

file: Risk Policy

THE WHITE HOUSE
WASHINGTON

February 14, 1994

MEMORANDUM FOR CAROL RASCO

FROM: BRIAN BURKE

SUBJECT: 2-15 Meeting regarding EPA Cabinet Bill/Risk Assessment, Risk Management

The meeting on 2-15-94 will be chaired by Jack Quinn and is intended to strategize on where we go from here with the EPA Cabinet Bill and how to develop an administration risk policy. The EPA Cabinet Bill was essentially tabled by an amendment which would have required that EPA do risk and cost/benefit analysis for all of its actions. This is seen by many on the Hill, most States and industry as a worthwhile way to force EPA to set science based environmental priorities. Needless to say, the issue is far more complicated than the easy solution suggests. Everybody agrees that priorities must be set, that risk analysis must be made, and that cost is an issue. The devil is in the details.

In an effort to get in front of the issue, the Administration, led by Jack Gibbons and Sally Katzen, began working several months to develop the basic principles for an administration policy. I participated in those discussions. Beyond the basic principles, disagreement remains about the details of how risk management/risk assessment should be handled. The meeting tomorrow is in part to get this process back on track so that the administration can announce a policy and preempt future, randomly added, risk assessment amendments.

Attached to this memorandum is a copy of Sally's recent testimony on risk which (after extensive interagency review) represents the most complete statement of the administration's risk policy.

Statement of Sally Katzen
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
before the
Committee on Government Operations
Subcommittee on Environment, Energy and Natural Resources
Subcommittee on Legislation and National Security
United States House of Representatives

February 1, 1994

Introduction

Good morning Mr. Chairman and Members of the Subcommittees. I am the Administrator of the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget. OIRA has specified statutory responsibilities and is charged under various Executive Orders with the task of coordinating and reviewing Executive Branch regulatory policy matters.

I appreciate the opportunity to testify on the issue of risk analysis. It is an issue that is very important to the Administration, and to OIRA in particular.

The discussion of risk analysis is not new -- policy makers, scientists, economists, and students of public administration have debated various aspects of risk analysis for years. There is a substantial (and growing) body of literature on the subject, and over the last few years, risk analysis has received increasing attention and visibility and as a result is finally, in a sense, coming into its own. But despite the raised attention, there is still some confusion as to what risk analysis is all about, and certainly no agreement as to the role it should play in public policy decision-making, and specifically when, how, and by whom it should be used.

The concept of risk analysis appears to be relatively straightforward and simple, although its implementation can be quite complex and challenging. As you know, life is full of risks and those engaged in public policy (elected and appointed officials in both the legislative and executive branches) are often called upon to act to reduce those risks or minimize their adverse effects. Risk analysis is a way of organizing what we know about risk. To reduce a particular risk, there may be several courses of action; each course may present its own risks, and there is obviously the risk of doing nothing. Consider, for example, the concern about injuries resulting from automobile accidents that was the subject of public policy debates several years ago. Risk analysis provides a method of estimating the frequency with which such injuries occur and the relative effectiveness of seat belts and/or air bags in reducing the injuries sustained; it also provides a mechanism for estimating the relative costs of the possible alternatives -- both the direct costs and the possible indirect costs (e.g., some drivers may drive even faster on the assumption that they can do so safely with passive restraints, thereby increasing the risk of injury to persons and property). Clearly risk analysis does not itself determine the outcome -- in this case, what protections should be mandated. The selection of the appropriate risk management strategy is for the public policy decision-makers, but risk analysis is a useful tool for assembling and arraying the information, so that those decision-makers can make more informed decisions.

The above discussion also should make clear that risk analysis may be useful for a broad range of risks. Recently, the subject has been discussed primarily in the context of the work done by the Environmental Protection Agency. Yet, risk analysis applies to all agencies with missions to reduce hazards to human health, safety or the environment, including the Department of Energy and the Department of Defense, which must clean up contaminated

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sites; the Food and Drug Administration, charged with managing food safety and approving drug and medical devices; the Occupational Safety and Health Administration, the Consumer Product and Safety Administration, the National Highway Traffic and Safety Administration and many others.

Given the importance and the cross-cutting nature of the issue, the Executive Office of the President has sought to provide leadership in this area. I'll be focusing in this testimony on activities in which the White House is specifically involved. There are, however, many important activities at the various agencies. You will be hearing later this morning from Lynn Goldman, the Assistant Administrator at the Environmental Protection Agency and the Director of its Office of Prevention, Pesticides, and Toxic Substances, who will be providing information about some of the fine work EPA is doing in this field.

Background

The Clinton Administration is committed to a sound, effective regulatory policy, and it recognizes the importance of risk analysis in the regulatory decision-making process. The Executive Order on Regulatory Planning and Review (E.O. 12866), signed by the President on September 30, 1993, seeks to establish a regulatory policy that "works for [the American people], not against them." It sets forth principles and processes to promote a regulatory policy that is not pro-regulation or anti-regulation but smart regulation -- regulation that limits pollution, increases worker safety, discourages unfair business practices, and contributes in many other ways to a safer, healthier, more productive and equitable society, without creating undue burden, retarding innovation, reducing productivity, distorting incentives or adversely affecting living standards.

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In the section on regulatory principles, the Executive Order begins by requiring agencies to identify the problem that they intend to address as well as assess the significance of that problem. (Section 1(b)(1)) Of particular relevance here, the Order states "in setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risk posed by various substances or activities within its jurisdiction." (Section 1(b)(4)) In the section on planning, the Executive Order states that Federal agencies are to consider "how the action [they propose] will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency." (Section 4(c)(1)(d)) While risk analysis has been discussed and debated for years, there is still some confusion as to what risk analysis is all about, and certainly no agreement as to the role it should play in public policy decision-making, and specifically when, how, and by whom it should be used.

The Executive Order also emphasizes the importance of good data: "each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation." (Section 1(b)(7)) Risk analysis thus is only one tool -- but a very important tool -- in the regulatory tool kit; it is a mechanism to incorporate science into regulatory decision-making and a means for organizing scientific, technical, social and economic information in a way that enables policy makers to make informed choices.

Given the convergence of science and regulatory policy, Dr. John H. Gibbons, Assistant to the President for Science and Technology and the Director of the Office of Science and Technology Policy (OSTP), and I convened representatives of the White House policy offices and the regulatory agencies that regulate risk to discuss

this issue. The purpose of the meetings was to build consensus for a comprehensive and consistent approach to risk across agencies that address environmental, health and safety issues; our goal is to promote the development of consistent methodologies, where appropriate, and preventing gaps and/or duplication of efforts across agencies.

Our initiative was well received, and after several meetings we developed a basic framework, a preliminary structure of principles of risk analysis. Our approach can be divided into four areas:

Risk Assessment. The first step in risk analysis is to assemble some of the relevant data. Risk assessment is the term used for the process of describing or characterizing the nature and magnitude of the risk. It includes, for example, a measure (whether it be a point or a range) both of the toxicity of the substance and the anticipated exposures. Characterization of risk should be both qualitative and quantitative (i.e., both descriptive and mathematical).

