UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

IN THE MATTER OF: E.I. du Pont de Nemours and Company Respondent Washington Works Facility Route 892 South DuPont Road Washington, Wood County, WV	)	Docket No. TSCA-HQ-2004-0016 Docket No. RCRA-HQ-2004-0016 ANSWER AND REQUEST FOR HEARING

E. I. du Pont de Nemours and Company ("DuPont" or "the company") denies that it committed any of the violations alleged in the Complaint and requests a hearing before an administrative law judge to contest the allegations in the Complaint.

SUMMARY OF DUPONT'S ANSWER

DuPont fully and promptly reported to EPA all of the information it was supposed to report regarding perfluorooctanoic acid ("PFOA"). The small amounts of PFOA that DuPont discovered in a blood sample and in drinking water did not suggest that there was any risk to human health, let alone the sort of "substantial risk" that is necessary to trigger reporting requirements.

EPA now claims that DuPont should have reported to EPA the results of a single blood sample taken in 1981 that suggested that a trace amount of PFOA could cross the human placenta if it is present in the maternal blood. However, EPA's own scientists already knew by 1981 that a chemical like PFOA would travel through the placenta, and in 1982 DuPont gave EPA the results of a study confirming that PFOA would cross the placenta. More importantly, all of the scientific evidence showed then, and new scientific evidence confirms now, that the

trace amount of PFOA found to have crossed the placenta would pose no risk to human health. For all these reasons, the law did not require DuPont to report the blood sample result to EPA.

EPA's claim that DuPont should have reported certain water samples also is directly contrary to EPA's own scientific conclusions. A multi-agency panel of scientists, including EPA experts, has concluded that drinking water containing up to 150 parts per billion of PFOA poses "no risk of deleterious effects" to human health. The water sampling information that DuPont had – all of which found less than 4 parts per billion of PFOA – showed that the amount of PFOA in the drinking water was substantially less than the amount that EPA scientists have determined is safe. While the level of PFOA in some of the samples was slightly higher than DuPont's voluntary internal guideline for community exposure, DuPont had set that voluntary guideline with an extra safety factor so that it was approximately 3,000 times safer than the lowest no effect level seen in animal studies at that time. In addition, DuPont had already told EPA that traces of PFOA were present in groundwater and drinking water around the DuPont facility.

EPA's final claim is that DuPont failed to provide the results of the single blood sample in response to an EPA request for "toxicological information" on PFOA – a request made after DuPont reported that PFOA was present in some of DuPont's waste disposal units. However, "toxicological information" is information that shows whether a chemical has a toxic effect on humans or animals, not whether there has been exposure. DuPont responded completely and accurately to EPA's request, providing the results of 22 toxicity tests on PFOA. DuPont did not provide the blood sample result, or any other blood sample result, because blood sample results only show the presence of PFOA and do not show PFOA to have any toxic effect. Moreover, the information DuPont provided exceeded its obligations to report under the applicable statute.

Count I

In Count I of its Complaint, EPA's Office of Regulatory Enforcement ("ORE") alleges that DuPont violated Section 8(e) of the Toxic Substances Control Act ("TSCA") because in 1981 the company did not report to EPA the results of a single blood sample that suggested that PFOA can cross the human placenta if it is present in the maternal blood.

The blood sample result is exposure information only. The TSCA § 8(e) requirement to report information is triggered only when the information reasonably supports the conclusion that exposure to a chemical actually presents a "substantial risk to human health." Based on the testing that has been done, prenatal exposure to PFOA does not cause such a risk. Thus, there was -- and is -- no "substantial risk" to trigger reporting requirements. The presence of a chemical, in the absence of an adverse effect, does not trigger reporting requirements.

TSCA § 8(e) also does not require a company to report information if EPA is already on notice of the information. ORE essentially claims that, without this one 1981 blood sample result, EPA was not on notice that this chemical could cross the human placenta.

For decades, however, and even before DuPont received that sample result, developmental toxicologists have known that virtually all chemicals the size of PFOA will pass through the human placenta. Moreover, in March 1982, DuPont reported to EPA the results of a designed, scientific study using radioactively labeled PFOA in rats, which showed that PFOA crosses the rat placenta. More than eight years ago, two of EPA's most senior developmental toxicologists authored a text stating that the differences between rodent and human placentas do not materially affect which chemicals will cross the placenta.

In short, as supported by the science, there is no known adverse effect from exposure at this trace level. As such, there was -- and is -- no substantial risk information to report. In addition, in 1981, when the blood sample was taken, EPA was already on notice that PFOA could cross the human placenta, thereby making the information not subject to reporting requirements.

Count II

The second count in ORE's complaint suggests that DuPont should be penalized for taking precautions in excess of regulatory requirements. In the early 1990s, before EPA ever set any standard for permissible levels of PFOA in drinking water, DuPont undertook a program of reducing its plant emissions so as to reach the company's voluntary goal -- seeking to reach a PFOA level in drinking water so low that there would be a 3000-fold margin of safety. Seizing on DuPont's voluntary guideline, ORE claims that DuPont should have reported water sample results that reflect PFOA concentrations above DuPont's self-imposed guideline. ORE essentially asserts that a sample that is only slightly above the self-imposed 3000-fold margin of safety amounts to a "substantial risk" of harm necessitating a TSCA § 8(e) report. Thus, ORE seeks to punish DuPont for establishing a level of safety that exceeds EPA's requirements and sends a message to the regulated community that it should never set a voluntary goal for an unregulated chemical for fear that EPA will label any exceedance of that goal a "substantial risk" that must be reported to the Agency.

Specifically, the second count in ORE's Complaint contends that DuPont should be penalized because the company did not report to EPA the results of drinking water samples containing residues of between 0.8 and 3.9 ppb PFOA that were taken in the area around DuPont's facility in the 1980s and early 1990s. ORE contends that those traces somehow

supported a conclusion of a "substantial risk," thereby triggering reporting obligations under TSCA § 8(e).

ORE's claim that 0.8 to 3.9 ppb PFOA in drinking water presents a "substantial risk" has been flatly contradicted by a multi-agency panel of scientists, which included three EPA representatives, and by two EPA regional offices. This panel of ten experts, including three EPA scientists and representatives from two West Virginia regulatory agencies, used standard, conservative risk assessment methods developed by EPA Regions IX and III to set a safe level in drinking water. The panel concluded in its final report that if citizens in the same area were exposed for their entire lifetimes to levels of up to 150 ppb of PFOA in the same drinking water, "no risk of deleterious effects is expected." For the past two years since the panel of scientists issued its report, EPA's Region III and Region V Offices have used this 150 ppb standard under a Safe Drinking Water Act ("SDWA") consent order with DuPont covering the same drinking water supplies.

EPA's own guidance on TSCA § 8(e) reporting states that when EPA sets such an acceptable level in drinking water, a company that detects the chemical in drinking water at concentrations below that acceptable level does not have to submit a report under TSCA § 8(e). The levels that ORE accuses DuPont of "failing" to report - 0.8 to 3.9 ppb – are 38 to 185 times lower than the 150 ppb level for which the multi-agency panel of scientists found "no risk of deleterious effects" is expected.

ORE has tried to avoid the EPA-sanctioned 150 ppb standard and the Agency's own § 8(e) reporting guidance by seizing on DuPont's voluntary internal guideline of 1.0 ppb in drinking water. ORE points to this voluntary, internal DuPont community exposure guideline,

which DuPont proposed in 1991, and leaps to the conclusion that any level above this presents a "substantial risk." ORE, however, appears to have misinterpreted DuPont's guideline.

The community exposure guideline is not a risk benchmark above which a risk exists. Rather, it is a demonstrably safe level that DuPont aspires to attain through engineering controls on releases. DuPont sets these guidelines very conservatively as part of DuPont's goal of minimizing the exposure to the community that surrounds a DuPont facility. It is incorrect to conclude that a level just above the guideline presents any risk to humans – much less the "substantial risk" necessary to trigger reporting requirements -- because DuPont set the community exposure guideline for PFOA at approximately 3000 times lower than the lowest "no effects" level that had been seen in any animal toxicity study as of 1991. Thus, ORE's contention that DuPont should have concluded that a "substantial risk" exists if residues in some of the drinking water samples exceeded the guideline by less than 3 ppb has no basis in science or fact.

In short, considering the concentrations at issue are well below the 150 ppb level set by the multi-agency panel of scientists and well within the safety margin incorporated into DuPont's voluntary guideline, there was -- and is -- no substantial risk information to report.

Count III

In Count III, ORE asserts jurisdiction that EPA does not possess under the Resource Conservation and Recovery Act ("RCRA") over supposed releases of PFOA from the Washington Works facility. Under RCRA, any permit issued after 1984 for a hazardous waste treatment, storage or disposal facility must require corrective action for releases of "hazardous waste or constituents" from any solid waste management unit ("SWMU") at that facility. EPA

regulations specify what wastes are "hazardous wastes" and list all of the "hazardous constituents" in such wastes. PFOA, however, is not a hazardous waste and does not appear on EPA's list of hazardous constituents.

DuPont's corrective action permit was issued in 1989 and required DuPont to investigate and, potentially, remediate releases of "hazardous wastes" and "hazardous constituents" from six specified SWMUs at the facility. The permit specifically incorporates EPA's RCRA regulations by reference.

ORE does not – and could not – allege that PFOA is regulated as a "hazardous waste" under RCRA or that PFOA is among the "hazardous constituents" whose release can trigger EPA authority to order corrective action. As a matter of law, EPA has no jurisdiction under RCRA to order DuPont to evaluate releases of PFOA from the facility, or to require DuPont to provide information regarding PFOA. As a result, Count III fails to state any claim upon which EPA would be entitled to recover any penalty from DuPont.

Even if it is assumed for the sake of argument that DuPont had some obligation under RCRA to evaluate (or provide information about) compounds that are not hazardous wastes or hazardous constituents, DuPont reported the relevant toxicological information. In Count III of the Complaint, however, ORE seeks to redefine the word "toxicological," give it a new meaning found nowhere in a statute, regulation, or EPA guidance document, then punish DuPont for not complying back in 1997 with ORE's new 2004 definition of the word.

In 1992, as part of a DuPont report to the EPA Region III RCRA office filed pursuant to the 1989 RCRA permit, DuPont advised Region III that PFOA had been detected in groundwater near three solid waste management units at the Washington Works facility. Five years later,

EPA Region III responded, noting that there were no standards for PFOA in drinking water, and in a single sentence, requested: "Please provide known toxicological information."

