III. Discussion

A. IS THERE A NEED FOR SOME SORT OF GOVERNMENT-WIDE POLICY GUIDANCE ON RISK ASSESSMENT AND RISK MANAGEMENT (THOUGH NOT NECESSARILY THROUGH AN EXECUTIVE ORDER)?

COMMENTS RECEIVED

The responses to this question generally framed the issue in terms either of the need for "consistency" or the need for reform of the risk assessment process to remedy excessive "conservatism" and to obtain more objective scientific analyses.

The subject of consistency drew a great deal of attention in the forum held for federal agency officials. In the other two forums, there was discussion of the subject, but not of the same intensity and detail, and the subject of conservatism drew more attention. Many of the agency attendees indicated that they supported issuance of some sort of government-wide guidance, but there was a great deal of divergence on what issues it should address and what form it should take.

Some argued that trying to achieve consistency with regard to risk *management* policy was futile in view of the many statutes and the differences in their terms. There was considerably more support for attempting to achieve consistency with regard to risk assessment policy, and particularly regarding risk characterization.[109] It was pointed out that inconsistencies in risk assessment and characterization make it difficult for risk managers to compare different programs and alternatives on a cost/benefit basis for risk management purposes and to make resource allocation decisions, and inconsistent assessments of the same risk by different agencies or programs confuse both risk managers and the public and hurt government credibility. Conflicting risk assessments of dioxin and formaldehyde were referred to in particular. Specific examples of inconsistency in risk characterization that were provided included differences in whether agencies provide a "best" esti-

109. "Risk characterization" is usually considered to be the last step in "risk assessment", following the hazard assessment, dose-response assessment, and exposure assessment steps. In this report, however, "risk characterization" is addressed separately from the preceding steps in the risk assessment process.

mate, a "maximum likelihood" estimate, or a "conservative" estimate, and differences in carcinogen classification systems.

On the other hand, some agency officials pointed out that some inconsistencies have a rational basis in particular statutory mandates. For example, it was pointed out that it might make sense for EPA to pay more attention to effects on sensitive populations in its risk assessments, whereas OSHA's programs are directed at the worker population and therefore generally affect healthier individuals. Or one agency's assessment of a risk might differ from another's because it is focusing on a different exposure pathway (*e.g.*, inhalation v. ingestion or dermal contact) under its statutory program. Others cautioned that risk assessment should be a scientific process that is based on the data for a specific risk, and attempts to impose consistency could put the scientists in a "straightjacket" and lead to distorted results. Still others commented that risk assessment is an evolving field, and attempts to impose consistency could stifle beneficial innovation.

The agency commenters also showed a great deal more interest in the issue of responsibility for implementation and oversight, which they saw as closely related to the subject of consistency. There were a variety of views on this, and it appeared that commenters' job responsibilities tended to influence viewpoints. Agency science advisors appeared to prefer addressing risk assessment issues through a scientific body, such as an interagency body of senior scientists chaired by OSTP (similar to the one that produced the 1985 OSTP report) or a committee of the National Academy of Sciences. On the other hand, agency and Administration *policy* officials pointed out that groups of this sort could not resolve policy issues, and that to resolve the many policy issues involved would require strong policy leadership.

Suggestions for such oversight included setting up a Domestic Policy Council work group or an interagency committee. Some commenters argued against involving an interagency body on grounds that it would inevitably reflect institutional biases that have become ingrained, and such a body should not be allowed to determine policy issues because this should be a Presidential prerogative. It was also pointed out that such committees usually depend on consensus, which appears to lead inevitably to the most conservative or amorphous positions. Others argued that if the White House was to be the ultimate decisionmaker on policy issues, OMB should not be in charge because it lacks scientific staff and has historically played a politically controversial role in the regulatory review process. Finally, some commented that whatever body or process was ultimately utilized, it would need to have adequate funding and staffing.

Specific areas in which commenters asserted a need for improvement included the following:

- tending to respond to uncertainty with multiple "conservative" or "worst case" assumptions in the risk assessment process;

- requiring convincing data to overcome default assumptions that are themselves not supported by substantial data—for example, assuming the absence of thresholds and linearity of dose response;

- relying on animal bioassays showing adverse effects at the maximum tolerated dose in sensitive species, and bias against negative bioassay and epidemiological data;

- presenting quantitative risk estimates that have such a high level of uncertainty that they are misleading and useless; and

- converting very imprecise risk probability numbers into incidence numbers that appear to have the precision of "actuarial" statistics.

A few commenters questioned whether issuance of any sort of guidance might not have the effect of slowing down the regulatory review process and further delaying the issuance of important regulations. Others took the view that more comprehensive guidance could actually speed up regulatory review by establishing common ground between the White House and the agencies so that similar policy issues would not have to be thrashed out each time a new regulation was proposed.

DISCUSSION

The need for government-wide guidance or consistency cannot be discussed rationally in general terms. Pertinent considerations vary according to whether the subject is the underlying science, science policy (or "inferences"), risk characterization policy, or risk management policy.

Positions on science issues obviously should be consistent and should be left to scientists, whether they are in the government, academia, or the private sector. The feasibility of reaching agreement on the state-of-the-science issues was demonstrated in the 1985 OSTP cancer document.[110]

Risk *management* policy issues on which Congress has not spoken directly involve many factors other than science and are clearly appropriate for Presidential guidance. The existence of varied Congressional directives does not rule out consistency of a limited nature. A good

110. As noted previously, the OSTP cancer document is currently being reviewed by an interagency FCCSET subcommittee.

example of this is policy on the regulation of *de minimis* or insignificant risks. Establishment of a *de minimis* or insignificant risk policy is consistent with all statutory mandates except the Delaney Clause in the Federal Food Drug and Cosmetic Act,[111] and possibly the "residual risk" provisions of the 1990 Clean Air Act Amendments. Another example would be a policy that final decisions on what constitutes an "adequate" or "ample" margin of safety, safety factor, or uncertainty factor should be left to policy officials as a risk management decision rather than being built into the risk assessment process through the choice of conservative assumptions.

Where things get muddled is in the area of risk *assessment* sometimes referred to as "science policy". This subject was addressed repeatedly in the 1983 NAS Red Book project. The NAS committee preferred to use the terms "inference" and "risk assessment policy". Under this terminology, the underlying science might allow for a number of "inferences" (such as linearity of dose response or absence of thresholds), and the choice among the potential inferences would be made by the risk assessor on the basis of "risk assessment policy".[112] The recognized difficulties posed by decisionmaking in this gray area between pure science and pure policy are reflected in this passage from the Red Book:

> The choices encountered in risk assessment rest, to various degrees, on a mixture of scientific fact and consensus, on informed scientific judgment, and on policy determinations (the appropriate degree of conservatism).
>
> That a scientist makes the choices does not render the judgments devoid of policy implications. Scientists differ in their opinions of the validity of various [inference] options, even if they are not consciously choosing to be more or less conservative. In considering whether to use data from the most sensitive experimental animals for risk assessment, a scientist may be influenced by the species, strains, and gender of the animals tested, the characteristics of the tumor, and the conditions of the experiment. A scientist's weighting of these variables may not easily be expressed explicitly, and the result is a mixture of fact, experience (often called intuition), and personal values that cannot be disentangled easily. As a result, the choice made may be perceived by the scientist as based primarily on informed scientific judgment. From a regulatory official's point of view the same choice may appear to be a value decision as to how conservative regulatory policy should be, given the lack of a decisive empirical basis for choice.[113]

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111. 21 U.S.C. secs. 348(c)(3)(A), 376(b)(3)(B). While one federal circuit court has found that application of a *de minimis* policy to color additives is in conflict with the Delaney Clause (n.30 *supra*), a similar issue concerning pesticide residues in processed food remains to be litigated.

112. See, *e.g.*, pp. 36-38 of the Red Book, *supra* section II,C,2.

113. *Id.* at pp. 36-37.

Such differences in perspective were often evident during the three risk forums we held, with some scientists indicating they believed that inference decisions should not be made by policy officials without scientific credentials, and policy officials indicating they thought important inference decisions should not be made by scientists without policy credentials.

In the end, the NAS committee strongly recommended that the federal government should, with the help of an expert board, develop generic risk assessment inference guidelines for all agencies. These guidelines would "provide specific guidance on components of data evaluation that require the imposition of risk assessment policy decisions and should clearly distinguish those decisions from scientific decisions ... [and] provide specific guidance on how an assessor is to present the results of the assessment and the attendant uncertainties."[114] The committee recognized, however, that uniform guidance for the exposure assessment aspect of risk assessment might not be feasible.

While inconsistency in risk assessment methodology among the various programs and agencies has not historically been a serious problem, it is a recognized problem to some degree and will assume more importance in the future as the need to prioritize increases. Comparisons of the potential benefits from various programs and regulatory alternatives are not possible without consistency in risk assessment. In addition, with various reviews of risk assessment and risk management underway within individual agencies and in a number of broader forums, including Congress, there is a clear potential for greater inconsistency in the future. Issues concerning conservatism or margins of safety are perhaps the most important of all the risk issues, and are related to the issue of consistency in that inconsistencies in these areas have such a high potential for contributing to misallocation of resources.

Risk assessment policy need not be reflected solely in specific risk assessment "inference" choices. The difficulty in reaching agreement on specific inference choices may be a major reason why the NAS committee recommendations have never been implemented. In trying to improve consistency, the underlying question is "Whose consistency?" Many agency officials appear to view consistency as necessitating some relinquishment of statutory authority or scientific judgment. In addition, while judgment concerning inference choices necessitates scientific expertise, many scientists are not comfortable with attempting to address the policy issues involved in risk assessment.

114. At 7-8, 162-64.

One way to surmount these problems and concerns would be to address the risk assessment process on the two different levels suggested by the NAS terminology: first, by promulgating general policy principles in an Executive order; and second, by also providing in the Executive order a process for formulating more specific inference guidance consistent with those principles after close coordination between scientists and policy officials in the White House, the departments and agencies, and outside experts. The general principles could remove from contention many of the more controversial issues and facilitate the subsequent development of the inference guidance. This is essentially the paradigm that was followed by E.O. 12291 in establishing certain general requirements for regulatory analysis and assigning OMB to develop detailed RIA guidance for major rulemaking actions; and by the Council on Competitiveness in laying down the four principles for regulation of biotechnology, to be followed by the more specific "scope" guidance developed under the direction of OSTP. It also could be viewed as the plan implied in promulgation of the Regulatory Policy Guidelines through E.O. 12498, to be followed by more specific guidance developed by OMB or OSTP—with that plan not having been fully realized, however, due perhaps to the Order not having assigned responsibility for the development of more specific binding guidance.

Such risk assessment principles and inference guidance could also be drafted with provisos stating that agency policy officials and scientists would have the latitude to accommodate unique facts pertinent to a particular risk or statutory mandate, as recommended by NAS and others. This approach should meet the objections of those commenters who expressed fears that Executive order guidance could put the scientists in a "straightjacket". Some might contend that agency scientists are already in a kind of straightjacket resulting from historically ingrained agency policy biases that restrict scientific judgment and the utility of new data that is not regarded as convincing enough to overcome established default assumptions that are not soundly based on science. If this is the case, generic guidance on policy principles and inferences has more of a potential to liberate science than to constrain it.

