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.

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