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ANALYSIS OF THE NATIONAL ACADEMY OF SCIENCES' REPORT **DECISION—MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT**

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Prepared by

OFFICE OF TOXIC SUBSTANCES
ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON,D.C.

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PREFACE

In July, 1975, the National Academy of Sciences, pursuant to a contract with the Environmental Protection Agency, published a Report entitled Decision-Making for Regulating Chemicals in the Environment. This Report included 34 specific recommendations for improving the decision-making process.

The Office of Toxic Substances, with input from all interested offices in the Agency, prepared the following analysis of the 34 recommendations. This analysis was undertaken to assist in further consideration of these recommendations but is not intended to represent the views and policies of the Environmental Protection Agency.

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General Comments and Recommendations

The 34 recommendations vary widely, from quite specific recommended practices to broad general precepts. Those at the latter end of the spectrum are useful in focusing attention on problem areas, but are somewhat difficult to evaluate. Several specific recommendations, though sound, would involve significant resource expenditures. Additional guidance as to how they are to be implemented, and clarification of the resource and policy implications, would be helpful. Recommendation 29, urging use of monitoring systems to detect changes in concentrations of toxic substances in biological tissues and changes in death patterns, is a case in point. These objectives are clearly worthwhile, and absent competing claims on scarce resources should be pursued. Without guidance as to what priority EPA should assign to this recommendation within the framework of its overall program and objectives, however, its utility is limited.

Many of the recommendations are general in nature and appropriate for almost any non-routine government decision (e.g., deregulation of crude oil prices). For example, recommendations 9-16, dealing with openness and access to the decision-making process, fall in this category. By and large the recommendations are more useful to the extent that they specifically address issues peculiar to regulating chemicals.

A primary problem is selecting those decisions to which these recommendations should apply, since the resources involved clearly preclude across-the-board application. The Report suggests limiting application to non-routine decisions, defined as those requiring the direct policy involvement of the agency-head. But the practical question remains: viz., how to determine which decisions require the Administrator's personal involvement. It would be most helpful if the Academy, in its current study, could recommend specific criteria or methods to (1) differentiate minor from major decisions, (2) establish gradations between these extremes, and (3) define the appropriate decision-making approaches to apply at each gradation. In defining these approaches, it would be useful to identify who within the Agency should be making what decisions.

An additional problem is that generalized precepts may conflict with one another. In the present report, for example,

recommendation 3 calling for revision of existing statutes to permit "consideration of any relevant factors in the decision-making process", seems somewhat inconsistent with recommendation 4 urging "increased and consistent statutory guidance as to the relative importance that should be given to health, environmental and economic factors". Another example is the apparent contradiction between the likely effect of recommendation 16, requiring that all ex parte communications be made public, and the objective, sought by recommendation 12, of encouraging inputs from all affected parties.

Recommendations 1, 9 and 30-32 are among the most important elements in the Report. Recommendation 1 is based on the sound principle that the costs of showing a net value to society resulting from a new chemical use should, when such a demonstration is required, be borne by those who will benefit from production or use of the chemical. Federal regulatory action in this area is justified in that the operation of the free market may fail to equitably distribute the costs and benefits. For example, persons who incur a cost, or risk, pursuant to the production of a chemical may not be adequately recompensed by the benefits accruing from the commercial production and use of the chemical. On the other hand, such Federal regulatory activity may unduly discourage research and development, product innovation and other essential economic ventures, and therefore any legislation placing the burden of proof upon the producer-to-be of a new chemical should require that the regulatory agency set forth by regulations and guidelines the type of data which must be submitted to the agency to determine if a chemical should be withheld from the market. Such guidance to potential producers will allow better estimates of the time necessary for market approval and also will help prevent the imposition of unnecessary data requirements for individual chemicals.

The Agency is taking steps to incorporate the valuable principles set forth in recommendations 9 and 30-32 into the decision-making process. Certainly all aspects and impacts -- including health, social, international and economic -- should be explicitly incorporated and considered in any decision to regulate chemicals.

In this regard recommendation 30 is perhaps misleading in its statement depreciating the utility of "highly formalized methods of benefit-cost analysis". This seems to conflict with the sense of recommendations 31 and 32, the excellent discussion and the definition of benefit-cost

analysis provided on page 39 of the Report:

> "Benefit-cost analysis ... refers to the systematic analysis and the evaluation of alternative courses of action drawing upon the analytical tools and insights provided by economics and decision theory. It is a framework and a set of procedures to help organize the available information, display tradeoffs, and point out uncertainties. In this way benefit-cost analysis can be a valuable aid; but it does not dictate choices, nor does it replace the ultimate authority and responsibility of the decision maker."

The above suggests that a rewording of recommendation 30 would more clearly state the intent -- i.e., not that benefit-cost analyses seldom can be used for making decisions, but that such methods cannot, in and of themselves, mechanistically make the decision.

The discussion on pp. 46-50, advocates making explicit the tradeoffs that any regulatory decision implicitly makes, including those between dollars and human life. Consideration will be given to the possibilities of achieving such explicit valuation of noncommensurables in the standard-setting process. Over and above any cost-benefit analytical advantages, adherence to this procedure should enhance both the quality and consistency of EPA's diverse regulations.

