UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

REGION III
1650 Arch Street
Philadelphia, PA 19103-2029

REGION V
77 West Jackson Boulevard
Chicago, IL 60604



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| IN THE MATTER OF: | |
| E.I. du Pont de Nemours and Company<br>1007 Market Street<br>Wilmington, DE 19898 | ORDER ON CONSENT |
| Respondent. | Proceeding under Section 1431(a)(1) of the Safe Drinking Water Act, 42 U.S.C. § 300i(a)(1) |
| Washington Works Facility<br>Route 892 South<br>Washington, WV 26181 | |
| | Docket Nos. SDWA-03-2007-0039-DS<br>SDWA-05-2007-0001 |

## I. STATUTORY AUTHORITY

1. This Order on Consent ("Order") is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency ("EPA") by Section 1431(a)(1) of the Safe Drinking Water Act ("SDWA" or "the Act"), 42 U.S.C. § 300i(a)(1), and supersedes the Order on Consent (Docket Nos. SDWA-03-2002-0019 and SDWA-05-2002-0002) issued on March 7, 2002 ("EPA-DuPont 2002 Order on Consent").

2. The authority to issue this Order was delegated to the Regional Administrators by Delegation No. 9-17, dated May 11, 1994.

3. Under the SDWA, Congress has authorized EPA to exercise broad authority for the protection of public health from contaminants entering a public water system or an underground source of drinking water.

## II. STIPULATIONS

4. DuPont consents to EPA's jurisdiction to issue this Order. DuPont does not admit to the EPA Findings in this Order.

5. DuPont waives any defenses it might have as to jurisdiction and venue and agrees not to contest any of the findings of fact or conclusions of law herein in any action to enforce this

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Order. Except as to any proceeding brought by EPA to enforce this Order, in agreeing to this Order, DuPont makes no admission of fact or law and reserves all rights and defenses available regarding liability or responsibility in any other legal proceeding related to the subject matter of this Order. DuPont further waives any rights to appeal this Order that would be otherwise applicable under the SDWA.

## III. DEFINITIONS AND BACKGROUND

6. The term "toxicokinetics" (or pharmacokinetics for pharmaceutically relevant substances) is the scientific determination and quantitation of the absorption, distribution, metabolism, and excretion of chemicals from the body.

7. "Half-life" is the time required to reduce the concentration of a chemical to one-half its initial concentration.

8. "Contaminant" means "any physical, chemical, biological, or radiological substance or matter in water." See 42 U.S.C. § 300f(6).

9. The term "underground source of drinking water" ("USDW") means an aquifer or a portion thereof which supplies a public water system ("PWS"), or which contains a sufficient quantity of ground water to supply a PWS and/or which currently supplies drinking water for human consumption, or contains fewer than 10,000 milligrams per liter total dissolved solids, and is not an exempted aquifer. See 40 C.F.R. § 144.3.

10. C-8, for purposes of this Order, is perfluorooctanoic acid, CAS # 335-67-1 (PFOA) and its salts, including ammonium perfluorooctanoate, CAS # 3825-26-1 (APFO). These are man-made perfluorinated compounds that do not occur naturally in the environment.

11. Micrograms per liter (µg/l) is the same as parts per billion (ppb).

12. The term "source water" shall mean water prior to any kind of treatment.

13. A "public water system," hereafter "PWS," provides piped drinking water for human consumption to persons within the meaning of Section 1401 (4) of the Act, 42 U.S.C. §300f(4) and 40 CFR §141.2.

14. A private water system is used by individual residents, or serves less than 25 persons per year from a well or other surface or ground water source and is otherwise not a "PWS."

15. The term "finished water" shall mean water that has passed through all the processes in a system's water treatment plant and is ready to be delivered to consumers.

## IV. EPA FINDINGS

E.I. du Pont de Nemours and Company ("DuPont") is a corporation and is therefore a son" within the meaning of Section 1401(12) of the SDWA, 42 U.S.C. § 300f(12).

DuPont owns and operates a manufacturing facility known as the Washington Works acility"), located in Washington, Wood County, West Virginia.

DuPont has used C-8, in the form of APFO, in its manufacturing processes at the Facility ıce the early 1950s.

). On November 15, 2001, DuPont, the West Virginia Department of Environmental rotection ("WVDEP") and the West Virginia Department of Health and Human Resources 'WVDHHR") entered into an agreement on consent ("WV Order"), which provided for, *inter lia*, a toxicological and human health risk assessment of C-8 to be conducted under the upervision of a C-8 Assessment of Toxicity ("CAT") Team. Ground water and surface water nonitoring and plume identification in West Virginia and Ohio was conducted under the supervision of a Ground Water Investigation Steering ("GIS") Team.

20. In April 2002, the CAT Team conducted a toxicological and human health risk assessment of C-8 and developed a screening level of 150 ppb for C-8 in drinking water.

21. From 2000 to 2006 DuPont implemented recycling and abatement technologies that reduced both air emissions and water discharges of C-8 from the Facility. Annual emissions to air in 2005 were reported to be approximately 12,600 kilograms lower than annual air emissions in 2000. Annual discharges to water in 2005 were reported to be approximately 20,400 kilograms lower than annual water discharges in 2000.

