

Office of Environmental Health Hazard Assessment (1997) Report on the Implementation of Governor Wilson's Executive Order W-137-96 to Improve the Science and Consistency of Risk Assessment in California. California Environmental Protection Agency.

Background

2.1 The SB 1082 Mandate and RAAC Review

The California State Legislature passed Senate Bill (SB) 1082 (Senator Charles Calderon) into law (Health and Safety Code, Section 57004); one part of this mandate called for an independent peer review of the risk assessment practices of Cal/EPA.

Specifically, the mandate called on the Director of the Office of Environmental Health Hazard Assessment (OEHHA) to convene an advisory committee consisting of distinguished scientists not employed by Cal/EPA to conduct a comprehensive review of the policies, methods, and guidelines used by the agency's programs for the identification and assessment of chemical toxicity. The law further specified that this review should (1) determine if these risk assessment methods and practices were based upon sound scientific knowledge, and (2) assess the appropriateness of any differences between Cal/EPA's practices and those of the National Academy of Sciences (NAS), the U.S. Environmental Protection Agency (US EPA) and other similar "

In response, in June 1995, OEHHA convened the Risk Assessment Advisory Committee (RAAC), a group comprised of 34 distinguished scientists drawn from academia, industry, local government, and national scientific research institutions. The Committee members contained experts from many disciplines related to risk assessment, including toxicology, medicine, engineering, epidemiology, public health, and biostatistics.

The RAAC held 10 public meetings and workshops over more than a year-long period to review each specific aspect of risk assessment practices. The topics of these meetings included hazard identification; dose-response assessment; exposure assessment; and uncertainty, and variability and risk characterization. Additionally, the RAAC held a meeting on issues that cut across all aspects of risk assessment such as incorporation of new science into risk assessment, peer review, guidelines, consistency and harmonization, and resources and organization. These meetings were supplemented with a workshop, early in the review process, to discuss case studies in risk assessment. This workshop served to uncover important issues for later discussion by the RAAC.

Throughout the review process, valuable insight was provided by the interested parties through written submissions to the RAAC as well as by participating in the discussions at the meetings. The RAAC held all of its meetings in public and encouraged the public to participate in the open meeting discussions.

In October 1996, following the completion of its review, the RAAC issued its final report of findings and recommendations in *A Review of the California Environmental Protection*

Agency's Risk Assessment Practices, Policies, and Guidelines. (The Executive Summary of the RAAC report is reproduced as Appendix B of this report.) The report contained over 100 recommendations, covering a wide range of topics in risk assessment, on ways that Cal/EPA might improve the science and consistency of its regulatory programs. Although many of the recommendations were quite specific, most fell within a few general themes, which the RAAC highlighted in the Executive Summary of its report.

2.2 Executive Order W-137-96

The Governor embraced the quality and content of the RAAC's recommendations and in response issued Executive Order W-137-96 (dated December 10, 1996) (Appendix A).

The Executive Order requires that all California state agencies which "assess the toxicity of, exposure to, or risk of chemicals in the environment to human health" to evaluate the RAAC's recommendations and develop plans to implement the recommendations, as part of a state-wide effort to improve the scientific basis of risk assessment practices as outlined by the RAAC's report.

Specifically, the Executive Order had three components. First, it required the Boards, Departments and Offices of Cal/EPA to develop plans to implement the RAAC's recommendations as part of their strategic planning processes. Second, the Executive Order called on the Secretary of Cal/EPA to convene a task force of agency heads within state government to identify other state agencies that also conduct chemical risk assessment. These identified agencies were also directed to develop plans to implement the RAAC's recommendations. Third, the Governor designated the Office of Environmental Health Hazard Assessment of Cal/EPA as the lead agency in facilitating and coordinating implementation of the Executive Order.

2.3 The Implementation Process and the Development of Implementation Plans

To facilitate in the development of a comprehensive response to the Executive Order, OEHHA convened a work group of management and technical representatives from each of the boards, departments, and offices of Cal/EPA. This group met frequently to work collectively and to discuss the development of departmental implementation plans. This group worked diligently to ensure a consistent and comprehensive response by Cal/EPA to the many recommendations in the RAAC report.

In evaluating the RAAC report, the work group noted that most of the over 100 recommendations could be grouped into a relatively small number of themes. These themes included consistency and harmonization, use of best scientific information and methods, peer review, organization and management, and the interface between risk assessment and risk management. The work group found it efficient to develop activities that addressed various aspects of these themes. Additionally, OEHHA set up ongoing processes, such as an intra-agency work group of scientists, the Cal/EPA Risk Assessment Coordination Work Group, to continually evaluate and address specific, technical recommendations of the RAAC.

On May 14, 1997, OEHHA convened a public meeting of the core members of the RAAC to provide a forum in which representatives of the Cal/EPA departments could present their draft plans and obtain feedback from the committee and the public. A number of excellent comments and suggestions were raised at the meeting and were summarized in a memorandum dated June 6, 1997, from Dr. Richard Becker, Director of OEHHA, to the Executive Officers and Board Chairmen of Cal/EPA. These comments were considered by the departments in making revisions to their plans.

As required by the second component of the Executive Order, the Secretary of Cal/EPA convened a task force of Agency and Department heads of within state government to identify boards, departments and offices that might be encompassed by the Governor’s directive. The task force met, February 5, 1997, and identified a number of State agencies that conduct chemical risk assessment as defined in the Executive Order. On February 13, 1997, OEHHA sponsored a technical workshop for these participating departments to discuss the specifics of the RAAC report and the implementation of the Executive Order. Following the workshop, the participating agencies evaluated the RAAC report and developed implementation plans. OEHHA staff worked with these agencies to help evaluate the RAAC report and facilitate, as needed, in the development of their implementation plans.

3 Implementation Plans

3.1 Implementation Plans of the Boards, Departments and Offices of Cal/EPA

The six Boards, Departments and Offices of Cal/EPA as well as the Office of the Secretary evaluated the RAAC report and the Executive Order and developed comprehensive implementation plans. Five of the departments, namely the Office of Environmental Health Hazard Assessment, the California Air Resources Board, the Department of Pesticide Regulation, the Department of Toxic Substances Control, and the State Water Resources Control Board/Regional Water Quality Control Boards, provided implementation plans to address the risk assessment activities within their regulatory programs. The California Integrated Waste Management Board noted that it does not conduct risk assessment to any significant degree and, therefore, indicated that on matters related to human health risk assessment, they would consult with, and rely upon the expertise of, OEHHA. The implementations plans and responses are presented below and are organized by department. Please note that these plans were developed by each department; differences in style and format are evident.

3.1.1 The Office of the Secretary, Cal/EPA

<i>The California Environmental Protection Agency</i>	
<i>RISK ASSESSMENT ADVISORY COMMITTEE RECOMMENDATIONS</i>	<i>PLANNED CAL/EPA ACTIONS</i>
<i>CONSISTENCY AND HARMONIZATION</i>	
1. Establish an Internal Agency Risk	The Office of Environmental Health Hazard Assessment

<p>Assessment Working Group to Promote Greater Harmonization and Consistency</p>	<p>(OEHHA) has been charged with this task. An internal working group, the Risk Assessment Coordinating Work Group has been created. This Work Group is chaired by OEHHA, and is comprised of representatives from all Cal/EPA Boards, Departments and Offices. It meets monthly. Its mission is to improve coordination and increase harmonization for hazard identification, dose-response, exposure assessment, risk characterization and communication across all Cal/EPA Boards, Departments and Offices.</p>
<p>2. Review Legal Mandates in the Interest of Improved Consistency</p>	<p>The legal mandates of Cal/EPA's Boards, Departments and Offices have recently been reviewed by the Unified Statute Commission. Cal/EPA and its member Boards, Departments and Offices are reviewing the Commission's findings and will develop a report on steps taken or planned to produce a more integrated approach to protection of human health and the environment.</p>
<p>3. Agency-Level Science Advisory Committee</p>	<p>In consultation with the Secretary for Environmental Protection, the Director of OEHHA will promote greater consistency and harmonization of science advisory committees.</p>
<p>4. Apply Central Leadership to Reduce Inconsistencies Within the Agency</p>	<p>Existing structures and interactions are being reviewed with respect to the decision to consolidate Headquarters of the Agency and all Boards, Departments and Offices within a single, new building in downtown Sacramento. A report on these efforts will be prepared by Cal/EPA.</p>
<p><i>USE OF BEST SCIENTIFIC INFORMATION</i></p>	
<p>1. Public forums for Incorporating New Science into Risk Assessment.</p>	<p>The Agency will ensure there are expanded forums for the identification, evaluation and promotion of new or existing knowledge to improve the scientific basis for risk assessment in California, by working with the universities and professional societies/organizations to hold workshops and training. This goal will be achieved by increasing the ongoing efforts within Cal/EPA's Boards, Departments and Offices, and assure greater coordination through delegation of this action to the</p>

	OEHHA in association with the Risk Assessment Coordination Work Group.
2. Mechanisms for Expert Advice to the Secretary for Environmental Protection.	The Director of OEHHA shall serve as the science advisor, and consult with expert scientists in the universities, private sector, research institutions and government programs to secure and provide scientific counsel to the Secretary for Environmental Protection on matters of risk assessment.
3. Administrative Structures for Applying New Science into Risk Assessment	Cal/EPA and each member Board, Department and Office have developed strategic plans to implement the recommendations of the Risk Assessment Advisory Committee. The application of new science to risk assessment will be achieved by fulfilling the goals and objectives of each organization strategic plan. Coordination and harmonization will be achieved through the Risk Assessment Coordination Work Group.
4. Agency-Level Advisory Group on Receptor-Based Exposure Assessment.	This task has been delegated to the Risk Assessment Coordinating Work Group.
5. Programs to Evaluate Indoor Air Contaminants.	Programs have already been established within the ARB, OEHHA, DHS and Cal/OSHA with respect to evaluating exposures to indoor contaminants.
<i>ORGANIZATION AND MANAGEMENT</i>	
1. An evaluation of the various scientific disciplines required for risk assessment should be conducted by Cal/EPA to ensure adequate resources are available within the Agency	Each Board, Department and Office will conduct such an evaluation on an annual basis as part of its budgeting process. Emphasis will be placed on development of relationships with other state agencies, the private sector, universities and cross-training and retraining of existing state scientists.
2. Review Environmental Data Collection Mandates and Practices	The Agency will review environmental data collection and mandates to decrease or eliminate overlap, improve accessibility of data, and ensure adequate measures for quality control. This task will be delegated to the Fate and Transport Subcommittee of the Risk Assessment Coordination Work Group (see OEHHA

	strategic plan).
3. Determine if Agency Structure and Function Are Optimal	Existing structures and interactions are being reviewed with respect to the decision to consolidate Headquarters of the Agency and all Boards, Departments and Offices within a single, new building in downtown Sacramento. A report on these efforts will be prepared by Cal/EPA.

3.1.2 The Office of Environmental Health Hazard Assessment (lead agency)

Office of Environmental Health Hazard Assessment Implementation Plan for Addressing the Recommendations of the Risk Assessment Advisory Committee

<i>Activity Description</i>	<i>Performance Measures</i>
<i>Consistency and Harmonization</i>	
Implement Executive Order W-137-96 of the Governor and assist the Secretary of Environmental Protection to harmonize and improve the scientific basis of chemical risk assessment practices in the state of California.	<p>Facilitate agencies and departments in preparing their workplans that address recommendations of the Risk Assessment Advisory Committee.</p> <p>Prepare a progress report to the secretary of Cal/EPA on the implementation of Executive Order W-137-96.</p> <p>Set up a mechanism by which the RAAC core members provide continuity and advice on agency process to implement the RAAC recommendations (such as yearly public meeting to discuss progress and obtain public and committee input)</p>
Convene and coordinate activities of the Cal/EPA Risk Assessment Coordination Work Group (RACWG) to promote consistency in risk assessment practice within Cal/EPA. Form a subcommittee to address issues in fate and transport modeling.	<p>Reduce inconsistencies within Cal/EPA by building consensus on cancer and non-cancer risk assessments, emphasizing chemicals of greatest concern.</p> <p>Release lists of cancer potency factors and toxicity values that are to be used by all</p>

	<p>programs of Cal/EPA.</p> <p>Adopt with modifications the US EPA Guidance for Risk Characterization for use by all Cal/EPA Boards, Departments and Offices.</p>
<p>Harmonize risk assessment activities with US EPA offices in Washington DC and Region IX</p>	<p>Sign and implement a Memo of Understanding with US EPA National Center for Environmental Assessment for collaboration on risk assessment activities.</p> <p>Develop a screening level risk assessment method applicable across Cal/EPA programs, US EPA Region IX, RCRA and Superfund.</p> <p>Harmonize potency estimates for PCBs and adopt the I-TEF approach for assessing health risks associated with dioxin-like compounds across all programs of Cal/EPA.</p>
<p><i>Best Use of Scientific Information and Development of Guidelines</i></p>	
<p>Develop and coordinate technical support on guidance documents, policy documents, and white papers</p>	<p>Finalize Stochastic Exposure Assessment Guideline. Release a new guideline for the "Air Toxics Hot Spots" program.</p> <p>Develop an unified multi-media, multi-pathway exposure assessment method that is acceptable to all Cal/EPA programs.</p> <p>Prepare a briefing book to the Secretary on identifying future emerging environmental challenges.</p> <p>Prepare white papers on scientific issues, e.g., criteria for generally accepted scientific principles and experimental protocols for toxicity tests.</p> <p>Issue a report that summarizes the pilot study results and recommendations of an inter-departmental work group on the implementation of the draft US EPA</p>

	<p>Guidelines for Carcinogen Risk Assessment.</p> <p>Prepare supplemental guidance documents to be used together with the draft US EPA Guidelines for Carcinogens Risk Assessment.</p>
Improve environmental contaminant data management	Through the RACWG fate and transport subcommittee, conduct a feasibility study for improving data management practices of Cal/EPA (determine scope of work, resources needed, and timelines).
Serve as designated science advisor to the Office of the Secretary on environmental and risk assessment issues	Provide advice and counsel to the Secretary (and to other BDOs), utilizing the current Science Advisory Board, RAAC core members and ad hoc panels of independent scientists with specialized expertise, on scientific, environmental and risk assessment issues.
Continue staff training and professional development activities	<p>Attend and make contributions to professional society and scientific meetings/forums.</p> <p>Actively participate in state and national coordinating and harmonization committee meetings, on risk assessment issues.</p>
<p>Continue ongoing efforts in methods development.</p> <p>e.g., physiologically-based pharmacokinetics, stochastic methods, benchmark dose, and molecular mechanisms of carcinogenesis (including receptor mechanisms).</p>	<p>Publish scientific papers in peer reviewed journals.</p> <p>Team up with University of California or other institutes of higher learning to organize seminars on new techniques or approaches in human health risk assessment, e.g., benchmark dose for cancer and non-cancer endpoints.</p> <p>Apply new scientific methods to Public Health Goals, Proposition 65 and the Air Toxic Contaminants programs.</p>
<i>Peer Review and Peer Involvement</i>	
Convene and provide technical and logistical support to the core members of the RAAC to	Hold 1-2 public meetings, coordinate the preparation of briefing materials.

advise Cal/EPA on implementation of the RAAC recommendations	
Assist Boards, Departments and Offices in developing and implementing scientific peer review processes.	Provide general guidelines and consultation of scientific peer review, processes and procedures.
Enhance and expand ongoing peer review and public outreach activities.	Develop Standard Operating Procedures for scientific peer review.
<i>Interface Between Risk Assessment and Risk Management</i>	
Organize training courses for risk assessors and risk managers on risk assessment and risk communication.	Partner with US EPA Region IX in providing training courses to state and local government staff in Risk and Decision Making and Risk Communication and Public Involvement.
Communicate with and educate stakeholders by means of seminars, articles in popular and business press, computer networks on issues related to environmental pollution and public health.	Provide educational materials and presentations on human health risk assessment to staff of other Boards and Departments of Cal/EPA, legislators, local governments, and the public. Develop and write a layman's guide to risk assessment. Post updates on the department's activities on the OEHHA world wide web site.
<i>Organization and Resources</i>	
Develop and implement proactive partnerships with other state departments, research and learning institutions, and private industry for problem-solving and to ensure environmental protection.	Increase collaboration and sharing of expertise with the Department of Health Services and other state agencies, where appropriate.

Narrative Descriptions of OEHHA's Implementation Activities and Performance

Consistency and Harmonization:

Implement Executive Order W-137-96 of the Governor

OEHHA has been designated by the Executive Order as the lead agency for coordinating a state-wide effort to improve the quality and consistency of risk assessment practices in California through the implementation of the recommendations of the Risk Assessment Advisory Committee. The Executive Order also required the Secretary of Cal/EPA to convene a task force of agencies and departments outside Cal/EPA to evaluate and implement the recommendations of the RAAC. OEHHA will provide technical assistance to the members of the task force and help them to evaluate the recommendations of the RAAC and prepare implementation plans that address the recommendations. (FY 96/97 and FY 97/98) (Completed)

In addition, OEHHA is also working with other Boards and Departments of Cal/EPA to facilitate their preparation of draft implementation plans that address RAAC recommendations as part of their strategic plan for the fiscal year 1997-1998. OEHHA held a public meeting on May 14, 1997 for the core members of the RAAC to review and provide inputs on the draft implementation plans of the Boards and Departments of Cal/EPA. (FY 96/97) (Completed)

After the June 30, 1997 Executive Order deadline, OEHHA will compile the implementation plans of the Cal/EPA Boards, Departments and Offices and the plans of agencies outside of Cal/EPA into a comprehensive report of plans and activities for the implementation of the Governor's Executive Order. (FY 97/98) (Completed)

In order to provide a mechanism to evaluate the progress of the implementation activities, OEHHA plans to hold 1-2 public meetings to provide a forum in which the boards, departments and offices of Cal/EPA could discuss progress on their implementation plans and receive input from participants in the RAAC review and the public. Through these public meetings, the participants of the RAAC review can evaluate the progress of the implementation activities of the Boards, Departments and Offices of Cal/EPA and provide suggestions and recommendations for "mid-course" corrections, if necessary. (FY 97/98) (Concept discussed with RAAC chair)

Performance measures of this activity include: (1) minutes from the public meeting of the participants of the RAAC review to provide advice on Cal/EPA implementation plans, (2) assist the Secretary in preparing a progress report to the Governor on the implementation of Executive Order W-137-96, resulting from the task force activities, (3) a progress report to the Secretary of Cal/EPA on the implementation of Executive Order W-137-96 by the Boards, Office and Departments of Cal/EPA, (4) convene 1-2 public meetings to discuss progress on RAAC implementation, and (5) improved overall scientific quality and consistency of application of chemical risk assessment in California state agencies.

Cal/EPA Risk Assessment Coordination Work Group (RACWG)

OEHHA chairs the Cal/EPA Risk Assessment Coordination Work Group (RACWG), which has been formally established within Cal/EPA. Comprised of technical representatives from each of the boards, departments and offices, this Cal/EPA Risk Assessment Coordination Work Group replaces the long-standing, informal Standards and Criteria Work Group. Consistent with the RAAC recommendations, the mission/objective of this group is to provide advice on toxicology and human health and ecological risk assessment issues to the executive officers and directors of boards and departments within Cal/EPA, and to the Secretary for Environmental Protection. By

providing an opportunity for scientists to meet, identify, discuss, debate and coordinate scientific issues and activities, the Cal/EPA-RACWG seeks to ensure that science-policy decisions and risk assessment criteria, guidance, and policies used for regulatory decision-making are based on a firm foundation of science. To the extent appropriate, the Cal/EPA -RACWG will also attempt to harmonize Cal/EPA's risk assessment practices with those of the US Environmental Protection Agency. The Cal/EPA-RACWG strives to achieve consensus among Cal/EPA scientists on technical issues relating to toxicology and risk assessment.

