

# COMMENTS

on **PROPOSED RISK ASSESSMENT BULLETIN**

By the National Association of Manufacturers

Submitted to the Office of Management and Budget on Proposed Risk  
Assessment Bulletin

June 15, 2006

## Executive Summary

The National Association of Manufacturers (NAM) supports the issuance of a Risk Assessment Bulletin in order to standardize and improve how risk assessments are performed. Risk assessments are a vital part of the rulemaking process and, when done well, can help convince skeptics of the need for the regulatory action. A suspect risk assessment, however, whether due to bias, methodology, data sets or any other problem can provide reason to oppose the action for which the risk assessment was performed even if the action is in the public interest.

Manufacturing is the economic sector most affected by regulations and regulatory standards. Therefore, our membership is very interested in having risk assessments that are of the highest quality. This would help to provide comfort that the action is warranted and also help our member companies explain to their employees, customers, and perhaps the public at large why the action is needed. It is important to remember that a risk assessment should not determine policy, but it is a significant factor for policymakers to consider.

Specific recommendations that the NAM urges OMB to consider are:

- Exceptions should be very limited, and all but public emergencies should be subject to a deferral/waiver process through OMB.
- Scientific objectivity is a critical determinant in the quality of a risk assessment. Therefore, agencies should be required to discuss why they chose the studies they relied upon and why they rejected other relevant studies. Weight of the evidence rather than a pre-determined policy choice should guide the risk assessment's outcome.
- Since reproducibility is so crucial to a risk assessment's credibility, this standard should be required for all risk assessments and not just those that are influential.
- The public should be allowed to comment and participate in the risk assessment process, including as early as determining the scope. In addition, the public should be allowed to petition for updates and receive an agency response.
- For risk assessments used in regulatory analysis, the effect on other risks regulated by the agency, as well by other agencies, should be taken into account.
- The Bulletin should note that since it is based on the Information Quality Act, the issue of judicial reviewability is not a matter of settled law.

**Comments of the  
National Association of Manufacturers  
on  
Proposed Risk Assessment Bulletin**

**June 15, 2006**

The National Association of Manufacturers (NAM) appreciates the opportunity to comment on the Office of Management and Budget's (OMB) Proposed Risk Assessment Bulletin ("Bulletin"). The NAM believes strongly that when sound science and economics underlie a regulation or other standard, voluntary compliance is easier to achieve because regulated entities will have a better understanding of the need for the government action and will be better equipped to explain to employees and others responsible for adhering to the standard why they need to do so.

The NAM is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states. Headquartered in Washington, D.C., the NAM has 10 additional offices across the country. Visit the NAM's award-winning Web site at [www.nam.org](http://www.nam.org) for more information about manufacturing and the economy.

The NAM's mission is to enhance the competitiveness of manufacturers by shaping a legislative and regulatory environment conducive to U.S. economic growth, and to increase understanding among policymakers, the media and the general public about the vital role of manufacturing to America's economic future and living standards.

**Risk Assessments Are Important**

A risk assessment can be the most important factor in determining the need for certain types of regulatory and administrative actions, as well as the levels and other

types of standards contained in them. A risk assessment done well can help to convince those most affected by it — as well as the general public — that what the agency has decided to do is needed and justified, thus leading to easy acceptance and compliance. A shoddy, biased, or suspect risk assessment, on the other hand, will draw concerns that the agency acted arbitrarily and/or capriciously and lead to compliance problems.

Put another way, a well-grounded risk assessment associated with the promulgation of a regulation that is controversial, at least at first, will make it easier for the agency and other groups (public interest organizations as well as trade associations) to explain to the public at large, as well as entities that are directly affected, why the agency action makes for good public policy. A risk assessment of questionable quality, however, could serve as a “golden arrow” in the quiver of arguments by the regulation's opponents, even if the action taken were, indeed, in the best interest of the nation.

If implemented, the Risk Assessment Bulletin would not in itself be an arbiter of policy. Its standards would, however, help to improve the quality of both the information that policymakers have before them and decisions that are based upon that information.

The quality of risk assessments used in the rulemaking process is of particular importance to the NAM and its membership. According to a recent report by the U.S. Small Business Administration (“The Impact of Regulatory Costs on Small Firms,” September 2005), the average annual regulatory compliance cost per employee for manufacturing firms is \$10,175, versus \$5,633 for firms in all sectors. The per-employee annual regulatory compliance cost for manufacturers with fewer than 20 employees is more than two-and-a-half times higher than it is for manufacturers with 500 or more employees. For manufacturers with fewer than 20 employees, the annual figure is

\$21,919, compared to \$8,748 for large firms. Manufacturers with between 20 and 499 employees bear an annual per-employee cost of \$10,042 for regulatory compliance.

As the cost figures indicate, manufacturers pay significant sums to comply with regulatory requirements. The quality of regulations, and the reasoning behind them, are therefore of great importance in helping manufacturers and other regulated entities (including state and local governments) in explaining to their employees why the requirement exists and the necessity (other than a fine for the employer) of complying with it.

### **General Comments**

Overall, the NAM supports OMB issuing a Bulletin for agencies to abide by when conducting risk assessments. The draft that OMB has issued is a good beginning with many useful ideas and features. The supplemental information supplied with the draft is particularly valuable in determining the meaning and intent of specific terms and sections of the Bulletin. The NAM therefore encourages OMB to include this background information as a formal part of the Bulletin.