Risk assessment -- even when it employs the best available evidence -- is not an exact or perfect science. There are many questions and uncertainties associated with the risk analysis process. Indeed, the literature is filled with debates on such technical issues as whether to extrapolate from lab animals to humans on the basis of body weight or surface area.

In addition, science does not have all of the answers; there are and will inevitably be -- no matter how much we learn -- gaps in scientific knowledge. It is essential, therefore, that when judgements and inferences are made to bridge these gaps, as they necessarily will be, they should be made explicit. There will also inevitably be uncertainties even about "scientific facts". Not only must risk managers be informed about the existence (and

magnitude) of the uncertainties that exist, they must also be informed when such factors as "conservative assumptions," "margins of safety," and "uncertainty factors" are incorporated in the analysis.

It is also important to separate the inferences grounded in the natural sciences, as well as the economic, technical, and behavioral sciences, from policy judgements (see "Risk Management" below). The former (the set of facts and inferences grounded in the sciences) should pass muster under peer review by those in the same discipline, who should have an opportunity for such review to ensure that the underlying work was done competently and that any assumptions made are reasonable. Public comment would also help to ensure that the highest professional standards are maintained.

Risk Management. Risk management is the process of weighing risk estimates with or against other key elements of public policy decisions, such as equity, quality of life, individual preferences, cost-effectiveness, and the distribution of costs and benefits. In other words, risk management is the process by which risk assessment data are augmented by analyses of other benefits (both direct and indirect, both quantifiable and non-quantifiable) associated with the selection or implementation of a risk management strategy, together with analyses of the costs (both direct and indirect, both quantifiable and non-quantifiable) associated with each strategy. These are the decisions that should be made by the elected and appointed officials charged with the responsibility (and accountable to the public) for public policy.

It is essential that those in public policy charged with risk management keep open the lines of communication with risk assessors to assure that risk assessments anticipate and address the widest range of risk-related issues that will be relevant to

the risk management decision. It is also essential for the risk managers to keep open the lines of communication with the public so that their perceptions can be incorporated into the decision-making process.

Risk Communication. The exchange of information about risks, and perceptions about risks, between the policy makers and the public is known as risk communication. When "experts" describe the risk, it is important to explain the basis for significant assumptions, data, models, and inferences used or relied upon; and to describe the extent and magnitude of significant uncertainties associated with the assessment or decision. Not only should risks be communicated accurately and objectively, but they should be communicated in a way that can be readily understood by the public in the context of other familiar risks.

The importance of communicating risks to the public is underscored by some studies that demonstrate little correlation between public perception and scientific judgements about the magnitudes of risks for a number of activities. Some have suggested that this is a function of media attention on certain risks that are more easily understood (and hence covered by the mass media) to the detriment of coverage of potentially more harmful, but more complicated, risks. Indeed, other studies show that when the public is provided with the relevant information in an understandable manner, their choices more closely parallel those of the "experts".

There are other possible explanations for the apparent divergence between "expert" and public perceptions. One is that the public's ranking of risks may reflect the incorporation of other or different values from those used by the "experts". For example, while it is widely accepted (and well publicized) that, on average, driving an automobile is more dangerous than flying some distance, many people choose to drive instead of fly because

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of an acute fear of air travel. Another explanation for the discrepancy may be the distinction between voluntary and involuntary risks. It may be that the public will react more adversely to the involuntary (if it is truly involuntary) risk of living next to a nuclear power plant (which has a relatively small health risk) than to the voluntary risk of smoking several packs of cigarettes a day (which is a well-documented high health risk). There is also the effect that the distribution of benefits may have; in the preceding example, most smokers say they enjoy smoking, whereas residents living next door to a power plant may not derive any benefit from their proximity to the site. In any event, given the different perspectives, it is important that risk communication truly be a two-way process.

The Setting of Priorities. Risk analysis provides an important input for the setting of priorities. It helps us allocate limited resources so they will have maximal impact -- in other words, so we can achieve the "biggest bang for the buck".

Accordingly, we believe that agencies should rank risks within their jurisdictions. When it is not feasible to do so with precision, the relevant decision-makers should attempt to group them in broad risk categories (e.g., high risk, moderate risk, and low risk).

As with risk management decisions, the setting of priorities should take into account the views of internal agency experts and a broad range of individuals in state and local governments, industry, academia and non-governmental organizations, as well as the public at large. Where possible, the relevant decision-makers (and again, these are the elected and appointed policy officers) should attempt to reflect consensus views in the setting of priorities and should attempt to coordinate risk reduction efforts wherever feasible.

Major Short-term Administration Objectives

Our intention is to continue the dialogue we began with the agencies and ultimately to produce a series of guidance memoranda beginning with a general statement of our basic approach and then subsequent memoranda as necessary addressing more specific issues of implementation. Like peeling layers of an onion, we intend to approach this issue step by step; we envision an evolving process, rather than a one-shot attempt to provide the Administration's definitive statement. We have chosen this course not only because of the number and complexity of risk analysis issues, but also because we perceive a need to develop a broad-based consensus, not only within the Executive Branch, but with those on Capitol Hill, State and local governments, business groups, and public interest and non-governmental groups. All of these stakeholders are affected and all can contribute to the process. Furthermore, risk analysis is an evolving process and we must retain sufficient flexibility to incorporate advances in thinking about the subject.

As we continue our work, our efforts will be focused through two particular activities on risk that are centered in the White House and that will be proceeding in parallel. First, the President recently signed Executive Order 12881 establishing the National Science and Technology Council (NSTC). Currently, OSTP is organizing an NSTC Subcommittee on Risk Assessment to evaluate the risk assessment aspects of risk analysis. This Subcommittee will examine the scientific issues associated with the evaluation of risk, including issues pertaining to cancer, noncancer, and ecological risk assessment methodologies in general. The Subcommittee will include most Federal agencies that regulate health, safety and environmental risks.

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Second, under E.O. 12866, the Administrator of OIRA chairs a Regulatory Working Group (RWG) consisting of representatives of the major regulatory agencies, the White House policy offices, and the Office of the Vice President. The Order charges the RWG with exploring the methods, efficacy and utility of comparative risk assessment. At the most recent meeting, we established a committee on risk analysis to be co-chaired by OSTP and EPA. One of the projects the committee will undertake is the compilation of statutes that in some way require regulation of risk. As you know, the manner in which statutes deal with risks varies widely -- some tolerate no risk, while others speak of "reasonable" or "not unreasonable" risk or "safe" or "significant" risk; some statutes preclude consideration of costs in risk management, while others use terms such as "affordability" or "feasibility" or "cost effectiveness". We will look for ways to work with the Congress to bring greater consistency to the process. The RWG committee will also explore the feasibility of comparing risks across agencies. We recognize that differences in available data, depth of knowledge, and the methods used to estimate risks make comparative risk analysis difficult. However, while it may be rough and inexact, the committee is charged with exploring whether such an undertaking would be useful.