Recently, Cal/EPA-RACWG drafted a risk characterization policy based on the US EPA Risk Characterization Guidelines (1995). The policy is currently undergoing review for adoption by all Cal/EPA Boards and Departments. (FY 96/97 and FY 97/98) (Completed)

An important function of the RACWG is to release lists of consensus cancer potency values and other toxicity criteria that are used by all programs in Cal/EPA. RACWG will continue to update and release these lists. (FY 96/97 -- Ongoing, annual)

The group will also begin work to compile noncancer risk assessments and try to come to consensus on noncancer toxicity values. The initial focus and emphasis of these efforts will be likely given to chemicals of greatest concern. (FY 97/98 and FY 98/99) (Project begun)

Performance measures of this activity include: (1) circulating meeting minutes, (2) update and distribute lists (via OEHHA web site and other media) of Cal/EPA consensus cancer potency factors and, possibly, non-cancer toxicity values, and (3) improved intra-agency consistency in risk assessment practice through the evaluation and implementation of the technical recommendations of the RAAC.

Harmonize risk assessment activities with US EPA offices in Washington DC and Region IX

1. Develop a memorandum of understanding (MOU) with US EPA National Center for Environmental Assessment. (FY 96/97 -- ongoing, annual)

OEHHA has recently signed a memorandum of understanding with its counterpart at the US EPA, the National Center for Environmental Assessment (NCEA). OEHHA and NCEA will work to foster harmonization of the State and federal risk assessment programs to reduce the potential for conflicting approaches and methods, to exchange work products, and to share resources more efficiently. This promises also to ensure close cooperation and collaboration between Cal/EPA and US EPA in other activities, including conducting new chemical-specific risk assessments, application of new scientific advances in risk assessment and implementation of the much anticipated, revised US EPA cancer guidelines.

Performance measures for this effort will include (1) a signed MOU between OEHHA and NCEA, and (2) collaborative or exchanged work products.

2. Develop a screening level risk assessment method for use by Cal/EPA and US EPA Region IX. (FY 96/97 and FY 97/98) (Ongoing)

Cal/EPA and US EPA Region IX have begun a collaborative effort to develop a screening-level

approach for assessing risk posed by chemicals as part of RCRA and Superfund programs. This method would be acceptable to both state and federal agencies for sites or hazards assessed in California, thereby, streamlining the overall regulatory processes. Possible approaches are being evaluated. For example, one approach would be to develop a "look-up" table of remedial values for different media that use the most conservative endpoint (e.g., cancer, ecological, reproductive) to screen for potential of hazard. Activities include periodic meetings and coordination of resources to develop the method.

Performance measures include: (1) a working screening level risk assessment method for use in the RCRA and Superfund programs, (2) increased state and federal harmonization, and a overall streamlined regulatory processes.

3. Harmonize the dose-response evaluations of PCBs and dioxin-like chemicals within Cal/EPA and US EPA. (FY 97/98)

US EPA regulates 2,3,7,8-TCDD and other dioxin-like compounds using an approach developed by the Northern Atlantic Treaty Organization (NATO) and the World Health Organization (WHO) based on the relative toxicity of these compounds to that of 2,3,7,8-TCDD. This approach is called the Toxicity Equivalent Factor (TEF) approach. Slight differences exist between the TEFs used by Cal/EPA and those developed by the NATO and WHO (designated I-TEF for International-TEF). OEHHA will take the lead in ensuring consistent potency factors and approaches are used across all programs and media.

In 1996, US EPA released its revised cancer potency values for polychlorinated biphenyls (PCBs). OEHHA is considering adopting the revised potency values for PCBs for consistent use throughout Cal/EPA.

The performance measure will be the adoption of the I-TEF approach for dioxin-like compounds, and the revised potency values for PCBs by Cal/EPA.

Use of Best Scientific Information

Develop and coordinate technical support on guidance documents, policy documents, and white papers

As stated in the RAAC report, guidelines can be used to promote quality and predictability, as well as improve consistency and administrative efficiency. A major undertaking has been the development of methods to better characterize variability and uncertainty in human exposure assessment. This project consists, in part, of the development and finalization of the Stochastic Exposure Assessment Guidelines as part of the Air Toxics "Hot Spots" program. OEHHA, in cooperation with other Cal/EPA departments and external scientific experts, has produced a first draft and submitted it for public comment. OEHHA will revise the guidelines in response to public comment and peer review. (FY 97/98) (Completed)

OEHHA, in conjunction of other boards and departments, is also in the process of reviewing and considering the adoption of the draft US EPA Guidelines for Carcinogens Risk Assessment. OEHHA has formed a team of scientists to apply the draft US EPA cancer guidelines to 4

selected chemicals. The team will evaluate the approaches and methods described in the guidelines. The team will issue a report evaluating the new guidelines, make recommendations for utilization of the guidelines for use by Cal/EPA, and indicate, where appropriate, areas where supplemental guidance or information is needed. (FY 97/98) (Project nearly completed)

Dependent on the report of the team evaluating the US EPA Carcinogen Guidelines, OEHHA will prepare supplemental guidance where appropriate, for example, in the area of physiologically-based pharmacokinetic modeling. (FY 98/99) (Planned future activity)

OEHHA is also coordinating an intra-agency effort to evaluate new scientific information for the purposes of identifying emerging environmental challenges. The goal of this project is to predict potential future environmental or public health problems (stemming from environmental exposures to chemicals) that may have a significant impact and for which the agency can plan to act upon in the near future. Activities include literature searches and evaluations, internal working sessions and public workshops. (FY 97/98, continue biannually) (Public workshops scheduled)

OEHHA will initiate a project in the Fall of 1997 to develop an unified, multi-media, multi-pathway, multi-chemical exposure assessment method that is applicable to all Cal/EPA programs. The methodology will be able to address variability as well as uncertainty in the estimated exposure/dose in a quantitative manner. (Initiate FY 97/98) (Funding obtained)

Performance measures for these efforts will include: (1) finalization of the Stochastic Exposure Assessment Guidelines for the Air Toxics "Hot Spots" program, (2) develop a multimedia, multipathway exposure assessment method acceptable for all programs, (3) a report that summarizes the findings and recommendations of the team established to evaluate the draft US EPA Guidelines for Carcinogens Risk Assessment, (4) issue supplemental guidance documents, if warranted, to be used together with the draft US EPA Guidelines for Carcinogens Risk Assessment, and (5) a briefing book to the Secretary on identifying emerging environmental challenges for the future.

Enhance staff training and professional development

Risk assessment is an evolving discipline, new approaches are being proposed and new information are being provided by scientists on a continuing basis. OEHHA will continue to encourage staff to attend and make contributions to professional society and scientific meetings, forums and conferences. OEHHA will also support, within the confines of budget limitations, other forms of training including continual education and professional development including publishing articles in the scientific literature. These activities will also include active participation in state and national coordinating and harmonization committee meetings on risk assessment issues. (Ongoing)

Performance will be measured by (1) the implementation of individual development plans to include time budgeted for preparation of publications, attendance at conferences, educational training opportunities and cross training to enhance staff capabilities to achieve OEHHA's mission, (2) number of official positions held by OEHHA staff in professional societies, (3)

overheads and handouts of lectures and technical training courses, and (4) satisfaction of attendees as gauged by responses on course evaluations.

Enhance efforts in methods development

OEHHA is also working to develop new methods and to apply new information and methods into risk assessment practice. In the area of dose-response assessment, new methods and approaches that are being evaluated include the use of biologically-based models, the use of the benchmark dose approach, the use of uncertainty factors in evaluating acute toxicity, and the evaluation of molecular mechanisms of carcinogenesis. OEHHA is developing methods to better characterize uncertainty and variability in human exposure assessment through the development and application of stochastic methods. As a matter of general practice, OEHHA will also look to partnering with university, industry and other scientific institutes to hold workshops to gain public and expert input on new techniques or approaches in risk assessment. OEHHA will consider developing guidance documents or white papers on these and other current issues. (Ongoing)

OEHHA has plans to develop partnerships with professional scientific organizations, and state universities to organize workshops on new techniques and issues in human health risk assessment. Tentative plans have been made for holding two workshops in FY 97/98. The topics of these workshops will be: (1) Proposition 65 authoritative bodies and (2) risk assessment of essential elements. (FY 97/98) (Completed)

Performance measures include: (1) published scientific papers in peer-reviewed journals, (2) minutes or reports stemming from any workshops on new methods, and (3) risk assessments (Public Health Goals, Proposition 65, Air Toxic Contaminants, etc.) incorporating new scientific information, methods or techniques.

Peer Review and Peer Involvement

Scientific peer review was a consistent and clear theme stressed by the RAAC throughout its review. The RAAC noted that peer review was an excellent means of assuring high quality scientific products and processes, increasing credibility of the final product, and bringing new scientific methods and information into the risk assessment process. OEHHA's plans for activities related to scientific peer review included convening and providing technical and logistical support to the core members of the RAAC to advise Cal/EPA on implementation of the RAAC recommendations. This is expected to entail holding 1-2 public meetings and coordinate the preparation of briefing materials. (FY 96/97) (Concept discussed with RAAC chair)

Hold public workshops to facilitate the exchange of scientific information and discussion of risk assessment methods and chemical-specific evaluations, as required by the Health and Safety Code Section 57003 (for example, in the development of Public Health Goals for the drinking water program for FY 97/98) (Ongoing; many workshops held FY 97/98, others planned for FY 98/99)

Also, OEHHA plans to assist, where appropriate, the other Boards and Departments of Cal/EPA in developing and implementing processes for scientific peer involvement and peer review. OEHHA will enhance and expand its ongoing scientific peer involvement and peer review processes as well as public outreach activities. To help improve these activities, OEHHA will develop Standard Operating Procedures for scientific peer involvement and peer review. (FY 97/98 and FY 98/99) (Worked with agency on Cal/EPA guidance/policy on peer review in response to SB 1320)

Performance measures include (1) minutes or memoranda from meeting(s) of the core members of the RAAC on Cal/EPA implementation plans, (2) the development of Standard Operations Procedures, and (3) improvements in the quality and credibility of risk assessments prepared by OEHHA.

Interface Between Risk Assessment and Risk Management

Organize training courses for risk assessors and risk managers on risk assessment and risk communication.

In response to the RAAC's recommendations to improve the interaction of risk assessors and risk managers, and to improve risk communication, Cal/EPA, with the assistance of US EPA Region IX, will provide a series of training courses. Two courses are currently underway, entitled (1) Risk Assessment and Decision Making and (2) Risk Communication and Public Involvement. The courses are being offered this spring and will be initially targeted for risk managers within the Cal/EPA Boards and Departments and other state and local regulatory agencies. Similar training courses will be modified for local and regional governmental staff and risk managers as needed. Specifically, OEHHA will develop a one-day course in risk assessment for local environmental health programs. OEHHA will coordinate this effort within Cal/EPA. (FY 96/97 and ongoing on a quarterly basis)

Performance measures will include the development of the training courses, including instructional materials. OEHHA and Region IX will set up a schedule and convene a series of courses for state and local governmental staff in Risk Assessment and Decision Making and Risk Communication and Public Involvement.

Communicate with and educate stakeholders by means of seminars, articles in popular and business press, computer networks on issues related to environmental pollution and public health.

The RAAC noted that communicating risk information to external stakeholders was an important and integral part of the risk assessment/risk management process. OEHHA plans to further its ongoing efforts in this area. OEHHA will continue its participation in meetings of professional societies and trade shows and provide educational materials, lectures and training sessions on risk assessment to layman and practitioners of the field. In addition, OEHHA will increase its efforts to reach a wider audience by placing technical documents and non-technical risk communication materials on the OEHHA's home page of the World Wide Web. (Ongoing)

The measures of this activities will include providing educational materials and making presentations on human health risk assessment to staff of other Boards and Departments of Cal/EPA, legislators, local governments, and the public. (Ongoing) In addition, OEHHA will develop and write a layperson's guide to risk assessment which will attempt to make the risk assessment process more transparent to general audiences. (Initiated FY 96/97 and will be completed in FY 97/98) (Draft completed) OEHHA will also post updates on the department's activities and important documents on the OEHHA world wide web site. (Ongoing)

Organization and Resources

Develop and implement proactive partnerships with other state departments and private industry for problem-solving and to ensure environmental protection.

The RAAC recommended that OEHHA and other departments of Cal/EPA assess whether the professional expertise of their staff is properly aligned with the needs of their programs. The Committee further recommended that a good means to obtain necessary expertise would be for the departments to enter into formal agreements with other agencies, universities, private industry or similar institution to gain the needed resources. Additional Committee recommendations called for Cal/EPA to seek out ways to streamline the risk assessment process. (FY 97/98 and ongoing)

The performance measures of this activity include: (1) signing inter-departmental agreements with other state agencies, such as Department of Health Services and Department of Pesticide Regulation, on increasing collaboration and sharing of expertise, and (2) establishing formal agreements or contracts with other non-governmental research and learning institutions for consultative services in areas of specialized scientific expertise not sufficiently available within OEHHA.

3.1.3 The California Air Resources Board

Air Resources Board Plan for Implementation of the SB 1082 RAAC Recommendations

In October 1996, the Risk Assessment Advisory Committee (RAAC) released its report entitled: A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines. In this report, the RAAC describes its findings and recommendations for improvements to the California Environmental Protection Agency's (Cal/EPA) risk assessment activities. In December 1996, Governor Pete Wilson signed Executive Order W-137-96 which, in part, requires the Boards, Departments, and Offices of Cal/EPA to evaluate the report and develop plans to implement the RAAC recommendations. This is the Air Resources Board's (ARB/Board) general plan to implement their recommendations.

The ARB's risk assessment practices are a collaborative effort with other Cal/EPA agencies. The ARB primarily works with the Office of Environmental Health Hazard Assessment (OEHHA) to perform risk assessments for the air toxics program. The ARB is responsible for exposure assessment information but relies on OEHHA to provide information required for areas of risk characterization including hazard identification, dose-response, and exposure assessment.

The ARB's implementation plan is organized into six main categories, which correspond to the RAAC recommendations that apply to the ARB. Each category includes a list of the recommendations, on-going ARB activities for the category, and the future goals for addressing the RAAC recommendations. Included also are brief narratives and estimated completion dates for the on-going activities and future goals. The future goals are intended to describe some of the anticipated activities of the ARB. However, we are continually assessing our program to respond to the needs of the agency; therefore, these future goals are subject to change.

1. Peer Review:

Recommendation:

- Evaluate peer review practices for scientific peer review

On-going Activities:

- Assembly Bill (AB) 1807 Air Toxics Program (Ongoing)

In 1983, AB 1807 established California's Air Toxics Program. This is a two phased program for the identification and control of air toxics. During the first phase (identification), the ARB and the OEHHA prepare draft reports on exposure assessment and health assessment. The draft reports are distributed for public review and comment. Comments can be made in writing or at public workshops. The report is then submitted to the independent Scientific Review Panel (SRP) who reviews the reports for scientific accuracy and submits its findings to the Board. The SRP is a nine-member group of professionals with backgrounds in disciplines such as medicine, atmospheric science, statistics, and toxicology. The SRP members are appointed by the Governor or the state legislature. At a public hearing, the Board decides whether to list the substance as a toxic air contaminant (TAC).

TAC and Indoor Exposure Research Projects (Ongoing)

The Research Screening Committee (RSC) reviews proposed research projects and Final Reports from ARB funded projects. The RSC consists of nine external scientists appointed by the Board to review all research projects funded through the Board's extramural research program and specially funded research programs. They review and recommend research proposals to the Board and review Final Reports and/or other project deliverables to assure that needed research is completed using appropriate scientific methods and practices at a reasonable cost to the State.

External peer review is obtained on some projects as needed. For example, external peer review may be requested on projects which are especially large, complex, or sensitive, or those for which the RSC requests additional review.

Future Goals:

Work with other Cal/EPA Boards, Departments, and Offices in developing a flexible standard operating procedure for scientific peer review (Worked with agency to develop Cal/EPA guidance on peer review in response to SB1320)

If OEHHA pursues the activity, the ARB will work with other Boards, Departments, and Offices on the suggestion presented at the May 14, 1997, public workshop to develop a flexible standard operating procedure for scientific peer review. This procedure can be adapted by each Board, Department and Office for its specific regulatory programs.

Continue to peer review the AB 2588 Air Toxics "Hot Spot" Integrated Software through a subgroup of the California Air Pollution Control Officers Association's (CAPCOA) Toxics Committee (anticipated)

The "Hot Spots" Integrated Software will assist industry, the air pollution control or management districts (districts), and the public with the requirements of the AB 2588 Air Toxics "Hot Spots" Program. This software will link: 1) the emission inventory (both toxics and criteria pollutants); 2) prioritization of facilities; 3) air dispersion modeling; and 4) multipathway health risk assessment, including the new OEHHA risk assessment guidelines. The initial software features were developed through a 34 member work group including industry, districts, OEHHA,

2. Interface Between Risk Assessment and Risk Management:

Recommendations:

- Early input from public, stakeholders, and risk managers
- Improve communication between risk assessors and risk managers
- Risk assessors translate emerging methods to risk managers

On-going Activities:

Continue to get early input from local, state and federal agencies, public, and stakeholders (Ongoing)

When a new project begins under the AB 1807 Air Toxics Program, a notice is sent to all interested local, state and federal agencies, public, and stakeholders. This notice is designed to inform, as well as, request all available risk assessment and risk management related information that may pertain to the new project.

Participate on CAPCOA Toxic Committee (meetings every second month) (Ongoing)

The ARB participates in meetings of the CAPCOA Toxics Committee. This Committee includes staffs from many districts, OEHHA, and ARB. The United States Environmental Protection Agency (US EPA) is also invited to attend these meetings. This committee discusses risk assessment and risk management issues, develops guidance documents, and provides a forum for open discussion to establish consistency for implementation of California's air toxics program.

AB 1807 Air Toxics Program (Ongoing)

Once the Board identifies a substance as a TAC, the ARB begins the second phase (control) of the State's TAC program. In this phase, an assessment is conducted to determine the need for, and degree of, further controls. As in the identification phase, public outreach is an essential element in the development of a control plan and any control measures. The ARB works with districts and holds numerous public workshops and individual meetings with stakeholders in an open public process. If appropriate, each airborne toxic control measure is then adopted by the Board at a public hearing.

SB 1731 Risk Reduction Audits and Plans (expected completion 7/1998) (Ongoing, over ¾ completed)

Under Senate Bill (SB) 1731 (Calderon, 1992), facilities determined by the districts to pose a significant potential risk to the public are required to conduct a risk reduction audit of their facility, develop a risk reduction plan, and implement the plan in order to reduce its risk below the significant risk level.

SB 1731 directs the ARB to assist smaller businesses in these efforts. With the assistance of the districts and affected industries, the ARB has developed six source-specific risk reduction audit and plan guidelines. The source categories covered by the specific guidelines are: aerospace, autobody refinishing, chrome plating, degreasing, dry cleaners, and gasoline service stations. In addition, a general guidance document was also developed. These guidelines will be useful to affected industries by providing easy-to-use guidance and checklists to conduct an audit and prepare a plan.

