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To: OMB_peer_review@omb.eop.gov

cc:

Subject: Revised Information Quality Bulletin on Peer Review

(See attached file: SIRC Comments - OMB Peer Review Revised Bulletin -
May
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- SIRC Comments - OMB Peer Review Revised Bulletin - May 13, 2004.pdf

May 13, 2004

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street NW
New Executive Office Building, Room 10201
Washington, DC 20503

Re: Revised Information Quality Bulletin on Peer Review

Dear Dr. Schwab:

The Styrene Information and Research Center¹ (SIRC) commends the Office of Management and Budget for revising the Peer Review Bulletin (“Bulletin”) and reaffirming its intention to proceed to final publication. While there were provisions of the original Peer Review Bulletin that we would have preferred to have seen retained, we are confident that the Bulletin, as revised, will have a major positive impact on the quality of science disseminated by the Federal agencies. The Bulletin should therefore be published as soon as possible.

Below are some changes that we recommend be made to the Bulletin prior to its final publication. We believe these changes would not increase the burden on the agencies but should improve the implementation of the policies the Bulletin is designed to foster.

Overarching Concern:

We begin with an overarching concern about the implementation of the criteria that determine whether a scientific assessment is “highly influential.” We accept the general premise of the revised Bulletin that the class of scientific assessments to which the more stringent peer review procedures apply should be limited. However, without further specification, the criteria listed are subject to serious potential abuse. We focus our comments here on the \$500 million criterion, but many of the same comments apply equally to the qualitative criteria.

¹ The Styrene Information and Research Center’s (SIRC’s) mission is to evaluate existing data on potential health effects of styrene, and develop additional data where it is needed. SIRC has gained recognition as a reliable source of information on styrene and helping ensure that regulatory decisions are based on sound science. For more information, visit www.styrene.org.

Our concerns are centered on the actual process of arriving at the \$500 million/year estimate. Many scientific assessments are not written to support a specific regulation—instead they are written to support a variety of potential separate actions, sometimes by outside parties, such as States, as well as Federal agencies. Even in those cases where a scientific assessment is written to support a specific regulatory action, the assessment itself may not—and one can argue, should not—support only one pre-conceived regulatory outcome. It is only when a specific regulatory outcome (as opposed to a regulatory action) is involved that one can make a relatively good estimate of the impact of the assessment in quantitative terms. Even in those circumstances, there can be wide differences of opinion about how costly a particular regulatory outcome may be, as OMB is fully aware in light of its experience under Executive Order 12866.

However, because a scientific assessment is not a regulatory action, but rather, at best, a compilation of data in support of a regulatory action, the estimating process is at least one step removed from the concrete regulatory outcome whose cost is normally estimated under Executive Order 12866. In many cases, as with EPA's update of its Integrated Risk Information System (IRIS) database that contains hazard assessment calculations, there is no associated regulatory action, much less a regulatory outcome, that can be specified; nevertheless these IRIS updates can have a very significant economic impact and as such should be considered to be highly influential information under this revised Bulletin.

An on-going IRIS review of styrene may serve to make this point more clearly. EPA is now updating the IRIS database for styrene and intends to make a determination for the first time whether or not, or to what extent, styrene should be classified as a carcinogen. Because complex scientific matters are involved in this review, it will not be clear until the final posting of the IRIS review what this classification determination will be. Nevertheless, one can imagine that if EPA were to decide to classify styrene as a carcinogen for the first time, the implications for a chemical with such wide-spread uses could be significant. But how would EPA determine whether these impacts might fall above the \$500 million/year threshold for designating the IRIS update of styrene as a "highly influential" assessment? In particular, how would EPA make this determination early in the process of the review in order to know whether the Agency must adhere to the more rigorous peer review requirements of the Bulletin?

As it happens SIRC recently contracted for and received an economic analysis of the importance of styrene in the U.S. economy from Global Insight, Inc. The report shows that the styrenics industry has over \$28 billion in annual sales and that a loss of styrene in the marketplace would result in products that would cost American consumers more than \$18 billion more than these styrene-based products do today. With this report in hand, SIRC may be able to make a case to EPA that a first-time classification of styrene as a carcinogen would likely have more than a \$500 million/year impact, since \$500 million is less than 2% of the \$28 billion in sales and is less than 3% of the \$18 billion in consumer value provided by styrene in products today. However, we want to make what we believe are two important points in this regard: 1) most industry groups do not have economic impact studies on the shelf they can use to make such an impact case to an agency, and certainly federal agencies do not normally have access to such general studies; 2) even with this

study in hand, SIRC does not have any quantitative means to prove to EPA that in fact the impact of a styrene classification could result in more than 2% or 3% damage to the economy in one year.