In addition to these two parallel tracks, the Administration is also in discussions with various non-governmental organizations to participate in, be aware of, and promote risk-related projects. For example, we are working with Resources for the Future on issues related to managing risk and setting priorities. Through the Keystone Center, we hope to initiate a policy dialogue on risk analysis, a broad-based discussion on how risk is evaluated and used in making regulatory decisions. We recently participated in the Interbranch Forum on Risk at the Brookings Institution, a discussion of risk policy among the executive, legislative and judicial branches of government. And we are having discussions with the National Research Council

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about a potential study on the scientific aspects of risk based priority setting.

Conclusion

Risk analysis is an undeniably important part of regulatory decision-making because of its usefulness as a tool, albeit an imperfect one, for setting priorities and for selecting among alternative courses of action. The Administration has made significant progress in this area, through Executive Order No. 12866 and with our interagency consultations. Because the principles of risk analysis are applicable across agencies that regulate risks to health, safety and the environment, it is important that we develop a broad-based consensus. It is also important that we consult extensively with other interested entities, including the Congress (and specifically the Members of this Committee), State and local government officials, and representatives from businesses, public interest groups, and the public at large. I look forward to continuing our work with your help.

TO: John Podesta
FROM: Carol H. Rasco
SUBJ: Decision memo: Administration Position on Risk
Assessment, Management and Communication
DATE: January 11, 1994

file

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Regarding the above referenced memo, I wish to go on record as feeling the President should check that option which states no statement should be issued by anyone in the administration at this time. While I recognize the desire to have a position for the Brookings conference this week I believe the administration position should be to use that conference as one of the steps in our outreach process for further formulating/refining our position.

It seems to me we need to develop a more thoughtful although prompt process for engaging the stakeholders in this process for collecting their views. This process for finalizing the draft policy should take priority over rushing to reach a final substantive position.

Thank you.

The White House
Washington

FAX COVER SHEET

OFFICE OF DOMESTIC POLICY

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TO: CAROL RASCO

FAX No. 703 370 -1340

FROM: BRIAN PHONE: 202 -456-2995

DATE: JANUARY 10, 1994

NUMBER OF PAGES (Including cover sheet) TEN

COMMENTS:

I ENJOYED TODAY'S DPC MEETING.

THE WHITE HOUSE

WASHINGTON

January 10, 1994

MEMORANDUM FOR CAROL RASCO

FROM: BRIAN BURKE

SUBJECT: Comments on the Decision Memo--Administration
Position on Risk Assessment, Management and
Communication

As an initial comment, I am distressed that this significant policy issue was sent to the President for decision, without first having been circulated to the DPC, or any of the relevant agencies, most importantly the health agencies (e.g., ATSDR, NIOSH, NIH, etc.). The interagency/inner White House policy processes is ripe for review.

At the risk (no pun intended) of stating the obvious, the debate over comparative risk processes is a highly controversial debate within the private sector, government and in academia. In short, it is a debate over how we should decide governmental policy on the environment, and who should participate in those decisions. As a result of the controversial nature of risk assessment/risk management issues, I am uncomfortable with the attached decision memorandum for the following reasons.

- As mentioned above, the memo was not circulated to the White House offices participating in the White House risk policy development process and thus they did not have an opportunity to comment on this draft. Furthermore, I did not know that the memorandum was sent to the President. In this regard, the DPC is not alone.
- Generally, I do not think it is appropriate to embrace these principles of risk management or to publicly discuss them as the administration's substantive position on Risk Assessment at the 1/14/94 conference. The conference at issue, sponsored by the Brookings Institute, will be attended by members of the judicial branch and by members of Congress and, therefore, any administration position should be well formulated. The present substantive position remains just short of thoughtful completion.
- PAGE 1; Section A (2), should be deleted. It is incorrect to suggest that risk assessment is a purely factual matter. The suggestion is inconsistent with all of the prevailing thought on this issue. Additionally, the memorandum contradicts itself (on PAGE 1; Section B (1)), by stating as a principle of risk assessment, that "agencies should employ

the best objective evidence...including analysis of significant assumptions, data, methods, and uncertainties." If risk assessment were a purely factual matter, there would be no significant assumptions or uncertainties."

• Additionally, the memorandum does not clearly identify who would complete the risk analysis/assessments. As I read the memorandum, the analysis would be completed by the same agencies that regulate and by those that are regulated. This may be inappropriate and is the exact reason why Congress created independent health agencies such as the National Institute for Health (NIH), the Agency for Toxic Substances and Disease Registry (ATSDR), and the National Institute for Occupational Safety and Health (NIOSH).

• Finally, it is unclear whether the memorandum refers to qualitative risk assessment. The prevailing view is that qualitative risk assessment is not credible.

RECOMMENDATION

The administration needs to take the offensive on such issues as risk assessment and "takings." This is particularly clear after last weeks meeting with NGA staffers and Governors representatives who will continue to support the Johnston amendment¹ until they are convinced that the administration is serious about helping them to set priorities with respect to the environmental statutes. This problem of priority setting is bonded with the dreaded issue of unfunded mandates.

The administration needs to quickly develop a process for engaging the stakeholders to get their views. Certainly there will be a meaningful exchange at the upcoming Brookings Conference on Friday. In the morning I will be meeting with Keith Mason, Sally Katzen, OSTP and OEP to discuss how best to work with the states and locals. Our focus should be on a process for finalizing our present draft policy, as opposed to rushing to reach a final substantive position.

¹ The Johnston amendment was attached to the EPA cabinet bill and would require the agency to do risk assessment at every stage in its program implementation. The administration has opposed the amendment on the grounds that the cabinet bill is not a policy piece, and a legislative amendment on risk is not the best method to attack the issue of setting environmental priorities.

Brian: Please consult w/ anyone else necessary & let me know of any comment by close of business

Document No. 048149

WHITE HOUSE STAFFING MEMORANDUM

annex 1/10
DATE: January 8, 1994

ACTION/CONCURRENCE/COMMENT DUE BY: 1/11/94

Decision Memo--Administration Position on Risk Assessment,
SUBJECT: Management and Communication.

