II. Background

A. THE LEGITIMATE SCOPE OF EXECUTIVE ORDERS AS INSTRUMENTS OF PRESIDENTIAL AUTHORITY

Presidential authority may be either Constitutionally or statutorily derived. The source of the Presidency as an independent branch of government lies in the Constitution, however. Article II vests the Nation's executive power in the President[9] and provides him or her with the authority and duty to appoint and remove Executive officers, to demand written opinions from them, to invoke Executive privilege to protect consultative privacy, and to "take Care that the Laws be faithfully executed".

Congress, at the same time, is vested with the power to make laws, and such laws may create specific Executive positions, which are to be filled by Presidential appointment, and may delegate to the officials occupying those positions the authority and duty to carry out specific statutory directives. The Constitution does not specifically recognize Executive departments and agencies as a separate branch of government with their own powers and responsibilities; all of their authority is derivative. The only other Constitutional branch of government is the judiciary. Federal agencies and their appointed officials are thus Constitutional creatures simultaneously of the Congress and the President, with the courts interpreting the statutory delegations from Congress and resolving any apparent conflicts between the statutory delegation and Presidential guidance.

It is generally recognized today that the President has the authority to guide agency implementation and interpretation of statutes, but that his guidance cannot contravene a specific Congressional directive, either as expressed in the clear wording of a specific statutory provision or as its intent might be clearly inferred from the overall structure and context of a statute and its legislative history. After exhaustively reviewing issues regarding the authority for Presidential review of agency rulemaking and statutory implementation, the Administrative

9. "The executive Power shall be vested in a President. . . ." Art. II, Sec. 1, cl. 1.

Conference of the United States[10] concluded recently that "the President has the authority to enunciate principles to guide agency rulemaking, even though the programmatic responsibilities are by statute delegated to agencies."[11] The Conference went on to recommend the following general principle:

> Presidential review should apply generally to federal rulemaking. Such review can improve the coordination of agency actions and resolve conflicts among agency rules and assist in the implementation of national priorities.

Some commenters have questioned the application of Presidential authority to "substantive" matters delegated by Congress to a particular agency, arguing that such authority could effectively override a Congressional directive[12]. However, the courts have effectively reconciled Presidential and Congressional authority by concluding that the President may guide the agencies in their interpretation of statutory responsibilities to the extent Congress has not clearly and directly spoken to the contrary in the wording of the law or its legislative history. The most prominent recent Supreme Court pronouncement on this subject, in *Chevron v. Natural Resources Defense Council,* states:

> [A]n agency to which Congress has delegated policy-making responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the government to make such policy choices—resolving the competing inter-

10. ACUS was established by statute in 1964 as an independent federal agency to promote improvements in the efficiency, adequacy and fairness of procedures by which federal agencies conduct regulatory programs, administer grants and benefits, and perform related governmental functions. 5 U.S.C. 571 *et seq.*

11. *ACUS Recommendation 88-9: Presidential Review of Agency Rulemaking,* 88 ACUS 42, 43 (1988). This recommendation was supported by a detailed report containing legal research and policy analysis prepared by Professor Harold Bruff, entitled "Presidential Management of Agency Rulemaking", 88 ACUS 527 (1988).

12. See "Presidential Control of Agency Rulemaking: An Analysis of Constitutional Issues That May be Raised by Executive Order 12291", prepared by M. Rosenberg of the Congressional Research Service (CRS) for the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, June 15, 1981, reprinted in House Committee Print 97-0, 97th Cong., 1st Sess., 6 (GPO 1981). The report argued that E.O. 12291 might be found illegal to the extent it displaced administrative agency discretion delegated by Congress or was inconsistent with the procedural requirements of the Administrative Procedure Act. This analysis was apparently aimed at rebutting a Department of Justice opinion finding that issuance of E.O. 12291 would be within the President's authority. The Justice opinion is reprinted after the CRS report in the Committee Print cited above.

> ests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities.[13]

In order to decide whether or to what extent an agency is free to exercise policy discretion in its choice of statutory interpretations, and whether it can rely on the administration's views to guide such a policy choice, the Court delineated a two-stage analysis:

> First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

467 U.S. at 842, 104 S.Ct. at 2781. The Court's opinion proceeded to make clear that a "permissible" construction was one that was "reasonable" in view of the entire statute, its objectives, and the legislative history, and that the agency's interpretation, in order to be upheld, need not be the only permissible one, nor the one the court would have preferred on its own.

The purpose of the above discussion is to outline the limits of Presidential authority; it should not imply that Presidential guidance to harmonize agency risk assessment and risk management practices is necessarily "regulatory review". As will be seen, in many instances such guidance would be directed mainly to the disclosure of information and the portrayal of data rather than to the substance of regulatory decision-making. Nevertheless, it is apparent that how the process of risk assessment is conducted and how the results are portrayed inevitably has a strong influence upon regulatory decision-making, and therefore it is likely that opponents of Presidential intrusion into this field would raise issues regarding legal authority.

In the last two decades, the scope and complexity of federal regulatory activities has vastly expanded, due in large part to a spate of environmental legislation. As a result, there is increased competition for scarce governmental and societal resources and an increased potential for inconsistency and conflict. Federal agencies are ill-equipped to deal

13. 467 U.S. 837, 865-66 (1984) (footnotes omitted).

with the need for coordination and priority-setting, since they are entrusted with specific programmatic responsibilities with jurisdictional constraints. As a result, their officials naturally tend to promote their own programs without regard for the wider ramifications of their decisions. Congress, likewise, is not well-suited to reconcile competing claims to resources and priorities, since its committee system tends to reinforce the single-minded zeal of the agencies it oversees.[14] The President, on the other hand, is the only elected official with a national constituency, and is best positioned to attempt to harmonize and to reconcile the executive functions of government in a manner consistent with the numerous Congressional directives. The uniqueness of the Chief Executive's responsibility to coordinate and to harmonize the manifold activities of the federal agencies has been clearly acknowledged by the courts.[15]

The primary instrument utilized by the Presidency to manage and guide subordinate Executive officers has been the Executive order. Prior to the last decade, Executive orders were generally aimed at specific Executive positions or programs—they set up committees or commissions to study matters, delegated authority, or ordered specific actions. In the last twelve years, however, driven by the necessity to coordinate the expanding mass of agency regulatory activity and to weigh its impacts, Executive orders have increasingly been employed to deliver uniform policy guidance in the form of general principles and criteria. For example —

14. Some commenters have observed that Congressional oversight can lead to "iron triangles" formed by agencies, political pressure groups, and Congressional committees. See, *e.g.,* Bruff, n. 11 *supra,* at 555. Bruff observed: "A President needs to be especially concerned with the formation of alliances between agency staff who oppose his policies and committees in a house of Congress that is organized by the party out of power [in the Executive Branch]."

15. In *Myers v. U.S.,* 272 U.S. 52, 135 (1926), the Supreme Court acknowledged the President's authority to "supervise and guide" Executive officers in "their construction of the statutes under which they act in order to secure that unitary and uniform execution of the laws which Article II of the Constitution evidently contemplated in vesting general executive power in the President alone." And see *Sierra Club v. Costle,* 657 F.2d 298 (D.C. Cir. 1981).

16. Presidential "proclamations", another type of Presidential document, are used to recognize accomplishments and designate special days, weeks, months, etc. Presidential authority is also exercised through various "administrative orders" "memoranda" or "determinations" when the purpose is to carry out a specific statutory function or communicate with a particular agency official. See, *e.g.,* the January 20, 1987 memorandum from President Reagan to the Administrator of EPA approving "Radiation Guidance to Federal Agencies for Occupational Exposure", which had been developed by EPA and an interagency committee. 3 CFR 279 (1987).

- E.O. 12044 (1979) established procedures for review of "significant" agency rules and required agencies to analyze the anticipated impacts of the rules and describe in detail why a particular approach was selected from among the available alternatives.

- E.O. 12291 (1981) established procedures for OMB review of "major" agency rules and laid out a number of guiding principles, such as that regulatory benefits should exceed costs ("to the extent permitted by law") and that the most cost/effective approach should be selected from among available alternatives.

- E.O. 12498 (1985) established a system for all agencies to report their plans for future significant regulatory actions to the White House and to explain how they are consistent with the Administration's policies and priorities. It also incorporated certain additional regulatory principles supplementing those that had been specified in E.O. 12291.

- E.O. 12612 (1987) set out various "federalism" principles and criteria to guide agencies in deciding whether to regulate at the federal level or to leave regulation to the States.

- E.O. 12630 (1988) specified principles and criteria to guide federal agencies in deciding whether to formulate or implement policies that would have the effect of "taking" or drastically interfering with private property rights.

- E.O. 12674 (1989) specified principles of ethical conduct for government officers and employees.

The use of Executive orders or other instruments is not specifically provided for in the Constitution or judicial decisions. Thus, there is nothing to prevent a President from issuing policy guidance through less formal means, whether verbal or written, or via a subordinate official. Issuance of an Executive order, however, is a means whereby the President is able to demonstrate in a very public manner his leadership and political accountability on important issues, and to ensure that Executive Branch officials will recognize that the guidance emanates from the highest level.

