



June 8, 2006

BY ELECTRONIC MAIL

The Honorable Steven D. Aitken
Acting Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
Eisenhower Executive Office Building, Room 262
17th Street and Pennsylvania Avenue, NW
Washington, DC 20503
Electronic Address: OMB_RAbulletin@omb.eop.gov

Re: Comments on OMB's Proposed Risk Assessment Bulletin

Dear Mr. Aitken:

The U.S. Small Business Administration's (SBA) Office of Advocacy (Advocacy) is pleased to submit the following comments on the Office of Management and Budget's (OMB) *Proposed Risk Assessment Bulletin*.¹ Advocacy strongly supports OMB's effort to improve the quality of scientific information used or relied upon by federal agencies when developing regulations. Advocacy believes this is particularly important given the disproportionate impact of federal regulations on small business.² Advocacy believes that a more open and transparent regulatory process will lead to better regulations that are less costly and less burdensome to small business.

Office of Advocacy

Advocacy was established pursuant to Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within SBA, so the views expressed by Advocacy do not necessarily reflect the views of SBA or the Administration. The Regulatory Flexibility Act (RFA),³ as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA),⁴ gives small entities a voice in the rulemaking process. Moreover, on August 13, 2002, President Bush signed Executive Order 13272,⁵ which requires federal agencies to give every appropriate

¹ *Notice of Proposed Risk Assessment Bulletin*, Office of Management and Budget, 71 Fed. Reg. 2600 (January 17, 2006) (see, http://www.whitehouse.gov/omb/infoereg/proposed_risk_assessment_bulletin_010906.pdf).

² See, W. Mark Crain, *The Impact of Regulatory Costs on Small Firms*, Report RFP No. SBAHQ-03-M-0522 for the Office of Advocacy, U.S. Small Business Administration (September 2005) at 5 (see, <http://www.sba.gov/advo/research/rs264tot.pdf>).

³ 5 U.S.C. § 601 et seq.

⁴ Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.).

⁵ 67 Fed. Reg. 53461 (August 16, 2002).

consideration to any comments on a proposed or final rule submitted by Advocacy. The agency must include, in any explanation or discussion accompanying publication in the *Federal Register* of a final rule, the agency's response to any written comments submitted by Advocacy on a proposed rule.

Advocacy and OMB

Advocacy and OMB's Office of Information and Regulatory Affairs (OIRA) perform complementary functions in the regulatory process. For example, Advocacy oversees agency compliance with the RFA (which requires agencies to analyze the impact of proposed regulations on small business and to consider less burdensome alternatives), and OIRA reviews agencies' compliance with Executive Order 12866⁶ (which requires agencies to assess the overall costs and benefits of proposed regulations).⁷ The two offices work together in reviewing regulatory proposals and recommending alternatives that make regulations more cost effective and less burdensome. Both offices also work closely with federal agencies in developing data, evaluating costs and benefits, and considering alternative approaches to regulations.

Advocacy's principal interest in the regulatory process is ensuring that regulations do not unduly burden small business. As such, Advocacy supports the use of sound science to develop better regulations and feasible alternatives that reduce unnecessary burdens while still meeting the agency's statutory objectives. Advocacy understands that assessing risks to human health, safety, and the environment is extremely complex, but believes that a more open and transparent approach to risk assessment will lead to better regulations. Advocacy consulted with small business representatives about OMB's Proposed Risk Assessment Bulletin and these comments reflect their views.

Background

OMB's Proposed Risk Assessment Bulletin would impose minimum and uniform requirements on federal agencies in order to enhance the technical quality and objectivity of risk assessments. Risk assessments are defined in the bulletin as documents that assemble and synthesize scientific or technical information to determine whether, and to what extent, a potential hazard exists to human health, safety, or the environment.⁸ Risk assessments play an important role in the regulatory process because they serve as the scientific underpinning of federal regulations. Risk assessments are used to assess the risks associated with environmental exposures, occupational health, food safety, traffic hazards, human health, agricultural pests, and technology.

⁶ Executive Order 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51735 (October 2, 1993)

⁷ Advocacy and OIRA also participate in SBREFA review panels, which are required for any proposed regulations promulgated by the U.S. Occupational Safety and Health Administration or the U.S. Environmental Protection Agency that are expected to have a significant economic impact on a substantial number of small entities. See, 5 U.S.C. § 609(b).

⁸ Footnote 1 at § I, 3.

