

Before the Office of Management and Budget

Proposed Risk Assessment Bulletin

Comments of the Coalition for Effective Environmental Information

The Office of Management and Budget (OMB) has issued a proposed Risk Assessment Bulletin (RA Bulletin) for public comment. The RA Bulletin, issued under authority of several statutes and Executive Orders, is intended to improve risk assessments conducted by federal agencies by fostering objectivity and transparency.

The Coalition for Effective Environmental Information (CEEI) is a group of leading corporations and business groups interested in the policies guiding how agencies collect, *manage, use and disseminate information about health and environmental matters.*¹ CEEI has a particular interest in promoting “information stewardship” – the responsibility of agencies to present information about health and environmental matters in an accurate, objective and understandable way. For this reason, CEEI has been actively involved in broad-based federal information quality initiatives, such as the implementation of the Information Quality Act (IQA).

CEEI sees the RA Bulletin as part of a larger set of policies that OMB has issued over the last several years, including the OMB Information Quality Act Guidelines (OMB Guidelines) and the Information Quality Bulletin for Peer Review (PR Bulletin). These policies, taken as a whole, recognize that the information developed and disseminated by the federal government carries great power in our society. Information, whether in the form of basic data or analytical conclusions, can influence the actions of governments at the federal, state, local and even international level. Moreover, as government information becomes more and more accessible through computer networks, a whole series of private sector and personal choices can be influenced by information that carries the government’s imprimatur of reliability. Thus, it is essential that high standards of quality be met for such information.

We are encouraged by the federal government’s effort to address questions of information quality in a more systematic way, and to do so comprehensively across agencies. As part of that effort, it is important that agencies give attention to “pre-dissemination review”, a key principle that is explicitly stated in Section III.2. of the OMB Guidelines:

¹ CEEI includes representatives from the aerospace, chemical, energy, automobile, pharmaceutical, petroleum, electronics and consumer products industries.

As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information.²

The RA Bulletin provides guidance to agencies in the conduct of pre-dissemination review of scientific information and thus should be seen as an important amplification of the OMB Guidelines.

CEEI supports the content of the RA Bulletin. It articulates a set of good practices in risk assessment that have been discussed and recommended by a variety of authoritative scientific bodies for many years. As OMB has documented in the preamble, many of the specific principles in the RA Bulletin are drawn directly from a series of reports by the National Academy of Sciences (NAS) and similar bodies that trace back to the 1980's.

Besides reflecting highly credible scientific opinion, the principles in the RA Bulletin also serve a broader public purpose that CEEI strongly supports: greater transparency in government decisionmaking. If implemented effectively, the RA Bulletin's provisions will press agencies to explain their decisions with greater clarity. It will require agencies to distinguish scientific questions about the degree of risk from value judgments about the acceptability of a specific risk. For example, if risk assessors provide a good analysis of risk ranges and present their best view of a central tendency, the risk assessors will necessarily be providing risk managers with options for determining what level of risk is acceptable. Decisionmakers, whether they be senior government officials or citizens deciding whether to make certain personal choices, can then reach their own conclusions about what actions are warranted. Such transparency can increase the accountability of public officials and protect the integrity of science as a *disciplined tool to facilitate understanding*, rather than a tactic to fit a political agenda.

Given the reasonableness of the best practices articulated in the RA Bulletin, CEEI will not be commenting on those principles per se. Instead, these comments will focus on two strategically important issues that we believe need further attention:

1. **Implementation** – *what actions are needed to ensure that the RA Bulletin's principles are integrated into the day-to-day operations of agencies; and*

2. **Risk Communication** – *an essential agency function that is particularly important for risk assessment information.*

² 67 Fed. Reg. 8452 (February 22, 2002), at 8459.

Effective Implementation of the Bulletin

While Section IX of the RA Bulletin makes a general reference to an oversight role for OMB and the Office of Science and Technology Policy (OSTP), the Bulletin itself is essentially silent on plans for implementation. This stands in contrast to other related policies that OMB has issued. The OMB Guidelines and related IQA memoranda from OMB, for example, have addressed questions about how agencies should address correction requests, coordinate IQA responsibilities with rulemaking, report to OMB and provide public access to information on correction requests.³ Similarly, the PR Bulletin establishes agency responsibilities concerning a peer review agenda, peer review plans, public comment opportunities, certification of the record for peer reviews and annual reporting.⁴

Establishing a set of implementation measures is particularly important in the case of the RA Bulletin. As noted in the preamble, there has been a long history of recommendations for the improvement of risk assessment in the federal government. The general principles outlined in the RA Bulletin reflect best practices in risk assessment that enjoy general support in the scientific community.

While there certainly are examples where agencies have conducted excellent risk assessments, the overall rigor of agency risk assessments has been uneven. Assumptions buried in models are not always identified and explained. Agencies typically quantify risks with point estimates, rather than presenting a risk range with a central estimate. Sensitivity analysis to determine the impact of key default assumptions is not a routine practice.

