AR 226 - 1129

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Oscar Hernandez

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Subject: SAB request

Vanessa, attached is a request for an SAB review of a preliminary risk assessment of Perfluorooctanoic acid (PFOA). We will work with SAB staff to assemble the formal submission. Thank you for your help.

Science Advisory Board
Proposed Project

1. Project Title / Subject: Preliminary Risk Assessment of Perfluorooctanoic Acid

2. Requesting Organization /Office: Office of Pollution Prevention and Toxics (OPPT)

3. Requesting Official: Oscar Hernandez, Director, Risk Assessment Division, OPPT

4. General Ranking: High within the Agency; High within OPPTS; High within OPPT

5. Applicable Goal, Objective, and Subobjective: Goal 4, 4.3.2,

6. Legal Obligation / Directive (if any): Toxic Substances Control Act (TSCA)

7. Endorsement by other offices: Not Solicited

8. Program Contact: Jennifer Seed, OPPT/RAD (7403M), 202-564-7634,
US EPA, 1200 Pennsylvania Ave., NW, Washington DC, 20460

9. Background: As part of the effort by the Office of Pollution Prevention and Toxics (OPPT) to understand health and environmental issues presented by fluorochemicals in the wake of unexpected toxicological and bioaccumulation discoveries with respect to perfluorooctane sulfonates (PFOS), OPPT has been investigating perfluorooctanoic acid and its salts (PFOA). OPPT released a preliminary *Draft Hazard Assessment of Perfluorooctanoic Acid and Its Salts*, dated February 20, 2002, on March 28, 2002, and issued a minor correction to that document on April 15, 2002. That draft assessment indicated potential systemic toxicity and carcinogenicity, and observed that blood monitoring data suggested widespread exposure to the general population, albeit at low levels. It also noted, however, that additional toxicity studies were underway on other endpoints and that further data would be available within a matter of months.

Numerous studies conducted by industry on PFOA and its salts have included toxicological studies in rodents and monkeys, biomonitoring studies of workers and the general US population, epidemiology studies, and biomonitoring studies of the wildlife in the US. These studies have shown that PFOA is also highly persistent in the environment and does not hydrolyze, photolyze or biodegrade under environmental conditions. PFOA is also highly persistent in humans, is not metabolized and has a half life of several years. The biomonitoring studies have shown that it is present in the general US population and the wildlife. At present, the sources and pathways of exposure are unknown. Toxicological studies in rodents and primates have shown that exposure to PFOA can result in a variety of effects including developmental/reproductive toxicity, liver toxicity and cancer.

Given that PFOA is present in the general US population and its toxicological profile, OPPT determined the need to conduct a risk assessment. This preliminary risk assessment places emphasis on the developmental/reproductive endpoints. The tumors (liver, pancreas and Leydig cell) observed in the cancer bioassays are thought to be directly or indirectly related to

the activation of PPARα. The relevance of this mode of action to humans is currently under scientific debate. The ILSI Risk Science Institute, under a cooperative agreement with EPA, has formed several workgroups to assess the state of the science which will be presented at a public workshop. The risk assessment of PFOA will be extended to include the systemic toxicity and cancer data once there is resolution of this issue.

10. Why the SAB Should Review this Project: This preliminary risk assessment utilized a margin of exposure (MOE) approach. Since there is no information available on the source or pathway(s) of human exposure, the preliminary risk assessment of PFOA utilized serum levels which were available for the general human population and were available for the rat toxicology studies. Since this preliminary risk assessment is of high priority with respect to Agency relevance, SAB review and comment is being sought. A scientifically sound assessment would play an important role in the analysis of options by the program offices.

11. Type of SAB Activity Requested: Peer review.

12. Tentative Charge: Review of the preliminary risk assessment with special emphasis on (a) the use of serum data as a measure of internal dose; (b) the use of serum levels from parental animals as a surrogate for levels in offspring; (c) the use of the data to provide a range of possible MOEs; (d) other assumptions that were made. A more detailed charge will be negotiated with SAB at a later date.

13. Tentative Schedule and Committee: Winter, 2003. Environmental Health Committee.

14. Principal Interested and Affected Parties: Fluoropolymer Manufacturers Group, Telomers Research Program, State of West Virginia, Region 3

15. Budget: The development of this preliminary risk assessment and the background hazard assessment was done by OPPT scientists during FY01 - FY02. An estimated 3 FTEs were required. No intramural or extramural funds were used.

16. Past Peer Reviews: None

17. Quality Management / Quality Assurance: This preliminary assessment has been through the following components of the Office's quality system: internal branch review, review through the management hierarchy, including Division and Office review.

18. Preparer: Jennifer Seed, OPPT/RAD, 202-564-7634

Date: September 23, 2002