Review and comment on District Toxic New Source Review Rules (Ongoing)

The ARB typically reviews and comments on district toxics new source review (T-NSR) rules at three stages of their development: 1) when they are drafted; 2) when they are proposed; and 3) when the districts formally adopt the rules. When reviewing district T-NSR rules, the ARB compares the T-NSR rule to the methods defined in the ARB's Risk Management Guidelines for New and Modified Sources (Guidelines), applicable Best Available Control Technology Guidelines, and existing T-NSR rules in other comparable districts. The Guidelines were approved in July 1993 and are based on the CAPCOA Air Toxics "Hot Spots" Program Risk Assessment

Future Goals:

Incorporate, when approved, the Cal/EPA Risk Characterization Policy into risk assessments, where needed (Ongoing)

The Risk Assessment Advisory Work Group (RACWG), formed by OEHHA, is developing the draft Cal/EPA Risk Characterization Policy. The ARB is a member of this workgroup. The Cal/EPA Risk Characterization Policy is intended to provide a framework to better assess the information in a risk assessment. This draft policy was modeled after the US EPA's Policy for

Risk Characterization; however, it is left flexible to allow the different Boards, Departments, and Offices within Cal/EPA to adapt the policy to the needs of their programs. The ARB will evaluate materials developed by the RACWG and work to implement this policy, where needed, into risk assessments performed by the ARB and the districts.

Develop risk management guidelines for inorganic lead in cooperation with OEHHA (estimated completion middle 1998) (Ongoing)

The ARB is developing risk management guidelines which will relate air lead levels to blood lead levels based on the Integrated Exposure Uptake Biokinetic (IEUBK) model. It will assist risk managers in making estimates of health impacts due to lead emissions and will help districts both in setting risk levels under AB 2588 and SB 1731 and in permitting lead-emitting sources. The risk management guidelines are needed because the techniques previously used to assess non-cancer risk are not suitable for evaluating the non-cancer effects of lead. This is because lead was determined to not have a threshold level for non-cancer effects. The health effect(s) (neurodevelopmental effects in children and hypertension and related effects in adults) are related to blood lead levels, which are affected by multiple interrelated routes of exposure and these routes can have differing effects on each age group.

Evaluate the need to update the Risk Management Guidelines for New and Modified Sources (estimated evaluation: post-1998) (Future activity)

The Board approved the Risk Management Guidelines for New and Modified Sources (Guidelines) in July 1993. The Guidelines were developed through a series of workshops and meetings with representatives from the districts, environmental groups, trade associations, industry, and governmental agencies. The Guidelines were developed to assist districts in making permitting decisions and designing toxic new source review programs. The guidelines use a combination of specific risk levels and an action range to evaluate new and modified sources of toxic air pollutants. The action range provides flexibility for considering, in addition to risk, other factors such as the uncertainty of the risk assessment. The suggested risk levels defined in the Guidelines are based on risk assessments done in accordance with the CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines (January 1992) using OEHHA risk factors. OEHHA is scheduled to release new risk assessment guidance in 1998. The ARB will reevaluate the Guidelines after the release of OEHHA's guidance to determine if changes are

Incorporate OEHHA Risk Assessment Guidelines into the "Hot Spots" Emission Inventory Criteria and Guidelines Report (middle 1998)

The AB 2588 Air Toxics "Hot Spots" Program currently relies on the CAPCOA Risk Assessment Guidelines as the designated risk assessment procedures for purposes of determining emission reporting requirements and exemptions. Once OEHHA has completed and approved their Risk Assessment Guidelines, the ARB will amend the Emission Inventory Criteria and Guidelines Report through a public regulatory process to incorporate the approved Risk Assessment Guidelines as the designated risk assessment procedures. The public regulatory process allows for public review and comment on the new procedures and fiscal impact. Public

meetings and workshops will be held with the general public, industry and environmental stakeholders, and the districts, followed by formal Board consideration and

3. Exposure Assessment:

Recommendations:

More emphasis on receptor-based exposure assessment when appropriate and cost-effective

Integrate fate and transport modeling efforts with human exposure assessment

Improve characterization of uncertainty and variability

Establish a cross-cutting external advisory group to identify issues and problems best addressed with a receptor-based exposure assessment approach

On-going Activities:

Fund projects to refine and validate the California Population Indoor Exposure Model (estimated completion 2003) (Ongoing)

The California Population Indoor Exposure Model was recently developed under contract to the ARB to provide a tool for estimating Californians' indoor air exposures to selected TAC's from the very limited data available. Results of simple model evaluation and verification tasks have been promising, but the model has not yet been validated. Various model refinements such as updating some of the model inputs also need to be conducted.

Examine ways to apportion human exposures to TAC sources (Ongoing)

Exposure source apportionment is best done through tracer studies, sample component analysis, and similar approaches in combination with personal exposure monitoring. Data from questionnaires and activity pattern studies, usually accompanied by selected indoor and outdoor measurements, provide alternate, although less robust, methods. The utility of these and other exposure source apportionment methods are being examined.

Continue to fund research to refine assumptions for fate and transport such as the current research efforts designed to study ozone and particulate matter in the San Joaquin Valley and South Coast Air Basins (Ongoing)

The ARB continues to fund research to refine assumptions for fate and transport such as the current research efforts designed to study ozone and particulate matter in the San Joaquin Valley and South Coast Air Basins. Although these projects are not designed to specifically study toxic air contaminants, the general understanding of fate and transport of ozone and PM10, and new models that may emerge, can lend themselves to improving the assessment of fate and transport of TAC's. Such is the case for evaluating the public exposure to diesel exhaust where results

from the San Joaquin Valley PM10 study are used as a point of origin. More details on each of the studies follow.

The California Regional PM10 Air Quality Study, a multi-year research project, is expected to provide comprehensive information about the origin and the effects of potential controls for the San Joaquin Valley's airborne particles. The study planning phase began in 1991 and other phases of the program will continue through 2000. The study objectives are to: 1) provide an improved understanding of emissions, PM10 and PM2.5 composition, and dynamic atmospheric processes; 2) establish a strong scientific foundation for informed decision making; and 3) develop methods to identify the most efficient and cost-effective emission control strategies to achieve the PM10/PM2.5 standards in Central California.

The San Joaquin Valley Air Quality Study was designed to improve the understanding of the causes of high ozone episodes and to develop tools that allow decision makers to identify the most effective control strategies to reduce ozone levels to within national clean air standards. An extensive field measurement project was conducted in 1990 to gather emission and meteorological data to help develop a computerized air quality model. The model is designed to identify the best methods for controlling air pollution throughout the study area. The model was designed to take into consideration the diverse geographic and atmospheric conditions that exist throughout the San Joaquin Valley and the potential effect that pollution formed in the Sacramento and San Francisco Bay areas has on San Joaquin Valley air quality. The model also includes information about the Valley's meteorology and air flow patterns in addition to data about population growth, local industrial emission sources and motor vehicle traffic.

The Southern California Ozone Study 1997 will focus on sources of ozone and how ozone moves from one area to another in Southern California. The study will cover the entire southern portion of the state, from Bakersfield into the northern fringe of Mexico and from the Pacific Ocean to the Arizona-Nevada border from June 15 through October 15, 1997. Groups participating in the study with ARB include the South Coast Air Quality Management District, the US EPA, the U.S. Navy, and four other Southern California air quality districts.

Provide uncertainty and variability measures in exposure estimates (Ongoing)

The ARB has recently incorporated the use of the California Population Indoor Exposure Model into the TAC exposure assessment process, and now provides a calculated standard deviation with each mean exposure value provided to OEHHA for calculation of risk. These steps have reduced the uncertainty and provided an indicator of variability with the exposure estimates. However, because both the outdoor and the indoor modeling exercises are complex and require a number of assumptions, further work is needed to provide calculated measures of uncertainty and variability in future exposure estimates.

Participate in OEHHA RACWG with other Cal/EPA Boards, Departments, Offices, and the OEHHA Ecotoxicology Interagency Work Group (Ongoing)

The ARB participates on two OEHHA working groups with other Cal/EPA Boards, Departments, and Offices. These working groups provide an open interagency forum for the

discussion of risk assessment and risk management methods and practices, and the development of both human and ecological guidelines or materials pertaining to risk assessment. Meetings are generally scheduled monthly, or on an as-needed basis.

Coordinate with Department of Toxic Substances Control (DTSC) on risk assessments which evaluate air impacts of hazardous waste sites. (Ongoing)

Under a Memorandum of Understanding, the ARB provides technical assistance to the DTSC on the exposure assessment portion of risk assessments. This assistance consists of reviewing and evaluating potential air impacts of hazardous waste treatment, storage, and disposal facilities, as well as site cleanups. The technical assistance includes evaluating results or recommending methods for: 1) estimating or measuring emissions; 2) dispersion modeling; 3) ambient air monitoring; and collection of meteorological data.

Continue to update stationary source test methods to provide more accurate and precise emissions data for risk assessment and emissions inventory (Ongoing)

The ARB has adopted over 60 stationary source test methods. Existing methods are updated periodically and new methods are adopted. These methods quantitate emissions from stationary sources and are used for risk assessment, emission inventory, and assessing the effectiveness of control devices. Development of test methods includes inputs or suggestions from the public, US EPA, testing organizations, districts, and industry. In addition, the ARB will work with US EPA to harmonize source test methods. To minimize the possibility of retesting, the ARB test methods generally include a more rigorous quality audit/quality control procedures than the US EPA test methods.

Future Goals:

Assess the advantages, disadvantages, feasibility, and cost implications of the development of an integrated indoor and outdoor exposure model (estimated target date of assessment - 2000)
(Future activity)

Currently, outdoor population-weighted average concentrations of TACs are estimated using models that incorporate ambient air quality data, meteorological data, emissions data, and population census data as appropriate. The results are then input (as distributions) into another model (the California Population Indoor Exposure Model) that incorporates mass balance principles, indoor environmental information, and activity pattern data to develop statewide and regional estimates of Californians' indoor and total air exposures to TACs. It is possible that combining portions of the models might lead to improved region-specific and population-specific estimates and might also be less time consuming or less costly. The ARB staff plans to examine whether the indoor and outdoor models can be easily integrated or whether a new model would need to be developed, and the pros, cons, and cost implications of pursuing either approach.

Seek co-funds to expand personal exposure and source apportionment, indoor air chemistry, and pollutant delivery research efforts. (Ongoing)

Such studies are expensive, and only a few have been conducted in California. US EPA funded the major portion of all but one of the studies. Co-funding will need to be obtained in order to pursue personal exposure research and exposure source apportionment research.

Pursue co-funds for research on improved ways to estimate and present uncertainty and variability in exposure estimates (Future activity)

As discussed above under the related ongoing activities, the assumptions and complexity of the modeling exercises increase the difficulty of improving uncertainty and variability estimates. Input from experts outside the Board is needed; however, funding may be needed to support their review and statistical assessment of characterizing uncertainty and variability in our current exposure assessment process.

4. Consistency With US EPA:

Recommendation:

Initiate steps to assure consistency and cooperation with federal counterpart

On-going Activities:

Follow US EPA Exposure Assessment Guidelines provided in the Federal Register dated May 29, 1992, and adhere to their definitions; utilize the US EPA, Scientific Advisory Board (SAB), and National Academy of Sciences (NAS) guidance for estimating human exposure (Ongoing)

The most recent SAB and NAS guidance documents for estimating exposure assessment were incorporated into US EPA's 1992 Exposure Assessment Guidelines. SAB and NAS typically issue reports on topics such as exposure assessment that are then developed into US EPA documents. Following SAB, NAS, and US EPA recommendations will promote harmonization with federal approaches to exposure assessment and assure that California assessments are based on current science and methods.

Continue to work closely with US EPA to integrate California data into US EPA's Exposure Factors Handbook (revised every 5 years) (Future goal)

A revised version of US EPA's Exposure Factors Handbook that includes the ARB's activity pattern data and pulmonary ventilation study data will be released soon. The ARB staff will work with the US EPA staff to assure integration of new information when the handbook is revised again in five years.

Participate in US EPA's Residual Risk Working Group (expected completion 2000) (Ongoing)

Section 112(f) of the federal Clean Air Act requires the US EPA to investigate and report to Congress on the residual risk to public health from sources subject to standards developed under section 112(d). The report must address a variety of issues, including the methods of calculating such risk, significance of the residual risks, available methods to reduce the risks, costs, health

effects of persons living in vicinity of sources, uncertainties in risk assessment, risk from background concentrations, negative consequences of efforts to reduce such risks, and finally, recommendations as to legislation regarding such remaining risk. The ARB is participating in US EPA's Residual Risk Working Group to integrate the federal residual risk program with existing California air pollution control programs. The ARB's involvement with US EPA will help to reduce unnecessary additional regulatory burdens on California businesses.

Participate in development activities for US EPA's Urban Area Source Program (expected completion 2000) (Ongoing)

Section 112(k) of the federal Clean Air Act establishes a national program intended to achieve a substantial reduction of the emissions of hazardous air pollutants (HAPs) from area sources. The US EPA must prepare a national strategy which identifies not less than 30 HAPs in the largest urban areas and identify the source categories of those emissions. The ARB is actively participating in efforts to develop a national strategy and is participating in a work group consisting of the US EPA, and state and local air agencies. In addition, we have provided information on monitoring data and emissions inventory, and are addressing risk from air toxics programs such as AB 2588 and SB 1731.

Future Goals:

Coordinate with US EPA on future exposure assessments under the AB 1807 Air Toxics Program (Ongoing)

As new compounds are evaluated under the AB 1807 Air Toxics Program, the ARB staff will evaluate research from around the world. The ARB staff will work closely with US EPA to share ideas and information on exposure assessment.

5. Continuing Education:

Recommendations:

Continuing education for staff on risk assessment, new models and new science.

Public Education

On-going Activities:

Staff attendance at meetings, seminars, scientific meetings, and training courses (Ongoing)

The ARB management encourages and supports the attendance of the ARB staff at seminars, scientific meetings, and training courses. This will allow the ARB staff to be kept abreast of state-of-the-art techniques related to risk assessment and risk management.

Continue to develop informational material for the public (Ongoing)

The ARB has a public information office and an on-going public outreach policy. Periodically, the ARB develops air toxics related materials including brochures, pamphlets, or advisory papers. These materials are designed to keep the public informed of ARB's programs. Examples include the 1994 brochure on the California Air Toxics Program and the California Toxics Program Updates 1 through 9, informational brochures on how to reduce indoor exposure to pollutants, and summaries of data collected from our monitoring programs.

Continue to publish indoor air quality guidelines that tell the public how they can reduce their exposures to pollutants (Ongoing, currently working on 3 air quality guidelines)

The ARB's Research Division has published two indoor air quality guidelines, one on formaldehyde and the other on indoor combustion pollutants. The guidelines tell the public about possible indoor sources of those pollutants, their potential health effects, and methods to prevent or reduce their indoor exposures. Additional guidelines on indoor chlorinated hydrocarbons, particles and dust (and toxic compounds associated with them), and ozone are in various stages of development.

Establish AB 2588 "Hot Spots" Page on the World Wide Web (Web) to access emission estimation information, and to provide tools necessary to complete accurate air toxics emission inventories and risk assessments (late 1997) (Initial phase complete, continual

The ARB has established an AB 2588 Air Toxics "Hot Spots" Program home page on the Web. The Web pages allow easy access to valuable information regarding the AB 2588 Air Toxics "Hot Spots" Program including the Program overview, Emission Inventory Guidelines Report, the Fee Regulation, emission estimation information and computer software tools, legislation, and connections to other air toxics agencies such as OEHHA and

Future Goals:

Periodically reassess staff's training needs (Future activity)

The ARB will periodically reassess training needs to assure that technical staff is aware of the latest science, skills, and technology.

Update the AB 2588 "Hot Spots" Web Page to provide additional "Hot Spots" Program information, especially in the area of risk assessment (late 1998) (Web page set up, information added

The ARB will be updating the AB 2588 "Hot Spots" Program Web Pages with new tools and information. The updated Web pages will allow access to the new OEHHA Risk Assessment Guidelines when approved, the completed "Hot Spots" Integrated Software, Prioritization Guidelines, Industry-wide Risk Assessment

6. Databases:

Recommendation:

Review data collection and management to minimize overlap and improve accessibility

On-going Activities:

Develop ways of providing monitoring data to public and government agencies through the Internet and compact discs (expected completion fall of 1997) (Distributed to approximately 500 CDs, ongoing)

Toxics air quality data monitored since 1990 are being made available through the ARB's Web site and on compact disc. The monitoring data on compact disc contains the Voyager Data Analysis Software. This software program allows the TAC monitoring data collected by the ARB to be viewed in a variety of ways; thereby, making the data more readily accessible for analysis by the public and other interested parties.

Continue to provide final reports from research contracts through the National Technical Information System (NTIS) (Ongoing, Internet link expected soon)

Final reports from all research funded through the ARB's research programs are available to the public from NTIS.

Add the Toxics Air Monitoring Database to the US EPA Aerometric Information Retrieval System (AIRS) (Ongoing)

Starting in January 1996, all TAC data collected from the ARB's TAC monitoring network are submitted to the AIRS database. Data generated prior to 1996 are also submitted to AIRS from the ARB's Technical Support Division database. This will allow for rapid retrieval of the California TAC data by people with access to AIRS. In addition, US EPA can furnish the data in a format compatible with the Voyager Data Analysis Software.

Update the AB 2588 Air Toxics Emission Data System with more current and accurate data (Ongoing)

The AB 2588 Air Toxics "Hot Spots" Program requires high priority facilities to update their air toxics emission inventories every four years. The ARB is responsible for maintaining the statewide air toxics emission inventory. As facilities update their inventories, and districts approve the updates, the information is forwarded to the ARB for entry into the Air Toxics Emission Data System

Distribute the California Air Toxics Emission Factor (CATEF) database to enable more accurate estimation of air toxics emissions (Ongoing)

In 1996, the ARB began distributing a database of air toxics emission factors for use in estimating emissions for the AB 2588 Air Toxics "Hot Spots" Program. The CATEF database was developed through an ARB research contract. The contractor collected facility air toxics source test data developed for the "Hot Spots" Program using ARB approved source test methods. The ARB has made CATEF available to districts, the US EPA, consultants and other

interested parties. CATEF enables facilities to accurately estimate their air toxics emissions and avoid the high cost of source testing.

Work with OEHHA to restructure their AB 2588 Risk Assessment database to enable data sharing and comparisons with ARB AB 2588 databases (late 1997) (Future activity)

Future Goals:

Update the CATEF database with new emission factors (late 1998) (Ongoing, update with new emission information, mid-1999)

Due to the success and interest in the development of CATEF, the ARB will soon begin a new research contract to collect more air toxics source test data and develop additional emission factors. Based on comments received from CATEF users, the contractor will also develop more user-friendly software and incorporate additional features to the software.

Merge the AB 2588 air toxics emissions data from ATEDS with the ARB's criteria pollutant emissions database from CEIDARS (late 1999) (Ongoing)

The ARB will continue to merge its criteria pollutant emission inventory with its air toxics emission inventory. This is a multi-year effort and requires working closely with districts to ensure the data are accurate and consistent. The end result will allow all air pollutant information for a facility to be located in a single database.

3.1.4 The California Integrated Waste Management Board

California Integrated Waste Management Board

In a letter to the Director of OEHHA, the California Integrated Waste Management Board (IWMB) indicated its response to the Executive Order W-137-96. A summary of the IWMB response is as follows.

The IWMB of Cal/EPA participated in the statewide RAAC meetings. The department reviewed the report of the committee and has determined that those areas covered by the report and Executive Order W-137-96 represent a negligible portion of our overall mandates. For that reason, IWMB will not be including any elements associated with assessment of toxicity, exposure to, or risk of chemicals in the environment to human health in the Board's Strategic Plan. On matters related to human health risk assessment, IWMB will consult with OEHHA or other state agencies.

IWMB will, however, continue to participate in the Risk Assessment Coordination Work Group (RACWG) meetings and any other RACWG activities which may have an impact on Board programs.

