December 14, 2005

MEMORANDUM

SUBJECT: Consent Agreement and Proposed Final Order to Resolve DuPont’s Alleged Failure to Submit Substantial Risk Information Under the Toxic Substances Control Act (TSCA) and Failure to Submit Data Requested Under the Resource Conservation and Recovery Act (RCRA)

FROM: Granta Y. Nakayama
   Assistant Administrator

TO: Environmental Appeals Board

The Office of Enforcement and Compliance Assurance requests that the Environmental Appeals Board (Board) approve the accompanying Consent Agreement and proposed Final Order executed by E.I. du Pont de Nemours and Company (DuPont) and the Environmental Protection Agency (EPA) that settles this matter for $10.25 million in penalties plus an additional $6.25 million expenditure for Supplemental Environmental Projects (SEPs).1 This memorandum conforms to the Board’s Consent Order Review Procedures dated January 5, 1993.

The Consent Agreement resolves violations of the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601 et seq., and the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. §§ 6901 et seq., as alleged in two administrative complaints filed on July 8, 2004 (subsequently amended on October 13, 2004), and December 6, 2004, copies of which are included with this transmittal package as attachments A and B.2 The Consent Agreement also

1 The term “EPA” is used throughout this memorandum to refer to EPA’s Enforcement program, other programs or the agency as a whole. The Environmental Appeals Board holds the delegated authority to issue the Final Order in this matter.

2 By Order of Administrative Law Judge Barbara Gunning dated December 7, 2004, the two administrative actions were consolidated. See attachment C. The allegations in the first Complaint are discussed in this memorandum as Counts 1, 2 and 3. The allegation in the
simultaneously commences and concludes four additional alleged violations of TSCA, as discussed below. All eight alleged violations are collectively referred to in this memorandum as EPA’s Action.

The Consent Agreement complies with Section 22.18(b) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Rules of Practice), 40 C.F.R. § 22.18(b). I have reviewed the Consent Agreement and determined that it is consistent with the statutes authorizing the Agency’s action and that the civil penalty is appropriate.

I. Background

A. TSCA Substantial Risk Reporting Requirement

TSCA § 8(e), 15 U.S.C. § 2607(e), provides that a chemical manufacturer, processor, or distributor who obtains information which reasonably supports the conclusion that a substance or mixture presents a substantial risk of injury to human health or the environment shall immediately inform the Administrator. The requirement to inform the Administrator continues until either the person submits the information or has actual knowledge that the Administrator has been adequately informed through another source. EPA relies upon TSCA § 8(e) information to be made aware of potential risks to human health and the environment posed by chemicals. Congress established the TSCA § 8(e) reporting requirement to ensure that EPA would be informed about potential risks so that it could be able to take any appropriate action to protect the public or the environment. Failure to receive TSCA § 8(e) substantial risk information deprives EPA of being fully apprised of potential risks about chemicals and impairs EPA’s ability to take those actions necessary to address potential risks to human health or the environment.

B. The Chemical at Issue

EPA’s enforcement action against DuPont involves the synthetic chemical Amonium Perfluorooctanoate (APFO), also known as C-8 and sometimes called PFOA (Perfluorooctanoic Acid) because APFO disassociates to PFOA in water. PFOA is a perfluorinated detergent/surfactant which has been used by DuPont since 1951 in connection with Teflon®-related products at its Washington Works facility outside Parkersburg, West Virginia. PFOA is produced synthetically and formed through the degradation or metabolism of other fluorochemical products, such as fluorinated telomers that are used in non-stick coatings on carpets, clothing, and food wrappers.

December 6, 2004 Complaint is discussed in this memorandum as Count 4. There are four additional allegations raised and resolved in the Consent Agreement that are discussed in this memorandum as Counts 5, 6, 7 and 8.
C. **Importance of Timely TSCA § 8(e) Reporting for PFOA**

EPA has placed a high priority on understanding the impacts of PFOA. EPA has determined that PFOA is biopersistent in certain animals and associated with developmental effects in animals. As noted in the “Draft Risk Assessment of the Potential Human Health Effects Associated with Exposure to Perfluorooctanoic Acid and Its Salts,” U.S. EPA, Office of Pollution Prevention and Toxics, Risk Assessment Division at 6; 11 (Jan. 4, 2005) (http://www.epa.gov/opptintr/pfoa/pfoarisk.htm), PFOA is considered to be bioaccumulative in humans with a long half-life of about 4.37 years and has the potential for developmental/reproductive toxicity and immunotoxicity in humans. The average human serum background level of PFOA in the general population of the U.S. is estimated to be approximately 5 parts per billion (ppb) and EPA expects this to be true worldwide. PFOA is not naturally occurring, thus all PFOA in human blood is attributable to human activity. EPA is seeking to identify the pathway or pathways (air, water, food, etc.) that result in human exposure to PFOA.3

D. **EPA’s Receipt of TSCA § 8(e) Information Regarding PFOA**

On March 6, 2001, Robert A. Bilott, Esq., of Taft, Stettinius & Hollister LLP, sent copies of documents to EPA that he had obtained as part of class action litigation against DuPont. The class action had been looking into claims of PFOA drinking water contamination in West Virginia and Ohio around the DuPont facility. Bilott’s documents indicated that DuPont had studied PFOA in pregnant workers and their offspring as early as May, 1981 and thus had obtained the first direct human evidence of PFOA crossing the placenta in humans. Bilott’s documents also indicated that DuPont had performed substantial sampling of drinking water in the homes and businesses near its facility, and that DuPont understood in 1987, and confirmed repeatedly in 1988 and 1991, that the drinking water in the homes near its Washington Works facility in West Virginia exceeded DuPont’s community exposure guideline for PFOA exposure.

On September 15, 2004, Bilott sent EPA the results of blood sampling not submitted by DuPont that showed elevated levels of PFOA in the blood of twelve people in the community near DuPont’s Washington Works facility. The samples showed levels of PFOA ranging from 15.7 ppb to 128 ppb.

On December 20, 2004, DuPont provided EPA with blood sampling results for persons that were not employed at the facility that had been performed sometime in 2002. These ten individuals lived in the vicinity of DuPont’s Washington Works Plant in West Virginia and reportedly drank water from private wells located near one or more DuPont landfills at which DuPont disposed PFOA.

While the parties were in negotiations to resolve Counts 1-4 (discussed in detail below), DuPont advised EPA that it had additional materials that it intended to submit to EPA, without conceding that the information was subject to the requirements of § 8(e). In December 2004 and January 2005, DuPont submitted forty-one boxes of information related to PFOA to EPA. EPA reviewed these documents to see if any of the information had not been submitted to EPA as required by TSCA § 8(e). Most of the information had been submitted previously to the Agency. Of the information that had not been previously submitted, EPA determined that three studies should have been submitted under TSCA. This information included two toxicity studies performed on August 11, 1997. One was an inhalation study that exposed male rats to an aerosol form of a perfluorinated chemical. The other was also an inhalation study and involved a different perfluorinated chemical sprayed on rats. DuPont has claimed the identity of these chemicals as Confidential Business Information (CBI). A third study involved an August 29, 1997 inhalation study on rats of a third perfluorinated chemical the identity of which has also been claimed as CBI.

E. Background of the RCRA Claim

The DuPont Washington Works facility operates under a permit pursuant to Section 3005(a) of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6925(a), and 40 C.F.R. Part 270. In 1989, EPA issued the portion of DuPont’s hazardous waste permit (“Permit”) that addresses the provisions of the Hazardous and Solid Waste Amendments of 1984. Pub. L. 98-616, Title II, Nov. 8, 1984. The Permit included provisions implementing, inter alia, RCRA § 3004(u), 42 U.S.C. § 6924(u), and 40 C.F.R. § 264.101. Section 3004(u) of RCRA and 40 C.F.R. § 264.101 require “corrective action for all releases of hazardous waste or constituents from any solid waste management unit at a treatment, storage, or disposal facility seeking a permit under [Subchapter C], regardless of the time at which waste was placed in such unit.” RCRA § 3004(u); 40 C.F.R. § 264.101.

Under Part I, § 1.7 of DuPont’s Permit, EPA may request any relevant information to determine whether cause exists to modify the Permit, revoke and reissue the Permit, terminate the Permit, or to determine compliance with the Permit. On May 5, 1997, EPA requested that DuPont provide “known toxicological information” about PFOA in EPA’s conditional approval of DuPont's Verification Investigation Report, a report required under the terms of the permit used to describe whether there has been a release of a hazardous waste from a solid waste management unit. On June 6, 1997, DuPont responded to EPA’s request for known toxicological information about PFOA but did not include the human blood sampling information concerning the transplacental movement of PFOA that DuPont obtained in 1981. Upon a review of the records associated with DuPont’s permit in early 2004, EPA confirmed that DuPont had failed to submit the 1981 data to EPA pursuant to the terms of the RCRA permit.
II. **Summary of the Violations**

Count 1 alleges that DuPont failed to comply with TSCA § 8(e) when it failed to submit to EPA the information from 1981 that demonstrated transplacental movement of PFOA in humans. This data was substantial risk information concerning PFOA.

Count 2 alleges that DuPont failed to comply with TSCA § 8(e) when it failed to submit to EPA the information concerning PFOA contamination of the drinking water inside people’s homes. This data was substantial risk information concerning PFOA.

Count 3 alleges that DuPont violated RCRA § 3005(a) when DuPont failed to comply with the EPA request for “known toxicological information” by failing to submit the 1981 toxicity data concerning PFOA.

Count 4 alleges that DuPont failed to comply with TSCA § 8(e) when it failed to submit the information from 2004 concerning the elevated PFOA blood levels in twelve individuals living in the vicinity of the Washington Works facility. This data was substantial risk information concerning PFOA.

Count 5 alleges that DuPont failed to comply with TSCA § 8(e) when it failed to report data concerning blood test results of ten individuals living near the Washington Works facility with elevated levels of PFOA. This data was substantial risk information concerning PFOA.

Counts 6, 7 and 8 allege that DuPont failed to comply with TSCA § 8(e) on three occasions when it failed to report toxicity data about the three different rat inhalation studies performed on July 11, 1997 and August 29, 1997. Each of the three studies was substantial risk information concerning the aerosol form of a perfluorinated chemical.

III. **Penalty Policy**

EPA uses its **Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA §§ 8, 12 and 13 (March 31, 1999)** (TSCA Penalty Policy) and the **RCRA Civil Penalty Policy (June 23, 2003)** to help interpret penalty factors contained in each statute and to be consistent in penalty assessment for similarly situated violators committing similar violations. The policies are not binding and are used on a case-by-case basis. TSCA § 16(a)(2)(B) requires EPA to take into account the statutory factors of “Nature,” “Circumstances,” “Extent,” and “Gravity.” RCRA § 3008 requires EPA to consider the seriousness of the violation and the violator’s good faith efforts to comply. EPA also considers the violator’s ability to pay, effect on ability to continue to do business, economic benefit, history of violations and other matters as justice may require.
The TSCA Penalty Policy addresses the potential seriousness of the failure to report under TSCA § 8(e) by providing for, under the proper circumstances, penalty assessments for each day of violation. The TSCA Penalty Policy provides that the full statutory maximum penalty for each day of violation may be appropriate if the new information that was not reported would have had a bearing on the Agency’s risk assessment and chemical control efforts. EPA considers human exposure data to be more important than animal data. EPA also considers whether the failure to report directly interfered with the Agency’s ability to address potentially unreasonable risks to human health. The TSCA Penalty Policy reflects the seriousness EPA attaches to violations of TSCA § 8(e) by not placing caps on the penalties assessed for these violations. Accordingly, for a violation that EPA determines to have directly disrupted EPA’s ability to address situations involving potentially imminent hazards, unreasonable risks, or substantial endangerment to health or the environment, the TSCA Penalty Policy provides that the penalty will be the statutory per day maximum authorized under TSCA for the full period of noncompliance. For those violations of TSCA § 8(e) where the failure to report would not have directly interfered with the Agency’s ability to address imminent hazards, unreasonable risks, or substantial endangerment, the Penalty Policy generally provides for penalties based on each month of violation (the statutory maximum for each day of violation divided by 30).

IV. The Settlement

EPA settled this case in two phases. The first phase resolved the first four Counts that had been alleged in the two complaints. The second phase resolved Counts five through eight that arose from information DuPont provided to EPA after the two complaints were filed.

A. Phase 1: The First Four Counts

Count 1 involves information that DuPont obtained in 1981 regarding human data demonstrating the rate of movement of PFOA from a mother to her fetus. EPA was not aware of this information until Bilott sent it to EPA in 2001. EPA considers the data to be highly significant because the Agency did not previously have any data from humans showing movement of PFOA from mother to fetus, only data from lab animals. The TSCA Penalty Policy notes that violations involving TSCA § 8(e) information that directly disrupt EPA’s ability to address situations involving potentially unreasonable risk or substantial endangerment to human health should be assessed the maximum penalty for each day of the violation. The policy further notes that “failure to comply with the TSCA § 8(e) reporting requirements can be the most serious violations of TSCA § 8. These reports alert the Agency to new information which may have a bearing on the Agency’s chemical hazard/risk assessment and chemical control efforts.”

For a violation such as Count I, the Penalty Policy provides for the statutory maximum penalty on a per-day basis. The statutory maximum for nearly twenty years of daily penalties for
Count 1 is $183,837,500.\textsuperscript{4} EPA believed that DuPont’s failure to provide the information regarding the transfer of PFOA across the placenta was significant human data and should be assessed under the circumstances factor of the statute with the highest penalty because of its potential harm to EPA’s ability to assess risk to human health. However, after calculating the theoretical maximum penalty, the Agency had to assess other factors in determining the appropriate penalty, particularly the risk that the theoretical maximum could not be obtained in litigation (i.e., the “litigation risk”).

There were several potential litigation risks that could have prevented EPA from obtaining the theoretical maximum. The first is whether the Administrative Law Judge (ALJ) would have found it appropriate to assess a penalty at the higher rate as information that “directly disrupts” the Agency’s risk management activities under TSCA. DuPont was prepared to argue that the information was not of such great significance. DuPont has asserted that it had submitted similar data in lab animals and that the data from 1981 was merely confirmatory and not conclusive of substantial risk. Moreover, DuPont would have noted that EPA has never obtained an ALJ assessment of a penalty under TSCA § 8(e) for per day assessment of the statutory maximum penalty. EPA believes it would have prevailed on this issue, but there is no certainty in litigation. If the ALJ determined that EPA did not prove that the failure to submit the information “directly disrupted” EPA’s risk assessment then, under the Penalty Policy, the maximum penalty would be divided by 30 to $6,127,917 for Count 1.

Second, the theoretical maximum assumes that EPA would succeed in obtaining penalties for each day between DuPont obtaining the information in 1981 and EPA receiving the information in 2001. However, there is case law on the statute of limitations that could significantly reduce the penalty that EPA could obtain. DuPont could have asserted that the five year statute of limitations for civil penalties, 28 U.S.C. § 2462, would prevent EPA from bringing Counts 1, 2, or 3, at all, as the action was filed more than five years after DuPont originally failed to submit the information. EPA would have responded that DuPont’s failure to submit the information constituted a continuing violation for each day the information remained unsubmitted. The Board’s decisions support EPA’s argument here and EPA believes it would have prevailed. (See, e.g., In re Lazarus Inc., 7 E.A.D. 318 (EAB 1997) and Newell Recycling, 8 E.A.D. 598 (EAB 1999)) Yet, even if EPA had prevailed on the continuing violations issue, DuPont could have further argued that the penalties should be limited to those violations which occurred within five years prior to the date of the Complaint. If DuPont prevailed on such a

\textsuperscript{4} This value assumes a penalty starting on June 15, 1981, the date the information became available to DuPont, and continuing until March 6, 2001, the date EPA learned of the information. The calculation involves two statutory maximum penalties because of the inflation adjustment rule. One portion of Count 1 would be for the time period prior to January 30, 1997 and includes 5,709 days at $25,000 which equals $142,725,000. For the days after January 31, 1997, the higher daily penalty of $27,500 for 1,495 days totals $41,112,500. Adding these two amounts together results in a hypothetical statutory maximum of $183,837,500 for Count 1.
theory for limiting penalties, the statutory maximum for Count 1 would have been $16,582,500.5

EPA also faced significant litigation risk that could have prevented any recovery of penalties under Count 2. Count 2 involved the contamination of drinking water in people’s homes well above the internal standard of 1 ppb that DuPont had set as part of its community exposure guidelines for PFOA in water. There is evidence that DuPont became aware of levels of PFOA exceeding 1 ppb coming out of the tap in homes in the 1980's but did not report those data to EPA as required under TSCA § 8(e). Prosecution of this Count carried a litigation risk, however, because EPA took a series of administrative actions contemporaneous with DuPont’s testing that may have altered the reporting obligations under TSCA. Starting in February of 1991, the Agency announced its desire to bring the chemical industrial sector into better compliance with TSCA § 8(e), and offered companies the chance to participate in the TSCA § 8(e) Compliance Audit Program, or CAP, and to settle past instances of noncompliance. While the program was designed to be a backward-looking audit of past unreported data, the series of Agency statements by which EPA announced and developed the CAP6 seem to have left some ambiguity regarding the reporting requirements in place during the time the CAP was being developed and eventually executed with DuPont, between February 1991 and June 27, 1996.

Judge Gunning recognized this litigation risk at the hearing on the motions for summary judgment on Count 2, noting in her Order Denying Motions for Accelerated Decision on Counts II and III, “quite frankly, I am having great difficulty making sense of the Revised Addendum with the four corners of the Consent Agreement, the CAP Agreement, and the Revised Addendum.” She indicated that she was unable to discern a clear meaning of the enforcement waiver that DuPont claimed had been given to all environmental contamination reporting under TSCA § 8(e) as part of EPA’s CAP. This language from the Judge raises the possibility that EPA would have recovered no penalty for Count 2 because EPA waived its enforcement authority as part of the settlement under the CAP. Even if the Judge were to have found EPA had not waived its statutory authority to take an action, there were questions about fair notice issues that may have prevented a penalty against DuPont under TSCA for its environmental contamination.

Therefore, as part of defending Count 2, EPA has agreed that it would limit the penalties for failure to provide data related to the drinking water contamination to the time period prior to the 1996 settlement under the CAP. The penalties for Count 2 would only be calculated from 1992 until 1996. The TSCA Penalty Policy assigns daily penalties where the alleged violations do not directly disrupt the EPA’s ability to address substantial risk by using the statutory

5 Using the time period of July 8, 1999 (five years before the filing date of July 7, 2004) and March 6, 2001 (the date EPA received the data) multiplied by $27,500.

6 These communications included Federal Register notices, letters to and agreements with individual participating companies, “enforcement waivers” granted during the audit period, as well as various amendments and addenda issued over the span of five years.
maximum amount and dividing by thirty. Thus, the unmitigated (gravity) penalty under the TSCA Penalty Policy for Count 2 is $1,036,433. As with Count 1, EPA would have asserted that collection of penalties is not prevented by the statute of limitations under a continuing violation theory. If, as with Count 1, DuPont prevailed on limiting collection of penalties for continuing violations to those which occurred within five years of the complaint, EPA would have recovered no penalties for Count 2.

Count 3 is a RCRA violation and, under that Penalty Policy, the gravity-based penalty could be $312,300. This gravity-based penalty is derived by treating the "potential for harm" as moderate and the "extent of deviation" as moderate, resulting in a penalty of $8,000 (which is within the range of $5,500 to $8,799). EPA selected the moderate category for the "potential for harm" axis of the matrix because the toxicological information that EPA requested would be used, *inter alia*, to develop a risk-based comparison level for PFOA to be used in the Health Assessment that DuPont was performing as part of corrective action at the facility. Because there was no health-based criteria available for PFOA, DuPont was required to propose to EPA a provisional risk-based comparison level based, conservatively, on toxicity data. Without having all toxicological information about PFOA, EPA could not completely assess whether the risk-based comparison level that DuPont proposed was appropriate. EPA also recognizes that the RCRA Penalty Policy expressly identifies failure to respond to a formal information request, the violation at issue in Count 3, may have serious implications and merit substantial penalties where the violation undermines the statutory or regulatory purposes or procedures implementing the RCRA program. EPA selected the moderate category for the "extent of deviation" axis of the matrix because while DuPont did provide some toxicological information, and therefore partially responded to the information request, it withheld rare and important human health data -- data that fits squarely within the category of requested information, i.e., "toxicological information."

Under the penalty policy, it is presumed that multi-day penalties are appropriate for days 2-180 of violations with a moderate-moderate gravity-based designation. Because this violation could be designated as moderate-moderate in the gravity-based penalty matrix, and because the violation continued from June 11, 1997 to at least March 7, 2001, the date that EPA received the transplacental movement information, it is appropriate to treat this violation as a multi-day violation. Accordingly, the multi-day penalty component, under the multi-day matrix, would be a per day penalty of $1700 (which is within the range of $1,760 to $275) for 179 days. To calculate the $312,300 penalty, the multi-day penalty component, $304,300 would be added to the $8,000. As with Count 1, EPA would have asserted that collection of penalties is not prevented by the statute of limitations under a continuing violation theory.
Count 4 is another TSCA violation, but it is only a few days long in duration and it is not of the nature that directly disrupted EPA’s ability to address an unreasonable risk situation. Thus the unmitigated (gravity) penalty under the policy is $42,250.\(^7\)\(^8\)

All four Counts were considered in settlement collectively since they all pertained to the Counts in the filed complaints. These first four Counts were settled in principle for a penalty of $10 million plus an additional $5 million to be spent on SEPs.

B. **Phase 2: The Last Four Counts**

DuPont provided information concerning PFOA blood levels in individuals who did not work at the Washington Works facility that gave rise to the violation in Count 5. EPA’s review of the boxes of documents submitted by DuPont after the complaints had been filed resulted in three additional alleged violations of TSCA § 8(e) in Counts 6, 7 and 8.

Since all four of the additional alleged violations involved TSCA § 8(e) violations for PFOA or other perfluorinated chemicals, they were collectively settled with the initial four violations. The failure to provide the blood level data on the residents involved less than three months of failure to report. EPA considered this violation to be a major violation for which per day penalties applied, but did not directly disrupt EPA’s ability to address situations involving unreasonable risk or substantial endangerment, and thus the Penalty Policy would assess one day at the statutory maximum and the remaining days would each have a penalty of the statutory maximum divided thirty. The proposed penalty for the three alleged violations for failure to report the three aerosol applications of the perfluorinated chemicals likewise would have been

\[^7\]32,500 + (10 days - 1) \times \frac{32,500}{30} = 42,250

This equation uses September 5, 2004 until September 14, 2004 for dates of penalty.

\[^8\]EPA determined that no additional penalty was necessary to recover the economic benefit of the violations contained in Counts 1-4 because, under the existing methods for determining economic benefit for reporting obligations under TSCA § 8(e) or RCRA corrective action permits, the economic benefit was much less than the penalty collected. EPA also decided that DuPont is such a large company that the ability to pay and the ability to continue to do business were not a problem for this company. Lastly, EPA noted that DuPont has prior violations under TSCA.
divided by thirty under the Penalty Policy. These violations were resolved for an additional $250,000 penalty and $1.25 million in SEPs.\(^9\)

These three violations again posed significant statute of limitations risk since DuPont obtained the information in 1997. It was possible that EPA would not have been able to recover any penalty had DuPont prevailed on that issue. There were also additional issues involving the clarity of the guidance with respect to inhalation exposure. These issues would have been issues of first impression.

C. Appropriateness of the Penalty as a Whole

EPA believes that the penalty it received for the eight counts in this action is appropriate under the statutory penalty factors of TSCA and RCRA. Since the theoretical maximum penalty for Count 1 is so much larger than for the other seven counts, EPA’s determination as to the appropriate penalty for the case was based largely on its evaluation of the seriousness of the violation and the other factors, particularly litigation risk, associated with Count 1. There was significant risk under Count 1 that EPA would not be able to prove successfully 1) that the violation directly disrupted EPA’s risk assessment activities under TSCA, and 2) that the violation was of a continuing nature and therefore not partly or totally barred by the statute of limitations. Thus, the Judge could have been weighing these issues in deciding whether it would be appropriate to assess nearly twenty years of penalties. EPA took all of these risks into consideration when determining an acceptable penalty for settlement. EPA faced similar litigation risks associated with the statute of limitations for Counts 2, 3, and 6-8. EPA also faced the risk of no recovery under Count 2 due to the lack of clarity surrounding the effect of the 1991 TSCA Compliance Audit Program. In light of the substantial litigation risk, EPA determined that a variance from the TSCA and RCRA penalty policies would be appropriate in this matter. EPA also considered the deterrent effect that a $10,250,000 penalty plus $6,250,000 expenditure for SEPs would have on the regulated TSCA community generally and DuPont in particular.

The $10.25 million penalty is the largest administrative penalty under any statute ever obtained by EPA. It is also more than ten times greater than the largest TSCA § 8(e) penalty EPA has ever obtained.\(^10\) Therefore, although the penalty is a significant reduction from the theoretical maximum penalty under the statute and the TSCA and RCRA penalty policies, EPA

\(^9\)Counts 6, 7 and 8 dealt with information obtained by DuPont in 1997 and submitted to the Agency in December 2004. The aggregate unadjusted gravity based penalty for these violations is approximately $4.5 million.

\(^10\)It is worth noting that the highest TSCA § 8(e) settlements prior to this action were the $1,000,000 payments several companies made as part of the TSCA § 8(e) Compliance Audit Program.
believes it will have a significant deterrent effect on the regulated community. In fact, since filing the initial complaint in July 2004, there has been a significant increase in TSCA § 8(e) and useful information sent into EPA by industry that does not rise to the level of substantial risk under TSCA § 8(e), but has been submitted to EPA as “For Your Information” (FYI).¹¹

This settlement also establishes a commitment by DuPont to spend $6.25 million to perform two voluntary SEPs. The first SEP is a Fluorotelomer-based Product Biodegradation SEP (Biodegradation SEP). Pursuant to this SEP, DuPont will investigate the biodegradation potential of certain chemicals to breakdown to form PFOA. The SEP, valued at $5 million and to be completed in three years, will evaluate nine of DuPont’s commercial fluorotelomer-based products in commerce prior to the settlement. Using two types of biodegradation studies, the SEP will help the public to better understand the inherent degradation potential of fluorotelomer-based products to form PFOA and the behavior of such products when released to the environment.¹² DuPont will use independent laboratories to perform all work associated with the Biodegradation SEP and will hire an independent third party to serve as a Panel Administrator for a Peer Consultation Panel. The Peer Consultation Panel will address specific charges related to the biodegradation studies. The public will have the opportunity to nominate Peer Consultation Panel members.

The scientific community, including EPA, does not have a full understanding of how people are exposed to PFOA. In 2003, EPA released a preliminary risk assessment for PFOA and started a public process, involving industry, stakeholders, and others, to identify and generate additional information to better understand the sources of PFOA and the pathways of human exposure. This Biodegradation SEP will help industry, scientists, the public, and EPA

¹¹FYI submissions often come from trade associations and industry consortia that submit TSCA § 8(e) notices on behalf of member companies covered under the reporting requirement. EPA has received FYI submissions covering a wide variety of chemical substances and mixtures from chemical companies, trade associations, unions, public interest groups, civic associations, private citizens, academic institutions, state and other federal agencies, as well as similar organizations/agencies in foreign countries. These notices contain information on human exposure, epidemiology, toxicity test results, monitoring studies, environmental fate, and other information that may be pertinent to risk assessment.