DuPont responded promptly with what it understood Region III was requesting -- a summary of the results then available from the acute, chronic, developmental, and genetic toxicity studies that had been run on PFOA or its ammonium salt, as well as reporting on the toxicity to aquatic organisms from such toxicology studies. By its plain meaning, "toxicological information" is information on the toxicological properties of the chemical, based on toxicological studies that have been run. That is, it is information on the types of toxic effects that the chemical can cause and the doses at which the chemical can cause such effects. Such toxicological information is reviewed as a first, threshold step when setting an acceptable level in ground water. DuPont reasonably assumed that when Region III requested "toxicological" information, the word carried its ordinary meaning.

EPA Region III's conduct demonstrates that EPA concurred with DuPont's understanding of the phrase "toxicological information" and applied its plain meaning. For seven years, Region III never indicated that DuPont's submission of this toxicological information was insufficient, or that Region III had wanted additional information that extended beyond the plain meaning of the word "toxicological." Now, however, ORE is attempting to redefine the plain meaning of "toxicological" to include the result from the umbilical cord blood sample taken in 1981, which shows only the presence of PFOA; it does not show any toxic effect and was not part of any toxicology study. ORE's Complaint does not cite any prior communication suggesting that EPA Region III interpreted "toxicological information" to be anything other than what DuPont submitted. ORE, however, contends that it can apply its newly-devised 2004 definition retroactively to 1997 in order to penalize DuPont for not

discussing the 1981 blood sample along with the discussion of toxicological effects. This sort of retroactive application of a new, totally unexpected and ad hoc redefinition of a common word in order to penalize a company is arbitrary and is offensive to standards of fundamental fairness.

STATEMENT OF FACTS REGARDING COUNT I

For more than 50 years, at DuPont's facility in Parkersburg, West Virginia known as "Washington Works," DuPont has used as a processing aid ammonium perfluorooctanoate ("APFO"), which is sometimes referred to as "C-8." When in contact with water, APFO disassociates to: (1) the perfluorooctanoic acid anion ("PFOA"); and (2) the ammonium cation. APFO and PFOA are two separate and distinct chemicals, and EPA treats them as such for regulatory purposes under TSCA. For example, each of the two chemicals has its own separate listing on the Chemical Substance Inventory that EPA maintains under TSCA § 8(b). APFO and PFOA are identified by different Chemical Abstract Service Registry Numbers, namely 3825-26-1 for APFO and 335-67-1 for PFOA. DuPont has never manufactured, processed, or distributed PFOA at the Washington Works facility. Rather, DuPont uses APFO there as a processing aid and to the extent that any residual chemical from the processing gets distributed, presumably it is APFO, not PFOA.[1] When analytical chemists test blood or environmental media for APFO, they generally estimate the level of APFO present by testing for the concentration of the anion, PFOA. Therefore, tests results may purport to measure levels of APFO, C-8 or PFOA in blood or water, but actually measure only PFOA.

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[1] DuPont now manufactures PFOA at a different facility, but did not start manufacturing and processing PFOA until sometime after March 6, 2001. Such manufacture is irrelevant to any issue raised by the Complaint, because ORE has acknowledged that as of March 6, 2001, EPA had received the information at issue in the Complaint and DuPont no longer had any reporting obligation.

The Single 1981 Blood Sample

In March 1981, the 3M Company ("3M"), which at the time manufactured APFO and was DuPont's supplier, notified DuPont (and EPA) that in preparation for a full-scale teratology study, 3M had run an oral rangefinder study in rats, designed to determine the maximum dosage rate that pregnant rat females could tolerate. During that rangefinder study, researchers observed what appeared to be treatment-related damage to the eye lenses of some rat pups.[2] Within a few months, however, the testing laboratory, 3M, and DuPont, as well as reviewers from the National Institute of Neurological Diseases and Blindness and the National Institutes of Health, all concluded that APFO did not cause this lens damage. Rather, they recognized that the damage to the pups' eye lens tissue occurred during the process of sectioning (cutting) the eye lens tissue for detailed observation. The EPA team of scientists studying APFO has concurred with these other researchers that the eye lens damage was caused by the tissue sectioning technique.[3] Subsequent studies that used proper sectioning techniques confirmed that APFO does not cause eye lens damage in fetal animals.

When DuPont first received word of the purported eye lens damage in 3M's preliminary study DuPont took a number of precautions to protect its workers pending further review and additional studies on APFO and PFOA.[4] As part of that assessment, DuPont conducted a

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[2] *See* Gortner, EG (1981) Oral Rangefinder Study of T-2998 CoC in Pregnant Rats. Riker Laboratories, Inc. Experiment No. 0680RR0018, February 1981.

[3] *See*, EPA, Office of Pollution Prevention and Toxics Risk Assessment Division Revised Draft Hazard Assessment of Perfluorooctanoic Acid and Its Salts (November 4, 2002), page 61. *See also,* EPA Preliminary Risk Assessment of the Developmental Toxicity Associated with Exposure to Perfluorooctanoic Acid and its Salts (April 10, 2003), Page 28 ("... the fetal lens finding . . . was later determined to be an artifact of the free-hand sectioning technique and therefore was not considered to be treatment-related.")

[4] DuPont's precautions were reported in the Wall Street Journal and New York Times.

voluntary blood testing program for employees at the plant site. In 1981, approximately 400 employees volunteered to have their blood tested for the presence of PFOA.

Among the 50 female employees who participated in the blood testing program in 1981 were eight women who worked or had worked in the fluoropolymer area at the plant and who either were pregnant or had given birth within the previous two years. It appears that a DuPont employee recorded the blood testing results and other information about these eight women on a single separate page. This 1981 one-page document also suggests that one of the women gave birth shortly after the initial blood tests and that blood taken from the umbilical cord was analyzed for PFOA concentration. The sample result suggested that PFOA might be present, although at a concentration level lower than the level in the mother's blood.

The Placental Transfer Study

In 1981, after receiving the results of the 3M study, DuPont scientists at the DuPont Haskell Laboratory for Toxicology and Industrial Medicine in Wilmington, Delaware began studies to assess whether PFOA could cause developmental toxicity. As part of this program, they conducted a study on radioactively-labeled PFOA that confirmed that PFOA would cross the rat placenta. DuPont scientists met with EPA scientists on March 12, 1982, and four days later a DuPont scientist wrote to one of the EPA scientists at the meeting, providing EPA with the results of the study confirming that PFOA transfers across the rat placenta.

The study showing that PFOA passes the placenta was unremarkable because, by 1981, developmental toxicologists were well aware that the placenta does not present a barrier to chemicals passing from the maternal blood to the fetus. The 1980 edition of Casarett and Doull's Toxicology states:

> [I]t is generally assumed that a placental barrier protects the embryo and/or fetus against most levels of chemical exposure. On the contrary, the placenta, which performs admirably in maintaining the growing embryo, does not selectively protect the intrauterine organism from harmful agents administered during pregnancy. The placental barrier has been found to act like a sieve. Except for compounds of large molecular weight, and those with strong electronegative or electropositive charges (heparin and most neuromuscular blocking agents), almost all pharmacologic substances and other chemicals can and do pass from the maternal to fetal bloodstream. Generally, substances with a molecular weight of less than 600 pass the placental barrier.

Casarett and Doull's Toxicology -- The Basic Science of Poisons, Second Edition, Macmillan Publishing Co., Inc., New York (1980), at page 160 (emphasis added). PFOA has no strong electronegative or electropositive charge, and its molecular weight is 414. Therefore, it is not among the few rare types of molecules that would not pass through the placenta and evidence that it crosses the placenta would not be new information.

EPA's Reaction and Subsequent Studies

Not surprisingly, EPA scientists also treated as unremarkable this DuPont study that simply confirmed that, like most chemicals, PFOA crosses the placenta. EPA did not mention this study in either its 103-page Revised Draft Hazard Assessment for Perfluorooctanic Acid and Its Salts, issued November 4, 2002, or in the EPA's 61-page Preliminary Risk Assessment of the Developmental Toxicity Associated with Exposure to Perfluorooctanic Acid and Its Salts, issued April 10, 2003. Nor is the DuPont placental transfer study cited anywhere among the over 200 papers that the EPA authors say that they reviewed in drafting these risk assessments.

During the 1980s, 3M, DuPont and EPA continued to study PFOA and to examine data to determine whether the chemical had any potential to cause birth defects. In 1981 and 1982, four

full-scale teratology studies using proper tissue sectioning and analysis techniques confirmed that PFOA did not cause eye lens defects, and in fact found no evidence that PFOA created any teratogenic effects in rats or rabbits.[5] These studies, of course, all were run with the assumption that PFOA transfers from the mother animals to the developing young. These four studies also showed that prenatal exposure to PFOA causes no developmental effects, except at dose levels so high that some of the mother animals die from the exposure. Because they occur only at levels at which some of the mother animals are dying from the dose and others are showing serious effects, EPA scientists have questioned whether those "effects" have any significance. Preliminary Risk Assessment of the Developmental Toxicity Associated With Exposure to Perfluorooctanoic Acid and Its Salts, April 10, 2003, Pages 28-30.[6]

Developmental toxicologists' conclusion that the placenta is a "sieve" has never changed and in fact has been repeatedly re-affirmed. In 1996, two senior EPA toxicologists wrote:

> It is important to note that virtually any substance present in the maternal plasma is transported to some extent by the placenta. . . . Weak acids appear to be transferred rapidly across the placenta. . . . (Nau and Scott, 1986).

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[5] Gortner, EG. (1981) Oral teratology study of T-3141CoC in rats. Safety Evaluation Laboratory and Riker Laboratories, Inc. Experiment Number: 0681TR0110, December 1981; Gortner, EG. (1982) Oral teratology study of T-3141CoC in rabbits. Safety Evaluation Laboratory and Riker Laboratories, Inc. Experiment number: 0681TB0398, February 1982; Staples, RE; Burgess, BA; Kerns, WD. (1984) The embryo-fetal toxicity and teratogenic potential of ammonium perfluorooctanoate (APFO) in the rat. Fundam. Appl. Toxicol. 4:429-440 (two studies -- inhalation and oral dose administration)

[6] A 2004 paper co-authored by the Chief of the Developmental Biology Branch, Reproductive Toxicology Division, of EPA's National Health and Environmental Effects Research Laboratory, commenting on these four studies by Gortner and Staples, states: "neither laboratory reported any significant findings with administered doses up to 100-150 mg/kg/day for rats and 50 mg/kg/day for rabbits." Lau, C., Butenhoff, J.L., and Rogers, J.M. 2004, The developmental toxicity of perfluoroalkyl acids and their derivatives, Toxicology and Applied Pharmacology 198, 231-241, page 236.

