

Toward Common Measures

RECOMMENDATIONS FOR A
PRESIDENTIAL EXECUTIVE ORDER ON
ENVIRONMENTAL RISK ASSESSMENT
AND RISK MANAGEMENT POLICY

FEDERAL FOCUS, INC.

Federal Focus, Inc. is a private non-profit 501(c)(3) corporation dedicated to research and education on governmental policy issues. It conducts symposia, disseminates information, and undertakes studies in areas such as alternative dispute resolution (ADR), risk assessment and risk management, health care financing, procurement, budgeting, federal pay, and Presidential powers. In addition, Federal Focus provides financial support and undertakes activities for the preservation and promotion of traditional American jazz, including sponsorship of the Federal Focus Jazz Band.

In April 1991, Federal Focus established the Institute for Regulatory Policy as an affiliated non-profit entity which concentrates solely on regulatory issues. Beginning with the release of this report, the Institute will take over responsibility for further activity on this risk policy review project.

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June 14, 1991

The Vice President
The White House

Mr. Vice President:

I am pleased to forward to you for appropriate action as Chairman of the Council on Competitiveness the enclosed report, Toward Common Measures: Recommendations for a Presidential Executive Order on Environmental Risk Assessment and Risk Management Policy. We propose that the Council, after review, sponsor submission of the recommended Executive order to the President, with any modifications it deems advisable, pursuant to the procedures in 1 CFR Part 19.

We believe that the Council is the most appropriate sponsor due to its regulatory oversight role under Executive Order 12291, the growing competitiveness implications of environmental risk expenditures, and the current involvement of numerous White House and agency entities in reviewing risk issues.

Intense controversy has surrounded environmental risk assessment and risk management policy issues for more than a decade. The purpose of the recommended Executive order would be to minimize such controversies in the future by providing uniform centralized guidance designed to make risk assessments as scientifically objective as possible, to make the results of risk assessments more accurate and understandable, and to establish the consistency needed for more effective prioritizing and allocation of limited governmental regulatory resources among the many involved agencies and programs.

Efforts in this direction were begun under the Carter Administration, were enhanced during the Reagan Administration, and have gathered additional momentum in the Bush Administration. The recommended Executive order would build upon and harness these efforts, and should, we believe, be acceptable to any succeeding Administration. More specifically, the order would clarify and expand upon the 1983 Regulatory Policy Guidelines that were incorporated by reference into Executive Order 12498 in 1985, and would take advantage of the risk analysis review efforts under way in the Office of Management and Budget, the Office of Science and Technology Policy, the Federal Coordinating Council on Science, Engineering and Technology, and the National Research Council.

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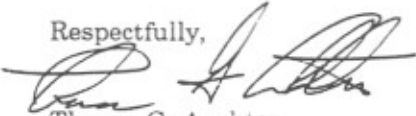
- 2 -

We have concluded that an Executive order is the only effective means for achieving the necessary coordination, consistency, and policy reforms, and that the maturation of thinking and activity on the key issues has created a clear opening for such a step forward. Failure to seize this opportunity would allow current deficiencies to become more entrenched and inconsistencies to grow, with a resultant inability to carry out the Administration's goals for Risk Management Budgeting and better strategic planning, and a growing likelihood that increased regulatory expenditures would not achieve the benefits we expect and would impair our ability to address more serious problems and remain competitive in the world economy.

This project was begun by Federal Focus more than two years ago, and the recommendations reflect comments received from participants in three forums attended by risk experts from virtually all concerned federal agencies, and academia, research organizations, public interest groups, corporations and trade associations. After the report has been distributed to the public, the Institute for Regulatory Policy, which is now affiliated with Federal Focus and is taking over all further activity on this project, will prepare and submit to the Council a summary of any additional public comments it receives, and will consider holding additional forums.

Due to the pace at which the diverse governmental risk policy review efforts and new environmental regulatory activities are proceeding, we urge that the Council address the enclosed recommendations as soon as possible with a view to presenting its final recommendations to the President prior to the end of this calendar year.