¹²OECD Guideline 303A, one of the two methodologies that will be followed for the biodegradation studies to be performed under the Biodegradation SEP, is subject to copyright. EPA has purchased a copy of OECD 303A and has included it in the CBI version of the settlement package. See CBI settlement package, Appendix A, Attachment C1. In the non-CBI version of this settlement package, EPA has not included a copy of OECD Guideline 303A but has prepared a document explaining where and how it can be purchased and where it can be viewed. See Attachment D to this memorandum. See also non-CBI settlement package, Appendix A, Attachment C1.
examine the potential sources of PFOA in the environment and potential routes of human exposure to PFOA. For instance, one of the biodegradation studies will help determine if commercial fluorotelomer-based polymer products breakdown to form PFOA, which could explain a source of PFOA in the environment. The other biodegradation study will examine the behavior of commercial fluorotelomer-based polymer products in a simulated waste water treatment plant, which could explain both a source of PFOA in the environment and a route of human exposure to PFOA. The results of these studies will assist EPA in determining a more accurate assessment of the potential risks posed by PFOA and by chemicals that may degrade to form PFOA, and to identify what voluntary or regulatory actions, if any, would be appropriate. In implementing the SEP, DuPont has agreed to require the laboratories it contracts with to follow the Agency's Good Laboratory Practices regulations as well as prepare and follow a Quality Assurance Project Plan.

The Second SEP is a Microscale Chemistry and Green Chemistry SEP in Junior High Schools and High Schools in Wood County, West Virginia. Pursuant to this SEP, DuPont will spend $1.25 million in five junior high schools and three high schools. The goals of this SEP include reducing the adverse impact to public health by minimizing the potential exposure to chemicals in schools, reducing the adverse impact to the environment in and around Wood County, West Virginia by minimizing hazardous waste generated at schools, and enhancing science safety in all of the schools involved in the SEP. The implementation of this SEP will involve close coordination with teachers and administrators in the participating schools. The SEP is expected to be completed over a three year period beginning on the date that the settlement is approved by the Board.

V. Human Health and Environmental Concerns

This administrative action involves information about the movement of PFOA from pregnant women to their babies, the contamination of public drinking water supplies in the vicinity of DuPont’s Washington Works Facility, additional substantial risk information related to PFOA and a request for PFOA toxicity information as part of RCRA corrective action. The Agency regards this information as potentially useful in its ongoing priority review to understand the potential risks that PFOA may pose to human health or the environment. TSCA § 8(e) information is extremely important to alert the Agency to potential risks so that EPA may prioritize its assessment of chemicals so that the most hazardous chemicals are studied immediately.

VI. Past or Pending Actions

DuPont has three prior TSCA § 8 reporting violations. On October 3, 1996, a Consent Order was signed resolving TSCA § 8(e) violations as part of the CAP. On December 2, 1997, a Consent Order was signed resolving TSCA § 8(a) violations concerning Notices of Commencement of production of a new chemical. On September 29, 2003, a Consent Order was
Consent Order was signed resolving TSCA § 8(a) violations concerning Notices of Commencement of production of a new chemical. On September 29, 2003, a Consent Order was signed resolving TSCA § 8(a) violations concerning Inventory Update Rule violations.

VII. Conclusion

For the foregoing reasons, I recommend that the EAB approve the Consent Agreement and sign the Proposed Final Order.

Attachments

cc: Peter Robertson, DuPont Counsel
INTRODUCTION

This First Amended Complaint and Notice of Opportunity for Hearing ("Complaint") is filed pursuant to the Toxic Substances Control Act ("TSCA") § 16(a), 15 U.S.C. § 2615(a), and the Resource Conservation and Recovery Act ("RCRA") §§ 3008(a) and (g), as amended by the Hazardous and Solid Waste Amendments ("HWSA"), 42 U.S.C. §§ 6928(a) and (g), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Consolidated Rules of Practice"), 40 C.F.R. Part 22. A copy of which was enclosed with the original Complaint filed July 7, 2004. See original Complaint, Enclosure A. The Complainant is Walker B. Smith, Director, Office of Regulatory Enforcement, Office of Enforcement and Compliance Assurance, United States Environmental Protection Agency ("EPA" or the "Agency"), who has been duly delegated the authority to institute this action. The Respondent, E. I. du Pont de Nemours and Company ("DuPont" or "Respondent"), with its Headquarters Office located at 1007 Market Street,
Wilmington, Delaware, is the owner and operator of a treatment, storage, or disposal facility, and manufacturer, processor or distributor of chemical substances and mixtures found in commerce.

This Complaint serves as notice that Complainant has reason to believe the Respondent failed to immediately submit information as required by TSCA § 8(e), 15 U.S.C. § 2607(e), thereby committing an unlawful act under TSCA § 15, 15 U.S.C. § 2614. This Amended Complaint further serves as notice that Complainant has reason to believe the Respondent has violated RCRA Subtitle C, 42 U.S.C. §§ 6921-6939e, West Virginia hazardous waste management regulations, the federal hazardous waste corrective action regulations in effect at the time of the violation, and Respondent’s RCRA Permit Number WVD 04 587 5291. Sections 15 and 16 of TSCA authorize EPA to take an enforcement action against any person that commits a prohibited action under TSCA. Sections 3008(a) and (g) of RCRA authorize EPA to take an enforcement action whenever it is determined that a person is in violation of any requirement of RCRA Subtitle C, EPA’s regulations thereunder, or any regulation of a state hazardous waste program that has been authorized by EPA.

On May 29, 1986, pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), and 40 C.F.R. Part 271, Subpart A, the State of West Virginia ("West Virginia") was granted final authorization to administer its base hazardous waste management program in lieu of the federal base hazardous waste management program established under RCRA Subtitle C, 42 U.S.C. §§ 6921-6939e. Through this final authorization, the provisions of the West Virginia hazardous waste management program ("Original Authorized Program") became requirements of RCRA Subtitle C and are, accordingly, enforceable by EPA pursuant to RCRA § 3008(a), 42 U.S.C. § 6928(a). A revised West Virginia hazardous waste management program, set forth at West
Virginia Code of State Rules. West Virginia Hazardous Waste Management Rule (WVHWMR), Title 33, Dep’t of Envtl. Protection, Div. of Waste Management. Series 20, Sections 33-20-1 through 33-20-15 ("Revised Authorized Program"), was authorized by EPA on July 10, 2000, and accordingly, the provisions of the Revised Authorized Program are enforceable by EPA on and after July 10, 2000, pursuant to § 3008(a) of RCRA, 42 U.S.C. § 6928(a).

On December 15, 2003, pursuant to RCRA § 3006(b), and 40 C.F.R. Part 271, EPA authorized revisions to the West Virginia hazardous waste management program. In particular, West Virginia was authorized to administer the Federal Corrective Action Program, Section 3004(u) of RCRA, 42 U.S.C. § 6924(u), created under the Hazardous and Solid Waste Amendments ("HSWA"), enacted on November 8, 1984 (Pub. L. No. 98-616), which amended Subtitle C of RCRA. See also 40 C.F.R. §§ 264.100 - 264.101. At all relevant times, for purposes of the violation of RCRA § 3008(a) at issue in this administrative Complaint, West Virginia was not authorized to implement the Federal Corrective Action Program. Sections 3008(a) and (g) of RCRA, 42 U.S.C. § 6928(a) and (g), authorize EPA to assess a civil penalty against any person who violates any requirement of Subtitle C of RCRA or a regulation or permit issued thereunder.

In accordance with RCRA § 3008(a)(2), 42 U.S.C. § 6928(a)(2), EPA has notified the State of West Virginia through the West Virginia Division of Environmental Protection ("DEP"), of EPA’s intent to issue a Complaint to Respondent for the violation of RCRA, as alleged herein. In support of this Complaint, Complainant hereby makes the following allegations:
COMPLAINT

GENERAL ALLEGATIONS FOR COUNTS 1-11

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

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

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

4. The Ammonium Perfluorooctanoate ("APFO") product, with CAS No. 3825-26-1 (Octanoic acid, pentadecafluoro-, ammonium salt), was marketed by the 3M Company under the tradename FC-143. At all times relevant to this Complaint, DuPont purchased FC-143, commonly referred to by DuPont as C-8 or C8, from 3M.¹

5. APFO is comprised of an ammonium cation and a perfluorooctanoic acid ("PFOA") anion. The "oate" suffix of APFO is the nomenclature tool used to signify the anionic form of a carboxylic acid. The suffix "oic" of pure PFOA is used to signify the neutral protonated form of a carboxylic acid. The pure form of PFOA, CAS number 335-67-1, consists of the PFOA anion and its associated cation which is a proton (H+), which is

¹ The 3M Company manufactured APFO and sold it to DuPont since 1951. In May 2000, 3M announced that it was discontinuing certain perfluorinated chemistries. DuPont began production of APFO between 2000 and 2002 after its supplier, the 3M Company, discontinued manufacturing APFO.
thus different from the PFOA anion alone. In water or biologic media, APFO quickly
dissociates to the ammonium cation and the PFOA anion.

6. When APFO is measured in humans or the environment, it is measured by its PFOA
anion presence and not by the intact APFO. Because there cannot be APFO without the
PFOA anion, and because APFO measured in humans or the environment is measured by
the PFOA anion, a short-hand for discussing APFO is “PFOA.” Consequently, reference
in APFO or C-8 is a reference to this form of PFOA and not the protonated form of
PFOA with CAS No. 335-67-1.

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

8. While most major toxicological studies and industrial exposures involve APFO, the
toxicological effects are likely related to the dissociated anionic form of the acid, i.e.,
PFOA.

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

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

11. PFOA is a perfluorinated detergent/surfactant manufactured, processed or distributed in
the United States by DuPont, in connection with Teflon®-related products.
12. Since 1951, DuPont has manufactured, processed or distributed PFOA at the Washington Works Facility.

13. At all times relevant to this Complaint, Respondent manufactured, processed, or distributed APFO, and consequently, Respondent manufactured, processed, or distributed the PFOA anion of APFO, also referred to as PFOA.

14. The DuPont Washington Works Facility has vented 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.

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

16. PFOA is biopersistent in animals and humans.

17. PFOA is bioaccumulative in humans.

18. PFOA is associated with developmental effects in animals.

19. PFOA is in the blood of the general population in all geographic regions of the United States.

20. PFOA is not naturally occurring, thus all PFOA in human blood is attributable to human activity. PFOA is produced synthetically and formed through the degradation or metabolism of other fluorochemical products, such as fluorinated telomers.

21. DuPont and other researchers have studied PFOA in lab animals. There are gender differences in the elimination of PFOA in rats.

22. There are substantial differences in the half-life of PFOA in rats and humans. There are considerable differences among species in the kinetics of PFOA.
23. In September 2002, the Director of the Office of Pollution Prevention and Toxics ("OPPT") initiated a priority review on PFOA. EPA published Federal Register Notice, 68 Fed. Reg. 18626 (April 16, 2003), to collect additional information. The Agency determined from recent studies that PFOA causes developmental toxicity and other effects in laboratory animals.

24. On April 10, 2003, EPA released a preliminary assessment indicating there was potential exposure to PFOA at very low levels to the U.S. general population. However, this risk assessment also reflected considerable scientific uncertainty regarding the potential risks.


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

26. At TSCA §§ 2(b)(2)and 2(b)(3), 15 U.S.C. §§ 2601(b)(2) and 2601(b)(3), respectively, it states as follows,

"Policy - It is the policy of the United States that - (2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and (3) authority over chemical substances and mixtures should be exercised in such a manner as to not impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."

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

**GENERAL ALLEGATIONS FOR COUNT III**

28. Respondent is a corporation incorporated in the State of Delaware and is a "person" as defined by WVHWMR § 33-20-2, RCRA § 1004(15), 42 U.S.C. § 6903(15), and 40 C.F.R. § 260.10. At all relevant times, for purposes of this Complaint, DuPont was a corporation organized under the laws of the State of Delaware.

29. DuPont owns and operates the Washington Works Facility located at Route 892 South DuPont Road, Washington, Wood County, West Virginia 26181.

30. DuPont is, and has been, at all times relevant to this Complaint, the "owner" and "operator" of the Washington Works Facility as those terms are defined by WVHWMR § 33-20-2 and 40 C.F.R. § 260.10.

31. DuPont’s Washington Works Facility is a "facility," as that term is defined by WVHWMR § 33-20-2 and 40 C.F.R. § 260.10.

32. Section 3004(u) of RCRA, and regulations promulgated thereunder, codified at 40 C.F.R. §§ 264.100 - 264.101, require corrective action as necessary to protect human health and the environment for all releases of hazardous waste or constituents from any solid waste management unit at a treatment, storage, or disposal facility, regardless of the time at which waste was placed in such unit, for all permits issued after November 8, 1984.
33. PFOA is in the soil and groundwater at, and within the vicinity of, DuPont’s Washington Works Facility.

34. PFOA, as described above, is a discarded material and a “solid waste” as defined under RCRA § 1004(27), 42 U.S.C. § 6903(27) and a “hazardous waste” as defined under RCRA § 1004(5), 42 U.S.C. § 6903(5).

35. On or about January 5, 1987, West Virginia issued to DuPont a RCRA “base” permit for the treatment, storage, or disposal of hazardous waste at its Washington Works Facility.

36. In March 1985, EPA requested DuPont provide information on the Solid Waste Management Units (“SWMUs”) at the Washington Works Facility.

37. On December 13, 1989, EPA issued to DuPont the corrective action portion of DuPont’s full RCRA Permit, EPA ID No. WVD 04 587 5291 (“Corrective Action Permit”), for the Washington Works Facility, pursuant to Sections 3005(c) and 3004(u) of RCRA, 42 U.S.C. §§ 6925(c), 6924(u). The Corrective Action Permit was based upon information EPA received in response to the March 1985 request for information.

38. On December 16, 1999, EPA extended the term of the corrective action portion of DuPont’s RCRA permit until the effective date of a new corrective action permit for the Washington Works Facility.

39. The corrective action portion of DuPont’s RCRA Permit, as extended, remains fully effective as of the filing of this Complaint.

**COUNT 1 - Transplacental Movement of PFOA**

40. Complainant re-alleges paragraphs 1-27, above, as if fully set forth below.
41. On or about March 20, 1981, the 3M Company, DuPont's supplier of PFOA, advised
DuPont about the potential for PFOA to cause birth defects in rats. Specifically, 3M
advised that researchers observed what appeared to be treatment related damage to the
eye lenses of some rat pups.\(^2\)

42. On or about May 14, 1981, DuPont revised an existing document that described the
results of a blood sampling of eight pregnant employees at the Washington Works
Facility.\(^3\) The following August 1981, DuPont revised this document again with
handwritten notations. This 'blood sampling' document identifies the levels of PFOA
measured in the blood of certain pregnant employees at the Washington Works Facility
along with a description of the status of a child.

43. DuPont's human blood sampling was conducted to monitor these pregnant employees
for their exposure to PFOA, to monitor umbilical cord blood for PFOA on at least one
occasion, and to test babies' blood for PFOA on at least two occasions.

44. The May 14, 1981 document provides certain details on one pregnant woman with 0.078
parts per million ("ppm") C-8 in her blood. She is described as having a "Normal child -
born April 1981. Umbilical cord blood 0.055 ppm."

45. The existence of the "0.055 ppm" of PFOA in the umbilical cord blood demonstrates
PFOA movement in humans, and specifically, that PFOA moved from the mother,
through the placenta, to the fetus.

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\(^2\) Later studies could not reproduce the fetal lens defect.

\(^3\) The document does not indicate the date it was created.
46. DuPont did not immediately submit, nor has it ever submitted, this human blood
sampling information concerning the transplacental movement of PFOA, a chemical
known then to be persistent, to demonstrate liver toxicity in animals and that DuPont was
reviewing for possible birth defects.

47. On or about December 18, 1981, by memorandum, DuPont discussed an inquiry from a
mother with a child with 0.4 ppm C-8 in its blood, asking whether a baby’s liver was
more susceptible to damage by PFOA than that of an adult. The memorandum from J. F.
Doughty, DuPont’s Washington Works Facility, to R.D. Ingalls, DuPont’s Wilmington,
Delaware office, also inquired as to whether the 3M studies on C-8 showed any
malformations other than eye defects.

48. On or about March 16, 1982, DuPont reported data to EPA, that EPA subsequently
regarded as substantial risk data under TSCA § 8(e), concerning the transplacental
movement of PFOA in rats. DuPont continued to fail or refuse to disclose that it had
obtained human blood sampling data in 1981 confirming the transplacental movement of
PFOA in humans.

49. DuPont reviewed the human blood sampling information as part of its litigation
preparation involving the Washington Works Facility in federal district court, Southern
District of West Virginia, when it produced the human blood sampling document to
opposing counsel on September 24, 2000.

50. DuPont continued to fail or refuse to submit to EPA the data concerning human blood
sampling confirming the transplacental movement of PFOA after it had included the
51. The human blood sampling information confirming the transplacental movement of PFOA is information that reasonably supports the conclusion that PFOA presents a substantial risk of injury to human health that the Administrator was not already adequately informed about at the time the information was obtained by DuPont or at any time prior to the date EPA finally received the data.

52. The 1981 data indicating that PFOA moves across the placental barrier between PFOA-exposed mothers and their fetuses suggest that such fetuses could experience toxic effects associated with PFOA, including persistence/bioaccumulation, and, as observed in animal tests, developmental toxicity and liver toxicity. The human data are more indicative of such possibility in humans than the data submitted to EPA by DuPont in 1982, which demonstrated that PFOA moved across the placental barrier in rats used in laboratory experiments. EPA's efforts to characterize effects of PFOA might have been more expeditious had the data on transplacental movement of the chemical in humans been submitted immediately by DuPont when DuPont obtained the information in 1981.


54. The Agency considers the human blood sampling information confirming transplacental movement of PFOA in humans to reasonably support the conclusion of a substantial risk of injury to health or the environment. The Administrator was not adequately informed
about this risk at the time the information was obtained by DuPont in 1981, and was not informed until March 6, 2001.4

55. DuPont was required to immediately inform the EPA about the human blood sampling information confirming transplacental movement of PFOA under TSCA § 8(e), 15 U.S.C. § 2607(e), as information which reasonably supports the conclusion that such substance or mixture presents a substantial risk to health.

56. DuPont was required under TSCA § 8(e) to inform the Administrator every day between June 15, 1981 and March 6, 2001, about the human blood sampling information confirming transplacental movement of PFOA.

57. DuPont failed or refused to immediately inform the Administrator about the human blood sampling information confirming transplacental movement of PFOA.

58. Section § 15(3)(B) of TSCA, 15 U.S.C. § 2614(3)(B), provides that it is unlawful for any person “to fail or refuse to submit reports, notices, or other information” as required.

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

COUNT II - Public Water Supply Contamination

60. Complainant re-alleges paragraphs 1-27, above, as if fully set forth below.

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4 Mr. Robert A. Bilott, Esq. of Taft, Stettinius & Hollister, LLP first supplied the human blood sampling document to EPA on March 6, 2001.
61. On or about June 14, 1984, DuPont compiled sampling results which determined that PFOA was present in the public water supply in communities in the vicinity of the Washington Works Facility.

62. On or about August 29, 1984, DuPont summarized the results from water samples collected on March 15, 1984, and a second set of water samples taken on June 4, 1984, in a letter to J. A. Schmid, from J. F. Doughty (signed John Doughty) entitled, SUMMARY OF C-8 IN WATER SAMPLING PROGRAM. This letter includes a table showing the location of samples of drinking water from such sites as an employee's home, a public drinking fountain, a private well, and other sites collected on March 15, 1984. These sampling sites were located in West Virginia and Ohio. The above-described 1984 drinking water sampling results detected PFOA in the public water supply for Lubeck, West Virginia and in Little Hocking, Ohio.

63. On or about March 13, 1987, DuPont recorded C-8 at 1.9 parts per billion ("ppb") in two water samples described as "Lubeck Business Tap." On or about May 12, 1988, November 2, 1988, May 7, 1989, May 23, 1991, May 29, 1991, and August 8, 1991, DuPont obtained "LPSD Home Tap" sampling showing PFOA at the respective levels of 2.2 ppb, 1.4 ppb, 0.7 ppb, 3.8 ppb, 3.8 ppb and 3.9 ppb in home tap water.

64. The two samples in paragraph 63 from "Lubeck Business Tap[s]" appear to be among the five samples discussed in a DuPont Interoffice Memorandum dated May 12, 1987, from Tony Playtis to Roger Zipfel. Sample number 2 and sample number 3 are identified as "taken on" March 13, 1987, and the analytical report showed C-8 at 1.9 ppb for both samples. Sample number 2 is identified as drinking water coming from Powell's General
Store, Washington, WV and sample number 3 is identified as drinking water from the
Lubeck Pennzoil, Lubeck, WV. Both samples were collected by C. L. Hill.

65. On or about August 29, 1988, a DuPont interoffice memorandum from Anthony J. (Tony)
Playtis to Roger J. Zipfel with the subject: “Test Results - C8 in Groundwater,”
contained information on the level of PFOA detected in six water samples. Four of the
six samples indicate PFOA over 1 ppb at the locations sampled. One sample, among the
six listed, is described as follows:

<table>
<thead>
<tr>
<th>Sample Description</th>
<th>C8 Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lubeck Water - Playtis Home</td>
<td>2.2 ppb</td>
</tr>
<tr>
<td>5/12/88, 17:00</td>
<td></td>
</tr>
</tbody>
</table>

66. On or about January 30, 1989, in a DuPont Interoffice memorandum from Anthony J.
(Tony) Playtis to Roger J. Zipfel with the subject: “Test Results - C8 in Water,” there are
results for four local water sources sampled. The results from two of the four samples
indicate PFOA in an amount greater than 1 ppb. One sample, among four listed, is
described as follows:

<table>
<thead>
<tr>
<th>Sample Description</th>
<th>ppb C8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lubeck Water - Playtis Home</td>
<td>1.4</td>
</tr>
<tr>
<td>11/2/88, 17:00</td>
<td></td>
</tr>
</tbody>
</table>

67. As of 1991, DuPont described its CEG as follows: Community Exposure Guidelines
(“CEGs”) are DuPont’s exposure guidelines that are expected to be without any effect to
members of the community during continuous 24-hour a day exposure to a chemical or
physical agent. CEGs are based on the best available information from industrial
experience, animal toxicity studies, controlled human exposure studies, and
epidemiological findings.
68. On or about June 6, 1991, DuPont set a Community Exposure Guideline for drinking water ("CEGw") at 1 microgram per liter ("1 μg/L" or "1 ppb") for PFOA. In June of 1991, DuPont's Washington Works Facility was aware of the 1 ppb CEGw that had been established for PFOA.

69. At the time DuPont adopted a CEGw at 1 ppb, it had collected results from drinking water samples as discussed above, and had information regarding the level of PFOA detected in such samples. DuPont took many drinking water samples and tested them for PFOA during the years 1984 through 1991. In a June 14, 1984, Personal and Confidential Update, titled "UPDATE ON C-8 IN WATER SAMPLES," some of the following sampling results were provided:

- Washington 3/25/84 .......... 1.2 ppb C-8
- Washington 6/4/84 .......... 1.0 ppb C-8
- Lubeck 6/4/84 .......... 1.5 ppb C-8
- Little Hocking 3/15/84 .......... 0.8 ppb C-8

70. In a July 11, 2003, letter to Rich Hefer of EPA, DuPont provided some but not all of the analytical results that it had obtained for PFOA in drinking water. Some of the analytical results provided to EPA in July 2003, are listed below:

<table>
<thead>
<tr>
<th>C-8 OFF SITE SAMPLING</th>
<th>C-8 PPB</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUBECK BUSINESS TAP (2) 3/13/87 ......</td>
<td>1.9, 1.9</td>
</tr>
<tr>
<td>LPSD HOME TAP -P 5/12/88 ................</td>
<td>2.2</td>
</tr>
<tr>
<td>LPSD HOME TAP -P 11/2/88 ..............</td>
<td>1.4</td>
</tr>
<tr>
<td>LPSD HOME TAP -P 5/7/89 ..............</td>
<td>0.7</td>
</tr>
<tr>
<td>LPSD HOME TAP -M 5/23/91 .............</td>
<td>3.8</td>
</tr>
<tr>
<td>LPSD HOME TAP -C 5/29/91 .............</td>
<td>3.8</td>
</tr>
</tbody>
</table>

The C-8 OFF SITE SAMPLING table also includes a sampling result dated after DuPont had adopted the CEGw standard of 1 ppb. It is listed on the chart as follows:
- LPSD HOME TAP -M 8/8/91 .............. 3.9
71. These results, discussed in paragraphs 69-70, above, indicate a substantial risk of widespread exposure to a chemical at a level of concern that requires informing the Administrator immediately.

72. DuPont purchased the drinking water supply wells from the Lubeck Public Service District (LPSD) during the 1986 to 1990 time period. New drinking water supply wells were established 2.7 miles away from the Washington Works Facility for the LPSD.

73. On or about June 23, 1991, after DuPont had purchased the drinking water supply wells from LPSD, DuPont detected PFOA at 2.4 ppb in a new well in the new Lubeck well field (2.7 miles south - southwest of Washington Works), as discussed in a September 19, 1991 memorandum to Walt Stewart from Terry Vandell with the subject: "Meeting Minutes Of The On-Site Washington Works Meeting (September 11, 1991, 9:00 AM-11:00 AM) Regarding The September 4, 1991 Proposed C-8 Sampling Program."

74. DuPont failed or refused to submit the information it had obtained on the widespread contamination of PFOA in public drinking water at levels exceeding its CEGw, even after reviewing it specifically to decide whether it should be submitted to EPA under TSCA § 8(e). On or about January 12, 2000, in a letter from DuPont's Senior Counsel Andrea V. Malinowski, Esq. to Douglas Johns, Esquire, Legal, General Electric Plastics ("GE"), DuPont replied to an e-mail concerning FC-143. The letter states, "Regarding item 1, DuPont did not submit a TSCA 8(e) notification to EPA concerning the presence of FC-143 in environmental media. The 8(e)-reportability of the presence of FC-143 in environmental media was reviewed within DuPont and determined to not be reportable."
The letter provides four bullets as the reasons for that decision. Those bullets are summarized as follows:

- Toxicology studies were submitted to EPA by the 3M Company for FC-143,
- Discharge of FC-143 in an outfall to the Ohio River had been reported to EPA,
- FC-143 was detected in the aquifer underlying a solid waste management unit identified as B-4, at the Washington Works Facility,
- The presence of “detectable levels” of C-8 in the public supply wells had been reported to EPA’s waste program in a February 9, 1990 letter.