Casarett and Doull's Toxicology, The Basic Science of Poisons, (1996) Fifth Edition, Chapter 10, page 314, by John M. Rogers, Ph.D., Chief, Developmental Biology Branch, Reproductive Toxicology Division, National Health and Environmental Effects Research Laboratory, US EPA, Research Triangle Park, North Carolina, and Robert J. Kavlock, Director, Reproductive Toxicology Division. In the same book, these two senior EPA developmental toxicologists also wrote that there is little difference between the rat and human placentas' permeability to chemicals:

> Although there are marked species differences in types of placentas, orientation of blood vessels, and numbers of exchanging layers, these differences do not seem to play a dominant role in the placental transfer of most chemicals.

Id.

In short, EPA knew before 1981 that the human placenta is "a sieve" that allows virtually any chemical to pass through it and that chemicals of PFOA's molecular weight cross the placenta with ease. Moreover, in 1982 EPA had scientific proof that PFOA crosses the rat placenta, due to DuPont's direct communication of its study results to the EPA scientists who were studying PFOA and, as two of EPA's most senior developmental toxicologists wrote eight years ago, EPA knew that there is little if any difference between the rodent and human placentas with respect to their permeability to chemicals.[7] Accordingly, ORE cannot reasonably claim that EPA did not know many years ago that PFOA would cross the human placenta.

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[7] EPA's 1978 guidance on TSCA § 8(e) reporting states that information concerning possible human health effects "can be obtained either directly, by observation of their occurrence, or inferred from designed studies as discussed in Part VI." Part VI of the guidance document states that "designed, controlled studies" include "[i]n vitro experiments and tests" obviously referring to animal tests.

In 2000, during discovery in a civil suit, attorneys for DuPont collected the 1981 one-page document and produced it to plaintiffs' counsel, who submitted it to EPA on March 6, 2001. Like the 1982 DuPont study on transfer across the rat placenta, the 1981 blood sample result does not appear to have been deemed relevant by the EPA scientists who were actively investigating whether PFOA could cause a risk of developmental effects. As was the case with the 1982 DuPont study on PFOA transfer across the rat placenta, the 1981 blood sample is not mentioned anywhere in EPA's November 4, 2002, 103-page Revised Draft Hazard Assessment of Perfluorooctanoic Acid and Its Salts, which includes several pages of discussion on blood sampling results. Nor is the 1981 document cited among the more than 200 studies that the EPA authors list as references that they used in the preparation of the report. EPA's 61-page April 10, 2003 Preliminary Risk Assessment of the Developmental Toxicity Associated With Exposure to Perfluorooctanic Acid and Its Salts, which thoroughly discusses prenatal exposure, likewise does not cite or otherwise mention the information in the 1981 one-page document. Nor did the EPA authors include it in the list of 58 documents that the EPA staff considered during the risk assessment process. EPA's actions after receiving the 1981 one-page document confirm that a single observation of trans-placental transfer did not suggest any risk to health, but rather was only indicative of exposure.

Absence of Risk to Health

There is another, even more compelling reason that the umbilical cord blood sample result did not trigger reporting requirements under TSCA § 8(e). TSCA § 8(e) reporting requirements are triggered only when the information in question reasonably supports the conclusion that the chemical presents a substantial risk of injury. Data showing exposure alone are not enough to support a conclusion that a risk exists. In 1981, even though it could be assumed that PFOA could cross the human placenta, there was no valid evidence that PFOA

could cause any developmental effects. Between 1981 and 1982, four full-scale developmental toxicity studies showed that even extraordinarily high doses of PFOA -- so high that the test animal mothers were dying or seriously affected – produced no developmental effect. Without evidence that PFOA could produce injury, the umbilical cord blood sample could only suggest exposure, not risk.

STATEMENT OF FACTS REGARDING COUNT II

DuPont's Washington Works facility is located on the south bank of the Ohio River, meaning that the river is the north boundary of the facility. In the 1980s, the Lubeck Public Service District ("LPSD") owned property adjacent to and southwest of the facility, with five water wells. In 1986 and 1987, LPSD approached DuPont regarding purchase of the property and wells and in 1988, DuPont agreed to purchase the property and wells, though the sale did not become final until 1990. LPSD needed additional water capacity and wanted to relocate its water supply wells to a site about two to three miles west of the location. LPSD continued to use the wells to provide water to customers at least until December 1990. LPSD maintained control of the old wells until April 1992, when LPSD turned control over to DuPont. DuPont has operated the purchased wells since then, using the water at the plant. Little Hocking, Ohio is on the north bank of the Ohio River, across the river and to the west of the Washington Works facility.

In the 1980s, DuPont occasionally conducted voluntary sampling of water in and around the Washington Works facility, including sampling of private drinking water wells and public water supplies. Among the areas sampled were sites thought to be served by LPSD and by the Little Hocking Water Association. Between 1984 and 1991, DuPont measured PFOA in public drinking water samples at levels ranging from non-detectable to 3.9 ppb.

DuPont did not report the detection of these trace levels of PFOA to EPA under TSCA § 8(e) because at these extremely low levels of concentration, based on studies performed to date, PFOA poses no risk of adverse effects, let alone the "substantial" risk that would be necessary to trigger reporting obligations under TSCA § 8(e).

DuPont's conclusion that these low levels posed no risk was confirmed in 2002 by a panel of scientific experts, that included EPA representatives. This panel, which was convened for the specific purpose of determining a safe level for PFOA in the drinking water serving the area around the Washington Works facility, concluded in its final report that if persons in the area of the Washington Works facility were exposed *for their entire lifetime* to 150 ppb PFOA in drinking water, "no risk of deleterious effects is expected."

The panel was convened on November 15, 2001 pursuant to a voluntary consent order between DuPont, the Division of Water Resources and Division of Air Quality of the West Virginia Department of Environmental Protection ("WVDEP") and the West Virginia Department of Health and Human Resources, Bureau for Public Health ("WVDHHR-BPH"). The consent order recognizes that APFO is an unregulated chemical that DuPont detected in varying concentrations in locations around the Washington Works facility, including private drinking water wells and public water supplies. Accordingly, the parties to the consent order agreed to establish a C8 Assessment of Toxicity Team ("CAT Team"), consisting of representatives of WVDEP, WVDHHR-BPH, DuPont, EPA Headquarters, EPA's Office of Research and Development, EPA Region III, the National Institute for Chemical Studies ("NICS") and the Agency for Toxic Substances and Disease Registry ("ATSDR"). NICS subcontracted certain work on human toxicology to the Toxicology Excellence for Risk Assessment ("TERA"), a Cincinnati-based non-profit organization dedicated to protecting public

health by applying toxicological data to the risk assessment process and developing and communicating risk assessment values.

CAT Team Report

As set forth in the CAT Team's final report (August 2002), the CAT Team was charged with setting "risk-based human health protective screening levels" for APFO (C-8). The CAT Team utilized a team of ten scientific experts, including:

EPA

John Cicmanec, D.V.M., M.S., USEPA Office of Research and Development

Samuel Rotenburg, Ph.D., USEPA Region III

Jennifer Seed, Ph.D., USEPA Headquarters, Risk Assessment Division, Office of Pollution Prevention and Toxics

TERA

Michael Dourson, Ph.D.

Joan Dollarhide, MS, MTSC, JD

Andrew Maier, Ph.D., CIH

Dan Briggs, Ph.D., D.A.B.T.

Agency for Toxic Substances and Disease Registry

John Wheeler, Ph.D.

DuPont

Gerald Kennedy

John Whysner, M.D., Ph.D., D.AB.T. (consultant)

Guests

John Butenhoff, Ph.D., 3M (study scientist)

Jim Sferra, M.S., Ohio Environmental Protection Agency (observer)[8]

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[8] Mr. Sferra was invited to observe and participate in discussions under a Memorandum of Understanding ("MOU") among the WVDEP, WVDHHR, DuPont, and the Ohio EPA, which the parties entered into in recognition of the fact that C-8 had been detected in Little Hocking, Ohio drinking water supplies.

As stated in the final report, Karen Johnson, Janet Sharke, Garth Connor, Roger Reinhart and Mary Dominiak of EPA, James Becker, M.D. and Tracy Smith, M.S. of Marshall University, and the National Institute for Chemical Studies also provided the CAT Team with additional support.

The CAT Team began work in January 2002 and by May 2002 had completed review of the toxicology data. The scientists on the CAT Team met for approximately 18 hours on May 6 and 7, 2002 to develop, among other things: (1) an oral provisional reference dose ("pRfD"), which is the daily dose of a chemical that is not expected to cause any adverse effect; and (2) a "screening level," which is defined as the level at which exposure is equal to or less than the pRfD, and therefore, the level at which "no risk of deleterious effects is expected" if exposure lasts a lifetime.

The CAT Team calculated the PFOA screening level using the standard methodology employed by U.S. EPA, as set forth in "Risk Assessment Guidance for Superfund" and as further explained by EPA Regions III and IX risk-based concentration guidance. Where there was any conflict between the guidance offered by Region III and Region IX, the CAT Team followed the Region IX guidance "because it is more conservative, *i.e.*, more health protective."

The meeting minutes were reviewed and approved by the panel of 10 scientists. Nine of the 10 scientists were present when the panel voted unanimously to accept as the pRfD 0.004 mg/kg/day, which, using Region IX's risk assessment equations, the CAT Team translated to 150 ppb as the screening level for C8 (PFOA) in drinking water.[9] Thus, the panel concluded

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[9] Dr. Seed was not present during that part of the meeting.

in its final report that with a lifetime of exposure to 150 ppb PFOA in drinking water the panel would expect "no risk of deleterious effects."

DuPont's conclusion that 0.8 to 3.9 ppb PFOA in drinking water posed no discernable risk also has been confirmed by EPA Regions III and V. On March 7, 2002, those EPA regional offices entered into a consent order with DuPont under the Safe Drinking Water Act ("SDWA"). This order notes that C-8 ("PFOA") has been detected in the underground source of drinking water used to supply Lubeck and Little Hocking. The order notes that DuPont, the WVDEP and WVDHHR had entered into the November 15, 2001 consent order setting up the CAT Team (discussed above) and that DuPont and EPA agree on a temporary screening level of 14 ppb, while the CAT Team was developing the more permanent screening level.[10] Under the order approved by these two regional offices, DuPont would not be obligated to act to provide alternative drinking water to the public in the Lubeck or Little Hocking areas unless the concentration in public drinking water exceeded 14 ppb. Thus, two EPA regional offices, in setting a very conservative interim level, accepted that 14 ppb PFOA in drinking water posed no substantial risk.