CONCLUSIONS

The establishment of "government-wide standards for performing risk assessments"[115], uniform guidance on specific science policy inferences needed to perform certain types of risk assessments, and broad risk management policy principles, has adequate justification from a policy perspective and is legally supportable.

115. FY 1992 *Budget* document, Part Two, p. 373.

Uniform risk assessment guidance should be of two types: general policy principles embodied in the Executive Order, and specific science policy and inference guidance to be developed through a process established by the Order. OSTP should be given the lead in developing the inference guidance, due to its science policy responsibilities and expertise; while OMB, in close consultation with OSTP, should be given the lead in developing more specific risk characterization guidance, due to the more prominent risk management and budgetary implications of risk characterization.

In general, although formulation of these risk assessment principles and uniform inferences would involve the exercise of policy discretion, their content should be developed with a view to de-politicizing risk assessment to the maximum extent possible.

Risk *management* guidance would have different objectives. While the problem with risk assessment (and risk characterization) has apparently been too much policy, and the objective would be to restrict policy discretion, many of the alleged deficiencies regarding risk management have had almost an opposite orientation: too narrow a focus on one specific risk, failure to consider broader implications, and too little flexibility towards innovative alternatives. Risk management principles promulgated by an Executive order would naturally be more general than risk assessment and characterization principles and guidance, since they would attempt to accommodate so far as possible a multitude of specific Congressional mandates.

Uniform risk assessment and risk management principles could consolidate and clarify a number of White House policy positions that have been expressed through various sources over the last decade, and hopefully would reduce controversy and delays historically experienced in the regulatory review process due to divergent views among agency and Administration officials. Many of the White House views expressed over the last decade are not recognized as binding "guidance" by agency personnel.

An Executive order incorporating risk assessment and risk management policy guidance should be issued by the end of this calendar year in order to avoid conflicts with individual agency efforts now under way and to provide a foundation for the views of Presidential appointees to the Risk Assessment and Management Commission. Development of inference and risk characterization guidance will take longer, but the Executive order should establish a commitment to this process, along with provisions for periodic review, and for flexibility to accommodate unique facts.

B. IS A PRESIDENTIAL EXECUTIVE ORDER A NECESSARY AND APPROPRIATE MEANS FOR PROVIDING GOVERNMENT-WIDE POLICY GUIDANCE?

COMMENTS RECEIVED

Views on this issue did not necessarily correlate with views on the previous issue. A fair number of those who favored some sort of government-wide policy guidance were not in favor of an Executive order.

Those who favored an Executive order pointed to the fact that many of the policy issues have been debated for the last decade with little progress in resolving them. They saw the variety of agency and individual views on the policy issues and the appropriate means for addressing them as being incapable of resolution by any means other than strong, centralized guidance of the sort that could be provided by an Executive order.

Those who felt an Executive order would not be appropriate raised fears that it would encroach into scientific and science policy issues where White House personnel lack the expertise to exercise oversight, with the result that inappropriate views could become locked in place and restrict innovation and good science. Some of these commenters suggested that the policy positions should be allowed to develop "organically" within the agencies, or else agency personnel would resent them and devise ways to evade the spirit of the directives. Others pointed out, however, that some Executive orders have had major beneficial impacts without having grown "organically" from within the agencies, and E.O. 12291 was given as an example.

Interestingly, not a single commenter, including agency officials, indicated awareness that many of the policy issues being debated in the forums and addressed in the original draft executive order had been addressed in E.O. 12498 or the *Regulatory Programs* of the Reagan Administration. This might be due to the very limited circulation of the 1983 Task Force Guidelines and the *Regulatory Program* and lack of media attention.

Since the 1990-91 *Regulatory Program* was issued, several agency officials have commented to us, in effect, that it would not result in any significant changes in agency approaches because it had not been "duly promulgated". By this they meant that it did not clearly have the Presidential seal on it and an opportunity had not been given to the agencies to comment. These commenters also indicated that, to the extent any such guidance is issued solely by OMB, it is likely to arouse rebellious reactions in the agencies (and possibly certain members of Congress) due to the history of adversarial interactions between OMB and agency personnel on regulatory review issues and a perceived lack of expertise within OMB to address risk assessment issues. Some policy

officials have also questioned whether any further Executive order guidance could accomplish much, noting that the Administration has a difficult enough time trying to obtain compliance with the Executive orders currently in force.

Finally, during the second and third forums a number of participants indicated that they could not be comfortable with the idea of an Executive order because they did not have a clear understanding of the nature and significance of an Executive order, and how one is developed.

DISCUSSION

If uniform government-wide policy guidance is advisable, an Executive order appears to be the most logical mechanism. Concerns expressed regarding the potential complexities of addressing science policy matters can be resolved by having the Executive order set up a process for developing the necessary guidance under the scrutiny of Administration science policy officials in OSTP, in consultation with OMB and other White House entities and the individual agencies.

There also appears to be no effective alternative to an Executive order. Current Executive order delegations are not adequate to allow OMB or the Council on Competitiveness to promulgate guidance that would be viewed by the individual agencies and their personnel as clearly within their authority.

OMB was delegated authority by E.O. 12291 to promulgate guidance for preparation of the Regulatory Impact Analyses required for "major" rulemaking actions, and that guidance was issued in the 1990-91 *Regulatory Program*. The only other broad substantive delegation in E.O. 12291, contained in section 3(e)(1), allows OMB and the Council on Competitiveness to review individual rulemaking actions to ensure that they comply with the requirements of the Order. While the final RIA guidance incorporates a number of key risk assessment policy views, and probably has more general application to the risk assessment process used to generate benefits estimates, the broader authority is not clear because RIA's are prepared as separate documents apart from rulemaking notices, and the RIA guidance does not apply to rulemaking actions that are not "major", to regulatory actions that are not of "general applicability" (*e.g.*, site-specific or substance-specific), or to risk assessments that are not used to justify rules.

E.O. 12498, while applying to "all regulatory actions", gave the lead responsibility for ensuring compliance with the 1983 Regulatory Policy Guidelines to agency heads, and gave OMB primarily advisory authority which appears to contemplate that the President would be responsible for issuing any new Guidelines or clarifications thereof. Section 3(a) of the Order states:

> In reviewing each agency's draft regulatory program, the Director [of OMB] shall (i) consider the consistency of the draft regulatory program with the Administration's policies and priorities and the draft regulatory programs submitted by other agencies; and (ii) identify such further regulatory or deregulatory actions as may, in his view, be necessary in order to achieve such consistency. In the event of disagreement over the content of the agency's draft regulatory program, the agency head or the Director may raise issues for further review by the President or by such appropriate Cabinet Council or other forum as the President may designate.

The lack of a specific delegation to OMB to address all risk assessments and risk management actions might explain why the continuing discussions of risk assessment policy in the *Regulatory Programs* have never been referred to as "guidance".

Although the Presidential Task Force on Regulatory Relief developed the 1983 Guidelines, it had no specific Executive order delegation from the President to do so, except insofar as they could be considered guidance for the preparation of Regulatory Impact Analyses.[116] The 1983 Guidelines were endorsed by the President through incorporation into E.O. 12498, and arguably any further guidance developed by the Council on Competitiveness would require similar Presidential endorsement by Executive order or other means in order to be fully recognized as binding by agency heads.

Likewise, neither OSTP nor FCCSET currently have the authority to promulgate uniform guidance binding on all federal departments and agencies. OSTP's statutory delegation provides explicit authority only to advise the President, although it also provides that the President can request that OSTP perform other duties and functions.[117] FCCSET likewise is an advisory body, and any positions agreed upon among its agency members would likely be presented to the President through the Director of OSTP for further appropriate action.

The modest substance of the key 1983 Guidelines still appears to be remarkably well-focused, particularly the accompanying explanatory text. Proper application of the Guidelines to all aspects of risk assessment and risk management could resolve many of the controversies that have raged over the last ten to fifteen years. Proper interpretation and enforcement of the Guidelines has been a problem, however, due apparently at least in part to the lack of specific Presidential delegations.

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116. The Task Force report containing the Guidelines characterized them as an application of the principles contained in E.O. 12291 to frequently encountered regulatory issues. Therefore, it might be argued that the Guidelines were simply guidance issued by the Task Force on how it would exercise its review authority if called upon to interpret E.O. 12291 with regard to a specific rulemaking action.

117. 42 U.S.C. 6611 *et seq.*

One objection to an Executive order approach, implied in some of the comments, was that drafting an Executive order is not necessarily a process that allows individual agencies or the public the opportunity to comment.[118] However, there is no legal constraint to prevent a sponsoring agency or OMB from circulating a draft order for agency or public comment, and the airing of risk assessment and risk management issues in a succession of *Regulatory Programs* (including the invitation to comment in the 1990-91 *Program*), individual rulemaking actions, and proposed agency risk assessment guidelines has very arguably already provided sufficient opportunities for public debate on the main issues, although additional comment might be useful with regard to the development of more specific inference and risk characterization guidance.

CONCLUSIONS

Because there are so many different departments and agencies, programs, and White House entities involved in environmental risk assessment and risk management, only the President has sufficient authority to impose some level of policy consistency in those areas that have not been directly addressed by Congress. No White House organizational entity currently has a clear and public Presidential mandate to issue additional appropriate guidance binding on all agencies and policy officials. The 1983 Regulatory Policy Guidelines incorporated into E.O. 12498 address some of the most critical issues, but there has not been an adequate delegation of authority to any entity to interpret and ensure compliance with the Guidelines, and more specific guidance, particularly on crucial "science policy" issues involved in risk assessment, could be very beneficial in de-politicizing what should be as objectively scientific a process as possible.

Concerns expressed regarding lack of White House science credentials and inappropriate or inflexible science policy guidance can be addressed by having OSTP involved in developing specific science "inference" guidance consistent with certain general principles and in consultation with other White House entities and individual agencies. There appears to be no inherent reason why an Executive order cannot be formulated that is restricted to policy rather than science and which retains sufficient flexibility to allow for innovative approaches and *ad hoc* professional judgment.

118. The requirements concerning form, routing, and approval of Executive orders are set out in 1 CFR Part 19. In brief, a proposed Executive order must ordinarily be approved by the Director of OMB and the Attorney General before being submitted to the President.

The degree of controversy surrounding many of the issues indicates that they have strong policy components and suggests that they can be resolved only with strong leadership.

C. WHAT ISSUES SHOULD THE EXECUTIVE ORDER ADDRESS AND HOW SHOULD IT RESOLVE THEM?

To a large extent, it is not possible to separate issues of content from the issues discussed above (need for government-wide guidance and appropriateness of an Executive order as the means). Implied in many comments was the viewpoint that whether the commenters would support government-wide guidance or an Executive order would depend on its scope and specific terms. For example, some thought any guidance should avoid addressing issues that involve scientific inference or science policy, unless it just "set the task"; others thought guidance would be simplistic and ineffective if it did not resolve some of the more controversial issues of this sort. There seemed substantial agreement[119] among commenters favoring government-wide guidance that the following points must be addressed in any policy guidance that is issued:

- The guidance should not be limited to cancer risk assessment and management; it should also encompass non-cancer health effects, both chronic and acute, and safety hazards.

- Greater consistency among agencies and programs is desirable for risk assessment policy and inferences. However, in any attempt to obtain such consistency, care must be taken to ensure that sound scientific judgment on a case-specific basis is not preempted and that science policy and inference choices are reviewed periodically.

