

Testimony of

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**Review of Arsenic and Drinking Water
September 2001 NRC Report**

**Before the Environment, Technology and Standards
Subcommittee**

House Science Committee

October 4, 2001

The Office of Advocacy of the U.S. Small Business Administration is pleased to have the opportunity to provide written testimony on the prepublication copy of the National Research Council's (NRC) report, *Arsenic in Drinking Water: 2001 Update* (hereinafter NRC II) released last month regarding the risks of arsenic in drinking water. 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. EPA tasked the National Research Council¹ to address the risks of arsenic in drinking water to aid EPA in its review of the arsenic final rule promulgated in January 2001 by the previous Administration.

The EPA final regulation at 10 parts per billion (ppb) will cost small water systems hundreds of millions of dollars to reduce arsenic risks that may be small or nonexistent. This will adversely affect tens of thousands of citizens, primarily in rural America, who can ill afford spending an additional several hundred dollars per year. Small water suppliers would likely shut down, forcing individual homeowners to drill their own wells, and be exposed to potentially higher levels of arsenic. Money allocated for treatment of arsenic is money that will not be available for other more pressing local needs such as police, fire, health and education. Therefore, the arsenic science review which would help EPA determine the magnitude of the arsenic health issue is critical to small water suppliers and small local governments.

We describe below our findings that the NRC did not follow its procedures under the Section 15 of the Federal Advisory Committee Act (FACA) Amendments of 1997, and the NRC II report does not fairly or comprehensively address the scientific issues that EPA asked the NRC to address. The NRC first refused to identify the FACA procedures that it was following, and then ultimately declined not to follow its own procedures that are designed to

ensure that a fair and balanced group of scientists were selected to write the report. As a result, to our knowledge, the panel consisted mostly or entirely of scientists who were predisposed toward increased control of arsenic in drinking water and against consideration of risk models not favored by current EPA policy. This was contrary to the 1992 NRC policy which dictates that panels should reflect the full diversity of viewpoints. The final report, although drafted with great care, is unfortunately clearly biased toward increasing the risk estimate.

As a result, the NRC II report very likely provides a substantial overestimate of the true risk of arsenic in drinking water. Unlike an environmental spokesperson who recently remarked that arsenic is “not complex . . . It is scary and dangerous,” playing to popular misconceptions about arsenic, the scientific issues are complex, and warrant the serious scrutiny that EPA has requested. The NRC II report, although elegantly and smoothly written, unfortunately provides a distorted picture of several aspects of this complex issue, and may do more to exaggerate than to illuminate the true risks fairly.

I. The NRC Did Not Follow Its Internal Procedures Under Section 15 of FACA To Ensure A Balanced Panel and the Resultant Report Reflects A Lack Of Balance

We provided comments on the scientific integrity issues associated with the NRC Subcommittee to Update the 1999 Arsenic in Drinking Water Report on several occasions to the NRC during May through July of this year. The Office asked that the NRC follow the scientific integrity procedures prescribed by the organization’s own procedures for implementing the 1997 Federal Advisory Committee Act (FACA) Amendments, including those which ensure public disclosure of the backgrounds of the members of the provisional arsenic subcommittee members. The FACA requires that the NRC take steps to ensure that a fair and balanced set of scientists are selected for preparation of advisory reports to the Federal government, and that there is public access to the data and information used by the scientists to facilitate public input into NRC. These specific procedures were established in August 1998 by the NRC to implement these statutory requirements. Unfortunately, the June

29th NRC response described only its compliance with the bare bones statutory FACA requirements, without reference to its more explicit internal procedures for compliance with the statute, despite our specific references to the NRC procedures in our June 19th letter.

