June 28, 2004

Associate Director for Communications
Office of the Director
National Institutes of Health
Building 1, Room 344
9000 Rockville Pike
Bethesda, MD 20892

Re: Information Quality Act Request for Correction of Information: RoC Procedures

Dear Sir or Madam:

We are submitting this Request for Correction ("RFC") of information disseminated by the National Toxicology Program ("NTP") in a *Federal Register* notice dated May 19, 2004, and published at 69 FR 28940 ("NTP Notice").[1] This RFC is submitted on behalf of the Center for

Regulatory Effectiveness ("CRE"); the Kansas Corn Growers Association; Missouri Corn Growers Association; Hawaii Agriculture Research Center; Kansas Grain Sorghum Producers Association; and California Citrus Mutual.[2]

Information Dissemination Being Challenged

[1] This RFC is submitted pursuant to the Information Quality Act ("IQA"), 44 U.S.C. § 3516 Statutory and Historical Notes; and pursuant to the implementing Guidelines issued by the Office of Management and Budget ("OMB Guidelines") (67 FR 8452 (Feb. 22, 2002)); by the Department of Health and Human Services ("HHS Guidelines") (Guidelines for Ensuring the Quality of information Disseminated to the Public (http://www.hhs.gov/infoquality/part 1 A-9-20.htm)); and by the National Institutes of Health ("NIH Guidelines") (Guidelines for Ensuring the Quality of Information Disseminated to the Public (http://www.hhs.gov/infoquality/NIHinfo2.htm)).

[2] The parties submitting this RFC will hereinafter be referred to as "Petitioners."

The NTP Notice states that two different, conflicting review procedures are simultaneously being used in the 12th Report on Carcinogens ("RoC"). The first set of procedures is described in the NTP Notice at 69 FR 28940. The second, conflicting set is provided on the NTP Web site. The NTP Notice incorporates these second, conflicting procedures when the Notice states that "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)...."[3]

The two procedures disseminated by the NTP Notice conflict with regard to

· how substances are selected for formal review in the RoC; and

· whether a substance selected for formal review can be removed from the review process before completion of all review stages.[4]

Both procedures cannot possibly apply to the 12th RoC nomination, selection and review process because they conflict; yet both do according the NTP Notice.

This conflict has very real consequences. For example, under the NTP Web site procedures, a substance selected for review can be dismissed early in the RoC review process. In contrast, under the procedures discussed in the text of the NTP Notice, a substance must undergo full RoC review once selected, and cannot be dismissed early.

The NTP Notice's Conflicting Information About RoC Procedures Violates IQA Standards

The NTP Notice's conflicting information about RoC procedures violates the objectivity standard in the IQA, OMB Guidelines, HHS Guidelines, and NIH Guidelines for the following reasons:

1. The information about RoC procedures is not presented in an accurate and clear manner;[5] and

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[3] 69 FR at 28941. A printout of the referenced NTP Web site description of the 12th RoC procedures is enclosed as an Appendix ("App.") to this RFC.

[4] The conflicting procedures are discussed in more detail in the ***Background*** section of this RFC.

[5] *E.g.*, OMB Guidelines, section V.3.a, 67 FR at 8459; NIH Guidelines, Introduction at first bullet item.

2. The information about RoC procedures is not accurate and reliable.[6]

The NTP Notice's conflicting information about RoC procedures also violates the utility standard in the IQA and Guidelines because it is not useful to its intended users.[7]

The NTP Notice Should Be Withdrawn

Petitioners request that NTP withdraw the Notice and not publish any other Notice regarding the 12th RoC until NTP decides what procedures apply. In addition, NTP should only apply final procedures to the RoC nomination, selection and review process. NTP should not apply any procedures that are only proposed at the time substances are nominated for review in the 12th RoC.

A more detailed discussion of the conflicting information about RoC procedures follows.

Background

The NTP Notice states that 21 substances have already been nominated and selected for review and possible listing as "known" or "reasonably anticipated" human carcinogens in the 12th RoC.[8]

The NTP Notice further states that the applicable procedures for the 12th RoC "can be obtained from the NTP Web site at http://ntp-server.niehs.nih.gov (See Report on carcinogens)...."[9] The procedures at the referenced NTP Web site state that substances are selected for review by an "NIEHS/NTP Review Group (RG1)," which also has subsequent, substantive review responsibility after it has selected substances for review in the RoC:

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6 *E.g.*, OMB Guidelines, section V.3.b, 67 FR at 8459; NIH Guidelines, Introduction at first bullet item.

7 *E.g.*, OMB Guidelines, 67 FR 8459, section V.2.

8 69 FR at 28940-44.

9 69 FR at 28941.