- Characterization of quantitative risk assessment data must be improved to avoid presentation of probability numbers based only on upper bounds and worst-case assumptions. Risk characterization should provide a best judgment based on all relevant data, with full and concise disclosure of limitations and uncertainties. The appropriate degree of conservatism should be provided for

119. This does not mean that all or even a majority of such commenters expressed such views; rather, it means that more than a few forum participants strongly expressed such views without disagreement from the other participants, and the general tendency of written comments and submitted literature appears to be in this direction.

through a margin of safety determined as part of the risk management process.

- A *de minimis* policy is necessary and prudent for risk management decisions, to the extent allowed under current law.

These and other issues of content are discussed below. The discussion is organized according to whether an issue is one of risk assessment, risk characterization, or risk management. The discussion on each issue describes how the issue was addressed in the Discussion Draft and whether any changes have been made. A recommended Executive order is set out in Chapter IV.

It will simplify the discussion below for us to state at the outset that, given the incorporation of the 1983 Regulatory Policy Guidelines into E.O. 12498, we regard those principles as controlling to the extent they apply, and we believe that any new Executive order should restate them and the substance of their accompanying explanatory text. Thus, much of the discussion in the remainder of this report in effect addresses the desirability of clarifying and expanding upon the 1983 Guidelines.

1. Types of Risks Covered

When the Discussion Draft was under preparation, we considered the issue of whether it should be limited to cancer risks or extend to all health and safety risks. We decided that the broader coverage should be proposed, but nevertheless inadvertently retained references to "cancer" in one of the sections pertaining to risk characterization. As a result, some forum participants and commenters assumed that the scope of the Discussion Draft was intended to be limited to cancer risks.[120]

COMMENTS RECEIVED

A number of commenters observed that federal agency preoccupation with cancer risks had resulted in shortchanging regulation of many non-cancer risks, such as infectious pathogens and safety hazards. They also pointed out that some of the same issues that plague cancer risk assessments and risk management are presented also by non-cancer risks, although those issues receive far less notice. Examples of such non-cancer issues are potential "conservative" biases in determining

120. In addition, the definition of "negative data" referred to a "toxic response", which could have indicated that a focus only on health effects was intended.

NOELs or NOAELs,[121] and in selecting uncertainty factors or safety factors, and lack of an explicit *de minimis* policy.

DISCUSSION

Guideline 4 in the 1983 Regulatory Policy Guidelines, which concerns risk assessment and risk management, extends to "health or safety risks", and the accompanying explanation also refers to "product, workplace, and environmental standards." Guideline 5, which concerns performance versus design standards, extends to "health, safety, and environmental regulations."

Although not much attention has been given to the subject of risk assessment and management for non-cancer health effects, this area has not been without its controversies.[122] One of the central issues has been application of a "significant risk" policy to non-cancer health effects. The usual risk assessment methodology for non-cancer endpoints focuses on determination of a NOAEL, to which a safety factor or uncertainty factor is then added prior to factoring-in exposure probabilities.[123] The NOAEL does not typically take into account the significance or severity of health effects, and the initial observable effects may not have any health significance or may be extremely superficial and self-reversing. Compounding this problem is the tendency to focus on observed effects in the most sensitive species tested. In addition, the scientific basis for some of the order-of-magnitude, multiplicative uncertainty factors traditionally employed is uncertain, as well as how they should be adjusted in relation to the severity of the effects and the quality of the experimental data.

The 1983 NAS Red Book recommended the development of uniform federal risk assessment inference guidelines for non-cancer risk assessments as well as cancer risk assessments.[124] The recent report by the Office of Technology Assessment[125] and Congressional hearings on

121. No Observable Effect Levels and No Observable Adverse Effect Levels.

122. See, *e.g.*, *Gulf South Insulation v. CPSC*, 701 F.2d 1137, 1147-48 (5th Cir. 1983). The court found (although it was technically dicta) that the agency's assessment of the acute irritant effects of urea formaldehyde foam insulation as "unreasonable" was not supported by substantial evidence because the agency did not calculate risks at expected exposure levels, consider the severity of the effect at different exposure levels, and factor severity with likelihood.

123. For EPA's current methodology see D. Barnes and M. Dourson, "Reference Dose (RfD): Description and Use in Health Risk Assessments", *Reg. Tox. and Pharm.*, vol. 8, No. 4, 471 (Dec. 1988).

124. See, *e.g.*, p. 82: "Uniform guidelines for effects other than cancer are desirable, but typically they would be based on a less extensive scientific data base."

125. "Neurotoxicity: Identifying and Controlling Poisons of the Nervous System" (OTA 1990).

neurotoxic risks[126] have served to increase awareness of the broad spectrum of non-cancer risks potentially involved in federal regulation. In addition, the need to address the full range of environmental risks in setting regulatory priorities has been recognized by EPA's current Administrator[127] and the Agency's Science Advisory Board as necessary to the Agency's Relative Risk Reduction Project.[128]

Coverage of "safety" risks should be included in order to allow relative risk prioritizing across all programs affecting human welfare, and this would be consistent with the scope of the discussions in the *Regulatory Programs* and the Risk Management Budgeting portion of the FY 1992 *Budget* document.

An issue which was not addressed in any substance by the comments on the Discussion Draft or in the various White House discussions to date is whether any uniform guidance should apply to ecological risks such as ozone depletion, global climate change, or endangered species. Although benefits estimates obviously would be based differently, given the close relationships between human health and ecological impacts, at this time we see no reason why similar risk analysis principles should not apply.

CONCLUSIONS/REVISIONS

Any new Executive order should cover all human health and safety risks in order to be consistent with E.O. 12498 and the 1983 Guidelines. Coverage should also extend to ecological risks. A new section has been added to the proposed order to addresses applicability:

> **Sec.** *Applicability.* To the extent permitted by law, this Order applies to all risk assessments and risk management decisions on health, safety, and ecological risks.

2. Types of Agency Actions Covered

The Discussion Draft spoke to this subject in the prefaces to each of the major sections. It stated that its principles were to be applied "[i]n conducting risk assessments, formulating risk assessment guidelines, and making risk management decisions". In addition, it stated that the criteria for risk assessments applied to "risk assessments and risk assessment guidelines"; and that the requirements for characteri-

126. Hearings on October 3, 1990, before the Subcommittee on Toxic Substances, Environmental Oversight, Research and Development of the Senate Committee on Environment and Public Works.

127. William K. Reilly, "Aiming Before We Shoot: The 'Quiet Revolution' in Environmental Policy", *supra* n. 99.

128. See text at n. 99 *supra*.

zation and communication of risk applied to "official documents such as rulemaking notices, health advisories, and health criteria documents".

COMMENTS RECEIVED

A number of commenters stressed that it would be important for any Executive order to be crystal clear in its application to risk assessments and regulatory decision of a non-rulemaking nature made with regard to specific sites, projects, substances, or activities under statutes such as FIFRA and CERCLA. In the view of some, the Discussion Draft needed improvement in this regard.

DISCUSSION

These types of non-rulemaking regulatory actions can have very substantial environmental and economic consequences, both individually and cumulatively, and they are presently immune from the regulatory review provisions of E.O. 12291 and appear to be mostly outside the terms of the pertinent 1983 Regulatory Policy Guidelines. Executive Order 12291, as noted before, applies only to regulations or rules of "general applicability"; and Regulatory Policy Guidelines 4 and 5 are primarily written in terms of "regulations" and "standards", although the explanatory text also refers to decisions regarding "whether certain products should be marketed at all" and decisions on "whether to issue a license or permit for a new project or product." The only reason to exclude regulatory actions of specific applicability from coverage apparently would be to avoid increasing regulatory review burdens and potential attendant delays. Concerns of this sort can be accommodated, however, by placing responsibility for compliance with agency heads.

CONCLUSIONS/REVISIONS

The Executive order should apply to all regulatory actions regardless of whether they are of a "rulemaking" nature, but regulatory review authority of OMB or other White House entities should not presently be extended to these actions. If experience under the new Executive order demonstrates inadequate compliance, the order can be expanded to include more oversight.

Accordingly, the definition of "risk assessment" has been revised to clarify that the order applies to "individual regulatory actions", and a clause has been added to the end of the "Applicability" section [illegible]

3. Risk Assessment (hazard assessment, dose response, and exposure assessment aspects)[129]

Consistency and Uniform Science Policy and Inference Guidance

This issue and the comments received have previously been discussed in section III,A *supra*. It was concluded that an Executive order should attempt to achieve a degree of consistency among agencies in risk assessment by establishing both broad risk assessment policy principles and by setting up a process by which OSTP would take the lead in developing and issuing uniform guidance on more specific science policy positions and inferences. The new recommended provisions concerning OSTP responsibility for issuing science policy and inference guidance are as follows. The content of the risk assessment principles is discussed in the remainder of this section.

> **Sec.** 5. *Science Policy and Inference Guidance for Risk Assessments.*
>
> (a) Within one year of the date of this Order, and from time to time thereafter as he deems necessary, the Director of the Office of Science and Technology Policy shall issue uniform guidance for all federal departments and agencies on aspects of risk assessment where there is a difference of scientific opinion or a lack of adequate data and the choice of a position involves policy or a mixture of policy and scientific judgment. Such guidance shall be consistent with and subordinate to the risk assessment policy principles stated in section 4 of this Order and shall be binding on all departments and agencies to the extent permitted by law.
>
> (b) The subjects addressed by such guidance shall be at the discretion of the Director, and he shall consider inclusion of guidance on at least the following subjects: interspecies scaling factors, dose-response modeling, treatment of tumors that do not appear to be malignant, thresholds, use of the maximum tolerated dose, weighting of positive findings from sensitive species, and definition of adverse health effects.
>
> (c) Such guidance shall be developed in consultation with the Federal Coordinating Council on Science, Engineering and Technology, the National Research Council, the Council on Competitiveness, the Office of Management and Budget, the Council on Environmental Quality, and such other departments and agencies, offices, organizations or persons as the Director deems advisable.
>
> (d) Any guidance promulgated under this section shall permit divergence by a department or agency in particular cases on the basis of overriding

129. The risk characterization aspect of risk assessment is addressed in section 4, *infra*.

scientific data or the requirements of law.

(e) Guidance promulgated under this section shall be reviewed by the Director at least every four years, after requesting comments from all entities and persons consulted in accordance with subsection c. A particular provision of the guidance shall be reviewed whenever any department or agency formally requests such review and supports its request with significant new data or scientific rationale. In addition, the Director shall consider supplementing the guidance upon formal request by any department or agency.

Sec. 4(e). A risk assessment that is significantly different from a risk assessment for the same substance, process, activity, or condition prepared by another department or agency, or by another office or under another program of the same department or agency, shall explain the scientific, policy, or legal justification for the inconsistency.

Implementation of the above provisions regarding the development of risk assessment guidance would necessarily involve a review of the 1985 OSTP cancer principles, although it is not necessary to explicitly revise those principles in order to issue the binding guidance called for here, since the OSTP document did not attempt to formulate binding policy.

It is recognized that issuance of such guidance would probably take place in a number of stages, and that the guidance would be a "living" document, updated as necessary to incorporate scientific advances and new policy views.

Conservatism and Margins of Safety

Section 3(a) of the Discussion Draft provided that "[r]isk assessments shall employ the most scientifically realistic assumptions."

