Society for Risk Analysis (SRA)

Committee of Past Presidents

Recommendations to OMB on Regulatory Review

March 16, 2009

This document responds to the memorandum from the U.S. Office of Management & Budget (OMB), published at 74 Fed. Reg. 8819 (Feb. 26, 2009), requesting public comment on how best to revise the system of Regulatory Review currently governed by Executive Order 12866 (Sept. 1993), following President Obama's memorandum seeking OMB's recommendations on such revisions, published at 74 Fed. Reg. 5977 (Feb. 3, 2009).

This document collects ideas suggested by a committee of 18 individuals, each of whom served a term as President of the SRA between 1981 and 2009. A list of these individuals is included on page 2. The committee has discussed and supports the communication of these ideas, although each individual member may have distinct views on each idea. This document does not represent the position of the Society for Risk Analysis (SRA), because the SRA does not take positions on policy issues.

The SRA Committee of Past Presidents intends this document to stimulate discussion. SRA intends to hold additional opportunities for discussion on these issues, including a public conference in June 2009. And we note that any individual SRA member, like any member of the public, is free to submit his or her own input on these matters directly to OMB. We have circulated OMB's request for public input to all SRA members. This document reflects the ideas collected by the individuals listed on page 2, and does not reflect the views of others, of the SRA Council, or of the SRA as a whole.

The Society for Risk Analysis (www.sra.org) is a multidisciplinary, scholarly, international professional and scientific society. It provides an open forum for all those interested in risk analysis. Risk analysis is broadly defined to include risk assessment, risk characterization, risk communication, risk management, and risk policy. Risk analysis addresses all types of risks, including health, safety, security, environmental, and financial risks; and all scales, including risks affecting individuals, private sector organizations, public sector institutions, and society at the local, regional, national, and global levels.

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Members of the Committee

Since its founding in 1981, the SRA has had 28 presidents, each elected for a one-year term. All 28 of these past presidents were invited to serve on this committee, and 18 volunteered to participate. The members of the committee are listed below, in order by their terms as president of the SRA.

Chris G. Whipple (1982-83)
Paul Slovic (1983-84)
Elizabeth L. Anderson (1984-85)
Richard C. Schwing (1988-89)
D. Warner North (1991-92)
Robert G. Tardiff (1993-94)
M. Elisabeth Paté-Cornell (1994-95)
Rae Zimmerman (1996-97)
Yacov Y. Haimes (1997-98)
Gail Charnley (1998-99)
Roger Kasperson (1999-2000)
John Ahearne (2000-01)
Robin Cantor (2001-02)
Bernie Goldstein (2002-03)
Baruch Fischhoff (2004-05)
H. Christopher Frey (2005-06)
Jonathan B. Wiener (2007-08)
Alison C. Cullen (2008-09)

President Alison Cullen convened the committee as an ad hoc committee of the SRA pursuant to its bylaws.
Past President Jonathan Wiener served as chair of the committee.

The committee was assisted by and thanks David Hassenzahl (a member of the SRA Council), Lisa A. Robinson (vice-chair of the SRA Economics and Benefits Analysis Specialty Group), and David A. Drupa (at the SRA Secretariat).

Recommendations to OMB

Much has been learned since President Clinton issued Executive Order 12866 (1993) (still in force), replacing President Reagan's Executive Order 12291 (1981), which in turn had succeeded President Carter's Executive Order 12044 (1978). To incorporate these decades of learning into improved processes and institutions of regulatory review, we suggest that OMB undertake, and recommend to the President as he prepares his new Executive Order, the following steps:

1. Enhance the quality of science and information for risk decisions.

    a. To support the President's initiative on Scientific Integrity (announced in his memorandum of March 9, 2009, seeking recommendations for Presidential actions from the Office of Science and Technology Policy (OSTP)), OMB should collaborate with OSTP to establish a more mutually respectful relationship between White House oversight and agency scientific research. This relationship would recognize that science cannot be isolated from policy, nor can science dictate policy, nor can policy dictate science; but rather that good policy decisions need to be based on good science, and good science can be policy-relevant.
        i. OMB and OSTP should collaborate on updated guidelines for good risk assessment methods by agencies, and on review of scientific questions as they arise in regulatory decisions, in order to clarify the criteria for high-quality science supporting agency decisions and at the same time to reduce the need for OMB to review and question particular scientific findings made by agencies.
        ii. OSTP should coordinate a network of the several research arms of the agencies to share learning, enhance their scientific accuracy, and enhance their value to decision making.
        iii. Such guidance and coordination should build on and learn from the experience of OMB and OSTP with their joint Updated Principles of Risk Analysis (Sept. 19, 2007), issued after the critique by NRC (2007b), and on the experience gained from the first several years of implementation of the Information Quality Act and its guidelines.
    b. OMB, OSTP and the agencies should develop an iterative and recursive process to promote high-quality information as the basis for decisions. Several reports by committees of the National Academies of Science (NAS) through its National Research Council (NRC) have espoused this approach. See NRC (1996); NRC (2007a); NRC (2008a). This iterative-recursive approach means that, rather than scientists delivering a one-way flow of information to policy makers, a continuing dialogue would occur among scientists, social scientists, policy makers, public stakeholders, and oversight bodies, in order to identify, generate and evaluate the

