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CHEMICAL MANUFACTURERS ASSOCIATION

ON THE REPORT OF THE

RISK ASSESSMENT AND RISK MANAGEMENT COMMISSION

Risk Assessment and Risk Management in Regulatory Decision-Making

August 13, 1996

1300 WILSON BOULEVARD
ARLINGTON, VA 22209 703-741-5000 FAX 703-741-6000

CHEMICAL MANUFACTURERS ASSOCIATION

M.L. MULLINS
VICE PRESIDENT
REGULATORY AFFAIRS

August 13, 1996

Dr. Gilbert S. Omenn
Chairman
Commission on Risk Assessment and Risk Management
529 14th Street, N.W., Suite 452
Washington, D.C. 20045

Dear Dr. Omenn:

The Chemical Manufacturers Association appreciates the opportunity to provide these comments on the draft report of the Commission on Risk Assessment and Risk Management, *Risk Assessment and Risk Management in Regulatory Decision-Making.*

The Chemical Manufacturers Association is a non-profit trade association whose member companies represent approximately 90% of the productive capacity for basic industrial chemicals in the United States. As part of an industry that is one of the most heavily regulated under federal environmental, health and safety laws, our members have an interest in making sure that the regulatory system is based on sound science, addresses the most serious problems and does so in a cost-effective manner. As you are aware, we have followed with interest, and participated where possible in, the Commission's deliberations.

We commend the Commission on its efforts and on the thoughtful report it has produced. The report significantly advances the debate on the future of environmental, health and safety risk assessment and risk management, adding new ideas and enhancing and underscoring others that have already been part of the debate on these issues.

In its enclosed comments, CMA states its support for many of the report's recommendations and makes suggestions for clarifying or modifying others. We would be pleased to discuss further any of those suggestions with the Commission. We also look forward to working with the Commission to assure implementation of its recommendations. Please call me, Jim Solyst (703/741-5207) of my office or Katy Kunzer (703/741-5177) of the Office of General Counsel if we can be of any assistance.

Sincerely,

Enclosures

cc: Members of the Commission
Gail Charnley, Executive Director
Fred J. Hansen, Deputy Administrator, EPA

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TABLE OF CONTENTS

TABLE OF CONTENTS

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The Chemical Manufacturers Association
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CMA commends the Commission's efforts to present a framework for risk management that incorporates a rigorous science-based approach to problem solving as well as full consideration of societal, economic and cultural conditions and needs. With the goal of accounting for the "connections between environmental health, human and economic well-being, and the processes by which our society's actions create long-term changes, both beneficial and adverse," the Commission established an intriguing framework for making decisions on the reduction of risks to public health, safety, and the environment.

CHAPTER 3. USES AND LIMITATIONS OF RISK ASSESSMENT IN REGULATORY DECISION-MAKING

CMA agrees with the Commission's position that risk assessments are critical to sound regulatory decision-making and that risk assessment should be tailored to meet the needs of the decision to be made.

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TABLE OF CONTENTS

TABLE OF CONTENTS

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INTRODUCTION

The Chemical Manufacturers Association (CMA) appreciates this opportunity to provide comments to the Risk Assessment and Risk Management Commission (the Commission) on its draft report, *Risk Assessment and Risk Management in Regulatory Decision-Making* (Report). First and foremost, CMA commends the Commission for its tireless efforts over the past two years, taking the time to listen to all points of view and meeting around the country to provide as many people as possible an opportunity to speak at and observe their meetings. The result is a thoughtful document that will help further the debate significantly on the appropriate direction for environmental health and safety programs during the next century. CMA strongly supports most of the recommendations and the overall thrust of the draft Report. However, we differ on some of the recommendations, and believe others could have gone further.

CMA is a non-profit trade association of chemical manufacturers. Our approximately 190 member companies represent over ninety percent of the capacity for basic industrial chemicals in the United States. As part of one of the most highly regulated industries under our environment, health and safety laws, our members want to make sure that federal risk management decisions are based on sound science and address the worst problems in a cost effective manner.

CMA, too, has been struggling with these issues both in its advocacy positions on matters of broad public policy and in the role of its individual members in protecting human health and safety and the environment. Two years ago a special committee of CMA's Board of Directors issued its own report on risk assessment and risk management issues. That report took the form of CMA's Risk Principles (Attached). Like the Commission's Report, those Risk Principles advocate policies to protect health, safety and the environment that yield the greatest overall protection possible for the amount of resources used through:

- risk assessments based on sound science,
- the use of comparative risk to set priorities,
- cost-effective and flexible risk management strategies, and
- vigorous public and stakeholder involvement.

Similarly, CMA's Responsible Care® initiative commits CMA members to codes of management practices that require them to work with their communities, employees, customers, government and among themselves to exercise environmental, health and safety responsibility in managing chemicals.

CMA's comments address, in order, most of the recommendations of the Report. Specifically, CMA's comments focus on recommendations that the Association and its members believe have the greatest potential to effect the future development of a more rational and effective risk management regulatory system. These comments generally support most of the Report's recommendations. They also offer suggestions for expanding the discussion in such areas as stakeholder involvement and parts of the proposed risk management framework, or suggestions for improvements and changes, principally in the areas of risk communication, judicial review, peer review and bright lines. CMA looks forward to discussing its suggestions further with the Commission and working with it to assure that its recommendations are implemented.

GENERAL COMMENTS

The Report provides a valuable contribution to the study of improving the federal regulatory system. It focuses on the one aspect of the need to modernize the regulatory system -- environment, health and safety -- that has been the most difficult and controversial. With the issuance of its draft Report, the Commission joins a prestigious collection of think tanks, scientific advisory bodies, and inter-agency councils that have clarified the issues presented in the debate about how to modernize our regulatory system and offers useful -- and hopefully implementable -- recommendations and frameworks to improve the system.

The Commission is generous in crediting the studies that influenced its work and served to generate positive discussion, potentially leading to real change: the

National Research Council (NRC) reports, *Science and Judgment in Risk Assessment* and *Understanding Risk: Informing Decisions in a Democratic Society;* the National Academy of Public Administration (NAPA) report, *Setting Priorities, Getting Results;* the Carnegie Commission report, *Risk and the Environment: Improving Regulatory Decision-Making;* and the work of the Harvard Group on Risk Management Reform. These efforts serve as useful companions to the Commission's draft report and provide valuable background material.

One influential document not referenced by the Commission, however, is Executive Order No. 12866, Regulatory Planning and Review, issued by President Clinton on September 30, 1993. The Executive Order is perhaps the most important of all the risk and regulatory reform initiatives undertaken in the past three years, as it is a statement of the Administration's intention to make the regulatory system more efficient and effective. As the principal existing, authoritative guideline for agency use of risk assessment in regulatory decision-making, the Executive Order deserves greater attention by the Commission in its Report. We suggest that, at a minimum, the Commission address how its recommendations relate to the requirements of that Executive Order. CMA believes faithful adherence to the principles stated in that Executive Order would go a long way toward achieving many of the recommendations of the draft Report. In any case, the mere existence of Executive Order 12866 provides hope that studies like those produced by NAPA, NRC, the Carnegie Commission and the Commission will not go unheeded.

In addition to recommending that the Commission discuss Executive Order 12866 in the Report and include it in the Appendix, CMA suggests that two related documents be appropriately referenced and added to the appendices: the March 4, 1995 White House memo regarding the Administration's Regulatory Reinvention Initiative, which was sent to heads of departments and agencies; and the Economic Analysis of Federal Regulations Under Executive Order 12866, issued by the Office of Management and Budget in January 1996. Finally, the Commission should consider referencing one other important document developed by the Administration and including it in the appendices -- the Draft Principles for Risk Assessment, Management, and Communication prepared by an inter-agency Committee on Risk Analysis. Issued in

draft form on August 2, 1994, the Draft Principles "are intended to be goals for agency activities with respect to the assessment, management, and communication of environmental, health and safety risks."[1]

CHAPTER 2. FRAMEWORK FOR RISK MANAGEMENT

General Comments

CMA commends the Commission's efforts to present a framework for risk management that incorporates a rigorous science-based approach to problem solving as well as full consideration of societal, economic and cultural conditions and needs. The importance of this chapter cannot be overstated. It is essential that the larger message being offered by the Commission does not get lost among technical discussions. That message, presented in this chapter, is the need to establish a framework that accounts for the "connections between environmental health, human and economic well-being, and the processes by which our society's actions create long-term changes, both beneficial and adverse."

CMA agrees with the Chapter's basic recommendation that a "systematic, comprehensive risk-management framework should be used to reduce environmental, health, and safety risks. (Report at 6)." We also fully support the recommended means by which this goal can be reached: approaches that rely on moving "beyond 'end-of-the pipe' command and control approaches" (Report at 6) and that examine problems "not just in a medium- and pollutant-specific manner, but in a comprehensive, multimedia, public-health context" (Report at 8).

CMA supports the Report's recommendations on the inclusion of stakeholders in risk management processes conducted by any regulatory agency with jurisdiction over health, safety and environmental issues. One of the fundamental tenets of CMA's Risk Principles is the need for an open public process with participation by stakeholders at every stage of the process. Nevertheless, we suggest that the Commission review the draft Report to assure that it cannot be construed to limit stakeholders' participation in this proposed new process, particularly in the area of peer review.[2] Further, we also

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[1] Draft Principles for Risk Assessment, Management and Communication, submitted for consideration to the Regulatory Working Group from the Committee on Risk Analysis, Section A at 1.

[2] See our comments on Section 5.5, Peer Review.

suggest the Commission should address the process for stakeholder selection and the means for participation. For example, the Report should discuss more specifically what EPA should do beyond the public outreach and notice and comment activities that it does now.

Two recent reports, one prepared by the National Research Council (NRC) and another by the California Risk Assessment Advisory Committee, support and confirm the Commission's conclusions about the need for stakeholder involvement at all key steps in the risk management process. The NRC report, *Understanding Risk : Informing Decisions in a Democratic Society*, challenges the regulatory system to create a paradigm shift in comprehensively opening the process to stakeholder involvement. The California report, *A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines*, largely follows the recommendations of the NRC report.

CMA also supports the notion of "participatory democracy" (Report at 7) in resolving environmental dilemmas and its call for risk-management partnerships among government, industry, and the public. A key element of CMA's Risk Principles is support for public input to the risk assessment and risk prioritization process. This commitment was also stated by Dr. Phillip Lewis of Rohm and Haas Company and a key member of CMA's risk policy development team, when he testified before the Commission (Report at 7). In the discussion period that followed his formal presentation, Dr. Lewis focused on the role of the community and his personal commitment to engage citizens in honest dialogue. Evidently, Dr. Lewis was one of many voices who expressed this message to the Commission, and CMA is pleased that the draft report places great emphasis on risk-management partnerships.

