

December 22, 2005

Comments of the
American Composites Manufacturers Association
Regarding the
Proposed Bulletin for Good Guidance Practices

The American Composites Manufacturers Association (ACMA) appreciates the opportunity to provide comments to the Office of Management and Budget regarding its Proposed Bulletin for Good Guidance Practices (70 FR 71866; November 30, 2005).

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 products such as 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, and bridge beams and concrete reinforcing bars. The composites industry employs 300,000 Americans and contributes \$45 billion annually to our nation's economy.

ACMA strongly agrees that guidance documents issued by federal agencies have profound impacts on competitiveness and employment, and that they are often issued and used without notice to stakeholders, opportunity for comment, Congressional oversight, or the potential for judicial review. We strongly support the intent and, in general, the content of the proposed Bulletin, and offer suggested improvements as described below.

1. “Significant guidance documents” should include assessments, analyses, summaries or characterizations of chemical hazard or risk made available to the public.

The draft Bulletin defines “guidance documents” as those that describe an agency’s “interpretation of or policy on a regulatory or technical issue.” The draft further provides that “significant guidance documents” include, among others, those that may concern “novel or complex scientific or technical issues.”

Federal agency documents describing hazard assessments, risk analyses, or other summaries or characterizations of chemical toxicity or related data are clearly “interpretation[s] of...technical issues[s]” and concern “complex scientific or technical issues.”

Further, such assessments or analyses are frequently conducted, and reports issued, submitted or otherwise made available to the public, without notice or opportunity for comment. These assessments and analyses, perhaps even more than many of the other significant guidance documents to be subjected to the procedures established in the Bulletin, can impose significant costs on the public.

Federal agency assessments or analyses of chemical hazard or risk, therefore, should be considered significant guidance documents, and their development and release to the public should be governed by the procedures established in the Bulletin.

2. The Bulletin should not exempt journal articles from the definition of “economically significant guidance document” in Section I.5.

Agency staff, in the course of their official duties, often submit draft articles to peer reviewed journals describing original research, or providing analysis, discussion, or review of the research or data provided by others. Such articles can have significant effects on important segments of the economy, but are typically drafted, submitted to journals, and published without notice or opportunity for comment. Unfortunately, the proposed Bulletin specifically exempts “journal articles” from the definition of “guidance document.”

OMB may believe that the process of peer review is sufficient to protect against the publication of incorrect, incomplete or misleading articles and the unwarranted harm that may result from their publication. In reality, the quality of peer review, and its success in ensuring the publication of only high quality scientific findings and analyses, depends on the commitment and ability of journal editors and their reviewers, and such commitment and ability varies widely. Further, many journals have undisclosed ideological bias, including some journals published by federal agencies.

These flaws can thwart the intention of peer review, and much of what is published in peer reviewed journals would not meet the highest standards for scientific quality. Nevertheless, peer reviewed journal articles are understandably received and understood by members of the public as quality science and, when one or more authors are federal agency employees, as the considered positions of the federal government.

In our view journal articles should be included in the definition of guidance document so that all of the provisions of the proposed Bulletin would apply to them. However, we recognize that the number of journal articles is very large and may significantly increase the administrative burden of the Bulletin on the agencies without fully compensating benefits. Therefore, we recommend that journal articles only be included in the definition of economically significant guidance documents. Most journal articles would thereby be exempted, but those that would “reasonably be anticipated to lead to an annual effect of \$100 million or more or adversely affect in a material way the economy or a sector of the economy” would be included.

To include journal articles, as we suggest, Bulletin Section I.5 could be amended as follows:

The term “economically significant guidance document” has the same meaning given in Section I(3)(i) of this Bulletin, except that economically significant guidance documents include journal articles but do not include documents on Federal expenditures and receipts.

3. A timely example supports making our suggested changes to the Bulletin.

ACMA offers the following recent EPA action as an example supporting our suggestion that OMB's Bulletin should specifically classify chemical hazard assessments and risk analyses as significant guidance documents and should not exempt journal articles.

In May, 2005, the journal *Environmental Health Perspectives* published an article describing a "meta-analysis" of data on neuropsychological impairment following occupational exposure to styrene (a chemical widely used in the composites industry). The primary author of this paper is an employee of EPA's Office of Research and Development, and the paper notes that the work described was performed with EPA funding.

Based on their analysis, the authors of the EPA paper claim that occupational exposure to styrene may result in a "significant increase in the probability of traffic accidents." Since there are more than 80,000 composites industry production workers exposed to styrene, and it can be safely assumed that many drive home from work every day, this finding is highly significant. If the authors' conclusion is valid, the industry may be reasonably expected to make whatever investment in controls, alternative raw materials, new manufacturing process or other methods are needed to reduce exposures.

Further, the journal article is readily available on the internet, is already being cited by advocacy groups concerned with plastic industry health effects, and will likely lead to heightened concern among workers and community members. Finally, whatever the validity of its conclusions, we fear that the EPA article will support numerous tort claims brought against composite manufacturing companies when their employees are involved in traffic accidents.

Despite the significant costs and impacts likely to result from publication of this journal article, EPA provided no notice and no opportunity for comment before submitting the article to the journal. And the journal editors, employees of NIH, subsequently declined to publish an industry rebuttal, on seemingly arbitrary "policy" grounds.

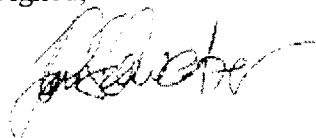
Had EPA provided notice to industry and accepted comments before submitting the article for publication, it is likely that the article would have been significantly modified and the negative impacts of its publication avoided.

An independent expert panel reviewed the methods and findings described in the EPA article and concluded that the authors of the EPA paper employed arbitrary and non-standard analytical techniques, that their conclusions are not supported by an analysis of individual studies, and that the data included by the authors in their analysis are not representative of the studies available. Had EPA provided notice and an opportunity for comment, this input could have been provided to the authors of the EPA paper before they prepared and submitted their journal article.

Additionally, the authors of the EPA paper could have contributed to the design of the major industry-sponsored styrene neurotoxicity study currently underway, and could have delayed their analysis until the data from this study becomes available in mid-2006.

It should be the effect of OMB's final Bulletin to require notice and opportunity for comment before federal agencies submit draft journal articles or otherwise make documents available to the public that can have significant impacts on segments of our economy ("economically significant guidance documents"). As demonstrated in this example, in requiring such dialogue with stakeholders, the Bulletin may also encourage and facilitate collaborative efforts on important public health matters and would avert either unintended or intended adverse effects on the economy without appropriate administrative review.

Signed,



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