information needed to make good regulatory decisions. This should include opportunities for public input as well as outreach to the public, see NRC (1996), NRC (2008a). Most recently, NRC (2008b) recommended that agency risk assessments address more directly the policy-relevant questions faced by risk managers. Similarly, as policy makers develop a range of alternative policy options to address a target problem, the iterative-recursive approach means that policy makers would consult scientists and social scientists regarding the direct and ancillary effects of each policy option.

c. OMB or the President should create a new institution to help improve analytic quality and decisions about major risks, while reducing the reality (or appearance) of political bias. After the Great Depression, Congress created the Council of Economic Advisers (CEA) to give voice to professional economics within government. Today, the crises of credit markets, counterterror conflict, and climate change (as well as other risks, such as pandemic disease, nuclear and bio-terrorism, and infrastructure accidents) show the need for much better risk analysis and decision making in government. Such an institution is needed not to address individual risks one at a time (a task the agencies pursue), but to help government think clearly about existing and emerging risks, set priorities and reconcile tradeoffs across diverse risks, and navigate national and international survival and success amidst these threats. A new institutional voice for risk analysis and decision making would assist (not supplant) existing expert bodies on economics, science, environment, national security, and other topics. This new body would be supportive of intelligent presidential supervision of the regulatory state, and would enable risk analysis to help inform vital national strategies, while fostering a higher-quality information base for decisions. This new body could be, e.g.:
    i. an external advisory board to OMB/OIRA (composed of experts in diverse fields), to advise on methods of risk analysis (including those for coping with uncertainty), opportunities for prompt letters (see below), and related topics.
    ii. a standing committee convened by the National Academy of Sciences to advise on the use of scientific information and risk analysis methods in regulation and related decisions, and to help resolve disputes about science or its use as they may arise.
    iii. a new White House Council on Risk and Decisions, charged with helping to shape the criteria and practice of high-quality analysis and decisions by the agencies and OMB; improving government-wide analysis, coordination, priority setting, and reconciliation of tradeoffs across risk domains such as health, safety, environment, national security, and finance; advising the President and OMB on the best ways to understand and address major risk crises such as the credit crisis, climate change, national security, disease, and extreme catastrophic risks; working in close collaboration with

other Executive Offices such as OMB/OIRA, NEC, CEQ, OSTP, NSC, Energy & Climate, and other Departments and agencies, to help improve risk decisions.

d. Enhance the role of social and behavioral sciences, regarding how and why people (as individuals or groups) behave and decide in response to risks, opportunities, and uncertainty. Seek empirical and experimental data on actual choices to test and update assumptions about human decisions. Understand that such decisions and their cognitive, social, and cultural drivers are complex, rendering predictions about human responses to conditions an uncertain science.

2. Provide in the Executive Order for a principle of "proportionate analysis," scaling the degree of analysis and review to the likely impact of the decision.

   In "value of information" terms, this principle advises investing time and resources in additional analysis where the expected value of such additional analysis in improving decisions justifies its costs in expense and delay. This principle would help orient agencies' and OMB's analytic efforts to the best opportunities to improve decisions without undue costs of analysis (such as delay). Proportionate analysis would help overcome pressures to analyze particular impacts very precisely to the neglect of other important but less-precisely characterized impacts, and pressures to focus narrowly on impacts within the agency's mission area to the neglect of important ancillary impacts (both harmful and beneficial) outside the agency's domain.

