



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

SEP 24 2005

OFFICE OF
RESEARCH AND DEVELOPMENT

Mr. Richard A. Samp
Chief Counsel
Washington Legal Foundation
2009 Massachusetts Avenue, NW
Washington, DC 20036

RE: Information Quality Act Request for Correction - Guidelines for Carcinogen Risk Assessment, Basing Hazard Categorization on Results of Animal Studies

Dear Mr. Samp:

Thank you for your request for correction (RFC) dated August 23, 2005, under the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* ("Information Quality Guidelines"). In your RFC, the Washington Legal Foundation and the American Council on Science and Health jointly request a number of changes to be made in the Environmental Protection Agency's (EPA) *Guidelines for Carcinogen Risk Assessment, March 2005* ("Cancer Guidelines"). This letter is a response to all of the issues you have raised and changes you have requested.

The Cancer Guidelines are intended as guidance only. They represent a non-binding statement of policy and provide a suggested framework to EPA scientists for assessing possible cancer risks from exposures to pollutants or other agents in the environment. This document also informs Agency decision makers and the public about these recommended procedures. Use of the guidelines in future risk assessments will be based on decisions by EPA that the approaches are suitable and appropriate in the context of those particular risk assessments. These judgments will be tested through peer review, and risk assessments will be modified to use different approaches, if appropriate.

As you are aware, EPA's Information Quality Guidelines apply to information disseminated by EPA to support a regulation or guidance, but not to the regulatory decisions or policy choices themselves, including policy choices expressed in guidance. Your RFC sets forth your position that the passages of the document which you are objecting to "do not merely announce EPA policy" and should be viewed as "disseminated information" subject to the guidelines. These passages do express EPA's policy and are not subject to the Information Quality Guidelines.

In developing the Cancer Guidelines, EPA provided three formal opportunities for public comment in 1996, 2001, and 2003. These comment periods provided the public with an opportunity to request correction of information that they believe is not of high quality. In addition to these public comment periods, the Guidelines were subject to three independent external reviews by the Science Advisory Board in which the public was given further opportunity to raise issues to the reviewers. Peer review is a very integral component of our process for ensuring high-quality information.

We made numerous changes to the Cancer Guidelines to clarify Agency positions and to provide additional guidance to risk assessors. Similar issues concerning the use of animal testing were raised and responded to in the response to comments document, which summarizes the comments that we received and identifies the changes that we made in response to these comments. We expanded the discussion in the Guidelines on the use of epidemiological data and clearly expressed our preference for epidemiological data within a weight of evidence approach. The response to comments document, as well as considerable other information on the Cancer Guidelines, can be found on the Agency's Web site, <http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=116283>.

If you are dissatisfied with this decision, you may submit a "Request for Reconsideration" (RFR). EPA recommends that this request be submitted within 90 days of the date of this letter. To do so, send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Ave., N.W., Washington D.C. 20460), electronic mail (quality@epa.gov), or fax (202-565-2441). The RFR should reference RFC #05006. Additional criteria for information that should be included in the request are listed on the EPA Information Quality Guidelines Web site, www.epa.gov/quality/informationguidelines.

Thank you for your interest in EPA's Cancer Guidelines.

Best regards,



George Gray
Assistant Administrator
Office of Research and Development