



**EDISON ELECTRIC
INSTITUTE**

QUINLAN J. SHEA, III
Executive Director, Environment

June 15, 2006

Submitted Electronically

Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
727 17th Street, NW
New Executive Office Building, Room 10201
Washington, D.C. 20503

Re: Proposed Risk Assessment Bulletin

Dear Dr. Beck:

The Edison Electric Institute (EEI) welcomes the opportunity to submit comments on the Office of Management and Budget's (OMB) *Proposed Risk Assessment Bulletin*.

EEI is the premier trade association for U.S. shareholder-owned electric companies, and serves international affiliates and industry associates worldwide. Our U.S. members serve 97 percent of the ultimate customers in the shareholder-owned segment of the industry, and 71 percent of all electric utility ultimate customers in the nation. They generate almost 60 percent of the electricity produced by U.S. electric generators.

The electric utility industry is affected by a broad range of federal and state statutes and regulations, and is one of the most regulated industries in this country. In 2004 alone, EEI member companies spent more than \$6 billion on compliance with federal environmental regulations. There are many additional regulations our industry must comply with in the coming years on the federal, state and local levels.

EEI strongly supports OMB's proposal to issue guidance that seeks to improve federal agencies' methodology in assessing environmental, health and safety risks. EEI believes that federal programs designed to protect the environment and human health should be based on unbiased and objective risk assessments that reflect the best scientific information available. EEI and its members support the use of risk assessment, cost-benefit analysis, and comparative risk analysis as fundamental tools for informing and improving the federal

regulation development process. Specifically, the following principles should be applied to all federal regulatory policies and programs:

- The public should have access to all information used to develop regulations, including but not limited to assumptions used, areas of uncertainty, populations intended for protection, and exposure assessment models.
- All costs of regulation should be estimated and compared with the range of potential benefits that the regulation can be realistically expected to achieve; the estimation of benefits must be predicated on the best available scientific data.
- Resources should be allocated most efficiently to protect the environment and public health and safety by placing all relevant risks in priority order.
- Risks addressed in regulations should be put in context by comparing them to risks to which the public is routinely exposed.

As outlined in the supplemental information, “The Requirements of This Bulletin,” OMB advocates an open and transparent regulatory process, encourages agencies to prioritize their activities, and suggests that agencies compare the risks that they regulate with other common risks. These themes are consistent with the principles noted above and generally address the electric utility industry’s concern that the federal government achieve the goal of smarter and more value-added regulation.

Specific Comments

Section II: Applicability

EEI agrees that all publicly available risk assessments shall comply with the standards of the Bulletin. Though there are legitimate and practical reasons to exempt some risk assessments – due to declared public emergencies for example – general exemptions should be limited. The Bulletin should be very clear that federal agencies must routinely operate under the presumption of performing a risk assessment if there is any doubt as to whether it is “appropriate.”

Section IV: General Risk Assessment and Reporting Standards

4. Standards Related to Objectivity

EEI believes that the Bulletin should emphasize that the data used by agencies to support risk assessments must be based on the weight of the *best* available scientific evidence in order to adequately ensure that information of the highest scientific quality is used, and not just any information regardless of quality. The Bulletin states that the use of both positive and negative studies, based on technical quality, is a component of scientific objectivity. It should be further emphasized that both positive and negative studies must be included in “available scientific evidence.” In addition to requiring that both positive and negative studies be given

weight in risk assessment, agencies should be required to explain clearly why a study or group of studies was used and why others were rejected.

In addition, the weight of the evidence approach should be the standard for agencies in determining the outcome of a risk assessment instead of arbitrary policy choices.

Caution should be taken in ensuring that agencies do not abuse the use of confidential and proprietary disclaimers in not identifying sources of underlying information, supporting data and models for risk assessments. OMB should require agencies to preferentially use *non-proprietary/non-confidential* data and models when they are available. If agencies insist that proprietary/confidential information is all that is available, OMB should require agencies in these instances to certify that such data and models are robust and reliable for the circumstances in which they are used and have been subject to rigorous scientific peer reviews applicable to the given circumstances for which such data and model information is used.

6. Standards Related to the Executive Summary

In putting estimates of risk in context/perspective with other risks, EEI observes that it is essential that this context/perspective be readily understandable to the “target audience” *and* the general public. Much evidence exists that risk estimates are poorly communicated to policymakers and the public by federal agencies. An effective risk communication program should explain to the public and policymakers in a readily understood manner those risks that ought to be of greatest concern and what ought not to be given priority attention.