22. Studies have found that C-8 is highly persistent in the environment with little or no degradation occurring in air, water, or soil.[1, 2, 3]

23. The toxicity of C-8 has been studied extensively, and studies on several animal species have recently been reviewed.[4, 5] Depending on the species, the dose of C-8, and the design of the

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1 Hanson, M. L.; Small, J.; Sibley, P. K.; Boudreau, T. M.; Brain, R. A.; Mabury, S. A. & Solomon, K. R., "Microcosm evaluation of the fate, toxicity, and risk to aquatic macrophytes from perfluorooctanoic acid (PFOA)," *Arch. Envtl. Contam. Toxicol.*, vol. 49, no. 3, pp. 307-316 (2005).

2 Kannan, K.; Corsolini, S.; Falandysz, J.; Oehme, G.; Focardi, S. & Giesy, J. P., "Perfluorooctanesulfonate and related fluorinated hydrocarbons in marine mammals, fishes, and birds from coasts of the Baltic and the Mediterranean Seas," *Envtl. Sci. Technol.*, vol. 36, no. 15, pp. 3210-3216 (2002).

3 Kannan, K.; Tao, L.; Sinclair, E.; Pastva, S. D.; Jude, D. J. & Giesy, J. P., "Perfluorinated compounds in aquatic organisms at various trophic levels in a Great Lakes food chain," *Arch. Envtl. Contam. Toxicol.*, vol. 48, no. 4, pp. 559-566 (2005).

4 Kennedy, G.L. , *et. al.*, "The Toxicology of Perfluorooctanoate," *Crit. Rev. Toxicol.* vol. 34, no. 4, pp. 351-384 (2004).

5 U. S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Risk Assessment Division, "Draft Risk Assessment of the Potential Human Health Effects Associated with Exposure to Perfluorooctanoic Aci

study, studies have shown varying kinds of toxicity, or have shown the absence of a particular effect. (*See* Appendix A for a summary of selected study results).

24. Available human studies on C-8 include multiple occupational studies and one community study. (*See* Appendix B for selected human studies and references). The available data do not provide a definitive picture of the presence or absence of C-8 effects on human health, and this subject merits further study. (*See* Appendix C for a summary of selected study results).

25. Various studies have shown that understanding the toxicokinetics of C-8 is complicated by highly variable elimination of the compound among test animal species and human subjects. While female rats eliminate C-8 from their bodies with a half-life of hours,[6] the half-life of C-8 elimination in monkeys is measured in months[7]. Further studies have suggested that the half-life of C-8 in human blood serum is approximately 3.8 years[8]. The half-life of C-8 in human blood serum appears to be much longer than the half-life of C-8 in the blood serum of other species tested to date. Because PFOA can remain in the body for a long time, drinking water that contains PFOA can, over time, produce concentrations of PFOA in blood serum that are higher than the concentrations present in the water itself.

26. Sampling conducted through the GIS Team effort since 2001, and by DuPont, has detected C-8 in private and public drinking water sources in Ohio and West Virginia at concentrations ranging from below the limits of quantitation up to 21.1 ppb.[9]

27. Based upon existing data, there are two public water systems that have demonstrated levels of C-8 that exceed 0.50 ppb in their finished water. Those public water systems are the Little Hocking Water Association ("Little Hocking") located in Ohio and the Lubeck Public Service District ("Lubeck") located in West Virginia.

28. DuPont has designed and pilot-tested a granular activated carbon water treatment ("GAC Treatment") system for Lubeck. The WVDHHR has approved Lubeck's permit modification and construction of the GAC Treatment system is expected to be completed within six (6) months after all necessary state and local approvals are received.

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and Its Salts" (Jan. 4, 2005).

6 Hinderliter, P. M.; DeLorme, M. P. & Kennedy, G. L., "Perfluorooctanoic acid: relationship between repeated inhalation exposures and plasma PFOA concentration in the rat," *Toxicology*, vol. 222, no. 1-2, pp. 80-85 (2006).

7 Butenhoff, J. L.; Kennedy, G. L., Jr., Hinderliter, P. M.; Lieder, P. H.; Jung, R.; Hansen, K. J.; Gorman, G. S.; Noker, P. E. & Thomford, P. J., "Pharmacokinetics of perfluorooctanoate in cynomolgus monkeys," *Toxicol. Sci.*, vol. 82, no. 2, pp. 394-406 (2004).

8 Olsen, G.; Ehresman, J.; .Froehlich, J.; Burris & Butenhoff, "Evaluation of the half-life ($t_{1/2}$) of elimination of perfluorooctanesulfonate (PFOS), perfluorohexanesulfonate (PFHS) and perfluorooctanoate (PFOA ) from human serumG," 3M Company, St. Paul, MN and Pace Analytical, St. Paul, MN. Presented at the First International Conference on Perfluoros in Toronto (August 2005).

9 Hartten, Andrew S., Project Director, DuPont, "Amended 3Q05, and 4Q05 and 1Q06 Residential Sampling Results, West Virginia and Ohio DuPont Washington Works, Washington, WV (EPA Docket ID Number OPPT 2004-0113 PFOA Site-Related Environmental Assessment Program," submitted to Chad Board, West Virginia Department of Environmental Protection (April 5, 2006).

