environmental Health Hazard Assessment, pursuant to Health and Safety Code Section 57004 (SB1082). The committee is reviewing Cal/EPA risk assessments to ensure that they (1) are based on sound scientific knowledge, methods and practices and (2) are consistent with the US Environmental Protection Agency (US EPA) and the National Academy of Sciences (NAS), to the extent appropriate. At this meeting, the Committee will revise their draft report of their review of the Cal/EPA's risk assessment practices.

9:00 a.m. **Welcome and opening remarks**
*James W. Stratton, Interim Director, Office of Environmental Health Hazard Assessment*

**Expectations for the meeting**
*James N. Seiber, Chair, RAAC*

9:15 a.m. **Draft executive summary**
*James N. Seiber, Chair, RAAC and*
*Robert C. Spear, Vice-Chair, RAAC*

**Committee discussion pertaining to preparation of the draft report**
- Introduction
- Other chapters and appendices

**Other Committee business**

12:00 p.m. **LUNCH**

1:30 p.m. **Committee discussion (continued)**

**Public comment**

5:00 p.m. **Meeting adjournment**

# Appendix G

# Reference Material Reviewed by the Risk Assessment Advisory Committee

The following is a list of reference documents examined by the Risk Assessment Advisory Committee at the topic-specific meetings and workshop during the course of their review. The references are organized by meeting topic. Please note that no additional published materials were reviewed for Meeting 6 (Cross-Cutting Issues), Meeting 8 (Synthesis) and Meeting 9 (Committee Working Session).

## Reference Material Related to Science and Consistency in Risk Assessment (Meeting 1)


California Environmental Protection Agency (1994). *Toward the 21st Century: Planning for the Protection of California's Environment.* California Comparative Risk Project.

National Research Council (1983). Executive Summary, *Risk Assessment in the Federal Government: Managing the Process*. National Academy Press, Washington, DC.

National Research Council (1994). Executive Summary, *Science and Judgment in Risk Assessment*. National Academy Press, Washington, DC.


## Reference Material Related to Variability, Uncertainty and Risk Characterization (Meeting 2)

### A. Examples of Risk Characterizations

#### (i) Examples of Risk Characterizations Prepared by Cal/EPA


Air Resources Board, Stationary Source Division, Cal/EPA (1992). *Proposed Identification of Formaldehyde as a Toxic Air Contaminant.*

Air Resources Board, Stationary Source Division, Cal/EPA (1992). *Proposed Identification of 1,3-Butadiene as a Toxic Air Contaminant.*

California Department of Pesticide Regulation, Medical Toxicology and Worker Health and Safety Branches, Cal/EPA (1994). Mevinphos. Risk Characterization Document.

California Department of Pesticide Regulation, Medical Toxicology and Worker Health and Safety Branches, Cal/EPA (1993). Cyromazine. Risk Characterization Document.

California Department of Food and Agriculture (1988). *Evaluation of Ethyl Parathion as a Toxic Air Contaminant.*

California Integrated Waste Management Board, Cal/EPA (1994). *Mary Long Illegal Disposal Site*.

California Integrated Waste Management Board, Cal/EPA (1995). *Solid Waste Ranking System, User's Guide. Version 2.*

California Department of Health Services, Health Hazard Assessment Division (1991). *Health Risk Assessment of Aerial Application of Malathion-Bait.*

Salmon AG, Zeise L, (Eds.) (1991). *Risks of Carcinogenesis from Urethane Exposure.* CRC Press, Boca Raton, Florida, pp1-3, 110-11, 165-167.

### (ii) Examples of Risk Characterizations Submitted to Cal/EPA

Dames and Moore (1995). Safety-Kleen Corporation, *Safety-Kleen Salida Service Center, Final Operational Health Risk Assessment*. (for DTSC)

Harding Lawson Associates, Department of the Army Corps of Engineers (1994). *Basewide Remedial Investigation/Feasibility Study Fort Ord, California. Volume III - Baseline Human Health Risk Assessment*. (for DTSC)

US Department of Defense (1995). *Relative Risk Site Evaluation Framework: Background, Concept Description, and Guidelines*. (with SWRCB)

### (iii) Examples of US EPA Risk Characterization Documents

US Environmental Protection Agency (1986). Office of Health and Environmental Assessment. Excerpts from *Carcinogenicity Assessment of Chlordane and Heptachlor/Heptachlor Epoxide*.

