SAB Member proposing the activity: **Dr. R. Thomas Zoeller**

Proposed Title/Subject: Near-term and intermediate strategies to advance the application of Computational Toxicology data into the development of EPA's health and environmental assessments and decision-making

Background: The SAB, as well as the NAS, has often encouraged the EPA to improve its risk assessment practices and to abandon its single chemical approach. With tens of thousands of chemicals currently in commerce, and hundreds more introduced every year, only a small fraction of chemicals have been adequately assessed for potential risk. The traditional chemical toxicity tests using animals are expensive and time consuming. As a result, EPA's Computational Toxicology Research Program (CompTox), which is under the purview of EPA's Chemical Safety and Sustainability (CSS), jointly with EPA's Human Health Risk Assessment research program is working with partners to change how chemicals are currently assessed for potential toxicity to humans and the environment. The CompTox Research Program conducts innovative research that integrates advances in molecular biology, chemistry and innovative computer science to more effectively and efficiently rank chemicals based on risks. The outcome from this research is rapid chemical screening data (ToxCast™) and other decision support tools that assess chemicals for potential risks to humans and the environment. The goal of the CompTox Research Program is to provide high-throughput decision support tools for assessing chemical exposure, hazard and risk.

Why should the SAB undertake this activity? :

- This activity relates to a high priority of the EPA Administrator and will have long-term impacts on the Agency's ability to perform its mandated functions.
- Technical advice is needed to understand the key linkages between the CompTox outputs and EPA assessment and decision-making.
- Social science expertise is needed to plan for effective communication of the use of CompTox program results in EPA assessments
- EPA's Office of the Chief Financial and OMB need to understand the practical value of the CompTox program.
- A proactive effort is needed to align the outputs of the CompTox program and EPA's practical assessment/management. External review and evaluation of the program will provide useful advice to help shape the program and the investments in it.
- The SAB's Exposure and Human Health Committee is well-poised to undertake this activity since it has received a complementary request from EPA's Office of the Science Advisor to evaluate EPA's planned response to the 2009 NRC report *Science and Decisions* and the SAB has previously reviewed the Framework for the CompTox program in 2003.

Tentative charge and expected outputs:

The SAB's Exposure and Human Health Committee would receive briefings from and engage in discussion with managers and senior scientists in the CompTox program, NCEA HHRA program, key potential clients of the CompTox program (e.g., IRIS managers, Risk Assessment Forum staff, the Office of Pesticide Programs and the Office of Pollution Prevention and Toxics, etc.), key federal partners, key non-governmental organizations (e.g., International Life Science

Institute), and representatives of international organizations on questions similar to those listed below. The EHHC will then develop a report outlining their findings and recommendations.

- How are the outputs of the CompTox program being used currently by EPA?
  - What are the challenges that EPA has had to overcome when using these outputs?
- How well do the outputs of the CompTox program match with EPA's environmental assessment and management goals and/or the needs of key partners?
  - Are there plans to align the outputs and needs more closely? What is the timetable and are those plans appropriate? How can EPA align the outputs of the CompTox program and EPA assessment/management needs more closely?
- Are there obstacles (conceptual, legal, policy, institutional, other) preventing EPA from using outputs from the computational toxicology program in EPA assessments and to support management decisions? How significant are these barriers? How might they be overcome? What would be a realistic timetable for overcoming them?
  - What are the requirements of data from HTP screening that would allow them to be informative to hazard characterization and/or risk assessment?
- How would the outputs of the computational toxicology program be effectively communicated to the public as part of a new EPA assessment approach? What research or other steps should be taken to build an effective approach for communicating this new science?

- Feasible for SAB members and staff
  - The EHHC would plan for a limited set of meetings /teleconferences to receive briefings and engage in discussions to answer the proposed questions.
  - The EHHC has the appropriate expertise and can be augmented with other SAB members.

Tentative Schedule:

Scope the project	Winter 2011
Hold public meetings and teleconferences to receive briefings	Spring 2012
EHHC develops draft advice	Summer-Fall 2012
Quality review and transmission of report	Winter 2012