In the SDWA consent order, EPA Regions III and V agreed to accept as the new screening level whatever level was set by the CAT Team. Therefore, for the past two years, since August 2002 when the CAT Team set the screening level of 150 ppb, EPA Region III and EPA Region V have expressly accepted that concentrations below 150 ppb pose no risk to public

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[10] At the time EPA Regions III and V set this conservative 14 ppb interim standard, EPA had been aware, for more than a year, of DuPont's 1.0 ppb community exposure guideline for PFOA in drinking water ("CEGw").

health that requires any action to reduce exposure. Most recently, in a December 23, 2003 letter, EPA Region III reaffirmed:

> In evaluating impacts concerning C8 from the DuPont Washington Works, the Region is using the concentrations established by the [CAT Team] at this time.

Thus, these two regional offices have flatly contradicted ORE's claim of a "substantial risk" from exposure to more than 1 but less than 4 ppb.

The 150 ppb safe PFOA level set under the SDWA consent order describes an appropriate threshold for TSCA § 8(e) reporting. Indeed, in the Comment and Response Document for Revised Policy Statement of Section 8(e) of TSCA, the OPPT notes that benchmarks established under such programs may be used in the Section 8(e) decision-making process.

DuPont Community Exposure Guideline

In its Complaint, ORE ignores the sound, scientifically-based conclusions of the scientific panel and of EPA Regions III and V that levels up to 150 ppb pose no risk. ORE claims that DuPont should have used as the trigger for "substantial risk" information reporting DuPont's own provisional 1.0 ppb community exposure guideline ("CEGw") for PFOA in water, which DuPont voluntarily set in 1991. ORE, however, appears to have been unaware that DuPont's provisional 1991 guideline incorporates an approximately 3,000-fold safety factor and is not any sort of a risk benchmark, but rather simply an extremely protective goal that assumes 24-hour-a-day exposure through air and water *over a person's entire lifetime* and which DuPont attempts to attain through engineering controls on releases. Temporary levels of exposure that are slightly above this extremely protective guideline, such as the levels mentioned in the Complaint, cannot reasonably be considered to pose a substantial risk.

In 1979, before DuPont set a CEGw for PFOA, DuPont set an acceptable exposure level ("AEL") to PFOA for its employees at the Washington Works Facility. To set that acceptable level, DuPont first reviewed the available toxicity studies on animals and selected the study that had the lowest "no observed effect level" ("NOEL"), *i.e.*, the lowest dose in any study at which researchers saw no adverse effect on the test animals. To this NOEL, or safe level, DuPont then applied a 100-fold safety factor, setting the acceptable "dose" for company employees at 100 times below this lowest dose where there were no observed effects in animals. Thus, there is at least a 100-fold margin of safety built into the AEL.[11]

To calculate a community exposure guideline for PFOA, DuPont took the AEL with its 100-fold safety factor, and applied an additional safety factor of approximately 30-fold. In other words, with this additional 30-fold safety factor, DuPont had set an acceptable daily exposure of one three-thousandth (one-thirtieth of one-hundredth) of the lowest NOEL, which worked out to an acceptable community exposure of 6.0 micrograms of PFOA per day. Using standard, health-protective EPA assumptions regarding exposure, DuPont set the drinking water portion of the community exposure guideline ("CEGw") at 1.0 ppb of PFOA. [12]

In short, the 1.0 ppb CEGw for PFOA in drinking water incorporates an approximately 3000-fold margin of safety.[13] Thus, ORE's contention that residues of PFOA in water that are

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[11] In 1986, the American Conference of Governmental Industrial Hygienists ("ACGIH") set the Threshold Limit Value-Time Weighted Average ("TLV-TWA") for workers exposed to APFO at a level ten times higher than DuPont's AEL. In other words, DuPont's AEL was ten times more protective than the initial ACGIH standard. A few years later, ACGIH adopted a lower TLV-TWA that matched DuPont's AEL.

[12] In June 1991, DuPont's AEL Committee, which also sets CEGs, proposed a provisional 1.0 ppb CEGw. DuPont did not adopt the provisional CEGw for PFOA as final until February 7, 1992.

[13] In fact, DuPont's 100X margin of safety for the AEL and the additional 30X margin of safety for the community exposure guideline are even more conservative than they seem, because the study that DuPont used was

(footnote continued on next page)

less than 3.0 ppb above the DuPont 1.0 ppb guideline (3.9 ppb is the highest level mentioned in ORE's Complaint) somehow would present a "substantial risk" has no basis in science or fact, because the DuPont guideline was set 3000 times below the lowest no observed effect level in any animal study available at that time.

Notice to EPA of PFOA in Drinking Water

TSCA § 8(e) requires reporting only if there is information that reasonably supports a conclusion of substantial risk and even then only if EPA has not been adequately apprised of the information. As discussed above, the presence of a few ppb of PFOA in drinking water does not present a risk. In addition, even prior to 1991, EPA already was adequately apprised that there were ppb levels of PFOA in the public drinking water. In DuPont's February 9, 1990 Verification Investigation plan for the Washington Works hazardous waste disposal facility, DuPont told the Agency:

> The Lubeck public supply wells have detectable levels (ppb) of ammonium perfluorooctanoate (also called C-8). Washington Works is in the process of purchasing these wells from Lubeck Water supply.

Verification Investigation Plan, Page 18.[14] This statement put EPA clearly on notice that: (1) there were ppb levels of PFOA in Lubeck's public drinking water supply wells; and, (2) DuPont had not yet purchased the wells from Lubeck, meaning that the public would

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(footnote continued from previous page)

a study of liver toxicity in animals. As EPA scientists have noted, a toxicological mode of action by which it is believed PFOA produces liver toxicity in animals at low doses – inducing peroxisome proliferation -- does not occur in humans.

[14] DuPont already had told the LPSD about the presence of ppb levels or PFOA in the drinking water. On June 13, 1989, DuPont wrote to the manager of the LPSD, noting that DuPont had tested LPSD water taps from 1984 to 1988 and found PFOA in concentrations from 1.0 to 2.2 ppb.

continue to be exposed. DuPont's plan gave no timetable for when purchase of the wells would be completed.

Having been put on notice of the presence of ppb levels in public drinking water supply wells, EPA did not respond. ORE's Complaint does not explain why, if ppb levels of PFOA in drinking water should have been seen to present a "substantial risk" as ORE claims, EPA did absolutely nothing when told that such levels of PFOA were present in "public supply wells." The answer, it seems, is obvious: like DuPont, EPA reasonably concluded that there was no risk to human health or the environment.

On other occasions, DuPont also reported to EPA the release of PFOA into the Ohio River and the presence of PFOA in aquifers underneath a hazardous waste disposal unit at the facility. In short, ORE cannot contend that EPA was never told about the release of PFOA to environmental media, including surface water, groundwater and drinking water, around the Washington Works facility.

TSCA § 8(e) Compliance Audit Program

ORE's position regarding Count II also is directly contrary to EPA's prior commitment that it would not bring an enforcement action against DuPont arising out of this water sampling data.

TSCA § 8(e) became effective in 1977, but TSCA does not provide EPA with authority to issue regulations to more clearly define terms and set reporting standards. In 1978 EPA issued interpretive guidance on § 8(e) reporting, but EPA did not set very clearly defined standards. As a result, each company was required to exercise individual subjective judgment to determine what information must be reported. In the late 1980s, it became obvious that there were differing

interpretations of § 8(e) reporting requirements. In consultation with the American Chemistry Council,[15] which was concerned about the potential for arbitrary enforcement actions using ad hoc standards, EPA developed a one-time voluntary TSCA § 8(e) "Compliance Audit Program" ("CAP") and the text of a CAP Agreement. On February 1, 1991, EPA announced the availability of the CAP. Any company that signed the CAP Agreement could audit its files for reportable information, including both toxicity studies and information on releases into environmental media, report any information that EPA might possibly consider reportable, and limit the company's liability for such "overdue" reports to $1,000,000.

Later in 1991, EPA announced modifications to the CAP and republished the terms of the CAP Agreement. EPA made these revisions because:

> EPA recognizes that proper application of § 8(e) requires the exercise of scientific judgment. EPA is not interested in creating an atmosphere in which companies view a "data dump" strategy as the best course of action for meeting their obligations.

EPA obviously wanted to avoid receiving more data than the agency could process.

DuPont and EPA executed the revised CAP Agreement, registering DuPont into the CAP, in 1991. DuPont then began auditing its records for, among other data, any potentially reportable data on chemical residues found in groundwater and drinking water.

On September 30, 1991, however, EPA extended indefinitely the § 8(e) CAP reporting deadline for information on the release of chemicals to and the detection of chemicals in environmental media, instructing companies that such information need not be reported until after EPA published its final refined guidance on reporting for such information. This began a period in which EPA and the CAP participants envisioned a second phase ("Phase II") for

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[15] Known at that time as the Chemical Manufacturers Association, ACC is a trade association representing chemical manufacturers and importers.

reporting chemical releases into the environment would be necessary to complete the CAP. Phase II would be triggered by publication of that revised guidance.

However, EPA's process for issuing revised guidance on reporting standards for detection of chemicals in environmental media went more slowly than EPA expected. In 1993, in a Notice of Clarification and Solicitation of Public Comment, EPA continued the indefinite extension of Phase II and proposed changes to the Agency's guidance. Then, in 1995, EPA issued a revised draft of the proposed guidance.

Based on comments to the 1993 proposed guidance and the 1995 proposed guidance, EPA determined that any final guidance would likely be significantly different from previous guidance and should therefore be applied prospectively. Since the CAP was a retrospective exercise, EPA terminated the CAP on May 15, 1996, without ever implementing Phase II.

In a letter to DuPont dated May 15, 1996 about these actions, EPA stated,

> EPA has decided that it is reasonable and equitable to enforce the final revised reporting guidance on a prospective basis only. Therefore, information on the release of chemical substances to and detection of chemical substances in environmental media . . . that predate[s] the effective date of the guidance will not be the subject of an EPA TSCA Section 8(e) enforcement action.

To effectuate the change to the CAP Agreement, EPA enclosed with the May 15, 1996 letter a Revised Addendum to the TSCA § 8(e) CAP Agreement. This Revised Addendum states,

> The Regulatee, therefore, is no longer required to conduct a file search for this information . . . Information on the release of chemical substances to and detection of chemical substances in environmental media . . . that predates the effective date of the final revised guidance will not be the subject of an EPA TSCA Section 8(e) penalty enforcement action.

In 1996, EPA and DuPont signed the Revised Addendum containing this language. EPA reached final settlements with CAP participants, and announced those settlements on October 15, 1996.

