Comments of Penelope A. Fenner-Crisp, PhD, DABT, for the June 5-6, 2019, Public Meeting of the EPA Chartered Science Advisory Board Regarding EPA's plans for updating its Guidelines for Cancer and Non-cancer Assessment

Good Morning. My name is Penelope Fenner-Crisp. I appreciate this opportunity to summarize my written comments on the risk assessment guidelines. For the Board members who are also on the phone, my slides can be found at the back of my written comments which are on the SAB website.

I have been a risk practitioner for more than 40 years, half of that time at EPA. Over the years, I have had a hand in the preparation of hundreds of hazard and risk assessments and many of the agency's guidance documents, including the 2005 cancer guidelines.

I have heard that the Administrator has asked that updated cancer and new non-cancer guidelines be issued before the end of next year. This timeline will not allow for robust and credible science policy to be developed and for full engagement of the SAB, the National Academies and other stakeholders in its review.

I have outlined specific activities, steps and timelines I believe are necessary to produce soundly-based and fully-vetted guidelines. While doing this, I came to several conclusions:

[Slide #2]

- **EPA must develop a realistic plan and request a formal review by the SAB before proceeding. This meeting does not qualify as that review.**

  The Charge document only became available shortly before the, giving the Board members little time to ponder the request and develop their thoughts on how best to engage in a fruitful discussion. Only sketchy background was provided. The Charge

presented a scattered array of questions to answer. It has a unreasonable deadline for response to EPA. There is no request for SAB peer review of outputs, as is required.

- **Plan for a four to six year process. This might be shortened somewhat by careful planning, but the idea of finishing by the end of 2020 is unrealistic.**

  To provide some context--- during the early 1980's, the agency attempted to write systemic toxicity or non-cancer guidelines. It failed. So, no formal non-cancer guidelines 35 years later. In 1989, EPA began the process of revising the 1986 cancer guidelines. Task completed in 2005, 16 years later.

  I would submit that EPA should NOT write separate guidelines for cancer and non-cancer. This idea of "separate" is driven primarily by the dichotomous approach the agency has taken historically in conducting dose response assessments. But there is a big push now to develop harmonized approaches. This will make it more appropriate to assess cancer and the other general endpoints in an integrated manner. Call them guidelines for the assessment of systemic toxicity, or general toxicity, or chronic toxicity---whatever. Treat the assessment of cancer as one of the many potential adverse outcomes that may occur in this setting. Think about it.

- **EPA must begin implementation of any Action Plan by addressing the unresolved issues from the 2009 NRC report *Science and Decisions: Advancing Risk Assessment* before writing any guidelines.**

  The agency has never articulated its responses to the recommendations in that report which addressed several intractable challenges that transcend any endpoint-specific guideline.

[Slide #3]

- **EPA must commit and sustain adequate agency resources and time, along with credible engagement of outside experts in both development and review roles.**

Writing guidelines is rightly an effort to be undertaken by career scientists from every corner of the agency, not political hires. Also critical to success is peer involvement of unconflicted external experts in the drafting phase, since the past two and a half years have seen the departure from EPA of many talented and seasoned scientists, leaving significant gaps in the expertise required to do this work.

- **It is critical to engage the National Academies in the review of issue papers, guidelines and the qualifications of the SAB peer review panel to confirm that the agency's outputs reflect an objective view of the state of the science.**

Peer review by the SAB should be conducted by a committee supplemented with representatives from the FIFRA Scientific Advisory Panel and the TSCA Science Advisory Committee on Chemicals, as well as additional outside experts to ensure both the necessary expertise and a balance of perspectives within the scientific community. This committee must be free of financial and other conflicts of interest.

[Slide #4]

This slide summarizes the steps I believe are necessary for the production of credible, science-based risk assessment guidelines. Every one of the steps can be derailed for one reason or another.

I will focus on two steps here. The first is #3 Discussions in public forums, by which I mean the engagement of the broader scientific community in a dialogue on the issues through workshops, presentations at professional society meetings, etc. These events serve to help shape the approaches for addressing the issues of concern, and are a convenient way of getting peer input.

The second is #5, Executive branch review. If tradition holds, the draft guideline(s) will go to the Office of Science and Technology Policy for interagency review, as other Federal agencies have an interest in what EPA does about science policy and its outputs have a direct impact on their own decision-making. The draft guideline(s) also will go to OMB's Office of Information and Regulatory Affairs for additional scrutiny to determine consistency with the Administration's point of view.

[Last Slide]

This slide presents my estimation of the time it will take before a credible guideline hits the street. There will be intense pressure to speed up the process of production and review. While there may be a number of efficiencies that could be integrated into the process, they must be executed with great caution. This effort requires participation of the key players early and often, from planning to completion.

I believe that if the issue papers and guideline are developed in coordination with one another and there are no significant hurdles, this exercise will take upwards of 4-5 years. But a more realistic estimate is 5-6 years, because unanticipated hurdles always arise. And, as the old saying goes "Haste makes waste."

Thank you for your attention.