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	GRIFFIN	<input checked="" type="checkbox"/>	<input type="checkbox"/>
McLARTY	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RASTER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
NEED LADER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	QUINN	<input checked="" type="checkbox"/>	<input type="checkbox"/>
PANETTA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RASCO	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BAGGETT	<input type="checkbox"/>	<input type="checkbox"/>	RUBIN	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EMANUEL	<input type="checkbox"/>	<input type="checkbox"/>	SEGAL	<input type="checkbox"/>	<input type="checkbox"/>
GEARAN	<input type="checkbox"/>	<input type="checkbox"/>	SEIDMAN	<input type="checkbox"/>	<input type="checkbox"/>
GERGEN	<input type="checkbox"/>	<input type="checkbox"/>	STEPHANOPOULOS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GIBBONS	<input type="checkbox"/>	<input type="checkbox"/>	TYSON	<input checked="" type="checkbox"/>	<input type="checkbox"/>
HALE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	VARNEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
HERMAN	<input type="checkbox"/>	<input type="checkbox"/>	WATKINS	<input type="checkbox"/>	<input type="checkbox"/>
LAKE	<input type="checkbox"/>	<input type="checkbox"/>	WILLIAMS	<input type="checkbox"/>	<input type="checkbox"/>
LINDSEY	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
McGINTY	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
MYERS	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
NUSSBAUM	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

REMARKS: At 1/6/94 meeting, we agreed that Sally and Jack would lay out substantive position on Risk Assessment at 1/14/94 conference. They will then seek input from affected interests on substance of the position and how to implement appropriate risk assessment principles (E.O., memorandum).

Please provide comments to Todd Stern by Noon Tuesday 1/11/94 on substance.

RESPONSE: attachment so that Jack and Sally can prepare reports. Thanks

John D. Podesta
JOHN D. PODESTA
Assistant to the President
and Staff Secretary
Ext. 2702

THE WHITE HOUSE

WASHINGTON

DEC 23 1993

MEMORANDUM FOR THE PRESIDENT

FROM: John H. Gibbons *JHG*
Sally Katzen *SK*

SUBJECT: Decision Memo – Administration Position on Risk Assessment,
Management and Communication

BACKGROUND

How agencies assess and compare risks within their jurisdictions, set regulatory priorities, and communicate risks to the public has quickly moved to the center of public debate. Dozens of bills relating to these subjects were introduced in the last Congress and, with tough issues such as Superfund and the Occupational Safety and Health Act Reauthorization on the table, we can expect the interest in Congress to only increase in the new year.

Recognizing the need for a consistent Administration position regarding -- and the benefit of a uniform approach to -- risk analysis, we convened an Interagency Working Group on Risk Policy. The group includes representatives from the relevant White House policy offices as well as senior staff from agencies that regulate health, safety, and environmental risks.

PRINCIPLES ON RISK ASSESSMENT, MANAGEMENT AND COMMUNICATION

The first product of the Working Group is a set of principles (attached) intended to guide risk policy within the agencies that regulate risks. The principles, which are built upon and complementary to provisions of the Executive Order on Regulatory Planning and Review (E.O. No. 12866 signed on September 30), provide a basic framework for agencies to consistently assess, manage and communicate risks.

We believe these principles should be adopted by the Administration and promulgated to the agencies, either through an Executive Order or a memorandum signed by the two of us. Thereafter we would continue to work this issue with our next effort directed to compiling and comparing all the various statutes setting risk policy that govern Executive Branch agencies so that differences in standards can be assessed and any changes proposed. We would also continue to provide assistance through the Office of Information and Regulatory Affairs and the National Science and Technology Council to agencies engaged in risk analysis.

RECOMMENDATION

The principles should be embodied in an Executive Order on Risk Policy and the further work described above should be pursued.

DECISION

- ___ Prepare an Executive Order on Risk Policy based on the attached principles.

- ___ Issue a memorandum from Jack and Sally to agency heads stating the Administration's policy on risk based on the attached principles.

- ___ Do not issue a statement of Administration policy on risk at this time.

- ___ Let's discuss.

Principles for Risk Assessment, Management, and Communication

A. General

1. As stated in Executive Order No. 12866, "In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risk posed by various substances or activities within its jurisdiction." [Section 1(b)(4)] Further, in developing regulations, Federal agencies should consider "...how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency." [Section 4(c)(1)(D)]
2. In undertaking risk analysis, agencies should establish and maintain a clear distinction between purely factual aspects (risk assessment) and value judgements and other policy considerations (risk management).
3. The range of facts considered during the risk assessment phase should include those issues anticipated at the risk management phase. Anticipating these issues requires regular communication between risk assessors and risk managers.

B. Principles for Risk Assessment

1. Agencies should employ the best objective evidence concerning the relationship between hazardous events and their effects on health, safety, and the environment, including analysis of significant assumptions, data, methods, and uncertainties.
2. Policy judgements used in developing a risk assessment, such as "uncertainty factors," "conservative assumptions," and "margins of safety," should be stated explicitly.
3. The range of risks considered in risk assessments should be broad, extending beyond cancer risks.
4. Each risk assessment should include the following four parts:

- a. hazard assessments, which detail the intrinsic nature of the risk;
 - b. exposure assessments, which detail the conditions and expected behavioral patterns under which humans and other biological systems may be expected to encounter such hazards;
 - c. dose-response assessments, which evaluate the relationship between the dose of an agent administered or received and the incidence of an adverse health or ecological effect; and
 - d. risk characterizations, which integrate the results of the hazards, exposure, and dose-response assessments in a manner that can be readily understood in the context of other risks.
5. Risk assessments should be peer-reviewed and subject to public comment to ensure that the highest professional standards are maintained.
 6. Agencies should strive to adopt consistent approaches to assessing the risks posed by hazardous agents or events.

C. Principles for Risk Management

1. In developing risk management strategies, agencies should consider risk assessments augmented -- when appropriate -- by analyses of other benefits (both direct and indirect, both quantifiable and non-quantifiable) associated with the selection or implementation of a risk management strategy, together with analyses of the costs (both direct and indirect, both quantifiable and non-quantifiable) associated with each such strategy. In doing so, agencies should employ the best objective economic and policy analysis, and such analyses should include explanations of the significant assumptions, uncertainties and methods of data development.
2. In choosing among alternative approaches to reducing risk, agencies should ensure that actions taken to manage risk achieve their purpose in a manner that offers the greatest net improvement in total societal welfare, including health, safety and environmental quality.

3. Risk management decisions should be responsive to and consistent with statutory mandates and Administration priorities. In making risk management decisions, agencies should consider a broad range of relevant social and economic considerations, such as equity, quality of life, individual preferences, and the distribution of costs and benefits.

D. Principles for Risk Communication

1. Risk communication should be a two-way process involving the open exchange of information between policy makers and the public.
2. Risk assessments and risk management decisions should be communicated accurately and objectively to the public -- in a way that can be readily understood in the context of other familiar risks.
3. In communicating with the public, agencies should:
 - a. explain the basis for significant assumptions, data, models, and inferences used or relied upon in the assessment or decision;
 - b. describe the extent and magnitude of significant uncertainties associated with the assessment or decision;
 - c. make appropriate risk comparisons, taking into account, for example, public attitudes with respect to voluntary versus involuntary risks; and
 - d. provide timely, public access to relevant supporting documents and a reasonable opportunity for public comment.

