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May 25, 2005

Mr. Jim Tozzi
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Dear Mr. Tozzi:

This letter constitutes a response to your Request for Correction (“RFC”) of information filed on behalf of the Center for Regulatory Effectiveness, Kansas Corn Growers Association, Missouri Corn Growers Association, Hawaii Agriculture Research Center, and California Citrus Mutual pursuant to the National Institutes of Health *Guidelines for Ensuring the Quality of Information Disseminated to the Public* (NIH Guidelines).¹ The RFC concerns the National Toxicology Program’s (NTP’s) “Call for Public Comments on 21 Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Twelfth Edition,” that NTP published in the *Federal Register* on May 19, 2004 (“NTP Notice”).² Specifically, you request that the “NTP withdraw that part of the NTP Notice regarding selection of atrazine for review in the 12th” *Report on Carcinogens* (RoC).³ Further, you state that the “NTP could not and should not select atrazine for RoC review until and unless NTP can explain that selection in a manner that meets IQA standards.”

We would like to thank you for your comments on atrazine and the information you provided. As background, and as the NTP explained in the NTP Notice, the RoC is “a Congressionally mandated listing of known human carcinogens and reasonably anticipated human carcinogens, and its preparation is delegated to the NTP by the Secretary, Department of Health and Human Services (DHHS).”⁴ The process for preparing the RoC is explained in the NTP Notice as follows:

“A nomination recommended for review in the RoC is evaluated initially by the NIEHS/NTP RoC Nomination Review Committee, composed of scientists from the NIEHS/NTP staff, to determine if the information available for a nomination indicated the criteria for listing can be applied and warrants formal consideration by the NTP. The scientific review of a nomination involves three separate scientific reviews: two Federal review groups and one non-governmental peer review body (a subcommittee of the NTP Board of Scientific Counselors) that meets in an open, public forum. Throughout the review process, multiple opportunities are provided for public input

¹ *Guidelines for Ensuring the Quality of Information Dissemination to the Public*, available at <http://www.hhs.gov/infoquality>.

² *Federal Register* Vol. 69, No. 97, May 19, 2004, pages 28940-28944.

³ Request at 5.

⁴ 69 FR at 28940.

including comment at the public meeting of the NTP Board RoC Subcommittee. In reviewing nominations for the RoC, all available data and public comments are considered in the application of the criteria for inclusion or removal of candidate agents, substances, mixtures, or exposure circumstances or for a change in a candidate's classification."⁵

With respect to the factors used to evaluate a nomination, the NTP Notice explains: "The criteria used in the review process and a detailed description of the review procedures, including the steps in the current formal review process, can be obtained from the NTP web site at <http://ntp-server.niehs.nih.gov> (see Report on Carcinogens) or can be obtained by contacting: Dr. C.W. Jameson, National Toxicology Program, Report on Carcinogens, ..." ⁶ Thus, the review of nominations to the RoC follows an established, multi-step process.

The NTP Notice represents the first step in this formal process for development of the RoC. It is a list of nominations proposed for review that is published in the Federal Register and NTP publications, such as its newsletter. The NTP Notice identifies and solicits public comments on the substances that are proposed for consideration for inclusion in the Twelfth RoC. It explains, under the heading "Public Comment Requested," that the document, through a table, "identifies the 21 nominations that the NTP may consider for review in 2004 or 2005, as either a new listing or changing the current listing in the Twelfth" RoC.⁷ Included in the table are clearly labeled columns for a substance's "Primary uses or exposures," "Nominated by," and "Basis for nomination." The last column, describing the basis for a nomination, typically includes one to two brief sentences describing the agency's reason for selecting a substance to consider for inclusion or revision in the RoC. For example, in the case of atrazine, the NTP Notice states:

Nomination to be reviewed/CAS No.	Primary uses or exposures	Nominated by	Basis for nomination
Atrazine (192-24-9)	Atrazine is an herbicide used to control grass and broad-leaved weeds. Atrazine has been detected at levels that exceeded or approached the MCL for atrazine in 200 community surface drinking water system.	NIEHS	IARC finding of sufficient evidence of carcinogenicity in animals (Vol. 73, 1999)

Thus, the NTP Notice is not a definitive statement that the agency will include or revise a listing, nor is it intended to provide all the relevant information or scientific data about a nomination. Such information is developed at later stages in the review process. Instead, the NTP Notice notifies the public that a substance is being considered and invites the public to

⁵ 69 FR at 28940-28941.

⁶ 69 FR at 28941.

