AR226-1441

TAFT, STETTINIUS & HOLLISTER LLP

252 pp

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

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

NORTHERN KENTUCKY OFFICE
SUITE 340
1717 DIXIE HIGHWAY
COVINGTON, KENTUCKY 41011-4704
859-331-2838
513-381-2838
FAX: 513-381-6613

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

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

MR-268605

8EHQ-0803-00373

July 31, 2003

8EHQ-80-373

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Richard H. Hefter, Chief
High Production Volume Chemicals Branch
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

Document Processing Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

Re: TSCA Section 8(e) Reporting For PFOA

Dear Mr. Hefter:

This letter serves as a supplement to our letter of July 3, 2003, in connection with the referenced matter providing additional information relating to the extent of E.I. duPont de Nemours and Company's ("DuPont's") knowledge of health effects related to exposure to ammonium perfluorooctanoate (a/k/a APFO/PFOA/FC-143/C-8) (hereinafter "C-8") at the time that DuPont obtained the pregnancy outcome and drinking water contamination information referenced in our July 3, 2003 letter. Because of the potential likelihood of substantial harm to our Class members or the public interest from a lack of complete information on this topic, we submit the following additional supplemental information obtained from DuPont for consideration in connection with your Agency's evaluations of the statements made by DuPont's counsel on this matter in its June 20, 2003, letter responding to your May 22, 2003, letter on this topic:

1. November 9, 1961 - DuPont's Toxicology Section Chief, Dorothy B. Hood, upon review of available information relating to toxicity of Teflon® dispersing agents, concluded that C-8 has "the ability to increase the size of the liver of rats at low doses," and "recommended that . . . these materials . . . be handled with extreme care. Contact with the skin should be strictly avoided." (Exhibit A (HLAB000232-233))

2. February 14, 1962 - DuPont studies on C-8 in rats "proved lethal in high dose concentrations through injury to the stomach, intestine, brain, lung and pancreas. At lower dose concentrations the chemical induced enlargement of the liver, pancreas and kidney, the least dose which included a change in liver being 1.5 mg/kg." (Exhibit A (HLAB000240))

3. August 19, 1965 - DuPont's medical research projects on the effects of C-8 and related chemicals on the livers of rats and dogs confirmed that "the most striking abnormality in animals surviving a single sub-lethal dose was gross enlargement of the liver." (Exhibit B (HLAB000003-20))

4. August 31, 1966 - DuPont determined that "[s]ome of the solids wastes from the Fine Powder and Dispersion Area of the [DuPont Washington Works] "Teflon®" plant contain small amount of toxic perfluorocarboxylic dispersing agents" and that "[w]ithout a pretreatment, a small amount of the perfluorocarboxylic acid dispersing agent would be leached into the groundwater." (Exhibit C (EID193614-8))

5. October 28, 1966 - DuPont's Washington Works decided that wet "'Teflon®' scrap is no longer going to the city land-fill" and that "[a]ll wet 'Teflon®' containing C-8 or C-9 dispersing agents (must be kept on the plant for disposal at sea at a future date)." (Exhibit D (EID193613))

6. February 18, 1970 - DuPont's Washington Works plant sent a memo to DuPont's Experimental Station in Wilmington, Delaware stating that:

> Past studies made at Haskell Laboratory have indicated that ammonium perfluorooctanoate (C-8 APFC), which is used in the preparation of Teflon®" dispersions, is highly toxic when inhaled and moderately toxic when injected. . . . We are interested in determining the systemic effect for repetitious skin contacts of short duration with C-8 APFC powder and with the aqueous dispersion of polytetrafluoroethylene containing C-8 (or chlorendic acid). We are also interested in determining the chronic effect of inhalation of minute quantities of C-8 APFC. In addition to knowing these effects, we would like guidance on

> the personnel equipment necessary for adequate protection against these effects.

