SUMMARY OF TESTIMONY FOR THE PUBLIC MEETING OF THE SCIENCE ADVISORY BOARD (SAB)
COMMENTS BY PENNY FENNER-CRISP

June 5, 2019

EPA held a two-day public meeting of the Science Advisory Board (SAB) on June 5 and 6, 2019. The SAB heard remarks from EPA Administrator Andrew Wheeler and discussed EPA's proposed Science and Transparency Rule, planned actions on EPA's 2018 Spring Regulatory Agenda, actions related to updating EPA guidelines for carcinogen and non-cancer assessment, a self-initiated SAB project to evaluate the "scientific" aspects of EPA's co-benefit calculations, EPA's proposed PFAS Plan, and proposed Waters of the U.S. rule. The SAB also heard testimony by phone and in person on agenda topics.

Penny Fenner-Crsip, former Senior Science Advisor to the Director, EPA Office of Pesticide Programs, and risk practitioner for more than 40 years, presented testimony on updating EPA guidelines for carcinogen and non-cancer assessment -- a task Administrator Wheelers would like to complete before the end of next year. However, Penny explains that this does 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.

The following are specific activities, steps, timelines, and conclusions necessary to produce soundly based and fully vetted guidelines:

- EPA must develop a realistic plan and request a formal review by the SAB before proceeding.
- EPA must 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.
- 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.
- EPA must commit and sustain adequate agency resources and time, along with credible engagement of outside experts in both development and review roles.
- 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.
- Two necessary steps for the production of credible, science-based risk assessment guidelines include:
    - Discussions in public forums that engage the broader scientific community in a dialogue on the issues through workshops, presentations and at professional society meetings
    - Executive branch review by the Office of Science and Technology Policy for interagency review and OMB's Office of Information and Regulatory Affairs for additional scrutiny to determine consistency with the Administration's point of view.
- 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.
- If the issue papers and guidelines 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 due to unanticipated hurdles that will inevitably arise.

Ultimately, the guidelines must be driven by what is understood about the biology underlying the information to be assessed and judged in accordance with these risk assessment guidelines, not by the manipulation of data using statistical techniques chosen to justify a predetermined policy position.