

SCIENCE PUBLICATION STRATEGY

DEC 10 1998

Publication of scientific and technical information on the FC issue should follow a strategic plan so that key findings can be understood in the context of the published scientific literature. Under this strategy, the science needed to evaluate the safety of PFOS (i.e. the available occupational and toxicology studies) will be published -- or in press -- and thus available to be cited when the publication on serum levels in the general population is published. This will allow the serum level findings to be placed in an understandable, credible context which demonstrates that there is no medical or scientific basis to attribute any adverse health effects to 3M products. In this strategy, the analytical methodology will be published concurrently with the serum level findings.

The strategy is described as a series of steps with a timeline for each activity. The strategy begins with a brief summary of the scientific and technical studies published or publically available:

Key Studies and Reports Available

Ubel, F.A., and others, "Health status of plant workers exposed to fluorochemicals - a preliminary report," *American Industrial Hygiene Association Journal*, vol. 41, pages 584-589, 1980. (*Published study of 3M workers showing no ill health effects of occupational exposure to fluorochemicals.*)

Gilliland, F.D. and Mandel, J.S., "Mortality among employees in a PFOA production plant," *Journal of Occupational Medicine*, vol. 35, pages 950-954, 1993 (*Published study of 3M employees showing no increased mortality due to occupational exposure to PFOA.*).

Gilliland, F.D. and Mandel, J.S., "Serum perfluorooctanoic acid and hepatic enzymes, lipoproteins and cholesterol: a study of occupationally exposed men," *American Journal of Industrial Medicine*, vol. 29, pages 560-568, 1996 (*Published study of 115 3M employees showing no toxicity to the liver due to occupational exposure to PFOA.*).

Key B.D., and others, "Critical review: Fluorinated organics in the biosphere," *Environmental Science and Technology*, vol. 31, pages 2445-2454, 1997. (*PFOS is described as "important commercially as a surfactant and as a precursor of other fluorinated surfactants," as "resistant to biological attack," and as an inhibitor of "gap junction intercellular communication (GJIC) in rat liver epithelial cells cultured in vitro." The paper reports that "inhibition of GJIC has been implicated in tumor promotion during carcinogenesis, teratogenesis and reproductive dysfunction."*)

Reich, C., "Re: TSCA Section 8(e) — Perfluorooctane Sulfonate — Docket Numbers 8EHQ-1180-373; 8EHQ-1180-374; 8EHQ-0381-0394," 3M letter to Office of Toxic Substances, United States Environmental Protection Agency, May 15, 1998. (*This document, which will soon*

**Exhibit
1535**

State of Minnesota v. 3M Co.,
Court File No. 27-CV-10-28862

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become publicly available through the TSCA 8e Office, reports the presence of very low (part per billion) levels of PFOS in blood sera samples for individuals with no known occupational exposure to fluorochemicals.)

Olsen, G.W., "An epidemiologic investigation of reproductive hormones in men with occupational exposure to perfluorooctanoic acid," *Journal of Occupational and Environmental Medicine*, vol. 40, pages 614-622, 1998. (Study by 3M Medical Department showing no significant hormonal changes in 191 men occupational exposed to PFOA.).

Reich, C., "Re: TSCA 8(E) SUBSTANTIAL RISK NOTICE ON: N-Ethyl Perfluorooctyl sulfonamido ethanol and Perfluorooctane Sulfonate, Docket Numbers 8EHQ-1180-373; 8EHQ-1180-374; 8EHQ-0381-0394," 3M letter to Office of Toxic Substances, United States Environmental Protection Agency, September 14, 1998. (This document, which will become publicly available through the TSCA 8e Office, reported that PFOS, when administered to female rats at oral doses of 1.6 or 3.2 milligrams per kilogram body weight per day during pregnancy, significantly reduced pup survival. PFOS also reduced the average gain in body weight of the female rats during pregnancy, with the weight gain at the 3.2 milligrams per kilogram dose of only 87% of the control (no PFOS) rats.)

Strategy for Publication of Key Studies

1. The PFOS worker study, prepared by Dr. Jeff Mandel and others in the 3M Medical Department, is in final review before submission to an occupationally-focused medical journal. (This paper will report no adverse biological health effects from exposure to PFOS, based on medical monitoring of workers.) Comment: publication of this paper is key to demonstrating there is no medical or scientific basis to attribute any adverse health effects to exposure to PFOS.
Recommendations:
 - 1) The journal should be selected on the basis of interest in the paper and ability to ensure peer review as quickly as possible.
 - 2) Target submission of the paper by December 15, 1998; acceptance for publication within three months of submission.
 - 3) With this plan, this key study could be cited as early as March 15, 1999.
2. PFOS mitochondria study, by Dr. Ken Wallace of the University of Minnesota School of Medicine in Duluth, is being prepared for submission to a peer-reviewed science journal. (Paper will demonstrate PFOS's mechanism of action on energy metabolism in a test tube (in vitro) system.) Comment: this paper will be useful for demonstrating a possible mechanism of toxicity of PFOS. However, without the toxicology studies discussed below, the findings are of limited utility for a safety assessment.

