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12/15/2003 03:06:10 PM

Record Type: Record

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cc:

Subject: Comments on Proposed Bulletin on Peer Review and Information Quality

(See attached file: SIRC Comments OMB Peer Rev Bulletin 121503.pdf)

- SIRC Comments OMB Peer Rev Bulletin 121503.pdf

December 15, 2003

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: Proposed Bulletin on Peer Review and Information Quality

Dear Dr. Schwab:

The Styrene Information and Research Center¹ (SIRC) is pleased to provide comments on the Office of Management and Budget's (OMB's) proposed bulletin on peer review (68 FR 54023, September 15, 2003). We commend OMB for taking this step to improve the quality of information used for regulatory purposes. We agree that the normal processes of notice and comment for regulations cannot substitute for the necessary scientific peer review of the underlying regulatory information on which the regulations are based. We are confident that the requirements of this Bulletin will have a very positive impact on the quality of information presented to decision makers and to the public and on their resulting decisions.

Our recommendations are focused primarily on fashioning a greater role for members of the public in the peer-review process as a way to enhance the transparency and accountability of the process. Specifically, we recommend that OMB should:

1. Finalize this Bulletin expeditiously, after review of submitted comments;
2. Expand the definition of "especially significant" regulatory information to include all influential analyses of risk, regardless of the quantification of the impact of these analyses;
3. Require the agencies to provide an opportunity for public input on the charge questions presented to the peer reviewers;
4. Require agencies to provide public comments to the peer reviewers as soon as they become available to the agencies;

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 <http://www.styrene.org/>.

5. Require agencies to provide a justification if they choose to use a peer- review method for “especially significant” regulatory information that does not promote an integration process among individual peer reviewers;
6. Establish a process for public comment and OMB critical review of each agency’s peer-review guidelines;
7. Require agencies to submit public reports to OMB on a semi-annual basis and encourage responses to these reports by the public;
8. Emphasize the scientific credentials and balance of the panel as a whole rather than the strict neutrality of each member; and
9. Consider avoiding the use of the term “significant” in this Bulletin in order to eliminate possible confusion.

We believe that these modest changes to the proposed Bulletin would substantially increase the benefits of the Bulletin without, in our judgment, appreciably increasing the Federal agencies’ compliance burdens.

1. Finalize this Bulletin Expeditiously, After Review of Submitted Comments.

The proposed Bulletin is an excellent concept and should be completed. We do not believe that the Bulletin imposes excessive burdens on Federal agencies or unduly restricts their flexibility to adjust the depth of peer review to the nature of information being peer reviewed. This is due in large part to OMB’s focusing appropriately on improvements in the processes for peer review, rather than on the content or outcome of that review.

It has been our observation that even in the case of agencies that have their own peer-review guidelines, such as the U.S. Environmental Protection Agency (EPA), the addition of the Bulletin’s requirements will ensure a much-needed transparency and accountability, as well as provide improved procedures drawn from the experiences of all the Federal agencies. Therefore, we strongly recommend that OMB expeditiously publish the Bulletin in final form after making appropriate changes, and not be deterred by concerns about unreasonable burdens on the Federal agencies.

2. Expand the Definition of “Especially Significant” Regulatory Information to Include Analyses of Risk, Regardless of the Quantification of the Impact of the Analyses.

We agree with the Bulletin’s establishment of two different categories of information subject to peer review, with different process standards applied to each. For the large majority of the items of regulatory information, the Bulletin leaves the details of the peer-

review procedures to the agencies' own guidelines that must be developed or amended under the terms of this Bulletin. A small subset of information items, however, is designated by the Bulletin as "especially significant," and detailed procedural requirements are specified for this category of information items.

This "especially significant" category applies if:

1. The agency intends to disseminate the information in support of a "major regulatory action" as defined in Executive Order 12866 § (f) (1).² The referenced section of the Executive Order describes this as any regulatory action that is likely to result in a rule that may:
 - a. [h]ave an annual effect on the economy of \$100 million or more, or
 - b. adversely affect in a material way:
 - i. the economy,
 - ii. a sector of the economy,
 - iii. productivity,
 - iv. competition,
 - v. jobs,
 - vi. the environment,
 - vii. public health or safety, or
 - viii. State, local or tribal governments or communities, or
2. The dissemination of the information could have a clear and substantial impact on important public policies or important private sector decisions with a possible impact of more than \$100 million in any year.

This requirement to estimate the impact of information is too restrictive. When a specific rule is being actively developed, an estimate of the dollar impact or material effect reasonably can be made, albeit, not without potential disagreement between the agency and outside parties. However, in the case of analyses of risk that may precede the development of any particular regulation at either the Federal or state/local level, such an estimate of dollar impact or effect is not normally made, and is highly speculative. In short, the *a priori* determination of the potential impact of a risk assessment or hazard determination on a sector of the economy or overall societal costs is exceptionally difficult and uncertain.