(Exhibit E (EID123138-43))

7. May 8, 1970 - DuPont's Bio-Sciences Group Research Manager informed DuPont's Washington Works plant that "C-8 APFC and C-9 APFC cause liver enlargement, but we don't know what is the lowest repeated oral dosage that will cause it. We have no repeated oral dosage study to indicate if C-8 APFC or C-9 APFC accumulates in the body to toxic levels. We do not know the eye or skin irritation potential for C-8 APFC or C-9 APFC and we do not know whether the liver enlargement effect occurs in rats or in other species as well." (Exhibit F (EID072196-99)) After summarizing the potential studies necessary to acquire the missing toxicology information, DuPont's Bio-Sciences Group Research Manager informed DuPont's Washington Works plant that "none of the repeated inhalation studies would be necessary" "if you can eliminate continuous exposure to C-8 APFC by inhalation." "Similarly, elimination of repeated exposure by skin absorption would eliminate the need for a repeated skin absorption toxicity study." (*Id.*)

8. 1975 - DuPont completed a Study of Myocardial Infarction at Washington Works Plant "to evaluate the incidence of cases of myocardial infarction among male wage and salary roll employees at the Washington Works Plant from 1956 to 1973 . . . because some workers had complained that the occurrence of heart attacks among employees seemed excessive." (Exhibit G (EID713127-35)) DuPont's study concluded that:

> Among salaried employees, the observed incidence of myocardial infarction is significantly higher than the expected number . . . The high overall incidence is largely the result of elevated rates in recent years. In the period from 1971 to 1973, the difference between observed and predicted numbers is great: 12 observed cases verus 5.3 expected cases (P = 0.008). . . . Further investigation of occupation reveals that the high frequency of M.I. cases among salaried employees is seen largely in foreman. . . . Patrolman, a group representing three percent of the Washington Works population, also showed a somewhat elevated incidence of M.I.

(*Id.*) With respect to the increased rate of M.I. among salaried foreman, DuPont concluded that "increased incidence in this group cannot be explained by their age distribution." (*Id.*)

9. May 15, 1978 - In connection with an upcoming meeting with 3M on May 30, 1978, DuPont's Haskell Laboratory forwarded to DuPont's Medical Director, Dr. Bruce Karrh, a copy of an article published in 1976 entitled "Organic Fluoro-Compounds in Human Plasma: Prevalence and Characterization." (Exhibit H (EID107111-29)) In the 1976 study, the authors collected plasma samples from "106 individuals living in five different cities with between 0.1 and 5.6 ppm fluoride in their public water supply." (*Id.*, at EID107113) The "[h]uman plasma was obtained from blood banks in five cities." (*Id.*, at EID107116) The five cities included in the blood study were Albany, New York, Rochester, New York, Corpus Christi, Texas, Hillsboro, Texas, and Andrews, Texas. (*Id.*, at EID107121) Analysis of the blood samples revealed "chemical shifts" consistent with C-8 and shifts "consistent with the presence of amide or ester derivatives, or possibly with the presence of a sulfonic acid derivative as the functional group. One explanation for the additional peaks in the spectrum is the presence of branched isomers." (*Id.*, at EID107124) The authors of the 1976 study concluded that:

> These findings suggest that there is widespread contamination of human tissues with trace amounts of organic fluorocompounds derived from commercial products. All available information on this subject is in accordance with this interpretation. A series of compounds having a structure consistent with that found here for the predominate form of organic fluorine in human plasma is widely used commercially for their potent surfactant properties. For example, they are used as water and oil repellents in the treatment of fabrics and leather. Other uses include the production of waxed paper and formulation of floor waxes. The findings presented here that the concentration of organic fluorine was not related to the concentration of inorganic fluoride either in blood or in the public water supply, and the early finding that they was little or no organic fluorine in the blood of animals other than human are all in keeping with environmental sources such as these.

> The prevalence of organic fluorine in human plasma is probably quite high since 104 of the 106 plasma samples tested here and all 35 in an earlier study had measurable quantities. The prevalence of the particular compounds isolated and characterized here, *i.e.*, perfluoro fatty acid (C-6 - C-8) derivatives, is not known since the starting material for each batch shown . . . was pooled from between 25 and 30 individuals and since only about one third of the original organic fluorine content was accounted for in the fractions containing these compounds.