We wondered why the NRC had failed to address the specific allegations in the June 19th letter until we later learned, to our surprise, that the procedures designed to effectuate public access to the NRC process that we cited in the letter were “not available to the public.” Dr. Alberts, President of the National Academy of Sciences, testified in 1998 that this law had a “positive effect by making our deliberations and processes more accessible and transparent to the interested public.” We find it quite odd that these procedures about transparency of the FACA process were no longer transparent. They first appeared, to our knowledge, in a December 1998 General Services Administration (GSA) Report to Congress, but somehow, in the interim, these procedures were quietly removed from the public domain and made known only to the NRC and staff. Indeed, the NRC public access reading room personnel did not have knowledge of any such procedures when we first inquired in May of this year. Ultimately, the NRC never notified us about the existence of any such specific procedures despite weeks of requests, until after we had received a copy elsewhere. We only learned of the existence of the actual procedures from communicating with GSA. We now know that, had the NRC attempted to describe its compliance with the internal procedures that it failed to acknowledge or provide, it would have been apparent that the NRC was not following its procedures.²

We are not the first organization to note that the NRC has not always been following its internal FACA procedures. Only last fall, Dr. William Colglazier, Executive Officer of the National Academy of Sciences, acknowledged an oversight regarding the provision of information to the public about panel biographies of the Committee on Environmental Impacts Associated with Commercialization of Transgenic Crops (EIACTC), in an October 2000 letter, after a complaint was filed by the Center for Science in the Public Interest.

In a July 12th letter to the NRC, the Office of Advocacy further questioned whether the composition of the panel reflected the diversity of viewpoints required by the NRC

procedures. In September, the NRC Arsenic Subcommittee released its pre-publication report (NRC II).

Although very elegantly written and footnoted, the NRC II report merely takes the very same Southwestern Taiwan dataset from the original NRC arsenic report in 1999 (hereinafter, NRC I), modifies some of the key assumptions used in NRC I, and revises the dose-response model, all of which had the effect of individually and collectively inflating the arsenic risk from the NRC I estimate. Simply stated, in large part, NRC II simply took many of the intermediate risk assumptions, and substituted assumptions that would increase the risks. Naturally, if one revises upward the risks calculated in the intermediate assumptions, the overall estimated risk, which is dependent on these intermediate building block assumptions, also increases. Consequently, the risks estimated by NRC II appear markedly higher, without consideration of any new data. Equally importantly, the NRC II report, although it is an “update” of NRC I, failed to tell the whole story. The report does not acknowledge the existence of several studies that are inconsistent with its new higher estimate, and omits or inadequately describes the implications of several recent studies that provide evidence of a threshold effect for various forms of cancer. In other words, NRC II failed to address properly studies that showed that elevated risks of skin, lung and bladder cancer only appear at drinking water concentrations in excess of approximately 100 ppb, which is contrary to the NRC II policy assumption that the risk increases linearly from zero concentration at the lower concentrations where US exposures commonly exist.

We were disappointed, but not surprised by the conclusions of this panel, given the NRC’s apparent disinterest in assembling a fair and balanced panel (also described further below). The NRC should carefully consider the constructive criticisms of its report offered here and by others, before it completes the final version of the report.

II. Background – Federal Advisory Committee Act Requirements at the NRC

The 1997 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.³ Here, however, the NRC chose at least four panelists of the eight that we could identify had public positions on arsenic. These same four were on the previous subcommittee that issued the NRC I report in 1999. Those four panelists (a total of five NRC I panelists served on NRC II) 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.”⁴ Thus, all five returning panelists appeared to be all on one side of the issue, favoring a significant decrease from the current standard.

A. Concern with Balance of Views of the 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.”⁵ We agree with EPA that the public positions taken by provisional panelists are important evidence of potential panel member bias (and normally would be treated as a factor for disqualification).

From a June search of the Westlaw database and other articles that we have reviewed, we have determined that Dr. Kosnett has endorsed a 5 ppb standard,⁶ 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,⁷ or Rogene Henderson, the three new panelists.

In addition, we noted 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 Southwestern Taiwan data risk extrapolations. In combination with the nomination of Dr. Kosnett, who has publicly supported the final 10 ppb standard now being questioned, we believe there is a serious question concerning the balance of the subcommittee members.

