July 16, 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: Atrazine

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"); Kansas Corn Growers Association; Missouri Corn Growers Association; Hawaii Agriculture

[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)).

Research Center; and California Citrus Mutual.[2]

Information Dissemination Being Challenged and Correction Requested

The NTP Notice states that atrazine has been selected for review for possible listing as a "known" or "reasonably anticipated" human carcinogen in the 12th Report on Carcinogens ("RoC").[3]

This RFC requests correction of the NTP Notice's dissemination of information about atrazine.

This RFC requests NTP withdraw that part of the NTP Notice which discusses atrazine.

The NTP Notice Misrepresents IARC's Atrazine Findings

According to the NTP Notice, atrazine was nominated for review by "NIEHS."[4] According to the NTP Notice, NTP accepted the nomination and decided to review atrazine for possible listing in the RoC for only one reason: "IARC...finding of sufficient evidence of carcinogenicity in animals (Vol. 73, 1999)."[5]

The animal tests in the cited IARC Monograph are Sprague-Dawley rat tests showing mammary tumors in the rats. The IARC Monograph states:

> "Atrazine at high doses in the diet is associated with an increased incidence and/or an earlier onset of mammary gland tumors in female Sprague-Dawley rats; however, it is not tumorgenic in Fischer 344 rats or in CD-1 mice of either sex." [6]

The NTP Notice is misleading and incomplete because it omits IARC's explanation that the Sprague-Dawley rat tests are irrelevant to human cancer. For example, the IARC Monograph states with regard to these animal tests: "[T]here is strong evidence that the mechanism by

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

[3] 69 FR at 28940-41.

[4] 69 FR at 28941.

[5] 69 FR at 28941 (footnote to IARC citation omitted).

[6] 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)("IARC Monograph"), copy attached as Appendix "A."

which atrazine increases the incidence of mammary gland tumors in Sprague-Dawley rats is not relevant to humans."[7] The IARC Monograph contains an extensive discussion of the mechanistic reasons why these rat tumors are irrelevant to humans.[8] The IARC Monograph also states: "There is inadequate evidence in humans for the carcinogenicity of atrazine." [9]

The NTP Notice's characterization of IARC's finding on atrazine is also misleading and incomplete because IARC's "Overall evaluation" is not provided by the Notice. IARC's "Overall evaluation" is: "Atrazine is *not classifiable as to its carcinogenicity to humans*."[10]

The NTP Notice Fails to Mention EPA's Recent Finding that Atrazine is Not Likely to Be Carcinogenic to Humans

During its FIFRA re-registration review of atrazine, EPA spent several years considering all the latest and best available evidence on atrazine and cancer, including the Sprague-Dawley rat tests relied on by the NTP Notice. In 2003, EPA determined "consistent with conclusions reached by the SAP (June 2000), that it is unlikely that atrazine's cancer mode of action in the Sprague-Dawley rat is operative in humans."[11] Dr. Christopher Portier was Chair of the referenced SAP.[12] Dr. Portier is Director of the NIEHS Toxicology Program and Associate Director of NTP.

In October, 2003, EPA concluded at the end of its multi-year review that atrazine is "not likely to be carcinogenic to humans."[13]

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[7] *Id*. at p. 99.

[8] *Id.* at pp. 94-96, 99.

[9] *Id*. at p. 99.

[10] *Id.* at p. 99 (emphasis in the original).

[11] Letter from Betty Shackleford, Acting Director, EPA OPPTS Special Review and Registration Division, to Atrazine Registrants, regarding EPA October 2003 Atrazine IRED, p. 2 ("Shackleford Letter"), copy attached as Appendix "B."

[12] USEPA Science Advisory Panel (C Portier, Member). (2000) Review of atrazine: hazard and dose-response assessment and characterization. FIFRA-SAP. USEPA Science Advisory Panel report No. 2000-05 ("Portier SAP"), copy attached as Appendix "C."

[13] App. B at p. 2.

The NTP Notice Fails to Mention the Ongoing NCI Agricultural Health Study and EPA's Planned Review of the Study When It Is Completed

The National Cancer Institute ("NCI") is conducting an epidemiological study of agricultural workers, pesticide exposure, and cancer. This study will not be complete until mid-2005 at the earliest. EPA plans to convene another SAP on atrazine once the Agricultural Health Study is completed.[14]

The NTP Notice announcing that NTP will immediately review atrazine for cancer fails to note that the NCI Agricultural Health Study of atrazine and cancer is not yet available and won't be for some time. The NTP Notice also fails to mention EPA's plans to review atrazine with another cancer SAP once the Agricultural Health Study data become available.