   In implementing the principle of proportionate analysis, agencies could use screening analysis to identify the range of policy options, identify important impacts of each option (including impacts outside the agency's policy domain), distinguish major from minor impacts, focus the agency's resources on assessing those options and outcomes most likely to affect the decision, and identify areas where new information and analysis are warranted to improve sound decision making. The principle of proportionate analysis would help agencies and OMB devote attention to the most important questions, consider the full portfolio of important consequences rather than putting excessive effort into precisely quantifying particular impacts, and invest optimally in the collection of new information and analysis.

   This principle applies to the following issues, among others:

   a. The number and types of policy options to be considered.
   b. The types of costs, benefits, and distributional impacts to be considered.
   c. The extent to which the impacts of these options should be assessed quantitatively or qualitatively.
   d. The extent to which the full portfolio of important impacts should be assessed, versus additional detailed analysis to increase precision

regarding particular impacts, depending on the relative importance to the decision.

e. The treatment of uncertainty, and the degree to which it is addressed by qualitative discussion, quantitative analysis, sensitivity analysis, scenario-building, or probabilistic analysis.
f. The extent to which time and resources should be devoted to collecting new information, and the type of information to be collected. In this regard, OMB should re-evaluate the factors it considers in clearing agencies' information collection requests under the Paperwork Reduction Act, applying a value of information approach to proportionate analysis, because good regulatory analysis requires good information.
g. Whether OMB review is required, and the extent of that review, replacing the current thresholds for economic significance (e.g., $100 million) with a multi-criteria approach to proportionate analysis.
h. How far agencies and OMB should go to identify and evaluate ancillary impacts (both harmful and beneficial), because some ancillary impacts may be important to the decision, but others may not significantly influence the decision.

3. Better address uncertainty.

   Update the Executive Order and OMB's guidance to:

   a. Account explicitly for uncertainty, including its characterization (qualitative and/or quantitative), and for the impacts of uncertainty on the attitudes, preferences and beliefs of the public and decision makers.
   b. Identify when efforts to reduce or further characterize uncertainty are warranted (see above regarding proportionate analysis and value of information).
   c. Use expert elicitation methods where appropriate to address complex issues of data uncertainty, causal uncertainty and model uncertainty.
   d. Account for new understandings of how people respond to uncertainty in their choices and decisions, including the general public, relevant subpopulations, and policy makers.
   e. Require in the Executive Order specific attention to extreme low-probability high-consequence catastrophic risks. This should include both appropriate methods to assess and manage such risks in general, as well as iterative discussion with other federal departments, agencies and offices to develop better responses to such extreme risks, including further research, priority-setting, and preventive policies.
   f. Call for a continued iterative research program to develop and update methods and practices to enable agencies to understand and characterize uncertainty, to differentiate usefully among types, sources and implications of uncertainty, and to develop approaches for reducing and/or managing uncertainty.

4. Enhance empirical analysis.

    a. Regularly review current research findings, and conduct new empirical research, on the actual impact of OMB regulatory review in the past on the outcomes of federal regulation – its benefits (including improved policies), costs (including delay), effects on innovation, and other aspects. This research should address questions such as: does OMB review actually help improve regulatory decisions? How and in what contexts could it do better?
    b. Provide in the Executive Order and in OMB's guidance for regular use by agencies and OMB of empirical (retrospective, *ex post*) impact analyses of previously promulgated regulations, in order to:
        i. test the accuracy of *ex ante* impact analyses conducted in the past (including overall estimates of benefits and costs, and their component elements such as assessments of emissions, transport, exposure, dose-response, valuation, policy effectiveness, ancillary impacts, and other elements).
        ii. improve the accuracy of *ex ante* impact analyses to be conducted in the future, and improve their use by agencies and by OMB.
        iii. evaluate options to revise existing regulations.
    c. In OMB's annual reports to Congress on the benefits and costs of regulations, accompanying the aggregate accounts of the *ex ante* impact assessments of regulations (as now provided), add new information on the *ex post* impact assessments of these (or representative samples of these) regulations and the implications of such *ex post* assessments for the interpretation of the *ex ante* impact assessments.
    d. Consider ways to better interpret cost and benefit estimates in future *ex ante* impact analyses, in light of empirical *ex post* analyses of the accuracy of prior *ex ante* analyses, in order to avoid or correct for systematic over- or under-estimates or other errors in the analysis.
    e. OMB, OSTP and agencies (perhaps with an external expert body as suggested above in Recommendation #1) should collaborate to review the models and classes of models used across the government to assess, evaluate and manage all types of risks (including health, safety, environment, security, and finance), and identify ways to improve those models for future applications. See NRC (2007a).