CMA has also had to define its view of an improved risk management framework. And not unlike the Commission, we have done so in a continuously changing business and regulatory environment. CMA has had the benefit of being able to build on a strong foundation provided by Responsible Care® and the CMA Risk Principles.

Section 2.1 – The Framework

The Commission has developed an intriguing context for making decisions on the reduction of risks to public health, safety, and the environment. Of particular interest is the notion that stakeholder collaboration is an integral part of each of the other six elements.

CMA generally supports the proposed framework which is apparently built on a continuous improvement model and offers the following comments on the individual elements.

Problem/Context. We particularly agree with, and wish to underscore, the following major points presented in this section:

- EPA should examine problems in a comprehensive, multimedia, public-health context, not just in a medium- and pollutant-specific manner. Looking at problems in this integrated fashion facilitates finding performance-based risk management alternatives that provide flexibility to the private sector to solve problems. However, we understand that along with flexibility comes accountability and that the intention is that the goal is continuous improvement.

- Stakeholders should be relied on heavily during problem identification and characterization. The chemical industry is often a principal stakeholder in environmental decision-making. Being a stakeholder allows industry to be part of the process. It also requires a commitment. For example, the commitment to provide the type of information that can lead to an improved risk assessment. A key element of CMA's Risk Principles is that CMA "advocates and supports governmental and private sector development of scientific data to improve the accuracy and relevance of risk assessments."

- It is important to place the risks in context. The context may be public health, other risks or interdependent problems. To properly place risks in context requires the use of comparative risk. CMA strongly encourages greater use of the tool of comparative risk for determining when and how to manage risks. As stated in the Report, comparative risk analysis "brings together science and public values" and assembles information "about the sources of problems and the risks that they pose to human health, ecosystems, and quality of life." (Report at 72.)

Risks. We support the general premise that when scientists and decision-makers assess the severity of a problem, they need to factor in a variety of concerns. Among these are the impact on human health and the environment and the public welfare, including economic well-being.

Options. CMA believes this is the key step in successful regulatory problem solving: identifying and evaluating as many of the option as can be reasonably identified. CMA particularly supports the notions that during this phase both regulatory and non-regulatory options and flexible alternatives should be considered and that the potential consequences, including costs, and expected benefits of intervention must be assessed. Too often regulatory fixes have unintended consequences that actually could have been predicted had adequate thought been given.

Decision. The opening statement of this section cannot be expressed often enough: "The most feasible, effective, acceptable, and cost-effective approaches to mitigating the problem would be identified, with the participation of affected and responsible parties." (Report at 10.) CMA strongly agrees with this statement and commends the Commission for having drafted a statement worthy of being an environmental slogan for the next century.

Actions. The Commission has identified a key question that must be answered if we are to achieve the environmental protection we all seek, and that is "How can the decision be implemented rapidly and flexibly?" Too often decisions are reached but action is delayed either because of administrative concerns or because of over-reliance on the use of tightly controlled, command-and-control-based solutions.

The Report correctly notes that taking action is a responsibility of all the stakeholders, industry included. CMA agrees industry needs to be prepared to take action. Ideally industry would do so in concert with other stakeholders, but if this is not possible, then industry must consider independent actions that will lead to greater environmental health protection.

Evaluation. CMA agrees that decisions need to be evaluated to determine "effectiveness and cost, or to compare the findings with estimates made in the decision-making stage." (Report at 10.) However, this section needs to clearly recommend that

an evaluation system be established. As written, there is support for evaluation measures but no finding that post-decision reviews are essential.

Stakeholder Collaboration. As stakeholders, we agree with the recommendation that there is "some level of participation of stakeholders or affected parties at each stage" of the decision framework (Report at 11). However, as stakeholders, we feel that we are obligated to bring more than just our parochial concerns to the process. Rather, it is incumbent on stakeholders to clearly communicate their views and to provide information and analyses. As stated in our Risk Principles, "CMA supports public education and communication programs to promote a credible public dialogue on the risks and benefits of chemicals."

CHAPTER 3. USES AND LIMITATIONS OF RISK ASSESSMENT IN REGULATORY DECISION-MAKING

General Comments

CMA agrees risk assessments are critical to sound regulatory decision-making and that risk assessment should be tailored to meet the needs of the decision to be made.

The importance of sound risk assessments for regulatory decision-making can not be overstated. Risk assessments can help determine if a problem exists and identify the characteristics of that problem. Risk assessments help the agency to select the optimal risk management options, when they are used to compare the risk reduction potential of different risk management options, or to determine whether there are any countervailing risks attached to those options. Risk assessments that form the basis for comparative risk analyses serve to identify the most serious problems so that resources are allocated most efficiently and effectively.

On the other hand, it is clear that not every regulatory decision requires the Cadillac version of a risk assessment to achieve those goals. We strongly support the notions expressed in the Report that risk assessments should be tailored to the risk management decision to be made and that "scaling the effort to the importance of the problem, with respect to scientific issues and regulatory impact, is crucial." (Report at 17-18.)

Section 3.1 Toxicity Assessment

CMA largely supports the recommendations made in this section relating to margin of exposure approach, rodent responses, and subpopulation susceptibility. However, we urge the Commission not to address the concept of bright lines in this section. Instead, all references should be included in Chapter 5.3.

Margin of Exposure. CMA agrees with the finding that the dichotomy in methods for assessing cancer and non-cancer risks causes inconsistencies in risk management actions and makes comparisons of risk difficult. A margin-of-exposure approach for carcinogens recommended by the Commission may be useful in addressing this dichotomy but potential confusion may arise when a risk manager is presented with somewhat inconsistent measures of risk for linear and non-linear carcinogenic agents. In addition, such a method must be clear about whether methods or assumptions are based on science or policy (e.g., defining an acceptable margin of protection).

Relevance of Rodent Responses. CMA also agrees with the recommendation that certain rodent responses should be classified as irrelevant to human cancer risk assessment. This recommendation is particularly applicable in cases where there are tumors that result from mechanisms that are unlikely to occur in humans or that occur at very high doses that are irrelevant to human exposures.

EPA's residual risk programs should clearly provide the opportunity for stakeholders to develop and submit information showing that rodent data that otherwise would be used to perform the assessment is irrelevant to human health, and provide a revised cancer risk assessment. The Commission's recommended scheme should be revised to explicitly state that this opportunity should be available to the stakeholder, and that EPA should be required to review and address any submitted information during development of any risk-based assessments, particularly residual risk based standards under the Clean Air Act.

Submission of such data should be allowed during both the "data collection" step prior to the "screening risk assessment" in the flow diagram of the scheme as shown in Figure 6.1, and during the "data collection" step prior to "detailed risk

assessment within source category", as well as at any time that newly acquired information becomes available.

CMA believes that clearly stating that stakeholders have the opportunity to submit information concerning the relevance or irrelevance of rodent data to human health (and that EPA should consider and address such data in a timely fashion) will encourage industry groups and others to support research to develop scientifically sound information beyond what is currently be available. CMA believes that better scientific information will lead to more efficient, more effective risk management. We see this as an opportunity for the Commission to encourage development of an expanded, more scientifically sound database.

CMA shares the Commission's belief that some rodent cancer responses are irrelevant to human risk assessment. Sources subject to a residual risk analysis under the Clean Air Act should be allowed to provide information to support revised cancer risk estimates if the cancer risk assessment was based on rodent data which is irrelevant for any reason. Also, the opportunity to submit data should be available to the source for non-carcinogenic effects, and the opportunity refute animal or other surrogate tests other than just rodent data.

Susceptible Subpopulations. We also agree with the recommendation that risk assessments should include considerations of differences in susceptibility. CMA believes subgroups must be considered and we support the Commission's assertion that recognition of subgroup susceptibility should not "result in more stringent regulations." (Report at 26.) However, we object to the reference to "additional 'bright lines' or standards." (Report at 25.)

Instead of using the most susceptible subpopulations to justify the most stringent bright line limitation, we believe that knowledge about differences in susceptibility should be used to identify where more stringent restrictions may be needed. Where and when protection of a more susceptible population is indicated, these situations should be dealt with on a case-by-case basis considering all aspects of the situation.

Where especially susceptible subpopulations are identified, the reasons for the unique susceptibility (i.e. iteration, lifestyle, location, etc.) should be identified if possible, and finding the most appropriate risk management action should be the objective. Susceptible subpopulations would not become a vehicle for maintaining the conservatism of the maximally exposed individual.

We suggest the following language be considered as an alternative to bright line standard: "Where appropriate, knowledge of differences in susceptibility should be used to tailor risk management responses for identified susceptible subpopulations." In general, we feel that any discussion of bright lines should be addressed in the risk management section of the Commission's report.

→ Section 3.2. Exposure Assessment

CMA generally supports the recommendations presented in this section: that exposure assessments should not be based on a maximally exposed individual; that some population groups are at greater risk; and that exposure assessments should be designed to be commensurate with the needs of the risk management decisions at issue.

CMA agrees with the Commission that exposure assessments should not be based on a maximally exposed individual. The approach suggested by the Commission of using "high-end exposure estimates" for screening assessments and distributions of a population's exposures for more refined assessments is reasonable. The draft report also points out correctly that EPA has published guidelines that endorse some of these ideas, but the Agency has not established a clear policy or guidance for how they should be implemented.

Collecting information on actual exposure and accounting for multiple sources of exposure will improve the information available for decision-making. However, the Commission should address how this information could be used in a risk management situation. Because current laws and regulations look at exposures and risks in a source-by-source or medium-by-medium approach, it is unclear how information about total exposures would be used to support regulatory decisions. For example, requiring stringent controls on a source that makes a minor contribution to total exposure on the

basis that total risks are unacceptable may consume considerable resources and fail to achieve meaningful risk reduction.

CMA agrees that exposure assessments should be designed to be commensurate with the needs of the risk management decisions at issue. The use of a tiered approach in exposure assessments is a good strategy for effective resource allocation.

Section 3.3. Uncertainty in Estimating Risk and Risk Reduction.

CMA urges the Commission to modify the Report's conclusions on providing quantitative estimates of ranges and distributions of risk. Specifically, the Commission should recommend that the risk assessors provide such estimates where appropriate. At a minimum, risk assessors should provide more than one point estimate to fully inform the risk manager and the public.

