A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines

Report of the
Risk Assessment
Advisory Committee

October 1996

Risk Assessment Advisory Committee

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Preface

In legislation passed 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 Risk Assessment Advisory Committee (Committee), a group of experts outside California state government, was appointed for this task. 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 set, and labored diligently to meet, an intensive schedule for the review which began with its first meeting in June 1995. The Committee convened roughly one meeting every month until its final meeting in May 1996. The hard work and diverse expertise of the Committee enabled it to conduct this comprehensive review. The members of this Committee included experts in public health, toxicology, epidemiology, engineering, chemistry, modeling, and statistics.

The Committee examined many complicated issues and attempted to provide thoughtful advice to Cal/EPA on how it might improve its risk assessment activities. The report in many instances describes the direction in which Cal/EPA should move in order to improve the scientific basis of its risk assessment efforts. 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 to provide consistency in its regulatory activities. Unfortunately, the Committee found no quick fixes. In considering implementation of the recommendations in this report, we recommended that Cal/EPA proceed with care and with much outside advice, taking the time and expending the resources necessary to move forward in these improvements.

The ability to complete such an intensive review required major support by the Cal/EPA staff. The Committee would like to thank Thomas McDonald and David Ting, two toxicologists from OEHHA, who coordinated the Committee activities and supported the Committee on toxicological and exposure issues. Lauren Zeise, Chief of the Reproductive and Cancer Hazard Assessment Section, the project manager, directed these activities. James Stratton, Interim Director of OEHHA, and Richard Becker, OEHHA Deputy Director for Scientific Affairs, were actively involved in the implementation of the risk assessment review and attended each of the Committee meetings. Richard Becker provided broad-based expertise throughout the process. Staff of other boards and departments served as liaisons and supported the Committee's efforts by providing information and answering Committee questions on the details of the programs under their purview. The department liaisons were as follows: Gerald Bowes (State Water Resources Control Board), Jon Marshack (Regional Water Quality Control Board, Central

Valley), Diane Kihara and Vince Paul (Integrated Waste Management Board), Jay Schreider (Department of Pesticide Regulation), Genevieve Shiroma (Air Resources Board), Joy Wisniewski (OEHHA), and Jeffrey Wong (Department of Toxic Substances Control). Additionally, the Standards/Criteria Work Group, an interagency group of Cal/EPA staff chaired by David Siegel (OEHHA), identified critical issues in risk assessment for discussion by the Committee and provided input to this risk assessment review process. Numerous other technical and managerial staff from the Cal/EPA boards and departments participated as speakers and panel members at the various Committee meetings.

Many distinguished scientists outside of Cal/EPA met with the Committee to share their knowledge and experience at the meetings. They include:

Carol Bohnenkamp (US EPA, Region IX)
Michael Callahan (US EPA, Washington, DC)
Robert Clay (Radian)
Joan Daisey (Lawrence Berkeley Laboratory)
Carol Henry (US Department of Energy)
Patricia Holmes (Bay Area Air Quality Management District)
James Kariya (US EPA, Washington, DC)
Richard Lee (San Francisco Department of Public Health)
Mark Maritato (ChemRisk)
Thomas McKone (University of California and Lawrence Livermore National Laboratory)
Mark Saperstein (ARCO)
Lee Shull (Foster Wheeler Environmental)
Rob Scofield (ENVIRON)
Greg Woodside (CH2M Hill)

Special thanks go to James Cogliano (US EPA, Washington DC), Arnold Den (US EPA, Region IX), Gerald Hiatt (US EPA, Region IX), and Richard Thomas (International Center for the Environment and Health) who participated extensively at our meetings. Our sincere thanks to them for providing their time on the Committee's behalf.

We commend all the expert members of the Risk Assessment Advisory Committee (listed inside the front cover of the report) for their hard work and dedication to this process. They provided technical expertise in each of the specialty areas, were invaluable in reviewing the extensive material provided, and wrote the chapters on the specific components of risk assessment. This review has been a productive experience, and we hope it will advance the scientific basis of risk assessment within California and beyond.

James N. Seiber Chairman	Robert C. Spear Vice-Chairman	Herschel E. Griffin Core member
Judith A. MacGregor Core member	John Moore Core member	

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EXECUTIVE SUMMARY

I. Background

This report describes the observations, findings, and recommendations of the California Environmental Protection Agency (Cal/EPA) Risk Assessment Advisory Committee (Committee), convened under the authority of Chapter 418, Statutes of 1993, Health and Safety Code, Section 57004, to review the health risk assessment policies and practices of Cal/EPA.

Chemical risk assessment is a process whereby information concerning threats to human health and the environment posed by a chemical substance is organized in a way useful to society and decision makers. Human health risk assessment, as formally described in a 1983 National Research Council report: *Risk Assessment in the Federal Government: Managing the Process*, consists of four steps: hazard identification; dose-response assessment; exposure assessment; and risk characterization. Uncertainty, variability, and incomplete data sets lead to risk estimates which are ranges, requiring special training and skill in applying the results in risk management. Yet, chemical risk assessment is a young and still evolving area in environmental health sciences, with new approaches and new data continually under development. Concepts regarded as basic principles a decade ago are now being questioned (cf. the 1996 National Research Council report, *Understanding Risk: Informing Decisions in a Democratic Society*). The study reported here took place in part because of several perceived disjunctions between practices, procedures, and policies employed by Cal/EPA and the needs of those who use the results of risk assessments to make decisions and to inform the public.

Risk assessment is attractive because it provides a systematic way for society to look at risks due to environmental chemicals and place them on a comparable basis. Federal agencies such as the US Environmental Protection Agency (US EPA), US Food and Drug Administration (FDA), US Department of Defense (DOD) and US Department of Energy (DOE), and state agencies such as Cal/EPA, routinely use risk assessment in reaching decisions in such diverse areas as toxic waste cleanup, pesticide registration and labeling, standards setting for air pollutants, and the permitting of facilities. Federal laws such as Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Resources Conservation and Recovery Act (RCRA), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Clean Air Act Amendments of 1990 (CAA-90), and Toxic Substances Control Act (TSCA) have sections where risk assessment may be appropriate or required. Similarly, implementation of state laws, such as the Toxic Air Contaminant Identification and Control Act (AB 1807), Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), and Birth Defect Prevention Act (SB 950) require risk assessment activities. Both chemical-specific and site-specific regulatory decisions may be, at least in part, based upon the results of risk assessment.

Risk assessment is known to have considerable uncertainty, and there are difficulties in applying this imperfect process to decision-making. Some are concerned that cancer is over-emphasized as a risk assessment endpoint, that the results of risk assessments are skewed on the side of health protection, placing unjustified economic burdens on California's industries, and that risk managers apply the results in an inflexible manner. Others, however, are concerned that the process serves as a means for risk assessors to control decision making, primarily to the benefit of industry. Nevertheless, risk assessment helps prevent arbitrary decisions by providing a systematic means of incorporating scientific information in decision-making. The Committee addressed concerns such as these in its deliberations along with a focus on the issue of consistency between Cal/EPA and US EPA and among units of California state government involved in risk assessment.

In carrying out risk assessments in response to the various legislative mandates under which it operates, Cal/EPA has centralized its risk assessments in three departments, the Office of Environmental Health Hazard Assessment (OEHHA), Department of Pesticide Regulation (DPR), and the Department of Toxic Substances Control (DTSC). In addition, the Air Resources Board (ARB), the California Integrated Waste Management Board (CIWMB), the State Water Resources Control Board (SWRCB), and the Regional Water Quality Control Boards (RWQCBs) also conduct risk assessment activities, primarily related to exposure assessments for specific sites, facilities and geographical regions in California.

Objectives

It was against this background, including the experience of a roughly three-year period following the organization of Cal/EPA and OEHHA, and a national trend toward regulatory reform, that the California State Legislature passed into law Senate Bill 1082 in 1993, mandating a peer review of the risk assessment practices of Cal/EPA. The language of that legislation described the review as follows:

> **Chapter 418, Statutes of 1993 (Senate Bill 1082, Calderon), Health and Safety Code, Section 57004**
>
> (a) On or before June 30, 1994, the Director of Environmental Health Hazard Assessment shall convene an advisory committee consisting of distinguished scientists not employed by the boards, departments, and offices within the agency, to conduct a comprehensive review of the policies, methods, and guidelines followed by the boards, departments, and offices for the identification and assessment of chemical toxicity.
>
> (b) The purpose of this comprehensive review shall be to make recommendations to the Director of Environmental Health Hazard Assessment and the secretary concerning whether or not any changes should be made to ensure that the State's policies, methods, and guidelines for the identification and assessment of chemical toxicity are based upon sound scientific knowledge, methods and practices. This

review shall include, but shall not be limited to, an assessment of the appropriateness of any differences between the policies, methods, and procedures employed by the State and those employed by the National Academy of Sciences, the Environmental Protection Agency and other similar bodies.

Structure of the Review

The year-long review mandated by SB1082 was conducted by a committee composed of scientists from academia, private industry, and national scientific research institutions. The Committee was convened by the Director of OEHHA, and as mandated by the bill to ensure that the review was independent, none of the Committee members were employed by Cal/EPA. The multidisciplinary nature of risk assessment necessitated that the Committee include toxicologists, epidemiologists, chemists, engineers, modelers, statisticians, and others. A unique structure for the Committee was adopted in order to address the review in a comprehensive way, but also with efficiency and timeliness. A Core Committee composed of five members, including a chair and a vice-chair, was constituted to oversee and conduct the review. The Core Committee provided consistency by attending all Committee meetings, and played a major role in coordinating and bringing to conclusion the review. In addition, expert committees of four to seven individuals constituted in the following areas provided for in-depth review:

- Hazard Identification
- Dose-Response Assessment
- Exposure Assessment (including both human intake and monitoring, and fate and transport)
- Variability, Uncertainty and Risk Characterization

To address recurring themes that arose in the discussion of these areas, the Committee also developed findings and recommendations on cross-cutting issues, namely: 1) the incorporation of new science into risk assessment, 2) consistency and harmonization, 3) peer review of Cal/EPA risk assessments, 4) guidelines, and 5) resources and organization. The Core Committee served as the lead experts in the drafting of the Executive Summary and in Committee discussions and deliberations on cross-cutting issues.

The review and report drafting process consisted of several meetings and one workshop. In addition to 2-day meetings on cross-cutting issues and on the four topics listed above, the Committee held an introductory planning meeting at the beginning of the year-long review, a synthesis meeting toward the end, and a final meeting, primarily to discuss the executive summary. A workshop was held early in the process, to allow the Committee and other participants to assess representative case studies in which risk assessment has been conducted and applied in California, and to identify issues to be addressed in the review.

The Committee focused its review on the present practices of Cal/EPA boards and departments involved in risk assessment. Although information of a comparative nature was obtained from US EPA, DOE and the National Academy of Sciences (NAS), and from other components of California State government and regional entities, the following caveats must be stated:

- Information on the NAS and the US EPA risk assessment policies and practices was obtained from representatives of the organizations that attended the meetings, policy documents, examples of risk assessments, and the knowledge of the Committee members. No in-depth study of these organizations was attempted.

- The approach of this study emphasized review of the functional components of the risk assessment process and not a detailed department-by-department organizational review.

- While several public comments pertained to inconsistencies between regional boards, time did not permit an evaluation of risk assessment issues at the regional level.

- Issues involving the risk assessment-risk management interface were addressed, whereas those pertaining solely to the risk management process were not evaluated.

All meetings were conducted in accord with the open meeting practices of the Bagley-Keane Act. In addition to Committee members and invited panelists, members of the public were encouraged to participate and provide comments. Staff support, including arranging the logistics of the meetings, preparing and distributing background information and specific items of information requested by the Committee, keeping records of all correspondence, oral testimony, and other input to the process, and assisting in assembling the elements of the report, was provided by OEHHA. Many individuals from other boards and departments of Cal/EPA, US EPA, both federal and from Region IX, and the local water districts as well as the regional and local air districts that are not formal components of Cal/EPA provided important input to the process. In addition to *Risk Assessment in the Federal Government: Managing the Process* and the National Research Council's recent publication *Science and Judgment in Risk Assessment,* the Committee made use of various other documents in conducting its review; these are listed in the Appendix G to this report.

II. General Findings and Recommendations

Our general finding is that Cal/EPA's risk assessment products are of good quality, both from the perspective of scientific credibility and professional practice. The policies and procedures of like units in Cal/EPA and US EPA are generally consistent, although somewhat less consistency exists across the various boards and departments of Cal/EPA itself, as is the case with US EPA. Of course, there is room for improvement and many recommendations are offered in this report that range from strengthening the peer review process for many of the agency products to the need to address seriously the implications of uncertainty in the risk assessment process for risk management decisions.

A recurring but often subliminal theme in the Committee's discussions and findings relates to the inherent conflict between a desire for standardization and formalization of the agency's risk assessment guidelines, policies and procedures and the desire for these same guidelines, policies and procedures to reflect the latest scientific thinking and methodology. To a large extent, the enthusiasm reflected throughout the report for the peer review process can be seen as a means of advancing the scientific agenda to balance the natural and legitimate pressures for consistency and standardization from both the regulated community and the various boards and departments of Cal/EPA itself. However, it is important to recognize that this tension is inherent in the regulatory process.

Another important issue to emerge from our review concerns the match of the current organization and resource distribution within Cal/EPA to effectively address its diverse responsibilities. It is clear that the structure of the organization is the result of a long and complex legislative and administrative history. It is equally clear that many of the inconsistencies in risk assessment policies and procedures across the agency are a result of this history. There are cases in which functions important to human health risk assessment were originally created to protect the State's air or water resources in more general terms and the organization has not evolved to meet both needs. The most notable example discussed in this report concerns the need for the environmental fate and transport expertise within the agency to better serve the interests of assessing risks to human health in addition to the protection of the State's water resources. Another example is represented by the apparent lack of expertise in human health effects assessment and epidemiology, within Cal/EPA. Examples such as these argue for a reassessment of staffing, functions, and planning within Cal/EPA. This is partly incorporated in a strategic planning exercise of Cal/EPA, which was underway independently of the Committee's activities.

These findings and recommendations fall into four categories and are described in the following paragraphs. For convenient reference, the major general recommendations are summarized in the table below. The Committee's major findings and recommendations on specific areas of the risk assessment process are summarized in Section III and the many recommendations made are presented in detail in the individual chapters of this report.

SUMMARY TABLE 1. HIGHLIGHTS OF GENERAL RECOMMENDATIONS

(Additional recommendations are provided throughout the report)

1. *Cal/EPA should take the lead in initiating steps to assure consistency and cooperation with US EPA and other federal counterparts.*
2. *An advisory committee consisting of scientists from outside State government should be established by Cal/EPA at the agency level with a charge of providing advice and oversight in the areas of risk assessment, risk assessment-risk management interactions, and risk communication.*
3. *An internal Cal/EPA working group should be established whose specific charge is to insure agency-wide consistency and harmonization.*
4. *The Agency should provide a forum for the identification, evaluation, and promotion of new or existing knowledge which can improve the scientific basis for risk assessment in California.*
5. *Cal/EPA should develop a formalized program for peer review.*
6. *Cal/EPA should encourage and, as needed, formalize participation by its staff in continuing education programs and national and international scientific organizations.*
7. *Cal/EPA should seek early input into the risk assessment process from risk managers and from external stakeholders. The Agency should identify effective and efficient mechanisms for participation by the general public and interested stakeholders and apply these throughout the Agency.*
8. *Cal/EPA should establish a process to bring together risk assessment and risk management personnel to better translate emerging methods in risk assessment into risk management policy.*
9. *The Cal/EPA Secretary should establish an internal mechanism through which he/she can receive expert advice on a broad range of issues in risk assessment.*
10. *An evaluation of the various scientific disciplines required for risk assessment should be conducted by Cal/EPA to ensure that adequate resources are available within the Agency.*
11. *The Committee recommends that Cal/EPA consider an approach in conducting chemical risk assessments that balances the level of effort and resources with the importance of the risk assessment.*

Consistency and Harmonization

There is general consistency in risk assessment practices and outcomes between the boards and departments of Cal/EPA and their counterparts in the US EPA. Where differences exist, they mostly arise from differences in the state and federal laws, or the fact that the State has some laws such as Proposition 65 which have no federal counterpart, or that US EPA has laws such as TSCA which have no state counterpart. Also, there are some differences in the details of risk assessment between the two organizations, which arise either from legitimate differences in interpretation of experimental results or variations in information available at the times when the two organizations made decisions. And there are cases where California differs significantly from the average for the US, such as in diet, weather, lifestyle, and population demographics, so that differing

risk characterizations may be legitimately derived for California versus the whole of the US. The Committee also found that some differences in risk assessments prepared by Cal/EPA and US EPA are difficult to explain. Cancer potency factors for a few chemicals and some exposure guidance limits are examples. It is important that such differences are justified, and this has not always been the case. There exist still other areas, such as in the generation of personal exposure information, where Cal/EPA lags behind its US EPA counterpart; this is a relatively new area in which sharing of information and techniques between the two organizations will very likely work to diminish differences in risk calculations.

The Committee notes with favor the beginning efforts made by Cal/EPA personnel in harmonizing their risk assessment activities with their federal counterparts. In 1995, for example, Cal/EPA's DPR and the US EPA Office of Pesticides Programs developed a "Memorandum of Understanding" for fostering harmonization of their risk assessment activities, to facilitate exchange of work product, and to use resources more efficiently. Cal/EPA personnel also participate frequently, and in many cases sponsor, workshops and other venues which result in federal/state information exchange and cooperation. A recent (February, 1996) example is the Diesel Exhaust Workshop in part sponsored by OEHHA and ARB but with heavy involvement by DOE and US EPA, as well as industry and academia. Although efforts such as this are laudable, they are uneven and ad hoc because there is no regular and clearly defined process to assure consistency, nor is there a standing process to resolve conflicts. Also, there appeared to be some cases of duplication of effort, where Cal/EPA conducted a risk assessment for a chemical for which US EPA had recently completed a risk assessment. Such redundancies waste resources and may place the regulated industry in a real or perceived "double jeopardy" situation.

With regard to consistency and harmonization between Cal/EPA and federal counterparts, the Committee makes the following broad recommendation:

> **Recommendation 1.** Cal/EPA should take the lead in initiating steps to assure consistency and cooperation with US EPA and other federal counterparts. Consistency in policies, guidelines, technical data, techniques, and work products should be the goal to the extent possible and consistent with applicable federal and state laws and policies. Sharing of workload and model development efforts are examples of such cooperation. Working together on prioritization of chemical waste sites requiring risk assessment is another. Setting up a regular forum for resolving differences is a third.

The Committee found that there is generally less consistency between the various boards and departments of Cal/EPA than exists between equivalent entities within Cal/EPA and US EPA. While much of this may have resulted from the divergent responsibilities and mandates under which the various boards and departments operate -- a result of the pathways and timing in which legislation has arisen in California and the relatively recent organization of Cal/EPA in California – some historical differences may have persisted due to a lack of mechanism for encouraging, promoting, and ensuring smooth and consistent working relationships. More generally, harmonization of risk

assessment activities should serve to focus efforts on integrating approaches assessing pollutant exposures from a single medium, such as the air, into a more unified and consistent approach which addresses exposures from multiple media (e.g., air, water, soil, food) resulting from a given pollutant release.

Recommendation 2. An advisory committee consisting of scientists from outside State government should be established by Cal/EPA at the agency level with the charge of providing advice and oversight in the areas of risk assessment, risk assessment-risk management interactions, and risk communication. This would promote consistency and harmonization in risk assessment policy, peer review, and incorporation of new science. The advisory group would address consistency between US EPA and Cal/EPA and within the Cal/EPA departments. The activities of this group should be coordinated with those of the existing scientific advisory groups within the Agency (e.g., ARB Scientific Review Panel, OEHHA Science Advisory Board hazard identification committees). This group should report to the Secretary of Cal/EPA.

Recommendation 3. 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 ensure agency-wide consistency. The working group's activities should be reviewed by the advisory committee noted in Recommendation 2 above.

A particular disconnect was noted between risk assessment at the statewide Cal/EPA level and risk management at the local and regional levels; this is discussed more fully in a subsequent section of this Summary where two recommendations are offered to improve this situation.

Best Use of Scientific Information

Risk assessment is an actively evolving discipline. There is, for example, much activity and interest in developing alternatives to current procedures used to estimate risks in humans from findings in experimental animals. Various types of data are being developed to provide the basis for alternative methods (e.g., pharmacokinetic data in humans and animals). As these data are developed, risk assessment methodologies and applications should correspondingly evolve. In the area of exposure assessment, for example, personal monitors and studies of human activity patterns hold the promise of more accurate exposure estimates for individuals and segments of the population. Also, techniques for evaluating uncertainty and variability in human risk (including examination of sensitive populations) are under development, and are of key societal and scientific interest. Clearly, keeping abreast of such developments and being a part of the process in which new approaches are conceived, applied, and validated are formidable challenges.

This Committee was impressed with many instances where Cal/EPA was reviewing or applying new scientific findings in a careful, timely, and effective manner (e.g., benchmark dose, CalTOX, workshops to obtain early input on assessments from interested

parties). In major part this compliments the quality and receptivity of Cal/EPA risk assessment staff. In some cases, such as development of the CalTOX multimedia model, Cal/EPA had taken the initiative to develop a new tool in order to carry out its risk assessment activities better than could be done with existing tools.

At the same time, however, it was not clear that either the identification of opportunities, or the commitment of resources to evaluate them, reflected other than the initiative of many of the staff. In a few cases, Cal/EPA's resource commitments to the collection and management of exposure data and information on sensitive populations are unbalanced or meager. A more systematic approach by the organization would be desirable.

The Committee recognizes the difference between the best practices and typical practices of the agency. As in all organizations, some analyses are better than average and more deserving of being considered state-of-the-art. Overall, the best practices of Cal/EPA are equal to, if not better, than those of US EPA. However, the Committee observed a few cases where Cal/EPA's routine practices do not appear to be using some of the leading-edge techniques, such as in the application of Monte Carlo uncertainty analysis, collection and use of receptor-based exposure data, and some areas of fate and transport modeling.

Considering the above, the Committee recommends the following:

Recommendation 4. The Agency should provide a forum for the identification, evaluation, and promotion of new or existing knowledge which can improve the scientific basis for risk assessment in California. This process should involve, in an ongoing way, important stakeholders, for example, experts from academia, the regulated community, government and public policy sectors. This forum should be structured to allow the identification and evaluation of suggestions and information that might improve risk assessment practices in California and the timely communication of such findings to the advisory committee suggested in Recommendation 2 and the internal coordinating committee suggested in Recommendation 3.

Recommendation 5. Given that one of the better ways to promote the use of "best" science in regulatory risk assessments is peer review, and that the nature and depth of the use of peer review appeared to the Committee to vary by Cal/EPA function and department, the Committee recommends that Cal/EPA develop a formalized program for external peer review. The extent of the review should be proportional to the importance of the work being reviewed. Policy/guidelines should receive much more review, whereas, decisions regarding a specific chemical would require somewhat less. For assessments with limited impact, a less extensive review process would be appropriate.

Recommendation 6. Cal/EPA should encourage and, as needed, formalize participation by its staff in continuing education programs and national and international scientific organizations. This will help to ensure that Cal/EPA

staff are conversant and prepared in the latest developments in risk assessment. This should include frequent interactions with the premier research groups in the universities, and with the industry and environmental consulting organizations.

The Interface Between Risk Assessment and Risk Management

While one can make a clear distinction between the roles of risk assessment and risk management in the regulatory process, in practice there is an interplay between the two which often extends to the regulated community and the general public. Effective communication between these various stakeholders is very important to the success and integrity of the enterprise and correspondingly difficult to achieve. The diverse functions and responsibilities of the boards and departments of the Agency present a broad array of communication challenges, both internally and externally. There is a need to improve these communication links and, in particular, to seek early input into the risk assessment process from risk managers and from external stakeholders.

Recommendation 7. Cal/EPA should seek early input into the risk assessment process from risk managers and from external stakeholders. The Agency should identify effective and efficient mechanisms for participation by the general public and interested stakeholders and apply these throughout the Agency. An important aid to this effort is the continued development of guidelines and procedures for risk assessment that can serve the communication function as well as the other important roles discussed elsewhere in this report.

A recurring theme in many of the Committee's meetings concerned the characterization of uncertainty in the risk assessment process and the impact of this uncertainty on risk managers and their decisions. On one level it appears that Cal/EPA personnel are aware of recent methodological advances in the characterization of uncertainty and the associated issue of variability in these processes that lead to distributions of risk across exposed populations. There are beginning efforts in the Agency to use these methods in practice. However, it is clear that many risk managers do not regard as useful, in reaching better management decisions, these more sophisticated descriptions of uncertainty and variability in risk estimates. Their preference is for clear and unambiguous decision rules, often referred to as bright lines, which expedite the decision-making process. However, testimony was offered to the Committee indicating that differences in risk estimates that lie within the range of scientific uncertainty can lead to differences in permitting decisions, for example, which have significant economic consequences. In such cases, management decisions based on the bright-line approach can lead to frustration and controversy.

Uncertainty and variability, described in both qualitative and quantitative terms, are important in characterizing the results of a risk assessment. Including such characterizations more accurately reflects the state of scientific knowledge which, in turn, should lead to more informed risk management decisions. It is a challenging task, however, to devise means of better integrating this type of information into risk

management decisions and to address how the implications of this information can be communicated to the public. However, the credibility of the entire process rests on the broadest possible understanding of what is known and what is not, and the policy options which are used to bridge that gap.

> **Recommendation 8.** The Agency should undertake a broadly based effort, including risk assessors and risk managers from both Cal/EPA and related health and environmental programs in California, to better translate emerging methods in risk assessment into risk management policy. For example, there is a need to assess the impact of the various types of uncertainty and variability on the final product of their various risk assessments, and to provide this information in a useful form to the risk manager. We anticipate improvements in this area will require an interactive process between assessors, managers, and representatives of the public to insure that this effort does not further complicate the process, but leads to an enhanced ability of all parties to comprehend the estimated level of health risk. The Committee recommends that Cal/EPA establish such a process, and in doing so bring together risk assessment and risk management personnel.

Organization and Management

As indicated by the legislative history shown in Chapter 1, the history of environmental regulation in California is long and complex. The administrative reorganization which resulted in the formation of Cal/EPA in 1991 brought into a single agency the diverse set of functions and responsibilities mandated by this body of legislation, together with the people and administrative procedures that it had engendered over the years. As discussed above under consistency and harmonization, both good and bad aspects of this legacy are apparent in the Agency's risk assessment practices and procedures. At this time in the Agency's history it is appropriate to consider further administrative initiatives to bring a greater degree of uniformity to both risk assessment and risk management activities across the boards and departments. A prelude to such efforts is to determine the degree to which such changes require legislation versus changes in administrative policy. This task is being carried out by the Unified Environmental Statute Commission whose report will be issued shortly. The need for their review was also identified in the deliberations of our Committee which, in addition, identified issues related to the prioritization of risk assessment activities, staffing, and resources allocation.

Much of the diversity in composition, staffing and operational procedures among the various boards and departments of the Agency are directly traceable to their legislative origins. While differences in function and responsibility often require different organizational arrangements, in the area of risk assessment there is a need to provide a greater degree of centralized management of the process. In addition to leading to greater uniformity and consistency across the Agency, a stronger central role in risk assessment should provide the Agency with information to adjust resources for protecting health or the environment according to risk-based criteria. The current staffing pattern within the

Agency may not be optimal for providing the central expertise needed to develop such criteria or to develop the various cross-cutting guidelines and procedures that are needed.

Recommendation 9. The Cal/EPA Secretary should establish an internal mechanism through which he/she can receive expert advice on a broad range of issues in risk assessment to address the myriad of environmental health risks facing Californians. The Cal/EPA Secretary can also benefit from advice on strategic matters in risk assessment. There are various means for achieving this end. For example, the Secretary could establish a small science advisors' office at the Agency level.

Recommendation 10. An evaluation of the various scientific disciplines required for risk assessment should be conducted by Cal/EPA to ensure that adequate resources are available within the agency. In particular, further resources are needed in risk assessment in the areas of contaminant fate and transport, several aspects of exposure assessment, and human health effects and epidemiology. Cal/EPA is encouraged to develop relationships with other state agencies, the private sector, universities and other research institutions to meet its needs for specialized expertise not currently available within the Agency. It is further recommended that consideration be given to establishing a core function within Cal/EPA to provide technical expertise on risk assessment to regional regulatory agencies beyond the current "Memorandum of Understanding" process.

Recommendation 11. The Committee recommends that Cal/EPA consider an approach in conducting chemical risk assessments that balances the level of effort and resources with the importance of the risk assessment. In this approach, risk assessors start with a simple, screening level analysis and move to a more resource-intensive analysis when it is warranted. Though many findings and recommendations of this report focus on technical details of understanding the importance of variability in the human population and uncertainty in our knowledge about toxicology and environmental transport of pollutants, it is important to realize that we should not "overanalyze" a problem and the depth of a risk assessment should be tailored towards the needs of the decision it is intended to support.

III. Specific Findings and Recommendations

The Committee has made a number of findings as well as detailed recommendations to improve the Agency's approach to chemical risk assessment in the areas of cross-cutting issues, hazard identification, dose-response evaluation, exposure assessment, and risk characterization. Some of the major findings and recommendations are summarized and briefly discussed in this section; for more in-depth discussion, please refer to Chapters 2 through 7 of the report. For convenient reference, the major specific recommendations are summarized in the table below.

SUMMARY TABLE 2. HIGHLIGHTS OF SPECIFIC RECOMMENDATIONS

(Additional recommendations are provided throughout the report)

Hazard Identification

- *Cal/EPA should develop and explicitly state provisions for re-evaluating past decisions on individual agents as well as processes used.*
- *Cal/EPA should standardize, to the extent possible, the collection and submission of pertinent information, and the content and construction of the hazard identification document.*

Dose-Response Assessment

- *Cal/EPA should explore alternative ways, other than using large uncertainty factors, to bridge gaps in toxicity data.*
- *Cal/EPA should develop guidelines on the appropriate use of uncertainty factors, and provide guidance on how severity of effect should be taken into account in setting these factors.*

Exposure Assessment

- *Cal/EPA should take steps to integrate fate and transport modeling efforts with human exposure assessment.*
- *Cal/EPA should put more emphasis on receptor-based exposure assessment when it is appropriate and cost-effective.*

Risk Characterization

- *Cal/EPA should improve the characterization of uncertainty and variability in its risk assessments and in the communication of this information to risk managers and the public.*
- *The extent and depth of Cal/EPA risk analyses should be responsive to the needs of the decision-maker and to the decisions they are intended to support.*

Data Management Issues

- *Cal/EPA should review present data collection/data management efforts and initiate measures to minimize overlap and to improve accessibility and quality of data.*

Cross-Cutting Issues

The Committee observed that Cal/EPA manages over a dozen databases, many of which do or could contain data needed for risk assessment. But the regulatory reasons for setting them up may not be appropriate to today's needs. In some cases, expenditures may be made for monitoring and other data which are looked at perhaps only once, if at all. Yet elsewhere in the Committee reviews, the need for data (e.g., indoor air levels of toxic air contaminants, multimedia exposure) for risk assessment has gone unfilled. The Committee recommends that Cal/EPA review the legislation and regulations which initiated the collection of specific data and review the present data collection/data management effort for overlap. Cal/EPA should institute measures to improve accessibility of present data, and measures for quality control of data presently in the databases, and those being added to the databases.

