



Office of Advocacy

May 16, 2001

Board of Environmental Studies and Toxicology
National Research Council of the
National Academy of Sciences
2101 Constitution Avenue, N.W.
Washington, DC 20418

Re: Comments on the Provisional Appointments to the Subcommittee to Update the 1999 Arsenic in Drinking Water Report; Project No. BEST-K-01-01-A

Dear Board Members:

We welcome the opportunity to provide comments on the provisional members of the National Research Council's (NRC) Subcommittee to Update the 1999 Arsenic in Drinking Water Report. The Office of Advocacy of the U.S. Small Business Administration was established by Congress pursuant to Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. One of the primary functions of the office is to measure the costs and other effects of Government regulation on small businesses and make recommendations for eliminating excessive or unnecessary regulation of small businesses.

We wrote to EPA Administrator Whitman in March commending the agency's decision to review the arsenic standard that was finalized late in the last Administration. We support the EPA's plan to review both the scientific and cost issues. Hundreds of small water companies, found predominantly in rural America, are faced with dramatically high treatment costs, if their water exceeds the arsenic drinking water standard set by the Environmental Protection Agency (EPA). Therefore, we are pleased to provide comments on the composition of the NRC subcommittee that has been charged by EPA with addressing the science issues. Based on the available scientific and cost evidence last year, we concluded that the 10 ppb standard was not justified. We welcome a review of the latest science, and a review of the 2000 EPA Science Advisory Board (SAB) Report by the new subcommittee.

We hope that the NRC process will yield a sound and unbiased review of the complex science involving arsenic in drinking water. Considering the intense political scrutiny associated with the arsenic issue, it is even more critical that the NRC carefully establish a panel of scientists that everyone can agree reflects a diversity of expertise, and avoids actual and potential conflicts of interest. In that light, we are providing a list of scientists to supplement the NRC panel, so that a fully balanced panel can address the scientific issues. We are also suggesting several scientists who provide expertise in areas that are missing from the current provisional subcommittee. These scientists have an array of backgrounds, and were recommended to us by persons from industry, academia and government. We also find that the inclusion of some of the provisional scientists are not consistent with the 1992 NRC Policy on Disclosure of Personal Involvements and Other Matters Potentially Affecting Committee Service (hereafter, "NRC Policy") for eliminating bias and avoidance of conflict of interest.

In order to establish some general principles that would guide an appropriate selection of scientists, we rely on the guidance published in the December 2000 EPA Science Policy Council Peer Review Handbook, and the NRC policy, which are substantially similar in approach.

I. Members Who Served on the 1999 Subcommittee Have A Conflict of Interest and

Should Not Serve on the 2001 Subcommittee.

We believe that, based on the NRC Policy, those scientists who served on the 1999 subcommittee should not be participants in the review and update of the 1999 NRC Report. "It is important that peer reviewers be selected for independence and scientific/technical expertise.... The peer reviewers of a work product should represent a balanced range of technically legitimate points of view." EPA Handbook at 55-56. "Conflict of interest is a situation in which, because of other activities or relationships with other persons, an individual is unable or potentially unable to render impartial assistance or advice to the agency, or the person's objectivity in performing the work is or might be otherwise impaired, or a person has an unfair competitive advantage. Clearly, peer reviewers should not be placed in the position of reviewing their own research and analyses that form the basis of the work product under review as this might impair their objectivity." *Id.* at 58.

In addition, like the SAB guidance, the NRC finds that "an individual should not serve as a member of a subcommittee engaged in a study in which a critical review and evaluation of the individual's own work ... is expected to be a central purpose of the study, but such an individual may provide relevant information to the study." NRC Policy at 4.

Consistent with these principles, we are also looking for a diversity of opinions and expertise in this panel, whose members are not burdened by bias or conflict of interest issues. Both guidances specifically talk about excluding members who are reviewing their own work. The NRC guidance specifically suggests that such persons may more appropriately present "relevant information" to the subcommittee. Therefore, we recommend that NRC exclude those participants in the 1999 panel, since a large part of the task of this subcommittee is to review the earlier NRC subcommittee work. Furthermore, the panel would be better served by Dr. Ryan presenting her work to the new subcommittee, rather than serving on the subcommittee, particularly since her work was the primary underlying basis for the 1999 Arsenic Report.

Finally, 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,..." Exclusion of the previous NRC panel members would be consistent with this legal requirement.

II. Members Who Have Expressed A Position on the Arsenic Standard Should be Excluded or the Panel Should Be Rebalanced With Someone With the Contrary View.