COMMENTS RECEIVED

Many of the comments received criticized the alleged current tendency in agency risk assessments to incorporate multiple "conservative" assumptions or inferences that reflect value judgments rather than science. Those comments argued that the result is frequently that quantitative assessments are greatly distorted and the risk manager's policy discretion is usurped. Others argued that it is prudent to select conservative assumptions and inferences, particularly in the case of potential carcinogens, because the likely long latency period means that by the time adequate human data can be obtained great numbers of people may already be affected. Others argued that conservative choices are often necessary to protect sensitive subpopulations

Several commenters challenged the proposition that agency risk assessments are usually biased in a conservative fashion resulting in overestimation of risks,[130] with some expressing the view that the real problem is that we do not really know for sure whether many risk assessments, particularly those for cancer risk, are too conservative or not, because many of the assumptions employed are clearly *designed* to ensure that risks are, if anything, over-estimated, or not under-estimated, although they might sometimes fall short of this intended result.

Several commenters characterized the problem of potential conservatism as an issue of how much evidence should be required in order to overcome a "default" position. They contended that the current agency risk assessment orientation often seems to be that in the absence of adequate scientific data an agency will employ a conservative default option, and will then take the position that "convincing" scientific data is necessary to override the default position. They added that oftentimes this puts industry in an almost impossible position if the default position is supported by some kind of positive test data, since scientists regard it as axiomatic that a negative cannot be proved, and consequently industry becomes involved is spending huge sums of money on testing in what turns out to be a futile attempt to "prove" a negative. The judgment implicit in these comments is that convincing data should not be required to override a position that does not have substantial support to begin with.

One commenter offered the political perspective that in the absence of clear policy guidance agency scientists are subject to political pressures and have no motivation to make "tough" decisions (*i.e.,* ones that are truer to the data and less conservative), and that when the appropriate degree of conservatism is determined by the risk assessors, the risk manager is placed in a "no win" situation, in that if he recognizes the conservatism of a risk assessment and therefore does not add

130. The Center for Risk Analysis of the Harvard School of Public Health in particular discussed this point in some detail in written comments submitted to OMB on the discussion of risk assessment in the 1990-91 *Regulatory Program*. The Center also made those comments available to Federal Focus. The comments briefly described seven factors that might cause underestimation of health risk: addressing a single pathway of exposure even though secondary pathways might dominate; assuming additive rather than synergistic effects; the possibility that some humans are more susceptible than test animals; assuming no carcinogenicity in the absence of adequate testing; the possibility that human response at low doses is "supra-linear" in some cases; and failure to address non-cancer risks in addition to cancer risk from the same chemical. A workshop to critique the Center's comments and the *Regulatory Program* discussion was held at Harvard in March 1991, and the Center expects to publish a summary of the workshop in June 1991.

a margin of safety, he cannot take credit for adding a margin of safety and some parties are likely to criticize him for not adding one.

With regard to the language of the Discussion Draft, some commenters criticized it on the basis that it was inadequate because everyone agrees that the "most scientifically realistic" assumptions should be employed; the controversy arises over particular issues where the scientific data are inadequate to make a decision on what constitutes the "most scientifically realistic" assumption. In such cases, they asserted, the choice of assumptions involves policy or value judgments, and should either be made by policy officials or should be explicitly identified as incorporating a policy judgment.

DISCUSSION

To the extent possible, science should be distinguished from policy. Most arguments over "conservatism" appear in reality to be arguments about what is the superior policy position. We believe that a primary objective of a new Executive order should be to ensure that, to the maximum extent possible, risk assessments reflect unbiased scientific judgment rather than policy judgments, especially since policy judgments might vary from Administration to Administration. Of course, a decision to revise current risk assessment philosophy and purge the process of policy positions by itself would represent a kind of policy view that of necessity should be included in the order.

The first general requirement for rulemaking stated in E.O. 12291 is that, to the extent permitted by law, regulatory decisions "shall be based on adequate information concerning the need for and consequences of proposed government action."[131] Ironically, however, it appears that the need to quantify benefits generated by the Order has sometimes led agencies to employ conservative assumptions when faced with a high degree of uncertainty, with the perverse result that the less that is known about a risk, the more it is regulated.

The text accompanying Regulatory Policy Guideline 4 addressed directly the subject of possible excess conservatism in risk management decisions; and it also addressed the relationship between conservatism in risk assessments and decisions on margins of safety:

> [R]isk assessments must be scientifically objective and include all relevant information. In particular, risk assessments must be unbiased best estimates, not hypothetical "worst cases" or "best cases." Extreme "best" or "worst" safety or health results should be weighted (along with intermediate results) by the probability of their occurrence to estimate the expected result implied by the available evidence. In addition, the distri-

bution of probabilities for various possible results should be presented separately, so as to allow for an explicit "margin of safety" in final decisions.

CONCLUSIONS/REVISIONS

The Executive order should incorporate the substance of the explanatory text accompanying Guideline 4. The Discussion Draft has been revised to substitute the following provision for the one quoted above:

> **Sec.** 4(a). Risk assessments and all of their components shall be, to the maximum extent possible, scientifically objective and include all relevant data. Determinations concerning the appropriate degree of conservatism, safety factors, uncertainty factors or margin of safety to be incorporated in a regulatory decision shall be reserved for the risk management decision process. To the extent that selection of any assumption, inference, or model for a risk assessment involves, wholly or partially, policy or value judgments that significantly affect the assessment, such policy or value judgments shall be clearly identified as such and explained and justified.

Procedures for calculating and displaying "expected" results would be provided by OMB through risk characterization guidance, as discussed in section III,C,4, below.

Low-Dose Extrapolation

The Discussion Draft contained a provision stating that "[a]gency risk assessment guidelines shall provide for the use of alternatives to linear dose-response models in cases where valid scientific data indicates the likelihood of a non-linear mechanism of action."

COMMENTS RECEIVED

One of the "conservative" assumptions most often criticized by commenters was the assumption of low-dose linearity/no threshold for potential carcinogens. Some of these commenters argued that use of a linear no-threshold model is not supported by the preponderance of scientific data and is inconsistent with general principles of toxicology ("The dose makes the poison."). Other commenters defined the problem as one of the burden of proof required to override a socially "prudent" default position: That is, while the use of a linear no-threshold model might be barely justified in cases where there was a very high level of uncertainty, the problem is that the agencies sometimes require "convincing" evidence to overcome this position, when the original position itself has insufficient scientific basis. Still others articulated the problem in terms of not considering all relevant data—*e.g.*, metabolism, pharmacokinetics, mechanism of action—when deciding what model

would be most consistent with the data. Several commenters pointed out that the difficulty in overcoming such default positions has the effect of discouraging investigation into the mechanisms of carcinogenic action, which is sorely needed, and that ideally any improvements should have the effect of providing incentives for new research.

DISCUSSION

The implication of these comments for the above-quoted provision of the Discussion Draft is that the language appeared to preserve and endorse an unwarranted bias in favor of linear dose-response models by requiring data sufficient to show a "likelihood" of non-linear response in order to overcome a linear default position. In addition, the provision could be read as requiring mechanistic data to overcome the default position, when there might be additional pertinent biological data, such as data on metabolism and pathway saturation.

The 1985 OSTP cancer principles addressed both selection of low-dose extrapolation models and thresholds. Principle 26 expressed a preference for linear models in the face of high uncertainty:

> 26. No single mathematical procedure is recognized as the most appropriate for low-dose extrapolation in carcinogenesis. When relevant biological evidence on mechanisms of action (e.g., pharmacokinetics, target organ dose) exists, the models or procedures employed should be consistent with the evidence. However, when data and information are limited, and when much uncertainty exists regarding the mechanisms of carcinogenic action, models or procedures which incorporate low-dose linearity are preferred when compatible with the limited information. . . .

This preference clearly represented a policy judgment, and was acknowledged as such in the Introduction.[132] At the same time, it appeared that this policy judgment was not intended to be binding on the agencies, since the *Federal Register* summary, as noted previously, stated that the document "does not attempt to formulate policy. . . ."

The OSTP document did not state a preference for any assumption regarding the existence or non-existence of thresholds for carcinogenesis. In Principle 3, however, it did address the subject to a limited extent:

> 3. At the present stage of knowledge, mechanistic considerations such as DNA repair and other biological responses, in general, do not prove the existence of, the lack of existence of, or the location of a threshold for carcinogenesis. The presence or absence of a threshold for one step of the

carcinogenic process does not necessarily determine the presence or absence of a threshold for the whole process. . . .

When this principle is combined with Principle 26, however, the net effect could be interpreted to be the setting up of a default judgment in favor of low-dose linearity/no threshold that could not be overcome by anything short of convincing mechanistic data (i.e., "proof").[133]

A recent report by the American Council on Science and Health on the validity of animal bioassays for estimating cancer risks concludes that regulatory assumptions regarding linearity and absence of thresholds for carcinogens are no longer scientifically supportable.[134]

The recent discussion of cancer risk assessment issues in the 1990-91 *Regulatory Program* highlighted agency preferences for the Linearized Multistage Model as one of the most important factors in introducing conservative policy biases into such risk assessments.

CONCLUSIONS/REVISIONS

While the general principle regarding conservatism and margins of safety discussed in the immediately preceding section could be interpreted to remove the apparent biases discussed in this section, we believe that in order to counteract the influence that the OSTP Principles might have had, and due to the importance of the issue, a separate Executive order provision addressing this subject is needed. The recommended provision has been revised to prohibit any bias either for or against linear models and thresholds.

> **Sec.** 4(b). Selection of low-dose extrapolation models and assumptions shall be based on all available scientific data, including biological, metabolic, pharmacokinetic, and mechanistic data. In the absence of clear supporting data and scientific rationale, no single model or threshold/no-threshold assumption shall be preferred.

The issue of how to characterize risk when there is a high level of uncertainty and no preferred model is discussed below in the section on risk characterization.

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133. See also the conclusions and recommendations on this subject by the National Research Council in vol. 6 of *Drinking Water and Health,* pp. 282-84 (National Academy Press 1986), which, while ambivalent, could be interpreted as supporting the use of a linearized multistage model in the face of uncertainty.

134. *From Mice to Men: The Benefits and Limitations of Animal Testing in Predicting Human Cancer Risk,* 21-33 (1990). For example, the report states: "There is now sufficient evidence and theory to indicate that the one hit/no threshold proposition is untenable." At 28. The report also discusses the view that "small amounts of toxic substances may often be *beneficial,* according to the concept of hormesis or 'sufficient challenge'." (Original italics; citations omitted)

Consideration of Negative Data

The Discussion Draft provided that "[d]ue weight shall be given to relevant negative laboratory and epidemiological data."

COMMENTS RECEIVED

A number of commenters felt that it was important to address this topic, but also felt that the draft language was unlikely to accomplish anything significant because many agency officials and scientists would contend that they already give "due weight" to negative data. The problem, as they perceived it, was a fairly subtle bias problem: Due to the recognized axiom that in science a negative cannot be proved, there has been a tendency to discount negative data even when its quality and power seem sufficient to cast considerable doubt on positive results, although it could not be used to totally "disprove" positive results. In such cases, they observed, the negative data should serve at least as a "reality check" on the positive data and should be considered in evaluating the overall weight of the evidence.