Some agency representatives and other groups have expressed publicly a variety of critiques of the RA Bulletin. The concerns have ranged from interference with statutory mandates to delays in needed government action to data limitations. Few of these critiques, however, question the general wisdom of the best practices outlined in the RA Bulletin.

This leads to an obvious question: Why haven't agencies already incorporated best practices in risk assessment, which are widely credible in the scientific community, into their ongoing operations?

Only through a focus on implementation will OMB be able to separate rhetoric from reality on these issues, and then address legitimate concerns. Certainly there will be situations where government responsibilities to act expeditiously will not be compatible with completion of the kind of fully informative risk assessment contemplated by the RA

³ See *id.*, generally; Memorandum from John D. Graham, OMB, to President's Management Council (October 4, 2002); Memorandum from John D. Graham, OMB, to President's Management Council (August 30, 2004).

⁴ See generally 70 Fed. Reg. 2664 (January 14, 2005).

Bulletin. Agencies will also have to implement the Bulletin with an eye toward constraints inherent in the available data and institutional limits, such as budgets.

At the same time, it must also be recognized that some of the complaints about the RA Bulletin will not materialize once effective implementation begins. It is not the case, for example, that agencies cannot afford to implement best practices for “influential risk assessments” as defined in the RA Bulletin. Agencies typically expend substantial resources on the risk assessments that *guide major federal policies*. Implementation of the RA Bulletin’s best practices, which provide primarily for greater analytical transparency, will not necessarily impose significant marginal costs for major risk assessments that *currently call on significant agency resources over several years*. In fact, greater transparency in these risk assessments from the beginning of the process will actually promote understanding and reduce the transaction costs with stakeholders and reviewers that occur when key choices made by a risk assessor are not understood or justified.

As another example, the fear that the good practices in the RA Bulletin will fuel industry strategies for regulatory delay and litigation overstates the ability or inclination of business to use these policies for such purposes. In part, this is because good risk assessment practice is inherently a neutral exercise; it does not favor one faction over another. Moreover, companies do not undertake the high costs and uncertainties of regulatory challenges, or certainly litigation, as a routine matter.

One of the better examples demonstrating that concerns about the impact of a new policy do not always materialize during the implementation stage involves the OMB Guidelines. During the development of the OMB Guidelines, a variety of commenters expressed concern that agencies would be *inundated with correction requests, as a means of stalling regulations*.⁵ In fact, this phenomenon has not occurred. As an example, EPA’s Website reports that EPA has received a total of 37 correction requests during the last four years.⁶

In offering this example, however, CEEI does not mean to suggest that there will be no obstacles to full implementation of the RA Bulletin. Our main point is that the only effective way to determine whether the concerns raised by agencies and commenters on the RA Bulletin have merit is to establish an effective implementation process that will allow those concerns to be identified and addressed.

More fundamentally, the broader goals for the RA Bulletin cannot be separated from the issue of implementation. OMB initiated the RA Bulletin because it had a concern. It recognized that agency use of best practices for risk assessment would create the right conditions for effective pre-dissemination review, as required in the OMB Guidelines. OMB also recognized that despite a long history of recommendations about those practices from the scientific community, agencies still need to improve how they conduct

⁵ See Office of Management and Budget, “Information Quality: a Report to Congress for Fiscal Year 2003”, April 30, 2004, at 8-9, for a discussion of this issue.

⁶ <http://www.epa.gov/quality/informationguidelines/iqg-list.html>, as of June 7, 2006.

and communicate risk assessments to the public. Without an effective implementation plan for the RA Bulletin, OMB cannot hope to achieve its stated goals.

Requirement for Agency Implementation Plans

CEEI believes that the cornerstone for implementation of the RA Bulletin should be an obligation that each agency develop and submit for OMB approval an Implementation Plan that sets forth how the agency will incorporate the Bulletin into its policies and procedures. This is a direct analogy to how the IQA was implemented. In that case, OMB issued the OMB Guidelines for agencies. Each agency was then required to develop, after an opportunity for public comment, its own guidelines that were to be consistent with the OMB Guidelines but also could be adapted and amplified to address unique aspects of the agency's mandate and operations. OMB then reviewed and approved the guidelines of the respective agencies.

For purposes of the RA Bulletin, OMB should ask agencies to address the following subjects in their Implementation Plans:

- Identify the kinds of risk assessments that the agency conducts in each of its programs;
- Explain what practices contained in the RA Bulletin are already part of routine practice;
- Explain what changes to agency practice would be needed to implement the RA Bulletin;
- Identify and justify, by program, where any waivers from specific provisions of the RA Bulletin would be necessary;
- Explain how each program will engage scientific experts outside the government as well as the general public in risk assessment activity, including the question of what is an "influential risk assessment";
- Explain any changes in formal agency policy, including the agency Information Quality Act guidelines, that will be made to implement the RA Bulletin;
- Identify who will be accountable for overall implementation of the RA Bulletin within the agency, and what powers will be available to that person to assure *effective implementation*; and
- Explain how the agency will address reporting obligations to OMB and the public about implementation of the RA Bulletin.