In short, in 1996, at EPA's request, DuPont agreed to cease auditing and enter into a Consent Agreement and Consent Order with EPA that brought the CAP to a close. In return, EPA agreed to issue new § 8(e) guidance on releases and detection in environmental media, and pledged that any information on detection of chemical substances in environmental media, such as groundwater or drinking water, that DuPont received prior to the effective date of EPA's new guidance "will not be the subject of an EPA TSCA § 8(e) penalty enforcement action."

The 1996 Consent Agreement specified that DuPont was "no longer required to conduct a file search for information on the release of chemical substances to and detection of chemical substances in environmental media," and that the Revised Addendum was "incorporated [t]herein by reference." Thus, the Consent Agreement contains the statement in the Revised Addendum that "Information on the release of chemical substances to and detection of chemical substances in environmental media . . . that predates the effective date of the final revised guidance will not be the subject of an EPA TSCA Section 8(e) penalty enforcement action." EPA then adopted as an EPA Finding of Fact in the matter that DuPont was "no longer required to conduct a file search for information on the release of chemical substances to and detection of chemical substances in environmental media . . . and that a second Final Report is no longer necessary."

EPA entered into and consented to the terms of the CAP Agreement and the Consent Order. By their terms, the Consent Agreement and Consent Order were a "complete settlement of all administrative claims and civil causes of action alleged in the Complaint." EPA also agreed that "The provisions of this Consent Agreement and Order shall apply to and be binding on the Parties . . . upon execution of the Consent Order by the Environmental Appeals Board or its delegate." The Consent Order was to have the same force and effect as a final order as defined in 40 C.F.R. § 22.03.

EPA did not publish final guidance on § 8(e) reporting of releases into environmental media until June 3, 2003. In the preamble to the 2003 final policy, EPA stated that, because of the number of changes made to the proposed guidance in the 1995 Federal Register notice and the fact that it represented a significant change from the original guidance suspended in 1991, the revised guidance should only be applied prospectively.

All of the data at issue in Count II was generated before the effective date of the new guidance, and before the close of the CAP. EPA received the data more than 2 years before EPA issued final guidance. Thus, under the CAP Agreement, Consent Order and Revised Addendum, EPA agreed that it would not bring a TSCA § 8(e) enforcement action arising out of the water sampling data at issue in Count II.

STATEMENT OF FACTS REGARDING COUNT III

At the Washington Works facility, DuPont maintains fourteen Solid Waste Management Units ("SWMUs"). In December 1989, EPA issued a permit under RCRA which, among other things, required DuPont to submit to EPA a Verification Investigation ("VI") Work Plan for six SWMUs and, upon EPA approval of the Work Plan, to conduct the VI and submit a VI Report. The permit expressly references RCRA § 3004(u) as requiring "corrective action for all release of hazardous waste or hazardous constituents from any solid waste management unit . . . ." The permit incorporates by reference EPA's regulations, directs DuPont to design a VI Work Plan to investigate the release of *hazardous waste* or *hazardous constituents* from six of the fourteen SWMUs and from any other SWMU that DuPont knew or suspected might be releasing hazardous waste or hazardous constituents.[16] "The VI plan must be capable of enabling DuPont to determine if a release of hazardous waste or hazardous constituents has occurred or is likely to

[16] The permit lists dozens of hazardous constituents. PFOA is not among those listed.

occur from these units." The permit specifies in Attachment I dozens of hazardous constituents to be investigated in soil and groundwater at the facility: "The VI Sampling Plan shall provide for the analyses identified in Attachment I and any other hazardous constituent that is known or suspected to have been released from the unit." The permit thus repeatedly limits the VI investigation to "hazardous constituents." The permit does not describe PFOA as a hazardous waste or a hazardous constituent. Nowhere in EPA's hazardous waste regulations is PFOA identified as either.

On February 9, 1990, DuPont submitted the draft VI Work Plan. DuPont indicated in the draft VI Work Plan that the company would sample groundwater associated with several SWMUs for two surfactants that it purchased from third-party vendors -- C-8 and TRITON® -- but DuPont did not say or suggest that either product was a "hazardous constituent" or that the plan to analyze some groundwater samples was anything other than voluntary.

On April 3, 1992, DuPont submitted to EPA Region III's RCRA office a VI report on the SWMUs at the Washington Works facility. Section 7.2 of the report notes that C-8 and TRITON®, are present on-site, are not listed in Appendix IX to EPA's regulations regarding standards for hazardous waste facilities (40 C.F.R. § 264), and that neither chemical had a Proposed Action Level ("PAL") or Maximum Contaminant Level ("MCL") assigned by EPA. The draft Work Plan included an "EPA Constituent List" that did not include C-8 or PFOA.

By letter dated September 25, 1990, EPA Region III advised DuPont of certain deficiencies in the Draft Work Plan, without discussing DuPont's proposal to sample for C-8 at some locations. On December 14, 1990, DuPont submitted a revised Work Plan in which DuPont repeated its plan to analyze groundwater under two of the SWMUs for "the parameters listed in Table 18 [the "EPA Constituent List"] plus . . . C-8 [and] TRITON®." On

September 30, 1991, EPA Region III conditionally approved the VI Work Plan, again without suggesting that C-8 (PFOA) should be deemed a "hazardous constituent."

When DuPont submitted the VI report in 1992, EPA had recently explained in a proposed (but never adopted) action to expand its corrective action regulations: "The term 'hazardous constituent' used in section 3004(u) means those constituents found in Appendix VIII to 40 C.F.R. Part 261." 55 Fed. Reg. 30,798, 30,809 (July 27, 1990). Appendix IX to Part 264, to which DuPont's VI Report referred, is a list of selected constituents for which the owner or operator of a hazardous waste management facility must be required to monitor groundwater quality and, potentially, to take corrective actions, together with suggested analytical methods for analyzing groundwater for each of the listed hazardous constituents. *See* 40 C.F.R. 264.98, 99, 100. As EPA has explained, Appendix IX "generally constitutes a subset of Appendix VIII constituents particularly suitable for groundwater analyses," plus some other constituents commonly analyzed as part of EPA's broader authority to clean up "hazardous substances" under its Superfund program. 55 Fed. Reg. at 30,809. As DuPont correctly noted in the VI Report, Appendix IX to Part 264 does not include PFOA (nor provide a method of testingfor PFOA).

In short, EPA's corrective action regulations, which were incorporated by reference in DuPont's Corrective Action Permit, are essentially unchanged since DuPont performed the Verification Investigation. They do not recognize PFOA as a "hazardous constituent" for which even monitoring was required at a permitted facility in 1992, much less do they suggest that releases of this non-hazardous constituent could trigger a requirement for corrective action under RCRA §§ 3004(u) or (v).

Five years after DuPont submitted the VI Report, on May 13, 1997, Region III responded with a Notice of Deficiency regarding the report. In response to DuPont's report regarding C-8, Region III states only:

> Section 7.2 discusses that C-8 and TRITON®, found in wells at the Riverbank Landfill, the Anaerobic Digestion Ponds, and the Burning Grounds, are not 40 CFR 264, Appendix IX constituents and PALs or MCLs assigned to them [sic]. Please provide known toxicological information.

On June 6, 1997, DuPont responded, submitting a seven-page discussion of the toxicological effects that had been found for PFOA in various toxicological tests. DuPont submitted the results of 22 studies: (1) acute toxicity tests to fish and algae; (2) a carcinogenicity study; (3) eye irritation studies in rabbits and rats; (4) a dermal toxicity study; (5) a skin irritation study; (6) a skin absorption toxicity study; (7) a respiratory system irritation study; (8) 4-hour and 1-hour inhalation toxicity studies; (9) a sub-chronic inhalation toxicity study; (10) acute oral, intragastric dosing, and repeated oral dosing toxicity studies; (11) a 28-day feeding toxicity study; (12) developmental toxicity studies in rats and rabbits; (13) genetic toxicity assays; and (14) a study on occupational exposure.

For seven years thereafter, Region III never indicated that the Region considered any other type of study to be "toxicological" information that DuPont was required to submit. Region III certainly had access to published studies and additional information in EPA's files collected in the 1980s during EPA's review of APFO at that time.

ORE now claims that EPA was authorized to require DuPont to submit "toxicological information" about PFOA under the terms of DuPont's corrective action permit and that EPA in fact did so in its request. The corrective action permit, however, did not purport to require DuPont to assess releases from any SWMU of substances that were neither hazardous wastes nor

hazardous constituents. By its terms the permit required investigation and potential remediation only of "hazardous wastes" and "hazardous constituents." Nor could the corrective action permit have lawfully done otherwise under RCRA §§ 3004(u) and (v).

PFOA does not exhibit any of the "hazardous characteristics" (ignitability, corrosivity, reactivity, toxicity) that would render it a "hazardous waste." *See* 40 C.F.R. 261.20-.24. It does not appear in 40 C.F.R. Part 261, Appendix VIII: "Hazardous Constituents" and EPA has conceded that substances that do not appear in Part 261, Appendix VIII are not "hazardous constituents." ORE thus cannot show that PFOA is regulated as a "hazardous waste" under RCRA or is among the "hazardous constituents" whose release can trigger mandatory corrective action under RCRA and EPA's implementing regulations, even though such proof is an essential element of ORE's claim for a civil penalty under Count III. Because ORE cannot show that PFOA is a hazardous waste or a hazardous constituent, EPA does not have jurisdiction under RCRA to require DuPont to evaluate releases of PFOA in the environment at the facility, nor to provide information to EPA about PFOA. Therefore, EPA is without authority to penalize DuPont under RCRA for alleged deficiencies in DuPont's voluntary response to an EPA request for information about PFOA's toxicology. As a result, ORE's Count III fails to state a claim upon which EPA is entitled to recover any penalty from DuPont.

Even assuming *arguendo* that DuPont had some obligation under RCRA to evaluate (or provide information about) compounds that are not hazardous wastes or hazardous constituents for purposes of potential corrective action, ORE incorrectly contends in the Complaint that the result of the umbilical blood sample discussed above is "toxicological" information, even though it shows no toxicological effect and was not derived from any toxicological study. Under any fair interpretation of the term "toxicological," however, the blood sample is not toxicological

information. In fact, standard texts define "toxicology" to mean "the science that concerns itself with the adverse effects of chemical or physical agents on living organisms."[17]

Nor is the sample, as ORE suggests, "relevant" to the conditions of DuPont's hazardous waste treatment permit. None of the studies run to date has shown any adverse effect from pre-natal exposure.

ANSWER TO SPECIFIC ALLEGATIONS

DuPont's responses to the allegations in the Complaint appear below. The paragraphs below are numbered to correspond to the numbered paragraphs in the Complaint.

