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# Comments on Inorganic Arsenic

## Key Science Issue 2: Risk of Bias Approach

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# Science Issue 2: Risk of Bias (RoB) Approach

- EPA Table 1-8 on pg. 1-53 - too complex to easily read and understand.
  - Suggest modifying the tabular presentation of the RoB analyses to facilitate understanding of scoring for each study (++, +, -) and use of scores to group studies into overall quality tiers
  - See example table below adapted from tables in a review of the cardiovascular effects of ozone (Goodman *et al.*, in press)

Table 1. Study Quality for Controlled Human Exposure Study Ratings – Morbidity

Reference	Study Design	Selection of Subjects	Study Size		Outcome Assessment	Exposure Type & Maintenance	Statistical Analysis	Blinding
			N	Sample Size Calculation	QA/QC Protocol			
XX <i>et al.</i> (1986)	Cross-over, randomized (1)	Competitive athletes; no discussion of recruitment procedure (-1)	10	No (-1)	None reported (-1)	Mouthpiece; routinely measured from sampled air connected to Daibi O <sub>3</sub> meter (1)	One-way ANOVA with repeated measures. Post hoc comparisons done using repeated paired t-tests with Bonferroni correction (1)	None (-1)

## Science Issue 2: Risk of Bias Approach (cont.)

- Rating guidelines should provide more specific information for consistent evaluation
  - *e.g.*, detail what covariates and confounders should be considered in the relevant studies
- No RoB analysis performed on ecological studies, but every piece of evidence should be evaluated for RoB if informing weight of evidence
  - Criteria for scoring may need to be adjusted based on design limitations of ecological studies
- Should incorporate QA/QC into quality criteria; especially important for biomarker studies in which storage of samples, assays, and measurement standards can affect results
- Overall: RoB analyses can add much value to iAs assessment; however, improvements needed to increase clarity and transparency in the process.