The Implementation Plans would then be subject to public comment and presented to OMB, according to a reasonable schedule. OMB could address any areas where waivers or other special arrangements are necessary for particular agencies, and then approve the

Plans.⁷ Final approved agency Implementation Plans should be made available on-line so the public understands the practical application of the RA Bulletin in agency operations.

Core Implementation Issues for OMB to Address

While the agency Implementation Plans will provide the practical mechanism for translating the best practices in the RA Bulletin into agency policy, CEEI believes that OMB will need to give particular attention to certain cross-cutting issues that will set the overall framework for implementation of the RA Bulletin by agencies. These issues include the following:

- Clarification of key terms in the RA Bulletin and how the Bulletin relates to other policies;
- Definition of the process and institutional roles in agency oversight;
- Building capacity in agencies to implement the RA Bulletin; and
- Engagement of external experts and the public in implementation of the RA Bulletin.

The remainder of this section discusses actions OMB should take to facilitate implementation in each of these areas.

1. Clarifications in the RA Bulletin

No policy can be implemented if it is unclear. Several aspects of the RA Bulletin will need further clarification and amplification in order to reduce uncertainty about expectations.

Several key terms in the RA Bulletin are generating uncertainty. First, it is not clear how OMB is classifying risk assessments by their relative significance. In the context of the RA Bulletin, there is an implication that there are “regular” risk assessments that are covered by the Bulletin and “influential” risk assessments with a broader impact that must meet higher standards under the Bulletin. In the context of the OMB Guidelines, there are three potentially relevant categories: (1) general information (required to meet the base standards of objectivity, utility and integrity); (2) “influential” risk assessments (for which the “reproducibility” standard is relevant); and “influential analysis of risk to human health, safety and environment” (for which the Safe Drinking Water Act standards on risk assessment and risk communication are relevant.) In contrast, the PR Bulletin refers to “influential” risk assessments (meeting the base standards for peer review) and “highly influential” risk assessments that require more rigorous peer review.

⁷ While CEEI believes that OMB will need to undertake an oversight role to make the RA Bulletin effective, we are also aware that OMB has limited staff resources to accomplish this function. It is fundamentally important that the Administration provide adequate resources to ensure that the RA Bulletin can be implemented, including an adequate resource base at OMB to provide necessary oversight.

Some readers of the various OMB policies in this area do not see how these various policies fit together as a whole. The problem is not solved by the fact that the one common term in all of the policies – “influential” – uses a consistent definition. At a minimum, it would be useful for OMB to provide examples of risk assessments that fall into these various categories. More useful, however, would be an explanation of how the policies associated with these various categories align with each other. For example, why doesn’t the text of the RA Bulletin explicitly refer to the Safe Drinking Water Act standards that apply under the OMB Guidelines? Should readers assume that any assessment meeting the PR Bulletin criteria for “highly influential” risk assessments automatically qualifies as an “influential” assessment for purposes of the other two policies?

The RA Bulletin also includes a standard indicating that agencies should “compare the results of the assessment to other results published on the same topic from qualified scientific organizations.” This is potentially an open-ended obligation. In the context of the RA Bulletin, it is logical that comparisons should only be made to other risk assessments that meet standards of quality and transparency comparable to what is required by the RA Bulletin. The standard, however, does not make that clear. A clarification of this nature would help frame the obligation in a manner that would make it practical for agencies.

In addition to clarifying some of the key terms in the RA Bulletin, the current wording of Section II (Applicability) creates a threshold ambiguity about the scope of the Bulletin. Specifically, the section states, “To the extent appropriate, all agency risk assessments available to the public shall comply with the standards of this Bulletin.” Two issues have arisen with this language. The term “to the extent appropriate” can be read to give agencies the choice of whether to comply with the RA Bulletin at all, basing that judgment on the highly discretionary standard of what is “appropriate.” This view of the language would, of course, create a major loophole that would essentially nullify the RA Bulletin as meaningful policy.

A reading of the preamble suggests that OMB did not have this intent. Instead, OMB was intending to express the concept that individual standards in the RA Bulletin could be waived if they were inappropriate in a particular context. The concept of a waiver for specific circumstances is already captured in Section VIII of the RA Bulletin. Assuming that implementation of the waiver has appropriate oversight by OMB, that would seem the better mechanism to provide flexibility, rather than an ambiguous phrasing of the *Applicability* section. CEEI recommends that OMB remove the phrase “to the extent appropriate” from Section II.1.

The same section also includes within the scope of the RA Bulletin all risk assessments “made available to the public.” The preamble indicates that this phrase covers all documents that must be released publicly in response to a Freedom of Information Act (FOIA) request. A FOIA request could, of course, cover a risk assessment in the possession of an agency that was prepared by a third party.