A mild demurrer is offered to recommendations 9-14 regarding compiling, organizing, summarizing and arraying the background information and cost-benefit data for regulatory actions and presenting the various options for the decision-maker. Numerous formal and informal mechanisms exist to achieve openness in decision-making: Advance Notice of Proposed Rulemaking, Working Groups with State and local government participation, solicitation of comment from affected and knowledgable parties, OMB Circular No. A-85 (providing for consultation with heads of State and local governments in development of Federal regulations), Interagency Review prior to proposal, public hearings and notification, Notice of Proposed Rulemaking with subsequent public comment periods of 30 to 60 days, Environmental Impact Statements, Inflation Impact Statements, Statements of Basis and Purpose, publication or notice of availability of Criteria or Development Documents and, finally, virtual daily contact with public interest and environmental groups. Given these extensive procedures the recommendations cited raise the following questions:

1. How many additional resources should EPA divert to this effort, and from where?

2. How much additional delay in the standard-setting process should be countenanced to further accommodate these objectives?

3. At what point does aggressively educating and obtaining support from the affected public become propagandizing?

4. In taking extraordinary steps to solicit comment from some affected parties how can the Agency avoid discriminating against, and being charged with discrimination by, others not so notified?

Other philosophical questions regarding this group of recommendations derive from the underlying principle set forth on page 23:

> "... the decision process is equitable when the consideration given to the interests of potentially affected individuals is proportional to the anticipated effects of the decision on those individuals. In other words, the groups represented in the decision process should reflect the groups in society impacted by the decision and the degree of impact of the decision on those groups."

Aside from the practical problem of identifying parties to a decision and the degree to which each is impacted, this principle is subject to various, perhaps unintended, interpretations. Does it mean, for example, that more per capita consideration should be given to a few shareholders of a company that will be heavily impacted economically, than to the many residents of the plant's community whose health may be somewhat adversely affected? Or, conversely, that the health interests of an extremely small and vulnerable segment of the population be stressed over a very large economic cost spread over the population as a whole? Perhaps the Academy's current study could reexamine this issue to (1) determine the feasibility of EPA attempting to assess the degree of potential impact of proposed regulations in order to differentially weight the consideration given diverse opinions, and (2) provide specific guidance on how to go about it.

The Report might have given more consideration to the programmatic or procedural framework necessary to provide the informational wherewithal for sound decisions. The Agency's efforts would profit from an outside investigation in this area. How can relationships be improved within EPA between (1) the decision-maker, (2) the regulation writers, (3) the

data gatherers, (4) the litigators, and (5) the enforcers? How can research programs be planned and instituted so as to provide the requisite information when it is needed to develop sound, defensible regulations? What offices should be involved in defining these research programs and what institutional arrangements should govern their interaction? How may it be assured that substantive and procedural enforcement issues as well as resources for enforcement, are adequately considered? These and similar questions go to the very heart of institutional decision-making and could be usefully addressed by the current Academy effort.

Another area which might be given more attention is how to select the most reasonable approach for controlling a given chemical problem from among the many options available. In addition to the various Federal statutes -- FIFRA, FWPCA, CAA, OSHA, FD&CA, CPSA, et al -- there are many State and local approaches and non-regulatory options including jawboning, publicizing the hazard, and reasoning with the source. Within each statute, moreover, there are several authorities that can be exercised. In practice a chemical control problem is rarely approached from the perspective of the various available means for control. More typically the available statutory authority determines the chemical hazard discerned -- i.e., problems are selected to fit authorities rather than the other way around. This too could be usefully explored in the current NAS study, with an eye to recommending one or more specific strategies for systematically evaluating alternative means of control.

Finally, a major problem in rationalizing the decision-making process not addressed by the Report is how to ensure that decision-makers actually want and use the prescribed process. The Report ably discusses the problem of scientists intruding their sociopolitical biases into their ostensibly objective analyses, thereby usurping the function of the politically accountable decision-maker to make the necessary value judgments. There is also a common counterpart frailty among some decision-makers -- namely, the willingness to have the controversial value-laden decisions remain obscured and buried in the form of extrapolation methods, "safety margins", "application factors", "no threshold" assumptions, reluctance to use uncertain data to assign dollar values to human life, and so forth. It would be extremely useful, in this regard, if the Academy would explore and present specific ways and means of (1) ensuring that the analyses received by the decision-maker are not only free of buried value judgments but, in addition, quite explicitly highlight those political and socioeconomic decisions that should be made, together with an array of options, and (2) maximizing the likelihood that the agency-head will use these analyses to make -- and make explicit -- these decisions. These ways and means should include

not only the essentially coercive methods suggested in the present Report -- simultaneous release of the background documents to the agency-head and the general public, mandatory external review by outside experts, autonomy for the Science Advisory Board, et al -- but also means of rendering the consequences of making these politically difficult decisions, if not pleasant, at least palatable. It would seem preferable not to employ methods based upon diluting the responsibility, such as panels or committees of advisors, since political (as opposed to technical or scientific) decisions emanating from such groups often tend more toward the less controversial options than decisions from a single, politically accountable, agency-head.