In short, we believe that the number of assessments that are designated by the agencies as “highly influential” will be very small, unless OMB directs the agencies to err on the side of inclusion rather than exclusion of assessments in the “highly influential” category, employing qualitative judgments in most cases. The qualitative criteria of “precedent setting, novel, and complex approaches, or significant interagency interest” are an essential addition to the revised Bulletin in this regard and should be retained; however, here too, it would be very helpful for OMB to direct the agencies to err on the side of inclusion. In addition, the Bulletin should indicate that OMB plans to exercise close oversight of which scientific assessments are included by the agencies in the “highly influential” category. OMB’s direction to the agencies in favor of inclusion could be placed in either the preamble language or the text of the Bulletin, but it needs to be included if the more stringent of the two tiers of peer review is to have any meaning in this Bulletin.

Technical Amendments:

1. Definition of “Influential Scientific Information”

Recommended technical change:

Amend the definition of “influential scientific information” as follows: “the term ‘influential scientific information’ means **influential information as defined in the OMB Guidelines for Information Quality (67 FR 8460) but excluding financial and statistical information--namely**, the dissemination of which the agency reasonably can determine...”

Justification for the recommended change:

Agencies have acted under the previous government-wide information quality guidelines to define what categories of their information fall within the definition of influential information. It is important, as you indicate in your Summary of Comments document, that these designations of categories apply to this Bulletin, with the exception of financial and statistical information explicitly excluded. However, the language of the Bulletin itself is not clear in this regard. Making the link explicit between the Bulletin and the guidelines’ definition of “influential” will prevent a narrowing of the category of information to which this Bulletin applies.

2. Choice of Peer Reviewers

Recommended technical change:

Revise section II.3 (“Choice of Peer Review Mechanism”) to read “Peer reviewers shall be selected on the basis of necessary technical or scientific expertise, and **shall not** ~~should not~~ have participated in development of the work product.”

Justification for the recommended change:

We can conceive of no circumstances when influential scientific information should be peer reviewed by someone who actually participated in the development of that work product. OMB should not support the concept that a person's review of his/her own work can be called "peer review."

3. Scope of Conflict of Interest

Recommended technical change:

Section II.4. ("Conflicts") should be amended to state: "**In addition**, for scientific assessments relevant to specific regulations, a reviewer's financial ties to ~~both~~ regulated entities (e.g. businesses), **other stakeholder organizations**, ~~and or~~ the agency should be examined.

Justification for the recommended change:

The insertion of "in addition" would clarify that this sentence is supplementary to the other provisions of this section, and not a substitute for them.

The addition of "other stakeholder organizations" would serve to recognize that a person's financial ties to organizations, such as public interest groups, could be just as much of a conflict as a person's financial tie to a regulated party. The success and well-being of both types of organizations (i.e., business entities and public interest organizations) may be equally tied to the outcome of the assessment, and both persons may have equal stakes in the results. The fact that one organization may purport to work for the "public interest" and the other organization may purport to work for its shareholders does not change the conflict of interest inherent in such financial ties to either type of organization. It is important that OMB provide for a level playing field so that financial ties are judged objectively without discrimination.

4. Criteria for "Highly Influential Scientific Assessments"

Recommended technical change:

Change Section III.1. (ii) ("Applicability") as follows: "(ii) involves precedent setting, novel ~~and or~~ complex approaches, or significant interagency interest."

Justification for the recommended change:

To require that a scientific assessment qualify under all three criteria (precedent setting, novel and complex approaches) sets an intolerably high hurdle. A scientific assessment should qualify as highly influential if it meets one of the criteria given.

5. Public Participation

Recommended technical change:

Amend the language of Section III.4 (“Opportunity for Public Participation”) to state: “If the agency decides to make a draft assessment publicly available **either before or** at the same time it is submitted for peer review (or during the peer review process), the agency shall, whenever practical, provide to peer reviewers, **with ample time to consider them**, ~~a compilation or summary of the~~ relevant public comments on the draft assessment that address significant scientific or technical issues. **However, the agency need not provide comments to the peer reviewers that are clearly duplicative of others that are provided.**”

Justification for the recommended change:

As noted in Section V.2.b (Peer Review Plans), peer reviewers receiving relevant public comments need to have them “prior to doing their work.” In OMB’s Summary of Comments, the suggestion is made that peer reviewers should receive copies of comments “with ample time to consider them.” However, this timeliness is not assured by the current wording of Section III.4 of the Bulletin itself. The two additions (“either before or” and “with ample time to consider them”) are intended to correct this problem, without being overly burdensome on the agencies.