The four bullets listed by DuPont in its January 12, 2000, letter to GE are misleading as follows:

- The toxicology studies provided by 3M do not include DuPont’s human blood sampling data concerning the transplacental movement of PFOA.
- DuPont’s statement that FC-143 is present in outfall 005 does not provide information about widespread contamination of home tap water with PFOA above DuPont’s CEGw of 1 ppb.
- DuPont’s detection of PFOA under the DuPont Local Landfill does not give the Administrator notice that any of the PFOA had migrated off site. The statement was made as part of a statement of “Releases, Spills, etc.” that dealt with leakage of surfactant when “the third basin was constructed . . .”
- DuPont’s statement to EPA in the Verification Investigation Workplan for Six Solid Waste Management Units on February 9, 1990, that C-8 was in the public water supply begins with the statement, “Releases have occurred in the past.” After discussing in the
Verification Investigation Workplan the construction of a dam in 1964 and the re-lined impoundments in 1973-74. DuPont states, “The Lubeck public supply wells have perfluorooctanoate (also called C-8). Washington Works is in the process of purchasing these wells from Lubeck Water supply.” This statement gives the impression that the C-8 release has ceased, was confined to a small area, and that DuPont purchased the contaminated area to prevent public exposure.

76. In DuPont’s January 12, 2000 letter to GE, discussed in paragraphs 74-75, above, DuPont fails or refuses to recognize that its C-8 contamination in public drinking water is ongoing, that C-8 contamination extends into people’s homes, and that DuPont had never informed the Administrator of levels of C-8 contamination of drinking water greater than three times higher than DuPont’s own CEGw set more than 8 years before DuPont wrote its letter to GE.

77. DuPont’s January 12, 2000 letter to GE does not discuss the 1 ppb CEGw for PFOA established by DuPont on June 6, 1991, and the subsequent samples obtained from one of the new public water supply wells showing over twice that level at 2.4 ppb PFOA on June 23, 1991.

78. DuPont reviewed the PFOA contamination of the public water supply information as part of its preparation for litigation in federal district court, Southern District of West Virginia, concerning PFOA contamination originating from the Washington Works facility. DuPont failed or refused to submit to EPA the substantial risk information concerning PFOA contamination in public drinking water that it provided to opposing counsel on or about October 18, 2000.
79. TSCA § 8(e), 15 U.S.C. § 2607(e), provides that "Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

80. The Agency considers the information concerning the contamination of the public water supply to reasonably support the conclusion of a substantial risk of injury to health or the environment. The Administrator was not informed at the time DuPont obtained monitoring data showing contamination of the public water supply prior to 1991, and subsequent to that time.

81. DuPont was required under TSCA § 8(e), 15 U.S.C. § 2607(e), to immediately report the information concerning DuPont's monitoring data of the contamination of the public water supply for the communities in the vicinity of its Washington Works Facility and this obligation continued as DuPont learned more about the contamination.

82. DuPont was required under TSCA § 8(e) to inform the Administrator every day between July 24, 1991 and March 6, 2001 about the information it had obtained on the widespread contamination of public drinking water at a level greater than its CEGw.

83. DuPont was required to inform the Administrator immediately about information concerning the PFOA contamination of public drinking water that DuPont obtained in

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5Robert A. Bilott, Esq. of Taft, Stettinius & Hollister, LLP, submitted the information as discussed in footnote 4.
1984. DuPont continued to fail or refuse to submit this information to the Administrator as it increased its understanding that the PFOA contamination extended into people's homes and was more than twice DuPont's own Community Exposure Guideline for water.

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

85. DuPont's failure or refusal to immediately submit to the Administrator its understanding that the PFOA contamination extended into people's homes at levels approaching and exceeding its Community Exposure Guideline for water as required under TSCA § 8(e) is an unlawful act under TSCA § 15(3)(B).

**COUNT III - RCRA Permit Violation**

86. Complainant re-alleges paragraphs 28-39, above, as if fully set forth below.

87. Section 3005(a) of RCRA, 42 U.S.C. § 6925(a), provides, in pertinent part, that each person owning or operating an existing facility or planning to construct a new facility for the treatment, storage, or disposal of hazardous waste is required to obtain a permit and comply with the regulations promulgated by EPA concerning permitting requirements. In addition, the treatment, storage, or disposal of hazardous waste or the construction of a new facility is prohibited unless in compliance with all applicable permitting requirements.

88. Section 3005(c) of RCRA, 42 U.S.C. § 6925(c), provides, in pertinent part, that upon a determination by EPA (or a state, if applicable), of compliance by a facility for which a
permit is applied for pursuant to RCRA §§ 3004 and 3005, 42 U.S.C. §§ 6924 and 6925, EPA (or the state) shall issue a permit for such facilities; and that each permit issued under RCRA § 3005 shall contain such terms and conditions necessary to protect human health and the environment.

89. Section 3004(u) of RCRA, 42 U.S.C. § 6924(u), requires, in pertinent part, that each permit issued after November 8, 1984, by EPA or an authorized state, shall require corrective action from any solid waste management unit at the treatment, storage, or disposal facility seeking such permit, regardless of the time at which waste was placed in such unit.

90. Section 3004(v) of RCRA, 42 U.S.C. § 6924(v), requires, in pertinent part, that corrective action be taken beyond the facility boundary at a treatment, storage or disposal facility where necessary to protect human health and the environment.

91. 40 C.F.R. § 270.32(b)(2) and WVHWMR § 33-20-11.1, provide, in pertinent part, that each permit issued under RCRA § 3005 shall contain terms and conditions as EPA determines necessary to protect human health and the environment.

92. Part I, Section C of DuPont’s’s Corrective Action Permit states, in pertinent part, that pursuant to RCRA § 3005(c)(3), the permit contains those terms and conditions determined necessary to protect human health and the environment.

93. 40 C.F.R. § 270.30(a) and WVHWMR § 33-20-11.1, provide, in pertinent part, that a RCRA permittee must comply with all conditions of its permit, and that any permit noncompliance, except under the terms of an emergency permit, constitutes a violation of
RCRA and is grounds for an enforcement action; for permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application.

94. Part 1, Section 1.1 of DuPont's Corrective Action Permit requires Respondent to comply with all conditions of the permit, except to the extent and for the duration such noncompliance is authorized by an emergency permit. Any other permit noncompliance constitutes a violation of RCRA and is grounds for enforcement action, permit termination, revocation and reissuance, or modification, or for denial of a permit renewal application.

95. 40 C.F.R. § 279.30(cii) and WVHWMR § 33-20-11.1, provide, in pertinent part, that the permittee shall furnish within a reasonable time, any relevant information that EPA may request to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit, or to determine compliance with the permit.

96. Part 1, Section 1.7 of DuPont's Corrective Action Permit requires, in pertinent part, that Respondent shall furnish, within the specified time, any relevant information that EPA may request to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit, or to determine compliance with the permit.

97. The Corrective Action Permit for the Washington Works Facility generally requires DuPont's to perform the following: 1) a Verification Investigation (VI), including a VI Workplan and VI Report, to evaluate to what extent hazardous constituents have been released to the soil, surface water, and groundwater as a result of historic plant operations at Solid Waste Management Units (SWMUs) and to define SWMU areas of concern where additional data are needed to determine the extent of constituent migration; 2) a
RCRA Facility Investigation (RFI), including an RFI Workplan and RFI Report, for suspected releases from specific SWMUs at the Washington Works Facility, and 3) a Corrective Measure Study. All plans, reports, schedules, and other submissions required by the terms of EPA’s portion of DuPont’s Corrective Action Permit are, upon approval by EPA, incorporated into the permit.

98. On or about December 14, 1990, DuPont submitted to EPA a revised VI Workplan. As required by Part II.B.1 of DuPont’s Corrective Action Permit, the VI Workplan is designed to, among other things, describe how the permittee will investigate the release of hazardous waste or hazardous constituents from all SWMUs and determine the need for further investigation and/or implementation of interim measures at the Washington Works Facility.

99. DuPont’s Verification Investigation was conducted in the winter of 1991 for the SWMUs at the Washington Works Facility. C-8 is one of the constituents that DuPont was required to investigate as part of the Verification Investigation.

100. On or about April 3, 1992, DuPont submitted to EPA a VI Report. As required by Part II.B.2 of DuPont’s Corrective Action Permit, the VI Report was to contain all data organized in a logical sequence and include, among other things, summaries of all findings, problems encountered during the investigation, actions taken to correct the problems, and copies of all daily reports, inspections reports, and laboratory/monitoring data. DuPont was also required to include in the VI Report, conclusions and recommendations.
101. C-8 (also referred to as PFOA or FC-143 as described in paragraph 6, above) is one of the constituents that DuPont detected as part of the Verification Investigation it performed at the Washington Works Facility, and included in its VI Report to EPA in April of 1992.

102. On or about May 5, 1997, EPA issued a Notice of Deficiency (Notice) to DuPont for the VI Report. In the Notice, EPA requested that DuPont provide a response to EPA, within 30 days of receipt, for all deficiencies identified in the Notice.

103. In the Groundwater portion of the Notice, EPA requested that DuPont provide to EPA “known toxicological information” regarding C-8.

104. In DuPont’s Response to the Notice of Deficiency (Response to the Notice) on or about June 6, 1997, and in its specific response to EPA’s request for “known toxicological information,” DuPont directed EPA to information that was included in the VI Report, and provided “[a]dditional C-8 toxicological information” at Attachment 2 of the Response to Notice, titled “Toxicological Information on C-8.”

105. The “Toxicological Information on C-8” included certain “Health Hazardous Data.”

106. In the section regarding “Health Hazardous Data,” DuPont did not provide EPA the human blood sampling information concerning the transplacental movement of PFOA that DuPont obtained in 1981 when performing blood sampling of pregnant workers at the Washington Works Facility.

107. Information regarding the transplacental movement of C-8 in humans is, and, at the time of EPA’s Notice and DuPont’s Response to the Notice was, “known toxicological information” about C-8.
108. Neither in its Response to the Notice in June 1997, nor at any other time, did DuPont provide to EPA the information regarding the transplacental movement of C-8 in humans.

109. In its Response to the Notice in June 1997, DuPont did not provide all “known toxicological information” it had regarding C-8 because it did not provide to EPA the information regarding the transplacental movement of C-8 in humans.

110. All known toxicological information about C-8 is “relevant information” that EPA might request “to determine whether cause exists for: modifying, revoking and reissuing or terminating [DuPont’s Corrective Action Permit,] or to determine compliance with this permit. Part I, Section 1.7; 40 C.F.R. § 270.30(h); WVHWMR § 33-20-11.

111. DuPont’s failure to provide this known toxicological information constitutes noncompliance with DuPont’s duty to provide information, as required by Part I, Section 1.7 of DuPont’s Corrective Action Permit, 40 C.F.R. § 270.30(h) and WVHWMR § 33-20-11.1

112. Because DuPont did not comply with this provision of its Corrective Action Permit to provide known toxicological information, DuPont did not comply with all conditions of its permit, as required by Part I, Section 1.1. of DuPont’s Corrective Action Permit, 40 C.F.R. § 270.30(a), and WVHWMR § 33-20-11.1.

113. From at least June 6, 1997, until at least March 6, 2001, DuPont violated RCRA § 3005(a), 42 U.S.C. § 6925(a), Part 1, Section 1.7 of DuPont’s Corrective Action Permit, 40 C.F.R. § 270.30(h), and WVHWMR § 33-20-11.1, by failing to provide the known toxicological information on C-8 described above.
CIVIL PENALTY ASSESSMENT FOR COUNTS I-II

Section § 16 of TSCA, 15 U.S.C. § 2615, authorizes the assessment of a civil penalty for the violations described herein of $25,000 for each day of violation occurring and continuing before January 30, 1997, and up to $27,500 for each day of violation occurring and continuing after January 30, 1997, to March 6, 2001, the date EPA received the TSCA § 8(e) information from a third-party.

Pursuant to 40 C.F.R. § 22.14(a)(4)(ii), Complainant is not proposing a specific penalty at this time, but will do so at a later date. See 40 C.F.R. § 22.19(a)(4). In determining the amount of a civil penalty for violations of TSCA, Complainant shall take into account the nature, circumstances, extent, and gravity of the violations alleged, as well as DuPont's ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. See also Enclosure B to the original Complaint.

CIVIL PENALTY ASSESSMENT FOR COUNT III

Sections §§ 3008(a)(3) and (g) of RCRA, 42 U.S.C. §§ 6928(a)(3) and (g), authorize the assessment of a civil penalty for violations described herein of $25,000 for each day of violation occurring and continuing before January 30, 1997, and up to $27,500 for each day of violation

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occurring and continuing after January 30, 1997, at least to March 6, 2001, the date EPA received the information regarding the transplacental movement of PFOA from a third-party.

Pursuant to 40 C.F.R. § 22.14(a)(4)(ii), Complainant is not proposing a specific penalty at this time, but will do so at a later date. See 40 C.F.R. § 22.19(a)(4). In determining the amount of a civil penalty for violations of RCRA pursuant to RCRA §§ 3008(a)(3) and (g), 42 U.S.C. §§ 6928(a)(3) and (g), Complainant shall take into account the seriousness of the violation and any good faith efforts by DuPont to comply with the applicable requirements. See also Enclosure C to the original Complaint.

NOTICE OF OPPORTUNITY TO REQUEST A HEARING

As provided in TSCA § 16(a)(2)(A), 15 U.S.C. § 2615(a)(2)(A), and RCRA § 3008(b), 42 U.S.C. § 6928(b), you have the right to request a formal hearing to contest any material fact set forth in this Complaint or to contest the appropriateness of the penalty. To avoid being found in default, which constitutes an admission of all facts alleged in the Complaint and a waiver of the right to a hearing and having a penalty assessed without further proceedings, you must file a written Answer within thirty (30) days of receiving this Complaint.

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

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7 The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, requires EPA to periodically adjust penalties to account for inflation. EPA’s Civil Monetary Penalty Inflation Adjustment Rule establishes $27,500 as the maximum civil penalty that may be assessed under RCRA §§ 3008(a) and (g), per violation, between January 31, 1997, through May 15, 2004, and $32,500 for violations occurring thereafter. See 40 C.F.R. § 19, 61 Fed Reg. 69,360 (Dec. 31, 1996); 69 Fed. Reg. 7121 (Feb. 13, 2004).
state, the allegation is denied. Failure to deny any of the allegations in this Complaint will constitute an admission of the undenied allegation.

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

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

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

Mark Garvey, Attorney  
Toxics and Pesticides Enforcement Division (2245A)  
Office of Regulatory Enforcement  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460-0001  
(202) 564-4168

Ilana Saltzbart, Attorney  
Toxics and Pesticides Enforcement Division (2245A)  
Office of Regulatory Enforcement  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460-0001
Any hearing requested will be conducted in accordance with the Administrative
Procedures Act, 5 U.S.C. § 551 et seq., and the Consolidated Rules of Practice. See Enclosure A
to the original Complaint.

INFORMAL SETTLEMENT CONFERENCE

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

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

Please be advised that the Consolidated Rules of Practice prohibit any *ex parte*
(unilateral) discussion of the merits of any action with the Administrator, Environmental Appeals
Board Judge, Administrative Law Judge, or any person likely to advise these officials in the
decision of the case, after the Complaint is issued.

By:

[Signature]

Date: 10-13-04

Walker B. Smith, Director
Office of Regulatory Enforcement
Office of Enforcement And Compliance Assurance
U.S. Environmental Protection Agency
IN THE MATTER OF:  

E. I. du Pont de Nemours and Company  

Wilmington, DE  

Respondent  

Washington Works Facility  

Route 892 South DuPont Road  

Washington, Wood County, WV  

Docket No. TSCA-HQ-2005-5001  

COMPLAINT AND NOTICE OF OPPORTUNITY FOR HEARING  

INTRODUCTION  

This Complaint and Notice of Opportunity for Hearing ("Complaint") is filed pursuant to the Toxic Substances Control Act § 16(a), 15 U.S.C. § 2615(a), ("TSCA"), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Consolidated Rules of Practice"), 40 C.F.R. Part 22, a copy of which is enclosed with this Complaint. See Enclosure A. The Complainant is Ann M. Pontius, Director, Toxics & Pesticides Enforcement Division, Office of Regulatory Enforcement, Office of Enforcement and Compliance Assurance, United States Environmental Protection Agency ("EPA" or the "Agency"), who has been duly delegated the authority to institute this action. The Respondent is E. I. du Pont de Nemours and Company ("DuPont" or "Respondent"), 1007 Market Street, Wilmington, Delaware, a manufacturer, processor or distributor of chemical substances and mixtures in commerce.
This Complaint serves as notice that Complainant has reason to believe that Respondent failed to immediately submit information as required by TSCA § 8(e), 15 U.S.C. § 2607(e), thereby committing an unlawful act under TSCA § 15, 15 U.S.C. § 2614. Section 16 of TSCA authorizes EPA to take an enforcement action against any person that commits a prohibited action under TSCA.

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

COMPLAINT

GENERAL ALLEGATIONS

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


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

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

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\(^1\) The 3M Company manufactured APFO and sold it to DuPont from 1951 until 2002 under the tradename FC-143.
5. APFO is comprised of an ammonium cation and a perfluorooctanoic acid ("PFOA") anion. The "oate" suffix of APFO is the nomenclature tool used to signify the anionic form of a carboxylic acid. The suffix "oic" of pure PFOA is used to signify the neutral protonated form of a carboxylic acid. The pure form of PFOA, CAS number 335-67-1, consists of the PFOA anion and its associated cation which is a proton (H+), which is thus different from the PFOA anion alone. In water or biologic media, APFO quickly dissociates to the ammonium cation and the PFOA anion.

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

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

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

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2 A synonym for this PFOA anion is "perfluoroctanoate."
9. Most animal toxicity studies have been conducted with APFO.

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

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

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

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

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

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

16. PFOA is persistent in the environment.

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

18. PFOA is associated with developmental effects in animals.

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

20. PFOA is not naturally occurring, thus all PFOA in human blood is attributable to human
activity. PFOA is produced synthetically and can be formed through the degradation or metabolism of other fluorochemical products, such as fluorinated telomers.

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

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

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

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

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

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

27. TSCA § 2(b)(2), 15 U.S.C. § 2601(b)(2) and TSCA § 2(b)(3), 15 U.S.C. § 2601(b)(3) state, “Policy - It is the policy of the United States that - (2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances
and mixtures which are imminent hazards; and (3) authority over chemical substances and mixtures should be exercised in such a manner as to not impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.”

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

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

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

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

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

32. Specifically, the letter describes the results of a DuPont serum sampling of twelve members of the general population living near the Washington Works Facility. The letter
claims that all twelve of the individuals tested were exposed to PFOA through drinking water provided by the Lubeck Public Service District (LPSD), where according to DuPont, the level of PFOA in the drinking water has averaged approximately 0.5 parts per billion (ppb) over the last several years.

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

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

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

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

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

38. The human serum sampling data are particularly useful because they represent an attempt to associate body burden in the general population with a specific exposure pathway and a source of exposure. This data is information that reasonably supports the conclusion that
PFOA presents a substantial risk of injury to human health that the Administrator was not already adequately informed about at the time the information was obtained by DuPont or at any time prior to the date EPA received the data.

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

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

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

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

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

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

45. DuPont’s failure to immediately inform EPA about the information concerning human
serum sampling from individuals exposed to PFOA in a community setting constitutes a violation of TSCA § 8(e), 15 U.S.C. § 2607(e).

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

CIVIL PENALTY ASSESSMENT

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

NOTICE OF OPPORTUNITY TO REQUEST A HEARING

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

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

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

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

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

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

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

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

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

Please be advised that the Consolidated Rules of Practice prohibit any ex parte (unilateral) discussion of the merits of any action with the Administrator, Environmental Appeals
Board Judge, Administrative Law Judge, or any person likely to advise these officials in the decision of the case, after the Complaint is issued.

By:

[Signature]

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

Date: Dec. 6, 2004
ENCLOSURE

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

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

by certified mail, return receipt requested to both parties below

and by fax without enclosures to:

Stacey J. Mobley
Senior Vice President, General Counsel, and Chief Administrative Officer
DuPont
1007 Market Street
Room D-7038
Wilmington, Delaware 19898
fax: 302 773-4679

Peter D. Roberston
Patton Boggs, LLP
2550 M Street, NW
Washington, DC 20037
fax: 202 457-6315

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

12-6-04
Date
ORDER DENYING MOTIONS FOR ACCELERATED DECISION ON COUNTS II AND III
ORDER SETTING PREHEARING EXCHANGE SCHEDULE FOR COUNTS II, III, AND IV

Procedural Background

The complainant in this matter is the Office of Civil Enforcement\(^1\) ("OCE" or "Complainant") of the United States Environmental Protection Agency ("the EPA"). OCE contends that Respondent, E.I. du Pont de Nemours and Company ("DuPont" or "Respondent"), committed violations of the Toxic Substances Control Act ("TSCA") and Resource Conservation and Recovery Act ("RCRA"). On July 8, 2004, OCE filed its first complaint in this matter, the Complaint and Notice of Opportunity for Hearing ("Complaint"), under docket numbers TSCA-HQ-2004-0016 and RCRA-HQ-2004-0016, to which DuPont filed its Answer and Request for Hearing ("Answer").

OCE alleges, in Counts I and II, that DuPont violated Section 8(e) of TSCA, which provides that:

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA]

\(^1\) The Office of Civil Enforcement is the new name for the Office of Regulatory Enforcement. Notice of Office Name Change (Feb. 17, 2005).
Administrator of such information unless such person has actual knowledge that the [EPA] Administrator has been adequately informed of such information.

15 U.S.C. § 2607(e). Specifically, OCE alleges in Count I failure to provide blood sampling information regarding transplacental movement of perfluorooctanoic acid (“PFOA”) in humans, and alleges in Count II failure to report PFOA contamination of the public water supply. In Count III, brought pursuant to Section 3008 the Resource Conservation and Recovery Act (“RCRA”), 42 U.S.C. § 6928, OCE alleges that DuPont violated its RCRA permit by failing to provide blood sampling information concerning the transplacental movement of PFOA (also referred to as “C-8” or ammonium perfluorooctanoate (“APFO”)) in humans.


On December 6, 2004, the EPA filed an additional Complaint against DuPont, under Docket Number TSCA-HQ-2005-5001, which brought a TSCA count titled “Results of PFOA Serum Testing.” In the latter count, OCE alleges failure or refusal to submit to the EPA data concerning human serum sampling of twelve members of the general population living near the Washington Works Facility, which DuPont obtained on or after July 29, 2004 but no later than August 5, 2004. DuPont filed an answer to the latter count. OCE moved to consolidate the new Complaint with the pending action, and I granted consolidation.2

2 Now that the two complaints have been consolidated, the TSCA count titled “Results of PFOA Serum Testing” shall be referred to as Count IV.

Standard for Adjudicating a Motion for Accelerated Decision

Section 22.20(a) of the Rules of Practice authorizes the Administrative Law Judge to “render an accelerated decision in favor of a party as to any or all parts of the proceeding, without further hearing or upon such limited additional evidence, such as affidavits, as he may require, if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law.” 40 C.F.R. § 22.20(a).

Motions for accelerated decision under 40 C.F.R. § 22.20(a) are akin to motions for summary judgment under Rule 56 of the Federal Rules of Civil Procedure (“FRCP”). See, e.g., BWX Technologies, Inc., RCRA (3008) Appeal No. 97-5, 9 E.A.D. 61, 74-75 (EAB 2000); In the Matter of Belmont Plating Works, Docket No. RCRA-5-2001-0013, 2002 EPA ALJ LEXIS 65 at *8 (ALJ, Sept. 11, 2002). Rule 56(c) of the FRCP provides that summary judgment “shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of any material fact and that the moving party is entitled to a judgment as a matter of law.” Therefore, federal court decisions interpreting Rule 56 provide guidance for adjudicating motions for accelerated decision. See CWM Chemical Service, TSCA Appeal 93-1, 6 E.A.D. 1 (EAB 1995).

The United States Supreme Court has held that the burden of showing that no genuine issue of material fact exists is on the party moving for summary judgment. Adickes v. S. H. Kress & Co., 398 U.S. 144, 157 (1970). In considering such a motion, the Tribunal must construe the evidentiary material and reasonable inferences drawn therefrom in the light most favorable to the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1985); Adickes, 398 U.S. at 158-59; see also Cone v. Longmont United Hospital Assoc., 14 F.3d 526, 528 (10th Cir. 1994). Summary judgment on a matter is inappropriate when

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3 The oral arguments took place in Washington, D.C., in the EPA Administrative Courtroom.

4 Accordingly, I need not consider reply briefs or similar filings, such as motions for clarification, filed after February 4, 2005, in response to the post-argument briefs.

5 Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits.
contradictory inferences may be drawn from the evidence. *Rogers Corp. v. EPA*, 275 F.3d 1096, 1103 (D.C. Cir. 2002).

In assessing materiality for summary judgment purposes, the Supreme Court has determined that a factual dispute is material where, under the governing law, it might affect the outcome of the proceeding. *Anderson*, 477 U.S. at 248; *Adickes*, 398 U.S. at 158-159. The substantive law involved in the proceeding identifies which facts are material. *Id.*

The Supreme Court has found that a factual dispute is genuine if the evidence is such that a reasonable finder of fact could return a verdict in favor of the non-moving party. *Id.* In determining whether a genuine issue of fact exists, the judge must decide whether a finder of fact could reasonably find for the non-moving party under the evidentiary standards in a particular proceeding. *Anderson*, 477 U.S. at 252.

Once the party moving for summary judgment meets its burden of showing the absence of genuine issues of material fact, Rule 56(e) requires the opposing party to offer countering evidentiary material or to file a Rule 56(f) affidavit. Under Rule 56(e), “When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue for trial.” The Supreme Court has found that the non-moving party must present “affirmative evidence” and that it cannot defeat the motion without offering “any significant probative evidence tending to support” its pleadings. *Anderson*, 477 U.S. at 256 (quoting *First Nat'l Bank of Arizona v. Cities Service Co.*, 391 U.S. 253, 290 (1968)).

More specifically, the Court has ruled that the mere allegation of a factual dispute will not defeat a properly supported motion for summary judgment, as Rule 56(e) requires the opposing party to go beyond the pleadings. *Celotex Corp. v. Catrett*, 477 U.S. 317 at 322 (1986); *Adickes*, 398 U.S. at 160. Similarly, a simple denial of liability is inadequate to demonstrate that an issue of fact does indeed exist in a matter. *In the Matter of Strong Steel Products*, Docket Nos. RCRA-05-2001-0016, CAA-05-2001-0020, and MM-05-2001-0006, 2002 EPA ALJ LEXIS 57 at *22 (ALJ, September 9, 2002). A party responding to a motion for accelerated decision must produce some evidence which places the moving party's evidence in question and raises a question of fact for an adjudicatory hearing. *Id.* at 22-23; see *In re Bickford, Inc.*, Docket No. TSCA-V-C-052-92, 1994 TSCA LEXIS 90 (ALJ, November 28, 1994).