For all their political significance, and although based upon explicit Constitutional powers, Executive orders are not legally enforceable, except possibly to the extent they are intended to carry out an explicit Congressional directive. Executive orders frequently contain an explicit "Judicial Review" provision stating that the order "is intended only to

improve the internal management of the Executive Branch, 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."[17] The courts have refused to force agency officials to comply with Executive orders not based on a Congressional directive.[18]

Since statutes frequently make a specific delegation of decision-making authority to a particular agency head, and since the President's authority to give policy guidance cannot contravene a statutory directive, what is to prevent an agency official from declining to follow the President's guidance? The Department of Justice spoke candidly to this point in its 1981 memorandum finding that E.O. 12291 (concerning regulatory review of "major" rules and application of cost/benefit analysis) was acceptable as to form and legality:

> This office has often taken the position that the President may consult with those having statutory decision making responsibilities, and may require them to consider statutorily relevant matters that he deems appropriate, as long as the President does not divest the officer of ultimate statutory authority. Of course, the President has the authority to inform an appointee that he will be discharged if he fails to base his decisions on policies the President seeks to implement.[19]

It is perhaps just as well that the courts do not involve themselves in enforcing Executive orders, since, as pointed out by the Administrative Conference review of Presidential authority, the courts are liable to enforce lower standards:

> [C]ourts do not attempt to require the "best" analyses, just acceptable ones. The executive can pursue both quality and consistency in the agencies' analytic techniques.[20]

B. THE SCOPE OF THE STATUTORY MANDATES INVOLVING RISK ASSESSMENT AND RISK MANAGEMENT

Since a Presidential Executive order can dictate guidance to

17. See, *e.g.*, Sec. 8 of E.O. 12612.

18. *In re Surface Mining Regulation Litigation*, 627 F.2d 1346, 1357 (D.C. Cir. 1980) (court declined to require an agency to prepare an inflation impact statement in accordance with E.O. 11821).

19. Memorandum dated February 13, 1981, by the Office of Legal Counsel, Department of Justice, "Re: Proposed Executive Order entitled 'Federal Regulation'", at 4-5.

20. 88 ACUS 556 (1988).

Executive officers only to the extent that such guidance does not conflict with a clear Congressional directive, it is necessary to review the scope of statutory mandates for environmental health and safety regulations to see whether and to what extent they leave room for Presidential guidance.

Congress has addressed the regulation of environmental health and safety risks in a multitude of statutes, and delegated regulatory responsibilities to numerous federal agencies. The following is a list of the principal environmental health and safety statutes and the responsible agencies, with a focus on the specific language dictating the scope of agency authority or duty.

Statute	*Resp. Agency*	*Mandate*
Atomic Energy Act, 42 U.S.C. 2011 *et seq.*	NRC, EPA	formulate standards to "protect the public health and safety" against radiation at nuclear power facilities and for handling of byproduct materials (NRC); set standards for the "protection of the public health, safety, and the environment" from uranium mill tailings and byproducts and other radiation hazards (EPA)
Comprehensive Environmental Response, Compensation and Liability Act ("Superfund"), 42 U.S.C. 9601 *et seq.*	EPA	hazardous waste cleanup levels must assure "protection of human health and the environment" against contaminants that "will, or may reasonably be anticipated to cause" certain adverse health effects, and must, under certain circumstances, meet standards set under other Acts, such as the Safe Drinking Water Act
Clean Air Act, 42 U.S.C. 7401 *et seq.*	EPA	issue ambient standards sufficient to "protect the public health" "with an adequate margin of safety"; issue "maximum achievable" standards for sources of hazardous pollutants which are "known or anticipated to cause adverse effects", and set supplemental emission standards if it is found that the "maximum achievable" standards do not provide an "ample margin of safety" (defined for known or potential carcinogens as a risk level of less than one in one million for the most exposed individual)
Clean Water Act, 33 U.S.C. 1251 *et seq.*	EPA	prohibit discharges of pollutants in quantities "which may reasonably be

Egg Products Inspection Act, 21 U.S.C. 1031 *et seq.*	DOA	prevent distribution of eggs or egg products that may be "injurious to health", that are "unfit for human food", or are "unsafe" due to a poisonous or deleterious substance
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*	HHS, EPA	prohibit, *inter alia,* distribution of foods, food and color additives, drugs, medical devices, and cosmetics that are "unsafe" or "injurious to health"; set standards for environmental contaminants in food as "necessary for the protection of public health"; set "safe" tolerances "to protect the public health" from pesticide residues on raw agricultural commodities (EPA sets the tolerances)
Federal Hazardous Substances Act, 15 U.S.C. 1261 *et seq.*	CPSC	declare substances and articles to be "hazardous" which "may cause" substantial injury or illness as a result of "reasonably foreseeable" handling, use, ingestion, damage, or abuse (and "hazardous" substances and articles are prohibited from being introduced into interstate commerce)
Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 *et seq.*	EPA	disallow use of pesticides that pose "any unreasonable risk to human health or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide"
Federal Meat Inspection Act, 21 U.S.C. 601 *et seq.*	DOA	prevent distribution of meat and meat food products that may be "injurious to health", "unfit for human food", or

		"unsafe" due to a poisonous or deleterious substance
Federal Mine Safety and Health Act, 30 U.S.C. 801 *et seq.*	DOL	set standards for the protection of life and prevention of injuries
Hazardous Liquid Pipeline Safety Act, 49 U.S.C. 1671 *et seq.*	DOT	set "reasonable" and "appropriate" standards for protection of public safety
Hazardous Materials Transportation Act, 49 U.S.C. 1801 *et seq.*	DOT	issue standards for "safe" transportation of materials posing an "unreasonable risk"
Lead-Based Paint Poisoning Prevention Act, 42 U.S.C. 4801 *et seq.*	HUD, HHS, CPSC	eliminate as far as practicable the hazards associated with unsafe levels of lead-based paint in housing
Lead Contamination Control Act of 1988, 42 U.S.C. 300j-21 *et seq.*	EPA, CPSC	recall and prevent distribution of drinking water coolers containing lead
Marine Protection, Research, and Sanctuaries Act, 16 U.S.C. 1431 *et seq.*	EPA, Army	do not issue permits for ocean dumping if it would "unreasonably degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities"
Motor Carrier Safety Act, 49 U.S.C. 2501 *et seq.*	DOT	issue "safety standards"
National Traffic and Motor Vehicle Safety Act, 15 U.S.C. 1381 *et seq.*	DOT	prevent "unreasonable risks"
Natural Gas Pipeline Safety Act, 49 U.S.C. 2001 *et seq.*	DOT	set "reasonable" and "appropriate" standards for protection of public safety
Nuclear Waste Policy Act, 42 U.S.C. 10101 *et seq.*	EPA	set standards "for protection of the general environment" from radioactive releases from high-level radioactive waste facilities
Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.*	DOL	set exposure standard at a level "which most adequately assures, to the extent feasible, on the basis of the best

		available evidence, that no employee will suffer material impairment of health or functional capacity . . . for the period of his working life" with a goal of "attainment of the highest degree of health and safety protection" as "reasonably necessary or appropriate to provide safe or healthful employment and places of employment"
Poison Prevention Packaging Act, 15 U.S.C. 1471 *et seq.*	CPSC	establish special packaging standards for household substances as determined to be necessary to "protect against serious personal injury or serious illness"
Poultry Products Inspection Act, 21 U.S.C. 451 *et seq.*	DOA	prevent distribution of poultry products that may be "injurious to health", "unfit for human food", or "unsafe" due to a poisonous or deleterious substance
Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.*	EPA	control disposal of solid wastes which "may cause, or significantly contribute to an increase in mortality or . . . serious irreversible, or incapacitating reversible, illness; or . . . pose a substantial present or potential hazard to human health or the environment" or which "endanger health [when present in excess of certain levels]"
Safe Drinking Water Act, 42 U.S.C. 300f *et seq.*	EPA	set maximum contaminant level goals (MCLGs) to prevent "known or anticipated adverse [health] effects" with an "adequate margin of safety", and set maximum contaminant levels "as close as feasible" to the MCLGs
Toxic Substances Control Act, 7 U.S.C. 136 *et seq.*	EPA	prevent "unreasonable risk of injury to health or the environment" from chemical substances or mixtures (as defined, with specified exceptions such as pesticides, drugs, and food additives)

As can be observed, Congressional delegations generally lack specificity. Terms such as "unreasonable", "safe", "protect", "adequate", and "anticipated" leave a great deal of latitude for interpretation and application to particular facts. The two main exceptions are the Delaney Clause of the Federal Food, Drug and Cosmetic Act, and the "residual

risk" provisions of the 1990 Clean Air Act Amendments. The Delaney Clause provides that a food or color additive will be considered "unsafe" if it causes tumors in animal tests.[21] The 1990 Clean Air Act Amendments require EPA to promulgate a second round of hazardous air pollutant emission standards if the first round does not reduce "lifetime excess cancer risks to the individual most exposed ... to less than one in one million."[22] It should also be noted that none of the statutes specify methodology for risk assessments.

As a result of this general lack of specificity, environmental health and safety statutes have given rise to substantial litigation in which industrial interests on the one side have sought judicial review alleging that agency regulatory decisions were overprotective or based on insufficient data, and environmental interests on the other side have alleged that the agency action was not protective enough, especially given the scientific uncertainties.

In the many cases challenging federal risk regulation decisions, the courts have generally shown a reluctance to dictate a particular statutory interpretation or regulatory outcome from among the range of rational alternatives, particularly where there is a high level of uncertainty in the scientific data.[23] Thus, although they have been willing to address the broad meaning of terms such as "safe"[24], "anticipated"[25], or

21. 21 U.S.C. 348(c)(3)(A), 376(b)(3)(B).

22. 42 U.S.C. 7412(f)(2)(A). The conference report explains that this provision also incorporates EPA policy for determining an "ample margin of safety" as in effect prior to the amendments and set forth in its rulemaking action on benzene emissions. H.R. Rep. No. 952 (Conf. Rep.), 101st Cong., 2d Sess. 339 (1990).

23. *Industrial Union Dept., AFL-CIO v. Amer. Petr. Inst.* ("*Benzene*"), 448 U.S. 607, 655-56, 100 S.Ct. 2844, 2870-71 (1980) (interpreting the Occupational Safety and Health Act, particularly the term "safe"; agency was free to use conservative assumptions in assessing risks, so long as they were supported by a reputable body of scientific thought); *Nat. Res. Def. Council v. EPA* ("*Vinyl Chloride*"), 824 F.2d 1146, 1165 (D.C. Cir. 1987) (interpreting section 112 of the Clean Air Act; once "safety" was assured, EPA had the discretion to diminish as much of the uncertain risk as possible by setting the standard at the lowest feasible level); *Nat. Res. Def. Council v. EPA* ("*Fluoride*"), 812 F.2d 721 (D.C. Cir. 1987) (upholding fluoride drinking water standards); *Amer. Mining Cong. v. Thomas*, 772 F.2d 617 (10th Cir. 1985) (upholding standards for controlling uranium mill tailings); *Env. Def. Fund v. EPA*, 636 F.2d 1267 (D.C. Cir. 1980) (upholding agency determination that certain uses of PCBs did not pose an "unreasonable risk" under TSCA).

