UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

September 1, 2017

EPA-SAB-17-008

The Honorable E. Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Subject: Science Advisory Board comments on EPA's response to recommendations on the Integrated Risk Information System

Dear Administrator Pruitt:

The EPA Chartered Science Advisory Board (SAB) met on August 29-30, 2017 and, as part of the meeting's agenda, received an update on the restructuring of the Integrated Risk Information System (IRIS). The Board was particularly impressed and pleased with the rapid progress that the Agency has made in responding to recommendations from the National Research Council of the National Academies of Sciences (NAS) and the SAB, with particularly notable improvements in the program over the past year. The SAB members in attendance voted unanimously that I communicate to you their enthusiasm for the IRIS program's progress.

As you may know, the NAS criticized several aspects of the IRIS program in their 2011 review of the formaldehyde assessment, recommending significant changes designed to make IRIS assessments more systematic and transparent.[1] The NAS recommended that the program establish clearer guidelines for study selection, standardize the presentation of studies, use clear weight-of-evidence guidelines, better describe and justify assumptions to determine points of departure, explain modeling processes used to develop risk estimates, and better document the conclusions and estimation of toxicity values. In its 2014 report, the NAS commended EPA for significant progress toward implementing the recommendations of the 2011 report, although there remained additional room for improvement.[2]

[1] National Research Council. 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Washington, DC: The National Academies Press. https://doi.org/10.17226/13142.
[2] National Research Council. 2014. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press. https://doi.org/10.17226/18764.

The SAB has observed significant enhancements in the IRIS program over the past few years, with impactful changes over the past year, and marked progress over the past six months. The changes are so extensive and positive that they constitute a virtual reinvention of IRIS. For example, it is now standard practice for the program to engage stakeholders in an early scoping and problem formulation phase, thereby allowing stakeholders to provide important input at the very beginning of the process. The program has fully adopted the principles of systematic review, and incorporated automation and publicly available software platforms to modernize the process. Finally, the IRIS documents are now more modular and structured to enhance transparency and readability.

The SAB notes that no other federal entity performs the IRIS functions, and that IRIS helps ensure consistency in chemical assessments within the Agency and across the federal government. IRIS serves the needs of regions, states and tribes, who often lack the ability to perform their own chemical risk assessments. IRIS is also well-positioned to incorporate new evidence streams such as cell-based screening and computational methods into risk assessment, which will be a major advancement over the coming years. The Board commends the Agency for making such significant improvements over a short period of time. We are optimistic that the restructured IRIS program will strengthen the scientific foundations of risk assessment and protect the health and safety of the American public.

Sincerely,

/s/

Dr. Peter S. Thorne, Chair
Science Advisory Board

Enclosure
(1) Roster of SAB Members

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NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA Web site at http://www.epa.gov/sab.

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