OMB's Proposed Risk Assessment Bulletin would require federal agencies to make risk assessments more transparent by requiring agencies to clearly state the goals and objectives of the risk assessment⁹ and make the risk assessment process more open by encouraging peer review and public participation.¹⁰ Federal agencies would be required to discuss in detail the informational needs of the decision maker and the scope of the risk assessment, characterize the risk they are assessing, ensure objectivity, disclose critical assumptions, and discuss uncertainty.¹¹ Further, the bulletin makes clear that risk assessments are subject to OMB's Information Quality Guidelines (IQGs)¹² and would require more rigorous detail when risk assessments are "influential"¹³ or used for regulatory analysis.¹⁴ Finally, the OMB bulletin requires federal agencies to certify that risk assessments comply with the bulletin¹⁵ and that risk assessments be updated as new information becomes available.¹⁶

Advocacy Supports OMB's Proposed Risk Assessment Bulletin

As indicated above, Advocacy strongly supports OMB's effort to improve the quality of scientific and technical information that is published, released, used, or relied upon by federal agencies when developing regulations. As such, Advocacy has supported OMB's efforts to issue government-wide guidelines on information quality,¹⁷ peer review,¹⁸ good guidance practices,¹⁹ and now, risk assessments. Advocacy believes that risk assessment is an important analytical tool in the regulatory process, similar in importance to regulatory impact analysis²⁰ (e.g., benefit-cost analysis) and regulatory flexibility analysis²¹ because these analyses influence the consideration of regulatory approaches. In our view, high quality analyses early in the regulatory process are essential to achieving better regulatory outcomes.

Advocacy agrees with OMB that minimum and uniform standards for risk assessment are warranted and that it is prudent to ground the risk assessment bulletin firmly in OMB's IQGs. This will allow both federal agencies and the public to understand the substantive

⁹ Footnote 1 at 10 and § III.

¹⁰ *Id.* at 11 and § III, 5.

¹¹ *Id.* at 12-16 and § IV.

¹² *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated By Federal Agencies*, 67 Fed. Reg. 8452 (February 22, 2002) (see, <http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf>).

¹³ Footnote 1 at 11 and § I, 2. (An influential risk assessment is defined as "a risk assessment that the agency reasonable can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.")

¹⁴ *Id.* at 15-16 and § IV, 7.

¹⁵ *Id.* at 16-20 and § VII.

¹⁶ *Id.* at 21 and § VI.

¹⁷ Footnote 12.

¹⁸ *Final Information Quality Bulletin for Peer Review*, Office of Management and Budget, 70 Fed. Reg. 2664 (January 14, 2005) (see, http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf).

¹⁹ *Draft Good Guidance Practices Bulletin*, Office of Management and Budget, November 23, 2005 (see, http://www.whitehouse.gov/omb/inforeg/good_guid/good_guidance_preamble.pdf).

²⁰ OMB Circular A-4, *Regulatory Analysis*, Office of Management and Budget, September 17, 2003 (see, <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>).

²¹ 5 U.S.C. § 603-604.

and procedural requirements that scientific and technical information must meet in order to be used or relied upon in the regulatory process. Further, it will also allow other federal agencies to compare risks where competing studies might differ. In order to clarify the relationship between OMB's IQGs and the Proposed Risk Assessment Bulletin, Advocacy suggests that OMB clarify the following issues in the proposed bulletin:

- In Section II, Applicability, Advocacy suggests that OMB explain why these particular exemptions (e.g., inspections, agency adjudications and permit proceedings, federally-approved product labels) are being provided and why these are not consistent with the exemptions in the IQGs.²² Advocacy understands that OMB seeks to exempt situations where procedural safeguards already exist, but Advocacy suggests that OMB attempt to reconcile the two standards as much as possible.
- Also, in Section II, Advocacy suggests that OMB clarify whether and how the term “available to the public” differs from the concept of “dissemination” in the IQGs. For example, in the preamble discussion of Section IV, the proposed bulletin states that “each risk assessment disseminated by a Federal agency is subject to OMB’s Information Quality Guidelines;” however, the risk assessment bulletin is said to apply to risk assessments “available to the public.”²³ Advocacy suggests that OMB attempt to provide consistent definitions are much as possible.
- Advocacy suggests that OMB specify that the bulletin applies to third party risk assessments that a federal agency has not prepared, but wishes to use or rely upon in developing federal regulations. OMB’s IQGs clearly apply to third party information when an agency disseminates the information “in a manner that reasonably suggests that the agency agrees with the information.”²⁴ The risk assessment bulletin should apply when an agency seeks to use or rely upon such third-party information.
- Advocacy suggests that OMB clarify that an affected person can utilize the IQGs’ administrative correction mechanism to seek and obtain the correction of an agency-disseminated risk assessment that it believes is inaccurate or incomplete. Advocacy notes that the IQGs’ administrative correction mechanism exists “to facilitate public review” of agency information practices.²⁵

²² OMB’s Information Quality Guidelines exempt from the definition of dissemination “distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.” 67 Fed. Reg. 8460.

²³ Further, the preamble to the IQGs specifically states that dissemination includes “a risk assessment prepared by the agency to inform the agency’s formulation of possible regulatory or other action.”

