



June 14, 2006

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

RE: Comments on OMB Proposed Risk Assessment Bulletin

Dear Mr. Aitken:

The Aerospace Industries Association of America (AIA) welcomes this opportunity to provide comments on the proposed OMB Risk Assessment Bulletin, released on January 9, 2006. AIA represents the leading manufacturers of civil, military, and business aircraft, helicopters, unmanned aerial vehicles, space systems, aircraft engines, missiles, and related components, equipment, services and information technology. AIA has more than 275 member companies that employ almost 700,000 people. Please find enclosed our comments, which are divided into two primary sections:

- I. Introductions and General Comments
- II. Comments on Specific Provisions of the Bulletin

Please feel free to contact me at 703.358.1050 or hoai.huynh@aia-aerospace.org if you have any questions or require further information.

Sincerely,

A handwritten signature in black ink, appearing to read 'Hoai B. Huynh', written in a cursive style.

Hoai B. Huynh
Director
Environment, Safety & Health

Attachment: AIA Comments on the OMB Risk Assessment Bulletin



**COMMENTS ON
OMB'S
PROPOSED RISK ASSESSMENT BULLETIN**

**Submitted by
THE AEROSPACE INDUSTRIES ASSOCIATION OF AMERICA
June 15, 2006**

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I. INTRODUCTION AND GENERAL COMMENTS

The Aerospace Industries Association of America (AIA) welcomes the opportunity to comment on OMB's Proposed Bulletin on Risk Assessment (the "Bulletin").¹ AIA represents manufacturers of commercial, military, and business aircraft, helicopters, aircraft engines, missiles, spacecraft, and related components and equipment. AIA has over 275 members in the aerospace sector, employing almost 700,000 people in the United States.

We endorse OMB's effort to standardize agency risk assessment practices by establishing uniform, minimum standards that will enhance the technical quality and objectivity of risk assessments prepared by federal agencies. The Bulletin is an appropriate part of OMB's wider effort to ensure that agency disseminations meet high standards for quality, objectivity, utility, and transparency.

A. The Scope of the Proposed Bulletin and AIA's Interests

AIA members' interests in federal risk assessment range broadly across the defense, transportation, and communications sectors, in addition to the health, environment, and safety risk analyses that appear to be the focus of many of the Bulletin's key provisions. While our specific comments also primarily address these latter areas, AIA is concerned that OMB not neglect opportunities to improve risk assessments performed by federal agencies in newer emerging areas such as homeland security, as well as in traditional areas such as airport communication systems and traffic control and military base siting and closures.

We recommend that OMB give more attention to how the new Bulletin will impact these concerns. In particular, we suggest that OMB consult with the Departments of Defense (DOD), Homeland Security, Transportation, and the National Aeronautics and Space Administration (NASA) before finalizing the Bulletin. The risk assessment practices of these agencies may vary considerably from those of the environment, health, and safety agencies.

B. Health, Environment, and Safety Risk Assessment

AIA agrees that the greatest potential for achieving more uniform and scientifically credible risk assessment lies in the federal analysis of health, environment, and workplace risks.

¹ AIA's comments were prepared with support from McKenna, Long, and Aldridge LLP, an international law firm that assists clients with regulatory and governmental issues, as well as provides transactional and litigation services.

1. Oversight by the OMB

The history of federal health risk assessment over the past 30 years shows that progress has been slow toward improving the scientific quality and objectivity of risk assessment on the neutral common ground of science. Despite prominent studies and agency risk guideline-writing efforts, federal health risk assessment has remained largely captive to congressional mandates to “get tough” on health risks. Further, throughout the past three decades, the agencies have been both the primary producers and consumers of risk assessments. Mandated to write and enforce stringent precautionary regulations, the agencies have created a regulatory science support infrastructure that needs extramural oversight. Inter-agency risk working groups, agency science advisory boards, and studies by the National Academy of Sciences (NAS) have not provided an adequate science oversight function. Proposals to split federal risk assessment from federal risk management into distinct independent offices have not received congressional approval.

Consequently, the Bulletin is an important step in developing an objective, comprehensive, science-based risk assessment baseline on which regulation and policy may be built. The Bulletin mandates application of many of the principles essential to scientifically defensible and unbiased risk assessment. Of particular note is the requirement that risk assessments set forth the central tendency of risk. Transparent and well-reasoned risk management decisions can only be made if the *risk assessor* provides the *risk manager* with an objective assessment of the most likely, or expected, risk.