29. DuPont has offered GAC Treatment to Little Hocking and has prepared designs for a new water treatment facility at a location acceptable to the Ohio Environmental Protection Agency ("OEPA"). OEPA has approved the permit modification.

30. DuPont has offered to install GAC Treatment to owners of residences using private water systems for which data have demonstrated levels of C-8 at or above 0.50 ppb in their finished water. DuPont has installed and is operating GAC Treatment at approximately 30 private water systems that have exceeded 0.50 ppb and that have accepted DuPont's offer.

31. EPA has identified additional geographic areas in the vicinity of the Facility where USDWs may contain C-8 at concentrations at or above 0.50 ppb.

32. C-8 is currently not a contaminant for which a national primary drinking water regulation, including a maximum contaminant level ("MCL"), has been established pursuant to the SDWA.

33. EPA is conducting a risk assessment of C-8 under the Toxic Substances Control Act ("TSCA"), 15 U.S.C. §§ 2601 *et. seq.*

34. DuPont has released C-8 to the air, discharged C-8 to surface waters, and disposed of residues containing C-8 at the Facility. DuPont has also disposed of residues containing C-8 to its Dry Run, Local and Letart Landfills in West Virginia and has otherwise shipped residues containing C-8 off-site for destruction and/or disposal.

35. The releases, discharges, and/or disposal referred to in Paragraph 34 have resulted in releases of C-8 to air, ground water, surface water, and soil.

36. The releases referred to in Paragraph 34 have entered USDWs and surface waters and resulted in levels of C-8 at concentrations at or above 0.50 ppb in some of the receiving waters.

37. Public and private water systems in the vicinity of the Facility are using water sources contaminated with C-8 at levels that may be at or above 0.50 ppb.

38. Although EPA has not yet completed its risk assessment for C-8, based upon studies available since April 2002, EPA has determined that the 150 ppb interim screening level requires revision.

39. Section 1431 of the SDWA requires a finding that "a contaminant which is present in or is likely to enter a public water system or an underground source of drinking water...may present an imminent and substantial endangerment to the health of persons...." It does not require a conclusive finding that a contaminant has, or definitely will, cause harm. As required by Section 1431 of the SDWA and for purposes of this Order, EPA has determined that C-8 is a contaminant present in or likely to enter a PWS or a USDW which may present an imminent and substantial endangerment to human health at concentrations at or above 0.50 ppb in drinking

water.[10] EPA has based this determination on its interpretation of animal and human studies, and on the results of environmental sampling and monitoring in the vicinity of the Facility. The 0.50 ppb action level is a precautionary level to reduce exposure to the population living in the vicinity of the Facility.

40. State and local authorities rely on the expertise and resources of EPA to review and evaluate unregulated contaminants. The WVDEP, WVDHHR, OEPA, the Ohio Department of Health ("ODH"), and local authorities are relying on the EPA to establish a Site-Specific Action Level for C-8 in drinking water that reduces exposure to C-8 for residents in the vicinity of the Facility. State agency actions taken to date, including actions taken by WVDEP, WVDHHR, OEPA, and ODH, have been based on the screening level of 150 ppb established by the CAT Team.

41. EPA has consulted with WVDEP, WVDHHR, OEPA, and ODH to confirm that the information upon which this Order is based is correct. The WVDEP, WVDHHR, OEPA, and ODH have requested that EPA take this action. Therefore, all requisite conditions have been satisfied for EPA action under Section 1431(a)(1) of the SDWA, 42 U.S.C. § 300i(a)(1).

## V. ORDER ON CONSENT

42. Pursuant to the authority given to the EPA Administrator by Section 1431(a)(1) of the SDWA, 42 U.S.C. § 300i(a)(1), and delegated to the Regional Administrators, DuPont is ORDERED and hereby consents to the following:

a) Private Water Systems Receiving Treatment. For private water systems at which DuPont has already installed GAC Treatment, DuPont shall provide for operation and maintenance of each GAC Treatment system in good working order, including but not limited to timely replacement of carbon filters, until it demonstrates to the satisfaction of EPA that the source prior to GAC Treatment contains less than 0.50 ppb of C-8 for four consecutive quarters, or the conditions of Paragraph 46 have been met. DuPont may also elect to satisfy any ongoing obligation under this Paragraph by connecting a particular location to a public water system that contains less that 0.50 ppb of C-8.

b) Lubeck and Little Hocking. For Lubeck and Little Hocking, once GAC Treatment is installed and operational, DuPont shall provide for operation and maintenance of each GAC Treatment system in good working order, including but not limited to timely carbon bed changes, until it demonstrates to the satisfaction of EPA that the source water in the system prior to GAC Treatment contains less than 0.50 ppb of C-8 for four consecutive quarters, or the conditions of Paragraph 46 have been met.