Resources in federal, state, and private sectors for risk assessment activities are unlikely to grow, and may in fact decrease. Some added expense may be incurred from an increase in peer review and quality control; yet, the workload is not likely to decrease. The Committee recommends that Cal/EPA 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. Among steps which should be considered for implementing this recommendation are:

1. Initiation of a "Lead Agency" concept and/or "Chemical Manager" concept.
2. Computerization, or "Risk Assessment On-line" programs.
3. Incentives to Cal/EPA staff for developing simplified and/or streamlined approaches.
4. Outsourcing of some risk assessment activities, but under Cal/EPA management and review.

Hazard Identification

In general, the Committee found no major inconsistencies between Cal/EPA and US EPA in the areas of hazard identification. However, some differences were found among Cal/EPA programs. They are in part due to the different nature of the mandates, and in part due to differences in data sources, the level of peer review and reporting. The Committee found that Cal/EPA hazard identification practices are generally scientifically sound. Nonetheless, the Committee recommends that Cal/EPA institute process improvements, especially in peer review, to ensure that the identification of chemical hazards in California uses sound and transparent practices.

In the past decade, tremendous advances have been made in our understanding of toxicological processes at a cellular and molecular level. Also, additional animal and human studies on specific chemicals are being conducted and the results published. As our knowledge about toxicology improves, there will be a need to revisit some of the past decisions. The Committee recommends that Cal/EPA develop and explicitly state

provisions for re-evaluating past decisions on individual agents, as well as processes to be used. Further, Cal/EPA should develop written criteria for each process of hazard identification including explicit criteria for moving away from default assumptions.

The Committee observed that the format for the submission of information as input to hazard identification varies from program to program. Cal/EPA should standardize the collection and submission of pertinent information in regard to hazard identification. Cal/EPA should also institute standardized content and construction, to the extent feasible, of the hazard identification document. In addition to a narrative discussion regarding uncertainties in the hazard identification, the Committee found the hazard identification document should include a categorical statement that can be used by a risk manager.

Dose-Response Assessment

Similar approaches are used by Cal/EPA and US EPA programs in evaluating the dose-response relationship of carcinogens and non-carcinogens. Interestingly, Cal/EPA and US EPA pesticide programs are more similar to each other than they are with other programs within their respective agencies. For example, a "margin of safety" approach is used by DPR of Cal/EPA and Office of Pesticide Programs and Toxics of US EPA in the evaluation of non-carcinogens. Other programs of the two agencies use the reference dose or reference concentration approach for the same type of evaluation.

The Committee observed that relatively large uncertainty/adjustment factors were used in the development of dose-response relationships of several non-carcinogenic chemicals. Using large uncertainty factors when data are poor is common practice; the Committee strongly encourages Cal/EPA to explore alternate ways to address this issue. Furthermore, the Committee recommends that Cal/EPA develop guidelines on the appropriate use of uncertainty/adjustment factors. Among other things, the new guidelines should address the role of severity of effect in setting uncertainty/adjustment factors.

The Committee observed that Cal/EPA has evaluated the feasibility of applying a number of new techniques in dose-response evaluation, namely, the benchmark dose approach, use of pharmacokinetic models, and use of probabilistic methods. The Committee supports these efforts and recommends that Cal/EPA continue its research in these areas.

Exposure Assessment

The general procedures used by Cal/EPA and US EPA in exposure assessment are similar, although in some cases, different input parameter values are recommended by the two agencies. Both Cal/EPA and US EPA do not regularly use a stochastic modeling approach in exposure assessment. However, Cal/EPA is slightly ahead of US EPA in terms of applying quantitative uncertainty analysis in risk assessment. For example, Cal/EPA has developed a computer model that is designed to facilitate this type of analysis for hazardous waste sites. The Committee looks at efforts such as this one favorably and recommends quantitative uncertainty analysis be applied to other areas where appropriate.

Due to the mandates of some Cal/EPA programs, modeling of fate and transport of pollutants is often used to support engineering design or risk management decisions. As such, these efforts are not always well integrated with human exposure assessment. To obtain better estimates on human exposure, the Committee recommends Cal/EPA take substantial steps to integrate fate and transport modeling efforts with other aspects of exposure assessment. With many world-class fate and transport modeling experts residing in California, the Committee believes Cal/EPA should make use of this asset and take a leadership role in setting and maintaining high standards in fate and transport modeling.

Both Cal/EPA and US EPA have investigated the use of receptor-based approaches in exposure assessment (for example to assess the importance of indoor versus outdoor exposures), but neither has widely applied this approach in their regulatory practices. The Committee recommends Cal/EPA put more emphasis on receptor-based exposure assessment when it is appropriate and cost-effective. Generally the study of human behavior is a critical, often overlooked, element in exposure assessment. Likewise, the Committee found that Cal/EPA risk assessment programs can benefit from inputs from behavioral scientists.

The Committee noted that Cal/EPA sometimes does not make a clear distinction between exposure assessments intended for the highest exposed individual and those for the average individual. 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. This can be especially important in risk-benefit analyses and risk-risk comparisons; for these situations, Cal/EPA should strive to use statistically unbiased exposure assessments.

Risk Characterization

The procedures and practices of Cal/EPA in risk characterization are quite comparable to those of US EPA, with some differences generally attributable to differences in the laws implemented by the two agencies. Both agencies' risk characterization practices fall somewhat short of what the profession now considers generally feasible; however, the Committee believes that Cal/EPA is moving forward to improve its practices. The Committee recommends that Cal/EPA improve the characterization of uncertainty and variability in its risk assessments and the communication of this information to risk managers and the public.

There should be considerably more communication between the risk assessor and risk manager. Risk assessors should better understand the needs of the risk managers in terms of expressions of uncertainty and variability – what the risk managers need and why they need it, and how it can be provided. Further, the extent and depth of the analysis should be responsive to the information needs of the decision-maker. In some cases a problem can be "overanalyzed", with an unnecessary expenditure of scarce resources. The depth of the risk assessment should be tailored towards the needs of the decision it is intended to support.

To improve the current structure of its risk characterizations, Cal/EPA should develop guidelines by building on the US EPA March 1995 "Policy for Risk Characterization" and the combined approach of DPR for analysis and characterization. In doing so, the Agency may want to be aware that some consider the current US EPA Policy insufficiently broad and too "reductionist."

IV. Conclusion

The findings and recommendations summarized above, and presented in full in the individual chapters of this report are meant to improve risk assessments required of California State government. The Committee expresses strong endorsement of risk assessment as the primary tool for characterizing, quantifying and prioritizing risk associated with chemical hazards in the State, reaffirming a process which has been an integral part of Cal/EPA and OEHHA since they were organized years ago, and started with their predecessor organizations. In that regard, California has been, and continues to be, on the correct path in safeguarding the health of the population with respect to environmental chemical hazards. The Committee strongly recommends a series of improvements above to further improve the State's capability in this area and notes that there ought to be an implementation plan with milestones.

References

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1

Introduction

This report is the product of an external peer review of the policies, methods and practices that the California Environmental Protection Agency (Cal/EPA) uses to conduct chemical risk assessment. The review was conducted by the Risk Assessment Advisory Committee (Committee). The purpose of the review was two-fold: (1) to determine if Cal/EPA risk assessment practices were based on sound science, and (2) to assess the appropriateness of any differences in these practices with those of the US Environmental Protection Agency (US EPA), the National Academy of Sciences (NAS) and other similar bodies. The Committee also examined the internal consistency among Cal/EPA boards, offices and departments.

Committee Charge

Regulatory reform of environmental programs is being advanced on national, state and local levels. An often-stated goal of reform efforts is to ensure adequate protection of the environment and public health while at the same time not placing an unnecessary burden on business. Achievement of that goal requires that decision-making is based on a sound scientific understanding of risk. In this climate, the California State Legislature passed into law Senate Bill 1082. One component of that legislation mandated a peer review of the risk assessment practices of Cal/EPA. The language of that legislation describing the review is as follows:

> **Chapter 418, Statutes of 1993 (Senate Bill 1082, Calderon), Health and Safety Code Section 57004**
>
> (a) On or before June 30, 1994, the Director of Environmental Health Hazard Assessment shall convene an advisory Committee consisting of distinguished scientists not employed by the boards, departments, and offices within the agency, to conduct a comprehensive review of the policies, methods, and guidelines followed by the boards, departments, and offices for the identification and assessment of chemical toxicity.
>
> (b) The purpose of this comprehensive review shall be to make recommendations to the Director of Environmental Health Hazard Assessment and the secretary concerning whether or not any changes should be made to ensure that the state's policies, methods, and guidelines for the identification and assessment of chemical toxicity are based upon sound scientific knowledge, methods and practices. This review shall include, but shall not be limited to, an assessment of the appropriateness of any differences between the policies, methods, and procedures employed by the state and those employed by the National Academy of Sciences, the Environmental Protection Agency and other similar bodies.

Introduction to Risk Assessment

The assessment of risks to human health involves the scientific examination and evaluation of information in three areas: (1) the hazardous nature of agents in the environment; (2) the degree of human exposure to such agents; and (3) the impact of such exposure on people's health. The product of a risk assessment is information about the likelihood of health degradation following an exposure to hazardous agents.

A formal, systematic risk assessment is similar to the informal risk assessments performed daily by individuals. A possible hazard is perceived. The observer estimates his/her vulnerability to the hazard and weighs the probability of occurrence and the extent of negative outcome. As a result of this informal process, taking action is the primary step in risk management; the appropriateness of the action is a direct function of the validity of the risk assessment, and always depends on the input information and the model(s) of the consequences.

The formal, systematic risk assessment is usually performed and interpreted in a statistical or probabilistic manner because the input information (data) embodies the results of measurements and modeling, both of which involve some degree of uncertainty and variability. Also the subjects and beneficiaries of the risk assessment are human beings, as individuals, subpopulations (e.g., infants, children, workers), and large populations (e.g., neighborhoods, cities), all manifesting variation in how they respond to chemical exposure.

Over the past several years regulatory agencies in the United States have developed a systematic scientific and administrative framework for risk assessment. Risk assessments can be conducted at multiple levels ranging from a quick assessment (i.e., screening) for regulatory priority setting, to a comprehensive, research-supported, computer-implemented assessment. The depth of the assessment is driven by resource constraints (time, money, stakeholder support, political considerations), by the confidence in data and models (experience with chemicals and the physical environment), and by the magnitude of possible consequences (size of target population, or nature of possible health effects).

The risk assessment process is iterative. It begins with a preliminary assessment to identify critical factors in order to focus available resources efficiently. The preliminary assessment is usually conservative (i.e., erring on the side of health protection). If risks are perceived to be acceptable the assessment process will stop at that point. The functional elements of risk assessment are well-defined and widely accepted by the Federal Government and other organizations such as the NAS. These are exposure assessment, toxicity assessment and risk characterization.

Exposure assessment is an examination of human exposure to a toxic chemical. As quantitatively considered in a risk assessment context, it can be described as the result of a series of factors including age, life style, occupation and activity patterns.

Toxicity assessment serves to examine available information on the applicable chemical's potential for causing adverse health effects in the exposed population, and to facilitate an understanding of the relationship between exposure levels and the likelihood and severity of those health effects. Possible health effects are generally divided for regulatory purposes, into two classes: cancer-related and noncancer-related.

Risk characterization is the integration and conclusion-formation step in risk assessment. The data which characterize the hazard of interest are combined with results of the assessments of exposure and toxicity to provide a quantitative estimate of the probability of specified health consequences arising in the exposed population as a result of the exposure.

Risk communication is a vital step which should be added to the risk assessment process. It involves communicating the results of the risk assessment to the population concerned, referred to as stakeholders. This group includes not only those whose health may be immediately threatened, but also those involved with environmental regulations and those dealing with possible health effects from medical and social perspectives.

Risk management is a key element in determining sound environmental policy. Risk management is the process of evaluating alternative regulatory actions and selecting from the proposed options. During this step, the risk manager applies the findings from risk assessment to real world situations. Risk management is carried out by the regulator or other officials who make decisions among the different administrative options.

Environmental Regulation in California

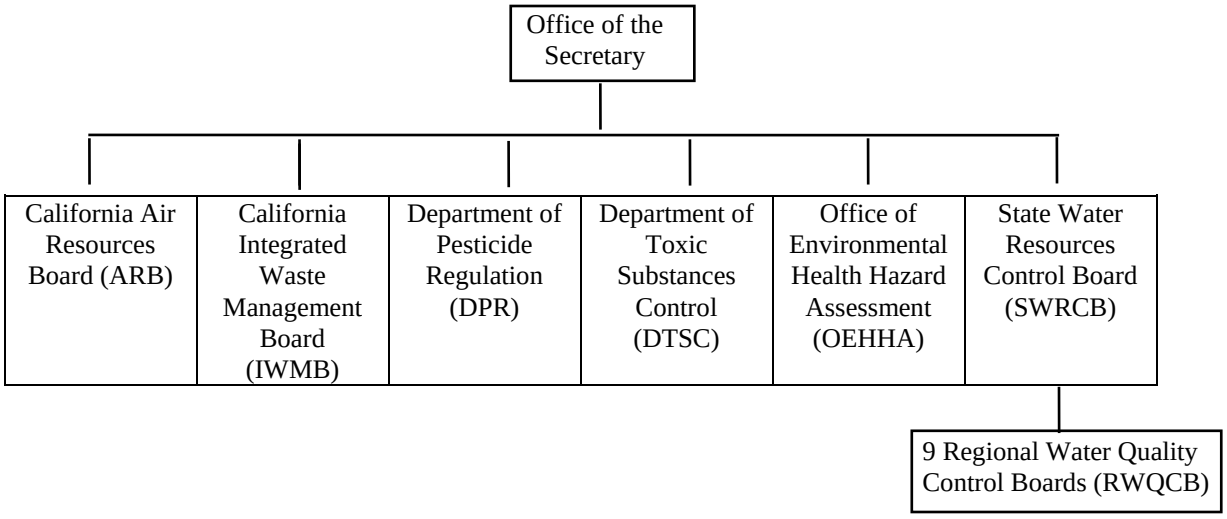
Environmental law in the US and in California has developed over many decades and continues to change. A timeline of environmental legislation at the state and federal levels is shown in Figure 1. Cal/EPA was created in 1991 as part of a reorganization of State government by Governor Pete Wilson. This action unified the State's environmental activities and provided a cabinet-level agency, accountable to the Governor. The reorganization created three new departments, the Department of Pesticide Regulation (DPR), formerly part of the California Department of Food and Agriculture; the Department of Toxic Substances Control (DTSC) and the Office of Environmental Health Hazard Assessment (OEHHA), both formerly part of the California Department of Health Services. These three departments were joined with existing regulatory Boards: the California Air Resources Board (ARB), the California Integrated Waste Management Board (IWMB), the State Water Resources Control Board (SWRCB), and the nine Regional Water Quality Control Boards (RWQCB).

Figure 1. State and Federal Environmental Laws

California Environmental Legislation	Year	Major Federal Environmental Legislation
Hazardous Substance Act	1961	
Mulford-Carrell Air Resources Act of 1967	1967	
Porter-Cologne Water Quality Control Act	1969	Clean Air Act
California Environmental Quality Act (CEQA)	1970	National Environmental Policy Act
		Federal Water Pollution Control Act (Clean Water Act)
Hazardous Waste Control Law	1972	Marine Protection, Research and Sanctuaries Act of 1972
	1973	Endangered Species Act
	1974	Safe Drinking Water Act
Occupational Carcinogens Control Act		Toxic Substances Control Act of 1976
California Safe Drinking Water Act	1976	Resources Conservation and Recovery Act of 1976 (RCRA)
Coastal Act of 1976		
State Coastal Conservancy	1977	Clean Air Act, amendments
		Clean Water Act, amendments
Hazardous Waste Haulers Act	1979	
Hazardous Substance Information and Training Act	1980	Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA)
Carpenter-Prestley-Tanner Hazardous Substance Account Act	1981	
Informant Reward Program	1982	
Toxic Air Contaminant Identification and Control Act		
Underground Storage of Hazardous Substances Law	1983	
SB 950 - Birth Defects Prevention Act		
Toxic Pits Cleanup Act		
Hazardous Waste Enforcement Coordinator and Strikeforce	1984	Hazardous and Solid Waste Amendments of 1984 (RCRA amendments)
Hazardous Substance Cleanup Arbitration Panel		
Hazardous Materials Release Response Plans and Inventory		
Toxic Injection Well Control Act	1985	
Hazardous Waste Reduction , Recycling, and Treatment Research and Demonstration Act		
Pesticide Contamination Prevention Act		
Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65; voter initiative)	1986	Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazardous Waste Management Plans		Emergency Planning and Community Right-to-Know Act
Air Toxics “Hot Spots” Information and Assessment Act	1987	Water Quality Act (Amendments to Clean Water Act)
California Clean Air Act		
Atmospheric Acidity Protection Act	1988	FIFRA amendments
AB 2161 - Food Safety Act of 1989		
California Integrated Waste Management Act	1989	
Amendments, California Safe Drinking Water Act		
Bay Protection and Toxic Clean-Up Act	1990	Clean Air Act amendments
Governor’s Reorganization Plan One (creation of the California Environmental Protection Agency)	1991	
SB 48 - Rail Accidents		
SB 1731 - Risk Reduction Audits and Plans	1992	
AB 2061 - Site Designation Committee	1993	
SB 1082 - Environmental Protection, Regulations, Unified Hazardous Waste Program		
SB 923 - Expedited Remedial Action Plan		
AB 2136 - Solid Waste Disposal and Codisposal Site Cleanup	1994	
SB 1299 - Facility Compliance Plans	1995	

Each of the six boards and departments of Cal/EPA (Figure 2) has multiple activities and mandates under which it functions. In most cases, Cal/EPA boards and departments directly oversee or play a cooperative role with other State, regional or local regulatory agencies in the implementation of many California environmental laws. These mandates dictate the primary activities of Cal/EPA boards and departments. The activities that have a risk assessment component are detailed in a set of 21 "Program Summary Sheets" in Appendix A of the report. These summary sheets were produced by Cal/EPA staff as background material for the Committee review. Each regulatory activity was categorized by media (e.g., air, water, waste sites, consumer products) and by chemical type (e.g., hazardous substances, pesticides), although clear overlaps exist. The Committee was charged with reviewing the risk assessment policies, methods and guidance related to these activities.

Figure 2. Cal/EPA Organizational Chart



Committee Structure

As stipulated in the language of the bill, the Director of OEHHA was responsible for convening the advisory Committee. The primary considerations in structuring the Committee were: (1) a manageable time frame for the review period, (2) the multi-disciplinary nature of risk assessment and the wide range of expertise that would be required to review the relevant scientific issues, and (3) the inefficiencies associated with a large committee. A unique structure for the Committee was adopted in order to address the comprehensive nature of the review. The Committee consisted of a core group of five members, who attended all meetings and served to guide the review process and provide continuity from meeting to meeting. The Committee Chairman or Vice Chairman served to chair each individual meeting and workshop. Additionally, four to seven experts were appointed as topic-specific Committee members who provided depth of knowledge on a specific topic. To each set of expert members was appointed an expert lead who often facilitated the discussion at the individual meetings. An open

invitation was given to all Committee members to participate in all meetings. Thus, each topic-specific meeting (e.g., hazard identification, dose-response assessment) was attended by at least nine Committee members. At these meetings, findings and recommendations were drafted by expert members with core and other Committee members providing insight and commentary.

Due to the multi-disciplinary nature of risk assessment, Committee members were drawn from many different disciplines, including toxicology, epidemiology, public health, biostatistics, and environmental sciences. Also, in order to elicit a range of expert opinions on a particular scientific issue, the Committee membership included distinguished scientists from academia, industry, and national scientific research institutions. A list of the Committee members and their affiliations is provided at the beginning of the report.

Scope of Review

From the Committee's inception and throughout the review process, the Committee, rather than Cal/EPA staff, decided the scope and course of the review. A planning meeting of the Committee was convened in June 1995 to lay out a series of meetings and topics which provided a forum for a comprehensive review of Cal/EPA's risk assessment practices. During the course of the June and subsequent meetings (Table 1), the Committee decided to cover the following topics:

- Uncertainty, Variability and Risk Characterization
- Hazard Identification
- Dose-Response Assessment
- Exposure Assessment (including human intake and monitoring, and contaminant fate and transport)
- Cross-Cutting Issues.

Although ecological risk assessment is part of the risk assessment activities of Cal/EPA, the focus of the Committee's review was intentionally limited to risk assessment issues related to human health. The primary reason was due to an ongoing and parallel effort in which OEHHA and other state staff and interested parties are developing, through a series of public workshops, interagency meetings, and other activities, new ecological risk assessment guidelines. This new guidance will go through an independent peer review process. The Committee notes, however, that the findings and recommendations made in this report could be applied to ecological risk assessment practices of Cal/EPA, where appropriate.

Table 1. Risk Assessment Advisory Committee Meetings and Workshops

	Topic	Date	Location
Meeting 1.	Orientation and Planning	June 15-16, 1995	Sacramento
Meeting 2.	Variability, Uncertainty and Risk Characterization	August 10-11, 1995	San Francisco
Workshop 1.	Case Studies	September 11-12, 1995	Davis
Meeting 3.	Hazard Identification	October 18-19, 1995	Los Angeles
Meeting 4.	Dose Response Assessment	November 15-16, 1995	Berkeley
Meeting 5.	Exposure Assessment I: Human Intake Parameters, Inter-media Transfers, and Exposure Monitoring	December 14-15, 1995	Berkeley
Meeting 6.	Cross-cutting Issues	January 24-25, 1996	Sacramento
Meeting 7.	Exposure Assessment II: Contaminant Fate and Transport	February 7-8, 1996	Palo Alto
Meeting 8.	Synthesis	April 10-11, 1996	Sacramento
Meeting 9.	Committee Working Session	May 10, 1996	Davis

The Committee focused its review on the present practices of Cal/EPA boards and departments involved in risk assessment. Although information of a comparative nature was obtained from US EPA, the US Department of Energy, NAS, and from other components of California state government and regional entities, the following caveats must be stated:

- Information on the NAS and the US EPA risk assessment policies and practices was obtained from representatives of the organizations that attended the meetings, policy documents, examples of risk assessments, and the knowledge of the Committee members. No in-depth study of these organizations was attempted.

- The approach of this study emphasized review of the functional components of the risk assessment process and not a detailed department-by-department organizational review.

- While several public comments pertained to inconsistencies between regional water boards, time did not permit an evaluation of risk assessment issues at the regional level.

Issues Addressed by the Committee and Conduct of Meetings

The Committee felt it needed a mechanism to help identify important issues in risk assessment in order to facilitate the planning of the agendas for future meetings so that it could spend its limited time on the most critical topics. To accomplish this, the Committee convened a workshop in September 1995, near the beginning of the review process, which investigated risk assessment case studies, either conducted by Cal/EPA or conducted by responsible parties and submitted to a regulatory agency for evaluation. A brief description of this workshop is found in Appendix F of the report.

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

Meeting agendas were set by the expert Committee members for the specific topic to which they would apply their expertise. Each expert member requested that certain topics be added to the agenda, based on issues raised at the case-studies workshop, on issues identified by the public or state staff, and on his or her knowledge of the topic. Background materials (i.e., briefing books prepared by OEHHA) containing Cal/EPA and US EPA risk assessment guidance related to the topic of the meeting, examples of Cal/EPA and US EPA risk assessments, and other relevant material were given to the Committee members prior to the meetings (Appendix G). Also included in these materials were documents developed by Cal/EPA in response to Committee requests.

The Committee meetings were organized to resemble a “site visit”, where the Committee met with Cal/EPA risk assessors to learn how risk assessments are actually performed by the different departments in order to make recommendations for improving these practices. In general, during the first day of each meeting, the Committee members heard presentations on the risk assessment activities of the US EPA and the NAS, and each of the boards and departments within Cal/EPA. The Committee discussed with the presenters and the audience how these risk assessment activities could be improved through the use of current scientific information or through consistency of application across departments of Cal/EPA. The Committee also assessed the appropriateness of differences between the risk assessment practices of Cal/EPA and those of US EPA, NAS and other similar bodies. Committee members reconvened on the second day to deliberate on their draft findings and make recommendations to improve the scientific basis and consistency of risk assessment at Cal/EPA.

The Committee acknowledged its charge to compare Cal/EPA risk assessment practices to those of NAS, but noted that NAS does not routinely practice nor has it adopted procedures for risk assessment. Because the NAS provides information on state-

of-the-art risk assessment practice, the Committee decided to use the NAS reports as an indication of the state-of-the-art, and in that matter respond to the SB 1082 mandate. A report frequently referred to by the Committee for this purpose was *Science and Judgment in Risk Assessment* (NRC, 1994).

The Committee's activities, as with all state governmental deliberative processes, were required to follow governmental fair practices including the Bagley-Keane open meeting law. All Committee meetings were conducted in public with the required public notification prior to each meeting; indeed, the public's input and participation in the meeting discussions were valued and encouraged. A court reporter was used to prepare transcripts of each meeting and workshop.

The general process that the Committee followed in drafting its report is as follows. The primary authors for each topic-specific chapter (e.g., hazard identification) were the designated expert members for the meeting covering that topic. For each group of expert members, one expert was designated the lead and was given the task of overseeing changes made to the draft chapter. At each meeting, the Committee spent the last portion of the meeting generating draft findings and recommendations which were compiled at the meeting and modified and expanded on by the expert members subsequent to the meeting. This draft text was compiled as a preliminary draft chapter by the expert lead and distributed to the expert members for comment. After subsequent revision by the experts, the draft chapter was sent for review to one core Committee member, designated as the core liaison for that chapter. All these draft chapters and other relevant documents were combined into a draft report and reviewed by the Committee at the April 1996 "Synthesis" meeting. The executive summary and introduction were drafted by the core members and discussed at the Committee meeting on May 10, 1996. A revised draft report was released, May 24, 1996, to the public for comment. Written comments from the public on the review draft were considered by the Committee in their final revisions to the report.

This Committee report is organized around the topics identified by the Committee for review. The cross-cutting issues chapter serves as a review of critical issues that are germane to all components of risk assessment process. The report concludes with a set of appendices, most of which were developed in response to specific Committee requests.

References

National Research Council (1994). *Science and Judgment in Risk Assessment.* National Academy Press, Washington, DC.

2

Cross-Cutting Issues

Introduction

This chapter discusses the findings and recommendations of the Risk Assessment Advisory Committee (Committee) related to issues that traverse many aspects of the risk assessment practices, policies, and guidelines of the California Environmental Protection Agency (Cal/EPA). These issues surfaced frequently during the topic-specific Committee meetings and were considered so critical that a separate meeting was scheduled to discuss them. The agenda for that meeting is provided in Appendix F.

The Core Committee members authored this chapter; they are: Drs. James Seiber (University of Nevada, Reno and University of California at Davis, emeritus) (lead), Herschel Griffin (California State University San Diego, emeritus), Judith MacGregor (consultant and California State University San Diego, adjunct), John Moore (Institute for Evaluating Health Risks), and Robert Spear (University of California at Berkeley).

The cross-cutting issues are organized around five topics:

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A. Incorporation of New Science into Risk Assessment

Findings

The risk assessment process, by its very nature, is a series of judgments that usually reflect the consideration of three types of information:

- a broad range of scientific knowledge dealing with physiological function and disease processes;
- specific data about the agent (chemical) of interest or closely related agents;
- default assumptions that represent policy directives as to procedures to be followed in the absence of broad scientific knowledge or in the absence of agent-specific data.

Risk assessments should strive to represent the best application of scientific knowledge. However, scientific knowledge on a particular subject is often incomplete leading to differing degrees of confidence as to the certainty of a particular judgment. It is believed that the public should be informed as to the rational basis for judgments on risk and once informed, be prepared to act on such information in an appropriate manner. While tolerant of risk judgments based on imperfect knowledge the public also has a right to expect that important decisions be periodically revisited to ensure that those judgments and default assumptions are consistent with newer scientific knowledge. The impetus to remain current needs to be reconciled with the need for any regulatory program to reflect an orderly and stable process.

The Committee observed several instances where Cal/EPA was reviewing or applying new scientific findings in a careful, timely and effective manner. It was the Committee's sense that the openness, receptivity and timeliness of these efforts were equal to, or perhaps superior to, those currently occurring in federal agencies. At the same time, it is not clear that either the identification of opportunities, or the commitment of resources to evaluate their utility, reflected other than *ad hoc* efforts, i.e., initiatives appear to reflect the perceptions and interests of one or several employees rather than an organizational structure that seeks out such opportunities.

The Committee structured its activities around science and its influence on elements of the risk assessment process. While it did not perform a statute-by-statute analysis, the role of risk assessment in a variety of statutes inevitably was a regular part of the Committee deliberations. Proposition 65, viewed by the Committee as unique to California, was discussed during its deliberations on hazard, risk characterization and cross-cutting issues. It appears that the hazard listing process by the State's experts has evolved into an effective structure. The hazard lists have been effectively integrated into

a variety of health related activities of the Office of Environmental Health Hazard Assessment (OEHHA) and Cal/EPA. The Committee believes it is appropriate to highlight an aspect of the Proposition that does lead to results that are at variance with practices at the federal level, and that differ from regular approaches within Cal/EPA regarding essentially all other forms of non cancer toxicity. The language of the Proposition has a net practical effect of requiring that the no-observed-adverse-effect level (NOAEL) for a reproductive toxicant be divided by a factor of 1,000. There is no scientific basis to support the rote application of such a factor to all risk assessments associated with this form of toxic effect and is contrary to a strong Committee belief that risk assessment process must foster the consideration of new scientific knowledge. Further, this requirement commonly will provide a greater margin of safety to reproductive toxicity than is accorded other forms of non-cancer toxicity. A preferred scientific approach would provide consistency in the assessment of all toxic effects and permit discretion in the selection of an appropriate numerical factor based on the nature and quality of the scientific data.

The Committee heard and read about concerns regarding the application of the "authoritative body" designation, a process defined in the Proposition's language. While the Committee did not explore this issue in detail, it believes the use of authoritative bodies can be an efficient means for utilizing scientific activities from national and international sources. In the belief that quality and consistency are essential values in accepting data or judgments from all sources, we believe there is merit to Cal/EPA convening a process that provides a thoughtful review of its practices and procedures in this area. Topics to be considered should include:

- The need for establishing general criteria for conferring the "authoritative body" designation;
- Ascertaining the nature and use of peer review as a factor in consideration of conferring the authoritative body designation;
- Conferring "authoritative body" designation for a fixed period of time so as to stimulate proactive consideration of continuing such a designation;
- Greater definition of specific activities within large organizations that are considered "authoritative", such as the US Environmental Protection Agency (US EPA), the US Food and Drug Administration (FDA) and the National Toxicology Program.

Finally, the Committee received correspondence alleging erratic quality and consistency of exposure estimates that are applied in a variety of Proposition 65 compliance proceedings. It was posited that publication of exposure assessment guidance with some explicit reference to their use in Proposition 65 matters would be an aid to realizing more appropriate risk assessments. Noting that this issue was raised to the Committee very late in its deliberations, we suggest that the review process recommended in the proceeding paragraph could be expanded to address this issue.

Recommendations on Incorporation of New Science

a1. 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 judgments as to human health risks. Attributes include a structure that:

- Is viewed as unbiased, responsive, and open so that an incentive is created for the development and submission of proposals and data that would enhance risk evaluative processes.