The agency may have had no involvement in the assessment and may fundamentally disagree with the quality or conclusions of such a study. Nonetheless such a document, without alteration, would need to be provided in response to a FOIA request or posted in a docket if it was submitted by commenters in a regulatory proceeding. In such a situation, it is not clear what could reasonably be expected of an agency to address the standards in the RA Bulletin. As a result, we do not believe that OMB should try to link the scope of the RA Bulletin to the range of documents that must be disclosed under FOIA.

Certainly it is logical that the RA Bulletin should cover all assessments that are publicly “disseminated”, as that term is understood under the IQA and the OMB Guidelines. The set of “disseminated” risk assessments, however, would not include agency internal assessments that are sometimes used to set policy. For example, agencies routinely conduct risk assessments of new products that may be submitted for approval. Due to confidentiality concerns surrounding some of the information contained in these submittals, these assessments are not generally made public.

The best practices set forth in the RA Bulletin have equal validity to these internal agency assessments. OMB should include such assessments within the scope of the RA Bulletin. At this time, CEEI is not recommending specific terminology for the RA Bulletin to capture this set of assessments. Instead, we recommend that OMB work with the agencies to develop the right formulation of the language in the Applicability section, which will make sense in the context of agency operations, to capture assessments that are not “disseminated” under the IQA but nonetheless provide the basis for policy decisions by the agencies.

Reviewers of the RA Bulletin have also found Section III (Goals) to be a confusing element of the Bulletin. As stated in the preamble, this section is intended to state aspirational goals. Overall these goals suggest an intent to provide flexibility in the implementation of the RA Bulletin. Section IV and V then state a series of standards that apply to various types of risk assessments. It is unclear how the Goals in Section III are intended to be used, if at all, in implementation of the specific standards set forth in the later sections. Some read these Goals as purely aspirational, as expressed in the preamble, and conclude that they do not change the core obligations in Sections IV and V. Others have seen the Goals as potential modifiers of the obligations in Sections IV and V, building in opportunities for waivers of the core obligations.

OMB should not allow such an ambiguity to remain in the RA Bulletin. CEEI recommends that the Goals be removed from the text of the RA Bulletin to avoid any confusion about the integrity of the standards in Sections IV and V. To the extent that OMB sees the Goals as criteria that can be used to define a “compelling rationale” that warrants a waiver, the Goals should be included in Section VIII of the RA Bulletin.⁸

⁸ As will be discussed later in these comments, CEEI believes that OMB must exercise its jurisdiction to review waivers of any provisions of the RA Bulletin that agencies may want to invoke.

Finally, it is absolutely essential that OMB make clear how the standards in the RA Bulletin relate to the overall requirements of the OMB Guidelines and the PR Bulletin. Agencies and the public need to see these policies on information quality as a coherent set of standards that reflect a common logic and that are internally consistent.

At a minimum, this means that common terms should have the same meaning. In addition, it means that if OMB wants one of these policies to control a specific issue, it should explicitly incorporate the controlling policy into the other documents, rather than trying to restate or paraphrase the controlling policy. So, for example, OMB may intend that Section IV.7., which concerns the presentation of risk assessment information in regulatory analysis, is simply intended to establish that agencies should follow the requirements of Circular A-4. If so, it would be better to provide that cross-reference without any further amplification. Separate phrasing of a concept that is intended to be uniform across policies will raise interpretive questions and frustrate implementation.

CEEI believes that the best long-term strategy to address concerns about the alignment of information policies is to incorporate the RA Bulletin and the PR Bulletin into the OMB Guidelines. This would facilitate clear communication of the ideas and avoid the complexities of cross-references, for both the agencies and the public.

At the same time, CEEI recognizes that an effort to revise the OMB Guidelines and related agency guidelines at this time would be a significant effort. In the short-term, CEEI recommends that OMB continue on the path of completing the RA Bulletin as planned, proceed with implementation and thereby identify potential refinements of the Bulletin that make sense, and then incorporate the Bulletin into the Guidelines at a later point in time when general revisions seem warranted, presumably for a range of reasons.

2. Establishing Effective Oversight

OMB is the primary sponsor of the RA Bulletin and thus should take responsibility for assuring that agencies incorporate its principles into their operations. This form of “top down” oversight is a necessary core component of most implementation plans, as has been recognized by scholars of public administration.⁹

Besides assuring that implementation is occurring in agencies, oversight is a means for communicating lessons learned among agencies. It also is a mechanism to assure that necessary changes in policy that may occur over time are made in a systematic and consistent way across agencies. Oversight also facilitates evaluation of a policy’s effectiveness as well as public communications about that effectiveness.

For purposes of the RA Bulletin, OMB will need to define two key aspects of the oversight function. First, OMB should clarify institutional roles. What decisions must be made by OMB? What decisions are best left to the individual agencies?