Section 3.3 of the Report recommends that qualitative descriptions of primary uncertainties and weight of evidence should be provided to risk managers and the non-technical public but that quantitative analyses of uncertainties are not necessary. The Report recognizes that quantitative descriptions of exposure variability can be useful and recommends that they be provided.

We agree with the conclusions of the Report about the importance of providing information on the uncertainty and variability of the risk in the risk estimate. We disagree, however, with the Report's conclusion that it is not necessary or useful to provide quantitative estimates or uncertainty for most risk assessments. We strongly disagree with the statement in the Report that even if a quantitative uncertainty estimate is done as part of the risk assessment it need not be given to the risk manager. (Report at 34.)

To communicate uncertainty to the risk manager or to the public effectively the agency should provide, where available, quantitative information about the ranges and distributions of risk that adequately reflect uncertainties. Such descriptions of risk are far more realistic than point estimates. Moreover, to the extent that the ranges and distributions can be depicted graphically, the degree of uncertainty can be conveyed most effectively.

One of the Commission's principal concerns appears to be that risk managers will have difficulty in understanding how to use a quantitative estimate of the range

and variability to make regulatory decisions. (See Report at 35, quote of Thomas Gentile.) The apprehension of risk managers is understandable. Point estimates provide a sense of certainty and the appearance of consensus on the estimate, but that sense is unreal. Instead of recommending retaining the status quo, however, the Commission should recognize the concerns of some risk managers with using quantitative estimates of uncertainty for decision making but suggest firmly recommend that quantitative uncertainty analyses should be used whenever possible. On the other hand, to help risk managers use these descriptions of risk, the Commission should either suggest a paradigm for how risk management decisions can be made from ranges and distributions of risk or, at least, recommend further research in this area. Even with qualitative descriptions, point estimates mislead the public and hide the policy choices in the assessment. CMA believes it is time to step away from using point estimates for risk management decisions and toward fuller descriptions or risk based on quantitative uncertainty analyses with recognition that there will be some need for a transition period.

The Commission points out that the ranges and distributions of risk will themselves contain uncertainty and are susceptible to bias. Nevertheless, if risks are described as ranges and distributions that there is uncertainty will be patent and that is preferable to the conveying the false sense that we really know precisely the extent of the risk.

The Commission also notes that some parties think that use of quantitative uncertainty analysis will overcome the bias toward overestimating risk with a concomitant effect on the risk management decision, seeming to imply that notion might be the basis for their support for quantitative uncertainty analysis. (Report at 35.) However, CMA does not assume that the resulting regulatory decisions will be less stringent because numeric estimates of ranges and distributions are provided. As the Report points out, the regulatory result will likely be the same because regulators and community groups will demand that regulations protect up to the high level of the range. We can argue about the wisdom of that result in all cases, but at least that decision will be made in the open by the manager and not hidden in the point estimate of risk. To preserve the transparency of the regulatory decision and place

accountability for decision-making with the appropriate party– the risk manager -- a full description of the risks should be provided. The public has a right to know about the conservatism or not of regulatory decisions.

At a minimum, the Commission should recommend that if a full range and distribution of estimates are not going to be provided, more than one point should be identified, including a central or most plausible estimate along with a high end estimate.

Section 3.4 Chemical Mixtures

CMA agrees with the Commission's recommendations to test mixtures and agrees that, in some cases, adding together risks from individual chemicals is generally appropriate and is unlikely to result in an under-estimate of risk.

CMA agrees with the finding that, at concentrations typically found in the environment, exposure and risk should only be additive for chemicals affecting the same target organ with the same mechanism of action. The rationale offered by the Commission makes it clear that this recommendation is a conservative one based on policy considerations and that scientific evidence indicates that such an approach will often overestimate risks at low environmental concentrations.

When addressing the identification of dose response kinetics and mechanisms for mixture effects, CMA recommends that the following questions be addressed:

- Is there a dose at which effects of mixtures do not occur?
- Does the dose vary for additivity, synergism, or antagonism?
- Is there an underlying mechanism for all mixture interactions? How does that mechanism vary according to chemical class?

Section 3.5 Ecological Risk Assessment

CMA agrees with the Commission's recommendation that EPA and other agencies and interested parties should continue to work together to refine ecological risk assessment and risk management approaches. Guidance on problem formulation, methods, characterization of uncertainty, and the appropriate role of stakeholder participation in the process is necessary and should incorporate the views and expertise of all practitioners of ecological risk assessment/risk management.

CMA supports the use of risk-based, scientifically sound methods to achieve environmental protection and believes that the goal of environmental protection should be to sustain the variety and functioning of the ecosystem. In contrast to the Commission's introductory statement regarding the importance of sustaining ecosystems because they are "crucial to our [human] well-being" (Report at 41), CMA points out that the sustainability of ecosystems is a benefit in and of itself and should not be viewed exclusively in human terms.

In assessing ecological risk, CMA believes the goals of the process should be to: (1) decide what determines the function of an ecosystem and how its function can be measured; and (2) describe the probability and magnitude of impacts on ecosystem function from existing or envisioned human activities. Furthermore, when managing ecological risks, final decisions should: (1) have maximized net environmental benefits; (2) have enhanced the function of ecosystems; (3) have reflected public input; and (4) have been cost-effective.

In contrast to the Commission's statement that ecorisk assessments have been used informally to make decisions about resource management and pollution control (Report at 41), CMA asserts that ecorisk assessment has been used for decades by government, industry and academia. CMA believes the methods of ecological risk assessment and risk management are developing rapidly and will continue to evolve. Therefore, it is important that regulatory and legislative action support flexible approaches and encourages improvement in our knowledge and techniques.

CMA supports the involvement of appropriate stakeholders in the ecological risk assessment and risk management process. Risk managers must recognize that the public places a range of meanings and values on environmental protection and that the ecological risk process should consider the range of public attitudes.

We believe government, environmental organizations and the business community should support open communication and education about environmental protection among the public and private sectors at the local, state, national and international levels.

Finally, CMA supports the comments on ecological risk assessment submitted by the American Industrial Health Council.

CHAPTER 4. USES AND LIMITATIONS OF ECONOMIC ANALYSIS IN REGULATORY DECISION-MAKING.

Section 4.1. Benefit-Cost And Cost-Effectiveness Analysis

CMA strongly supports the Report's conclusions regarding the importance of benefit-cost and cost-effectiveness analyses in making regulatory decisions.

The Report recognizes economic analyses and legitimate and useful tools for evaluating regulatory options in the risk management framework. CMA's Risk Principles include benefit-cost analysis as a requisite tool among several to inform regulatory decision-making. We are pleased to note, and strongly support, the Commission's recommendation on the usefulness of benefit-cost analysis. We also agree with the Commission that not all benefits and costs can readily be assigned monetary values. Nevertheless, such values should be explicitly included in decision-making. When making regulatory decisions, the decision-maker should ultimately be able to determine whether the benefits of the rule – including non-quantifiable factors – justify the costs.

The Report recommends that economic analysis should not be the sole or overriding factor in making regulatory decisions. CMA believes protecting people's health and safety and the environment should always be the primary goal of risk management regulation. Nevertheless, benefit-cost analyses and cost-effectiveness analyses should always be a factor in deciding when and how to take regulatory action. This will ensure that will be used to obtain the overall optimal level of protection. Further, the role of benefit-cost analysis and cost-effectiveness analysis and the explicit use of their results in regulatory decisions should be clearly set out in the law.

The Commission also notes that economic analysis should present more information, where practicable, on the inequitable distribution of benefits and costs. We also agree with the Commission's comment that weighting benefits and costs quantitatively based on equity would be highly subjective and inappropriate. Economic analysis cannot adequately incorporate equity considerations quantitatively. The better approach, as recognized by the Commission, is to inform the decision-maker about who

receives benefits and who pays the costs in a more appropriate way to consider equity in benefit-cost analysis. The risk manager can use that information explicitly in making the regulatory decision.

Section 4.2. Uncertainty And Inconsistency In Economic Analysis

CMA agrees that the preference for transparency in risk assessments applies to economic analyses as well and that there is a need to develop consistent methodologies for conducting such analyses for use in regulatory decisions.

The Report points out that, like risk assessments, economic analyses have significant uncertainties and are imprecise. As with risk assessments, the Report recommends that those uncertainties be clearly articulated: "The primary sources of uncertainty associated with the results of economic analysis should be identified, characterized, stated explicitly, communicated clearly, and quantified where appropriate." CMA agrees that the value of transparency in risk assessment applies equally to economic analyses. Moreover, to achieve more consistent benefits valuation among regulatory agencies, CMA believes the value of risks should be stated explicitly and valued using best estimates or ranges of estimates, and using consistent procedures and basic assumptions. We believe the method the Commission proposes is an acceptable one where decision-makers apply consistent values to risks.

We suggest the Commission also consider recommending that the Guidelines for Regulatory Decision-Making published by the Office of Management and Budget in January 1996, especially the section on Benefit-Cost Analysis, as well as "Benefit-Cost Analysis in Environmental, Health, and Safety Regulation. A Statement of Principles,"[3] be adopted formally by administrative agencies and codified by Congress.

Section 4.3. Linking Risk Assessment and Economic Analysis

CMA agrees on the need to more closely coordinate the analyses of the risk assessors and the economists.

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[3] Arrow, K.J., Cropper, M.L., Eads, G.C., Hahn, R.W., Lave, L.B., Noll, R.G., Portney, P.R., Rulless, M., Schmalensee, R., Smith, V.K., Stavins, R.N., "Benefit-Cost Analysis in Environmental, Health, and Safety Regulation: A Statement of Principles." (1996) American Enterprise Institute, The Annapolis Center, and Resources for the Future. Washington, D.C.

The Report recommends that risk assessors and economists collaborate to improve economic analyses of risks and risk reduction options. (Report at p. 59.) Risk assessors have to prepare risk estimates with a variety of purposes in mind. It has often been observed that they must accurately describe the risk in a way that answers the questions the risk manager needs answered and that they must present the information in a way that fairly communicates to the public the magnitude and seriousness of a risk and places it in context. Frequently overlooked, however, is the point that the Report raises in this section. There is a need to find ways to present risk information, and to craft economic analyses to use that information, in a way that will best enable a risk manager to determine which risk management alternative is the most cost effective or provides the best balance of benefits and costs. We are pleased that the Commission has highlighted this issue.

CHAPTER 5. RISK MANAGEMENT AND REGULATORY DECISION-MAKING.