One commenter pointed out that there is a generalized bias against negative findings in the scientific community, and that publications are very reluctant to accept articles presenting such findings.[135]

DISCUSSION

While recognizing that it is not possible to "prove" a negative or "disprove" a positive result,[136] the issue still remains as to what weight should be given to negative data when it is of good quality and adequate statistical power and the positive data is of doubtful probative value.

The answer to this question appears to depend on whether the competing results are derived from animal data or human data. If there is high-quality positive human data, it is clearly not possible to disprove that result with negative human data. However, if the positive results are from animal bioassays performed at high doses, the results might be called into question by failed attempts to replicate the positive results, failure to obtain positive findings at mid-level doses, or by epidemiological data of good quality and sufficient statistical power.[137]

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135. A recent commentary article contains an assertion that "[n]egative science is inherently more trustworthy, at least when it comes out of the academic community, than positive science, because reports of non-causes are much less personally advantageous to the scientist making them." P. Huber, "Pathological Science in Court", *Daedalus*, vol. 119, no. 4, 97, 109 (Fall 1990) (issue entitled "Risk").

136. See Chapter 4, Section VI of the 1985 OSTP document.

137. See OSTP Principle 25 ("Decisions on the carcinogenicity of chemicals in humans should be based on considerations of relevant data, whether they are indicative

CONCLUSIONS/REVISIONS

Although the general principle prohibiting bias in risk assessments recommended in section 4(a) might cover this issue, issues regarding the weight to be given to negative data can be a subtle and subjective matter that might easily be overlooked if not focused on separately. Therefore, it is recommended that the following provision be included in an Executive order:

> **Sec.** 4(c). Negative laboratory or epidemiological data of sufficient quality that are not consistent with positive experimental results or low-dose extrapolations shall be considered on the basis of scientific judgment, and without any bias based on "conservatism" or value judgments, and if they are not incorporated into the risk assessment, the scientific basis for not incorporating them shall be explained.

Exposure Estimates

Section 3(b) of the Discussion Draft provided that "[w]here practicable, empirical data shall be employed in risk assessments rather than assumptions or modeling."

COMMENTS RECEIVED

Industry commenters and environmental consultants thought that conservative exposure assumptions and modeling are often the factors that contribute most to bias in risk assessments. Their comments encompassed the maximally exposed individual (the MEI), ambient air dispersion models, groundwater plume dispersion models, and bioavailability from soil. Several commenters asserted that typically the exposure estimates at a Superfund site are reduced substantially when empirical exposure data are substituted for assumptions and theoretical modeling.

Several commenters pointed out that while it might be appropriate to model for a "worst case" in addition to a best estimate, the exposures used for a worst-case model scenario should be based on the highest exposures that are *reasonably* expected, not ones that are highly unlikely.[138]

DISCUSSION

There does not appear to be any disagreement over the advisability of using the most realistic exposure data, and preferably empirical data if it is available. The explanatory text accompanying 1983 Regulatory

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pp. 17-18 in the 1990-91 *Regulatory Program* on "Selective Use of Alternative Studies" and "Selective Interpretation of Results".

138. The general subject of exposure assessment is discussed in the 1990-91 *Regulatory Program* at pp. 22-23.

Policy Guideline Number 4 emphasized that "real-world exposure" must be considered in making regulatory decisions.

There is an underlying issue concerning who should be responsible for the cost and effort associated with obtaining better exposure data. Agency use of conservative exposure assumptions seems at times a strategy for shifting the burden to private industry.

CONCLUSIONS/REVISIONS

Without taking a position on whether industry or government should assume the burden of obtaining more realistic exposure data, we recommend that the Executive order clearly provide that even if empirical data is not available to the agency, it should attempt to employ realistic exposure assumptions and modeling.

> **Sec.** 4(d). If reasonably available, empirical exposure data shall be employed rather than assumptions or modeling. To the extent empirical data are not available, exposure assumptions or modeling, whether for an average-case scenario or a worst-case scenario, shall reflect exposures that are reasonably expected.

4. The Risk Characterization Aspect of Risk Assessment

GENERAL COMMENTS RECEIVED

Of all the topics addressed in the forums and written comments, there seemed to be the most agreement on the need for improvements in this area of the risk assessment process, especially with regard to potential carcinogens. In general, the reasons given were public fears that were not warranted by the data, the potential to develop insensitivity to serious risk through inundation with data on trivial risks, and the potential for distortion of regulatory priorities and waste of valuable resources. Agreement was not universal, however, and there was far less agreement on remedies.

A few commenters stated emphatically that they believed that most of the problems attributed to risk characterization and communication were the result of "misuse" of risk assessment data by the media[139] and interest groups. The types of "misuse" these commenters focused on were—

- use of terminology such as "carcinogenic", "cancer-causing" or "linked to cancer" without discrimination between known and potential human carcinogens and with little or no explanation of

139. For a recent perspective on this subject, see S. Klaidman, "How Well the Media Report Health Risk", *Daedalus*, vol. 119, no. 4, 119 (Fall 1990).

the extent of uncertainties or the importance of exposure magnitudes;

- use of conservative upper-bound risk probability numbers (*e.g.*, 2.5 x 10^{-4}) as if they represented actual risk probabilities and without explaining that they are conservative upper confidence limits; and

- translation of highly uncertain upper-bound risk probability numbers into population incidence numbers (*e.g.*, one fatality or cancer case for every 4,200 persons exposed).

According to these commenters, since the problem is "misuse", it is futile to attempt to improve public education and perception through changes in the means for characterizing risk, and the main emphasis should be on improvements in the science rather than to this aspect of risk assessment. Some of these commenters also remarked that most agency risk managers in reality do not place great reliance on single-point estimates of risk, and they are briefed fully on all aspects of the risk assessment before they reach a decision. Other commenters responded, however, that the current methods of risk characterization easily lend themselves to misuse or oversimplification, and the result is that public perceptions are strongly influenced, and these perceptions generate intense political pressure on risk managers, even if they have been fully briefed.

Several commenters expressed doubts that much could be achieved in the way of correcting public perceptions of risk, since public reactions are often based on factors that are clearly subjective, such as voluntariness, dread, and cultural/political leanings.[140]

DISCUSSION

As noted earlier in this report, "risk communication" can, and should, be distinguished from "risk characterization". "Risk characterization", as used in this report, is intended to refer to the way in which the scientists performing a risk assessment frame their conclusions for the risk manager, and the considerations are mainly technical and objective, but there is a recognition that the conclusions might be conveyed to a more general audience. "Risk communication", on the other

140. In a recent article, Professors Aaron Wildavsky and Karl Dake presented survey findings from which they concluded that perceptions of environmental risk correlate most highly with cultural/political biases. "Theories of Risk Perception: Who Fears What and Why?", *Daedalus, supra* n. 98, at 41. Also see H. Sapolsky, "The Politics of Risk" in the same publication at 83.

hand, indicates a process that encompasses all aspects of describing risk primarily to a lay audience; accordingly, it attempts to take into account a wide array of psychological and social factors that influence subjective perceptions of risk.

The subject of "risk communication" was recently studied in detail by the National Research Council. Its report, *Improving Risk Communication*,[141] underscores the complexity of communicating with the lay public, and emphasizes that it would be a mistake to assume that better crafting of "risk messages" will, by itself, correct public misconceptions regarding risk. "Risk messages", they concluded, "necessarily compress technical information, which can lead to misunderstanding, confusion, and distrust."[142]

CONCLUSIONS

The risk communication *process* is too complex a subject to attempt to address comprehensively through an Executive order, and it might not be amenable to any sort of uniform rules; however, risk characterization, and to a lesser extent risk communication, can be made more accurate and understandable in some obvious ways. Whether these improvements would have any substantial impact on public perceptions would remain to be seen, but they would have that potential, could not make the situation worse, and would assist the regulatory process by establishing a higher degree of objectivity and consistency.

The provisions of the Discussion Draft dealt with three aspects of risk characterization: quantitative expression of risk probabilities; risk comparisons; and substitution risks. The following discussion of comments received and conclusions/revisions is divided into those three areas.

Quantitative Expression of Risk

The Discussion Draft contained the following provisions:

> (a) Provide (1) an estimate of the most likely risk for the average individual as well as sensitive populations and highly exposed individuals, (2) an estimate of the most likely risk to the entire exposed population in terms of expected annual cancer incidence, as well as the most likely risk to sensitive or highly exposed populations in terms of annual cancer incidence, and (3) an estimate of the "worst case" risk for (1) and (2).

141. Prepared by the Committee on Risk Perception and Communication (National

(b) If available scientific data are inadequate to permit statement of most likely risk levels, state risk in terms of a range with upper and lower bounds.

COMMENTS RECEIVED

Many commenters were of the opinion that any presentation of conservative, upper-bound probability numbers needs to be accompanied by some kind of "best estimate" of risk, or an indication of the "central tendency" of the data, and/or a lower-bound number. They emphasized that they thought the key was that any numbers presented must somehow reflect the scientists' best objective judgment on the entire range of data, with clear explanations of any limitations to the data. A few commenters were of the opinion that in cases where there is a fairly high level of uncertainty, which is often the case regarding potential carcinogens at low exposure levels, the presentation of any probability numbers is unscientific and inherently misleading. Some even asserted that in the case of most cancer risk assessments, the use of the term "risk" was ill-advised, since it implies to the public a reasonable degree of certainty comparable to risks of highway fatalities or accidents around the home, for which concrete statistics are available, whereas cancer risk probability numbers are more indicative of a "risk of a risk" rather than a "risk".

Some commenters pointed out that where the general public is concerned, exponential risk probability numbers such as 5×10^{-5} are simply not understood, and this leads to the media's habit of translating such numbers into population incidence numbers.

Some commenters observed that risk assessments can also be misleading in that they are often limited to a single pathway of exposure (*e.g.,* respiration), when in fact the substance poses a hazard to many individuals through multiple pathways (*e.g.,* ingestion and dermal contact in addition to respiration).

A few commenters provided specific recommendations for ways to quantify uncertainties. One involved graphic displays of the relative strengths of different elements of the risk analysis, and another involved weighting probability numbers by a numerical uncertainty factor similar to that recommended for use in the National Acid Precipitation Action Plan.

Some commenters were critical of the provisions of the Discussion Draft because they believed they were too "simplistic" and confining and there should be more freedom to innovate and experiment in this area. Others responded that it was more important that risk managers and regulatory reviewers have risk data presented to them in a uniform way so that they could set priorities and understand the magnitude of

the risk in comparison with risks that had been regulated by other agencies or under other programs.

Finally, a few commenters pointed out that some of the problems presented by characterization of carcinogenic risks are similar for non-cancer risks in cases where there is substantial uncertainty involved, and that the Discussion Draft appeared to address only cancer risks. These problems include presentation of "conservative" probability numbers as if they represented actual risks, and the incorporation of safety factors or uncertainty factors into the risk assessment process rather than the risk management process. They also pointed out, however, that characterization of non-cancer risks presents at least one distinct problem. This problem stems from the fact that, while cancer is obviously a serious health endpoint, non-cancer health endpoints associated with a single substance or activity might be arranged along a spectrum of severity, and it is necessary to relate risk probabilities to severity somehow, so that risk managers and the public know, for example, that the risk of getting a temporary headache, skin rash, or minor burn from a particular exposure might be one in ten thousand, while the risk of suffering some significant lasting impairment might be one in one million.