24. in *Benzene* and *Vinyl Chloride, supra,* the courts held that "safe" does not mean "risk-free". The *Vinyl Chloride* decision also held that use of the term "safety" in the legislation required the agency to determine what constitutes an "acceptable risk", taking into account the types and levels of risks to which we are normally exposed in day-to-day living.

25. In *Fluoride, supra,* the court held that "anticipated" adverse effects are to be distinguished from those that the data indicates are merely "possible".

"unreasonable"[26] when an agency action has been challenged as "contrary to law", and to examine the strength of the evidence supporting the agency's risk assessment in order to determine whether the agency determination was supported by substantial evidence[27] or was not "arbitrary, capricious, or an abuse of discretion"[28], they have been careful to preserve maximum agency discretion to the extent it does not run counter to the clearly expressed legislative intent or clear scientific findings. In recent years, agency discretion to interpret Congressional directives has been bolstered by the Supreme Court's decision in *Chevron,* discussed in the previous section.

One major exception to this judicial restraint has been the judicial position that a broad Congressional delegation, such as the Occupational Safety and Health Act, should not be interpreted to allow regulation without an agency finding that the risk to be regulated is "significant", and unless there would be significant benefits from regulation.[29] But when a Congressional mandate has been clear in dictating a particular regulatory outcome regardless of the significance of the risk, as in the case of the Delaney Clause, the courts have enforced the clear directive.[30] And the courts have generally upheld agency findings of significant risk in deference to agency expertise.[31]

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26. *Chemical Mfrs. Assn. v. EPA,* 859 F.2d 977 (D.C. Cir. 1988) (Toxic Substances Control Act); *Center for Auto Safety v. Peck,* 751 F.2d 1336, 1344-48 (D.C. Cir. 1985) (National Traffic and Motor Vehicle Safety Act); *Gulf South Insulation v. CPSC,* 701 F.2d 1137 (5th Cir. 1983) (Consumer Product Safety Act); *Forester v. CPSC,* 559 F.2d 774 (D.C. Cir. 1977) (Federal Hazardous Substances Act).

27. *Benzene, supra* (agency could employ conservative assumptions regarding carcinogenesis, so long as they were supported by a body of reputable scientific thought); *Gulf South Insulation, supra* (agency risk assessment rejected because exposure data was biased).

28. *E.g., Center for Auto Safety v. Peck,* 751 F.2d 1336 (D.C. Cir. 1985) (risk involved in change of bumper standards under the National Traffic and Motor Vehicle Safety Act).

29. *Benzene, supra,* 448 U.S. at 614-15, 100 S.Ct. at 2850 (interpreting the Occupational Safety and Health Act, particularly the word "safe"). A combined majority appeared to think that they might have to find that the statutory provision was a Constitutionally over-broad delegation unless a significant risk requirement were read into it. And see *U.S. v. General Motors Corp.,* 841 F.2d 400, 404 (D.C. Cir. 1988) (determination of "unreasonable risk" under the National Traffic and Motor Vehicle Safety Act requires finding of a significant or non-*de minimis* number of component failures). But compare *Vinyl Chloride, supra,* n. 23, and *Nat. Res. Def. Council v. EPA* (VOC drinking water goals), 824 F.2d 1211 (D.C. Cir. 1987) (court indicated that the agency had discretion to adopt a zero-risk approach when confronted with uncertainty in the scientific data).

30. *Public Citizen v. Young,* 831 F.2d 1108 (D.C. Cir. 1987).

31. See *Bldg. and Constr. Trades Dept. v. Brock,* 838 F.2d 1258 (D.C. Cir. 1988) (upholding OSHA finding of significant risk from asbestos); *Public Citizen Health Research Group v. Tyson,* 796 F.2d 1479 (D.C. Cir. 1986) (upholding EPA finding of significant risk from ethylene oxide); *Asarco v. OSHA,* 746 F.2d 483 (9th Cir. 1984) (upholding OSHA finding of significant risk from arsenic).

This great breadth of discretion generally provided by the various statutory mandates and court decisions poses the potential for inconsistencies and coordination difficulties among the many federal agencies with risk assessment and risk management authority and responsibility.

In addition to agencies that have been delegated statutory responsibility for regulatory actions, a number of other agencies prepare health risk assessments pursuant to advisory functions established by statute. These agencies include the Agency for Toxic Substances and Disease Registry and the National Toxicology Program in the Department of Health and Human Services, and the National Institute for Occupational Safety and Health. Others, such as the Centers for Disease Control and the National Institute of Environmental Health Sciences in the Department of Health and Human Services, conduct risk assessments in the course of preparing health advisories that fall outside any regulatory program (*e.g.*, solar radiation or soil contamination outside a Superfund or waste disposal site).

More generally, all agencies must comply with the requirements of the National Environmental Policy Act to assess the environmental impacts of major federal actions, and some agencies have responsibilities for assessing broad ecological risks of a non-toxic nature—*e.g.*, the Department of Commerce (NOAA) and NASA are assessing the risks of global climate change, and the Department of the Interior assesses risks to endangered species and other wildlife and natural resources from federal projects and permitting activities.

In a number of instances, different agencies perform risk assessments on the same hazard. The Department of Health and Human Services, the Environmental Protection Agency, the Department of Labor, and the Consumer Product Safety Commission may all assess the risks of a particular chemical, such as formaldehyde, PCBs or dioxin, that can be found in food, water, air, the workplace, and consumer products.

The multitude of statutes requiring risk assessment and risk management activities not only poses potential coordination and harmonization problems *among* federal agencies, it can also pose problems *within* them. Both EPA and HHS have numerous offices conducting risk assessments under different programs and statutory mandates.

Finally, agencies such as the Department of Defense and the Department of Energy are participants in the risk assessment and risk management process not as a result of specific statutory responsibilities for such functions, but because they have facilities that are subject to statutes such as CERCLA and RCRA, and the compliance costs are a substantial part of their appropriations.

C. RECOMMENDATIONS BY GOVERNMENTAL ADVISORY ORGANIZATIONS

1. The Administrative Conference of the United States

In 1982, the Administrative Conference of the United States[32] presented a series of recommendations concerning the institutional arrangements and procedures affecting the regulation of carcinogens. The areas addressed by the ACUS recommendations included: regulatory priority setting, inter-agency coordination, chemical selection and guidelines for testing and evaluation, use of advisory panels, generic rulemaking, and quantitative risk assessment.[33] The most pertinent portions of the recommendations follow:

> [*Interagency Coordination*] To the extent permitted by statute, agencies responsible for regulating carcinogens should adhere to common criteria for evaluating and interpreting health effects data. Agencies should avoid inconsistency in their approaches to mixed scientific-policy issues, such as whether to assume a no-threshold model of carcinogenesis, whether to perform quantitative estimates of human risk, or whether to allow evidence that a chemical produces an increase in cancer in laboratory animals through mechanisms that do not suggest human risk.
>
> [*Advisory Panels*] To the extent compatible with existing law, agencies should structure their decisional processes to incorporate mechanisms for scientific peer review.... When an agency rejects an advisory panel's scientific judgment, it should explain the basis for that rejection. When an agency selects a regulatory approach whose bases appear inconsistent with a panel's advice, it should explain the legal, social, or other reasons that dictate or justify that choice.
>
> [*Agency Generic Risk Assessment Guidelines*] [Such guidelines] should attempt to distinguish between elements that are intended to summarize current scientific consensus and others that represent policy judgments reached in the absence of consensus. Policy judgments are an inevitable component of regulatory decisions and, where similar issues arise recurrently, are appropriately resolved on a generic basis.... Many issues involved in identifying, evaluating, and regulating potential carcinogens are common to all agencies and should be resolved consistently. These issues range from the criteria for interpreting scientific studies to the selection of mathematical models for estimating human risk. Though scientific uncertainty surrounding many of these issues requires considerations of values and policy, disparate agency responses should be avoided or convincingly justified.

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32. See n. 10, *supra*.

33. 3 CFR 305.82-5 (1991). The recommendations were based on the detailed background study prepared by R. Merrill, n. 42, *infra*.

[*Quantitative Assessment of Risk*] Quantitative estimates of risk associated with exposure to a substance—particularly when expressed in terms of lives likely to be lost or cases of cancer likely to occur—have a power to captivate public and press attention. Such estimates should be accompanied by statements stressing their imprecision and uncertainty. When the available health effects data are seriously deficient or little is known about human exposures to a substance, the risk of misinterpretation may justify an agency decision not to attempt quantitative estimates of risk or health benefits.

2. The National Academy of Sciences (National Research Council)

In 1983, the National Research Council[34] issued its well-known "Red Book" on federal agency risk assessment and risk management, entitled *Risk Assessment in the Federal Government: Managing the Process.*[35] As stated in the report Summary, its purpose was to explore "the intricate relations between science and policy" and "the institutional mechanisms that best foster a constructive partnership between science and government."

The Red Book report is often cited for its recommendation that a clear conceptual distinction be maintained between risk management and risk assessment; however, the Council made a total of three major recommendations, and the other two appear to have been largely eclipsed. It also recommended that "uniform inference guidelines" (for both cancer and non-cancer effects) be developed for use by all federal agencies in performing risk assessments; and it recommended that Congress establish a "Board on Risk Assessment Methods" to assess critically the scientific bases for risk assessment, to draft and periodically review the uniform inference guidelines, and to identify research needs.

D. PAST AND CURRENT WHITE HOUSE EFFORTS TO COORDINATE AND GUIDE AGENCY RISK ASSESSMENT AND RISK MANAGEMENT ACTIVITIES

1. The Nixon, Ford and Carter Administrations

34. The National Research Council is the principal operating agency of the National Academy of Sciences and the National Academy of Engineering for advising Congress and federal government agencies. The Institute of Medicine is also involved in administering the NRC.