Section 5.1. Risk Characterization: Communicating and Comparing Risks

CMA generally agrees with many of the Commission's recommendations on the need for agency risk communication programs and the need for appropriate risk comparisons in communicating risk but urges the Commission to reconsider its preference for providing qualitative descriptions of the range and distribution of risks over quantitative ones.

5.1.1. Qualitative versus Quantitative Descriptions of Risk and Data Sufficiency.

Our comments on quantitative estimates of the range and variability of risk in section 3.3 apply to the Commission's Finding 5.1.1 as well as the accompanying recommendation. Qualitative information, including descriptions of the major assumptions, uncertainties and policy judgments embodied in the risk assessment, are always necessary to more clearly describe a risk and place it in context. However, CMA does not believe a point estimate accompanied by qualitative information describing uncertainties sufficiently informs the risk manager or the public. It does not adequately overcome the perception of accuracy and certainty conveyed by a single point estimate. In the end, it is those single numerical estimates that will become the shorthand measure of the risk and the only one most of the public will see. The Commission should recommend the use of quantitative descriptions of both uncertainty and variability for all risk assessment that are likely to underpin regulatory decisions that

will have a significant impact on the economy or on health, safety or the environment. The Commission should also recommend that central or most plausible estimates be provided in addition to the upper bound point estimates where quantitative descriptions of uncertainty and variability are not feasible.

The Report also recommends that participants should agree on how much information is necessary to make a risk management decision so that "endless data-gathering does not become an instrument for delaying or obstructing a decision or increasing costs." CMA believes that the issue of data sufficiency is ultimately addressed by law under the current environmental regulatory scheme and cannot be resolved by mere agreement among stakeholders. Statutes authorizing regulatory action contain a variety of standards for decision-making, for example: "reasonable certainty of no harm,"[4] "known to cause or is reasonably anticipated to cause...,"[5] and "... criteria for water quality accurately reflecting the latest scientific knowledge...."[6] Similarly, there are standards for sufficiency of evidence necessary to sustain a regulatory finding or determination in court. For most regulatory actions, an agency determination or finding that it has sufficient information to act will only be overturned if it is "arbitrary and capricious."[7] Other statutes, such as the Toxic Substances Control Act, set a higher standard, "substantial evidence" in that case.[8]

CMA believes that the Commission's the goals of avoiding unnecessary conflict and delay over data sufficiency are good ones, but the legal standards, such as those mentioned here will resolve that question. Under the current system, unless all affected parties agree to forego any judicial test of the agency's decision in court, no agreement early in the process, as the Report suggest, will completely resolve that issue.

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[4] See §405 of the Food Quality Protection Act of 1996, amending § 408(b)(2)(A)(ii) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 346; see also 21 CFR § 180.1.

[5] Emergency Planning and Community Right-To-Know Act, 42 U.S.C. § 11023(d)(2); Clean Air Act, 42 U.S.C. § 7412 (b)(2).

[6] Federal Water Pollution control Act, 42 U.S.C. § 1314 (a)(1).

[7] Administrative Procedure Act, 5 U.S.C. § 706 (2).

[8] Toxic Substances Control Act, 15 U.S.C. § 2618 (c).

5.1.2. Risk Communication Programs

CMA strongly concurs with the Commission's recommendation that agencies should develop rigorous risk communication programs.

The Report identifies the need for agencies to adopt comprehensive risk communication programs to help reduce misunderstanding about risks and risk reduction proposals. CMA agrees that a comprehensive risk communication program is necessary to provide adequate information about the risks agencies regulate. At a minimum that information is needed to participate as stakeholders in the risk management process in any meaningful way. CMA believes that a good risk communication program will provide information in terms that the public understands and will be tailored to answer the public's questions. A good risk communication program should also inform the public: (1) about the characteristics of risks; (2) about their relative seriousness; (3) about what we know and about what we are uncertain about; and (4) about the benefits associated with those risks. Most importantly, CMA believes that risk communication must be on-going. It must also be two-way and iterative – that is, part of a dialogue.

CMA also agrees with the Commission that these efforts are most effective on a community level where local facilities can communicate with nearby residents. CMA member companies are engaged in just such efforts. As part of the Community Awareness and Emergency Response Code of its Responsible Care® initiative, CMA members set up community advisory panels with local citizens to discuss issues of concern to the community. The Report cites, as an example, the efforts of member company Rohm & Haas. (Report at 68.)

Finally, CMA strongly supports the recommendation that agencies need to improve their risk communication skills and make that a higher priority.

5.1.3 Placing Risks in Context Through Comparison

CMA fully supports the Report's recommendations regarding the value of using comparative assessments of risk to convey information about the nature and magnitude of risks. CMA agrees with the types of comparisons that the Report recommends but suggests some additional information.

The Report recommends that information comparative risks are useful to convey information about the nature and magnitude of risks. The report suggests specific types of comparisons as useful:

- comparisons with chemically related agents,
- comparisons with different exposures to the same agent,
- comparisons with different kinds of agents with the same exposure pathways, or
- comparisons with different agents that produce similar effects.

Whatever may be said for the benefits or shortfalls of numeric estimates of risk, CMA believes they are inadequate for fully communicating information about risks. What is needed, as the Report notes, is information that places the risk in context. CMA supports the recommendation that comparative risk information should be provided. We also believe that the Report suggests the appropriate types of comparisons that should be made.

CMA would add to the Report's recommendation in two respects, however. First, CMA believes that information about the benefits associated with the risk should also be provided along with information about "substitution risks" -- the risks associated with avoiding that risk by changing behavior or substituting different substances for the same purpose. That additional information is necessary to place the risk fully in context and to identify the potential trade-offs inherent in any risk management decisions. Second, the Report notes that comparisons of unlike risks should be avoided. However, when used appropriately, comparisons of unlike risks can be illustrative in certain situations and can convey a sense of magnitude in terms familiar to the recipients of that information. We recommend that the Commission acknowledge the potential usefulness of such comparisons and suggest appropriate scenarios for their use.

Section 5.2. Comparative Risk Assessment for Risk Management

CMA shares the Commission's support for the use of comparative risk assessment by federal agencies for prioritization purposes but disagrees with the Commission that comparative risk should be conducted only on a

demonstration or experimental basis. CMA believes that there has been enough experience with comparative risk to begin using it now to prioritize agency activities.

The draft report presents a solid rationale of why comparative risk is a potentially valuable process for "priority-setting (that) brings together science and public values by making clear what is known and what is not known about the environmental challenges we face." (Report at 71.) In addition, the draft report properly characterizes the significant contributions made by state, local and tribal governments to the state of the art of comparative risk.

CMA strongly concurs with the part of the recommendation that states that comparative risk "should influence agency resource-allocation decisions." (Report at 71.) We strongly believe that federal agencies need to do a better job of prioritizing risks for budget purposes and that comparative risk is an essential tool in that endeavor. A central tenet of CMA's Risk Principles is the importance of "setting risk reduction priorities to address public health, safety, and environmental risks in a way that ensures protection to all segments of society." We believe comparative risk projects can lead to effective priority setting as well as offer a forum for stakeholder communication.

Our primary disagreement with the Commission's recommendation is one of timing. The draft report calls for the use of comparative risk on "an experimental or demonstration basis." (Report at 71.) We believe comparative risk is a mature process that warrants more than just a trial run. CMA believes that the sooner federal agencies undertake comparative risk projects the sooner there will be a body of knowledge and experiences upon which to draw.

We urge the Commission to expand its recommendation to require agencies to make explicit how they use comparative risk ranking as a priority setting tool to make decisions. This analysis should be part of an agency's justification of its annual appropriation request to the Office of Management and Budget and the Congressional Appropriations Committees. Given their documented interest in comparative risk, the House and Senate Appropriations Committees would be good candidates for further discussion on how this concept would work in practice.

CMA agrees with the Commission's finding that state, local and tribal comparative risk projects "constitute a worthy starting point for federal agencies to use in ranking priorities and making resource-allocation decisions." (Report at 73.) We also agree with the Commission finding that the state and local experience has shown that "there is no guarantee that the process will produce consensus among stakeholders, agencies, and funding authorities." (Report at 73.) However, we believe that an absence of consensus is certainly not a mark of failure. As the draft report notes in Chapter 2, Framework for Risk Management, "Those difficulties in reaching a decision should be viewed not as a failure of the process envisioned by the framework, but simply as a recognition that in some instances, notwithstanding the best efforts of all affected parties, consensus will not be achievable." (Report at 10.)

Section 5.3. Bright Lines

CMA believes that the Commission's recommendation on "Bright Lines" is equivocal and needs further clarification. We believe that bright lines may be successfully used only as a criterion to differentiate those problems, issues, sites, etc. that do not require further inquiry from those that do require further evaluation by a more exhaustive and extensive analytic process to determine if action is necessary.

This section of the report finds that while often relied upon by risk managers, bright lines, strictly applied, "cannot explicitly reflect uncertainty about risks, population variation in susceptibility, community preferences and values, or economic considerations, all of which is required by the Commission's risk-management framework." CMA agrees with these conclusions. Yet CMA does not necessarily agree with the Commission's proposed response: that bright lines should be used flexibly for decision-making as goals or guidepost and that multiple bright lines should be used, protecting particular populations. These recommendations seem to mischaracterize the value of bright lines by joining them with decision-making, as opposed to linking bright lines to screening or first-tier analysis.

CMA agrees with The National Academy of Sciences report, *Science and Judgment in Risk Assessment* (as referenced in Report at 74) which characterized bright lines as "magic numbers" that are inconsistent with knowledge about the distributions of risk and their inherent uncertainty.

CMA Risk Principles also address bright lines, stating that "CMA does not support the setting of precise numerical risk levels in legislation or regulatory standards." In adopting this policy CMA has sought to avoid a detrimental oversimplification of the science of risk assessment and to increase the transparency of the risk management process. While regulators and risk managers find comfort in the risk/no-risk determination that a bright line provides, science does not support such a precise boundary between adequate safety and unacceptable risk. Viewing bright lines as "magic numbers" obscures the uncertainty, variability and assumptions inherent in every risk assessment. In addition, risk management decisions based on bright lines fail to include important site-specific parameters such as variations in populations susceptibility, community preferences and values, or economic considerations.