DISCUSSION

A great many cancer risk assessments, and also many risk assessments for non-cancer, safety, and ecological hazards, involve high levels of scientific uncertainty. Nevertheless, agencies feel compelled to provide estimates of risk that have the appearance of precision because Congressional mandates and the directives of E.O. 12291 and E.O. 12498 appear to require some sort of concrete quantitative estimate.

Current agency practice with regard to known or potential carcinogens is to provide an upper-bound likelihood estimate (or, in more technical terms, a 95% upper confidence limit), and/or some kind of maximum likelihood estimate, usually expressed in exponential form (*e.g.*, 4×10^{-5}, or four in one hundred thousand), together with a weight-of-the-evidence classification (such as B2, which indicates a "probable human carcinogen" under EPA's current carcinogen classification scheme). Several different classification systems and criteria are in use among federal agencies and institutions. These include the systems used by EPA, the National Toxicology Program, the American Conference of Governmental Industrial Hygienists, and the International Agency for Research on Cancer.[143]

143. These systems are summarized in Issue Summary 4 of the CEQ handbook on risk analysis, p. 96 *supra*. The summary of the IARC classification system is [illegible]

An obvious problem with the current system for cancer risks, as pointed out by many critics, is that it tends to gloss over the true level of uncertainty and leads to misunderstanding as to the likely levels of actual risk. An upper bound by its very nature will tend to overstate, while the cancer classifications do not take into account the increasing uncertainties of dose response at lower levels of exposure.[144]

For non-cancer health hazards, the agencies usually generate a "reference dose" or ADI (acceptable daily intake), which is based on a no-effect level demonstrated experimentally, reduced by an "uncertainty factor" or "safety factor" (often 10x or 100x, up to several thousand x). Risks for safety hazards are generally expressed as best estimates of likelihood based on a fault-tree analysis. Ecological risks may be expressed in a more *ad hoc* manner, and sometimes are only qualitative or conclusory.[145] As some commenters correctly observed, non-cancer risk assessments can be misleading by not factoring likelihood with the severity of the various potential health or safety effects (or "endpoints").

Suggested alternatives to the current practices have often focused on providing a fuller portrayal of the risk assessment data. OMB has consistently argued in the annual *Regulatory Program* that the primary quantitative estimate of risk probability should be a "best estimate" rather than an upper bound, and that upper bounds should be presented only in conjunction with best estimates. OMB has also argued for some form of quantification of uncertainty other than that implied by the various current carcinogen classification schemes. The 1985 OSTP document favored quantification of uncertainties in cancer risk assessments, including the presentation of both upper and lower confidence limits, the use of an "envelope" of risk estimates from various plausible low-dose extrapolation models, and qualitative consideration of the basic strengths and weaknesses of the data in addition to any numerical estimates.[146] The recent report by the National Research

144. For example, benzene is classified as a "Group A" or a "known human carcinogen". This could be taken to indicate that *at whatever level of exposure is under review,* the substance is known to cause cancer. However, this is not accurate, since benzene and other "known" human carcinogens are only "known" to cause cancer at certain levels which may be far higher than any exposure level under consideration. Low-dose response to benzene is still under investigation. The same is true for other classification categories. In other words, application of cancer classifications to particular exposure scenarios is often premised on an underlying science policy assumption that carcinogens are "non-threshold toxicants".

145. By "conclusory" is meant a determination that a particular level of risk either does or does not exist. An example would be an agency determination that a federal action would "jeopardize" an endangered species or its critical habitat.

146. Principles 27 and 31.

Council on risk communication contains the following general recommendation:

> Risk messages and supporting materials should not minimize the existence of uncertainty. Data gaps and areas of significant disagreement among experts should be disclosed. Some indication of the level of confidence of estimates and the significance of scientific uncertainty should be conveyed.[147]

In addition, various experts have suggested specific methodologies for quantifying uncertainty by displaying the relative probability that various likelihood estimates represent the actual risk.[148]

The explanatory text accompanying Regulatory Policy Guideline Number 4 addressed clearly the overall subject of risk characterization, and, more specifically, how to present likelihood estimates along with quantitative expressions of uncertainty:

> [R]isk assessments must be unbiased best estimates, not hypothetical "worst cases" or "best cases." Extreme "best" or "worst" safety or health results should be weighted (along with intermediate results) by the probability of their occurrence to estimate the expected result implied by the available evidence. In addition, the distribution of probabilities for various possible results should be presented separately, so as to allow for an explicit "margin of safety" in final decisions.

OMB's final guidance for preparation of Regulatory Impact Analyses for major rulemaking actions, issued as part of the 1990-91 *Regulatory Program,* follows the 1983 Guidelines while refining some of the terminology and explanations.

CONCLUSIONS/REVISIONS

Executive order provisions on this subject are needed to expand, clarify, and more fully implement the 1983 Regulatory Policy Guidelines. These provisions must also be consistent with OMB's RIA guidance. This can be accomplished by including in the order, as with the recommendations made above for other aspects of risk assessment, certain general risk characterization principles together with authority for OMB to issue, in consultation with OSTP and other White House offices, more specific guidance on implementation of those principles.

OMB is more appropriate than OSTP to take the lead in preparing such guidance because risk characterization is primarily a tool to be

used by the risk manager and has far less of a scientific component than the other aspects of risk assessment for which OSTP is given lead responsibility for issuing guidance.

The recommended provisions are as follows:

Sec. 6. *Risk Characterization Principles.* In characterizing risk in risk assessment documents, regulatory proposals and decisions, budget documents, and legislative recommendations, departments and agencies shall:

(a) If a numerical estimate of risk is provided, provide an unbiased expected-value estimate for the average individual. Upper-bound or conservative estimates or estimates for sensitive or more-highly-exposed populations may be provided in addition to the expected-value estimate. If an upper-bound estimate is provided, the lower-bound estimate will also be provided. If the available data are, in the best judgment of the department or agency, inadequate to provide an estimate of the expected value, this judgment shall be clearly stated along with a narrative explanation of the limitations and uncertainties, and both upper- and lower-bound estimates shall be provided.

(b) Present, to the extent possible, along with expected-value and upper-bound or conservative estimates of risk, to the extent possible, the distribution of probabilities for various possible results.

(c) Where a number of different health, safety, or ecological effects are possible from exposures to the same substance, process, activity, or condition, provide separate estimates for each of the various significant effects. If the risk assessment is intended to address only a single route of exposure, provide any available estimates or qualitative information regarding risks from other pertinent routes of exposure, and any information regarding the likelihood of synergism or antagonism as a result of exposures from other sources.

(d) Clearly and succinctly acknowledge any significant limitations in the data or current scientific understanding.

Sec. 7. *Risk Characterization Guidance.*

(a) Within one year of the date of this Order, and from time to time thereafter as he deems necessary, the Director of the Office of Management and Budget shall issue uniform guidance for all departments and agencies on risk characterization. Such guidance shall be consistent with and subordinate to the risk characterization principles stated in section 6 and shall be binding on all departments and agencies to the extent permitted by law.

(b) The subjects addressed by such guidance shall be at the discretion of the Director, and he shall consider inclusion of guidance on at least the following subjects: expression of uncertainties, distribution of probabili-

ties for outcomes, calculation of expected values, a uniform concise format for summarizing risk assessment results, and a system for integrated ranking of different risks.

(c) The Director shall develop such guidance in consultation with the Director of the Office of Science and Technology Policy, the Federal Coordinating Council on Science, Engineering and Technology, the National Research Council, the Council on Competitiveness, the Council on Environmental Quality, and such other departments and agencies, offices, organizations or persons as the Director deems advisable.

It is to be expected that the current classification schemes for carcinogenicity which do not take into account dose response would disappear under this new guidance.

Risk Comparisons

The Discussion Draft provided:

(c) Where possible, describe risk (1) by comparison with risks from other activities or exposures familiar to and routinely encountered by individuals....

COMMENTS RECEIVED

Some commenters agreed that if agencies are to continue using exponential risk assessment numbers (*e.g.*, 10^{-6}) it would help public and media understanding to provide any risk probability estimate with some context that would enable the public to grasp more readily the significance of the estimate. At the same time, they pointed out that there could be many pitfalls with the provision on comparative risks in the Discussion Draft. It could be misleading, they pointed out, to compare risks involving great uncertainty (such as many cancer risks) with more certain risks (such as being struck by lightning or contracting hepatitis from eating raw shellfish), or to compare risks perceived as involuntary with ones that involve an element of perceived voluntariness or avoidance skills (such as highway fatalities or sports injuries).

DISCUSSION

It is generally difficult for individuals to comprehend the magnitude of a risk without some frame of reference. At the same time, attempting to provide a frame of reference by comparison with other risks can be difficult and controversial. After studying this subject, the National Research Council recently stated the following conclusions and recommendations:

decisions, not as the primary determinant. There are proven pitfalls when risks of diverse character are compared, especially when the intent of the comparison can be seen as that of minimizing a risk by equating it to a seemingly trivial one. More useful are comparisons of risk that help convey the magnitude of a particular risk estimate, that occur in the same decision context (e.g., risks from flying and driving to a given destination), and that have a similar outcome. Multiple comparisons may avoid some of the worst pitfalls. More work needs to be done to develop constructive and helpful forms of risk comparison.[149]

One type of pitfall that is of particular concern given the changes that might be effected by the recommended Executive order is that best estimates could be compared with upper bounds and "conservative" estimates, or risk estimates with widely differing levels of uncertainty could be compared without indications of such differences.

In addition to providing a frame of reference for better understanding of risks, comparisons could also serve the purpose of helping to educate the public about more significant risks over which they have some personal control.

CONCLUSIONS/REVISIONS

The provision from the Discussion Draft has been modified to ensure that *multiple* comparisons are provided, that the best estimates required by the Executive order are compared only with other best estimates, and that any differences in levels of uncertainty are conveyed.

> **Sec.** 6(f). Where possible, describe risk by multiple comparisons with best estimates of other risks that are familiar to and routinely encountered by individuals. Any differences in the levels of uncertainty for such risk estimates shall be noted.

The more specific risk characterization guidance which OMB would take the lead in developing would probably take into account the need for some degree of uniformity in making such comparisons.

Substitution Risks and Risk Tradeoffs

The Discussion Draft provided:

> (d) Include an explanation and assessment of any risks that could be increased through regulation of the substance or activity under review—for example, by reason of substitution products or activities, or diminishment of resources available for other programs.

149. *Improving Risk Communication, supra* n. 141, at 12.

COMMENTS RECEIVED

There appeared to be general agreement on the desirability of providing available information on substitution risks when specific regulatory action that would lead to identifiable substitution risk is under consideration.

DISCUSSION

A frequent consequence of regulatory decisions (or even of the publicizing of risk without any regulatory action) is that another product or process or method of operating is substituted for the "risky" one. In many instances, however, what is substituted carries its own risks, although sometimes less is known about the new risks at the time of substitution.