2. Specific Oversight and Action-Forcing Mechanisms

AIA is concerned that the Bulletin leaves too much discretion to the agencies to determine its applicability. Federal health risk assessment has been controversial from the beginning, and many agencies are insular and defensive, and use risk assessment to further policy goals. To be effective in changing agency practice, the Bulletin needs to be more concrete and specific in its expectations for federal risk assessments, so that stakeholders can determine if agencies have complied with the Bulletin. AIA provides specific recommendations below on how the Bulletin can be strengthened.

In addition, while the Bulletin requires that an agency certify that it has complied with the Bulletin, it does not address how the Bulletin can be enforced if agencies fail to comply with it. AIA believes that developing a review and enforcement mechanism is critical to the

Bulletin's ability to meet its goals. AIA recommends that OMB establish a risk assessment review panel that could (1) assist agencies in determining the applicability of the Bulletin's requirements to specific assessments, (2) serve as a resource for agencies as risk assessments are performed, (3) receive and review complaints from the public or other agencies regarding how an agency implemented the Bulletin's requirements, and (4) with the assistance of the Office of Science and Technology Policy (OSTP), serve as the final arbitrator on issues concerning the quality, utility, objectivity, and integrity of an agency risk assessment.

3. Reinforcing Critical Steps in a Well-Performed Risk Assessment

Although the Bulletin sets forth minimum standards for all federal risk assessments, it focuses on assessing risks associated with chemical exposures. Numerous assessments are performed by a variety of federal agencies, including the Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA), Agency for Toxic Substances and Disease Registry (ATSDR), and National Institute for Occupational Safety and Health (NIOSH). The Bulletin does not, however, clearly distinguish between the four steps of risk assessment that were set forth in the NAS' "Redbook:"² (1) hazard identification, (2) dose-response, (3) exposure assessment, and (4) risk characterization. These four steps of the risk assessment process determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment.

4. Conforming Agency Risk Assessment Guidelines

The success of the Bulletin in standardizing federal risk assessment will depend upon how it is implemented by each agency. To facilitate this process, AIA recommends that the OMB include a provision in the Bulletin directing agencies to develop their own guidance on implementing the Bulletin, and to conform their existing risk assessment regulations or guidance, if any, to the Bulletin's requirements. This will avoid confusion within agencies and provide a unified statement on how each agency intends to implement the Bulletin.

² National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (1983).

II. COMMENTS ON SPECIFIC PROVISIONS OF THE BULLETIN

A. Definitions (Section I of the Bulletin)

Risk assessment. AIA supports OMB's broader definition of risk assessment to include documents that address some but not all aspects of risk assessment, such as margin of exposure estimates, hazard determinations, and entries in EPA's Integrated Risk Information System (IRIS). These documents inform agency decisions and will benefit from the Bulletin's standards of objectivity and transparency.

AIA is aware that some federal agencies have expressed concern that because the Bulletin's definition of risk assessment is broad, the coverage of more risk assessments under the Bulletin may delay the dissemination of timely information, particularly related to public health issues. One example given at the NAS' May 22, 2006 public comment session was that if a Data Safety and Monitoring Board were to decide to interdict a clinical trial based on its judgment that there is risk to human health in continuing the trial, that determination would be subject to the Bulletin and there would be undue delay in stopping the trial. AIA believes that the Bulletin allows agencies the flexibility to address these types of situations. Nevertheless, the Bulletin should clarify that the showing required to demonstrate compliance with the Bulletin must be judged in relation to nature of the risk assessed, the strength of the available relevant evidence, and the urgency for risk managers to make a decision. More examples of these types of situations should be provided in the Preamble.

Influential Risk Assessment. OMB's definition of influential risk assessments is consistent with its definition of "influential" under the Data Quality Act. As OMB notes, a risk assessment can have significant economic impact even if it is not part of a rulemaking. The Preamble provides examples of what OMB would consider "influential risk assessments." Absent from the list, however, are risk assessments performed under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) or Resource Conservation and Recovery Act (RCRA) for the purpose of making remediation or corrective action decisions. Given both the high costs of typical CERCLA and RCRA clean-ups (including the costs of remedial investigations, which themselves can run into the millions of dollars), risk assessments under these statutes must be considered "influential risk assessments." This conclusion is strengthened in the case of CERCLA by the lack of

opportunity for pre-enforcement judicial review under that statute.³ AIA recommends that the definition of influential risk assessment in the Bulletin incorporate the examples given in the Preamble and also include risk assessments performed under CERCLA and RCRA for purposes of remediation and corrective action. The definition should state:

“influential risk assessment” means a risk assessment that the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. At a minimum, documents falling within the following categories are presumed to be influential and subject to the requirements of this Bulletin: assessments that determine the level of risk regarding health (such as reference doses, reference concentrations, and minimal risk levels), safety and environment; margin of exposure estimates, hazard determinations, EPA Integrated Risk Information System (IRIS) values, risk assessments which support EPA National Ambient Air Quality Standards, FDA tolerance values, ATSDR toxicological profiles, HHS/NTP substance profiles, NIOSH current intelligence bulletins and criteria documents, risk assessments performed as part of economically significant rulemakings; and risk assessments performed under CERCLA, RCRA, and the CWA for purposes of remediation, corrective action, and permitting.