Respectfully,



Thorne G. Auchter
Director

Enclosure

Toward Common Measures

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AND RISK MANAGEMENT POLICY

FEDERAL FOCUS, INC., WASHINGTON, D.C. 1991

Table of Contents

EXECUTIVE SUMMARY	1
CHAPTER I. INTRODUCTION	7
A. The Growing Importance of Scientifically Sound Risk Assessment and Discriminating Risk Management	7
B. The Federal Focus Risk Policy Review Project	10
C. The Purpose and Perspective of This Report	12
CHAPTER II. BACKGROUND	14
A. The Legitimate Scope of Executive Orders As Instruments of Presidential Authority	14
B. The Scope of the Statutory Mandates Involving Risk Assessment and Risk Management	19
C. Recommendations by Governmental Advisory Organizations	27
1. The Administrative Conference of the United States	27
2. The National Academy of Sciences (National Research Council)	28
D. Past and Current White House Efforts to Coordinate and Guide Agency Risk Assessment and Risk Management Activities	28
1. The Nixon, Ford and Carter Administrations	28
2. The Reagan Administration	30
Executive Orders 12291 and 12498	30
The 1983 Regulatory Policy Guidelines	32
The 1985 Office of Science and Technology Policy Cancer Document	33
The Reagan Administration <i>Regulatory Program</i> Policy Discussions	35
President Reagan's Final Observations	38

3. The Bush Administration 39

The Initial *Regulatory Program* of the
Bush Administration 39

The Fiscal Year 1992 *Budget Document* 44

The 1991 *Economic Report of the President* 45

The Council on Competitiveness 45

The Office of Science and Technology Policy 46

The Council on Environmental Quality 47

The Council of Economic Advisors 48

E. Current Related Agency and Advisory Organization Activities 48

1. The Environmental Protection Agency 48

2. The Department of Health and Human Services 49

3. Food Safety Legislation 50

4. The Consumer Product Safety Commission 50

5. The National Academy of Sciences (National
Research Council) 50

6. The Risk Assessment and Management Commission
Recently Established by Congress 51

F. The Original Federal Focus "Discussion Draft" Executive Order 51

CHAPTER III. DISCUSSION 55

A. Is there a need for some sort of government-wide policy guidance
on risk assessment and risk management (though not necessarily
through an Executive order)? 55

B. Is a Presidential Executive order a necessary and appropriate
means for providing government-wide policy guidance? 62

C. What issues should the Executive order address and how should
it resolve them? 66

1. Types of Risks Covered 67

2. Types of Agency Actions Covered 69

3. Risk Assessment (hazard assessment, dose response, and
exposure assessment aspects) 71

Consistency and Uniform Science Policy and
Inference Guidance 71

Conservatism and Margins of Safety 72

Low-dose Extrapolation 75

Consideration of Negative Data 78

Exposure Estimates 79

4.	The Risk Characterization Aspect of Risk Assessment	80
	Quantitative Expression of Risk	82
	Risk Comparisons	88
	Substitution Risks and Risk Tradeoffs	89
5.	Peer Review	91
6.	Assessment of Benefits	91
7.	Risk Management Principles	92
	Consistency	92
	Consideration of Substitution Risks and Risk Tradeoffs	93
	Application of the <i>De Minimis</i> Principle	93
	Margins of Safety	96
	Ends v. Means	98
8.	Review of Pre-Existing Risk Assessments and Risk Management Decisions	99
9.	Oversight Responsibility and Discretion of OSTP, OMB, and the Council on Competitiveness	101
10.	Judicial Review	102
CHAPTER IV RECOMMENDED EXECUTIVE ORDER		103
APPENDIX A:	Federal Focus "Discussion Draft" Executive order (May 1989)	109
APPENDIX B:	Regulatory Policy Guidelines 4 and 5, Accompanying Explanatory Text, and Supplemental Discussion of Risk Assessment (Presidential Task Force on Regulatory Relief, Aug. 1983)	113
APPENDIX C:	Office of Science and Technology Policy Cancer Principles (U.S. Interagency Staff Group on Carcinogens, Feb. 1985)	126
APPENDIX D:	Discussion in the 1990-91 <i>Regulatory Program</i>	130
APPENDIX E:	Final Guidance for Preparation of Regulatory Impact Analyses, 1990-91 <i>Regulatory Program</i>	147
APPENDIX F:	Section on Risk Management Budgeting in the Fiscal Year 1992 <i>Budget</i>	156
APPENDIX G:	"Principles of Regulatory Review for Biotechnology" (Council on Competitiveness, Aug. 1990)	167