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10 Weis, C., "Memorandum Re: Hazard Evaluation and Revised Site-Specific Threshold for Perfluorooctanoate (PFOA or C8; CAS # 335-67-1) in drinking water near the DuPont Washington Works facility, West Virginia" (2006).

c) Survey and Identification of Additional Private and Public Water Systems. For geographical areas defined by EPA (upon consultation with West Virginia and Ohio), DuPont shall conduct a water system survey and where any new private or public water system is identified, monitor the locations for the presence of C-8. DuPont shall also notify EPA and owners or operators of private and public water systems of monitoring results within 7-10 days after the data are finalized through DuPont's internal data quality control/quality assurance procedures.

d) Water Treatment Plan. If any additional private or public water systems covered by this Order contain C-8 at or above 0.50 ppb, DuPont shall, within 30 days of receipt of validated data, submit to EPA for approval, and to WVDHHR, WVDEP, OEPA, and ODH for review, a written Water Treatment Plan for each of these water systems. DuPont shall perform all monitoring using a reliable procedure published in the scientific literature by Moody,[11] Exygen Research,[12] or other equivalent publication. The Water Treatment Plan shall include:

   i. a written offer to install and provide for operation and maintenance of GAC Treatment (including a draft operation and maintenance agreement);

   ii. identification of anticipated necessary permits;

   iii. a schedule for design and implementation of the GAC Treatment system; and

   iv. identification of technical and other information needed from the owner or operator of the water source in order for DuPont to design and install the system.

e) Implementation of Water Treatment Plan. Following approval from EPA, DuPont shall implement the Water Treatment Plan for any additional water system whose owner or operator accepts DuPont's offer. DuPont shall act with all deliberate speed to design treatment, seek necessary regulatory permits, and install GAC Treatment or an alternative approved by EPA. If an owner or operator of a water system rejects DuPont's offer, either through express rejection or silence, DuPont shall inform EPA of this rejection and provide documentation.

f) DuPont's Operation and Maintenance Obligations. DuPont has or will execute operation and maintenance agreements ("O&M Agreements") with each water system owner or operator who has accepted the offer for treatment. DuPont will

11 *See* Moody, C.A. *et al., Anal. Chem.* vol. 73, pp. 2200-2206 (2001).
12 Risha, K. *et al.*, "Method for Trace Level Analysis of C-8, C-9, C-10, C-11, and C-13 Perfluorocarbon Carboxylic Acids in Water," *Anal. Chem.*, vol. 77, pp. 1503-1508 (2005).

provide for operation and maintenance of the GAC Treatment or an alternative approved by EPA consistent with the specific terms of these O&M Agreements until it demonstrates to the satisfaction of EPA that the water system's source water prior to treatment is less than 0.50 ppb of C-8 for four consecutive quarters, or the conditions of Paragraph 46 have been met.

g) Follow-up Monitoring. After GAC Treatment is terminated, DuPont shall monitor annually the source water at EPA-specified public and private water systems for a period of five (5) years.

h) Temporary Provision of Alternate Drinking Water. If, due to extenuating circumstances, as determined by EPA, DuPont is unable to meet any requirement of Paragraph 42(d), hereto, and EPA grants DuPont an extension pursuant to Paragraph 55 of this Order, DuPont shall provide a temporary alternate drinking water supply to users of any private water system and PWS where the level of C-8 are at or above 0.50 ppb within thirty (30) days from the initial date EPA determines the existence of extenuating circumstances. A "temporary alternate drinking water supply" shall mean: water from some other source, acceptable to EPA, that meets the water quality requirements of 40 C.F.R. Part 141 and has a level of C-8 less than 0.50 ppb; is in sufficient quantity for drinking and cooking; and is provided in a manner convenient to the users. DuPont shall continue to provide a temporary alternate drinking water supply for ninety (90) days or until it can fully implement the permanent remedies described *infra* pursuant to Paragraph 42 of this Order, whichever is sooner. After ninety (90) days of providing a temporary alternate drinking water supply, EPA may, within its discretion, continue to grant DuPont up to ninety (90) day extensions pursuant to Paragraph 55 of this Order. DuPont shall be responsible for all operation and maintenance costs of the temporary provision of alternate drinking water.

43. Progress Reports. DuPont shall submit Progress Reports as follows:

a) Beginning January 1, 2007, and quarterly thereafter, DuPont shall submit to EPA, WVDHHR, WVDEP, OEPA and ODH written reports summarizing all actions taken in response to Paragraph 42 herein ("Progress Reports"). This reporting requirement shall remain in effect until DuPont submits a written request to EPA to submit Progress Reports on an annual basis and EPA approves such a request. DuPont shall continue to submit Progress Reports until such time as EPA provides written notice that the reports are no longer necessary, or this Order is terminated.

b) All Progress Reports required by this Paragraph shall contain the following certification, which shall be signed by a responsible corporate officer:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

c) For purposes of this Order, a responsible corporate official shall be:

(A) a president, secretary, treasurer, or vice-president of DuPont in charge of a principal business function, or any other person who performs similar policy or decision-making functions for DuPont; or

(B) the manager of DuPont's Washington Works, West Virginia Facility, so long as authority to sign documents has been delegated in writing to the manager in accordance with corporate procedures.

## VI. GENERAL PROVISIONS

44. The Administrative Record to this Order is incorporated herein by reference.

45. Nothing in this Order is intended to supersede, impede, interfere with or otherwise affect the development of an MCL or other regulatory limit for C-8 that may be established by EPA through its regulatory processes in the future.