B. Applicability (Section II of the Bulletin)

The Bulletin states that federal agency risk assessments shall comply with its standards “to the extent appropriate.” The Preamble states that a “rule of reason” should be used to assess Bulletin applicability. It provides the example of screening level assessments that do not need to comply with the Bulletin’s standard of “neither minimizing nor exacerbating the nature and magnitude of the risk.” The Preamble goes on to state that, “it is expected that every risk assessment (including screening level assessments) will comply with

³ Under Section 113(h) of CERCLA, a person potentially responsible for payment of CERCLA response costs at a site may not seek judicial review of EPA’s selection of a remedy for the site prior to the EPA’s initiation of judicial enforcement action against that person. That means that a person who has been ordered by EPA under Section 106 of CERCLA to clean up a site, under threat of penalties of \$27,500 per day of non-compliance plus triple the cost of the remedy, refuses to comply at his serious peril.

other standards in Section IV,” including describing the data, methods, and assumptions with a high degree of transparency; identifying key scientific limitations and uncertainties; placing the risk in perspective/context with other risks familiar to the target audience, and, for quantitative risk assessments, providing a range of plausible risk estimates when there is scientific uncertainty or variability.

AIA understands that there is a need to provide agencies with some flexibility in applying the Bulletin’s standards. AIA believes, however, that as written, the Bulletin leaves too much discretion to the agencies to determine the Bulletin’s applicability or the standards to which agencies should adhere.

1. The Scope of Agency Discretion in Implementing the Bulletin

At a minimum, the expectations described in the Preamble (e.g., describe the data, methods, and assumptions; identify key scientific limitations and uncertainties, etc.) should be specified in the Bulletin itself. In addition, the Bulletin provides no guidance to agencies regarding who should make the determination as to which Bulletin standards may or may not apply in a particular risk assessment. If the determination is left to individual risk assessors on a case-by-case basis, there will likely be a high degree of variability in the interpretation and implementation of the Bulletin within each agency. To ensure that the Bulletin’s requirements are applied consistently within each agency, AIA recommends that, in addition to requiring the agencies to prepare agency-specific guidance for implementing the Bulletin, OMB direct each agency to establish an intra-agency group to be responsible for determining which of the Bulletin’s requirements should apply to each assessment performed. The Bulletin encourages risk assessors to engage in an iterative dialogue with the relevant agency decision makers to formulate the objectives, scope, and content of the assessment. Once these decisions are made, the risk assessor should, in the first instance, determine the applicability of the Bulletin standards. The intra-agency group should then review the assessors’ determinations and either concur or offer recommendations for enhanced compliance with the Bulletin. The intra-agency group review will also help ensure that the certification requirement of the Bulletin is a deliberative process, rather than a mere “rubber stamp” approval.

In 2003, the U.S. Department of Agriculture’s (USDA) Food Safety Inspection Service established a similar type of intra-agency review group to strengthen the use of risk

assessments within the agency and to build a solid scientific basis on which to base regulatory and policy decisions. The committee, made up of representatives from multiple USDA offices, was charged with (1) prioritizing risk assessments, (2) providing guidance related to carrying out risk assessments, and (3) identifying outside experts and/or universities to assist in the development of risk assessments. OMB should require similar types of committees within all agencies.

2. Public and Confidential Risk Assessments

The Bulletin states that all “publicly available risk assessments shall comply” with its standards. “Available to the public” is defined in the Preamble, but not in the Bulletin, as documents that are made available to the public by the agency or that are required to be disclosed under the Freedom of Information Act. The definition of “available to the public” should be included in the Bulletin itself. However, even though an agency may not be required to share its risk assessment work with the public, it should nevertheless be required to comply with the requirements of the Bulletin. The Bulletin should not exclude nonpublic documents because they can have significant effects if used or relied upon by an agency.

3. Site-specific Risk Assessments

The Bulletin states that it generally “does not apply to risk assessments that arise in the course of individual agency adjudications or permit proceedings.” This seems to mean that the Bulletin does not apply to important site-specific risk assessments, which may include, airport facility approvals, facility siting decisions, NEPA analysis, Superfund site cleanups, RCRA corrective action proceedings, RCRA Part B permitting, and NPDES permitting. AIA does not believe that OMB should exclude such a wide range of risk assessments that significantly impact agency decision making. OMB should revisit this issue and ensure that the Bulletin is fully applicable to agency risk assessments performed in the context of site-specific permit proceedings.