Response to General Allegations Relating to Counts I and II

1. DuPont admits that the company has owned and operated a facility known as "Washington Works" located at Route 892 South DuPont Road, Washington, West Virginia 26181 in Wood County, at all times relevant to the Complaint.

2. DuPont admits that the company 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. Paragraph 3 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

4. DuPont admits that the company currently manufactures and processes PFOA (Octanoic acid, pentadecafluoro-Chemical Abstracts Service Registry Number (CAS No.) 335-67-1). DuPont denies that at any time material to this Complaint it was a manufacturer, processor or distributor of PFOA (Octanic acid, pentadecafluoro – Chemical Abstracts Service

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[17] Encyclopedia of Toxicology 338 (1998).

Registry Number (CAS No.) 335-67-1). Some DuPont personnel may have referred to PFOA as "C-8," but DuPont uses the term "C-8" to refer to APFO, referring to the chain of eight carbons in APFO's molecular structure. FC-143 is the tradename of the APFO marketed by 3M. FC-143 is not another name for PFOA. As explained above, when testing for the presence of FC-143 in blood or water, analytical chemists test for the presence of PFOA. DuPont denies the remaining allegations of Paragraph 4.

5. DuPont notes that EPA has published two documents regarding the Agency's assessment of potential risks of PFOA, "Revised Draft Hazard Assessment of Perfluorooctanoic Acid and Its Salts (November 4, 2002) and Preliminary Risk Assessment of the Developmental Toxicity Associated With Exposure to Perfluorooctanic Acid and Its Salts" (April 10, 2003). Those documents speak for themselves. To the extent that paragraph 5 contradicts or is not in accordance with those documents, it is denied. DuPont lacks adequate knowledge to determine the truth or falsity of ORE's allegations that APFO is the most widely used salt of PFOA and that most animal toxicity studies have been conducted with APFO. Hence, those allegations are deemed denied.

6. DuPont denies that PFOA is a perfluorinated detergent/surfactant. PFOA is primarily used as a chemical intermediate to make the salts and esters of the acid. DuPont admits that the 3M Company manufactured APFO and sold it to DuPont beginning in 1951, but DuPont denies that the purpose was to make PFOA solution. DuPont notes that in May 2000, 3M announced that it was discontinuing its perfluorinated chemistries. DuPont denies that it manufactured, processed or distributed PFOA at any time relevant to this Complaint. DuPont began manufacture and processing of PFOA in 2002.

7. DuPont denies that the company has manufactured, processed or distributed PFOA at its Washington Works Facility outside Parkersburg, West Virginia.

8. DuPont admits that the company's Washington Works facility has released PFOA into the air, treated waste containing PFOA in anaerobic digestion ponds, disposed of waste containing PFOA into landfills and discharged PFOA into the Ohio River.

9. DuPont admits that at high enough doses and durations of exposure, PFOA has been shown to produce liver toxicity in some test animals, and that at lower doses can produce such toxicity through a process known as induction of peroxisome proliferation. Humans, however, are not susceptible to peroxisome proliferation.

10. The Complaint does not define the term "biopersistent." Based on DuPont's understanding of the term, DuPont admits that PFOA is biopersistent in animals and humans. DuPont further notes that studies have reached different conclusions regarding the persistence of PFOA.

11. The Complaint does not define "bioaccumulative." Based on DuPont's understanding of the term, DuPont denies that PFOA is bioaccumulative in humans.

12. DuPont denies that PFOA is associated with developmental effects in animals.

13. DuPont notes that PFOA has been reported to have been found in the blood of the general population. DuPont, however, lacks adequate information to determine the truth or falsity of the allegations of paragraph 13. Hence, they are deemed denied.

14. DuPont admits that, based on current knowledge, PFOA is not naturally occurring, that all PFOA present in human blood is attributable in some sense to human activity and that PFOA is produced synthetically. DuPont denies the remaining allegations of paragraph 14.

15. DuPont admits that the company has studied PFOA in animals. DuPont further states that there are differences in the elimination rates of PFOA in rats between the genders.

16. DuPont admits that there are differences in the half-life of PFOA in rats and the half-life of PFOA in humans. DuPont admits that there are differences among species in the kinetics of PFOA. DuPont denies the remaining allegations of paragraph 16.

17. DuPont admits that in September 2002, the Director of the Office of Pollution Prevention and Toxics ("OPPT") initiated a priority review of PFOA and that EPA published a Federal Register Notice, 68 Fed. Reg. 18,626 (April 16, 2002), as part of its effort to collect additional information. DuPont lacks sufficient knowledge of the Agency's motivations to admit or deny the Agency's interests. The third sentence of paragraph 17 of the Complaint is too vague to permit a response and therefore is denied. DuPont admits that EPA's preliminary assessment, released April 10, 2003, indicates potential exposure of the U.S. general population to PFOA at very low levels and that this risk assessment also reflects that EPA believes that there is considerable scientific uncertainty regarding the potential risks. DuPont denies the remaining allegations of paragraph 17.

18. Paragraph 18 states a conclusion of law that requires no answer. To the extent it might be deemed to allege facts, those allegations are denied.

19. Paragraph 19 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

20. Paragraph 20 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

Response to General Allegations for Count III

21. DuPont admits that the company is a corporation incorporated in the State of Delaware and that at all relevant times, DuPont was a corporation organized under the laws of the State of Delaware. The remaining allegations of paragraph 21 are conclusions of law that require no response. To the extent they are deemed to allege facts, those allegations are denied.

22. DuPont admits that the company owns and operates the Washington Works facility located at Route 892 South DuPont Road, Washington, Wood County, West Virginia, 26181.

23. Paragraph 23 states a conclusion of law that requires no answer. To the extent that it is deemed to allege facts, those allegations are denied.

24. Paragraph 24 states a conclusion of law that requires no answer. To the extent that it is deemed to allege facts, those allegations are denied.

25. Paragraph 25 states a conclusion of law that requires no answer. To the extent that it is deemed to allege facts, those allegations are denied.

26. Paragraph 26 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

27. DuPont states that on or about January 5, 1987, West Virginia Department of Natural Resources, Division of Waste Management issued to DuPont a RCRA permit for the treatment, storage, or disposal of hazardous waste at DuPont's Washington Works Facility.

28. DuPont admits that in March of 1985, EPA requested that DuPont provide information on Solid Waste Management Units (SWMUs) at the Washington Works facility.

29. DuPont admits that on December 13, 1989, EPA issued to DuPont the corrective action portion of DuPont's permit for the Washington Works facility.

30. DuPont admits that on December 16, 1999, EPA extended the term of the corrective action portion of DuPont's RCRA permit for the Washington Works Facility until the effective date of a new corrective action permit for the Washington Works Facility.

31. Paragraph 31 states a legal conclusion that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

Response to Count I

32. DuPont incorporates its responses to paragraphs 1 through 20 of the Complaint.

33. DuPont denies the allegations of paragraph 33. On or about March 20, 1981, 3M Company, who at that time was DuPont's supplier of APFO, advised DuPont that in an oral rangefinder study in rats, designed to determine the maximum dosage rate that pregnant female rats could tolerate, and run in preparation for a full-scale teratology study, researchers observed what appeared to be treatment-related damage to the eye lenses of some rat pups. Within a few months, however, the testing laboratory, 3M, DuPont, and researchers from the National Institute of Neurological Diseases and Blindness and the National Institutes of Health all concluded that PFOA did not in fact cause any developmental eye lens abnormalities in the fetal rats. This determination was based primarily on a conclusion that the lens damage observed in the 3M study in fact were artifacts resulting from the process of sectioning (cutting) the tissue for microscopic analysis. EPA scientists who reviewed these findings state on Page 28 of the Agency's April 10, 2003 Preliminary Risk Assessment of the Developmental Toxicity Associated with Exposure to Perfluorooctanoic Acids and Its Salts:

> [A] fetal lens finding initially described as a variety of abnormal morphological changes localized to the area of the embryonal nucleus, was later determined to be an artifact of the free-hand sectioning technique and therefore not considered to be treatment-related. Under the conditions of the study, a NOAEL [No

> observed adverse effect level] for developmental toxicity of 150 mg/kg/day (highest dose group) was indicated.

The same conclusion – that PFOA did not cause the noted lens damage -- is reflected in OPPT's November 4, 2002 Revised Draft Hazard Assessment of Perfluorooctanoic Acid and Its Salts, at Page 61. Four subsequent full-scale developmental toxicity studies in rats and rabbits confirmed that PFOA does not cause eye lens defects, or any other teratogenic effects.

34. DuPont admits that the document contains no date of original creation on its face. DuPont admits that it contains numbers that purport to be levels of PFOA detected in the blood of eight DuPont employees. DuPont denies that all eight employees were pregnant at the time of sampling. The document reflects that at least three of the employees already had given birth, up to two years prior to the taking of the blood sample. The remaining allegations of paragraph 34 are denied.

35. DuPont denies the allegations in paragraph 35. As noted above in paragraph 34, the document reflects that at least three of the employees already had given birth, up to two years prior to the blood sample. When DuPont received word of the 3M study discussed above, DuPont offered blood testing to all employees. The eight women on the document were among the approximately 400 employees who volunteered to have their blood tested.

36. DuPont lacks adequate knowledge of the truth or falsity of the allegation regarding the precise date of the document. The document is the best evidence of its content. To the extent that paragraph 36 contradicts or is not in accordance with the document, it is denied.

37. DuPont denies the allegations of paragraph 37. DuPont notes that the sampling results suggest, at most, that PFOA moved across the placenta. DuPont further states that the potential for transplacental movement of PFOA, like any other chemical with a molecular weight less than 600, was known to EPA in 1981.

38. Because the events giving rise to this allegation began approximately 23 years ago, DuPont has found it very difficult to account for all occasions when DuPont might have provided information to EPA personnel incorporating a description of the 1981 blood sample results. Throughout the 1980s, DuPont scientists communicated regularly with EPA personnel regarding PFOA and related chemicals. DuPont is attempting to reconstruct events that occurred throughout the 1980s, but because so much time has passed, DuPont cannot, at this time, determine whether the company provided this specific information to EPA personnel. Accordingly, DuPont currently lacks adequate knowledge to determine the truth or falsity of this portion of paragraph 38. Hence, it isdeemed denied. Certainly, EPA was well aware that DuPont and others were studying whether PFOA and related substances had potential to cause birth defects and, to the extent that paragraph 38 asserts that DuPont did not inform EPA of this effort, the allegation is denied. To the extent that paragraph 38 makes other allegations, DuPont lacks adequate knowledge to determine their truth or falsity. Hence, they are deemed denied.