46. The Site-Specific Action Level identified in this Order for C-8 in drinking water is a temporary value that will be re-evaluated when EPA determines a reference dose under TSCA or establishes a drinking water standard for C-8, whichever comes first.

47. Notwithstanding any other provision of this Order, the EPA reserves the right to modify the Site-Specific Action Level identified in this Order if information previously unknown to EPA is received and EPA determines that this previously unknown information, together with any other relevant information, indicates that the Site-Specific Action Level may not be protective of human health, and DuPont reserves all rights and defenses should EPA take action under this Paragraph.

48. All submissions, including Progress Reports, required under this Order shall be submitted to the following addressees:

As to EPA:

Roger Reinhart
SDWA Branch
U.S. EPA Region III
1650 Arch Street (3WP22)
Philadelphia, PA 19103-2029

Charlene Denys
Ground Water and Drinking Water Branch
U.S. EPA Region V
77 West Jackson Boulevard (WG-15J)
Chicago, IL 60604

As to WVDHHR:

Walter Ivey, Director
Division of Environmental Engineering
Office of Environmental Health Services
Dept. of Health and Human Resources
Capital and Washington Streets
One Davis Square, Suite 200
Charleston, WV 25301-1798

As to WVDEP:

Chad Board
Groundwater Protection Section
Division of Water and Waste Management
W.Va. Dept. of Environmental Protection
601 57th Street, SE
Charleston, WV 25304

As to OEPA:

Mike Baker, Chief
Division of Drinking and Ground Waters
Ohio EPA
122 South Front Street
Columbus, OH 43214

As to ODH:

W. Gene Phillips, RS, Bureau Chief
Bureau of Environmental Health

Ohio Department of Health
246 North High Street
P.O. Box 118
Columbus, OH 43216

49. This Order shall apply to and be binding upon DuPont and its agents, successors and assigns.

50. Nothing in this Order shall be construed as prohibiting, altering or in any way eliminating the ability of EPA to seek any other remedies or sanctions available by virtue of DuPont's violations of this Order or of the statutes and regulations upon which this Order is based or for DuPont's violation of any applicable provision of law.

51. This Order shall not relieve DuPont of its obligation to comply with all applicable provisions of federal, state or local law, nor shall it be construed to be a ruling on, or determination of, any issue related to any federal, state or local permit.

52. Nothing in this Order is intended to nor shall be construed to operate in any way to resolve any criminal liability of DuPont. Compliance with this Order shall not be a defense to any actions subsequently commenced for any violation of federal laws and regulations administered by EPA, and it is the responsibility of DuPont to comply with such laws and regulations. EPA reserves the right to undertake action against any person, including DuPont, in response to any condition which EPA determines may present an imminent and substantial endangerment to the public health, public welfare or the environment.

53. The undersigned representative of DuPont certifies that he or she is fully authorized by DuPont to enter into the terms and conditions of this Order and to execute and legally bind DuPont to it.

54. Pursuant to Section 1431(b) of the SDWA, 42 U.S.C. § 300i(b), and the Adjustment of Civil Monetary Penalties for Inflation, 40 C.F.R. Part 19, as revised (64 Fed. Reg. 7117 (Feb. 13, 2004)), the violation of any term of this Order, or failure or refusal to comply with this Order, may subject DuPont to a civil penalty not to exceed $16,500 for each day in which such violation occurs or failure to comply continues.

55. When DuPont knows or should have known, by the exercise of due diligence, of an event that might delay completion of any requirement of this Order, DuPont shall provide notice to EPA, in writing, within two (2) business days after DuPont first knew, or in the exercise of due diligence, should have known, of such event. The notice shall describe in detail the basis for the delay, including whether it is a *force majeure* event, and describe the length of, precise cause(s) of, and measures taken or to be taken to prevent or minimize such delay. If EPA agrees that such event constitutes *force majeure*, EPA shall extend the time for performance of such requirement, in writing, to compensate for the delay caused by the *force majeure* event. DuPont's failure to notify in writing in accordance with this Paragraph shall render this Paragraph void and of no

effect concerning such event. For purposes of this Order, *force majeure* is defined as an event arising from causes beyond the control of DuPont, and any entity controlled by DuPont, which delays or prevents the performance of any obligation under this Order. Unanticipated or increased costs or expenses associated with implementation of this Order and changed financial circumstances shall not, in any event, be considered *force majeure* events. In addition, failure to apply for a required permit or approval or to provide in a timely manner all information required to obtain a permit or approval that is necessary to meet the requirements of this Order, or to obtain or approve contracts, shall not, in any event, constitute *force majeure* events.

56. This Consent Order may be executed in any number of counterpart originals, each of which shall be deemed to constitute an original agreement, and all of which shall constitute one agreement. The execution of one counterpart by any party shall have the same force and effect as if that party had signed all other counterparts.

57. All of the terms and conditions of this Order together comprise one agreement, and each of the terms and conditions is in consideration of all of the other terms and conditions. In the event that this Order is not executed by all of the signatories in identical form, or is not approved in such identical form by the Regional Administrators, then the entire Order shall be null and void.

58. The effective date of this Order is the date on which, after approval by the Regional Administrators, this Order is filed with the Regional Hearing Clerks of both Region III and Region V; if not on the same day.

