

June 29, 2005



Sue Shallal, Ph.D.
Designated Federal Officer
U.S. EPA Science Advisory Board
Via e-mail: shallal.suhair@epa.gov

Re: PFOA Review Panel - Draft Report

Dear Dr. Shallal:

I am writing in response to the PFOA Review Panel's June 27, 2005 release of its draft report regarding EPA's draft risk assessment for PFOA. Since written comments are due today and time does not permit a comprehensive discussion, I would like to highlight two issues: discussion of the human data, and the cancer descriptor.

Human Data

3M's multiple mortality studies and nearly 30 years of medical surveillance data on PFOA manufacturing workers provide evidence of the lack of adverse effects in humans. We are surprised to see the Panel's reference, in response to charge question 5, to "positive results" and "certain adverse health effects (cancer, heart disease, blood chemistries)." This statement is made with no references, no specificity, and no context. We believe it is contrary to the weight of evidence.

Table 1 below provides data from the most recent retrospective cohort mortality studies conducted at the 3M Cottage Grove and Decatur facilities (Alexander 2001a; 2001b).¹ The Alexander 2001a studied workers at 3M's Cottage Grove plant where PFOA was manufactured for over forty years. We are not aware of mortality data on other PFOA-exposed cohorts.

- Neither study's data suggest an indication of an adverse health effect for all malignant neoplasms (i.e., cancer), as implied in the Panel's draft report, which refers generically to cancer and not any particular type of cancer.
- The data in Table 1 for liver, pancreas and prostate cancers at each facility show few deaths for these outcomes, and none of the SMRs for these specific cancers is statistically significant.²

¹ The highest serum levels of PFOA reported in the literature have occurred among employees at 3M's Cottage Grove, Minnesota facility. PFOA has also been measured at lower levels in workers at 3M's Decatur, Alabama facility.

² An excess of bladder cancer mortality was reported in the Decatur study, but was not confirmed by a subsequent incidence study (Alexander 2004).

Further, the data do not support a finding that heart disease is a potential adverse health effect of PFOA, also illustrated in Table 1. The "Low" exposure group in this study would be expected to have sera concentrations at least an order of magnitude higher than the 90th percentile concentration used in the EPA draft risk assessment.

In summary, the conclusory statements in the draft report are not supported by the epidemiological data. We urge the Panel to revise the statement or document its validity. More detail is provided in our comments of April 18, 2005.

Descriptor of Carcinogenic Potential

We know the Panel has struggled with fitting the PFOA dataset into the EPA definitions for the descriptors. As noted above, the human data do not support a conclusion of human cancer risk. The mammary tumors have also now been addressed by a Pathology Working Group report finding that "the incidence of mammary gland neoplasms in the study was not affected by chronic dietary administration of PFOA." (See letter dated June 27, 2005 submitting PWG report). We urge the panel to again consider the proper descriptor in light of the conclusion of the Pathology Working Group. The author of this report will be available for questions during the July 6 teleconference.

Finally, the initial working draft circulated at the Panel's February meeting clearly articulated that the Panel does not agree with the notion that cancer in humans is more likely than not. We urge the Panel to include this statement in the report. The statements on pages 3 and 17 in the current draft report do not adequately convey that concept.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "L. Zobel" with a stylized flourish at the end.

Larry Zobel, M.D., M.P.H.
Staff Vice President and Medical Director

Table 1. Observed, Expected, Standardized Mortality Ratio and 95% Confidence Intervals for the Cottage Grove and Decatur Retrospective Cohort Mortality Studies

Cottage Grove (Alexander 2001a)					High (min 1 yr)**					Low or High (min 1 yr)***				
Obs	Exp	SMR	95% CI		Obs	Exp	SMR	95% CI		Obs	Exp	SMR	95% CI	
All malignant neoplasms														
11	13.79	0.80	0.40 – 1.43		4	6.33	0.63	0.17-1.62		68	77.33	0.88	0.68-1.11	
Liver														
0	0.30	0.00	0.00-12.12		0	0.14	0.00	0.00-26.38		1	1.70	0.59	0.01-3.27	
Pancreas														
1	0.75	1.34	0.03-7.42		0	0.35	0.00	0.00-10.67		6	4.17	1.44	0.53-3.13	
Prostate														
1	0.77	1.30	0.03-7.20		1	0.38	2.63	0.07-14.62		6	5.19	1.16	0.42-2.52	
All heart disease														
17	15.69	1.08	0.63-1.73		7	7.28	0.96	0.39-1.98		68	90.90	0.75	0.58-0.95	
Cerebrovascular disease														
5	1.94	2.58	0.84-6.03		3	0.89	3.36	0.69-9.82		11	13.03	0.84	0.42-1.51	
Decatur (Alexander 2001b)														
All malignant neoplasms														
18	21.54	0.84	0.50-1.32		14	16.67	0.84	0.46-1.41		19	28.45	0.67	0.40-1.04	
Liver														
1	0.50	2.00	0.05-11.10		1	0.39	2.57	0.06-14.26		2	0.65	3.08	0.37-11.10	
Pancreas														
0	0.86	0.00	0.00-4.30		0	0.67	0.00	0.00-5.52		0	0.15	0.00	0.00-3.21	
Prostate														
0	0.49	0.00	0.00-7.53		0	0.40	0.00	0.00-9.26		0	0.88	0.00	0.00-4.21	
All heart disease														
14	24.78	0.56	0.31-0.95		12	19.52	0.61	0.32-1.07		19	32.73	0.58	0.35-0.91	
Cerebrovascular Disease														
2	2.76	0.72	0.09-2.62		2	2.14	0.93	0.11-3.37		4	3.79	1.05	0.29-2.70	

* "High" defined in the Cottage Grove mortality study was "definite (high) PFOA exposure." "High" defined in the Decatur mortality study was "high potential workplace exposure to perfluorooctanesulfonyl fluoride-based fluorochromicals (includes cell operators, chemical operators, maintenance workers, mill operators, waste operators and crew supervisors." These individuals would also have had the highest PFOA levels (Olsen 2003).

** "High (min 1 yr)" defined as above for workers employed for at least one year in a "High" exposure job.

*** "Low" defined in the Cottage Grove mortality study as probable exposure to PFOA. "Low" defined in the Decatur mortality study was "low potential workplace exposure to POSF-based fluorochromicals (includes such jobs as engineers, quality control technicians, environmental, health and safety workers, administrative assistants and managers)." These individuals would also have had lower PFOA levels than those categorized as high potential workplace exposure (Olsen 2003).