That concludes the general comments. Following are specific comments on each of the 34 recommendations.

Recommendation 1: As a general principle the burden of proof that society will obtain a benefit should rest with those proposing a new use of a chemical. It may be desirable to make statutory changes to reflect this principle.

This important recommendation is based on the sound principle that the benefits of using a chemical should outweigh the risks, and the reasonable precept that, where it is necessary to demonstrate that a net benefit will accrue from a new chemical, or new use, the costs and other burdens so imposed will be borne by those who stand to profit from the commercial use proposed.

In distributing the burden, however, it should be kept in mind that the "beneficiaries" of a new chemical use include not only the producers but also the employees, wholesalers, retailers and consumers involved, and these groups are difficult to identify prior to commercial production -- and impossible if production is disapproved. The Agency is considering ways to determine the cost-benefit information necessary to support various decisions which will include evaluating these costs and the roles and interests of the parties involved.

The open market may fail to equitably distribute the true costs of commercial use of a chemical, clearly justifying Federal regulatory action, however research and development, product innovation or other essential economic ventures must not be unduly discouraged in the process. To this end any legislation imposing upon the producer-to-be the burden of demonstrating the desirability of a new chemical (which burden, in the nature of things, can evolve into a series of requirements to prove negative hypotheses) should obligate the regulatory agency to establish, by regulations and formal guidelines, the scope and cost of the evidence it will require. This will allow the producer to better estimate the time the agency will take to reach a decision and will preclude imposition of arbitrary or onerous requirements in specific cases.

Finally, the recommendation might be reworded to explicitly include the initial use of new chemicals as well as the new use of existing chemicals.

Recommendation 2: Once the government has made a reasonable case that the challenged use of an existing chemical creates an excessive hazard to human health or to the environment, the burden of producing evidence should shift to the proponent of use, who must then make an appropriate showing that the continued use is desirable.

This is a sound recommendation. It would be helpful if NAS would define the key term "reasonable case" and indicate what changes this recommendation implies for the current procedures of FDA, CPSC, OSHA and EPA.

The word "excessive" might also be clarified, or perhaps deleted. It is difficult to envision a situation in which the proponent of use would be able to demonstrate the "desirability" of any substance that creates an "excessive" hazard. Generally, in such instances, the Agency would invoke the "imminent hazard" provisions of one or more of its authorities, in which case the burden of proof does tend to shift to the proponent of use. Presumably a less clear-cut situation is envisioned here, and deleting the word "excessive", or substituting "unreasonable", would seem more appropriate.

Recommendation 3: Statutory provisions should not preclude consideration of any relevant factors in the decision-making process. Those provisions that prevent such consideration should be considered for possible amendment.

This important admonition is sound but appears somewhat inconsistent with recommendation 4, calling for increased statutory guidance as to the "relative importance" to be given these "relevant factors". Inflexible legislative proscription, on either the factors that may be considered or the relative importance that may be assigned to those factors, is undesirable.

Recommendation 4: Whenever possible, and without precluding administrative consideration of relevant factors, Congress should provide increased and consistent statutory guidance as to the relative importance that should be given to health, environmental, and economic factors in regulating chemicals.

Clear statutory guidance is certainly desirable. However, inflexible legislative priorities that impair the Agency's ability to respond, in a changing environment, to the exigencies of particular rulemaking situations are undesirable. On the one hand the legislative intent should be clear; on the other, Congressional legislation is often a remote and inflexible vehicle for making judicious regulatory tradeoffs among various competing and changing interests.

Congressional guidance should not necessarily be "consistent" in any strict sense of the word. Different statutes have different purposes, deal with different substances, and have different frameworks. The relative weight assigned to health, economic, and social considerations in regulating food additives, for instance, could quite reasonably differ from the relative emphasis assigned in a law to regulate industrial effluents.

Finally, and as noted above, it may be difficult for Congress, in practice, to give "increased ... statutory guidance" without "precluding administrative consideration of relevant factors" in the decision-making process.

Recommendation 5: EPA should undertake a study to (1) identify neglected areas in hazard or pollution control and (2) determine whether existing legal authorities are available and unused or whether new laws should be sought from Congress. Examples of such needs include the problem of choosing optimal waste disposal methods considering the total environment and the question of indoor air pollution.

This recommendation defines a major aspect of EPA's mission. The Agency continuously reviews environmental problems and the existing legislative framework to identify programmatic gaps that can be filled either by more aggressive utilization of existing authorities or by seeking new legislation. In addition, EPA conducts a comprehensive annual review of its regulatory framework for this purpose. Although the Agency, of course, could improve its utilization of these reviews to better anticipate problems, it seems unlikely that additional studies would produce significant new information at this time.

Insofar as the two cited examples of legislative needs are concerned, the proposal to seek Federal legislation to regulate waste disposal has been deferred in accordance with Administration policy concerning new spending authorities. It is not clear that additional authority to regulate indoor air pollution is necessary, in large part because the Consumer Product Safety Commission, under the definition of "Consumer Product" in Section 3(a)(1) of the Consumer Product Safety Act and under Sections 7, 8, 9 and 12 of that Act, may already have some authority in this area.