3.1.5 The Department of Pesticide Regulation

Outline of the Department of Pesticide Regulation (DPR) Work Plan for the Implementation of the Recommendations of the Risk Assessment Advisory Committee (RAAC)

1. Harmonization and Consistency

A. Utilize the DPR-US EPA harmonization process to reduce duplication of effort.

1. Expand the harmonization process to include areas in addition to toxicology and exposure study review and human health risk assessment.

a. Coordinate regulatory actions. Initiate FY 1997/98 (Initiated Section 18 registration actions)

b. Integrate environmental fate reviews into the harmonization process. Implement FY 1998/99 (Future activity)

2. Increase the exchange of reviews and sharing of work products and workload to avoid duplication of effort.

a. Track the number of work sharing instances used for registration decisions. Initiate FY 1997/98 (Formal tracking not yet initiated)

b. Develop a quality assurance system to be implemented if the work sharing becomes a frequent procedure. Implement FY 1997/98 (Not yet applicable)

3. Work cooperatively with the US EPA in implementing the Food Quality Protection Act (FQPA).

a. DPR assistance to US EPA in meeting time frames. Ongoing

b. DPR representation on FQPA implementation panels. Ongoing

4. Continued DPR participation, with US EPA, on national and international harmonization work groups. Ongoing

a. Track the number of harmonization work groups in which DPR participates. Initiate FY 1997/98 (US EPA OPP resources have been primarily directed towards FQPA. DPR working with OPP on FQPA)

B. Continued participation within Cal/EPA to achieve consistency of risk assessment methods.

1. Continued participation in the Cal/EPA Risk Assessment Coordination Work Group (RACWG). Ongoing

2. Continued participation in the RACWG Environmental Fate and Transport Subcommittee. Ongoing

3. Develop an agreement between OEHHA and DPR defining organizational roles and responsibilities. Implement FY 1997/98 (Formal agreement will not be developed at this time)

II. Peer Review

A. Develop a consistent DPR institutional peer review process. (DPR worked with agency to develop Cal/EPA peer review guidance, in response to SB 1320)

1. Identify the types of DPR documents that are appropriate for internal or external peer review. Complete FY 1997/98 (Initiated)

2. Identify different levels and types of review that are currently used by DPR. Identify additional means of providing peer review (internal and external). Complete FY 1997/98 (Initiated)

3. Adopt a peer review policy. The policy and procedures should be consistent with the general peer review policy of Cal/EPA. The level of peer review should be commensurate with the document being reviewed. Implement FY 1998/99 (Development of the policy initiated)

III. Best Use of Scientific Information and Development of Guidelines

A. Implement a program to encourage and support staff training and professional development.

1. Develop a DPR policy that facilitates participation of staff in continuing education and scientific societies, based on institutional needs and Individual Development Plans. Implement FY 1997/98 (Under development)

2. Encourage and support staff participation in state and national scientific forums and publication of scientific papers on work related topics. Implement FY 1997/98 (Initiated, policy under development)

B. Document the procedures and assumptions used for scientific analyses.

1. Update scientific guidance documents. Include a documentation of the procedures as well as an identification of the default options and assumptions. Include a description of the criteria for using data obtained from various sources (e.g., open literature, manufacturer generated) for risk assessment. Include a documentation of characterization of uncertainty in the risk characterization process to ensure that the level of uncertainty is adequately and appropriately presented.

a. Medical Toxicology Branch guidance document on the conduct of risk assessments. Initiate FY 1997/98, Complete FY 1998/99 (Guidance document initiated)

b. Worker Health and Safety Branch guidance document on the conduct of exposure assessments. Initiate FY 1997/98, Complete FY 1998/99 (Initiated)

2. Develop a procedure to regularly examine and update the risk assessment process and guidance documents.

a. Medical Toxicology and Worker Health and Safety Branches will meet on a regular basis to specifically make recommendations for changes. Ongoing

C. Institute a process to ensure that the data collected and generated by DPR are in usable formats and are used in departmental analyses. (Internal work group has been formed to address the issues)

1. Catalog the data bases that are collected and maintained by DPR. Initiate FY 1997/98 (Initiated)

2. Implement a program to ensure that the data bases are in formats that are amenable to use in the appropriate programs. Implement FY 1998/99 (Under development)

3. Implement procedures to ensure that the appropriate data bases are fully utilized in departmental scientific analyses. Implement FY 1998/99 (Under development)

D. Institute a process to facilitate the incorporation of new scientific knowledge and technology.

1. Institute a seminar series for external scientists to present advances in science and technology. Implement FY 1999/2000 (Future activity)

2. Establish an interdisciplinary technical team to develop recommendations for the incorporation of new technological developments into the appropriate DPR procedures. Implement FY 1997/98 (Future activity)

IV. Interface Between Risk Assessment and Risk Management

A. Institute a process to ensure that the risk assessments meet the needs of the DPR risk managers.

1. Implement meetings between the risk managers and risk assessors to document the risk management needs. Initiate FY 1997/98 (Initiated)

2. Develop a process to ensure early consultation with risk managers in a risk assessment. Initiate FY 1997/98 (Initiated)

3. Finalize the process for external stakeholder scientific input into a risk assessment. Complete FY 1997/98 (Completed)

4. Improve the Departments responsiveness to public concerns about pesticide application and potential impacts, through a public outreach program. Implement FY 1998/99 (Future activity)

V. Organization and Resources

A. Optimize the operational efficiency and consistency of the risk assessment process.

1. Evaluate the risk assessment process and identify appropriate methods of increasing the efficiency of the process, while still maintaining scientific quality.

a. Task each branch to address those portions of the risk assessment process in the branch's area of responsibility. Initiate FY 1997/98 (Initiated)

b. Implement appropriate changes in procedures identified in (a). Implement FY 1998/99 (Future activity)

2. Evaluate the DPR resource requirements with regards to risk assessment. Initiate FY 1997/98 (Future activity)

VI. Continual Improvement

A. Consider additional RAAC recommendations.

1. Update the implementation work plan on a yearly basis to incorporate additional RAAC recommendations. Initiate FY 1997/98 9 (Ongoing)

Narrative Description of the Department of Pesticide Regulation Work Plan for the Implementation of the Recommendations of the Risk Assessment Advisory Committee (RAAC)

Harmonization and Consistency

Utilize the DPR-US EPA harmonization process to reduce duplication of effort.

The Department of Pesticide Regulation (DPR) has a memorandum of understanding (MOU) with the Office of Pesticide Programs (OPP) of the U.S. Environmental Protection Agency (US EPA). A major focus of the MOU is the harmonization of review and evaluation procedures. A major goal of the harmonization effort is to reach a level of consistency that will permit and promote sharing of resources and decrease duplication of effort. A primary focus of the harmonization effort has been on the review of toxicology and exposure studies as well as human health risk assessments. DPR will work with US EPA to expand the project to include environmental fate and effects.

DPR will work to develop a closer coordination of regulatory activities. If DPR evaluates a chemical that OPP does not plan to evaluate for several years, a joint review becomes difficult. However, if both agencies plan regulatory action on or evaluation of a specific chemical in the same time frame, the sharing of resources for addressing that chemical will be helped.

DPR and OPP have shared study evaluations both to compare the conclusions of each agency and to utilize each other's evaluations. The comparison of conclusions leads to a harmonization of evaluation and assessment procedures. This, in turn, establishes a basis for using the evaluations of the other agency in place of a de novo evaluation. The initial exchanges have

focused on acute toxicity studies; however, the exchange of reviews of chronic toxicity studies is increasing. It is important to remain focused on the fact that the goal is not the exchange of reviews for comparison alone, but the sharing of work to reduce duplication of effort. DPR will work to increase the number of instances in which work is shared in the process of reaching regulatory decisions. As the sharing of work products becomes more frequent, DPR will develop quality assurance procedures for the evaluations conducted by OPP and used by DPR in its regulatory decisions.

The federal Food Quality Protection Act (FQPA), passed in 1996, contains many new requirements for US EPA. DPR is currently working with OPP to identify various areas in which DPR can provide assistance in meeting the requirements and time frames. DPR is currently exploring the possibility of doing evaluations for Section 18 Emergency Exemptions from Registration and in setting time-limited tolerances for these exemptions. In addition, DPR personnel serve on advisory panels for the implementation of the FQPA, such as the Working Group on Common Mechanism of Toxicity and Organophosphate Pesticides, and participate in the meetings of other work groups, such as the Endocrine Disrupter Screening and Testing Advisory Committee. OPP and DPR are working to increase such DPR representation.

Besides the above work groups, DPR is also working to increase its participation in international technical groups. DPR will continue to provide comments, through US EPA, on relevant draft Organization for Economic Cooperation and Development (OECD) guidelines. DPR representatives are participating in the North America Free Trade Agreement (NAFTA) Technical Working Group including participation on the subcommittee on Pesticides: Occupational/ Bystander/Residential Exposure. The goal of this working group is to harmonize the default assumptions and data analyses for worker and residential exposure assessments. Draft position papers have been prepared on several topics including protection factors for personal protective equipment and standard reference values.

DPR, US EPA, and Health Canada are participating in a work share project for the review of data for a new active ingredient. In the current work share project, Canada will provide reviews of data related to exposure, reentry, and residue chemistry; US EPA will provide reviews related to product and residue chemistry; and DPR will provide toxicology reviews. The three agencies will determine the adequacy of the shared data and will arrange a joint peer review process. Depending on the results of the current work share project, this cooperative process could be a model for future efforts.

Continued participation within Cal/EPA to achieve consistency of risk assessment methods.

The RAAC recommended that Cal/EPA form an internal technical advisory group to ensure agency-wide consistency. The Standards and Criteria Work Group served this purpose on a more informal basis. In response to the RAAC recommendation, the Cal/EPA Risk Assessment Coordination Work Group (RACWG) was formally established under the lead of the Office of Environmental Health Hazard Assessment (OEHHA). DPR is committed to participate in the efforts of the RACWG and has assigned resources, in the form of personnel, to the efforts. Also, in response to a recommendation of the RAAC, the RACWG formed the Environmental Fate and

Transport Subcommittee. DPR is participating in this work group and in the initial efforts to catalog the various fate and transport models in use within Cal/EPA.

DPR and OEHHA are currently working to develop an agreement defining roles and responsibilities. The purpose of this agreement will be to eliminate duplication of effort, streamline the interagency review process, and share technical expertise.

Peer Review

Develop a consistent DPR institutional peer review process.

DPR recognizes the importance of peer review (internal and external) to ensure the high quality of its scientific documents. At the same time, DPR also recognizes the importance of ensuring that the level of review is commensurate with the importance of the document being reviewed and that the peer review process does not prevent the fulfillment of statutory mandates. While DPR currently uses peer review, it does not have a consistent approach. DPR will develop a consistent institutional peer review process that is in concert with Cal/EPA peer review policies. The first step will be to identify the various types of documents produced by DPR for which technical review is appropriate. DPR will then identify the types and levels of review that are currently being used and will identify additional peer review procedures (internal and external) that could be used. DPR will adopt a formal policy for a consistent and systematic approach to the peer review of DPR scientific documents.

Best Use of Scientific Information and Development of Guidelines

Implement a program to encourage and support staff training and professional development.

DPR recognizes the need to employ high quality science in its risk assessment activities. A highly trained technical staff, conversant with the latest scientific information, is critical to meeting this need. At the same time, DPR recognizes the need to remain focused on its mission and to work within budgetary constraints. DPR will evaluate its existing procedures and develop or modify a professional development policy that will facilitate the participation of staff in continuing education. The continuing education may be sponsored by DPR or Cal/EPA or may occur through scientific societies. The continuing education will be based on the Individual Development Plans of staff as well as on DPR's institutional needs. Participation in scientific societies and state and national forums also play important roles in professional development. The publication of scientific papers in peer reviewed journals is a means of receiving external input, remaining current on scientific issues, and promoting the activities of DPR. Therefore, the professional development policy will also specifically address participation in scientific forums and publication of scientific papers on work related topics and will address the pursuit of additional financial support.

Document the procedures and assumptions used for scientific analyses.

Written guidelines can be used to promote consistency, transparency, and quality in the scientific analyses conducted by DPR. DPR has used guidance documents for specific phases of the risk

assessment process. These guidance documents will be expanded, updated, and completed. Special attention will be paid to both documenting procedures as well as identifying default assumptions and options. The guidance documents will address uncertainty to ensure that uncertainty is adequately and appropriately presented in each risk assessment. In addition, the documents will include descriptions of the criteria for using data obtained from various sources (e.g., open literature, manufacturer generated). The first efforts will be focused on completing a Medical Toxicology Branch guidance document on the conduct of risk assessments, and updating the Worker Health and Safety guidance document on the conduct of exposure assessments. A process will be instituted to regularly examine and update the risk assessment process and the guidance documents. The Medical Toxicology and Worker Health and Safety Branches will meet on a regular basis specifically to make recommendations for such changes.

Institute a process to ensure that the data collected and generated by DPR are in usable formats and are used in departmental analyses.

A large amount of data are collected and generated by DPR. In many cases, these data are assembled into data bases. However, there is no procedure to ensure that these data bases are meeting the needs for which they were initially intended, are in useable formats for both internal and external use, and are utilized to their fullest extent in departmental analyses. DPR will initiate a process to catalog all the data bases developed and maintained by DPR. DPR will then implement a program to transform the data bases, as needed, into consistent formats that are amenable to use in the appropriate program applications. DPR will also implement procedures to ensure that scientific analyses, including risk assessments, fully use these data bases. This will be an ongoing and iterative process.

Institute a process to incorporate new scientific knowledge and technology.

There is sometimes a tendency for government agencies to become insular in their scientific activities, which can impede the incorporation of new scientific knowledge and technology. To help combat this tendency, DPR will institute a seminar series in which external scientists will present advances in science and technology. DPR will also establish an interdisciplinary technical team that will develop recommendations for the incorporation of new technological developments into the appropriate DPR procedures.

Interface Between Risk Assessment and Risk Management

Institute a process to ensure that the risk assessments meet the needs of DPR risk managers.

The RAAC concentrated on risk assessment issues; however, the review also addressed risk management. The value of a risk assessment will be judged based on its utility in enabling and supporting a sound risk management decision. While it is important to maintain a distinction between risk assessment and risk management, it is equally important to foster close communication and cooperation between the risk assessor and risk manager. The RAAC recognized this need and made recommendations addressing communication and cooperation.

DPR will initiate a series of meetings between its risk assessors and risk managers. These meetings will not address specific chemicals, risk assessments, or risk management decisions, but will concentrate on the overall structure of the risk assessment process within DPR. The purpose of this interchange will be to document the needs of the risk managers and to decide if the risk assessments meet these needs. Potential changes to the risk assessment and risk management processes may be identified. A process will be developed to ensure early consultation with risk managers on a risk assessment. The purpose of this consultation will be to give the risk assessor as much relevant information as possible (e.g., actual use practices for the application of the pesticide in question, probable exposure durations, identification of exposed populations, etc.).

A process is under development to facilitate early external shareholder scientific input into a risk assessment. A notice will be prepared that announces the initiation of a risk assessment, identifies the toxicology studies that are expected to be of primary importance in the risk assessment, identifies the toxicological values and endpoints (e.g., No Observed Affect Levels) that are expected to drive the risk assessment, and identifies some of the initial exposure values (e.g., dermal exposure) that may be used. The notices will also invite any additional relevant scientific data. DPR is currently evaluating procedures with which to release drafts of the risk characterization documents for comment. Some procedures may be initiated on a trial basis.

Like risk management, risk communication can also not be divorced from risk assessment. Public outreach is an important component of any risk assessment process. DPR will initiate a public outreach program to improve its responsiveness to public concerns about pesticide application and potential impacts.

Organization and Resources

Optimize the operational efficiency and consistency of the risk assessment process.

Increasing pressures on available resources and expanding departmental risk assessment needs demand that the risk assessment process be as efficient as possible, while not sacrificing scientific quality. The most appropriate means for increasing the efficiency can best be identified by the people performing the risk assessments, based on appropriate information from the risk managers regarding their needs. Each DPR branch that contributes to the risk assessment process will address those portions of the risk assessment process in the branch's areas of responsibility and will identify various ways to increase efficiency, while still maintaining the appropriate level of scientific quality. This process will also identify the resource needs regarding risk assessment. This will be an iterative process.

Continual Improvement

DPR recognizes that this initial work plan primarily addresses the major areas of RAAC recommendations. DPR will revisit and update this work plan on a yearly basis. Such modifications may also identify the need for changes to the Department's strategic plan.

3.1.6 The Department of Toxic Substances Control

STRATEGY FOR IMPROVING THE SCIENCE AND APPLICATION OF RISK ASSESSMENT

SB 1082 RAAC IMPLEMENTATION WORK PLAN

Human and Ecological Risk Division (HERD)
California Environmental Protection Agency
Department of Toxic Substances Control
Science, Pollution Prevention, and Technology Program

I. Harmonization and Consistency

A. Continue work within Cal/EPA to achieve consistency of risk assessment methods and the use of the best available science.

1. Work within the Cal/EPA Risk Assessment Coordination Work Group(RACWG) to develop DTSC guidance on the application of stochastic approaches to risk assessment process for hazardous waste sites and facilities. DTSC has already developed initial distributions for various exposure parameters for use in Monte Carlo analysis. Need to work with OEHHA to develop distributions on toxicological input parameters. (Ongoing)
2. Serve as lead for the Cal/EPA RACWG Environmental Fate and Transport Subcommittee. Need to overcome institutional barriers and resource limitations to gain more participation in the development of a Cal/EPA wide inventory of expertise and resources focusing on fate and transport issues. Need to develop a proposed Cal/EPA-wide framework for interaction and mutual support to address barriers related to legal authority and special fund expenditure restrictions. (Initial phase completed)
3. Participated as a member of OEHHA's Exposure Assessment and Stochastic Analysis External Advisory Group (in support of the OEHHA Air Toxics Hot Spots Program). Will use this effort above to support choices on an expanded database of default distributions in Cal/TOX for the various exposure parameters. Must develop overall DTSC guidance on the use of Cal/TOX in performing stochastic analysis of risk and in the estimating of risk-based preliminary remediation goals. (Completed)
4. Completed initial work with the ARB technical staff to identify and integrate an analytical dispersion model for contaminants in the air compartment into Cal/TOX. Future work with ARB technical staff will include the incorporation of a wider suite of air dispersion and transport models. (Completed)
5. Initiate work with water board technical staff to expand and improve on the fugacity model currently incorporated in Cal/TOX to estimate contaminant concentrations and content in subsurface compartments. Identify and integrate a numerical and/or analytical unsaturated and saturated flow, transport, dispersion, and transformation model(s) for contaminants in the

subsurface and groundwater compartment into Cal/TOX. (Pursuing work with UC, USGS and other institutions)

B. Continue work with US EPA to achieve consistency of risk assessment methods and the use of the best available science.