The Supreme Court has noted, however, that there is no requirement that the moving party support its motion with affidavits negating the opposing party's claim or that the opposing party produce evidence in a form that would be admissible at trial in order to avoid summary judgment. *Celotex*, 477 U.S. at 323-324. The parties may move for summary judgment or successfully defeat summary judgment without supporting affidavits provided that other evidence referenced in Rule 56(e) adequately supports its position. Of course, if the moving party fails to carry its burden to show that it is entitled to summary judgment under established principles, then no defense is required. *Adickes*, 398 U.S. at 156.
The evidentiary standard of proof in the matter before me, as in all other cases of administrative assessment of civil penalties governed by the Rules of Practice, is a “preponderance of the evidence.” 40 C.F.R. § 22.24. In determining whether or not there is a genuine factual dispute, I, as the judge and finder of fact, must consider whether I could reasonably find for the non-moving party under the "preponderance of the evidence" standard.

Accordingly, a party moving for accelerated decision must establish through the pleadings, depositions, answers to interrogatories, and admissions on file, together with any affidavits, the absence of genuine issues of material fact and that it is entitled to judgment as a matter of law by the preponderance of the evidence. On the other hand, a party opposing a properly supported motion for accelerated decision must demonstrate the existence of a genuine issue of material fact by proffering significant probative evidence from which a reasonable presiding officer could find in that party's favor by a preponderance of the evidence. Even if a judge believes that summary judgment is technically proper upon review of the evidence in a case, sound judicial policy and the exercise of judicial discretion permit a denial of such a motion for the case to be developed fully at trial. See Roberts v. Browning, 610 F.2d 528, 536 (8th Cir. 1979).

DISCUSSION

I. Count II

A. The Alleged Groundwater Notification Violation

DuPont admits that it has owned and operated a manufacturing facility, known as Washington Works in Washington, West Virginia at all times relevant to this matter. Amended Answer ¶ 1. DuPont further admits that it manufactured, processed, or distributed in commerce a chemical substance or mixture as those terms are defined in Section 3 of TSCA, 15 U.S.C. § 2602, and Section 8(f) of TSCA, 15 U.S.C. § 2607(f). Amended Answer ¶ 2. DuPont admits that it used ammonium perfluorooctanoate ("APFO") as a processing aid at its Washington Works Facility. Id. ¶ 13. It is undisputed that APFO is composed of an ammonium cation and a perfluorooctanoate acid ("PFOA") anion. Id. ¶ 5. Furthermore, when in contact with water, APFO dissociates to: (1) the PFOA anion; and (2) the ammonium cation. Id. ¶ 13. DuPont refers to APFO as “C-8.” Id. ¶ 4.

DuPont admits that 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. Id. ¶ 6. Therefore, test results may purport to measure levels of APFO, C-8, or PFOA in blood or water, but actually measure only PFOA. Id. DuPont admits that the Washington Works facility has released PFOA into the air, treated water containing PFOA in anaerobic digestion ponds, disposed of water containing PFOA into landfills, and discharged PFOA into the Ohio River. Id. ¶ 14.
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. *Id.* ¶ 15. However, DuPont states that humans are not susceptible to peroxisome proliferation. *Id.* DuPont admits that PFOA is “biopersistent” in animals and humans, as well as “bioaccumulative” in humans, based on DuPont’s understanding of those terms. *Id.* ¶¶ 16-17. DuPont further 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.6 *Id.* ¶ 20.

Under Count II, titled “Public Water Supply Contamination,” OCE alleges that on or about June 6, 1991, DuPont set a Community Exposure Guideline for drinking water (“CEGw”) at 1 microgram per liter (“1 µg/L” or “1 ppb”)7 for PFOA, and that in June of 1991, DuPont’s Washington Works Facility was aware of the 1 ppb CEGw that had been established for PFOA. Amended Complaint ¶ 68. In contrast, DuPont contends that on or about June 6, 1991, DuPont’s acceptable exposure level committee set a provisional CEGw for PFOA at 1 microgram per liter, and that DuPont did not adopt the provisional CEGw for PFOA in water until on or about February 7, 1992.8 Amended Answer ¶ 68.

OCE alleges that at the time DuPont adopted a CEGw at 1 ppb, it had collected results from drinking water samples, documented in various memorandums, and had information regarding the level of PFOA detected in such samples. Amended Complaint ¶ 69. In response, DuPont states that the documents to which OCE refers are the best evidence of their contents, and to the extent that OCE’s allegations do not accurately state the contents of that document, those allegations are denied. Amended Answer ¶ 69.

OCE alleges that the EPA was not informed at the time DuPont obtained monitoring data showing “contamination” of the public water supply prior to 1991, and subsequent to that time. Amended Complaint ¶ 80. OCE alleges that DuPont was required under Section 8(e) of TSCA to immediately report the information concerning DuPont’s monitoring data of the “contamination” of the public water supply for the communities in the vicinity of its Washington Works Facility and this obligation continued as DuPont learned more about the contamination. *Id.* ¶ 81. Finally, OCE alleges that DuPont was required under Section 8(e) of TSCA to inform the EPA every day between July 24, 1991 and March 6, 2001 (when the EPA received

6 In response to my question at the oral argument, “[I]s the EPA alleging human health effects, or is it strictly an environmental media,” OCE stated, “Count II is strictly the environmental contamination data that DuPont became aware of in mid to late 1991 . . . .” Oral Arg. Tr. at 62.

7 The acronym “ppb” means “parts per billion,” and “µg/L” means micrograms per liter.

8 The dispute of fact about the CEGw is not determinative for purposes of this order on DuPont’s motion for accelerated decision.
information about the alleged contamination) about the information that it had obtained on the “widespread contamination” of public drinking water at a level greater than its CEGw, and that DuPont was required to inform the EPA immediately about information concerning the PFOA “contamination” of public drinking water that DuPont obtained in 1984. *Id.* ¶¶ 82-83. DuPont denies that the information in question reasonably supports any conclusion of substantial risk, and moreover, denies that the EPA considers the information at issue to reasonably support the conclusion of a substantial risk of injury to health or the environment. Amended Answer ¶¶ 78, 80.

As alleged in Count II, on or about June 6, 1991, DuPont set its community exposure guideline for drinking water at 1 part per billion (“ppb”). Oral Arg. Tr. at 70. OCE further alleges that on June 23, 1991, DuPont detected PFOA in a new well in Lubeck, which was approximately 2.7 miles from DuPont’s Washington Works Facility. *Id.* According to OCE, “on June 26, 1991, DuPont began analyzing its water contamination data collected, admittedly, from ‘84 until ‘91 to decide whether or not to report to the [EPA] under TSCA 8(e).” *Id.* at 70-71. DuPont allegedly found that there had been levels of PFOA in wells, with one of the samples reading 3.9 ppb. *Id.* at 71; see OCE’s Count II Response, Ex. 23. However, according to OCE, DuPont decided that no Section 8(e) notification was warranted. Oral Arg. Tr. at 71. OCE submits that “Where EPA’s Count II comes into play is in two more dates, September 11, 1991, and November [19], 1991.” *Id.*; see also *id.* at 62.¹⁰ On September 11, 1991, DuPont allegedly had a meeting and discussed all prior water sampling events in the context with what was going in mid to late 1991 terms of DuPont’s dealing with the Lubeck Water Authority. *Id.* at 71 (referring to OCE’s Count II Response, Ex. 23); see also OCE’s Count II Response at 11. In its pre-argument brief, OCE contends that DuPont took additional water samples on November 19, 1991, with levels above the alleged CEGw level of 1 ppb and that a November memorandum reports these results. OCE’s Count II Response at 12 (citing OCE’s Count II Response, Ex. 24).

DuPont moves for accelerated decision and for dismissal of Count II on the ground that OCE is barred from bringing such an enforcement action as a matter of law by the parties’ prior consent agreement and a consent order entered into as part of the TSCA § 8(e) Compliance Audit Program. DuPont’s Motion for Acc. Dec. at 2.

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⁹ See OCE’s Count II Response, Exs. 23 and 24.

¹⁰ In response to my question, “[I]s the EPA alleging human health effects, or is it strictly an environmental media,” OCE stated, “Count II is strictly the environmental contamination data that DuPont became aware of in mid to late 1991 and withheld from the [EPA], Your Honor. It does build on prior data, some data points that may have preceded 1991.” Oral Arg. Tr. at 62.
B. Introduction to Section 8(e) of TSCA and the TSCA Section 8(e) Compliance Audit Program

Section 8(e) of TSCA became effective on January 1, 1977. DuPont points out that Congress did not grant the EPA any rulemaking authority with respect to Section 8(e), nor did it grant the EPA any general rulemaking authority under TSCA. Id. at 7; see TSCA § 8(e), 42 U.S.C. § 2607(e). Thus, in 1977 the EPA proposed guidance on its interpretation of and policy concerning the provisions of Section 8(e) and solicited and received comments. 43 Fed. Reg. 11,110 (Mar. 16, 1978). On March 16, 1978 the EPA published a Statement of Interpretation of Enforcement Policy for Notification of Substantial Risk Under Section 8(e) (“1978 Enforcement Policy”), which the EPA published in the Federal Register. Id.

The 1978 Enforcement Policy provides that “A ‘substantial risk of injury to health or the environment’ is a risk of considerable concern because of (a) the seriousness of the effect [see Subparts (a), (b), and (c) below for an illustrative list of effects of concern], and (b) the fact or probability of its occurrence.” Id. at 11,111. 1978 Enforcement Policy, Part V (brackets in original). For purposes of determining what constitutes substantial risks, Part V of the 1978 Enforcement Policy categorizes effects for which substantial-risk information must be reported under three main categories: (a) “human health effects,” (b) “environmental effects,” and (c) “emergency incidents of environmental contamination.” Id. at 11,112. The 1978 Enforcement Policy further subcategorizes those effects. Id. Subcategory (b)(1) is “widespread and previously unsuspected distribution in environmental media, as indicated in studies (excluding materials contained within appropriate disposal facilities).” Id. Subcategories (b)(2)-(5) include the following environmental effects: (b)(2) “Pronounced bioaccumulation. Measurements of indicators of pronounced bioaccumulation heretofore unknown to the [EPA] Administrator . . . should be reported when coupled with potential for widespread exposure and any non-trivial adverse effect”; (b)(3) “Any non-trivial adverse effect, heretofore unknown to the [EPA] Administrator, associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media”; (b)(4) “Ecologically
significant changes in species’ interrelationships . . . ,” and; (b)(5) “Facile transformation or degradation to a chemical having an unacceptable risk . . . .” Id.

On February 1, 1991, the EPA announced the opportunity to register for the TSCA Section 8(e) Compliance Audit Program (“CAP”). 56 Fed. Reg. 4,127, 4,128. The CAP called for registrants to audit and report for Section 8(e) information, provided for stipulated penalties for each study or report submitted pursuant to the CAP, and set an overall limit on penalties to be assessed pursuant to the CAP.

On June 20, 1991, the EPA announced suspension of Part V(b)(1) (“widespread and previously unsuspected distribution in environmental media, as indicated in studies (excluding materials contained within appropriate disposal facilities)”) and Part V(c) (“emergency incidents of environmental contamination”) of the 1978 Enforcement Policy. 56 Fed. Reg. 28,458, 28,459. The EPA stated that, despite the suspension of V(b)(1) and V(c) of the 1978 Enforcement Policy, “regulatees auditing their files for reportable environmental risk information under the TSCA Section 8(e) Compliance Audit Program should be guided by the statutory language of section 8(e) and Part V(b)(2) through (b)(5) of the [1978 Enforcement Policy].” Id. Moreover, “In assessing whether information or studies involving widespread and previous unsuspected environmental distribution, emergency incidents of environmental contamination, or other previously unknown situations involving significant environmental contamination should be submitted under the TSCA Section 8(e) Compliance Audit Program, or under section 8(e) in general, regulatees should make a reasonable judgement whether such information meets the statutory standards of TSCA section 8(e) instead of relying on Parts V(b)(1) or V(c) of the [1978 Enforcement Policy].” Id. EPA’s June 1991 Federal Register notice concluded, “Even though EPA is suspending the applicability of Parts V(b)(1) and V(c) of the [1978 Enforcement Policy], persons are still responsible under TSCA section 8(e) to report information that reasonably supports a conclusion of substantial risk of injury to the environment. This is a continuing statutory obligation.” Id.

On or about July 5, 1991. DuPont registered for the TSCA Section 8(e) CAP by signing the Registration and Agreement for TSCA Section 8(e) Compliance Audit Program (“CAP Agreement”) See DuPont’s Motion for Acc. Dec., Ex. 12, Attach. A.

On September 30, 1991, the EPA split the CAP into two phases. 56 Fed. Reg. 49,478, 49,479. It announced, “Because refinement of guidance on reportability of information on chemical release/detection in environmental media is underway, EPA is extending the reporting deadline for reporting such information under the TSCA Section 8(e) CAP to 6 months after publication of final reporting guidance.” Id. According to the parties’ Consent Agreement, on or about January 31, 1992, the EPA mailed an “Addendum” to DuPont to modify the CAP Agreement “only regarding the reporting of information on the release of chemical substances to and detection of chemical substances in all environmental media.” DuPont’s Motion for Acc. Dec., Ex. 12 (Consent Agreement, Docket No. TSCA-96-H-47 (Oct. 1, 1996) (“Consent Agreement”), Part I.C.
DuPont and the EPA subsequently agreed to a Revised Addendum to the TSCA Section 8(e) CAP Agreement ("Revised Addendum"), dated June 27, 1996, which sets forth the waiver of enforcement action at issue in this matter. See Consent Agreement, Attach. B. Part IV.A of the Revised Addendum reads:

Information on the release of chemical substances to and detection of chemical substances in environmental media, or environmental toxicity data for plant effluents, 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.

On October 1, 1996, the parties signed a Consent Agreement, which incorporates the terms of the CAP Agreement and the Revised Addendum. The EPA Environmental Appeals Board ("EAB") then executed a Consent Order, approving the Consent Agreement. Id., Ex. 13 ("Consent Order," Docket Number TSCA-96-H-47 (Oct. 3, 1996)).

C. Introduction to the Parties’ Arguments

In summary, DuPont argues that the charges in Count II are barred by the CAP Agreement entered into by DuPont and the EPA, as amended by the Revised Addendum, which were incorporated into the Consent Agreement signed by the parties and approved by the EAB in the Consent Order. Specifically, DuPont argues that under the Revised Addendum, dated June 27, 1996, the EPA clearly and unambiguously promised not to bring a Section 8(e) enforcement action based on information that existed prior to the effective date of the final revised guidance on the reportability of Section 8(e) information, which was published in the Federal Register on June 3, 2003. DuPont asserts that the information on which Count II is based existed prior to the final revised guidance. Therefore, DuPont argues, the EPA is barred from enforcing the alleged violations under Count II.

OCE counters that DuPont oversimplifies the matter by highlighting only limited language of the Revised Addendum that supports its argument, and that when the language of the Revised Addendum and the CAP is viewed in whole it is apparent that DuPont’s assertions are false. OCE contends that the CAP instituted a backwards-looking audit of limited duration to resolve past compliance. Specifically, OCE variously contends that the EPA waived its ability to

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11 The Revised Addendum states that the Revised Addendum supersedes the original Addendum to the CAP Agreement ("Addendum"). According to the parties’ Consent Agreement, on or about January 31, 1992, the EPA mailed the Addendum to DuPont to modify the CAP Agreement “only regarding the reporting of information on the release of chemical substances to and detection of chemical substances in all environmental media.” Consent Agreement, Part I.C.

12 TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33,129 (June 3, 2003).
press enforcement actions as to information on the release of chemical substances to and
detection and chemical substances in environmental media “generated” prior to the
announcement of the CAP on February 1, 1991 (or alternatively, prior to the CAP
commencement date of July 1, 1991, or; prior to DuPont’s registration for the CAP, on or about
July 5, 1991), and prospectively, from June 27, 1996 forward.

OCE contends that, under Section 8(e) of TSCA, DuPont was subject to an ongoing
statutory obligation from 1991 through 1996 to report information on the release of chemical
substances to and detection and chemical substances in environmental media, and that this
obligation was not affected or eliminated by the CAP or the CAP Agreement. OCE argues that
Paragraph IV.A of the Revised Addendum does not bar Count II, as advanced by DuPont.
Admitting that the Revised Addendum waived enforcement, OCE asserts that such waiver of
enforcement does not apply to the period from the beginning of the CAP in 1991 to 1996, when
the EPA eliminated “Phase 2” of the CAP, via the Revised Addendum.

In the alternative, DuPont submits that even if the CAP were a “lookback” audit, then it
was a lookback from February 28, 1992 backwards, which was the original deadline for
reporting data under the CAP. As noted, OCE contends that Count II “comes into play” on
September 1991 and November 1991. Accordingly, DuPont argues that even under OCE’s
“lookback” theory, the EPA waived enforcement of the matters alleged in Count II.

As another basis for accelerated decision, DuPont argues that Count II is barred by the
EAB’s Consent Order, by virtue of res judicata. DuPont contends, inter alia, that the instant
matter arises out of the same nucleus of facts as the 1996 complaint the EPA filed against
DuPont pursuant to the CAP Agreement and by the EAB’s Consent Order on that matter, which
incorporated the Revised Addendum. DuPont further contends that the EPA could have asserted
the current Count II in the 1996 complaint but did not. OCE counters that the Revised
Addendum did not waive enforcement over the September and November 1991 dates that
allegedly form the basis for Count II, and that the Consent Order, incorporating the parties’
Consent Agreement, specifically permits matters of non-compliance to be litigated.

D. Contract Law and Parol Evidence (Extrinsic Evidence)

Consent agreements have many of the attributes of ordinary contracts and as such they
should be construed, basically, as contracts. United States v. ITT Cont’l Banking Co., 420 U.S.
233, 237-38 (1975); accord Village of Kaktovic v. Watt, 689 F.2d 222, 230 (D.C. Cir. 1982);
United States v. N. Colo. Water Conservancy District, 608 F.2d 422, 430 (10th Cir. 1979). This
type of settlement contract may not be unilaterally rescinded. Village of Kaktovic, 689 F.2d at
230. Consent agreements in settlement of EPA administrative enforcement actions are
“enforceable like any other agreement; the fact that the subject matter of the agreement does not
limit itself to the assessment of a civil penalty is irrelevant to its enforceability.” In re Chem.
Waste Management, Inc., 1 E.A.D. 851, 857 n.11 (JO 1984) (citing Village of Kaktovic, 689 F.2d
at 230). Therefore, I turn to contract law in examining the enforcement waiver contained in the
Revised Addendum, which was incorporated into the parties’ Consent Agreement.
Language within a contract must be read “in the context of the entire agreement” and must be construed “so as not to render portions of it meaningless.” *Dalton v. Cessna Aircraft*, 98 F.3d 1298, 1305 (Fed. Cir. 1996); *Murphy v. Keystone Steel & Wire Co.*, 61 F.3d 560, 565 (7th Cir. 1995); accord *In re Julie’s Limousine & Coachworks, Inc.*, CAA Appeal No. 03-06, 2004 EPA App. LEXIS 23, slip op. at 21-22 & n.31 (EAB, July 23, 2004), 11 E.A.D. ___ (fundamental principles of textual interpretation dictate that the adjudicator must interpret the text so as to give each word meaning and to avoid creating surplusage). When a contract term is unambiguous, the courts determine its meaning as a matter of law at the summary judgment stage. *LeJune v. Bliss-Salem, Inc.*, 85 F.3d 1069, 1073 (3rd Cir. 1996) (applying federal common law); accord *Murphy*, 61 F.3d at 564-65; *NRM Corp. v. Hercules, Inc*, 758 F.2d 676, 681-82 (D.C. Cir. 1985). “Determining whether contract language is ambiguous is also a question of law, and contract language is ambiguous if the terms are inconsistent on their face, or if the terms allow reasonable but differing interpretations of their meaning.” *Rodrigues-Abreu v. Chase Manhattan Bank*, 986 F.2d 580, 586 (1st Cir. 1993) (citing cases).

“If the language of the contract is ambiguous, we turn to surrounding circumstances, undisputed extrinsic evidence, to divine the parties’ intent.” *Id. (citing, inter alia, Lumpkin v. Enviroydine Industries, 933 F.2d 449, 456 (7th Cir. 1991)); accord NRM, 758 F.2d at 682 (“Only if the court determines as a matter of law that the agreement is ambiguous will it look to extrinsic evidence of intent to guide the interpretive process.”). “Summary judgment based upon the construction of contract language is appropriate only if the meaning of the language is clear, considering all the surrounding circumstances and undisputed evidence of intent, and there is no genuine issue as to the inferences which might reasonably be drawn from the language.” *Rodrigues-Abreu*, 986 F.2d at 586 (citing cases); accord *NRM*, 758 F.2d at 682 (“When, however, the language is unclear and the search for intent extends beyond the four corners of the agreement, the intended meaning of the contract is a disputed and, necessarily, material question of fact and summary judgment is improper.”).

As discussed previously, the burden for summary judgment is on the movant. For Count II, DuPont is the only party moving for summary judgment. Therefore, the narrow issue before me is whether the contractual provision at issue — the waiver of enforcement — is unambiguous in favor of the movant, DuPont, when taking into account that the movant has the burden on this count and that all reasonable inferences of material fact are drawn in favor of the non-moving party, OCE.

**E. Description of the Consent Agreement, Including the CAP Agreement and the Revised Addendum**

As discussed, the starting point for contractual interpretation is to look within the four corners of the contract, to determine whether the contract is unambiguous. The settlement agreement (i.e., contract) in this matter consists of the “Consent Agreement,” Docket No. TSCA-96-H-47, executed by the “Regulatee” (DuPont) and the EPA, and filed on October 1, 1996 with
the following attachments: Attachment A – the CAP Agreement, and; Attachment B – the Revised Addendum to the CAP Agreement. DuPont’s Motion for Acc. Dec., Ex. 12. On October 3, 1996, the EAB executed a “Consent Order,” under Docket Number TSCA 96-H-47, which approved the Consent Agreement. \textit{Id.}, Ex. 13. The Consent Order consists of a brief recitation of the penalty amount and payment procedures, and expressly incorporates the Consent Agreement by reference. \textit{Id.} The Consent Agreement is attached to the Consent Order. \textit{See id.}

The Consent Agreement provides, “All of the terms and conditions of this Consent Agreement together comprise one agreement, and each of the terms and conditions is in consideration of all of the other terms and conditions.”\textsuperscript{14} Consent Agreement, Part VI.H. Accordingly, the Consent Agreement and its attachments are an integrated contract and the parol evidence rule applies.

DuPont contends that the plain language of the Revised Addendum waived enforcement over all the allegedly reportable information OCE cited as the basis for Count II. In particular, DuPont focuses on the language in Part IV.A of the Revised Addendum, which reads:

\begin{quote}
\textit{Information on the release of chemical substances to and detection of chemical substances in environmental media, or environmental toxicity data for plant effluents, 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.
\end{quote}

Revised Addendum, Part IV.A (emphasis added). DuPont emphasizes that Part IV.A states plainly that the EPA waived all Section 8(e) claims based on “environmental data” that existed before the revised guidance, published in 2003. DuPont’s Count II Reply at 3. Further, DuPont argues that if the EPA had intended to qualify “predates” it could have easily done so. \textit{Id.}

\begin{footnotes}
\item[13] The CAP Agreement is undated, as are the date(s) of the signatures to the CAP Agreement. However, Unit (i.e., Part or Section) I.D. of the CAP Agreement provides, “the TSCA Section 8(e) Compliance Audit Program shall commence no later than July 1, 1991.” The Consent Agreement states that on or about July 5, 1991, DuPont registered for the TSCA section 8(e) CAP by signing the CAP Agreement. Consent Agreement at 1. However, OCE asserts that DuPont signed the CAP Agreement on June 28, 1991. OCE’s Count II Response at 8 (citing OCE’s Count II Response, Ex. 26); Oral Arg. Tr. at 77 (citing to DuPont’s Motion for Acc. Dec., Ex. 8); OCE’s Post-Argument Br. on Count II at 5. A review of the cited exhibits as well as the rest of the record currently before this Tribunal does not indicate the purported June 28, 1991 registration date.

\item[14] \textit{See also} CAP Agreement, Unit II.D.5: “All of the terms and conditions of this CAP Agreement together comprise one agreement, and each of the terms and conditions is in consideration for all of the other terms and conditions.”
\end{footnotes}
The Consent Agreement recounts that on February 1, 1991, the EPA published a Federal Register notice (56 Fed. Reg. 4,128) that set forth the TSCA Section 8(e) CAP and announced the opportunity for all regulated parties to register for and participate in the CAP. Consent Agreement, Part I.A. Reportedly, 122 companies registered for the CAP. On April 26, 1991 and June 20, 1991, the EPA published Federal Register notices (56 Fed. Reg. 19,514 and 56 Fed. Reg. 28,458) that modified certain terms of the TSCA Section 8(e) CAP. Consent Agreement, Part I.A. The Consent Agreement states that “on or about July 5, 1991,” DuPont registered for the TSCA Section 8(e) CAP by signing the CAP Agreement. Consent Agreement, Parts I.B and II.B.

The CAP Agreement provides, “The Regulatee [DuPont] agrees to conduct a TSCA Section 8(e) Compliance Audit Program to determine its compliance status with TSCA section 8(e).” CAP Agreement, “Unit” (i.e., Part or Section) I.A. Thus, the CAP Agreement provides for DuPont to audit its records to find Section 8(e) violations and to report such to the EPA. As originally written, the CAP was to commence no later than July 1, 1991 and terminate on February 28, 1992, and all submissions under the CAP would have to be delivered to the EPA no later than February 28, 1992. CAP Agreement, Unit I.D-E. The parties agreed, “This CAP Agreement and the Consent Agreement and Consent Order in this matter shall be a complete settlement of all civil and administrative claims and causes of action which arose or could have arisen under TSCA section 8(e) in connection with any study or report listed or submitted pursuant to the terms of this CAP Agreement.” CAP Agreement, Unit II.A.1.

The CAP Agreement provides, “In conducting the TSCA Section 8(e) Compliance Audit Program, the Regulatee [DuPont] shall follow the statutory language of TSCA section 8(e) and [the 1978 Enforcement Policy], with the exception of Parts V(b)(1) and V(c) of the [1978 Enforcement Policy] to determine whether the reviewed study or report is:” (a) not reportable, (b) reportable, or (c) data that would have been reportable under Section 8(e) when initially obtained by the Regulatee, and that subsequent to the Section 8(e) reporting deadline (and before June 18, 1991), were previously submitted. CAP Agreement, Unit II.B.1. However, Footnote 1 of the CAP Agreement qualifies, “In determining whether the kind of information or studies referenced in Parts V(b)(1) and V(c) (i.e., widespread and previously unsuspected distribution in environmental media and emergency incidents of environmental contamination) should be submitted under the TSCA Section 8(e) Compliance Audit Program, the Regulatee [DuPont] should make a reasonable judgement whether such information meets the statutory standards of TSCA section 8(e) instead of relying on the guidance in Parts V(b)(1) and V(c) of the [1978 Enforcement Policy].” CAP Agreement at 3 n.1.