Yet, "analyses of risk" are singled out in the OMB Guidelines for Information Quality³ for special quality standards —namely, the standards of the Safe Drinking Water Act of 1996. It would be a mistake for these extremely important types of significant regulatory information to be excluded from the "especially significant" category for peer-review purposes.

EPA's hazard assessments, conducted under the Integrated Risk Information System (IRIS), are a good example of analyses of risk which should undergo rigorous peer

² 58 Fed. Reg. 51735 (Oct. 4, 1993)

³ 67 FR 8460

review. Clearly, a wide variety of regulatory outcomes and private sector purchasing decisions are driven by IRIS hazard determinations. These include both hazard determinations and exposure assessments, as reflected in hazard determinations of whether a substance is considered, or not considered, a carcinogen, sensitizer or reproductive toxicant, or in exposure determinations of whether a substance is deemed environmentally persistent or to bioconcentrate. Indeed, even estimated environmental exposure levels might have significant repercussions in toxic tort litigation.

However, EPA's IRIS hazard assessments are, as a rule, incorporated into Federal regulatory actions and state and local decisions only months or years after they are completed. At the time these hazard analyses are being undertaken, the agency is not likely to have the information to make any impact determination, and therefore these hazard assessments are not likely to be included by the Agency in the category of "especially significant" regulatory information subject to the stricter peer-review requirements of the OMB draft Bulletin. Yet, when ultimately incorporated into decisions, the impact of these hazard assessments can be very substantial.

In summary, a small, but very important expansion of the universe of "especially significant" regulatory information for the purposes of peer review would be to include, explicitly, all influential analyses of risk, such as risk assessments, hazard determinations, and exposure assessments in the definition of "especially significant," without regard to any estimate of eventual dollar impact or material effect of this information once it is incorporated into a rule or other policy, and without regard to whether a clear link to regulation can be made. This expansion of the universe of "especially significant" regulatory information would make the Bulletin more congruent with the OMB Information Quality Guidelines, where analyses of risk are singled out for special standards of quality.

In addition, we would suggest some preamble language that clarifies one point of possible confusion in the OMB Information Quality Guidelines—namely, that "analyses of risk" under those Guidelines include "hazard analyses" (such as IRIS files) and "exposure analyses," not just full "risk assessments" that have both a hazard and an exposure component. EPA's current Information Quality Guidelines can be read to the contrary.

3. Require the Agencies to Provide an Opportunity for Public Input on the Charge Questions Presented to the Peer Reviewers.

The development of the charge questions for the peer reviewers is, of course, crucial to the success of the peer review itself. In the case of EPA, we have observed that the authors of the information to be reviewed often are active participants in the development of the charge questions for the peer reviewers. This is reasonable because the authors often are familiar with the unresolved scientific questions on which peer-review comments might prove useful. But at the same time, the authors have an inherent conflict of interest in the outcome of the peer review. As a check on their discretion and as a way of increasing the likelihood that the charge questions will include a focus on the key scientific questions, the public should have an opportunity to

comment (via a website, for example) on the draft charge to the peer reviewers of “especially significant” information.

This change in the Bulletin would increase the transparency and accountability of the peer-review process. Although it might appear that public comment could unacceptably slow the process of peer review, it is our judgment that this would not be so. We believe that this change likely would make the peer review itself more efficient, because it would tend to minimize attempts by public commenters (in submitting comments to the peer-review panel) to raise additional questions that were not included in the charge to the panel, or to challenge the scope of the peer review after its completion. In addition, suggestions from the public for changes to the charge might in many cases help the agencies more clearly identify policy questions that must be addressed separately as required by the proposed Bulletin. This is because members of the public are likely to be keenly aware of policy issues associated with the regulatory information being peer reviewed, and might inappropriately suggest their incorporation into the charge.

As an additional matter associated with the charge to the peer reviewers, we recommend that the language of the Bulletin explicitly mention the Safe Drinking Water Act standards as one of the items to be highlighted for the peer reviewers, where these standards are applicable under the Information Quality Guidelines. In our discussions with EPA staff, we have found a general lack of awareness of these standards as they apply to analyses of risk, and we would expect the peer reviewers to be even less well informed of the applicability of these important standards.

4. Require Agencies to Provide Public Comments to the Peer Reviewers As Soon As They Become Available to the Agencies.

We commend OMB for including a requirement that the agencies provide an opportunity for other agencies and the public to submit comments for consideration by the peer reviewers. Although the Bulletin emphasizes that the peer reviewers have as their primary qualification the requisite expertise to review the regulatory information in question, often there is also a high level of expertise in other agencies and among the public on scientific questions to be considered in the peer review. It is important that this expertise be made available to the peer reviewers in a timely manner so that their deliberations can proceed from the beginning on a fully-informed basis.

