UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

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| IN THE MATTER OF: | ) | |
| | ) | |
| | ) | Docket No. TSCA-HQ-2005-5001 |
| | ) | |
| E. I. du Pont de Nemours | ) | |
| and Company | ) | |
| | ) | COMPLAINT AND NOTICE OF |
| Wilmington, DE | ) | OPPORTUNITY FOR HEARING |
| | ) | |
| | ) | |
| Respondent | ) | |
| | ) | |
| Washington Works Facility | ) | |
| Route 892 South DuPont Road | ) | |
| Washington, Wood County, WV | ) | |

## INTRODUCTION

This Complaint and Notice of Opportunity for Hearing ("Complaint") is filed pursuant to the Toxic Substances Control Act § 16(a), 15 U.S.C. § 2615(a), ("TSCA"), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Consolidated Rules of Practice"), 40 C.F.R. Part 22, a copy of which is enclosed with this Complaint. See Enclosure A. The Complainant is Ann M. Pontius, Director, Toxics & Pesticides Enforcement Division, Office of Regulatory Enforcement, Office of Enforcement and Compliance Assurance, United States Environmental Protection Agency ("EPA" or the "Agency"), who has been duly delegated the authority to institute this action. The Respondent is E. I. du Pont de Nemours and Company ("DuPont" or "Respondent"), 1007 Market Street, Wilmington, Delaware, a manufacturer, processor or distributor of chemical substances and mixtures in commerce.

This Complaint serves as notice that Complainant has reason to believe that Respondent failed to immediately submit information as required by TSCA § 8(e), 15 U.S.C. § 2607(e), thereby committing an unlawful act under TSCA § 15, 15 U.S.C. § 2614. Section 16 of TSCA authorizes EPA to take an enforcement action against any person that commits a prohibited action under TSCA.

In support of this Complaint, Complainant hereby makes the following allegations:

## COMPLAINT

## GENERAL ALLEGATIONS

1. Respondent owns and operates a manufacturing facility, known as Washington Works ("Washington Works Facility"), located at Route 892 South DuPont Road, Washington, Wood County, West Virginia, 26181. Respondent was the owner and operator of this facility at all times relevant to this Complaint.

2. Respondent "manufactures," "processes," or "distributes in commerce" a "chemical substance" or "mixture" as those terms are defined in TSCA § 3, 15 U.S.C. § 2602, and TSCA § 8(f), 15 U.S.C. § 2607(f).

3. Respondent is a person subject to the requirements of TSCA § 8(e), 15 U.S.C. § 2607(e).

4. At all times relevant to this Complaint, DuPont manufactured Ammonium Perfluorooctanoate ("APFO"), CAS No. 3825-26-1 (Octanoic acid, pentadecafluoro-, ammonium salt).[1]

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[1] The 3M Company manufactured APFO and sold it to DuPont from 1951until 2002 under the tradename FC-143.

5. APFO is comprised of an ammonium cation and a perfluorooctanoic acid ("PFOA") anion.[2] The "oate" suffix of APFO is the nomenclature tool used to signify the anionic form of a carboxylic acid. The suffix "oic" of pure PFOA is used to signify the neutral protonated form of a carboxylic acid. The pure form of PFOA, CAS number 335-67-1, consists of the PFOA anion and its associated cation which is a proton (H+), which is thus different from the PFOA anion alone. In water or biologic media, APFO quickly dissociates to the ammonium cation and the PFOA anion.

6. When APFO is measured in humans or the environment, it is measured by its PFOA anion presence and not by the intact APFO. Because there cannot be APFO without the PFOA anion, and because APFO measured in humans or the environment is measured by the PFOA anion, a short-hand for discussing APFO is "PFOA." Consequently, reference to APFO, C-8, C8 or PFOA is a reference to the dissociated (anionic) form of PFOA and <u>not</u> the protonated form of PFOA with CAS No. 335-67-1.