²⁴ Footnote 12 at 8454.

²⁵ *Id.* at 8459.

- In Section III, Goals, Advocacy suggests that OMB consider adding that a goal of the bulletin is to produce a high quality risk assessment that meets OMB’s IQGs. Also, in Section III, subsection 2, Advocacy suggests that OMB state that any risk assessment must meet the OMB IQGs standards before it could be used or relied upon by a federal agency.
- In Section IV, General Risk Assessment and Reporting Standards, Advocacy suggests that OMB consider moving subsection 6 (executive summary) to either the beginning or end of the section (to improve the flow of the document) and include a requirement that risk assessments that are influential or used for regulatory analysis include a specific discussion of the additional information required by Section IV, 7 and Section V of the bulletin, respectively.
- In Section VII, Updates, Advocacy suggests that OMB clarify that under no circumstances should a risk assessment be used or relied upon by a federal agency if the agency knows, or has reason to believe, that the risk assessment is outdated. This is especially important for risk assessments used for regulatory analysis under Section IV, 7.

Advocacy believes that OMB has prepared a high quality document. In particular, Advocacy agrees with OMB’s requirements that agencies place risk in its proper context²⁶ and clearly discuss uncertainty.²⁷ Likewise, Advocacy agrees with the requirements that agencies provide a “response-to-comment” document for influential risk assessments²⁸ and compare the results of the assessment to other studies on the same topic.²⁹ Agencies should not be allowed to “cherry pick” which studies they use or rely upon. Frequently, when Advocacy is reviewing proposed regulations and considering the feasibility of various alternatives, it is extremely helpful to understand the strengths and limitations of the underlying analyses. Because the regulatory process is so frequently mired in controversy over the risks associated with a particular substance or activity, a more uniform approach to risk assessment should instill greater confidence that regulatory proposals are sound, thereby reducing opposition and creating greater public confidence in regulatory decisions that agencies make.

Advocacy also believes OMB has provided a proper degree of flexibility to federal agencies in preparing and using risk assessments. For example, OMB makes clear that the proposed bulletin applies “to the extent appropriate”³⁰ and provides a “deferral and waiver” provision that allows federal agencies to avoid compliance for compelling reasons.³¹ This flexibility is appropriately balanced with requirements that agency heads “certify” their compliance with the bulletin³² and update risk assessments if new

²⁶ Footnote 1 at 14 and § IV, 4.

²⁷ *Id.* at 9 and § II and p. 11-21 and § IV.

²⁸ *Id.* at 20-21 and § V, 9 .

²⁹ *Id.* at 17 and § V, 2.

³⁰ *Id.* at 9 and § II.

³¹ *Id.* at 22 and § VIII.

³² *Id.* at 21-22 and § VII.

information changes their findings.³³ As indicated above, Advocacy notes that an essential purpose of OMB's IQGs' administrative correction mechanism is "to facilitate public review" of agency information practices;³⁴ therefore it is important that affected persons, particularly small businesses, have the ability to monitor agency information practices. Also, as stated above, no risk assessment should be used or relied upon that an agency knows, or has reason to believe, is outdated.

Federal Regulations Have a Disproportionate Burden on Small Business

Advocacy's principal interest in the regulatory process is ensuring that regulations do not unduly burden small business. It is clear from research sponsored by Advocacy³⁵ that small businesses bear a disproportionate share of the regulatory burden. The research indicates that businesses employing fewer than 20 employees face an annual regulatory burden of \$7,647.00 per employee, nearly 45 percent above that facing a firm employing 500 or more employees (\$5,282.00).³⁶ Advocacy supports OMB's Proposed Risk Assessment Bulletin because we believe it will help assure that risk assessments are sound and that federal regulations do not inadvertently impose unnecessary costs and burdens on small business. For this reason, Advocacy believes that minimum standards for risk assessments across federal agencies are warranted and that OMB's proposed bulletin will result in significantly improved agency information practices.

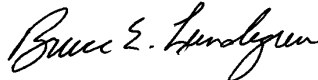
Conclusion

Advocacy supports OMB's effort to improve the quality of scientific information used by federal agencies when developing regulations. Risk assessment is vitally important in the regulatory process because risk assessments serve as the scientific underpinning of federal regulations. Advocacy believes that a more open and transparent regulatory process will lead to better regulations that are less costly and burdensome to small business. We appreciate the opportunity to comment on this important topic. Please feel free to contact me or Bruce Lundegren at (202) 205-6144 (or bruce.lundegren@sba.gov) if you have any questions or require additional information.

Sincerely,



Thomas M. Sullivan
Chief Counsel for Advocacy



Bruce E. Lundegren
Assistant Chief Counsel for Advocacy

³³ Footnote 1 at 21 and § VI.

³⁴ Footnote 25.

³⁵ Footnote 2 at 5.

³⁶ *Id.*