We are concerned, however, that the Bulletin is not as explicit as it might be about the need for the peer reviewers to have the benefit of any such public comments at the earliest possible stage of their deliberations. The Bulletin specifies that the comments should be provided to the peer reviewers with ample time for consideration before they conclude their review and prepare their report. A small, but important, change to this requirement would require the agency to make the comments available to the peer reviewers **“as soon as they become available to the agency.”**

We have observed that in the case of the EPA Science Advisory Board, for example, peer reviewers often are encouraged to come to the first meeting of the panel with draft

comments, prepared in their areas of expertise, for inclusion in the panel's report. This is an excellent approach for improving the speed and efficiency of the peer review, but this process would be much improved, we believe, if any public comments available at that stage of the process were given to the peer reviewers BEFORE they begin to formulate their initial opinions and commit words to paper. Of course, some public comments may not be available at that time. But our suggested wording change would ensure that if comments are available, they would be provided to the peer reviewers. This small change would not impose significant burdens on the agency, but could make a large difference in the quality of the peer reviewers' work.

5. Require Agencies to Provide a Justification If They Choose to Use a Peer-Review Method for "Especially Significant" Regulatory Information that Does Not Promote an Integration Process Among Individual Peer Reviewers.

The Bulletin correctly allows agencies to choose between having peer reviews conducted by letter only, or by the convening of an "in-person" panel or some variation thereof. Certainly, letter-only reviews can be conducted much more inexpensively than in-person panel reviews, and agencies should not be required to use in-person panels for peer reviews of all "especially significant" information. However, we believe that this Bulletin should encourage agencies to carry out peer review of this "especially significant" information in a manner that promotes active integration of the reviewers' views.

We emphasize this point because the science applicable to a specific set of regulatory information rarely conforms to the arbitrary divisions between various scientific disciplines, and even more importantly, the arbitrary divisions of scientific expertise of the individual peer reviewers selected to serve on a particular peer-review panel. It has been our observation that these "imperfections" in reviewers' areas of expertise often can be mitigated by active interaction among the reviewers in an in-person panel setting, resulting in an integration of scientific expertise across scientific disciplines.

Because the regulatory information specified as "especially significant" will have a large potential impact on society, such an integrated review of the scientific information can be especially important. It is not sufficient to depend on the agency staff to bring about such integration once the individual reviews are submitted. Consequently, we recommend that the Bulletin establish a presumption in favor of a process of active integration of the peer reviewers' views. Specifically, we recommend that the Bulletin require agencies to justify instances where they wish to use a method, such as a letter-only process, which does not actively encourage such an integration of scientific expertise among the peer reviewers. In response to this requirement, agencies may find creative ways to encourage this type of active integration, even among reviewers who do not meet in person— through the use of conference calls, for example.

The results of a peer review, and particularly the results of a peer review by letter, should also comport with the transparency goals of the draft Bulletin. To this end, it would be helpful for the Bulletin to suggest, from a procedural perspective, minimal

content or criteria for peer-review records or letters. For example, minimal content for peer-review letters might include a list of the materials, studies or resources that the reviewer consulted, the topics or issues considered, any particular scientific focus or specialty, and the qualifications of the reviewer. This should not be terribly burdensome. The reviewers should incorporate the relevant provisions of the charge to reviewers and include their *curriculum vitae*.

6. Establish a Process for Public Comment and OMB Critical Review of Each Agency's Peer-Review Guidelines.

The Bulletin requires agencies to supplement or amend their information quality guidelines to incorporate the requirements of this Peer Review Bulletin. OMB should require that any such supplements or amendments (as well as any underlying agency "peer-review guidelines") be subjected to notice and comment by the agencies, after which OMB should critically review the resulting agency guidelines.

As the Bulletin notes, EPA already has peer-review guidelines. However, these guidelines have never been open to public comment, the language is vague in key areas, and the extent to which EPA program offices follow the guidelines appears to be inconsistent. As already drafted, the Bulletin will bring more transparency and accountability to the peer-review process in Federal agencies, but we believe this transparency and accountability would be enhanced significantly by a review by both the public and OMB of the procedures that the agencies propose to follow in carrying out the new requirements of the Bulletin.

7. Require Agencies to Submit Public Reports to OMB on a Semi-Annual Basis and Encourage Responses to these Reports by the Public.