The Information Quality Act (aka “Data Quality Act,” Section 515 of the Fiscal Year 2001 Treasury, Postal Service and General Government Appropriations Act) requires OMB to develop policies and practices that will encourage agency adherence to both their own Information Quality Guidelines and the government-wide Information Quality Guidelines. The NAM therefore views the issuance of the Proposed Risk Assessment Bulletin as part of OMB’s responsibilities and duties under the Information Quality Act.

The NAM suggests that either in the supplemental information, or under Section XI (Judicial Review), OMB should acknowledge that the question of whether agency actions under the Information Quality Act are subject to judicial review is not a matter of settled law.

### **Specific Comments**

#### **Section II: Applicability**

**Exceptions:** The Bulletin essentially collects and summarizes recommendations for improvements in agency risk assessments made over the past two decades by multiple authorities. As such, compliance with the Bulletin should be the norm, and exceptions should be rare. Including a provision for declared public emergencies, however, that defers the obligation to meet the requirements of the Bulletin until after the emergency has been addressed would be understandable, reasonable and consistent with other documents relating to the promulgation of regulations. Since risk assessments are vital to a good understanding of the policy choice they have been used to analyze, there should be no other general exceptions. The NAM recognizes, however, that there may be times (as discussed in the supplemental information) where a full-scale risk assessment may not be necessary. In those particular circumstances, the NAM recommends that the agency apply to OMB for a waiver, either for a category of assessments or a particular assessment. If OMB determines that general exceptions should be included in the Bulletin, they at least should be consistent with the exceptions found in the Paperwork Reduction Act (P.L. 96-511).

Agencies may argue that that they do not have the time or resources to adhere to the Bulletin's standards in all cases. Agencies likely will be able to find time later, however, if threatened with litigation or other challenges to either the risk assessment or actions based upon the risk assessment. The NAM therefore encourages OMB to err on the side of providing policymakers with the best information possible at the beginning of the promulgation process, rather than allowing the regulation or other action to proceed absent a good risk assessment.

**Permits:** A permit that is intended to protect human health or the environment can do so only if the terms of the permit are based upon a scientifically credible risk assessment. Risk assessments performed in connection with permit applications should not, therefore, be exempted from the Bulletin.

### **Section III: Goals.**

The NAM believes that the listed goals are a good description of what risk assessments should accomplish.

### **Sections IV and V: General and Influential Risk Assessment and Reporting**

#### **Standards.**

**Scientific Objectivity:** In addition to “giving weight to both positive and negative studies in light of each study’s technical quality,” as required under subsection 4(b) of Section IV, agencies should also be required to discuss why they chose the studies that they relied upon, and why they rejected other relevant studies. In addition, agencies need

to adhere to an objective “weight of the evidence” standard in determining the outcome of the risk assessment, rather than allowing a policy choice to guide that determination.

**Reproducibility:** Reproducibility should be required for all risk assessments, not just influential risk assessments. If the results of a risk assessment are not reproducible, the risk assessment has little, if any, scientific credibility.

**Public Participation:** The NAM encourages OMB to include a requirement that agencies provide meaningful opportunities for public comment at the inception of, and throughout, the risk assessment process. This is the surest way to ensure that the risk assessors focus on the right issues and consider all relevant information appropriately.

**Comparative Risk:** For risk assessments that are used for regulatory analysis, as discussed in subsection 7 of Section IV, there should be a discussion about the comparison with other risks regulated by the rule and the agency, as well as by other rules and agencies.

**Extraction:** Agencies should be directed to give more weight to real-world data than to experimental data.

**Adverse Effects:** The discussion in the supplemental information is helpful, but there should be a clearer, more precise meaning. Additional examples also should be provided.

## **Section VI: Updates.**

**Public Participation:** There should be a provision allowing the public to petition for an update of a risk assessment. Agencies should be required to respond publicly to such requests with an explanation as to why the request was accepted or rejected.

**Section VII: Certification.**

**OMB Approval.** At least in the case of controversial risk assessments, if not generally, OMB should review the risk assessment for compliance with the Bulletin's procedures before a certification can be issued.

**Section VIII: Deferral and Waiver.**

**OMB Approval:** Since agency heads are often deferential to career personnel, especially with respect to technical issues, the agency head should be required either to seek the approval of OMB before a deferral or waiver can be issued or to seek public comment on a proposed deferral or waiver. There should be a time limit for OMB's response, with a presumption in favor of the deferral or waiver, so that the agency's hands are not tied if OMB does not respond in a timely manner.

**Agency Head:** Since this term is not defined, it is not clear whether it refers to a Cabinet-level official or equivalent or the head of an agency within a Cabinet Department that OMB treats as a separate agency for regulatory review purposes. This term should be clarified.

**Section X: Effective Date.**

**Implementation:** The Bulletin should be effective six months after being issued.

**Application:** Since this is a good practices document, and agencies should be aware of the draft, all pending risk assessments should be covered.

## **Section XI: Judicial Review**

As noted under General Comments, either in this section or in the supplemental information, OMB should note that since the Risk Assessment Bulletin was developed and implemented in conformance with the Information Quality Act, judicial review of compliance with the Bulletin is not a matter of settled law.

### **Conclusion**

The National Association of Manufacturers appreciates OMB's intention to improve the quality of risk assessments and to standardize the procedures for conducting a risk assessment. These studies are essential to the credibility of regulations and the standards within them and other agency actions that are based on risk assessments. Issuance of the Risk Assessment Bulletin should help to enhance the quality of agency activities, including rulemaking, and further the goals of the Information Quality Act.