A separate issue is presented by the issue of subcommittee member bias. The EPA guidance specifies that peer reviewers must be free "from institutional, ideological, or technical bias regarding the issues and the review...As 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." EPA Handbook at 58. Under the NRC guidance, "bias" is also identified by the expression of a particular point of view. However, unlike the EPA guidance, a finding of bias is deemed as "not necessarily disqualifying." NRC Policy at 3. Instead, the NRC may seek to present a "balance of potentially biasing backgrounds or professional or organizational perspectives." NRC Policy at 2. Thus, the EPA guidelines require exclusion, whereas the NRC guidelines permit bias where necessary, but insist instead on "balance" where the biased individuals are permitted.

The bias questionnaires require the disclosure of public positions by all provisional members, but we do not have access to these disclosures under the NRC procedures. Frankly, we think this is a significant defect in the public notice and comment procedure, because any potential subcommittee member should be willing to reveal his or her public statements, or professional affiliations, in order to inform these public comments. We are unable to comment fully on these provisional appointments without this information. In the case of one of the provisional members, we understand that Dr. Michael Kosnett has expressed an opinion that the 20 ppb standard was "not acceptable" in an article published by *Reuters Health* on October 13, 1999, and that he has expressed similar views on other

public occasions. We assume that this will be confirmed in the papers filed with the Council and suggest that either he be excluded, or that a more appropriate balance be established on the subcommittee.

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 about the balance of the present composition of the provisional subcommittee appointees.

We also ask that the information about the public views and professional affiliations be made public, such that, if any one of the provisional members has a potential bias or conflict of interest, an additional comment period should be allowed.

III. An Additional Comment Period Is Warranted After the New Information Is Provided.

As stated above, comments should be allowed after the identification of stated positions of the provisional subcommittee members. Furthermore, in order to fully inform the public notice and comment process, the NRC should publicly disclose contracts with NRC or the sponsoring agency, EPA, with respect to arsenic or any other environmental policy contracts, as these facts are revealed in the confidential questionnaires submitted by potential subcommittee members. Since the SAB regularly requires disclosure of these potential conflicts of interests, we are unclear as to why the NRC finds it necessary to keep this information private. The research support information is sought for the very reason of identifying potential sources of bias and conflict of interests, and it is in the public interest for commenters to have access to this information. We do not believe that Federal agencies can legally withhold information about which persons are funded by them, and therefore, logically, the provisional appointees should not object to this procedure.

IV. Future Public Notices Should Be More Widely Noted.

The 1997 FACA amendments require that the names and biographies of the provisional subcommittee members be subject to public notice and comment, without being specific about how this occurs. The only public notice about the provisional appointments and the comment period that we could find was a web page buried well inside the National Academy of Sciences website. Although we have actively participated in arsenic proceedings over the past several years, working with the NRC and the EPA, no one notified us about the pending appointments. There is no Federal Register notice, and no other notice to the public of which we are aware. As of yesterday, even the EPA arsenic website provided no information about the provisional names, nor the opportunity to comment, although there is a reference to the May 21 NRC meeting. Thus, while the NRC may have met the letter of the law in providing the single notice on the website, it certainly has not met the spirit of the law in soliciting public comment on the appointments, as required by the 1997 Amendments to the Federal Advisory Subcommittee Act.

In addition, as discussed above, in order to comment intelligently on the names submitted for nomination, we would be interested in learning more than a few sentences about the background of the named individuals. We need to know: (1) whether the panelists already stated views on the arsenic standard; (2) what contracts have the panelists or their institutions had with EPA or the NRC; and (3) the extent of their knowledge and expertise with respect to arsenic. Meaningful public comment has been compromised because the public is denied this information about these important issues. We suggest that NRC make this information known and have an additional twenty-day comment period, in addition to making changes in the potential membership of the subcommittee. Also, the NRC should expeditiously move to improve its procedures for all subcommittee appointments, and not just the arsenic subcommittee.

V. The Panel is Missing Expertise in Certain Critical Areas.

With respect to balance, the Panel is missing expertise in two key areas: arsenic mode of action mechanisms and epidemiology. Some of the experts listed below fulfill these missing subject areas. Furthermore, none of the eight provisional members were members of the 2000 SAB Drinking Water Committee Review group, whose eleven members are very familiar with the arsenic issues and provided some views independent of the original 1999 NRC subcommittee. The EPA also relied on the SAB's advice in formulating the final rule. If the NRC includes the 1999 NRC panel members, it should include some of the 2000 SAB Drinking Water Committee members, who could provide the appropriate balance of expertise and viewpoints.