E. Principles for Setting Risk-based Priorities

1. Agencies should seek to rank risks; where they cannot do so with precision, they should group them in broad risk-based priorities (e.g., high-risk, moderate-risk, low-risk).
2. The setting of priorities should take into account the views of both internal agency experts and a broad range of individuals in state and local government, industry, academia, and nongovernmental organizations, as well as concerned

citizens. Where possible, consensus views should be reflected in the setting of priorities.

3. Where possible, agencies should set priorities for managing risks so that those actions resulting in the greatest net improvement in societal welfare are taken first.
4. Agencies should attempt to coordinate risk reduction efforts wherever feasible and appropriate.

OFFICE OF DOMESTIC POLICY

THE WHITE HOUSE

CAROL H. RASCO
ASSISTANT TO THE PRESIDENT
FOR DOMESTIC POLICY

TO: _____

DRAFT RESPONSE FOR POTUS AND
FORWARD TO CHR BY: _____

DRAFT RESPONSE FOR CHR BY: _____

PLEASE REPLY DIRECTLY TO THE WRITER
(COPY TO CHR) BY: _____

PLEASE ADVISE BY: _____

LET'S DISCUSS: _____

FOR YOUR INFORMATION: _____

REPLY USING FORM CODE: _____

FILE: _____

SEND COPY TO (ORIGINAL TO CHR): _____

SCHEDULE ? : ACCEPT PENDING REGRET

DESIGNEE TO ATTEND: _____

REMARKS:

_____ *file: RISK (assessment?*
_____ *management?)*

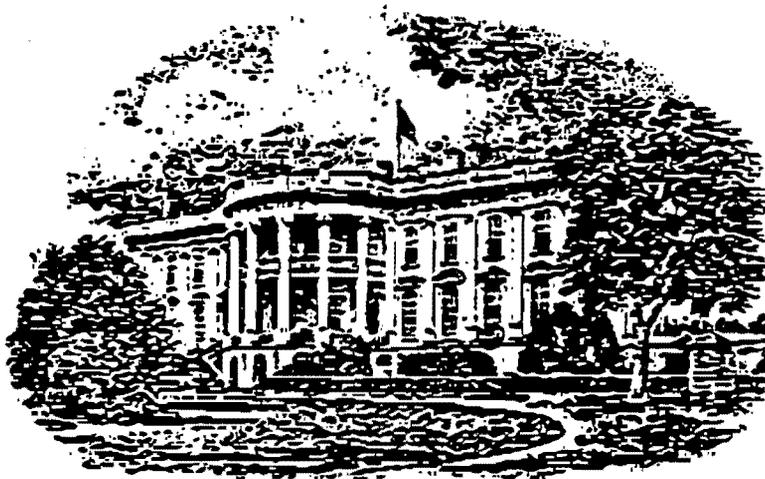
DATE: _____

TIME: _____

THE WHITE HOUSE

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WASHINGTON



FAX COVER SHEET

TO: CAROL RASCO

PHONE: () _____

FAX: () _____

FROM: BRIAN

PHONE: (202) 456- _____

CAROL; MARK HAS BEEN WORKING ON RISK ISSUES FOR MANY YEARS AND IS BY FAR THE MOST KNOWLEDGEABLE IN THE WHITE HOUSE. ATTACHED ARE HIS SUGGESTIONS FOR MODIFYING THE JOHNSTON AMENDMENT SO THAT IT IS ACCEPTABLE FROM THE ADMINISTRATIONS POINT OF VIEW AND CONSISTENT WITH WHAT THE HILL SEEKS TO ACCOMPLISH.

PAGES FOLLOWING COVER SHEET: _____

**JOHNSTON (AND LEVIN) AMENDMENT TO S. 171,
THE DEPARTMENT OF ENVIRONMENTAL PROTECTION ACT OF 1993**

At the appropriate place in the bill, insert the following:

"(a) In promulgating any final ~~a major~~ regulation relating to public health and safety or the environment after the date of enactment of this Act, the Secretary of the Environment shall publish in the Federal Register—

~~"(1) an qualitative or quantitative estimate, performed with as much specificity as practicable, of the risk to the public health and safety or the environment of individual members of the public addressed by the regulation and its effects on human health or the environment and the costs associated with implementation of, and compliance with, the regulation;~~

~~"(2) a comparative analysis comparison of the risk addressed by the regulation relative to other risks to which the public is exposed regulated under the Secretary's jurisdiction.~~

~~"(3) the Secretary's certification shall certify that—~~

~~"(A) the estimate under paragraph (1) and the analysis under paragraph (2) are based upon a scientific evaluation of the risk to the health and safety of individual members of the public and to human health or the environment and are supported by the best available scientific data;~~

~~"(B) the regulation will substantially advance the purpose of protecting the public health and safety or the environment against the specified identified risk in a fair and cost-effective manner; and~~

~~"(C) the regulation will produce benefits to the public health and safety or the environment that will justify the cost to the Government and the public of implementation of and compliance with the regulation.~~

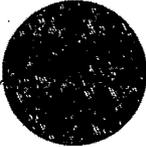
~~"(b) In the event that the Secretary cannot make the certification required under subsection (a), the Secretary shall report to Congress that such certification cannot be made and shall include a statement of the reasons therefor in such report and in the final regulation.~~

~~"(c) The certification actions required by this section shall not be construed to amend, modify or alter any statute and shall not be subject to judicial review. Nothing in this section shall be construed to grant a cause of action to any person."~~

~~We believe it would be preferable to replace (a)(2) with a comparative analysis of the risk with a statement regarding the value of comparing risks in setting broad regulatory priorities. Since this would be a generic statement, it would need to be included in a new section.~~

¹ A "major regulation" is defined here as a regulation that has "an annual effect on the economy of \$100 million or more." This definition is consistent with the term "significant regulatory action" used in Executive Order 12866.

THE WHITE HOUSE
OFFICE OF DOMESTIC POLICY



CAROL H. RASCO
Assistant to the President for Domestic Policy

To: _____

Draft response for POTUS
and forward to CHR by: _____

Draft response for CHR by: _____

Please reply directly to the writer
(copy to CHR) by: _____

Please advise by: _____

Let's discuss: _____

For your information: _____

Reply using form code: _____

File: _____

Send copy to (original to CHR): _____

Schedule ? : Accept Pending Regret

Designee to attend: _____

Remarks: _____



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APR 21 1994

THE WHITE HOUSE
WASHINGTON

April 19, 1994

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES
(See attached distribution list)

From: John H. Gibbons ^{JHG} Assistant to the President for Science and Technology
Robert M. Sussman, Deputy Administrator, U.S. Environmental Protection Agency

Subject: Formation of Interagency Committee on Risk Analysis

As you may know, last Fall the President signed Executive Order No. 12866 on Regulatory Planning and Review which established a Regulatory Working Group consisting of the Vice President, the heads of regulatory agencies, and senior White House officials. Within the Regulatory Working Group, we are organizing a Committee on Risk Analysis to evaluate issues and devise policy with respect to the use of risk analysis in regulatory decision-making processes. This Committee supersedes a previous interagency working group on risk policy co-chaired by John Gibbons and Sally Katzen, Administrator of OMB's Office of Information and Regulatory Affairs.

