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An Analysis of the Government's Proposed Risk Assessment Guidelines

Robert Hahn and Robert Litan [*]

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Executive Summary

This paper critically reviews the government's proposed risk assessment guidelines. While we believe that such guidelines may be helpful, we make two recommendations that could improve their effectiveness: first, that agencies prepare a Risk Assessment Summary and that OMB summarize the degree of compliance with its risk assessment guidelines; second, that OMB consider adding a credible enforcement mechanism to the proposed guidelines. We also suggest that Congress may want to consider endorsing the use of risk assessment guidelines.

Establishing guidelines to help ensure the quality of risk assessments is potentially a useful exercise. The Office of Management and Budget deserves to be commended for its efforts to establish such guidelines. At the same time, scholars should take seriously the OMB's invitation to provide feedback on how such guidelines could be improved.

An Analysis of the Government's Proposed Risk Assessment Guidelines

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1. Introduction

The Office of Management and Budget (OMB), in consultation with the White House Office of Science and Technology Policy, has recently released a Proposed Risk Assessment Bulletin. This bulletin provides technical guidelines for risk assessments that are done by the federal government.

Risk assessments are an important tool for ranking the risks of different kinds of activities and helping to set priorities. These assessments can also serve as a basis for informing the public about the likely magnitude of different kinds of risks, such as being struck by lightning or getting hit by a car when crossing the street.

Risk assessments are sometimes used to help determine whether a particular risk should be reduced and, if so, to determine an appropriate standard. They can also be used as a part of cost-benefit analysis, which then is often used to determine an appropriate standard or approach for regulating.

The U.S. government has been doing risk assessment on a wide range of activities for some time. For example, the government assesses risks from consumer products, workplace hazards, drugs, environmental pollution, and nuclear energy. Based on those assessments, the government sometimes decides to act, as in the case of educating the public on the adverse health impacts of smoking.

Guidance on risk assessment provided by an oversight agency, such as OMB, can potentially serve several useful functions. First, it can define standards for the agencies who have responsibility for doing risk assessments. Second, it can inform the public and interested parties about what should be included in a risk assessment and the magnitude of various risks, thus enhancing accountability. Third, it can help to improve the quality of a risk assessment by helping to ensure that appropriate standards for carrying out an assessment will be met.

The purpose of this paper is to provide a brief analysis of OMB's Proposed Risk Assessment Bulletin.[1] We make three key points. First, it would be useful to have some kind of scorecard, or Risk Assessment Summary, that summarizes what is included in each risk assessment. It would also be useful to have a scorecard that provides an overall evaluation of risk assessments in a given year and over time. Second, we should not assume that issuance of guidelines will necessarily help improve the quality of risk assessments. We provide summary data on regulatory impact assessments, some of which include risk analyses, to suggest that economic guidelines may not have had an impact on the quality of analysis. Arguing by analogy, we are not optimistic that this proposed Risk Assessment Bulletin will necessarily have much impact. Third, in order for such guidance to have a significant impact, some enforcement mechanism is probably needed.

2. Summary of Draft Risk Assessment

The risk assessment guidelines aim to improve the technical quality and objectivity of risk assessments prepared by the federal regulatory agencies.[2] It applies to "all publicly available agency risk assessments."[3] Wisely, the guidance would allow the level of effort for different types of risk assessments to differ.[4] At the same time, "…it is expected that every risk assessment shall describe the data, methods, and assumptions with a high degree of transparency; shall identify key scientific limitations and uncertainties; and shall place the risk in perspective/context with other risks familiar to the target audience. Similarly, every quantitative risk assessment should provide a range of plausible risk estimates, when there is scientific uncertainty or variability."[5]

[1] See Office of Management and Budget (2006). In this paper, we use the phrases risk assessment guidelines and proposed Risk Assessment Bulletin interchangeably.
[2] Our aim is not to critique specific guidelines here, though they do have some problems both in terms of their specific application and general application. For example, we think that more attention might have been paid to assessing risk qualitatively, which may be a key component of assessments for the Department of Homeland Security. For comments that make a similar point and also address other technical issues, see Farrow (2006).
[3] Office of Management and Budget (2006), p. 9.
[4] The Bulletin states as one of its goals that "The level of effort put into the risk assessment shall be commensurate with the importance of the risk assessment." See Office of Management and Budget (2006), p. 21.
[5] Office of Management and Budget (2006), p. 9.