In addition, the permission for the agency to provide only a compilation or summary of the relevant comments should be deleted because it is an apparent, if not real, conflict of interest on the part of the agency that wrote the scientific assessment document. The nuances of any person’s scientific critique could be easily lost in such a compilation or summary, especially if such compilation or summary is made by an agency staff person not trained in the same scientific discipline. In addition, if an agency incorrectly summarizes a relevant comment from the public, no matter how innocently, the appearance of a conflict of interest could undermine the credibility of that peer review process. Finally, the creation of a compilation or summary could be time-consuming for the agencies and could therefore discourage timely delivery of the public’s relevant comments to the peer reviewers.

There should be no serious danger of over-burdening the peer reviewers in most cases because, according to the Bulletin, only “relevant” public comments on “significant” scientific or technical issues need be provided, and the agencies are also allowed to take practical considerations into account (“whenever practical”). The provision for eliminating duplicative public comments should keep the volume of comments provided to the peer reviewers to a reasonable level.

6. Peer Review Reports

Recommended technical change:

Amend Section III.5 (“Peer Review Reports”) as follows: “The agency shall disseminate the final peer review report and the agency’s written statement of response on the agency’s web site **in a timely manner**, and all the materials related

to the peer review (charge statement, peer review report, and agency response) shall be included in the administrative record for any related agency action **no later than the date of dissemination of the agency action.**”

Justification for the recommended change:

Although certain statutes, such as the Clean Air Act, require the agency to compile and make available the administrative record for a decision no later than the date of signature of the administrative action, many other statutes are not as explicit, and agency performance varies in this regard. It is important that members of the public have access to the final peer review report and the agency’s response in time to avail themselves of their legal rights, including suing the agency in an attempt to overturn the decision, if this is deemed necessary. These peer review documents could be directly relevant to any such decision to bring a lawsuit. OMB should insert, as shown, a criterion of timeliness with regard to the web dissemination and a deadline for inclusion of the information in the administrative record.

7. Peer Review Planning

Recommended technical change:

Insert at the end of Section V.1. (Peer Review Planning) the following: “**Agencies shall include in their web posting all of the information specified in subsections 2.a. and 2.b. below. Agencies shall post their plans for peer review with ample time both for the public to comment and for the agency to consider those comments before implementing the peer review plan.**”

Justification for the recommended changes:

A generalized agenda posting without the actual summary information for each plan, as specified in subsections 2.a. and 2.b. would be of very little use to the public. It would be a serious mistake to make these items of information available only if requested from the agency contact person. Because OMB oversight of the peer review process is significantly reduced in this revised Bulletin from that in the earlier draft, it is important not to erect unnecessary barriers to the public’s ability to monitor the agencies’ performance and to participate.

The sentence on the timely posting of the plans on the website is an expression of OMB’s intent, indicated in the Summary of Comments document (p. 9), that the public comment process be made timely in order to be meaningful.

8. Peer Review Planning—Policies on Conflict of Interest and Independence

Recommended technical change:

Add at the end of Section V.1. (Peer Review Planning) the sentence: “**Each agency shall also post on its Internet website its policies with regard to conflict of interest and independence of peer review panels, including the agency’s**

decisions regarding the adoption or adaptation of the federal ethics requirements for reviewers who are not federal employees and their consideration of the conflict of interest and committee selection practices of the National Academy of Science.”

Justification for the recommended changes:

It is not sufficient for agencies to deal with the conflict of interest and independence requirements of this Bulletin on a case-by-case basis without the formulation and publication of their policies on these matters on an across-the-board basis. This is especially true because these policies can result in the secret exclusion of persons from serving on peer review panels. Obviously, the inclusion of inappropriate persons on the panels is more subject to review by the public where the names of the panel members are made public, but the exclusion of persons for conflict of independence reasons would not normally be made public. At the minimum, the agencies' policies should be made public so that the policies that the agencies plan to apply are known and, where appropriate, can be criticized before the peer review process is undermined by the inappropriate exclusion of persons from the panels.

It should be noted that in the previous version of the Bulletin, agencies were required to develop complete peer review guidelines. This requirement has been dropped in the current revision. The publication of the agencies' decisions on conflict of interest and independence is the bare minimum that should be retained from this previous guideline-development requirement.

We hope that you find these comments helpful. We would be glad to answer any questions that you might have. Feel free to contact me at 703-741-5012.

Sincerely,

This document delivered electronically.

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