39. The document in question is the best evidence of its contents. To the extent that paragraph 39 contradicts or is not in accordance with the document, it is denied. DuPont notes that the document indicates that the DuPont plant physician had just given the woman a report on the status of 3M's and DuPont's ongoing research into PFOA.

40. The document in question is the best evidence of its contents. To the extent that paragraph 40 contradicts or is not in accordance with the document, it is denied. DuPont notes that the document indicates that the DuPont plant physician had just given the woman a report on the status of 3M's and DuPont's ongoing research into PFOA and had told her that:
(1) researchers had determined that the supposed eye lens defects in the preliminary 3M study had been caused by flaws in the preparation of the fetal eye tissue for detailed analysis, not by

PFOA; and (2) in the ongoing studies, the animal pups examined as of that time had not shown any eye lens defects. According to the document, the woman responded with the question noted.

41. DuPont admits that on or about March 16, 1982, DuPont scientist Gerald Kennedy wrote a letter to an EPA scientist, the late Joseph Seifert, recounting the methods and results of a study of the potential for PFOA to cross the rat placenta. The study used radioactively labeled PFOA, meaning that researchers could track the movement of radioactivity and did not have to rely on chemical analytical methods. Dr. Kennedy's letter to Dr. Seifert concludes that the study demonstrates that PFOA moves across the rat placenta. This letter was not a formal "report," but rather a scientist-to-scientist letter. DuPont notes that although ORE's Complaint alleges vaguely that "EPA subsequently regarded" the letter as "substantial risk data," ORE fails to allege that EPA at any time communicated to DuPont any such interpretation of the DuPont data and letter. DuPont also notes that in two extensive assessments of the potential risks of PFOA that EPA published in 2002 and 2003 and which are cited above, the EPA scientists who wrote the reports do not mention, cite or in any way indicate that they considered or reviewed this supposed "substantial risk data." The remainder of the allegations in paragraph 41 are denied.

42. DuPont denies the allegations of paragraph 42. The one-page document in question was collected through the discovery process from employee files as part of a litigation pending in West Virginia. The document was produced to plaintiffs' counsel in response to a discovery request in that litigation.

43. Paragraph 43 states a legal conclusion that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

44. DuPont denies the allegations of paragraph 44 of the Complaint.

45. DuPont denies the allegations of paragraph 45 of the Complaint.

46. Paragraph 46 states a legal conclusion that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

47. DuPont admits that Mr. Bilott sent EPA a copy of a one-page document reporting results of blood sampling. DuPont denies the remaining allegations of paragraph 47.

48. Paragraph 48 states a legal conclusion for which no answer is required. To the extent that it might be deemed to allege facts, those allegations are denied.

49. Paragraph 49 states a legal conclusion for which no answer is required. To the extent that it might be deemed to allege facts, those allegations are denied.

50. Paragraph 50 states a legal conclusion for which no answer is required. To the extent that it might be deemed to allege facts, those allegations are denied.

51. Paragraph 51 states a legal conclusion for which no answer is required. To the extent that it might be deemed to allege facts, those allegations are denied.

52. Paragraph 52 states a legal conclusion for which no answer is required. To the extent that it might be deemed to allege facts, those allegations are denied.

Response to Count II

53. DuPont incorporates its responses to paragraphs 1 through 20 of the Complaint.

54. DuPont denies the allegations of paragraph 54. DuPont states that on or about June 14, 1984, an employee prepared a memorandum containing information related to analysis of water samples for PFOA, and that the water samples were taken from locations described in the document.

55. The letter in question is the best evidence of its contents. To the extent that the allegations of paragraph 55 do not accurately state the contents of that letter, those allegations are denied.

56. The allegations in paragraph 56 are believed to be based on a document that DuPont provided to EPA on or about July 11, 2003. DuPont states that the document in question is the best evidence of its contents. To the extent that the allegations of paragraph 56 contradict or do not accurately reflect the contents of that document, they are denied.

57. The memorandum in question is the best evidence of its contents. To the extent that the allegations of paragraph 57 do not accurately state the contents of that memorandum, those allegations are denied.

58. The memorandum in question is the best evidence of its contents. To the extent that the allegations of paragraph 58 do not accurately state the contents of that memorandum, those allegations are denied.

59. The memorandum in question is the best evidence of its contents. To the extent that the allegations of paragraph 59 do not accurately state the contents of that memorandum, those allegations are denied.

60. DuPont admits that continuous 24-hour-a-day exposure for a lifetime to a chemical at the level of the company's community exposure guidelines ("CEGs") is expected to have no effect on a member of the community. DuPont also admits that CEGs are based on the best available information from company experience, animal toxicity studies, controlled human exposure studies, and epidemiological findings. To the extent that paragraph 60 alleges or implies that any exposure above a CEG could affect members of the community, that allegation is denied.

61. DuPont denies the allegations of paragraph 61. DuPont states that on or about June 6, 1991, DuPont's acceptable exposure level committee set a provisional Community Exposure Guideline for drinking water (CEGw) for PFOA at 1 microgram per liter (1 ug/L or 1 ppb). DuPont adopted the provisional CEGw for PFOA in water on or about February 7, 1992.

62. The document in question is the best evidence of its contents. To the extent that the allegations of paragraph 62 do not accurately state the contents of that document, those allegations are denied.

63. The letter in question is the best evidence of its contents. To the extent that the allegations of paragraph 63 do not accurately state the contents of that letter, those allegations are denied.

64. DuPont denies the allegations of paragraph 64.

65. DuPont denies the allegations in paragraph 65. DuPont states that in December 1990 the company completed a purchase of a property containing drinking water supply wells from the LPSD, not "between 1986 and 1990." DuPont first began operating those wells in April 1992. DuPont states that LPSD established new drinking water supply wells approximately 2.7 miles away from the Washington Works facility. DuPont does not know when LPSD began using the new wells.

66. The memorandum in question is the best evidence of its contents. To the extent that the allegations of paragraph 66 do not accurately state the contents of that memorandum, those allegations are denied.

67. The first sentence of paragraph 67 states a conclusion of law that requires no answer. To the extent that the first sentence might be deemed to allege facts, those allegations are denied. DuPont's January 12, 2000 letter to General Electric ("GE") is the best evidence of

its contents. To the extent that the allegations of paragraph 67 do not accurately state the contents of that letter, those allegations are denied. DuPont notes that the letter in question was written in response to GE's question regarding why DuPont's discovery of PFOA in a GE well near the Washington Works facility did not trigger reporting requirements under TSCA § 8(e). DuPont further notes that Complaint paragraph 67 misleadingly implies that DuPont's letter to GE gave only four reasons as DuPont's explanation to GE as to why the data on PFOA detection in public drinking water was not reportable under TSCA § 8(e). In fact, in Complaint paragraph 67, ORE fails to mention DuPont's primary reason, which DuPont states in the letter as follows:

> [A]s you know, EPA guidance on the criteria for environmental TSCA 8(e) reporting is vague, uncertain, and currently (for the past several years) being rewritten. In its last Notice of Clarification on TSCA 8(e) reporting criteria (58 Fed Reg 37735; July 13, 1993), EPA stated that
>
> > "With regard to non-emergency environmental contamination information, EPA interprets section 8(e) to require reporting of information that provides evidence of widespread environmental distribution of a chemical substance or mixture, and which because of the extent, pattern, and amount of the contamination seriously threatens or may seriously threaten: (1) Humans with cancer, birth defects, mutation, death or serious or prolonged incapacitation. . . or (2) non-human organisms with large-scale or ecologically significant population destruction. Thus, the mere presence of a chemical substance in an environmental media, absent some other relevant information as noted above, would not trigger reporting under section 8(e)."
>
> At the levels FC-143 is present in the environmental media, DuPont concludes that FC-143 does not pose the threat or potential threat described above.

The remaining allegations of paragraph 67 are denied.

68. DuPont denies that the January 12, 2000 letter to GE was in any way misleading. DuPont notes that: (1) at the time of the letter in question, EPA had been on notice for many years that PFOA can pass across the placenta; (2) by the time of the letter, four developmental

toxicity studies had demonstrated that even though PFOA can cross the placenta, prenatal exposure to PFOA causes no developmental effect; (3) EPA scientists appear to have ignored the blood sample data in two extensive risk-assessment papers, strongly suggesting that it has been irrelevant to EPA's risk assessments; (4) DuPont's 1981 report to EPA of the detection of FC-143 in Outfall 005, which empties into the Ohio River, DuPont's 1985 report to EPA that PFOA was detected at ppb levels in the groundwater aquifer under the DuPont Local Landfill, DuPont's 1990 report to EPA stating the ppb levels of PFOA had been detected in the Lubeck public drinking water supply wells and that (in 1990) DuPont was still in the process of purchasing those wells, were all included in the 2000 letter to GE to support the letter's statement that EPA had been put on notice of PFOA contamination in various environmental media around the Washington Works facility; and, (5) the letter in question also enclosed a 1989 letter to the manager of the LPSD, telling him that PFOA contamination at ppb levels had been detected at levels between 1.0 and 2.2 ppb between 1984 and 1987 in various LPSD water taps. The February 9, 1990 letter is the best evidence of its contents. To the extent that the allegations of paragraph 68 do not accurately state the contents, those allegations are denied. DuPont denies the remaining allegations of paragraph 68.

69. The letter in question is the best evidence of its contents. To the extent that the allegations of paragraph 69 do not accurately state the contents, those allegations are denied. DuPont notes that the January 12, 2000 letter to GE includes as an attachment an eleven-year-old letter to the LPSD that discusses DuPont's detection of PFOA in LPSD water taps. DuPont also notes that the highest level mentioned in the Complaint is at least 35 times below the level that EPA Regions III and V have accepted as posing no actionable risk.

70. The letter in question is the best evidence of its contents. To the extent that the allegations of paragraph 70 do not accurately state the contents, those allegations are denied. Because the subject of DuPont's letter was whether the information in question triggered reporting requirements under TSCA § 8(e), there was no need to discuss DuPont's CEGw, which is a level at which a greater than 3000-fold margin of safety exists. Similarly, there was no need to discuss a finding of 2.4 ppb in one sample, because that level poses "no risk of deleterious effects" as confirmed by CAT Team.

71. DuPont denies the allegations in paragraph 71. Attorneys for DuPont collected documents as part of its response to discovery requests in a lawsuit and provided those documents to plaintiffs' counsel. DuPont denies that the information in question reasonably supports any conclusion of risk, let alone a substantial risk, and further denies that DuPont "failed or refused" to submit it to EPA.