Executive Summary

Introduction

Our public and private resources are finite, and environmental investments must be made wisely. Expenditures for environmental risk reduction have increased steadily over the last twenty years, and are expected to continue growing over the next decade. At present, compliance costs for the major anti-pollution laws exceed \$115 billion and are more than two percent of GNP. In addition to direct cost impacts, further increases in environmental expenditures could put U.S. companies at a significant competitive disadvantage. It is essential, therefore, that governmental decisions on risk reduction be as sound and balanced as possible in order to ensure that we receive from our investments the health, safety, and environmental benefits we expect.

Over the last decade, there has been increasing criticism directed at the propensity of federal agencies to intermingle policy or value judgments with scientific risk analysis, with the alleged result that regulatory decisions are often based on risk estimates (and estimates of risk reduction benefits) that do not reflect scientifically objective appraisals of all the relevant data.

In the Spring of 1989, Federal Focus began a project to explore whether the issuance of policy guidance on risk assessment and risk management through a Presidential Executive order could improve risk reduction efforts. During the last two years, Federal Focus held three Risk Forums on the Executive order concept, using a "Discussion Draft" Executive order to focus discussion, and obtained written comments from numerous parties. This report presents the findings and recommendations of Federal Focus (and its new affiliate, the Institute for Regulatory Policy) concerning the issuance of an Executive order.

Background—Past and Pending Efforts to Improve the Process

It is generally recognized by the courts and legal scholars that the Chief Executive has the authority to provide policy guidance to subordinate Executive Branch officials to the extent such guidance is not inconsistent with statutory directives. Executive orders are the primary instrument for Presidential guidance encompassing a number of agencies and governmental programs.

Congressional mandates concerning risk regulation involve a multitude of federal departments and agencies, and most of the directives are very general, allowing for substantial discretion in interpretation and implementation. At times, as many as four or five agencies may be involved in assessing and regulating risks from the same substance, and different agencies and different programs within the same agency compete for limited governmental resources for risk reduction. Thus, in addition to improving the objectivity of risk analysis, centralized policy guidance could achieve the benefits of minimizing inconsistencies that impair government credibility, and harmonizing agency practices to enable more efficient allocation of resources among agencies and programs.

Efforts to improve and harmonize regulatory analysis date from the Nixon and Ford Administrations; and efforts to improve and harmonize risk reduction analysis and decision-making date at least from the Carter Administration. Current centralized policy guidance and coordination mechanisms affecting risk reduction programs are contained in E.O. 12291 (signed in 1981) and E.O. 12498 (signed in 1985). E.O. 12291 established certain analytical principles for regulatory decision-making, such as use of cost/benefit and cost/effectiveness analyses, and delegated oversight authority for rulemaking actions, particularly "major" rulemakings, to the Office of Management and Budget and a Presidential Task Force (chaired by the Vice President). E.O. 12498 directed agencies to comply with ten Regulatory Policy Guidelines that had been developed by the Presidential Task Force and which were incorporated by reference into the Order. Two of those Guidelines, numbers 4 and 5, and their accompanying explanations, are directly pertinent to health, safety, and other environmental risk reduction programs, directing agencies to focus their attention on "best estimates" of significant risks, and to give preference to performance standards over design standards as risk reduction measures.

In addition, in 1985 the White House Office of Science and Technology Policy issued non-binding guidance principles for the evaluation of carcinogens which incorporated some significant policy views. Prior to this, in 1983, the National Academy of Sciences had issued recommendations that efforts be made to harmonize agency risk assessment through centralized guidance. The Administrative Conference of the United States had made similar recommendations in 1982.

