

June 2, 2006

Comments Regarding the
Office of Management and Budget
Proposed Risk Assessment Bulletin

The American Composites Manufacturers Association appreciates the opportunity to provide comments to the Office of Management and Budget regarding its Proposed Risk Assessment Bulletin (71 FR 2600; January 17, 2006).

ACMA is the national trade association for the composites industry, which is comprised of more than 3,000 small and medium sized businesses using fiber reinforced polymers to make automotive and truck components, swimming pools, wind turbine blades, modular tub/shower units and bathroom vanities, fiberglass boats and personal watercraft, ladder rail and tool handles, underground gasoline storage tanks and pollution control equipment, bridge beams and concrete reinforcing bars, and thousands of other products. The composites industry employs 300,000 Americans and contributes \$45 billion annually to our nation's economy.

We strongly support OMB's efforts to improve the "quality, objectivity, utility, and integrity of information disseminated by the federal government to the public." In particular, the various and several federal government chemical health hazard assessment programs, and related communications activities, have long suffered from a lack of transparency, a limited openness to contributions from knowledgeable outside parties, and an insensitivity to either the intended or unintended consequences of their assessments.

Especially for smaller businesses, the risk assessment and related programs conducted by EPA, HHS/NTP, OSHA and other agencies can seem irrational and impenetrable, and yet these programs can have profound impacts on industry employment and competitiveness. Federal government chemical hazard assessments and related communications can have more widespread and damaging impacts than regulatory programs such as EPA's emission standards and ambient air quality standards, or OSHA's chemical exposure limits and hazard communication requirements, but chemical assessments are developed and communicated almost completely without the stakeholder participation, agency management oversight, and sensitivity to reasonably anticipated consequences now common in regulatory programs.

The impacts of chemical hazard and risk assessments can include unwarranted concern among workers, plant neighbors and product users; denial of operating permits; employee turnover; regulation of worker or community exposures where negative impacts to employment and competitiveness outweigh public health benefits; tort actions by workers, plant neighbors or products users needlessly concerned that they may have been injured as a result of exposure; consumer choice driven by mistaken perception of risk; and inability of smaller business owners to purchase affordable liability insurance, obtain financing, or sell businesses on retirement.

Many of the unwarranted negative impacts resulting from federal government chemical health effects assessments can be mitigated by changes in the procedures used to make hazard or risk determinations and communicate them to the public. In establishing clear, minimum standards for risk assessments, OMB's Bulletin properly aims to require such changes. Other interested parties are already being quoted in the trade press as opposing the OMB Bulletin on grounds that it is unnecessary and overly burdensome. We urge OMB to stand its ground. In our experience, the current health effects assessment programs leave considerable room for improvement, and are generally less open to suggestions for change from those affected by their actions than comparable regulatory programs. We do not believe there are incentives within the current programs that actively encourage the kinds of reforms that OMB is proposing, and therefore cannot endorse the concept that each agency should be allowed to develop their own procedures without oversight.

In order to enhance the efficacy of the Bulletin in accomplishing OMB's worthy objectives, we offer the following suggestions:

- 1. To have the desired impact of reforming risk assessment, OMB must not limit the Bulletin to purely technical or scientific matters.**

OMB's introduction to the proposed Bulletin (p. 3) notes,

The purpose of this Bulletin is to enhance the technical quality and objectivity of risk assessments prepared by federal agencies... it does not address in any detail the important processes of risk management and risk communication. The technical guidance provided here addresses the development of the underlying documents that may help inform risk management and communication, but the scope of this document does not encompass how federal agencies should manage or communicate risk.

Perhaps we are misreading OMB's intent, but to reform the *technical* stages of risk assessment without addressing how agencies *communicate* hazards and risk would represent at best a meager improvement. As we discuss in many places in our comments below, how agencies communicate their scientific conclusions can have more profound impacts – can completely determine, in fact, the balance of public health benefits and economic impacts – than the underlying scientific decisions.

Does OMB consider EPA's IRIS database to be an "underlying document" that will be entirely covered by the proposed Bulletin? Or are only the scientific reviews associated with the IRIS database updates intended to be addressed by the Bulletin? What about the National Toxicology Program's Report on Carcinogens? The science-policy and communications aspects of these and similar programs are at least as important as the associated scientific processes in determining whether the programs achieve a reasonable balance of benefits and costs.