1. Continue to support the US EPA (Region 9)-Cal/EPA harmonization project on "Preliminary Soil Remediation Goals (PRGs)." HERD has provided Cal/TOX outputs (input parameter varied) for exposure scenario-specific PRGs using the Cal/TOX. Continue to work with the project on the development of a full multimedia multi-pathway risk assessment approach for calculating PRGs for (1) hazardous waste sites and (2) closure and corrective action at permitted facilities. HERD will continue to oppose the development of "cleanup number" lists to be used in the absence of a well developed and rationale implementation strategy. (Ongoing)

2. Incorporate toxicological properties, chemical properties, exposure and fate/transport parameters, environmental compartment and media characteristics and probability distributions into a database for Cal/TOX. This will include that which has been developed by/for US EPA and various Cal/EPA agencies and reported in the peer reviewed scientific literature. This effort will be dependent on continued US EPA funding. HERD is currently working with Lawrence Livermore National Laboratory (LLNL) for US Department of Defense (DOD) funding. (Ongoing, majority of work completed)

3. Complete joint research with US EPA headquarters, the University of California, Davis Risk Sciences Center, and Lawrence Berkeley Laboratory on the development of a plant uptake and distribution model for Cal/TOX. This effort will be dependent on continued US EPA funding. (In progress)

4. Finished initial DTSC guidance for ecological risk assessment. For the past year, this guidance has been distributed via the DTSC World Wide Web site. DTSC will continue its joint efforts with OEHHA, US EPA Region 9 and other State and Federal Agencies on the development of more comprehensive risk assessment guidelines and procedures for ecological risk assessment. (Completed)

5. Will initiate the use of an Rock Environmental Systems (RES) approach to characterizing "Features, events and processes" related to exposures from hazardous waste sites and facilities. This technique was developed by the Swedish SKB and modified by QuantiSci, Ltd. for the Electric Power Research Institute (EPRI). HERD will work with EPRI to develop this approach for DTSC. (Project begun, concept introduced to the RACWG)

II. Peer Review

Continue a formalized program of internal and external scientific peer review. (Completed work with agency to develop Cal/EPA guidance on peer review in response to SB 1320)

1. DTSC Internal - Continue Senior Toxicologist scientific peer review of Associate and Staff Toxicologist analysis of site and facility risk assessments submitted by responsible parties and permit applicants, respectively.
2. DTSC Internal - Continue additional scientific peer review by project management staff of Associate and Staff Toxicologist analysis of site and facility risk assessments submitted by responsible parties and permit applicants, respectively for policy and procedural inconsistencies.
3. Cal/EPA Internal - Continue HERD scientific peer review of OEHHA analysis of site and facility risk assessments for which DTSC has assigned OEHHA to be lead on a risk assessment under the interagency agreement. Develop a schedule and process to submit four RP generated risk assessments and HERD analysis to OEHHA for peer review per fiscal year.
4. External - Broaden external/internal scientific peer review of Cal/TOX, that is in concert with the peer review policy of Cal/EPA. HERD is currently negotiating with NAS/NRC for the scientific peer review of its risk-based approach to hazardous waste management and cleanup.

III. Best Use of Scientific Information and Development of Guidelines.

A. Encourage and support scientific training and professional development.

1. Continue to use of the "Individual Development Plan" process to encourage and facilitate scientific staff efforts to publish scientific papers in peer reviewed journals. (Ongoing)
2. Continue to use of the DTSC "Individual Development Plan" process to encourage and facilitate participation of scientific staff in (1) continuing education and scientific societies and (2) state and national scientific forums. (Ongoing)
3. At the start of each of the fiscal year planning phase, continue to ask for allocation of funds sufficient for continuing education, participation in scientific societies, and "Diplomat of the American Board of Toxicology" certification. (Continuing practice)
4. Have developed course material for exposure assessment, stochastic analysis and Cal/TOX training. Plan to teach one quarter upper division course for UC Davis Department of Environmental Toxicology in the Fall of 1997 (Course taught in the Spring of 1997). Continue offering 3-day course for UC Davis Extension (Course already given at the Annual Meetings of the Society of Risk Analysis). Develop 3-day course for Cal/EPA staff. (UC course deferred; all other courses completed)

B. Document the procedures and assumptions used in the conduct of the stochastic multi-media, multi-pathway risk assessment using the best available science.

1. Complete the HERD guidance manual on the theory, background, and operation of the multi-media risk assessment program, Cal/TOX, to document behavior of Cal/TOX. Develop training course manual for Cal/TOX. Make material available on World Wide Web site (Material already converted to Adobe PDF files). (Completed)

2. Continue to examine and update the structure, process and data embedded in Cal/TOX. Continue "sensitivity runs" on various input parameters to study behavior of Cal/TOX. Will incorporate the Swedish SKB RES approach to the description of the assumed exposure condition. (Completed)
3. Have developed air dispersion models for the offsite fate and transport of chemicals in the air with ARB. Will write an associated chapter in Cal/TOX guidance. (Completed)
4. Continue to seek water board assistance in the development of groundwater transport and dispersion models for prediction of the offsite fate and transport of chemicals in unsaturated and saturated groundwater compartments. Will need to integrate into Cal/TOX and write an associated chapter in Cal/TOX guidance. (Ongoing)
5. Continue the development of guidance on the characterization of uncertainty and variability, both for the risk assessment process in general and specifically for Cal/TOX. Develop the process to ensure that the level of uncertainty is accurately characterized and appropriately portrayed. Will work with other Cal/EPA Boards, Departments and Offices through the RACWG on the general policy of risk characterization. (Ongoing)
6. Continue enhancement of the world-wide-web site for the distribution of Cal/TOX, associated documents, updates, advice and user-input. Continue expansion of links to the DTSC HERD world-wide-web site by other risk assessment/risk management involved sites. (Ongoing)

IV. Interface Between Risk Assessment and Risk Management

A. Continue coordinated interaction between HERD scientists and DTSC Program risk managers.

1. Continue to meet with DTSC Program risk managers by attendance of monthly Division and Branch Level Meetings on the Hazardous Waste Control Account (HWCA), Department of Defense and State Memorandum of Agreement (DDSMOA), and Responsible Party (RP)-lead sites and projects to ensure (1) early consideration of the risk assessment process, resources, and limitations within the risk management process, (2) that the resources devoted to the risk assessment are commensurate with the significance of the risk management decision that is needed and (3) the risk assessment product is fully considered in the final risk management decision. (Ongoing)
2. Continue training of DTSC Program risk managers on the fundamental concepts, process and outputs of risk assessment by HERD scientists at monthly DTSC Division and Branch Level Meetings on HWCA, DDSMOA, and RP-lead sites and projects. (Ongoing)
3. Continue scientific support of DTSC's Hazardous Waste Management "Regulatory Structure Update" in the development of risk-based regulatory classification of hazardous waste. (Support ongoing, supplemental materials prepared for NAS review)

4. Continue scientific support of DTSC's Site Mitigation's Program's "Site Mitigation Update" in the development of acceptable risk ranges, risk-based remediation goals, and risk-based tiered approach to site-mitigation and cleanup. (Ongoing)

5. Continue scientific support of DTSC's Office of Pollution Prevention and Technology Development "Tiered Certification Program" in the consideration of potential risks posed by a technology during routine operation, off-spec operation, catastrophic process failure, or transportation related accidents. (Ongoing)

6. Continue to provide scientific support at public meetings whereby external stakeholders provide review and comment on a specific risk assessment. (Ongoing)

3.1.6 The State Water Resources Control Board/Regional Water Quality Control Boards

State Water Resources Control Board's Plan for Implementing the Recommendations of the SB 1082 Risk Assessment Advisory Committee

The State Water Resources Control Board (SWRCB) and its nine Regional Water Quality Control Boards (RWQCB) have primary responsibility for the coordination and control of water quality in California. As mandated by the Porter-Cologne Water Quality Control Act of 1969, the SWRCB implements a number of water quality control programs to protect the beneficial uses of surface and ground waters of the State. In implementing this State law as well as the federal Clean Water Act, the SWRCB develops ambient water quality standards to protect human health as well as the health of aquatic life.

The SWRCB and the RWQCBs are mainly risk management agencies. Nevertheless, SWRCB and RWQCBs are directly or indirectly involved in all phases of ecological and human risk assessment activities. The SWRCB's Division of Water Quality is primarily involved in risk assessment activities dealing with surface water, whereas the Division of Clean Water Programs is primarily involved in risk assessment activities dealing with ground water and land disposal programs. The RWQCBs implement both surface and ground water programs (Attachment 1). The SWRCB and the RWQCBs do not conduct any research involving human health dose-response relationships. The SWRCB and RWQCBs rely primarily on other state and federal agencies [such as Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA) and the U.S. Environmental Protection Agency (US EPA)] for this information which is reviewed and evaluated by staff particularly during the development and adoption of ambient water quality standards.

The SWRCB and the RWQCBs are conducting ongoing strategic planning efforts to establish multi-year, organization-wide directions and priorities. The SWRCB Strategic Plan was initially adopted in June 1995 and revised in May 1997. The revised Strategic Plan includes strategies to implement the Risk Assessment Advisory Committee's (RAAC) recommendations pursuant to Governor Wilson's Executive Order # W-137-96 of December 10, 1996 (Attachment 2).

The SWRCB's action plan for implementation of five major categories of RAAC recommendations is summarized in Attachment 3, and is briefly discussed below.

I. Consistency and Harmonization

The SWRCB and all the nine RWQCBs will work to achieve consistency on issues such as designation of beneficial uses of water bodies, procedure for development of site-specific water quality objectives, and ground water cleanup levels. The RWQCBs will consider taking steps to improve consistency in accepting risk assessment results in site cleanup efforts.

While working to achieve statewide consistency, RWQCBs will use their discretion to consider regional conditions when conducting human and ecological risk assessment activities leading to site-specific risk management decisions.

The SWRCB and RWQCBs will continue to work within Cal/EPA to achieve consistency of risk assessment methods and the use of the best available science through participation in:

Cal/EPA's working group to develop an agency-wide implementation plan for RAAC's recommendations, and monitor progress on the implementation of the performance measures. (Ongoing)

Cal/EPA's Risk Assessment Coordination Work Group (RACWG) of technical representatives of the Agency's boards, offices, and departments. This Work Group, chaired by OEHHA, provides advice on toxicology and human health and ecological risk assessment issues to the boards, offices, and departments. The mission of RACWG is to ensure that boards, offices, and departments' risk management decisions are based on scientifically defensible and internally consistent risk assessment practices and methods. (Ongoing)

Cal/EPA's RACWG Environmental Fate and Transport Subcommittee to assimilate and disseminate information on environmental fate and transport data bases, models, and expertise at SWRCB and RWQCBs for Cal/EPA's inventory report being drafted by the Subcommittee with the Department of Toxic Substances Control as the lead. (Initial phase completed)

A Management Agency Agreement with the Department of Pesticide Regulation (DPR) to assess the risk of pesticides on water quality. The Agreement provides a mechanism to coordinate SWRCB/RWQCB and DPR water quality monitoring efforts for pesticides. SWRCB will consider coordinating water quality monitoring efforts with other boards, offices, and departments to make best use of available resources. (Completed)

OEHHA's Ecotoxicology Inter-Agency Work Group to develop internally consistent guidelines based on the best available science for the ecotoxicological risk assessments. (Ongoing)

The SWRCB and RWQCBs will continue to work with US EPA to achieve consistency of risk assessment and the use of the best available science through:

Participation in the Cal/EPA-US EPA (Region 9) Risk Harmonization Interagency Work Group which is evaluating the existing state and federal human health risk assessment paradigms (such as Risk Based Cleanup Actions, and Preliminary Soil Remediation Goals). This effort has been undertaken in order to increase consistency in how human health risk assessments are conducted and evaluated in California. The current focus is to develop an approach to assess soil contaminated sites using a tiered approach which incorporates the use of screening level tables at the initial tier and progressive use of site-specific data at subsequent tiers leading to a site-specific risk assessment. (Ongoing)

Participation in US EPA's Biological Technical Advisory Group for ecological risk assessment at military facilities and Superfund sites. (Ongoing)

Coordination with US EPA (Region 9) in developing the two statewide water quality control plans -- Inland Surface Waters Plan (ISWP), and Enclosed Bays and Estuaries Plan (EBEP). The two phase approach involves developing a policy in Phase 1 that includes implementation provisions for the federal water quality criteria to be promulgated by US EPA (Region 9) via the California Toxic Rule. The Phase 1 implementation policy will be used by SWRCB and RWQCBs to implement the federal criteria until the SWRCB adopts the final ISWP/EBEP. Phase 2 will build upon Phase 1 products to develop full State water quality control plans that include State-adopted objectives and a program for their implementation. The Phase 1 policy, with appropriate modifications, will become the program of implementation for the ISWP/EBEP in Phase 2. The Phase 1 schedule calls for the release of a draft policy and Functional Equivalent Document for public review by September 1997, public hearings in November and December 1997, and adoption by the SWRCB in the spring of 1998. An additional 12-18 months will be needed to complete Phase 2. (Ongoing)

II. Best Use of Scientific Information and Development of Guidelines

The SWRCB and RWQCBs will continue to use the best scientific information and water quality data in risk assessment and management practices. Some of the implementation measures include:

Keeping staff updated on recent scientific developments through training, subscription to scientific journals, and participation in the scientific conferences and workshops. (Ongoing)

Inviting scientific experts to the State Board workshops and meetings for presentations of informational items of current interest. (Ongoing)

Conducting the scientific peer review process as outlined in Section III below. (Begun)

The following measures will be taken in the area of water quality data base management:

- Develop a proposal for a Comprehensive Water Quality Data Management Project to collect, validate, and disseminate water quality data. Review statewide water quality data collection and management practices for overlap, institute quality control measures, and improve accessibility of present data. (Begun for coastal programs)

- Continue the SWRCB Information Management Team's ongoing efforts to improve data accessibility. (Ongoing)
- Continue to maintain and improve the quality control measures of the US EPA's STORET (Storage and Retrieval) water quality data base, and make it available to interested parties. (Ongoing)
- Continue to provide SWRCB and RWQCB information on pesticide contamination of ground water to DPR for the annual report to the Legislature. (Ongoing)
- Continue to participate and provide input into Cal/EPA's Environmental Indicators Report. (Ongoing)
- Coordinate with other agencies in data collection and management activities, such as Department of Water Resources' California Environmental Resource Evaluation System, Land Use Planning Information Network, and Watershed Information Technical System data bases. (Ongoing)
- Provide on electronic bulletin board and web site SWRCB's water quality monitoring data from State Mussel Watch Program, Toxic Substances Monitoring Program, and Aquatic Toxicity Program, and sediment quality data from the Bay Protection and Toxic Cleanup Program. (Completed)

The SWRCB and RWQCBs staff will participate, where appropriate, in the RACWG and other agency-wide groups in the development of risk assessment guidelines (e.g., Cal/EPA's development of guidance for communicating the basis for "science based" policy decisions). These guidance documents are intended to provide the scientific and policy basis for default options (such as cleanup to background levels), and uncertainty/safety factors for extrapolating laboratory toxicity data with test animals to humans, including sensitive populations

III. Peer Review and Peer Involvement

In March 1996, the SWRCB adopted a peer review and peer involvement program which consists of several ad hoc subcommittees, including the (1) Marine Bioassay Project Scientific Review Committee, (2) Microbiological Advisory Committee, (3) Marine Toxicity Committee, and (4) Bay Protection and Toxic Cleanup Program's (BPTCP) Scientific Planning and Review Committee. New scientific peer review committees were to be formed on an as needed basis. This approach has been an efficient way of receiving impartial scientific advisory services in a timely manner considering the complexity of water quality issues faced by the SWRCB and the nine RWQCBs. However, since the passage of SB 1320, the SWRCB and other boards, offices and departments of Cal/EPA are in the process of establishing a formalized peer review process. The Agency proposes to negotiate a memorandum of understanding (MOU) with the University of California to implement this new mandate. (Outdated, succeeded by SB1320).

The SWRCB will continue the internal Cal/EPA scientific review process by sharing draft risk assessment and management documents with the scientists of the boards, offices, and departments to solicit their review comments. Further, these draft documents will also be shared with other pertinent State agencies such as the Department of Health Services (DHS) and the Department of Fish and Game. (Ongoing)

IV. Interface between Risk Assessment and Risk Management

The SWRCB will continue to seek early input from risk managers, external stakeholders and general public during the risk assessment process. Staff will continue the external stakeholder involvement through existing and ad hoc committees such as the Nonpoint Source Committee, ISWP and EBEP Task Forces, and the BPTCP's Advisory Committee. The SWRCB has also convened a stakeholder group consisting of the regulated community, environmental groups, and local and State agencies to provide input on proposed revisions to regulations concerning discharges of waste to land. SWRCB will coordinate with OEHHA in developing a public education and outreach program for risk assessment, risk management, and risk communication. (Ongoing)

Cross training will be provided to SWRCB risk assessors and risk managers to enhance early communication involving risk assessment and risk management decisions. Although risk assessment is a well defined scientific process while risk management is based on socio-economic factors and best professional judgment concerning feasible treatment technologies, SWRCB and RWQCBs will foster positive interactions of risk assessors and risk managers. (No action at this time)

SWRCB will identify program areas that would benefit from the translation of emerging risk assessment methods into risk management policies (e.g., pollution prevention practices such as double lined underground fuel storage tanks for replacement of leaking tanks). SWRCB and RWQCBs will participate in Cal/EPA's Emerging Environmental Challenges Program to provide management with early warning of future water quality problems which may potentially impact human health and the environment. (Ongoing)

V. Organization and Resources

The SWRCB and RWQCBs will continue to balance the level of effort and resources with the importance and extent of a particular risk to humans and environment. The SWRCB's tiered approach for characterizing nature and extent of ground water pollution incorporates a balancing of effort and resources in ground water cleanups through an evaluation of technological considerations and economic feasibility. (Ongoing)

SWRCB lacks adequate resources for various scientific disciplines required for a risk assessment process, particularly in the areas of contaminant fate and transport, environmental chemistry, and modeling. Therefore, we are dependent upon other organizations (e.g., OEHHA, DHS) to fulfill some of our risk assessment needs. Any increase in our present responsibilities would require an augmentation of our capabilities. The SWRCB Strategic Plan's training program will continue to provide staff with training in the scientific fields of environmental fate and transport of toxicants, statistics, modeling, hazard identification, exposure assessment, toxicological dose-response relationships, risk characterization, and other pertinent areas of risk assessment. Staff will be encouraged to join scientific professional organizations such as the Society of Environmental Toxicology and Chemistry, attend national and international scientific conferences and workshops, present platform or poster papers, and publish papers in peer-reviewed journals. (Ongoing)

**STATE WATER RESOURCES CONTROL BOARD (SWRCB) AND
REGIONAL WATER QUALITY CONTROL BOARDS (RWQCB)
RISK ASSESSMENT/RISK MANAGEMENT ACTIVITIES¹**

ACTIVITY	HUMAN HEALTH			ECOLOGICAL HEALTH		
	DWQ2	DCWP3	RWQCB	DWQ	DCWP	RWQCB
RISK ASSESSMENT						
Hazard Identification	O	X4	X4	X5	O	X5
Exposure Assessment	X5	X6	X6	X5	O	X6
Dose-Response Evaluation	O	O	O	X7	O	X7
Risk Characterization	X7	X8	X7	X7	O	X7
RISK MANAGEMENT	X	X	X	X	O	X

1 X = Significant effort

O = Secondary effort (rely primarily on other agencies such as the Office of Environmental Health Hazard Assessment, Department of Health Services, Department of Fish and Game and the U.S. Environmental Protection Agency).

2 Division of Water Quality, SWRCB

3 Division of Clean Water Programs, SWRCB

4 Human health hazards associated with Underground Storage Tanks (UST), landfills and other programs

5 Water quality monitoring including toxicity testing

6 Site monitoring and modeling (UST, landfills and land discharge programs).

7 Chemical or site specific ambient water quality objective development.

8 On a site specific basis.

**ATTACHMENT 2
SWRCB'S STRATEGIC PLAN**

GOAL

Our goal is to preserve, enhance, and restore water resources while balancing economic and environmental impacts.

STRATEGIES

1. Employ risk assessment practices in decision-making to ensure public health and resource protection.
2. Base all technical activities on sound science with periodic peer review.
3. Ensure fair, firm, and consistent regulation and enforcement that is cost-effective and responsive.

PERFORMANCE MEASURES INCLUDED IN SWRCB'S PROJECT TRACKING REPORT

1. Develop implementation plan for the RAAC recommendations as per Governor Wilson's Executive Order # W-137-96 (6/30/97)
2. Implement pertinent recommendations (1/1/99)

**SUMMARY OF STATE WATER RESOURCES CONTROL BOARD
DRAFT ACTION PLAN FOR IMPLEMENTATION OF THE SB 1082
RISK ASSESSMENT ADVISORY COMMITTEE RECOMMENDATIONS**

ACTIVITY DESCRIPTION	PERFORMANCE MEASURES
I. Consistency and Harmonization Establish internal Cal/EPA working group to insure agency-wide consistency and harmonization.	Participate in Cal/EPA RAAC work group. Participate in Cal/EPA Risk Assessment Coordination Work Group (RACWG).Participate in Cal/EPA RACWG Environmental Fate and Transport Subcommittee.