7. EPA consistently uses APFO, C-8, and PFOA interchangeably as evidenced in the 2003 fact sheet, available to the public at www.epa.gov/opptintr/pfoa/pfoafcts.pdf, in which EPA stated that "[t]he 'PFOA' acronym is used to indicate not only perfluorooctanoic acid itself, but also its principal salts. The most commonly used chemical in this grouping is the ammonium salt, ammonium perfluorooctanoate or APFO, which is sometimes called 'C8'. "

8. While most major toxicological studies and industrial exposures involve APFO, the toxicological effects are likely related to the PFOA anion.

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[2] A synonym for this PFOA anion is "perfluorooctanoate."

9. Most animal toxicity studies have been conducted with APFO.

10. EPA has identified potential human health concerns from exposure to PFOA.

11. APFO is a perfluorinated detergent/surfactant manufactured, processed, or distributed in commerce in the United States by DuPont, in connection with its Teflon®-related products.

12. At all times relevant to this Complaint, Respondent manufactured, processed, or distributed in commerce APFO, and consequently, Respondent manufactured, processed, or distributed the PFOA anion associated with APFO.

13. Thus, at all times relevant to this Complaint, Respondent has manufactured, processed or distributed PFOA (i.e., the PFOA anion) at its Washington Works Facility.

14. PFOA is in the soil, groundwater, and drinking water at, and/or within the vicinity of, DuPont's Washington Works Facility.

15. PFOA is hepatotoxic (liver toxin) to animals.

16. PFOA is persistent in the environment.

17. PFOA is bioaccumulative in humans in that it has a half-life estimated at 4.4 years.

18. PFOA is associated with developmental effects in animals.

19. PFOA is believed to be present in the blood of the general population in all geographic regions of the U.S. As stated in the Agency's April 2003 Preliminary Risk Assessment, "[t]he highest serum PFOA levels of the general public were reported in a sample of children from different geographic regions in the U.S. (mean, 5.6 ppb [parts per billion]; range, 1.9 – 56.1 ppb)."

20. PFOA is not naturally occurring, thus all PFOA in human blood is attributable to human

activity. PFOA is produced synthetically and can be formed through the degradation or metabolism of other fluorochemical products, such as fluorinated telomers.

21. DuPont and other researchers have studied PFOA in lab animals.

22. There are gender differences in the elimination of PFOA in rats.

23. There are substantial differences in the half-life of PFOA in rats and humans.

24. There are considerable differences among species in the kinetics of PFOA.

25. In September 2002, the Director of the Office of Pollution Prevention and Toxics (OPPT) initiated a priority review of PFOA in all its forms. EPA published a Federal Register Notice, 68 Fed. Reg. 18,626 (April 16, 2003), as part of its effort to collect additional information. The Agency is interested in collecting information because certain studies indicated that PFOA causes developmental toxicity and other effects in laboratory animals. EPA's preliminary assessment, released April 10, 2003, indicates potential exposure of the U.S. general population to PFOA at very low levels. However, this risk assessment also reflects considerable scientific uncertainty regarding the potential risks.

26. TSCA § 2(a)(2), 15 U.S.C. § 2601(a)(2) states, "Findings - The Congress finds that - (2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use or disposal may present an unreasonable risk of injury to health or the environment."

27. TSCA § 2(b)(2), 15 U.S.C. § 2601(b)(2) and TSCA § 2(b)(3), 15 U.S.C. § 2601(b)(3) state, "Policy - It is the policy of the United States that - (2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances

and mixtures which are imminent hazards; and (3) authority over chemical substances and mixtures should be exercised in such a manner as to not impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."

28. TSCA § 8(e), 15 U.S.C. § 2607(e), provides that, "Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

**Count I - Results of PFOA Serum Testing**

29. Complainant re-alleges paragraphs 1 through 28, above, as if fully set forth below.

30. On or about September 15, 2004, Robert A. Bilott, an attorney representing plaintiffs in litigation against DuPont for APFO/PFOA contamination of drinking water in West Virginia and Ohio, submitted a letter to EPA containing "the results of PFOA exposed community serum sampling" performed by DuPont and its contractor, Exygen.