CMA believes that bright lines should not be applied to any other purpose than for screening, and not for risk management decision-making. Further, CMA believes that the use of bright lines or multiple bright lines as risk level goals for the general or susceptible populations is inappropriate. It negates the entire six-step framework for Risk Management that the Commission proposes by stating that there "is a single numerical value between unacceptable and negligible magnitudes of risk or exposure concentrations of concern." (Definition contained in Report at 74.) The goal is to manage the risk to an acceptable level as determined by a reasoned process exemplified by the six-step framework. The goal is not some predetermined "magic number, bright line."

There are references to bright lines in other sections of the draft report including those relating to Exposure Assessment and the EPA Office of Air and Radiation. These references are all slightly different, and often confusing variations of the same theme. Some of the statements we can support, others we cannot, and still others are too ambiguous. CMA believes that the use of bright lines or "flexible bright lines" (Report at 102) are an acceptable element in decision-making.

Bright Lines in Residual Risk

The concept of bright lines is addressed in the Screening Risk Assessments and Detailed Risk Assessments segments of Section 6.1.1. CMA supports the use of 10^{-6}

"bright line" in the Screening Risk Assessment because, as stated earlier, bright lines are a key element of screening analyses. We also support the use of a 10^{-5} "bright line" in the Detailed Risk Assessment because as stated "additional controls or process changes should be evaluated [emphasis added] if more detailed risk assessments performed within source categories found to have high priority yield incremental lifetime cancer risks of $\geq 10^{-5}$ . . . ." (Report at 99, lines 42-44.) We do not support the confusing remainder of the sentence on page 99, line 44 and page 100, line 1. That part of the sentence reads ". . . to reduce them below 10^{-5} or 1, respectively" and is an inappropriate use of the 10^{-5} "bright line" as some predetermined risk management level that must be met regardless of what occurs in the six-step evaluation framework.

This sentence exemplifies the confusion contained in the report which the Commission seems to recognize on page 102, line 9, where 10^{-5} is called a "flexible bright line." We observe that if "bright lines" are used only as screening tools that trigger a further evaluative process, this confusion is remedied. The evaluative process, as it should, then determines the acceptable level of risk.

Section 5.4. Alternatives to Command and Control

CMA agrees with the need to explore alternatives to command-and-control regulations and concurs with what we believe the Commission has emphasized in the Report.

The greatest future progress in protecting health, safety and the environment will come from use of alternatives to command and control as regulatory strategies. CMA supports what it sees as the major conclusions of the Report in this area, which are:

1. Alternatives are needed because the existing system is fast approaching (or has arrived) at the level of diminishing returns, and no one -- corporations, municipalities, states, EPA -- has resources to use where they are not doing the most good.

2. The greatest potential for reductions in environmental loadings is with non-point sources and small point sources (such as individuals), neither of which lend themselves -- politically or practically -- to one-size-fits-all, command-and-control

approaches (consider the outcry over Clean Air provisions addressing auto emission inspection and carpooling).

3. The Report identifies tools for understanding the consequences of economic activity and environmental protection and tools that can be used as alternatives to command and control regulation. Those tools, identified as just that -- tools, should be used when and where they make sense. The tools identified may not be appropriate in all circumstances, but should be employed when and where they are appropriate. We must not replace one command-and-control system with another that just happens to be composed of different elements.

4. Most importantly, these tools should be risk-based or used to identify and respond to risk reduction opportunities. CMA does not believe enough emphasis was placed on the goal of risk reduction as a key component in each of these tools. Several of the tools, for example, tradable permits and TRI, emphasize reductions in loadings with no consideration of potential exposures or risks presented by the loadings. A firm or facility managing to reduce substances on a list is not necessarily managing to reduce risk. The usefulness of a tool should be measured by its ability to identify, compare, and reduce risks in a way the permits the optimal use of resources.

The following are comments on the tools identified in the report.

Environmental Accounting: Specific "green accounting" systems will need to be designed and developed for individual companies based on their own needs and internal managerial accounting systems. It would be inappropriate to try to mandate specific accounting requirements or standards. When firms see merit in the concept, they will adopt it.

Industrial Ecology & Life Cycle Analysis: The closed-loop system concept is appealing, but the environmentally utopian phrases such as "no resources are depleted," "all materials are perpetually reused," and "no waste is produced or discarded" distract from the needed and technically achievable goal of optimization. The key word is *"optimize"* (Report at 79, line 14) which implies that decisions and

designs are a series of trade-offs, not simply a maximization, and that decisions must be made depending on the conditions presented.

Life cycle analysis is a specific methodology that is very expensive and still under development. What we want is better consideration of the product or process over its life-cycle rather than a resource and time intensive, prescribed methodology which may or may not be appropriate in all cases.

Environmental Audits: CMA agrees that audits improve performance and should be considered in an agency's penalty policy. Environmental audits are effective and are being used now. They should not be classified as a "tool" being developed.

Market-based Incentives: CMA also agrees the value of tradable or bankable credit system .

Right-to-know etc.: CMA agrees that programs such as the Toxic Release Inventory have been successful in creating incentives to reduce releases, and have done so by providing each company the flexibility to determine the best way to do so. Flexibility in achieving environmental goals, however, will do more to spur pollution prevention where it also linked to the ability to prioritize reduction opportunities based on risk reduction potential.

Programs that artificially target a list of substances (through reporting, labeling or other "environmentally preferable product" programs) without regard to the relative risks posed by those substances as they are used or released in a given situation are not as efficient or effective as they could be. For example, facilities have reduced those substances on the TRI list and those identified through the 33/50 program – regardless of whether reduction of those substances offered the greatest overall benefit and reduction in risk for a given facility or community. We suggest the Commission recommend programs be developed, or enhanced, to take into account both relative risk and substitution risk issues.

On the other hand, the report cites no empirical data to support the assertion that the kind of information required to be disclosed under Proposition 65 has done anything to reduce risk or pollution. The report quotes David Roe of the Environmental Defense Fund, who co-authored the original proposition, as stating that

Proposition 65 "...has had widespread support from environmental and business communities." (Report at 80). No such support has been forthcoming from our member companies due to numerous scientific and technical shortcomings in the Proposition 65 program. Furthermore, in contrast to the Mr. Roe's belief, we are aware of numerous legal challenges that have been initiated by the regulated industries and are continuing to date not only over important implementation and enforcement provisions, but also over chemical-specific issues. Moreover, as a matter of risk communication, the blanket statement required by Proposition 65 is ineffective and likely creates more misinformation and confusion, or worse, devaluates the accuracy and credibility of hazard warnings.

CMA believes appropriately informative disclosures and labeling can be useful alternatives to command and control regulations, but due to the shortcomings of Prop 65, CMA suggests that the Commission eliminate references to it as an incentive for pollution prevention and risk reduction.

Alternative Compliance: The concept of alternative compliance offers significant opportunities for risk reduction and cost savings. CMA fully supports this concept; however, we believe that at this point it should be listed with the tools being developed rather than those shown to be effective. The XL projects listed are under negotiation, with the biggest outstanding issue being EPA's legal authority to allow waivers from the existing command-and-control system.

Consensus, Mediation & Dialogue Projects: Intuitively, such programs hold significant promise and CMA supports their use where appropriate. The Common Sense Initiative (CSI), however, has yet to demonstrate significant results beyond facilitating discussions among the parties. CSI should, at best, be classified as a tool under development not as an alternative shown to be effective.

Section 5.5 -- Peer Review

CMA strongly endorses the Report's recommendations to expand the use of peer review to economic analyses, social science information and the use of scientific and economic data in decision-making but has serious concerns regarding the recommendations on effect of potential conflicts of interest on the eligibility of potential peer reviewers.

The Commission makes a number of important recommendations regarding the use of peer review. Specifically, they recommend expanding the use of peer review to cover review of how information is used in decision-making and to cover other types of information, such as economic and social science analyses. It also calls for peer review guidelines and varied levels of peer review depending on the decision to be made. CMA agrees with these recommendation on peer review. If anything, we would urge the Commission to enhance its recommendation to suggest to Congress and the President that "the role of peer review be expanded to consider not only the quality of the information, but the use of that information in regulatory decision-making." Better use of scientific and economic information in the regulatory process should produce better decisions.

Peer review is the best way to continuously improve both the information and its use. An auxiliary benefit to peer review – one not often discussed – is that it can ameliorate the intrusiveness of judicial scrutiny into both the science and the agency's use of that science, an issue addressed in the next section. If the courts are satisfied that the peer review process was a rigorous one, they will likely be guided by the expert opinions of the peer reviewers.

The value of peer review, however, will depend on the consistent quality of the process. As the Report notes, "Clear written guidelines for peer review should be established by the regulatory agencies and the effectiveness of agency peer review programs should be evaluated regularly." We agree. We also believe that the peer review process should be an open one. Peer review panels should consist of independent and external experts who are broadly representative and balanced, to the extent feasible. Most importantly, peer reviewers should be highly qualified with substantial expertise in their respective fields.

In that regard, we believe the Commission is wrong in its recommendation that "potential peer reviewers with clear conflicts of financial interest should be disqualified from service on peer-review panels that could directly influence decisions related to the products or interests of their organization." We believe that full disclosure of all financial or organizational interests best serves as a criterion for selection of peer reviewers.

As the Commission points out, biases of all sorts exist and history suggests that they cannot be easily detected or defined for purposes of qualification. All too often in the past industry's scientists or industry-financed scientists have been disqualified while others from academia or the environmental community who also have biases (not perceived to be financial) are permitted to serve. This dual standard should cease. The scientific expertise of the otherwise qualified individuals should not be lost to peer review panels merely because those individuals have a relationship with financially interested stakeholders on either side of the debate. Full disclosure of interest remedies this imbalance and qualifies all who may be competent peer reviewers with the safeguard of disclosure. It is important to bear in mind that peer reviewers are not analogous to judges or juries. They do not make the decision, but are, in essence, the expert witnesses. The risk manager, as true decision-maker, must weigh the quality of their opinions along with any information about their biases, financial or otherwise.

Finally, we refer the Commission to AIHC's Fundamental Scientific Peer Review Principles (5&6) for further elucidation.

Section 5.6 Judicial Review

CMA urges the Commission to reconsider this section on judicial review and refocus it away from issues raised in specific past legislative proposals toward articulating the general principles that should govern judicial review in the event Congress adopts a new framework for risk assessment and risk management decisions. Those principles should be based upon current standards of judicial review of administrative actions.

The Report contains an extensive discussion of the role of the courts in reviewing agency risk assessments and risk management decisions. The thrust of this discussion is that regulatory reform proposals pending in the current Congress would result in a dramatic and unproductive expansion of judicial oversight of the regulatory process. According to the Commission's draft report, "new opportunities for judicial review would result in costly and unacceptable delays in the rulemaking process" and lead to "increased and more complex litigation over agency decision-making on highly scientific substantive matters." (Report at 87.)