We were also surprised that NRC initially resisted providing any background information about the panelists (beyond the short biographies), indicating that the panelist questionnaires were “confidential” under internal NRC rules. This was before we learned of the 1998 guidelines and the correspondence about the EIACTC subcommittee where we then learned that the internal procedure was to reveal the background, public positions, etc. of all panelists for public comment. After the inquiry from the Center for Science in the Public Interest last year, the NRC posted new, more complete panelist biographies, and solicited new panelist names. However, when we made a similar plea to provide this information on the Web site, the NRC did not respond directly to our request, indicating only that the NRC was in compliance with all statutory requirements. To this day, we still don’t know why NRC did not comply with our straight-forward request. Is the public not supposed to know that Dr. Kosnett publicly favored a 5 ppb standard, and that his view is not balanced by any panelist who favors consideration of retaining the current 50 ppb standard, or who favored examination of a threshold model with some dataset, as some industry scientists suggested to the NRC? Does the NRC have a double standard here: one for public interest groups and one for industry?

B. Members Who Served on the 1999 Subcommittee Have A Conflict of Interest and Should Not Have Served on the 2001 Subcommittee.

We provided detailed comments on this issue on May 16th and July 12th to the NRC. We believe that, based on the 1992 NRC Policy on Disclosure of Personal Involvements and Other Matters Potentially Affecting Committee Service (hereinafter, "NRC Policy"), those

scientists who served on the 1999 subcommittee (for the NRC I report) should not be participants in the review and update of NRC I. The NRC Policy states 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.

The 1997 Federal Advisory Committee Act 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.

We explained in our July 12th note to Dr. Reisa, Director, NRC Board of Environmental Studies and Toxicology, how it was clear from the charge to the NRC that this subcommittee was reviewing the work of the earlier panel.⁸

Indeed, we know now that the entire focus of the "update" was a re-examination of the same Southwestern Taiwan data discussed in NRC I, but employing new assumptions. It clearly is a review of the earlier work, and should not have been undertaken by the same panelists who, under the explicit NRC policy, have an interest in defending the use of the earlier data. Not surprisingly, NRC II simply repeats the puzzling mantra that the new panel was not reviewing, but simply "updating" the earlier work, without explanation, and did not respond to the specific discussion in our July 12th note where we explain this point in detail. NRC II at 18. A more objective panel might have been favorably disposed toward a more thorough examination of the conflicting data providing evidence of sublinear risks from Utah, Inner Mongolia and Northeastern Taiwan, rather than simply reaffirming that the data from Southwestern Taiwan is the best available for performing the risk assessment.⁹ Another panel might not have overlooked the important studies by Guo and Tseng (2000) or Engel and Smith (1994), which also lend support to the establishment of a threshold level for

bladder and lung cancer well above arsenic concentrations commonly found in the US drinking water sources.

III. The NRC II Report Is Neither Comprehensive Nor A Fair Presentation of the Risks from Arsenic in Drinking Water and Probably Significantly Overestimates the True Risks.

We present here some examples found in the NRC II report where NRC de-emphasizes valid points made in NRC I which pointed to lower risks, mischaracterizes studies that show threshold effects, and omits other significant reports with contrary results. We rely on others to present a more detailed presentation of the risks from arsenic, outlining an alternative view that cancer incidence from low-level arsenic has not been demonstrated in the United States or any other part of the world, and that the growing body of evidence points to the establishment of a threshold in excess of 100 ppb for skin, lung and bladder cancer risks. This non-exhaustive list serves as a caution for EPA not to rely solely on the NRC II report, due to the incompleteness of the discussion, and the apparent bias by the authors. As a result, we respectfully suggest that NRC II probably significantly overestimates the true risks.

A. Sublinear vs. Linear Extrapolation

The EPA default policy is to employ a linear extrapolation from zero concentration where the cancer mechanism for a given chemical is not clearly established. However, other scientists point to studies showing that a sublinear (or lower than linear) dose-response model is more appropriate. This would lead to potentially much lower risk estimates. The NRC I report stated, “[o]f the several modes of action that are considered most plausible, a sublinear dose response curve in the low dose range is predicted, though linearity cannot be ruled out,” implying clearly that sublinear (e.g. lower risk) was the more likely scenario. NRC I at 3. That language pointing to lower risks apparently didn’t satisfy the authors of NRC II. NRC II at 175 states only that the “[t]he current mode of action data are insufficient

to guide the selection of a specific dose-response model." It appears that the new report attempts to downplay the likelihood of a threshold effect, although we could not find any discussion of new evidence that NRC is now relying on that makes the sublinear prediction in NRC I less likely today.