35. Published by National Academy Press. The study was authorized by Congress (P.L. 96-528) and carried out by the NRC's Commission on Life Sciences under contract with the Food and Drug Administration.

White House involvement in review of agency regulatory analyses accompanied the expansion of environmental laws and regulations during the 1970s and 1980s. In 1971, President Nixon instituted the first formal process for reviewing environmental regulations. The Quality of Life Review provided for interagency review of draft regulations and a comment and issue-resolution process prior to promulgation of the regulations. President Ford issued Executive Order 11821, which required the preparation of Inflation Impact Statements for regulations, and provided for review of the Statements by the Council on Wage and Price Stability.

The Carter Administration terminated these two processes in 1977 and, in 1978, substituted a review process under Executive Order 12044.[36] That Order required agencies to perform analyses of "significant" rulemaking actions and to describe how the agency had considered various alternatives. Agency regulatory analyses under the Order were reviewed by three separate groups chaired by the Executive Office of the President: the Council on Wage and Price Stability, the Regulatory Council, and the Regulatory Analysis Review Group ("RARG"). OMB later issued guidance to the agencies in the form of a memorandum on how to perform the requisite regulatory analysis. RARG, made up of four members (OMB and CEA as permanent members and two rotating members from six Cabinet agencies and EPA), commented on selected regulations during the public comment period.

During 1978 and 1979, an Interagency Regulatory Liaison Group (composed of EPA, FDA, OSHA, CPSC, and later DOA) developed, published, and requested public comments on a report that was intended to represent an interagency consensus on the scientific aspects of carcinogenic risk assessment.[37] In 1979, this report was adopted by the Regulatory Council (prior to analysis of public comments) as the scientific basis for a statement by the Council on regulation of chemical carcinogens.[38] In the Council's view, the IRLG report represented a needed step forward in achieving consistency and coordination among agencies, and quantitative risk assessment was favored as a "rough indicator" of risk in cases where available scientific data was "adequate".[39] The fate of this report and the IRLG are discussed in section 2, below.

These early regulatory review efforts by Presidents Nixon, Ford, and Carter were largely procedural—*i.e.*, there was no effort to lay

36. 3 CFR 152 (1978).

37. "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks", 44 Fed. Reg. 39858, July 6, 1979; 63 J. Nat. Canc. Inst. 242 (1979).

38. "Regulation of Chemical Carcinogens" (Sept. 1979).

39. 44 Fed. Reg. 60038 (1979).

down broad and comprehensive rulemaking principles or criteria. Undoubtedly, though, substantive policy guidance, at least in the form of "comments", was provided with regard to specific rulemakings through these processes.[40]

The Carter Administration also began the process of examining the need for institutional improvements in the areas of risk assessment and risk management. During 1978 and 1979, the White House Office of Science and Technology Policy (OSTP) circulated a "concept paper" proposing to create a centralized governmental body to conduct risk assessments on potential human carcinogens for all concerned federal agencies. Under this proposal, risk assessment functions would have been divorced from risk management responsibilities and would be placed in an expanded National Toxicology Program (NTP), and the NTP would develop uniform federal guidelines for epidemiological studies, animal tests, and quantitative risk assessment.[41] This concept was not actively promoted after the Reagan Administration took office, perhaps due to heavy criticism directed at a somewhat similar proposal embodied in a Congressional bill (the "Wampler bill").[42]

2. The Reagan Administration

Executive Orders 12291 and 12498

In 1981, President Reagan expanded these review processes incrementally through Executive Order 12291.[43] This Order was novel in that it not only provided a new review process for "major" rulemaking actions, but also laid down certain substantive principles and criteria to guide agency discretion. The two central principles were that, to the extent permitted by law, federal regulations should not be promulgated unless their benefits (including those not quantifiable in monetary terms) would exceed their costs, and that agencies should (again, to the

40. For more detailed descriptions and source citations for these various early regulatory review processes, see the ACUS reports by Bruff, n. 11 *supra*, at 546-49, and Merrill, *infra* n. 42, at 176-78, and the CRS report by Rosenberg, n. 12 *supra*, at 10-12.

41. Office of Science and Technology Policy, Executive Office of the President, "Identification, Characterization and Control of Potential Human Carcinogens: A Framework for Federal Decision Making" (Feb. 1, 1979).

42. For a discussion of the OSTP proposal, and similar proposals, including criticisms of the Wampler bill put forward in agency testimony, see the detailed background report prepared for the Administrative Conference by Richard Merrill, "Federal Regulation of Cancer-Causing Chemicals", 82 ACUS, vol. II, 21, 154-63 (1982). The main criticism was that the removal of risk assessment functions from the agencies would complicate the bureaucratic process and make it difficult for agency risk management officials to interact with the risk assessment scientists with regard to the impacts of various regulatory alternatives.

43. 46 Fed. Reg. 13193, Feb. 19, 1981.

extent permitted by law) choose from among the available regulatory alternatives the one that would be most cost/effective.[44] The review process stipulated by the Order included preparation of a Regulatory Impact Analysis ("RIA") by the agency, which would be subject to review by the Director of the Office of Management and Budget, who in turn would be subject to the direction of a Presidential Task Force on Regulatory Relief chaired by then-Vice President Bush and comprised of the Director of OMB and Cabinet officers. OMB and the Task Force were also given the power to promulgate uniform standards for the development of RIAs, to require agencies to consider additional relevant information, and to require interagency consultation to eliminate overlap or conflict in agency rules.

On January 4, 1985, President Reagan issued E.O. 12498, which was intended to supplement E.O. 12291.[45] That Executive order is familiar to many as the one which set up the process under which agencies establish their regulatory priorities and send them to OMB for review before they are compiled in an annual Regulatory Program. Before regulatory actions are put in the Program, they are reviewed by both the agency head and OMB for consistency with the goals of the Administration.[46] In order to establish a better basis for determining whether specific regulatory actions were consistent with Administration policies, this Order also adopted certain regulatory policy guidelines that expanded upon those enunciated in E.O. 12291. Section 1(d) of the Order states:

> To assure consistency with the goals of the Administration, the head of each agency subject to this Order shall adhere to the regulatory principles stated in Section 2 of Executive Order No. 12291, **including those elaborated by the regulatory policy guidelines set forth in the August 11, 1983, Report of the Presidential Task Force on Regulatory Relief, "Reagan Administration Regulatory Achievements."** [Emphasis added]

44. Two other requirements contained in the order that are pertinent to risk assessment and risk management issues are that decisions shall be based on "adequate information concerning the need for and consequences of proposed government action", and that "[a]gencies shall set regulatory priorities with the aim of maximizing the aggregate net benefits to society". The need for "adequate" supporting information is very pertinent to risk assessment situations involving high levels of uncertainty; and setting priorities to maximize net benefits requires realistic risk assessments, some degree of uniformity among risk assessments under different programs, and consideration of substitution risks and risk tradeoffs.

45. 50 Fed. Reg. 1036, Jan. 8, 1985.

46. The Presidential Task Force on Regulatory Relief was not specifically given oversight authority under E.O. 12498, as it was under E.O. 12291.

It is important to note that E.O. 12498 is not limited in application to rulemaking actions of "general applicability", as is E.O. 12291; rather, it applies to "all regulatory actions".[47] This is important because many significant risk assessment and risk management actions are site-specific (*e.g.*, Superfund or facility permits) or substance-specific (*e.g.*, pesticides or consumer products) and are not governed by rules of "general applicability".

The 1983 Regulatory Policy Guidelines

The Task Force report referenced in E.O. 12498 contained ten "Regulatory Policy Guidelines", two of which are directly pertinent to agency risk assessment and risk management activities.[48] Those two principles (numbers 4 and 5) state:

> 4. Regulations that seek to reduce health or safety risks should be based upon scientific risk-assessment procedures, and should address risks that are real and significant rather than hypothetical or remote.
>
> 5. Health, safety, and environmental regulations should address ends rather than means.

The statement of each of these principles was followed by several pages of narrative explaining it in more detail. The full text of these explanations is reproduced in Appendix B of this report. The core of the explanation for Guideline 4 is contained in the following excerpts:

> In many circumstances, it is indeed appropriate that government should err on the side of caution in protecting public health and safety. But a sense of balance is required, and a sense of the limits of regulatory policy in affecting the overall level of private and public risk in society. All decisions involving risk—public and private—have costs as well as benefits, and excessive costs in any one area can be counterproductive on the whole, reducing resources or incentives for increased health and safety in other areas. . . .
>
> To be useful in determining overall benefits and costs, risk assessments must be scientifically objective and include all relevant information. In particular, risk assessments must be unbiased best estimates, not hypo-

47. Sec. 1(b).

48. Guideline 1, while not directly pertinent to risk assessment and risk management, is pertinent to the broader issue, discussed above, of the scope of Presidential authority. That Guideline, and the accompanying explanation, while stating that "[r]egulatory objectives ... should be chosen to maximize the net benefits to society", also acknowledges that in some instances Congress has clearly directed a particular regulatory outcome, while in others the statute confers "wide discretion to pursue general statutory goals such as 'safe' products and workplaces."

thetical "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.

The 1983 Task Force report also contained a further discussion of risk assessment that focused on the Administration's plans for issuance of policy guidance. The report stated that OSTP was "developing a consensus regarding the scientific principles needed for assessment of carcinogenic risks, so that all federal agencies will have a common scientific foundation upon which to base regulatory policies concerning potential carcinogens and other hazardous substances." The report also stated that within the next year the Administration would "issue a consistent set of policies that, to the extent allowed by the individual regulatory statutes, would permit all federal agencies to employ risk assessment procedures based on modern scientific thinking and the general policies of Executive Order 12291."[49]

Because the Regulatory Policy Guidelines were incorporated by reference into E.O. 12498, and that Order remains in effect, the Guidelines remain binding on all Executive Branch officials.[50]

The Task Force report was not widely distributed, however, and was not printed by the Government Printing Office or published in the *Federal Register* along with E.O. 12498. Consequently, it appears that at the outset few officials and agency risk assessors had the opportunity to become familiar with these expanded principles.[51] Subsequently, however, there were efforts to publicize, emphasize, and explain Guidelines 4 and 5 in the annual issues of the *Regulatory Program*, as discussed below.