US Environmental Protection Agency (1992). Office or Research and Development, and Office of Air and Radiation. Excerpts from *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*.

### (iv) Examples of NAS Risk Characterization Documents

National Research Council (1987). Excerpts from *Drinking Water and Health, Disinfectants and Disinfectant By-Products*. National Academy Press, Washington DC.

National Research Council (1993). Excerpts from *Pesticides, Diets of Infants and Children*. National Academy Press, Washington DC.

## B. Guidelines

Air Resources Board, Cal/EPA (1993). *Risk Management Guidelines for New and Modified Sources of Toxic Air Pollutants.*

National Research Council (1983). Selected Excerpts, *Risk Assessment in the Federal Government: Managing the Process*. National Academy Press, Washington, DC.

National Research Council (1994). Selected Excerpts, *Science and Judgment in Risk Assessment*. National Academy Press, Washington, DC.

US Environmental Protection Agency, Office of Emergency and Remedial Response (1989). Excerpts from *Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part A).*

US Environmental Protection Agency (1992). Excerpts from *Guidelines for Exposure Assessment.* Federal Register.

US Environmental Protection Agency (1995). *Policy for Risk Characterization at the US EPA*.

US Environmental Protection Agency (1995). *Guidance for Risk Characterization*.

## C. Scientific Papers on Variability and Uncertainty Analysis

Bois FY et al. (1995). Modeling of human interindividual variability in metabolism and risk: the example of 4-aminobiphenyl. *Risk Analysis*, 15(2): 205-213.

Bois FY et al. (1990). Precision and sensitivity of pharmacokinetic models for cancr risk assessment: tetrachloroethylene in mice, rats and humans. *Toxicology and Applied Pharmacology*, 102: 300-315.

Bois FY et al. (1994). A toxicokinetic analysis of tetrachloroethylene metabolism in humans. Cal/EPA, Office of Environmental Health Hazard Assessment Technical Report.

Burnmaster DE, Anderson, PD (1994). Principles of good practice for the use of Monte Carlo techniques in human health and ecological risk assessments. *Risk Analysis*, 14(4): 477-482.

Cullen AC (1994). Measures of compounding conservatism in probabilistic risk assessment. *Risk Analysis*, 14(4): 389-394.

Evan, JS et al. (1994). A distributional approach to characterizing low-dose cancer risk. *Risk Analysis*, 14(1): 25-34.

Finkel A (1995). Toward less misleading comparisons of uncertain risks: the example of aflatoxin and Alar. *Environmental Health Perspectives*, 103(4): 376-385.

Finley B et al. (1994). Recommended distributions for exposure factors frequently used in health risk assessment. *Risk Analysis*, 14(4): 533-554.

Haimes YY et al. (1994). When and how can you specify a probability distribution when you don't know much? *Risk Analysis*, 14(5): 661-703.

Hattis D, Silver K (1994). Human interindividual variability - a major source of uncertainty in assessing risk for noncancer health effects. *Risk Analysis*, 14(4): 421-432.

McKone TE (1994). Uncertainty and variability in human exposures to soil contaminants through home-grown food: a Monte Carlo assessment. *Risk Analysis*, 14(4): 449-464.

Renwick AG (1993). Data-derived safety factors for the evaluation of food additives and environmental contaminants. *Food Additives and Contaminants*, 10(3): 275-305.

Salinas JA (1994). Stochastic health risk assessment for a hazardous waste incinerator. In: Andrews et al. (eds.) *Hazardous Waste and Public Health - International Congress on the Health Effects of Hazardous Waste*. Princeton Scientific Pub. Inc., Princeton, NJ.

Shlyakhter AI (1994). An improved framework for uncertainty analysis: accounting for unsuspected errors. *Risk Analysis*, 14(4): 441-448.