Section 6 of the Bulletin directs each federal agency to provide the Office of Information and Regulatory Policy (OIRA) a report on Agency Peer Reviews "at least once a year." We believe this requirement should be improved on two counts: 1) the reports should be semi-annual and filed in conjunction with their submissions to the Regulatory Agenda, and 2) responses from the public should be encouraged.

The public has a strong interest in ensuring that the requirements of this Bulletin are faithfully fulfilled. Problems with agency processes are best identified in the planning stage. It is very difficult to correct for an inadequate peer review after it has been conducted, because the impact of the results of a poorly conducted peer review on specific decisions may be very difficult to identify and correct.

We recommend that the agencies submit their reports on Agency Peer Reviews as part of their submissions of the semi-annual Regulatory Agenda. This is particularly appropriate because the planning of regulation development encouraged by the Regulatory Agenda should go hand-in-hand with the planning for peer review of the underlying regulatory information. More importantly, this advance planning and notice,

if made available semi-annually, would allow OMB and members of the public to raise issues in a timely fashion about agency plans. Upon reviewing an agency's report on peer reviews, the public could raise questions of classification of regulatory information as "significant" or "especially significant," and the timing and manner in which the peer review is to be carried out. The public's involvement in the review of the agencies' reports should enhance the consultation between the agencies and OIRA and the Office of Science and Technology Policy and help these two oversight organizations effectively monitor compliance with this Bulletin.

OMB should require, as well, that these agency reports on peer reviews include information about completed peer reviews. This will ensure that OMB and the public have one central source for information about the completion of peer reviews, the development of the requisite peer-review reports, and where to obtain the completed documents. Having to seek out each instance separately would be difficult, particularly because the underlying regulations may not be published for a year or more.

Finally, the Bulletin should make it clear that these Reports on Peer Reviews are to cover not just the reviews of "especially significant" regulatory information, but also reviews of all significant regulatory information subject to this Bulletin.

8. Emphasize the Scientific Credentials and Balance Of the Panel as a Whole Rather Than the Strict Neutrality of Each Member.

While scientific studies may generate data, scientific analysis relies on human interpretation and reasoning. At the level of the individual, it is difficult to separate such human interpretation and reasoning from a person's "point of view."

In the current climate, we have heard arguments that all industry scientists are biased, that all agency scientists are biased, that all scientists working for environmental groups are biased, and that all academic scientists are biased because they or their institutions rely on funding from the government, industry or environmental groups. Nonetheless, we continue to support the application of the scientific process of investigation and validation as a cornerstone to many regulatory programs, and we support OMB's draft Bulletin language that "[p]eer reviewers shall be selected primarily on the basis of necessary scientific and technical expertise." While this statement is made with regard to "especially significant" regulatory information, we believe that the principle should apply broadly to all peer reviews covered by the Bulletin.

Consistent with comments being filed by the American Chemistry Council on this draft Bulletin, SIRC believes that OMB should carefully distinguish between conflicts of interest as opposed to bias or impartiality considerations. We laud the goal embodied in the draft Peer Review Bulletin of locating leading experts in the field that are free of potential biases, but doubt that this will be possible in the majority of cases. Thus, as an alternative, we support a more realistic goal of balancing the composition of-peer review panels as a whole. We believe that the Bulletin may be too restrictive in its directive that: "If it is necessary to select a reviewer who is or appears to be biased in

order to obtain a panel of appropriate expertise, the agency shall ensure that another reviewer with a contrary bias is appointed to balance the panel.” Requiring that the panel have two directly opposing points of view, or bias, may not be the best way in every case to provide for a balanced panel as a whole.

In summary, therefore, we believe OMB’s Bulletin should emphasize the scientific credentials and the overall balance of the panel as a whole rather than insisting that each member be balanced on a one-to-one basis with another reviewer.

9. Consider Avoiding the Use of the Term “Significant” In This Bulletin In Order To Eliminate Possible Confusion.

If we read the Bulletin correctly, the term “significant regulatory information” means “influential regulatory information,” with influential being defined in the OMB Information Quality Guidelines and corresponding agency guidelines. The term “significant” might be read to imply a linkage to Executive Order 12866; however, the degree to which this Bulletin picks up the criteria of that Executive Order is spelled out carefully elsewhere in the detailed language of the Bulletin and, therefore, that specific word—and the confusion it may cause—is not needed in this definition. Consequently, some confusion could be eliminated if the word “significant” were dropped from the specification of the two categories, and the word “influential” were substituted instead. This would be a more direct and clearer definition, and would not change the substantive content of the Bulletin.

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We hope that you find these comments helpful as you make enhancements to the Bulletin. If you have any questions, please do not hesitate to call me at 703-741-5012 or Chuck Elkins, our regulatory consultant, at 202-686-3518.

Sincerely yours,

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Document Submitted Electronically