The guidelines lay out several "aspirational" goals related to problem formulation, completeness of the assessment, expenditure of effort, expenditure of resources, peer review and public participation.

Section IV specifies a number of standards, including:

1. Standards Relating to Informational Needs and Objectives;
2. Standards Relating to Scope;
3. Standards Related to Characterization of Risk;
4. Standards Related to Objectivity;
5. Standards Related to Critical Assumptions;
6. Standards Related to the Executive Summary; and
7. Standards Related to Regulatory Analysis

Section V defines special standards for influential risk assessments. An influential risk assessment is defined as "a risk assessment the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions."[6]

The special standards include the following:

1. Standard for Reproducibility;
2. Standard for Comparison to Other Results;
3. Standard for Presentation of Numerical Estimates;
4. Standard for Characterizing Uncertainty;
5. Standard for Characterizing Results;
6. Standard for Characterizing Variability;
7. Standard for Characterizing Human Health Effects;
8. Standard for Discussing Scientific Limitations; and a

[6] Office of Management and Budget (2006), p. 9.

9. Standard for Addressing Significant Comments[7]

Among other things, influential risk assessments would need to be "capable of being substantially reproduced."[8] This is a fairly high threshold, and is not always met in academic work.[9] We think it is important for assessments that could have a substantial public policy impact.

3. Analysis of the Proposed Guidelines

OMB appropriately highlights the importance of the executive summary. We would go further, however, and suggest that OMB adopt a Risk Assessment Summary (RAS) that is standardized. We provide an illustrative example of such a summary in Table 1. The RAS is similar to the Regulatory Impact Summary we have suggested in previous submissions to OMB.[10] We recognize that specific kinds of risk assessments may have particular characteristics that may not easily fit in the RAS. Where appropriate, these could be noted in a separate executive summary. The purpose of the RAS is to standardize the presentation of key issues that are common to all government risk assessments, or at least to those risk assessments that are routinely reviewed by OMB.

The RAS could be used to provide a summary of the risk assessments that have been done in a given year and over time. The government could tally up the relevant information and present that information in a different type of scorecard, which could be a summary table. This information could be useful in providing a preliminary assessment of compliance with the risk assessment guidelines.[11] Such scorecards have the strength that they can provide some objective measures of compliance. A risk assessment that performs well on a wide variety of objective measures need not be a good risk assessment; however, a risk assessment that generally scores

[7] Office of Management and Budget (2006), pp. 16-20.
[8] Office of Management and Budget (2006), p. 16.
[9] Errors in published papers are probably widespread. In the early 1980s, a now-famous study requested the data used in every published paper with statistical analyses published in *The Journal of Money, Credit and Banking*, a leading economics journal. The study authors found errors in nearly every paper that were sufficiently serious that the results could not easily be replicated Dewald, Thursby, and Anderson (1986).
[10] See, for example, Hahn, Litan, and Malik (2005) and Hahn and Sunstein (2002), p. 1519.
[11] See, for example, Hahn (1996), p. 213, Table 10-1.

poorly is likely to have some problems.[12] The reason that a risk assessment that scores well need not be good is that objective scores need not always correlate with more subjective measures of quality—for example, whether the risk assessor chose the correct model and estimated it properly, or whether the data meet particular standards.

The preceding discussion leads to our first recommendation:

Recommendation 1: OMB should require that agencies fill out a Risk Assessment Summary, or RAS, for each risk assessment. OMB should then summarize the results of those Risk Assessment Summaries, and any other pertinent information, in an annual summary of risk assessments.

A key benefit of the OMB summary would be to help agencies, along with other interested parties, get a sense of whether the guidelines are making any difference at all.[13]

The issue of whether the guidelines will actually make a difference is an important one. In general, we should not assume that the simple issuance of guidelines would necessarily help improve the quality of government risk assessments, though it may. Other related work suggests that guidelines may not have made much of a difference in improving regulatory impact analyses done by the government or specific cost-effectiveness analyses done by scholars in published journals.[14] Indeed, there is evidence suggesting that regulatory impact analyses are not done well in the United States and Europe.[15]

An illustration of some of the potential problems with regulatory impact analyses, of which risk assessment is often an important part, is shown in Figure 1. The figure is based on a sample of 74 environmental regulations, spanning the Reagan, Clinton and first Bush administrations. Hahn and Dudley (2004) find a significant percentage of the analyses in all three administrations do not provide some very basic economic information, such as information on net benefits and policy alternatives. For example, 69 percent of the analyses in the sample failed to provide any quantitative information on net benefits. A little over half of the analyses quantified at least some benefits of policy alternatives. The authors also find no evidence that

[12] For a critique of scorecards in the context of regulatory impact analyses, see generally Parker, (2003); for an analysis of how scorecards contribute to our knowledge base, see Hahn (2004).

