

Science Advisory Board Process Backgrounder

When it was discovered that PFOA was widely present in blood in the U.S. population, the U.S. EPA began a process to determine the risk to the general population from this level of exposure. This effort has progressed in two main parts:

- A risk assessment designed to determine human risk from PFOA, and
- A voluntary process with industry to determine potential pathways of PFOA exposure to the general population.

The EPA intends to develop their regulatory approach for PFOA using the Risk Assessment once it is finalized.

The EPA's Office of Pollution Prevention and Toxics (OPPTs) issued an initial draft of the PFOA Risk Assessment in April 2003. A second Draft Risk Assessment was issued in January 2005 based on the available science as of July 2004. As they often do, the EPA chartered a public peer review of the second draft, as described below in language from the EPA's designated web site <http://www.epa.gov/opptintr/pfoa/pfoarisk.htm>:

"The EPA Office of Pollution Prevention and Toxics has submitted a *Draft Risk Assessment of the Potential Human Health Effects Associated With Exposure to Perfluorooctanoic Acid and Its Salts (PFOA)* (<http://www.epa.gov/opptintr/pfoa/pfoarisk.pdf>) to the EPA Science Advisory Board (SAB) for public peer review. In order to ensure the most rigorous science is used in the agency's ongoing evaluation of PFOA, EPA is seeking scientific peer review from an outside panel of scientific experts on the agency's draft PFOA risk assessment. It is important to note that this draft is preliminary and does not provide conclusions regarding potential levels of concern. It does highlight the scientific approaches that will be used in developing the agency's revised PFOA risk assessment. EPA is seeking review and comment from the agency's Science Advisory Board (SAB) to ensure that these approaches are scientifically sound."

This SAB Panel was formed in January of 2005, made up of 17 scientists from various fields and selected from a list of 31 candidates after seeking public comment as part of the selection process. The EPA directed the Panel's scientific review of the Draft with a charge letter that asked the Panel to respond to nine questions on four issues upon which the EPA desired comment (http://www.epa.gov/sab/pdf/pfoa_final_charge_questions.pdf). The Panel met via teleconference on January 25, 2005 for initial discussions with EPA and in full session on February 22 and 23, 2005 to develop their responses to the charge questions. The SAB process is designed to incorporate public input and the February meeting therefore included several presentations from interested parties including Industry. Additional written information was subsequently submitted for the Panel's consideration after the February meeting.

The SAB Panel issued their draft report (http://www.epa.gov/sab/pdf/rev_draft_pfoa_ex_sum-report_w-intro_062705.pdf) on June 27, 2005. This report will be reviewed and revised during a second teleconference scheduled for July 6, 2005. Additional input by interested parties is scheduled for this conference call, and may also follow later as new data becomes available.

Once completed, the Panel's final report will be reviewed by the SAB staff for quality assurance purposes before being submitted to EPA. EPA/OPPTs will then draft and issue a Final PFOA Risk Assessment after considering using the SAB Panel's input.

The latest discussion with SAB's report has centered on the descriptor of PFOA as a "likely" vs. a "suggestive" carcinogen. Taken from EPA's website,

<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=119032> here are the descriptors for these 2 categories:

Likely to be Carcinogenic to Humans: The Guidelines recommend this descriptor when the available tumor effects and other key data are adequate to demonstrate carcinogenic potential to humans, but does not reach the weight-of-evidence for the descriptor "carcinogenic to humans."

Suggestive Evidence of Carcinogenic Potential: The Guidelines recommend this descriptor when the evidence from human or animal data is suggestive of carcinogenicity, which raises a concern for carcinogenic effects but is judged not sufficient for a stronger conclusion.