> A nomination for listing or delisting in the RoC is evaluated initially by the NIEHS/NTP Review Group (RG1) to determine if the information provided indicates that the nomination warrants further consideration by NTP.
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> The RG1 then proceeds with scientific review of the nomination and makes a recommendation for listing or delisting in the RoC.[10]

This nomination, selection and review process conflicts with the process discussed in the text of the NTP Notice itself. According to the text of the NTP Notice, substances are selected for review by a "NIEHS/NTP RoC nomination review committee" which has no subsequent, substantive RoC review responsibility.

> A nomination recommended for review in the RoC is evaluated initially by the NIEHS/NTP RoC nomination review committee, composed of NIEHS/NTP staff, to determine if the information available for a nomination indicates 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 a non-government peer review body....[11]

Under both sets of procedures, after a substance has been selected for review in the 12th RoC, substantive reviews are conducted by RG1; by an inter-agency review group known as RG2; and by an external peer review subcommittee of the NTP Board of Scientific Counsellors. RG1 conducts the first substantive review and builds much of the administrative record for the entire RoC review. [12]

The two procedures conflict, however, with regard to whether a substance must undergo the entire, lengthy RoC review process once it has been selected for review.

The NTP Web site procedures state that RG1 can stop the review of a substance already selected for review if it determines, after a literature search and after reviewing public comments on the selection, that "there is insufficient information to apply the criteria for listing in ...the RoC." [13] If RG1 makes this determination, then RG2 and RG3 do not proceed with their review

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[10] App. at pp. 1, 3.

[11] 69 FR at 28940.

[12] App at p. 3-4.

[13] App. at p. 3.

of the substance, and the RoC listing process for the substance stops.[14]

In contrast, the review procedures described in the text of the NTP Notice do not contain any mechanism for stopping review of a substance once it has been selected for review by the NIEHS/NTP RoC nomination review committee.[15]

The confusion caused by the NTP Notice is compounded by the fact that the procedures discussed in the text of the Notice appear to be new procedures that are only proposed and are not yet final.[16] NTP has apparently applied the proposed new procedures to the 21 substances selected for review in the 12th RoC--while at the same time applying the conflicting current procedures--even though there are no final new procedures; and even though any final new procedures may differ from the proposals.

The conflicting information disseminated in the NTP Notice about the 12th RoC procedures is not presented in an accurate and clear manner; and it is not accurate and reliable.[17] The conflicting information disseminated in the NTP Notice about the 12th RoC procedures is also not useful to its intended users because the users do not know which procedures apply.[18]

Petitioners Are Affected Persons

Petitioners are "affected persons" for purposes of this RFC.

Petitioner CRE has commented extensively on the RoC procedures. CRE's comments include written comments and oral comments at, *e.g.*, the January, 2004 public meeting on NTP's review of its RoC procedures. CRE also submitted written comments on the selection of talc for review in the 12th RoC. CRE has a right under the IQA and Guidelines to accurate, reliable, clear and useful information about what procedures are used for the 12th RoC.

The other Petitioners are groups of growers who use atrazine. Atrazine is one of the 21 substances selected for review in the 12th RoC. 69 FR at 28941. Any listing of atrazine as a

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[14] App. at p. 3.

[15] 69 FR 28940-41.

[16] *Compare* 67 FR 67692, 67694 (Dec. 13, 2003)("Proposed Listing/Delisting Procedures") *with* 69 FR at 28940 (procedures described in text of NTP Notice).

[17] Consequently, the conflicting NTP Notice information about RoC procedures violates the IQA and Guidelines. *E.g.*, OMB Guidelines, sections V.3.a .and V.3.b, 67 FR at 8459; NTP Guidelines, Introduction at first bullet item.

[18] Consequently, the conflicting NTP Notice information about RoC procedures violates the IQA and Guidelines. *E.g.*, OMB Guidelines, 67 FR 8459, section V.2.

"known" or "reasonably anticipated" human carcinogen in the 12th RoC would adversely affect their ability to use atrazine. They have a right under the Act and Guidelines to accurate, reliable, clear and useful information about what procedures are used for the 12th RoC to nominate, select, and review atrazine.

Consequently, Petitioners have the right to file this RFC regarding the NTP Notice's conflicting information about RoC procedures.[19]

Conclusion and Correction Requested

Petitioners request that NTP withdraw the Notice and not publish any other Notice regarding the 12th RoC until and unless NTP decides what procedures apply to the 12th RoC nomination, selection and review process. Only then could NTP disseminate accurate, reliable and useful information regarding the procedures governing the 12th RoC nomination, selection and review process.

If the NTP decides to use any new procedures, then it should publish them as final before using them for the 12th RoC nomination and review process. NTP should not use merely proposed procedures in the 12th or any other RoC.

Contact

Please contact Jim Tozzi, 11 DuPont Circle, Suite 700, Washington, D.C. 20036, 202/265-2383, Tozzi@TheCRE.com regarding this RFC .

Petitioners,

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[19] *E.g.*, 44 U.S.C. § 3516 Statutory and Historical Notes; OMB Guidelines, section III.3, 67 FR 8459; HHS Guidelines, section E; NIH Guidelines, section VI.

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