The statement that the Bulletin does not apply to “inspections relating to health, safety or environmental” is vague and should be clarified. This language suggests that the Bulletin does not apply to Hazard Ranking System (HRS) scoring under CERCLA. The HRS is the principal mechanism EPA uses to place waste sites on the National Priorities List (NPL). It is a numerical scoring system that assesses the relative potential of sites to pose a threat to human health or the environment. As with site specific assessments discussed above, the HRS

significantly influences EPA decisions regarding NPL listings. We suggest that the Bulletin be made specifically applicable to Hazard Ranking System scoring under CERCLA.

C. Goals (Section III of the Bulletin)

AIA supports the five aspirational goals OMB has identified for each risk assessment. AIA recommends, however, that OMB add a sixth goal related to transparency. While the goal of transparency is implicit throughout the Preamble and the Bulletin, it should be specifically identified as an aspirational goal.

1. Goal Related to Problem Formulation

A risk assessment must be guided by a thorough understanding of the risk management decision to be made and the need for risk communication. Thus, AIA supports the Bulletin's goal of encouraging an iterative dialogue between risk managers and risk assessors. Risk assessors and risk managers must clarify the hazard that is the subject of the assessment and any possible policy options that are under consideration. AIA recommends, however, that the Bulletin address in more detail the factors that comprise each discipline in order to delineate the respective roles of the risk assessor and risk manager. For example, the Bulletin should make clear that the risk assessor is responsible for evaluating the relationship between a hazard and adverse effects, determining the conditions under which populations may be exposed, and characterizing the risk by describing the nature of adverse effects that can be attributed to the hazard, estimating their likelihood in exposed populations, and evaluating the strength of the evidence and the uncertainty associated with them. Risk management involves using all of the information gathered during the assessment to evaluate policy options. Risk managers consider the results of the risk assessment in the context of other policy considerations such as cost, feasibility, and the social impact of implementing certain policies. The risk manager identifies, selects, and implements measures that can be applied to reduce the risk identified during the assessment.

2. Goal Related to Completeness

The Bulletin states that the scope and content of the risk assessment shall be determined based on the objectives of the assessment and best professional judgment, considering the benefits and costs of acquiring additional information before undertaking the assessment. The Preamble states that agencies should refer to the OMB Information Quality Act (IQA) guidelines, the OMB peer review guidelines, and OMB Circular A-4 in deciding

on scope, content, and acquisition of additional information. This guidance should be in the Bulletin itself. Thus, AIA recommends that *goal 3* of the Bulletin state:

The type of risk assessment prepared shall be responsive to the nature of the potential hazard, the available data, and the decision needs. Agencies should refer to the OMB Information Quality Guidelines, Information Quality Bulletin for Peer Review, and Circular A-4 for further guidance on weighing the benefits and costs of acquiring further information for use in a risk assessment.

3. Goals Related to Effort and Resources Expended

AIA agrees that that an agency's level of effort and the resources it expends in developing a risk assessment should be commensurate with the importance of the risk assessment and the strength of the available evidence. However, AIA believes that the Bulletin should be more explicit regarding its expectations that every risk assessment is expected to comply with the standards set forth in section V of the Bulletin, unless an agency provides a compelling rationale for why those standards should not apply. Moreover, that rationale should be subject to public review and comment.

4. Goal Related to Peer Review and Public Participation

The Bulletin states that agencies shall follow appropriate procedures for peer review and public participation in the process for preparing the risk assessment. As OMB notes in footnote 24 of the Preamble, "public comments can play an important role in providing information that should be used in risk assessments and in identifying specific health and ecological concerns that they would like to see addressed" (quoting the Risk Commission Report). However, the Bulletin is unclear as to when agencies should involve the public and seems to suggest that agencies need only do so when a draft risk assessment is put out for peer review. The public should have an opportunity for input into risk assessment at all times during the risk assessment process, including when the risk assessment is in the problem formulation or planning stage. As discussed below, public input during scoping is vital to furthering the Bulletin's goals of utility, transparency, and objectivity. Public input should be vigorously solicited by federal agencies. AIA recommends that *goal 5* be restated as follows:

The agency shall follow appropriate procedures for peer review and public participation throughout the risk assessment process. This includes, but is not limited to, the risk assessment scoping and problem formulation or planning stages.