Since the issuance of E.O. 12498, the Office of Management and Budget has attempted to clarify application of the Regulatory Policy Guidelines through a number of detailed discussions in the annual *Regulatory Program*, repeatedly focusing on the extent to which many agency risk assessments inappropriately incorporate policies that are inconsistent with the Regulatory Policy Guidelines.

During the last year, there have been renewed, intensified, and diverse efforts to improve the federal risk assessment and risk management processes by governmental and quasi-governmental entities:

- President Bush reaffirmed the applicability of the Regulatory Policy Guidelines that he helped develop as Chairman of the Presidential Task Force.
- The Office of Management and Budget issued its most detailed risk assessment critique in the 1990-91 *Regulatory Program*, promulgated final guidance for the estimation of risk reduction benefits in Regulatory Impact Analyses, and indicated it was considering issuance of further guidance on risk issues. OMB also initiated a Risk Management Budgeting Program which aims to allocate risk reduction budget resources more efficiently across agencies and programs.
- The Office of Science Technology and Policy has convened two interagency committees, a high-level Ad Hoc Working Group on Risk Assessment and a Subcommittee on Risk Assessment, under the Federal Coordinating Council on Science, Engineering and Technology, to address the need to reconcile disparate agency risk assessment approaches.
- The Council on Competitiveness, a Cabinet-level group which is chaired by the Vice President and is the successor to the Presidential Task Force that formulated the Regulatory Policy Guidelines incorporated into E.O. 12498, has developed policy guidance for the regulation of biotechnology.
- The National Research Council has formed a Committee on Risk Assessment Methodology to address key interagency risk assessment issues.
- Congress has mandated reviews of current risk analysis practices by the National Academy of Sciences and a Risk Assessment and Management Commission.
- The Environmental Protection Agency and the Department of Health and Human Services are engaged in comprehensive reviews of their risk assessment approaches, and EPA has begun a Relative Risk Reduction Project designed to enable the agency to better prioritize its risk reduction targets.

- EPA and the Consumer Product Safety Commission are developing or considering revisions to a number of risk assessment guidelines.

Comments Received by Federal Focus

Discussion in the three forums and the written comments indicated wide support for some sort of uniform government-wide guidance on risk assessment policy and scientific inferences (including risk characterization), though many commenters indicated that they could only support such an effort if the responsibility for developing guidance on science policy issues were given to officials with adequate scientific credentials. There was less support indicated for uniform risk *management* policy guidance, though it appeared that this lower level of support might be due to uncertainty over how much consistency could be achieved in the face of the great variety of statutory mandates.

Substantial support was indicated for an Executive order as the instrument for guidance, but views on the appropriateness of an Executive order did not necessarily correlate with views on the need for government-wide guidance, and the views appeared to depend more on related issues, such as whether the Executive order would address science policy issues and who would have oversight authority.

Numerous comments were received pertinent to the provisions of the Federal Focus "Discussion Draft" Executive order. Some common themes ran through the comments:

- Risk assessments should be more scientifically objective. Currently, risk assessments often incorporate numerous policy or value judgments that may be leading to inflation of risk estimates and misallocation of resources.
- Current systems for risk characterization are widely misunderstood or misused by the media, the general public, and interest groups. This generates political pressures that can result in serious inefficiencies and misallocation of resources.
- The appropriate degree of "conservatism" should be addressed in the risk management decision-making process, and that process should take into consideration the wider implications of the regulatory alternatives.

The full report contains detailed discussions of the comments received on specific issues.

Federal Focus Conclusions and Recommendations

The general comments, views and attitudes summarized above are justified and are consistent with White House policy views currently established through E.O. 12291, E.O. 12498, the Regulatory Policy Guidelines incorporated into E.O. 12498, the final Regulatory Impact Analysis guidance recently issued by the Office of Management and Budget, and recommendations of the National Academy of Science and the Administrative Conference of the United States.