Intelligent risk management should take into account both the primary risks and substitution risks in order to arrive at the net change in risk. The concept of "net risk" is especially important when a cost/benefit analysis is accompanying a rulemaking proposal, since the concept of benefits necessarily implies net benefits.[150]

One example of a substitution risk could be the cancellation of a pesticide registration, only to find out later that it had been replaced in use by another synthetic pesticide that was more toxic, or by a genetically engineered crop species that manufactures its own "natural" pesticide in amounts that present a higher risk to humans. Sometimes substitution risks are of a different type than the primary risk. For example, elimination of chlorination of drinking water would reduce cancer risk but would increase the risk from pathogenic organisms, and an attempt to restrict use of an ozone-depleting substance in the workplace could result in increased use of substances that do not deplete ozone but which increase injuries and fatalities due to their flammability or explosiveness.

Sometimes net risks and benefits are affected not by substitution risks but by "tradeoffs". An example of a situation where there is a tradeoff but no substitution might be banning the use of a pesticide for which there is no substitute, with the result that there could be reduced availability of a food product which has important health benefits.

In order for substitution or tradeoff risks and net benefits to be considered in the regulatory decision-making process, the necessary information must be gathered and presented as part of the risk assessment process. A key issue with regard to gathering and presenting such

data is whether, or under what circumstances, the agency must conduct a complete risk assessment for a substitution or tradeoff risk. While development of risk assessments for more than one product or process might entail more effort initially and slow down the development of regulatory proposals, it could result in greater long-run efficiency if the likelihood of a particular substitution or tradeoff is high and a preliminary assessment shows that a full evaluation of the substitution risks is likely to alter significantly the assessment of net risks and benefits.

CONCLUSIONS/REVISIONS

The Executive order should address this subject in a manner that limits its applicability to situations where substitution or tradeoff risks are likely to occur and would significantly affect the assessment of net benefits. A full assessment of substitution risks or risk tradeoffs under the Executive order would be required only for major rulemaking actions and would be based on data that is reasonably available.

> **Sec.** 6(g). Risk assessments for discretionary proposed and final regulatory actions shall include an evaluation of substitution risks and risk tradeoffs that are likely to occur and that would significantly affect assessment of net benefits. If the regulatory action is a major rulemaking action within the meaning of Executive Order 12291, such evaluation shall consist of a risk assessment under the provisions of this Order based on all reasonably available data.

5. Peer Review

Consistent with the recommendations of the Administrative Conference of the United States,[151] a new provision is included requiring risk assessments to present the results of a review by any independent agency peer review body, such as EPA's Science Advisory Board or Science Advisory Panel or an expert drug review panel convened by FDA:

> **Sec.** 6(h). Risk assessments shall explain any differences of opinion between the department or agency and an official peer review body, and explain why the agency does not agree with that body's opinion.

6. Assessment of Benefits

The Discussion Draft contained a provision that would have required basically that assessment of the benefits of regulatory action be based on an estimate of most likely risk. (Sec. 5(c)) No comments were received on this particular provision. As noted previously, since

151. See section II,C,1 *supra*.

the last of the Federal Focus forums was held the Office of Management and Budget has issued final guidance on the preparation of Regulatory Impact Analyses that addresses this subject. Therefore, a provision of the sort contained in the Discussion Draft is not necessary.

However, OMB's final RIA guidance could be considered incomplete in that it does not provide uniform guidance on the specific dollar values to be assigned to various types of health and safety benefits.

7. Risk Management Principles

The Discussion Draft focused on the following issues in risk management:

- consistency
- consideration of substitution risks
- regulation of *de minimis* risks
- determining margins of safety
- allowing flexibility in achieving objectives

Consistency

The Discussion Draft contained two provisions pertaining to consistency in risk management. The first one was in the "Fundamental Principles" section and it stated:

> (a) Consistency should be achieved to the maximum extent possible in risk assessment procedures and risk management decisions among federal agencies and programs and environmental media.

The second provision, in the risk management "criteria" section, stated:

> (a) [Executive departments and agencies shall] Strive for consistency among departments and agencies and across programs and environmental media. Where a department or agency regulates a substance or activity which has also been regulated by another department or agency, or has been regulated by the same department or agency under a different program or authority, the regulatory decision shall explain the extent to which it is consistent or inconsistent with such preexisting regulatory actions and provide a clear and reasonable justification for any inconsistency.

discussed previously in section III,A. It was concluded that consistency in risk assessment is needed, but that consistency in risk management is appropriate only to a more limited extent due to differences in statutory mandates and the need to address each regulatory decision on the basis of its own unique facts. Therefore, the above provisions as they pertain to risk management have been removed from the recommended draft Executive order. In the sections that follow, we address those areas in which we believe it is feasible and appropriate to attempt to achieve some degree of consistency in risk management. It will be noted that in the new recommended Executive order, all of the provisions addressing these subjects are prefaced by the qualification "to the extent permitted by law".

Consideration of Substitution Risks and Risk Tradeoffs

The Discussion Draft contained a provision, in the "Fundamental Principles" section (Sec. 2(e)), stating that "[r]isk management decisions should be made ... with due regard for substitution risks."

COMMENTS RECEIVED

Several participants in the forums expressed support for this requirement, and no negative comments were received.

DISCUSSION

The need to include information on substitution risks and risk tradeoffs in risk assessments is discussed above in section III,C,4, and a revised provision was presented that pertains to the risk assessment portion of the process. The revised provision on risk management presented below is similar to the provision in the Discussion Draft, but has been expanded to incorporate the concept of "risk tradeoffs" in addition to "substitution risks".

CONCLUSIONS/REVISIONS

The provision from the Discussion Draft has also been revised to incorporate the concept of "net benefits" in E.O. 12291.

> **Sec.** 8(a). [Departments and agencies shall] Take into consideration the magnitude and likelihood of substitution risks and risk tradeoffs when assessing "net benefits" under Sections 2(c) and 3(d)(1) and (3) of E.O. 12291.

Application of the De Minimis Principle

The Discussion Draft provided, as one of the criteria for risk management decisions, that officials should "[a]void the regulation of *de minimis* risks." (Sec. 5(b)) A related provision was contained in the "Fundamental Principles" section which stated: "Risk management

decisions should be based to the maximum extent possible on scientific data and judgment concerning actual risks rather than assumptions concerning hypothetical risks." (Sec. 2(d)) The term "*de minimis* risk" was defined as "risk which is clearly insignificant in relation to the ordinary day-to-day risks faced by the average individual." (Sec. 1(e))

COMMENTS RECEIVED

Some of the strongest comments in the forums were directed to these provisions, particularly by experts from academia. In general, such comments strongly supported the concept of *de minimis,* with some even supporting it on grounds that it was "immoral", with all the ills in the world that need attention, to devote substantial resources to trivial risks.

Several of the commenters pointed out that what is "*de minimis*" may depend on the context. For example, what might be considered a trivial risk in terms of workplace exposures, might be considered significant by the general population; and a less significant risk that can be eliminated at a low cost might not be *de minimis,* while a considerably higher risk that would be costly to reduce or eliminate should perhaps be considered *de minimis.*

Several commenters also questioned whether *de minimis* risk should be equated with "insignificant" risk (as had been done, in effect, in the Discussion Draft), suggesting that a *de minimis* risk should be considered to be one that is considerably lower than an "insignificant" risk.

Several commenters pointed out that while the concept of *de minimis* risk had become fairly well established with regard to cancer risk, the concept was perhaps needed even more in distinguishing between significant and insignificant non-cancer health risks, and that application of the principle to such risks had received little or no attention. This comment was made in connection with noting that the Discussion Draft might be interpreted to address only cancer risks.

DISCUSSION

Regulatory Policy Guideline Number 4 states that "[r]egulations that seek to reduce health or safety risks ... should address risks that are real and significant rather than hypothetical or remote."

The cost/benefit principles and analysis dictated by E.O. 12291 are in large part an adjunct to this distinction, since, presumably, if the benefits of risk reduction would exceed the cost, it is less likely that the risk is insignificant; and, vice versa, if the costs of reducing a risk exceed its benefits, the risk is less likely to be significant. Moreover, even the process of risk assessment plays an essential role in distin-

to ascertain what risks are significant if "best estimates" rather than conservative upper-bound estimates are not employed, and benefits cannot be assessed realistically without best estimates of expected risk reductions.

The concepts of *de minimis* and significant risk are also rooted in the law.[152] The term *de minimis* comes from the ancient (Latin) legal maxim, "De minimis non curat lex", which can be translated "The law does not concern itself with trifles." The federal courts have acknowledged the applicability of this principle to health and safety risks of a number of different types.[153] In the recent litigation contesting FDA application of the principle to color additives,[154] the court impliedly acknowledged the validity of the principle, but decided it could not be applied in the particular case due to the explicit mandate of a statutory provision (the Delaney Clause).[155]

As a consequence of both Executive Branch policy and court decisions, federal agencies have evolved over the last five years an informal *de minimis* policy with regard to cancer risks. As a practical matter, a *de minimis* level of cancer risk is currently perceived as lying generally somewhere between upper-bound risk levels of 1×10^{-6} and 1×10^{-4}, calculated on the basis of conservative assumptions, depending on the weight of the evidence and the costs of regulation.

To date, however, no similar general policy has evolved for non-cancer health effects, although there is perhaps even more of a need for such a policy in those cases.[156] The problem of devising such a policy is somewhat different for non-cancer effects. Everyone can agree that cancer as an adverse health effect is qualitatively significant; thus, the problem is to agree on a risk probability level that is significant. A *de minimis* policy for non-cancer health effects, however, must have both qualitative and quantitative dimensions, since the effects can range

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152. The courts generally equate the terms "*de minimis*" and "insignificant" risk. See, *e.g., Center for Auto Safety v. Peck*, 751 F.2d 1336, 1347-48 (D.C. Cir. 1985).

153. *Benzene, supra* n. 23 (benzene emissions under the Occupational Safety and Health Act); *Monsanto v. Kennedy*, 613 F.2d 947, 955 (D.C. Cir. 1979) (food packaging residues under the Federal Food, Drug & Cosmetic Act); *U.S. v. General Motors, supra* n. 29 (regulation of safety risks under the National Traffic and Motor Vehicle Safety Act).

154. *Public Citizen v. Young, supra* n. 30.

155. Congress has also explicitly recognized the need for application of the *de minimis* principle in at least one law. The Atomic Energy Act contains a provision allowing the NRC to set standards exempting specific radioactive waste streams that it determines are "in sufficiently low concentrations or quantities as to be below regulatory concern" 42 U.S.C. 2021j.

156. In 1985, an HHS task force, after reviewing the Department's risk assessment and risk management practices, proposed the following broad Departmental "Philosophy of Risk" that recognized the *de minimis* principle: "Individuals have always

from superficial and quickly and spontaneously reversible (*e.g.*, a minor headache and watering eyes from a neurotoxic solvent) to serious morbidity that is nonreversible (*e.g.*, serious central nervous system deficits from mercury or lead).

CONCLUSIONS/REVISIONS

It does not appear possible to define a "bright line" *de minimis* policy for either cancer or non-cancer health effects; rather, it appears that the best that can be done is to specify that such a determination should be made, and the factors that at a minimum should be considered.

> **Sec.** 8(b). [Departments and agencies shall] Avoid the regulation of insignificant or *de minimis* risks. In deciding whether a risk is significant, the following factors shall be considered at a minimum: the probability of a given effect occurring, the level of uncertainty or confidence associated with the risk assessment data, the severity of the health effect, and the number of persons potentially exposed. In considering the severity of an effect, officials shall take into account factors such as reversibility and whether significant morbidity, damage, or functional impairment is involved.