(*Id.*, at 107126-7)

10. June 16, 1978 - DuPont reported that the 3M Company "has reported finding FC143 plus other unidentified fluorochemicals in the blood of potentially exposed workers." (Exhibit I (EID080229-31)) In response, DuPont's Medical Director, Dr. Bruce Karrh, recommended that DuPont "[r]eview the medical records of all . . . persons [who currently work or have worked jobs in which there is or was potential for exposure to "Telomer A and its non-polymeric derivatives"] still employed by DuPont, looking for consistent or unusual health occurrences or trends," and to begin obtaining "blood fluorochemical levels" of exposed and unexposed workers. (*Id.*)

11. June 22, 1978 - DuPont initiated a program to inform employees of its Chambers Works, New Jersey facility of 3M's finding of organic fluorine in the blood of its employees and DuPont's program to begin analyzing the blood and medical records of Chambers Works employees exposed to Telomer A sold under the "Zonyl" trademark. (Exhibit J (EID110651-3)) (*See also* Exhibit K (EID080241-46)) DuPont also informed its Chambers Works "supervision" at the time that the testing was prompted by a "1976 report [referenced in the memo as the one authored by Guy, et al.] indicating "that the blood serum of the general population in the U.S. contains trace quantities of fluorine in both organic and inorganic form" and that the "concentration of inorganic fluorine has been shown to be related to fluoride ion in water supplies (natural and added)" but that "[t]here is no ready explanation for the presence of organic fluorine." (Exhibit J, at EID 110653) In response to the anticipated question of : "Will DuPont be informing the appropriate regulatory agencies of this situation?" DuPont's prepared response was: "At this point in time we see no significant risk associated with the fluorine content in the blood. The existence of fluorine in blood has been known for 10 years and is published in open literature." (Exhibit K, at EID 080245)

12. August 3, 1978 - DuPont's Medical Director, Dr. Bruce Karrh, advised DuPont's Washington Works plant that DuPont recommended "the same medical surveillance program" for DuPont's Washington Works employees exposed to C-8 through production of Teflon and FEP dispersions that Dr. Karrh had recommended for the DuPont Chambers Works employees exposed to Telomers through Zonyl production. (Exhibit L (EID080236-40))

13. September 20, 1978 - DuPont Washington Works' Medical Director, Dr. Younger Power, prepared a memo summarizing his "review of the medical records of eleven operators and eighteen laboratorians [at the Washington Works Plant] who have had long-term exposure to C-8." (Exhibit M (EID080233-4)) Dr. Power concluded that:

> [A]s you would anticipate, a great variety of illnesses and physical findings were found . . . [s]ome of the illnesses found are two heart attacks and five employees with high blood pressure. One questionable case of skin cancer was found during an employee's physical examination in 1976. No further mention of this possible tumor could be found. Minor elevations of many blood tests did occur in larger-than-anticipated numbers. . . . One of the liver function tests (SGOT) is most frequently elevated in the operator group. . . . Since it has been previously determined that C-8 is an hepatatoxin, it is possible that C-8 may be causing very minimal, and certainly not clinically apparent, toxic effects to the liver.

(*Id.*)

14. December 22, 1978 - DuPont's Medical Director, Dr. Bruce Karrh, prepared a memo summarizing DuPont's "Chambers Works Fluorosulfactant [sic] Study," stating that "there does not seem to be any adverse health effects reported in this study, with a possible exception of an effect on the liver." (Exhibit N (EID096510))

15. February 7, 1979 - 3M forwarded to DuPont copies of 3M's new 90-day subacute C-8 rat toxicity study and 3M's 90- day subacute C-8 Rhesus monkey toxicity study. (Exhibit O (EID071855))

16. March 5, 1979 - DuPont reviewed 3M's new C-8 rat and monkey studies and agreed that there are compound-related effects indicated in both studies, and that additional adverse effects apparently were revealed in the data but not reported by 3M in the text of the studies. (Exhibit P (EID123133))

17. March 15, 1979 - DuPont's Epidemiology Section Manager, Sidney Pell, prepared a memo summarizing "a tabulation of the Dispensary Visits and Disability Wage incidence in the [Telomer /Zonyl] exposed and control groups" at DuPont's Chambers Works facility. (Exhibit Q (GK000378-79)) Mr. Pell found that:

> In the category, "Allergic, Endocrine, and the Metabolic" disorders, a significantly higher incidence was found in the exposed group for both Dispensary Visits and Disability Wage incidents. This was attributed in the report to a higher number of diabetics in the exposed group. The exposed group also showed significantly higher numbers for "mental and psychoneurotic" disorders and for disorders of "skin and cellular tissues." . . . Explanations for these differences cannot be found from the available data. . . . Although the number of employees with abnormal liver function tests was notably higher in the exposed group (6 compared to 1), the difference is not statistically significant ($P < 0.05$). Nevertheless, the data do suggest that the exposed group may be at an excess risk of developing liver disease, so continued surveillance would be advisable.