We are inviting you to designate a representative at the Assistant Secretary/Administrator level to the Committee. The Committee will engage in a range of activities in the risk area, including evaluating legislative proposals, seeking to ensure appropriate consistency in risk analysis across agencies, and examining broad agency policies and procedures. Risk issues within the domain of the Committee include health, safety, ecological, natural hazards, engineering, and other risks. The Committee will provide suggestions for improving federal policies to the Regulatory Working Group and will disseminate information to departments, agencies, and White House offices; the group will also interact with the National Science and Technology Council's Subcommittee on Risk Assessment, which is examining scientific aspects of risk analysis.

The first meeting of the Committee will take place on Monday, May 2, 1994, 3:00-4:30 p.m. in Room 476 of the Old Executive Office Building. A preliminary agenda is attached; please note that we have scheduled time for attendees to present any emerging risk issues of general interest in their agencies, and we will seek suggestions on activities the Committee should undertake. Committee members should come prepared to discuss examples of where risk assessment has been particularly helpful in policy decisions in your agency and where risk assessment would not have been helpful or appropriate.

**COMMITTEE ON RISK ANALYSIS
REGULATORY WORKING GROUP**

May 2, 1994, 3:00-4:30 p.m., OEOB Rm. 476

TENTATIVE AGENDA

- **Welcome and Introductions**
John H. Gibbons, Assistant to the President for Science and Technology
Robert M. Sussman, Deputy Administrator, U.S. Environmental Protection Agency

- **Political Context of Risk Issues**
White House Office of Legislative Affairs
EPA Office of Congressional Liaison and Legislative Affairs

- **Emerging Risk Issues of General Interest**
Group Discussion

- **Risk Analysis Background: Definitions, Policy Context, and Other Issues**

- **Discussion of Potential Committee Activities**
Group Discussion
Potential activities include:
 - Evaluate and compare the current use of risk analysis in making policy decisions across agencies.
 - Identify and address key, high-leverage, cross-cutting issues on specific risks of interagency concern.
 - Develop broad principles for risk assessment, management, and communication.
 - Examine the utility of comparative risk analysis as a tool in setting priorities.
 - Develop criteria for determining when to undertake risk analysis and what level of precision is appropriate.
 - Evaluate statutory provisions that require or limit the use of risk analysis and promote consistency across statutes.

- **Review of Action Items and Next Meeting**
Mark Schaefer, Assistant Director, Office of Science and Technology Policy

Please contact Christy Halvorson at OSTP (phone: 202-456-6075; fax: 202-456-6025) by Thursday, April 28, with the full name and date of birth of your agency's designee to this Committee so that he or she can be cleared into the building for the meeting.

If you have any questions about the Committee, please contact Mark Schaefer (202-456-6202), OSTP's Assistant Director for Environment, or William Farland (202-260-7315), Director of EPA's Office of Health and Environmental Assessments.

DISTRIBUTION

Departments and Agencies

Mike Espy, Secretary, Department of Agriculture (F: 202-720-5437)
Ronald Brown, Secretary, Department of Commerce (F: 202-482-4576)
Jim Baker, Administrator, National Oceanic and Atmospheric Administration (F: 202-408-9674)
William Perry, Secretary, Department of Defense (F: 703-697-9080)
Hazel O'Leary, Secretary, Department of Energy (F: 202-586-7644)
Donna Shalala, Secretary, Department of Health and Human Services (F: 202-690-7595)
David Kessler, Commissioner, Food and Drug Administration (F: 301-443-3100)
Henry Cisneros, Secretary, Department of Housing and Urban Development (F: 202-708-2476)
Bruce Babbitt, Secretary, Department of the Interior (F: 202-208-6956)
Janet Reno, Attorney General, Department of Justice (F: 202-514-4371)
Robert Reich, Secretary, Department of Labor (F: 202-219-7659)
Joseph Dear, Administrator, Occupational Safety and Health Administration (F: 202-219-6064)
Warren Christopher, Secretary, Department of State (F: 202-647-0122)
Federico Peña, Secretary, Department of Transportation (F: 202-366-7202)
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Ann Brown, Chair, Consumer Product Safety Commission (F: 301-504-0768)
Carol Browner, Administrator, Environmental Protection Agency (F: 202-260-0279)
James Lee Witt, Director, Federal Emergency Management Agency (F: 202-646-3930)
Neal Lane, Director, National Science Foundation (F: 202-357-9725)
Ivan Selin, Chair, Nuclear Regulatory Commission (F: 301-504-1757)

White House Offices

Laura D'Andrea Tyson, Chair, Council of Economic Advisors
Carol Rasco, Chair, Domestic Policy Council
Robert Rubin, Chair, National Economic Council
Kathleen McGinty, Director, Office of Environmental Policy
Jack Quinn, Chief of Staff, Office of the Vice President

cc:

Sally Katzen, Administrator, Office of Information and Regulatory Affairs, OMB



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

File: RISKS

AUG 10 REC'D

TRANSMISSION NUMBER: 202/395-5836
VERIFICATION NUMBER: 202/395-6827

ENVIRONMENT BRANCH
ROOM 8222
NEW EXECUTIVE OFFICE BLDG.

	Name	Fax #
To:	Carol Rasco	x62878
From:	Rob Fairweather, Chief, Environment Br./OMB	
Message:	T. J. Glauthier asked me to send you a draft of the talking points for Chief of Staff Panetta's phone call to Representative Condit concerning the Representative's risk amendment to the House Agriculture Reorganization bill. As the intention is for the call to be placed tomorrow, we need comments ASAP. Please fax comments to me at 395-5836 or have someone call me at 395-6827. If you would like to speak to T.J. directly, he can be reached at 395-4561.	

Number of Pages to Follow: 1

Date: August 10, 1994

Time: 5:45PM

Draft

**Talking Points for Leon Panetta Phone Call to Congressman Condit re: Risk
August 10, 1994**

1. **HR 3171, the USDA reorganization bill, is important to the Administration. We want to resolve the risk issues to enable passage of bill.***

(*We're not opposed to risk amendments per se, but it has to be done in a way that can improve the process without unintended consequences and gridlock.)
2. **Sally Katzen called you recently to underscore this message and to tell you we appreciate your working with the "Group of 6 Committee Chairs" to resolve this (Dingell, Waxman, Minetta, Studds, Brown, Miller).**
3. **You told her that, while you had earlier agreed to the version developed by the "Group of 6," the activity at the Subcommittee on Science and Technology and on the floor (the amendments to Klein bill and to Environmental Technology bill) made the Republicans in your coalition urge you to hold to your original position.**
4. **We know that you do not want to embarrass the President; you've said you would work with us.**
5. **We need you to work with the "Group of 6" Chairmen in order to go forward with some joint position on risk and pass our USDA Reorganization bill.**

DRAFT

1616
RISK MEETING

Date/Time/Room [To be determined]

AGENDA

1. Background and update
2. Discussion of decisions:

Decision I:

Agree that legislation is appropriate -- either as an amendment to an existing piece of legislation or as a stand-alone bill.