VI. Suggestions for Additional Subcommittee Members.

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; email kevin.bromberg@sba.gov).

Sincerely,

Susan M. Walthall
Acting Chief Counsel for Advocacy

May 19, 2001
Attachment A

Preliminary List of Recommended Scientists for Arsenic Update Subcommittee By US Small Business Administration Office of Advocacy

Dr. Yvonne Dragan, Ohio State University, Assistant Professor of Environmental Health Studies (614) 292-5125. Dr. Dragan's research in recent years has been focused on toxicology, mechanisms of carcinogenesis, and mechanisms of individual susceptibility to cancer. She is a member of EPA's Scientific Advisory Board (SAB), Drinking Water Committee, 1998-2001. She also served on the Arsenic 2000 SAB review panel.

Dr. H. Vasken Aposhian, Professor of Molecular and Cellular Biology and Pharmacology, University of Arizona. Dr. Aposhian served on the prior 1999 NRC Arsenic Panel. Dr. Aposhian is a biochemist with expertise in the biochemistry of arsenic and has conducted research on the metabolism and excretion of arsenic *in vivo*.

Dr. Denise Lewis, US Department of Agriculture. Dr. Lewis is a researcher with experience conducting epidemiological studies on arsenic in drinking water. During Dr. Lewis' previous employment with EPA, she was the principal investigator involved in perhaps the best designed and executed epidemiological study of the effects of arsenic in drinking water on US populations (Utah study).

Steven H. Lamm, MD, DTPH, Consultants in Epidemiology and Occupational Health, Washington, D.C. Dr. Lamm is a physician-epidemiologist in the private practice of medical epidemiology. He is on the faculty at Johns Hopkins School of Hygiene and Public Health, and the Uniformed Services University for the Health Sciences School of Medicine and Georgetown University School of Medicine. He is currently head of a study in Inner Mongolia examining the long-term exposure to high levels of arsenic in drinking water, sponsored by CEOH, the Inner Mongolia Government and ASTDR.

Suresh Moolgavkar, Fred Hutchison Cancer Research Center in Seattle. Expertise in low-dose modeling. 206-667-4145.

Michael Waalkes, NIEHS at RTP, Editor in Chief of Toxicology and Applied Pharmacology. Expertise in low-dose mechanisms.

Dr. Samuel Cohen, University of Nebraska Medical Center. Dr. Cohen has had experience with

experimental work in bladder cancer. Dr. Cohen served on the NRC 1997 arsenic dose-response Panel and is familiar with arsenic issues.

Warner North, Decision Focus. Mr. North was a member of the SAB SDWA Subcommittee and worked on the December 2000 SAB Report.

Ken Brown, Kenneth Brown, Inc. Mr. Brown served on the NRC 1997 arsenic dose-response Panel and is familiar with arsenic issues. He was a member of the 1999 NRC Arsenic Subcommittee, and previously worked at EPA.

Barbara Beck, Gradient Corporation.

Dr. Richard Wilson, Harvard University, Professor of Physics (617) 495-3387. Mr. Wilson's research in recent years has been focused on risk assessment. He co-authored a paper on the "Carcinogenic Risks of Inorganic Arsenic in Perspective" in 1996, and is currently actively involved with arsenic issues. Among his many memberships and committee appointments, he was a member of the National Science Foundation, Physics Advisory Board, 1967-1970 and the National Academy of Sciences Energy Engineering Board, 1982-1991. In addition, he has been a member of the editorial board of "Risk Analysis" since 1980.

Ronald Wyzga, Sc.D., EPRI, Palo Alto, California (650) 855-2577. Member of the National Academy of Sciences, 1985-1992; Consultant to EPA Science Advisory Board, 1991-1996; Member of EPA Science Advisory Board, 1991-1996. Expertise in biostatistics;

Note: A few of these suggested panelists may have stated positions on arsenic (not researched by SBA), or have served on the earlier SAB or NRC panels (and are identified). These particular panelists are suggested only if the NRC decides finally not to exclude panelists based on (1) earlier participation, or (2) having announced views on the arsenic standard. At this time, as we interpret the NRC guidelines, the NRC panel contains both types of individuals, which are permitted only if a "balance" of viewpoints is maintained by the full subcommittee.

Furthermore, SBA has requested the opportunity to receive information about the provisional panelists to allow it and other commenters to be more fully informed about the potential bias and conflict of interest issues, and therefore may want to modify and or supplement these recommendations in the near future.