The policy positions currently in place have not been successfully implemented, however, and risk policy controversies have had to be addressed frequently on a piecemeal, *ad hoc* basis. This has apparently been due to several factors: The policy guidance in E.O. 12498 and the Regulatory Policy Guidelines is not sufficiently detailed and comprehensive, is not familiar to many government officials, and is now liable to be viewed as the policy of a prior Administration but not necessarily the current one.

With the many diverse projects under way to attempt to correct this situation, there is an urgent need for strong centralized leadership to coordinate and to harmonize those efforts while preserving and strengthening current policy positions and making the review process for major rulemaking activities more efficient. This can only be accomplished by Presidential directive, since no subordinate entity currently has sufficiently explicit delegated authority to develop, issue, and obtain compliance with the necessary guidance. In the absence of such leadership, the current efforts could result in individual agency or inter-agency consensus positions that erode current policy, entrench existing inconsistencies, or create new inconsistencies.

The Executive order being recommended can, we believe, readily accomplish the above objectives while accommodating all significant concerns expressed by commenters and remaining acceptable to succeeding Administrations of either party. The recommended order has the following key features:

- The order would establish a number of general policy principles to guide risk assessment, risk characterization, and risk management.
- Following issuance of the order, the Office of Science and Technology Policy and the Office of Management and Budget would issue more detailed guidance consistent with the principles established by the order. OSTP would issue detailed guidance on risk assessment policy and scientific inferences after consultation with OMB, the Council on Competitiveness, and other parties;

OMB would issue more detailed guidance on risk characterization after consultation with OSTP, the Council on Competitiveness, and other parties. There is no provision for more detailed risk management guidance.

- The order would be applicable to all risk assessment and risk management actions, including those of a site-specific (e.g., Superfund) and product-specific (e.g., FIFRA) nature; however, responsibility for compliance with the order would lie with agency heads except to the extent regulatory actions are currently reviewable by OMB and the Council pursuant to E.O. 12291.
- The order would establish a petition process for review of pre-existing risk assessments and risk management decisions.
- Provisions for periodic review and modification of the order and subsequent guidance would be included.

Federal Focus and the Institute for Regulatory Policy are inviting comments on the report and recommendations. A summary of the comments received within ninety days will be prepared and presented to the Council on Competitiveness and the Executive Office of the President, and the holding of additional forums will be considered.

It is recommended that an Executive order be issued this calendar year in order to take maximum advantage of the various risk policy review projects currently under way or soon to commence.

I. Introduction

A. THE GROWING IMPORTANCE OF SCIENTIFICALLY SOUND RISK ASSESSMENT AND DISCRIMINATING RISK MANAGEMENT

Risk assessment and risk management are essentially attempts to conduct the soundest possible analysis and decision-making with regard to environmental regulations and expenditures. The "risk assessment" process provides information on the nature and extent of a hazard, while the "risk management" process determines what risks are significant or unacceptable and how or to what degree they should be controlled. Risk assessment is primarily scientific, while risk management takes into consideration other factors such as cost, technical feasibility, and timing. Together, these two processes attempt to answer questions like "How clean is clean?" and "Is this safe enough?". The desired outcome of these inquiries is that benefits, whether quantifiable or non-quantifiable, will exceed costs and there will be a net improvement in individual and societal health, security, and economic well-being.

Risk assessments and risk management decisions drive a high proportion of total governmental regulatory costs. These costs include the costs of compliance, the costs of governmental and private services (*e.g.*, research, monitoring, rulemaking, enforcement), the costs of products, and "opportunity costs"—*i.e.*, loss of revenues and competitive advantages as a consequence of having to forego investment of those funds in other activities such as product research and market expansion. While these costs are often hidden, they can affect every U.S. citizen through higher taxes, higher prices, and potential unemployment and reduced economic growth resulting from lack of international competitiveness with companies abroad that have lower costs.