59. This Order shall remain in effect until DuPont fulfills its obligations pursuant to Paragraphs 42 and 43 herein, submits a written request to EPA to terminate this Order, and EPA approves such termination request.

60. This Order constitutes final agency action.

SO ORDERED:

Donald S. Welsh

Date: _____

Donald S. Welsh
Regional Administrator
U.S. Environmental Protection Agency,
Region III

_____

Date: _____

Mary A. Gade
Regional Administrator
U.S. Environmental Protection Agency,
Region V

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60. This Order constitutes final agency action.

SO ORDERED:

_____ Date: _____

Donald S. Welsh
Regional Administrator
U.S. Environmental Protection Agency,
Region III

_____ Date: 11/20/06

Mary A. Gade
Regional Administrator
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AGREED TO:

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# Appendix A

Summary of Selected Animal Studies:

Rodent studies show that C-8 affects liver function.[1] In a two-year study on rats, high levels of C-8 caused benign (non-cancerous) tumors of the liver, testes, and pancreas.[2] In a two-generation study of reproduction, rats subjected to high doses of C-8 showed delayed sexual maturation, and pups showed decreased weight and reduced survival.[3] A developmental study of mice indicated C-8 toxicity in the form of early pregnancy loss, reduced survival of newborn mice, delays in general growth and development, and some specific changes in sexual maturation.[4] Exposure to C-8 did not cause birth defects when tested in rats and rabbits.[5] A six-month study of the effects of C-8 on one species of monkey showed a relatively mild effect (liver weight increase) at low and medium doses, but the effects became severe (dramatic weight loss and one death) at the high dose which was about 2-3 times the medium dose.[6] Different species can react differently to C-8 because of differences in physiology.

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1 Goldenthal, E.I., "Final Report: Ninety Day Subacute Rat Toxicity Study on Fluorad Fluorochemical FC-143," International Research and Development Corporation, Study No. 137-089, 3M Reference No. T-3141, U.S. EPA AR 226-0441 (Nov. 6, 1978).

2 Biegel, L.B. *et al.*, "Mechanisms of extrahepatic tumor induction by peroxisome proliferators in male CD rats," *Toxicol. Sci.*, vol. 60, no. 1, pp. 44-55 (2001).

3 Butenhoff, J.L.; Kennedy, G.L.; Frame, S.R.; O'Connor, J.C.; York, R.G., "The reproductive toxicology of ammonium perfluorooctanoate (APFO) in the rat," *Toxicology*, 196:95-116 (2004).

4 Lau, C.; Thibodeaux, J. R.; Hanson, R. G.; Narotsky, M. G.; Rogers, J. M.; Lindstrom, A. B. & Strynar, M. J., "Effects of perfluorooctanoic acid exposure during pregnancy in the mouse," *Toxicol. Sci.*, vol. 90, no. 2, pp. 510-518 (2006).

5 Kennedy, G.L. *et. al.*, "The Toxicology of Perfluorooctanoate," *Crit. Rev. Toxicol.* vol. 34, no. 4, pp. 351-384 (2004).

6 Butenhoff, J.; Costa, G.; Elcombe, C.; Farrar, D.; Hansen, K.; Iwai, H.; Jung, R.; Kennedy, G., Jr.; Lieder, P.; Olsen, G. & Thomford, P., "Toxicity of ammonium perfluorooctanoate in male cynomolgus monkeys after oral dosing for 6 months," *Toxicol. Sci.*, vol. 69, no. 1, pp. 244-257 (2002).

# Appendix B

Selected Human Studies and References on Perfluorooctanoate:


1) Emmett, E.A.; Zhang, H.; Shofer, F.S.; Freeman, D.; Rodway, N.V.; Desai, C. & Shaw, L.M., "Community exposure to perfluorooctanoate: relationships between serum levels and certain health parameters," *J. Occup. Environ. Med.*, vol. 48, no. 8, pp. 771-779 (2006).

2) Emmett, E.A.; Shofer, F.S.; Zhang, H.; Freeman, D.; Desai, C. & Shaw, L.M., "Community exposure to perfluorooctanoate: relationships between serum concentrations and exposure sources," *J. Occup. Environ. Med.*, vol. 48, no. 8, pp. 759-770 (2006).

3) Leonard, R.C., "Ammonium Perfluorooctanoate: Phase II Retrospective Cohort Mortality Analyses Related to a Serum Biomarker of Exposure in a Polymer Production Plant," DuPont Haskell Laboratory Report (submitted to USEPA Administrative Record 226 (2006).

4) Olsen, G.W. & Zobel, L.R., "An analysis of the 2000 fluorochemical (perfluorooctanoate, PFOA) Medical Surveillance Program at 3M Company's Antwerp (Belgium), Cottage Grove (Minnesota), and Decatur (Alabama) facilities," 3M Medical Department, *Epidemiology* 220-3W-05 (2006).

5) Leonard, R.C., "Ammonium Perfluorooctanoate: Cross-Sectional Surveillance of Clinical Measures of General Health Status Related to a Serum Biomarker of Exposure and Retrospective Cohort Analyses in a Polymer Production Plant," USEPA AR226-1924 (Jan. 10, 2005).

