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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 27 2002

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Revision of PFOA Hazard Assessment and Next Steps

FROM: Charles M. Auer, Director *Charles M. Auer*
Office of Pollution Prevention and Toxics

TO: Oscar Hernandez, Director
Risk Assessment Division

Mary Ellen Weber, Director
Economics, Exposure, and Technology Division

Ward Penberthy, Acting Director
Chemical Control Division

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OPPT HQ

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 perfluorooctyl 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.

The Agency has since received considerable additional data. The additional toxicology data submitted to the Agency suggest a potential for reproductive/developmental toxicity, and additional blood sample analysis data indicate low level exposures to the general population that are unexplained at this time.

Stephen Johnson, Assistant Administrator of the Office of Prevention, Pesticides, and Toxic Substances (OPPTS), met with representatives from the manufacturers and users of PFOA and related chemicals on August 13, 2002. He requested continued discussion with

manufacturers and users of PFOA and related chemicals to further investigate these issues, and raised the importance of and need for communicating with the public. Following that meeting, OPPTS met with toxicologists from industry on August 30, 2002, to discuss the recent study submissions and any additional anticipated work. OPPT also met by conference call with manufacturer representatives on September 12, 2002 to explore existing exposure information and identify gaps in those data that may help to explain the presence of PFOA in the blood of the general population. Summaries of these meetings are being placed in the public administrative record for this investigation, AR-226: PFOS, PFAS, PFOA, Telomers, and Related Chemicals.

An interim revised hazard assessment updating the original *Draft Hazard Assessment* to incorporate OPPT's reviews of these data has been prepared. As soon as this document completes internal review procedures, it should be placed in AR-226. Please proceed to finalize this interim revised hazard assessment within the next four to six weeks, at which time we will place the document in the public file.

The reproductive/developmental toxicity data, the carcinogenicity data, and the blood monitoring data reviewed in the interim revised hazard assessment raise the possibility that PFOA might meet the criteria for action under section 4(f) of the Toxic Substances Control Act.

The Agency established a process in 1991 for determining whether the TSCA §4(f) criteria are met, and published that process in a *Federal Register* notice concerning refractory ceramic fibers (RCF) (56 FR 58693; November 21, 1991). With this memo, I am requesting that you now initiate a priority review, as described in that notice, to determine the significance of the risks presented by PFOA and its salts. This priority review should begin while you proceed with the finalization of the interim revised hazard assessment. It is my understanding that you have also initiated a request with the Science Advisory Board (SAB) for a peer review of the preliminary risk assessment focused on developmental/reproductive toxicity that will be developed based on this priority review.

It is my expectation that the hazard assessment priority review will be completed in the next four to six weeks. Please be prepared to discuss these issues when we meet with the Assistant Administrator on next steps

cc: S. Johnson
S. Hazen
M. Schneider
Administrative Record AR-226: PFOS, PFAS, PFOA, Telomers, and Related Chemicals