- Is composed of members from the academic, regulated, municipal management, and public policy sectors that will review submissions and recommend those deemed worthy of more detailed study. Solicitation of nominations from within government and the broad public community should also be within the aegis of this group. Selection should be influenced by several factors: 1) general impression that there is a scientific basis for the proposal, 2) breadth of interest, and 3) a belief that such a change would impact regulatory programs in a material way.

- Possesses an administrative structure with broad responsibilities within Cal/EPA for oversight and stewardship for selected initiatives. Their stewardship should utilize administrative processes that are open, interactive and participatory in nature. Duties could include initial review and analysis of the specific scientific data underpinning the proposed activity. From such a review should evolve an objective analysis of probability of success, a clear path forward including key milestones and the mechanism whereby the acceptance and utility of the proposed change is evaluated. Peer review, performed by scientists from outside the agency who have expertise in relevant scientific disciplines or in risk assessment, should serve as an ongoing, critical resource to the program.

- Contains processes that identify or quantify human health hazard which are interactive and iterative. Such processes can be contrasted with traditional mechanisms which may be under the exclusive purview of the regulatory community. The public has indicated a keen interest in having access to and expressing views on such matters. A process whereby there is interaction between the policy maker, the risk manager, risk assessors and the interested public in identifying risk was clearly defined by a recent National Academy of Sciences, National Research Council (NAS/NRC)

report[1]. While this report focused on issues surrounding nuclear waste sites, it is viewed by the Committee as equally relevant to most risk evaluation processes.

- Is responsible for, or interdigitate with, programs that foster the implementation and compliance by Cal/EPA employees. This continuing education role should be interactive and commence as soon as it is determined that a proposed change is likely to be accepted. The true value of a change in practice only commences when it is understood and accepted by those who use such procedures in their work. A component of the program should also incorporate processes whereby the affected community, outside of Cal/EPA, also receives timely and informative information.

[1] National Resource Council (1994). *Building Consensus Through Risk Assessment and Risk Management*. National Academy Press, Washington, DC.

B. Consistency and Harmonization

There is general consistency in risk assessment practices and outcomes between the boards and departments of Cal/EPA and their counterparts in the US EPA. Where differences exist, they mostly arise from differences in the State and Federal laws, or the fact that the State has some laws such as Proposition 65 which have no Federal counterpart, or that US EPA has laws such as the Toxic Substances Control Act (TSCA) which have no State counterpart. Also, there are some differences in the details of risk assessment between the two organizations, which arise either from legitimate differences in interpretation of experimental results or variations in information available at the times when the two organizations made decisions. There are cases where California differs significantly from the average for the US, such as in diet, weather, lifestyle, population demographics, so that differing risk characterizations may be legitimately derived for California versus for the whole of the US.

Finding:

There is a greater degree of consistency in risk assessment practices and outcomes between the boards and departments of Cal/EPA and their federal counterparts than there is within Cal/EPA itself. This has arisen largely as a reasonable response to the divergent responsibilities and mandates under which they operate.

However, it is important to recognize that there is an inherent conflict in the regulatory process between a desire for standardization and formalization of the agency's risk assessment guidelines, policies and practices and the desire for these to reflect the latest scientific thinking and methodology. The Committee notes the need for flexibility in moving toward greater internal and external consistency and harmonization.

Recommendation:

b1. 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.

b2. 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.

Finding:

Significant economic and operational impacts can arise from different risk management options, even when each is based on risk estimates which lie within the bounds of scientific uncertainty. While this is inherent in the regulation of environmental risks, it is the source of significant frustration and dispute between Cal/EPA and the regulated community.

Recommendation:

b3. 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.

Finding:

The legislative mandates under which Cal/EPA operates are many and they have accumulated over a period of almost 30 years. Much of the diversity in composition, staffing, and operational procedures among the various boards and departments is directly traceable to these legislative origins. It is not clear that the current level of diversity in organization and operations is optimal. For example, there is some evidence that cases exist in which the rationale and justification for continuing to respond to legislative requirements to collect specific types of data may no longer be compelling.

Recommendation:

b4. In the interests of consistency and harmonization of risk assessment practices and procedures and with a view towards conserving increasingly scarce resources, the body of law under which Cal/EPA programs are mandated and funded should be reviewed. This review should focus not on each piece of legislation individually, but on the entire body of law in order to determine what changes may be required to produce an integrated and coherent basis for the future in protecting the health of Californians and of the California environment.

C. Resources and Organization

Introduction

The purpose of this session was the same as for the previous three, namely, to surface issues which do not fit clearly under just one of the components of risk assessment, but still impact on the state's ability to conduct risk assessments in the best possible way. Several areas were raised to stimulate discussion:

- Is risk assessment in California overly complicated and cumbersome? If so, how can the process be streamlined and simplified?

- Do the personnel and resources within Cal/EPA fit the tasks at hand now, and those envisioned for 5-10 years in the future? If not, a reassessment may be warranted.

- Should Cal/EPA be cast more in the role of a manager of risk assessment activities in the state, and less of a performer of risk assessments? If so, how can a process of risk assessment be envisioned which ensures timeliness and high quality, and who should do the assessments?

- Is monitoring and other data important to risk assessment collected and maintained in the forms suitable for use in risk assessment? If not, improvements in the system may need to be identified and initiated.

- Are the risk managers and stakeholders adequately accounted for in the resource and organization of Cal/EPA? If not, what changes could be initiated to see that this happens?

The session began with brief presentations by each of five invited panelists:

Dr. Richard Becker, OEHHA. Dr. Becker addressed the issue of distribution of personnel and expertise within OEHHA and the other boards/departments of Cal/EPA, and the coordination between the sections of Cal/EPA (primarily OEHHA and the Department of Pesticide Regulation (DPR)) which conduct risk assessments. Dr. Becker's presentation was accompanied by handouts documenting staffing with the various boards/departments of Cal/EPA, including a summary of numbers of people involved in risk assessment (Table 1).

Dr. Steve Hanna, Cal/EPA. Dr. Hanna addressed databases maintained by Cal/EPA, and how they are used for assessing trends and as a source of specific information. Dr. Hanna's presentation was accompanied by handout materials, including a listing of the databases (see Table 2). Data needs are driven by statutes, and Dr. Hanna

illustrated this by using the Toxic Release Inventory and the AB 2588 requirements as examples.

Dr. Carol Henry, US Department of Energy (DOE). Dr. Henry addressed streamlining, pointing out several steps that DOE is contemplating, or doing, under the general philosophy of "thinking and acting smarter", with fewer resources. The lead regulator concept, and ways to minimize the generation of duplicative documents, are examples. There is a challenge ahead for the states: As the federal effort decreases, there may be more for the states to do.

Mr. Dick Kruetzen, Kahl Associates. Mr. Kruetzen presented some of the reasons underlying the formulation of SB 1082, noting that it was intended to improve several aspects of state toxics regulation, including functioning of the Scientific Review Panel of Air Resources Board (ARB), increase public input, and establish the Risk Assessment Advisory Committee review process. Some underlying concerns were due process, extra-governmental review, inertia on the part of state service, and duplication with federal efforts. Specific concerns were with the carcinogen guidelines, California Air Pollution Control Officers Association (CAPCOA) potency values, and perchloroethylene assessment, specifically the response time of the latter.

Mr. Ron Oshima, DPR. Mr. Oshima addressed the role of DPR in risk assessment-related activities, which is conducted in the two areas of worker health and safety and pesticide registration, and steps which DPR is taking to harmonize its activities with those of US EPA. In the risk assessment area, DPR performs the assessments with OEHHA providing a review. This system appears to be working smoothly. DPR is using the Internet to communicate more, standardizing the Oracle platform with US EPA and providing a home page of DPR databases and information on access.

The ensuing question-answer period surfaced many facts, opinions and suggestions, which were crystallized in the following set of findings and recommendations:

Findings and Recommendations on Resources and Organization

<u>Personnel and Resources</u>

Finding:

Cal/EPA and its constituents may not have the optimum mix of scientific and other expertise to address its (1) present workload and (2) 5-10 year projected workload. For example, epidemiology is not well represented in Cal/EPA, nor is expertise in community relations. On the other hand, toxicology is a dominant expertise with primary experience in interpreting toxicology studies conducted under controlled exposure conditions.

Table 1. Cal/EPA Human Resources for Risk Assessment

Board or Department	Number of Positions in Department	Number of Technical People Engaged in Risk Assessment Activity*
ARB	~950	Not estimated*
CIWMB	447	0
DPR	~400	60
DTSC	1175	21
OEHHA	145	~80
SWRCB	175	0
RWQCB-Central Valley Region	141	Not estimated*

* Information provided by Cal/EPA Boards and Departments. Detailed information on ARB and RWQCB, Central Valley Region, was provided at the Committee's January meeting.

Recommendation:

c1. 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.

Databases

Finding:

Cal/EPA manages over a dozen databases (Table 2), many of which do or could contain data needed for risk assessment. But the regulatory reasons for setting them up may not be appropriate to today's needs. In some cases, expenditures may be made for monitoring and other data which is looked at perhaps only once, if at all. And yet elsewhere in the Committee reviews, the need for data (e.g., indoor air levels of toxic air contaminants, multimedia exposure) for risk assessment has gone unfilled.

Recommendations:

c2. Review the legislation and regulations which initiated the collection of specific data.

c3. Review the present data collection/data management effort for overlap.

c4. Improve accessibility of present data.

c5. 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.

Table 2. Monitoring or Exposure Databases that Cal/EPA Generates, Manages or Contributes to†

CALSITE (contaminated sites) (DTSC)
Emissions Data System (ARB)
Facility Inventory Database (DTSC)
HAZNET (hazardous waste) database (DTSC)
Marketplace Surveillance Program (fresh produce residue database) (DPR)
Priority Pesticide Program (fresh produce residue database) (DPR)
Pesticide Use Report Database (not specifically exposure or monitoring) (DPR)
Pesticide Related Illnesses (DPR)
RCRA Permits and Enforcement (DTSC)
Solid Waste Ranking System (IWMB)
Tiered Permitting (non-RCRA) (DTSC)
Toxic Air Contaminant Ambient Monitoring Network Database (ARB)
Toxic Release Inventory (DTSC)
US Department of Agriculture Pesticide Data Program (DPR)
Waste Discharge System (SWRCB)
Well Monitoring/Inventory Database (DPR)

† *This is not a complete list, but does include the major quantitative databases.*

Access of Risk Managers and Stakeholders to Cal/EPA Risk Assessment Process

Findings:

A feeling of disenfranchisement was a part of the reason for setting up the SB 1082 risk assessment review process. For risk managers, a sense of separation may result, in part, from a misreading of the *Risk Assessment in the Federal Government: Managing the Process* (the "Red Book") (NAS/NRC, 1983), and in part from the nature of the far flung operations in California. The stakeholder involvement has improved during the past 3 years, but further improvement may be warranted.

Recommendation:

c6. 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.

Streamlining and Simplifying Risk Assessment

Findings:

Resources in federal, state, and private sectors for risk assessment activities are unlikely to grow, and may in fact decrease. Some added expense may be incurred from increase of peer review and quality control. Yet the workload is not likely to decrease.

Recommendations:

c7. 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.

c8. Cal/EPA needs to establish measures of success for gauging the effectiveness of efforts to streamline and simplify.

Among steps which should be considered for implementing these two recommendations are:

(a) Initiation of a Lead Agency concept and/or Chemical Manager concept.
(b) Computerization, or "Risk Assessment On-line" programs.
(c) Tiered approaches, with relatively straightforward screening models in the first tier to handle those assessments which appear to pose no risk under all envisioned conditions.
(d) Incentives to Cal/EPA and other personnel for developing simplified and/or streamlined approaches.
(e) Privatization of some/most risk assessment activities (but under Cal/EPA management and review).

Focus and Prioritization

Findings:

Much state effort in risk assessment is spent on duplicating or redoing assessments which have already been done by US EPA and other agencies. Also, much effort of Cal/EPA is spent on assessments which afford little potential for impacting human health or environmental quality.

Recommendations:

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

c10. Cal/EPA should clearly articulate a set of principles for justifying independent assessments for chemicals/locations which other agencies have assessed previously.

Strategic Planning

Recommendation:

c11. Cal/EPA should initiate, with outside involvement, a strategic planning for resource organization, and process of risk assessment. This strategic plan should consider all of the recommendations (above) in this section, as well as many of those contained in other sections of this report.

D. Guidelines

D.1 Introductory Remarks

It is appropriate that the issue of "Guidelines" be included in this "comprehensive review" mandated by SB 1082 (Calderon 1993, HSC Section 57004).

1. The OEHHA mission statement declares: "The Office is responsible for developing scientific guidelines for hazard identification and risk assessments".

2. Further, SB 1082 states that the purpose of this "comprehensive review" shall be, *inter alia*:

   (a) to conduct a comprehensive review of the guidelines followed for the identification and assessment of chemical toxicity.

   (b) to make recommendations to ensure that the state's guidelines are based upon sound scientific knowledge, methods and practices.

Appropriate, yes, but a monumental task. Section D.6 consists of a representative list of major guidelines documents currently used by Cal/EPA or under development. In addition, there are literally hundreds of other publications which provide guidance or direction regarding Cal/EPA's regulatory actions.

One outstanding characteristic of these guideline documents which becomes immediately apparent in a comprehensive review is that most are highly program-specific. They were created to comply with specific legislation or implementing regulations. The concepts and methodologies covered are those germane to the specific program, e.g., carcinogen identification, air pollution, discharge of wastes.

This portion of the report is concerned with "Cross-cutting Issues." There are, indeed, certain concepts, policies and practices which apply - at least in part - to all guidelines documents. These direct the content of this part of the review.

Fortunately, this subject has been extensively studied in related contexts. Thus, it is not necessary nor desirable to approach it *de novo*. It will be more productive, first, to review the findings and recommendations in these earlier studies.

In particular, these include the NAS/National Research Council studies prepared relative to risk assessment activities of the US EPA and the DOE.

Four have been selected for review:

1. National Research Council (1983). *Risk Assessment in the Federal Government: Managing the Process.* National Academy Press, Washington, DC.

2. National Research Council (1994). *Science and Judgment in Risk Assessment*. National Academy Press, Washington, DC.

3. National Research Council (1994). *Building Consensus Through Risk Assessment and Risk Management*. National Academy Press, Washington, DC.

4. National Research Council (1995). *Improving the Environment. An Evaluation of the DOE's Environmental Management Program*. National Academy Press, Washington, DC.

D.2 Definitions

The terms "guidelines", "inference guidelines", "default options" are subject to multiple interpretations and definition. Citations from the references above will clarify the issue for the purposes of this review, although it is recognized that some agencies use the terms somewhat differently.

Risk Assessment in the Federal Government.

"An inference guideline is an explicit statement of a predetermined choice among the options that arise in inferring human risk from data that are not fully adequate or not drawn directly from human experience." p.51.

"Inference guidelines are the principles followed by risk assessors in interpreting and reaching judgments based on scientific data." p.51.

"A guideline usually prefers one option, although some guidelines permit the selection of more than one or all of the options. The preferred inference option may be viewed as a default option, i.e., the options chosen on the basis of risk assessment policy that appears to be the best choice in the absence of data to the contrary." p.63.

Science and Judgment in Risk Assessment

"EPA's risk-assessment practices rest heavily on "inference guidelines", or, as they are often called, "default options." These options are generic approaches, based on general scientific knowledge and policy judgment, that are applied to various elements of the risk-assessment process when the correct scientific model is unknown or uncertain." p.85.

"Default options are not rules that bind the agency; rather, as the alternative form *inference guidelines* implies, the agency may depart from them in evaluating the risks posed by a specific substance when it believes this to be appropriate." p.85.

Thus, guidelines are considered to be a set of codified principles addressed to a particular subject. In any case, it would be prudent for any guidelines document to specify its purpose and scope.

D.3 Utility of Guidelines

The *Risk Assessment in the Federal Government* document contains a section entitled "ARGUMENTS FOR AND AGAINST THE USE OF GUIDELINES". It presents the advantages and disadvantages of guideline use. For our purposes, however, these attributes may be considered qualities which distinguish desirable and useful guidelines from those which are lacking in the cited advantages or are characterized by what are classed as disadvantages.

Separation of Risk Assessment from Risk Management

This argument contends that, when selected inference options are clearly delineated in a formal document, risk assessments will not likely be influenced to fit prior conclusions about regulation of a particular substance. Compared with reliance on the *ad hoc* selection of inference options, the use of guidelines could reduce the controversy focused on individual assessments.

However, elsewhere in the document is found the cogent statement "The importance of distinguishing between risk assessment and risk management does not imply that they should be isolated from each other; in practice they interact, and communication in both directions is desirable and should not be disrupted." p.6.

Quality Control

Proponents of guidelines argue that their use would ensure the application of selected inference options based on the informed judgment of experts. Thus, guidelines would help ensure that assessors apply judgments that are in accord with current

scientific thinking in each field. Furthermore, to be effective in this regard, guidelines should be reviewed periodically so that new scientific developments can be accommodated. p.69.

Consistency

Almost all guideline documents have stated, in their introductions, that consistency is a major rationale for guideline use. Consistency in risk assessment is important to the agencies, because it helps to ensure fairness and rationality by precluding the arbitrary application of selected inference options that differ from one time to the next. Consistency also permits comparison of risks associated with different chemicals, and this is useful for priority-setting and for facilitating regulatory decision-making.

Predictability

The regulated community should be told explicitly which inference options the government will select to evaluate health-effects data. Without uniformly applied guidelines, a regulated party may have to call on the agencies for judgments and have no assurance that the judgments will not change unexpectedly.

Evolutionary Improvement of the Risk Assessment Process

The use of guidelines provides a focus for debate, examination, and revision of the selected inference options generally used in risk assessment. By contrast, when chemicals are evaluated on an *ad hoc* basis, the focus of debate is shifted from generic issues to case-specific issues.

Public Understanding

Proponents of guidelines argue that comprehensive, detailed guidelines setting forth the scientific and policy bases of risk assessment could improve public understanding and help to dispel the impression that government actions are based on tenuous and inadequate reasoning.

Administrative Efficiency

When risk assessments are performed without the use of guidelines, too many agency resources are devoted to reargument of the same issues with regulated parties. Guidelines could reduce repetitious discussion by specifying which types of interpretations are acceptable, given the current state of scientific understanding.

There are some parts of risk assessment, however, particularly those dealing with the quality of data and the magnitude of uncertainty, that defy or at least resist generic interpretation. Individual judgment is most important in such cases. A guideline should

not be viewed as a formula for producing risk assessments without the need for such judgment.

D.4 Discussion of Specific Issues

The discussion was focused on four major issues:

1. The viewpoints of the regulated community.
2. Harmonization of guidelines development with other agencies.
3. Difficulty with revision of complex guideline documents, and
4. The utility of planned involvement of the regulated community and others with environmental interests in guideline development.

Dr. Mark Saperstein of ARCO addressed the first issue. He pointed out that the regulated community generally treated guidelines as formal rules, because of the cost and difficulty of generating sufficient data to depart from default values, even when they may not be considered the most scientifically appropriate. (This might occur when the agency routinely adopts the most conservative default option as a matter of policy.) Another issue is the use of guidelines to mandate practices or standards which exceed the underlying statute. Finally, he deplores the portrayal of what should be a risk-management decision as a guideline based on "the best scientific evidence."

Dr. Jay Schreider of DPR, Cal/EPA described how DPR and the Office of Pesticide Programs of US EPA have developed a Memorandum of Understanding for joint development of procedures to foster harmonization, to facilitate exchange of work product, and to use resources more efficiently. This process will be watched with great interest, especially as to how it contributes to development of guidelines for both agencies.

Dr. Lauren Zeise of OEHHA, Cal/EPA recounted the decade-long effort to revise the "Guidelines for Chemical Carcinogen Risk Assessments and Their Scientific Rationale." Problems included controversy about specific issues, the parallel development of similar guideline documents by the International Agency for Research on Cancer and US EPA, competition for resources with other high priority programs, among others. She did note, however, where common knowledge and acceptance of new scientific principles could be identified, they were incorporated in agency publications where appropriate.

Alexander J. Santos of ARB, Cal/EPA recounted in detail how the document "Risk Management Guidelines for New and Modified Sources of Toxic Air Pollutants" was developed. Two features were of special note. First was the early and iterative involvement of large numbers of interested parties. Second was the clear explanation throughout why chosen policies and defaults were selected, as well as the degree of

uncertainty and variability inherent in the risk-assessment process. He reported these factors as being largely responsible for the document's being considered successful by those affected.

D.5 Recommendations on Guidelines

Recommendations selected from *Risk Assessment in the Federal Government*

d1. Uniform inference guidelines should be developed for use by regulatory agencies in the risk assessment process.

d2. The inference guidelines should be comprehensive, detailed, and flexible. They should make explicit the distinctions between the science and policy aspects of risk assessment.

d3. The guidelines should be reviewed periodically with the advice and recommendations of the expert board. The process for revising the guidelines, like the process for adoption, should afford an opportunity for comment by all interested individuals and organizations.

d4. The guidelines should have the status of established agency procedures, rather than binding regulations.

Recommendations selected from *Science and Judgment in Risk Assessment*

d5. Use default options as a reasonable way to cope with uncertainty about the choice of appropriate models or theory.

d6. Clearly identify each use of a default option.

d7. Clearly state the scientific and policy basis for each default option.

d8. Clearly state the criteria for departure from default options.

d9. Explicitly identify each generic default option in the risk-assessment process.

Recommendations based on the January 24-25, 1996 meeting.

Finding:

The selected recommendations from the *Risk Assessment in the Federal Government* and the *Science and Judgment in Risk Assessment* documents are valid for the SB 1082 Risk Assessment Advisory Committee comprehensive review.

Recommendation:

d1-9. Include the cited recommendations in the Risk Assessment Advisory Committee report.

Finding:

The development of guidelines is an efficient process to bring new scientific advances and developments into use for regulation. However, such new scientific advances and developments are not always incorporated in the guidelines expeditiously, i.e., when they have reached the status of "generally accepted principles" because the entire document revision cannot receive timely and universal concurrence.

Recommendation:

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

Finding:

The severity of predicted response is important to some kinds of decisions. Granted, it is not significant when the question is whether the chemical is "known to the State to cause cancer", as in the listing process of Proposition 65. In this case it is "list" or "not list". In contrast, at waste sites both stakeholders and regulators want to know the magnitude of an identified adverse health effect, e.g., where it is on the scale from "trivial/reversible" to "life-threatening/irreversible". That knowledge makes a difference when the issue is acceptance of clean-up proposals.

Recommendation:

d11. The agency should consider initiating a policy-development process that will result in an accepted policy for dealing with severity in risk assessment guidelines.

D.6 List of Guidelines

The following is a list, compiled by Cal/EPA staff, of guidelines: (i) developed by Cal/EPA, (ii) developed outside and used by Cal/EPA, (iii) currently being developed by Cal/EPA, and (iv) that Cal/EPA would like to develop.

i. Guidelines Developed by Cal/EPA

Hazard Identification and Dose Response

- Guidelines for Chemical Carcinogen Risk Assessments and Their Scientific Rationale. (CDHS, 1985) -- (Revision plan: Guidelines for Carcinogen Identification and Risk Assessment: Revision Overview (OEHHA, 1992); Draft revision documents: Interspecies Scaling -- Setting Guidelines (OEHHA, 1993); Outline of Recommendations of Interspecies Scaling for Cancer Risk Assessment (OEHHA, 1992); Guidelines Chapter: Use of Pharmacokinetics in Risk Assessment (OEHHA, 1994))
- Draft Guidelines for Hazard Identification and Dose-response Assessment of Agents Causing Developmental and/or Reproductive Toxicity. (OEHHA, 1991)
- (Related white paper: Safety Assessment for Non-Cancer Endpoints: The Benchmark Dose and Other Possible Approaches. (OEHHA, 1994))
- A Joint Review of Existing Federal and State Pesticide Registration and Food Safety Programs. (DPR, 1994)
- Cal/EPA Methods for Deriving Acute Inhalation Health-based Exposure Levels. (OEHHA, 1995)

Exposure Assessment - Hazardous Waste and Leaky Tanks

- Supplemental Guidance for Human Health Multimedia Risk Assessments of Hazardous Waste Sites and Permitted Facilities. (DTSC, 1992)
- Preliminary Endangerment Assessment Guidance Manual. (DTSC, 1994)
- CalTOX, A Multimedia Total Exposure Model for Hazardous Waste Sites. (DTSC, 1993)
- Leaking Underground Fuel Tank Task Force. Leaking Underground Fuel Tank Manual (LUFTs). (State of California, 1989) (for petroleum related sites)
- Los Angeles Region. Interim Guidance for Remediation of Petroleum Impacted Sites, Soil Screening Levels. (RWQCB, 1994)

Exposure Assessment - Incinerators

- Format for Health Risk Assessments for Hazardous Waste Incinerators. (OEHHA, 1994)

Exposure Assessment - Pesticides

- A Joint Review of Existing Federal and State Pesticide Registration and Food Safety Programs, A Report to the California Legislature by the Pesticide Exposure to Children Committee. (DPR, 1994)
- Guidelines for Dietary Risk Assessment. (DPR Internal working document, revised 11/20/95)
- Thongsinthusak et al. Guidance for the Preparation of Human Pesticide Exposure Assessment Documents, HS-1612. (May 4, 1993, DPR)

Exposure Assessment - Solid Waste Sites

- Solid Waste Ranking System User's Guide. (IWMB, 1995)

Exposure Assessment - Water Pollutants and Fish Contamination

- The designated level methodology for waste classification and cleanup level determination. (RWQCB-Central Valley Region, 1989) (covers hazardous and solid waste sites, site cleanups and pesticides)
- Draft Functional Equivalent Document. Amendment of the Water Quality Control Plan for Ocean Waters of California. (SWRCB, 1995)
- Regional Water Board Basin Plans
- Thermal Plan

- Lake Tahoe Basin Plan

Other
- Risk Management Guidelines. (ARB, 1993)

ii. Guidance Developed Externally and Used by Cal/EPA

- Air Toxics Hot Spots Program. Revised 1992 Risk Assessment Guidelines. (California Air Pollution Control Officers Association, 1993)
- Guidelines for Risk Characterization in Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part A), Interim Final. (US EPA, 1989)
- Risk Assessment Guidance for Superfund, Human Health Risk Assessment (Interim Final). (US EPA Region IX, 1989)
- Dermal Exposure Assessment: Principles and Applications. (US EPA, 1992)
- Preliminary Remediation Goals (PRGs). (US EPA Region IX, 1995)
- Guidelines for Exposure Assessment. Federal Register Volume 57. (US EPA, 1992)
- Estimating Exposure to Dioxin-Like Compounds, Volume III: Site-Specific Assessment Procedures. Review Draft. Chapters 2 and 4. (US EPA, 1994)
- Human Exposure Assessment for Airborne Pollutants: Advances and Opportunities, Committee on Advance in Assessing Human Exposure to Airborne Pollutants. (NRC, 1991)
- Science and Judgment in Risk Assessment. (NRC, 1994)
- Guidelines for Developing Community Emergency Exposure Levels for Hazardous Substances. (NRC, 1993)
- American Society for Testing and Materials (ASTM). Emergency Standard Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites, ASTM Designation : ES 38-94. (under consideration for adoption by SWQCB/RWQCB for petroleum site assessment and cleanup)

Hazardous Waste Incinerators
- Attachment: Implementation Guidance for Conducting Indirect Exposure Analysis at RCRA Combustion Units, Draft (US EPA, 1994). Refers to Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions (US EPA, 1990) and the 1993 Draft Addendum to the same report.
- Methodology for Assessing Health Risk Associated with Indirect Exposure to Combustor Emissions. (US EPA, 1990)
- Guidance for Assessing Health Risks of Emissions from Hazardous Waste Incineration Facilities, Attachment 9. (US EPA Region IX, 1993)
- Exposure Factors Handbook, Review Draft. (US EPA, 1995)
- Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual, Supplemental Guidance, Standard Default Exposure Factors, Interim Final. (US EPA, 1991)

Fish Consumption
- Technical Support Document for Water Quality-Based Toxics Control. (US EPA, 1991)
- Guidance for Assessing Chemical Contamination Data for Use in Fish Advisories
  - Volume I. Fish Sampling and Analysis. (US EPA, 1993)
  - Volume II. Risk Assessment and Fish Consumption Limits. (US EPA, 1994)
  - Volume III. Risk Management. (US EPA, 1995, Draft)
  - Volume IV. Risk Communication. (US EPA, 1994)
- Final Water Quality Guidance for the Great Lake System. (US EPA, 1995)

Pesticides

- Office of Pesticide Programs, Pesticide Assessment Guidelines, Subdivision F, [Hazard to] Humans and Domestic Animals. (US EPA, 1984)
- Office of Pesticide Programs, Pesticide Assessment Guidelines, Subdivision M, Microbial Pest Control Agents and Biochemical Pest Control Agents. (US EPA 1989)
  (The above two are guidelines for toxicology and exposure studies required by the US EPA. They encompass standards for conducting acceptable tests, evaluation and reporting of data, when data are required, definitions of terms, and examples of protocols. A number of addenda exist.)
- Guidelines for Developmental Toxicity Risk Assessment. Federal Register Volume 56. (US EPA 1991.)
- Guidelines for Reproductive Toxicity Risk Assessment. Review Draft. (US EPA, 1994)
- Guidelines for Carcinogen Risk Assessment. Federal Register Volume 51. (US EPA, 1986)

Exposure Assessment of Water Pollutants

- National Ambient Water Quality Criteria documents for the Priority Pollutants under the Clean Water Act (various dates). Some of these documents are published reports (e.g., *Quality Criteria for Water, 1986*), while others appear in federal regulations (e.g., the National Toxics Rule).
- For exposure assessment related to water pollutants, the RWQCB uses many other criteria documents including the California and Federal drinking water standards, State Action Levels from CDHS, Proposition 65 regulatory limits from OEHHA, Health Advisories from US EPA and National Academy of Sciences, and IRIS cancer potency factors and reference doses from US EPA. The water boards also use fish consumption limits developed by the National Academy of Sciences and the US Food and Drug Administration.

iii. Guidelines Currently Being Developed by Cal/EPA

DPR

- There are plans to complete the internal risk assessment guideline which is currently a draft working document. Generally, DPR does not develop guidelines other than for internal use but does participate in work groups that develop Cal/EPA guidelines. DPR primarily uses guidelines developed and used by US EPA Office of Pesticide Programs (OPP). There is currently a Memorandum of Understanding between DPR and OPP, the goals of which are to harmonize scientific methods and develop consistency in the interpretation and application of the existing guidelines. In addition, DPR actively comments on US EPA guidelines and those of Organization for Economic Cooperation and Development.

OEHHA

- AB 1731, Air Toxics Hot Spots Risk Assessment Guidance
- Guidance on assessing arsenic, methyl mercury, dioxins, and PCBs in fish tissues, identification of appropriate fish consumption rates, and approaches to protection of public health from consumption of chemically contaminated fish and shellfish
- Ecotoxicity Guidelines

SWRCB/RWQCB

- Water Quality Threats from Contaminants in Soil Gas
- Enclosed Bays and Estuaries Plan
- Inland Surface Waters Plan

iv. Guidelines that Cal/EPA Would Like to Develop

OEHHA

- Supplemental Guidance to the US EPA's Exposure Factors Handbook - would contain California-specific data

E. Peer Review and Public Input

E.1 Overview

Review of regulatory activities is an important function that lends credibility to risk assessment while providing a mechanism for external input into the process. There are several different types of internal and external review, and the depth of a review can vary in complexity and purpose. The types of review as delineated in and adapted to Cal/EPA from *Science and Judgment in Risk Assessment* [2] are as follows:

A. ***Internal Review***. Review within the Cal/EPA. May consist of a co-worker, management, or another Cal/EPA Board or Department. This is not considered peer review.