- PROs:
- An opportunity to exercise leadership and get credit for our efforts. Moves Administration from defensive, reactive posture to one of leadership.
 - A chance to clear the air and enable health, safety, and environmental legislation to move along.

- CONS:
- Departs from our position that this is a management matter within the prerogative of the President.
 - Reduces our ability to control the outcome of this issue.

Agree _____

Disagree _____

Decision II:

If Decision I is accepted, agree to government-wide legislation or (boilerplate to be used for any/all agency and/or bill by bill that risk amendment is attached to), rather than agency-by-agency legislation.

- PROs:
- The issue could be resolved once and for all.
 - The legislation would necessarily be at a level of generality that would not be prescriptive for any agency.

- CONS:
- Departments/agencies vary widely, and we would be precluded from tailoring requirements to fit each situation.
 - Unforeseen results of legislation would be Executive branch-wide.

• It would involve a number of constituencies (labor unions, health groups, etc. in addition to the environmentalists), making the process of reaching agreement more difficult. In addition, we would have to get the commitment of key Republicans to agree to not offer any more risk amendments this year.

Agree _____

Disagree _____

Decision III:

Agree to endorse specific statutory language rather than general principles. (Principles previously circulated and two approaches to specific statutory language -- [A] is Johnston II (Safe Drinking Water); [B] is Committee Chairs.)

PROs:

- Gives greater certainty to Administration position.
- Avoids general language that can produce mixed signals.
- Provides Administration with something concrete to point to when responding to press and State and local groups.

CONs:

- Provides less flexibility to respond to events.
- May be viewed as our picking sides on this issue.

Agree _____

Disagree _____

Decision IV:

Agree to use Johnston II as the starting point rather than the Committee Chair draft. [Primarily political rather than substantive issue.]

PROs: • Senate voted twice for Johnston; he thinks it's his issue.

CONs: • The Chairs will likely consider this approach a breach of faith and as seriously undercutting their efforts.

Agree _____

Disagree _____

Purpose: To require risk assessment and cost-benefit analysis regarding major human health or environmental regulations promulgated by the Environmental Protection Agency.

IN THE SENATE OF THE UNITED STATES 103rd Cong., 2nd Session
S. 2019

An original bill to reauthorize and amend title XIV of the Public Health Service Act (commonly known as the "Safe Drinking Water Act"), and for other purposes.

() Referred to the Committee on _____ and
ordered to be printed

() Ordered to lie on the table and to be printed

Intended to be proposed by Mr. JOHNSTON

Viz:

At the appropriate place in the bill, add a new section as follows:

Sec. _____ (a) REQUIREMENT.--Except as provided in subsection (b), in promulgating any proposed or final major regulation relating to human health or the environment, the Administrator of the Environmental Protection Agency shall publish in the Federal Register along with the regulation a clear and concise statement that--

(1) describes and, to the extent practicable, quantifies the risks to human health or the environment to be addressed by the regulation (including, where applicable and practicable, the human health risks to significant subpopulations who are disproportionately exposed or particularly sensitive);

(2) compares the human health or environmental risks to be addressed by the regulation to other similar risks chosen by the Administrator, including within the jurisdiction of the agency. In stating comparisons,

the Administrator shall identify relevant distinctions among categories of risks and limitations to comparisons;

~~(A) at least three other risks regulated by the Environmental Protection Agency or another federal agency; and~~

~~(B) at least three other risks that are not directly regulated by the federal government;~~

(3) estimates--

(A) the costs to the United States Government, state and local governments, and the private sector of implementing and complying with the regulation; and

(B) the benefits of the regulation; including both quantifiable measures of costs and benefits, to the fullest extent that they can be estimated, and qualitative measures that are difficult to quantify; and

(4) contains a ~~statement signed certification~~ signed by the Administrator that:

(A) the analyses performed under subsection

(a)(1) through (a)(3) are based on the best reasonably obtainable scientific information;

(B) the regulation is likely to significantly reduce the human health or environmental risks to be addressed;

(C) there is no regulatory alternative that is allowed by the statute under which the regulation is promulgated and that would achieve an equivalent reduction in risk in a more cost-effective manner, along with a brief explanation of why other such regulatory alternatives that were considered by the Administrator were found to be less cost-effective; and

(D) the regulation is likely to produce benefits to human health or the environment that will justify the costs to the United States Government, state and local governments, and the private sector of implementing and complying with the regulation.

~~(E) or the reasons why (a)-(d) above cannot be affirmed.~~

(b) SUBSTANTIALLY SIMILAR FINAL REGULATIONS.--If the Administrator determines that a final major regulation is substantially similar to the proposed version of the regulation with respect to each of the matters referred to in subsection (a), the Administrator may publish in the Federal Register a reference to the statement published under subsection (a) for the proposed regulation in lieu of publishing a new statement for the final regulation.

~~(c) REPORT.--If the Administrator cannot certify with respect to one or more of the matters addressed in subsection (a)(4), the Administrator shall identify those matters for which certification cannot be made, and shall include a statement of the reasons therefor in the Federal Register along with the regulation. Not later than March 1 of each year, the Administrator shall submit a report to Congress identifying those major regulations promulgated during the previous calendar year for which complete certification was not made, and summarizing the reasons therefor.~~

(d) OTHER REQUIREMENTS.--Nothing in this section affects any other provision of federal law, or changes the factors that the Administrator is authorized to consider in promulgating a regulation pursuant to any statute, or shall delay any action required to meet a deadline imposed by statute or a court.

(e) JUDICIAL REVIEW.--Nothing in this section creates any right to judicial or administrative review, nor creates any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or

instrumentalities, its officers or employees, or any other person. If a major regulation is subject to judicial or administrative review under other provision of law, the adequacy of the certification prepared pursuant to this section, and any alleged failure to comply with this section, may not be used as grounds for affecting or invalidating such major regulation, although the statements and information prepared pursuant to this section, including statements contained in the certification, maybe considered as part of the record for judicial or administrative review conducted under such other provision of law.

(f) DEFINITION OF MAJOR REGULATION.--For purposes of this section, "major regulation" means a regulation that the Administrator determines may have an effect on the economy of \$100,000,000 or more in any one year.

(g) EFFECTIVE DATE.--This section shall take effect 180 days after the date of enactment of this Act.

SEC. PROMOTING SOUND SCIENCE IN REGULATORY ANALYSIS

(a) Functions.--The Secretary shall coordinate among the various agencies within the Department the preparation, publication, and dissemination of the information required by this section.

