



August 13, 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

Dear Ms. Dickson

The American Society for Microbiology (ASM) is responding to the request to comment on the proposed guidelines for implementing Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554), published in the *Federal Register* on June 28, 2001. The ASM is the largest single life science Society in the world with over 42,000 members, including scientists and science administrators in academic, industrial and government institutions, working in a broad spectrum of subdisciplines, including medical and clinical microbiology, applied and environmental microbiology, virology, and molecular biology.

Section 515 directs the Office of Management and Budget (OMB) to issue guidelines that "provide policy and procedural guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by federal agencies." Furthermore, "within one year after OMB issues these guidelines, agencies must issue their own guidelines that include administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the OMB guidelines."

The proposed guidelines raise many significant questions that deserve thoughtful and time-consuming consideration because of their impact on the scientific enterprise. However, notice of the proposed guidelines was published in the *Federal Register* on June 28, 2001, with only six weeks for comment, and a mere six weeks from the end of the comment period to the deadline for the OMB to issue final guidelines. We strongly urge the OMB to petition Congress to extend the September 30 deadline for issuance of final guidelines, and to use the time gained by an extension for continued communication with the scientific community. We believe that the public interest will not be served by procedures that provide public access to research data, without adequate provision for protection of the process and people that comprise the research enterprise.


The June 28 notice leaves many terms and concepts unclear. The OMB is directed to issue guidelines "for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies". However, quality, objectivity, utility, and integrity are defined only as

“closely interrelated concepts” that are subject to broad interpretation. The June 28 notice refers to “underlying data” and calls for “statistical information” on “substantially reproducible” research results without any consideration of experimental design or the nature of the data from which that information is to be derived. Research results are “substantially reproducible” with varying degrees of uncertainty. Their significance is measured by statistical analyses of data. However, there are many kinds of data: raw data; abstracted data; coded data; aggregated data; edited data; analyzable data; and, finally, there is the analyzed and interpreted data that appears in published papers.

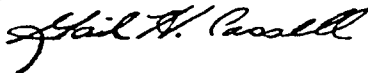
We are greatly concerned that the requirement of an “administrative mechanism allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency” will create opportunity for harassment of agencies and researchers by individuals or organizations with personal or economic interests, but who lack a challenge that is scientifically based. We agree that federal agencies should make information available on request. They do so now, using procedures that assure that the information they disseminate has a high degree of reliability. We are very uneasy also with the requirement that agencies consider whether the information they disseminate is “useful to all users of the information, including the public”. This is, of course, an impossible and unworkable assignment. The results of scientific research are initially useful to a limited number of individuals. Public utility is a desirable goal of the research process, but much time is needed for the results of research to be transformed into useful products. We are uncertain of the extent the proposed guidelines apply to extramural researchers funded by federal agencies. We believe it would be inappropriate to include university faculty and scientific personnel, and we seek reassurance that under the proposed guidelines, scientists would not be required to make their grant funded research data available to the public, prior to completion, peer review and publication. Finally, we note that the costs of implementation of the proposed guidelines are not addressed.

We hope that the OMB will carefully consider the issues raised by the proposed guidelines which may adversely affect the scientific research process. The ASM appreciates the opportunity to comment on an issue of great interest and concern to its membership.

Sincerely,



Abigail Salyers, Ph.D.
President, ASM



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Chair, Public and
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