The 1985 Office of Science and Technology Policy Cancer Document

Upon entering office in 1981, the Reagan Administration decommissioned the Interagency Regulatory Liaison Group and no document was ever issued responding to the public comments that had been

49. Task Force report at 100-02. (These pages are also included in Appendix B.) These supplemental policies were never issued.

50. While not explicitly stated in E.O. 12498, presumably the explanatory text accompanying the ten Guidelines is also binding.

51. Although the regulations for publication of Executive orders in 1 CFR Part 19 provide for inclusion of attachments referred to in an order (see, *e.g.*, E.O. 12622 regarding federal pay, 3 CFR, p. 264, 1988), the text of the ten Guidelines and accompanying explanations was not published as an attachment, perhaps due to their length (36 double-spaced pages).

received on its report concerning regulation of chemical carcinogens.[52] In its place, a new and broader interagency group, the Interagency Staff Group on Carcinogens, was assembled under the auspices of the White House Office of Science and Technology Policy for the purpose of developing a new consensus document on the scientific basis for cancer risk assessment. The interagency group was made up of senior scientists representing OSTP and eleven different program offices in five agencies (HHS, DOL, EPA, DOA, and CPSC). By 1982, OSTP was distributing for public comment a partial discussion draft entitled "Potential Human Carcinogens: Methods for Identification and Characterization."

In February 1985, as the first *Regulatory Program* pursuant to E.O. 12498 was being prepared, OSTP and the Interagency Staff Group on Carcinogens issued their final report entitled "Chemical Carcinogens: A Review of the Science and Its Associated Principles" (hereafter referred to as the "OSTP cancer document").[53]

The document was comprised of two major parts. The first part set out thirty-one "principles" applicable to cancer risk assessment, which were characterized as "general principles that may be used by regulatory agencies as they review their own specific guidelines for performing cancer risk assessments."[54] (This part of the OSTP document is attached as Appendix C). The second part reviewed the current state of the science concerning carcinogenesis and cancer risk assessment and formed the underlying scientific basis for the "principles".

When the OSTP cancer document was published in the *Federal Register*, the introductory summary stated that "[t]he document does not attempt to formulate policy or develop standardized methods of risk assessment".[55] Apparently this was intended to mean that, although the document did express policy views, those views were not binding on the agencies. The introduction to the "Principles" portion of the document went to some lengths to explain that the principles represented a "mixing of scientific knowledge with risk assessment science policy"[56]:

> Many components of the risk assessment process lack definitive scientific bases. Often a choice must be made among several different scientifically plausible options.... This document attempts to leave the majority of these necessary scientific inferences to the scientific regulatory agencies.

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52. See section D, 1, *supra*.

53. 50 Fed. Reg. 10371, Mar. 14, 1985; 67 *Env. Health Persp.* 201 (1986).

54. *Id.* at 203 (1986).

55. 50 Fed. Reg. 10371 (Mar. 14, 1985).

56. The introductory abstract of the document when it was printed in *Environmental Health Perspectives*, n. 53 *supra*, similarly stated that "the principles contain judgmental (science policy) decisions on major unresolved issues...."

> However, some are so important and fundamental to all cancer risk-assessment procedures ... that they are included in some of the principles. Where this has occurred we have attempted to indicate, in the wording of the principle itself, that a public health science policy decision is embodied in it.

Three of the principles were singled out as examples of such science policy views or "inferences". Those principles addressed the relevance of animal bioassay data for determining human cancer risk (Principle 8), the appropriateness of high-dose testing in animal bioassays (Principle 11), and the use of dose-response models incorporating low-dose linearity (Principle 26). Additionally, Principle 29 addressed the need to distinguish science from policy:

> While several considerations often enter the risk assessment process, it is important to try to maintain a clear distinction among facts (statements supported by data), consensus (statements generally held in the scientific community), assumptions (statements made to fill data gaps), and science policy decisions (statements made to resolve points of current controversy)....

The advisory nature of the cancer Principles no doubt resulted at least in part from the absence of any specific delegation to OSTP or the interagency group from the President or Congress to issue binding policy guidance.[57]

The Reagan Administration Regulatory Program *Policy Discussions*

The first annual *Regulatory Program of the United States Government* pursuant to E.O. 12498 was issued in the Spring of 1985. (Each annual *Program* covers a period from April 1 through March 31 of the next year.) It contained a policy discussion preamble that included a section entitled "Protection of Health, Safety, and the Environment", which quoted the fourth Regulatory Policy Guideline and added:

> Comparable standards of analysis and cost-versus-benefit tradeoffs should be used by all agencies in order to ensure that the government's efforts to

57. However, in the current *Regulatory Program*, OMB, which, as discussed previously, does have a specific Presidential delegation under E.O. 12291 to issue RIA guidance, cites a number of the Principles in an approving note as being consistent with OMB risk assessment policy views and as not being followed at times by the agencies. See, *e.g.*, the text associated with footnotes 27, 29, 36, 44, 48, 51, 52, and 68 in the 1990-91 *Program*.

reduce risk are addressing the most significant and the most manageable risks.[58]

Interestingly, the *Program* did not note that the Task Force Guidelines had been incorporated into E.O. 12498.

The next *Regulatory Program,* issued in the Spring of 1986 for the period April 1, 1986 to March 31, 1987, reflected a heightened attention to environmental risk assessment and risk management issues related to interpreting the Task Force Guidelines in specific regulatory situations. In this issue of the *Program,* the ten Guidelines were quoted fully, with the introductory statement that "Section 1 of Executive Order 12498 reaffirmed the following guidelines. . . ."[59] The introductory chapter to the *Program* highlighted the problem that agency risk assessments appeared to often overstate actual risk and that margins of safety were not explicit.[60] Additionally, the introduction discussed methylene chloride as a specific example of a substance falling under the jurisdiction of several federal agencies (FDA, EPA, OSHA, and CPSC) and several different statutory regimes (TSCA, CAA, SDWA, and CWA) and for which coordination and consistency would be needed to achieve sound and credible regulatory decisions.[61]

A separate chapter of this *Program,* entitled "Improving Coordination and Consistency in Risk Regulation"[62], discussed the need to (a) accurately prioritize and assess the costs and benefits of risk regulation, and (b) provide best estimates of risk rather than conservative estimates. The discussion, which covered more than seven pages, included the following analytical issues:

- comparing toxic chemical risks with natural and safety risks
- determining the value to assign to a statistical fatality avoided in assessing the benefits of health and safety regulations[63]
- determining what constitutes a "best estimate" of a risk

58. 1985-86 *Regulatory Program* at xv.
59. 1986-87 *Regulatory Program* p. xiii, Table 1.
60. *Id.* at xii.
61. *Id.* at xvii-xviii.
62. *Id.* at xix-xvi.
63. The discussion noted that there were wide variations (between $400,000 and $7 million) in estimates of the monetary value of a statistic fatality avoided, but OMB declined to recommend a single specific value to be used by federal agencies, while at the same time noting that the benefits of different regulatory activities could not be compared without uniform measures for estimating benefits.

- confusion of upper-bound risk estimates with actual risks

- using conservative assumptions in risk assessments, including treating benign tumors as malignant, using test results from the most sensitive animal species and sex, using conservative models to extrapolate from high animal doses to low human doses, assuming worst-case environmental conditions (*e.g.,* wind speed and direction, soil type), assuming lifetime exposure, and regulating for the maximum exposed individual

- impacts of compounded conservative risk assessment assumptions

The discussion concluded by noting that the White House Office of Science and Technology Policy had recently issued a document that established a framework for assessing cancer risks that recommended a weight-of-the-evidence approach that was consistent with the use of best estimates. It also noted that OMB expected to issue guidelines on preparation of Regulatory Impact Analyses that would address methods for evaluation of the costs and benefits of regulatory alternatives.

The introductory sections to the 1987-88 *Regulatory Program* reiterated OMB concerns over the use of unduly "conservative" risk assessments (*i.e.,* risk assessments that are intended generally to overstate risk in order to reduce the possibility of understating it) and the effect this had on overstating the benefits of regulations:

> As was noted last year in the 1986 *Regulatory Program,* there is a pressing need to improve Federal risk assessment and risk management activities used to assess potential health and safety regulatory actions. Often these risk assessments so overstate risks that the chance that they approximate actual risks is remote. This overstatement—and the uncertainty as to the degree of overstatement—are likely to cause policymakers to overestimate the benefits of regulatory action. As a result, they often select what are, in fact, the wrong targets for reducing risks to society and apply stringent and costly regulatory measures that may actually have little or no risk-reducing benefits, but that may impose significant costs.
>
> This Nation can ill afford to commit limited resources to the wrong targets.... Spending these scarce resources inefficiently will preclude us from pursuing better opportunities to reduce risks and to improve the Nation's standard of living.[64]

The discussion went on to address the desirable elements of an effective cost/benefit analysis.[65] The primary principle identified for

64. 1987-88 *Regulatory Program* at xv.
65. *Id.* at xxi, xix, xvii Table 1.

health and safety regulations was that benefits should be "best" or "most likely" estimates, rather than hypothetical "worst case" estimates, with adequate information on uncertainties and with any "margin of safety" added explicitly to the best estimate in the final stage. Worst-case estimates might be presented, it noted, but should not be a substitute for best estimates. A number of recent federal agency RIAs for environmental and health and safety regulations were compared regarding their treatment of uncertainties and other factors, and the OSHA RIA for ethylene oxide was singled out as an example of the adverse effects of using worst-case estimates of benefits.[66] The discussion also recommended that reductions in fatality risks be monetized by using either willingness-to-pay estimates or direct cost valuation (*i.e.*, medical costs and lost earnings).[67] At the end of the discussion, OMB noted that it was "in the process of drafting more specific guidance to help the agencies improve their analyses."[68]

The last *Regulatory Program* issued under the Reagan Administration was for 1988-89. It reviewed the ten Guidelines issued in 1983 (though it did not mention they were incorporated into E.O. 12498), including numbers 4 and 5, the ones pertaining to environmental health and safety.[69] Again, the discussion focused on the need to ascertain "real expected" reductions in significant risks.[70] Moving a step closer to providing the RIA guidance promised in earlier *Programs,* this one set out draft guidelines and solicited comments on their "completeness, usefulness, and appropriateness".[71] The draft guidelines discussed methodology for sensitivity analysis of risk and for uncertainty, the need to base benefits estimates on the agency's "mean expected value" of the anticipated reduction in risk or the "unbiased most likely" estimate of risk (with conservative estimates presented as part of the sensitivity analysis), and principles for placing monetary values on non-fatal illnesses or injuries and fatalities.[72]

President Reagan's Final Observations

In his last *Economic Report* to Congress[73], President Reagan took the opportunity to reiterate his concern with maintaining the

66. *Id.* at xxi.