Frankly, to distinguish between science and policy, between the objectives and procedures of technical reviews on the one hand and program management and communications on the other, if this is indeed OMB's objective, is naïve. The selection of important health effects, the identification of substances to be evaluated, the development of methods for conducting and reviewing scientific studies, the setting of schedules and allocation of resources for conducting scientific reviews – are all *policy* decisions that are made *before* anyone gets to do actual science. Further, policy is informally but inexorably intertwined with science, as scientists decide, beyond official policy dictates, how to conduct scientific studies and how to weigh and summarize the results. Finally, the effect and usefulness of science, no matter of what quality, is always a matter of how it is communicated. (With regard to communication of science, we note that the Safe Drinking Water Act Amendments, which form an integral part of OMB's Information Quality Guidelines, deal extensively with communication of results. This expanded scope should extend to this Risk Assessment Bulletin as well.)

As we will show below, the objectives of OMB's proposed Bulletin – to increase the objectivity and transparency of the Federal government's risk and hazard assessment programs – should apply equally to the science, science-policy, and communication stages of risk and hazard assessments. To do otherwise will be to miss an important and historic opportunity.

2. The Bulletin should define "risk assessment" broadly, to include all federal government chemical health effects descriptions, summaries, and characterizations.

The proposed Bulletin (Sect. I.3) defines "risk assessment" as "a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment." This definition

properly includes the many federal government chemical hazard assessment and communication programs, such as EPA's Integrated Risk Information System and NTP's Report on Carcinogens, which are technically "hazard assessments" instead of "risk assessments" since they do not include consideration of quantitative site-specific exposure data.

However, the Bulletin should also specifically include the many informal assessments and communications of chemical hazards and risk conducted and issued by federal agencies. For example, agencies often describe possible chemical hazards or risks in journal articles, preambles or fact sheets associated with proposed or final regulations, introductions to technical studies of exposures or controls, agency web pages, and other communications not included in the formal risk or hazard assessment programs such as IRIS or the RoC. These informal assessments and communications can have significant impacts, since they are designed to be widely disseminated and are often written for non-technical audiences.

In ACMA's December 22, 2005 comments to OMB on its Proposed Good Guidance Bulletin, we described the negative business impacts likely to result from a recent EPA journal article describing possible health effects from occupational exposure to a chemical widely used in our industry, and suggested certain changes to EPA's administrative procedures that would have reduced the negative impacts, which are likely to significantly outweigh any public health benefits. We recognized that the number of journal articles and other informal risk and hazard assessments and related communications is very large and may significantly increase the administrative burden of the Good Guidance Bulletin on the agencies without fully compensating benefits. Therefore, we recommend that journal articles and other informal assessments and communications only be included in the definition of "influential risk assessment."

A similar consideration of journal articles is appropriate under the Risk Assessment Bulletin. We suggest that Section I be amended as follows:

2. ... "influential risk assessment" means a risk assessment, including journal articles and other formal or informal chemical hazard or risk assessments, which the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions;

3. The Bulletin should apply to all agency risk assessments, not just those that are available to the public.

The requirements of the proposed Bulletin (Sect. II.1) are to apply to "...all agency risk assessments available to the public..." This limitation invites agencies to evade the requirements of the Bulletin by avoiding official public release of assessments that are nonetheless used internally to inform policy or regulatory decision making. The emphasis of the Bulletin should be on improved decision making based on scientific risk assessment and hence include both risk assessments used by Federal agencies and those distributed by them, not just the latter group. The Bulletin should specifically include "internal" hazard and risk assessments, the effects of which are likely to be especially pernicious and insidious precisely because their existence is unknown to the public. We suggest that Sect. II be modified as shown:

1. To the extent appropriate, all agency risk assessments ~~available to the public~~ shall comply with the standards of this Bulletin.

4. The Bulletin should specifically require agencies to provide stakeholders with meaningful opportunities to participate in the science-policy stages of risk assessment programs.

The proposed Bulletin (Sect. III.5) states that agencies are to "follow appropriate procedures for peer review and public participation in the process of preparing the risk assessment." Many agencies manage the *scientific process* of performing hazard and risk assessments separately from the *science-policy processes* of setting priorities and schedules, allocating resources and assigning staff, establishing guidelines for conducting assessments, summarizing and characterizing scientific conclusions, and communicating with the public regarding assessments. The proposed Bulletin may lead agencies to conclude that public participation is required during scientific reviews but is not required during science-policy decision making.

However, as we noted above, in many cases it is an agency's science-policy decisions that have the largest impacts on stakeholders. Risk-assessment-related science-policy decisions that can determine the balance of public health benefit to negative impacts to employment and competitiveness include: the general procedures used for the evaluation of scientific evidence; the setting of schedules for these assessments; the relative weights allocated to different studies during the review of substances with controversial, novel or rapidly evolving science; the summarizing, classifying or characterizing of scientific findings; the use of assessments in subsequent rulemaking or other agency actions; and communicating with the public regarding the results of these assessments.

