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Attila E. Pavlath
President-Elect, 2000
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August 9, 2001

Ms. Brooke Dickson
Office of Information and Regulatory Affairs
Office of Management and Budget
Old Executive Office Building, Room 252
Washington, D.C. 20503

Comments on Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

Dear Ms. Dickson

The American Chemical Society (ACS) is pleased comment on proposed data quality guidelines for information disseminated by federal agencies (*Federal Register* 66: 34489-34493) as mandated by Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001. The Society appreciates this opportunity to share its views.

ACS is a nonprofit scientific and educational organization, chartered by Congress, with more than 163,000 chemical scientists and engineers as members. The world's largest scientific society, ACS advances the chemical enterprise, increases public understanding of chemistry, and brings its expertise to bear on state and national matters.

ACS applauds Congress' call for federal agencies to ensure that the data they provide are suitable for their intended purpose. The Society commends the Office of Management and Budget for recognizing that federal agencies already have a considerable investment in ensuring the quality of the data they disseminate. However, ACS is concerned that as currently drafted, broad guidance on data quality could adversely impact the government's scientific information dissemination activities.

In the process of developing appropriate guidelines, the Office of Management and Budget must be careful not to undermine the scientific peer review process, place an undue burden on scientists whose data is disseminated by the government, interfere with the right of government scientists to publish the results of their research, or hamper government dissemination of scientific information. The enclosure explores these concerns in detail. OMB should address these significant concerns in the final guidance.

ACS recommends that the Office of Management and Budget take an alternative approach to establishing data quality. Guidance should focus on administrative mechanisms that the federal agencies can establish to demonstrate that they followed appropriately rigorous processes to show that

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data are suitable for their intended purpose. Information should be open to challenge if the agency did not follow these procedures.

The American Chemical Society believes that the desire to ensure data quality is sound. The Society urges your careful consideration of these and other public comments that your office is receiving. If ACS can be of assistance to you in this process, please do not hesitate to call us at (202) 872-4386.

Sincerely,

A handwritten signature in black ink, appearing to read "Attila E. Pavlath". The signature is written in a cursive style with a large initial "A".

Attila E. Pavlath

Enclosure

American Chemical Society Comments on Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

1. Subjective definitions of “quality,” “objectivity,” “utility,” and “integrity” could have significant impacts on scientific information dissemination.

Scientific information is disseminated as part of the regulatory process and as part of federal agencies' other activities. Subjective definitions of quality, objectivity, utility and integrity could cause agencies to delay data release or disregard data for fear of challenge. This would inadvertently undermine the ability of government to disseminate public information on a timely basis and could inhibit the public's access to information. Scientific research and government action may not always be in synchrony. When the government needs to act and scientific uncertainties are large, even limited scientific information can be helpful. In other cases, the government may determine that disseminating scientific data is important as part of the public's right to know, to lay the foundation for further studies, or to help prioritize research directions. Assessing whether “the information is useful to all users of the information” or is “presented in an accurate, clear, complete, and unbiased manner” could be subjective judgments, especially in these contexts.

2. Peer review ensures the quality, objectivity, utility, and integrity of scientific information.

The peer-review process is integral to the scientific enterprise from the grant application phase through publication of findings. Technically qualified individuals familiar with the field of research determine whether the reasoning behind the experiments is sound, that the data have been plausibly generated by the given experimental methods, and that the conclusions arise from the data without distortion of the facts. Nothing about the peer review system precludes reviewers from finding research to be based on sound science, even if its results are controversial. By ensuring the objectivity and utility of scientific research, the peer review process provides validation of information being reported to any user.

Although conclusions based on scientific data are debatable, “correcting” data by modifying or deleting the actual data is a serious ethical breach. The federal government has policy in place to correct the research record when federal funds are involved and the integrity of data is questioned (*Federal Register* 65: 76260-76264). ACS recommends that the guidance should emphasize that “correction” of peer-reviewed scientific information means providing better contextual information so that the public and professional data users can assess for themselves the quality, objectivity, utility, and integrity of the information.

3. Accurate, reliable, and unbiased information is not necessarily assured under proposed definitions.

Section V proposes that one measure of data quality is that scientific research information is “substantially reproducible” upon “independent analysis.” In some cases, such as in environmental research or longitudinal studies in which data are collected over long periods, it may not be feasible to reproduce the experiment that was used to generate data. This fact alone should not imply that a dataset is invalid. Again, peer review helps ensure quality, objectivity, utility and integrity of these data. In addition, all federal agencies that conduct research and development have internal procedures in place for reviewing information before it is disseminated. Scientific commissions and review boards analyze peer-reviewed research when developing new regulations or health standards. The guidance is unclear whether these procedures constitute adequate “independent analysis.”

The larger implications of the proposed definitions are especially troublesome. The guidance does not place limits on what scientific research information would be disclosed in the name of assuring reproducibility, define what entity would be responsible for demonstrating that the information is reproducible, assure the reanalysis is independent, or provide for the cost of such reanalysis.

Data definitions vary from agency to agency. Some information maintained by an agency, such as preliminary data or confidential reports, is not meant for dissemination in its present form; additional study may be needed or be underway, or the project may have been abandoned. These kinds of data raise

issues of access, confidentiality, and intellectual property. ACS believes that the definition of “research information” should not undermine definitions of research data provided in OMB Circular A-110.36(d)(2).

Under the proposed guidance, any “affected person” could seek “correction” of scientific information. As science and engineering research become increasingly complex, critical interpretation of data can best be done by those with the necessary training and experience to do so. Judging technical and scientific information without the proper expertise may result in confusion and misinterpretation despite agency efforts to provide a context for the data. The guidance should ensure that the public demonstrate very convincing evidence that peer-reviewed scientific information does not meet high data-quality standards in seeking any correction of government-disseminated information. The potential for significant costs associated with requests for data correction suggest that a high standard is needed to evaluate the merits of requests for data correction. The complainant should have technical expertise in the area and be required to disclose any stake or conflict of interest in resolving the matter.

4. Agencies, researchers, and universities face additional burdens under the proposed guidance.

ACS is pleased that the guidance document encourages agencies to utilize their existing information dissemination and management processes to reduce administrative burdens, and to weigh the costs and the benefits of higher information quality. Complying with requests to correct scientific information disseminated by the government could place significant new requirements and potentially high costs on federal agencies, researchers, and universities. The burden is compounded by the lack of any identifiable statutes of limitations for data correction requests on information maintained by the federal government. Information to be corrected should be prospective in nature.

ACS agrees that agencies should respond promptly to valid complaints about data quality. However, the number of complaints is not necessarily linked to an agency’s performance; it simply could be linked to the controversial nature of a regulation. In addition, federal guidance for research misconduct imposes reporting requirements (*Federal Register* 65: 76260-76264). Reports under the proposed guidance should not double count cases of research misconduct. Limiting the definition of “corrections” for peer reviewed scientific information to the addition of appropriate contextual information could address this concern. ACS also recommends that agencies report the cost of compliance with the data quality guidance.

5. Information on websites should meet the same standards.

Agency reports represent the good faith efforts of many people working to bring information to light. The public should have no less confidence in information on a web site than information published elsewhere.