Travis CC et al. (1987). Cancer risk management a review of 132 federal regulatory decisions. *Environmental Science and Technology*, 21: 415-420.

# Reference Material Related to Case Studies in Risk Assessment (Workshop)

ChemRisk (1995). *A RCRA Site contaminated with PCBs*. Document selectively blacked out to keep site anonymous, full citation not possible.

ENVIRON Corporation (1995). *Draft Human Health Risk Assessment and Ecological Screening Evaluation Report, Chatam Site, Escondito, California, 03-4335A*. Prepared for Chatam Site PRP Group Trust.

Clement Associates (1990). *Final Baseline Public Health Evaluation for the AMD/Signetics/TRW Site*. Prepared for the California Regional Water Quality Control Board.

South Coast Air Quality Management District (1995). *Risk Assessment Procedures for Rules 1401 and 212*, July. (Copies of the two specified rules were attached.)

Department of Pesticide Regulation, Cal/EPA (1994). *Interim Risk Assessment of 1,3-Dichloropropene for the Proposed Use of Telone II* (1994-95).

California Department of Health Services (1988). *Proposed maximum Contaminant Level 1,3- Dichloropropene*.

US Environmental Protection Agency (1990). Petigrewm HM, Memorandum, Telone II - Quantitative Risk Assessment, Mouse (B6C3F1) Inhalation Study.

Office of Environmental Health Hazard Assessment, Cal/EPA (1992). *Toluene, Recommended Public Health Level for Drinking Water.*

# Reference Material Related to Hazard Identification (Meeting 3)

## A. Guidelines, Policies and Practices of Hazard Identification on Carcinogens

**Cal/EPA**

California Department of Health Services (1985). Excerpts from *Guidelines for Chemical Carcinogen Risk Assessments and Their Scientific Rationale.*

Office of Environmental Health Hazard Assessment, Cal/EPA (1992). *Guidelines for Carcinogen Identification and Risk Assessment: Revision Overview.*

Office of Environmental Health Hazard Assessment, Cal/EPA (Draft, 1994). *Comparison of Classification Schemes.*

Office of Environmental Health Hazard Assessment, Cal/EPA (Draft, 1995). *Summary of Carcinogen Identification Criteria.*

**US EPA**

US Environmental Protection Agency (1987). *The Risk Assessment Guidelines of 1986*, EPA/600/8-87/045, August.

US Environmental Protection Agency (1995). *Proposed and Interim Guidelines for Carcinogen Risk Assessment, Review Draft*, NCEA-1-024, July.

**NAS/NRC**

National Research Council (1983). Excerpts from *Risk Assessment in the Federal Government: Managing the Process*. National Academy Press, Washington, DC.

National Research Council (1994). Excerpts from *Science and Judgment in Risk Assessment*. National Academy Press, Washington, DC.

**NIEHS/NTP**

National Institute of Environmental Health Sciences (1994). Identification criteria, given in *Seventh Annual Report on Carcinogens, Summary 1994.* Prepared by the US Department of Health and Human Services.

Thigpen KG (1995). Biennal Report on Carcinogens, A Work in Progress. *Environmental Health Perspectives*, 103(9): 806-807. (Article on NTP's progress on revising their carcinogen classification criteria).

Huff J, Hoel D (1992). Perspective and Overview of the Concepts and Value of Hazard Identification as the Initial Phase of Risk Assessment for Cancer and Human Health. *Scand. J. Work Environ. Health*, 18 Supplemental 1:83-9.

**OSHA**

Code of Federal Regulations, Title 29, Chapter XVII (1989). *Occupational Safety and Health Administration Regulations Identification, Classification, and Regulation of Potential Occupational Carcinogens*. Carcinogen Regulations, Sec. 1990.102., 27:1701-1710. Published by the Bureau of National Affairs, Inc., Washington, DC 20037.

**IARC**

International Agency for Research on Cancer (1994). *IARC Monographs Programme on the Evaluation of Carcinogenic Risks to Humans: Preamble*. World Health Organization, IARC, Lyon, France, pp. 13-33.