6) Olsen, G.W.; Church, T.R.; Hansen, K.J.; Burris, J.M.; Butenhoff, J.L.; Mandel, J.H. & Zobel, L.R., "Quantitative evaluation of perfluorooctanesulfonate (PFOS) and other fluorochemicals in the serum of children," *J. Children's Health*, vol. 2, pp. 1-24 (2004).

7) Olsen, G.W.; Church, T.R.; Larson, E.B.; van Belle, G.; Lundberg, J.K.; Burris, J.M.; Mandel, J.H. & Zobel, L.R. "Serum concentrations of perfluorooctanesulfonate (PFOS) and other fluorochemicals in an elderly population from Seattle, Washington." *Chemosphere*, vol. 54, pp.1599-1611 (2004).

8) Olsen, G.W.; Burris, J.M.; Burlew, M.M. & Mandel, J.H., "Epidemiological assessment of worker serum perfluorooctanesulfonate (PFOS) and perfluorooctanoate (PFOA) concentrations and medical surveillance examinations," *J. Occup. Environ. Med.*, vol. 45, pp. 260-270 (2003).

9) Olsen, G.W.; Church, T.; Miller, J.P.; Hansen, K.J.; Lundberg, J.K.; Armitage, J.;

Herron, R.; Medhdizdehkashi, Z.; Nobiletti, J.; O'Neill, M.; Mandel, J.H. & Zobel, L.R., "Perfluorooctanesulfoanate (PFOS) and other fluorochemicals in the serum of American Red Cross adult blood donors," *Environ. Health Perspec.*, vol. 111, pp. 1892-1901 (2003).

10) Alexander, B., "Mortality Study of Workers Employed at the 3M Cottage Grove facility," Final Report. Div. Of Envtl. & Occup. Health, School of Public Health, University of Minnesota, U.S. EPA Public Docket AR-226-1030a018, Washington, D.C. (April 26, 2001).

11) Olsen, G.W.; Burlew, M.M.; Burris, J.M.; & Mandel, J.H., "Final report: A longitudinal analysis of serum perfluorooctanesulfate (PFOS) and perfluorooctanoate (PFOA) levels in relation to lipid and hepatic clinical chemistry test results from male employee participants of the 1994/95, 1997, and 2000 fluorochemical medical surveillance program," 3M Medical Department, *Epidemiology* 220-3W-05 (2001).

12) Olsen, G.W.; Burlew, M.M.; Hocking, B.B.; Skratt, J.C.; Burris, J.M. & Mandel, J.H., "An epidemiologic analysis of episodes of care of 3M Decatur chemical and film plant employees. 1993-1998," (2001).

13) Olsen, G.W.; Burris, J.M.; Burlew, M.M. & Mandel, J.H., "Final Report: A cross-sectional analysis of serum perfluorooctanesulfonate (PFOS) and perfluorooctanoate (PFOA) in relation to clinical chemistry, thyroid hormone, hematology, and urinalysis results from male and female employee participants of the 2000 Antwerp and Decatur fluorochemical medical surveillance program," 3M Medical Department, *Epidemiology* 220-3W-05 (2001).

14) Olsen, G.W.; Burris, J.M.; Burlew, M.M. & Mandel, J.H., "Plasma cholecystokinin and hepatic enzymes, cholesterol and lipoproteins in ammonium perfluorooctanoate production workers," *Drug Chem. Toxicol.* 23(4): 603-620 (2000).

15) Olsen, G.W.; Burris, J.M.; Burlew, M.M. & Mandel, J.H, "An epidemiologic investigation of reproductive hormones in men with occupational exposure to perfluorooctanoic acid," *J. Occup. Envtl. Med.* 40(7) 614-622 (1998).

16) Biegel, L.B., Senior Research Toxicologist, DuPont, "Hazard characterization for human health C8 exposure CAS registry no. 3825-26-1" (1997).

17) Gilliland, F.D. & Mandel, J.S., "Serum perfluorooctanoic acid and hepatic enzymes, lipoproteins, and cholesterol: a study of occupationally exposed men," *Am. J. Ind. Med.* 29(5): 560-568 (1996).

18) Gilliland, F.D. & Mandel, J.S., "Mortality among employees of a perfluorooctanoic acid production plant," *J. Occup. Med* 35(9): 950-954 (1993).

19) Fayerweather, W.E., "Liver study of Washington Works employees exposed to C8: results of blood biochemistry testing" (1981).

20) DuPont, Memo from Fayerweather (epidemiologist) to Power: (medical superintendent), "Status report on Washington Works liver function survey and coronary heart disease mortality study" (August 28, 1979).

21) DuPont, "Lab test summaries for DuPont PFOA workers" (Sept. 20, 1978).