D. General Risk Assessment and Reporting Standards (Section IV of the Bulletin)

The Preamble states that OMB’s Information Quality Guidelines require that risk assessments “meet the three key attributes of utility, objectivity and integrity.” The Data Quality Act, however, requires OMB to issue guidelines assuring “*quality*, utility, objectivity and integrity.” “Quality” refers to the excellence, completeness, timeliness, and accuracy of information, all of which are vital for risk assessments. AIA recommends that OMB revise the introductory sentence to Part IV of the Bulletin to read as follows:

Each agency risk assessment shall meet the four key attributes of quality, utility, objectivity, and integrity and shall:

1. Standards Relating to Informational Needs and Objectives

AIA strongly agrees that the risk assessment should clearly states the informational needs driving the assessment, as well as the objectives of the assessment. This informs the public “why” or “for whom” the risk assessment is written.

The reason for, as well as the purpose of, a risk assessment should be established at the beginning of the risk assessment process. In addition, the proposed methodology of the risk assessment should be considered thoroughly and stated clearly before the assessment work begins. The proposed methodology should further the purpose of the risk assessment and be consistent with the reason for doing the risk assessment.

2. Standards Relating to Scope

(a) The Scope of Content in a Risk Assessment

The Bulletin correctly includes a standard related to the scope of a risk assessment. As the Bulletin recognizes, a risk assessment should summarize the scope of the assessment by describing the subject of the assessment, the hazard of concern, and the affected entities. The scope should also define the exposure or event scenarios relevant to the purpose of the assessment, as well as the type of event-consequence or dose-response relationship for exposure or event ranges that are relative to the objectives of the risk assessment. The

Bulletin should go further and provide guidance regarding the advisable scopes of federal agency risk assessments. As the American Chemistry Council (ACC) discussed in its previous comments to OMB⁴, EPA risk assessments frequently focus on highly improbable exposure events and, accordingly, hypothetical people. To prevent such use of highly improbable risk assessment scenarios, the Bulletin should stress that all exposure assumptions used in federal agency risk assessments must be based on actual data or, at a minimum, be probable and reasonable. Risk assessors must provide solid, scientific rationales for conservative or precautionary policy choices and fully analyze the scope, scale, severity of risks, and other effects that would arise directly or indirectly from a decision to make these choices. These rationales must be supported by both scientific theory and empirical evidence and not be merely the product of supposition, hypothesis, or speculation.

(b) The Scoping Process

While the Bulletin describes what should be addressed in the scope of a risk assessment, it does not discuss the scoping process itself. OMB's goal is to establish uniform standards that apply across multiple agencies performing diverse types of risk assessments that address even more diverse sets of problems. Because of the diversity of risk issues that will be addressed across agencies, there is likely to be a great deal of variability within and among agencies in how the Bulletin is implemented and applied. While it will be difficult for OMB to achieve uniformity in application of the Bulletin's requirements, it can ensure that agencies engage in a uniform and transparent process that will determine the scope of the risk assessment. OMB can strengthen the Bulletin by requiring agencies to engage in a scoping process, similar to the process agencies follow under the National Environmental Policy Act (NEPA).

Under NEPA, before agencies embark on preparing an environmental impact statement (EIS), they engage in an "early and open" scoping process to determine the scope of the issues to be addressed in the statement. Scoping engages both the public and other affected agencies to participate in the process in order to: (1) identify the affected public and agency concerns; (2) facilitate an efficient EIS preparation process, through assembling the cooperating agencies, assigning EIS writing tasks, ascertaining all the related permits and reviews that must be scheduled concurrently, and setting time or page limits; (3) define the

⁴ ACC, *Comments to the Office of Management and Budget Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations*, Feb. 3, 2003.

issues and alternatives that will be examined in detail in the EIS while simultaneously devoting less attention and time to less important issues; and (4) save time in the overall process by helping to ensure that draft statements adequately address relevant issues, reducing the possibilities that new comments will cause a statement to be rewritten or supplemented.

Similarly, scoping should precede all risk assessment activities and should engage relevant stakeholders in risk assessment and risk management. Agencies should encourage public and agency participation in the scoping process. During the scoping process, the perspectives and values of the stakeholders should be evaluated and given careful consideration. This will allow risk assessors to understand the issues and concerns of the various stakeholders affected by the risk assessment. As OMB acknowledges, when people are engaged early in the process, the public typically has an easier time concurring with government documents and decisions that might affect them.