Pursuant to the CAP Agreement, DuPont agreed to pay stipulated civil penalties for all studies or reports submitted under the CAP as Section 8(e) data. CAP Agreement, Unit II.B.2. The stipulated penalty amounts were “$15,000 per study for any submitted study or report involving effects in humans” and “$6,000 per study for any other submitted study or report

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15 However, the CAP Agreement provided that the EPA could grant extensions to the termination date. CAP Agreement, Unit I.E.
submitted as TSCA section 8(e) data,” and $5,000 for each late-submitted study or report that was received by the EPA prior to June 18, 1991. CAP Agreement, Unit II.B.2-3. The parties agreed to a $1,000,000 cap on the total civil penalty for each Regulatee.16 CAP Agreement, Unit II.B.3.

Upon termination of the CAP, the Regulatee was to provide the EPA with a Final Report certifying that the CAP has been completed. CAP Agreement, Unit II.B.5. As provided in the CAP Agreement, following termination of the audit, the EPA agreed to present the Regulatee with a Consent Agreement and Consent Order summarizing the results of the CAP and specifying the terms of payment of stipulated civil penalties. CAP Agreement, Unit II.B.6.

Under “Other Matters,” the CAP Agreement provides that “Nothing in this CAP Agreement shall relieve the Regulatee from complying with all applicable TSCA regulations or other applicable environmental statutes.” CAP Agreement, Unit II.D.

On or about January 31, 1992, the EPA mailed the “Addendum to the CAP Agreement” (“Addendum”) to DuPont to modify (as stated in the Consent Agreement) the CAP Agreement “only regarding the reporting of information on the release of chemical substances to and detection of chemical substances in all environmental media.” Consent Agreement, Part I.C. “The deadline for reporting all other information under the CAP remained unchanged at February 28, 1992 unless otherwise extended.”17 Consent Agreement, I.C.

On or about June 27, 1996, DuPont entered into an agreement, referred to as the Revised Addendum, to supersede the Addendum and to modify the CAP Agreement to specify that DuPont (referred to as the Regulatee in the Revised Addendum) “[i]s 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, or for environmental toxicity on plant effluents; and that a second Final Report is no longer necessary.” Consent Agreement, Part I.D. According to the Consent Agreement, DuPont timely submitted the Final Report on or about October 26, 1992. Consent Agreement, Part II.D.

Therefore, the first Final Report, which DuPont submitted on or about October 26, 1992, became the only Final Report. The Final Report indicated that a total of 1,380 studies were listed or submitted as Section 8(e) data pursuant to the CAP Agreement, with: 24 human health effects studies, at $15,000 per study; 1,287 studies listed under the category for “any other study

16 For instance, DuPont’s overall penalty under the Section 8(e) CAP was $1,000,000. Consent Agreement, Part V.E. However, DuPont’s penalty would have been $8,427,000 without the $1,000,000 limit. DuPont’s Motion for Acc. Dec., Ex. 11 (Docket No. TSCA-96-H-47, Complaint, Sept. 30, 1996) at 6.

17 According to the Consent Agreement, “[DuPont] submitted the Addendum to EPA on September 26, 1992; however, EPA presently has no record of an Addendum for [DuPont].” Consent Agreement, I.C.
or report submitted as TSCA Section 8(e) data” (i.e., for studies that were not human health effects studies), at $6,000 per study, and; 69 late-submitted studies given to the EPA prior to June 18, 1991, at $5,000 per study. Consent Agreement, Parts II.D and IV. Pursuant to the limitation on overall penalties under the CAP Agreement, DuPont’s total civil penalty was $1,000,000. Consent Agreement, Part IV. The Consent Agreement provided, under “Other Matters,” that “Nothing in this Consent Agreement and Consent Order shall relieve [DuPont] of the duty to comply with all applicable provisions of TSCA and other environmental statutes.” Consent Agreement, Part VI.

Turning to the Revised Addendum to the CAP Agreement, Paragraph I of the Revised Addendum provides:

The TSCA Section 8(e) Compliance Audit Program, which the Regulatee agreed to conduct in the Registration requirement I.A. does not include: information on the release of chemical substances to and detection of chemical substances in environmental media; or environmental toxicity data on plant effluents. The Regulatee, therefore, is no longer required to conduct a file search for this information. Further, footnote 1 of the [CAP] Agreement pertains solely to chemical release and detection information and therefore, is no longer applicable to the administration of the TSCA Section 8(e) Compliance Audit Program.

Paragraph II of the Revised Addendum provides that the first Final Report shall be considered the Final Report and controlling document for purposes of determining the information listed or submitted under the CAP. The Revised Addendum, at Paragraph III, states that “EPA intends to publish final revised guidance in the Federal Register on reporting information on the release of chemical substances to and detection of chemical substances in environmental media.” Furthermore, “EPA also intends to publish a question and answer document to illustrate application of the guidance. The final revised guidance will not be effective prior to EPA’s publication of the question and answer document.” Revised Addendum, Paragraph III.

Paragraph IV of the Revised Addendum reads as follows:

IV. Impact of the final revised guidance on:

A. Information on the release of chemical substances to and detection of chemical substances in environmental media, or environmental toxicity data for plant effluents, 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.
B. Information on the release of chemical substances to and
detection of chemical substances in environmental media, or
environmental toxicity data for plant effluents, that may have been
submitted under Phase 1 of the CAP Program will not result in the
assessment of penalties for such studies or reports submitted under
this TSCA Section 8(e) Compliance Audit Program.

The Revised Addendum, at Paragraph V, provides that “Information generated after the
effective date of the new final revised guidance on the release of chemical substances to and
detection of chemical substances in environmental media, or environmental toxicity data for
plant effluents, will be submitted prospectively pursuant to TSCA Section 8(e) and the new final
revised guidance, not the CAP Agreement. Therefore, no penalty will accrue under the CAP
Agreement for the submission of such information.”

F. The Parties’ Arguments Regarding the Duration of the Waiver of
Enforcement

1. DuPont’s Arguments As to the Waiver of Enforcement

DuPont contends that in the Revised Addendum (in Part I), the EPA stated explicitly that
DuPont need not search its files for data regarding detection of chemicals in environmental
media, and that the EPA then promised (in Part IV.A) that the EPA would not bring a Section
8(e) enforcement action based on information in DuPont’s files prior to the effective date of
the final reporting guidance, which was published in 2003. DuPont’s Motion for Acc. Dec. at 24-25.
Under DuPont’s view, the contract language that is embodied in the Revised Addendum clearly
and unambiguously states that DuPont need not search its files for preexisting data regarding
detection of chemicals in water samples, and that the EPA would not bring a Section 8(e)
enforcement action for any failure to report information prior to EPA’s final guidance for that
reporting. Id. at 25. DuPont points out that the water samples at issue in Count II are data that
existed before the 2003 guidance. Id. According to DuPont’s argument, due to the “plain
language” of the Revised Addendum, the EPA promised not to assert, and waived any right to
pursue, the enforcement action that the EPA now pursues in Count II. Id.

DuPont emphasizes that the word “predates” in Paragraph IV.A of the Revised
Addendum “means what it says.” DuPont’s Count II Reply at 3. DuPont contends that the term
predates “is not qualified by anything suggesting that it really means . . . ‘predates, but only if it
is after June 27, 1996.'” Id. DuPont argues that if the EPA intended to qualify ‘predates,’ it
could have easily done so. Id. Furthermore, DuPont submits, “There is a strong presumption
against reading into contracts provisions that easily could have been included but were not.” Id.
(quoting Fix v. Quantum Indus. Partners LDC, 374 F.3d 549, 553 (7th Cir. 2004)).

Regarding Paragraph IV.B of the Revised Addendum, DuPont argues that IV.A and IV.B
actually address two different topics. Id. at 4. DuPont argues that IV.A tells DuPont and the
other CAP registrants that were each asked to sign the Revised Agreement that they need not

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submit “environmental data” that existed before the EPA issues its final revised guidance, and that the EPA would not bring any Section 8(e) enforcement action based on “environmental data” that existed before the EPA issues its final guidance. *Id.* Paragraph IV.B on the other hand, assures DuPont and the other CAP registrants that, if they already had submitted “environmental data” to the EPA under the CAP, they would not be fined under the original CAP for such submissions. *Id.* Paragraph IV.B was an effort to level the playing field between such submitters and those who had not made such a submission. *Id.* at 5; Oral Arg. Tr. at 18-20.

Furthermore, DuPont interprets Paragraph IV.A as stating that those persons who had not submitted environmental data would not be subject to Section 8(e) enforcement actions, but that IV.A does not address the fine status of those companies who had already submitted environmental data under the CAP and were facing automatic stipulated fines of $6,000 per study submitted. DuPont’s Count II Reply at 5; Oral Arg. Tr. at 18-20. According to DuPont, the EPA added Paragraph IV.B to clarify that those who had already submitted “environmental data” would be placed on the same footing as those who had not submitted the data, by adding that those who had submitted such data would not be penalized for having reported the data. DuPont’s Count II Reply at 5; Oral Arg. Tr. at 18-20. DuPont contends that Paragraph I of the Revised Addendum, only eliminates the requirement to audit for “environmental data”, and that it does not address penalties or enforcement actions. Oral Arg. Tr. at 20. Therefore, according to DuPont’s argument, Paragraph IV.B would be necessary to remove the threat of stipulated automatic penalties for “Phase 2” information submitted during “Phase 1.” *Id.* at 20-21.

Finally, DuPont raises an argument as to the cutoff date for the CAP. DuPont submits, *in arguendo*, that even if the CAP were a “lookback” audit, then it was a lookback from February 28, 1992 backwards, which was the original deadline for reporting data under the CAP.18 *Id.* at 108-09; DuPont’s Post-Argument Br. at 8-9. February 28, 1992 comes after the September 1991 and November 1991 dates on which Count II allegedly “comes into play.” Oral Arg. Tr. at 71; see also *id.* at 62. DuPont’s argument is, “Thus, even if we assume, *arguendo*, that [OCE] is correct when it asserts that EPA only waived enforcement for data that existed prior to the original cut-off date for including data in the CAP, EPA still waived enforcement of Count II because all of the data in question in Count II existed prior to February 28, 1992. Thus even under [OCE’s] ‘look back’ theory, EPA waived enforcement of the matters alleged in Count II.” DuPont’s Post-Argument Br. at 9.

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18 DuPont’s deadline for submitting Phase 1-type information appears to have been extended beyond February 28, 1992, as the Consent Agreement states that DuPont timely submitted the its Final Report for audited information on or about October 26, 1992. See Consent Agreement, Part II.D.
2. OCE’s Arguments As to the Waiver of Enforcement

In contrast to DuPont’s position, OCE argues that DuPont was subject to an ongoing statutory obligation under Section 8(e) of TSCA to report information on the release of chemical substances to and detection of chemical substances in environmental media that ran from 1991 through 1996, and that the EPA never eliminated this obligation through the CAP or the Revised Addendum.

First, OCE indicated that the language “Phase 2” of the CAP refers to “information on the release of chemical substances to and detection and chemical substances in environmental media.” OCE’s Count II Response at 15. Later, OCE clarified its position to mean that “Phase 2” of the CAP requires the submission of environmental contamination data not just under Part V(b)(1) of the 1978 Enforcement Policy, but also under Parts V(b)(2)-(5), even though the guidance for V(b)(2)-(5) had never been called into question. OCE’s Post-Argument Br. on Count II at 3; see also Oral Arg. Tr. at 69-70. Count II, which mentions bioaccumulation and biopersistence, among other effects, (Amended Complaint ¶¶ 15-20), may be interpreted as alleging not just V(b)(1)-type violations, but also other environmental effects-type violations that would fall under V(b)(2)-(5).

Initially, OCE posited that the plain language of Paragraph I of the Revised Addendum removed the CAP’s applicability to Phase 2 data generated after June 27, 1996 (the date of the Revised Addendum), in effect voiding the Phase 2 portion of the CAP program. OCE’s Count II Response at 18. Furthermore, OCE stated that Paragraph IV.A of the Revised Addendum is consistent with EPA’s interpretation of Paragraph I of the Revised Addendum. Id. According to OCE, Paragraph IV.A of the Revised Addendum operates as a prospective waiver of OCE’s right to enforce Section 8(e) claims from June 27, 1996 until the issuance of a final “Phase 2” reporting deadline, thereby temporarily relieving regulatees of their obligations until promulgation of final reporting guidelines. Id. OCE stated that it is for the latter reason that OCE is not seeking additional penalties from DuPont at this time for the period from 1996 until today. Id. at 18 n.15.

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19 At oral argument, I asked OCE whether Paragraph IV.A of the Revised Addendum, using the language “release of chemical substances to and detection of chemical substances in environmental media,” is the same as Part V(b)(1) of the 1978 Enforcement Policy, which uses the language “widespread and previously unsuspected distribution in environmental media.” Oral Arg. Tr. at 68-69. OCE responded, “I believe that the terminology used by EPA in the 1996 Addendum is subsumed within the broader category of V(b) environmental contamination.” Id. at 69. Then, in response to my question: “So, it’s not limited to V(b)(1), the charges that you’re alleging in Count II,” OCE responded, “In Count II, it is environmental contamination, so it is V(b).” Id. at 69-70.

20 However, at oral argument, OCE submitted that the EPA may have actually granted a prospective waiver as early as May 15, 1996, which is the date of the Cover Letter to the Revised Addendum. Oral Arg. Tr. at 79.
Regarding Paragraph IV.B, OCE contends that the EPA reached back to waive its right to enforce penalty actions against regulatees who may have submitted “Phase 2” data at any time prior to the issuance of the Revised Addendum on June 27, 1996. OCE’s Count II Response at 19. As argued by OCE, to give Paragraph IV.A of the Revised Addendum the reading advocated by DuPont – that the EPA waived the right to enforce Section 8(e) for Phase 2 data generated at any time prior to finalization of the guidance – is incorrect, because that reading would render Part IV.B. meaningless. Id.

OCE further argues, “If Respondent’s reading of IV.A were correct, there would be no need for an explicit waiver for Phase 2 data that had been submitted during the Phase 1 reporting period, because under Respondent’s interpretation of the Addendum, regulatees would be off the hook for all Phase 2 data generated at any time before issuance of the final guidance in 2003, including that submitted under Phase 1.” Id. (footnote omitted). Therefore, “Respondent’s reading would render IV.B of the Revised Addendum meaningless, violating well-established principles of contract interpretation.” Id.

In its post-argument brief, OCE argues that Paragraph I of the Revised Addendum eliminated the Phase 2 reporting requirement, which OCE interprets as meaning “[t]here could be no CAP penalties for Phase 2 information.” OCE’s Post-Argument Br. on Count II at 10-11 (emphasis added). In doing so, OCE points out the language of Paragraph I stating that the “TSCA Section 8(e) Compliance Audit Program . . . does not include: information on the release of chemical substances to and detection of chemical substances in environmental media; or environmental toxicity data on plant effluents.” Id. at 10 & n.4. OCE states that Paragraph I of the Revised Addendum “eliminated the Phase 2 reporting requirement, meaning that by definition, there could be no CAP penalties for Phase 2 information.”21 Id. at 11. “However, industry was then subject to potential penalties for pre-1991 information that was no longer covered by the CAP.” Id. “(In essence, elimination of the Phase 2 CAP removed the protection industry would have received for pre-1991 violations.)” Id. “[Paragraph] IV(B) was therefore added to address this unintended exposure for Phase 2 information submitted pursuant to the CAP, and ensure that all parties were treated the same regarding their historic violations of TSCA § 8(e).” Id. As noted, OCE contends that reading Paragraph IV.A as a retroactive waiver would render Paragraph IV.B superfluous. See id. at 10.

Regarding the cutoff date for information falling under the CAP, OCE indicates a cutoff date as early as February 1, 1991, when the EPA first announced the CAP in the Federal Register, and as late as July of 1991.22 OCE asserts that, “It was made extremely clear, like...

21 See also OCE’s Count II Response at 19 n.16.

22 In its pre-oral argument brief, OCE stated that “the purpose of the CAP in 1991 was to allow companies that signed up to conduct an audit of their compliance status under TSCA § 8(e) as of that point in time.” OCE’s Count II Response at 14. The latter statement would indicate that the CAP covered information generated prior to the date when DuPont signed the (continued...)
many EPA enforcement initiatives, that the purpose was to address past noncompliance, to allow
defendants to pay stipulated penalties and then move on.” Oral Arg. Tr. at 77. Furthermore,
OCE argues that the CAP refers only to violations committed prior to February (or July) 1991
backward, by pointing to the CAP Agreement’s “Other Matters” provision, which states:
“Nothing in this CAP Agreement shall relieve the Regulatee from complying with all applicable
TSCA regulations or other applicable environmental statutes.” Oral Arg. Tr. at 78 (quoting
CAP Agreement, Unit II.D). In sum, according to OCE, the EPA would have a window of
opportunity to enforce Section 8(e) violations for information generated after February (or July)
1991 up to the June 27, 1996 Revised Addendum.

3. Arguments Regarding the Extrinsic Documents

In support of their positions concerning the duration of the enforcement waiver in Part
IV.A of the Revised Addendum, the parties have submitted various documents outside the four
corners of the Consent Agreement. Principally, these documents include the cover letter to the
Revised Addendum and various Federal Register notices concerning the CAP, and a comment
and response document.

The parties refer to the following Federal Register notices: (1) Registration and
Agreement for TSCA section 8(e) Compliance Audit Program; Notice, 56 Fed. Reg. 4,127
(Feb. 1, 1991) (“February 1991 notice”); (2) Registration and Agreement for TSCA section 8(e)
notice”); (3) Registration and Agreement for TSCA section 8(e) Compliance Audit Program
Modification; Notice, 56 Fed. Reg. 28,458 (June 20, 1991) (“June 1991 notice”), and; (4)
Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification, 56

22(...)continued)

CAP Agreement. Furthermore, in its post-argument brief, OCE contends that the CAP audit
period was designed to review information generated up to the date DuPont signed to participate
in the CAP. OCE’s Post-Argument Br. on Count II at 5. OCE asserts that DuPont signed the
CAP Agreement on June 28, 1991. (However, the Consent Agreement, at 1, states that DuPont
signed the CAP Agreement “on or about July 5, 1991,” and there is not yet support in the record
before me for a specific date of June 28, 1991.) OCE also indicates a cutoff date of July 1, 1991
in its pre-argument briefs, where OCE states that DuPont had an ongoing obligation to report
between July 1, 1991 and June 27, 1996. OCE’s Count II Response at 17, 20. Finally, at the
oral argument, OCE put forth a cutoff date of February 1, 1991: “During what I’m calling the
entire CAP development period, which was from announcement of the CAP in February of 1991
through the closing of the CAP in July of 1996, DuPont was obligated to stay in ongoing
compliance with TSCA Section 8(e).” Oral Arg. Tr. at 59. Nevertheless, all three dates are prior
to the September and November 1991 dates that OCE put forth to support Count II.

23 DuPont signed the CAP Agreement “on or about July 5, 1991.” Consent Agreement
at 1.
Addendum, which is dated May 15, 1996, was sent from Jesse Baskerville, Director of the Toxics and Pesticides Enforcement Division, EPA, and addressed to DuPont. DuPont’s Motion for Acc. Dec., Ex. 9 (“Cover Letter to Revised Addendum”). Finally, there is the February 20, 2003 Comment and Response Document for Revised Policy Statement of Section 8(e) of TSCA. DuPont’s Motion for Acc. Dec., Ex. 14 (“2003 Comment and Response Document”).

DuPont argues that Count II is barred not only by the “plain meaning” of the Revised Addendum, but also when taking into account the context in which the contract was executed and common sense. Oral Arg. Tr. at 10, 15, and 21.

DuPont contends that the 1978 Enforcement Policy speaks in general terms and does not set clearly defined standards. DuPont’s Motion for Acc. Dec. at 7. As a result, states DuPont, each company subject to Section 8(e) was required to exercise individual subjective judgment to determine what information must be reported, and that the lack of guidance led to a number of disagreements between the EPA and regulated entities. Id. at 7-8. For example, in 1984, 1989, and 1990, respectively, the EPA filed enforcement actions against Union Carbide Corporation, Monsanto Company, and Halocarbon Products Corporation, in each case for allegedly failing to submit a single study or piece of information. Id. at 8. In settling these matters, the EPA and the respondent took what DuPont describes as the “unusual step” of setting forth in the respective consent agreements a detailed discussion of their continuing substantial differences of opinion regarding the clarity of the reporting standards, the scope of reporting obligations under Section 8(e), and whether the information in question actually triggers Section 8(e)’s mandatory reporting obligations. Id. (citing DuPont’s Motion for Acc. Dec., Exs. 5, 6, and 7).

DuPont notes that on February 1, 1991, the EPA announced a one-time voluntary Section 8(e) CAP, February 1991 notice, 56 Fed. Reg. 4,127, “to avoid similar disputes.” DuPont’s Motion for Acc. Dec. at 8. Under the CAP Agreement that the EPA had developed, any company that registered for the CAP pledged to audit its files for reportable information not previously submitted to the EPA, report any information that the EPA might consider reportable, and pay a stipulated penalty of $6,000 to $15,000 for each previously unreported study or report. Id. In return, the EPA agreed, among other things, that each company’s total liability would be limited to $1,000,000, regardless of how many previously unreported studies the company submitted. Id. (citing February 1991 notice, 56 Fed. Reg. at 4,130).

Shortly after announcing the CAP, the EPA announced modifications to the CAP program. Id. at 9 (citing April 1991 notice, 56 Fed. Reg. at 19,514). The EPA was concerned about a so-called “data dump”; that without further guidance on what information must be submitted under TSCA Section 8(e), companies would give the EPA too much information. Id. (citing 56 Fed. Reg. at 19,514)). Therefore, states DuPont, the EPA pledged to issue, prior to the July 1, 1991 deadline for the CAP registration, an 8(e) Reporting Guide that would include a record of all previous initial submissions made under 8(e), a compilation of Question and Answer (“Q&A”) documents EPA had recently prepared, and a written review of several hypothetical “case histories” prepared by the Chemical Manufacturers Association, each of
which illustrated various issues for which guidance was lacking. *Id.* (citing 56 Fed. Reg. at 19,515)).

On June 20, 1991, the EPA issued the “TSCA Section 8(e) Reporting Guide” (“1991 Reporting Guide”) and announced its availability.²⁴ *Id.* (citing June 1991 notice, 56 Fed. Reg. at 28,458). In the June 1991 notice, the EPA acknowledged that the 1978 Enforcement Policy needed “additional clarification” and that “possible misinterpretation” likely would lead to “over-reporting.” *Id.* (quoting 56 Fed. Reg. at 28,458). Accordingly, the EPA formally “suspended” Parts V(b)(1) and V(c) of the 1978 Enforcement Policy and declared that it would prepare new guidance on reporting standards. *Id.* (citing 56 Fed. Reg. at 28,459). DuPont points out that, according to the June 1991 notice, CAP participants were to be guided solely by the statutory language when auditing company records of “detection of chemicals in environmental media.” *Id.* at 9. Shortly after this announcement, DuPont registered for the CAP by signing the standard form CAP Agreement. *Id.* at 10. Under the (original) terms of the CAP Agreement, each participant was to complete its audit and submit a final report to the EPA no later than February 28, 1992. *Id.*

DuPont notes, “On September 30, 1991, however, EPA extended indefinitely the CAP reporting deadline for information on the detection of chemicals in environmental media, instructing companies that such information need not be audited and reported until six months after EPA published its final revised guidance on reporting for such information.” *Id.* (citing September 1991 notice, 56 Fed. Reg. at 49,478). The September 1991 notice predicted that the EPA would issue the final revised guidance in Spring 1992. *Id.* (citing 56 Fed. Reg. at 49,479). In issuing the September 1991 notice, the EPA split the CAP into two phases, which DuPont interprets as follows: “‘[P]hase I’ of the CAP would be limited to auditing for reportable toxicology studies, with final reports still due to EPA by February 28, 1992, while ‘Phase II’ (regarding information on detection of chemicals in environmental media) would involve a six-month auditing period triggered by publication of EPA’s revised guidance.” *Id.* (citing 56 Fed. Reg. at 49,479).

DuPont emphasizes the importance of the September 1991 notice. DuPont’s Count II Reply at 8. DuPont points out that the September 1991 notice was EPA’s final Federal Register statement on the reporting deadline for “environmental data” until the EPA circulated its Revised Addendum five years later. *Id.* DuPont points out that the September 1991 notice “states clearly” that the deadline for all CAP participants, which includes DuPont, to report environmental data was extended until six months after publication of final reporting guidance. *Id.* DuPont argues that the September 1991 notice is a “clear statement” of EPA’s intent to waive enforcement during that period, which “strongly corroborates” DuPont’s interpretation of

²⁴ DuPont asserts that the 1991 Reporting Guide did not include any EPA standards for “reporting detection of chemicals in environmental media.” DuPont’s Motion for Acc. Dec. at 9. Neither DuPont nor OCE, to date, have provided this Tribunal with a copy of the 1991 Reporting Guide. (Although its availability was announced in the Federal Register, it does not appear to have been published in the Federal Register.)
the Revised Addendum. *Id.* As for the Addendum to the CAP Agreement, DuPont asserts that the Addendum it signed gave the same assurance that the EPA had given in the September 1991 notice. 25 *Id.* at 9.

DuPont contends that EPA’s 1993 notice confirms that EPA’s September 1991 notice waived any Section 8(e) penalty enforcement action. Oral Arg. Tr. at 14 (referring to 1993 notice, 58 Fed. Reg. at 37,736). DuPont goes on to argue, “then comes the Revised Addendum . . . and at no time did EPA ever say to any of the CAP participants well, now, you have to hurry up and report.” *Id.* Instead, argues DuPont, in 1991 the EPA extended the time for reporting and in 1993 the EPA confirmed that, and in the Revised Addendum the EPA states that it is waiving any Section 8(e) penalty enforcement action. *Id.*

DuPont argues that the Cover Letter to the Revised Addendum assured CAP participants that the EPA would not bring an enforcement action based on *any* environmental data that existed before the effective date of the final guidance. DuPont’s Count II Reply at 9 (citing Cover Letter to the Revised Addendum at 2). In particular, DuPont quotes two sentences from the Cover Letter to the Revised Addendum, which read as follows:

[E]PA 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 the effective date of the guidance will not be the subject of an EPA TSCA Section 8(e) enforcement action.

*Id.* (quoting Cover Letter to Revised Addendum at 2) (emphasis added). DuPont quotes the dictionary definition of “therefore,” meaning “for that reason, consequently.” *Id.* at 9 (quoting *Webster’s New Collegiate Dictionary*, G.&C. Merriam Co. 1201 (1979)). Accordingly, DuPont argues that “the only reasonable reading of these two sentences is that EPA had concluded that ‘it is reasonable and equitable to enforce the final guidance on a prospective basis only’ and, *for that reason,* environmental data that ‘predate the effective date of the guidance will not be the subject of an EPA TSCA Section 8(e) enforcement action.’” *Id.* at 9-10.