**Canada**

Department of National Health and Welfare, Canada (1989). *Part I, Derivation of Maximum Acceptable Concentrations and Aesthetic Objectives for Chemicals in Drinking Water*, pp. 1-5.

## B. Guidelines, Policies and Practices of Hazard Identification on Reproductive and Developmental Toxicants

**Cal/EPA**

Office of Environmental Health Hazard Assessment, Cal/EPA (Draft, 1991). *Draft Guidelines for Hazard Identification and Dose-Response Assessment of Agents Causing Developmental and/or Reproductive Toxicity*.

**US EPA**

US Environmental Protection Agency (1991). *Guidelines for Developmental Toxicity Risk Assessment*. Federal Register 56(234):63797-63826. December 5.

US Environmental Protection Agency (Review Draft, 1994). *Guidelines for Reproductive Toxicity Risk Assessment*.

US Environmental Protection Agency (US EPA 1995). Excerpts from *An SAB Report: Guidelines for Reproductive Toxicity Risk Assessment*. (Review of the Office of Research and Development's Guidelines for Reproductive Toxicity Risk Assessment by the Environmental Health Committee.)

**NAS/NRC**

National Research Council (1994). Executive Summary, *Science and Judgment in Risk Assessment*. National Academy Press, Washington, DC.

## C. Guidelines, Policies and Practices of Hazard Identification on Chemicals That Can Cause Neurotoxicity or Other Adverse Health Effects

**Cal/EPA**

Office of Environmental Health Hazard Assessment, California Air Pollution Control Officers Association, Air Resources Board (1993). Excerpts from *Air Toxics 'Hot Spots' Program. Revised 1992 Risk Assessment Guidelines.*

Department of Pesticide Regulation, Cal/EPA (1994). Excerpts from *A Joint Review of Existing Federal and State Pesticide Registration and Food Safety Programs.*

**US EPA**

US Environmental Protection Agency (1994). *Final Report: Principles of Neurotoxicity Risk Assessment*. Federal Register 59(158): 42359-42396. August 17.

US Environmental Protection Agency (1986). *Guidelines for Mutagenicity Risk Assessment*. Federal Register 51(185): 34005-34012. September 24.

**NAS/NRC**

National Research Council (1993). Excerpts from *Pesticides in the Diets of Infants and Children.* National Academy Press, Washington DC.

**World Health Organization**

International Programme on Chemical Safety (1994). *Environmental Health Criteria 104. Principles for the Toxicological Assessment of Pesticide Residues in Food*. World Health Organization, Geneva.

## D. Examples of Hazard Identification Performed by Regulatory Agencies

### (i) Carcinogens

**Cal/EPA**

Department of Pesticide Regulation, Cal/EPA (1993). *Case Study for Hazard Identification of Cyromazine*.

Office of Environmental Health Hazard Assessment, Cal/EPA (1994). *Summary of Evidence Regarding the Carcinogenicity of Soluble Nickel Compounds.*

Office of Environmental Health Hazard Assessment, Cal/EPA (1995). *Proposition 65 Code and List of Carcinogens.*

Office of Environmental Health Hazard Assessment, Cal/EPA (1995). *Procedure for Prioritizing Candidate Agents for Consideration Under Proposition 65 by the OEHHA Science Advisory Board*

Office of Environmental Health Hazard Assessment, Cal/EPA (1995). *Evidence on the Carcinogenicity of Chloral Hydrate.*

Office of Environmental Health Hazard Assessment, Cal/EPA (1995). Summary, *The Speciation of Nickel Compounds with Respect to Their Carcinogenicity.*

Report of the International Committee on Nickel Carcinogenesis in Man (1990). Excerpts, *Scand. J. Work Environ. Health*, 16(1, special issue): 1-82.

**US EPA**

US Environmental Protection Agency (1991). Cyromazine, Integrated Risk Information System.

US Environmental Protection Agency (1992). Nickel Refinery Dust, Integrated Risk Information System.

US Environmental Protection Agency (1993). Nickel Subsulfide, Integrated Risk Information System.