Initiate steps to assure consistency/ cooperation with US EPA and other federal counterparts.	Participate in US EPA and Cal/EPA Risk Harmonization Work Group. Participate in US EPA's Biological Technical Advisory Group. Policy meeting with US EPA to use US EPA standards for ambient and health risk criteria (ISWP/EBEP).
II. Best Use of Scientific Information and Development of Guidelines Review data collection/management for overlap, institute quality control measures, and improve accessibility of present data.	Develop proposal for Comprehensive Water Quality Data Management for collection, validation, dissemination. Continue the SWRCB Information Management Team efforts to improve data accessibility.
Clearly state the scientific and policy basis for each default option (e.g., cleanup to background levels).	Participate in Cal/EPA development of guidance for communicating the basis for "science based" policy decisions.

ACTIVITY DESCRIPTION	PERFORMANCE MEASURES
III. Peer Review and Peer Involvement Formalize peer review program.	Participate in the peer review process established by Cal/EPA through a MOU with the University of California (SB 1320)..
IV. Interface between Risk Assessment and Risk Management Seek early input from risk managers, external stakeholders and general public during the risk assessment process.	Continue external stakeholder involvement through existing and ad-hoc committees (e.g., surface water NPS/ISWP/EBEP/BPTCP, and disposal to land - Chapter 15 stakeholders groups).
Better translation of emerging risk assessment methods into risk management policy.	Identify SWRCB program areas that would benefit from this translation (e.g., underground tanks policy and ambient water quality standard program).
V. Organization and Resources Balance level of effort and resources with the importance of the risk assessment.	Incorporate economic/technical feasibility in ground water assessment. Continue using a tiered approach for characterizing nature and extent of

	groundwater pollution.
Evaluate adequacy of resources for various scientific disciplines required for risk assessment.	Prepare (as appropriate) BCPs for in-house expertise in contaminant fate and transport, environmental chemistry, and modeling.
Formalize staff participation in continuing education programs/ national and international scientific organizations.	Continue existing Strategic Plan's training program, encourage staff participation in scientific organizations (e.g., SETAC).

3.2 Implementation Plans of Additional State Agencies Encompassed by the Executive Order

The Executive Order mandated that other state agencies, outside of Cal/EPA, that conduct chemical risk assessment (broadly defined) also must evaluate the RAAC report and develop plans to implement the recommendations. As directed by the Executive Order, the Secretary of Cal/EPA convened a Task Force of agency heads from within California State government. This Task Force met to identify state agencies that may be potentially encompassed by the scope of the mandate. Following the meeting, OEHHA contacted these identified groups and facilitated their evaluation of the RAAC recommendations.

After evaluating the Executive Order and the RAAC report, four agencies indicated that they conducted health risk assessments and, thus, provided plans for implementation of the RAAC recommendations. These agencies were the California Energy Commission, the Department of Health Services, the Department of Transportation, and the Governor’s Office of Emergency Services. The implementation plans of these agencies are provided below.

A number of other agencies, contacted by OEHHA as being potentially encompassed by the Executive Order, also evaluated the report and concluded that they do not conduct risk assessment per se and, thus, are not taking any further action at this time with respect to risk assessment sciences. These agencies included the California Water Commission, Department of Boating and Waterways, Department of Consumer Affairs, Department of Forestry and Fire Protection, Department of Food and Agriculture, Department of Industrial Relations, Department of Parks and Recreation, and Department of Water Resources. These responses are described in more detail in Section 3.2.5.

3.2.1 The California Department of Health Services

California Department of Health Services

Implementation of Executive Order W-37-96

The implementation plans for the California of Department of Health Services (DHS) is presented in two parts. The first response was prepared jointly by the Division of Environmental

and Occupational Disease Control and the Division of Food, Drug and Radiation Safety. The second part was prepared by the Division of Drinking Water and Environmental Management.

Division of Environmental and Occupational Disease Control and the Division of Food, Drug and Radiation Safety

On December 10, 1996, the Governor issued Executive Order W-137-96, which addresses risk assessment from chemical exposure done by state agencies. The Executive Order requires all state agencies that "assess the toxicity of exposure to, or risk of chemicals in the environment to human health" to be included in a state-wide effort to enhance consistency and foster uniformity in risk assessment methods and practices. Such agencies are to establish plans for the implementation of the recommendations of the Risk Assessment Advisory Committee (RAAC). The committee developed general recommendations that would encourage consistency and harmonization and specific recommendations in each of the four areas of risk assessment, hazard identification, dose-response assessment, exposure assessment,

While the DHS embraces the spirit of these recommendations, we recognize that DHS works very closely with federal agencies whose policies and guidelines were not a part of the committee's review and thus we may find that the RAAC recommendations that were directed at Cal/EPA may not be appropriately applied beyond the committee's scope.

The Executive Order places the Office of Environmental Health Hazard Assessment (OEHHA) as the principal state agency to coordinate the implementation of the RAAC recommendations. As such, OEHHA needs to communicate effectively with all other affected boards, departments and offices. We also recommend that appropriate DHS staff and other affected groups outside Cal/EPA be made voting members of the working group that the RAAC committee recommend be established to ensure consistency and harmonization (General Recommendation #3).

Within DHS, risk assessment of chemical exposure is conducted by several groups. These groups are contained within the Division of Environmental and Occupational Disease Control, the Division of Food, Drug, and Radiation Safety, and the Division of Drinking Water and Environmental Management. None of the groups within the DHS are mandated to establish risk assessment regulatory guidelines or conduct chemical risk assessment in order to establish health-based regulatory numbers.

In general, DHS uses health-based regulatory numbers developed through the risk assessment process at Cal/EPA or federal agencies such as the U.S. Environmental Protection Agency (US EPA), the U.S. Food and Drug Administration, the Agency for Toxic Substances and Disease Registry, and the Occupational Safety and Health Administration. On the occasion when there are no applicable health-based regulatory numbers and a timely response to a public health issue is needed, DHS staff may conduct a chemical risk assessment based on available information either independently or in conjunction with OEHHA. In general, these risk assessments are performed in a manner consistent with the recommendations of RAAC. However, because DHS works closely with several other federal agencies besides the US EPA, efforts to harmonize may be influenced by these other agencies' policies and guidelines.

In responding to citizen concern, establishing exposure levels for epidemiological studies, responding to an emergency or outbreak, and other activities carried out by DHS, we may use hazard identification and dose response information developed by Cal/EPA and others, but develop our own exposure assessment and risk characterization parts of the risk assessment. In doing so, DHS already emphasizes receptor-based exposure assessment (Exposure Assessment Recommendation #2), which tries to determine if people are actually exposed to environmental pollutants, and if so, by how much and from what source, rather than source-based exposure assessment with default assumptions and theoretical receptor populations.

DHS also supports the recommendation of integrating fate and transport models (Exposure Assessment Recommendation #2); however, DHS is often engaged in measuring actual receptor point concentrations rather than depending on modeling. When it is not possible to measure receptor point concentrations, DHS will work with Cal/EPA in the application of modeling for human health exposure assessment.

DHS is often the risk manager for risk assessments conducted by OEHHA and as such this requires a close working relationship that would allow for improved communication between the risk assessor and the risk manager. By understanding the needs of the risk manager, the risk assessor may better understand how to communicate risk information, including the uncertainty and variability in the risk assessment, to the risk manager (Risk Characterization Recommendation #1). Thereby, the extent and depth of Cal/EPA risk assessments may be more responsive to these needs (Risk Characterization Recommendation #2). DHS has much capability in the area of risk communication and public education and would offer assistance to Cal/EPA in its attempt to improve the characterization of uncertainty and variability in risk assessment to the public (also part of Risk Characterization Recommendation #1).

In summary, DHS supports the implementation of the RAAC recommendations as they may apply to our activities and looks forward to collaborating with or assisting Cal/EPA and OEHHA in implementing these recommendations within their agency.

Division of Drinking Water and Environmental Management (DDWEM)

The DDWEM in DHS is responsible for the regulation of chemicals in the State's drinking water. As such, DDWEM is the "risk manager" for the establishment of allowable levels of chemical contaminants and other substances in drinking water. DDWEM establishes allowable concentrations of chemicals in drinking water; called maximum contaminant levels (MCLs). MCLs are based on several inputs, including human health risk assessments, technical feasibility

The risk assessments utilized by DDWEM in establishing MCLs are performed by OEHHA, the lead agency for the State's effort in developing risk assessment consistency and uniformity. (OEHHA's methods for risk assessment are summarized in the report of the RAAC's October 1996 report. Specific methods for calculating risk-based levels of chemical contaminants in drinking water are described on pages C-38 and C-39 of that report.)

On occasion, when unregulated chemical contaminants are found in a drinking water system, a rapid evaluation is required to determine whether or not a public health concern exists. In such

circumstances, DDWEM consults with OEHHA to determine whether an appropriate reference dose or slope factor for the chemical in question exists, and, if so, applies the standard exposure parameters mentioned above to determine the appropriate action. If a reference dose or slope factor does not exist, then DDWEM may request OEHHA to provide one.

One of the reasons for the establishment of Cal/EPA in 1991 by the Governor was to provide for separation of risk assessment and risk management. As a risk manager, DDWEM does not perform risk assessments for chemical contaminants in drinking water supplies. However, DDWEM nevertheless will review the risk assessments provided by OEHHA to ensure that OEHHA's evaluations are consistent with the recommendations of the RAAC, as they apply to hazard identification, does-response assessment, exposure assessment, and risk characterization.

DDWEM agrees with the recommendation that risk assessors communicate with risk managers throughout the risk assessment process, and DDWEM, as a risk manager, intends to continue its long-standing practice of working closely with OEHHA, which provides risk assessment support for the drinking water program.

The other programs in DDWEM do not utilize risk assessments for chemical contaminants. These other programs include:

- Nuclear Power Plant Emergency Preparedness--This program deals with accidental releases of radioactive materials from electric power-generating nuclear reactors.
- Department of Defense base closure activities--This program provides consultation of Cal/EPA's Department of Toxic Substances Control on remedial actions associated with radioactive materials at closing military bases.
- Low-level radioactive waste disposal--This program oversees the development of California's low level radioactive waste disposal sites. As such, its focus is on radioactive materials.
- Medical waste--This program regulates medical waste. It is principally concerned with biological wastes and other medical related materials (e.g., "sharps"). It does not regulate chemicals used in medicine.
- Shellfish monitoring--This program regulates estuarine/bay water in which commercial shellfish are raised. Its concern is with microbiological contamination.
- Environmental services---This program oversees the maintenance and general healthfulness and sanitation of state facilities (e.g., prisons and other institutions).

DDWEM, in its risk management role, collects information on chemicals in drinking water on statewide basis. DDWEM has a long history of good interaction with other boards and departments, and regularly provides data to them upon request. DDWEM will continue to provide drinking water monitoring data to other boards and departments, as appropriate.

3.2.3 The Governor's Office of Emergency Services

Executive Order W-137-96 mandated the formation of a task force to identify those state agencies that conduct chemical risk assessment; more specifically, assess the toxicity of, exposure to, or risk from chemicals to the environment or human health. The Office of Environmental Health Hazard Assessment (OEHHA), as the lead agency in the Executive Order, sent a questionnaire to the Office of Emergency Services (OES) to include us in the effort to

unify and improve risk assessment practices. In response to the questionnaire, OES became peripherally involved as a participant in the risk assessment discussions. In this capacity, OES has reviewed the report of the Risk Assessment Advisory Committee (October, 1996) and has evaluated the recommendations contained in the report as they pertain to OES.

OES recently met with your staff to discuss our limited involvement in the risk assessment process. OES recognizes OEHHA as the lead agency for risk assessment practices. In all aspects of risk assessment or chemical impact analysis, OES uses existing guidelines and methodologies approved by the United States Environmental Protection Agency (US EPA) or guidance from OEHHA.

The new California Accidental Release Prevention Program (Cal ARP) involves both state and federal requirements and includes elements which require hazard identification, exposure assessment, and risk characterization. To the extent that OES becomes involved in specific chemical risk assessment, all program elements will depend upon established US EPA or OEHHA guidance. In support of our programs, OES consults with OEHHA on a regular basis for chemical listing, threshold issues, and chemical impact analysis. OES will also consult with US EPA and OEHHA on new program developments including chemical impact modeling and establishing toxic endpoints for emergency planning.

3.2.4 The Department of Transportation

CHAPTER INTRODUCTION

This report presents a study conducted by the California Department of Transportation (Caltrans) in response to Executive Order W-137-96 requiring the implementation of recommendations made by the Risk Assessment Advisory Committee (Committee) to improve the risk assessment process in all California state agencies, departments, boards and offices. The study included a detailed review of the Committee recommendations, selection of recommendations that apply to Caltrans' programs, review of the current status of those programs in context with the recommendations and an implementation plan to make any needed improvements to the current Caltrans policies and procedures.

1.1 Legislation

In 1993, the California state legislature directed the Office of Environmental Health Hazard Assessment (OEHHA) within the California Environmental Protection Agency (Cal/EPA) to conduct an external scientific peer review of the risk assessment practices used by Cal/EPA. The Committee, a group of experts outside the California state government, was appointed for this task. The members of the Committee include experts in public health, toxicology, epidemiology, engineering, chemistry, modeling, and statistics. Specifically, the Committee was to examine whether the risk assessment practices of Cal/EPA are based on sound science and, secondly, to assess the appropriateness of any inconsistencies between the practices of Cal/EPA and those of the US Environmental Protection Agency (US EPA) and the National Academy of Sciences.

The Committee completed its comprehensive, external peer review of the risk assessment practices used by Cal/EPA. The Committee's final report, A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines (October 1996), describes the observations and findings and presents the recommendations of the Committee.

On December 10, 1996, Governor Wilson issued Executive Order W-137-96 which requires all California state agencies, departments, boards and offices that "assess the toxicity of exposure to, or risk of chemicals in the environment to human health" to develop implementation plans, as part of their strategic planning process, that address the recommendations of the Committee.

1.2 Caltrans Risk Assessment Study

Caltrans responded to Executive Order W-137-96 with a review of the Committee's recommendations and identified the actions described in this report to respond to the Order. Many of these identified actions have already been implemented by Caltrans. The recommendations of the Committee were implemented by Caltrans in a four step process that is presented in this Report:

Step 1 Chapter 1 Introduction: In this step, the purpose for conducting this study is described.

Step 2 Chapter 2 Risk Assessment Advisory Committee Recommendations: In this chapter, an overview of the Committee's recommendations is presented and those recommendations by the Committee which are applicable to Caltrans programs are identified. Some recommendations are not applicable to specific departments, such as Caltrans, because they address setting consistent scientific standards that apply to all California state agencies, departments, boards. These recommendations are most appropriate for Cal/EPA to address.

Step 3 Chapter 3 Caltrans Risk Assessment Practices and Policies: In this step, Caltrans identifies the offices with programs that use risk assessment policies. Two Offices of Caltrans: the Office of Environmental Engineering (OEE) and the Office of Hazardous Waste Management (OHWM) use risk assessment policies and procedures in some of their programs. A review of the programs in these offices was conducted to determine which programs should be included in this study. Next, each of the applicable programs was reviewed to identify current policies and procedures in each of the eight subcategory areas.

Step 4 Chapter 4 Caltrans Implementation Plan: In this chapter, the implementation plan that will be used as part of the Caltrans strategic planning process to address the recommendations of the Committee is presented.

CHAPTER 2.0 RISK ASSESSMENT ADVISORY COMMITTEE RECOMMENDATIONS

The Committee examined current risk assessment practices and made a series of recommendations to Cal/EPA to improve risk assessment practices and protocols in California state agencies, departments, offices, and boards that use risk assessment. Risk assessment

practices and protocols are those which assess the toxicity of exposure to, or risk of chemicals in the environment to human health. This chapter presents an overview of the Committee's recommendations and the specific recommendations that were identified in this study as applicable to Caltrans.

2.1 Overview of Risk Assessment Advisory Committee Recommendations

The Committee's recommendations focus on improving the scientific basis of the risk assessment efforts, assuring consistency in practices of data management and quality control, and development of continuous improvement programs. The recommendations also encourage Cal/EPA to take the lead in working with US EPA to harmonize activities in order to use State resources most efficiently and provide consistency in its regulatory activities.

The Committee grouped their recommendations into five categories: cross-cutting issues, hazard identification, dose-response evaluation, exposure assessment, and risk characterization.

Cross-Cutting Issues: These are issues that traverse many aspects of the risk assessment practices, policies, and guidelines of Cal/EPA and include - incorporation of new science into risk assessment, consistency and harmonization, resources and organization, guidelines, and peer review and public input.

Hazard Identification: Evaluates toxicological properties of chemicals to determine whether exposure to that chemical can cause an increase in the incidence of an adverse health condition.

Dose-Response Assessment: Assigns a toxicity factor to each chemical which quantitatively describe the relationship between an exposure (in terms of dose to the individual) and the potential for an adverse effect.

Exposure Assessment: Describes the potential ways that people might come into contact with chemicals present in the environment. Recommendations were made on the two phases of exposure assessment - human intake parameters and fate and transport properties.

Variability, Uncertainty, and Risk Characterization: Discusses the relationship between exposure and toxicity of a chemical and how certain a risk assessor is that the assumptions made accurately describe the ways people can come into contact with chemicals and the potential for adverse health effects.

2.2 Selection of Applicable Recommendations

The Committees' recommendations apply to all risk assessment practices and policies. Some of these recommendations can not be implemented by Caltrans because they address consistency of practices and policies that apply to all California state agencies, departments, and boards. To determine the applicable recommendations, Caltrans met with Dr. David Ting of OEHHA which has been given the responsibility of overseeing the response to Executive Order W-137-96 and implementing the Committee's recommendations.

Dr. Ting and Caltrans representatives agreed that the Committee's recommendations within the categories discussed in Section 2.1 of this report, Hazard Identification and Dose-Response, needed to be addressed uniformly for all California state agencies, departments, offices and boards. Therefore, Caltrans will coordinate with Cal/EPA on those recommendations.

This study reviewed the recommendations in the remaining three categories, Cross-Cutting Issues, Exposure Assessment and Variability, Uncertainty and Risk Characterization, to frame the criteria for evaluating Caltrans current practices and policies and determining an implementation plan. Forty-five narrative recommendations were identified.

The Caltrans review of the recommendations noted general similarities and grouped the applicable recommendations into eight subcategories. The specific recommendations, made by the Committee, that fall into these eight subcategories, are summarized in Attachment A. These subcategories, described below, were used to evaluate the policies and procedures used by Caltrans.

Training: Continuous education is needed to be certain that expert personnel keep abreast of new developments. Continue to look for, and implement ways of involving risk managers and stakeholders in risk assessment, including the development of guidelines, assessments, workshops, and reviews. Mechanisms such as two-way temporary staff exchange programs, forums and training sessions.

Data Management: Institute measures for quality control of data in databases and data being added to the databases. For example, the quality of data relies, in part, on the sampling strategy employed. Additionally, improve the accessibility of data to all interested parties.

Peer Review: Develop a formalized policy for internal and external peer review of program activities and re-examine systems currently in place.

Receptor-Based Exposure Assessments: Additional monitoring of human exposure is needed. Receptor-based exposure assessment means assessing exposure where the receptors are located. Cal/EPA should acknowledge the uncertainty that results from the reliance on scenario based exposure assessments.

Exposure/Fate and Transport Models: More effort is needed to validate fate and transport models with real experimental data. In assessing transport and dispersion models, the quality and characteristics of input data to the models, such as emissions data and dispersion parameters, should be considered in addition to the validity of the models themselves.