⁹ See Michael Hill & Peter Hupe, *Implementing Public Policy*, 44-51 (Sage Publications 2002). A classic text describing this perspective on implementation studies is Pressman, J.L. & Wildavsky, A., *Implementation*, (3rd edn. Berkeley: University of California Press 1984) (1973).

At the outset, OMB will need to take a larger role in implementation decisions as a means to assure that the intent of the RA Bulletin is served. For example, OMB will need to be involved in initial decisions, under Section VIII, about when it is appropriate to defer or waive one of the standards in the RA Bulletin. This is necessary to establish key precedents about the right balance between agency flexibility and the maintenance of a consistent government policy. Over time, as the conditions for appropriate waivers become more defined, OMB may decide to delegate that responsibility to agencies, subject to a reporting obligation.

Some have argued that OMB should not be responsible for substantive oversight over the RA Bulletin's implementation because the office is not a scientific expert. CEEI does not see this as a substantial concern. OMB does have technical expertise on its staff. In addition, some of the important issues for consideration, such as what constitutes an "influential" risk assessment, are primarily policy questions involving a range of information about the potential impact of a decision. This type of issue falls within OMB's traditional expertise. Moreover, the RA Bulletin already makes clear, in Section IX, that oversight of the Bulletin will be a joint responsibility between OMB and OSTP, which clearly has staff with scientific and technical expertise. If either of these agencies needs assistance to understand an issue or dispute, they can also seek help from qualified experts in other agencies or outside the government.

OMB should also clarify what roles it expects agencies to perform. The specifics of those roles and responsibilities can then be clarified in the agency Implementation Plan described above. An example where agencies might be expected to take a lead role is the Section VI requirement for periodic updates of risk assessments. Since that obligation is explicitly tied to the availability of agency resources and must necessarily be aligned with program priorities, it might make sense for agencies to take responsibility for this function.

The overall need in this area is for OMB to determine who should be responsible for the key decisions in implementing the RA Bulletin and provide that framework to agencies. OMB may want to consider the structure of the Paperwork Reduction Act as a model for that framework.¹⁰ In §3504 the responsibilities of the OMB Director are clearly articulated; the parallel responsibilities of federal agencies are specified in §3506 of the statute.

The second critical aspect of oversight that OMB must address is the procedural framework for implementation. The management of any organizational change, in either a private or public institution, involves management of the change process. How will agencies work with OMB and other actors in the government to assure that the goals of the RA Bulletin are met? How should agencies manage their own internal processes to assure effective implementation?

¹⁰ 44 U.S.C. §3501, et seq.

OMB will need to address several key questions in defining this process. For example, when will OMB and OSTP review particular assessments to assure compliance with the RA Bulletin and when will they rely on existing agency processes? As indicated earlier, there is a need to explain how the RA Bulletin aligns with other OMB policies. On this question of procedural clarity, it will be important to explain how the process for agency and OMB oversight of the RA Bulletin will align with the peer review (and public review) process anticipated by the PR Bulletin.

In the case of risk assessments used to support rules, there already are extensive procedures in place. What procedural refinements make sense to assure effective implementation of the RA Bulletin in rulemakings? For example, Section VII of the PR Bulletin requires agencies to include in rulemaking records a certification “explaining how the agency has complied with the requirements of this Bulletin and the applicable information quality guidelines.” A similar kind of obligation for the RA Bulletin also would make sense.

Procedural requirements become particularly important in areas of the RA Bulletin where the criteria for decisions are broadly drawn and agencies must necessarily exercise some policy judgment. As an example, the question of whether a particular risk assessment is “influential” necessarily involves a consideration of multiple factors. The process for such decisions, including the role for the public, should be addressed by OMB.

3. Building Capacity

As noted earlier, some form of “top down” oversight is a core component of any implementation strategy. At the same time, some form of “bottom up” strategy also plays a critical role. For policies to take root in day-to-day operations, agency staff must develop the expertise, tools and commitment to the policy. Such a goal will not take place automatically; it must be pursued as a conscious strategy.

This strategic interest has been recognized in the scholarly research analyzing implementation of public programs.¹¹ This research focuses on implementation from the perspective of public employees engaged in direct service delivery, such as police officers or teachers. The questions of implementation in this context focus on how best to empower these individuals to deliver services that align with broader policy goals.

This aspect of implementation is particularly important with a highly technical set of best practices such as the ones set forth in the RA Bulletin. A key issue that OMB should be addressing on a larger scale is how the obligations of agencies under the RA Bulletin should be aligned with the budgets of those agencies. As indicated earlier, agencies will tend to assemble appropriate resources and expertise to address the risk assessments that accompany major policy decisions. That same commitment, however, may not be possible for the less significant risk assessments that do not qualify as “influential”.

