

March 21, 2006



**Dr. Granger Morgan**  
Chair, EPA Science Advisory Board (1400 F)  
c/o Designated Federal Officer Tom Miller  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460-0001

Re: SAB Review of EPA's Draft Risk Assessment of Potential Human Health Effects  
Associated with PFOA and Its Salts

Dear Dr. Morgan:

This letter provides follow-up information relating to an important matter discussed at the February 15, 2006 Science Advisory Board teleconference, which reviewed the Draft SAB Panel Report on EPA's Draft Risk Assessment of Potential Human Health Effects Associated with PFOA and Its Salts.

I participated in the teleconference, which focused at some length on the report of a Pathology Working Group (PWG) peer review of mammary gland tissues from the Sibinski (Riker Pharmaceuticals) chronic feeding study in rats with ammonium perfluorooctanoate (PFOA) -- the only bioassay in female rats. The PWG peer review report is significant because of its finding that the "incidence of mammary gland neoplasms in the study was not affected by chronic dietary administration of PFOA," -- a result that differs markedly from the conclusions reached in the Draft SAB Panel Report (PWG Report, p.12).

The PWG report was submitted to the PFOA Review Panel in June 2005 during the Panel's deliberations. During the February 2006 teleconference, a question arose regarding the Panel's decision not to consider the PWG Report in its analysis. The Panel chair offered the explanation that the PWG peer review report had not been reviewed by EPA, but also noted that the PWG had not followed National Toxicology Program procedures.

We wish to emphasize that the PWG was conducted in accordance with the comprehensive peer review method specified in the Pesticide Registration (PR) Notice 94-5 (1994), with the exception that the pathologist from the original study done in the mid-1980s was not a participant. The EPA procedure is modeled on the procedures used by the National Toxicology Program. This process involved a chair, Dr. Hardisty, a peer review pathologist, Dr. Willson, and consulting pathologists, Drs. Brown and McConnell. All of the pathologists involved in this review are very experienced in rodent histopathology. It is worth noting that the PWG went beyond typical procedure for peer review in that all mammary tissues were examined by the peer-review pathologist, and all tumors were examined by the working group, instead of only differences in diagnosis between the laboratory pathologist and the reviewing pathologist, as required by PR Notice 94-5.

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We urge that the SAB in its report avoid any statement regarding the adequacy of the PWG procedures unless the Board reviews those procedures.

I have attached a copy of 3M's February 7, 2006 comments to the SAB.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John L. Butenhoff". The signature is written in a cursive, flowing style.

John L. Butenhoff, Ph.D., CIH, DABT

cc: Mr. Thomas Miller, DFO