US Environmental Protection Agency (1994). Chloral Hydrate, Integrated Risk Information System.

US Environmental Protection Agency (1995). Nickel, Soluble Salts, Various, Integrated Risk Information System.

**IARC**

International Agency for Research on Cancer (1990). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Chromium, Nickel and Welding,* Volume 49. World Health Organization, IARC, Lyon, France.

### (ii) Reproductive and Developmental Toxicants

**Cal/EPA**

Department of Pesticide Regulation, Cal/EPA (1993). *Case Study for Hazard Identification of Cyromazine*.

Donald JM, Hooper K, Hopenhayn-Rich (1991). Evidence on Toluene as a Reproductive and Developmental Toxicant. *Environmental Health Perspectives*, 94: 237-244.

Office of Environmental Health Hazard Assessment, Cal/EPA (1995). *Proposition 65 List of Reproductive and Developmental Toxicants.*

**US EPA**

US Environmental Protection Agency (1994). Toluene, Integrated Risk Information System.

## (iii) General Toxicity Evaluation

**Cal/EPA**

Department of Pesticide Regulation, Cal/EPA (1988 and 1992). *Identification of Ethyl Parathion*.

Department of Pesticide Regulation, Cal/EPA (1995). *Use of Cholinesterase Inhibition Data in Risk Assessments for Pesticides.*

Office of Environmental Health Hazard Assessment, Cal/EPA (1993). An Approach for Using Cholinesterase Inhibition in Risk Assessment. Poster #1640. Society of Toxicology Meeting.

Department of Pesticide Regulation, Cal/EPA (1995). *Pesticide Toxicology Data Requirements*.

Office of Environmental Health Hazard Assessment, Cal/EPA (1994). Fact Sheet on Chemical Contaminants in Drinking Water. Nitrate and Nitrite.

Fan AM, Willhite CC, Book SA (1987). Evaluation of the Nitrate Drinking Water Standard with Reference to Infant Methemoglobinemia and Potential Reproductive Toxicity. *Regulatory Toxicology and Pharmacology*, 7: 135-148.

Fan AM (1994). Health Implications of Nitrate in Drinking Water. In: Conference Proceedings, Nitrate in Wisconsin's Groundwater: Strategies and Challenges, Sponsored by: Central WI Groundwater Center (UWEX), Golden Sands RC&D, WI Dept. of Natural Resources, WI Dept. of Health & Social Services.

**US EPA**

US Environmental Protection Agency (1991). Nitrate, Integrated Risk Information System.

US Environmental Protection Agency (1992). Nitrite, Integrated Risk Information System.

**NAS/NRC**

National Academy of Sciences, Safe Drinking Water Committee (1977). *Drinking Water and Health*. National Academy Press, Washington DC.

**World Health Organization**

International Programme on Chemical Safety (1986). *Environmental Health Criteria 63. Organophosphorus Insecticides: A General Introduction*. World Health Organization, Geneva.

# Reference Material Related to Dose-Response Assessment (Meeting 4)

## A. General

### (i) Regulatory Language Regarding Cal/EPA Dose-Response Assessment Practices

California Code of Regulation, Title 22 (1995). Department of Social Services-Department of Health Services, 191-198, Register 95, Nos. 1-3; 1-20-95. *Proposition 65 implementing regulations*.

Toxic Air Contaminants (Chapter 3.5, California Code of Regulations)

Pesticides (California Code of Regulations, SB 950 and AB 2161).

### (ii) Selection of Toxicity Values by Cal/EPA Risk Management Programs

Department of Toxic Substances Control, Cal/EPA (1991). Health Risk Criteria for Use in Risk Assessments Prepared for or by Department of Toxic Substances Control.

California Integrated Waste Management Board, Cal/EPA (1995). Standard Criteria Work Group (SCWG) Issues for Dose-Response Assessment.