7. Standards Related to Regulatory Analysis

EEI reiterates the importance of including a range of plausible risk estimates, including central estimates in risk characterizations. Communicating risks in this manner will better inform the public about the nature and severity of risks and the uncertainty associated with the estimate. Emphasizing the importance of unbiased, central risk estimates as an input will improve the reliability of cost-benefit analyses, as the disparity in uncertainty surrounding estimates of costs and estimates of benefits would be recognized and taken into account.

Section V: Special Standards for Influential Risk Assessments

4. Standard for Characterizing Uncertainty

EEI commends OMB for the discussion on the significance of model uncertainty in performing risk assessments. We agree with the recommendations to address model uncertainty that would require agencies to perform multiple assessments with different models and report the extent of the differences in results as well as using a weighted average of results from alternative models based on expert weightings.

One area of particular concern is the importance of identifying the *overall* uncertainty associated with very complex multi-media issues. To address these issues, regulatory agencies have used not just one model with a high degree of uncertainty, but have coupled several models and assumptions, each with a high degree of uncertainty. The resulting overall uncertainty therefore becomes the product of multiplying the individual uncertainties, and in some instances may be quite large.

For example, for the Great Lakes Initiative (GLI) water column criteria, EPA either assumed or modeled each of the following:

- The ratio of methyl to dissolved mercury in the water column (assumed to be linear).
- The ratio of dissolved to total mercury in the water column (assumed to be linear).
- The biomagnification of methylmercury in the water column to algae (assumed to be linear).
- The bioaccumulation of methyl mercury in algae to: trophic 2, trophic 3, trophic 4 fish (all assumed to be linear).
- The toxic dose of methylmercury for a mallard duck.
- The conversion of mallard duck toxicity into eagle toxicity (because EPA lacked eagle data).
- The amount of fish versus upland food consumed by an eagle.
- Similar analyses for other wildlife species.

EPA abandoned application of the GLI mercury water column approach to any water bodies outside of the Great Lakes, concluding that the overall uncertainty of its multiple assumptions and models was too great and that a more direct approach with less overall uncertainty was to express a standard in terms of fish tissue rather than water column values. This is only one example out of many more that could be listed that highlights the importance of considering the cumulative uncertainty of all models and assumptions, particularly when addressing complex multimedia issues.

Section VI: Updates

The requirements of this section are extremely critical to the efficacy and credibility of the federal regulatory process. As science continues to evolve over time, more useful information is available to policymakers. As the Bulletin notes, agencies should have procedures in place to utilize new relevant high quality information when it will improve the quality of a previously conducted risk assessment. In order to ensure that agencies are aware of new information and that they consider it, there should be a provision in the Bulletin to allow the public to petition an agency to perform an updated risk assessment. Similar to an agency's Information Quality Guidelines, an agency must be required to respond to such petitions and explain why the request was accepted or denied.

Additional Comments

It appears that the Bulletin is primarily focused on assessing human health risks. EEI believes it would be beneficial for the applicability of the Bulletin to include ecological risk assessments explicitly. How federal agencies assess ecological risks affects regulatory decisions related to ecological endpoints, such as assessments of natural resource damages or permitting of business operations. The same standards for quality and objectivity for human health risk assessments should apply to ecological risk assessments.

The Bulletin is not clear on its applicability to existing agency guidance, risk-based standards, determinations and regulations. It would be helpful for OMB to clarify this matter. EEI recommends that the correction request procedures under agencies' Information Quality Guidelines be applied to risk assessments that are the basis of guidance, risk-based standards, determinations and regulations that are currently in effect if such risk assessments are found not to be in accordance with the Bulletin.

EEI believes that agency risk assessments should be more transparent, consistent and of high technical quality. We appreciate OMB's efforts to improve the technical quality and objectivity of risk assessments prepared by federal agencies and believe the technical guidance provided in the Proposed Bulletin will help in achieving that goal.

Thank you for the opportunity to comment on this important public policy issue. Again, EEI commends OMB, and particularly the Office of Information and Regulatory Affairs, for its efforts in furthering the Administration's policy of "smarter regulation" at all federal regulatory agencies. Please contact Michael Rossler at (202) 508-5516 or mrossler@eei.org if you have any questions about these comments.

Sincerely,



Quinlan J. Shea, III

cc: Michael Rossler