DuPont further argues that in the 2003 Comment and Response Document, regarding the proposed final revised guidance, the EPA again expressed that any data that existed before the final guidance would not form the basis of any EPA enforcement action. *Id.* at 10. In particular, DuPont points to the follow exchange:

COMMENT: Once EPA finalizes its new section 8(e) guidance, it should only be applied prospectively. The Agency [EPA] itself has admitted that the nature and scope of section 8(e) reporting

25 The parties have not provided this Tribunal with a copy of the Addendum that DuPont signed.
requirements for environmental information have not been clear, and it took the unusual step of suspending its prior guidance. Moreover, many additional Federal and state reporting requirements have been enacted since TSCA became effective in 1976,[26] further muddying the regulatory waters.

The confusion associated with the scope of environmental reporting under section 8(e), and the absence of Agency attention to the issue, contrasts sharply with the long history of health-related section 8(e) guidance and reporting. Given this history, and the continuing questions raised about the Agency’s proposal [sic] new guidance, it would be inappropriate to apply the guidance retroactively.

RESPONSE: Given the circumstances noted by the commenter, the suspension of the previous guidance, the emphasis on health and environmental effects reporting, the length of time required to propose revised guidance, and the greater specificity of the revised guidance, EPA has concluded that the revised guidance will be enforced prospectively. This means that companies will not have to review preexisting files for information that may be subject to section 8(e) reporting. These preexisting files would only come into “play” if data obtained by a company after the effective date of the guidance triggered a review of such data and in doing so the combination of data met the section 8(e) reporting criteria.

Id. (emphasis added). DuPont interprets EPA’s response to the comment as expressly stating that the preexisting files would trigger potentially enforceable reporting obligations only if new data caused the company to go back and review its old data, and the combination of the new and old data met the Section 8(e) reporting criteria. Id. at 10.

OCE, on the other hand, sees two separate tracks: one track for information generated prior to February 1, 1991 (or prior to July 1991) and a separate track for information generated after those dates up to 1996. Oral Arg. Tr. at 59, 65. To support this argument, OCE points to the Federal Register notices. Regarding the period from early to mid 1991 through 1996, OCE contends there was an ongoing statutory obligation to report information on the release of chemical substances to and detection of chemical substances in environmental media. Id. at 65; OCE’s Count II Response at 14-15. Furthermore, OCE contends that the September 1991 notice suspended “Phase 2” under the CAP program’s lookback audit, but that it did not suspend the reporting obligation for ongoing compliance with the statute. Oral Arg. Tr. at 64-66.

Regarding the Cover Letter to the Revised Addendum, OCE argues that instead of promising to not bring any Section 8(e) claims for information generated at any time prior to the

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26 TSCA became effective on January 1, 1977.
2003 guidance, OCE promised to not bring such claims for information generated prospectively – from June 27, 1996, forward – until the final guidance.\footnote{In response to my question, “What happened in 1996 that caused EPA to change its position?,” EPA counsel made the bald assertion that “EPA was facing potential statute of limitations problems with the closeout of Phase 1.” Oral Arg. Tr. at 73; see also Complainant’s Post-Argument Br. on Count II at 3 (no citation of support provided). I place no reliance on factual assertions unsupported by the record presently before me.}

EPA’s Count II Response at 20 (citing Cover Letter at 2: “EPA has decided that it is reasonable and equitable to enforce the final revised reporting guidance on a prospective basis only” (emphasis added)). OCE asserts, “There is a very big difference between the CAP audit program, which was an enforcement initiative undertaken in 1991, and then the [1996 Revised Addendum and its Cover Letter],\footnote{By “the letter that came out in 1996,” OCE appears to be referring to the Cover Letter to the Revised Addendum, which included the Revised Addendum as an attachment.} which arguably affected more than just the CAP program.” Oral Arg. Tr. at 65; see also OCE’s Count II Response at 14-15. As for the 2003 Comment and Response Document, OCE submits that DuPont ignores the requirement that still existed between February 1, 1991, and June 27, 1996, to comply with the statutory provisions of Section 8(e) of TSCA, irrespective of the guidance. Oral Arg. Tr. at 86.

G. Discussion of the Waiver of Enforcement and the Cutoff Period for the CAP

1. Analysis Within the Four Corners of the Consent Agreement

As discussed, when a party moves for accelerated decision on the ground that a consent agreement bars enforcement, summary judgment is inappropriate unless the consent agreement unambiguously bars enforcement in favor of the movant. Furthermore, only if the language of the consent agreement is ambiguous, does the adjudicator turn to surrounding circumstances, undisputed extrinsic evidence, to divine the parties’ intent. The Consent Agreement expressly incorporates, and therefore includes within its four corners, the CAP Agreement and the Revised Addendum.

Quite frankly, I am having great difficulty making sense of the Revised Addendum within the four corners of the Consent Agreement, the CAP Agreement, and the Revised Addendum. Not helping matters, as discussed supra, OCE has adjusted its interpretation throughout these proceedings as to many key aspects of the Revised Addendum, which may suggest that the EPA – who drafted the Revised Addendum – does not have a clear vision of the meaning of the Revised Addendum. Nevertheless, the burden at this juncture is on DuPont to prove that the language of the Consent Agreement is unambiguous.
I note that some of the key terms, or potentially key terms, used in the Revised Addendum are not defined or not clearly defined within the four corners of the Consent Agreement, the CAP Agreement, and the Revised Addendum, or within the Consent Order. Looking solely within the four corners, the undefined or not clearly defined terms include: “Phase I,” “environmental toxicity data for plant effluents,” “information on the release of chemical substances to and detection of chemical substances in environmental media,” and “final revised guidance.”29 As these terms are not defined within the four corners of the Consent Agreement, CAP Agreement, and Revised Addendum, I cannot discern a clear meaning of the enforcement waiver at issue, and therefore cannot interpret such waiver unambiguously in favor of the movant.30 For this reason alone, a denial of DuPont’s motion for accelerated decision is warranted.

Additionally, DuPont has not sustained its burden under the accelerated decision standard because OCE’s arguments concerning the language of the Consent Agreement, CAP Agreement, and Revised Addendum are adequate to defeat DuPont’s motion. Within their four corners, the Consent Agreement, CAP Agreement, and Revised Addendum, may be read as creating a lookback audit, for information existing prior to early to mid-1991, separate from ongoing statutory obligations to comply with TSCA. For instance, these three documents may be read as indicating that the EPA announced the CAP on February 1, 1991,31 that the CAP was to commence no later than July 1, 1991,32 that DuPont registered on or about July 5, 1991,33 and

29 The absence of definitions for “information on the release of chemical substances to and detection of chemical substances in environmental media, or environmental toxicity data for plant effluents” is particularly troublesome. The parties agree that Paragraph IV.A of the Revised Addendum waives enforcement over such information, but disagree as to whether the waiver is retroactive or prospective. However, without a definition of these terms, within the confines of the Consent Agreement, it is not clear whether such waiver affects all of the types of information alleged in Count II. For instance, in Count II OCE suggests a very wide range of effects, by entitling Count II as “Public Water Supply Contamination,” and alleging that PFOA has been shown to produce liver toxicity in test animals, that PFOA is biopersistent in animals and humans, as well as bioaccumulative in humans.

30 Although the Consent Agreement, at Part I.A., references the February, April, and June 1991 Federal Register notices, it does not expressly incorporate such notices as part of the Consent Agreement, and therefore such notices do not become part of the Consent Agreement. Moreover, such notices do not readily clarify the meanings of these terms introduced by the Revised Addendum.

31 Consent Agreement, Part I.A.

32 CAP Agreement, Part I.B and I.D.

33 Consent Agreement, Part I.B.
that the CAP did not relieve DuPont of the duty to comply with TSCA, which suggests a lookback audit separate from statutory compliance. Moreover, all three documents make reference to the Compliance Audit Program. Within the context of the CAP being a lookback audit, Paragraph I of the Revised Addendum may be read as terminating the audit as to the so-called “Phase 2” information dated prior to 1991, but then exposing CAP registrants to penalties and/or enforcement actions as to such information already reported pursuant to the CAP under the so-called “Phase 1.” Paragraph IV.B of the Revised Addendum may be read as eliminating the assessment of penalties for Phase 2 reports and studies submitted under Phase 1.

Accordingly, one may read Paragraph IV.B as providing some protection against the assessment of penalties for information submitted prior to the termination of the CAP in Paragraph I. DuPont argues that Paragraph IV.A creates a retroactive waiver of enforcement, but the protection against the assessment of penalties in Paragraph IV.B would arguably render such a retroactive waiver superfluous, in violation of contract law principles. Moreover, the CAP Agreement itself provides: “All of the terms and conditions of this CAP Agreement together comprise one agreement, and each of the terms and conditions is in consideration for all of the other terms and conditions.” Finally, Paragraph IV.A may be read as a prospective waiver of enforcement action, commencing in 1996, when reading it within the context of there being a lookback audit and that ongoing statutory compliance was required from early to mid-1991 through 1996.

With regards to the language in Paragraph IV.A, DuPont quotes Fix v. Quantum Industrial Partners, LDC, 374 F.3d 549, 553 (7th Cir. 2004), for the following principle: “There is a strong presumption against reading into contracts provisions that easily could have been included but were not.” OCE’s Count II Reply at 3. In the latter case, however, the court held that the contract’s terms were unambiguous on the face of the contract, rendering summary judgment appropriate, and thus the court excluded extrinsic evidence that contradicted the language of the contract; in particular, the parties had expressly adopted a term from a separate document, but chose not to adopt language from that very same document that was at odds with the terms of the contract. Id. Clearly, based on the facts that are presently before me, the factual situation in the Fix case is distinguishable from the instant matter.

34 Consent Agreement, Part VI.A (“Other Matters”); see also CAP Agreement, Part II.D.1 (“Other Matters’”). But see infra note 38.

35 It is an axiom in contract law that language within a contract must be read “in the context of the entire agreement” and must be construed “so as not to render portions of it meaningless.” Dalton v. Cessna Aircraft, 98 F.3d 1298, 1305 (Fed. Cir. 1996); Murphy v. Keystone Steel & Wire Co., 61 F.3d 560, 565 (7th Cir. 1995).

36 CAP Agreement, Unit II.D.5.

37 I would point out that Fix is a diversity case in which state law was the controlling law rather than federal law.
In conclusion, DuPont has not sustained its burden on summary judgment. I emphasize to the parties that my determination that an evidentiary hearing is warranted and that summary judgment is inappropriate does not suggest that I have developed or adopted a particular interpretation of the Consent Agreement and Consent Order, the CAP Agreement, or the Revised Addendum to the CAP Agreement. It simply means that the language is susceptible to interpretation contrary to the interpretation put forth by the movant. Furthermore, I note that I may deny a motion for accelerated decision (i.e., summary judgment) as a matter of discretion in order to fully develop the evidence concerning the disputed language, particularly in light of the potential ramifications such a determination may have on the other CAP registrants. See Roberts v. Browning, 610 F.2d 528, 536 (8th Cir. 1979).

2. Analysis Taking Into Account Extrinsic Documents

As discussed supra, summary judgment on Count II is not appropriate. Nevertheless, I examine the extrinsic evidence proferred by the parties, which primarily consists of several Federal Register notices, the Cover Letter to the Revised Addendum, and the 2003 Comment and Response Document. Both parties argue that the proferred extrinsic evidence supports their respective interpretations of the language of the Consent Agreement, the CAP Agreement, and the Revised Addendum.

With the February 1991 Federal Register notice, the EPA announced the opportunity to register for EPA’s TSCA Section 8(e) Compliance Audit Program (“CAP”). 56 Fed. Reg. at 4,128. The CAP was originally set to commence February 1, 1991, and close on May 2, 1991, id., but the commencement and closing dates were later amended. The CAP was a “one-time voluntary” program, designed to strongly encourage companies to voluntarily audit their files for studies reportable under Section 8(e). Id. at 4,129 (emphasis added). Persons interested in registering for the CAP were required to request a CAP Agreement and submit a signed CAP Agreement to the EPA no later than May 2, 1991. Id. at 4,128.

The February 1991 notice stated that “Up-to-date information on hazard and exposure is vital in supporting EPA efforts to protect human health and the environment from risks from toxic chemicals,” and that the “EPA has the responsibility under TSCA to perform needed risk assessments on chemicals.” Id. “Companies that do not report vital information are undermining the effectiveness of the early warning system intended under section 8(e).” Id. EPA recognized that there was, at the very least, a perception of significant disincentives to dissuade companies from auditing “past studies” and reporting them to EPA, due to high monetary penalties. Id. at 4128 (emphasis added). Furthermore, in evaluating some enforcement cases, the EPA found that some companies may have been misinterpreting Section 8(e) of TSCA and the 1978 Enforcement Policy. Id. The EPA emphasized that it had not changed its interpretation. Id. at 4,128-29. However, the EPA clarified that if serious health effects are discovered, then companies must submit the information without further evaluation (i.e., without using a weight-of-the-evidence method of discounting the significance of the information). Id. at 4,128; see also Oral Arg. Tr. at 72. The February 1991 notice stated that the CAP “has been developed” to encourage industry reporting by setting forth guidelines that identify in advance
EPA’s enforcement response and allow companies to assess liability prior to electing to participate. 56 Fed. Reg. at 4,129.

Following that announcement were the initially proposed terms of the CAP Agreement. Id. at 4,129-31. Under “Other Matters” under the proposed terms for the CAP Agreement was the following provision: “Nothing in this CAP Agreement shall relieve the Regulatee from complying with all applicable TSCA regulations or other applicable environmental statutes.” Id. at 4,130. The latter provision also exists in the CAP Agreement DuPont signed. CAP Agreement, Unit II.D; see also Oral Arg. Tr. at 78.

The February 1991 notice can be reasonably read as providing some support for OCE’s position that the CAP was designed as a “lookback” auditing program. The February 1991 notice first announced OCE’s disagreement with companies’ use of the weight-of-the-evidence method for health effects and then the notice set forth limitations for that method. Once that clarification had been made, EPA announced a “one-time” auditing program for “past studies.” Moreover, the requirement under the “Other Matters” provision that CAP registrants continue to follow the law is written in the present tense.38 See Oral Arg. Tr. at 74, 78.

The April 1991 Federal Register notice announced modifications to the CAP and the CAP Agreement. 56 Fed. Reg. at 19,514. The April 1991 notice states that the CAP is a “one-time voluntary audit program developed in order to achieve EPA’s goal of obtaining any outstanding TSCA section 8(e) data.” Id. (emphasis added).

Principally, the April 1991 notice expressed concern about an overflow, or “data dump,” of information resulting from the audits.39 Id. The EPA recognized that proper application of

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38 On the other hand, the precise wording of the “Other Matters” provision at issue states that “Nothing in this CAP Agreement shall relieve the Regulatee from complying with all applicable TSCA regulations or other applicable environmental statutes.” There is no regulation that implements Section 8(e) of TSCA, and as correctly observed by DuPont, Congress did not confer any rulemaking authority on the EPA as to Section 8(e). See DuPont’s Motion for Acc. Dec. at 7. Rather, the EPA implements TSCA by way of policies, such as the 1978 Enforcement Policy and the 2003 guidance. In contrast, the Consent Agreement, which was executed in 1996, has its own “Other Matters” provision, which reads: “Nothing in this Consent Agreement and Consent Order shall relieve Respondent of the duty to comply with all applicable provisions of TSCA and other environmental statutes.” Consent Agreement, Part VI.A (emphasis added).

39 Indeed, the CAP program’s $1,000,000 limitation on overall penalties may have acted as an incentive for companies to overreport. A person regulated by Section 8(e) might submit as many studies as possible in order to shield the company from enforcement actions involving those studies. If such a person had already reached the $1,000,000 limit, there would no longer be the threat of stipulated penalties for the extra studies submitted under the CAP program. For (continued...)

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Section 8(e) requires the exercise of scientific judgment. *Id.* The April 1991 notice announced EPA’s plans to disseminate a Section 8(e) reporting guide, comprised of status reports, a compilation of question and answer (“Q&A”) documents, and a written review of several hypothetical ‘case histories’ prepared by the Chemical Manufacturers Association. *Id.* at 19,515. The latter review of case histories was in response to a written request from the Chemical Manufacturers Association for additional guidance in the areas of neurotoxic effects and environmental effects/releases. *Id.* The April 1991 notice stated that EPA would make every effort to complete the reporting guide in early June 1991 and release it prior to the revised registration deadline/audit commencement date of June 18, 1991. *Id.* “However, if necessary because of a delay in completion of the guidance on the environmental effects/release information, reporting of this information under the TSCA Section 8(e) Compliance Audit Program will be put on a specific schedule . . .” *Id.* at 19,514.

The April 1991 notice extended the CAP registration deadline/audit commencement date for 45 days, to June 18, 1991. *Id.* Furthermore, it extended the CAP audit termination date/deadline date for approximately 90 days, to February 28, 1992 (which is the same termination date used in DuPont’s CAP Agreement). *Id.*

The April 1991 notice can be reasonably read as indicating that there was a lookback audit under the CAP for prior studies, consistent with OCE’s argument. In particular, the April 1991 notice reiterated that this “one-time” audit program was developed in order to obtain “any outstanding” TSCA Section 8(e) data. *Id.* (emphasis added).

The June 20, 1991 notice announced the availability of a Section 8(e) reporting guide and announced modifications to the CAP program and to the CAP Agreement. June 1991 notice, 56 Fed. Reg. at 28,458. The June 1991 notice stated that the “TSCA Section 8(e) Compliance Audit Program is a one-time voluntary compliance audit program developed to obtain outstanding TSCA section 8(e) data and foster compliance with the statutory obligations of TSCA section 8(e).” *Id.* (emphasis added). The CAP modifications again extended the registration deadline, this time to July 1, 1991 (which became the final registration deadline), and modified EPA’s guidance for reporting information concerning “widespread and previously unsuspected

39(...continued)

instance, in absence of the $1,000,000 limit on stipulated penalties under the CAP, DuPont would have owed $8,427,000 for the over 1,380 studies it submitted to the EPA. DuPont’s Motion for Acc. Dec., Ex. 11 (Docket No. TSCA-96-H-47, Complaint, Sept. 30, 1996 (“1996 Complaint”)) at 6.

40 As noted previously within this decision, the Consent Order states that DuPont registered for the CAP on or about July 5, 1991. However, the latter date would make the registration untimely due to the deadline of July 1, 1991, unless the EPA granted a registration extension to DuPont. Nevertheless, OCE does not raise an argument as to the timeliness of DuPont’s registration. Moreover, OCE makes the (unsupported) assertion in its briefs that DuPont registered on or about June 28, 1991, which would render DuPont’s registration timely.
distribution in environmental media” and “emergency incidents of environmental contamination” under Section 8(e). Id. Moreover, the June 1991 notice added a stipulated penalties provision, at $5,000 each, regarding studies or reports that were received by the EPA prior to June 18, 1991, but were late in meeting the 15-day reporting deadline under the 1978 Enforcement Policy. See id. at 28,458-59. The CAP Agreement DuPont signed reflects the modifications from the April 1991 and June 1991 Federal Register notices. Furthermore, the CAP Agreement DuPont signed on or about July 5, 1991 provides that the CAP “shall commence no later than July 1, 1991.” CAP Agreement, I.D.

With the June 1991 notice, the EPA suspended Parts V(b)(1) and V(c) of the 1978 Enforcement Policy, which concern “widespread and previously unsuspected distribution in environmental media, as indicated in studies (excluding materials contained within appropriate disposal facilities)” and “emergency incidents of environmental contamination,” respectively. 56 Fed. Reg. at 28,459. The June 1991 notice states that in reviewing the 1978 Enforcement Policy “in connection with the TSCA Section 8(e) Compliance Audit Program,” the EPA has determined that Part V(b)(1) and Part V(c) of the 1978 Enforcement Policy need additional clarification and that possible misinterpretation with regard to the guidance in these sections could lead to overreporting under the TSCA Section 8(e) Compliance Audit Program.” Id. (emphasis added). Therefore, the EPA announced plans to review the reporting of information in order to determine what information of these types should “continue to be considered for submittal” under Section 8(e), and that interested persons would be allowed the opportunity to comment on proposed revisions to Parts V(b)(1) and V(c). Id.

The June 1991 notice stated that, despite the suspension of V(b)(1) and V(c) of the 1978 Enforcement Policy, “regulatees auditing their files for reportable environmental risk information under the TSCA Section 8(e) Compliance Audit Program should be guided by the statutory language of section 8(e) and Part V(b)(2) through (b)(5) of the [1978 Enforcement Policy].” Id. Moreover, “In assessing whether information or studies involving widespread and previous unsuspected environmental distribution, emergency incidents of environmental contamination, or other previously unknown situations involving significant environmental contamination should be submitted under the TSCA Section 8(e) Compliance Audit Program, or under section 8(e) in general, regulatees should make a reasonable judgement whether such information meets the statutory standards of TSCA section 8(e) instead of relying on Parts V(b)(1) or V(c) of the [1978 Enforcement Policy].” Id. (emphasis added). The June 1991 notice concluded with the admonition that, “Even though EPA is suspending the applicability of Parts V(b)(1) and V(c) of the [1978 Enforcement Policy], persons are still responsible under TSCA section 8(e) to report information that reasonably supports a conclusion of substantial risk of injury to the environment. This is a continuing statutory obligation.” Id.

Thus, the June 1991 notice can reasonably be read as having been addressed towards two groups: (1) regulatees auditing for information pursuant to the CAP (“under the Compliance
Audit Program”) and (2) persons acting “under Section 8(e) in general.” See id. Furthermore, the second group, for persons acting “under Section 8(e) in general,” would appear to address ongoing compliance. Despite the notice’s announcement of considering revisions to Parts V(b)(1) and V(c) of the 1978 Enforcement Policy, it only announced an extension for registration under the CAP and an extension for submitting audited information under the CAP. Moreover, the June 1991 notice did not announce an extension of the normal 15-day reporting deadline information that was not gathered pursuant to the CAP.

I observe that there is a dispute as to the cutoff date for defining the latest time included in the CAP audit period, with DuPont asserting, in arguendo, that even if the CAP constituted a lookback audit, then it was a lookback from 1992, the original reporting deadline, rather than July or February 1991. As noted in the above discussion, the CAP was a one-time program involving “outstanding” data, and the June 1991 notice can be read as requiring ongoing compliance as of June 1991; the CAP Agreement was signed shortly after the June 1991 notice. Therefore, it is possible to draw an inference in favor of one or more of the cutoff dates submitted by OCE.

The September 1991 notice described the June 1991 notice as follows: “With regard to Parts V(b)(1) and V(c) of the [1978 Enforcement Policy], the regulated community was informed that until such time as EPA refined its guidance regarding the types of information on the release of chemical substances to and the detection of chemical substances in environmental media that are reportable under section 8(e) of TSCA, regulatees should focus on the statutory language of TSCA section 8(e) and make a reasonable judgment whether such information is reportable for purposes of TSCA Section 8(e) CAP as well as ongoing compliance with section 8(e).” September 1991 notice, 56 Fed. Reg. at 49,478 (emphasis added).

The September 1991 notice split the CAP into two phases. Id. at 49,479. It announced, “Because refinement of guidance on reportability of information on chemical release/detection in environmental media is underway, EPA is extending the reporting deadline for reporting such information under the TSCA Section 8(e) CAP to 6 months after publication of final reporting guidance.” Id. (emphasis added). At the time of the September 1991 notice, the EPA reportedly anticipated publishing the final guidance in Spring 1992. Id.

41 The CAP Agreement DuPont signed, on or about July 5, 1991, reflects the CAP modifications announced in the February, April, and June 1991 Federal Register notices. Additionally, the Consent Agreement references those Federal Register notices. Consent Agreement, Part I.A.

42 As discussed previously, supra note 22 and accompanying text, OCE has put forth cutoff dates of February 1, 1991, June 28, 1991, and July 1, 1991. The September 1991 and November 1991 dates that OCE contends “come[] into play” in Count II postdate even the latest of the cutoff dates suggested by OCE.
To reflect the September 1991 modification to the CAP program, an Addendum, entitled “Addendum to CAP Agreement,” was to be sent to all persons registered for the CAP and to be added to all CAP Agreements. Id. The September 1991 notice includes an Addendum, providing that the CAP for the reporting of “information on the release of chemical substances to and detection of chemical substances in environmental media” shall terminate six months after the EPA publishes final refined guidance on such reporting.43 Id. Furthermore, “This modification applies only to reporting of information on the release of chemical substances to and detection of chemical substances in environmental media. The deadline for reporting all other information under the TSCA Section 8(e) CAP remains unchanged at February 28, 1992.” Id. (emphasis added). The Addendum further provided, “All TSCA Section 8(e) Compliance Audit Program submissions regarding information on the release of chemical substances to and detection of chemical substances in environmental media must be delivered to EPA no later than six months after EPA publishes final guidance refining the [1978 Enforcement Policy] as it pertains to such reporting.” Id.

The Addendum provided for there to be two Final Reports, with the first Final Report listing all studies or reports listed or submitted to the EPA by the Regulatee other than those regarding information on the release of chemical substances to and detection of chemical substances in environmental media, and was to be submitted no later than February 28, 1992. Id. The second Final Report was to list each study or report listed or submitted to the EPA by the Regulatee regarding information on the release of chemical substances to and detection of chemical substances in environmental media, and was to be submitted no later than six months after the EPA published final refined guidance on the reporting of such information. Id. The Addendum further provided that one Consent Agreement and Consent Order would be presented to the Regulatee, and that the Consent Agreement and Consent Order would be presented after EPA’s receipt of the second Final Report, regarding information on the release of chemical substances to and detection of chemical substances in environmental media, and would cover all information submitted by the Regulatee under the CAP. Id.

The September 1991 notice may be reasonably read as supporting OCE’s position. Although the September 1991 notice extends the deadline for reporting “information on the release of chemical substances to and detection of chemical substances in environmental media,” the notice repeatedly states that it is extending the deadline for “reporting information under the CAP.” At no point does the September 1991 notice extend the deadline for ongoing compliance with Section 8(e).