There are clear economic benefits that stem from many environmental regulations—benefits such as higher worker productivity, lower health care costs, enhanced recreational opportunities, and reduced deterioration of materials—as well as less quantifiable benefits such as health, aesthetics, general sense of well-being, and longer life spans. But there are also substantial questions, even with regard to current

programs, as to the benefits actually realized and whether the benefits exceed the costs.¹

Estimates of the current direct costs for compliance with many of the nation's pollution control laws are in the neighborhood of \$100-115 billion per year, and comprehensive cost estimates that take into account all health, safety and environmental laws and both direct and indirect costs would be considerably higher.² The recent enactment of amendments to the Clean Air Act, more stringent hazardous waste regulations recently issued by EPA, and slated hazardous waste cleanups at federal facilities could easily increase these estimated annual costs by more than fifty percent within the next ten to fifteen years.³

While some point out that the cost of environmental compliance is not very high when compared on a macro-economic basis with other categories of expenditures such as food, clothing, and housing, on a micro-economic level environmental costs and liabilities can severely impact the viability and competitiveness of individual companies and industries. A variation in the agency-mandated cleanup level for a Superfund site can alter the costs by tens of millions of dollars. Public fears and liability exposures regarding radiation from nuclear power plants can make it infeasible to finance new power plants that would reduce other significant types of air pollution,⁴ or limit siting options for hazardous waste disposal facilities. Federal assessments of the

1. See, e.g., Resources for the Future, *Public Policies for Environmental Protection*, 125-27, 180-83 (P. Portney ed. 1990). And compare *Environmental Quality* (the 21st Annual Report of the Council of Environmental Quality) 68-73 (GPO, April 1991).

2. U.S. EPA, *Environmental Investments: The Cost of a Clean Environment* (Summary document, EPA-230-12-90-084, Dec. 1990; full report is NTIS No. PB91-153783, Nov. 1990); *Annual Report of the Council of Economic Advisors* (1990), in *Economic Report of the President*, 187 (Feb. 1990); *Environmental Quality*, supra n. 1, 49-68, 267-83. The \$115 billion estimate is from the EPA study; the \$100 billion figure is a CEA estimate adjusted for inflation. The EPA estimate takes into account only major pollution-control programs administered by EPA and similar State and local programs, as well as State and local drinking water and solid waste disposal compliance costs. The federally-mandated component is roughly eighty percent. The estimate does not include costs associated with programs such as those administered by OSHA, CPSC, DOA, and DOT, or environmental programs that are not for pollution control. (And not all EPA pollution control programs are included. See, e.g., p. 3-5 of the full EPA report.) In addition, the costs estimated by the EPA study are only *direct* compliance costs; other types of costs, such as opportunity costs or costs resulting from diminished competitiveness, are not included. The study notes that "[s]ome recent research suggests that compliance cost estimates may understate substantially the true long-term costs of pollution control." At 1-3 of full report (citation omitted).

3. See EPA Summary, supra, at 2-1.

4. See M. Eisenbud, letter on "Disparate Costs of Risk Avoidance", *Science*, Sept. 9, 1988 (discussing how low-level radioactive waste disposal standards in some States involve expenditures equivalent to trillions of dollars per estimated statistical fatality avoided).

safety of a product such as asbestos or a pesticide that are perceived as negative can drive it off the market, push a company into bankruptcy, or require the development of expensive substitutes. Extensive safety testing for a new drug, medical device, plant product or pesticide can cost tens of millions of dollars. Stricter standards for new facilities can discourage investment in modernization. Increases in capital investment requirements, or diminished efficiency in utilization of capital, can also create *de facto* barriers to market entry or expansion that limit competition and lead to higher prices, lower quality, and less innovation.

Macro estimates of environmental costs can also disguise the fact that the costs tend to be regressive in their impact on smaller communities. For example, the per household costs for drinking water treatment and waste disposal in a small community can be many times higher than in a large city. Environmental costs also fall disproportionately on lower-income groups because such costs are generally fixed increments built into necessities such as food, housing, and utilities, and increases in the cost of such necessities can reduce their availability as well as the amount of income available for basic health care.