Margins of Safety

The Discussion Draft contained a specific provision on margins of safety in the risk management "criteria" section:

> (d) In determining margins of safety, give due regard to (1) the extent to which the selection of assumptions for the risk assessment incorporates a margin of safety into the ultimate risk assessment, and (2) the margins of safety utilized in other programs.

COMMENTS RECEIVED

No comments were received that explicitly addressed this provision.

DISCUSSION

Margins of safety are utilized in large part to account for uncertainties in the risk assessment, and to guard against the consequences

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lived with risk, presently live with risk, and will continue to live with risk in the future. Some degree of risk of adverse health effects from toxic substances is inevitable, as a consequence of exposure to both naturally occurring and manmade toxicants. The public should be made aware of the nature of the risk. Public health risks that are not acceptable should be reduced or eliminated when feasible. Means to accomplish this goal should not pose additional significant risks." "Risk Assessment and Risk

of making a wrong choice in the face of that uncertainty.

For most potential hazards associated with the basic human necessities—food, air, and water—statutory provisions either explicitly require the agency to provide a margin of safety or the statute itself, in effect, provides one. The "residual risk" provisions of the Clean Air Act, as recently amended,[157] require an "ample margin of safety" and specify what this means in terms of numerical risk for chemicals for which there is some evidence of carcinogenicity.[158] The Safe Drinking Water Act requires an "adequate margin of safety".[159] The Delaney Clause of the Federal Food, Drug & Cosmetic Act provides, in effect, a statutory margin of safety through an absolute, or near absolute, prohibition on food additives for which there is any evidence of carcinogenicity.[160]

The repeated discussions of risk assessment in the *Regulatory Program* have suggested that determinations on margins of safety were being usurped by the use of conservative risk assessment methodologies, and that selection of a margin of safety should be an explicit separate step following assessment of risk on a "best estimate" basis. The explanation of Regulatory Policy Guideline Number 4 states that margins of safety should be determined and made explicit in the risk management decision, as opposed to the risk assessment. However, neither the Guidelines nor the *Regulatory Program* discussion suggest criteria to govern the determination of margins of safety.

The discussions in the *Regulatory Program* have focused on cancer risk assessment. Assessment of non-cancer risks also poses significant "margin of safety" issues, because federal agencies have traditionally applied "safety factors" or "uncertainty factors" in risk assessments for

157. Sec 112(f), 42 U.S.C 7412(f).

158. A risk under one in one million for the most exposed individual is presumed to afford an adequate margin of safety. The Conference Report on the 1990 Clean Air Act Amendments states that this provision incorporates EPA's decision-making approach as set out in its recent decision on benzene emissions. H.R. Rep. 952 (Conf. Rep.), 101st Cong., 2d Sess. 339 (1990). The Report also states that in determining what constitutes an ample margin of safety under the Atomic Energy Act, the decision in *Vinyl Chloride, supra* n. 23, will remain applicable. *Vinyl Chloride* required that, as a first step of analysis, the Administrator must determine a "safe" or "acceptable" level or risk, considering only health factors (and "safe" need not be considered to be "risk-free"); in the second step, the Administrator can consider cost, feasibility, and other relevant factors in addition to health in determining an ample margin of safety.

159. 42 U.S.C. 300g-1(b)(4). Under this provision, EPA has adopted a virtual zero-risk policy in setting maximum contaminant level goals for known or "probable" human carcinogens, while at the same time indicating that the policy would remain under review. See 56 Fed. Reg. 3526, 3532-35 (Jan. 30, 1991).

160. It has yet to be settled judicially whether the Delaney Clause prohibits application of the *de minimis* principle to additives in processed foods, particularly pesticide residues. At the time of this report, a suit is reportedly being filed against EPA to test this issue.

non-cancer health effects.[161] These factors are used to lower the estimate of a practical no-effect dose in order to account for uncertainty in areas such as extrapolation from animal test results to humans and variations in human sensitivity. Incorporation of such factors into a non-cancer risk assessment has the potential to bias the risk assessment results in the same manner as the use of conservative assumptions in the cancer risk assessment process, and can usurp the discretion of policy official to set the margin of safety and to consider cost, feasibility, and other factors in doing so when permitted by law.[162]

CONCLUSIONS/REVISIONS

The subject of conservatism and margins of safety is addressed to some extent in section 4(a) of the recommended Executive order, which provides that judgments on margins of safety shall not be made in the risk assessment process, but rather, shall be reserved for the risk management process.

Due to the wide discretion allowed by the statutory mandates and court decisions in setting margins of safety, it clearly would be advisable to provide guidance on how that discretion should be exercised. Such guidance should, at a minimum, specify the factors to be considered and provide some broad standard of reasonableness that will act as a check on any tendency to be excessively conservative when faced with uncertainty. The following provision is recommended:

> **Sec.** 8(c). [To the extent permitted by law, risk managers shall] Set margins of safety, safety factors, and uncertainty factors so as to protect against health, safety, or ecological effects that are significant and can be reasonably expected to occur, and shall consider the following factors, among others: the significance or severity of the health, safety, or ecological effect to be prevented; the level of uncertainty in the risk assessment; technical feasibility; cost; and the range of sensitivity in the human or biotic population likely to be affected.

Ends v. Means

The Discussion Draft provided that risk management decisions should "[t]ake into account alternative means to obtain benefits, and approaches that would allow regulated parties maximum flexibility in achieving the regulatory objectives."

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161. See Barnes and Dourson, *supra* n. 123.

COMMENTS RECEIVED

The several comments received on this provision supported it unequivocally.

DISCUSSION

This subject is addressed by 1983 Regulatory Policy Guideline Number 5, incorporated into E.O. 12498, which states: "Health, safety, and environmental regulations should address ends rather than means." The discussion accompanying the Guideline also phrases the distinction as being between "performance standards" and "design standards", and asserts that *"[t]o the degree that performance can be measured or reasonably imputed, a standard based on this level of performance is always superior to more means-oriented regulation."* (Original emphasis)

CONCLUSIONS/REVISIONS

The provision from the Discussion Draft has been revised to be more consistent with the terminology of Guideline Number 5:

> **Sec.** 8(d). To the extent permitted by law, and to the degree that performance can be measured or reasonably imputed, risk management decisions shall utilize performance standards or ends, rather than design or technology standards or means.

8. Review of Pre-Existing Risk Assessments and Risk Management Decisions

The Discussion Draft did not address this subject.

COMMENTS RECEIVED

At the third Forum, industry representatives stressed that one of their most critical needs was to have an established system for obtaining review of risk assessments and regulatory decisions when they have lost their accuracy and validity as a result of improved hazard or exposure data or advances in scientific understanding.

DISCUSSION

This matter is dealt with by current statutory law only to a limited extent. The Administrative Procedure Act requires agencies to give interested persons the right to "petition for the issuance, amendment, or repeal of a rule" and to provide prompt notice of a denial together with a brief statement of the grounds.[163] These provisions leave a number of aspects of the problem unaddressed, however:

163. 5 U.S.C. 553(e), 555(e).

- The APA provisions do not apply to all types of regulatory actions; they apply only to rules of general applicability.

- Risk assessments by themselves (i.e., absent any regulatory decision or "rule") can have a strong impact on State regulations and public perceptions, and prospective or "chilling" effects on investment decisions and opportunities.

- If the agency does not intend to deny the petition, there is no time constraint on its review.

In addition, if an Executive order is issued, there should be some means for applying its provisions in an orderly fashion to risk assessments and risk management decisions that were issued before its promulgation.

This is not just an "industry" problem, of course. New data or scientific understanding might result in upward revisions in risk assessments.

A possible objection to review provisions is that petitions for review could overwhelm the agencies' resources. However, numerous petitions might be filed even if specific review provisions are not included.

CONCLUSIONS/REVISIONS

Although there is the potential for additional burdens on agency resources, reviews should be undertaken if there is sufficient justification, and setting up some orderly procedure would be better than *ad hoc* decisions which have more potential for subjective bias. The following provisions are recommended:

> **Sec.** 9. *Review of Risk Assessments and Risk Management Decisions.* This Order shall not affect any risk assessments or risk management decisions previously made, except as follows:
>
> (a) Any interested person may petition a department or agency for revision of a risk assessment or risk management decision in accordance with the foregoing provisions of this Order or on the basis that significant new scientific data or understanding has become available.
>
> (b) Within six months of receipt of a petition, the department or agency shall determine whether the potential benefits and the significance of the new data or understanding are sufficient to justify a review and shall inform the petitioner.

Establishment of this process would not create any new rights to judicial review, as stated in the Judicial Review provision at the end of the recommended order.

9. Oversight Responsibility and Discretion of OSTP, OMB, and the Council on Competitiveness

This subject was not addressed in the Discussion Draft.

COMMENTS RECEIVED

Various commenters recommended that the subject of implementation oversight be addressed. Some urged that, although OMB policy oversight was advisable to some degree, to the extent possible issues concerning science or science policy should be reserved for OSTP. Others urged that any oversight provisions should be drafted so as to minimize any regulatory review delays in addition to those already experienced with regulatory review under E.O. 12291.

Some commenters noted that if the Executive order were to apply to all types of regulatory actions rather than just rules of general applicability, giving any White House office oversight responsibility for all types of regulatory actions would represent a tremendous expansion of regulatory review authority and burdens. Even if the oversight authority could be exercised on an *ad hoc* discretionary basis, the oversight officials could be exposed to tremendous political pressures that would be disruptive.

DISCUSSION

The other recommended provisions establish a division of responsibility between OSTP and OMB generally along the lines recommended by the commenters.

While additional regulatory review provisions could result in additional delays, it is just as likely that the establishment of uniform risk assessment and risk management guidance should lead overall to a reduction in delays. A compromise approach would be not to include substantial new oversight authority at this time, but rather provide some system for agency reporting on experience with the Executive order to the White House so that, if necessary, a decision can be made in the future concerning any new review authority.

CONCLUSIONS/REVISIONS

Oversight authority be should be limited initially to that which is already provided in E.O. 12291, and a reporting provision should be included in order to provide sufficient information for review of this issue in the future.

Sec. 10. *Implementation and Oversight.*

(a) The Director of the Office of Management and Budget shall be responsible, subject to the direction of the Council on Competitiveness, for ensuring that departments and agencies comply with the requirements of this Order when proposing and issuing rules that are subject to Executive Order 12291.

(b) The Director of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, and the Council on Competitiveness shall, from time to time, recommend, jointly or separately, after consultation with each other, revisions to this Order as they deem advisable.

(c) The head of each department and agency shall designate a senior policy official to be responsible for ensuring that the department or agency complies as fully as possible with the requirements of this Order, and shall publish notice of such designation in the Federal Register. The duties of the designated official shall include: (1) educating other officials, employees, and contractors concerning the requirements of this Order; (2) accepting petitions for review under section 9 of this Order, and ensuring that the department or agency complies with that section's time requirements; (3) preparing and submitting annually to the Director of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, and the Council on Competitiveness a concise report on petitions for review received and action taken, any complaints received concerning non-compliance by the department or agency, and any problems experienced in interpreting the Order; and (4) transmitting, on behalf of the agency head, to the entities specified in subsection (b) any recommendations for clarification or revision of this Order.

10. Judicial Review

A standard provision concerning judicial review has also been added:

Sec. 11. *Judicial Review.* This Order is intended only to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person.