(*Id.*)

18. May 22, 1979 - DuPont prepared a "Status Review: Fluorochemicals in Blood" report confirming that DuPont's blood testing had detected organic fluorine in a "control group" of presumably "non-exposed" DuPont Wilmington, Delaware employees at between 0-0.38 ppm (average of 0.094 ppm), and that DuPont had detected organic fluorine in the blood of its Chambers Works, New Jersey employees at a range of 0-0.37 ppm (average of 0.15 ppm), with one individual in the "Wilmington Control Group" testing as high as 10.6 ppm for organic fluorine in blood. (Exhibit R (EID80274)) Because the levels of organic fluorine in the blood of DuPont's Chambers Works employees were not viewed as significantly

different from the "control group" of Wilmington, Delaware employees, the recommendation was made to "discontinue program to determine fluorine in blood, advise employees that blood analysis program has been discontinued due to uniformly favorable results." (*Id.*, at EID080282) (*See also* Exhibit S (EID080267-70))

19. July 20, 1979 - DuPont representatives met with 3M to discuss the status of organic fluorine blood testing and health studies. (*See* Exhibit U (EID107173)) During the meeting "3M described a gas chromatographic method to determine perfluorooctanoic acid (FC-143) in blood, urine, liver, and other biological materials. It can measure as little as 1.5ppb." (*Id.*) 3M also disclosed to DuPont during the meeting that "3M got blood samples from 8 peasants in a Chinese village 30 miles from Canton. The organic fluorine was significantly lower (0.004-0.017 ppm), than values found in developed countries (e.g., 3M found 0.002-0.13 in 106 members of the general U.S. population)." (Id., at EID107174) DuPont also apparently planned to discuss with 3M the reportability of the blood data information to U.S. EPA under TSCA Section 8(e). (*See* Exhibit T (EID107194-95))

20. July 25, 1979 - DuPont prepared a memorandum summarizing the status of its work relating to organic fluorocompounds in human blood, indicating that organic fluorine levels had been detected in DuPont Washington Works employees at between 0.4 and 21.1 ppm. (Exhibit V (EID107199)) The memorandum also confirmed that DuPont "[d]ecided not to report to EPA under 8(e) of TOSCA [sic] because fluorine in blood per se was disclosed in 1976 article and because no adverse health effect is known, therefore, no substantial risk." (*Id. See also* Exhibit W (EID107196))

21. July 30, 1979 - DuPont prepared a memorandum summarizing information discussed with 3M on July 26, 1978, including DuPont's decision not to report the recent blood data to U.S. EPA. (Exhibit W (EID 107196)) During the conversation with 3M, DuPont:

> Advised Robert Prokop of 3M of our . . . conclusions with regard to Section 8(e) and our general practice of reporting or otherwise publicizing relevant findings even if they are not required to be reported under Section 8(e). [Eugene Berman of DuPont] asked Prokop to clarify what plans 3M had with regard to publicizing this

> fluorine blood level information and/or directly advising the relevant health agency of this information. Prokop indicated that he believed 3M was favorably disposed toward disclosing this information and promised a more definitive response next week after reviewing the matter with Lester Krogh (3M's Division Vice President).

(*Id.*)

21. August 28, 1979 - DuPont Epidemiologist, William E. Fayerweather sent a memo to DuPont Washington Works' Medical Director, Dr. Younger Power, stating that DuPont's Medical Director, Dr. Bruce Karrh, had asked him "to look into the liver function test results for workers with C-8 exposure, and [that Dr. Younger] Power asked me to examine myocardial infarction cases and deaths at the Plant. Mr. Fayerweather concluded that:

> My preliminary results suggest that C-8 exposed workers may possibly have positive liver function tests more often than the plant population as a whole, and that the number of active wage role employees having myocardial infarctions from 1974 through 1977 was somewhat higher than was expected based on company-wide experience. As a consequence of these preliminary findings, the following steps are being taken: (1) Liver function survey ... (2) Coronary heart disease mortality [study].