There is a growing international competitiveness dimension to the matter of environmental costs. Some recent estimates of U.S. environmental expenditures amount to a little over two percent of our GNP.⁵ While direct comparisons with other countries are difficult due to a paucity of data, current U.S. spending on the environment appears to be at the high end of the spectrum among OECD nations, and substantially more than non-democratic and developing countries.⁶ As the U.S. substantially increases its environmental expenditures over the next decade, U.S. companies could be subject to significant competitive disadvantages.

Great advances have been made in pollution control in the United States over the last twenty years. During the next decade, further gains will require increasingly discriminating assessment and control of risks. Typically, the costs of control increase as the easy gains are achieved and attempts are made to eradicate small marginal hazards. At the same time, our means for detecting and measuring contamination have improved to the point where the environment appears to be pervaded

5. See EPA *Summary* document, *supra* n. 2, at 2-1. As noted, however, these are not comprehensive estimates.

6. R. Kopp, P. Portney, D. DeWitt, "International Comparisons of Environmental Regulation", and related commentary by C. Hahn and R. Schmalensee in *Environmental Policy & the Cost of Capital* (American Council for Capital Formation Center for Policy Research, Sept. 1990); *Environmental Investments: The Cost of a Clean Environment*, *supra* n. 2).

UNIFORM RISK ASSESSMENT AND RISK MANAGEMENT SYSTEM SHOULD ALSO
comparison of the cost/effectiveness of potential regulatory targets both within programs and across various agencies, so that society receives the maximum return from its investment.

There is a growing recognition of the correlation between societal prosperity and its health and welfare, and how the federal government performs its risk assessment and risk management functions for environmental programs clearly has the capability to either enhance or diminish our overall standard of living depending on the intelligence and balance with which it is conducted.

B. THE FEDERAL FOCUS RISK POLICY REVIEW PROJECT

In early 1989, Federal Focus began to explore ways in which the current federal agency risk assessment and risk management processes could be improved consistent with the concerns discussed above. After a preliminary review of current literature and conversations with government policy officials, Federal Focus determined that much of the controversy currently surrounding these subjects pertained to disagreement concerning the appropriateness of certain policy or "science policy" decisions being made by a number of federal agencies operating under different statutory mandates. Due to the variety of agencies and programs affected, and the apparent lack of adequate coordination and policy guidance by the White House, Federal Focus determined to

7. During the last two decades, the detectable levels of chemical contamination have decreased from parts per million to parts per billion or less in some cases, and there are now over six hundred substances that have been shown to cause tumors in laboratory animals. Thus, minute cancer risks can be found virtually everywhere. In addition, there are widespread non-chemical risks such as low-energy electromagnetic fields and radon.

explore the need for a Presidential Executive order to address key policy principles that could form a uniform and stable foundation for better and more consistent federal decisionmaking.

To assist in identifying key issues and to provide a focus for public discussion, Federal Focus prepared a draft Executive order in May 1989. A copy of the draft is attached as Appendix A. (This draft is hereafter referred to as the "Discussion Draft".) The contents of the Discussion Draft are discussed below in section II, F.

In May 1989, Federal Focus announced its intention to hold a series of public forums on the need for an Executive order, using the Discussion Draft as a basis for discussion. Three forums were held: The first, for federal officials, was held in June 1989; the second, for academics, non-profit "think tanks", and public interest groups, was held in January 1990; and the third, for representatives of industry and labor, was held in May 1990.

Each of the forums was attended by twenty-five to thirty-five individuals with a high level of knowledge and experience in the issues. For each forum, Federal Focus attempted to avoid any selection bias regarding invitees. The first forum included policy officials and scientists from ten federal departments and agencies (and a far larger number of program offices, administrations, etc. within those departments and agencies). The second forum included participants from nine universities, ten research foundations and professional societies, and three public interest groups. The third forum included participants from twenty different corporations and two trade associations.⁸ Each forum consisted of a three-hour roundtable discussion led by a moderator. Participants were asked for their views on three basic issues: (1) Is some sort of government-wide guidance on risk assessment and risk management policy issues desirable?; (2) Is an Executive order an appropriate vehicle for such guidance?; and (3) Is the Federal Focus Discussion Draft well-conceived and well-formulated?