67. *Id.* at xix & n. 19, xx. OMB again avoided providing guidance on a specific monetary value for a statistical fatality avoided, but did refer to "the range of current estimates being between $500,000 and $2 million." At xx.

68. *Id.* at xxii.

69. 1988-89 *Regulatory Program* at 16-17.

70. *Id.* at 17.

71. *Id.* at 37. The draft RIA guidance was set out in Appendix V.

72. *Id.* at 566-71.

73. Dated January 10, 1989.

cost/effectiveness and flexibility of environmental regulation:

> Few would doubt that some rules are needed to protect the Nation's water and air from pollution. However, it is imperative that all such rules and regulations be based on sound economic principles that minimize the intrusion on private decisions. Whether well or poorly designed, whether aimed at worthy or dubious objectives, these rules have one thing in common: They "tax" and "spend" billions of dollars of private funds, unconstrained by public budget or appropriation controls.

3. The Bush Administration

The initial years of the Bush Administration have been marked by heightened activity directed towards improving upon the risk policy guidance and views that evolved during previous administrations, especially with a focus on the need to achieve greater consistency and coordination in order to permit more effective prioritizing. This section details recent and pending activities relating to risk assessment and risk management by the following White House offices, federal departments and agencies, and advisory organizations:

- The Office of Management and Budget
- The Council on Competitiveness
- The Office of Science and Technology Policy
- The Council on Environmental Quality
- The Council of Economic Advisors
- The Environmental Protection Agency
- The Department of Health and Human Services
- The Department of Agriculture
- The Consumer Product Safety Commission
- The National Academy of Sciences (National Research Council)
- The Risk Assessment and Management Commission

The Initial Regulatory Program of the Bush Administration

No *Regulatory Program* was issued in the Spring of 1989, the first

year of the Bush Administration; the next one was issued in the Summer of 1990, for the year from April 1990 to April 1991.

In announcing the release of the *Program,* President Bush established a clear link with the regulatory perspective of the previous Administration and reaffirmed the applicability of the 1983 Regulatory Policy Guidelines:

> Federal regulations impose estimated direct costs on the economy as high as $175 billion annually—more than $1,700 for every taxpayer in the United States. These costs are in effect indirect "taxes" on the American public—taxes that should only be levied when the benefits clearly exceed the costs .
>
> I strongly believe in the commonsense regulatory principles that I helped develop and implement when as Vice President I chaired the Task Force on Regulatory Relief. . . .[74]

The 1990-91 *Regulatory Program* is noteworthy in a number of important respects:

- It reaffirms the policy viewpoints of the previous Administration on environmental health and safety risk assessment and risk management as they had been expressed in E.O.s 12291 and 12498, the 1983 Task Force Regulatory Policy Guidelines, and the policy discussions in the prior *Regulatory Programs.* This is important because the 1983 Guidelines and subsequent explanations of them in the *Regulatory Programs* had been linked to the "goals of the [Reagan] Administration"[75], with the implication that they would not necessarily be binding in a new Administration.

- It calls attention to establishment of the Council on Competitiveness, chaired by the Vice President, as the successor to the Presidential Task Force on Regulatory Relief (which had been chaired by then-Vice President Bush) in overseeing OMB's regulatory review functions under E.O.s 12291 and 12498, and announces that the Council "will work closely with OIRA to augment the regulatory review process. . . ."[76]

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74. White House press release dated August 3, 1990.

75. Section 1(d) of E.O. 12498.

76. OIRA is the Office of Information and Regulatory Affairs of the Office of Management and Budget. OIRA has lead responsibility within OMB for regulatory review. The Council on Competitiveness was established by President Bush on March 31, 1989.

- It sets out final guidance on the preparation of RIAs that includes specific instructions regarding the quantification of environmental health and safety benefits as they are derived from risk assessments.

- It indicates that OMB would be developing guidance and coordination for risk assessment, risk management, and risk communication, and invites comments on the "introductory discussion of these topics" contained in the chapter on "Current Regulatory Issues in Risk Assessment". (The possibility of public workshops and conferences is also indicated.)[77]

The 1990-91 *Regulatory Program* contains an extensive discussion of risk assessment policy issues. (The relevant pages are attached as Appendix D.) Unlike the discussions of risk assessment and risk management contained in previous *Regulatory Programs,* the current one does not have the tone of guidance; rather, it explicitly states that it is intended to "explore some of the continuing difficulties that plague risk assessment and their policy implications", especially cancer risk assessment, with an eye to "further action".[79] Nevertheless, the viewpoints expressed in the discussion echo previous *Regulatory Programs*:

- Agency regulatory analyses should provide "credible estimates of the likely risks" or "expected values" rather than "conservative" or "upper-bound" estimates, but this practice has usually not been followed. Reflexive use of worst-case scenarios and conservative scientific methodology choices and policy assumptions can result in vastly overstated risks. (Examples given are use of sensitive rodent species for bioassays, using response data from the most sensitive pathway, using animal response data based on response to the maximum tolerated dose (MTD), assuming the animal response data is valid for gauging human response, assuming exposure at the highest level without empirical testing for actual conditions, use of the Linearized Multistage Model to extrapolate from high-dose response to low-dose response, and use of body-surface-area scaling factors to extrapolate from test animals to humans.) Conservative

77. 1990-91 *Regulatory Program* at 4-5. At the same time, the *Program* discussion appears to constitute advance comments for EPA's proposed revision of its cancer risk assessment guidelines. EPA has indicated that it expects to issue a notice of proposed rulemaking for those revisions sometime within the next year.

78. *Id.* at 13-26.

79. *Id.* at 4-5, 14.

estimates are appropriate if stated along with "most likely" estimates and if clearly acknowledged as such.

- Uncertainties should be clearly acknowledged, and, if possible, quantified, in the final characterization of risk.

- Margins of safety should be determined as part of the risk management process, rather than being hidden in the risk assessment process via conservative methodologies and assumptions.

- Risk management decisions and allocation of government resources based on conservatively biased risk assessments can distort health and safety priorities and result in increases in risk rather than lessening of risk, and can discourage innovation that would benefit society.

What distinguishes the current *Program* discussion from previous "discussions", however, aside from its greater detail, is its two major underlying theses that: (1) previous Presidential, OMB, and OSTP guidance has not been followed, and (2) it has not been followed due to the fact that a multitude of "conservative" policy decisions have been obscured within the allegedly "scientific" aspects of risk assessment, when such decisions should be the prerogative of policy officials. It is this premise that drives the *Program*'s discussion into the gray area of "science policy" that lies between pure science and manifest policy. This theme is touched on repeatedly during the discussion. The following excerpts in particular illustrate this viewpoint:

> Unfortunately, risk-assessment practices continue to rely on conservative models and assumptions that effectively intermingle important policy judgments within the scientific assessment of risk. Policymakers must make decisions based on risk assessments in which scientific findings cannot be readily differentiated from embedded policy judgments. This policy environment makes it difficult to discern serious hazards from trivial ones, and distorts the ordering of the Government's regulatory priorities. In some cases, the distortion of priorities may actually increase health and safety risks.[80]
>
> * * *
>
> Instead of leaving policy decisions to policymakers, the LMS [use of the linearized multistage dose-response model] disguises fundamental policy decisions concerning the appropriate margin of safety behind the veil of science.[81]
>
> * * *

80. *Id.* at 14.
81. *Id.* at 21.

> Plausible estimates of likely cancer risk can often be found buried in regulatory background documents. However, *Federal Register* rulemaking notices seldom present such estimates alongside upper-bound estimates.[82]
>
> * * *
>
> When risk assessments contain hidden value judgments, their scientific credibility is inevitably compromised.[83]

While the discussion of risk assessment issues in the *Program* clearly is not "guidance", the final Regulatory Impact Analysis Guidance in Appendix V (attached to this report as Appendix E) is of a clear directory nature and covers the subject of risk assessment and risk characterization impliedly through its requirements for estimating benefits. (Recall that the 1988-89 *Program* contained draft guidance and requested comments.) The key RIA guidance principles relevant to this report are summarized in the following excerpt:

> For regulations addressing health and safety risks, the calculation of potential benefits should derive from the agency's estimate of the mean expected value of the reduction in risk attributable to the standard. Estimates of the prevailing level of risk and of the reduction in risk to be anticipated from a proposed standard should be unbiased expected-value estimates rather than hypothetical worst-case estimates. Extreme 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, to the extent possible, the distribution of probabilities for various possible results should be presented separately, so as to allow for an explicit margin of safety, where required, in final decisions. If a margin of safety is to be provided, the proper place for it is the final stage of the decision-making process, not by adjusting the risk or benefit estimates in a conservative direction at the information-gathering or analytical stages of the process. Conservative estimates should be presented as alternatives to best estimates for sensitivity analysis but should not substitute for them.[84]

The OMB authority for issuing and enforcing this guidance, while not cited, is clearly contained in Section 6(a)(2) of E.O. 12291, which states:

> (a) To the extent permitted by law, the Director [of OMB] shall have authority, subject to the direction of the Task Force [now the Council on Competitiveness], to ... (2) Prepare and promulgate uniform standards for ... the development of Regulatory Impact Analyses.

82. *Id.* at 24.
83. *Id.* at 26.
84. *Id.* at 660.