(Exhibit X (EID080214-15))

22. October, 1979 - DuPont prepared tables summarizing the levels of organic fluorine detected in Washington Works employee blood. (*See* Exhibits Y (EID080255-60), Z (EID080732-37), and AA (EID107158-60))

23. January 17, 1980 - DuPont obtained organic fluoride levels in blood from mechanics at its Washington Works plant, indicating an average of 0.66 ppm organic fluorine in the employees' blood. (Exhibit BB (EID080193))

24. January 28, 1980 - DuPont's Assistant Medical Director, Dr. Vann Brewster, prepared a memo summarizing conclusions reached by DuPont during a meeting on January 25, 1980 to discuss an ongoing "Liver Enzyme Study of Workers Exposed to C-8 at Parkersburg." (Exhibit CC (EID099433-34)) Dr. Brewster noted that "the mean SGOT in the TFE process operator group and the mean AP in the FEP process group are elevated when compared to other plant groups" and that "we are unable to explain why only the mean SGOT would be elevated in one group and only the mean AP would be elevated in another group." (*Id.*)

25. February 25, 1980 - DuPont prepared a memorandum summarizing the results of total, inorganic, and organic fluorine in worker blood at its Spruance, Virginia plant. (Exhibit EE (EID107155-56))

26. February 28, 1980 - DuPont prepared a memorandum summarizing the levels of total and organic fluorine in worker blood in relationship to workplace C-8 air levels at DuPont's Toledo, Philadelphia, Marshall Lab, and Fairfield sites. (Exhibit DD (EID079084))

27. March 3, 1980 - DuPont prepared a memorandum summarizing the level of organic fluorine detected in the blood of its employees at its Washington Works, Wilmington, Delaware, Chambers Works, Experimental Station, and Spruance facilities, along with DuPont's "Finishes Plants." (Exhibit FF (EID079036))

28. June 9, 1980 - DuPont's Assistant Medical Director, Dr. Vann Brewster, prepared a memo expressing his concern that a draft communication to DuPont's Washington Works employees regarding the outcome of DuPont's liver study of employees "implies that the Medical Division will not continue the study of liver tests on those employees potentially exposed to C-8." (Exhibit GG (EID102477)). In response, Dr. Brewster states that:

> Even though we have found no "conclusive evidence of a occupationally related health problem," we still cannot explain why the mean SGOT was significantly higher among TFE process workers and that the mean AP was significantly higher among FEP process and service workers. Therefore, I recommend the following changes to the draft: At the end of the second paragraph, . . . add: "However, it was recommended that the study of liver tests continue." [and] [a]t the bottom of

page 2, add a fourth item: "Continue to evaluate the liver tests of employees with potential exposure to C-8."

(*Id.*)

29. July 31, 1980 - DuPont conducted a "C-8 communications meeting" and provided an "Outline, Talk & Charts." (Exhibit HH (EID079399-418)) In those documents, DuPont confirmed that "C-8 is toxic but can be handled safely. People working with C-8 generally accumulate organic fluorine in the blood, and levels generally correlate with job exposure potential. Although this has caused no adverse health effects, continued exposure is not tolerable." (*Id.*, at EID079401. *See also* Exhibit II (EID077237-62))

30. November, 1980 - DuPont prepared an analysis of Washington Works employee blood results, including a new analysis of the results "obtained by the C-8/GC method." (Exhibit JJ (EID080726-31) *See also* Exhibits KK (EID080717-18), LL (EID080719-24), MM (EID079382-85) and NN (EID079386))

Very truly yours,

Robert A. Bilott

RAB:mdm
Enclosures
cc: Dr. Charles M. Auer (USEPA OPPT) (w/o encls.) (letter by telecopy)
Mary Dominiak (USEPA OPPT) (for inclusion in AR-226) (w/encls.)(letter by telecopy)
Jennifer Seed (USEPA) (w/encls.) (letter by telecopy - enclosures by hard copy)
R. Edison Hill, Esq. (w/ encls.)
Larry A. Winter, Esq. (w/ encls.)
Gerald J. Rapien, Esq. (w/o encls.)