Recommendation 6: Congress should review the adversary procedures that have led to unduly protracted hearings (such as pesticide cancellation) and determine how best such marathon decision making can be shortened.

The amount of time consumed in such proceedings is a major source of concern and all possible means to expedite the process should be explored.

Congress is, in fact, conducting a detailed review of all aspects of the Agency's activities, including hearing procedures. EPA has responded to a detailed questionnaire from the House Special Subcommittee on Oversight and Investigations and the results of this study might provide a basis for the Academy's current analysis of EPA's operations.

Recommendation 7: Exposure to many chemicals comes simultaneously from two or more media. An interagency committee should be established to ensure that each agency's standards reflect appreciation of such multiple exposures.

The desirability of ensuring that standards are set taking total exposure into account is clear. Recently EPA's Office of Research and Development initiated a program to produce STAR Documents, which emphasize all routes of exposure, to assist in this process.

However, standing interagency committees are unlikely to be particularly useful or vigilant in this regard. Actually the necessary and sufficient institutional arrangements already exist in the Interagency Review administered by the OMB; the purpose would be served if steps were taken to ensure that all agencies adhered to this established review procedure.

Recommendation 8: Within the Committee there were divergent opinions on the optimum organizational structure for making chemical regulatory decisions. It is recommended that Congress give consideration to alternative decision-making structures. In particular, it should consider whether responsibility should be vested in a board or commission with fixed terms in office or in a single administrator.

There are advantages and disadvantages associated with each type of decision-making organization. Congressional consideration of the issue may well be useful in further clarifying the considerations involved.

Recommendation 9: The essential elements of decision making should be part of the public record. The agency should publish a "white paper" for each important regulatory action undertaken. The paper should include the key details of the economic, legal, scientific, and other considerations taken into account in reaching the decisions. It should be issued when the agency decides to take an action but sufficiently in advance of a final decision to permit considered response. An important decision to take no regulatory action, or to defer such action, should be accompanied by a "white paper".

Since most if not all the essential elements of decision-making are already part of the public record, in one form or another, this will largely be a coordinative task. Consolidation of these diverse documents into a single, comprehensible, standard format, eliminating redundancy, is required. Indeed this recommendation is so critical that steps are being taken to ensure that its principles, along with those set forth in recommendations 30-32, are incorporated into the formal rule-making process.

Recommendation 10: Any information available to an agency on the hazards of a chemical that is regulated by that agency should not be considered proprietary and thus should be available for public inspection in a timely fashion during and after the decision-making process.

Such information is available to the public unless it is deemed protected by Title 18 USC 1905, in which case it is inviolable. This, in turn, is an ad hoc determination made in accordance with the requirements set forth in the law in question. Some laws prohibit disclosure of any information which, in the Administrator's judgment, contains or relates to trade, commercial or financial information. In contrast, Section 308 of FWPCA and Section 114 of CAA require that any information obtained under those authorities be made available to the public except upon a showing satisfactory to the Administrator that such information would divulge methods or processes entitled to protection as trade secrets. These latter sections seem to strike an equitable balance between competing but legitimate concerns, and are preferable.

Two other legislative changes would be helpful:

1. Vest authority in EPA to obtain information needed to develop standards regardless of whether or not the information source is to be subject to the proposed regulation. While EPA has ample authority under both FWPCA and CAA to obtain information from sources that are the focus of the proposed regulatory action, difficulties arise when they are not.

2. Exclude, in statutes administered by EPA, all narrowly defined (e.g., toxicological) health data on chemicals currently in commerce from the protective umbrella of the Trade Secrets Act.

In any event EPA will still receive some information legitimately protected under the Trade Secrets Act which is relevant to regulatory decisions. Therefore, the Agency will continue to set standards on the basis of information not completely shared with the public. There is no obvious way out of this dilemma. It is unreasonable to deprive a company of its legitimate competitive advantage, and it would be irresponsible not to utilize all of the available, pertinent information.

Recommendation 11: The early and open exchange of information and opinions on a proposed decision should be encouraged to reduce the current dependence on subsequent judicial challenge. The EPA Administrator should hold public hearings at the earliest feasible stages of the decision process. He also should facilitate pre-hearing exchange of information among parties (for example, through depositions, interrogatories, and other discovery procedures).

Such "early and open exchange of information" is certainly desirable, although there is no assurance that this will "reduce the current dependence on judicial challenge". The Agency already goes to some length to ensure such information exchange occurs and has adequate authority to obtain information.

Specific comments from NAS would be helpful regarding the adequacy or focus of these efforts. If additional steps are considered necessary, it should be noted that such procedures could be used by those with an interest in impeding rather than facilitating rule-making.

Recommendation 12: At appropriate points in the decision-making process the agency should actively seek to identify the affected parties and solicit suggestions and comments from them. Ways should be explored to better represent the interests of future generations.

EPA already pursues this goal. To go beyond current practice would require arrogation of the responsibility for defining "affected" parties and the degree of impact. Also, active identification and solicitation of comments from affected parties would probably draw charges of favoritism or discrimination from those whose suggestions and comments were not sought. It would also attract disruptive political pressures early in the decision-making process.

