

Comments of

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Arsenic Workgroup
Science Advisory Board
US Environmental Protection Agency

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I thank you for the opportunity to present to you today, and I express my appreciation to your diligence concerning today's matter. My comments build upon those we have already submitted to the SAB and on the papers we have published.

I speak as a scientist, physician, and epidemiologist who has been professionally concerned with the human health effects from arsenic exposure for more than 30 years. I have examined arsenic exposed workers since 1977 and have published 17 papers on arsenic and human health. I have conducted analyses of data from Taiwan, Inner Mongolia, and the United States. I speak today on specific epidemiological aspects of the February 2010 Toxicological Review on Inorganic Arsenic.

The purpose of the document is to provide guidance to the public and private risk managers who have to develop or design technological responses to the determination of environmental arsenic exposures in the United States. These managers generally have to deal with what are historically considered to be low-level exposure, i.e., less than 100-200 ug/L and the equivalent in soil. The document should be informative for the task to which it is intended.

The quantitative assessment by EPA is based on the adult data from the 42 villages of the Wu et al. (1989) study with Southwest Taiwan as a reference village. I believe that these are the wrong data upon which to base the assessment. First, the assessment should be based on the totality of the literature, not on a single study. Second, the data for the quantitative analysis should be limited to the relevant data and both the reliability of those data and of the statistical methodology should be assessed.

With regard to the particular analysis before you, we have submitted documents that make a number of points:

1. In Appendix F, Table F-1, the risk estimates for the 42 villages are presented both with and without the reference population. In Appendix F, Table F-2, the risk estimates for the 18 low-dose villages are presented only with the reference population and not without. Those results should be shown.
2. The low-dose villages are not the low-exposure villages. The low-exposure analysis should be limited to the villages that do not have high arsenic level wells. Analyzing villages with known high exposures does not make them low exposure villages.
3. The reference population should not be used in a way that overwhelms the data from the low-exposure villages. In the F-2 analyses, the reference population accounts for 98% of the observation years.
4. It makes no sense to assume that the reference population has no arsenic in its drinking water. Neither the assay methodology nor the Taiwan geology will support that. Further, there is no quality assessment for the arsenic levels from the study villages. Where are the underlying data? When were they collected? What was their quality control? How many samples per well? Etc. etc.
5. EPA reports robust and significant positive associations for the low-dose villages. We report negative associations, which are in some cases significant. The two differences are that -

- a. While they state that their data analysis is limited to villages with low arsenic water concentrations, it is not limited to villages with only low arsenic water concentrations.
- b. EPA's analysis does not distinguish within study area differences that might be related to arsenic exposure from between area differences. The reference population is significantly different from the totality of the study village population.

Additionally, we have included each methodological concern that EPA has raised regarding our previous analyses. Our analyses were submitted to EPA last year, are being presented at scientific meetings this year (last month at SOT), and are in your records.

6. The US 133 county study has been ignored or rejected. It has multiple strengths and relevancies to the EPA task that the Taiwan study does not have. Multiple publications have compared the results of the US study, the Taiwan study, and the unit risk calculations. These should be included within the document and reviewed and contrasted with EPA's similar rendition. We do not hold that the ecological studies are the best basis for the risk assessment, but we do contend that the US study should be considered in similar manner as the Taiwan study. For both of them, EPA should seek more information. It should determine what additional information is necessary to answer what questions. Then, EPA should seek that data and have open discussions on it.

I look forward to reviewing the next version of the risk assessment.

Thank you,

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