The NTP Notice's Information About Atrazine Violates IQA Standards

The NTP Notice's information about atrazine and cancer violates the objectivity standard in the Information Quality Act ("IQA"),[15] OMB Guidelines,[16] HHS Guidelines, [17] and NIH Guidelines[18] for the following reasons:

1. The information is not presented in an accurate, clear, complete, and unbiased manner;[19]

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[14] App. B at p. 6.

[15] 44 U.S.C. § 3516 Statutory and Historical Notes.

[16] 67 FR 8452 (Feb. 22, 2002).

[17] Guidelines for Ensuring the Quality of information Disseminated to the Public (http://www.hhs.gov/infoquality/part 1 A-9-20.htm).

[18] Guidelines for Ensuring the Quality of Information Disseminated to the Public (http://www.hhs.gov/infoquality/NIHinfo2.htm).

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

2. The information is not accurate, reliable and unbiased;[20] and

3. The information is not based on the best available science and supporting studies.[21]

These violations are evidenced by the Notice's omission of:

- EPA's conclusions after 10 years of scientific review that considering the animal data and the human epidemiological data, atrazine is "not likely to be carcinogenic in humans....Further, any weight attributable to these (epidemiologic) data is weakened by the data in animals that fail to reveal any mechanism of action for atrazine consistent with the cancers ovserved in the studies. Accordingly, EPA concludes that atrazine is "not likely to be a human carcinogen"; [22]

- the conclusion of United Kingdom regulatory body that use of atrazine, consistent with good plant protection practices will not have any harmful effects on human or animal health or any unacceptable effects on the environment;[23]

- the regulatory review in Australia that determined data regarding the formation of tumors in one species of laboratory rat exposed to high levels of atrazine has no relevance to humans; [24]and

- incomplete and misleading representation of the IARC conclusions on the carcinogenicity of atrazine.

The NTP Notice's information about atrazine and cancer also violates the utility standard in the IQA and Guidelines because it is not useful to its intended users.[25] Instead, the NTP Notice misleads users regarding atrazine and cancer. Moreover, given EPA's recently

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

[21] *E.g.*, NIH Guidelines, V.2.d.

[22] App. B at p. 5.

[23] Atrazine Report and proposed Decision of the United Kingdom made to the European commission under Article 7(1) of Regulation 3600/92 Council Directive 91/414/EEC Regulation 3600/92, October 1996.

[24] The National Registration Authority for Agricultural and Veterinary Chemicals Review of Atrazine, November 1997.

[25] *E.g.*, OMB Guidelines, 67 FR 8459, section V.2.

completed atrazine review, no further review of atrazine and cancer risk could have any utility until completion of the NCI Agricultural Health Study. EPA plans to review atrazine again then. Why is NTP reviewing atrazine now? NTP's apparent intent to duplicate EPA's years of work on atrazine and cancer can only be interpreted as a biased desire to reach an outcome contrary to the conclusions reached by a decade of EPA research and scientific analyses.

Correction Requested

Petitioners request that NTP withdraw that part of the NTP Notice regarding selection of atrazine for review in the 12th RoC. 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.

Petitioners Are Affected Persons

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

Petitioner CRE has commented extensively in RoC proceedings. CRE also participated extensively in EPA's review of atrazine. CRE's work at EPA would be pointless and wasted if NTP duplicates EPA's review in lengthy RoC proceedings. Yet that is what NTP currently intends to do with atrazine.

The other Petitioners are groups of growers who use atrazine. Any listing of atrazine as a "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 the dissemination accurate, reliable, clear, complete and useful information about atrazine and cancer. Petitioner California Citrus Mutual is a group of growers who also use simazine. Atrazine and simazine are chemically similar herbicides. Consequently, any assessment of atrazine's cancer risk in the 12th RoC would have a collateral effect on simazine use.

Consequently, Petitioners have the right to file this RFC regarding the NTP Notice's mis-information about atrazine. [26]

[26] *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.

Contact

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Petitioners,

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