With the 1993 Federal Register notice, the EPA published proposed revisions to the 1978 Enforcement Policy in regards to “mandatory reporting of information on the release of chemical substances to, and the detection of chemical substances in, environmental media,” and other

43 The parties have not provided this Tribunal with a copy of the Addendum that DuPont signed. The Consent Agreement states, “Respondent submitted the Addendum to EPA on September 26, 1992; however, EPA presently has no record of an Addendum for Respondent.” Consent Agreement, I.C.
matters, and it solicited public comment on that proposal. TSCA Section 8(e); Notice of Clarification and Solicitation of Public Comment, 58 Fed. Reg. 37,735 (July 13, 1993) (“1993 notice”). The 1993 notice recounted the history of the CAP, stating that on February 1, 1991 EPA announced a “one-time” voluntary compliance audit program designed primarily to: (1) achieve the EPA’s goal of obtaining any “outstanding” Section 8(e) information, and (2) encourage companies to voluntarily audit their files for Section 8(e)-reportable data. Id. at 37,736. In exchange, the CAP incorporated stipulated monetary penalties and an overall monetary penalty ceiling. Id. In reviewing existing guidance as the result of questions raised by companies considering participating in the CAP, the EPA suspended the applicability of Parts V(b)(1) and V(c) of the 1978 Enforcement Policy. Id. The regulated community was informed that the EPA would modify the Section 8(e) policy to provide greater specificity regarding the types of information that should be submitted under Section 8(e). Id. In the interim, the “regulated community” was directed by EPA to focus on the statutory language of Section 8(e) as the standard by which to determine the reportability of such information “for purposes of the Section 8(e) CAP as well as ongoing compliance with section 8(e).” Id. (emphasis added). On September 30, 1991, the “EPA announced an extension of the section 8(e) CAP reporting deadline for information relating to the release of chemical substances to and detection of chemical substances in environmental media until such time as [the EPA] develops final refined section 8(e) reporting guidance on this point.” Id. (emphasis added). The September 1991 notice “addresses only the reportability of information concerning non-emergency situations on ‘widespread and previously unsuspected distribution in environmental media.’” Id. The 1993 notice announced that the EPA was deferring publishing refined and/or amending the Section 8(e) guidance regarding emergency incidents of environmental contamination information, considering that such guidance should be developed as part of the EPA’s over-all policy concerning Federal chemical emergency/accident prevention, reporting, response, and/or remediation. Id.

The 1993 notice announced that the EPA was in the process of resolving enforcement and compliance issues concerning reporting of “section 8(e) ‘environmental’ information under ‘Phase 2’ of the CAP, and under section 8(e) more generally.” Id. (emphasis added). It further stated that after the EPA considers comments in response to the 1993 notice, the EPA would issue in the Federal Register final refined guidance for reporting information concerning non-emergency situations regarding “environmental contamination.” Id. Following was Section 8(e) policy changes, including proposed changes to Part V(b)(1) (“widespread and previously unsuspected distribution in environmental media”) of the 1978 Enforcement Policy, but it did not propose changes to Part V(b)(2)-(5). Id. at 37,741.

Again, the 1993 notice may be read as supporting OCE’s view. As with the June 1991 and September 1991 notices, it suggests reporting “under Phase 2 of the CAP” and reporting “under Section 8(e) more generally” were separate. It describes the September 1991 notice as extending the CAP deadline. There is no mention of an extension of the deadline for ongoing compliance.
Through a 1995 Federal Register notice, the EPA solicited additional public comment on revisions to Part V(b)(1) of the 1978 Enforcement Policy. TSCA Section 8(e); Notice of Availability of Draft Policy and Reopening of Comment Period, 60 Fed. Reg. 14,756 (Mar. 20, 1995) (“1995 notice”). The 1995 notice stated that the EPA had used the comments received in response to the 1993 proposed revisions to draft revised policy text that the EPA believed responded to the main comments. Id. Further, the 1995 notice announced that the EPA was making available for public comment the draft guidance text in the public docket.44 Id. Comments were to be submitted and received by the EPA no later than May 4, 1995. Id.

The Cover Letter to the Revised Addendum, dated May 15, 1996, as well as the Revised Addendum, was signed by the EPA’s Mr. Jesse Baskerville, who was Director of the Toxics and Pesticides Enforcement Division. The Cover Letter was addressed to DuPont, and below DuPont’s address the salutation reads “Dear CAP Participant:” and then states that the September 1991 notice “[a]nnounced . . . an extension of the TSCA Section 8(e) CAP reporting deadline for submission of information regarding release of chemical substances to and detection of chemical substances in environmental media.” Cover Letter at 1 (emphasis added). The Cover Letter states that the September 1991 “[a]nnouncement established a Phase Two of the CAP for section 8(e) information on the release of chemical substances to and the detection of chemical substances in environmental media and environmental toxicity data for plant effluents.” Id. (emphasis added). The Cover Letter provides, “All TSCA Section 8(e) CAP submissions under Phase 2 were to be delivered to EPA no later than six months after EPA publishes final revised environmental guidance (‘guidance’),” and “The exact date would appear in the Federal Register notice announcing the revised guidance.” Id. (emphasis added). The Cover Letter further states:

On January 30, 1992, EPA provided CAP participants with an “Addendum to CAP Agreement” and policy statements that formally established the Two Phases to the CAP, and permitted the submission of the following information during Phase Two:

information on the release of chemical substances to and detection of chemical substances in environmental media, and environmental toxicity testing performed on plant effluents.

Id. The Cover Letter advised CAP participants: “The deadline for reporting all other information under the TSCA section 8(e) Compliance Audit Program remained unchanged at February 28, 1992 unless otherwise extended,” and “The Addendum was to be executed by the Regulatee and returned to EPA for ratification and entry.” Id.

44 Neither party has submitted to this Tribunal the 1995 draft revisions.
The Cover Letter recounts, “Since ratification of the Addendum, EPA has twice issued, for notice and comment, revised draft reporting guidance.” Id. at 2. The Cover Letter states, “After review of extensive comments, EPA has decided that it is reasonable and equitable to enforce the final revised reporting guidance on a prospective basis only.” Id. (emphasis added). “Therefore, information on the release of chemical substances to and detection of chemical substances in environmental media; or environmental toxicity data on plant effluents that predate the effective date of the guidance will not be the subject of an EPA TSCA Section 8(e) enforcement action.” Id. (emphasis added). Next, the Cover Letter states, “We are aware that some CAP participants may have submitted this data under Phase 1 of the CAP program. Accordingly, penalties will not be assessed for any Phase 2 type studies or reports submitted under the TSCA Section 8(e) CAP as TSCA Section 8(e) data.” Id. (emphasis added).

Mr. Baskerville states in the Cover Letter, “To effectuate this decision it is necessary to revise the previously ratified Addendum, and modify the [CAP Agreement]. Id. Accordingly, he states, “The attached Revised Addendum to the CAP Agreement supersedes the previous Addendum and specifies the following:

The Regulatee no longer is required to conduct a file search for information on the release of chemical substances to and detection of chemical substances in environmental media, or for environmental toxicity data on plant effluents.

A second Final Report is no longer necessary. Therefore, the first Final Report becomes the controlling document described in Unit II.A.8. of the CAP Agreement.

Id.

The Cover Letter may reasonably be read as OCE argues: as indicating a prospective waiver of enforcement, because the Cover Letter states that the EPA has decided to enforce the final revised reporting guidance “on a prospective basis only.” Id. (emphasis added). The Cover Letter (and Revised Addendum) is to be read within the overall context, which includes the Federal Register notices. As discussed, the Federal Register notices indicate that up to the date of the Cover Letter and Revised Addendum, the EPA had been requiring persons to make a reasonable judgment whether V(b)(1)-type information (“widespread and previous unsuspected environmental distribution”), V(c)-type information (“emergency incidents of environmental contamination”), “or other previously unknown situations involving significant environmental contamination” should be submitted under the CAP or under Section 8(e) in general. See June 1991 notice, 56 Fed. Reg. at 28,458. EPA’s September 1991 extension of the reporting deadline for information on the release of chemical substances to and detection of chemical substances in environmental media only applied for reporting information “under the TSCA Section 8(e)

The 2003 Comment and Response Document, dated February 20, 2003, comes before the final revised guidance and comments on the proposal to finalize that guidance. The 2003 Comment and Response Document states that companies will not have to review “preexisting files” for information that may be subject to Section 8(e) reporting, and “These preexisting files would only come into ‘play’ if data obtained by a company after the effective date of the guidance triggered a review of such data and in doing so the combination of data met the section 8(e) reporting criteria.” 2003 Comment and Response Document at 1. Nevertheless, this document may be read within the context of OCE’s theory that ongoing compliance with the statute was required from February or July 1991 through 1996, which can be seen from the Federal Register notices, and that Paragraph IV.A of the Revised Addendum only prospectively waived enforcement up to the date of the final revised guidance.

In sum, the extrinsic evidence proffered by the parties does not render the Consent Agreement, including the CAP Agreement and Revised Addendum, unambiguous in favor of the movant. Taking into account the extrinsic evidence, as argued by OCE one may reasonably view the CAP as a “lookback” audit that includes information generated before February or July 1991; that ongoing compliance was required for information generated on or after February or July 1991, and was required from February or July 1991 up to June 27, 1996 – the date of the Revised Addendum, and; that the EPA never suspended reporting for ongoing compliance but only suspended the auditing and reporting for information under the CAP (i.e., only information generated before February or July 1991). Therefore, one may reasonably interpret Paragraph IV.A of the Revised Addendum as a prospective waiver, meaning it applies only as to the information generated from June 27, 1996 forward up to the effective date of the final revised guidance, which was issued in 2003. In essence, one may reasonably view the Compliance Audit Program as not applying the alleged Count II violations, as argued by OCE.

Pursuant to the summary judgment standard, DuPont has not proven that the waiver of enforcement in Paragraph IV.A of the Revised Addendum waives enforcement over the September and November 1991 dates that OCE contends “comes into play” in Count II. As

45 I recognize, however, that even if reporting of information obtained from February or July 1991 through May or June of 1996 was required, the EPA may have decided to change course in 1996, to completely waive enforcement even for pre-1996 violations. After all, as discussed supra, even prior to the 1996 Cover Letter and Revised Addendum, the EPA had recognized, as indicated in the Federal Register notices, that there were problems with the 1978 Enforcement Policy that could result in overreporting. E.g., June 1991 notice, 56 Fed. Reg. at 28,459.

46 See Oral Arg. Tr. at 65; OCE’s Count II Response at 14-15.
such, summary judgment is not appropriate on this issue and an evidentiary hearing is warranted.\textsuperscript{47}

**H. Genuine Issues of Material Fact**

In addition to finding that accelerated decision is not warranted as a matter of law, I further find that genuine issues of material fact exist. For example, there is a genuine dispute of material fact as to whether the levels of PFOA allegedly detected in DuPont’s wells at levels as high as 3.9 ppb reasonably support a conclusion of substantial risk of injury to health or the environment. In particular, DuPont contends that there is “overwhelming scientific evidence” that levels of 3.9 ppb or less PFOA in drinking water pose no risk, and that a multi-agency scientific panel, which includes EPA scientists, has determined that a lifetime of daily exposure to PFOA concentrations of up to 150 ppb in all drinking water that a person ingests would not be expected to result in any deleterious effects. DuPont’s Motion for Acc. Dec. at 3; \textit{but see} OCE’s Count II Response at 4; \textit{see also}, e.g., EPA’s Count II Response, Ex. 1 (discussing standards set at 1 ppb versus 150 ppb). A prerequisite to TSCA Section 8(e) liability is that the information obtained by the respondent must reasonably support the conclusion that a substance or mixture presents a substantial risk of injury to health or the environment. 15 U.S.C. § 2607(e).

**I. Res Judicata**

DuPont argues that, regardless of whether the EPA waived enforcement over the Count II claim, the doctrine of res judicata bars the EPA from bringing those claims due to the EAB’s Consent Order that approved the parties’ Consent Agreement. DuPont’s Motion for Acc. Dec. at 27.

The doctrine of res judicata, also known as claim preclusion, applies both to judicial consent decrees and to administrative consent agreements. \textit{In re Int’l Paper Co.}, RCRA (3008) Appeal No. 90-3, 3 E.A.D. 562, 567 (CJO 1991). Typically, when a court enters a final judgment on the merits in an action, the doctrine of res judicata bars the parties from re-litigating the same cause of action in a subsequent suit. \textit{In re Wego Chem. & Mineral Corp.}, TSCA Appeal No. 92-4, 4 E.A.D. 513, 520 (EAB 1993); \textit{Int’l Paper}, 3 E.A.D. at 567; accord \textit{Nevada v. United States}, 463 U.S. 110, 129-30 (1983). Under the doctrine of res judicata, the moving party bears the burden to show the following requirements: (1) there was a final judgment on the

\footnote{Although not necessarily determinative, it would be helpful to be informed about the actions of the parties and other CAP participants with regards to “Phase 2” information generated from February 1, 1991 through June 27, 1996. In particular, prior to the instant case being filed, has the EPA ever brought any Section 8(e) enforcement action(s) against any CAP participant for failure to report any Section 8(e) information generated from February 1, 1991 through June 27, 1996? From February 1, 1991 up to the current date, did DuPont, or any other CAP participant, report to the EPA any “Phase 2” Section 8(e) information generated from February 1, 1991 through June 27, 1996? Arguably, such information may establish the parties’ course of performance.}
merits in a prior action, (2) involving the same parties, and (3) the subsequent proceeding is based on the same cause of action. *Wego*, 4 E.A.D. at 520. The parties disagree as to whether the subsequent proceeding is based on the same nucleus of operative facts. Oral Arg. Tr. at 80-81. At oral argument, OCE also asserted that there was not a final judgment on the merits in regards to the violations alleged in Count II such that is has preclusive impact over the instant action. *Id.* at 81-84. It is not necessary to reach the latter issue at this time because, as discussed below, I conclude that DuPont has not proven that there is no genuine issue of material fact regarding whether the instant proceeding is based on the same cause of action as in the prior action.

“Whether two cases implicate the same cause of action turns on whether they share the same ‘nucleus of facts.’” *Apotex, Inc. v. FDA*, 393 F.3d 210, 217 (D.C. Cir. 2004); accord *Int’l Paper*, 3 E.A.D. at 568 (barring a claim on the ground of res judicata where the issues arose out of the “same nucleus of operative facts” as those raised and settled previously and therefore involved “the same cause of action”). “In pursuing this inquiry, the court will consider ‘whether the facts are related in time, space, origin, or motivation, whether they form a convenient trial unit, and whether their treatment as a unit conforms to the parties’ expectations or business understanding or usage.’” *Apotex*, 393 F.3d at 217 (quoting *I.A.M. Nat’l Pension Fund v. Indus. Gear Mfg. Co.*, 723 F.2d 944, 949 n. 5 (D.C. Cir.1983), quoting 1B J. Moore, Moore’s Fed. Practice ¶ 0.410[1] (2d ed. 1983)); see also *Wego*, 4 E.A.D. at 520 (whether or not a cause of action in a judgment and a case are considered the same also hinges, among other things, on: (1) whether the acts complained of are the same; (2) whether the material facts are the same; and (3) whether the proof required is the same (citing *United States v. Athlone Inds.*, 746 F.2d 977, 984 (3rd Cir. 1984)).

On October 3, 1996, the EAB executed a Consent Order, which approved the Consent Agreement. DuPont’s Motion for Acc. Dec., Ex. 13. The Consent Order provides that “Respondent shall comply with all terms of the Consent Agreement, incorporated herein by reference.” *Id.* Attached to the Consent Order is the Consent Agreement, and the attachments thereto: the CAP Agreement and the Revised Addendum. *See id.*

DuPont argues that Count II arises out of the same nucleus of operative facts resolved by the Consent Order, and that res judicata therefore bars Count II. DuPont’s Motion for Acc. Dec. at 27. Specifically, DuPont argues, “Here, the Consent Order and Count II do not just arise out of the same nucleus of operative facts[,] they involve the very same issue: whether TSCA § 8(e) required DuPont to report information on the detection of chemical substances in environmental media received by or known to DuPont before EPA issued its final guidance for such reporting.” *Id.* at 28. DuPont contends that the Consent Order, by incorporating by reference the Revised

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48 It may be that the EAB received correspondence or other communications from the Office of Regulatory Enforcement or other EPA offices before or contemporaneous with the EAB’s approval of the Consent Order. *See* Preamble to Rules of Practice, 64 Fed. Reg. 40,138, 40,149 (July 23, 1999) (discussing the TSCA Section 8(e) CAP within the context of ex parte communications). To date, this Tribunal has not been provided such information.
Addendum, specifically addresses DuPont’s obligation to report the detection of chemical substances in drinking water and finally resolves that DuPont need not report such information prior to the EPA issuing its final guidance. *Id.* at 28-29. DuPont argues, “Because the Consent Order addresses DuPont’s obligation under TSCA § 8(e) to report detection of any chemical in water samples if the detection occurred before EPA issued its final guidance, and because Count II alleges that DuPont obtained and failed to report detection of PFOA in such samples before EPA issued its final guidance, Count II arises out of the same nucleus of operative facts . . . resolved in the Consent Order.” *Id.* at 29.

Furthermore, DuPont argues that *res judicata* bars OCE from asserting Count II on the ground that OCE could have asserted but did not assert the current Count II in the prior litigation. *Id.* (citing *Nevada*, 463 U.S. at 129-30); DuPont’s Post-Argument Br. at 10. DuPont argues, “Not only do Count II and the Consent Order arise from the same nucleus of operative facts, but it is readily apparent that EPA could have brought the current Count II in the [1996] Complaint that led to the Consent Order.” DuPont’s Motion for Acc. Dec. at 29 (referring to DuPont’s Motion for Acc. Dec., Ex. 10: Complaint, Docket No. TSCA-96-H-47 (“1996 Complaint”)). DuPont points out that in the 1996 Complaint, the EPA noted DuPont’s obligation to report the presence of chemical substances in environmental media. *Id.* (citing 1996 Complaint at 2, 7). DuPont states that, in 1996, the EPA could have alleged that DuPont was liable for failing to make such reports, but rather than allege that DuPont was liable for failing to report such information, the EPA instead stated that DuPont was no longer required to conduct a file search for such information. *Id.* (citing 1996 Complaint at 7). Finally, DuPont points to a February 9, 1990 Verification Investigation Workplan (“VIW”) addressed to the EPA, “[t]elling the [EPA] that DuPont in 1990 had detected C8 or PFOA in the Lubeck wells. These are the same water samples that form the basis of Count 2. EPA was aware of that. Clearly they could have brought those claims.” Oral Arg. Tr. at 28 (citing OCE’s Count II Response, Ex. 20 at 18).

OCE counters that the Revised Addendum does not cover the September and November 1991 dates on which Count II is based. Oral Arg. Tr. at 81. OCE also quotes the Consent Agreement/Order: “This Consent Agreement and Consent Order shall be a complete settlement of all administrative claims and civil causes of action alleged in the Complaint.” OCE’s Count II Response at 22 (quoting Consent Order at 1). OCE argues that the Complaint in the instant case is limited to the studies that were submitted by DuPont, and does not encompass studies withheld by regulatees. *Id.* According to OCE, it is that alleged withholding that has given rise to this action, the question being whether DuPont violated Section 8(e) when it failed to provide certain data, and that OCE’s case in chief turns on DuPont’s violations of Section 8(e) notwithstanding the existence of the CAP. *Id.* at 22-23. OCE argues that the instant case concerns DuPont’s failure to report studies to the EPA between 1991 and 1996, which is the time period OCE contends was not covered by a waiver of enforcement and during which ongoing compliance with Section 8(e) was required. Oral Arg. Tr. at 81. Therefore, so argues OCE, the Consent Order in the instant case did not arise from the same claims and does not act as a bar. *Id.* Furthermore, OCE points out that the Consent Agreement/Order specifically permits matters of non-compliance to be litigated. *Id.* (referring to Consent Agreement, Part VI.A, and; CAP Agreement, Unit II.D.1). As for the February 1990 VIW that purportedly put the EPA on notice
of the alleged violation prior to the announcement of the CAP, OCE contends that the EPA rejected this submission in toto as deficient, and when DuPont resubmitted its revised VIW in December 1990, it had omitted the statement regarding Lubeck public supply well contamination. OCE’s Post-Argument Br. on Count II at 13 (citing OCE’s Count III Response, Ex. 6 (Dec. 14, 1990 VIW), at 26).

As discussed supra, the Revised Addendum could be read as not covering the September and November 1991 dates that allegedly form the basis for Count II. Accordingly, there is a genuine dispute of material fact regarding whether the Consent Order and Count II are based on the same nucleus of operative facts. In addition, looking at the Consent Order, I observe that the EAB expressly incorporates the terms of the parties’ Consent Agreement, which includes the CAP Agreement and the Revised Addendum. As correctly observed by OCE, the Consent Agreement does provide that matters of non-compliance may be litigated. Consent Agreement, Part VI.A; CAP Agreement, Unit II.D.1.

Finally, there may be a genuine dispute of material fact as to whether the information on which Count II is based is pre-February or pre-July 1991 information. OCE submits that Count II is based on environmental contamination data that DuPont allegedly became aware of in mid to late 1991, more specifically September 11, 1991 and November 19, 1991. Oral Arg. Tr. at 62, 71. OCE points out that the TSCA reporting obligation accrues when a company becomes aware of information that indicates substantial risk to health or the environment. Id. at 62. However, OCE admits that the environmental contamination data at issue “[d]oes build on prior data, some data points that may have preceded 1991,” id., and OCE has stated that DuPont became aware of the environmental contamination prior to signing the CAP Agreement in 1991. Id. at 72.

Accordingly, DuPont has not sustained its burden on summary judgment. Therefore, I DENY DuPont’s Motion for Accelerated Decision on Count II.

49 However, one could argue that the Consent Agreement and CAP Agreement reserve EPA’s enforcement authority to litigate pre-1991 violations of the CAP. See Oral Arg. Tr. at 81; Consent Agreement, Part VI.A; CAP Agreement, Unit II.D.1.

50 One of OCE’s exhibits, the minutes from a meeting on September 11, 1991, indicates that in 1984, C-8 (i.e., PFOA or APFO) was found at levels less than 1.5 ppb, downgradient from DuPont’s Washington Works facility. OCE’s Count II Response, Ex. 23. The minutes further state, “However, data do not indicate large increases in C-8 concentration since 1987, (from 2.0 to 5.9 ppb).” Id. The minutes continue that “Off-site water samples from home taps (i.e. from the existing Lubeck wellfield) indicate C-8 from .7 to 3.9 ppb, with the 3.9 ppb measured from a sample taken on 8/8/91.” Id. “C-8 was detected in a new well in the new Lubeck wellfield (2.7 miles south-southwest of Washington Works), at 2.4 ppb on 6/23/91.” Id. Considering that OCE has stated that the mid to late 1991 information forming the basis for Count II “does build on prior data, some data points that may have preceded 1991,” there is a genuine dispute of material fact as to whether the data on which Count II is based should be viewed as pre or post 1991 information.
II. Count III

The parties have filed cross-motions for accelerated decision as to Count III. For the reasons discussed herein, resolution of this matter is more appropriate for an evidentiary hearing, and therefore, the parties’ motions for accelerated decision are denied.

A. The Allegations Forming the Basis of Count III

DuPont admits that on or about January 5, 1987, the 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. Amended Answer ¶ 35. DuPont admits that on December 13, 1989, the EPA issued to DuPont the corrective action portion of DuPont’s permit for the Washington Works facility. Id. ¶ 37. Moreover, on December 16, 1999, the 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. Id. ¶ 38.

OCE alleges that in 1981, when performing blood sampling of pregnant workers at the Washington Works Facility, DuPont obtained human blood sampling information concerning the transplacental movement of PFOA (i.e., “C-8” or “APFO”). Amended Complaint ¶¶ 42, 106 (referring to OCE’s Count III Response, Ex. 3 (titled “C-8 Blood Sampling Results”). DuPont admits that the document at issue contains numbers that purport to be levels of PFOA detected in the blood of DuPont employees. Amended Answer ¶ 42.

In Count III, OCE alleges that DuPont committed a RCRA permit violation by failing to comply with its duty to provide information, as provided by Part One, Section I.7, of DuPont’s RCRA Corrective Action Permit for the Washington Works facility. Amended Complaint ¶¶ 111-113; see OCE’s Count III Response, Ex. 1 (“DuPont’s Corrective Action Permit”), Part One, § I.7. Specifically, OCE alleges that on or about May 5, 1997, the EPA issued a Notice of Deficiency to DuPont for a Verification Investigation Report (“VI Report”). Amended Complaint ¶ 102. In the Notice of Deficiency, the EPA reportedly requested that DuPont provide to the EPA, within 30 days of receipt, for all deficiencies identified in the Notice. Id. In the “Groundwater” section of the Notice of Deficiency, the EPA allegedly requested that DuPont provide to the EPA “known toxicological information” regarding C-8.51 Id. ¶ 103. In DuPont’s “Response to Notice of Deficiency,” DuPont allegedly directed the EPA to information that was included in the VI Report and provided “[a]dditional C-8 toxicological

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51 Specifically, the request for information states: “Section 7.2 [of DuPont’s VI Report] 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 Part 264, Appendix IX constituents and PALs [“Proposed Action Levels”] or MCLs [“Maximum Contaminant Levels”] assigned to them. Please provide known toxicological information.” EPA’s Count III Response, Ex. 9 at 2-3.
information” as Attachment 2 of the Response to Notice of Deficiency, titled “Toxicological Information on C-8.” *Id.* ¶ 104. OCE alleges that DuPont’s “Toxicological Information on C-8” document included a section regarding “Health Hazardous Data.” *Id.* ¶ 105. Furthermore, OCE alleges that in the Response to the Notice in June 1997, DuPont did not provide “all ‘known toxicological information’” it had regarding C-8 because it did not provide to the EPA the information regarding the transplacental movement of C-8 in humans, and that DuPont has not provided such information to the EPA. *Id.* ¶¶ 108-109. OCE alleges that all known toxicological information about C-8 is “relevant information” that the EPA might request to determine whether cause exists for modifying, revoking and reissuing, or terminating DuPont’s Corrective Action Permit, or to determine compliance with this permit. *Id.* ¶ 110 (citing, inter alia, EPA’s Count III Response, Ex. 1 (DuPont’s Corrective Action Permit), Part One, § I.7; 40 C.F.R. § 270.30(h)).

OCE further alleges that DuPont’s failure to provide “known toxicological information” constitutes noncompliance with DuPont’s duty to provide information as required by Part One, Section I.7, of DuPont’s Corrective Action Permit, and therefore DuPont did not comply with all conditions of its permit. *Id.* ¶¶ 111-112 (citing 40 C.F.R. § 270.30(h) and West Virginia Hazardous Waste Management Rule (“WVHWMR”) § 33-20-11.1).52 In conclusion, OCE alleges that from at least June 6, 1997, until at least March 6, 2001, DuPont was in violation of: Section 3005(a) of RCRA, 42 U.S.C. § 6925(a); Part One, Section I.7 of DuPont’s Corrective Action Permit, and; 40 C.F.R § 270.30(h), and WVHWMR § 33-20-11.1, by failing to provide the information requested by EPA. Amended Complaint ¶ 113.

DuPont admits that its June 1997 Response to Notice did not expressly inform the EPA about the 1981 document mentioning the umbilical cord blood sample. Amended Answer ¶ 108. However, DuPont denies that such information is “known toxicological information.” *Id.* ¶¶ 107, 108.