(b) In General.--Effective six months after the enactment of this Act, each proposed major regulation relating to the public health, public safety, or the environment that is promulgated by the Department shall include, when published in the Federal Register, ~~a description of the procedure used to prepare the analysis in support of the regulation, including any methods used to evaluate~~ a clear and concise estimate of --

- (1) the reduction of risks to the health or the safety of individuals, or the reduction of risks to the environment;
- (2) the other benefits of the regulation in improving public health, public safety or the environment;
- (3) the costs associated with implementation of, and compliance with, the regulation; and
- (4) other options to the regulation that were considered, including the reduction or prevention of any such risks, such benefits, and such costs associated with such options.

(c) Construction.--This section shall not be construed to amend, modify, or alter any other provision of this Act or any other statute, or to justify delaying the promulgation or implementation of regulations mandated by statute or judicial order. This section shall not be construed to grant a cause of action to any person. Any alleged failure to comply with this section may not be used as a ground for

modifying or invalidating any agency action.

(d) Definition.--As used in this section, the term "major regulation" means any regulation that is likely to have annual impact on the economy of \$100 million in 1994 dollars.

(e) Contact Person.--The Secretary shall designate a contact person for responding to public inquiries regarding actions under this section.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

JUL 26 1991

Carol
SET UP MEETING
Carol
LEON

MEMORANDUM FOR THE CHIEF OF STAFF
FROM SALLY KATZEN *Sally*
SUBJECT MEETING ON COST-BENEFIT/RISK ANALYSIS

A few weeks ago, we had scheduled a meeting of principals on cost-benefit/risk analysis which was postponed because you and Secretary Espy were to accompany the President to Georgia that afternoon.

Since then, we have been in productive discussions with the six Committee Chairmen on the Condit Amendment to the USDA Reorganization bill.

The Klein bill, which was an effort by Science and Technology to head off a Johnston Amendment-type approach, was marked up last week. Unfortunately, what could have been a low-key, research-oriented focus on risk assessment methodology (as contrasted with risk management principles) attracted a number of highly undesirable amendments.

We have heard from several staff members on the Hill who say they are hearing mixed messages from EPA and EOP, as well as within EOP.

All of the above reinforces my strong suggestion that we convene as soon as possible the meeting of principals to settle on an Administration position on cost-benefit/risk analysis so that we can carry a single message to the Hill.

Attached is a draft agenda for such a meeting. The participants would include Jack Quinn, Bob Rubin, Carol Rasco, Laura Tyson (Joe Stiglitz), Katie McGinty, Jack Gibbons, Christine Varney, TJ, and myself, along with Secretaries Espy, Reich, Babbitt, Pena, and Administrator Browner. (Treasury may also have an interest, as might Commerce.)

I will be happy to do whatever you would like to make this happen. Thanks.

DRAFT

RISK MEETING
Date/Time/Room [To be determined]
AGENDA

1. Background and update
2. Discussion of decisions:

Decision I:

Agree that legislation is appropriate -- either as an amendment to an existing piece of legislation or as a stand-alone bill.

- PROs:
- An opportunity to exercise leadership and get credit for our efforts.
 - A chance to clear the air and enable health, safety, and environmental legislation to move along.

- CONS:
- Departs from our position that this is a management matter within the prerogative of the President.
 - Reduces our ability to control the outcome of this issue.

Agree _____

Disagree _____

Decision II:

If Decision I is accepted, agree to government-wide legislation rather than agency-by-agency legislation.

- PROs:
- The issue could be resolved once and for all.
 - The legislation would necessarily be at a level of generality that would not be prescriptive for any agency.

- CONS:
- Departments/agencies vary widely, and we would be precluded from tailoring requirements to fit each situation.
 - It would involve a number of constituencies (labor unions, health groups, etc. in addition to the environmentalists), making the process of reaching agreement more difficult.

Agree _____

Disagree _____

Decision III:

Agree to endorse specific statutory language rather than general principles. (Principles previously circulated and two approaches to specific statutory language -- [A] is Johnston II (Safe Drinking Water); [B] is Committee Chairmen.)

- PROs: • Gives greater certainty to Administration position.
- Avoids general language that can produce mixed signals.
- CONs: • Provides less flexibility to respond to events.
- May be viewed as our picking sides on this issue.

Agree _____

Disagree _____

Decision IV:

Agree to speak with a single voice, coordinating and clearing all comments, responses to questions, etc. through the White House.

- PROs: • Avoids mixed signals and misunderstandings.
- CONs: • Departments/agencies vary widely, and each has a different perspective and special relationship with Congressional Committees.

Agree _____

Disagree _____

THE WHITE HOUSE
WASHINGTON

MEMORANDUM FOR SYLVIA PANETTA

FROM: Carol H. Rasco *CHR*
SUBJ: Meeting requested by Leon Panetta
DATE: July 24, 1994

Leon recently returned the attached memo asking that we discuss the matter further. I have talked to Paul and after August 1 when some of his assigned legislation and the initial inventory of urban programs/policies is due as requested by Bob Rubin and myself, Paul is available to take on this task. However, Paul and I do think we need to meet with Leon briefly on the matter. We would prefer the meeting to be no earlier than the week of August 1 if that is agreeable to Leon.

Pat Romani in my office (456-2216) will be happy to work with you on scheduling this meeting.

Thank you.

cc: Paul Weinstein
Pat Romani

EXECUTIVE OFFICE OF THE PRESIDENT

22-Jul-1994 02:09pm

TO: Carol H. Rasco

FROM: Paul J. Weinstein, Jr
Domestic Policy Council

SUBJECT: Panetta Memo on Unfunded Mandates etc.

I read with considerable interest the Panetta memorandum on Unfunded Mandates, Cost-Benefit, Takings, etc.

I am not quite sure what this is all about. I guess Sally Katzen decided she doesn't want to deal with this issue any more.

Obviously, if you want me to take this on, I will. I think after next week, I will have some time to start putting together an options memo. However, the EZ/EC, CDBFI implementation, and this whole urban development issue will continue to require a lot of my time. I will however make time. Unfunded Mandates and Waivers are already part of my regular work load.

I would only raise a couple of concerns. First, it was my understanding that the Vice President's staff was the overall lead on these issues, since POTUS designated the VP as head of the regulatory council. Along those lines, it was my understanding that Linda Lance was to be the lead on Cost-Benefit and Takings (I have sort of been the main person along with Sally on Unfunded Mandates). I assume therefore, that the VP Office is OK with this proposal.

Second, I must admit that I have only a cursory background on cost-benefit and takings. These are actually different issues. Unfunded mandates is a reinventing government/federalism issue that falls within the purview of the DPC. Takings and Cost-Benefit are regulatory issues relating more to the private sector.

My recommendation would be that I would work closely with Linda Lance on an options memo. Just let me start it after August 1, when you have asked the urban document to be completed.