B. ***External Review by Individuals***. This review is conducted by someone outside Cal/EPA and it may be informal in nature or conducted by paid technical consultants who are providing written reports. Typically, this is often not independent and therefore, would not constitute peer review.

C. ***External Review by Panels***. Panels of technical experts that do not work within Cal/EPA that may be convened for a focused purpose to review a specific issue, topic, or chemical. Usually open for public input and/or comment.

D. ***Public Review***. The public and stakeholders are invited to give written and/or oral comments. Public review is not the same as external technical review as the appropriate experts may or may not participate. This is not a form of peer review.

E. ***Formal External Review***. This involves a formal Advisory Board consisting of members who come from outside Cal/EPA and who meet at regular intervals to review issues that have significant impact.

Peer review implies review by technical experts who have independence from the agency. In general, safeguards need to be in place to insure that any peer review is, in fact, independent and that mechanisms exist to appropriately consider the comments generated from the review. Frequently, reviews of type (B) that are undertaken by individuals are not handled in such a manner as to insure their independence. Reviews undertaken by groups such as panels or formal advisory boards (E) usually, but not always, have the independence to qualify as peer review.

To assist with obtaining the existing Cal/EPA review processes, each Board and Department was asked to complete a form delineating their major functions and the

[2] National Resource Council (1994). *Science and Judgment in Risk Assessment*. National Academy Press, Washington, DC, p. 297.

existing mechanisms for internal review (within Cal/EPA) and external peer review (outside Cal/EPA). The form used together with the responses obtained from each part of Cal/EPA are provided in the last part of this section (E.4). A list of all the current formal advisory boards is also included. All of the Boards and Departments responded with the requested information. This information was then compared to the current review practices within the NAS and the US EPA.

Information about the a) application of the review process b) composition of the reviewers c) reviewer selection process d) independence of the review and e) opportunity for public comment was obtained for both the NAS and US EPA, and is included as Table 3. This information provided a framework to compare the Cal/EPA current situation with that of NAS and US EPA and also to compare the practices within and among the current Cal/EPA Boards and Departments.

Table 3. Comparison of NAS and US EPA peer review programs

CHARACTERISTIC	NAS	US EPA
Application	Uses a tiered approach on all of its work products. Typically budgeted separately in project costs.	All regions now must have an external peer review program in place. SOPs required.
Composition	Individuals are fully qualified and selected from a list used from the committee members.	From 3 to full Science Advisory Panel.
Reviewer Selection	Seeks many nominations from professionals in the field.	
Independence	Reviews kept without revealing name of reviewer. A separate Report Review Committee gets comments. Seeks resolution. Monitors process.	Process required to be independent. Independence defined in SOP.
Opportunity for Public Comment	Not typical. Uses members of the professional community as reviewers.	Varies. Depends on function.

There was a great deal of discussion both from the panel members and the public attending the meeting. Excellent agreement was reached among those making comments and offering opinions. The following findings and recommendations were developed within the meeting and had widespread support.

E.2 Findings

NAS conducts peer review on all of their reports using a tiered approach that varies the intensity of the review with the importance of the function. They have a formalized program and the budget for NAS's projects includes an estimate of the cost for peer review. In the most extensive cases, as much as 25% of the cost of a project may be spent on external peer review.

US EPA has recently developed, but not fully implemented, a formal requirement for Peer Review and adopted formalized Standard Operating Procedures (SOP) at the program and regional level. A copy of the SOPs for Region IX was made available and is referenced. National Institutes of Health and National Science Foundation are examples of governmental organizations that value and utilize peer review processes more extensively than US EPA.

Internal review processes were, in general, utilized within Cal/EPA. The nature and depth of the internal review varied by the function, both within and among the various Boards and Departments. In some cases, a formalized process exists and that process includes having risk assessments reviewed by technical reviewers in other parts of Cal/EPA. For example, DPR sends evaluations to OEHHA for review. In other cases, formalized processes were not in place.

Cal/EPA's **external** peer review processes vary among the Boards and Departments with several formal scientific review boards in place while for other functions or for some Departments no external reviews are conducted.

The purpose of the external peer review is to ensure that all of the facts and data are available and to give credibility, quality and confidence to the final product. It should be recognized as an important function and the peer review component of the Risk Assessment process should be budgeted for properly.

All functions within Cal/EPA do not require the same degree of review. The extent of the review should be proportional to the importance of the work being reviewed. Policy/guidelines should receive much more review, whereas, decisions regarding a specific chemical would require somewhat less. For other functions that have even less of an impact (i.e., a small site assessment) review processes may be less extensive.

Public/stakeholder involvement is an important part of the review process. It is a separate activity and should not substitute for, or be substituted by external peer review.

E.3 Recommendations on Peer Review and Public Input

e1. 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.

The review process should consist of the following: A) Internal review (inside Cal/EPA). This may consist of review by co-workers, management or other Cal/EPA Boards and Departments; and B) External-peer review (outside Cal/EPA).

Cal/EPA should develop guidelines for peer review and Standard Operating Procedures for how the process will be used and how the input will be utilized. These SOPs should include a method for how conflicting comments will be handled, when a response to comments will be made, how revisions will be reviewed, and how Cal/EPA will determine when the process is finished. It is important that the peer review process have the qualities delineated below.

Qualities for the PEER REVIEW program:

a. *Managed by an independent body with sufficient seniority within the Cal/EPA organization to maintain the integrity and independence of the process.*
b. *Cost effective.*
c. *Tiered, in that some functions may require much more extensive review (policy, guidelines) than other functions.*
d. *Flexible, in that it is designed to cover the range of activities encountered in the risk assessment activities within Cal/EPA.*
e. *Budgeted as a separate component of the Risk Assessment process.*
f. *Open, in that all of the comments and recommendations are made available to interested parties.*
g. *Credible, in that the most qualified individuals serve as reviewers and any potential conflict of interest of any of the reviewers is revealed.*
h. *Timely, to insure their use.*

e2. The public and interested stakeholders should be involved early in the risk assessment process and maintain involvement at key decision points throughout the process.

Public input is not the same as external peer review and should not be a substitute for peer review. Peer review should not be a substitute for public input. Public involvement early and throughout the process is important for maintaining an open

process, encouraging communication, and insuring that important concerns are understood and addressed.

E.4 Existing Cal/EPA Review Processes

The following is a list of existing Cal/EPA advisory boards that conduct formal external review, defined as scientific advisory boards consisting of members from outside Cal/EPA who meet at regular intervals to review issues that have significant impact.

Cal/EPA Department	Formal External Scientific Advisory Bodies
ARB	Scientific Review Panel
OEHHA	Ambient Air Quality Assessment Committee OEHHA Science Advisory Board • Carcinogen Identification Committee • Developmental and Reproductive Toxicant Identification Committee • Risk Assessment Advisory Committee (ARB Scientific Review Panel reviews OEHHA's work)
SWRCB	Ocean Plan Advisory Committees • Marine Bioassay Project Scientific Review Committee • Microbiological Advisory Committee • Marine Toxicology Protocol Committee Bay Protection and Toxic Cleanup Program • Scientific Planning and Review Committee Underground Tanks • SB 1764 Advisory Committee

The Committee asked Cal/EPA Boards and Departments to provide information on existing internal and external review processes. In providing information on internal review processes, they were asked to address reviews within Cal/EPA only, including level of management review and reviews by other boards or departments. In describing external peer review processes, they were asked to discuss formal advisory committees, paid individual experts, formal regulatory review under the Administrative Procedures Act, and other processes. The following pages provide the responses to this request, in the form requested.

Air Resources Board (ARB)

MAJOR FUNCTION	INTERNAL CAL/EPA REVIEW	EXTERNAL PEER REVIEW
AB 1807 Air Toxics Program (Exposure Assessment)	• reviewed up through Division Chief level; • OEHHA peer review; • DPR - when pesticides are involved; • Adopted by ARB after external peer review	• formal public comment periods; • independent scientific review conducted by Scientific Review Panel; • research contracts; • public hearings; • Air District review • Office of Administrative Law process; • see attachment
AB 2588 CAPCOA Risk Assessment Guidelines	• developed through a joint Air District, OEHHA, & ARB committee; • reviewed up through Division Chief; • reviewed by OEHHA	• initial guidelines had public review, a public comment period, and a public workshop; • Air District review.
CAPCOA also developed AB 2588 Prioritization Guidelines which helps the Districts to determine who does a risk assessment, and Notification Guidelines which helps the District establish public notification procedures for risk assessment results.	• developed through a joint Air District, OEHHA, & ARB committee; • reviewed up through Division Chief; • reviewed by OEHHA	• Prioritization & Notification Guidelines had public review, comment periods and workshops; • Notification Guidelines reviewed by Attorney General's Office; • Air District review.
AB 2588 Facility Risk Assessment Review	• ARB (when requested) reviews emission impact & dispersion modeling data. This is reviewed by the staff. • OEHHA reviews data and findings related to health effects.	• risk assessments are available for public review; • Air Districts review & approve risk assessment.
OEHHA Risk Assessment Guidelines (currently in development)	• OEHHA is developing; • ARB is reviewing up through the manager level; • DTSC/DPR review.	• public comment period, public workshops, and an external advisory group for uncertainty analysis are on-going or will be scheduled for individual sections of the guidelines; • Scientific Review Panel review and comment will be scheduled in the future; • Air District review.

California Integrated Waste Management Board (CIWMB)

MAJOR FUNCTION	INTERNAL CAL/EPA REVIEW	EXTERNAL PEER REVIEW
ASSEMBLY BILL (AB) 2136 Solid Waste Disposal and Codisposal Site Cleanup Program. This Program uses the Site Investigation Process (SIP) and the Solid Waste Ranking System (SWRS), as mandated by Public Resources Code (PRC) 44105 (b)		
Priority for site investigations is based on a two-phase ranking system. The first is the SIP, with the second being the SWRS. The SWRS was developed as a part of the SIP and is used as a basis for determining corrective actions or orphan site expenditures (i.e. when responsible parties are unwilling or unable to implement necessary remediation).	CIWMB Permitting and Enforcement Division staff including several levels of management review a site for SWRS ranking and the availability of potential AB 2136 funding. Once a site has been ranked, staff recommend a site for consideration of funding to the CIWMB Permitting and Enforcement Committee for action.	Local Enforcement Agencies (LEAs) and Health Departments can submit a site for a grant application for site investigation/characterization prior to ranking via SWRS. Such a site is dependent upon data from the ARB, SWRCB and health departments in the form of Solid Waste Assessment Test (SWAT).
The objectives are to: 1) identify sites and to determine if any of these sites require administrative or corrective action; 2) assist LEAs in investigation and inspection of sites requiring remediation; 3) determine applicable closure or remediation requirements.	Approval of a site for AB 2136 funding by the Permitting and Enforcement Committee is forwarded to the CIWMB as an item for consideration by the CIWMB. This approval occurs at one of the CIWMB's monthly meetings.	A SWAT is a technical document that makes a determination of whether hazardous constituents are migrating from a solid waste disposal site into state waters. The SWRCB is the lead agency responsible for the SWAT program for state waters. Air SWAT documentation is required by AB 3374 under the Air Toxics Hot Spots Program for Air Pollution Control Districts (APCD) and Air Quality Management Districts (AQMD).

CIWMB (continued)

MAJOR FUNCTION	INTERNAL CAL/EPA REVIEW	EXTERNAL PEER REVIEW
The CIWMB is authorized to expend funds for: clean-up or emergency actions, loans to responsible parties with the ability to repay; matching grants to local governments; abatement of illegal disposal sites; and grants to certified LEAs.		CIWMB staff will continue to work with the regulated community to remediate environmental problems caused by solid waste disposal sites.
The SIP and SWRS are not risk assessment models. The SIP and SWRS rank a site for the purposes of AB 2136 funding allocation. If the CIWMB were to encounter a situation where a risk assessment were required, the CIWMB would consult within Cal/EPA for guidance and assistance regarding any risk assessment activity. The CIWMB does not staff a toxicologist for risk assessment activities. The CIWMB's Health and Safety Program has been developed to comply with State and Federal laws and regulations designed to protect employees' from toxic, hazardous or infectious materials and physical hazards they may be exposed to in the work environment. If a site poses a major risk to the public or environment for cleanup personnel, it would follow CIWMB criteria and would be referred to DTSC or OEHHA for assistance.		

Department of Pesticide Regulation (DPR)

A statutory basis for the peer review of risk assessments conducted by DPR is found in the Food and Agricultural Code, Section 11454.1, which states "The Department of Pesticide Regulation shall conduct pesticide risk assessments as appropriate to carry out its responsibilities set forth in Section 11454. The Office of Environmental Health Hazard Assessment shall provide scientific peer review as appropriate to carry out its responsibilities set forth in Section 59004 of the Health and Safety Code."

Pesticide risk assessments, which address dietary, occupational and residential exposures, are conducted by the Medical Toxicology Branch. The risk assessment, which is presented in a Risk Characterization Document and incorporates the occupational or residential exposure assessment (presented in an Exposure Assessment Document), is prepared by the Worker Health and Safety Branch. Both the Risk Characterization Document and the Exposure Assessment Document receive internal branch peer review. Following this internal peer review, the documents are submitted for peer review by OEHHA and for external peer review by the Office of Pesticide Programs of the US EPA. Drafts of the documents, prepared in response to the OEHHA and US EPA comments, are circulated for review by the other branches in DPR. A final draft is approved by the Assistant Director, Division of Registration and Health Evaluation. Any resulting risk management is approved by the Director of DPR.

In addition, risk assessments conducted under the Toxic Air Contaminants Program receive external review in the form of both public comments and scientific review by the Scientific Review Panel.

Department of Toxic Substances Control (DTSC)

MAJOR FUNCTION	INTERNAL CAL/EPA REVIEW	EXTERNAL PEER REVIEW
Review of health risk assessment work plans prior to generation of documents by responsible parties, applicants, or DTSC contractors	1. Review of Draft by DTSC Project Officer and Office of Scientific Affairs staff toxicologist(s). 2. Review by senior toxicologist and OSA Regional Liaison	
Review of draft health risk assessment documents submitted by responsible parties, applicants, or DTSC contractors	1. Review of Draft by DTSC Project Officer and Office of Scientific Affairs staff. 2. Review by senior toxicologist and Regional Liaison	
Review of health-based remedial goals calculated by Office of Scientific Affairs staff, responsible parties, or DTSC contractors	Review by other Office of Scientific Affairs staff, senior toxicologist and Regional Liaison	
Generation of exposure assessment guidance (e.g., DTSC Supplemental Guidance to RAGS, CALTOX etc. (Note: this was procedure *prior* to the SB 1082 process)	1. Review of Draft by DTSC Regional Offices and Office of Scientific Affairs staff. 2. Review by other Cal/EPA agencies (OEHHA, ARB, SWRCB, DPR)	1. External peer review of working draft by DTSC-selected experts. 2. Distribution of draft for public comment.

Office of Environmental Health Hazard Assessment (OEHHA) (4 sections)

OEHHA, Air Toxicology and Epidemiology Section

MAJOR FUNCTION	INTERNAL CAL/EPA REVIEW	EXTERNAL PEER REVIEW
Identifying Toxic Air Contaminants (TAC) (AB 1807)	Risk characterization documents are jointly produced by OEHHA (Part B: Health Effects) and ARB staff (Part A: Exposure). Part B drafts are widely circulated through OEHHA for comment and receive management review through the Director's level. In the development of documents, scientific consultation is sought as appropriate from members of the ARB Scientific Review Panel, and other outside experts. Efforts are also made to coordinate and exchange information with the US EPA.	An open, public process of review is mandated by law and regulation. Documents are released and widely distributed to stake-holders and peers for public comment, and workshops are held to facilitate the interchange. Upon completion of public comment and subsequent revisions, TAC documents are submitted to the ARB Scientific Review Panel for their review. Once approved by the SRP, the documentation is sent to the ARB for further review and listing. The SRP and ARB deliberations are open to the public.
Risk Assessment Guidelines for the "Hot Spots" Program (SB 1731)	Drafts are to be widely circulated through OEHHA and the ARB for comment and should receive OEHHA management review through the Director's level. In the development of documents, scientific consultation is sought as appropriate from members of the ARB staff and Scientific Review Panel, and other outside experts. Efforts are also made to harmonize with the US EPA.	An open, public process of review is mandated by law and regulation. Documents are released and widely distributed to stake-holders and peers for public comment, and workshops are held in northern and southern California to facilitate the interchange. Upon completion of public comment and subsequent revisions, the guidelines documents are submitted to the ARB Scientific Review Panel for their review and approval. These guidance documents do not require approval by the ARB but are adopted by OEHHA.
California Ambient Air Quality Standards (CAAQS) Recommendations	Drafts are widely circulated through OEHHA and the ARB for comment and receive OEHHA management review through the Director's level. In the development of documents, scientific consultation is sought as appropriate from members of the ARB staff and Scientific Review Panel, and other outside experts. Efforts are also made to harmonize with the US EPA.	An open, public process of review is mandated by law and regulation. Documents are released and widely distributed to stake-holders and peers for public comment, and workshops are held to facilitate the interchange. Upon completion of public comment and subsequent revisions, CAAQS documents are submitted to the OEHHA Ambient Air Quality Assessment Committee for review and to the ARB for adoption.

OEHHA, Hazardous Waste Toxicology Section

MAJOR FUNCTION	INTERNAL CAL/EPA REVIEW	EXTERNAL PEER REVIEW
Site-specific health risk assessments (e.g., BKK)	Reviewed internally by section chief, other section staff, Deputy Director and Director.	Reviewed externally by ad hoc panel of scientific experts from academia, consulting firms, etc., and US EPA Region IX.
Hazardous Waste Incinerators - Supplemental Guidance for Health Risk Assessments	Reviewed internally by section chief and ARB (air modeler), DTSC/OSA and Permits.	Reviewed by ENVIRON; US EPA Region IX.
Hazardous Materials Commodities List	Reviewed internally by section chief, PHMO III, Deputy Director, and Director.	Reviewed by external scientific experts from other state boards and departments, consulting firms, etc.; undergoes public review and comment.

OEHHA, Pesticide and Environmental Toxicology Section

MAJOR FUNCTION	INTERNAL CAL/EPA REVIEW	EXTERNAL PEER REVIEW
Drinking Water -- *internally* produced risk assessments	Documents are reviewed within OEHHA at staff and management levels. They may be reviewed by other departments (particularly California Department of Health Services (CDHS)).	SB 1082* and public as part of the regulation adoption process for MCLs.
Drinking Water -- *externally* produced risk assessments (on contract)	Externally produced documents are used by PETS staff to produce internal documents in support of risk assessments used by CDHS to set drinking water standards.	These documents are formally reviewed by two external expert reviewers before being used by PETS staff for development of internal document in support of risk assessments used by CDHS to set drinking water standards.
Risk assessments and evaluations of pesticides or other chemical contaminants in food or environment (e.g., malathion, metam, chloroform in beverages, lead in ceramic ware); investigations of pesticide related illnesses.	Documents are reviewed within OEHHA by section staff and management, including the director. Depending on the chemical or substance undergoing evaluation, the document may be reviewed by other Cal/EPA departments (e.g., DPR) or by the Agency.	Documents may be reviewed by external advisory committees, if formed (e.g., MPHEAC); other departments (e.g., CDFA, CDHS), local governments, if applicable or the public.
Bay Protection and Toxic Cleanup Program -- Advise program concerning health risks of consuming chemically contaminated fish and shellfish	Documents are reviewed within OEHHA by section staff and management. They also are reviewed by SWRCB staff.	A new advisory committee (i.e., SPARC) is in place to review documents.
Develop consumption advisories as appropriate based on risk assessment of chemically contaminated fish and shellfish	Draft documents are reviewed by section staff and section chief, management within OEHHA. If applicable, other Cal/EPA departments (i.e., RWQCB) may review.	PETS staff may collaborate with CDHS in preparation of the consumption advisories.

*Under SB 1082, Chapter 418, Section 57003, before any Cal/EPA board, department, or office adopts risk assessment guidelines or policies for evaluating chemical toxicity or prepares a health evaluation of a chemical that is used in the regulatory process by another board, department, or office, the board, department, or office must convene a public workshop to discuss the guidelines, policies, or health evaluation. Any revisions made to the guidelines, policies, or health evaluation as a result of the workshop must be circulated for public comment for at least 30 days. This review process was designed to be followed by all Cal/EPA boards, departments, and offices.

OEHHA, Reproductive and Cancer Hazard Assessment Section

MAJOR FUNCTION	INTERNAL CAL/EPA REVIEW	EXTERNAL PEER REVIEW
De novo Development and Reproductive Toxicant (DART) and Carcinogen Identification (Proposition 65)	Drafts hazard identification documents are widely circulated through OEHHA and other Cal/EPA for comment and receive OEHHA management review through the Director's level. In the development of documents, scientific consultation is sought as needed from Cal/EPA, CDHS staff, and federal scientists (at e.g., NTP, NIEHS, US EPA) and other outside experts. (Agents are selected for consideration by the SAB through a formal, open public process involving similar extensive internal review as well).	An open, public process of review is followed. Documents are widely distributed to identified stakeholders and scientific peers for public comment. DART documents are reviewed by the Science Advisory Board (SAB) DART Identification Committee (DART IC), and carcinogens by the SAB Carcinogen Identification Committee (CIC) in an open public meeting. Prior to that meeting a public workshop may be held for an airing of critical scientific issues. The SAB committee determines in an open meeting if the evidence is sufficient for listing under Proposition 65. (Selection of agents for consideration involves extensive external review, including two public comment periods and two SAB meetings.)
DART and Carcinogen hazard identification via authoritative bodies and labeling mechanisms (Proposition 65)	Documents are widely circulated to an interdepartmental working group which in addition to Cal/EPA departments includes California CDHS. They also receive management level review through the Director's level.	Process involves a formal, open public process including public noticing and comment periods for agents that appear to meet the criteria for listing, a public workshop to hear comments, contacting stakeholder to solicit comments, and public noticing and comment period on the notice of intent to list.
Dose-response assessment of DARTs and carcinogens	Draft documents are widely circulated through OEHHA and other Cal/EPA departments for comment and receive OEHHA management review through the Director's level. In the development of documents, scientific consultation is sought as needed from Cal/EPA, CDHS staff, and federal scientists (at e.g., NTP, NIEHS, US EPA) and other outside experts.	Specific dose response assessments and new methodology have been reviewed by the Scientific Advisory Panel (antecedent to the current SAB CIC and DART IC). All values adopted in 22 CCR have undergone formal public review and comment processes which includes public hearings. In addition, analyses and methodological procedures have been discussed with the scientific community at national and international scientific gatherings.
DART guidelines development and carcinogen guidelines update	Draft guidelines receive management review. In revising the carcinogen guidelines, toxicologists and epidemiologists in state government were queried about issues they felt important to address. Inter-departmental working groups were established to revise the carcinogen guidelines - develop text, consider new methodology, and air issues and concerns. Extensive intra- and inter-departmental discussions were involved in the development of the current draft of the DART guidelines.	An overview outlining possible revisions to the carcinogen guidelines was released for public comment. At least 2 public releases of draft revisions are anticipated. Two drafts of the DART guidelines have been released to the public for comment (in 1990 and 1991). Also, the 1991 draft guidelines were discussed at a meeting of the ARB Scientific Review Panel and the Proposition 65 Scientific Advisory Panel.

Regional Water Quality Control Board (RWQCB), Central Valley Region

Introduction

California's water quality standards for the protection of beneficial uses of surface and ground waters contained in Water Quality Control Plans (Basin Plans) adopted by the SWRCB and the nine RWQCBs. For surface waters, the Basin Plans are also used to satisfy Section 303 of the Clean Water Act, which requires states to adopt water quality standards to meet federal regulatory requirements. Basin Plans are adopted and amended by the Regional Water Boards using a structured process involving full public participation and state environmental review. A Basin Plan or amendments thereto, do not become effective until approved by the SWRCB and the Office of Administrative Law (OAL). Water quality standards for surface waters must be reviewed and approved by US EPA for conformance with Clean Water Act requirements.

Following is a summary of the peer review process the Regional Water Board uses when adopting new or revised water quality standards. This description may not be complete for all types of Water Board actions. For example, the adoption of health protective limits in waste discharge permits are not required to be approved by the State Water Board and the Office of Administrative Law, although actions by the Regional Water Board are appealable to the State Water Board.

Preparation and Internal Review

Regional Water Board staff prepares a draft amendment, an environmental checklist form, and a Functional Equivalent Document (FED) containing rationale for the amendment and alternatives considered, in conformance with the California Environmental Quality Act (CEQA) and the Water Code. In many cases, input from interested parties and other agencies - e.g., State Water Board, Department of Fish & Game (DFG), California Department of Health Services (CDHS), OEHHA, US EPA - is obtained prior to drafting Basin Plan amendments.

In-house review of draft amendments includes program managers of all programs potentially affected by the amendment and Regional Water Board management. Technical and legal staff of the State Water Board are also involved at this level of review. Draft amendments may also be circulated to other appropriate state environmental agencies for review at this time.

External Review

A hearing notice sent to all interested parties, including other potentially affected agencies. Notice for the public hearing generally must be given 45 days prior to hearing, and the documents to be considered at the hearing must be available to the public 30 days prior to the hearing. If a controversial issue, the Regional Water Board can hold a workshop to obtain comments prior to the hearing. Notice must be published for one day in a newspaper of wide circulation. Because the Basin Planning process has been certified as a "functional equivalent" to the environmental documentation requirements of CEQA, a Notice of Filing must be published. Usually, both the hearing notice and the Notice of Filing must be published at least 45 days prior to the hearing.

The Regional Water Board circulates the draft amendment, environmental checklist form and FED to State Water Board, DFG, OEHHA, US EPA, etc., and either send automatically or upon request to interested parties.

Regional Water Board staff initiate California Endangered Species Act consultation with DFG.

The Regional Water Board must hold a public hearing to adopt Basin Plan amendments. Staff must respond to comments on the draft amendment. Changes to the draft amendment may be made in response to comments. Where changes in the final draft are significant or not a logical outgrowth of the original proposal, an additional notice, hearing and opportunity to comment must be provided.

The Regional Board must keep an administrative record of the Basin Plan amendment process, including a transcript or tape of any Board hearings or meetings, notices of hearings, the Notice of Filing, the environmental checklist, a docket of comments, written comments, responses to comments, all materials referenced in the FED, and all materials relied upon by the Regional Board in making its decision. The Regional Board submits two copies of the administrative record to State Water Board.

State Water Board approval of Basin Plan amendments is required. If the State Board is satisfied that the amendment is consistent with Water Board statutes, plans, policies, and regulations, it holds a workshop to receive public comments on proposed approval and a public hearing. The same notice requirements apply as with the Regional Water Board workshop and hearing. State Board review results in either approval or return to the Regional Board for reconsideration and resubmission. Upon resubmission, the State Board may approve or, after a hearing in the affected Region, revise and approve the proposed plan amendment.

After State Board approval of the Basin Plan amendment, the State Board is required to submit the document to OAL for approval. OAL is authorized to review only "new" regulatory language in Basin Plan amendments for conformance with the Administrative Procedures Act. The submittal must include, a summary of any

regulatory provisions which were adopted or approved as part of the action, the administrative record for the State and Regional Water Board proceedings, a summary of the necessity for the regulatory provisions, and a certification by the Chief Counsel of the State Water Board that the action was taken in compliance with all applicable procedural requirements of the Water Code. Once OAL has approved the amendment, it becomes effective. To comply with CEQA, a Notice of Decision is filed with the Office of the Secretary for Resources after OAL approval.

If water quality standards for surface waters are revised or adopted in the Basin Plan amendment, the amended Basin Plan must be submitted to US EPA for approval. If the standard is disapproved by US EPA, the standard remains in effect until revised by the Basin Planning process, or until US EPA promulgates its own rule which supersedes the standard.

State Water Resources Control Board (SWRCB)

MAJOR FUNCTION	INTERNAL CAL/EPA REVIEW	EXTERNAL PEER REVIEW
California Ocean Plan Review of microbiological standards for marine recreational and shellfishery beneficial uses: epidemiological studies, monitoring data, recommendations to SWRCB.		Microbiological Advisory Committee membership: • CDHS • Regulated Community (Sanitation Districts) • Academia (UC Berkeley and UC Irvine
Marine Bioassay Project: (1) development and revision of marine toxicity testing protocols; (2) Technical advice on matters of Marine Aquatic Toxicology		Scientific Review Committee membership: • Research Institutes • Academia (Occidental College) • Aquatic testing laboratories
Review of chronic toxicity test protocols listed in California Ocean Plan (specified protocols are used to measure effluent compliance with Ocean Plan's chronic toxicity requirements.		Protocol Review Committee membership: • US EPA (Region 9 and ORD Labs) • Regulated Community (Pulp and Paper, Sanitation Districts, Oil Refineries) • Academia • Testing Laboratories • Research Institutes
California Inland Surface Waters Plan and Enclosed Bays and Estuaries Plan: Both plans are in early stages of development. They will both include water quality objectives for protection of human health and aquatic life. (Risk assessment values for human health will be based on OEHHA and US EPA recommendations)	OEHHA	US EPA
Bay Protection and Toxic Cleanup Program: Monitoring activities	Monitoring and Surveillance Task Force (includes Regional Water Board, OEHHA, and Department of Fish and Game representatives)	1. Public Advisory Committee (Industry, environmental and public interest group representatives) 2. Scientific Planning and Review Committee (academic, US EPA and non-profit organization scientists)
Regulations for Waste Discharges to Land (23CCR2510-2610) (Revisions)	• SWRCB approval • CIWMB review • DTSC review • Cal/EPA review	• AB 1220 workgroup • SB 1082 Sec. 2 • Advisory Committee • Other Interested Parties • Office of Administrative Law
Underground Petroleum Tanks - Cleanup	• SWRCB approval • Cal/EPA review	• SB 1764 Advisory Group • Lawrence Livermore (contract) • Other Interested Parties
General Cleanup Policy (Res. No. 92-49 amendments)	• SWRCB approval • DTSC review • Cal/EPA review	• Interested Parties

3

Hazard Identification

Introduction

Hazard identification is the formal process of evaluating human, animal and other relevant data to determine whether exposure to an agent can cause an increase in the incidence of a health condition (e.g., cancer, neurological effect). The Risk Assessment Advisory Committee (Committee) evaluated the scientific basis of the California Environmental Protection Agency (Cal/EPA) hazard identification practices, and also assessed the consistency of Cal/EPA methods and policies with those of the US Environmental Protection Agency (US EPA) and those recommended by the National Academy of Sciences (NAS). In its review, the Committee examined written material including guidelines and specific examples of the hazard identifications of these and other institutions.