Communication/Information Sharing: Efforts towards consistency and harmonization between boards and departments and their federal counterparts have begun, appear to be useful, and should be encouraged.

Decision Making and Risk Management Policies: Policies and procedures for addressing the translation of risk assessment uncertainties into risk management policy should be developed.

Continue to look for, and implement, ways of involving risk managers and stakeholders in risk assessment, including the development of guidelines, assessments, workshops, and reviews.

Process Improvement: Seek out and implement ways of simplifying and streamlining the process of risk assessments.

CHAPTER 3.0 CALTRANS RISK ASSESSMENT PRACTICES AND POLICIES

In this chapter, Caltrans identifies the offices with programs that use risk assessment protocols as described in the Committee's recommendations. The Executive Order applies to programs that conduct quantitative risk assessment. Risk assessment practices and protocols are those which assess the toxicity of exposure to, or risk of chemicals in the environment to human health.

Two Offices of Caltrans: the Office of Environmental Engineering and the Office of Hazardous Waste Management use risk assessment policies and procedures in some of their programs. A review of the programs in these offices was conducted to determine which programs should be included in this study. Those programs that estimate health risk or collect data used to protect human health were included in this evaluation. The following three programs were identified:

Quantitative Risk Assessment (Office of Hazardous Waste Management): This program includes preparation of quantitative risk assessments which measure the potential for adverse health effects due to exposure to chemicals in impacted soil and groundwater. The risk assessments are out-sourced and not prepared by Caltrans staff. This program was evaluated in this study although the recommendations of the Committee do not apply to out-sourced risk assessments.

Air Quality Research (Office of Environmental Engineering): This program does not use quantitative risk assessment but does collect air samples to determine receptor-based exposure to chemicals of concern and also conducts fate and transport modeling.

Storm Water Monitoring (Office of Environmental Engineering): This program collects data on concentrations of constituents in storm water but does not use quantitative risk assessment. These data are used to comply with National Pollution Discharge Elimination System (NPDES) permits as well as obtain information relevant to implementation of the storm water management program. NPDES permit limits are designed to protect human and ecological receptors.

3.1 Quantitative Risk Assessment (Office of Hazardous Waste Management)

The Office of Hazardous Waste Management uses risk assessment in a variety of projects to assess the potential impact to human health and/or the environment by chemicals in the soil and groundwater at sites where projects will be constructed or on existing Caltrans owned sites. Caltrans uses external consultants to prepare these risk assessments. Caltrans is also conducting research into lead impacted soil, a particular issue with soil along roadways.

3.1.1 Risk Assessments on Project Sites and Caltrans Owned Parcels

The Committee's recommendations were evaluated on those aspects of the review and approval process that are conducted by Caltrans on the risk assessment reports. The areas where risk assessment is used include:

Caltrans Owned Parcels: These parcels include sites where soil and groundwater have been impacted by constituents of concern due to past practices; such as sand blast waste under steel bridges and leaking underground fuel tanks on maintenance facilities. In these cases Caltrans is retaining the property and working to ensure that public and worker health and the environment are not adversely impacted by the presence of these constituents. For these sites, risk assessments, including Risk-based Corrective Action (RBCA) assessments, are used to assess the impact of contamination and determine appropriate cleanup action, if necessary. Risk assessments involving lead are reviewed by DTSC.

Excess Parcels: These parcels are first assessed for the presence of contamination, then a determination is made whether the constituent concentrations are sufficient to require cleanup or if the parcel can be sold "as is". A policy is being developed by Caltrans to standardize these decisions. If necessary, risk assessments or RBCA assessments are conducted.

Sites within Project Boundaries: Caltrans purchases these sites as part of the project development process. Risk assessments or RBCA assessments may be performed depending on the severity and extent of contamination, regulatory oversight, and the potential risk to workers and the public. Not all of these sites warrant this level of effort.

Caltrans continually provides internal and external training to staff, to keep staff members abreast of new developments and issues regarding risk assessment. Reports are reviewed internally at the local level and then by a select group of staff at headquarters to maintain consistency. For intricate sites, Caltrans may request a third party review in addition to their own internal review. Additionally, these reports are reviewed by a regulatory agency. At this time, all risk assessment work is contracted out to private consultants. In the future, RBCA reports may be prepared internally by Caltrans staff; all work will be conducted in a manner consistent with current practices.

Risk assessment reports are kept on file in the District and at Headquarters and are available for review. At this time, Caltrans does not have a standard report format that must be followed. The content of a non-RBCA risk assessment report is left up to the consultant provided that current risk assessment guidelines are followed. For a RBCA report the consultants are required to follow the ASTM standard that requires certain items be addressed.

3.1.2 Lead Impacted Soil

Freeway construction projects involving excavation of soils along the shoulder and median areas have encountered lead contamination in surface soils resulting from the historic use of leaded gasoline. This contamination is found along highways with high traffic flow such as those located in San Diego, the San Francisco/Oakland metropolitan area and the Los Angeles Basin. Reliable characterization of the concentration and lateral and vertical extent of this lead contamination is important since the results of the characterization will affect the design and

execution of the construction project. If the characterization is inaccurate, the construction project can experience significant delays and increased costs.

The fraction of excavated soil containing total lead in excess of the total threshold limit concentration (TTLC, 1000 mg/kg) or containing soluble lead in excess of the soluble threshold limit concentration (STLC, 5 mg/L) is legally a hazardous waste. However, the Human and Ecological Risk Division (formerly Office of Scientific Affairs) within the Department of Toxic Substances Control (DTSC) determined that this soil can be managed on Caltrans rights of way in a manner that presents no significant threat to human health or the environment under certain conditions. This approach is consistently used in issuing Variances to Caltrans Districts 4, 6, 7, 8, 11, and 12 and addresses regulatory requirements and the protection of human health.

Caltrans contracted a private consulting firm to evaluate the fate and transport of lead in soil to determine the potential for lead in soil to leach to groundwater. A comprehensive literature review found that lead was not leachable except under certain conditions. Caltrans has applied to SWRCB for a Caltrans Statewide NPDES/WDR Permit for stormwater and non-stormwater discharge.

Currently, Caltrans implements a recommended sampling strategy for consistency between Districts which provides guidance on sample location and depth. Caltrans samples soils for the presence of total and soluble lead in advance of construction projects and has generated a large body of information for major metropolitan areas in California. Caltrans contracted with a private consulting firm to conduct a statistical analysis on these data that will support development of a tiered lead contamination sampling methodology. This lead contamination sampling methodology may be used pending a third party review of the statistical approach.

3.2 Air Quality Research (Office of Environmental Engineering)

Federal conformity rules require that state agencies responsible for approval and/or funding of transportation projects ensure that such projects conform to an approved or promulgated State implementation plan and to all applicable State and Federal air quality standards. Because of this requirement, Caltrans needs to evaluate the potential local impacts of carbon monoxide and particulate matter from a project

Caltrans uses computer models to evaluate potential impacts. Because of the need to heavily rely on the model output, Caltrans continually undertakes research projects to evaluate receptor locations, emission models, and model input parameters. Each of these research projects is developed by staff at the University of California at Davis and the methodology is peer reviewed by other members of the faculty. Results are also reviewed internally, by staff at Caltrans and if published in a journal, the research goes through another level of review. Results of the research projects are distributed to staff at the Air Resources Board, Cal/EPA, US EPA and Metropolitan Planning Organizations. The rest of this section describes research projects aimed at using the best science available to predict potential impacts of a project.

3.2.1 Selecting Receptor Sites

The receptor-siting criteria suggested by Caltrans recognize the concept of exposure to levels of carbon monoxide that have a reasonable likelihood of leading to a carbon monoxide hemoglobin level greater than that achieved by current standards. Caltrans methodology moves the receptor, for evaluating an 8-hour exposure, from the location recommended by the US EPA to a location where a person could actually be exposed to carbon monoxide for an 8-hour period. The receptor locations in US EPA's siting guidance tend to predict problems when none actually exist. Caltrans believes this happens because the receptors are being located in areas where exposure doesn't actually occur.

Caltrans based its recommendations for receptor siting on the data used to develop the carbon monoxide ambient air quality standards and the Denver Carbon Monoxide Exposure Study. This methodology was prepared for Caltrans by the University of California at Davis. Caltrans and the US EPA are discussing the recommendations made by Caltrans and determining if the US EPA will change its siting guidance document.

3.2.2 Evaluation of Two Carbon Monoxide Intersection Models

Microscale air dispersion models are essential tools used to assess the impacts of carbon monoxide on air quality. Two of the most widely used dispersion models are CALINE4 and CAL3QHC 2.0. Recently, there has been a growing concern that some of the algorithms built into CALINE4, implemented to perform intersection analyses, are not appropriate for today's vehicle fleet. As part of Caltrans study, a new modeling technique was developed that uses CALINE4 combined with an "average speed" to analyze intersections. The calculation of the "average speed" is based on the algorithms given in the Highway Capacity Manual and requires traffic volume, percentage of red time and average approach speed. In the new modeling technique, the built-in CALINE4 intersection algorithms are not used.

A comparison of the performance of this new CALINE4 modeling approach and CAL3QHC 2.0 was made using the same data set used by US EPA. Common statistical measures were used to assess model performance including scatter plots, average residual, root-mean-square-error and correlation coefficient. The results indicate that the carbon monoxide concentrations predicted by the new approach using CALINE4 are comparable to those predicted using CAL3QHC 2.0. An algorithm was developed by Caltrans for implementation in CALINE4 to take into account the potential effects of buoyancy.

Caltrans has also conducted specific research on uncertainty in fate and transport model. One study evaluated the ability of the models to estimate modeling buoyancy. An additional research project being undertaken based on the buoyancy experiment, is evaluating situations in which the source is not at ground level.

3.2.3 Transportation Project Level Carbon Monoxide Analysis Protocol

Caltrans is preparing a carbon monoxide analysis protocol. Procedures and guidelines are provided in this project-level protocol for use by agencies that sponsor transportation projects, to evaluate the potential local level carbon monoxide impacts of a project. The procedures and guidelines comply with the necessary regulations. Upon approval, the procedures and guidelines

described will constitute a protocol that is intended to replace the procedures for determining localized carbon monoxide concentrations that are given in 40 CFR section 93.131.

The new protocol proposes a streamlined, tiered approach for determining conformity. The overall idea of this protocol is to provide a framework for consistency and limit the number of projects which have to run time consuming and expensive, detailed models to determine conformity.

Based on concerns from the regulatory community, additional research is being conducted to determine if the protocol is adequate for addressing Level of Service D intersections.

3.2.4 Emissions Models

To comply with the requirement from the Metropolitan Planning Organizations and the US Department of Transportation, Caltrans uses the California Air Resources Board's Motor Vehicle Emissions Inventory (MVEI) models to estimate emissions from proposed projects.

Each time the Air Resource Board updates its MVEI, Caltrans evaluates the changes to determine the potential impacts and determines if the new MVEI can still be used to estimate emissions.

3.2.5 Modeling for Particulate Matter (PM)

Caltrans has been required to evaluate the effect of roadway projects on local particulate matter concentrations. This has focused attention on the lack of information on particulate matter emissions from California roadways. Few emission rate studies carried out in the past twenty years collected particulate matter data, and fewer still attempted correlation of particulate matter aerosols with traffic in real systems. Currently, information derived by the US EPA from studies in the mid western United States forms the basis for air quality modeling in every state. However, US EPA's "AP-42" emission factors were derived in conditions very different from those in California. Areas which are geologically and meteorologically different from California. The use of these emission factors in current air quality models may be inadequate for predicting downwind particulate matter levels.

In 1994, Caltrans contracted with the Air Quality Group at the University of California at Davis to determine if the AP-42 emission factors over estimate the downwind particulate matter levels. The results of this study showed that measured emission factors fall far below the AP-42 emission factors.

In 1995, the Air Quality Group investigated paved road particulate matter emissions in greater depth. This study included measuring roadway silt loading and monitoring for particulate matter and PM_{2.5}. PM_{2.5} was included because future PM standards may focus on particles having an aerodynamic diameter of 2.5 μm or less.

The results of the 1995 study show that the measured emissions were very close to the modeled emissions. It is believed that the 1994 study suffered from a sparse data set. The measured silt

loadings, though, were much lower than the values found in AP-42. This reinforces the need to use measured roadway silt loading when emission rates are estimated using the AP-42 method. Further studies are needed to expand the database of roadway silt loading data for California.

3.3 Storm Water Monitoring (Office of Environmental Engineering)

Caltrans monitors the concentrations of constituents in storm water. The overall objective of the storm water monitoring program is to comply with their National Discharge Elimination System (NPDES) permits. In turn, the NPDES program is designed to protect human health and the environment. This program was included in the evaluation even though no quantitative risk assessments are conducted.

3.3.1 Program Overview

Caltrans is committed to implementing storm water management practices to manage pollutants as required by applicable legislation and regulations and is applying for a statewide NPDES storm water permit.

Caltrans has determined that a single NPDES storm water permit and a comprehensive and consistent statewide storm water management plan (SWMP) would be the most effective approach to addressing its activities statewide. Compliance with the permit could then be attained by implementation of the SWMP. Caltrans developed its SWMP, in conjunction with senior faculty members from the University of California at Davis, California State University at Sacramento, and University of California at Riverside, to provide a framework for consistent and efficient implementation of storm water management practices in all districts. This approach will facilitate the development of more standardized and uniform internal guidance, contracts, and training. Included in the SWMP is a time schedule for implementing the SWMP elements. Although the statewide NPDES permit will be issued by the State Water Resources Control Board (SWRCB), Caltrans will continue to work closely with the RWQCB.

Caltrans' overall strategy for maintaining compliance with all aspects of its proposed statewide NPDES storm water permit and its corresponding SWMP involves the use of a process of continuous improvement and refinement of its storm water management program. A 3-Year Storm Water Monitoring Action Plan (Action Plan) is being prepared by Woodward-Clyde in conjunction with the California State University at Sacramento and University of California at Davis to implement the Planning-Support Monitoring and Evaluation Program described in the SWMP. A draft Action Plan was submitted to the SWRCB for review in the Spring of 1997.

The Planning-Support Monitoring and Evaluation Program is a program of applied research designed for continuous improvement and refinement of the storm water monitoring program. The overall goals of the program are to: advance the state of knowledge regarding management of storm water from highways and related facilities, provide a sound basis for re-directing or refining aspects of the storm water management program, and recommend ways to revise the SWMP as needed.

This program consists of eight interrelated information-gathering activities that Caltrans will conduct to gain insights into storm water-related water quality issues and pollution control issues. These eight activities include the following: 1) identify receiving waters and constituents of concern, 2) identify factors that affect the concentration and loads of constituents of concern in highway runoff, 3) examine physical and chemical mechanisms that affect mobilization, transport, and transformation of constituents in highway runoff, 4) develop a methodology for prioritizing highway facilities, 5) prioritize highway drainage segments, 6) define types of locations that warrant focused control efforts, 7) identify practices to be evaluated and plan the pilot studies, and 8) implement and monitor the effectiveness of candidate practices through pilot studies. The knowledge gained from these activities will help Caltrans management understand how to establish priorities for allocating resources available for storm water management and to periodically revise and refine Best Management Practices, Caltrans' overall storm water management program, and/or the SWMP, as needed.

The Action Plan consists of studies that have been designed to meet the objectives of one or more of the eight activities that form the core of this program. These studies can be thought of as the "building blocks" that Caltrans will use to gain the information and understanding it needs to meet its stated goals. Every study is reviewed by the Oversight Committee (made up of senior faculty members from the California State University at Sacramento and University of California at Davis) before being included in the Action Plan. Additionally, Caltrans plans on engaging the regulatory community for research ideas and review comments. The Action Plan also presents the process that will be used to revise and update this plan each year and a tentative schedule for conducting these studies. Studies are currently underway to meet these objectives.

3.3.2 Data Quality Issues

Caltrans has been conducting various types of field monitoring at the District level (e.g., highway runoff characterization, source characterization, evaluation of storm water management practices) to comply with the NPDES Permits issued by various RWQCBs. In order to improve the quality, consistency, and comparability of data that are being collected by the Districts, Caltrans contracted Woodward-Clyde to independently review current practices and provide recommendations for improvement. Woodward-Clyde evaluated the following components of the storm water monitoring program: monitoring sites and sampling locations, storm selection, storm water monitoring preparation, sample collection, monitoring frequency, sample analysis, QA/QC sample collection and independent data review.

3.3.3 Best Management Practices

Senior Caltrans personnel, with input from RWQCB staff, personnel of several municipal storm water management programs, and representatives from the Natural Resources Defense Council, performed an evaluation to decide which storm water management practices should be recommended as Best Management Practices for broad application. The storm water management practices were evaluated and scored, and were then rated by tallying the scores for the three evaluation criteria (pollution control benefit, implementation feasibility, and economic feasibility). These Best Management Practices will continuously be evaluated and refined.

3.3.4 Training and Public Education and Participation Program

The SWMP presents three types of training: personnel training, informational exchanges with construction contractors, and public education and participation.

The training courses included in the Personnel Training Program will provide a comprehensive review of storm water pollution prevention concepts and practices. The curriculum will consist of three courses: 1) storm water management for maintenance activities, 2) storm water management related to construction sites, and 3) storm water management for project development. During the first year of implementation, Caltrans personnel will attend training courses that are relevant to their job classification and responsibilities. Refresher courses will be held every four years. Caltrans personnel and outside consultants will provide this training.

The purpose of the informational exchanges is to teach Caltrans construction contractors about the following topics: 1) the provisions, conditions, and requirements of the permit that apply to their projects, 2) the availability of guidance material prepared by Caltrans for construction contractors and 3) general responsibilities of construction contractors regarding implementation of the SWMP, the requirements of a SWPPP and how to prepare a SWPPP. Two types of sessions will be used: 1) storm water permit compliance requirements - pre bid meeting and 2) storm water permit compliance requirements - pre construction meeting. Topics included in these sessions will be updated as needed to reflect modifications to the SWMP. Caltrans personnel and outside consultants will provide this training.

In addition to the training sessions discussed above, Caltrans will periodically make presentations at the Association of General Contractors (AGC) meetings and other contractor group meetings. The presentations will focus upon issues related to implementation of the SWMP. Caltrans will annually conduct a workshop with AGC to discuss storm water issues and Caltrans requirements. Additionally, Caltrans will annually prepare and distribute an information newsletter to inform construction contractors of recent storm water quality developments and requirements for Caltrans Construction Projects.

The Public Education and Participation Program will provide a variety of practices for educating the public about the importance of managing storm water. Caltrans has existing programs to educate the public about storm water problems related to illegal dumping of litter and debris. One such program is the "Adopt a Highway/Adopt a Wall" program. Additionally, Caltrans will install "No Dumping", "litter fine", and "cover load" signs as well as stencil storm drain inlets at Caltrans owned locations. Caltrans will also commit from \$100,000 to \$150,000 annually (beginning Spring 1997) to a public education grant program. Public education programs that receive funding from this grant program will be required to submit a report of the results and effectiveness of the public education program that was implemented. The report will also include recommendations on whether to continue the program or methods for enhancing the program that was implemented.

These training programs will keep people up to date on the current standards, involve the public and private sector. The programs also present ways to evaluate the effectiveness of the training programs.

3.3.5 Sampling Analysis and Collection Plan

As part of the statewide NPDES storm water permit, private consultants prepared a sampling collection and analysis plan. This manual was submitted to the regulatory community for review on April 4, 1997. Prior to submission to the regulatory community, the manual was peer reviewed by professors at California State University at Sacramento, Caltrans staff, and external private consultants.