[13] One way of addressing that particular issue is to analyze risk assessment before and after the guidelines were issued.

[14] For a discussion of the former, see Hahn and Dudley (2004); for a discussion of the latter, see Hahn, Kosec, Neumann, and Wallsten (2005).

[15] See Hahn (2006) and Renda (2006).

these analyses are getting better over time or that economic guidelines had any impact. The concern here is that the risk assessment guidelines may not have much of an effect in practice, and this would be an unfortunate result.[16]

We think the guidelines are not likely to have a marked impact on the quality of government risk assessments unless there is some credible enforcement mechanism. Agencies will not generally spend additional resources to improve their risk assessments unless they have an incentive to do so. There are several such mechanisms that OMB might consider, including budgetary incentives and judicial review. In addition, Congress may want to consider codifying some requirements related to risk assessment.

This leads to our second recommendation:

Recommendation 2: OMB should consider a variety of credible enforcement mechanisms if it is interested in having agencies comply with the risk assessment guidelines.

We do not recommend a specific mechanism because we have not given adequate thought to the possible costs and benefits of various mechanisms. We do, however, believe that without such a credible enforcement mechanism, the current effectiveness of the current proposal is likely to be limited. Still, the guidelines could represent an important first step in getting government agencies to improve their risk assessments of important issues.

4. Conclusion

We think that government risk assessments are a very important part of public policy. Large amounts of resources are often at stake in decisions involving risk assessment and risk management.

This paper critically reviews the government's proposed risk assessment guidelines. While we believe that such guidelines may be helpful, we make two recommendations that could improve their effectiveness: first, that agencies prepare a Risk Assessment Summary and that OMB summarize the degree of compliance with its risk assessment guidelines; second, that

[16] Even if agencies strictly adhered to the proposed risk assessment guidelines, the risk assessments may still not be done well. Suppose, for example, the quality of the data underlying the risk assessments was not as good as it could be. In principle, this problem could be remedied by imposing data quality standards, but it is difficult to address in practice.

OMB consider adding a credible enforcement mechanism to the proposed guidelines. We also suggest that Congress may want to consider endorsing the use of certain risk assessment guidelines.

Establishing guidelines to help ensure the quality of risk assessments is potentially a useful exercise. The OMB deserves to be commended for its efforts to establish such guidelines. At the same time, scholars should take seriously the OMB's invitation to provide feedback on how such guidelines could be improved.

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Table 1
Risk Assessment Summary

I. BACKGROUND ON RISK ASSESSMENT AND AGENCY	
AGENCY AND DEPARTMENT/OFFICE NAME	
CONTACT PERSON	TELEPHONE NUMBER
TITLE OF THE RISK ASSESSMENT	
MAIN WEB ADDRESS(ES) FOR ANALYSIS AND SUPPORTING DOCUMENTS	
STATUTORY AUTHORITY FOR THE ASSESSMENT	WHY ASSESSMENT WAS DONE
BRIEF DESCRIPTION OF OBJECTIVES OF THE ASSESSMENT AND TARGET AUDIENCE	
SUMMARY OF KEY FINDINGS	
PRECISE RISKS MEASURED	
PUT RISK IN CONTEXT OF OTHER FAMILIAR RISKS FOR TARGET AUDIENCE	
KEY SCIENTIFIC LIMITATIONS OF THE RISK ASSESSMENT	
MAIN APPROACH CONSIDERED FOR REDUCING RISK (IF APPLICABLE)	
THIS PART SHOULD BE COMPLETED ONLY IF THE RISK ASSESSMENT IS ASSOCIATED WITH A RULEMAKING	
RIN NUMBER	DOCKET NUMBER
TYPE OF RULEMAKING (FINAL/ INTERIM/ PROPOSED/ NOTICE)	TYPE OF RULE (REGULATORY/ BUDGET IMPACT)