The Committee experts on hazard identification who authored this chapter are: Drs. Thomas Mack (University of Southern California) (lead), Andrew Hendrickx (University of California, Davis), Charles Lapin (ARCO), Ronald Melnick (National Institute for Environmental Health Sciences), John Peters (University of Southern California), and Richard Thomas (International Center for the Environment and Health). The core liaison member, Dr. Herschel Griffin, served as the primary reviewer.

The Committee organized its discussion around six topic areas: A) the definition of adverse effects; B) the predictability of human responses by an animal response; C) the use of mechanistic and other relevant data in identifying chemical hazards; D) the regulatory process of hazard identification; E) sensitive populations; F) chemical mixtures, impurities, and concomitant exposures. This chapter is similarly organized, with findings and recommendations made on each of these topics. Committee findings explicitly address the following questions:

- Is Cal/EPA consistent with US EPA?
- Are Cal/EPA hazard identification practices internally consistent?
- Are Cal/EPA hazard identification practices based on sound scientific knowledge, methods and practices?

Summary Findings and Recommendations

Overall the Committee found that Cal/EPA hazard identification practices were consistent with US EPA. Some inconsistencies within Cal/EPA were observed (e.g., sources of data, peer review, and final form of the document), with few formal means of assuring consistency, and the Committee made recommendations for improvements in this regard. Cal/EPA was found to be generally abreast of scientific developments in the prediction of human responses from animal responses, and its evaluations of mixtures. In its use of mechanistic information, Cal/EPA is consistent with US EPA practice, but the degree to which its practice represents current state-of-the-art could not be judged due to the heterogeneity and changing nature of such information.

The Committee made several detailed recommendations to improve Cal/EPA hazard identifications, and condensed several of these into six directed toward the Agency's hazard identification processes:

1. Cal/EPA should standardize the collection and/or submission of pertinent information for hazard identification.

2. Cal/EPA should institute uniform processes to ensure the use of state of the art knowledge, including peer review of guidelines and individual hazard identification processes and products. The agency should establish a mechanism to institute such peer reviews as standard practice.

3. Cal/EPA should have written criteria for each process in hazard identification, including explicit criteria for rejecting default approaches.

4. Cal/EPA should standardize the content and construction, to the extent possible, of its hazard identification products. Although some informative narrative regarding uncertainty should be provided, categorical statements should also be available for use by the risk manager.

5. Cal/EPA should develop a formal provision for instituting re-review of individual products as well as processes and criteria used to identify hazards.

6. Cal/EPA should develop a formal process to promote interstate and internal consistency

The Committee also would like to highlight three additional recommendations which address particular scientific concerns:

7. Cal/EPA should institute standard definitions of both systemic or general and organ specific adverse effects. The definitions should distinguish

between physiological and true adverse effects.

8. Cal/EPA should regularly apply mechanistic knowledge to hazard identifications on a case-by-case basis, taking care to avoid both generic and scientifically premature considerations. The agency should have some formal provision for periodic review of the state-of-the-art.

9. In its hazard identifications, Cal/EPA should consistently incorporate guidelines for the treatment of chemical mixtures and concomitant exposures and for the consideration of sensitive populations.

Specific Findings and Recommendations

A. Defining Adverse Effects

Findings on Defining Adverse Effects

1. Is Cal/EPA consistent with US EPA?

- *The Committee found no major inconsistencies between Cal/EPA definitions of adverse effects and those of the US EPA. However, the Committee noted that there was no clearly defined process to assure consistency with US EPA nor is there a process to resolve conflicts between the two agencies.*

For carcinogens and reproductive toxicants there is formal guidance at Cal/EPA. But for the remaining endpoints there is no formal guidance within the agency. In practice there are no major or obvious differences in practice for those endpoints for which there are no formal Cal/EPA guidelines.

2. Are Cal/EPA practices of defining adverse effects internally consistent?

- *The Committee found no major inconsistencies within Cal/EPA for definitions of adverse effects. The Committee noted that there was no clearly defined process to assure internal consistency, such as with respect to internal or external peer review, nor is there a process to resolve conflicts within Cal/EPA.*

The Committee noted that Cal/EPA has their Standards/Criteria Work Group which has sought to achieve consistency within Cal/EPA. However, it was unclear how effective their efforts have been. In addition, Cal/EPA has used their guidelines process to promote consistency on carcinogen, reproductive toxicant, and site assessments. The guidelines are peer reviewed externally as well.

3. Are Cal/EPA practices of defining adverse effects based on sound scientific knowledge, methods and practices?

- *The Committee found no major indications that Cal/EPA definitions of adverse effects are not scientifically sound. However, the Committee noted that there was no clearly defined process to assure that Cal/EPA practices were based on sound scientific knowledge, methods and practices.*

The Committee is particularly concerned with how both current and new science become incorporated into the assessment process and that it be done in a way that is not idiosyncratic nor up to the whim of an individual. The Committee felt that a peer review process with opportunity for public participation is the best way to address this concern. The Committee further noted that the hazard identification process has uncertainty associated with it which should be conveyed to the risk manager. Finally, the Committee noted the need for a formalized re-review process, initiated internally or externally, to assure that hazard identifications continue to be scientifically sound.

Recommendations on Defining Adverse Effects

A1. Cal/EPA should undertake to develop a peer-reviewed general definition of adverse effect, and as needed and appropriate, definitions for adverse effects for organ systems. The definition should distinguish deleterious adverse effects from effects that are adaptive responses or transitory in nature.

A2. Cal/EPA should consider adverse effects observed in animal toxicity studies in the perspective of what is known medically about humans.

A3. Cal/EPA should develop a clearly defined process to assure consistency and to resolve conflicts both within Cal/EPA and with US EPA. The process should include both internal and external peer review and opportunities for public participation.

A4. Cal/EPA should develop a clearly defined process to assure that Cal/EPA practices are based on sound scientific knowledge, methods and practices. The process should include both internal and external peer review, opportunities for public participation, and ability to initiate re-review.

A5. Cal/EPA should develop a process to communicate uncertainty about hazard identification to the risk manager.

B. The Predictability of Human Response by an Animal Response

Findings on Predictability of Human Response

1. Is Cal/EPA consistent with US EPA?

- *For the most part, Cal/EPA and US EPA are consistent in their approach in using animal data to predict human hazard. The scientific basis underlying listing under Proposition 65 and other regulatory mandates within Cal/EPA is the same as it is within US EPA.*

The Committee held a general consensus that there is a clear distinction between written policy and current practice within each agency when comparing the characterizations of uncertainty and variability by the two agencies. The US EPA has a guidance document on the policy of risk characterization, and the National Academy of Sciences has recently provided recommendations on communicating model and parameter uncertainty. However, the practices of characterizing uncertainty and variability within US EPA and Cal/EPA has, for the most part, not attained the goals described in the US EPA policy or NAS recommendations, but both are striving in that direction.

The Committee noted that differences exist between practice and policy for both agencies. It remains to be determined if Cal/EPA is consistent with the written US EPA Policy for Risk Characterization (March 1995); however, recent policies have not been fully implemented by either agency. Both agencies have different mandates, so some differences in practice and policy may be appropriate.

2. Are Cal/EPA hazard identification practices internally consistent?

- *The scientific approach to hazard identification within Cal/EPA is reasonably consistent. There may be some differences in final outcome associated with the different legal mandates (e.g., Proposition 65) under which Cal/EPA operates.*

3. Are Cal/EPA hazard identification practices based on sound scientific knowledge, methods and practices?

- *Cal/EPA is doing a good job keeping up with advances in the field. The interrelationship between some of the prominent toxicological and other scientific societies with Cal/EPA scientists is an important link which keeps the agency aware of and acting on issues based on a sound scientific basis. In general, the application of sound scientific principles in the hazard identification process is consistent with that of the US EPA.*

- *The default assumption regarding site concordance between animals and humans is a reasonable one, given what is currently known about cancer and developmental and reproductive toxicity.*

Recommendations on Predictability of Human Response

B1. Cal/EPA should establish Committees on an ad hoc basis to look at emerging issues in hazard identification, such as the identification of sensitive human populations (e.g., postnatal developmental effects from postnatal exposure) not adequately addressed in Proposition 65.

C. The Use of Mechanistic and Other Relevant Data in Identifying Chemical Hazards

In recent years there has been much emphasis on using mechanistic data to judge the potential human relevance of adverse effects observed in experimental animals. As our understanding of toxicological and carcinogenic processes has increased, there has been increased effort to apply this information to public health decisions. Although mechanistic data can greatly increase our understanding of the nature of events that occur between exposure to a potentially hazardous agent and toxicological effects, it is not always obvious how and when mechanistic data should be used in hazard identification or which data are most appropriate. In some cases, authoritative bodies such as US EPA and the International Agency for Research on Cancer have begun to use mechanistic information to discount or downgrade the human relevance of animal findings, and to a more limited extent, to upgrade classifications of hazardous agents. Because mechanistic data generally reflect the state-of-the-art of scientific research, general peer-reviewed guidelines for their use in hazard identification may need to be updated on a regular basis as the science advances. For this reason and because the use of mechanistic data in hazard identification requires scientific judgment, there are differences among authoritative bodies on how this emerging mechanistic data should be used. What is important is that Cal/EPA adopts a rational approach that includes evaluations based on all available and valid scientific data, and that the agency does not base public health decisions on overly speculative hypotheses. Within this broad framework, internally consistent state-of-the-art principles can be established for the use of mechanistic data in hazard identification.

Findings on the Use of Mechanistic Data

1. Is Cal/EPA consistent with US EPA?

- *In general, Cal/EPA and US EPA are consistent in their use of mechanistic data to identify chemical hazards.*

- *Both agencies examine all data that are relevant for the identification of chemical hazards, e.g., comparative metabolism and toxicokinetics, genotoxicity and other short-term tests, structure-activity relationships, and cellular and molecular changes in target tissues. However, on specific issues related to more hypothetical mechanisms (e.g., $\alpha_{2\mu}$-globulin nephropathy and kidney cancer in rats), Cal/EPA has not adopted all positions taken by US EPA.*

2. Are Cal/EPA hazard identification practices internally consistent?

- *The Committee did not make a finding on this question.*

3. Are Cal/EPA hazard identification practices state-of-the-art?

- *The Committee did not make a specific finding on this question because "state-of-the-art" is a rapidly moving target in toxicology research.*

- *The application of state-of-the-art science to public health decisions should proceed with caution to ensure adequate validation and proper interpretation of new research findings. By considering all data that are potentially relevant to hazard identification, Cal/EPA's practices are as much state-of-the-art as can be expected for a scientific field that is constantly advancing. However, before simply applying new mechanistic data to hazard identification several questions must be examined, e.g., is the mechanism biologically plausible? Are the data of sufficient quality to reasonably link the specific mechanistic process to the toxicological outcome? Are competing explanations valid? Is the particular mechanism (mode of action) the determinant of the toxicological effect or are multiple processes possibly involved? These questions are addressed at Cal/EPA.*

Recommendations on Use of Mechanistic Data

C1. Cal/EPA should use mechanistic data in its hazard identification assessments to upgrade, downgrade, or affirm past decisions. Mechanistic data should continue to be used in making future decisions.

C2. Cal/EPA should be judicious in its application of or deference to generic conclusions made by authoritative bodies that toxicological outcomes observed in animals are not relevant to humans for mechanistic-based reasons. Evaluations should proceed on a chemical-by-chemical basis, with the case for each agent judged on all relevant data that are available in the open literature. Because of the relatively rapid changes in mechanistic-based research concerning chemically induced cancer and other toxicities over time, Cal/EPA should be cautious in applying new research findings that impact on the identification of chemical hazards. Because the use of mechanistic data in hazard identification requires scientific judgment, general policies for classes of chemicals must be carefully peer-reviewed and revised or updated on a regular basis as the science advances.

C3. Cal/EPA should use mechanistic data consistently in evaluating and making judgments about hazards of classes of structurally related chemicals, including those chemicals that have not been adequately studied in humans or in traditional animal studies for the adverse effect in question.

D. The Regulatory Process of Hazard Identification

Findings on the Regulatory Process

1. Is Cal/EPA consistent with US EPA?

- *Cal EPA and US EPA are similar in their approaches for prioritizing agents for consideration, for gathering the necessary data, and for weight of evidence determinations.*
- *The differences are minor, and are in part due to the different nature of the mandate, in part to regional variation in priorities, and in part to the availability on the national scale, of a large roster of highly specialized consultants to participate in the deliberations.*

2. Are Cal/EPA hazard identification practices internally consistent?

- *External peer review among the Cal/EPA programs is inconsistently employed.*
- *The form of the final product is variable.*
- *The criteria for inclusion with respect to sources of data for input is heterogeneous.*

3. Are Cal/EPA hazard identification practices based on sound scientific knowledge, methods and practices?

- *This question cannot be answered, because all practices have not been carefully examined. With respect to the better documented practices, such as those employed in satisfaction of Proposition 65, the practices appear to be soundly based.*

Recommendations on the Regulatory Process

D1. Cal/EPA should develop written criteria for every deliberative process. Cal/EPA should have explicit criteria for moving away from default assumptions.

D2. All hazard identification processes should have some form of external peer review. The Office of Environmental Health Hazard Assessment (OEHHA) should document the methods for external peer review of the various Cal/EPA programs and develop a set of recommendations for improvements in that process. In some cases peer review of the process will be sufficient, in other cases peer review of the products of the process should be undertaken. In some cases scientific advisory groups to discuss emerging science should be convened. Some form of peer review should probably be systematically considered for each Cal/EPA process.

D3. Processes should be in place for revisiting past decisions. Uniform criteria should be developed and a uniform process should be set up to facilitate petitions for changes in process as well as for revisitation of past decisions on individual substantive questions. In particular, regular reviews of criteria for acceptance of mechanistic information should be made.

D4. Consideration should be given to determining whether or not hazard identification should be employed within processes wherein it is not currently utilized.

D5. At present the format followed for the submission of information as input to hazard identification varies from program to program, and should be standardized. Publication bias, and in particular the unavailability of well conducted negative studies is always a problem. It was felt that while publication was not essential to review, the presentation of material in written form suitable for peer review should be mandatory. It should always be made clear that all decisions are necessarily made in partial ignorance.

D6. A difficult issue is the form of the hazard identification product. Some form of categorical product is essential if risk managers are to be protected from setting separate standards. However, the use of a category created for the purpose of judging a compound free from toxic or carcinogenic effects would seem to be scientifically unwarranted, since unexpected conditions may appear. On the other hand, something can be said for providing a narrative description, dealing with specific caveats with respect to the nature of and the uncertainties in the pertinent

evidence and the complexities of the known risk pattern. The goals of and criteria for any accompanying narrative should be thoughtfully agreed upon and recorded, and the nature of the narrative should be made consistent from report to report and, if possible, from process to process.

E. Sensitive Populations

Unique subpopulations can often be identified during the preparation of risk assessments. The risk assessor should consider population-specific factors that may enhance or mitigate the health effects associated with exposures to toxic chemicals.

Some of the most crucial factors that the assessor must weigh are those that influence differential susceptibility to the effects of a specific compound. Age, sex, genetic background, nutritional status, health status, and lifestyle all may influence the effects of chemical exposure. The risk assessor should carefully consider the impact that each of these factors may have on a specific sensitive population.

Age and Sex Factors

Age-related susceptibility to the toxic effects of chemical exposure is probably more widespread than many public health professionals realize. For example, it is well documented that the elderly are more sensitive to many pharmaceutical agents than other members of the population and infants are at increased risk from mutagenic agents and radiation used to treat childhood cancers.

US EPA and NAS have acknowledged that infants and children are particularly high-risk groups that must be protected from the adverse effects of chemical exposures. The US EPA primary drinking water standard for nitrate focuses on the danger in infants of developing methemoglobinemia as the basis for risk assessment and regulation. Similar age-related factors are reflected in risk assessments for lead in ambient air and drinking water, and for mercury in aquatic systems.

Infants are not always the age group of most enhanced risk. In some cases, adults are at greater risk than infants or children, e.g., effects of fluoride and uranyl nitrate in the kidneys, and organophosphate pesticides on the central nervous system.

Some adverse effects may be mediated by hormonal influences and other factors that are sex-linked. Even though sex-linked differences in susceptibility have not been extensively investigated, it is well documented that pregnant women are often at increased risk from exposure to beryllium, cadmium, lead, manganese, and organophosphate insecticides.

Genetic Factors

Studies at US EPA and NAS have clearly shown that some subpopulations possess certain inherent biochemical or genetic differences from the general population that predispose them to differences in risk. For example, some members of various ethnic groups are known to suffer from inherited serum alpha-1-antitrypsin deficiency, which makes them especially susceptible to alveolar destruction and pulmonary emphysema. Such individuals are particularly susceptible to certain air pollutants, such as ozone. Persons with hereditary blood disorders, such as sickle-cell anemia, have increased susceptibility to the effects of benzene, cadmium, and lead. These substances, which cause chemical anemia, can enhance anemia in those with such constitutional disease.

Environmental Factors

Some persons may exhibit nutritional deficiencies or habits that may enhance susceptibility to toxic chemical exposure. For example: dietary deficiencies in vitamins A, C, and E may increase susceptibility to the toxic effects of polychlorinated biphenyls, chlorinated hydrocarbons, pesticides, ozone, and other substances; smokers may have prior restrictions in pulmonary function; and chronic alcoholics may have diminished hepatic reserve.

Any suspected high-risk groups should be specifically identified in the risk assessment. The assessor should indicate concentrations of persons at high risk (e.g., schools, playgrounds, recreational areas, and retirement or convalescent homes) to potential hazards.

Findings on Sensitive Populations

1. Is Cal/EPA consistent with US EPA?

- *Cal/EPA is examining data, especially mechanistic data, for determination of increased susceptibility in subpopulations.*

There is recognition that some individuals are more sensitive to certain environmental agents. However, data are often lacking to define increased hazards.

- *Cal/EPA is ahead of US EPA in considering sensitive populations*.

US EPA has been slow to consider sensitive populations. Nonetheless, Cal/EPA has moved ahead to implement new mechanistic data and new risk assessment procedures.

2. Are Cal/EPA hazard identification practices internally consistent?

- *Cal/EPA is developing procedures to identify hazards for sensitive populations, but these are different within programs.*

Several state groups are beginning to address sensitive populations. There needs to be more interactions between groups to share approaches and develop common "successful" approaches.

3. Are Cal/EPA hazard identification practices based on sound scientific knowledge, methods and practices?

- *Cal/EPA does not have guidelines or any established written procedures to assess effects on sensitive populations.*

This represents a relatively new area of regulatory assessment. The State will need to develop procedures to assess hazards.

- *Current test methods are inadequate to identify sensitive populations.*

Cal/EPA should begin influencing investigators to develop new animal testing methods.

Recommendations on Sensitive Populations

E1. Develop a data base to accumulate information useful for the understanding of sensitive populations.

E2. Work with investigators and other producers of data to enhance the development of new testing methods and data to better understand these issues.

E3. Begin the development of procedures to assess hazards in sensitive populations, based on the review of current successful approaches.

E4. Work with risk managers and site assessors to better communicate state concerns for sensitive subpopulations and approaches for dealing with concerns.

E5. Where a hazard is identified in a sensitive subpopulation, it should be documented so that the exposure groups are adequately and appropriately addressed at later phases in the risk assessment.

F. Chemical Mixtures, Impurities, and Concomitant Exposures

Findings on Chemical Mixtures

1. Is Cal/EPA consistent with US EPA?

- *Yes. Cal/EPA and US EPA use similar approaches in assessing mixtures.*

2. Are Cal/EPA hazard identification practices internally consistent?

- *Mostly, but in some cases Cal/EPA could do more to ensure consistency across programs.*

3. Are Cal/EPA hazard identification practices based on sound scientific knowledge, methods and practices?

- *Yes, to the extent that the Committee can judge.*

Recommendations on Chemical Mixtures

F1. To ensure greater internal consistency, the existing internal structure used in the development of the carcinogen guidelines should be utilized to develop other guidelines, such as those used for assessing risks of mixtures. If such a structure no longer exists, organize a mechanism to accomplish these efforts.

F2. Approaches and guidelines to deal with recurring problems with assessing mixtures, such as oil spills, could be codified for more general use across the State.

4

Dose-Response Assessment

Introduction

In dose-response assessment, risk assessors attempt to quantitatively describe the relationship between an exposure to a toxicant (in terms of dose to the individual) and an adverse effect. Dose to the individual is calculated from an assumed concentration of the toxicant in air, food, or water and an estimate of a (usually) worst case scenario for intake of the toxicant by an exposed individual. Response of an individual is often calculated by extrapolation from the responses of animals, usually rats or mice, to known concentrations of the compound being evaluated (usually at higher concentrations than are encountered by exposed humans) in carefully controlled toxicological studies. To derive acceptable exposures for non-cancer endpoints, animal data are usually described by a no-(or lowest)-observed-adverse-effect level (NOAEL/LOAEL) observed in an experiment; this level is then divided by one or more factors of 10 (uncertainty factors) to account for interspecies extrapolation, the possibility of especially sensitive individuals in the human population, and other areas of uncertainty. For cancer endpoints, models are used to extrapolate to risk estimates at low exposure levels. Thus, assumptions are made in the estimates of dose, of response, and in the extrapolation of data from animal studies to humans. When data from exposure of humans are available (usually from occupational exposures), they often have very high uncertainties in the actual dose to a given individual, adding to the total uncertainty of the resulting risk estimate.

The Risk Assessment Advisory Committee (Committee) experts on dose-response assessment who authored this chapter are: Drs. Jerold Last (University of California, Davis) (lead), Richard Clark (UNOCAL), Kenny Crump (ICF Kaiser), Clay Frederick (Rohm & Haas), and Chrisopher Portier (National Institute for Environmental Health Sciences). The core liaison member, Dr. Judith MacGregor, served as the primary reviewer.

Overall, the Committee observed the following:

- Dose-response methodology is generally consistent between different the California Environmental Protection Agency (Cal/EPA) departments. (Some exceptions were noted.)

- Dose-response methodology is generally consistent between the US Environmental Protection Agency (US EPA) and Cal/EPA. (Some exceptions were noted.)

- Significant differences in the final products of similar risk assessments between Cal/EPA and federal agencies occasionally occurred and usually reflect different treatment of data sets rather than use of different or new data.

- Cal/EPA has often taken a leadership role in developing methodology for dose-response assessment, and there is no *a priori* reason to believe that federal agencies have done the job better when there are differences in outcome.

The Committee organized its discussion, made findings and developed recommendations on technical issues related to dose-response assessment for (A) non-cancer effects and (B) cancer.

The Committee findings and recommendations arose from addressing the following questions:

1. Is Cal/EPA consistent with US EPA, the National Academy of Sciences (NAS) and other similar bodies?

2. Are Cal/EPA dose-response practices internally consistent?

3. Are Cal/EPA dose-response practices based on sound scientific knowledge, methods and practices?

A. Non-Cancer Effects

Dose-response assessment of non-cancer effects from acute exposures is conducted by Cal/EPA's Department of Pesticide Regulation (DPR) in the registration and use of pesticides. The methodology used by DPR appears to be of good quality and consistent with US EPA practices. The DPR approach identifies a NOAEL from data submitted for pesticide registration. A margin of safety is calculated for various exposure scenarios (worker, resident, dietary) by dividing the NOAEL by the exposure level (both in mg/kg/day). This information is used for regulatory decision making for pesticide labeling and other use restrictions.

In addition to these DPR activities, the Air Toxicology and Epidemiology Section in the Office of Environmental Health Hazard Assessment (OEHHA) uses dose-response assessment to evaluate acute and chronic inhalation exposures. This activity is primarily directed toward volatile industrial emissions and spills. Although the methods and procedures for this risk assessment activity have not been finalized, the Committee was provided with an interim update on methodology and some case studies of the application of this methodology. The regulatory application of these values was not clear to the

Committee, but the Chemical Risk from Air Emissions, Toxic Permitting Program (Health and Safety Code Sections 39666, 42300 and 44300; Clean Air Act Section 112g) appears to provide the justification for this activity. Although not fully promulgated, interim acute inhalation risk assessments have evidently proven useful in Cal/EPA's response to spills and emergency releases of volatile hazardous materials.

Subchronic and chronic non-cancer dose-response assessment is used extensively within Cal/EPA to establish exposure guidelines for pesticides, evaluate reproductive and developmental toxicants under Proposition 65, and develop water and air guidance levels and standards. In addition, assessments are conducted for addressing chronic inhalation exposure to federally-defined priority pollutants. The regulatory mandates for several of these programs carry differing methodological requirements for the establishment of safe exposure levels. For example, Proposition 65 statute requires a 1000-fold safety factor to be applied to the NOAEL for reproductive and developmental toxicants. These regulatory mandates have significant implications with regard to internal consistency in risk assessment methodology, consistency of methods with external bodies, and for considerations relative to sound scientific practices.

Various external bodies conduct inhalation risk assessments or make recommendations on inhalation risk assessment methodology, e.g., US EPA, NAS, American Industrial Hygiene Association, a variety of foreign regulatory bodies, and American Conference of Governmental Industrial Hygienists (worker exposure only). A scientist from US EPA has recently provided an excellent comparison of the functional definitions, risk assessment methodology, and target populations for the most common acute exposure limits (Jarabek, 1995). Recent research related to the time-dependence of toxicity may be relevant here (e.g., note the proceedings of a recent conference on this topic: Proceedings of the Conference on Temporal Aspects in Risk Assessment for Non-cancer Endpoints, *Inhalation Toxicology*, Volume 7, Issue 6, 1995).

1. Is Cal/EPA consistent with US EPA, NAS and similar bodies?

Among the summaries of dose-response evaluations included as an appendix to the meeting briefing materials, several Cal/EPA non-cancer dose-response assessment practices were described that are different than those used by the US EPA. An example is given:

-- Atrazine (drinking water) --- Cal/EPA provides Proposed Maximum Contaminant Levels to the California Department of Health Services (CDHS) who promulgates the State's drinking water standards. After calculating the reference dose (RfD), the recommended exposure limit incorporates an additional uncertainty factor of 10 that was justified, according to CDHS policy, to "account for possible carcinogenicity." The US EPA generally either treats a compound as a carcinogen or as a non-carcinogen, and it does not use uncertainty factors for "possible carcinogenicity." The Committee was assured, however, by a representative of US EPA that a comparable uncertainty factor of 10 is used at the risk management level by the federal agency in deriving drinking water health advisories for US EPA Group C carcinogens. If this is the case, US EPA practices are similar to those

of Cal/EPA but descriptions are not, and lead to unnecessary confusion by those unfamiliar with them.

US EPA has indicated that there are practical limits to the magnitude of the uncertainty factors that should be applied to establish an exposure limit (US EPA, 1994; Kimmel, 1990). Appendix B of this report indicates several Cal/EPA exposure guidance values for drinking water with large uncertainty factors (e.g., of 52 values listed, one has an overall uncertainty factor of 100,000, and seven have an overall factor of 10,000).

The definition and application of DPR acute risk assessment methodology appears to be consistent with the corresponding methodology used by the Office of Pesticide Programs and Toxics of the US EPA. A letter of understanding has been exchanged between DPR and US EPA regarding joint development and non-duplication of effort in the development of these values.

The Air Toxicology and Epidemiology Section in OEHHA is in the process of developing Acute Toxicity Exposure Levels (Levels I-III) for 1-hour inhalation exposure duration. These values have primarily been developed for volatile industrial chemicals. The draft definitions used by Cal/EPA for Acute Toxicity Exposure Levels I-III are very similar to the definitions used by the National Academy of Sciences for Community Emergency Exposure Levels 1-3 (CEELs 1-3) (which were developed for US EPA). Neither US EPA nor NAS have as yet applied these guidelines to any chemicals. However, during the Committee's discussion with Cal/EPA it became apparent that substantive differences may exist in the interpretation and application of these guidelines by Cal/EPA relative to these outside bodies. During the public discussion, it was noted that NAS has not promulgated final guidance levels, and that US EPA has asked Cal/EPA to work with them to develop guidance levels. The Committee strongly supports the collaborative development of values to encourage sharing of labor and consistency of application and outcome among the various state and national regulatory agencies to the extent possible under existing laws.

Generally, the default procedures used (or being evaluated by Cal/EPA) for interspecies extrapolation are consistent with US EPA and NAS. However, occasional lapses in quality control in data evaluation were noted during the course of the Committee's hearing (e.g., a case study on toluene presented at the prior "case studies" workshop that mixed animal and human data sets when applying uncertainty factors for a drinking water exposure limit). Avoiding the inherent uncertainty in interspecies extrapolation by the use of available human data should generally be encouraged (even though the available human data is rarely as well-controlled as an animal study). Cal/EPA has been a leader in the responsible evaluation and use of physiologically-based pharmacokinetic models and other mechanistic approaches as tools to assist in data-based interspecies extrapolation and risk assessment. Use of data-based methods facilitates the use of probabilistic methods that accurately capture the best estimate and range of the available data. Accurately capturing the distribution of the underlying data and/or policy assumptions can be a basis for improved communication between risk assessors and risk managers. Given the academic talent and resources available to Cal/EPA, this activity is encouraged by the Committee.

The benchmark dose approach is currently used rarely relative to NOAEL/LOAEL methodology by US EPA for acute risk assessment. NAS has examined benchmark dose while developing Emergency Exposure Guidance Level (EEGL) values for acute risk assessment. It is recommended that the use of benchmark dose by Cal/EPA be further explored.

The Committee examined Cal/EPA's practice of adjusting for discontinuous exposures, including methods to account for length of exposure, age at the time of exposure, and other exposure regimen considerations. The Committee found that the Air Toxicology and Epidemiology Section in OEHHA generally uses Haber's law methodology (Ten Berge, 1986; AICE, 1989), similar to other outside agencies.

With regard to the use of uncertainty/adjustment factors for computing exposure limits, the Committee detected inconsistencies between Cal/EPA and US EPA in the derivation of guidance levels, e.g., more liberal use of uncertainty factors by Cal/EPA. Cal/EPA values are more recent; however, often times new data did not appear to be the cause of the differences; rather the differences arose from methodological and interpretation differences.

The draft interpretation of the definition used by Cal/EPA for Level I acute risk may be different than that developed by NAS and a non-governmental body, which is acceptable if a sound scientific rationale is presented for this choice. As a consequence, the application of uncertainty factors may be different. In the draft acute inhalation risk assessment methodology, Cal/EPA proposes to explicitly state, which is to be commended, what the uncertainty factors are (including their basis), whereas other bodies tend to use expert judgment in defining uncertainty factors on a case by case basis. However, for important exposures, review of uncertainty factors for a specific compound is warranted and supported by the Committee.

2. Are Cal/EPA dose-response assessment practices internally consistent?

Risk assessment practice for reproductive toxicants under Proposition 65 is based upon legislative mandate and differs significantly from the other procedures. Risk assessment methodology and application for priority pollutants (ozone, SO_2, carbon monoxide, etc.) differs significantly from other subchronic and chronic risk assessment in that it primarily uses acute human inhalation data and treats chronic inhalation exposure of ambient air pollutants as a series of acute inhalation exposures.

Acute dose-response assessment is conducted by Cal/EPA's DPR related to the registration and use of pesticides. The methodology used by DPR appears to be of good quality and is consistent with US EPA practices. The DPR approach identifies a NOAEL from data submitted for pesticide registration. A margin of safety is calculated for various exposure scenarios (worker, resident, dietary) by dividing the NOAEL by the exposure level (both in mg/kg/day). This information is used for regulatory decision-making for pesticide labeling and other use restrictions. The Air Toxicology and Epidemiology Section in

OEHHA is in the process of developing Acute Toxicity Exposure Levels (Levels I-III) for 1-hour inhalation exposure duration. These values have primarily been developed for high volume volatile industrial chemicals. OEHHA has explored the use of benchmark dose on a limited basis for acute risk assessment of hazardous air pollutants. NOAEL/LOAEL is used commonly by DPR.