The manual is designed and organized to provide a comprehensive, step-by-step description of the processes used to plan a successful water quality monitoring program, including a thorough QA/QC data evaluation, specific to runoff from transportation-related facilities. It is essential that monitoring data are collected so as to ensure that the data are accurate, precise, and scientifically defensible. It is also important for monitoring programs to be conducted in a consistent manner, to provide for data comparability throughout the Districts. This will then ensure that regional differences, if any, can be accurately addressed, and that the data can be utilized in a statewide database.

The focus of this guidance manual is on monitoring protocols that are used to plan and implement sampling and analysis for chemical and physical constituents, as part of a water quality monitoring program. The emphasis throughout the manual is on storm water monitoring that will provide data to support the planning functions of the SWMP. Water quality constituents that may be present in highway runoff generally have been identified by previous monitoring efforts. Therefore, the statewide program takes a slightly different approach to monitoring and instead of just monitoring for what is present, Caltrans will be:

Monitoring to discern the specific sources, transport mechanisms, and fate of constituents known to be present in transportation facility runoff, and

Monitoring to determine which control measures are most effective in reducing the discharge of constituents that may have an adverse impact on receiving water quality.

3.3.6 Methyl Tertiary Butyl Ether (MTBE) Monitoring

As part of its proactive stance, Caltrans voluntarily included MTBE in its FY 1996/1997 storm water sampling at three sites in District 7. The purpose of this monitoring is to discover if MTBE is present in rainfall and to what extent, if any, it is impacting storm water runoff. Depending on the results in District 7, MTBE may be included in the sampling of all Districts. Unfortunately, no data were collected during the FY 1996/1997 season due to lack of rain. This program will be continued in the FY 1997/1998 season.

Caltrans has also contributed to Air Board Research needs by addressing analytical issues with laboratory false positives of MTBE in water.

CHAPTER 4.0 CALTRANS IMPLEMENTATION PLAN

Table 4.1 presents Caltrans Implementation Plan. The reader is referred to the SWMP for time lines regarding storm water monitoring activities. There are no timelines for the Air Quality Research activities or Quantitative Risk Assessments as these projects are conducted on an as needed basis.

Table 4.1 CALTRANS IMPLEMENTATION PLAN

<i>Category</i>	<i>Items to Implement</i>
<p>1. Training</p> <p>Continuous education is needed to be certain that expert personnel keep abreast of new developments. With rapid change, one's university education is inadequate to sustain a career without frequent updating. Mechanisms such as two-way temporary staff exchange programs, forums and trainings should be encouraged.</p>	<p>OEE</p> <p>Implement training program outlined in the Statewide Storm Water Management Plan (SWMP), including personnel training, informational exchanges with construction contractors, and public education and participation. Continue to use private consulting firm and university staff in house for their expertise.</p> <p>OHWM</p> <p>Send staff members to workshops, meetings and conferences as well as having internal seminars.</p>
<p>2. Data Management</p> <p>Institute measures for quality control of data in databases and data being added to the databases. For example, the quality of data relies, in part, on the sampling strategy employed. Additionally, improve the accessibility of data to all interested parties.</p>	<p>OEE</p> <p>Implement storm water Sampling Analysis and Collection Plan, which provides a comprehensive, step-by-step description of the process to be used by every District. Create a database and make data available via the Internet</p> <p>OHWM</p> <p>Evaluate the recommendations made for the lead sampling program for their usability.</p>
<p>3. Peer Review</p>	<p>OEE</p>

<p>Develop a formalized policy for internal and external peer review of program activities.</p>	<p>Continue to have project designs and outcomes reviewed by staff of private consulting firms, universities, and regulatory agencies.</p> <p>OHWM</p> <p>Continue to use regulatory agencies and objective private consulting firms in the review process.</p>
<p>4. Receptor Based Exposure Assessments</p> <p>Receptor-based exposure assessment is a powerful tool that could help to prioritize efforts to reduce exposures and protect public health. Cal/EPA should acknowledge the uncertainty that results from the reliance on scenario based exposure assessments.</p>	<p>OEE</p> <p>Evaluate the necessity for further research efforts regarding receptor locations for the carbon monoxide program.</p> <p>OHWM</p> <p>Not Applicable</p>
<p>5. Exposure/Fate and Transport Models</p> <p>A well run modeling exercise provides our best view into the future. More effort is needed to validate models with real experimental data. In assessing transport and dispersion models, the quality and characteristics of input data to the models, such as emissions data and dispersion parameters, should be considered in addition to the validity of the models themselves.</p>	<p>OEE</p> <p>Conduct additional research projects to evaluate the validity of air models and their input parameters as needed.</p> <p>OHWM</p> <p>Evaluate the applicability of models to site specific conditions as needed.</p>
<p>6. Communication/Information Sharing</p> <p>Efforts towards consistency and harmonization between boards and departments and their federal counterparts have begun, appear to be useful, and should be encouraged.</p>	<p>OEE</p> <p>Continue to share work product information with regulatory agencies.</p> <p>OHWM</p> <p>Continue to share work product information with regulatory agencies.</p>
<p>7. Decision Making and Risk Management Policies</p> <p>Policies and procedures for addressing the translation or risk assessment uncertainties into</p>	<p>OEE</p> <p>Not Applicable.</p>

<p>risk management policy should be developed. Continue to look for, and implement, ways of involving risk managers and stakeholders in risk assessment, including the development of guidelines, assessments, workshops, and reviews.</p>	<p>OHWM</p> <p>Work towards finalizing the draft guidance document that will be used to close site.</p>
<p>8. Process Improvement</p> <p>Seek out and implement ways of simplifying and streamlining the process of risk assessments.</p>	<p>OEE</p> <p>Implement the Storm Water Monitoring Plan and Sampling Analysis and Collection Plan, both of which contain methods for yearly reflection and modification.</p> <p>OHWM</p> <p>Work towards finalizing the draft guidance document that will be used to close Sites.</p>

ATTACHMENT A SUMMARY OF SPECIFIC RECOMMENDATIONS, MADE BY THE RISK ASSESSMENT ADVISORY COMMITTEE, FOR THE EIGHT CATEGORIES

1. Training

It is imperative that the public have confidence that Cal/EPA human health risk assessments reflect the best possible scientific judgments. Therefore, it is recommended that an overarching administrative structure be established that has as a principal duty, stewardship for selecting areas where the application of new or existing knowledge could enhance the certainty of scientific judgment as to human health risks (a1, p. 2-4).

Cal/EPA should do an assessment, both of activities and of needs, relative to staffing, manpower, and expertise. This could include cross-training and retraining opportunities for present staff where appropriate (c1, p. 2-10).

Continue to look for, and implement ways of involving risk managers and stakeholders in risk assessment, including the development of guidelines, assessments themselves, workshops, and reviews. Particularly strive for involvement as early as possible in the process (c6, p. 2-11).

Continuous education is needed to be certain that Cal/EPA’s most expert personnel keep abreast of new developments and that front-line personnel are educated about the availability of advanced, yet robust opportunities for improving fate and transport modeling capabilities. Society is coming to a deeper understanding of environmental processes over time, and that deeper understanding needs to be reflected in regulatory processes. With rapid change, one’s university education is inadequate to sustain a career without frequent updating. Agencies can

remain current by growing: new ideas enter with new staff. Significant growth at Cal/EPA appears unlikely for the foreseeable future, so other mechanisms must be sought. Cal/EPA management must recognize that it is a legitimate activity for staff to spend at least a few hours per week engaging in continuing education activities. The Agency should consider implementing mechanisms such as two-way temporary staff exchange programs, creating forums, individual training (A5, p. 6-5).

2. Data Management

Review the present data collection/data management effort for overlap (c3, p. 2-10).

Improve accessibility of present data (c4, p. 2-10).

Institute measures for quality control of data in the databases, and that being added to the databases. For example, the quality of monitoring data relies, in major part, on the sampling strategy employed – an area requiring continuing attention by the units responsible for the monitoring activity (c5, p. 2-10).

3. Peer Review

Cal/EPA should develop a formalized policy for internal and external peer review of its activities. It should identify the goals and objectives of the program and Cal/EPA should design a program to meet those objectives (e1, p. 2-27).

The systems currently in place within Cal/EPA for reviewing assessments need to be reexamined; if necessary, new systems should be implemented to ensure consistency of practice (A4, p. 6-5).

4. Receptor Based Exposure Assessments

Receptor-based exposure assessment is a powerful tool that could help Cal/EPA prioritize its efforts to reduce exposures and protect public health. To make productive use of this tool, we recommend the establishment of an external advisory group at the Agency level. This cross-cutting group would identify which issues and problems are best addressed with a receptor-based exposure assessment approach. Further, this group would oversee the introduction of receptor-based exposure assessment into the diverse programs of Cal/EPA in a coordinated and consistent manner (A1, p. 5-3).

Additional monitoring of human exposures is needed to complement the efforts to implement receptor-oriented exposure models. For example, in addition to a fixed-station air toxics network, it would be beneficial to develop an ongoing personal exposure monitoring program. Such data should be used to validate exposure models (A2, p. 5-3).

First, Cal/EPA should require an explicit statement of the nature of the exposure assessment related to the purpose of the overall risk assessment being performed. Such a statement (often called a problem formulation statement) should clearly state whether the estimate is intended to

be an unbiased characterization of individual's dose rates or a conservatively biased estimate that should be viewed as an estimate of the upper bound of exposure. Second, the Agency should provide guidance on how the conservative biases of screening-risk estimates should be interpreted by risk managers and the general public. Third, when performing risk/benefit or risk/risk comparisons, Cal/EPA should strive for risk estimates that are unbiased and that take into account all assumptions inherent in the exposure assessment (A4, p. 5-4).

Cal/EPA should acknowledge the uncertainty that results from the reliance on scenario-based exposure assessments and the biases in exposure estimates that are introduced by the adoption of simplifications in the design and use of scenarios. Where practical, the Agency should perform personal exposure monitoring surveys to determine the frequency distribution of actual dose rates and confirm the results of scenario-based exposure assessments (A5, p. 5-5).

Where Cal/EPA requires the use of specific scenarios, it should provide justification as to why the specific scenario is appropriate or necessary at a site. This justification should include a discussion of the land use and behavioral assumptions implicit in the scenario (A6, p. 5-6).

Cal/EPA should strike a new balance between exposure monitoring and ambient monitoring by devoting more attention to exposure monitoring. The new receptor-oriented approaches permit the exposures from more than one environmental medium to be measure simultaneously in a single field study, making them especially appropriate for Cal/EPA's multimedia mission (B3, p. 5-10).

5. Exposure/Fate and Transport Models

Procedures should be developed to use such techniques as working papers, white papers (narrow issues) and guidelines to move new scientific developments into regulatory practice (d10, p. 2-20).

In adopting models or default assumptions, or approaches to exposure assessment, Cal/EPA should design mechanisms for updates and changes. Also, mechanisms by which Cal/EPA scientists are kept informed of scientific developments are needed. Providing opportunities for Cal/EPA staff to attend scientific meetings, workshops, seminars, etc., is very important (B4, p. 5-10).

Cal/EPA should assert leadership in setting and maintaining high modeling standards. A well-run modeling exercise by a competent modeler provides our best view into the future. Although Cal/EPA's principal focus is not in model development, the Agency does have a responsibility to deep abreast of advances in fate and transport modeling and to inform the regulated community about which models are relevant and which are proven less useful. If the State of California, through Cal/EPA, insists on high standards, the models developed within the State will generate expertise that can be exported. California has several premier research laboratories, world-class universities, and a strong environmental consulting industry. Cal/EPA can facilitate the movement of fate and transport models out of the research institutions and into use (A3, p. 6-5).

More effort is needed to validate models with real experimental data. The Committee is concerned about the potential erosion of effort to monitor concentrations and exposures because of budget constraints (A6, p. 6-6).

Cal/EPA should seriously explore incorporating stochastic approaches, as appropriate, in their risk assessment activities beyond the welcome introduction of CalTOX. Uncertainty and variability are hard facts of environmental sampling and assessment. Stochastic modeling approaches that produce distributional information about possible media concentrations and the corresponding risks constitute the best available means to account for the effects of uncertainty and variability (A7, p. 6-6).

Cal/EPA should work towards incorporating chemical breakdown schemes and focus on products of reaction as it further develops its modeling capability (A8, p. 6-6).

Cal/EPA should increase its knowledge of developments in groundwater modeling and provide encouragement to modelers to use these improved models where justified by the situation. This should not be construed, however, as a mandate to use advanced models, which may be costly and difficult to understand, when the importance of the risk management decision does not require them or when screening models are sufficient to dismiss risks as insignificant (B1, p. 6-9).

It is important that accurate vadose zone models be available. It is recommended that Cal/EPA assert leadership in fostering dialogue between different departments within Cal/EPA, academia, and the regulated community with the objectives of (a) identifying parameters that should impact vadose zone model development and selection, and (b) identifying specific application and models that appear to provide better estimates. The Agency should also provide more explicit guidance to modelers as the acceptability of vadose zone models, or to make it clear how to predict fate and transport in the vadose zone if not with mathematical models (B2, p. 6-9).

Cal/EPA should develop guidance for modelers on how to provide uncertainty characterizations that are sufficiently quantitative to permit good risk management decisions (B3, p. 6-10).

Cal/EPA should explore the application of stochastic methods, including Monte Carlo Simulation, to help define the probability of failure of remedial measures, such as pump-and-treat technologies (B4, p. 6-10).

Cal/EPA should couple the large amount of monitoring data which it collects on well water and groundwater contamination with modeling efforts, so as to promote validation of groundwater fate and transport models (B5, p. 6-10).

The validity and applicability of current fate and transport models recommended by Cal/EPA for atmospheric release of contaminants should be reassessed. This activity should be undertaken by an assembled group of academics, Cal/EPA technical personnel and scientific representatives from the regulated industry. In assessing transport and dispersion models, the quality and characteristics of input data to the models, such as emissions data and dispersion parameters, should be considered in addition to the validity of the models themselves. Risk management

decisions for atmospheric releases of toxic air pollutants depend critically on short-range (<10 km) transport and dispersion. Although it is widely believed that the most popular atmospheric dispersion models have been validated within a factor of 2 or 3 for annual average concentrations, the experimental basis for that belief is actually relatively weak. Cal/EPA should consider reevaluating the validity of atmospheric dispersion models to confirm that these models are acceptably accurate for the decisions being made (in comparison to the accuracy of decision tools for other pathways of exposure). If the combination of theoretical considerations and empirical determination is not compelling in this regard, Cal/EPA should look for opportunities to improve the empirical basis for the models, possibly in conjunction with US EPA. For example, tracer studies might prove useful (C1, p. 6-12).

Cal/EPA should increase its knowledge of developments in air quality modeling and provide encouragement to modelers to use these improved models where justified by the situation. This recommendations should not be construed, however, as a mandate to use advanced models, which may be costly and difficult to understand, when the importance of the risk management decision does not require them or when screening models are sufficient to dismiss risks as insignificant. Cal/EPA should also consider further developing fate and transport modeling techniques that could be used in case specific instances where conventional air dispersion modeling is not appropriate, for example in the indoor environment. The US EPA, in conjunction with the American Meteorological Society, has initiated an effort to update the treatment of transport and dispersion in the ISC model. While the new model (AERMOD) will automatically become of the Cal/EPA's approved models when it becomes publicly available, the Agency should review it and be prepared to recommend its use under appropriate conditions (C2, p. 6-12).

Cal/EPA is advised to make surveillance of developments in the science of intermediate fate and transport a continuing priority and to institute procedures for systematic updates of multimedia risk assessment procedures with the goal of improving the accuracy of estimates. To the extent possible within legislative constraints, Cal/EPA should also attempt to cross-fertilize and harmonize procedures across the boards and departments and to use the best of US EPA science to improve its own. In doing so, it should give due consideration to the specifics of California conditions such as precipitation and temperature to be sure that model parameters from US EPA or elsewhere are reasonable in the specific situation being assessed. Finally, Cal/EPA should consider providing for the dissemination of the best science among the boards and departments. Such dissemination could occur through formal continuing education requirements, temporary or permanent reassignment of personnel, regular interdepartmental meetings, newsletters, or other techniques. The most effective combination of techniques may need to be discerned by trial and error. In addition, an implementation plan should be developed for CalTOX with a timetable and objectives (D1, p. 6-15).

Cal/EPA should review the effect of choices of assumptions, models, use of quantitative uncertainty analysis, etc., on decision outcomes, including a review of the impact of assumptions in the CalTOX program (3, p. 7-5).

The uncertainties in models, data sets, and parameters and their relative contributions to total uncertainty in a risk assessment should be reported in written risk assessment documents (A4, p. 7-11).

When different models may be employed in a risk analysis, perhaps leading to different conclusions, parameter uncertainty should be analyzed at a similar level of detail for all the models (A5, p. 7-11).

Cal/EPA should more fully communicate the impacts of model and parameter choice in the risk assessment. How model uncertainty was accounted for should be discussed in the final characterization (B3, p. 7-15).

6. Communication/Information Sharing

Efforts towards consistency and harmonization between Cal/EPA boards and departments and their federal counterparts have begun, appear to be useful, and should be encouraged (b1, p. 2-6).

In order to facilitate consistency and harmonization in the practice of risk assessment at Cal/EPA, an internal agency working group should be established whose specific charge is to insure agency-wide consistency (b2, p. 2-6).

7. Decision Making and Risk Management Policies

An agency-wide effort should be undertaken to develop policies and procedures for addressing the translation of risk assessment uncertainties into risk management policy. Consideration should be given to replacing single value or "bright line" criteria with strategies that acknowledge the range of risk uncertainty and allow cost and benefits within the uncertainty band to be dealt with at a local level (b3, p. 2-7).

Cal/EPA needs to establish a mechanism for prioritizing candidates for full risk assessment, so that resources are spent primarily on the major problems (c9, p. 2-12).

Cal/EPA should clearly articulate a set of principles for justifying independent assessments for chemicals/locations which other agencies have assessed previously (c10, p. 2-13).

The public and interested stakeholders should be involved early in the risk assessment process and maintain involvement at key decision points throughout the process (e2, p. 2-27).

The extent to which Cal/EPA's practices are aligned with their broad mission should be reexamined. Such an activity may require articulating a clear mission for the Agency. The current practice of fate and transport assessments may only require incremental improvement if the primary goal is protection of environmental resources, such as air or water. However, if the Agency's primary mission is environmental health protection, then it needs to take substantial, fundamental steps to improve its understanding of the relationships between fate and transport and human exposure (A1, p. 6-4).

8. Process Improvement

Efforts towards consistency and harmonization between Cal/EPA boards and departments and their federal counterparts have begun, appear to be useful, and should be encouraged (b1, p. 2-6).

In order to facilitate consistency and harmonization in the practice of risk assessment at Cal/EPA, an internal agency working group should be established whose specific charge is to insure agency-wide consistency (b2, p. 2-6).

Cal/EPA needs to seek out and implement ways to simplify and streamline the process of risk assessment for assessments conducted in-house and those required of outside entities (c7, p. 2-12).

Cal/EPA need to establish measures of success for gauging the effectiveness of efforts to streamline and simplify (c8, p. 2-12)

3.2.5 Other State Agencies Who Evaluated The Report And Concluded That They Are Not Subject To The Executive Order

A number of California State agencies evaluated the report and language of the Executive Order W-137-96 and concluded that they are not encompassed by the directive. These agencies indicated in their responses to OEHHA that either (1) their programs did not perform activities involving chemical risk assessment, or (2) that their activities were purely enforcement of state or federal laws, regulations or guidance for which they did not develop.

These agencies included:

- The California Water Commission
- The Department of Boating and Waterways
- The Department of Consumer Affairs
- The Department of Forestry and Fire Protection
- The Department of Food and Agriculture
- The Department of Industrial Relations
- The Department of Parks and Recreation
- The Department of Water Resources.

Thus, the agencies listed above did not develop plans to implement the RAAC recommendation and do not contemplate taking any further action at this time with respect to risk assessment sciences.