Unfortunately, the Commission's Report bases its recommendations on generalizations about the contents and impact of the many regulatory reform proposals

introduced in this Congress. In fact, the bills Congress has considered have been diverse and constantly evolving, and the Commission's generalizations simply do not represent an accurate description of the proposals that have received most serious consideration. As a result, the Commission's report presents a one-sided and distorted characterization of the Congressional regulatory reform debate.[9]

CMA is uncertain why the Commission elected to address the subject of judicial review at such great length. Although this issue is clearly important, it seems to lie outside the scope of the Commission's deliberations, which have focused mainly on the risk assessment and risk management practices of federal agencies. If the Commission includes comments on judicial review in its final report, we recommend that the Commission refocus this discussion. Instead of criticizing pending legislation, the Commission would do better to address the general relationship between judicial review and agency decision-making and outline the broad principles which should shape the role of the courts under any future legislation which Congress considers.

Because the Commission has mischaracterized the regulatory reform debate in the current Congress, its draft report conveys the impression that any legislation establishing general guidelines for agency risk assessments and cost-benefit analyses will inevitably engender wasteful litigation and involve the courts in complex issues which they lack the expertise to address. This conclusion is at odds with the historical role of the courts in reviewing agency action. It also fails to recognize the extensive oversight role that the courts now play under existing health, safety and environmental statutes – a role that legislation creating a new framework for risk assessment and cost-benefit analysis would not measurably enlarge.

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[9] For example, the Commission's concern about delays in rulemaking due to judicial review is based on the premise that, under the proposed legislation, "a number of initial and intermediate determinations in the rulemaking process were deemed final agency action." (p. 86). This is simply not true of the regulatory reform bill, H.R. 1022, which was passed in the House. As debated on the floor of the Senate, S.343 provided for interlocutory review solely of the agency's determination that a rule was not "major" and only because judicial consideration of this issue could result in delay and unnecessary expenditure of agency resources if deferred until the end of the rulemaking process. The Commission report provides an extremely misleading picture of these bills by suggesting that "interested parties could prematurely, and in piece-meal fashion, seek judicial review of discrete issues and effectively delay and hamstring the regulatory process."

The long-standing principles which govern judicial review of agency action are reflected in Section 10 of the Administrative Procedure Act (APA) and the judicial review provisions of several individual regulatory statutes. The APA provides that: "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. This right of review applies to "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court. . . ."5 U.S.C. § 704.

The Commission is simply not correct in asserting that courts reviewing agency action have limited their examination to "questions of law [and] constitutional and procedural issues". (p.87.) The standard that reviewing courts apply under the APA is set forth at 5 U.S.C. § 706. That provision directs reviewing courts to –

> "hold unlawful and set aside agency action, findings, and conclusions found to be –
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> * * *
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law;
>
> (E) unsupported by substantial evidence in a case . . . reviewed on the record of an agency hearing provided by statute. . . ."

The APA provides that in making these determinations, "the court shall review the whole record or those parts of it cited by a party and due account shall be taken of the

rule of prejudicial error." Some individual enabling statutes, such as the Clean Air Act, contain their own special judicial review provisions which generally reflect the same principles as the APA.[10]

If the well-established principles for judicial review developed under the APA and individual laws are reflected in regulatory reform legislation, the courts would continue to perform their long-standing responsibility to assure principled decision-making by agencies without creating new litigation opportunities or subjecting rules to unproductive judicial oversight. For example:

- Under the doctrines of "finality" and "ripeness," the adequacy of a cost-benefit analysis or risk assessment would be reviewable only at the end of the rulemaking process.[11] The courts would not intervene at preliminary or interim stages of agency rulemakings; rather, interlocutory appeals would be barred.

- Risk assessments, cost-benefit analyses and peer review materials would not be reviewed in a vacuum. Rather, they would be included in the rulemaking record and would be reviewable as part of the record as a whole.

- Minor imperfections in otherwise reasonable and supportable rules would not cause the courts to overturn those rules. Based on the doctrine of prejudicial error in the APA, the courts would not search for technical deficiencies in a risk assessment or cost-benefit analysis

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[10] Some statutes such as the Toxic Substances Control Act substitute the "substantial evidence" standard for the APA "arbitrary and capricious" test. Contrary to the Commission's draft report, the courts view those standards as closely equivalent in cases reviewing complex rulemaking records. See, e.g., Sierra Club v. Costle, 657 F.2d 298; 323, n. 67 (D.C. Cir. 1981); Lead Industries Association v. EPA, 647, F.2d 1130, 1146 n. 30 (D.C. Cir. 1980)

[11] Abbott Laboratories v. Gardner, 387 U.S. 136 (1967); Franklin v. Massachusetts, 112 S. Ct. 2767 (1992); DRG Funding Corporation v. Secretary of Housing and Urban Development, 76 F.3d 1212 (D.C. Cir. 1996).

that did not impair the agency's decision-making process.[12] Rather, the guidelines for conducting risk assessments and cost-benefit analyses provided by Congress would assist in determining whether, based on the entire record, the agency's scientific conclusions and policy choices are rational and supportable.

- In keeping with well-recognized limits on the scope of judicial review, courts would defer to the scientific and technical expertise of regulatory agencies.[13] Thus, agencies that provide a reasoned and thorough explanation of their interpretation of complex scientific evidence should have little to fear from reviewing courts.

- The application of new "decisional criteria" -- such as a requirement to determine that a rule's benefits "justify" its costs -- would not overturn well-settled standards of judicial review.[14] Agencies now apply extensive "decisional criteria" in response to the detailed and often intricate standard-setting provisions of existing health, safety and environmental statutes. Courts reviewing agency rules under these statutes are accustomed to

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[12] Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 521 (D.C. Cir. 1981); Braniff Airways v. C.A.B., 379 F.2d 453, 465-466 (D.C. Cir. 1967).

[13]. See, e.g., Ethyl Corp. v. EPA, 541 F.2d 1 , 26-27, 36 (D.C. Cir. 1976); National Lime Association v. EPA, 627 F.2d 416, 454 (D.C. Cir. 1980); Public Citizen Health Research Group v. Tyson, 796 F.2d 1479, 1495 (D.C. Cir. 1986).

[14] Versions of these decisional criteria have been included in several of the regulatory reform bills considered by Congress. The draft Commission report asserts that, as a result of these criteria," the findings of cost and risk evaluation, conflicts with regard to scientific data, the postulates regarding the most reasonable inferences from supporting toxicology and epidemiological data, and determinations of whether an agency sufficiently used the appropriate information in its analysis, would become inexorably part of the agency record and, therefore, the subject of judicial scrutiny." Report at 88. However, as discussed in the text, courts already review these portions of the rulemaking record and new decisional criteria should not change the standard which governs that review.

> examining whether the agency has applied the correct legal standard and its conclusions are supported by the record. If agencies must apply a further benefit-cost standard,[15] reviewing courts would perform their customary function of assuring that applicable legal requirements have been observed and the agency has not abused its discretion.

If these principles are applied, litigation challenging agency actions should not become more protracted and complex. Nor will there be any risk of a "new wave of litigation causing more delay and more costs to agencies and parties."[16] It is important to recognize that nearly all major rules issued by health, safety and environmental agencies are now reviewed judicially at the behest of activist groups or affected parties disappointed with the outcome of the rulemaking process. Thus, the number of judicial review proceedings is unlikely to increase if risk and cost-benefit legislation is enacted. Moreover, such proceedings already involve extensive records and numerous legal and technical disputes because of the complex technical and legal issues that arise under existing regulatory statutes. For this reason, legislation creating new guidelines for risk assessments and cost-benefit analyses should not measurably add to the workload of litigants or appellate courts.

Most importantly, the Commission's report does not recognize the benefits of judicial review in assuring the quality and integrity of agency analyses of complex health and environmental issues. The case law emphasizes the obligation of agencies to engage in "reasoned decision-making," to rationally address all major issues raised and explain all policy choices made during the rulemaking process, and to identify evidence in the record supporting all factual findings and conclusions. The courts will be expected to take a "hard look" at agency rules and supporting analyses to determine if

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[15] For major rules, a determination that benefits justify costs is already required by the President's executive order for regulatory decision-making (E. O. 12866).

[16] Commission Report at 91.

these obligations have been discharged.[17] Courts applying these traditional standards of review to agency rules promulgated under existing health and environmental laws have not hesitated to scrutinize highly technical issues and set aside scientific findings that are not supported by the record or linked to the agency's policy choices. Thus, even without new legislation, courts already look critically at the quality of risk assessments and reject regulations accompanied by risk assessments that do not identify major assumptions or address key issues raised by interested parties.[18]

For these reasons, legislation establishing general principles for conducting risk assessments and weighing costs and benefits is unlikely to result in unnecessary scrutiny of the scientific and economic findings of agencies. At the same time, such legislation should simplify the task of reviewing courts by providing a useful framework for judging the adequacy of the risk assessments and cost-benefit determinations which support complex agency rules. Rather than allowing courts to form their own judgments about the quality of agency technical analyses, clear and understandable legislative guidance should thus provide criteria which clarify the issues on review and expedite the judicial review process.

In conclusion, the Commission should reconsider and refocus its discussion of judicial review. Legislation pending in the 104th Congress should not be addressed by the Commission. Instead, it should identify the general principles that should govern judicial review in the event Congress adopts a new framework for risk assessment and risk management decisions. As demonstrated above, application of the judicial review provisions of the APA and accompanying case law should enable the courts to perform

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[17] See, e.g., Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971); Motor Vehicle Mfrs. Ass'n of the United States v. State Farm Mut. Automobile Insurance, 463 U.S. 29, 43 (1983); Burlington Truck Lines, Inc. v. U.S., 371 U.S. 156, 168 (1962); Edison Electric Inst. v. EPA, 2 F.3d 438, 446 (D.C. Cir. 1993); American Mining Congress v. EPA, 907 F.2d 1179, 1187 (D.C. Cir. 1990).

[18] Industrial Union Dep't v. American Petroleum Institute, 448 U.S. 607 (1980) (setting aside OSHA benzene standard); Gulf South Insulation v. CPSC, 701 F.2d 1137 (5th Cir. 1983) (overturning CPSC standard for formaldehyde insulation); Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991) (setting aside EPA asbestos ban); NRDC v. EPA, 824 F.2d 1146 (D.C. Cir. 1987) (reversing air rule on vinyl chloride); Chemical Manufacturers Association v. EPA , 28 F.3d 1259 (D.C. Cir. 1994) (reversing designation of chemical as high risk pollutant).

their traditional role of assuring the integrity of agency decision-making without creating unnecessary litigation or limiting the expert judgment of agencies.