31. Mr. Bilott first received the results of this community serum sampling from DuPont, or an agent for DuPont, on or around August 5, 2004.

32. Specifically, the letter describes the results of a DuPont serum sampling of twelve members of the general population living near the Washington Works Facility. The letter

claims that all twelve of the individuals tested were exposed to PFOA through drinking water provided by the Lubeck Public Service District (LPSD), where according to DuPont, the level of PFOA in the drinking water has averaged approximately 0.5 parts per billion (ppb) over the last several years.

33. The letter from Mr. Bilott states that all twelve of the individuals tested claim to have stopped using the contaminated public drinking water as their primary source of drinking water approximately three years ago.

34. The serum sampling consisted of five females and seven males, of which only one, a seventy-year old male, had previously worked at the Washington Works Facility.

35. Human serum sample levels of PFOA for these 12 individuals were reported to range from 15.7 ppb to 128 ppb, with a mean of 67 ppb. The median value is in the range of 60 ppb PFOA. As stated above, the average background serum level of PFOA in individuals residing in the United States is estimated to be approximately 5 ppb.

36. These human serum sample levels of PFOA for these 12 individuals represent the first human serum sampling results the Agency has seen concerning individuals exposed in a community setting.

37. DuPont failed or refused to submit to EPA the data concerning human serum sampling of twelve members of the general population living near the Washington Works Facility after it had obtained this information from its contractor, Exygen.

38. The human serum sampling data are particularly useful because they represent an attempt to associate body burden in the general population with a specific exposure pathway and a source of exposure. This data is information that reasonably supports the conclusion that

PFOA presents a substantial risk of injury to human health that the Administrator was not already adequately informed about at the time the information was obtained by DuPont or at any time prior to the date EPA received the data.

39. The Agency considers the human serum sampling information to reasonably support the conclusion of a substantial risk of injury to health or the environment. The Administrator was not adequately informed about this risk at the time the information was obtained by DuPont.

40. DuPont obtained this information on or after July 29, 2004 but no later than August 5, 2004, the date at which DuPont transmitted this information to Mr. Bilott, as described in Paragraph 31, above.

41. DuPont was required to immediately inform EPA about the human serum sampling data under TSCA § 8(e), 15 U.S.C. § 2607(e), as information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health unless DuPont had actual knowledge that the Administrator had been adequately informed of the serum data.

42. DuPont failed or refused to immediately inform the Administrator about the community human serum sampling information.

43. DuPont became aware on or around October 12, 2004, that the Administrator had been informed about this human serum sampling data.

44. TSCA § 15(3)(B), 15 U.S.C. § 2614(3)(B), provides that it is unlawful for any person "to fail or refuse to submit reports, notices, or other information" required by TSCA.

45. DuPont's failure to immediately inform EPA about the information concerning human

serum sampling from individuals exposed to PFOA in a community setting constitutes a violation of TSCA § 8(e), 15 U.S.C. § 2607(e).

46. DuPont's failure or refusal to submit the human serum sampling information as required under TSCA § 8(e) is an unlawful act under TSCA § 15(3)(B).

## CIVIL PENALTY ASSESSMENT

Section 16 of TSCA, 15 U.S.C. § 2615, authorizes the assessment of a civil penalty for the violations described herein of $32,500 for each day of violation.[3] In determining the amount of a civil penalty for violations of TSCA, Complainant shall take into account the nature, circumstances, extent, and gravity of the violations alleged, as well as Respondent's ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. See also Enclosure B. Pursuant to 40 C.F.R. § 22.14(a)(4)(ii), Complainant is not proposing a specific penalty at this time, but will do so at a later date. See 40 C.F.R. § 22.19(a)(4).