Indeed, agencies affected by federal risk assessments want to be more engaged in the process. For example, DOD and other affected federal agencies could play a larger role in EPA IRIS assessments beginning with identification of the chemicals to be assessed or reassessed, and continuing through to the final assessments. DoD has suggested that an Executive Office-led IRIS inter-agency working group be created, based on the Inter-agency Working Group model. If the Bulletin requires a scoping process that ensures the early involvement of affected federal agencies in the risk assessment, concerns expressed by DoD would be largely eliminated because the assessments would reflect inter-agency consensus on the problem to be addressed in the assessment.

Scoping should not be viewed simply as another "public relations" meeting requirement. Rather, it has specific and fairly limited objectives: (a) to identify the affected public, and agency concerns, (b) to identify the perspectives and values of the stakeholders regarding the risks to be assessed, (c) to identify relevant and available information and data needs, and (dc) to save time in the overall process by helping to ensure that draft documents adequately address relevant issues. For example, in risk assessments that address human health effects, the perceived credibility of risk assessment requires acquiring information from the public on the sources and impacts of exposure. Identification of nontraditional

routes of exposure that reflect local customs, culture, and populations can provide important information for risk assessment.

The scoping process should begin as soon as the risk assessor and risk manager determine that a risk assessment should be conducted. As under NEPA, the agency should publish in the Federal Register a notice of its intent to prepare a risk assessment that describes the problem to be addressed in the risk assessment and informs the public and other agencies on how they can participate in the process. The agency should also maintain on its web site a roster of risk assessments to be performed, similar to the Peer Review Agenda agencies maintain for all planned and ongoing "influential scientific information" subject to OMB's Peer Review Bulletin.

Selection of the actual scoping format should be determined by the nature, complexity, and number of concerned individuals. Generally, scoping should be conducted in a meeting or a series of meetings. Obviously, meetings with a small, limited number of participants can be conducted in an informal atmosphere. Large-scale scoping meetings may require a stricter protocol of proceedings (e.g., public hearing). Another option is a workshop series where numerous groups of participants can discuss pertinent issues.

3. Standards Related to Characterization of Risk

AIA strongly agrees that every risk assessment should provide a characterization of risk. However, the Bulletin states that a qualitative characterization should be provided for all risk assessments and a quantitative characterization should be provide "whenever possible." All quantifiable risk assessment contain uncertainties and therefore all quantifiable risk assessments should provide a range of plausible risk estimates and discuss a range of risk estimates, including how likely it is that each estimate is correct. This information should then be used to state the central tendency of all of these estimates, *i.e.*, the weighted average of the separate estimates with each estimate determined by a percentage probability that it is correct.

The Preamble sets forth the Safe Drinking Water Act (SDWA) standard for the dissemination of public information about risks of adverse health effects and states that these standards should be met, where feasible in all risk assessments which address adverse health effects. Under the SDWA, agencies are directed "to ensure that the presentation of information on public health effects is comprehensive, informative, and understandable."

Agencies are further directed “in a document made available to the public in support of a regulation [to] specify, to the extent practicable— (i) each population addressed by any estimate [of applicable risk effects]; (ii) the expected risk or central estimate of risk for the specific populations [affected]; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data.” AIA agrees that these standards should be met for all risk assessments which address adverse health effects and recommends that OMB incorporate the SDWA standards into the Bulletin itself.

4. Standards Related to Objectivity

The Bulletin’s standard of objectivity is critical to ensuring science-based risk evaluations.

(a) Use of Available Data

AIA agrees that risk assessments must give weight to both positive and negative studies in accordance with their technical quality and should “neither minimiz[e] not exaggerat[e] the nature and magnitude of risks.” AIA also agrees that risk assessments should use the best available data and should be based on the weight of the available scientific evidence. The Bulletin should instruct federal agencies to put policies and procedures in place that will ensure that agencies use of the best available data consistent with OMB Data Quality Law requests and guidelines.

(b) Dose-Response Relationships

Risk assessment documents addressing human health effects should include a range of biologically plausible dose-response relationships. Risk assessors should use all available data, including those on mechanism of action, Physiologically Based Pharmacokinetic (PBPK) relationships, threshold-governed effects, and substance-specific human-animal differences. The biological plausibility of each dose-response relationship selected should be stated probabilistically (e.g., 65 percent likelihood of true risk), but as rigorously as possible in light of scientific uncertainty. This approach would be more faithful to the current state of actual scientific knowledge. It would identify specific risks having the greatest scientific

support by drawing on the data that are available, and by using the best biological models, ensuring that assumptions are based on science.

(c) Weight of the Evidence

AIA strongly recommends that the Bulletin be expanded to discuss weight-of-evidence assessments and establish the elements that must be contained in an acceptable weight-of-evidence assessment. This is important because although agencies may endorse a weight-of-evidence approach, the approach is not consistently applied.