# Appendix C

Summary of Selected Human Studies:

Studies by the Centers for Disease Control and other researchers indicate that the median human blood serum concentration of C-8 in the general population is approximately 5.0 ppb.[1, 2, 3, 4] Exposures reported in occupational studies are significantly higher and generally average 500 – 7000 ppb.[5, 6, 7, 8, 9, 10] One worker health study initially observed increased mortality rates for prostate cancer.[11] A follow-up to this study discounted the prostate cancer observation but reported a modest increase in cerebrovascular disease (stroke).[12] A more recent worker study in a different company did not show an increase in mortality associated with C-8 exposure, nor did it confirm the findings of increased prostate cancer or cerebrovascular disease.[13] This study showed a statistically significant increase in ischemic heart disease mortality in one analysis of many, but this was an inconsistent finding across the three different models used. A cross-

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1 Calafat, A. M.; Kuklenyik, Z.; Caudill, S. P.; Reidy, J. A. & Needham, L. L., "Perfluorochemicals in pooled serum samples from United States residents in 2001 and 2002," *Envtl. Sci. Technol.*, vol. 40, no. 7, pp. 2128-2134 (2006).
2 Olsen, G.W.; Church, T.; Miller, J.P.; Hansen, K.J.; Lundberg, J.K.; Armitage, J.; Herron, R.; Medhdizdehkashi, Z.; Nobiletti, J.; O'Neill, M.; Mandel, J.H. & Zobel, L.R., "Perfluorooctanesulfoanate (PFOS) and other fluorochemicals in the serum of American Red Cross adult blood donors," *Environ. Health Perspec.*, vol. 111, pp. 1892-1901 (2003).
3 Olsen, G.W.; Church, T.R.; Larson, E.B.; van Belle, G.; Lundberg, J.K.; Burris, J.M.; Mandel, J.H. & Zobel, L.R. "Serum concentrations of perfluorooctanesulfonate (PFOS) and other fluorochemicals in an elderly population from Seattle, Washington." *Chemosphere*, vol. 54, pp.1599-1611 (2004).
4 Olsen, G.W.; Church, T.R.; Hansen, K.J.; Burris, J.M.; Butenhoff, J.L.; Mandel, J.H. & Zobel, L.R., "Quantitative evaluation of perfluorooctanesulfonate (PFOS) and other fluorochemicals in the serum of children," *J. Children's Health*, vol. 2, pp. 1-24 (2004).
5 Gilliland, F.D. & Mandel, J.S., "Mortality among employees of a perfluorooctanoic acid production plant," *J. Occup. Med* 35(9): 950-954 (1993).
6 Alexander, B., "Mortality Study of Workers Employed at the 3M Cottage Grove facility," Final Report. Div. Of Envtl. & Occup. Health, School of Public Health, University of Minnesota, U.S. EPA Public Docket AR-226-1030a018, Washington, D.C. (April 26, 2001).
7 Olsen, G.W.; Burlew, M.M.; Burris, J.M.; & Mandel, J.H., "Final report: A longitudinal analysis of serum perfluorooctanesulfate (PFOS) and perfluorooctanoate (PFOA) levels in relation to lipid and hepatic clinical chemistry test results from male employee participants of the 1994/95, 1997, and 2000 fluorochemical medical surveillance program," 3M Medical Department, *Epidemiology* 220-3W-05 (2001).
8 Olsen, G.W.; Burris, J.M.; Burlew, M.M. & Mandel, J.H., "Epidemiological assessment of worker serum perfluorooctanesulfonate (PFOS) and perfluorooctanoate (PFOA) concentrations and medical surveillance examinations," *J. Occup. Environ. Med.*, vol. 45, pp. 260-270 (2003).
9 Leonard, R.C., "Ammonium Perfluorooctanoate: Phase II Retrospective Cohort Mortality Analyses Related to a Serum Biomarker of Exposure in a Polymer Production Plant," DuPont Haskell Laboratory Report (submitted to USEPA Administrative Record 226 (2006).
10 Leonard, R.C., "Ammonium Perfluorooctanoate: Cross-Sectional Surveillance of Clinical Measures of General Health Status Related to a Serum Biomarker of Exposure and Retrospective Cohort Analyses in a Polymer Production Plant," USEPA AR226-1924 (Jan. 10, 2005).
11 Gilliland, F.D. & Mandel, J.S. (1993).
12 Alexander, B. (2001).
13 Leonard, R.C. (2006).

sectional worker study reported in 2005 showed slight elevations of cholesterol and triglycerides in blood in workers at the highest levels of C-8 exposure.[14] However, the relevance of this association remains uncertain.

A study conducted by the University of Pennsylvania in people who use the Little Hocking public water system showed blood serum levels ranging from 7 – 4520 ppb in study participants.[15] This study observed no health effects associated with C-8 for the indicators studied in this community; however, the study was somewhat limited in size and scope and is therefore not definitive.[16]

14 Leonard, R.C. (2005).

15 Emmett, E.A.; Zhang, H.; Shofer, F.S.; Freeman, D.; Rodway, N.V.; Desai, C. & Shaw, L.M., "Community exposure to perfluorooctanoate: relationships between serum levels and certain health parameters," *J. Occup. Environ. Med.*, vol. 48, no. 8, pp. 771-779 (2006).

16 Emmett, E.A.; Shofer, F.S.; Zhang, H.; Freeman, D.; Desai, C. & Shaw, L.M., "Community exposure to perfluorooctanoate: relationships between serum concentrations and exposure sources," *J. Occup. Environ. Med.*, vol. 48, no. 8, pp. 759-770 (2006).