## NOTICE OF OPPORTUNITY TO REQUEST A HEARING

As provided in TSCA § 16(a)(2)(A), 15 U.S.C. § 2615(a)(2)(A), you have the right to request a formal hearing to contest any material fact set forth in this Complaint or to contest the

[3] The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, requires EPA to periodically adjust penalties to account for inflation. EPA's Civil Monetary Penalty Inflation Adjustment Rule establishes $32,500 for violations occurring after March 15, 2004. See 69 Fed. Reg. 7121 (Feb. 13, 2004).

appropriateness of the penalty. To avoid being found in default, which constitutes an admission of all facts alleged in the Complaint and a waiver of the right to a hearing and having a penalty assessed without further proceedings, you must file a written Answer within thirty (30) days of receiving this Complaint.

Pursuant to the Consolidated Rules of Practice, your Answer must clearly and directly admit, deny, and/or explain each of the factual allegations contained in this Complaint with regard to which you have any knowledge. If you have no knowledge of a particular fact and so state, the allegation is denied. Failure to deny any of the allegations in this Complaint will constitute an admission of the undenied allegation.

The Answer shall also state the circumstances and arguments, if any, which are alleged to constitute the grounds of defense and the basis for opposing any proposed penalty, and shall specifically request an administrative hearing if desired. EPA will consider, among other factors, Respondent's "ability to pay" to adjust the civil penalty to be assessed in this proceeding. If you deny any material fact or raise any affirmative defense, you will be considered to have requested a hearing. The Answer must be filed with the:

Headquarters Hearing Clerk (1900L)
United States Environmental Protection Agency
1200 Pennsylvania Ave. N.W.
Washington, DC 20460

Please send a copy of the Answer and all other documents that you file in this action to the following attorneys assigned to represent EPA in this matter:

Mark Garvey, Attorney
Toxics and Pesticides Enforcement Division (2245A)
Office of Regulatory Enforcement

U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
(202) 564-4168

Ilana Saltzbart, Attorney
Toxics and Pesticides Enforcement Division (2245A)
Office of Regulatory Enforcement
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
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(202) 564-9935

Any hearing requested will be conducted in accordance with the Administrative Procedures Act, 5 U.S.C. § 551 *et seq.*, and the Consolidated Rules of Practice. See Enclosure A.

## INFORMAL SETTLEMENT CONFERENCE

Whether or not you request a hearing, you may confer informally with EPA to discuss the facts of this case, or amount of the penalty, and the possibility of settlement. An informal settlement conference does not, however, affect your obligation to file a written Answer to the Complaint.

EPA has the authority, where appropriate, to modify the amount of the penalty to reflect any settlement reached with you in an informal conference. The terms of such an agreement would be embodied in a Consent Agreement and Final Order ("CAFO"). A CAFO signed by EPA and you would be binding as to all terms and conditions specified therein upon signature by the Environmental Appeals Board.

Please be advised that the Consolidated Rules of Practice prohibit any *ex parte* (unilateral) discussion of the merits of any action with the Administrator, Environmental Appeals

Board Judge, Administrative Law Judge, or any person likely to advise these officials in the decision of the case, after the Complaint is issued.

By:

[redacted]

Date: Dec. 6, 2004

Ann M. Pontius, Director
Toxics & Pesticides Enforcement Division
Office of Regulatory Enforcement
Office of Enforcement And Compliance Assurance
U.S. Environmental Protection Agency

## ENCLOSURE

| | | |
|---|---|---|
| A | - | Consolidated Rules of Practice - 40 C.F.R. Part 22 |
| B | - | TSCA Enforcement Response Policies |
| C | - | Notice of Securities and Exchange Commission Registrants' Duty to Disclose Environmental Legal Proceedings |

CERTIFICATION

I hereby certify that the original of the foregoing Complaint and Notice of Opportunity for Hearing, Docket Nos. TSCA-HQ-2005-5001 has been filed with the Headquarters Hearing Clerk and that copies were sent:

by certified mail, return receipt requested to both parties below

and by fax without enclosures to:

Stacey J. Mobley
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1007 Market Street
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[redacted]

Brenda F. Mosley, Ph.D. (2245A)
Toxics and Pesticides Enforcement Division
Office of Regulatory Enforcement
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W..
Washington, DC 20460

12-6-04
Date