⁷ 69 FR at 28941.

submit relevant information on the nomination's carcinogenicity, production, use, and human exposure. The NTP Notice also invites the public to identify and provide information concerning any scientific issues related to the listing that should be addressed during review of a nomination. Finally, in addition to describing the review process and referring readers to additional information sources regarding it, the document clarifies that other substances may be nominated at a later time through a similar notice and comment process: "Additional nominations for the Twelfth Report or modifications to the nominations in the attached table may be identified and would be announced in future **Federal Register** notices."⁸

Your RFC states with regard to atrazine that the NTP Notice "violates the objectivity standard" in the NIH Guidelines. The objectivity standard indicates that the agency should ensure that "information" (meaning, "facts or data") it disseminates is "accurate, clear, complete, and unbiased."⁹ You assert that this standard is not met in the NTP Notice because it failed to include findings:

- a. by the Environmental Protection Agency (EPA) regarding the potential human carcinogenicity of atrazine.
- b. from a proposed decision the United Kingdom submitted to the European Commission in 1996.
- c. of a 1997 Australian report concerning the potential carcinogenicity of atrazine in humans.
- d. from a 1999 IARC report concerning the potential human carcinogenicity of atrazine.

The RFC also asserts that the NTP Notice "violates the utility standard" because "it is not useful to its intended users." The "utility" standard refers to "the usefulness of the information to its intended users, including the public."¹⁰ The RFC asserts that this standard is not met in the NTP Notice because:

- (a) "the NTP Notice misleads users regarding atrazine and cancer."
- (b) "no further review of atrazine and cancer risk could have any utility until completion of the NCI Agricultural Health Study."¹¹

Thus, the RFC criticizes the agency for failing to include and consider in the request for comments, concerning the nomination of substances certain information concerning atrazine, that you and your clients believe should be included and considered in the notice.

We respectfully disagree with your conclusions. Insofar as you are challenging the agency's policy choice to nominate atrazine as a substance to be reviewed for consideration or revision in the Twelfth RoC, we note that such policy decisions are not reviewable under the IQA complaint process. Rather, the IQA addresses the agency's presentation of facts or data. With

⁸ 69 FR at 28941.

⁹ 67 FR at 8459.

¹⁰ 67 FR at 8459.

¹¹ Request at 5.

respect to the facts or data contained in the NTP Notice, we believe that the minimal information presented fully satisfies the objectivity and utility standards.

As noted above, the NTP issued the NTP Notice to announce our intention to review additional nominations for the RoC, not to identify or catalog the range of information relevant to any particular nomination. The Notice accurately identified a list of 21 nominations, including atrazine, that the NTP may consider for review in 2004 or 2005, solicited public input on them, and requested relevant information concerning their “carcinogenesis, as well as current production data, use patterns, or human exposure information.”¹² The NTP accurately identified the nominator of atrazine, NIEHS, and provided useful information to the reader regarding the basis for atrazine’s nomination to the RoC. As stated in the table in the NTP Notice, atrazine was nominated based on the finding of sufficient evidence of carcinogenicity in animals by the International Agency for Research on Cancer (IARC) (Vol. 73, 1999).¹³ Thus, the information contained in the NTP Notice accurately and usefully identifies atrazine and communicates to the public the basis for the NTP’s policy choice to select atrazine for inclusion or revision in the Twelfth RoC.

In addition to soliciting comments on the nominations and information about them, the NTP also invited “interested parties to identify any scientific issues related to the listing of a specific nomination in the RoC that they feel should be addressed during the reviews.”¹⁴ The NTP’s procedure of issuing notices to identify nominations that it may review for the RoC provides a means to solicit public input on them and identify relevant information and issues. Comments received in response to the NTP Notice, such as the ones provided in your RFC, help us to identify issues that should be addressed in the background documents for the nominations.

The quality of information that the NTP disseminates is very important and we strive, at every opportunity, to maximize it. Your input, including the studies you described, is important to us. Consistent with the process described above, we will also be treating your RFC as a public comment in response to the NTP Notice and your concerns will be considered, along with other public comments we receive on atrazine, in our review of the atrazine nomination. The NTP will review the information on these 21 nominations for the Twelfth RoC obtained from a comprehensive literature search and included in the public comments. Following completion of this review, the NTP will publish in the Federal Register an update on the status of these nominations, including atrazine, before proceeding with their formal reviews, if still warranted.

We 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

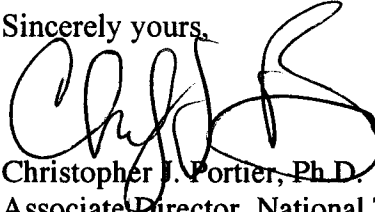
¹² 69FR at 28941.

¹³ IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, “Some Chemicals that Cause Tumors of the Kidney or Urinary Bladder in Rodents and Some Other Substances,” Vol. 73, p. 94 (1999).

¹⁴ 69 FR at 28941.

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,



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cc:

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