72. Paragraph 72 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

73. DuPont denies that the Agency considers the information discussed in the preceding paragraphs to reasonably support the conclusion of a substantial risk of injury to health or the environment. EPA as an Agency has made no such determination. One office within EPA -- ORE -- has alleged in the Complaint in this matter that the information at issue in Count II reasonably supports such a conclusion, but the actions and positions taken to date by OPPT and by the EPA offices that administer the Safe Drinking Water Act for EPA Regions III and V indicate that none of them have concluded that 3.9 ppb PFOA in drinking water poses any appreciable risk, let alone a substantial risk. In fact, the two Regional Offices have concluded the levels up to 150 ppb pose no risk of any deleterious effect. DuPont also notes that in a letter

dated February 9, 1990 to EPA, DuPont states: "The Lubeck public supply wells have detectable levels (ppb) of ammonium perfluorooctanoate (also called C-8)." DuPont does not have sufficient information to determine what Mr. Bilott gave EPA. DuPont denies the remaining allegations in paragraph 73.

74. Paragraph 74 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

75. Paragraph 75 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

76. Paragraph 76 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

77. Paragraph 77 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

78. Paragraph 78 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

Response to Count III

79. DuPont incorporates it response to paragraphs 21 through 31 of the Complaint.

80. Paragraph 80 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

81. Paragraph 81 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

82. Paragraph 81 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

83. Paragraph 83 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

84. Paragraph 84 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

85. Paragraph 85 recites a portion of DuPont's Corrective Action Permit. The Corrective Action Permit is the best evidence of its content. To the extent that the allegations of paragraph 85 are not in accord with the contents of that Permit, those allegations are denied.

86. Paragraph 86 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

87. Paragraph 87 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

88. Paragraph 88 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

89. Paragraph 89 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

90. Paragraph 90 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

91. DuPont admits that on or about December 14, 1990, DuPont submitted to EPA a revised VI Work plan. The remainder of paragraph 91 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

92. DuPont admits the allegations in the first sentence of paragraph 92. The remainder of paragraph 92 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied. DuPont specifically denies that

C-8 is a constituent that DuPont was required under RCRA to investigate or, potentially, remediate.

93. DuPont admits the allegations in the first sentence of paragraph 93. The remainder of paragraph 93 states a conclusion of law that requires no answer. To the extent that it might be deemed to allege facts, those allegations are denied.

94. This paragraph paraphrases the VI Report. The VI Report is the best evidence of its contents of the VI Report. To the extent that the allegations of paragraph 94 do not accurately state the contents of the VI Report, those allegations are denied. DuPont incorporates its response to paragraph 4, footnote 1, of the Complaint.

95. DuPont admits that on or about May 5, 1997, over half a decade after receiving DuPont's VI Report, EPA sent DuPont a letter, titled a "Notice of Deficiency," requesting additional information about that five-year-old report (but still, at last, approving DuPont's 1992 request for a RCRA Facility Investigation). The Notice is the best evidence of its contents. To the extent that the allegations of paragraph 95 do not accurately state the contents of the Response to the Notice, those allegations are denied.

96. The Notice is the best evidence of its contents. To the extent that the allegations of paragraph 96 do not accurately state the contents of the Notice, those allegations are denied.

97. DuPont's Response to the Notice is the best evidence of its contents. To the extent that the allegations of paragraph 97 do not accurately state the contents of the Response to the Notice, those allegations are denied.

98. DuPont's Response is the best evidence of its contents. To the extent that the allegations of paragraph 98 do not accurately state the contents of the Notice, those allegations are denied.

99. DuPont's Response is the best evidence of its contents. To the extent that the allegations of paragraph 99 do not accurately state the contents of the Response, those allegations are denied. DuPont notes that the mere fact that a substance could, like almost all others, be transferred across the human placenta is not, without evidence of a health hazard, "health hazardous data."

100. DuPont denies the allegations of paragraph 100. Data on metabolism, kinetics, transplacental movement and the like are not "toxicological information." Neither RCRA nor its related regulations define "known toxicological information," but the plain meaning of the phrase is information about a substance's known toxicity. That C-8, like most substances, can traverse the human placenta, is not "toxicological information."

101. DuPont admits that the June 1997 Response did not expressly inform EPA about the 1981 document mentioning the umbilical cord blood sample. DuPont had no obligation to report this sample to the EPA as "toxicological information" because the sample is not toxicological information. Moreover, DuPont had reported to EPA in 1982 the results of a carefully controlled study showing transplacental movement of C-8 in rats. DuPont reiterates that transplacental movement of virtually all substances in humans has been well-documented for several decades, and further that EPA has known for some time that the anatomical differences between rat and human placentas do not significantly affect what substances are passed through the placenta of each species.

102. DuPont denies the allegations of paragraph 102. For the reasons stated above, the information regarding possible transplacental movement is not "toxicological information."

103. The allegations of paragraph 103 are conclusions of law that require no answer. To the extent that they might be deemed to allege facts, those allegations are denied.

104. DuPont denies that it failed to provide known toxicological information to EPA. The remaining allegations of paragraph 104 are conclusions of law that require no answer. To the extent that they might be deemed to allege facts, those allegations are denied.

105. The allegations of paragraph 105 are conclusions of law that require no answer. To the extent that they might be deemed to allege facts, those allegations are denied.

106. DuPont denies that it failed to provide "known toxicological information" on C-8. The remaining allegations of paragraph 106 are conclusions of law that require no answer. To the extent that they might be deemed to allege facts, those allegations are denied.

107. To the extent that any allegation in the Complaint is not specifically admitted herein, it is denied.

AFFIRMATIVE DEFENSES

DuPont states the following affirmative defenses, and expressly reserves the right to amend this Answer to raise additional affirmative defenses as may arise during the course of discovery and information exchange in this matter:

FIRST AFFIRMATIVE DEFENSE

(Statute of Limitations)

Complainants' claims for relief are barred in whole or in part by the applicable statutes of limitation, including but not limited to 28 U.S.C. § 2462.

SECOND AFFIRMATIVE DEFENSE

(Collateral Estoppel and Res Judicata)

Complainant is barred from asserting the claim it purports to allege in Count II of the Complaint under the doctrines of collateral estoppel and res judicata, because the claim alleged

in Count II was previously litigated and determined under the 1996 Consent Order involving Complainant and DuPont.

THIRD AFFIRMATIVE DEFENSE

(Equitable Estoppel)

Complainant is estopped from asserting the claim it purports to allege in Count II of the Complaint by virtue of the 1996 Consent Agreement, the CAP Agreement, the Revised Addendum, and the Complainant's May 15, 1996 letter to DuPont.

FOURTH AFFIRMATIVE DEFENSE

(Contract)

Count II of the Complaint is barred by EPA's breach of the 1996 Consent Agreement, the CAP Agreement, and the Revised Addendum.

FIFTH AFFIRMATIVE DEFENSE

(Reliance on Complainants' Representations)

DuPont reasonably relied to its detriment on Complainant's letter to DuPont dated May 15, 1996 revising the CAP agreement and stating, "EPA has decided that it is reasonable and equitable to enforce the final revised reporting guidance on a prospective basis only. Therefore, information on the release of chemical substances to and detection of chemical substances in environmental media . . . that predate[s] the effective date of the guidance will not be the subject of an EPA TSCA Section 8(e) enforcement action." DuPont also reasonably relied to its detriment on Complainant's proposal of and agreement to the Revised Addendum, the terms of which state, "The Regulatee, therefore, is no longer required to conduct a file search for this information . . . Information on the release of chemical substances to and detection of chemical

substances in environmental media . . . that predates the effective date of the final revised guidance will not be the subject of an EPA TSCA Section 8(e) penalty enforcement action."

SIXTH AFFIRMATIVE DEFENSE

(Reasonableness and Good Faith)

DuPont at all times acted reasonably and in good faith, based on all relevant facts and circumstances known by DuPont at the time it acted.

SEVENTH AFFIRMATIVE DEFENSE

(Waiver)

Complainant's letter dated May 15, 1996 and the Revised Addendum waived Complainant's right to assert the claim it purports to allege in Count II of the Complaint.

EIGHTH AFFIRMATIVE DEFENSE

(Jurisdiction)

Count III of the Complaint must be dismissed because EPA has no authority to require DuPont to investigate, monitor, report on, or take corrective action for any release of PFOA from any solid waste management unit at DuPont's Washington Works facility, because PFOA is not a hazardous waste nor a hazardous constituent of such waste. Therefore, any such release is beyond the scope of EPA's jurisdiction under RCRA Sections 3004(u) or (v), on which Complainant solely relies for Count III.

NINTH AFFIRMATIVE DEFENSE

(Laches)

Complainant is barred from asserting the claim it purports to allege in the Complaint under the doctrine of laches, because Complainant has brought this action (i) more than 20 years after the events giving rise to Count I, (ii) more than eight years after events bearing on Count II including execution of the CAP Agreement and sending DuPont the May 15, 1996 letter revising the CAP Agreement, and (iii) more than seven years after DuPont provided the toxicological information in response to EPA's letter request sent pursuant to the corrective action referenced in Count III of the Complaint.

TENTH AFFIRMATIVE DEFENSE

(No Right to Relief)

Complainant has no right to relief. 40 CFR §§ 22.04(c)(7), 22.20(a).

ELEVENTH AFFIRMATIVE DEFENSE

(Arbitrary and Capricious, and Abuse of Discretion)

Complainant's allegations constitutes agency action that is arbitrary and capricious, and an abuse of discretion under the Administrative Procedure Act. 5 U.S.C. §§ 553 and 706(2).

TWELFTH AFFIRMATIVE DEFENSE

(Lack of Fair Notice)

EPA's unclear reporting standards did not provide DuPont with fair notice of what information EPA believed DuPont was required to report to EPA.

DISCUSSION OF PENALTY

ORE's Complaint does not propose any specific penalty. Rather, ORE reserves its right to propose a penalty at a later time. DuPont likewise reserves its right to respond to any future proposal of a specific penalty amount.

REQUEST FOR HEARING

DuPont requests a hearing on the facts alleged in the Complaint and the civil penalties proposed thereunder, pursuant to TSCA § 16, RCRA § 3008(b) and the Consolidated Rules of Practice.

Respectfully submitted,

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CERTIFICATE OF SERVICE

A true copy of the foregoing was served via facsimile and first class mail, postage prepaid, this 11th day of August, 2004, upon

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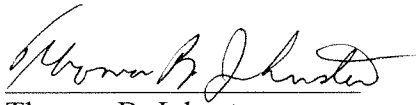

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