In addition to views expressed in the forums, Federal Focus received and considered commentary from additional sources. This additional commentary includes written comments submitted by individuals who were invited to the forums but were unable to attend, supplemental written comments by those who attended, verbal communications from outside the forums by a great variety of interested parties, and recent literature cited or submitted as pertinent by interested parties. Finally, Federal Focus personnel have continued to review per-

8. The number of organizations that participated does not necessarily reflect the number invited. For example, in the case of public interest groups, the number that attended compared to the number invited was proportionately much less than for other types of groups.

minent literature and governmental documents and interview policy officials.

C. THE PURPOSE AND PERSPECTIVE OF THIS REPORT

The purpose of this report is to present an informed perspective on the issue of whether there is a need for Presidential policy guidance on key issues involved in federal agency risk assessment and risk management. The report also presents specific recommendations for the content of such guidance and its implementation.

We intend that the report will provide the analytical framework and impetus for further review of the need for an Executive order by the White House Council on Competitiveness, the Executive Office of the President, and the affected departments and agencies, and will lead to a firm decision on whether to recommend that the President issue an Executive order.

The most recent *Regulatory Program of the United States* (see section D, 3, below), contains an extensive discussion of risk assessment policy issues and invited comments. It also identifies the Council on Competitiveness as the highest-level body for coordinating federal regulatory policy. Accordingly, this report and recommendations are being submitted to the Council as "comments" on that discussion, as well as to the Office of Management and Budget, the Office of Science and Technology Policy, the Council on Environmental Quality, and the Council of Economic Advisors, as well as the individual departments and agencies. The report will also be distributed to individuals who participated in the three forums, and will be made available to the general public.

Federal Focus and the Institute for Regulatory Policy invite comments on this report and recommendations from interested parties; and a summary of any comments received within ninety days of release of this report will be prepared by the Institute for Regulatory Policy and submitted, along with any modifications or additions to this report and recommendations, to the Council and the other White House offices.

Comments, and requests for additional copies of this report, should be addressed to:

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202/939-6976

This report does not purport to be “scientific”, since Federal Focus staff does not claim specialized scientific credentials, and it does not attempt to take sides in any of the current scientific controversies—for example, the existence of thresholds for carcinogenesis or the relevance of animal bioassay data based on Maximum Tolerated Dose for determining carcinogenic potential. Therefore, while this report assumes some familiarity with the governmental risk analysis and regulatory process, it does not assume a detailed technical knowledge of scientific matters such as human metabolism, cell dynamics, and statistical theory. It does, however, attempt to address whether certain issues in risk assessment and risk management involve policy rather than science, or that sometimes perplexing hybrid, “science policy”.

A challenge sometimes made to commentary by non-scientists on risk assessment and risk management issues is that they do not have the appropriate credentials for such commentary. We do not consider such criticism to be valid. If an issue goes beyond science and into policy, then it is more arguable that it is the non-scientists with economic and public policy analysis training who are better equipped to address it. We believe that the most sensible point of view is that framing the policy issues requires an intelligent dialogue and exchange of information between scientists and policy officials, with resolution of the policy issues ultimately being the province of the policy officials, and resolution of the science issues ultimately being the province of the scientists. Some issues, of course, may remain in the penumbra between policy and science, and would require close consultation between policy and science policy officials.

The debate over many of the issues contained in this report has been going on for over a decade now, and the volume of pertinent literature, both of a scientific and policy nature, is daunting. We have attempted to make this report as comprehensive as possible while keeping it to a manageable length. Accordingly, we have not attempted to provide the kind of extensive citations that would be familiar to those acquainted with that body of literature; instead, we have tried to limit citations to those that we believe are necessary for attribution, are very recent, or are not likely to be familiar to the usual audience. Regardless of whether supporting citations are provided, however, we do claim that all statements in the report have substantial support, and that the analysis is as forthright and unbiased as we could endeavor.

Finally, Federal Focus is solely responsible for the content and views expressed herein. No outside party has participated in the writing of this report, and it is not intended to represent the views of any particular outside party or governmental entity.