B. Uncertainty of Risk Estimates

In NRC I, the report stated, “[r]egardless of the data set that is ultimately used for the arsenic risk assessment, the subcommittee recommends that a range of feasible modeling approaches be explored. The final calculated risk should be supported by a range of analyses over a fairly broad range of assumptions. Performing a sensitivity analysis ensures that the conclusions do not rely heavily on any one particular assumption.” NRC I at 250. NRC I pointed out that simply making one change in the modeling – making different choices of which village wells to analyze, would change the risk “fairly substantially by several orders of magnitude.” NRC I at 247. In contrast, we could not locate any significant discussion about the model uncertainty relating to well exclusions in NRC II. In fact, it appears that in all the NRC II discussions, there is no discussion of any variability that exceeds more than one order of magnitude, nor is there any serious attempt to account for a “fairly broad range of assumptions,” including the possibility of a threshold or sublinear dose response relationship.

C. Inner Mongolia Study – Tucker et al (2001) Is Mischaracterized in NRC II

The very important peer-reviewed Tucker et al. (2001) study showed that the data was “best described” by a threshold at 100-150 ppb, in contrast to the default linear model, employing an examination of skin cancer data in Inner Mongolia, where arsenic levels were found between below detection (10 ppb) to 2000 ppb. However, NRC II instead described the data as being “adequately described” by a threshold model, but “also well described by a nonthreshold linear model.” NRC II at 51. We find that these descriptions should be reversed, because the text implies that the default model is the better fit, which is contrary to the study’s explicit findings.

D. Other Threshold Studies Are Missing from NRC II

The Guo and Tseng (2000) study doesn't show a significant increase in bladder cancer mortality and incidence until concentrations are reached over 640 ppb, using the same Southwestern Taiwan data as NRC II. We didn't see a reference to this study in the NRC report. This apparently was overlooked by the panel although it was charged with updating the NRC I (1999) Arsenic Subcommittee Report. This was an important omission that conflicts with the panel's linear default assumption.

Secondly, the Engel and Smith (1994) analysis showed a deficit of lung cancer for arsenic concentrations for 10+ ppb counties compared to 5-10 ppb counties in the United States. Although this was included as a reference in NRC I, neither NRC I nor NRC II included a discussion of the lung cancer results.

E. The Southwestern Taiwan Data Shows No Increase in Bladder Cancer Risk Between 0 and 400 PPB

Using table 5 of the Morales (2000) report, the best linear fit for the concentrations between 0 and 400 ppb shows no increase in bladder cancer mortality in SW Taiwan (which is the same data set used by NRC II and EPA) . We believe that this data is more consistent with a threshold effect, than with a linear extrapolation from zero concentration, but NRC II fails to comment on this observation.

F. NRC II Failed to Model Southwestern Taiwan Data or Other Data to A Threshold Model Although The Threshold Model Is Among the Most Plausible

Several scientists and studies have suggested that it is appropriate to examine the available data for sublinear as well as linear models. The NRC II report does not reflect the growing evidence for a threshold effect since the publication of NRC I in 1999, nor does it examine the Southwestern Taiwan data for a threshold effect, which certainly fits within the "fairly broad range of assumptions," considering the fact that the sublinear dose response

curve is predicted by “the several modes of action that are considered most plausible.” NRC I at 3. Since Guo and Tseng (2000) were able to fit the Southwestern Taiwan data using a threshold model, the NRC certainly should do so, at least as an alternative model.