¹¹ See Hill & Huber, at 51-56. This tradition in academic research draws heavily from theories set forth in Michael Lipsky, *Street-level Bureaucracy: Dilemmas of the Individual in Public Services*, (New York: Russell Sage Foundation 1980).

Moreover, agencies may not be making the necessary investments in infrastructure and training to enhance or even maintain their current level of capacity. This is an area where OMB must necessarily align its “management” and “budget” agenda.

Building capacity also requires a commitment to training of agency personnel. Some of this obligation will simply involve focused training on the elements of the RA Bulletin. More broadly, it will also be necessary to provide opportunities for federal employees to enhance their skills in additional areas. For example, agency staff may need further educational opportunities to address specialized issues like sensitivity analysis and probabilistic risk assessment.

Another common element of capacity-building activity is the establishment of information networks that allow federal employees to learn from the experience of others. This activity area may range from the simple act of creating e-mail networks for information-sharing to the establishment of periodic conferences where federal employees can update their knowledge base about enhancements in risk assessment methodology and share best practices.

Finally, building capacity necessarily involves the creation of incentives for federal employees to innovate. OMB should encourage agencies to fund projects that experiment with new approaches and mechanisms that can advance the objectives of the RA Bulletin. In addition, agency staff who find creative ways to implement the RA Bulletin should be rewarded for those efforts. Besides providing insights about how to improve implementation as a more general matter, such efforts help enhance the commitment of agency staff to the RA Bulletin’s objectives.

4. Engagement of External Experts and the Public

Over the last several decades, efforts to address public issues have increasingly looked toward a “governance” model for implementation.¹² What this means is that society does not expect governments to accomplish all of the implementation activities necessary to reach policy goals. A network of public and private institutions collaborate on implementation activities, bringing their own unique comparative advantage to the process. Interestingly, these models of implementation often draw heavily from the organizational models associated with highly integrated information networks that are non-hierarchical and typically much more nimble in delivering services.

OMB should consider how this trend can be used to enhance implementation of the Bulletin. This should take place at two levels. First, OMB should consider how it can find more effective ways to engage the risk assessment community to improve implementation of the RA Bulletin. On individual assessments, of course, peer review practices help bring external expertise into the process.

¹² See Hill & Huber, at 160-195.

Yet that kind of external expertise may also be of assistance in addressing cross-cutting issues that might arise around the RA Bulletin. OMB has already made significant use of the NAS in the development of the RA Bulletin, the OMB Guidelines and the PR Bulletin. CEEI suggests that OMB consider establishing a more permanent ongoing relationship with NAS to address issues that will inevitably arise in the implementation of the RA Bulletin. For example, the first round of agency Implementation Plans may surface issues of general applicability that would benefit from further scientific inquiry by experts who can combine *substantive scientific expertise with a deeper understanding of the context of the RA Bulletin.*

The other essential “partner” in any governance model is the general public. While risk assessments often raise complex technical issues, there is substantial expertise among the various stakeholder groups that might participate in the development of a risk assessment. These voices should be heard. Section III of the RA Bulletin says that agencies “shall follow appropriate procedures for . . . public participation in the process of preparing [a] risk assessment.” CEEI believes that the RA Bulletin should simply say that agencies shall seek public participation.

To maintain the integrity of the public participation process, it is also essential that agencies provide meaningful responses to public comments they receive. Currently the RA Bulletin obligates agencies to respond to public comments on “influential” risk assessments. That obligation should not, however, be limited to a subset of risk assessments. Agencies should be expected to respond to all public comments that they receive on risk assessments, whether or not those assessments technically qualify as “influential” assessments.

In fact, agencies will not typically receive comments on routine screening-level assessments. Where such assessments do draw significant comment, however, the government is receiving a clear signal that important public interests are at stake. For that reason alone, a response to comment is needed.

Public comment opportunities are particularly important in those areas where agencies are necessarily considering, and balancing, a variety of factors. A prime example in the RA Bulletin is the question of what assessments qualify as “influential” risk assessments. The public has an important perspective on this that should be heard. Specifically, one of the principles that guides the determination of whether an assessment is influential is whether an assessment has “a clear and substantial impact” on private sector decisions. The primary expertise on that question lies outside the government. Thus, opportunities for public comment in such areas both improve the quality of an agency’s decision and enhance its public credibility.

Risk Communication

CEEI was encouraged to see that the RA Bulletin takes an important step toward addressing one of the most difficult challenges that government faces: communicating

effectively with the public about the nature of health, safety and environmental risk.¹³ Specifically, Section IV.6. directs agencies to provide executive summaries for risk assessments that supplement the key findings of the assessment with information about the “scientific limitations and uncertainties” in the assessment and “information that places the risk in context/perspective with other risks familiar to the target audience.” In support of this standard, OMB cites the seminal NAS report, *Improving Risk Communication*.¹⁴

CEEI believes that the policy objectives underlying the RA Bulletin necessarily involve risk communication. For example, the RA Bulletin establishes a higher level of rigor for influential risk assessments that affect important public policy choices and private sector decisions. In essence, the RA Bulletin recognizes that greater care is needed when important interests are at stake. It would not make sense for agencies to undertake that extra level of care and then communicate the results of the assessment in a way that was not understandable to the audience whose interest drove the “influential” finding.