The Agency will consider including with the NPRM a list of known affected parties, such as trade associations, which might have an interest in commenting, but to actively, and exclusively, seek such comments and suggestions would be risky from a regulatory standpoint. Anyone whose particular comments were not expressly solicited could make an arguable case that implementation of the ensuing regulation should be further delayed until he was given an equal opportunity to comment. The whole point of the Federal Register notice is to even-handedly provide notice to all interested parties. The system may not be perfect but the recommended solution seems less desirable.

Future impacts of decisions may certainly be significant and need to be addressed. However, in this rapidly changing environment, it is extremely difficult to anticipate technological or scientific breakthroughs, natural or man-made catastrophes, or other such radical changes. Thus any decision made could easily be rendered meaningless, no matter what framework had been employed to accommodate future generations. The Agency should consider chronic effects of chemicals in any decision to regulate, however, methods utilized to deal with the issue of the future social, economic and health impacts of such decisions are severely limited; any insights or guidance from the Academy would be helpful.

Recommendation 13: The press as well as other interested parties should be told when a standard-setting process begins and when the proposed standard is ready for publication; further discussions during this process should occur as often as warranted.

This reasonable suggestion largely reflects current EPA practice. To ensure it, the Office of Public Affairs should routinely notify the press whenever a standard-setting process is initiated. This event is rarely newsworthy, however, and that fact prompts the following comment on the text supporting this recommendation.

The extent and nature of press coverage of any toxic "story" is often unrelated to an analysis of scientific, toxicological or economic data but is, rather, a function of the story's "news value" -- i.e., its dramatic appeal. For this reason the press must be viewed as an uncertain ally in the effort to mount a deliberate and considered regulatory program.

In this same vein, the following passage from page 27 apparently misapprehends EPA's role:

> "Regulation of toxic substances is, by its very nature, a subject that will evoke sympathetic reactions from the press. It is a story with a built-in advantage for the government which is, after all, engaged in the business of protecting the same public the press sees itself as representing."

This suggests that EPA's position will and should coincide with popular opinion and against the regulated industry. In point of fact, however, EPA's responsibility and intention is, to the maximum extent possible under the applicable statutes, to strike the optimum balance among the relevant costs, risks and benefits associated with the use of a chemical. In so doing, the Agency will not necessarily reach the "popular" position.

Recommendation 14: EPA and other agencies should initiate programs aimed at training and encouraging citizens to participate in the decision-making process.

The Agency does have an obligation to lay before the public, as clearly and concisely as possible, the hazards, costs and benefits associated with a range of alternatives, and to listen with an attentive ear to the ensuing response before reaching any major regulatory decisions.

However, there are three reservations concerning this recommendation. First, the propriety of EPA's training citizens to participate in the decision-making process is questionable. Such programs tend to turn, in time, into publicly-funded but agency-directed efforts to sway public opinion.

Secondly, there is an inherent tension, if not conflict, between the idea that "training and encouraging citizens to participate in the decision-making process" is worthwhile, and the suggestion in recommendation 17 that the quality of chemical regulatory decisions is largely dependent upon the adequacy of the scientific data base.

Finally, the statement on pp. 29-30 in the supporting text that

> "... many significant decisions have taken far too long to make, but this has more often been due to parties with a specific interest in delaying a decision than to public participation ..."

highlights the fact that either party to the dispute, against which the imminent decision seems to be going, will generally resort to delaying tactics. This is the price of open decision-making.

Recommendation 15: The Department of Commerce should develop an educational resource to help small businesses acquire the information on chemical regulatory matters that is at present routinely available to large corporations and major trade associations.

The Department of Commerce might well be useful in this area. Trade associations (which usually participate in the review of standards proposed by EPA) also generally perform this function and the DOC would need to take care not to duplicate the efforts of these groups.

Recommendation 16: All ex parte communications, including those from Congress, members of the Executive Branch, private corporations, and citizen groups, on any adjudicatory decision pending before a regulatory agency should be made public with sufficient time for comment before a decision is made.

Strictly speaking this recommendation is already mandated by law -- i.e., ex parte communications in adjudicatory proceedings must be made public. Presumably the intent here is to apply this requirement to less formal proceedings and to expand the definition of ex parte communications to include communications from sources other than direct parties to the dispute (e.g., Congress), and to persons other than the "decision-maker" (e.g., to staff members of EPA). The crux of the proposal is spelling out the precise coverage and definitions intended so as to create a workable method that does not unduly inhibit productive information exchange.

The objective of exposing to public scrutiny any pressures, entreaties, or persuasion received from vested interests, while laudable, works at cross-purposes with recommendation 12, designed to encourage comment and criticism from affected parties. Many of the most affected and knowledgable sources will be inhibited by the exposure sought here.

In any event, the recommendation addresses a serious and legitimate concern. It would be useful if the Academy's current study could sort out the definitions intended by the term "ex parte communication", and provide specific workable methods for attaining the objectives.

Recommendation 17: The quality of chemical regulatory decisions is dependent largely upon the adequacy of the available information. To develop an adequate data base research efforts in basic clinical and environmental toxicology and epidemiology and in economic analysis must be strengthened, and professional training in these areas must be supported. An interagency committee consisting of the relevant federal research and regulatory agencies should be established to gain maximum use of existing information.