The Fiscal Year 1992 Budget Document

The FY 1992 Budget document, published in January 1991, contains a discussion section entitled "Reforming Regulation and Managing Risk-Reduction Sensibly".[85] (Attached as Appendix F) In this section, the Office of Management and Budget announces that it is initiating a "Risk Management Budgeting" program, described as a project in "careful risk assessment and analysis of programmatic alternatives" that "should enable decision makers to reallocate scarce resources to produce both lower risks and lower costs." The discussion of the program notes that the goal of rational allocation of resources to reduce risk has been complicated by wide variances in individual perceptions of risk and by disagreements among the experts, and that there have been huge disparities in the cost-effectiveness of individual risk management regulations issued over the last ten years. The document sets out a table showing the estimated cost/effectiveness of fifty-three regulations, and the cost/effectiveness in the table ranges from $100,000 (space heater ban) to over $5 trillion per premature death averted (hazardous waste listing for wood preserving chemicals).

Of special importance to the Executive order concept are the observations regarding the risk-reduction analysis building blocks required in order to implement the new program:

> Risk Management Budgeting *requires the establishment of common units of measurement* that enable risk reduction benefits and costs to be compared across a range of options and incremental funding levels within a program. This will allow the allocation of resources to achieve the greatest net benefits. Initially, Risk Management Budgeting will be applied to resource allocation within individual programs. In subsequent years, as many programs employ the technique, it will be possible to allocate resources across programs. Thus, benefit estimation *requires the establishment of uniform government-wide standards for performing risk assessments.* [Emphasis added][86]

The remainder of the discussion does not set out specific guidance on government-wide units of cost/effectiveness measurement or risk assessment standards; rather, it presents some general observations, among which are the following:

- The metric for health benefits might more appropriately be life-years saved instead of fatalities avoided;

85. *Budget of the United States Government, Fiscal Year 1992,* Part Two, 367-76 (GPO 1991).

86. *Id.*, Part Two, p. 373.

- Benefits estimates should possibly take into account ancillary benefits as well as health benefits;

- Good risk analysis must avoid upper-bound estimates or "worst-case" scenarios;

- Sensible regulatory decisions must be based on comparative cost/effectiveness, rather than on comparative risk alone.

Finally, the document announces that in calendar year 1991, OMB will undertake Risk Management Budgeting with respect to seven specified regulatory programs: (1) food safety regulation by the Department of Agriculture with regard to meat and poultry inspection and by EPA with regard to pesticides; (2) seafood safety regulation by FDA and NOAA; (3) OSHA workplace exposure limits for cadmium; (4) HHS quality assurance standards for clinical laboratories participating in Medicare; (5) EPA regulations for RCRA corrective action at Solid Waste Management Units; (6) ranking of workplace hazards by OSHA for the 1992 Regulatory Agenda; (7) DOT's evaluation of highway safety risk reduction strategies.

The 1991 Economic Report of the President

The President's 1991 report to Congress reaffirmed the central principle of White House guidance issued over the last decade:

> Economic growth and environmental protection are compatible, but only if environmental goals reflect careful cost-benefit analysis and if environmental regulation provides maximum flexibility to meet those goals at least cost. My Administration will continue to be guided by the responsibilities of global stewardship; we will seek both to protect the environment and to maintain economic growth to give all the world's children the chance to lead better lives than their parents.[87]

The Council on Competitiveness

The Council on Competitiveness was established by President Bush on March 31, 1989. The Council is chaired by the Vice President, and its permanent Members are the Attorney General and Chairman Pro Tempore of the Domestic Policy Council, the Secretary of the Treasury and Chairman Pro Tempore of the Economic Policy Council, the Director of the Office of Management and Budget, the Chairman of

87. At p. 8 (GPO, Feb. 1991).

the Council of Economic Advisors, the Secretary of Commerce, and the President's Chief of Staff. Additional Cabinet Members and Senior Officials, including the Assistant to the President for Science and Technology (the head of OSTP), the Administrator of EPA, the Chairman of the Council on Environmental Quality, and the Director of the National Science Foundation, are invited to participate in the consideration of specific topics.

On August 14, 1990, the Vice President's Office issued four "Principles of Regulatory Review for Biotechnology" developed by the Council on Competitiveness. The White House press release (attached to this report as Appendix G) states that the principles have been approved by the President.[88] The first three principles are applicable to biotechnology, and the fourth is applicable to all environmental and health regulations. The three biotechnology principles state essentially that (1) products that pose little or no risk should not be subject to unnecessary agency regulatory review[89]; (2) agency regulatory review of biotechnology products should minimize regulatory burdens; and (3) performance standards are preferred over design standards. The fourth principle, applicable to all health and safety regulations, also states that performance standards are preferred over design standards.

Since development of the biotechnology regulatory review Principles, the Council on Competitiveness has also been working, through a Biotechnology Working Group,[90] to develop supplemental guidelines on the "scope" of regulatory oversight for the introduction of genetically altered organisms into the environment—that is, clarification as to what types of activities will and will not be subject to regulatory oversight.[91]

The Office of Science and Technology Policy

While OSTP is an office within the Executive Office of the President, it is also Congressionally chartered. The Presidential Science and Technology Advisory Organization Act of 1976[92] authorizes the

88. The principles are also set out in the Council's February 1991 *Report on National Biotechnology Policy,* but they are characterized as "recommendations". At 12-13, vii.

89. The use of the term "regulatory review" in the first principle is potentially confusing, but in context it is clear that the Council is addressing agency review of private sector activities as opposed to White House review of proposed agency rulemaking.

90. The Working Group is co-chaired by the Special Assistant to the President for Policy Development and the Director of the Office of Science and Technology Policy. Its Members are policy officials from all concerned federal departments and agencies and other White House offices.

91. *Id.* at 13-14, viii.

92. 42 U.S.C. 6611 *et seq.*

Director, a Presidential appointee subject to Senate confirmation, to provide advice to the President on scientific and science policy issues involved in the areas of health and the environment, and to "perform such other duties and functions ... with respect to matters of policy ... as the President may request."[93]

The Director of OSTP chairs the inter-agency Federal Coordinating Council on Science, Engineering, and Technology ("FCCSET"), a Cabinet-level group which is playing an increasingly important role in risk assessment issues. Recently, FCCSET established an Ad Hoc Working Group on Risk Assessment, chaired by EPA's Deputy Administrator. While the charter and deliberations of the Working Group are not public, the Director has announced that the purpose of the Working Group is to "seek agency consensus on common principles that these agencies can apply in their approaches to risk assessment."[94]

The Ad Hoc Working Group on Risk Assessment reports directly to FCCSET. In addition, FCCSET has a Committee on Life Sciences and Health, chaired by the HHS Assistant Secretary for Health, which in turn has a Subcommittee on Risk Assessment co-chaired by officials from HHS and EPA.[95] This Subcommittee has a very large representation of scientists from all of the concerned federal agencies, and it serves essentially as staff for the Council's Ad Hoc Working Group. To date, the Subcommittee has begun work on a review of the 1985 OSTP cancer document, issues concerning reproductive toxicity and neurotoxicity risk assessment, and risk assessment research needs.

The Council on Environmental Quality

At the end of 1989, CEQ issued a publication entitled *Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks.*[96] The book covers all aspects of risk assessment and risk communication, with emphasis on cancer risks, and includes a number of discussions of key issues as they relate to specific chemicals and exposure situations. The Preface states that it is intended to be a "readily accessible reference manual" offering "a balance between the

93. 42 U.S.C. 6614(a)(13). In addition to his Congressionally authorized position, the Director of OSTP holds the office of Assistant to the President for Science and Technology.

94. Written Statement by the Director on "Research and Development in the President's FY 1992 Budget", Feb. 4, 1991. In another statement, Dr. Bromley noted that the Working Group "could feed information into the other policy bodies within the White House and Executive Branch." Speech to the American Industrial Health Council on "Science in the White House", Nov. 28, 1990.

95. Another FCCSET committee that is significantly involved in risk assessment issues is the Committee on Interagency Radiation Research and Policy Coordination.

96. Available through NTIS, Springfield, VA, Order No. PB 89-137772.

technical and nontechnical literature". It does not purport to contain any policy guidance.

The Council's recently-released 21st Annual Report, *Environmental Quality,* shows increasing attention to the economic implications of environmental regulation, devoting thirty-seven pages to the subject.[97]

The Council of Economic Advisors

Although it has no direct responsibility with regard to risk assessment or risk management issues, and does not have any specific risk-related projects under way, the Council has shown a continuing interest in the impacts of risk issues on the nation's economic productivity and competitiveness. In its 1990 Annual Report, the Council included a chapter on "The Economy and the Environment" and enunciated three "principles for environmental regulation"[98]:

- Goals for pollution abatement and risk reduction should be based on a comparison of the costs and benefits involved. Elimination of all risk is almost never a sensible goal.

- Where possible, market-based approaches that provide flexibility, encourage innovation, and support economic growth should be used to achieve environmental goals in a cost-effective manner.

- Government policy should encourage the development and sharing of scientific and technical information relevant to environmental quality issues.

E. CURRENT RELATED AGENCY AND ADVISORY ORGANIZATION ACTIVITIES

1. The Environmental Protection Agency

The Environmental Protection Agency is currently in the process of revising or issuing new risk assessment guidelines for all areas of risk. During 1991, it expects to issue proposed revisions to its cancer

97. Footnote 1, *supra.*

98. *Annual Report of the Council of Economic Advisors* 190, 187-224 (contained in the *Economic Report of the President* for 1990) (Feb. 1990). CEA Member Richard Schmalensee has related that this chapter was prepared at the specific direction of the President. *Environmental Policy and the Cost of Capital* 104, *supra* n. 6. See also the Council's 1989 Annual Report at 215, 217 (Feb. 1989) (discussing how zero-risk strategies can increase risk), and the Annual Report for 1987 at 179-207 (Feb. 1987) (chapter on "Risk and Responsibility").

risk assessment guidelines, proposed guidelines for neurotoxicity risk assessment and general non-cancer risk assessment, and final revisions to its guidelines for mutagenicity and reproductive risk assessment. The Agency's Risk Assessment Council has also been developing an "interim" risk characterization guidance document, which apparently would lay the foundation for the risk characterization guidance that would appear in the individual risk assessment guidelines.

