



Office of Advocacy

June 19, 2001

Dr. Bruce Alberts
President, The National Academy of Sciences
and,
Chair, National Research Council
2101 Constitution Avenue, N.W.
Washington, DC 20418

Subject: NRC Conflict of Interest/Bias Disclosure Re: Arsenic Update Subcommittee

Dear Dr. Alberts:

The Office of Advocacy of the U.S. Small Business Administration is writing to you about compliance with the appropriate science integrity procedures with regard to the National Research Council's (NRC) Subcommittee to Update the 1999 Arsenic in Drinking Water Report. The Office of Advocacy was established by Congress pursuant to Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Over the last two years, we have worked closely with the Environmental Protection Agency (EPA) in the development of the proposed and final regulations for arsenic in drinking water. This includes a review of the draft arsenic regulation in a formal proceeding under the Small Business Regulatory Enforcement Fairness Act (SBREFA) in 1999, involving the Office of Management and Budget and EPA.

In December 1997, when the amendments to the Federal Advisory Committee Act (FACA) were signed into law, you stated, "I want to assure the President, Congress, and the public that we will take all steps necessary to comply with the law and to provide substantial public access . . . we believe that the increased transparency of our processes will benefit both the Academy and the nation." We hope that you will now take the appropriate steps to comply with these requirements as set out in the current NRC FACA procedures. In previous comments and testimony before the NRC (enclosed), we asked the NRC to make certain public disclosures with respect to the potential bias and conflict of interest of the arsenic subcommittee members. (1) To date, the NRC staff has declined to make those disclosures. We have subsequently learned that the NRC's own procedures require such disclosures beyond what we had initially asked the Council to reveal. We now ask that you make those disclosures, as required by the NRC procedures, allow an additional twenty days for public comment, and re-establish the balance of views of the subcommittee as required by the 1997 FACA amendments.

Background – Federal Advisory Committee Act Requirements at the NRC

The 1997 Federal Advisory Committee Act (FACA) Amendments specifically require that "[t]he Academy shall make its best efforts to ensure that (A) no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable" As part of this procedure, the Academy posts provisional panel biographies on the Internet, and provides for a twenty- day comment period on those provisional nominations. After a review of the comments, the NRC determines the final composition of the panel.

The NRC procedure is either to find panelists without biases, or to identify a "balance of potentially biasing backgrounds or professional or organizational perspectives," where it cannot do so. (2) The

NRC has chosen at least five panelists of the eight who have public positions on arsenic. These same five were on the previous subcommittee that issued the report in 1999. Those panelists concluded that "that the current [Maximum Contaminant Level] MCL for arsenic in drinking water of 50 ug/L does not achieve EPA's goal for public health protection and therefore requires downward revision as promptly as possible." (3) Thus, all five panelists with public positions appear to be all on one side of the issue, favoring a significant decrease from the current standard.

Concern with Balance of Views of the Current Arsenic Subcommittee

In contrast to the NRC, the Environmental Protection Agency finds that "[a]s a general rule, experts who have made public pronouncements on an issue [e.g., those who have clearly "taken sides"] may have difficulty in being objective and should be avoided." (4) We agree with EPA that the public positions taken by provisional panelists are important evidence of potential panel member bias (and normally would be disqualifying).

We have provided the public positions of the eight panelists (see enclosure), as revealed by a Westlaw search on June 15, 2001. This review turned up public statements by Goyer, Cantor, Aposhian, Eaton and Kosnett, who are the five returning panelists. From this search and other articles that we have reviewed, we have determined that Dr. Kosnett has endorsed a 5 ppb standard, (5) and all five returning panelists favor a "prompt" reduction in the standard from 50 ppb. No information on public positions was found regarding Bailus Walker, Kimberly Thompson, (6) or Rogene Henderson, the ttabindex="90" href= new panelists.

In addition, we note that of all five returning subcommittee members, none were among the four who expressed concern about being pressured by NRC staff in the writing of the report, nor were they among those who expressed doubts about the validity of the Taiwan data risk extrapolations. In combination with the nomination of Dr. Kosnett, who has publicly supported the final 10 ppb standard now being questioned, there appears to be a serious question concerning the balance of the present composition of the subcommittee appointees.