CHAPTER 6. RECOMMENDATIONS FOR SPECIFIC REGULATORY AGENCIES AND PROGRAMS.

Section 6.1.1 Office of Air and Radiation

CMA agrees with the Risk Commission's support of the use of screening assessments to determine which facilities within source categories or subcategories need to take additional risk assessment or risk management steps. CMA believes MACT standards will greatly reduce emissions of HAPs, and that further reductions should be based on site-specific considerations of remaining risk.

The Commission recommends evaluating risks together at facilities that have more than one high priority source category. (Report at 100, lines 4-5) CMA supports the source-category-by-source-category approach (e.g., chemical manufacturing, oil refining, polymer and resin manufacturing, etc.) to risk assessment required by 112(f). CMA recognizes, however, that in some instances, a multi-manufacturing facility with more than one source category may wish to evaluate risks from high priority categories at one time, rather than go through several, separate rounds of risk screening and risk assessments under the source category approach. An integrated risk management strategy can be developed to address sources of remaining risk, which will be a more effective use of resources. Such an approach should not be taken until the entire facility has achieved the emission reductions required by all applicable MACT standards. Also, a different set of risk criteria should be used to evaluate groups of source categories than the risk criteria applied on a source category basis.

Sub-section 6.1.1.1. Implementation of the Residual-Risk Provisions

CMA agrees with the Commission's proposal of a tiered scheme to determine and manage residual risk after implementation of MACT. In particular, CMA supports the statement that screening risk assessments must rely on default assumptions that are realistic and chosen with care. CMA also agrees that the hypothetical maximally exposed individual (MEI) concept should not be used.

The Commission's draft report calls for a screening risk assessment for sources in a category or subcategory of sources using, a screening model. (Report at 99) This step of the process is to guide the decision as to whether sources in the category or

subcategory need to be evaluated in more detail. Given this purpose, the use of realistic and carefully chosen default assumptions is appropriate.

The draft report also specifically cautions against the use of the hypothetical maximally exposed individual (MEI) as a default assumption of exposure. (Report at 101) This is very important and appropriate guidance which CMA strongly supports. The MEI assumption, which has previously been used by the EPA, and has guided some decisions regarding Hazardous Air Pollutants (HAPs) under the Clean Air Act, is so overly conservative and unrealistic that the results are misleading. Concern regarding the use of MEI lead Congress to select a different term to describe their intent to protect the "individual most exposed" to HAP emissions from a source. They did not use the term "MEI" because it does not represent a realistic and carefully chosen default. Rather, it represents an unrealistic, "worse than worst" case assumption which can only contribute to misleading assessments. CMA strongly supports the Commission's recommendation regarding MEI and agrees that this is advice requested of the Commission by Congress in the Clean Air Act.

CMA understands that the default assumptions used in the screening risk assessment are intended to be replaced with more specific data and information when more detailed risk assessments are conducted. However, while this is implied by certain statements in Section 6.1.1.1, it is not explicitly stated. CMA therefore recommends that the need to replace default assumptions when more detailed risk assessments are done, be explicitly stated in Section 6.1.1.1.

Sub-section 6.1.1.2 MACT Partnership Program

CMA supports the recommendation in 6.1.1.2 that an evaluation process for the partnership program be established. Expansion of the program, as also recommended, should await the results of such an evaluation process.

As stated in finding 6.1.1.2, the intent of the partnership program is to optimize the knowledge, skills, and resources devoted to standard development[19]. The evaluation process should provide insight as to the optimum mix and timing of partner

[19] A word is missing in the Commission's recommendation under finding 6.1.1.2. The second sentence should read: "EPA should establish an evaluation process for the partnership program."

participation. It may be that an untimely expansion of the partners could inhibit rather than enhance the sharing of information and such a result should be avoided. Therefore, the Commission should recommend that EPA initiate and rely on the recommended partnership evaluation process and delete recommendations that prejudge the results of that process.

Sub-section 6.1.1.3 Multiple MACT Standards

CMA agrees with the key point made in this finding that the impact of multiple regulatory requirements must be considered. However, the situation is created by the overlapping and duplicative application of a variety of standards. There should not be more than one MACT standard applied to a single emission point.

While CMA does not disagree with the recommendation regarding the integration of multiple requirements and flexibility for sources with multiple compliance schedules, it is not clear how the Commission intends this to function with respect to any residual risk rules pursuant to the Clean Air Act section 112(f). Therefore, the Commission should refocus this finding to address multiple requirements including MACT standards and clarify that this finding is intended to affect the implementation on residual risk requirements in the Clean Air Act section 112(f).

Section 6.1.2. Superfund

CMA has reviewed the chapter on Superfund and supports the Committee's thoughtful recommendations for broad-based reform of a deeply troubled program. However, CMA would suggest further clarification on a number of points.

In Finding 6.1.2.2 the Commission correctly acknowledges that applicable or relevant and appropriate state or federal requirements (ARARs) impede the selection of protective, site-specific remedies. The Commission goes on to recommend that the Congress amend the ARARs provision of Superfund to delete the "relevant and appropriate" language while retaining "applicable requirements." CMA would make the further distinction that "applicable requirements" are of two types: some applicable requirements set remediation or cleanup levels while others are relevant to the

implementation of a remedy (e.g., NPDES or Clean Air Act emission standards). The applicable requirements that set "bright line" cleanup standards do so without consideration of site-specific information. As a result, many state applicable standards could be impediments to site-specific remediation. CMA suggests that the Commission refine its recommendation to retain only the implementation applicable requirements.

In Finding 6.1.2.3, the Commission recognizes that statutory preferences for permanent and treatment-based technologies are an impediment to the selection of protective, cost-effective remedies. However, the Commission then appears to reinstate the preferences for treatment of "highly hazardous material." CMA opposes any preference to require permanent or treatment-based remedies as they negate the value of risk-based remedy selection. EPA should have the flexibility to choose a remedy that is protective and is most appropriate for the specific site. Remediation of highly concentrated or especially problematic areas of contamination should be considered as part of the overall site cleanup. A more appropriate criteria for the selection of specific remedies would be to balance the following factors: 1) the effectiveness of the remedy in protecting human health and the environment; 2) the reliability of the remedy in achieving the standard over the long-term; 3) any short-term risk to the affected community, to those engaged in the remedial action effort and to the environment posed by the implementation of the remedy; 4) the acceptability of the remedial action to the affected community; 5) implementation and technical practicability of the remedial action; and 6) the reasonableness of the cost.

On the issue of revising Records of Decision (RODs) in light of improved technology or experience, CMA strongly supports the Commission's recommendation that such remedies should be reopened (Finding 6.1.2.5). The greatest challenge on this issue is to develop a criteria for reopening RODs that would benefit from this review, without overwhelming the Agency's or the states' ability to respond. CMA has engaged a number of states and agencies in discussions on this issue and is familiar with the specific concerns such a program would face. CMA would be willing to participate in a stakeholders' group to develop such a program.

CMA also supports the Commission's finding 6.1.2.6 that would continue support of the Agency for Toxic Substances and Disease Registry (ATSDR). In addition,

CMA would suggest that ATSDR be formally joined with the Centers for Disease Control and Prevention (CDC), a position that ATSDR itself has advocated in Congressional testimony. This realignment would provide ATSDR with greater access to the expertise and resources of the larger public health agency.

On the issue of the National Institute of Environmental Health Sciences (NIEHS), CMA agrees that a greater understanding of the issues relating to Superfund sites can benefit the remediation of these sites. However, for the Superfund program to benefit from this research, NIEHS must remain vigilant in overseeing the quality of its research, and must also focus on research projects that will have practical applications within the next 5 to 10 years. After that time, the majority of Superfund sites will have completed the remedy selection phase and will be under construction.

Section 6.1.3 Office of Pollution Prevention and Toxic Substances.

This subsection of the Report raises a number of issues. CMA provides comments only on the recommendation with respect to TSCA and endocrine disruptors.

6.1.3.3 Toxic Substances Control Act (TSCA)

> **CMA does not agree that Congress needs to rewrite or revise TSCA. TSCA is a risk-based statute and provides EPA with all of the authority and flexibility necessary for EPA to protect human health and the environment from unreasonable risks posed by new and existing chemicals. CMA does agree that EPA should continually review and improve its administration and implementation of TSCA, and CMA continues to work cooperatively with EPA to this end.**

The Commission maintains in the Report that the Toxic Substances Control Act (TSCA) needs to be updated by the EPA and Congress, specifically to identify the types of data that should be required under sections 4 and 8 of TSCA. While CMA believes that administrative improvements to keep pace with changing science are always necessary, we do not see the need for any legislative activity regarding TSCA and CMA disagrees with the Commission's recommendation in 6.1.3.3.

TSCA occupies an important position among the numerous health and environmental statutes. It is the only law that provides EPA with the authority to: regulate new and existing chemical substances not otherwise regulated by other

statutes; gather chemical use, exposure, and toxicological information; require testing; and regulate unreasonable risk. There are no fundamental flaws in TSCA; it provides EPA with the authority and flexibility EPA needs to protect human health and the environment from unreasonable risk. Problems in its administration and implementation have been, and are being, constantly evaluated by EPA, industry, and other stakeholders.

CMA believes the Commission misinterpreted EPA's authority to require testing of chemical substances for toxicity under section 4 of TSCA. Section 4 gives EPA broad authority to require health or environmental testing of existing chemicals if EPA finds that a chemical substance may present an unreasonable risk or there is substantial production with substantial release or potential human exposure. One example of the flexibility accorded EPA by TSCA is the cooperative effort between industry and EPA in the voluntary joint Use and Exposure Information Project (UEIP) pursuant to which industry provides EPA with use and exposure information on high priority chemicals identified by EPA to assist the agency in the implementation of its Risk Management (RM-1) program. Such data can be used by EPA to ascertain any need for additional testing of these chemicals.

