

Subject: RE: EPA Draws Broad Criticism Over Limited Review Of Low-Dose Arsenic Risks

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Mike, You have sent me a copy of the Inside EPA article from February 26, 2010 on low-dose arsenic risk assessment and have asked for my comments. I have two comments, as noted below:

SHL Comment - 3/1/10

The SW Taiwan study is both mischaracterized and incorrectly analyzed.

1. The SW Taiwan study is not "the largest existing data set on arsenic exposure." Its exposed population (high-dose and low-dose) has 486,959 person-years of observation and a total of 441 cancer deaths (Bladder and lung cancer; male and female).

In contrasting size, the US 133-county study, which is limited to white male bladder cancer deaths, has 75,000,000 male person-years of observation and 4,537 male bladder deaths. These are all with low exposure (median 3-60 ug/L).

By comparison, the SW Taiwan study has only 253,000 male person-years of observation and 85 male bladder deaths. Among the low-dose (median 10-126 ug/L) villages, the SW Taiwan study has only 123,569 male person-years of observation and 23 male bladder deaths.

Thus, the arsenic exposed population in US study is 154 times larger than that of the SW Taiwan study [75million/487 thousand person-years).

Alternatively, the US study population is comprised of 2.5 million exposed people observed for 30 years, and the SW Taiwan population is comprised of 35,000 exposed people in the study area and an additional 2.0 million unexposed people in the reference area, both observed for 14 years. If the comparison is to be of low-dose exposed people, then the US study is of 2,500,000 people and the SW Taiwan study is of 17,000 people, or the US study is about 150 times larger than the SW Taiwan study.

2. The analytic model that the EPA uses has an underlying assumption that arsenic exposures are the sole explanatory variable (adjusted for age) for cancer risk in the BDF-endemic area. This is not known to be true, and the data indicate that it is not true.

The EPA (2010) toxicology review of inorganic arsenic thus has an incomplete analytic model. Their model (Equation 5-2; page 127) may be correct for the analysis of the 18 low-dose villages, but it is incomplete if the analytic set will include the SW Taiwan regional data. If the SW Taiwan regional data are to be included, then the model should include an "area" term in order to distinguish whether the differences in cancer distribution among the villages is due to being in the study ("BFD-endemic") area or due to the differences in arsenic exposure among the villages in the study area. The statistical analyses will indicate how the source of the variation distributes by the area and by the arsenic exposure.

Cordially, Steve (3/1/10)