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DFO INSERT:

Dear Mr. Miller: I am writing on behalf of the American Chemistry Council Biocides Panel Chromated Copper Arsenate Work Group (CCA Work Group) to submit the attached copy of Dr. Chaisson's comments from February 28, 2006 Arsenic Review Panel teleconference. Because there were some audio problems on the call, we think it is important for the Panel members to have a hard copy of her comments.

Thank you for distributing these comments to the Panel.

(See attached file: Arsenic SAB comments1 030206.pdf)

Has Shah

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Good afternoon.

I am Christine Chaisson, a toxicologist and risk assessment model developer. Throughout my career, including with EPA, I have worked with development and application of models and statistical approaches employed for hazard and exposure analyses. My remarks today are focused toward EPA's "**default**" to a linear model for delineating the low dose-effect relationship for arsenic.

I have 3 points for your consideration:

1. A **Default** approach:

- is not necessary – by scientific principl e nor OMB and EPA requirements,
- is not up to contemporary scientific standards – and,
- is not protective to public health.

Contemporary standards call for utilization of multiple models, which in this case would be consideration of threshold as well as non-threshold approaches, application of the empirical epidemiology data as well as the metrics and mechanistic suggestions from animal testing.

Capitulation to default methodology is not necessarily protective public health policy.

> If "default" tempts us to overlook risk where risk could exist, OR to infer risk where evidence suggests none exists, the resulting answer is "more wrong than right".

Such assessments force the hand of regulators without the assurance that all options were based on the most informed science. The public deserves the most informed/most likely **right** answer.

2. The "default" approach for hazard assessment is in contrast to the

approach taken for exposure assessment.

The two equally important factors defining risk are hazard and exposure. With Exposure Assessment, OMB, EPA and the scientific community agree that there is great value in application of all credible data to multiple models and then understanding the reasons for differences in resulting answers. This enables regulatory action while also promoting evolution of the models.

3. For arsenic's low dose hazard assessment, a fulsome scientific approach can be undertaken.

Acknowledging that this is a difficult task, much scientific homework remains to be done by EPA.

- Previous presentations provide a glimpse on how empirical data from epidemiology studies inform the choice about threshold models.
- Meta analysis may be useful.
- Genotoxicity evidence for linear low dose extrapolation has been seriousl y challenged.
- Mechanistic studies offer support for alternative interpretations and additional epidemiology studies have been identified which are relevant t o human exposure scenarios.

Even EPA's own guidelines for setting Points of Departure call for such scientific deliberation.

My message is to encourage the SAB to strongly recommend that EPA reconsider its default to a linear low dose hazard assessment in face of the imperfect but well articulated alternative options.

Thank you for your consideration.