II. OVERALL IMPACT OF RISK AND CHANGES IN RISK

1. Provide best estimate(s) of the current risks (both in terms of present values and annual).

_____
_____
_____

2. Discuss level of confidence in the preceding estimate(s) and key uncertainties. Include range(s) for current risks.

_____
_____
_____

3. Identify any potentially important risks that were not quantified and explain briefly why relevant.

_____
_____
_____

4. Estimated Incremental Benefits from main approach for reducing risk:

Benefits and breakdown of quantifiable benefits by type

	Annual	Years in Which Benefits Occur	Present Value
Total Benefits	_____	_____	_____
Health Benefits	_____	_____	_____
Pollution Benefits	_____	_____	_____
Other Benefits	_____	_____	_____

Notes

_____
_____
_____

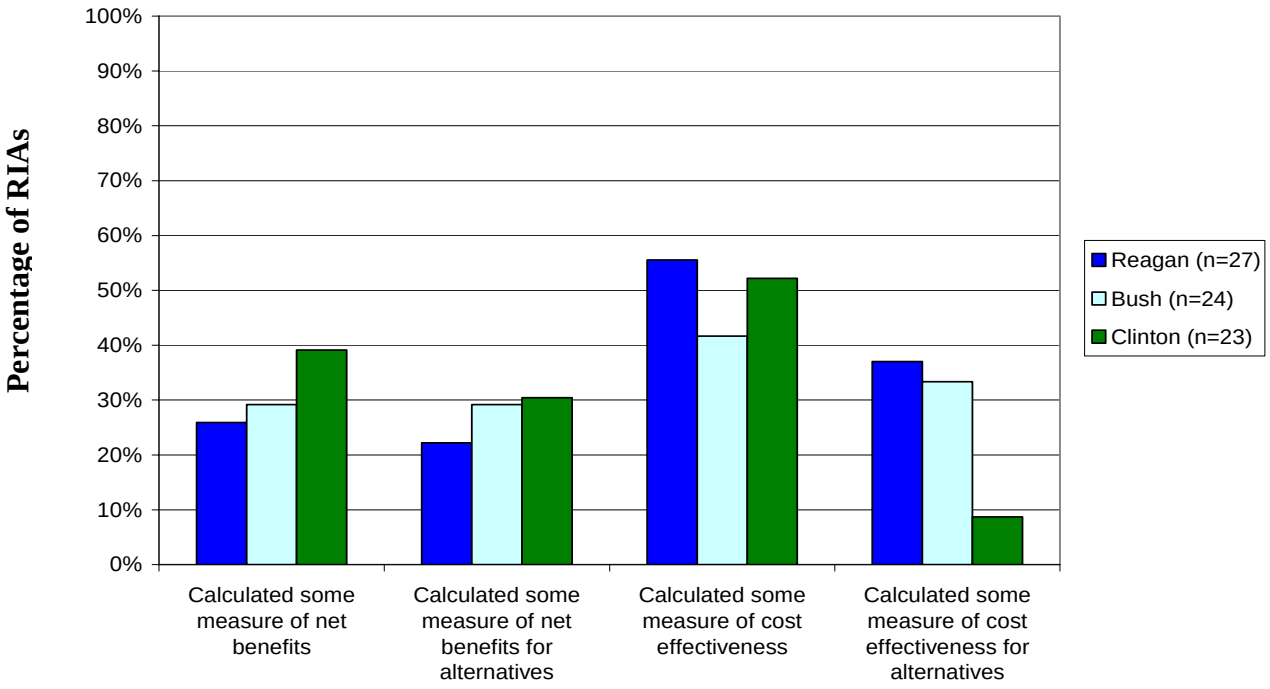
4. Brief description of who will bear the risks if they are not mitigated.

_____
_____
_____
_____

5. List and briefly describe the alternative ways of reducing risk that were considered, including a summary of benefits of those alternatives. If no alternatives were considered, explain why not.

_____
_____
_____

Figure 1
Analysis of Net Benefits and Cost Effectiveness of Regulatory Impact Analyses (n=74)



Source: Hahn and Dudley (2004).