The RA Bulletin and the preamble also make several references to the quality standards specified in the OMB Guidelines, including the requirements for “objectivity” and “utility”. Both of these standards establish obligations regarding how information is communicated to the public. The “objectivity” standard includes “whether disseminated information is presented in an accurate, clear, complete and unbiased manner” and “whether the information is presented with the proper context.”¹⁵ Similarly the “utility” standard is concerned with the “usefulness of the information to its intended users, including the public.”¹⁶

More fundamentally, effective communication of risk information to the public is a central responsibility of government. The public expects government agencies to be knowledgeable and reliable sources of objective information about public health and environmental protection. This core function of government cannot be served unless agencies accept that responsibility and give special attention to how they present risk information publicly.

Significant damage can occur if information from government risk assessments is misunderstood by the public. One of the watershed examples of failed risk communication is the controversy that erupted in 1989 over the use of the pesticide Alar

¹³ The preamble to the RA Bulletin contains a somewhat ambiguous statement that the Bulletin “does not address in any detail the important process of risk management and risk communication.” Preamble, at 3. In the context of the later discussion of the executive summary, which clearly addresses the need to provide contextual information, CEEI assumes that this general statement simply means that OMB is not attempting to address the full range of issues, many of which are procedural in nature, that may be involved in effective risk communication.

¹⁴ National Research Council, *Improving Risk Communication* (Washington DC: National Academy Press 1989)

¹⁵ 67 Fed. Reg. 8452 (February 22, 2002), at 8459.

¹⁶ *See id.*

on apples. The available science on the active ingredient in the product, UDMH, was the subject of much disagreement among scientists from EPA, industry and NGO groups, which led to a long-running regulatory battle. Eventually the dispute crystallized into a famous episode on the television show *60 Minutes* in which the chemical was presented as a significant risk to children. Several NGO groups followed the show with broad public campaigns against the chemical. In response, the public focused on the risks of apples, rather than the need for any particular action on Alar. Consumers and school systems discarded apples and apple juice, leaving apple growers with an estimated loss of \$100 million.

Since then, the Alar controversy has generated fierce debate about the adequacy of EPA's regulatory program for pesticides, the merits of the underlying science, the policies guiding risk assessment in the federal government and the tactics used in environmental politics. The issues are still debated today. Yet there is a common theme that runs through the debate, from those who take differing views of the underlying policy issues: the controversy was a failure of risk communication. The story of Alar has become a classic case study, often used in academic courses on risk communication, to demonstrate how failures of risk communication can cause unanticipated and detrimental effects.

In other contexts, well-planned efforts to explain complex public health issues have succeeded. An example of such success can be found in the long, and somewhat torturous, history of EPA's effort to develop a comprehensive risk assessment of dioxin compounds. This assessment, which began in 1991 and has still not been completed, has produced many draft review documents. These documents have been the subject of several peer reviews and rounds of public comment.

The process associated with the dioxin reassessment has required EPA and other agencies, on several occasions, to provide public statements addressing potential public concerns about dioxin risks. A particularly sensitive issue to address has been the clearly documented presence of dioxin in breast milk of women around the world. Consistently the government has acknowledged the concern but also made a convincing case that the benefits of breastfeeding outweigh the potential risk of dioxin exposure for infants. Notably, this message has been reinforced by a wide range of governmental bodies, medical experts and NGO groups, including organizations that have pressed for strong governmental action to reduce environmental loadings of dioxin. As a result, there has been no widespread trend of mothers abandoning breastfeeding due to concerns about dioxin risks.

The need for effective communication of information in government risk assessments has never been greater. In the modern world, consumers receive a very diverse set of messages about the health, safety and environmental implications of many products, commercial activities and personal behaviors. The information comes from many sources. It is challenging for the public to make sense of this information. It is even difficult for journalists to report on complex scientific studies and explain what is important for the public to understand and consider.¹⁷

¹⁷ Barbara Kantowitz & Claudia Kalb, "Food News Blues", *Newsweek* (March 13, 2006), at 44.

Recognizing that the societal and technological trends that fuel this wave of public information are now inevitable, it is important for public agencies to step up to the task of risk communication. Government has the credibility and can marshal the expertise to provide useful explanations of complex risk issues, providing the contextual information that will put new pieces of information in perspective. This is a valuable voice that the public should hear. This is particularly true when the public relies on agency risk assessments that are, as a policy matter, built upon conservative assumptions that are likely to overstate the actual risks that the average citizen faces.