5. Improve methods of valuation.

    a. Update OMB's guidance to account for new understandings of the valuation of life, life-saving, health, and quality of life. For example, take account of research shedding light on the potential difference between true well-being and monetary measures of willingness to pay, incorporate the

best understanding of the relationship between income and well-being, and ensure that impacts on lower-income people are well-considered. Take account of research on the value of life and health for: risks with differing characteristics, risks affecting differently situated individuals, and risks occurring at different periods in the human life cycle. .

b. Update OMB's guidance to account for new understandings of the value of non-human health impacts, such as ecosystem services (on which an EPA/SAB report is forthcoming).
c. Provide in the Executive Order for more rigorous assessment of distributional equity concerns. Update OMB's guidance to better account for the distribution of costs and benefits, paying particular attention to the effects on the wellbeing of disadvantaged or vulnerable subpopulations, and encouraging the development of regulatory options that better protect the wellbeing of such subpopulations.

6. Broaden the scope of regulatory impact analysis.

   The Executive Order and OMB guidance should:

   a. Reorient the traditional focus of regulatory review on health and environmental regulation by adding broader coverage of other areas, such as trade measures, financial markets regulation, natural resource management, national security measures, research and applications of science and engineering, and international agreements. This may involve oversight of additional agencies, in order to help inform better decisions on important risks across government and society.
   b. In place of the arbitrary monetary thresholds OMB has used to trigger analysis (e.g. $100 million), provide in the Executive Order for a principle of "proportionate analysis" to focus agencies' and OMB's analytic efforts on the best opportunities to improve decisions while avoiding undue costs of analysis (such as delay), and to ensure that all major impacts are considered without undue effort to quantify particular subsidiary impacts. (See Recommendation #2, above.)
   c. Include international impacts. These may be identified as distinct from domestic (U.S.) impacts, but the two sets of impacts should also be aggregated to show the full impacts of the policy option.
   d. Conduct impact analyses of major legislative proposals before enactment. These legislative impact analyses could be conducted by OMB, by relevant agencies, or by OMB and agencies in collaboration with relevant Congressional offices or committees.
   e. Require attention to the full portfolio of important consequences of policy options, including multiple, simultaneous and cumulative risks, and ancillary impacts (both harmful and beneficial), subject to the principle of proportionate analysis (as described in Recommendation #2 above). Iterative-recursive risk assessments (as described in Recommendation #1

above) should be conducted as warranted to recognize and evaluate these ancillary effects. Interagency consultation should be conducted regarding ancillary impacts that affect another agency's domain.

f. Recognizing that some statutes require agencies to consider costs and benefits in their rulemakings, while other statutes restrict such considerations, the Executive Order should direct OMB and the agencies to employ regulatory impact analysis of benefits and costs as a tool to inform and provide insight, so that important consequences are transparent to decision makers, to the President, and to the public, even if the statute restricts an agency's attention to such consequences in rulemaking. Benefits of federal policies should "justify" costs (broadly construed, including *inter alia* qualitative, ancillary, distributional, and international impacts, as described elsewhere in these Recommendations), where statutes do not require otherwise. In addition, OMB and the agencies should use the information generated by regulatory impact analysis to provide insights on the need for legislative changes.

7. Prompt desirable new regulations.

   a. Build on the innovation of "prompt" letters by making them a routine part of OMB's activities.
   b. Provide explicit authority for prompt letters in the Executive Order.
   c. Create a mechanism for routine identification of new prompt letters to promote regulations that would generate net benefits. This could be, e.g.:
      i. an annual collection of the petitions for rulemaking that agencies have denied, reviewed by OMB to identify the best opportunities to generate net benefits.
      ii. an external advisory board of experts from multiple fields (such as the new external board identified in Recommendation #1.c, above) charged with identifying opportunities for prompt letters, as well as a formalized process for soliciting such opportunities from interested and affected parties, collecting and organizing the opportunities identified by the board of experts and by other parties, evaluating these opportunities, and proposing priorities.

8. Strengthen the global role of OMB/OIRA.

   a. Improve regulatory coordination and leadership with other countries.
   b. Work with agencies and international counterparts to improve preparedness in our increasingly interconnected world, in order to anticipate and address the increasingly rapid spread of risks through travel, infectious disease vectors, terrorism, pollution, financial markets, and other global networks.

c. Create an international committee of regulatory oversight officers, to help share ideas on better regulation and analytical methods, and to coordinate regulatory policy across countries in the increasingly interconnected global system. Include both (at least) key OECD member countries and rising new world powers.

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