IV. The Default Model Does Not Drive the Selection of the MCL

Finally, we believe that there is considerable confusion about the role of the default linear assumption in the determination by EPA of the MCL under SDWA. Much of the discussion surrounding EPA’s use of the default model in this rulemaking, in our view, is a red herring. The Safe Drinking Water Act (SDWA) requires consideration of costs and benefits, and by implication, consideration of the uncertainty that affects the calculation of the costs and benefits. Setting a risk estimate using a default model does not obviate or eliminate the uncertainty surrounding the estimate derived from the default model. The default policy choice, irrespective of its correctness, does not obviate the SDWA requirement to properly evaluate the costs and benefits, and therefore, ultimately it is the range of uncertainty, and not the default policy choice, that forms the basis for consideration by decisionmakers. In other words, EPA still cannot avoid examination of alternative models in the regulatory analyses required by SDWA, and therefore the default model alone does not drive the selection of the MCL. EPA’s default science policy choice does not permit the agency to ignore the uncertainty factor which is an integral part of SDWA determinations. The default model is only the starting point, not the end of the analysis.

V. Conclusion

We find that the NRC did not follow the procedures required under section 15 of FACA, did not allow informed public comment on the composition of the panel, and formed a panel that did not fairly and objectively complete the analyses requested by the EPA. We strongly suggest that the NRC revise its prepublication copy in response to these and other criticisms, so that EPA may be able to use the NRC work product with confidence. In the

alternative, EPA should be very cautious in using this report as a guide in the completion of its rulemaking activity.

Endnotes

¹ The National Research Council is the operating arm of the National Academy of Sciences, and is the entity responsible for the compilation of the arsenic update report.

² Although the NRC declined to provide the current version of the internal procedures, we understand informally that the procedures are basically identical to the August 1998 procedures. Details of the NRC noncompliance are found on the Advocacy Web site, www.sba.gov/advo, and later in this testimony.

³ 1992 NRC Policy on Disclosure of Personal Involvements and Other Matters Potentially Affecting Committee Service at 2

⁴ 1999 Arsenic NRC Report at 254.

⁵ 2000 EPA Science Policy Council Peer Review Handbook at 58.

⁶ "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.

⁷ We understand that Kimberly Thompson is on the Board of Directors of the American Council on Science and Health, and may have provided some balance to the views of the others. However, 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 and Dr. Morales (also from the Harvard School of Public Health) provided the methodology using the Taiwan data provided the basis for the EPA risk estimates being reviewed by the subcommittee. Dr. Morales again provided analyses to support NRC II.

⁸ The text of the July 12th note on this topic appears as follows: As you know, the May 16th letter from Susan Walthall, Acting Chief Counsel for Advocacy, expressed concern about the NRC's apparent violation of its 1992 bias policy by including five members of the 1999 panel in the new panel of eight members who will be reviewing their own work in the 1999 report. Dr. Goyer's remarks indicating that the panel will be "updating," but not reviewing the previous panel's work was puzzling. The five returning NRC subcommittee members must be reviewing their earlier work because the EPA charge includes a review of the basis of EPA's 2000 risk assessment, which in turn relies on the 1999 NRC report, as I explain below.

The April 2001 NRC charges include a review of whether the Southwestern Taiwanese studies "remain the best data for dose response and risk estimation." In addition, the charge includes the following requirement, "[d]etermine if EPA's risk estimates at 3, 5, 10, and 20 ug/L are consistent with available scientific information, including information from new studies." In other words, the NRC must review both the EPA risk estimation methodology and the Taiwanese data. That almost identical methodology and that use of the Southwestern Taiwanese data were the basis for the 1999 NRC "sample" risk "assessment" performed by Dr. Louise Ryan, who also serves on the current panel. Any evaluation of the EPA risk assessment necessarily requires a review of the 1999 report methodology and data.

Will the subcommittee avoid assessing the EPA methodology and the Taiwanese data? Frankly, Advocacy believes that the panel must do both assessments to meet its charge. If the subcommittee were simply reviewing new references, Advocacy would agree with Dr. Goyer's description. However, EPA asked the committee to review the agency assessment, which cannot be separated from the NRC work, because EPA did little more than slightly adjust the methodology (interestingly enough, despite the very clear and explicit NRC instructions not to do so alone).

⁹ In fact, NRC II language implies that some of the panel members may have been interested in performing additional work on the Northeastern Taiwan data. NRC II states at page 174: "The Northeastern Taiwanese study has several strengths, including exposure assessment and data on potential cofounders, which could inform the dose-response assessment. At present, however, the follow-up time is insufficient to provide the precision necessary for quantitative does-response assessment."