With regard to the averaging procedures employed to adjust for discontinuous exposures, the handling of transient peaks of exposure may be done differently in different parts of Cal/EPA. The Committee heard of instances of systematic differences between various Cal/EPA agencies when federal versus state differences in non-cancer guidance levels were compared (e.g., DPR values less stringent than US EPA's, while OEHHA's might be more stringent). In general, risk assessment practices for pesticides, contaminants in water and air, and for site remediation appear to be generally consistent with each other.

On the subject of weighing human versus animal data in study selection, the criteria for the selection of the appropriate data set appears to be generally based on professional judgment. No general criteria have been adopted by Cal/EPA to guide this decision.

3. Are Cal/EPA practices based on sound scientific knowledge, methods and practices?

Dose-response assessment methodology used by Cal/EPA appears to be based upon traditional risk assessment methodology. However, selected risk assessment decisions differ from tradition and may point to need for external peer review to guarantee quality control in risk assessment practices. With regard to draft inhalation acute dose-response assessment methodology, the Committee noted that development of the guidelines was not complete; these should be completed and peer reviewed to avoid criticism.

The Committee discussed the use of adjustment/uncertainty factors for non-cancer endpoints in extrapolating across species and the criteria for using alternate approaches (e.g., physiologically-based pharmacokinetic models and other mechanistically-based approaches). The Committee was concerned with the practice of using multiple uncertainty factors, noting that this practice was often indicative of weak or severely limited data sets.

With regard to dose-averaging procedures employed to adjust for discontinuous exposures, Cal/EPA practices appear to be generally reasonable. Cal/EPA frequently uses a single number to indicate toxicity, where appropriate information suggest subpopulations may experience different risks due to discontinuous exposures; in these cases, other procedures are warranted and should be explored.

The Committee acknowledges the difficulty in establishing regulatory levels when there are large data gaps, or data are very poor. In computing chronic exposure limits, there were several examples in the tables (provided as briefing materials for the meeting) of large uncertainty factors being used. The Committee questioned the value of using data that required uncertainty factors of this magnitude since the excess use of uncertainty factors can lead to overly conservative values. Use of an uncertainty factor of 100,000 (as noted for 1,1-

dichloroethane in Appendix B) has never been justified and is not routinely used by other agencies. The Committee discussed the need for Cal/EPA to consider the severity of the effect being evaluated in assigning the uncertainty factor.

The use of NOAEL and benchmark dose methodology to develop standards represents generally sound scientific practice, although benchmark dose has not been extensively used. Cal/EPA has explored the use of benchmark dose on a limited basis for acute risk assessment of hazardous air pollutants. OEHHA sponsored a workshop on this methodology and has extensively evaluated the strengths and weaknesses of this method.

Animal data should not be substituted for relevant human data (e.g., for Level I guidance values) unless there is a strong scientific justification for doing so. The draft acute inhalation risk assessment for a Level I guidance value for carbon tetrachloride presented to the Committee suggests that in this case relevant human inhalation data (and rodent inhalation data) were set aside in favor of rodent oral data. While this is recognized to be a draft document, the inherent uncertainty present in route-to-route extrapolation and interspecies extrapolation may not have been appropriately weighed in discarding the human data in this specific instance.

At the Dose-Response Assessment review meeting, the agencies discussed how they address the risk from more than one non-carcinogenic substance. Much of the discussion addressed the methodology when the target organs were different or when mechanism of uptake varies. A hazard index is an estimate of the degree to which a reference dose is exceeded. When there are two (or more) chemicals present in a mixture, the hazard index should provide an estimate of the combined hazard of the chemicals in the mixture. The agencies did not, however, address (1) the validity of hazard indices, and (2) whether it is ever proper to sum hazard indices.

Recommendations on Dose-Response Evaluation of Non-cancer Effects Resulting from Acute and Chronic Exposures

A1. Continued collaboration between Cal/EPA and US EPA should be encouraged to prevent duplication of effort. Where federal guidance levels exist, Cal/EPA should work with US EPA, and not independently, to revise. In those instances where Cal/EPA's assessment differs from another regulatory body, a short explanation and justification should be included in the introduction to the assessment.

A2. Continued reliance on NOAEL/LOAEL methodology for most dose-response assessments appears to be appropriate. Evaluation of the utility of the benchmark dose, categorical regression, and other methods should continue. The Committee notes with favor that Cal/EPA has evaluated the feasibility of the benchmark dose approach, and recommends that this work be supported and continued.

A3. An important goal in improving the accuracy of the risk estimates is the replacement of default values with more rigorous scientific data. Cal/EPA should move aggressively to update assessments when significant new scientific data become available. Cal/EPA should also be encouraged to develop guidance for agency risk assessors to assist in identifying appropriate departures from standard default values. In addition, the Agency should encourage the submission of relevant data where data gaps exist and consider mechanisms to expedite the review of new information. Cal/EPA should work closely with US EPA to ensure that differences in risk estimates between the two agencies are not based solely on differences in the choice of default values.

A4. Increased use of probabilistic methods of dose-response assessment to better define ranges and best estimates of risk is to be encouraged. Use of probabilistic methods as a form of default to express the absence of data in probabilistic terms is not appropriate.

A5. Mechanisms for improving communication between risk assessors and risk managers should be developed. At the least, this could include a clear statement of uncertainty in the final risk estimate. Use of default values should be clearly presented and their impact on overall uncertainty described.

A6. Cal/EPA should develop guidance on the appropriate use of uncertainty factors. This guidance should consider the appropriateness of the existing data and the severity of the effect in the overall magnitude of the uncertainty factor. Consider setting a cap on the magnitude of uncertainty, above which data should be considered unreliable for use in deriving guidance levels.

A7. Cal/EPA should consider accepting, or even actively soliciting, externally prepared guidance levels. Cal/EPA would review these for consistency with agency criteria and approve them prior to implementation.

A8. Reasonable scientific judgment should be used relative to exposures to hazardous material that might not follow the principle of Haber's Law (i.e., that concentration multiplied by time is equal to a constant value in terms of the response of an exposed subject). Issues related to exposure of sensitive subpopulations should be closely monitored.

A9. Current reliance on the hazard index fails to account for risk from multiple exposures. Cal/EPA should work with other groups to develop risk-based methods to replace the hazard index.

A10. On a case-by-case basis, Cal/EPA should be careful to assess whether joint exposures will be independent or additive. The risk-based methods developed under (A9) should provide a means for dealing with these two cases. Poor data sets present a problem. Application of a series of uncertainty/adjustment factors to poor data results in a large overall value. Cal/EPA should consider alternate ways to combine these factors and should justify values greater than 1000 (with review) or a detailed assessment of the shape of the dose-response curve.

A11. To assist in risk communication, Cal/EPA should consider providing guidance information on the risk associated with a small exceedance in guidance values when the value is established by the allocation of uncertainty factors.

A12. Where possible, Cal/EPA should consider the biological basis for a toxic response in applying its dose-response assessment methodology. For example, overloading lung clearance mechanisms for the clearance of nontoxic particles has been demonstrated to have adverse consequences. Understanding of these processes has implications for data interpretation and for the appropriate allocation of uncertainty factors for the resulting risk assessment.

A13. The Committee recommends that Cal/EPA maximize its use of human data where available, and the decision to discard human data in favor of animal data should only be done if the resulting uncertainty in the risk assessment is decreased.

B. Cancer

1. Is Cal/EPA consistent with US EPA, NAS and other regulatory bodies?

Generally, dose-response methods for cancer at Cal/EPA and US EPA are consistent. However, differences exist that can result in significant differences, including presentation of a mid-range (e.g., maximum likelihood) estimate of potency factors estimated from human

data (US EPA) versus presentation of a 95% upper bound by Cal/EPA. In addition, US EPA current potency values are based on two-thirds power of body weight method to scale from animals to humans, although they have proposed using the three-quarters power scaling. One exception is the US EPA Office of Pesticide Programs and Toxics which is currently using three-quarters power. Most Cal/EPA programs use the two-thirds power of body weight method, with the exception of DPR which uses three-quarters power.

Even though Cal/EPA practices are generally consistent with those of US EPA, there are often disagreements between risk estimates of the two agencies, some of which are substantial. These differences appear to be due mainly to differences in scientific judgment, differences in the interpretation of scientific data in individual cases, or to development of new scientific data, rather than to fundamental differences in the approaches taken by Cal/EPA and US EPA. There was some evidence that specific departments in Cal/EPA may occasionally be more conservative (OEHHA) or less conservative (DPR) than US EPA in their scientific judgments.

The NAS (1994) report *Science and Judgment in Risk Assessment* made a number of recommendations to US EPA regarding its risk assessment methodology. Some of the NAS recommendations that pertain to dose-response assessment that are not currently being followed by Cal/EPA are listed in the Recommendation section below.

2. Are Cal/EPA risk assessment methods internally consistent?

In general, Cal/EPA's practice of risk assessment appears to be internally consistent. One exception is the fact that DPR uses a scaling factor for animal-to-human extrapolation (three-quarters power of body weight) different than the rest of Cal/EPA (two-thirds power of body weight). Cal/EPA is not alone in having some internal inconsistency, as the US EPA also uses a similar dual approach between the US EPA pesticides group and the remainder of US EPA. Cal/EPA is encouraged to draft a consistent internal policy on this issue or to cite scientifically defensible reasons why it is appropriate to have a differing science policy for pesticide risk assessments. None of the procedures used by Cal/EPA appear to be out of line with modern risk assessment practices.

Recommendations on Dose-Response Evaluation of Cancer

B1. Cal/EPA appears to take great care in the collection, analysis, and interpretation of scientific information relating to environmental hazards. Cal/EPA should strive, in as far as is operationally feasible and scientifically appropriate, to take the lead in developing and encouraging consistency between Cal/EPA and US EPA risk assessments. At this time, choosing a preferred scientific approach is more important than maintaining consistency. When Cal/EPA is developing a new risk assessment, existing risk assessments, including particularly any by US EPA, should be reviewed, and scientific or policy reasons for differences between those assessments and that of Cal/EPA should be explained. The role of the Standards/Criteria Work Group within

Cal/EPA should be expanded to ensure a coherent policy within the Agency, and to serve as an effective liaison among federal agencies with overlapping interests.

B2. In addition, Cal/EPA should endeavor to develop future risk assessments in concert with US EPA, especially for high volume and/or high risk compounds. Before Cal/EPA conducts an independent risk assessment for a substance, it should first review any existing US EPA risk assessment. Unless important new scientific information is available that is not reflected in the US EPA assessment, and that would have a meaningful impact, rather than conducting its own independent assessment (unless specifically required to do so by state law), Cal/EPA should consider adopting those portions of the US EPA assessment that are responsive to the needs of Cal/EPA. Formal memoranda of understanding, such as the one that presently exists between US EPA and Cal/EPA for pesticides, are encouraged. It is recommended that Cal/EPA and the US EPA identify any major science policy differences between the two agencies and strive towards a common approach. For specific high profile compounds for which the two agencies have different risk profiles, it may be useful to develop joint interagency working groups to address the reasons for these differences and to attempt to achieve consistency or to justify such differences based on the subjective nature of risk assessment policy choices.

B3. Cal/EPA should make clear whenever a decision is a policy decision and what the implications of any policy decision are to the results and interpretation of a risk assessment. Insofar as possible, Cal/EPA should strive to harmonize its policy decisions both internally and with those of other agencies. The Committee agrees that data to improve extrapolation from animals to humans are very limited. Consequently, the approach selected for animal to human extrapolation is basically a policy decision. Cal/EPA should have a uniform policy on this issue.

B4. It has been a common practice to use different approaches for dose-response assessment for cancer and non-cancer endpoints. Several groups (NAS, US EPA) have argued that this dual approach is not really justified by the scientific evidence and have been searching for a common dose-response approach, and the US EPA draft cancer guidelines recommend an approach that is closer to the traditional approach for non-carcinogens. This Committee agrees with this overall concept and suggests that Cal/EPA strive towards a common method as well. Again it is recommended that Cal/EPA work with national regulatory agencies and advisory panels wherever possible to achieve consistency in any new approaches that may be taken in this area. Similarly, methods for animal to human extrapolation are different for cancer than for non-cancer even though the data and intellectual framework used to support the approach applied to cancer applies equally to cancer and non-cancer. Cal/EPA is encouraged to develop a consistent method for both types of endpoints.

B5. Cal/EPA should strive to develop guidance for dealing with inter-individual variation in carcinogenic potency. In particular, carcinogen dose-response should consider

impacts on susceptible subpopulations. Technical approaches for estimating the degree of sensitivity and the size of sensitive subgroups should be developed.

The NAS (1994) report *Science and Judgment in Risk Assessment* made a number of recommendations for improving its risk assessment methodology. Some of those that pertain to dose-response assessment and which the Committee recommends to Cal/EPA are as follows:

B6. Cal/EPA should continue to explore and, when scientifically appropriate, incorporate pharmacokinetic models of the link between exposure and biologically effective dose (i.e., dose reaching the target tissue).

B7. Science gaps in risk assessment can only be addressed when regulatory agencies provide feedback to the scientific community. Mechanistic models, sensitivity analysis, and uncertainty analysis are key tools in identifying science gaps. Cal/EPA is encouraged to utilize these tools when data and resources permit.

B8. Cal/EPA should strive to develop guidance for quantifying and communicating uncertainty (e.g., for models and data sets) as it occurs in each step in the risk assessment process.

B9. It is common practice of many regulatory agencies, including Cal/EPA, to aggregate cancer slope factors when estimating risk for mixtures of compounds. Many research groups are studying this issues in great detail and Cal/EPA is encouraged to closely monitor this research. Where appropriate, this default and probably conservative approach to mixtures should be replaced.

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5

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

Introduction

Determining human exposures to contaminants is a critical component in chemical risk assessment. Consequently, the Risk Assessment Advisory Committee (Committee) devoted substantial attention to reviewing California Environmental Protection Agency (Cal/EPA) methods, policies and guidelines for exposure assessment. The review was divided into two phases, reflecting two complementary perspectives. The first phase, reported in this chapter, focuses on the human receptor. Exposure assessment from this perspective stresses the ways in which humans interact with their environment. Key factors in assessing exposure are 1) the concentrations of contaminants in air, water, food, and soil at the point of contact between the human and the respective medium and 2) the quantities of these materials that are inhaled, ingested or otherwise come into contact with the human receptor. The second stage of the Committee's review of exposure assessment emphasizes the fate and transport of contaminants in the environment and is presented in Chapter 6.

The expert panel charged with writing this chapter was comprised of seven scientists: Alison Cullen (co-lead), University of Washington, Seattle; William Nazaroff (co-lead), University of California, Berkeley; Gladys Block, University of California, Berkeley; Howard Maibach, University of California, San Francisco; Fumio Matsumura, University of California, Davis; Paul Price, ChemRisk, Maine; and Wayne Ott, Stanford University. Dr. Robert Spear served as the liaison to this panel and reviewed this chapter on behalf of the Core Committee.

As background for the review, Cal/EPA staff prepared and distributed a briefing book to the expert panel that summarized the exposure assessment methodology and practices of Cal/EPA and US Environmental Protection Agency (US EPA). An overview of exposure assessment methodology and practice of Cal/EPA and US EPA, prepared as part of the Committee's briefing material, is presented in Appendix C.

The review meeting was divided into five sessions that addressed the following topics: overview of policies and practices at Cal/EPA, US EPA, and National Academy of Sciences (NAS); physiological characteristics and input parameters; human activity

patterns, behavioral and dietary characteristics; contact medium concentrations; and cross-cutting issues in exposure assessment. The expert panel and other Committee members in attendance heard presentations from practitioners of exposure assessment at Cal/EPA and US EPA, as well as from the broader scientific community, including participants in NAS efforts. Panelists, members of the public, and attending members of the Committee participated in the discussions. The agenda for the meeting is provided in Appendix F. The expert panel's general findings and recommendations are presented below along with responses to three specific questions posed to each of the expert panels.

Findings and Recommendations

A. General Issues

Finding:

Cal/EPA focuses extensively on source-based environmental analyses rather than on receptor-based exposure assessment, despite indications that the latter is an important tool for human exposure assessment. By contrast, while the US EPA continues to base much of its regulatory effort on individual sources, the research arm of US EPA (Office of Research and Development) has made a major commitment to programs that focus on receptor-based exposure assessment, and the regulatory arm uses receptor-based exposure data for many agency risk assessments.

Elaboration:

Exposure assessment is an active field of research that has matured substantially in recent years in scientific knowledge, approaches and tools. A major advance that deserves serious attention by regulators is the introduction of receptor-based exposure assessment approaches as a complement to the traditional source-based approaches. Receptor-based approaches are designed to determine if people are actually exposed to environmental pollutants, and, if so, by how much and from what sources.

In the technical and scientific community, there has been significant movement in the direction of receptor-based exposure assessment. Although the regulatory community has lagged behind, at the federal level the US EPA is working to set priorities for protecting public health with an approach that combines measured exposure data collected at the receptor with more traditional predictive exposure approaches that begin with the source of contamination and model the resulting human impacts. California would benefit if Cal/EPA likewise blended source-based and receptor-based exposure assessment approaches.

A significant finding from the research on receptor-based assessments is that for certain chemicals industrial point sources make negligible contributions to human exposure. In addition, human activities and indoor sources of exposure are critical factors in determining the variation in exposures among individuals. This finding suggests that, for certain chemicals, the current policy of controlling human exposures by

controlling releases from industrial processes and sites may not be an effective strategy for reducing human exposures. This is not to say that the current program's focus on industrial and transportation sources is inappropriate for certain classic air pollutants such as O_3 and SO_x. However, existing programs need to move beyond the current strategy of controlling sources that have little impact on individuals' exposures.

A second problem identified by receptor-based exposure studies is that a significant fraction of human exposure to certain toxic chemicals is largely overlooked. Problems that appear to be receiving little attention at present include accidental carbon monoxide poisonings, exposure to indoor radon, and exposure to toxic organic compounds from sources such as residential wood smoke, building materials, and consumer products. Average lifetime risks of fatality caused by indoor air pollutants can be of the order of 10^{-4} to 10^{-3}, and individual risks are sometimes an order of magnitude higher than the average (Nero, 1988). These are high risks in comparison with the thresholds that currently trigger regulatory actions for an industrial pollution source.

The finding of these large unaddressed risks indicates that the State of California must move beyond the current environmental control strategy that emphasizes sources emitting the largest mass of pollutants to a strategy that emphasizes sources contributing the most to exposure. The panel recognizes that such a major change in the strategy for environmental health protection would require significant changes to current legislative authorities.

Recommendations:

A1. 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.

A2. 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.

A3. Cal/EPA should also consider instituting a program that evaluates the risks associated with common levels of indoor air contaminants. Such a program could serve to place in context the results of current programs to control exposures from industrial and transportation activities.

Finding:

Cal/EPA does not always make a clear distinction between exposure assessments intended for screening purposes and those intended to be statistically unbiased characterizations of exposure (US EPA, 1992; NAS, 1994).

Elaboration:

Screening approaches use conservative default assumptions to compensate for uncertainties in parameters and models. Estimates of dose rates from such assessments are useful for identifying low-risk situations which do not require further attention. Assessments that are not used for such screening purposes should provide unbiased estimates of dose rates and risks and fully disclose the uncertainty in these estimates. Such unbiased characterizations are required in risk/risk comparisons or cost/benefit analyses. In addition, such characterizations make the assessment process more accountable to decision makers, the public, and the regulated community. Exposure assessments that retain conservative assumptions are valid tools for risk assessors; however, they should be identified as refined screening approaches rather than unbiased estimates of future risks.

Recommendation:

A4. 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.

Finding:

Cal/EPA relies on scenario-based exposure assessments that have a limited ability to accurately characterize exposures. In addition, scenarios may be developed with certain policies in mind that are not always apparent to the risk manager. As a result, the estimates from scenario-based exposure assessments should be carefully evaluated by risk assessors and risk managers.

Elaboration:

An exposure scenario is a set of behaviors that describes the interaction between individuals and contaminants in an environmental medium. These behaviors define the parameters (and parameter values) in algorithms that predict toxicologically relevant dose rates occurring as the result of individuals' interaction with contaminated environmental media. The algorithms are typically simple algebraic statements that combine

information on the frequency, intensity, and duration of exposure, and physiological parameters such as rates of uptake and body weight.

Dose-rate models based on exposure scenarios make a number of simplifying assumptions that do not accurately reflect the complexities of either long-term or short-term exposures to environmental contaminants. These simplifications are used to accommodate the limited amount of data typically available at many sites or because the analysis is intended for screening purposes. Examples of such simplifications include the following:

- Exclusion of factors that have relatively small impacts. Processes that are well-known but are not anticipated to make significant changes in the final estimates of dose rates typically are not included in exposure scenarios.
- Exclusion of factors that may significantly reduce exposure but are highly uncertain. Some processes can have a dramatic effect on exposure but the magnitude of the effect at any given site is highly uncertain.
- Assumption of consistent parameter values over long periods of time. Exposure scenarios tend to assume that the values of certain parameters remain constant when, in fact, the values may vary from year to year.
- Application of similar assumptions to all locations. The same scenario is often used at all locations, including locations where key assumptions do not hold.

While these simplifications can result in either overestimates or underestimates of individuals' exposures, there is a tendency to favor simplifications that are protective of health. As a result, estimates of dose rates that are based upon scenarios are often overestimates of the actual exposure.

Recommendation:

A5. 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.

Finding:

Cal/EPA has generally not considered the uncertainties and biases in dose-rate estimates that occur as a result of the land-use assumptions implicit in the exposure scenarios used in environmental site assessments and in permitting industrial waste discharges. Consequently, the Agency is often unable to present a complete description of the uncertainties in exposure assessments.

Elaboration:

Many exposure assessments that purport to estimate the dose rates for the "typical" individual (or a distribution of doses in an exposed population) do not present

statistically unbiased estimates of exposures that are likely to occur. Rather they are estimates of dose rates that are likely to occur if certain exposure-related events happen, such as someone building a residence at a site or digging a drinking water supply well into a contaminated aquifer. The probability of such events occurring (scenario probability) is not taken into account in presenting the results of the risk assessment. Failure to consider scenario probability results in an incomplete description of uncertainty in risk estimates. In addition, assuming that certain events will occur may result in biased estimates of exposure and associated risks.

A related problem is ambiguity in the definition of target populations in many exposure assessments. While future or "hypothetical" populations may be appropriate bases for regulatory actions, a lack of rigor in the definition of the exposed population can lead to confusion and a lack of credibility in the State's actions, and may obscure opportunities for more effective controls.

Recommendations:

A6. 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.

A7. Cal/EPA should support the development of information on likely future land uses at industrial sites. One approach for developing such data would be an investigation of historical patterns of urban and suburban redevelopment of industrial properties. This investigation would seek to determine where, and under what conditions, industrial properties have been converted to land uses that result in a significant potential for exposure to contaminated soil, such as those associated with residential, recreational, and agricultural activities. As part of this study, it would be useful to determine if the soils around the industrial sites were substantially modified (covered by fill or topsoil, substantial mixing of soils, or removal) during the redevelopment process.

A8. In addition, Cal/EPA should consider supporting studies on key data in the commonly used exposure scenarios. For example, there are few objective studies on the frequency, intensity, and duration of contact with urban soils or subsoils that occur as a result of the typical behaviors associated with common urban land uses.

Finding:

Human behavior is a critical and mostly overlooked phenomenon in priority setting, in choosing data to be collected, and in other factors that influence human exposure.

Elaboration:

Recent data from receptor-based assessments highlight the importance of the behavior of the receptor, a human individual, in determining exposure. Exposure to airborne toxic pollutants can only be evaluated with knowledge of human activity patterns. Understanding waterborne and foodborne exposures requires knowledge of behavior patterns and lifestyle factors.

Recommendation:

A9. Input from behavioral scientists and survey research experts should be included in Agency decision-making processes.

B. Specific Findings and Recommendations

I. Is Cal/EPA consistent with US EPA?

Finding:

Although Cal/EPA is generally consistent with US EPA on exposure factors, some differences exist without an underlying scientific basis. In some cases, such as in monitoring ambient concentrations of toxic air pollutants, Cal/EPA is out in front of US EPA in terms of information and abilities. In other areas, such as in the use of receptor-based approaches for assessing exposure, Cal/EPA lags behind US EPA.

Elaboration:

Currently Cal/EPA and US EPA use similar but not identical numbers for default exposure parameter values. There are cases in which the California population differs from the national population (e.g., with respect to fish consumption, age structure, mobility, etc.); also, there are cases in which Cal/EPA estimates exposure for both children and adults, whereas US EPA considers only adults, the Committee observes for these cases, exposure factors should reflect these differences. However, sometimes the values are derived from the same technical data but differ because of slightly different interpretations of the data. These variations in approach and exposure factors have no significant effect on the final estimates of dose rates and the differences are small in comparison to the uncertainties in toxicological estimates, or exposure modeling. Changing the values of such parameters to be consistent with US EPA will not make any meaningful change in the quality of the final risk estimates; however, consistency would eliminate possible sources of confusion and facilitate public acceptance of risk findings between the two organizations.

The implementation of an ambient air toxics monitoring network represents an example where Cal/EPA practice commendably exceeds federal activities. Also, Cal/EPA's use of the estimated pesticide residue approach is appropriate and state-of-the-art, while US EPA's use of tolerances for the regulation of pesticides is out of date. In

this case, US EPA is beginning to update its approaches and is moving toward the approach used by Cal/EPA.

Recommendation:

B1. Cal/EPA should seek to use the same default values for exposure parameters as US EPA when there is agreement between Cal/EPA and US EPA on the technical basis for selecting values, or when there is no demographic or geographic reason that an alternate value is more valid for individuals in the State of California.

Finding:

US EPA is moving toward using measurements of actual exposure and frequency distributions of exposures of the population to a given pollutant more rapidly than Cal/EPA.

Elaboration:

This shift at US EPA has occurred after nearly two decades of total exposure field studies conducted and supported by the agency. Frequency distributions of exposure in the population are increasingly used by US EPA in its regulatory decision-making role. Field studies and personal monitoring have allowed US EPA to validate some of the exposure models they use. In most instances, exposure models used by Cal/EPA are similar to those used by US EPA. Some of the models used by Cal/EPA are not satisfactorily validated or are not specifically designed to predict exposures. In some contexts, US EPA is using measurements of exposure based on field studies in its regulatory and risk assessment programs (see Appendix 5-1). To a lesser extent US EPA also is using models specifically designed to predict exposure that combine both activity patterns and microenvironmental concentrations based on field measurements (see Appendix 5-2).

Although previous Total Exposure Assessment Methodology (TEAM) studies and other field studies have shown the importance of measured frequency distributions of exposures, it appears that Cal/EPA is not giving adequate emphasis to observed distributions of exposure across the population, even when the studies have been conducted in California with joint support from Cal/EPA and US EPA. Cal/EPA would contribute enormously to improving the overall quality of the risk assessment process by conducting personal monitoring research to test, validate, evaluate, and refine human exposure models. New exposure models, once validated, can help predict the reduction in exposures that would occur for different control strategies and regulatory approaches. These data and models could help Cal/EPA assess the cost-effectiveness of alternative regulatory strategies for reducing health risks of the California population, thereby achieving a more efficient allocation of scarce resources.

Recommendation:

B2. Cal/EPA should take greater advantage of the data from field studies of personal exposure for its risk assessments. Cal/EPA should compare its exposure model predictions with the actual exposures measured in these studies. Regulatory

programs are likely to benefit if Cal/EPA continues the progress it is making in conducting personal monitoring studies of the California population, either jointly with US EPA or on its own, and launches new studies for those pollutants for which exposure data are lacking.

II. Are Cal/EPA exposure assessment practices internally consistent?

Finding:

There is some variability in the practices within Cal/EPA; however, the differences may be appropriate. Some differences are historical and some are based on distinctions in the mandates that individual programs are required to implement.

Elaboration:

The activities of different branches of Cal/EPA are driven by different regulatory frameworks and distinct rational objectives. This leads to some difference in practice. For example, exposure pathways such as food chain and mother's milk are only considered in the Air Toxics "Hot Spots" analyses; however, if these pathways are unimportant for other programs, this may be appropriate. In addition, in the Air Toxics "Hot Spots" analysis, the actual exposures measured at the point of contact with humans are not given sufficient emphasis. Also, soil ingestion and food ingestion rates vary by program. However, consistency within or between these values should not be a priority until the scientific validity of any set of values is better established.

Finding:

It appears that certain parts of Cal/EPA collect important exposure data but other parts do not use it. For example, some excellent exposure data have been collected by the Indoor Exposure Assessment Section of the Air Resources Board (ARB), but other Cal/EPA offices do not seem to be aware of these data, or to be actively using these data in their risk assessments.

Elaboration:

At present, the greatest emphasis is on ambient monitoring, and, by comparison, relatively little monitoring is conducted on human exposure. Most air pollutant monitoring measures ambient air concentrations and not personal air exposures. Also, Cal/EPA seems to be doing relatively little monitoring of contaminants in food (concentrations in the food actually eaten) and in drinking water (concentrations in the water actually consumed by the population in their residences), although excellent data are being collected on the drinking water supply. Very few data exist on pesticides in prepared food. The ARB has joined with US EPA to conduct major TEAM field studies of volatile organic carbons (VOCs) and respirable particles in both southern and northern California. These studies have led to many new and important findings about the exposure of Californians (Clayton et al., 1993; Pellizzari et al., 1993a, 1993b, 1987b; Thomas et al., 1993; Wallace et al., 1988a).

Recommendation:

B3. 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 measured simultaneously in a single field study, making them especially appropriate for Cal/EPA's multimedia mission.

III. Are Cal/EPA exposure assessment methods based on sound scientific knowledge, methods and practices ?

Finding:

Overall, much of Cal/EPA exposure assessment methods are based on sound scientific knowledge, methods, and practices as allowed by statutory mandate and resources. The key is to keep up with the latest developments and to adopt new concepts and data sources as they become available. There are approaches such as those embodied in the TEAM and National Human Exposure Assessment Survey (NHEXAS) efforts, as well as tools and resources such as CalTOX and time-activity databases that are available and not always used.

Elaboration:

Exposure assessment is an iterative process subject to continuing refinement, improved information, and updated science; thus it is always valuable to consider whether collecting additional data or refining the approach to a problem is warranted. However, in the current realities of budget and mandate, reevaluation of approaches may be discouraged.

Recommendation:

B4. 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.

Finding:

Intake parameters for air and water are adequately understood and probably do not merit further study for exposure assessment. However, some important intake parameters in the dietary exposure calculations are seriously incorrect.

Elaboration:

Some important parameters in the dietary exposure calculations are based on intake data that are inappropriate for estimating distributions, high-end exposures, or the probability of being exposed. In addition, some parameters used in the calculations (such as proportion of home grown foods) are derived from such data using faulty assumptions. The values used by US EPA share the same defect.