The NRC Needs to Follow Its Own Public Disclosure Procedures, Post New Biographies and Accept Additional Public Comment on the Nominees

Specifically, the NRC Section 15 FACA Interim Policy provides that "... the chair of a committee at the first data-gathering meeting which is open to the public should ask each member of the committee to state briefly in open session those aspects of his or her background, experience, expertise and previously-stated positions that appear relevant to the functions to be performed by the committee." (7) In an October 2000 letter from the NRC Executive Officer, Dr. Colglazier, the FACA policy was clarified to include the following: "RSOs [Responsible Staff Officers] should ensure that each biographical posting provides an appropriate statement of the member's qualifications to serve on the committee, highlighting the member's expertise and technical credentials related to the committee's charge and his or her relevant current and past affiliations, e.g., consulting for the sponsor, research support from public and private sources, service on related committees within the National Academies and outside, etc." (8): (9)

At the initial May 21st data gathering meeting, Advocacy did not observe the panelists disclose their public positions, funding sources or affiliations, nor do we recall that the panelists were asked to make such disclosures. At the second data gathering meeting scheduled for tomorrow, we would advise the NRC to request that such disclosures be made. These disclosures should include the publicly stated positions, affiliations, and funding sources, such as work performed for EPA, if any. Similarly, in line with Dr. Colglazier's recent clarification, the biographies should explicitly address the same issues. In Dr. Colglazier's letter cited above regarding the Committee on Environmental Impacts Associated with Commercialization of Transgenic Crops (EIACTC), Dr. Colglazier admitted a similar oversight regarding the posting of the EIACTC biographies, and determined that the biographies should be reposted with the relevant information, starting another twenty-day comment period. We request that the same procedure be followed here.

We do not assume that the current subcommittee is unbalanced. We simply want the Academy to follow its own well crafted public procedures, make the appropriate disclosures and allow the public to participate. Then, as Dr. Colglazier stated in a recent letter to the *Washington Times*, we can "let science -- and fact -- guide our work."

We trust that these comments will prove useful to the NRC. Please provide the additional information requested above to Kevin Bromberg of my staff (phone 202-205-6964; fax 205-6928; e-mail kevin.bromberg@sba.gov).

Sincerely,

Susan M. Walthall
Acting Chief Counsel for Advocacy

Enclosures

cc: Bill Colglazier, NRC
Jim Reisa, NRC
Diane Regas, EPA

ENCNOTES

1. We also made some additional points regarding panel member qualifications, which we will not address in this letter, such as the inappropriateness of the five returning panel members reviewing their earlier work in the development of the update report.
2. 1992 NRC Conflict of Interest Policy at 2.
3. 1999 Arsenic NRC Report at 254.
4. 2000 EPA Science Policy Council Peer Review Handbook at 58.
5. "The evidence indicates that a substantial risk to human health exists at 50 parts per billion and merited lowering the standard to 5, if not even 10 parts per billion." Richard Keil, Bloomberg Report, March 27, 2001.
6. We understand that Kimberly Thompson is on the Board of Directors of the American Council on Science and Health, and may provide some balance to the views of the others. We also note that she and Dr. Louise Ryan (also on the panel) are both on the faculty of Harvard School of Public Health. Dr. Ryan's methodology using the Taiwan data provided the basis for the EPA risk estimates being reviewed by the subcommittee.
7. Interim Policy on Compliance with Section 15 of FACA, dated August 10, 1998, authored by Jim Wright, at 3.
8. Letter from Dr. Colglazier, NAS to Ronald Collins, Center for Science in the Public Interest, Integrity in Science Project, dated October 6, 2000.
9. There is a related instruction in the NRC guidance. ". . . it is possible that the public could perceive a potential conflict [of interest] . . . If there is a potential for such perceptions, it would be advisable for the RSO (after obtaining the member's consent) to indicate the consultant or organizational relationship explicitly in the member's biography that is posted in the project record in the CP system." 1998 Updated Checklist for RSOs for Compliance Section 15 of FACA, updated 8/10/98 (originally issued 12/17/97); authored by Bill Colglazier, pp. 7-8. We have requested the latest NRC guidance revisions, but none have been received to date, if there are any.