Ongoing concern with the possibly severe impacts resulting from EPA's review of a number of chemicals for updating the IRIS database illustrates how science-policy decisions can have significant impacts on industry. Critical to the scientific review of the carcinogenic potential of number of chemicals will be EPA's evaluation of the mode-of-action data regarding the formation of tumors in laboratory animals following chemical exposure. EPA's Cancer Guidelines specifically highlight and encourage the use of mode-of-action data in evaluating a substance's carcinogenic potential. However, EPA has not been able or willing, to date, to engage industry scientists in the science-policy determinations regarding how mode-of-action data will be employed in IRIS reviews, either generally or in specific cases. Yet decisions regarding how mode-of-action data will be evaluated and weighed in EPA's scientific analysis will likely have a significant impact on the outcome of the analyses and on the resulting impacts to industries like ours with chemicals currently undergoing IRIS review.

We are further concerned that for substances for which there is no or negative human evidence of carcinogenicity, but with limited animal evidence of questionable or doubtful relevance to humans, EPA will make the science-policy decision to classify such substances as "suggestive evidence" carcinogens. This classification would almost certainly cause many of the people potentially exposed to such chemicals to believe that EPA is "suggesting" that they may get cancer. In the case of our industry, such a confusing message, resulting from a science-policy decision by the agency, would place a severe and in many cases unmanageable communications burden on thousands of small business owners across the country. EPA has not engaged industry scientists in a meaningful and open dialogue regarding the science-policy decisions regarding the classification and communication of the scientific analysis and conclusions, either generally or in the case of specific substances, even though these decisions represent important opportunities to better balance negative economic impacts with public health benefits.

We suggest that the OMB Bulletin specifically require agencies to allow meaningful public participation in the science-policy stages of risk assessments. This could be accomplished by modifying Sect. III of the Bulletin as shown:

5. The agency shall follow appropriate procedures for peer review and public participation in the process of preparing the risk assessment, including stages related to the prioritization and scheduling of assessments, and the characterization and summarization of key data, classification determinations and communication of the assessment results.

5. The Bulletin should encourage agencies to reduce unintended negative impacts resulting from reasonably anticipated uses of risk assessments.

Agency hazard and risk assessment programs typically include statements of purpose and limitations. For example, EPA states that its IRIS database is intended be combined with site specific exposure information in the course of performing risk assessments, but that the database listings should not be used by themselves to draw conclusions about risk in specific exposure scenarios. However, as EPA well knows, many workers, plant neighbors and product users, and even state and local regulators, use IRIS classifications as authoritative indications of actual risk.

In such cases where misuse of assessments is reasonably anticipated, we suggest that the Bulletin require agencies to consider providing additional information that will lessen the risk of serious unintended negative consequences. Providing disclaimers or other warnings against uses for which the assessments are not intended should not be enough to satisfy this requirement.

In the case of the misuse of the IRIS database listings, for example, EPA could provide short qualitative assessments of the likelihood of adverse health or environmental impacts in typical exposure scenarios. Stakeholders could participate in this process by identifying exposure scenarios and providing draft assessments of possible health or environmental impacts based on agency hazard and potency analyses.

We suggest that Section V of the proposed Bulletin should be modified by inserting a new paragraph, as shown:

10. Anticipate, to the extent practical, the likely or typical uses of the assessment. If such likely or typical anticipated uses exceed, or are contrary to or inconsistent with, the objectives and limits of the assessment program, reasonable efforts shall be made to actively discourage, and limit the likely consequences of, such uses.

6. The Bulletin should encourage use of the Internet to manage and communicate about assessment programs.

We believe that the Internet should be extensively used by agencies for establishing publicly accessible workspaces for posting agency data and analyses, facilitating efficient stakeholder contributions of data and analyses, and promoting productive scientific dialogue over the course of developing assessments. Increased use of the Internet can only serve to further OMB's objectives of increasing the objectivity and transparency of hazard and risk assessment programs.

While some agency programs already make extensive use of the Internet for managing and communicating regulatory efforts, others, notably risk assessment programs, have not generally taken this step. OMB should be more active in encouraging transparency and stakeholder access via the Internet in this important area of risk assessment.

We suggest that a new paragraph be added to Section III of the proposed Bulletin, as shown:

6. Agencies shall, to the extent practical, and as determined by the importance of a given risk assessment program, make use of the Internet to make available, distribute, and obtain stakeholder comments on, the objectives, procedures, data, relevant stakeholder comments and data, and intermediate (draft) and final workproducts, as such materials become available.

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Thank you for considering our comments. If appropriate and useful, we would be please to discuss our suggestions with you further.

Signed,



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