For purposes of the RA Bulletin, CEEI believes that OMB should provide additional guidance to agencies on what should be considered when developing an executive summary for a risk assessment that “places the risk in context/perspective with other risks familiar to the target audience” as specified in Section IV.6. In particular, OMB should draw directly from the recommendations of the NAS report entitled *Improving Risk Communication* (NAS Report) that it cites in the preamble of the RA Bulletin.¹⁸

The portion of the NAS report cited in the RA Bulletin’s preamble provides a variety of specific recommendations that would help agencies in improving how they speak about risk with the public. While CEEI believes that all of the recommendations on pages 165-79 should be considered for incorporation into the standard for an executive summary, we emphasize the importance of several aspects of those recommendations:

- Messages should be personally relevant to the reader and be designed to “inform the discretion” of the reader, rather than attempt to dictate a particular action;
- Agencies should make it clear where uncertainty exists and where experts disagree and provide a qualitative sense of the significance of the areas of scientific uncertainty;
- Comparative risk statements, which can be helpful in understanding the probabilistic nature of risk, should be grounded in realistic choices that people make and recognize the many factors that influence those choices; and
- The risk message should be as complete as possible, with the list of questions found at p. 175 of the NAS Report (replicated in Appendix 1 of these comments) providing a potentially useful checklist of questions for agencies to consider.

While CEEI believes that the RA Bulletin should expand its guidance on communicating risk in an executive summary, we recognize that such a step is not a complete solution to the challenges of risk communication. The NAS Report provides an excellent overview of the larger issue and includes many more recommendations concerning how to build public credibility, how to view risk communication more as a process for exchange of

¹⁸ Footnote 29 in the preamble of the RA Bulletin explicitly cites pp. 165-79 of National Research Council, *Improving Risk Communication* (Washington DC: National Academy Press 1989). The cited section provides useful recommendations on the content of risk messages that are intended for “those within the communicating organization who are responsible for preparing formal risk messages.” At 165.

information rather than a one-way communication exercise, and how to build greater public “literacy” on matters of risk assessment.

In the future, we urge OMB to address in a more systematic way the challenges of risk communication that federal agencies must face. This topic could be addressed as a new “Bulletin on Risk Communication” or, consistent with CEEI’s earlier recommendations, as part of later revisions to the OMB Guidelines. Specifically, OMB should consider providing federal agencies with further guidance on risk communication as an extension of the “objectivity” and “utility” standards of the IQA.

Conclusions

CEEI supports the RA Bulletin and hopes that OMB will be able to issue it in final form as soon as possible. As indicated in these comments, we believe that the issuance of a policy of this nature is only the first step in an important journey to transform the best practices found in the RA Bulletin into standard practices in federal agencies. We believe that agencies will need to develop Implementation Plans addressing how they will incorporate the RA Bulletin into their operations. We also believe that effective implementation will require OMB to refine the RA Bulletin itself, explain and execute an oversight process, help agencies build capacity and engage a broader community of interested parties.

CEEI is particularly encouraged by the RA Bulletin’s effort to bring a greater focus to the risk communication responsibilities of federal agencies and we urge OMB to expand its guidance in this area. We hope that the initial steps on risk communication reflected in the RA Bulletin can be part of a larger effort, suggested by the NAS Report, to address the full scope of this topic.

***Coalition for Effective Environmental Information
June 15, 2006***

Appendix 1

NAS Report Recommendation on Questions to Consider in Developing a Risk Message

INFORMATION ABOUT THE NATURE OF RISKS

1. What are the hazards of concern?
2. What is the probability of exposure to each hazard?
3. What is the distribution of exposure?
4. What is the probability of each type of harm from a given exposure to each hazard?
5. What are the sensitivities of different populations to each hazard?
6. How do exposures interact with exposures to other hazards?
7. What are the qualities of the hazard?
8. What is the total population risk?

INFORMATION ABOUT THE NATURE OF BENEFITS

1. What are the benefits associated with the hazard?
2. What is the probability that the projected benefit will actually follow the activity in question?
3. What are the qualities of the benefit?
4. Who benefits in what ways?
5. How many people benefit and how long do benefits last?
6. Which groups get a disproportionate share of the benefits?
7. What is the total benefit?

INFORMATION ON ALTERNATIVES

1. What are the alternatives to the hazard in question?
2. What is the effectiveness of each alternative?
3. What are the risks and benefits of alternative actions and of not acting?
4. What are the costs and benefits of each alternative and how are they distributed?

UNCERTAINTIES IN KNOWLEDGE ABOUT RISK

1. What are the weaknesses of the available data?
2. What are the assumptions on which estimates are based?
3. How sensitive are the estimates to changes in assumptions?
4. How sensitive is the decision to changes in the estimates?
5. What other risk and risk control assessments have been made and why are they different from those now being offered?

INFORMATION ON MANAGEMENT

- 1. Who is responsible for the decision?**
- 2. What issues have legal importance?**
- 3. What constrains the decision?**
- 4. What resources are available?**