It would be useful to document the conclusion, on page 52 in the supporting text, that:

> "... society suffers large and unnecessary expense because of inadequate investment in determining the hazards of chemicals."

And similarly, for the statement on page 53, that:

> "It usually will cost more to institute the more stringent controls resulting from the larger safety (ignorance) margin than it would to improve the precision of the data base."

The validity of the recommendation hinges largely upon the soundness of those arguments and, since implementation will require substantial resources, they should be buttressed with the supporting cost-benefit data.

The recommendation and supporting text apparently urge increased Federal outlays to achieve these objectives. If so, the recommendation conflicts with the thrust of recommendations 1 and 2, which would shift this burden to the private sector. The Academy's present study might address this issue. There are arguments for "internalizing" the costs of controlling chemical hazards by creating a regulatory framework that compels the private sector to assume the burden. There are also counter-arguments for imposing these costs and responsibilities on the general taxpayer. It would help to obtain clarification from the Academy regarding which of these policies should be pursued. If, indeed, a mix -- expanding both approaches -- is desirable, advice on the relative emphasis to be placed on each would be useful.

The proposal for another standing interagency committee, in this case to gain maximum use of existing scientific and technical information, is unappealing. Informal ad hoc arrangements among the technically involved and qualified personnel would be more effective.

Recommendation 18: Existing toxicological and other information systems related to the regulation of chemicals should be examined with a view to improving their coordination and utilization.

The Agency is supporting the current efforts of the Department of Health, Education and Welfare directed to improving systems concerning health effects information. In addition, EPA is evaluating ways to better use its own data, and is involved in international efforts to develop mechanisms for the exchange and use of information on toxic chemicals.

Recommendation 19: For optimal regulatory decision making, a procedure to conduct retrospective analyses of the impact of given decisions should be adopted. This should emphasize evaluation of the accuracy of the predictive models for health, economics, and environmental sciences in the original decision-making process. EPA should also develop a formal system that reviews and identifies information necessary for optimal future decision making and implements the appropriate programs to generate this information in a timely fashion.

While most EPA offices informally do this to some extent, the Agency does not have a formal procedure for retrospectively assessing the consequences of major decisions. Clearly, in the absence of such feedback, many opportunities to learn from experience will be lost.

Guidance is needed on how to mount such follow-up analyses and the priority they deserve. Would it be better, for example, to assign the task to the individual units that were responsible for the decision and its implementation in the first place, on the assumption that any possible bias stemming from self-evaluation would be more than compensated by the high level of interest and competence in the subject matter; or to a centralized and impartial, but relatively uninformed and less interested "auditing" unit? What criteria should be used to select those decisions requiring retrospective assessment? How can it be assured that the results of such analyses will actually be used to guide future decisions or consider revision of past ones if necessary? How soon can tangible results be expected from this process? How can the probable output and limitations be defined to create realistic expectations of these efforts? This is fertile ground for the Academy's current study.

Recommendation 20: All agencies that regulate chemicals should establish mechanisms for external scientific review of the technical data base presented to the decision maker. The results of the review should be available directly to the decision maker and to the public as early as feasible. The major research and development programs undertaken by EPA specifically should be reviewed routinely by panels of qualified experts.

External review by outside experts is one important approach to ensuring the validity of the scientific data base used to reach regulatory decisions. Views of affected parties during the public comment period following Notices of Proposed Rule-Making are also often very effective.

Increased emphasis on review by external experts raises a number of questions the Academy might address. Of paramount importance is the question of how to select these experts in such a way as to minimize, or at least equitably distribute, the sociopolitical biases represented -- an issue of no less concern here than with in-house EPA scientists.

Should the outside experts operate independently or should they sit as a committee? If the reviews are prepared independently, who should arbitrate in the case of conflicting assessments, and within what framework? If they deliberate and report as a committee, how should discrepancies between their findings and those of the in-house scientists be handled?

On some occasions the outside review should not be made available to the decision-maker and the public simultaneously. Often responsible rule-making will be better served if the in-house staff has an opportunity to digest and react to such reviews before they are made public.

When these reviews are necessary, and to the extent that committees rather than individual assessments are used, ad hoc groups or the existing standing committees are preferable to new committees.

Recommendation 21: EPA should make greater use of expert committees that represent the spectrum of potential viewpoints, particularly in helping to anticipate future chemical control problems.

Many EPA Offices are concerned with anticipating future chemical control problems. With regard to advisory committees, better use of existing committees is preferable to additional committees.

It is not clear exactly how advisory committees would go about anticipating "future chemical control problems", and advice in this area would be useful.

Recommendation 22: EPA's Science Advisory Board should be permitted to formally request the Administrator to subpoena information needed for the Board's consideration and to allow the Board to investigate new areas. The request and the Administrator's response should be a matter of public record. The existence and responsibilities of the Science Advisory Board should be mandated by legislation.