Recommendation:

B5. Estimates of the distribution of individual's food consumption rates should be reexamined using data sets such as the 1987 or 1992 National Health Interview Survey (NHIS) and the National Health and Nutrition Examination Survey (NHANES) III food frequency questionnaire. Factors for proportion of home-grown vegetables and fruits or proportion of self-caught fish should be reexamined and alternative estimates derived or developed.

Appendix 5-1

Findings from Personal Exposure Monitoring Field Studies

Over the past two decades, many personal exposure field studies have been conducted by US EPA to measure the frequency distribution of exposures of populations using receptor-oriented approaches (Ott, 1985, 1990, 1995; Ott et al., 1986; Wallace, 1993a, 1993b, 1995). These studies have yielded findings with far-reaching implications for risk assessments and regulatory decisions. The Total Exposure Assessment Methodology (TEAM) studies, for example, used probability sampling to measure the exposures of a representative random sample of the population. These studies utilized small monitors and portable pumps, carried by respondents throughout a day, to measure actual exposures in the air that each person breathes. Also, for some pollutants, concentrations were measured in the water that people drink and in the food they eat. For other pollutants, dermal exposure was measured using skin patches and other techniques. Finally, in many cases, measurement of "body burden" was included, such as measurement of pollutant concentrations in the blood or urine.

The objective of a TEAM study is to characterize, with known accuracy, the full frequency distribution across the population of the exposures to a pollutant, or group of pollutants, and to determine the sources responsible for these exposures. Because respondents are selected according to a statistically representative sampling plan, it is possible to make inferences from the resulting exposure data in a relatively small survey sample size (e.g., about 1000 persons) about the exposures of the larger population from which the sample is drawn. In summary, the TEAM studies have the following characteristics previously not associated with conventional ambient or microenvironmental monitoring data:

- Statistically designed representative population sample.
- Measurement using a personal monitor of the pollutant concentrations in the air breathed by each person.
- Measurement of the pollutant concentration in the food eaten by that person.
- Measurement of the pollutant concentration in the water drunk by that person.
- Measurement of the pollutant concentration contacting the person's skin, where appropriate.
- Measurement of the body burden using the pollutant concentration in the breath, blood, or urine.

TEAM studies have been conducted in over a dozen cities throughout the US (including California) and Canada. In addition to the TEAM studies conducted by US EPA as part of its research and monitoring programs, the agency now requires private companies to conduct TEAM studies under its fuels/fuels additive program and to

provide the exposure data to the agency so it can conduct a risk assessment. The published TEAM studies have provided representative data on the exposures of more than 3 million people in 7 states, and past studies include pollutants such as carbon monoxide (Johnson, 1983; Hartwell et al., 1984; Akland et al., 1985), volatile organic compounds, including many toxic pollutants (Wallace, 1987, 1990a, 1991b, 1993a, 1993b, 1993c, 1995; Wallace and O'Neill, 1987; Wallace et al., 1982, 1984, 1985, 1986, 1987a, 1987b, 1987c, 1988, 1989; Pellizzari et al., 1987a, 1987b; Zweidinger et al., 1982), respirable particles, including particle-bound organics and metals (Clayton et al., 1993; Ozkaynak et al., 1993; Pellizzari et al., 1993a, 1993b; Thomas et al., 1993), and pesticides found in nonoccupational settings (Immerman et al., 1990; Whitmore et al., 1994). Many of the pollutants covered in the TEAM studies coincide with those found on California's list of carcinogens and reproductive toxicants under Proposition 65 (Ott, 1995). The findings from these studies show that the chief sources of exposure to toxic chemicals experienced by Californians include consumer products, personal activities, and building materials — not the traditional sources that are the primary emphasis of current regulations, such as point source emissions, underground storage tanks, and hazardous waste sites.

Comparative risk analyses based on these and similar exposure data (Smith, 1988a, 1988b, 1993, 1994) suggest that some conventional regulatory approaches have large costs but relatively little benefit in reducing risks, while other low-cost alternatives have great potential for reducing risks but are not adequately emphasized. For example, less than 3% of the population exposure to benzene in Contra Costa county is attributable to industrial point sources (Pellizzari et al., 1987a; Wallace, 1989, 1990b; Wallace et al., 1986, 1988). Many of the toxic pollutants monitored in these population field studies are on the Superfund list, but the principal causes of Californians' exposures to these chemicals are consumer products and not hazardous waste sites (Wallace, 1986, 1991a, 1993a, 1995). For example, most of the exposure to tetrachloroethylene caused by dry cleaners comes from clothes that people take home with them and relatively little exposure comes from air transport from dry cleaners to surrounding neighborhoods (Wallace et al., 1989). As noted by the NAS report on human exposure, "The findings of TEAM are at odds with conventional approaches used to control VOC exposure. Therefore a major rethinking of the approaches used to identify public health risk is warranted" (NAS, 1991).

The findings from field studies of total human exposure, in general, do not agree with exposure estimates made by fate and transport models, which ignore a whole range of ubiquitous toxic pollutant sources found in everyday life (Sheldon et al., 1988a, 1988b; Thomas et al., 1993; Vorhees et al., 1995; Wallace, 1991a, 1996; Wallace et al., 1986, 1987a, 1987b; Wilson et al., 1993a, 1993b, 1994, 1995) and sources found in common consumer products (Sack et al., 1992; Wallace et al., 1991; Westat, Inc., 1987).

Appendix 5-2

Models Specifically Designed to Predict Human Exposure

Since the early 1980's several receptor-oriented exposure models have been developed by US EPA and others. These new "human activity pattern/exposure" models consider these key factors: (1) all the sources of pollutants actually making contact with people — both indoors and outdoors; and (2) human activity patterns — the locations people visit and the activities in which they engage. Although these models are designed to predict actual exposures by combining measured concentrations with observed activity patterns of humans, the tools and methods for population exposure assessment for toxic air contaminants and particles still require substantial development.

Exposure models currently in development or validation include the Simulation of Human Activity Patterns and Exposure (SHAPE) model developed by US EPA (Ott, 1984; Ott et al., 1988, 1992), the Total Human Exposure Model developed for the San Francisco Bay Area (Klepeis, et al., 1994), the Regional Human Exposure Model (REHEX) developed for the South Coast Air Quality Management District and Bay Area Air Quality Management District (Lurmann and Korc, 1994), and other ozone models (Johnson, 1995). These models account for the times people spend in each microenvironment, based on diary data such as the California Activity Pattern Survey, a study of the activity patterns of a representative sample of 1579 California adults, supported by the ARB (Wiley et al., 1991; Jenkins et al., 1992).

The SHAPE model has been validated using data from a large-scale personal monitoring field study of more than 1200 persons in Denver and Washington, DC (Akland et al., 1985; Ott et al., 1986). The REHEX model is still in the process of being validated, in part through a large ARB-sponsored epidemiology study (Peters, 1995). Both the SHAPE and REHEX models were designed for estimating exposure to criteria pollutants, and would require additional development and validation prior to use for toxic air contaminants, for which long-term exposures and effects are of concern.

Existing fate and transport models are generally not suitable for, nor were they designed for predicting human exposures, because these models do not include indoor air quality. The California Activity Pattern Survey found that Californians, on the average, spend 98 minutes per day in a vehicle and 1256 minutes indoors (at home, work, stores, and restaurants), with only 86 minutes, or 6% of the day, spent outdoors (Jenkins et al., 1992). In addition to the large amount of time spent indoors, indoor air quality field studies consistently reveal that indoor pollutant concentrations differ markedly from those measured outdoors for a large number of pollutants (Ott, 1995). With the notable exceptions of ozone and sulfur dioxide, nearly all pollutants, especially toxic air contaminants, have significant indoor sources. The newer human exposure models are designed to include these indoor sources, either by incorporating stochastic indoor exposure variables based on indoor field measurements or by using a mass-balance

equation in combination with known indoor source strengths. The models also include processes that modify pollutants as they infiltrate indoors or interact with indoor surfaces. These new models are designed to predict the same types of population exposure frequency distributions that have been measured in the TEAM personal exposure monitoring field studies. Once validated, the models also allow assessment of the effect on exposures and risks of controlling different sources.

Although the ARB has made substantial progress in developing a human activity pattern/exposure model for indoor applications, Cal/EPA's overall modeling activities continue to emphasize source-oriented fate and transport models. Cal/EPA would benefit from a more balanced approach to exposure modeling, with more emphasis given to receptor-oriented exposure models.

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6

Exposure Assessment 2: Contaminant Fate and Transport

Introduction

Chapter 5 focused on exposure assessment from a perspective that begins with a human receptor. In this chapter, a complementary perspective is adopted for assessing exposure. This perspective begins either with the release of a contaminant into the environment or the observation that contamination is present at some sites. The assessor then seeks to understand how human exposure is influenced by the transport and transformation of these contaminants from the source location to a receptor. Exposure assessments conducted from this perspective are essential to support decisions for permitting of environmental contaminant releases and to define appropriate restoration criteria at contaminated sites. Effective contaminant fate and transport evaluations utilize both experimental monitoring data and mathematical models. Monitoring data are used to test or calibrate models. Properly validated models are used to predict concentrations at points in time and space that are not, or cannot be, measured.

The expert panel charged with writing this chapter was comprised of seven scientists: William Nazaroff (lead), University of California, Berkeley; Stephen Brown, Risks of Radiation and Chemical Compounds; Steve Gorelick, Stanford University; Andre Journel, Stanford University; Kent Udell, University of California, Berkeley; Akula Venkatram, University of California, Riverside; and William Yeh, University of California, Los Angeles. Dr. James Seiber served as liaison from the core group of the Risk Assessment Advisory Committee (Committee) and as chapter reviewer.

To support the panel's review, a briefing book was prepared by California Environmental Protection Agency (Cal/EPA) staff and distributed to expert panel members and other Committee members to provide background information on contaminant fate and transport modeling and monitoring as practiced by Cal/EPA. Some of the background information available to the Committee is summarized in Appendix D.

The panel's review was organized around three sessions that focused on contaminant fate and transport in (a) groundwater, vadose zone and surface water, (b) air, and (c) systems involving inter-media transfer. The expert panel, the Core Committee, and other attending Committee members heard presentations from Cal/EPA staff, US Environmental Protection Agency (US EPA) Region IX staff, and environmental consultants. They all participated in the discussion as did members of the public. The agenda for the review meeting is reproduced in Appendix F.

Some of the conclusions that emerged from the panel's review address issues in specific media. Others cut across media boundaries. The panel's findings and recommendations are, therefore, presented in four subsections: a) General Fate and Transport Issues; b) Fate and Transport in Groundwater, Vadose Zone and Surface Water; c) Fate and Transport in Air; and d) Inter-Media Fate and Transport. Several general issues were identified that have significance beyond the boundaries of fate and transport assessments. In that sense, some of the points raised in this chapter echo findings and recommendations presented elsewhere in this report.

Findings and Recommendations

A. General Fate and Transport Issues

Findings

Fate and transport evaluations are performed by several boards and departments of Cal/EPA. Often, the primary purpose is not for human exposure assessment, but rather to support engineering design or risk management decisions. In general, but with a few exceptions, fate and transport assessments are not well integrated with human exposure assessments in Cal/EPA.

There are inconsistencies within Cal/EPA in how boards and departments view their roles and responsibilities with respect to the modeling of contaminant fate and transport. Some parts of Cal/EPA, such as the State Water Resources Control Board (SWRCB), are reactive, responding primarily to what is presented to them by the regulated community. For example, the SWRCB does not perceive that it has a responsibility to guide model development. Other parts of Cal/EPA have been more proactive. For example, the Air Resources Board (ARB), through the California Air Pollution Control Officers Association (CAPCOA) guidelines, provides modeling guidance to the regulated community. The Department of Toxic Substances Control (DTSC) has asserted a strong leadership role in fate and transport modeling by supporting the development of CalTOX. Fundamental reasons for these differences in approach were not apparent to the expert panel.

The apparent internal divisions within Cal/EPA are problematic for ensuring that fate and transport issues are addressed in ways that lead to consistently sound, well-integrated human exposure assessments. To a large degree, Cal/EPA staff are sorted among boards and departments by intellectual discipline, and the boards and departments are not well integrated within the Agency. Examples of well-integrated assessments (the Telone investigation) were presented to the Committee; however, such examples do not appear to be the norm.

Much of the fate and transport effort within the media-specific boards (SWRCB and ARB) is for ad hoc risk management rather than for exposure assessment and risk assessment. The SWRCB emphasizes the protection of groundwater as a resource and uses fate and transport assessments to ensure that the water quality criteria will be met. This approach can ensure environmental health protection, provided that all important exposure pathways are considered. It may not be the most efficient means to achieve that end.

Thus, there is a gap between Cal/EPA activities undertaken for the purpose of risk assessment, where the immediate aim is protecting human health, and the activities that focus on the protection of environmental media. The panel heard presentations pertaining to fate and transport of contaminants in subsurface environments in which the direct intent is to protect groundwater as an environmental resource. These activities do not focus on protecting human health, although the objectives overlap. The data and information that are collected may be useful for predicting concentrations of contaminants in groundwater but are less useful in predicting human exposure, especially via pathways other than groundwater ingestion. Consider, for example, a site with vadose zone contamination. When discovered, the responsible party does an assessment, presents the results to a Regional Water Quality Control Board (RWQCB), applies for a permit, negotiates cleanup levels, etc. Although other parts of Cal/EPA may be consulted regarding other pathways of exposure, it is not clear that adequate expertise is applied to accurately assess contaminant fate and transport by all important exposure pathways other than via groundwater contamination.

Considering the broad problem of environmental pollution from a public health perspective, point sources are not the only causes of exposure and, for some substances, may be only minor contributors to total exposure for a typical person. Furthermore, as society continues to regulate point-source emissions, they will diminish in importance as a contributor to total exposure. To understand environmental risks to human health, we need to know the distribution of aggregate exposures to all toxic substances from all sources by all routes. While Cal/EPA can regulate only those sources and routes within its authority, it could do a better job of placing proposed regulations in context by characterizing other sources and routes of exposure to toxic substances. Society could then more easily judge whether different approaches, including nonregulatory ones, might better serve the goal of protecting human health.

The response of DTSC to the need to examine exposure holistically is embodied in the CalTOX modeling framework. This multimedia, multipathway model incorporates stochastic features, and, commendably, has been subjected to a high degree of outside peer evaluation. However, the CalTOX framework constitutes only part of what would be classified as fate and transport modeling. It uses a fugacity approach that treats each contaminant within each environmental medium as homogeneously distributed. Transport between media and transformation processes are explicitly addressed, but CalTOX is not configured to determine the spatial heterogeneity of concentrations within a single environmental medium.

Cal/EPA reviews a very large number of individual site assessments that involve some aspects of fate and transport evaluation. With this large throughput, it is important to have systems in place to ensure consistency. Current Cal/EPA practices do not appear to be structured in any formal way.

The level of expertise within Cal/EPA in the area of fate and transport assessment is sporadic. Some staff are knowledgeable about groundwater models, vadose zone models, surface water models and atmospheric fate and transport models. However, many staff are not well versed in these areas and more training would be very useful. As budgets and resources have decreased, the training function within Cal/EPA has decreased by grave proportion.

Cal/EPA does not regularly use stochastic analysis or stochastic modeling to evaluate uncertainty in their risk assessment, whether air, water, or soil. Rough, order of magnitude error intervals may be given *a posteriori*, based on experience. They are not forward calculated through a rigorous stochastic analysis, i.e., transfer of uncertainty from input data and model parameters to the output response. CalTOX is a notable exception, but only recently developed, and not yet regularly used. The Agency does not appear to have rigid barriers that preclude stochastic modeling by the regulated community. However, with the exception of its efforts in developing CalTOX, neither does it appear to be encouraging stochastic approaches.

Apart from CalTOX, transformation processes are not well captured in current fate and transport assessments. Chemical degradation products can be generated from the release of primary pollutants. Examples include photolytic reactions in the atmosphere and degradation of chlorinated solvents in subsurface environments. The products of environmental transformations may be more hazardous than the originally released compound. The potential for human exposure to toxic degradation products is largely ignored in current Cal/EPA practice.

Recommendations on General Fate and Transport Issues

A1. Reexamine alignment of practice with mission

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.

A2. Apply central leadership to reduce inconsistencies within the Agency

Judicious exercise of strong central leadership within Cal/EPA is recommended to help eliminate inconsistencies and improve public relations. To this expert panel,

Cal/EPA appears to be an accretion of boards and departments that suffers from a lack of integrated management at the Agency level. From the perspective of the regulated community and the public, the Agency is highly heterogeneous.

A3. Assert leadership in setting and maintaining high modeling standards.

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 keep 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.

A4. Ensure adequate systems are in place for reviewing exposure assessments

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.

A5. Provide for continuing education of staff

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 one or more of the following mechanisms to promote continuous education of its staff:

- a systematic two-way temporary staff exchange program between Cal/EPA and academia and/or industry where advanced expertise exists;
- creating a forum within Cal/EPA to disseminate expertise in contaminant fate-and-transport issues;
- instituting procedures to ensure that individual project staff are knowledgeable; making sure that people working on the front lines understand the use of fate and transport models and how to support the regulated community's proper use of those models;
- implementing seminar programs;

- providing for staff attendance at national or regional meetings on a periodic basis; and
- organizing a group of academics coached by communications experts to teach the front-line staff about tools and techniques in fate and transport assessment.

A6. Promote model validation

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.

A7. Explore greater use of stochastic approaches

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 (Keith, 1988). 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.

A8. Incorporate degradation products in fate and transport assessments

Cal/EPA should work towards incorporating chemical breakdown schemes and focus on products of reaction as it further develops its modeling capability.

B. Fate and Transport in Groundwater, Vadose Zone, and Surface Water

Findings

There are two processes, driven by two groups within Cal/EPA with two different statutory authorities, that occur at most sites for determining what needs to be done in the way of remediation. DTSC and the Office of Environmental Health Hazard Assessment (OEHHA) are involved in multimedia assessments to determine whether people's health is directly threatened and then to discern appropriate action. The SWRCB and RWQCBs try to ensure compliance with water quality standards. These activities are not well coordinated.

In DTSC efforts, groundwater modeling is not widely used; rather, assessments tend to be based on a distribution of measurement results taken at a site.

Bodies of water are assigned beneficial uses by the SWRCB and RWQCBs based on the capability of that resource to supply the beneficial use. Water quality objectives are assigned to those bodies of water. The water quality objectives are either narrative or numerical limits that are required to be met so that the body of water can support the designated use. Current groundwater law in California provides no state-wide control over whether someone can install a well and extract groundwater for use as potable

water. The regulatory system is therefore designed to protect that potential use of groundwater. If vadose zone contamination is discovered, Cal/EPA seeks to know: will our water quality objectives be met at the site if we allow a certain amount of pollution to remain in the vadose zone? Risk assessment is conducted from the perspective of risk to the resource, and the health of the resource is measured by compliance with the water quality objectives.

The SWRCB, within Cal/EPA, has an oversight role for all of the regional boards. A decision that is made by a regional board can be appealed to the SWRCB for review. The SWRCB provides regulations that the regional boards follow. The general policies for water quality control are also provided by the SWRCB along with guidance materials to implement those policies.

The SWRCB and RWQCBs system has no regulatory requirements for model development, model application or model evaluation. The SWRCB and RWQCBs do not develop fate and transport models, nor do they directly use them; however, they are involved in the evaluation of model applications. Furthermore, Cal/EPA has prepared and issued a document titled *Ground Water Modeling for Hydrogeologic Characterization* (Cal/EPA, 1994) that provides some guidance to the regulated community on groundwater modeling applications.

The regional boards place the responsibility on a permit applicant to define a rationale that will justify that water quality standards are being met as a result of the applicant's discharge of waste. In the regulator's view, it is the job of the responsible parties to discern the best available science and bring it to the regional boards for review. Typically, a responsible party hires consultants from the environmental industry who propose models to the regional board. Statutorily, the SWRCB and regional boards are not allowed to specify how one must comply. Instead, the manner of compliance is proposed to the RWQCBs by the responsible party (or their consultants) for review.

In the groundwater area, about 90 percent or more of the applications presented to the SWRCB and RWQCBs only consider groundwater transport (as opposed to fate and transport of contaminants). A primary use for these models is to support the design of remedial measures involving pump-and-treat technologies. The focus has been on hydraulic capture of a contaminant plume. In the future, fate and transport modeling is likely to become more important because pump-and-treat measures will not be as uniformly used at contaminated sites. There is essentially no stochastic modeling, including Monte Carlo simulation and sensitivity analysis, in groundwater applications presented to the SWRCB and RWQCBs.

The experience of the SWRCB and RWQCBs, based on monitoring data, has shown that in many instances estimates based on vadose models are quite inaccurate. It may be that poor performance of vadose zone models is related to continued use of simple models that are inappropriate for the complex parameters found within the vadose zone (Hern and Melancon, 1986; Stephens, 1996). The expert panel believes that models

that are applied in other areas of research or commerce, such as the petroleum industry, may have utility in vadose zone modeling in areas such as the Central Valley. Highly nonhomogeneous porous media with preferential flow paths are routinely described in flow simulations for predicting the requisite time involved to recover oil. This is in stark contrast with the examples presented to the panel where the vadose zone was modeled as a homogeneous medium, or, at best, a layered system.

There also appears to be an inconsistency in the way vadose zone modeling and groundwater modeling are done in the crucial component of calibration. Vadose zone models can be calibrated through the use of a soil venting experiment; however, this opportunity does not appear to be practiced.

Thus, fate and transport modeling for groundwater, the vadose zone, and surface water contamination is not well coordinated with exposure and risk assessment within Cal/EPA. There are evident gaps in communication between engineers and geologists who focus on fate and transport and risk assessors and toxicologists who focus on exposure and health effects.

Is Cal/EPA consistent with US EPA?

From the evidence presented to the expert panel, there is little reason to suspect that Cal/EPA is inconsistent with US EPA in any major regard. Both agencies allow considerable leeway to the groundwater modeler in choosing an appropriate model and input parameters. Both provide methods for evaluating different models for different purposes. Cal/EPA itself has apparently not developed nor sponsored the development of new groundwater models. US EPA has undertaken or sponsored development of groundwater models, many of which are accepted by Cal/EPA under appropriate conditions. Assignment of staff responsibilities within the US EPA for specific sites under Resources Conservation and Recovery Act (RCRA) and Superfund is managed in a similar fashion as within Cal/EPA.

Are Cal/EPA contaminant fate and transport evaluation practices internally consistent?

The expert panel heard some evidence that different RWQCBs might give different advice to modelers under similar conditions, but to the extent that this occurs, it does not appear to be due to Cal/EPA policies. From the evidence presented to the expert panel, there is little reason to suspect that different policies on groundwater modeling are in place in different parts of Cal/EPA. This conclusion is tempered by the relatively narrow scope of the material reviewed, which focused more on general policies than on specific examples. Moreover, the presentation on models of fate and transport in the vadose zone suggested that little guidance has issued from Cal/EPA on this subject other than a general distrust of the conclusions from such models. This lack of guidance could result in different practices among the Cal/EPA boards and departments, but no specific evidence of such discrepancies was presented.

Are Cal/EPA contaminant fate and transport evaluation practices based on sound scientific knowledge, methods, and practices?

Many of the models that are acceptable to Cal/EPA are generally accepted as reasonable for appropriate purposes and are widely used in the scientific community. However, Cal/EPA does not appear to be aware of some of the leading edge modeling techniques available and some of these may be superior in performance to the models routinely used. There does not seem to be any strong incentive for modelers to use these near-leading edge techniques. Moreover, by Cal/EPA's own assessment, the models are not routinely used for risk assessment as opposed to remedial design or compliance assessment, which may pose problems when groundwater models are needed to predict the concentration of chemicals in drinking water over time at various locations. The characterization of reliability and uncertainty in groundwater model results is largely qualitative, which prevents a risk assessor from using stochastic model outputs as inputs to a stochastic risk assessment and prevents risk managers from understanding as well as they should the degree of reliance they should place on the model results and risk calculations stemming from them.

Recommendations on Fate and Transport in Groundwater, Vadose Zone and Surface Water

B1. Improve knowledge of groundwater modeling

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.

B2. Assert leadership in catalyzing development and use of vadose zone models

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 to 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.

B3. Develop guidance for uncertainty characterization

Cal/EPA should develop guidance for modelers on how to provide uncertainty characterizations that are sufficiently quantitative to permit good risk management decisions.

B4. Explore applications of stochastic methods

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.

B5. Couple monitoring data with modeling efforts for validation

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.

C. Fate and Transport in Air

Findings

The manual and the exposure assessment model used in the Air Toxics "Hot Spots" program, a joint effort of ARB and OEHHA, was prepared by CAPCOA in conjunction with ARB and OEHHA. In this program, facilities that manufacture, formulate, use, or emit a listed substance, or emit any substance which reacts to form a listed substance, that is routinely released to the air are required to conduct an emissions inventory and report it to the local air pollution control district (APCD). The local district prioritizes facilities into high, medium, and low concern categories, based on the toxicity of emissions, the quantity of emissions, and the proximity of receptors. Facilities in the "high concern" category must conduct a risk assessment using the CAPCOA manual to estimate public health impacts for their air toxic emissions. The district is responsible for setting the "significant risk level." When the results of the risk assessment indicate that the facility poses either a cancer risk or a noncancer hazard above the significant risk level, the facility is required to notify the affected public of the risk posed by facility emissions. In addition, if a facility exceeds either that significant risk level, or a separately designated one, depending on the district, then the facility must prepare a risk reduction audit to reduce their emissions. OEHHA reviews all risk assessments conducted under the Air Toxics "Hot Spots" program across the State (approximately 800 over the past several years).

Air dispersion modeling using a Gaussian plume formulation is the workhorse for air pollutant fate and transport models. Cal/EPA recommends the use of the Industrial Source Complex (ISC) model, or its equivalent, for permitting emission sources by local air districts. The ISC model is also recommended by US EPA. The ISC model incorporates a dispersion scheme developed by Pasquill in 1961. The dispersion parameters used in this scheme are based on experiments conducted above uniform flat terrain in Nebraska in 1956. These experiments only involved releases close to the ground surface and so the dispersion parameters do not necessarily apply to elevated releases.

Emission estimates are frequently based on a US EPA guidance document, AP-42. These emission factors were originally developed for the purposes of emission inventories, rather than for risk assessment.

More sophisticated fate and transport models, such as the Urban Airshed Model, are widely used for the development of State Implementation Plans for criteria pollutants, such as ozone. These models are typically not used for exposure and risk assessments. Likewise, dispersion models for complex terrain are not widely used because of data requirements.

Is Cal/EPA consistent with US EPA?

From the evidence presented to the expert panel, there is little reason to suspect that Cal/EPA is inconsistent with US EPA in any major respect. Most of the models recommended by Cal/EPA are from the list of acceptable US EPA models for the appropriate purposes. Both Cal/EPA and US EPA are continuing to support the development of improved air quality models over a range of scales. US EPA appears to be more active than Cal/EPA in developing methods and information needed for evaluating fate and transport in unconventional applications such as for indoor air quality.

Are Cal/EPA contaminant fate and transport evaluation practices internally consistent?

There was some suggestion that different air quality management districts in California might give different advice to air modelers under similar conditions. As these districts are not part of Cal/EPA, these differences are largely beyond its control unless it chooses to be very prescriptive in its own recommendations, which this panel does not recommend. From the evidence presented to the panel, there is little reason to suspect that the several departments within Cal/EPA that themselves do or review air modeling are inconsistent, especially with respect to conventional models for stationary sources. There may be some inconsistency between the Cal/EPA boards and departments in their treatment of unconventional model situations. For example, some risk assessments may use a simple box model for volatile emissions from soil, whereas others may use a dispersion model with an area source term.

Are Cal/EPA contaminant fate and transport evaluation practices based on sound scientific knowledge, methods, and practices?

Most, if not all, of the models that are acceptable to Cal/EPA are generally accepted as reasonable for appropriate purposes and are widely used in the scientific community. However, Cal/EPA does not appear to be aware of some of the leading edge modeling techniques available and some of these may be superior in performance to the models routinely used. At present, there does not seem to be any strong incentive for modelers to push for use of these leading-edge models; in fact, one member of the regulated community suggested that there were significant disincentives for them to use newer models, because permitting agencies might well preferentially accept modeling runs that showed higher risks and reject runs that showed lower risks than the conventional models. This statement assumes that new models will estimate lower risks

and older models will predict higher risks. However, this may or may not be true since the data are not available to substantiate the statement. The characterization of reliability and uncertainty in air model results is largely qualitative, limiting the ability of risk assessors to use stochastic model outputs for exposure as inputs to a stochastic risk assessment; these qualitative characterizations also prevent risk managers from understanding as well as they should the degree of reliance they should place on the model results and risk calculations stemming from them. The evidence presented was insufficient to determine whether Cal/EPA uses sound science in unconventional air quality modeling. For example, indoor air is often modeled as a simple, well-mixed box with a source term and an air-exchange rate. Alternative models have been developed that consider multiple compartments with different source terms, varying rates of air exchange among compartments, complex pollutant interactions with other pollutants and with surfaces and so on (Nazaroff and Cass, 1987 and 1989; Tichenor et al., 1991).

Recommendations on Fate and Transport in Air

C1. Reassess validity of current fate and transport models

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 determinations 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.

C2. Increase knowledge of developments in air quality modeling

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 recommendation 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 one of 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.

D. Inter-media Fate and Transport

Findings

Is Cal/EPA consistent with US EPA?

There are substantial inconsistencies between Cal/EPA and US EPA in their treatment of inter-media fate and transport and its influence on risk assessment for multimedia exposures. Some are due to fundamental differences in enabling legislation, such as in air programs, where US EPA regulates toxic air contaminants with technology-based rules, while Cal/EPA uses risk-based rules. Nevertheless, even before the Clean Air Act Amendments of 1990, when US EPA was issuing risk-based National Emissions Standards for Hazardous Air Pollutants, it considered only the inhalation pathway; the ARB, through CAPCOA, was already considering multimedia assessment including, ingestion of soil, vegetables, meat, and mother's milk as well as dermal exposure to soil. As another example, while US EPA Superfund guidance is echoed in some of the DTSC guidance for multimedia exposures to contaminants in soil (e.g., parts of the Preliminary Endangerment Assessment [PEA] guidance), the new CalTOX model uses a different conceptual framework. In many cases, Cal/EPA is more advanced than US EPA in the sense of considering more pathways with better models. This may not be true in the area of the RCRA guidelines for boilers and industrial furnaces. Cal/EPA also sometimes uses different parameter values in otherwise similar models for inter-media exchanges.

Are Cal/EPA contaminant fate and transport evaluation practices internally consistent?

Although presentations to the expert panel focused mainly on procedures in the air and hazardous waste programs, the evidence available does suggest inconsistencies among the programs within Cal/EPA. Some of these differences stem from differences in what the programs are attempting to accomplish, while others stem from differences in the medium into which chemicals are initially released. For example, the pathways considered in the CAPCOA guidelines are different from those considered in the PEA guidance, largely because transfers out of soil are emphasized in the latter and transfers out of air in the former. CalTOX in some ways accounts for both sets of pathways, although it too is different from either. In the Department of Pesticide Regulation, inter-media transfers are assessed through use of historical measurements and scaling procedures rather than by mathematical models, as in most of the other programs. This difference is partly explained by the different regulatory context and partly by historical preference.

Are Cal/EPA contaminant fate and transport evaluation practices based on sound scientific knowledge, methods, and practices?