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## B. Toxicity Assessment for Acute Exposures

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| Chemical | Program |
|---|---|
| Acetaldehyde | Toxic Air Contaminant |
| Acrylonitrile | Proposition 65 |
| Abamecin | Pesticides |
| Aflatoxins | Proposition 65 |
| Amitrole | Pesticides |
| Arsenic | Drinking Water |
| Arsenic (inorganic) | Proposition 65 |
| Arsenic | Toxic Air Contaminant |
| Asbestos | Proposition 65 |
| Asbestos | Toxic Air Contaminant |
| Atrazine | Drinking Water |
| Benzene | Drinking Water |
| Benzene | Proposition 65 |
| Benzene | Toxic Air Contaminant |
| Benzidine | Proposition 65 |
| Benzotrichloride | Proposition 65 |
| Benzo[a]pyrene | Toxic Air Contaminant |
| Bensulfuron Methyl (Londax) | Pesticides |
| Bifenthrin (Capture 2 EC) | Pesticides |
| Bis (2-chloroethyl) ether | Proposition 65 |
| Bis (2-chloromethyl) ether | Proposition 65 |
| Bromodichlormethane | Drinking Water |
| Bromoform | Proposition 65 |
| 1,3-Butadiene | Proposition 65 |
| 1,3-Butadiene | Toxic Air Contaminant |
| Butylated hydroxy anisole (BHA) | Proposition 65 |
| Cadmium | Proposition 65 |
| Cadmium | Toxic Air Contaminant |
| Carbofuran | Drinking Water |
| Carbon Tetrachloride | Drinking Water |
| Carbon Tetrachloride | Proposition 65 |
| Carbon Tetrachloride | Toxic Air Contaminant |
| Chlordane | Drinking Water |
| Chloroform | Drinking Water |
| Chloroform | Proposition 65 |
| Chloroform | Toxic Air Contaminant |
| Chromium | Proposition 65 |
| Chromium | Toxic Air Contaminant |
| Clofentezine | Pesticides |
| Chloropyrifos (Dursban, Lorsban) | Pesticides |
| Cyromazine | Pesticides |
| Diesel Exhaust | Toxic Air Contaminant |
| 3,3-dichlorobenzidine | Proposition 65 |
| 3,3-dimethylbenzidine | Proposition 65 |
| 3,3-dimethoxybenzidine | Proposition 65 |
| Cis-1,2-dichloroethylene | Drinking Water |
| Trans-1,2-dichloroethylene | Drinking Water |

| | |
|---|---|
| 1,2-dibromo-3-chloropropane | Drinking Water |
| 1,2-dibromo-3-chloropropane | Proposition 65 |
| 1,2-dibromomethane (EDB) | Drinking Water |
| Dichlorodifluoromethane (Freon 12) | Drinking Water |
| 1,1-dichloroethane | Drinking Water |
| 1,2-dichloroethane | Drinking Water |
| 1,1-dichloroethylene | Drinking Water |
| 1,2-dichloropropane | Drinking Water |
| 1,3-dichloropropane | Drinking Water |
| 1,3-dichloropropene (Telone II) | Toxic Air Contaminant |
| Di (2-ethylhexyl) phthalate | Drinking Water |
| Diquat (Aquacide, Dextron) | Pesticides |
| Epichlorohydrin | Proposition 65 |
| Ethylbenzene | Drinking Water |
| Ethylenedibromide | Proposition 65 |
| Ethylenedichloride | Proposition 65 |
| Ethylenedichloride | Toxic Air Contaminant |
| Ethylene oxide | Proposition 65 |
| Ethyl parathion | Toxic Air Contaminant |
| Fenpropathrin | Pesticides |
| Folpet | Pesticides |
| Fenoxaprop-Ethyl (Whip) | Pesticides |
| Formaldehyde, airborne | Toxic Air Contaminant |
| Glycidol | Proposition 65 |
| Glyphosate | Drinking Water |
| Heptachlor | Drinking Water |
| Hexachlorobenzene | Proposition 65 |
| Hexachlorocyclohexane | Proposition 65 |
| HMPA | Proposition 65 |
| Hydrogen cyanamide | Pesticides |
| Isofenphos | Pesticides |
| Mevinphos | Pesticides |
| Molinate | Drinking Water |
| Nickel | Toxic Air Contaminant |
| Nitrogen Dioxide | Criteria Air Pollutant |
| N-nitroso-N-dibutylamine | Proposition 65 |
| N-nitroso-N-ethylurea | Proposition 65 |
| N-nitroso-dimethylamine | Proposition 65 |
| N-nitroso-diphenylamine | Proposition 65 |
| N-nitroso-N-methylurea | Proposition 65 |
| Ozone | Toxic Air Contaminant |
| Paclobutrazol (Bonzi) | Pesticides |
| Pentachlorophenol | Drinking Water |
| Permethrin (Permanone tick repellent) | Pesticides |
| Phenyl glycidyl ether | Proposition 65 |
| Polybrominated biphenyl | Proposition 65 |
| Polychlorinated biphenyl (PCBs) | Proposition 65 |
| Tetrachlorodibenzodioxin (TCDD) | Proposition 65 |
| Tetrachlorethylene | Drinking Water |
| Thiobencarb | Drinking Water |