With respect to the recommendation that TSCA should be clarified regarding specific testing and reporting requirements, the Commission report states that the "OECD recommends a basic set of testing requirements for new chemicals" and "Congress should consider providing EPA with similar authority to specify studies." The report does not make clear that an OECD recommendation does not carry the weight of an OECD enforceable decision; nor does it clarify that, in practice, the "base set of testing" referred to equates to the Minimum Pre-Market Data (MPD) in use by the European Union (EU), which exerts a significant influence on OECD activities. This attempt to justify a specific set of testing based upon a recommendation to OECD member states does not reflect a fundamental and important difference between the U.S. and EU approaches to testing of chemicals. Specifying a list of tests, as is the practice in the EU, would be counter-productive to giving EPA the flexibility to respond to new issues and emerging science. Further, it would hinder the agency's authority

under TSCA to appropriately and adequately assess the risk of chemicals in the marketplace.

With respect to record-keeping and reporting requirements under Sections 8(c), (d), and (e) of TSCA, EPA is currently reevaluating the regulations and guidance it has issued to implement these subsections of the law. CMA is among those entities working cooperatively with EPA to update these requirements.

The Commission's finding that under TSCA, the EPA "is mostly limited to review of data submitted, without being able to specify what studies should be conducted" is inaccurate. In the case of new chemicals, although the statute does not specify which tests to conduct, the agency has complete flexibility to require test data in order to meet its obligation to make a finding of no unreasonable risk. Manufacturers preparing to introduce a new chemical into the marketplace are well aware of this agency obligation, and in practice provide a wealth of data which will enable the agency to meet its obligation and appropriately assess any potential risk for that new chemical. Currently, under Section 5 of TSCA, EPA has the authority to review new chemicals through the pre-manufacturing notification process. EPA promotes the submission of data on new chemicals, and, through the use of consent orders under Section 5(e), EPA can require testing or delay or regulate the marketing of a new chemical. In the case of existing chemicals, under TSCA section 4 specific testing protocols and/or testing guidelines accompany proposed rules for end points of concern. In summary, CMA maintains that Congress should not mandate any particular tests lest such legislation freeze the development of new tests for toxicological endpoints and not allow the flexibility to set rational testing priorities based on the exposure potential of individual chemicals, potentially misdirecting testing resources.

CMA disagrees with the inference of the comment that TSCA could "potentially provide a richer database than the National Toxicological Program (NTP), although *without the systematic quality control* of NTP bioassays." (Emphasis added) This statement does not reflect the fact that all TSCA testing requires adherence to Good Laboratory Practices (GLP) which ensures systematic quality in testing procedures.

CMA concurs that many of the scientific issues related to endocrine disrupters are now being framed. The questions posed by the Commission are among the questions industry and government scientists have been grappling with over the last couple of years. Resolving these questions will be the primary challenge in implementing the requirements of the newly legislated screening test requirements contained in the Safe Drinking Water Act Amendments and the Food Quality Protection Act of 1996. We believe the multi-stakeholder dialogue on screening and testing recently launched by EPA is a positive first step. As noted in the Commission's report, industry, through the Chemical Industry Institute of Toxicology as well as other programs, is making research on endocrine effects a priority.

Section 6.1.4. Office of Water

CMA generally agrees with the Commission's recommendation to use comprehensive, integrated watershed-management approaches and to use risk assessment to focus priorities.

Subsection 6.1.4.1 of the Commission's Report recommends amending the Clean Water Act to employ comprehensive, integrated watershed-management approaches to protecting our nation's waters. CMA agrees and believes that a well-crafted comprehensive watershed approach can be an appropriate approach to water quality protection of our nation's waterways. However, there may be a number of significant barriers that could hinder appropriate actions. These potential barriers include, but are not limited to, existing institutional structures such as discharge permits, anti-backsliding provisions, and lack of inter-state jurisdiction.

CMA recommends that the Commission expand this recommendation to ensure that any comprehensive watershed approach must: 1) prioritize watersheds in order to focus resources on the more significant problems; 2) allow for a cooperative effort among the stakeholders in a watershed and encourage public participation; 3) clearly identify the sources and causes of impairment in order to focus efforts on significant risks; 4) ensure a long-term phased approach based on sound scientific and technical information; 5) ensure equability of funding sources, entities to be controlled and the extent of such controls; and 6) be implementable through an appropriate balance of incentives and enforcement.

In general, we support a watershed management approach and agree that the approach should focus on identifying priorities and tailoring cost-effective solutions to the problems that are specific to each individual watershed. The process of setting priorities for each watershed must be structured properly and should emphasize remaining significant risks.

Section 6.2 Occupational Safety and Health Administration.

> **The Report makes three valuable recommendations for improving the administration of the Occupational Safety and Health Act, calling for better surveillance and intervention-effectiveness research, better coordination between NIOSH and OSHA and creation of health assessment guidelines. CMA supports these recommendations.**

The Commission recognizes the important role of the Occupational Safety and health Act in reducing occupation-related risk for workers but identifies areas where the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) could administer the act more effectively. CMA supports those recommendations, which, if followed, will enable those administrative bodies to better identify the most serious problems and their appropriate solutions. Specific comments are as follows:

Better Surveillance and Intervention-Effectiveness Research 6.2.1: CMA agrees that Congress should encourage NIOSH to strengthen its surveillance and intervention-effectiveness research program and OSHA expand its evaluation program. Better surveillance data should assist OSHA in setting its regulatory agenda.

Coordination Between NIOSH and OSHA 6.2.2: OSHA's regulatory needs should guide NIOSH's research efforts and NIOSH's research efforts should contribute directly to OSHA's regulatory agenda.

Guidelines for Health Risk Assessments. 6.2.3: OSHA should publish one or more sets of guidelines that lay out its scientific and policy defaults. Appropriate public input will be critical in developing these guidelines. CMA agrees these guidelines should help OSHA decide how extensive a risk assessment is needed in different situations. CMA also agrees that OSHA should be required to explain and justify its

actions when it evaluates or regulates a substance differently than other federal agencies that regulate the same substance.

CONCLUSION

Again, CMA commends the Commission for its efforts in putting together this thoughtful and far reaching Report. We look forward to working with the Commission in preparing the final Report and to encouraging the implementation of the Report's recommendations.

ATTACHMENT A

CHEMICAL MANUFACTURERS ASSOCIATION

RISK PRINCIPLES

CMA supports health, safety and environmental protection policies that incorporate risk-based priorities and cost-effective management of risk. The industry's Responsible Care® initiative embodies these values. Responsible Care's® six Codes of Management Practices address management of risks in product development and use (Product Stewardship), manufacture (Process Safety, Employee Health and Safety, Pollution Prevention, and Community Awareness and Emergency Response), and distribution (Distribution).

Risk management actions should provide meaningful risk reductions using scientifically sound risk assessment methods and should reflect public participation. The costs and benefits provided, including lost investment opportunity, employment and international competitiveness impacts, should play a key role in management option selection.

Given the above, CMA holds the following beliefs regarding the role of risk:

I. *Role of Government and Industry*

A. CMA advocates risk-based health, safety and environmental protection policies at all governmental levels, from local to international.

B. CMA members are committed to responsible management of chemical risks throughout a product's life cycle. This commitment is embodied in the Responsible Care® Guiding Principles and Codes of Management Practices.

II. *Risk Assessment*

A. CMA supports public input to the risk assessment process.

B. CMA supports the use and continued improvement of scientifically valid risk assessment methods for evaluating and prioritizing health, safety, and environmental risks. CMA does not support the setting of precise numerical risk levels in legislation or regulatory standards.

C. CMA advocates and supports governmental and private sector development of scientific data to improve the accuracy and relevance of risk assessments. CMA supports the use of all valid scientific data in conducting risk assessments.

D. CMA supports the development and further use of comparative risk ranking approaches for setting priorities across the universe of health, safety, and environmental risks.

III. *Risk Management*

A. CMA supports public participation in the risk management prioritization process.

B. CMA advocates and supports setting risk reduction priorities to address public health, safety, and environmental risks in a way that ensures protection to all segments of society.

C. CMA advocates allocation of governmental and private sector resources for risk management actions that achieve the most substantial, cost-effective risk reduction benefits.

D. CMA advocates and supports governmental and private sector development of information needed to set health, safety, and environmental risk reduction priorities and to assess their cost-effectiveness.

E. CMA supports development and further use of analytical tools for evaluating the consequences of risk reduction actions to take into account the range of factors that may affect individual and societal well-being.

F. CMA, as reflected in the Responsible Care® Product Stewardship Code of Management Practices, encourages companies to work toward characterizing products with respect to their risks. When risks are identified and prioritized, the range of risk management options and risks associated with alternatives should be evaluated and appropriate actions taken. Only when unreasonable risks remain for a specific use of a specific chemical are targeted use restrictions appropriate.

IV. *Risk Communication*

A. CMA supports clear and open communication by public policy makers of the results of comparative risk rankings, priorities and uncertainties, and the cost and benefits of risk reduction actions.

B. CMA supports public education and communication programs to promote a credible public dialogue on the risks and benefits of chemicals.

C. CMA supports continued research to gain meaningful insight into the basis of public concerns about chemicals.

D. CMA commits to lead in clarifying the relative risks posed to public health from all sources, including risks from chemical manufacturing and use.

V. ***Pollution Prevention and Technology***

A. CMA affirms its commitment to continuous improvement in pollution prevention in the Responsible Care® Pollution Prevention Code of Management Practices.

B. CMA supports and encourages technological innovation to reduce risks to human health and the environment from chemical manufacture and use.

Approved by CMA Board of Directors - September 1993

Definitions

In developing the preceding Risk Principles, the terms "risk," "risk assessment," "risk management," and "risk communication" have been used in their broadest sense. As used in the Risk Principles:

> Risk refers to the likelihood of harm, including both acute or chronic effects, to human health, the ecology, the economic system or the quality of human life.
>
> Risk Assessment refers to the process by which the form, dimension, and characteristics of a risk are estimated. Risk assessment encompasses the array of qualitative and quantitative tools available for estimating risk.
>
> Risk Management refers to the process by which a risk is controlled or reduced.
>
> Risk Communication refers to the process by which government agencies, the business, environmental, and scientific communities, the media, and the public discuss risk with each other.

These definitions were adapted from ***Reducing Risk: Setting Priorities and Strategies for Environmental Protection,*** the report of the EPA Science Advisory Board (September 1990) and ***Risk and the Environment: Improving Regulatory Decision Making,*** the report of the Carnegie Commission on Science, Technology, and Government (June 1993).

Comparative risk ranking and relative risk are relatively new concepts within the health, safety, and environmental protection public policy arena. No commonly understood definitions have evolved at this time to provide common currency for public and scientific debate. It is clear, however, that comparative risk ranking is more dependent on consistency of methods and assumptions across risk assessments than the precision of any individual risk assessment.