The general state of science regarding inter-media fate and transfer of environmental contaminants is not well developed, and the use of science in Cal/EPA risk assessments suffers accordingly. There is little evidence to suggest that Cal/EPA is substantially behind the state-of-practice in inter-media modeling, and CalTOX (if properly used) may approach the state-of-the-art, especially if some further attempts are made to validate and calibrate it with observed data. On the other hand, some of Cal/EPA's models still use an infinite or nondepleting source assumption, which can lead to substantial, occasionally absurd overestimates of risk. As with many other areas of risk assessment, the best of Cal/EPA's multimedia assessments may be near the state-of-the-art, while many of the routine assessments may fall well short. The CAPCOA multimedia equations are substantially conservative and lead to predictions that sometimes do not seem realistic based on qualitative judgments, for example when indirect pathways such as dermal absorption from soil or ingestion of locally grown vegetables dominate the assessment by large margins, when intuition suggests that the direct inhalation pathway should be more important. No formal system for self-evaluation or dissemination of good science within Cal/EPA was evident from the information available to the expert panel.

Recommendations on Inter-Media Fate and Transport

D1. Focus on inter-media fate and transport

Cal/EPA is advised to make surveillance of developments in the science of inter-media 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.

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7

Variability, Uncertainty, and Risk Characterization

Introduction

This chapter deals with two different topics, related by the fact that in risk assessment report documents, discussion of variability and uncertainty is usually part of the "risk characterization" section. That section normally can be found at the end of these reports. However, attention needs be paid to how results will be characterized very early in the process of doing a risk assessment, almost as soon as the problem to be evaluated has been identified (NRC, 1996). Similarly, early attention needs to be paid to how to deal with issues of uncertainty and variability in the information on which an assessment depends. Thus the meeting of the Expert Panel convened to deal with these two issues occurred early in the Risk Assessment Advisory Committee (Committee) process.

Risk assessors use the term "variability" to describe measurable quantities that cannot be characterized by a single number, such as the height of some group of people. The height of any one person, in this example, probably will not represent that of any other person, except by accident. We use statistics to help select appropriate representative quantities when it is necessary to draw mathematical conclusions in which the properties of groups or populations are important to a decision. We use the term "uncertainty" to denote ignorance of the true value of some measurable quantity or other ascertainable "state of nature," including such things as which theory best describes some natural phenomenon. We use basically the same statistics to help describe the consequences of our ignorance for decision makers. These two conceptually different notions often blend into each other in practice, and one theory of knowledge holds that for the kinds of purposes this study addresses, the two are the same. Because both real variability and ignorance primarily act to affect the risk assessors' confidence in conclusions they may draw and recommendations they may make about courses of action, and because uncertainty and variability are treated by the same kind of mathematics, the "walks like a duck" principle implies that they be considered the same. Nonetheless it is useful for risk assessors to attend to the difference between uncertainty and variability: at least in principle, uncertainty can be reduced by obtaining more information while variability is irreducible.

Risk characterization includes much more than a discussion of uncertainty and variability, however. The National Academy of Sciences (NAS) Committee on Risk Characterization described this activity with the following passage.

> "Risk characterization is a synthesis and summary of information about a potentially hazardous situation that addresses the needs and interests of decision makers and of interested and affected parties. Risk characterization is a prelude to decision making and depends on an iterative, analytic-deliberative process." (NRC, 1996)

Clearly implied by this definition is the notion that the characterization of risk assessment results must include all the information necessary for decision makers and those interested in or affected by the decision to understand how and why conclusions were drawn. This demands, first, a clear statement of these conclusions, appropriate contextual information, and a description of the limitations on the reliability of those conclusions. Uncertainty about and variability in input data most often affect, or are the cause of, these limitations.

Because uncertainty and variability affect the reliability of risk assessment conclusions, risk assessors must attend to these throughout the assessment process so that they may be able to understand how they limit conclusions and then communicate those limits.

Risk assessors also need to attend to the demands of the characterization from the first in order to collect the information that will be needed, not just for the analysis itself but also for placing results and conclusions in an understandable context and in communicating the extent to which these conclusions provide a basis for selecting among decision options.

Conventionally, the information presented to decision makers consists of a predicted level of exposure compared with one considered safe, i.e., causing no harm in essentially all the population of the US. For some laws, such as those covering food additives, this requirement is absolute: exposures less than the standard are permitted, exposures greater than it are prohibited. Similarly, Proposition 65 requires a warning of those exposed to levels deemed to be significant (e.g., those resulting in cancer risks greater than 1 in 100,000). Other laws, such as drinking water standards under the Safe Drinking Water Act, permissible exposure limits under the Occupational Safety and Health Act, National Ambient Air Quality Standards under the Clean Air Act, and clean-ups under Superfund, allow this absolute requirement to be tempered by considerations of technical feasibility or other values. Decisions of this latter kind, which are often reached by a balancing of sometimes conflicting objectives, require more information from a risk assessment than do those in which the requirement for safety is absolute. However, conventional risk assessments seldom provide all the necessary information. For instance, they do not usually provide any indication of the likelihood harm will occur if there are exposures just above the safety levels. Not having this information makes it difficult to weigh risks against values such as economic livelihood, disruption of

neighborhoods, and so on. As a result, heavy burdens may unnecessarily be placed on California industry, citizens may feel shut out of negotiations over clean-up strategies, etc. Furthermore, the conventional focus on finding a single safe level leads to neglect of information on how someone may be harmed, were exposure above that level to occur. Since many standards are set based on avoiding cancer, it appears to non-experts that other kinds of possible harm are ignored.

Finally, as the recent NAS, National Research Council report, *Understanding Risk: Informing Decisions in a Democracy* suggests, assessors need to understand who will be the audience for their conclusions and any recommendations they may make. The nature of the audience shapes the characterization. For decisions that the public has essentially completely delegated to technically-trained regulatory agency personnel, a useful characterization may be quite brief and written in technical language; the conventional means of characterizing the results of risk assessment focuses on communicating to experts. These practices evolved from those developed by the Food and Drug Administration and its sister agencies worldwide to deal with synthetic food additives. Decisions on approving such additives are made by highly technically trained government employees, and so the profession grew up with simple characterization heavily dependent on scientific jargon. However, if members of the public will be intimately involved in the decision process, as is often the case with waste sites, the characterization must be comprehensive and written in language accessible to those lacking technical training. The National Research Council study suggests that risk assessments and their characterizations need to be structured by the decisions to be made; those in which the public plays an important role must differ from those in which decisions have actually been entrusted to a technical elite, so non-experts potentially affected by decisions do not feel shut out. This chapter includes some recommendations intended to address this problem.

Formal "Guidelines" have proved to be a means of effectively communicating both typical and standardized practices of risk assessors to interested and affected parties. As noted in the listing of guidance documents in Chapter 2, the California Environment Protection Agency (Cal/EPA) makes use of a variety of different kinds of guidance documents, and had several in preparation at the time this report was written. Many of the recommendations considered by this Expert Panel focus on guidelines, in one way or another. We have departed from the format of other chapters in addressing guidance separately from other issues, even though it was not an advertised topic of the meeting from which emanated most of the findings and recommendations reported here.

Risk assessments organize and interpret technical information so that it might be used by decision makers. The risks considered here are those which deal with threats to public health. Public health officials may or may not have an independent interest in the sometimes arcane science used to inform their decisions, but they must make decisions whether they have such an interest or not. In this chapter we present a number of findings and recommendations whose intent is to ease the making of decisions and improve their effectiveness. Many of these findings and recommendations focus on

technical details of understanding the important qualities of variability in the human population and uncertainty in our knowledge about ourselves. Yet no one should conclude from this focus that we advocate indeterminate and interminable analysis. The scope of analyses should comport with the needs of whatever decision(s) it is intended to support. Our object, all sublime, is to let the risk assessment fit the people's needs.

Principal Observations and Recommendations

Stepping back from the details in this chapter, our broad observations are these:

- The procedures and practices of Cal/EPA are quite comparable to those of the US Environmental Protection Agency (US EPA), with the outstanding differences generally attributable to differences in the laws implemented by the two agencies.

- Both agencies' risk characterization practices fall somewhat short of what the profession now considers good practice; we believe that Cal/EPA is moving tolerably quickly to improve their practices.

- Many of the most serious problems brought to our attention arise from a mismatch between the information needed by decision makers and that provided by the analyses intended to support these decisions. These are particularly notable when those decisions involve a need to balance different, and important, social policy objectives; conventional risk assessment does not serve these at all well. Thus we suggest that the most effective improvements available to Cal/EPA will be realized by identifying and then closing these gaps between needs and practices.

In this chapter we make a number of recommendations for consideration by Cal/EPA. Many derive in part from observations and findings made in the course of our review of the Agency's policies and practices. Some derive solely from more general observations we have made independently. We have attempted to separate the two insofar as that can be done. Recommendations and findings concerning guidelines, both their utility and their content, derive mainly from information obtained outside of this study, and are thus separated. Comments and recommendations on form and general content of guidelines appear in the next part of this chapter, while some technical recommendations on content of certain guidelines appear in the "Technical Issues" part, below.

The most important recommendations based on review of the Agency's policies and practices are these:

1. Cal/EPA should examine how decisions are made under each of its principal statutes. It should then consider whether the decision making processes are optimal, given the need for the decision, and also whether the way the risk assessments are structured is optimal, given the information needs of the decision-maker. In particular, it should look closely at the use of single-valued "safe exposure limits" in decisions concerning air permits and site cleanups. It should include in this examination, a review of how quantitative uncertainty analyses are used by its several units.

2. The Agency should review the overlap and differences that appear to exist among the roles and responsibilities of various programs of its Boards, Departments and Offices to determine if the structure and function is optimal. The structure of the Agency should follow from its various responsibilities.

3. 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.

4. The Agency should take steps to improve the knowledge and understanding of uncertainty and its implications among both technical staff and policy makers.

Guidelines

As has been noted above, the topic of guidance documents was an important one during deliberations of the Committee as a whole, and for this Expert Panel. Gathered together below are some general recommendations of the Expert Panel concerning guidelines. (As noted, a number of recommendations on the technical content of guidelines dealing with uncertainty and variability appear in the "Technical Issues" part.) In general, the comments and recommendations appearing here are more narrowly focused than those which appear in the chapter on Cross-Cutting Issues, above.

We observe that existing guidelines of both the federal and California agencies typically include two kinds of contents, and note a trend towards separating these two. One kind of content comprises descriptions of what might be called "good professional practice;" a nearly pure example can be found in the "Cancer Principles" issued by the US Office of Science and Technology Policy in 1985 (OSTP, 1985). The other kind of content comprises technical instructions to risk assessors. These are functionally policy statements by regulatory agencies concerning choices to be made in the course of developing information for use in specific decision making. The "CAPCOA Guidelines"

provide a nearly pure example of this kind of document. These two kinds of documents are fundamentally different; the "good practices" guidance provide generic support for the narrowly focused technical instructions. We suggest that separation of these two types of guidance is desirable, in that doing so helps to clarify and distinguish generally accepted practice from those policy choices that incorporate public values and other considerations.

Recommendations concerning publication of guidance documents

5. As Cal/EPA develops new guidance documents and updates existing ones, it should give serious consideration to distinguishing those that focus on describing good practice from those which convey technical instructions. The latter need to be tailored to the needs of specific decisions. Consideration should be given to joining with US EPA and other organizations to develop the "good practice" type.

6. Cal/EPA should consider fostering the development of "good practice" guidelines for uncertainty analysis. These guidelines should consider in some depth all the types of uncertainty (e.g., model, parameter, etc.) in all the stages of risk assessment.

7. To improve the current structure of its risk characterization, Cal/EPA should develop guidelines by building on the US EPA March 1995 *Policy for Risk Characterization*, and the combined approach of Department of Pesticide Regulation (DPR) for analysis and characterization. In doing so, the Agency may want to consider that some consider the current US EPA Policy insufficiently broad and too "reductionist." The Agency should also consider any pertinent recommendations from the report by the NAS Committee on Risk Characterization (NRC, 1996).

The Process

The Expert Panel organized its discussion around the following issues.

A. **Technical Issues:** the technical aspects of quantitative variability and uncertainty analyses.

B. **Models and Defaults/Assumptions:** consideration of models, assumptions, and their impact on the risk characterization, and the clarity of the risk characterization in conveying this information.

C. **Issues of Structure and Decision-making:** the structure of the decision, the risk characterization process, the overall decision making process, and how Cal/EPA is organized to carry out these activities.

For each issue, findings were made pursuant to the following questions, and recommendations were shaped by the findings.

1. Is Cal/EPA consistent with US EPA?

2. Are Cal/EPA risk characterization practices internally consistent?

3. Are Cal/EPA risk characterization practices "state-of-the-art"?

The Committee was charged to compare Cal/EPA's practices and policies to those of the NAS. Because the Academy has published nothing formally describing how its units conduct risk assessments, *per se*, the Expert Panel chose to regard the several recent publications of the National Research Council (*cf.* NRC, 1994; NRC, 1996) as describing the state of the art of the profession.

A distinction which became important in discussions leading to findings and recommendations was that between written policy and current practice. The US EPA has recently delineated the direction it intends to go in its March 1995 document *Policy for Risk Characterization*, and is beginning to implement this policy in some of its programs. The Expert Panel took this to represent US EPA policy, and note that that Agency's practices are being developed to comply with its requirements.

Expert Panel Findings and Recommendations

A. Technical Issues

Findings on Technical Issues

The Committee considered the technical aspects of uncertainty and variability analyses and how the results of these analyses were incorporated in risk characterizations. In answering the three key questions it posed, Committee found as follows:

1. Is Cal/EPA consistent with US EPA?

- *In general, current practices at Cal/EPA and US EPA are consistent.*

Both agencies similarly address uncertainty and variability in practice; for example, they both address statistical noise in the main study used to calculate dose response. However, the general recommendations of the NAS regarding parameter and model uncertainty are not fully integrated into the practices of uncertainty and variability analysis and risk characterization at either agency. It is interesting that there appears to be much greater similarity and consistency between like programs at the two agencies than across different programs within each agency.

- *Some differences in practice are appropriate given the different mandates*

There are differences between practices at Cal/EPA and US EPA that relate to the different laws under which they operate, and thus some of the observed differences appear to be appropriate.

- *Practices and procedures are evolving rapidly and in apparently similar directions at both US EPA and Cal/EPA.*

US EPA has recently released its *Policy for Risk Characterization* (March 1995), and Cal/EPA is in the process of developing procedures such as CalTOX to address uncertainty and variability. Most of the testimony heard in the presented examples and read in the written materials reviewed by the Committee pre-date the changes that are now taking place. However, in addition to other materials discussed at the meeting, the US EPA policy and the CalTOX procedure suggests that both agencies are changing rapidly in technical approaches to uncertainty and risk characterization, and that in making these changes they are moving in the same direction. Cal/EPA is a little ahead in practice in some areas and US EPA is further ahead in developing guidance.

- *Written policies differ from practice at both US EPA and Cal/EPA.*

In general, the practices of uncertainty, variability and risk characterization at both US EPA and Cal/EPA differ from those indicated in the US EPA March 1995 *Policy for Risk Characterization*. The US EPA policy does not prescribe techniques to be used in technical assessment, but the more general guidance given suggests clear differences between practices in several programs at the two agencies and US EPA policy.

- *Cal/EPA and US EPA share the same goals and vision regarding how to treat uncertainty and variability in risk analyses.*

Examples of policies and procedures from the US EPA and Cal/EPA suggest that both organizations share the same goals and vision for improvement in risk characterization practices. Both treat with seriousness the goals put forward in the US EPA 1995 policy, and Cal/EPA has indicated it is trying its best to move forward with the recommendations of the NAS, developing procedures and tools such as CalTOX.

2. Are Cal/EPA risk characterization practices internally consistent?

- *There is inconsistency within Cal/EPA.*

There is variability among the different Cal/EPA programs. There clearly are differences that are appropriate that relate to the different laws under which the different programs operate. There appears to be much greater similarity and consistency between like programs at the Cal/EPA and US EPA than across different programs within each agency. One consequence of these differences among programs and between the State and Federal agencies is confusion in the public. For instance, indices of safe exposure (such as the Federal "Reference Dose") that differ either within Cal/EPA or between the California and Federal agencies greatly confuses the processes of selecting remedies at waste sites and identifying acceptable permitted emission rates from industrial facilities. In addition, significant differences lead to doubts about Cal/EPA's competence and credibility.

3. Are Cal/EPA risk characterization practices "state-of-the-art"?

- *"State-of-the-art" should be considered in light of what is currently "practical," in addition to what is "conceptual" and might be achieved with greater resources and better tools.*

In considerations of "state-of-the-art," one should distinguish between the "practical," or what can be accomplished with current tools and resources, and the "conceptual," that which potentially could be accomplished with better data,

improved tools and increased resources. If the best technically possible is done with current tools and data, one is at "practical" state-of-the-art.

- *Cal/EPA uses "practical" state-of-the-art in some cases, but not routinely.*

In terms of practical applications, when Cal/EPA implements uncertainty analysis, it does an admirable job, given the tools and resources at hand. However, Cal/EPA does not routinely implement such analyses and procedures and data available for practical state-of-the-art uncertainty analysis are not applied to the extent possible across the Agency. Neither does Cal/EPA develop or provide decision makers information on consequences of exposure at levels near to, but only slightly above the standard indices of safe exposure (such as the "Reference Dose"). This information is often necessary when weighing, for example, degree of cleanup against other societal values.

- *Cal/EPA seems to be headed toward state-of-the-art, but the "conceptual" state-of-the-art analysis outlined by the NAS has not yet been achieved..*

The state of this art has been evolving very rapidly in recent years, in response to deficiencies that had become quite apparent to professionals in Cal/EPA, in US EPA and in private practice, to decision makers, and to members of the public. Cal/EPA clearly is engaged in working to put in practice the principles outlined in recent NAS reports (NRC, 1994; NRC, 1996). We expect that one outcome of the study reported here will be increased attention to and support for developing the necessary technologies and methods, and their use. We would reiterate that one concept given much weight in both National Research Council reports, namely the need to identify levels of analysis appropriate to decisions being made, comprises an important aspect of the state of the art. Thus "full blown" simulation-based explorations of the details of uncertainty will not always be called for. We also note the concern expressed by several people who testified during the course of the Committee's deliberations that many decision makers do not understand what professionals try to convey by discussions and treatments of uncertainty and variability, at least as these are commonly done.

Recommendations on Technical Issues

The following recommendations are designed to improve technical aspects of Cal/EPA's treatment of uncertainty and the Agency's risk characterizations. Note that recommendations concerning guidance appear separately below. Several of these were adapted from recommendations in the NAS report *Science and Judgment in Risk Assessment* (NRC, 1994).

A1. Cal/EPA should develop a means to communicate information of the consequences of exposures greater than the safe exposure level but less

than exposures expected to produce frank effects. In addition, it should develop means to communicate experts' degree of confidence in these conclusions, perhaps through some appropriate uncertainty analysis. (In general, it should move toward less reliance on single estimates for any purpose.)

A2. Cal/EPA should be explicit about the assumptions made regarding distribution of susceptibilities to hazards when evaluating risk. We suggest it would be useful for the Agency to encourage exploration of the problems associated with variability in susceptibility among individuals.

A3. Cal/EPA should develop a program to train risk managers and risk assessors in the understanding of uncertainty and its effects on risk-based decision making. The manager should better understand uncertainty analysis, how to use the information from such analyses in making their decisions, and how to efficiently reach closure when descriptions of risk provided are more complex. The assessor should better understand the needs of the decision maker and decision context so that risk information is provided in an understandable and useful form.

Technical recommendations concerning contents of guidance regarding treatment of uncertainty and risk characterization

A4. 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.

A5. 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.

A6. Point-estimation techniques used to determine the "high-end exposure estimate" when data are sparse should be designed to yield a reliable estimate at the desired location within the overall distribution of exposure. Simulation techniques such as "Monte Carlo" analysis give promise for filling these needs; however, the current US EPA practice of combining an arbitrary mix of "worst-case," central-tendency, and other estimates of unknown provenance, and calling it "reasonably high-end" should not be considered reliable.

A7. Cal/EPA should explicitly consider and communicate in appropriate technical instruction documents the models and default assumptions to be selected for particular risk assessments. The processes employed to choose these models and assumptions should include deliberation

involving affected and interested parties, and be transparent and understandable to the risk assessor and users of the risk assessment.

A8. Model uncertainty should be addressed explicitly and guidance provided on how to deal with issues arising from this source, including how it should be treated in risk assessment reports.

A9. Cal/EPA should decide if it will require consideration of all uncertainties and all models that have any weight, or will continue to perform regulatory risk assessments giving consideration to only one of the possible models at each step of the assessment process. (That is, in current practice many of the possible input data are usually held constant, treating them as "defaults"; we recommend that this practice be generally retained, unless review of specific decision contexts leads to a contrary conclusion.)

A10. Appropriate technical instruction documents should include guidance for assuming how long people reside in one location. We note that statistics on length-of-time-at-one-address may underestimate actual exposures because some moves occur over only a very short distance.

One member of the Expert Panel wanted the following Technical Recommendations to be included, but there was not consensus. These are adapted from recommendations appearing in Science and Judgment in Risk Assessment (NRC, 1994).

A11. "For any decisions involving risk-trading or priority setting, Cal/EPA should take into account information on uncertainty in quantities being ranked so as to ensure that such trades do not increase expected risk and such priorities are directed at minimizing expected risk. When one or both risks are highly uncertain, Cal/EPA should consider the probability and consequences of greatly erring in trading one risk for another because in such cases one can lower the risk on average and yet introduce a small chance of greatly increasing the risk.

A12. Cal/EPA should adopt a default assumption for susceptibility. It could choose to incorporate into its cancer risk estimates a "default factor" greater than the implicit factor of 1 that results from treating all humans as identical. Preferably, Cal/EPA could develop a "default distribution" of susceptibility and then generate the joint distribution of exposure and cancer potency (in light of susceptibility) to find the upper 95th percentile (or 99th percentile) of risk for each risk assessment.

A13. Cal/EPA should prefer to use distributions reflecting actual duration of individual residence time in a high-exposure areas and the length of diurnal exposures; such information can be gathered through

neighborhood surveys, etc., in these high-exposure areas. If appropriate distributions are not available, conservative point estimates of these quantities should be used, e.g., the mean of current life expectancy as the assumption for residence times. (This accounts for the likelihood that changing residences might not result significantly lower exposure.)

B. Models and Default Assumptions

The Expert Panel assessed how Cal/EPA explains the choice of models and assumptions, from among the many possible selections and decision pathways for the analysis, as well as whether the impact of model selection on outcome of the risk assessment is made clear. "Model", in this context, refers to a mathematical or conceptual theory or framework used to organize observations in order to make predictions about some natural phenomenon. Mathematical models form an important part of the prediction of exposures, and certain conceptual models form the basis of predicting hazard to humans. "Default assumption" refers to an assumption routinely used in evaluations of some particular kind, primarily as a means to fill gaps from missing information. Most of these are like the "rules of thumb" used in all professions as aids for developing recommendations from uncertain input information. They are based on what is generally known from relevant areas of science that can be used to set bounds on possible values of unknown parameters. Some represent "best estimates" (median values) of the absent parameter, while other values are purposefully biased for risk management purposes. There is currently a long-running debate in the profession about use of these default assumptions, and their relation to policy.

The issue of disclosure can be characterized as one of "transparency" in the risk assessment. A second issue is also addressed — how model and parameter choice are treated in the uncertainty analysis, and whether the choices are treated formally, for example, by assigning weights to each in a range of choices as in a decision tree, or in a narrative fashion.

Findings on Models and Default Assumptions

1. Is Cal/EPA consistent with US EPA?

- *In terms of transparency, Cal/EPA and US EPA risk characterizations are generally consistent, based on the materials reviewed.*

Risk characterizations of US EPA and Cal/EPA do a good job in describing how the risk was assessed and which models and data sets were used in the analysis. However, neither agency does an adequate job of routinely describing its reasoning in choosing certain models or assumptions over others.

- *In terms of formal policies and guidelines, US EPA and Cal/EPA are not consistent.*

US EPA released in March 1995 its *Policy for Risk Characterization* and is developing guidance for agency-wide use; Cal/EPA does not have a uniform policy or guidelines.

2. Are Cal/EPA risk characterization practices internally consistent?

- *Differences exist among Cal/EPA programs.*

The practices of examining and describing the impact of model choice and parameter and data set selection on the characterization vary considerably among Cal/EPA programs. It may be very transparent in one case, less so in others. Several programs within Cal/EPA have written guidance on risk characterization, generally as part of other guidelines.

- *Cal/EPA may be somewhat ahead of US EPA in sensitivity analysis of models and parameters.*

One example of an area where Cal/EPA leads is technology, such as CalTOX. This and similar programs allow for a relatively straightforward and simple exploration of the impacts of different assumptions regarding model structure and parameter values.

3. Are Cal/EPA risk characterization practices "state-of-the-art"?

- *Cal/EPA risk assessments are not transparent in terms of model and other choices and their impact on the risk assessment.*

Currently Cal/EPA does not routinely provide a full explanation of model, data and parameter choices and their impact on the risk characterization. In many of the

assessments there is little reference to the impact of default and alternative assumptions on the overall risk characterization.

Recommendations on Models and Default Assumptions

The following recommendations are made regarding the transparency of risk characterizations - that is, the extent to which the decisions regarding model and other choices in the characterization process are disclosed and their impacts explained.

B1. Cal/EPA should examine the impact of defaults or model choices on the outcomes of the risk assessment. This should include, in particular, the influence of assumptions in the CalTOX program on its output. We suggest that it would be useful to perform retrospective analysis on risk assessments to determine what may "drive" the assessment. Such an analysis should be able to address model or structural uncertainty as well as parameter uncertainty, and can indicate the extent to which the result depends on and is sensitive to a particular parameter or model default.

B2. Cal/EPA should consider adapting the CalTOX program to provide support for decisions other than analysis of hazardous waste sites. In doing so, Cal/EPA should take care to assure that the information provided by such analyses serves the needs of the other decisions to be made.

B3. 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.

B4. Cal/EPA should consider evaluating whether or not users of their risk assessments understand sufficiently how the decisions regarding model choice and other factors in the risk characterization are made.

B5. Cal/EPA should explicitly consider and communicate the processes it will use to choose default models and assumptions. These processes and the risk assessments themselves should be transparent and understandable to the risk assessor and users of the risk assessment.

On two issues members of the Expert Panel disagreed.

B6. One member believes that an analyst's choice to use some model or information other than the default should be constrained, with a requirement to meet some evidentiary standard before an alternative may

be used. Another believes that universal standards can't exist, and that one of two situations must prevail:

- In an analysis intended to provide a scientifically accurate description of potential risks, all available information must be used.
- In an analysis intended to provide a recommendation for action, if expert judgment is required to interpret some information the expert doing the analysis must be allowed to choose the appropriate models and input data.

B7. One member believes that Cal/EPA should be wary of assigning quantitative weights to various models: such weights are highly subjective, hard to replicate, and hard to interpret. Therefore, model uncertainty should be handled by presenting separate models, combined with a narrative discussion of the reasons why each distribution might be the most plausible. In his opinion, model uncertainty is essentially the question of how to characterize uncertainty due to the fact that models other than the default may be plausible. A National Research Council report (1994) said that model uncertainty should only be treated qualitatively, while recommending that parameter uncertainty be treated quantitatively. This member goes on to caution that, if Cal/EPA does wish to explore the assignment model weights, it should, (1) be very careful about using such weights to derive a single "unified" uncertainty distribution; and (2) be extremely wary of using such a distribution for the purpose of deriving a single point estimate, and under no circumstances refer to this as a "best" or "unbiased" estimate.

Another member of the expert panel distinguishes between uncertainty and variability in inputs to an analysis, on the one hand, and the analyst's confidence in the result she or he obtains from that analysis, on the other. In the latter case, the distinction among sources of uncertainty vanishes — all contribute to lack of confidence. In this case it is appropriate to combine all of these various uncertainties into one metric that characterizes the degree of confidence in the result.

C. Issues of Structure and Decision-Making

Here we address the structure of the risk characterization process and the overall decision making process, and how Cal/EPA is organized to carry out these activities. In assessing this issue we considered the process of developing the risk characterization, including the problem formulation stage, dialog between risk assessors and risk managers, formal risk characterization policies, risk characterization practices, and whether the organizational structure of the Agency is optimal for these purposes. The relationship of organizational structure to the risk characterization was discussed in terms

of the organization of the Boards and Departments, their missions and mandates in risk assessment functions, the separation of risk assessment and management functions within the various programs, and the quality and consistency of risk characterizations that result.

Findings on Issues of Structure and Decision-Making

1. Is Cal/EPA consistent with US EPA?

- *In general, in terms of organizational structure, yes, there are US EPA analogs to Cal/EPA programs.*

There are some direct analogs to US EPA in Cal/EPA. In particular, Cal/EPA units responsible for pesticides and air toxics appear to have structures similar to the analogous US EPA units. The units responsible for drinking water were structured similarly; the corresponding US EPA unit has recently been reorganized, and may now enjoy a different structure. The Office of Environmental Health Hazard Assessment has some similarity to US EPA's Center for Environmental and Health Assessment (although their responsibilities differ). The structure and *modus operandi* of units dealing with hazardous wastes appear to be very different. In addition, Cal/EPA implements some statutes, such as "Proposition 65" and Air Toxics "Hot Spots" that have no Federal analog, whereas California has no analog to the national Toxic Substances Control or Food, Drug, and Cosmetic Acts (except for pesticide residues, the latter is implemented by the Food and Drug Administration).

2. Are Cal/EPA risk characterization practices internally consistent?

- *Cal/EPA uses a variety of different approaches in developing risk characterizations.*

In reviewing the twenty-two processes related to Cal/EPA mandates presented in the briefing book for the meeting (shown in Appendix A of this report), it became apparent that a variety of different and complex practices are used which correspond to the myriad of statutes and other mandates with which Cal/EPA has to comply.

3. Are Cal/EPA risk characterization practices "state-of-the-art"?

- *The degree to which the structure for Cal/EPA risk characterizations differs from what might be considered state-of-the-art varies programmatically, but in general can be substantially improved.*

This finding should be considered in the broader context of current decision-making, in which assessments are narrowly conceived as summary information about quantitative health risks. Several instances in which current policies and practices are not now state-of-the-art have been noted above.

Recommendations on Issues of Structure and Decision-Making

C1. Cal/EPA should examine how decisions are made under each of its principal statutes. It should then consider whether the decision making methods are optimal, given the need for the decision, and also, whether the way the risk assessments are structured is optimal, given the information needs of the decision-maker. This may indicate ways of simplifying, unifying and making more effective its twenty-two or so processes for risk assessment.

C2. There should be considerably more communication between the risk assessor and risk manager. Risk assessors should better understand the needs of the risk managers in terms of expressions of uncertainty and variability -- what the risk managers need, why they need it, and how they can provide it.

C3. Cal/EPA should explore how to use the results of quantitative uncertainty analysis in the existing regulatory decision-making processes. It is unclear how these results should be used, and the Committee encourages Cal/EPA to explore and develop new methodologies and practices.

C4. Cal/EPA should review the overlap and differences that exist in the roles and responsibilities of various programs of its Boards and Departments to determine if the structure and function is optimal. The structure of the Agency should follow from its various responsibilities. The structure of the risk assessments and how the assessments are done should follow from how the decisions are made and what information is going to be used in those decisions.

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