In September 1990, EPA announced that it was initiating its Relative Risk Reduction Project. The goal of the project is to develop an integrated strategy for prioritizing and addressing all environmental hazards subject to EPA jurisdiction, including high-risk ecological problems, on the basis of relative risk. In introducing the program, the Administrator expressed his pleasure "that EPA's own efforts to bring more uniformity to our risk assessments are to be reinforced by Allan Bromley's [Director of OSTP] initiative to ensure greater coherence Government-wide in risk assessment." As the initial stage in these strategic planning efforts, the Administrator stated that he had recently asked each EPA program to select approximately fifteen toxic exposures that are of greatest concern to them, and targets would be set for overall reductions in those contaminants.[99]

2. The Department of Health and Human Services

HHS is undertaking a complete review of its risk assessment methodologies and risk management policies, particularly in the area of food safety, with a view to making improvements and obtaining greater internal consistency among all its programs.[100]

Meanwhile, the Agency for Toxic Substances and Disease Registry has been developing a Health Assessment Guidance Manual for Superfund and RCRA sites. A draft Manual was made available for public comment in August 1990,[101] and issuance of the final Manual is expected in July 1991.[102]

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99. Address by Administrator William K. Reilly before the National Press Club, "Aiming Before We Shoot: The 'Quiet Revolution' in Environmental Policy" (Sept. 26, 1990). In his speech, Mr. Reilly also reviewed the recommendations made by his Science Advisory Board (SAB) in its just-released report, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection* (SAB-EC-90-021, Sept. 1990). The SAB report emphasized the need for an improved ability to compare all types of environmental risks in common terms in order to allow identification of the most effective risk-reduction options. *Id.* at 2.

100. Keynote Address to the Food and Drug Law Institute Seminar on Risk Assessment and Risk Communication by Assistant Secretary for Health James O. Mason, Washington, D.C., November 7, 1990.

101. 55 Fed. Reg. 35463, Aug. 30, 1990.

102. The Manual will be for the purpose of carrying out ATSDR responsibilities under section 104(i) of CERCLA, 42 U.S.C. 9604(i), as enacted in the Superfund Amendments and Reauthorization Act in 1986.

3. Food Safety Legislation

HHS, EPA, and the Department of Agriculture are working with the Executive Office of the President in developing recommendations for new food safety legislation.

4. The Consumer Product Safety Commission

In April 1991, CPSC proposed guidelines for cancer risk assessments and criteria for neurotoxicity and developmental and reproductive toxicity.[103]

5. The National Academy of Sciences (National Research Council)

Committee on Risk Assessment Methodology

During 1990, the NRC began a new project that it considers to be, in effect, a continuation of its Red Book project. This project, which is under a new committee called the Committee on Risk Assessment Methodology ("CRAM"), was set up to review issues associated with the scientific bases for risk assessment.[104] In September 1990, CRAM held a public workshop on the use of maximum tolerated dose ("MTD") in animal bioassays; in November 1990, it held a workshop on two-stage models of carcinogenesis; and at the end of February 1991 it held a workshop on ecological risk assessment. Workshops on PB-PK modeling[105] and exposure assessment have been scheduled for mid-1991. The Committee plans to complete its project in approximately two more years.

The Clean Air Act Risk Assessment Study

The 1990 Clean Air Act Amendments, enacted on November 15, 1990, contain provisions for an NAS review of EPA's risk assessment methodology for hazardous air pollutants with cancer risks or other adverse health effects "for which safe thresholds of exposure may not exist". The review must be completed by May 1993, and EPA must then issue revised risk assessment guidelines that incorporate the NAS recommendations, or explain why they will not be followed.[106]

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103. 56 Fed. Reg. 15672, April 17, 1991.

104. CRAM coordinates with federal agencies through a Federal Liaison Committee.

105. PB-PK stands for physiologically-based pharmacokinetic modeling, which incorporates data on absorption, distribution, metabolism, and excretion to estimate the amount of a substance which effectively reaches a target organ, as opposed to the total amount to which a human or animal subject is exposed in the environment.

106. Sec 301(o).

6. The Risk Assessment and Management Commission Recently Established by Congress

In addition to the NAS study directive described above, the 1990 Clean Air Act Amendments established a "Risk Assessment and Management Commission" with a sweeping charter to review risk assessment and risk management issues relating to all federal laws and all chronic health effects.[107]

The Commission will be composed of ten members, three of whom will be appointed by the President, two by the Speaker of the House, one by the House Minority Leader, two by the Senate Majority Leader, one by the Senate Minority Leader, and one by the President of the National Academy of Sciences.

The Commission will prepare a report, after public comment, for submission to the President and the Congress by November 15, 1994 (eighteen months following the deadline for the NAS study). In preparing its report, the Commission must consider the recommendations of the National Academy of Sciences prepared under Section 301(o) (summarized above under section 5).

The charter of the Commission goes substantially beyond the "scientific" charter of the NAS study under section 301, encompassing subjects such as risk characterization and risk management policy as well as the "science policy" issues (or "inferences", as the NAS Red Book termed them) that are intertwined with risk assessment science.

F. THE ORIGINAL FEDERAL FOCUS "DISCUSSION DRAFT" EXECUTIVE ORDER

Basic Premises

The Federal Focus decision to explore the feasibility and desirability of an Executive order grew out of the following observations:

- Many of the most controversial and important issues regarding environmental health and safety risks are policy issues rather than science issues; or at least they have a policy component.

- The President is ultimately responsible for providing policy guidance to all Executive Branch departments and agencies, to the extent such guidance is consistent with statutory mandates.

107. Sec. 303.

- Environmental health and safety risk assessment and risk management authority resides in a variety of federal agencies and offices under a multitude of statutory programs. As a result, significant inconsistencies have developed that have called into question (by all interested parties) the credibility and judgment of the Executive Branch. In addition, there have been numerous allegations that policy judgments are being made by government officials and staff personnel who lack policy responsibility and political accountability, and who are not receiving adequate policy guidance from Presidentially-appointed superiors.

- An effort was made by President Reagan to provide limited general policy guidance through the principles in E.O. 12291, more specifically through Regulatory Policy Guidelines 4 and 5 that were incorporated into E.O. 12498, and through OMB's regulatory oversight role. However, these forms of Presidential guidance have so far proved inadequate to resolve the many policy controversies.

- Significant effort has been, and continues to be, expended by the Executive Branch to resolve policy debates on an *ad hoc* basis, when many of the issues are generic and appear capable of being resolved with general centralized policy guidance.

Content

At the time when Federal Focus was preparing its Discussion Draft Executive order (Appendix A), in the Spring of 1989, there was no explicit policy guidance on these issues that had been issued by the Bush Administration. Consequently, there was an effort on the part of Federal Focus to formulate content of the Discussion Draft that would be consistent with the continuum of policy views expressed by the President and his staff in recent years, since President Bush, as Vice President, had played a prominent role in formulating and reviewing those views. At the same, we kept in mind that there is a need for temporal consistency of policy guidance on these issues, as well as for consistency among agencies. Therefore, nothing was proposed for the Draft that did not appear to be a sensible position that could be accepted by a subsequent Administration, regardless of political party. Furthermore, it was recognized that whatever was drafted must be general and flexible enough to accommodate advances in scientific understanding, unique facts presented by different hazard and exposure situations, and new or altered Congressional mandates. In short, the substance had to be limited to policy, and had to be politically realistic, balanced, sufficiently encompassing, and flexible.

The content of the Discussion Draft fell into three categories: (1) risk assessment policy; (2) risk characterization and communication policy; and (3) risk management policy. The topics that were addressed within each of these categories are briefly summarized below:

Risk assessment

- consistency among agencies and programs
- periodic review of scientific bases of assumptions
- use of "most realistic" assumptions
- use of empirical data rather than assumptions or modeling
- choice of low-dose extrapolation models
- use of negative data

Risk characterization and communication[108]

- presenting "expected" or "most likely" risk estimates, bounds, and information on highly-exposed or sensitive populations in addition to an upper-bound estimate for a worst-case (or "conservative") scenario
- providing a frame of reference for risk estimates through comparison with other risks so they can be better comprehended by the public
- providing sensitivity analysis
- explaining uncertainty factors
- assessing the weight of the evidence

Risk management

- consistency among agencies and programs

108. As used here, risk "characterization" refers to the portrayal of the risk assessment results for the risk manager; while risk "communication" is a more encompassing term, including all of the various factors that might be involved in the *process* of conveying risk information to the general public, such as media, tone, timing, credibility, etc.

Federal Focus consciously avoided addressing certain categories of issues in the Discussion Draft:

First, we avoided provisions dictating decisions on "science" issues, such as what risk assessment assumptions are the most scientifically supportable or plausible. Scientific conclusions or opinions are not, we believe, an appropriate subject for an Executive order. However, the Discussion Draft did address some areas that some would contend are in the realm of "science policy". It was our basic view that to the extent there is not a most scientifically supportable or plausible position, and the result is not dictated by a statute or court decision, the decision is a matter of policy and is appropriate for Presidential guidance.

Second, the Discussion Draft did not address implementation and oversight responsibility or mechanisms. As is apparent from the above review of the various White House entities currently involved in risk analysis activities, there would be a number of candidates for the oversight role, and at times in the past oversight has been combined with coordination through interagency committees chaired by White House staff. The Discussion Draft did not address these issues because it was our view that if provisions of this sort were included, it would tend to lead to a great deal of commentary and draw attention away from the more substantive policy issues that are of primary concern. Nevertheless, these issues are admittedly very important, and they are discussed further below and are addressed in our recommendations.

Finally, the Discussion Draft did not directly address the issue of scope of coverage—*i.e.*, to what kinds of risks an Executive order should apply. However, the term "cancer" was inadvertently employed in one of the sections, which led some commenters to assume that the coverage would extend only to cancer risks.