TAFT, STETTINIUS & HOLLISTER LLP

NORTHERN KENTUCKY OFFICE
SUITE 340
1717 DIXIE HIGHWAY
COVINGTON, KENTUCKY 41011-4704
606-331-2838
513-381-2838
FAX 513-381-6613

1800 FIRSTAR TOWER
425 WALNUT STREET
CINCINNATI, OHIO 45202-3957
513-381-2838
FAX: 513-381-0205
www.taftlaw.com

CLEVELAND OHIO OFFICE
3500 BP TOWER
200 PUBLIC SQUARE
CLEVELAND, OHIO 44114-2302
216-241-2838
FAX 216-241-3707

COLUMBUS, OHIO OFFICE
21 EAST STATE STREET
COLUMBUS, OHIO 43215-4221
614-221-2838
FAX 614-221-2007

AR 226 - 1173

ROBERT A. BILOTT
(513) 357-9638
bilott@taftlaw.com

March 8, 2002

TELECOPY AND
REGULAR U.S. MAIL

Donald S. Welch
Regional Administrator
U.S. Environmental Protection Agency
Region III
1650 Arch Street
Philadelphia, PA 19103-2029

Thomas V. Skinner
Regional Administrator
U.S. Environmental Protection Agency
Region V
77 West Jackson Blvd.
Chicago, IL 60604

Janet E. Sharke, Esq. (3RC30)
U.S. Environmental Protection Agency
Region III
Office Of Enforcement, Compliance and
Environment Justice (Mail Code 3EC00)
1650 Arch Street
Philadelphia, PA 19103-2029

Kelley Moore (W6-15J)
U.S. Environmental Protection Agency
Region V
77 West Jackson Blvd.
Chicago, IL 60604

Re: Public Health Concern Involving C-8 Drinking Water Contamination In West Virginia And Ohio

Ladies and Gentlemen:

As indicated in our November 1, 2001, letter to the United States EPA, ATSDR, and the West Virginia Department of Environmental Protection, our law firm is currently working with two other law firms in West Virginia in the representation of numerous individuals who have brought a class action lawsuit against E.I. duPont de Nemours and Company ("DuPont") and the Lubeck Public Service District of Wood County, West Virginia ("LPSD") in connection with the contamination of human drinking water supplies with ammonium perfluorooctanoate (a/k/a APFO/FC-143/PFOA) ("C-8") originating from DuPont's Washington Works in Wood County, West Virginia. A copy of our clients' Amended Complaint in that matter previously was forwarded to your agencies. As indicated in that Amended Complaint, our clients are concerned that there is a current, imminent, and substantial threat to their health based upon the past and current presence of excessive levels of C-8 in local drinking water supplies. We have asked the

Circuit Court in West Virginia to order, among other things, appropriate medical monitoring for those who have been exposed to C-8 in their water.

It has come to our attention that your agency is in the process of finalizing a Consent Order with DuPont to provide for alternate water supplies to those whose drinking water has been contaminated with C-8 originating from DuPont. It also has come to our attention that your agency has not been able to obtain DuPont's agreement to immediately provide any alternative water unless the levels of C-8 exceed a 14 ppb level advocated in a January 24,2002, report prepared by DuPont's consultant, Environ.

As indicated in the attached document prepared by Tetra Tech, which has thoroughly reviewed the same information referenced and relied upon in DuPont's Environ report, our clients believe that the 14 ppb number selected by Environ is in error and substantially underestimates the potential health threat to those drinking C-8 contaminated water. The current data actually confirms that C-8 levels in excess of 0.3 ppb in human drinking water may present an imminent and substantial endangerment to human health and the environment. Thus, on behalf of our clients, we request that your agency consider the issues raised in the attached document from Tetra Tech before agreeing to any Order with DuPont that does not require DuPont to immediately provide alternate drinking water to those exposed to C-8 levels in excess of 0.3 ppb.

Please let us know if you have any questions about any of the issues raised in the attached document. Thank you.

Very truly yours,

Robert A. Bilott

RAB/mdm
Attachment
cc: Armando Benincasa, Esq. (WVDEP)
Greg Smith, Esq. (OhioEPA)

DISCUSSION POINTS RELATING TO THE ASSESSMENT OF HEALTH RISK FROM EXPOSURE TO AMMONIUM PERFLUOROOCTANOATE (PFOA)

The following issues are critical to the development of a public health protective assessment of human health risk for populations exposed to ingested PFOA. The discussion is particularly relevant to an evaluation of a recent assessment of risk to human populations exposed to PFOA (A Hazard Narrative for Perfluorooctanoate (PFOA). prepared by Environ International Corporation for DuPont, January 24,2002).

I. Relevance of the PFOA study in cynomolgus monkeys to human health risk assessment

The following issues relate to the interpretation of a six-month study in cynomolgus monkeys dosed with PFOA (Covance 6329-231, December 18, 2001). This study formed the basis for the calculation of a drinking water criterion proposed in DuPont's Environ report.

A. Severity of the endpoint

Severe toxicity was reported in the cynomolgus monkey study. The use of severe toxicity as an endpoint from which to calculate safety levels is not consistent with EPA practices and is not adequately protective of public health. A critical endpoint that could be used quantitatively in development of an RfD was not identified in the cynomolgus monkey study.

B. Mode or mechanism of action

The mode or mechanism of action for the severe toxicity exhibited by the nonhuman primates monkeys has not been reported. The lack of such information leaves open the possibility that as yet undiscovered effects specific to primates may be occurring at dose levels much below those used in this cynomolgus monkey study, adding great uncertainty to any assessment of human health risk.

C. Humans may be an especially sensitive species

Rats tolerate PFOA toxicity better than monkeys and monkeys may eliminate PFOA more efficiently than humans. Since elimination of PFOA is a major factor in determining species differences in toxic response, humans, which most likely possess the same critical endpoint as nonhuman primates may be the more sensitive to PFOA toxicity than any of the experimental animal models.

D. The absorbed PFOA dose in the monkey study may be in question

There is evidence that PFOA is not well absorbed in the rat gut. There may also have been poor absorption in the gut with possible emesis in the monkey study. The possibility of these effects is a further uncertainty in extrapolating to humans.

II. Drinking Water Criterion Calculation

The issues described above regarding the PFOA study in cynomolgus monkeys indicate that the study should not be used as the primary basis in deriving a level of PFOA in drinking water that is safe for human consumption. The monkey study should, however, be considered **a** supplemental study indicating a need for a very conservative approach to the development of a safe exposure level for humans. If a chronic rat study is used to derive a safe level of exposure in drinking water using EPA procedures, a drinking water criterion of no higher than **0.3** parts per billion (ppb) is obtained using a benchmark dose response, an uncertainty factor **of** 30,000, and a relative source contribution factor of **0.2.**

III. Assessment of Cancer Risk

In addition to tumors of the liver, rodents dosed with PFOA exhibit testicular and pancreatic tumors. While it is not clear whether PFOA induced tumors of the liver occur in exposed human populations due to biochemical differences between rodents and humans, the mechanism of action of tumors at the two other sites are different than for the rodent liver and their relevance to human health **risk** assessment is **unknown.** In accordance with the recommendations of an expert panel convened to consider testicular tumors, testicular tumors should be considered legitimate endpoints for a cancer **risk** assessment in the absence **of** evidence to the contrary. For similar reasons, pancreatic tumors attributable to PFOA exposure to rodents should also be considered a legitimate endpoint for cancer risk assessment.