The Science Advisory Board was established to increase the Administrator's options by providing, at his request, informal advice from a broad spectrum of relevant interests and expertise. This recommendation would thrust the Science Advisory Board into a quasi-adjudicatory role, thereby nullifying the informal advisory function, and would constrict rather than expand the Administrator's discretion. Thus, the Science Advisory Board should not be permitted to formally request the Administrator to subpoena information, and its existence and its responsibilities should not be mandated by legislation.

Recommendation 23: The power to subpoena expert witnesses, now available to EPA under the Federal Environmental Pesticide Control Act, should be extended to proceedings under other statutes to develop the fullest and fairest public record.

The lack of such authority has not been overly troublesome, but the suggestion is sound and should be supported.

Recommendation 24: To improve the quality of scientific evidence, the right of counsel to cross-examine expert witnesses should be guaranteed.

As formal proceedings do, in fact, include provisions for cross-examination, it is assumed this proposal refers to informal rule-making procedures. In these cases it could diminish rather than enhance the quality of scientific evidence generated. The inquisitorial nature of cross-examination -- particularly the limitations placed on the mode and scope of response -- while appropriate for retrospectively ascertaining facts, is counter-productive for assaying the goodness of prospective conjecture, which is generally the nature of the testimony of expert witnesses at these proceedings. Adoption of this recommendation moreover, would deprive these procedures of the counsel of many able experts unwilling to subject themselves to this form of inquiry.

Recommendation 25: Other federal agencies should have the opportunity to participate in internal EPA deliberations early in the consideration of regulatory options. The same opportunity should be given to EPA by other agencies that regulate chemicals.

As noted earlier in another context, if all agencies participated in the existing interagency review process administered by the Office of Management and Budget there would be ample coordination in the Federal standard-setting process. Interagency coordination at an earlier stage should (and generally does) occur on an informal basis among the technical personnel.

Recommendation 26: Federal agencies regulating chemicals should establish a formal and regular method for obtaining information from state agencies.

The statement on page 27 in the supporting text that

> "the general trend of environmental legislation and regulatory activities in the toxic substances area is clearly away from the direct involvement of state and local units of government and toward a pre-eminent federal role"

is not entirely accurate. Large and increasing State and local responsibility is envisioned under the Federal Clean Air, Water Pollution Control, and Safe Drinking Water Acts. Insofar as the specific recommendation is concerned, for example, Sections 110 and 111 of the CAA and Sections 208, 303, 305 and 516 of the FWPCA establish formal mechanisms for the regular submission of information from States and localities.

Generally speaking there is a reasonably free and adequate flow of information to and from EPA and States and local communities under existing formal and informal arrangements. In those areas where improvement is necessary fewer, rather than more, formal procedures may be in order. Adding more formal procedures to the existing paper-work burden might dry up the existing, extremely useful, informal flow.

Recommendation 27: The Department of Health, Education, and Welfare in conjunction with EPA, should attempt to develop a hazard rating system, placing particular emphasis on evaluation of use patterns.

More attention needs to be devoted to the task of developing criteria and procedures for assessing the relative risks posed by various toxic substances. The notion of developing a comprehensive "hazard rating system" to serve the diverse needs of various programs within DHEW and EPA will be useful only to the extent that these several programs are concerned with correlative uses of, or exposures to, the same chemicals. This is infrequently the case. A hazard rating system appropriate for controlling pesticides, for example, would not serve well the purposes of the Clean Air Act. Similarly, a hazard rating system designed to facilitate implementation of the Food, Drug and Cosmetic Act would have limited utility with the Federal Water Pollution Control Act. Any rating system designed to meet these multiple needs would serve none well.

While important, "use patterns" are only one of a number of factors that should be incorporated in a hazard rating system. Depending upon the regulatory purpose to be served, one would also stress such variables as persistence, biodegradability, bio-concentration, bio-accumulation, intermedia transport, levels of production, and synergism. It is the differential weight that must be assigned to these various factors to meet specific regulatory purposes, incidentally, that makes a general scheme unworkable.

The Agency should improve its several hazard assessment efforts, however, for the same reasons that are so ably set forth in the Report's discussion of benefit-cost analysis. Indeed, it is hard to see how such analyses can usefully proceed without substantial improvement of EPA's ability to assess and rank the relative risks presented by the universe of toxic substances. Experience suggests that such hazard evaluation systems are much easier to discuss than develop. Any insights that the present NAS effort may be able to provide in this area would be very useful.

Recommendation 28: The Department of Health, Education, and Welfare and EPA should establish a task force including, among others, representatives of the chemical industry and the scientific community to develop a system for making unpublished or proprietary data about chemicals available to governmental agencies.

A task force for this purpose is neither necessary nor helpful. If Section 114 of the Clean Air Act or Section 308 of the Federal Water Pollution Control Act cannot obtain the data sought, there is little a task force can accomplish. What is really needed in this area is legislation such as the proposed Toxic Substances Control Act, and the reporting provisions it contains which would permit EPA to obtain pertinent data from a source that is not the target of the proposed regulations. Legislative amendments to the CAA and FWPCA would also be helpful.