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Recommendations:

- 1) The journal should be selected on the basis of interest in the paper and ability to ensure peer review in a timely manner.
- 2) Target: submission of the paper by March 1999; acceptance for publication within six months of submission.
- 3) With this plan, this study could be cited by September 1999.

3. The PFOS teratology study, conducted by the 3M Toxicology Department, has been completed. A manuscript of the results, possibly including blood level measurements, could be prepared for publication or presentation at a science conference. *(Paper will demonstrate that exposure to high doses of PFOS to pregnant animals does not cause birth defects in the offspring. The blood level measurements will allow correlations between doses administered in this study and blood levels in animals and humans.)*
 Comment: since the study reports largely negative findings (no birth defects), it may be difficult to publish even with the blood level measurements. Consideration should be given to combining this study with the results of the 3M and published subchronic toxicity studies discussed below.

Recommendations:

- 1) Dr. Chris Wilkinson, a well respected toxicologist with Jellinek, Schwartz & Connolly, Inc., in Washington, D.C., who has been briefed on the FC issue, should be hired to review the study and provide a recommendation on publication of a paper on the teratology study and blood level measurements.
 - 2) Assuming that Dr. Wilkinson and the 3M Toxicology Department agree to submit a paper on the teratology study, Dr. Wilkinson should draft the paper, make final revisions based on 3M review and comments, and submit the paper for publication in a peer reviewed toxicology journal.
 - 3) Target: one month for the recommendation and decision on publication. If the decision is made to proceed with publication, target is three months for completion of the draft paper, one month for 3M review and comment, one month for final revision and submission to a peer-reviewed toxicology journal and three months for acceptance.
 - 4) With this plan, the teratology study could be cited as early as August 1999.
4. PFOS subchronic toxicology studies, conducted by 3M or reported in the scientific literature, could be summarized and a manuscript prepared for publication. *(The paper would review what is known about the toxicity of PFOS from animal studies, prior to conduct of the current studies by 3M.)*

Recommendations:

- 1) This paper should review, or at least cite, other published toxicity studies on PFOS in addition to the subchronic studies, i.e. all of the published toxicity studies discussed under "Summary of Toxicology Studies" in the "Current Summary" document.

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- 2) Dr. Wilkinson should be hired to review the studies and draft a paper for publication.
 - 3) Target: six months for completion of the draft paper, one month for 3M review and comment, one month for final revision and submission to a peer-reviewed toxicology journal and three months for acceptance.
5. The analytical methods developed to allow specific detection of PFOS in serum levels with a low part per billion detection limit should be written up for publication in a peer reviewed analytical chemistry journal. *(This paper would need to contain data on PFOS levels in serum to document the utility and accuracy of the analytical method.)*
- Recommendations:**
- 1) Dr. Wilkinson should be asked to recommend an analytical chemist to prepare a paper for publication on the analytical methods.
 - 2) Assuming that Dr. Wilkinson's recommendation is acceptable to the Analytical Department, the analytical chemist consultant should draft the paper with Dr. Wilkinson's assistance, make final revisions based on 3M review and comments, and submit the paper for publication in a peer reviewed analytical chemistry journal.
 - 3) Target: one month for the recommendation and decision on the consultant. Once a decision is made on the consultant, the target is three months for completion of the draft paper, one month for 3M review and comment, one month for final revision and submission to a peer-reviewed toxicology journal and three to six months for acceptance.
 - 4) With this plan, the analytical study could be cited as early as August 1999.
6. Additional serum level data is needed to document blood levels of PFOS for publication of a peer reviewed science publication. *(This paper would document what is known about PFOS levels in serum and assess the safety of current exposure levels based on the worker study [paper #1 above], and the toxicology studies [papers 2-4 above] that have been completed. The paper would need to reference the analytical methods cited in paper #5).*
- Recommendations:**
- 1) A decisions should be made by the 3M Medical Department with the advise of the Legal Department and the Core Team as to what additional data is needed and a plan developed to generate the needed data.
 - 2) The 3M Medical Department should supervise the collection of serum samples with analysis of PFOS levels by the Analytical Department or a contract laboratory approved by them.
 - 3) Dr. Wilkinson should be hired to review the serum data and draft a paper for publication.
 - 4) Target: finalize plans by January 1, 1999, three months to collect samples and analyze the data, three months for completion of the draft paper, one month for 3M review and comment, one month for final revision and submission to a peer-

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reviewed toxicology journal and three months for acceptance.

5) With this plan, the serum study could be cited as early as November 1999.