



Healthy Plants • Healthy World

June 26, 2002

Evangeline Tsibris Cummings
U.S. EPA (2842T)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Subject: Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by EPA, Docket No. OEI-10014, 67 Fed. Reg. 21234 (April 30, 2002).

Dear Ms. Cummings:

The American Phytopathological Society (APS) is pleased to respond to the request for comments on the subject draft guidelines from the Environmental Protection Agency (EPA, the Agency).

APS, founded in 1909, is the premier educational, professional and scientific society dedicated to the promotion of plant health and plant disease control for the common good. The Society represents more than 5,000 plant pathologists, including scientists and science administrators in academic, industrial and government institutions working in a variety of areas, including applied and environmental plant pathology, food, horticultural and forestry science, and biotechnology, including basic and applied research on producing transgenic plants resistant to pathogens and abiotic stresses.

APS supports this information quality initiative as an outstanding way to further improve the scientific integrity of EPA regulatory actions and the quality of information relied upon and disseminated by EPA in the regulation of pesticides under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA) and other Agency statutes, including the Food Quality Protection Act (FQPA). We agree with the EPA statements that information quality is integral to the Agency's goals of protecting human health and safeguarding the environment.

Recognizing the need to improve the quality of information disseminated to the public by the Federal Government, Congress recently directed the Office of Management and Budget (OMB) to issue government-wide 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*. These guidelines must include mechanisms to allow the public to initiate correction of disseminated information that does not comply with the information quality standards provided by the OMB.

APS would like to comment on the draft guidelines developed by the EPA in response to the OMB guidelines. We believe that the EPA guidelines, in their current draft form, fail to accomplish the mandates of the Data Quality Act and do not meet the standards expected of all Federal agencies by the OMB. The EPA draft guidelines make the assumption that the Agency's current procedures are sufficiently sound to comply with the spirit of the OMB guidance. However, throughout the EPA's draft guidelines there is generous utilization of potential exclusion criteria that could allow the Information Quality Guidelines to be applied arbitrarily. This is counterproductive to the spirit of the OMB Guidelines in that use of guidance exceptions may conceal the actual quality of the data used, and the process for deciding whether to use or not use the guidelines will not be clear. Based on the above, APS concludes that these draft guidelines, in their current form do not meet the requirements of the Paperwork Reduction Act to *promote the theme of improving the quality and use of information to strengthen agency decision making and accountability and to maximize the benefit and utility of information created, collected, maintained, used, shared, disseminated, and retained by or for the Federal Government.*

Throughout the EPA draft guidelines the use of qualifiers and exceptions make it difficult to determine exactly what information is subject to the guidelines. APS submits that EPA should utilize the definitions of information and dissemination provided by OMB to establish the scope of these guidelines. The EPA draft guidelines should be revised to contain significantly greater detail on how EPA will ensure that disseminated information (which *will have or does have a clear and substantial impact on important public policies or important private sector decisions*) meets the requirements for quality, objectivity, utility and integrity.

EPA should further clarify that objectivity; utility and integrity are constituents of the term "quality". Additionally, EPA should adopt the quality principles applied by Congress to the Safe Drinking Water Act (SDWA) amendments of 1996(42 U.S.C. § 300g-1(b)(3)(A), (B)). Under that law an Agency is directed, *to the degree an agency action is based on science, to use (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if reliability of the method and the nature of the decision justifies use of the data).* 42 U. S.C. § 300g-1(b)(3)(A). The Agency should define clearly where and why the SDWA amendments require adaptation (as opposed to complete adoption) and what that adaptation will include.

The EPA guidelines on ensuring data quality should contain a framework for revision of the EPA's current system to incorporate the new requirements as required by the Information Quality Guidelines. This should include a process to ensure that the quality of information having the potential for dissemination is evaluated well in advance of possible public access.

"Influential information" must include information on all influential aspects of regulatory decision-making such as environmental fate and effects, environmental risk assessment, endangered species assessments, etc. The EPA draft guideline definition currently applies only to "human health"; however, the EPA routinely makes significant regulatory decision on other types of risk that OMB clearly intended to be covered in the guidelines. The draft guidelines should be revised to include risk assessments on environmental fate and effects under the principles of the SDWA by the October 1, 2002 finalization deadline.

EPA should eliminate the provision that the best available peer-reviewed science is to be used only "as appropriate", as this suggests the arbitrary use of less-rigorous standards. Additionally, under the draft guidelines EPA should define "best available" to specify availability at the time the risk assessment is

disseminated, rather than at the time it is conducted. Otherwise, if best new science became available between the time EPA proposed a regulation or remedial decision based on an older, possibly flawed assessment, the quality of the data would not meet the mandates of the Act.

The standards of data quality and transparency apply to Agency analysis of a single study as well as to analyses that combine information from multiple studies, including risk assessments. The EPA should draft consistent standards for quality, validity, reproducibility and transparency used in generation of analytical results, including the specific data used, the various assumptions employed, the specific analytical methods applied, and the statistical procedures employed for scientifically valid risk assessments. In cases where compelling interests, such as confidentiality of data, preclude dissemination of such, the Agency should draft a framework that describes how robustness checks will be used to ensure quality of the risk assessments.

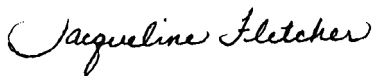
The Agency guidelines should be revised to require disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions (including default inputs) that have been employed for conduct of the risk assessments. As OMB points out in its guidance, this will not only provide for prompt error correction but, more importantly, that the public will be able to clearly assess how much the Agency's analytic results hinge on the specific analytic choices it makes.

Reproducibility of data is a basic principle of scientific investigation. The EPA guidelines should reflect OMB's intent that reproducibility standard is practical and appropriate for information that will or does have a clear and substantial impact on important decisions. APS agrees with OMB's statement, "*The reproducibility standard applicable to influential scientific, financial, or statistical information intended to ensure that information disseminated by agencies is sufficiently transparent in terms of data and methods of analysis that it would be feasible for a replication to be conducted.*"

Reproducibility should be required of information submitted by third parties and used by the Agency. Finally, EPA should not disseminate information that is generated by models or other software that is claimed to be proprietary, unless the owner of the model or software is willing to freely license it to persons interested in reproducing the data in question.

APS appreciates the opportunity to provide these comments and hope that the EPA finds them useful input from the scientific community.

Sincerely,



Jacqueline Fletcher
APS President