In the absence of any incentive to induce industry to release proprietary data, there is little point to convening representatives of the chemical industry, or anyone else, to develop a system for making such data available. Unless and until the Toxic Substances Control Act or similar legislation is enacted it is unrealistic to assume that industry will voluntarily release data that (1) were expensive to generate, (2) may aid their competitors, and (3) will frequently be used by the Government to impose unwanted restrictions.

Recommendation 29: EPA in cooperation with the Department of Health, Education, and Welfare should develop and use monitoring systems that can detect changing patterns in concentrations of specific toxic substances in biological tissues. They should also develop and use population surveillance systems that reflect changes in illness and death patterns due to environmental pollutant exposure. Data from monitoring systems and from other sources should be used to adjust past decisions, if necessary.

This is an excellent concept. Unless such efforts are initiated now, and sustained, future efforts will be plagued with the same information gaps that hamper current ones. However, the recommendation may be difficult to implement. A major obstacle is that such programs are so long-range that the payoff falls beyond the "practical utility" timeframe of any given set of decision-makers. This and the relatively heavy expense involved give these proposals relatively low priority in spite of their obvious importance. The Academy would perform an extremely valuable service if it initiated activities to generate the resources and commitment necessary to develop these monitoring and surveillance systems.

It is not clear from the Report exactly how the results of the population surveillance system or the epidemiologic studies are to be related to "environmental pollutant exposure". Given the problems associated with multi-pollutant exposures, long latency periods between exposure and manifestation, and migration in and out of the target areas such relationships are virtually impossible to establish.

Monitoring for concentrations of specific substances in tissue should be an invaluable aid to both "early warning" and standard-setting activities. Presumably this would include tissues from both indicator organisms and humans. The recommendation might also have included provision for a tissue "data bank" to permit retrospective analyses, in future years, of questions unanticipated at the time the tissue was excised.

Recommendation 30: Highly formalized methods of benefit-cost analysis seldom can be used for making decisions about regulating chemicals in the environment. Thus the development of such methods should not have high priority. However, the benefit-cost and decision frameworks described in this report can be useful in organizing and summarizing relevant data on regulatory alternatives which the decision maker must review.

It is true that "highly formalized methods of benefit-cost analysis" cannot, in themselves, mechanistically make the decisions. However, the sense of the text, in apparent contrast to the first sentence of the recommendation, is that such methods can, and should, in fact be used within the decision-making process to identify and evaluate relevant data. This comes through clearly in the approbative definition of "benefit-cost analysis" provided on page 39, together with the "highly formalized method" recommended on pp. 44-46.

In this regard, the agency is considering ways to develop and use methods which would, as is recommended in the text of the Report, ensure that the evaluation of costs and benefits implied in most decisions are made explicit and dealt with in equivalent terms.

Recommendation 31: Value judgments about noncommensurate factors in a decision such as life, health, aesthetics, equity, and risk aversion should be explicitly dealt with by the politically responsible decision makers and not hidden in supposedly objective data and analysis.

This is an excellent principle. It is desirable to reduce the implied values used in reaching the decision concerning the benefits and hazards to common terms whenever possible. As noted above, EPA plans to consider ways of ensuring that this occurs in the course of its decision-making process.

Recommendation 32: The decision process should require the agency's technical staff to present a full set of options with a corresponding range of cost-benefit-hazard data and explicit statements on the confidence limits of each analysis.

This recommendation helps to clarify the intended meaning of recommendation 30. Clearly, such analyses should be provided to the decision-maker by the agency staff. The Agency is exploring ways of implementing this recommendation.

Recommendation 33: EPA should adopt, whenever scientifically possible, a generic approach, as opposed to an ad hoc procedure, for the regulation of chemicals.

If "generic approach" simply means grouping chemicals in classes and, when attention is focused on any one in the class, looking at the others to determine if they also require (not necessarily the same) attention, then the recommendation seems sound. If it means automatically applying the same regulation to all chemicals in a class, the approach is inappropriate.

Recommendation 34: EPA should ask the American Bar Association to cooperate in a study of the way health and environmental information and economic analyses should be introduced and considered in judicial proceedings.

In a judicial proceeding to review an Agency regulation or adjudicatory decision, data and evidence in the record are examined to determine if an adequate case has been presented to justify the action. The Courts do not judge the technical or scientific appropriateness of an Agency action, but rather determine only if it is supportable as a matter of administrative law -- i.e., were the proper procedures followed and was there sufficient evidence to make the decision. As Federal Courts have exercised this responsibility for many years, the value of the study as proposed is questionable.

However, the Agency does have a responsibility to hear and evaluate all testimony and evidence prior to taking action such that decisions are well-founded and, if need be, legally defensible. EPA's fundamental task and goal is, to the maximum extent provided under applicable statutes, to develop standards and regulations which are environmentally sound and effect the optimum balance among the relevant costs, risks and benefits. This requires a knowledge of what health and environmental information, economic analyses, assessments of social, international and intergenerational impacts, etc. are required under relevant authorities; what burden-of-proof responsibilities are applicable; and how such information may be obtained from other agencies, outside experts and other interested parties, coordinated and presented so as to be useful to the decision-maker, intelligible to the public and sustainable before the Courts. Therefore, studies to ensure that the necessary evidence is adequately developed and justified during and within the decision-making process could be useful.