



NATIONAL TOXICOLOGY PROGRAM
Department of Health and Human Services

NATIONAL INSTITUTE OF
ENVIRONMENTAL HEALTH SCIENCES
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February 16, 2005

Mr. Jim J. Tozzi
Center for Regulatory Effectiveness
Suite 700
11 DuPont Circle, N.W.
Washington, D.C. 20036-1231

Dear Mr. Tozzi:

I am writing in response to your Information Quality Act Request for Correction (“RFC”) of information dated June 28 and filed pursuant to the Information Quality Act¹ and the guidelines issued by the Office of Management and Budget,² the Department of Health and Human Services,³ and the National Institutes of Health (NIH)⁴ on behalf of the Center for Regulatory Effectiveness (“CRE”), Kansas Corn Growers Association, Missouri Corn Growers Association, Hawaii Agriculture Research Center, Kansas Grain Sorghum Producers Association, and California Citrus Mutual. You request that the National Toxicology Program (NTP) withdraw a May 19, 2004, *Federal Register* notice⁵ (“NTP Notice”) and not publish any other notice regarding the 12th Report on Carcinogens (RoC) until the NTP clarifies what procedures apply to the 12th RoC nomination, selection and review process. I reviewed your request and appreciate your bringing your concerns about publication of the RoC review process to our attention.

I would like to point out that the NTP published the NTP Notice to announce our intent to review nominations proposed for listing in the 12th RoC. As you are aware, the NTP held a public meeting on January 27, 2004, at the NIH where we outlined the establishment of a RoC nomination committee and some proposed modifications to the procedures for preparing

¹ 44 U.S.C. 3516 Statutory and Historical Notes.

² *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information by Federal Agencies*, 67FR8452 (February 22, 2002)

³ *Guidelines for Ensuring the Quality of Information Dissemination to the Public*, available at <http://www.hhs.gov/infoquality/part1.html>

⁴ *Guidelines for Ensuring the Quality of Information Dissemination to the Public*, available at <http://aspe.hhs.gov/infoquality/Guidelines/NIHinfo2.shtml>

⁵ 69FR28940 (May 19, 2004), available at <http://ntp-server.niehs.nih.gov/ntpweb/index.cfm?objectid=035E57E7-BDD9-2D9B-AFB9D1CAD8D09C1>

background documents for nominations to the 12th and future RoCs. The *Federal Register* notice⁶ for that public meeting presented the proposed modifications and invited the submission of written comments and/or the presentation of oral public comments on them at the meeting. After considering the comments received, the NTP finalized the procedures for nominations to the 12th RoC and subsequent editions. These revised procedures can be found at <http://ntp-server.niehs.nih.gov/ntpweb/index.cfm?objectid=720162B0-BDB7-CEBA-FE2B27BBA2785BA5>. They describe the revised RoC nomination review process including the new RoC nomination committee and modifications for the preparation of background documents.

The NTP Notice at issue in your complaint identifies a list of 21 nominations the NTP may consider for review in 2004 or 2005 and includes a brief description of the RoC nomination review process for the 12th RoC. This brief description was not intended as a complete explanation of the review process. You state that you are confused because the procedures given in the NTP Notice appear to be proposed procedures that are not yet final. You also express confusion because the NTP Notice referred the reader to the NTP web site at <http://ntp-server.niehs.nih.gov> (see Report on Carcinogens, Nomination Review Process) where the review procedures described appear to conflict with the process described in the NTP Notice. NTP acknowledges and appreciates your confusion. In May, when we published the NTP Notice, the NTP web site contained a description of procedures used for review of nominations to the 11th RoC, not the updated procedures described in the NTP Notice for the 12th RoC. Unfortunately, the revised process for the 12th and future RoCs was not finalized and posted on our web site prior to publication of the NTP notice. However, as noted above, the NTP has now finalized those procedures, and they were posted on the NTP web site on October 20, 2004.

You are correct that it is important for the NTP to be clear about the procedures applicable to the 12th RoC nomination, selection, and review process before the formal review of any nominations begins. Thank you for allowing us an opportunity to respond to your concerns. Although all Information Quality Requests for Correction are handled on a case-by-case basis, in this incidence, the NTP is concerned that others who read the NTP Notice might also have some confusion about the procedures that will be used for review of nominations to the 12th RoC. Therefore, the NTP published a supplemental notice in the *Federal Register* on October 25, 2004,⁷ clarifying the process for review of nominations to the 12th RoC and extending the comment period on nominations under consideration for that report.

⁶ 68FR67692 (December 3, 2003), available at <http://ntp-server.niehs.nih.gov/ntpweb/index.cfm?objectid=720162CF-BDB7-CEBA-FC560DF109D40A44>

⁷ 69FR6276 (October 25, 2004), available at <http://ntp-server.niehs.nih.gov/ntpweb/index.cfm?objectid=035E57E7-BDD9-2D9B-AFB9D1CADC8D09C1>

I would like to let you know that you may appeal the agency's decision either in writing or electronically within 30 days of receiving this response. Your request should state the reasons for your appeal. It does not need to reference a tracking number. The request may be sent electronically to InfoQuality@od.nih.gov or in hard copy to the Associate Director for Communications, Office of the Director, National Institutes of Health, Building 1, Room 344, 1 Center Drive, Bethesda, Maryland 20892. If the appeal is sent in hard copy, please clearly mark the appeal and outside envelope with the phrase "Information Quality Appeal."

Sincerely yours,

/s/

Christopher J. Portier, Ph.D.
Associate Director

cc:

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