The weight of the evidence approach involves analyzing the evidence from the data contained in all available, relevant studies and weighing those data against well-accepted criteria for causation. At least ten criteria have been proposed for establishing cause and effect relationships.⁵ However, as typically applied, the scientific demonstration of causation requires the observation of a specific endpoint and the satisfaction of all or most of six fundamental “causation criteria.” OMB should incorporate these six criteria in the Bulletin to set forth OMB’s expectations for weight-of-evidence assessments: (1) strength of association, (2) the presence of dose-related responses, (3) specificity of association, (4) consistency of results across studies, (5) biological plausibility, and (6) the existence of temporal relationships.⁶

Finally, the Preamble suggests, but the Bulletin does not clearly state, that available human data, should be used in lieu of animal data in risk assessments. The Bulletin should be revised to stress that human data should be used in human health risk assessments. The Bulletin should also stress the use of field data over laboratory data in ecological risk assessments.

5. Standards Related to Critical Assumptions

OMB’s brief discussion of “Standards Related to Critical Assumptions” should be modified. The main premise of the section is correct – all risk assessments should thoroughly consider and discuss any important assumptions that are being made, as well as the impacts of using alternative or multiple assumptions. However, one statement should be revised. The Bulletin states that if an assumption is supported by, or conflicts with, empirical data, “that

⁵ See e.g., Hill, A.B., The Environment and Disease: Association or Causation?, 58 *Prod. R. Soc. Med.* 295 (1965); Evans, A.S., Causation and Disease: The Henle-Koch Postulates Revisited, 49 *The Yale Journal of Biology and Medicine* 175 (1976).

⁶ See e.g., Mausner, J.S. and S. Kramer, Epidemiological Study Cycles, in Mausner & Bahn, *Epidemiology: An Introductory Text*, pp. 154-194 (1985).

information should be discussed.” The Bulletin should be revised to state that if an assumption conflicts with the weight-of-evidence of empirical data, the assumption should be rejected.

6. Standards Related to the Executive Summary

AIA endorses the Bulletin’s inclusion of an executive summary that discloses the objectives and scope, the key findings of the assessment, and the key scientific limitations and uncertainties in the risk assessment. This introductory information will be very helpful in fostering communication about risk.

7. Standards Related to Regulatory Analysis

The Bulletin sets forth five additional requirements for risk assessments that will be used for regulatory analysis. These include (a) evaluating alternative options, clearly establishing the baseline risk analysis and the risk reduction alternatives that will be evaluated, (b) comparing the baseline risk against the risk associated with the alternative mitigation measures being considered, (c) providing information on the timing of exposure and the onset of the adverse effect(s) as well as the timing of control measures and the reduction or cessation of adverse effects, (d) estimating population risk when estimates of individual risk is made available, and (e) providing a range of plausible risk estimates, including central or expected estimates, when a quantitative characterization of risk is made available.

AIA supports each of these requirements for risk assessments that will be used for regulatory decision making. Requirement (d) is particularly important because estimates of human population risks are necessary to compare the overall costs and benefits of regulatory alternatives. AIA recommends that the Bulletin also include site-specific exposure estimates. Default assumptions should be used only when site-specific data are unavailable. Exposure assumptions are often so conservative that the hypothetical person the agency imagines could not be expected to exist.

AIA also recommends that the Bulletin make clear in requirement (a) that the “baseline risk analysis” must be based on conditions as they exist at the time of the risk assessment. This would include any measures already in place to mitigate the risk.

E. Special Standards for Influential Risk Assessments (Section V of the Bulletin)

Section V sets forth additional requirements for influential risk assessments. AIA offers its comments on each of these requirements below. As a threshold matter, however, the Preamble states that when an agency determines that it is not appropriate for an influential risk assessment to adhere to one or more of the standards of the Bulletin, the risk assessment should contain a rationale explaining why the standard(s) were not met. AIA questions whether there would ever be a situation when it would not be appropriate for an influential risk assessment to comply with the Bulletin's standards, given that influential risk assessments by definition have clear and important impacts on important public policies and private sector decisions. The presumption should be that the standards apply and that the agency has a heavy burden to demonstrate otherwise. AIA also believes that agencies should obtain concurrence from OMB that the Bulletin's standards are not appropriate for a particular risk assessment.

1. Standard for Reproducibility

AIA supports the Bulletin's requirement that all influential risk assessments be capable of being substantially reproduced. OMB's goal of transparency in the risk assessment process is at the heart of the reproducibility standard. As the Information Quality Guidelines state, "the purpose of the reproducibility standard is to cultivate a consistent agency commitment to transparency about how analytic results are generated: the specific data used, the various assumptions employed, the specific analytic methods applied, and the statistical procedures employed. If sufficient transparency is achieved on each of these matters, then an analytic result should meet the reproducibility standard." In others words, transparency – and ultimately reproducibility – is a matter of showing how the results being disseminated were derived.