| | |
|---|---|
| Toluene | Drinking Water |
| 1,1,1-Trichloroethane | Drinking Water |
| 1,1,2-Trichloro-1,2,2-trifluoroethane | Drinking Water |
| 1,1,2,2-Tetrachloroethane | Drinking Water |
| Toxaphene | Proposition 65 |
| Trichloroethylene | Drinking Water |
| Trichloroethylene | Proposition 65 |
| Trichloroethylene | Toxic Air Contaminant |
| 2,4,6-Trichlorophenol | Proposition 65 |
| Urethane | Proposition 65 |
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| Vinyl chloride | Toxic Air Contaminant |

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## (iv) Contaminant Fate and Transport Models

Models Used to Estimate Air Releases

US Environmental Protection Agency (1988). Excerpts from *Superfund Exposure Assessment Manual* (release of contaminants into air). Office of Remedial Response, EPA/540/1-88/001.

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Air Models

US Environmental Protection Agency (1988). Excerpts from *Superfund Exposure Assessment Manual* (Air Models). Office of Remedial Response, EPA/540/1-88/001.

US Environmental Protection Agency (1992). Excerpts from *Screening Procedures for Estimating the Air Quality Impact of Stationary Sources. Revised*. Office of Air Quality Planning and Standards, EPA-454/B-95-004.

US Environmental Protection Agency (1995). Excerpts from *SCREEN3 Model User's Guide*. Office of Air Quality Planning and Standards, EPA-454/B-95-004.

Brief descriptions of some air models, including Complex Terrain Dispersion Model, Urban Airshed Model, SARMAP and Fugitive Dust Model

Models Used to Estimate Water Source Releases

US Environmental Protection Agency (1988). Excerpts from *Superfund Exposure Assessment Manual* (release of contaminants into surface or ground water). Office of Remedial Response, EPA/540/1-88/001.

Brief descriptions of some water source release models, including VLEACH, SESOIL, HELP, and CALVUL

Ground Water Models

US Environmental Protection Agency (1988). Excerpts from *Superfund Exposure Assessment Manual* (ground water models). Office of Remedial Response, EPA/540/1-88/001.

Brief descriptions of some ground water models, including MULTIMED, FLOWPATH, BIOPLUME II, RESSQ, MODFLOW, MT3D, and AT123D

<u>Surface Water Models</u>

US Environmental Protection Agency (1988). Excerpts from *Superfund Exposure Assessment Manual* (surface water models). Office of Remedial Response, EPA/540/1-88/001.

<u>Inter-Media Transfer Models</u>

California Integrated Waste Management Board, Cal/EPA (1994). Excerpts from *Solid Waste Ranking Systems. User's Guide.*

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# Contents of Appendices

**(Materials developed by Cal/EPA staff in support of the Committee's review)**

A Cal/EPA Risk Assessment Procedures by Mandate ("Program Summary Sheets")

B Comparison of Cal/EPA and US EPA Toxicity Values

C An Overview of Exposure Assessment Methodology and Practice of Cal/EPA and US EPA

D An Overview of Fate and Transport Models Commonly Used in Analyses Developed or Reviewed by Cal/EPA

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