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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:
Subject: Comments of Rohm and Haas Company

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

Dear Dr. Schwab,
Attached are an electronic copy of the comments of Rohm and Haas Company regarding the Proposed Bulletin on Peer Review and Information Quality. The comments are also copied in full below.

Thank you for this opportunity to comment.

mbazany@rohmhaas.com
- RandHComments.doc

COMMENTS
ON OFFICE OF MANAGEMENT AND BUDGET
PROPOSED BULLETIN ON PEER REVIEW
AND INFORMATION QUALITY
68 Fed. Reg. 54023 (September 15, 2003)

Submitted by
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On behalf of
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Rohm and Haas Company ("Rohm and Haas") strongly supports the Office of Management and Budget's ("OMB's") effort to improve federal regulations through independent, objective, and meaningful peer review of significant regulatory information. Rohm and Haas considers peer review to be an essential part of ensuring that scientific or technical information is of high quality and is sufficiently reliable and reproducible to serve as the basis for regulatory decision-making. As a member of the American Chemistry Council ("Council"), Rohm and Haas supports comments submitted by the Council, and incorporates such comments as if set forth in full herein.

In addition, Rohm and Haas provides additional comments on several areas particular concern.

Scope

The scope of OMB's proposal, which is limited to "significant" regulatory information, is not sufficiently broad to adequately address the problems with deficient scientific information that form the basis for many regulatory decisions. A case in point is the setting of water quality standards and the designation of impaired waters under the Clean Water Act. In many cases, the concentration of a particular contaminant in the water column, for example polychlorinated biphenyls, may be below the ability to obtain reliable and reproducible results with available test methods. Many waters have been identified as "impaired" based on flawed modeling of potential bioaccumulation in sensitive receptors. These models are often based on a series of cascading conservative assumptions, the results of which bear little resemblance to the real world. Therefore, a water may be designated as "impaired" without any real evidence of actual impairment. In fact, New Jersey has proposed extremely low water quality standards to address potential bioaccumulation in sensitive raptor populations, where there is evidence that raptor populations are increasing.

The designation of a water as "impaired" creates the obligation to address that impairment. Where impairment is identified based on suspect science, the ability to address that impairment also suffers from similar problems. For example, the Delaware

River Basin Commission ("DRBC"), a federal compact responsible for implementing certain Clean Water Act requirements in the Delaware River, attempted to gather data regarding impairment of the river by 1,2 dichloroethane ("DCE"). The water quality standard is 0.383 mg/l. The highest available ambient river sampling data showed that DCE was detected, but could not be accurately quantified, at 0.20 mg/l. In testing parlance, this data is described as a "J" value; it means that the substance in question was detected, but at levels below what can be accurately characterized by the test method. Based on this evidence of "impairment," which was below the water quality standard, the DRBC asked dischargers to test their effluent. The detection limit established for this testing was 0.5 mg/l, above the water quality standard. Dischargers testing their effluent to the appropriate detection limit and finding that DCE was not detected were assigned half the detection limit as a default value; half the detection limit is commonly used in testing as a conservative estimate of possible constituent levels. If these dischargers had a large flow volume, however, the calculation of their "load" of DCE to the river could be substantial, even though no DCE was actually detected in their discharge. This particular regulatory effort has been postponed until better data can be obtained following objections by the scientific and regulated communities. However, if regulatory decisions were made based on the calculated "loadings," the result would be that the discharger would be forced to impose additional controls on its effluent to address a contaminant that was not shown to be present at all. This could result in expenditure of resources by the regulated entity resulting in no environmental benefit to the river; the controls would not reduce DCE to the river if there was none in the effluent. Reasonable peer review would identify these issues in advance, potentially saving time and resources to conduct the study and obtain valid data.

The preceding examples also illustrate the need for broader scope of the peer review proposal with respect to the type of agency and the "significance" of the study. Studies may be performed by States and federal compacts that are implementing federal statutes; these should be covered by the peer review guidelines.

Waivers

Rohm and Haas cautions against the use of waivers of peer review where it is otherwise warranted in order meet court-ordered or regulatory deadlines. Under these circumstances, adequate peer review becomes even more important. In an agency's effort to meet a court-ordered deadline, or to take prompt action to address a perceived problem, errors are most likely to occur. If a panel of experts determines that a court-ordered deadline is unattainable, courts are capable of evaluating expert testimony and, if necessary, revising the deadlines to allow for a scientifically supportable result. An effective way of reducing such deadline revisions would be to involve scientific peer review earlier in the process, either when the deadlines are initially set, or during the initial study designs. Such early involvement would result in higher quality data and sufficient time for study, so that the results are acceptable to all parties.

Conclusion

In conclusion, Rohm and Haas supports OMB's efforts to reliably impose independent, objective, and meaningful peer review policies and procedures on

government actions. Rohm and Haas also supports the Council's comments regarding the peer review process proposed in the Bulletin. Thank you for this opportunity to submit comments.