2. Standard for Comparison to Other Results

AIA agrees that influential risk assessments must be compared to previously conducted risk assessments on the same topic. Too often risk assessments yield very different estimates of risk. It is important to understand why the results vary and which assessment is the most accurate estimate of risk.

3. Standard for Presentation of Numerical Estimates

AIA supports the Bulletin's directive that agencies present a range of plausible risk estimates, along with a central estimate, rather than present a single estimate of risk. The central tendency of risk is supported by a widely accepted, solidly grounded theory of how rational decisions should be made under conditions of uncertainty. Risk managers need to understand more fully the uncertainties involved in risk estimates, especially the much lower likelihood that upper bound estimates will approximate the true risk. The central tendency of risk estimates gives risk managers a realistic and undistorted sense of what is actually necessary to optimize risk reduction under risk-adverse regulatory programs.

Unfortunately, many agencies fail to rely, or even prepare, central tendency estimates. Their repeated reliance on upper-bound risk estimates to make risk management decisions may result in less overall risk reduction. It also results in a misallocation of public resources toward reduction of low-probability harms. Public statements based on overly conservative risk estimation techniques, rather than central tendency, alarm the public, arm interest groups with "phantom facts," and lead to misplaced public priorities. The greater the uncertainty surrounding upper-bound statements of risk, the greater these concerns. Moreover, when aggregated over numerous management decisions, private and public investment in reducing low-probability, highly uncertain risks is virtually certain to have been substantially higher than was necessary.

Risk assessments that lack central tendency risk estimates provide a misleading basis for comparative risk ranking. Indeed, the more the uncertainty regarding low-probability, high magnitude risks, the greater the distortion created. Absent central tendency risk estimates, expected value estimates would lead to extreme predictions. Central estimates also provide a meaningful context for risk-risk comparisons. Using societal resources to reduce phantom risks is one thing, but if by doing so, a more likely risk is created or tolerated, that is another. The public needs to understand this latter point.

4. Standards for Characterizing Uncertainty, Results, Variability, and Human Health Effects

As discussed above, AIA supports the Bulletin's direction to characterize uncertainty, results, variability, and human health effects in all influential risk assessments.

5. Standard for Discussing Scientific Limitations

AIA supports the Bulletin's direction to provide a discussion regarding the nature, difficulty, feasibility, cost, and time associated with undertaking research to resolve a report's key scientific limitations and uncertainties.

6. Standard for Addressing Significant Comments

AIA supports the Bulletin's direction to agencies to consider all significant comments received on a draft risk assessment report and to issue a "response-to-comment" document that summarizes the significant comments received and the agencies responses to those comments. This provision is critical to ensuring public involvement in the risk assessment process and furthering the Bulletin's goal of transparency.

F. Updates (Section VI of the Bulletin)

The Bulletin requires that as relevant and scientifically plausible information becomes available, and as resources are available, each agency shall consider revising its risk assessment to incorporate such information and updating or replacing its assumptions to reflect new data or scientific understandings. AIA believes that is an important requirement to ensure that regulatory decisions are based upon the most recent science. However, as written, agencies may easily ignore the requirement by allocating their resources elsewhere. AIA recommends that OMB be more specific as to how and when risk assessments are to be updated. For example, OMB could require agencies to assess whether the new information would be likely to significantly modify the hazard or exposure data the assessment relies upon. Risk assessment updates could then be prioritized according to the level of impact that the new information may have on the assessment.

G. Certification (Section VII of the Bulletin)

While the Bulletin requires that an agency certify that it has complied with the Bulletin, it does not specify who within an agency may sign the certification. Given the importance of risk assessment, AIA recommends that the Bulletin require a named agency official at the Assistant or Deputy Assistant Administrator level or equivalent, to certify compliance with the Bulletin.

H. Deferral and Waiver (Section VIII of the Bulletin)

As discussed above under Applicability, the Bulletin would benefit by providing more examples of the limited situations in which agencies may waive or defer some or all of the requirements of the Bulletin.

I. Effective Date (Section X of the Bulletin)

The Bulletin states that it applies to “final public risk assessments disseminated after 12 months following the publication of this Bulletin in final form.” AIA does not understand the reason for the delay in the effective date of the Bulletin. AIA recommends that the Bulletin be made applicable to all agency risk assessment efforts six months after the Bulletin is published in final form.