UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP - 5 2006

Mr. Richard A. Samp
Chief Counsel
Washington Legal Foundation
2009 Massachusetts Avenue, N.W.
Washington, D.C. 20036

OFFICE OF
ENVIRONMENTAL INFORMATION

RE: Information Quality Act Request for Reconsideration of RFC #05006 Guidelines for Carcinogen Risk Assessment

Dear Mr. Samp:

This letter is in response to the Washington Legal Foundation's (WLF) and the American Council on Science and Health's (ACSH) Request for Reconsideration (RFR), which was received by the United States Environmental Protection Agency (EPA) on March 30, 2006. In the RFR, WLF, and ACSH request that EPA reconsider its response to Request for Correction (RFC) #05006. In the RFC, WLF, and ACSH requested that EPA eliminate eight statements in the EPA *Guidelines for Carcinogen Risk Assessment* (Cancer Guidelines), EPA/630/P-03/001F (March 2005). WLF and ACSH believe these statements are not consistent with the Information Quality Act, the Office of Management and Budget *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*,[1] and EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*[2] (EPA's IQGs).

Consistent with EPA's IQGs, EPA convened an executive panel to reconsider the Agency's response to the RFC. The members of the executive panel were the EPA Chief Information Officer, Economics Advisor, and the Deputy Assistant Administrator for the Office of Water.

WLF and ACSH assert that the eight challenged statements are covered by EPA's IQGs. The executive panel has concluded, however, that these statements are EPA's policy choices and are therefore not covered by EPA's IQGs. As EPA explained in its response to public comments during the development of EPA's IQGs, the administrative mechanism described in EPA's IQGs applies to information disseminated by EPA, not to the Agency's discretionary decisions or policy choices themselves.[3] Attachment 1 shows the specific statements that you would like to see corrected. EPA believes these statements are clear Agency policy choices. These choices stem from not only what we know about cancer risks in animals and humans but

[1] 67 Fed. Reg. 8452 (February 22, 2002). http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf
[2] 67 Fed. Reg. 63657 (October 15, 2002).
http://www.epa.gov/quailty/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf
[3] See Page 42 in Section A.3.2 of Appendix A to EPA's IQGs.

also stem from the fact that there is much information which is still not known. In light of this lack of information, EPA has made policy choices which the Agency believes provide public health protection. Therefore, since EPA's IQGs apply to information disseminated by EPA to support regulation or guidance, but not to the regulatory or policy choices themselves, including policy choices expressed in guidance, the executive panel has concluded that the Agency's response to the RFC was appropriate.

The executive panel discussed the process used to develop the Cancer Guidelines. It was noted that during three transparent public review and comment periods for the Cancer Guidelines, EPA considered and addressed concerns similar to those raised in the WLF and ACSH RFR. In the *Summary Response to Public Comments on EPA's Draft Cancer Risk Assessment Guidelines of 1996, 1999, and 2003,*[4] EPA acknowledged the concern about the impact of the use of default positions and explained that the Agency is continuing to re-examine methods for appropriately addressing uncertainty and variability when data are not available.

The executive panel also discussed the intended application of the Cancer Guidelines. The Cancer Guidelines provide a framework for EPA scientists to conduct risk assessments. This framework involves a critical analysis of available information and the use of defaults when data are not available. Persons who are concerned about the applicability of the default assumptions in the context of any particular carcinogen risk assessment will generally have the opportunity to raise those concerns and to offer alternative approaches, with supporting information, in the context of that specific risk assessment.

EPA values input from the public on the quality of information it produces and embraces opportunities for improvement. EPA is committed to promoting transparency in our process and providing the public with information that is objective and useful. If you have any questions about our decision on this RFR, please do not hesitate to contact Reggie Cheatham, Director, Quality Staff, at (202) 564-6830.

Sincerely,

Linda A. Travers
Acting Assistant Administrator
and Chief Information Officer

cc: Brian F. Mannix, Associate Administrator, Office of Policy, Economics and Innovation
Michael H. Shapiro, Deputy Assistant Administrator, Office of Water
George Gray, Assistant Administrator, Office of Research and Development

[4] Summary Response to Public Comments on EPA's Draft Cancer Risk Assessment Guidelines of 1996, 1999 and 2003, March 2005. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=116283

Attachment 1

Below are the eight statements that WLF and ACSH would like to see corrected (cite RFC for full description of requested changes). These statements represent EPA's policy decisions in the *Guidelines for Carcinogen Risk Assessment.*

1. "The primary goal of EPA actions is protection of human health; accordingly, as an agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective (U.S. EPA, 1999b)."

2. "In the absence of sufficiently, scientifically justifiable mode of action information, EPA generally takes public health-protective, default positions regarding the interpretation of toxicological and epidemiologic data: animal tumor findings are judged to be relevant to humans, and cancer risks are assumed to conform with low dose linearity."

3. "In the absence of adequate human data for dose-response analysis, animal data are generally used. If there are sufficient quantitative data and adequate understanding of the carcinogenic process, a biologically based model may be developed to relate dose and response data on an agent specific basis. Otherwise, as a default procedure, a standard model can be used to curve-fit the data."

4. "In these cancer guidelines, tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."

5. "Generally, 'sufficient' support [for making a mode of action determination] is a matter of scientific judgment in the context of the requirements of the decision maker or in the context of science policy guidance regarding a certain mode of action."

6. "Is the Presence or Absence of Effects Observed in an Animal Population Predictive of Effects in Exposed Humans? The default option is that positive effects in animal cancer studies indicate that the agent under study can have carcinogenic potential in humans. Thus, if no adequate human or mode of action data are present, positive effects in animal cancer studies are a basis for assessing the carcinogenic hazard to humans. This option is a public heath-protective policy, and it is both appropriate and necessary, given that we do not test for carcinogenicity in humans."

7. "Target organ concordance is not a prerequisite for evaluating the implications of animal study results for humans."

8. "Absent data to the contrary, the default assumption is that the cumulative dose received over a lifetime, expressed as a lifetime daily dose or lifetime average daily exposure, is an appropriate measure of dose or exposure."