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52 OCE points out that on May 29, 1986, the EPA granted the State of West Virginia final authorization to administer its base hazardous waste management program in lieu of the federal base hazardous waste management program, and that the provisions of the West Virginia hazardous waste management program became requirements of RCRA and are enforceable by the EPA pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a). Amended Complaint at 2. OCE further points out that on July 10, 2000, the EPA authorized revisions to West Virginia’s base hazardous waste program, and that the provisions of the revised program are enforceable by the EPA. *Id.* at 2-3. However, OCE also points out that at all relevant times for purposes of the Count III violation, West Virginia was not authorized to implement the Federal Corrective Action Program. *Id.* at 3. See In re Pyramid Chem. Co., Docket No. RCRA-HQ-2003-0001, 2004 EPA App. LEXIS 32, at *34 (EAB, Sept. 16, 2004), 11 E.A.D. ____ (State regulations only become the operative standards in lieu of the Federal program as to “[t]hose aspects of RCRA for which the state program is authorized.”). I would point out that the West Virginia regulation cited in the Amended Complaint, WVHWMR § 33-20-11.1, adopts and incorporates by reference 40 C.F.R. part 270, except as to provisions that do not appear to be determinative for Count III.
B. EPA’s Authority to Request Information

In its initial Complaint (and Amended Complaint), OCE alleged that C-8 is a “hazardous constituent,” and then amended its Complaint in response to DuPont’s Motion for Accelerated Decision, to add an allegation that PFOA (i.e., “C-8” or “APFO”) “is a discarded material and a ‘solid waste’ as defined under RCRA § 1004(27), 42 U.S.C. § 6903(27) and a ‘hazardous waste’ as defined under RCRA § 1004(5), 42 U.S.C. § 6903(5).” Amended Complaint ¶ 34; see also id. ¶¶ 99, 101. In seeking amendment of the Complaint, OCE stated that the allegation was added for the purpose of responding to DuPont’s legal arguments about EPA’s authority to address PFOA under Section 3004(u) of RCRA and to address the factual issue raised by DuPont regarding whether PFOA is a hazardous waste, but that OCE need not establish that PFOA is a hazardous waste, and that therefore the allegation is not necessary in order to prevail on Count III. Motion for Leave to File First Amended Complaint (Oct. 13, 2004) at 2.

In essence, DuPont argues that the EPA did not have the authority to request “known toxicological information” about C-8 under the statutory provisions of RCRA because C-8 is neither a hazardous constituent nor a hazardous waste listed or identified under EPA’s regulations. DuPont’s Count III Reply at 2-3. DuPont argues that Congress expressly limited EPA’s authority to require corrective action under Section 3004(u) of RCRA, 42 U.S.C. § 6924(u), to hazardous wastes and hazardous constituents identified or listed by EPA in its regulations, rather than the statutory definition in Section 1004(5) of RCRA, 42 U.S.C. § 6903(5). DuPont’s Count III Reply at 1-3; see also DuPont’s Post-Argument Br. at 20-27. Furthermore, DuPont argues that its corrective action permit expressly incorporated EPA’s regulatory definition of hazardous waste rather than the statutory definition and that the Permit did not “expand” EPA’s statutory authority. Id. at 1-3.

Section 3001 of RCRA, titled “Identification and listing of hazardous waste,” provides, inter alia:

Section 3004(u), 42 U.S.C. § 6924(u), titled “Continuing releases at permitted facilities,” of RCRA provides:

Standards promulgated under this section shall require, and a permit issued after November 8, 1984, by the [EPA] Administrator or a State shall require, corrective action for all releases of hazardous waste or constituents from any solid waste management unit at a treatment, storage, or disposal facility seeking a permit under this subchapter, regardless of the time at which waste was placed in such unit. Permits issued under section 6925 of this title [i.e., Section 3005 of RCRA] shall contain schedules of compliance for such corrective action (where such corrective action cannot be completed prior to issuance of the permit) and assurances of financial responsibility for completing such corrective action.
[t]he [EPA] Administrator shall, after notice and opportunity for public hearing, and after consultation with appropriate Federal and State agencies, develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, which should be subject to the provisions of this subchapter, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics. Such criteria shall be revised from time to time as may be appropriate.

42 U.S.C. § 6921(a). In contrast, Section 1004(5) of RCRA, 42 U.S.C. § 6903(5), defines the term “hazardous waste” as:

a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may –

(A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or

(B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.

DuPont responded in part to EPA’s request for “known toxicological information” regarding C-8, but did not provide the EPA with the 1981 blood sample results, which DuPont contends are not “known toxicological information.” Oral Arg. Tr. at 50-52; see Response to Notice of Deficiency (OCE’s Count III Response, Ex. 10). DuPont contends that in providing some information about C-8 but omitting the 1981 blood sample results it was not concealing the results but rather trying to respond in good faith, albeit “voluntarily.” Oral Arg. Tr. at 52. Moreover, DuPont posits that because the information request did not specifically ask for “all” toxicological information, that DuPont did not have to provide the 1981 blood sample results. See id. at 50. DuPont suggests that its response to the information request explained to the EPA that its response was limited. See id. at 52 (referring to Response to Notice of Deficiency, Attach. 2 (titled “Toxicological Information on C-8”), at 1: “The following information pertains to the Environmental and Human Health Effects of Ammonium Perfluorooctanoate.”). Furthermore, DuPont contends that its correspondence with the EPA indicates that it “[w]as very clear in saying that [the EPA] should understand that this substance is not a hazardous constituent.” Id. at 52-53.

OCE alleges that the information that the EPA requested from DuPont concerning the C-8 is “relevant information” that the EPA may request to determine whether cause exists for modifying, revoking and reissuing or terminating DuPont’s Corrective Action Permit, or to
determine compliance with that permit. Amended Complaint ¶ 110 (citing DuPont’s Corrective Action Permit, Part One, § I.7; 40 C.F.R. § 270.30(h)). OCE argues, “The only limitation on [EPA’s] information request authority is that the Request for Information is relevant to determining whether cause exists to modify, revoke and re-issue, terminate, or to determine compliance,” and that such authority is not limited to requesting information regarding substances known to be regulatory hazardous wastes or hazardous constituents. Oral Arg. Tr. at 89 (emphasis added); see also OCE’s Count III Response at 8-13; OCE’s Count III Reply at 17-18; OCE’s Post-Argument Br. on Count III at 2, 5-14. Therefore, OCE argues that EPA’s authority to request information regarding a substance, such as C-8, is not defeated even if such substance is not a regulatory hazardous waste or a hazardous constituent. OCE’s Count III Response at 8-9; OCE’s Post-Argument Br. on Count III at 8-14.

OCE points out that, generally, an administrative agency’s request for information will be enforced where: (1) the investigation is within the agency’s authority, (2) the request is not too indefinite, and (3) the information requested is reasonably relevant. OCE’s Post-Argument Br. on Count III at 7-8. Furthermore, OCE states that the EPA Chief Judicial Officer (“CJO”) adopted this three part test in the case: In re Environmental Protection Corp. (East Side) Disposal Facility, RCRA (3008) Appeal No. 90-1, 3 E.A.D. 318 (CJO 1990), adopting, Docket No. RCRA-09-86-0001, 1987 EPA ALJ LEXIS 22 (ALJ, Apr. 8, 1987), aff’d but rev’d and remanded in part on other grounds, Environmental Protection Corp. v. Thomas, No. CV F-87-447-EDP (E.D. Cal, July 13, 1988) (unpublished mem.), decision on remand, 1989 EPA ALJ LEXIS 24 (ALJ, Oct. 24, 1989).

I observe that, pursuant to Section 3007(a) of RCRA, 42 U.S.C. § 6927(a), Congress conferred upon the EPA broad authority to request information. National-Standard Co. v. Adamkus, 881 F.2d 352, 360-61 (7th Cir. 1989). I further observe that the Duty to Provide Information section of the Permit reads as follows:

The Permittee shall furnish, within the specified time, any relevant information which the [EPA] . . . may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. The Permittee shall also furnish to the [EPA], upon request, copies of records required to be kept by this permit. (40 C.F.R. §§ 270.30(h) and 264.74(a)).

DuPont’s Corrective Action Permit, Part One, § I.7. Furthermore, under the regulation titled “Conditions applicable to all permits,” there is a “Duty to provide information,” which states:

The permittee shall furnish to the [EPA], within a reasonable time, any relevant information which the [EPA] may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. The permittee shall also furnish to the [EPA], upon request, copies of records required to be kept by this permit.
40 C.F.R. § 270.30(h).

To borrow language from the ALJ in *Environmental Protection Corp.*, I too observe,

“It would show a startling suspension of common sense and be a strange and ineffectual enforcement policy if respondents and possible violators were given the discretion and authority to determine what is and is not . . .” relevant to a hazardous waste information request. “To accede to such an argument smacks of relying upon a fox to be completely objective concerning the number of hens in a chicken house.”

*Environmental Protection Corp.*, 3 E.A.D. at 320-21 (quoting the ALJ).54 Furthermore, I read *Environmental Protection Corp.* as indicating that, at the time that the respondent in that case partially responded to the information request, the respondent offered its rational for not submitting other documents requested. See 1989 EPA ALJ LEXIS 24, at *18. An argument that the recipient of an EPA information request may unilaterally make the relevancy determination and withhold information without notifying, or without sufficiently notifying, the EPA of such withholding is untenable.

I am persuaded by OCE’s arguments concerning its broad authority under DuPont’s Corrective Action Permit to request information that is reasonably relevant in determining whether cause exists for modifying, revoking and reissuing, terminating, or determining compliance with the Permit, and that EPA’s 1997 request for “known toxicological information” regarding C-8 was not precluded simply because C-8 is not or may not be a regulatory hazardous waste or a hazardous constituent.55 I point out that the text of neither the duty to provide

54 *Accord In re Montco Research Products, Inc.*, Docket No. RCRA-83-165-R-KMC, 1986 EPA ALJ LEXIS 20, at *16 (ALJ, Mar. 4, 1986) (“[T]he purpose of [RCRA] would be thwarted if the decision whether to respond to a § 3007 information request was left to the discretion of the person from whom the information was requested.”).

55 I have considered the Declaration of Marcia E. Williams, which was proffered by DuPont in support of its motion for accelerated decision. DuPont’s Count III Reply, Ex. A (Nov. 14, 2004) (“Williams’s Declaration”). Ms. Williams was a former long-term official at the EPA from 1970 to February 1988. *Id.* at ¶ 1. Ms. Williams was the Director of EPA’s Office of Solid Waste from mid-1985 through February 1988, where she reportedly directed the implementation of RCRA and the Hazardous and Solid Waste Act Amendments of 1984. *Id.* I note that DuPont’s Corrective Action Permit was issued after Ms. Williams’s tenure at the EPA, as it was issued in 1989 and then amended in 1999. Amended Answer ¶¶ 37, 38.

Nevertheless, Ms. Williams opines that the types of information that were intended to be covered under 40 C.F.R. § 270.30(h) included the types of information that formed the basis for (continued...)

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information provision of the permit, nor the duty to provide information regulation, contains any proviso that the EPA can only request information about a substance if it is a regulatory hazardous waste or hazardous constituent. See DuPont’s Corrective Action Permit, Part One, § I.7; 40 C.F.R. § 270.30(h). Instead, the language of the permit and the regulation provides for information requests relevant to whether cause exists for modifying, revoking and reissuing, or terminating the permit, or to determine compliance with the permit. Id. Accordingly, I reject DuPont’s attempt to interject limitations to EPA’s information request authority that do not exist within the text of either DuPont’s Corrective Action Permit or the information request regulation.

Nonetheless, I find that both parties have raised genuine issues of material fact. An evidentiary hearing will afford the parties the opportunity to develop the facts with regard to whether EPA’s information request was reasonably relevant to determining whether cause existed for modifying, revoking and reissuing, terminating, or determining compliance with DuPont’s Corrective Action Permit. For instance, OCE contends that there are numerous examples of how a request for toxicological information about PFOA (C-8) is reasonably relevant to a determination of whether cause exists to modify, revoke and reissue, or terminate DuPont’s Corrective Action Permit, or to determine compliance with the Permit. OCE’s Post-Argument Br. on Count III at 10. OCE contends that such examples include: understanding the potential interactions with other contaminants at the site, determining whether to use the omnibus authority to include any terms or conditions in the Permit necessary to protect human health or the environment, ascertaining whether PFOA contains hazardous constituents, developing a risk-based comparison level for PFOA, and that the EPA can request information out of concern for the safety of EPA inspectors. Id. at 10-11; OCE’s Count III Reply at 22-23.

55(...continued)
the Permit. Id. Ms. Williams further opines that these standard information submission requirements were not intended to address the submission of health-related information about a compound that was not an Appendix VIII hazardous constituent or a RCRA hazardous waste under 40 C.F.R. § 261.3. Id. DuPont’s arguments expressed through Ms. Williams’s opinions are rejected, as they contradict the broad information request authority within the text of the Permit and the text of the regulation, and contradict the caselaw.

I note, however, elsewhere within her declaration, Ms. Williams lends support to OCE’s position that the EPA may request information reasonably relevant to modification of a corrective action permit, regardless of whether the EPA is requesting information about a substance that would be subject to corrective action as a hazardous waste or hazardous constituent. Specifically, after asserting that PFOA (i.e., C-8) is not a hazardous waste or constituent, Ms. Williams admits that PFOA “[c]ould be selected as a monitoring parameter in a RCRA operating or corrective action permit . . . ,” even though Ms. Williams states that PFOA would not be subject to corrective action release provisions of RCRA that require cleanup of hazardous waste. Id. ¶ 12.
Another factual issue not resolved at this juncture is whether DuPont unilaterally made the relevancy determination and withheld information without notifying, or without sufficiently notifying, the EPA of such withholding. Furthermore, as discussed in the following sections, DuPont raises factual questions concerning whether the blood sampling results constituted “known toxicological information” at the time of the 1997 information request and whether the statute of limitations bars Count III.

Accordingly, the parties’ respective motions for accelerated decision on Count III are DENIED. See Roberts v. Browning, 610 F.2d 528, 536 (8th Cir. 1979).

C. Question As to Whether the Blood Sampling Results Constituted “Known Toxicological Information”

The issue of whether the blood sampling results in the 1981 document constituted “known toxicological information” at the time of the 1997 information request is better addressed in an evidentiary hearing.

The blood sampling document at issue in Count III is an undated one-page document titled “C-8 BLOOD SAMPLING RESULTS” and contains a subheading, “Births and Pregnancies.” OCE’s Count III Response, Ex. 3. Most of the document is typed, but there are also some handwritten notes on the document. The blood sampling document indicates that the blood of all eight of the employees tested contain C-8, and it indicates the level of C-8 present within the blood of each employee. In a corresponding column, the document indicates whether the child born to each employee is “normal” or has birth defects, it states the birth date of each child with birth dates from 1980 to 1981, and it indicates levels of C-8 in two of the children. For instance, under the column titled “PPM C-8 in Blood,” the document indicates .078 ppm of C-8 in one of the employee’s blood samples, and the corresponding reference under the “Status” column states: “Normal child – born April 1981. Umbilical cord blood 0.055 ppm.”

In support of OCE’s motion for accelerated decision on Count III, OCE proffers the affidavit of Oscar Hernandez, Ph.D. OCE’s Count III Response, Ex. 2 (Oct. 6, 2004) (“Dr. Hernandez’s Affidavit”). Dr. Hernandez states that the blood sampling results “[c]onstitute toxicological information, since the data provide insights into the biological disposition of a chemical in humans.” Id. at 1. Dr. Hernandez further states:

56 At this time, it is unnecessary to address OCE’s argument that DuPont waived its right to challenge EPA’s authority to request toxicological information about C-8 because DuPont allegedly chose not to take advantage of the dispute resolution provision in its permit. See OCE’s Post-Argument Br. on Count III at 14-15.

Regarding OCE’s contentions that DuPont is challenging the terms of its Permit, see OCE’s Count III Response at 17-19, one may read DuPont’s arguments as challenging OCE’s interpretation of the Permit rather than being solely confined to challenging the terms of the Permit as written. At this time, it is premature to reach a determination on OCE’s argument.
Because human data are not readily available, toxicologists most frequently rely on animal data to draw conclusions and develop assumptions about the biological behavior of chemicals. The latter conclusions and assumptions become the basis for the evaluation of comparable effects in humans, an extrapolation that introduces uncertainty in the analysis. Availability of human data reduces the uncertainty associated with extrapolation of animal data.

*Id.* Based on the principles stated above, Dr. Hernandez opines that the language below “adequately characterizes the nature of the 1981 information”:

The 1981 data indicating that PFOA moves across the placental barrier between PFOA-exposed mothers and their fetuses suggest that such fetuses could experience toxic effects associated with PFOA, including persistence/bioaccumulation, and, as observed in animal tests, developmental toxicity and liver toxicity. The human data are more indicative of such possibility in humans than the data submitted to EPA by DuPont in 1982, which demonstrated that PFOA moved across the placental barrier in rats used in laboratory experiments. EPA’s efforts to characterize effects of PFOA might have been more expeditious had the data on transplacental movement of the chemical in humans been submitted immediately by DuPont when DuPont obtained the information in 1981.

*Id.* at 1-2.

DuPont contends that there is a factual dispute as to OCE’s contention that the 1981 blood sample results were “known toxicological information.” DuPont’s Count III Reply at 33-34. In particular, DuPont contends that the 1981 observation that C-8 was present in the blood supplied to a fetus was not “toxicological” information as that term is ordinarily defined. *Id.* In support of this position, DuPont proffers the declaration of Dr. Jonathan Borak, M.D., D.A.B.T., who states:

“a reasonably knowledgeable toxicologist would have expected that PFOA crossed the human placenta” and “[t]he datum [cited by Dr. Hernandez] essentially only restates that which would have been obvious to a reasonably knowledgeable toxicologist, that PFOA can cross the placenta. In other words, it is essentially neither toxicological nor informative.”

DuPont’s Count III Reply, Ex. C (“Dr. Borak’s First Declaration”), ¶¶ 12, 20 (Nov. 15, 2004). Furthermore, Dr. Borak opines that
the analysis of the cord blood sample “[s]erved only as an indication that there had been exposure to PFOA, a fact that was known in advance and was the specific reason that the sample had been obtained” and “It is my professional opinion that because the cord blood datum contained no information regarding the potential hazards of exposure, the mechanisms of action, the adverse effects anticipated or known about PFOA and because it provided no information useful for evaluating the adequacy of proposed exposure standards . . . , it was neither toxicological nor informative and, therefore, does not represent ‘toxicological information.’”

.Id. ¶ 24.

Dr. Borak states that he assumes that Dr. Hernandez does not rely on the “First Law of Toxicology,” which provides, “All substances are poisons; there is none which is not a poison. The right dose differentiates a poison from a remedy,” but rather that he relies on a more restrictive definition. Id. ¶ 18. Accordingly, Dr. Borak focuses more narrowly on adverse effects or outcomes: “Most other definitions of ‘toxicology’ explicitly include the concept of adverse effects or outcomes.” Id. ¶ 19 (emphasis added). Dr. Borak offers a definition of “toxicology” as follows:

Toxicology is the scientific study of the mechanisms of action and effects of exposure caused by chemical agents in living organisms. The objectives of toxicology are to characterize the potential hazards of exposure to specific agents and to estimate the probability that such effects will follow anticipated types and levels of exposure.

.Id.

Accordingly, Dr. Borak opines that the analysis of the “single blood cord datum” served only as an indication that there had been exposure to PFOA, which he states is a fact that was known in advance and was the specific reason why the sample was obtained. Id. ¶¶ 20, 24. Moreover, Dr. Borak contends that “toxicological information” must be informative: “[b]ecause the cord blood datum contained no information regarding the potential hazards of exposure, the mechanisms of action, the adverse effects anticipated or known about PFOA and because it provided no information useful for evaluating the adequacy of proposed exposure standards . . . it was neither toxicological nor informative and, therefore, does not represent ‘toxicological information.’” Id. ¶ 24. DuPont has contended that at the very least the conflicting testimony of Dr. Borak and Dr. Hernandez demonstrates that there is a disputed issue of material fact about whether the blood sample observation was “toxicological information.” DuPont’s Count III Response at 34.
In reply, OCE quotes a definition of “toxicology” as a “science that deals with poisons and their effects” and “toxicological” as “of or relating to toxicology.” OCE’s Count III Reply at 19 (quoting Merriam Webster’s Collegiate Dictionary (10th ed. 1997)). OCE also proffers the affidavit of David Gray, Ph.D., who opines that “[t]oxicological information is generally accepted to mean information that relates to toxic (poisonous) substances, their detection, their avoidance, their chemistry and pharmacological actions, and their antidotes and treatments.” OCE’s Count III Reply, Ex. 1 (Dec. 13, 2004) (“Dr. Gray’s Affidavit”), at ¶ 5 (citing Tabor’s Medical Dictionary (2001)). Regarding whether the blood test data contains “toxicological information,” the EPA cites a dictionary definition of “information” as “the communication of knowledge,” “facts,” or “data.” OCE’s Count III Reply at 20.

Furthermore, OCE summarizes Dr. Gray’s opinion as stating that the particular human PFOA transplacental movement information at issue, as distinguished from rat transplacental movement information, demonstrates not only that this chemical (PFOA) actually (not just theoretically) crosses the human placenta, but that it readily passes the human placenta; the concentrations at which it was detected in the human fetus through transfer from the mother, and; that it acted differently than what toxicologically theoretically would have expected. OCE’s Count III Reply at 20 (citing Dr. Gray’s Affidavit at ¶¶ 9, 10, 13, 14). OCE points out that Dr. Gray explains that it is of great importance whether or nor the rate of transfer is sufficient to result in significant concentrations within the fetus and that PFOA readily passing the placenta would not be anticipated by a toxicologist since PFOA is a large ionized molecule. Dr. Gray’s Affidavit ¶¶ 9, 13.

In response to the opinions expressed by Dr. Gray, DuPont proffers a second declaration of Dr. Borak, and contends, inter alia, that as a matter of logic the 1981 observation was incapable of providing any information about the rate of movement [of C-8] from mother to fetus because it was a single observation at a single point in time, and that no benchmark existed when the observation was made, or at any subsequent time, against which to measure how “readily” C-8 had crossed the placenta “in that single instance in 1981.” DuPont’s Post-Argument Br. at 25-26 (citing DuPont’s Post-Argument Br., Ex. EE, ¶¶ 7-13).

On review of the competing affidavits and declarations and the parties’ arguments, I conclude that the issue of whether the blood sampling results constituted “known toxicological information” at the time of the information request warrants an evidentiary hearing. See Roberts v. Browning, 610 F.2d 528, 536 (8th Cir. 1979).

D. Statute of Limitations

The statute of limitations is an affirmative defense, and therefore the burden is on the respondent to prove such defense. In re Britton Constr. Co., CWA Appeal Nos 97-5 & 97-8, 8 E.A.D. 261, 275 (EAB 1999). Although RCRA does not contain a statute of limitations, RCRA civil penalty actions such as the action in the instant case are subject to the general federal statute of limitations set forth at 28 U.S.C. § 2462. In re Mayes, RCRA (9006) Appeal No. 04-01, 2005 WL 528542, slip op. at 12-13 (EAB, Mar. 3, 2005), 12 E.A.D. ___ (citing cases); see In re Harmon Electronics, Inc., RCRA (3008) Appeal No. 94-4, 7 E.A.D. 1, 16-23

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DuPont argues that Count III is barred by the five-year statute of limitations. DuPont’s Count III Reply at 28. DuPont points out that OCE’s penalty claim on Count III is based on the Notice of Deficiency, dated May 5, 1997, that required DuPont to submit “known toxicological information” regarding C-8 to the EPA within 30 days of receipt of the Notice, or by June 11, 1997, whichever is later. DuPont’s Count III Reply at 28.; see Notice of Deficiency at 2-3, 5. DuPont also points out that it provided a Response to Notice of Deficiency, dated June 6, 1997. DuPont’s Count III Reply at 28. DuPont argues that if any violation occurred regarding Count III, it accrued on June 1997, and that OCE was required to file its claim prior to June 2002. Id. In response, OCE argues that the statute of limitations does not bar Count III due to the “three distinct doctrines” of continuing violation, fraudulent concealment, and equitable tolling. OCE’s Count III Reply at 3-4. As discussed below, dismissal of Count III on statute of limitations grounds is not appropriate at this juncture.

DuPont contends, “Based on the plain language of [28 U.S.C.] section 2462, the statute of limitations for DuPont’s alleged failure to comply with EPA’s Notice of Deficiency began to run when the EPA’s claim first accrued on June 12, 1997 at the latest.” DuPont’s Count III Reply at 30. In making this argument, DuPont relies on the D.C. Circuit case 3M Co. v. Browner, 17 F.3d 1453, 1461-62 (D.C. Cir. 1994).57 In the 3M case, the EPA sought civil penalties under TSCA for failure to file premanufacture notices and for submitting inaccurate customs certifications. In that case, the EPA contended that the limitations period should begin when the EPA discovered the violation, not when the violation occurred. The D.C. Circuit held that in light of the meaning of the word “accrued” within the general federal statute of limitations, “[a]n action, suit or proceeding to assess or impose a civil penalty must be commenced within five years of the date giving rise to the penalty” and rejected the discovery of the violation rule. Id. at 1462-63. However, in 3M the D.C. Circuit recognized fraudulent concealment as an exception to its general ban on the discovery rule. Id. at 1461 n.15.

One of OCE’s defenses to the statute of limitations argument is that the alleged violation in Count III constitutes a continuing violation. The continuing violation doctrine does not hinge upon when the complainant discovered a violation. Rather the doctrine of continuing violations is an exception to the general rule of accrual, and the doctrine of continuing violations provides that limitations periods for violations deemed to be continuing in nature do not begin to run until

57 I note that the law of the D.C. Circuit is not necessarily controlling for purposes of the instant case. There is more than one route for appealing this matter to the courts, although an appeal within the D.C. Circuit is one of those potential avenues.
the unlawful course of conduct is completed.\footnote{58} \textit{Mayes}, slip op. at 16; \textit{Harmon}, 7 E.A.D. at 21-22; \textit{In re Lazarus, Inc.}, TSCA Appeal No. 95-2, 7 E.A.D 318, 364 (EAB 1997). If a violation is a continuing violation, the complainant must bring an action for civil penalties either during the period of violation or within five years after the violation ceased. \textit{Lazarus}, 7 E.A.D. at 364-65 (citing, \textit{inter alia}, \textit{Harmon}, 7 E.A.D at 22). OCE contends that the violation continued at least through March 6, 2001, which is the date when OCE allegedly received the information at issue in Count III from a third party. Amended Complaint ¶ 113. OCE filed its initial Complaint in this matter on July 8, 2004.

OCE submits that in determining whether requirements are continuing in nature, the adjudicator looks to the language establishing the legal obligation for words or phrases connoting continuity or descriptions of activities that are typically ongoing. OCE’s Count III Reply at 5 (citing \textit{Lazarus}, 7 E.A.D. at 366). OCE further submits that this methodology to determine the nature of a violation would include the statute and regulations, but should begin with DuPont’s Corrective Action Permit “[f]or it establishes the required course of conduct in the case at bar.” \textit{Id.} (citing Section 3005(a) of RCRA, 42 U.S.C. § 6925(a)); see also Oral Arg. Tr. at 102. OCE contends that Section 3005(a) of RCRA, titled “Permit Requirements,” establishes a continuing obligation to operate in compliance with the Permit. Oral Arg. Tr. at 102.

OCE further argues that several provisions within the DuPont’s Corrective Action Permit establish a continuing violation. OCE’s Count III Reply at 5-7; Oral Arg. Tr. at 100-02. Under the heading “Duty to Provide Information,” Part One, Section I.7 of DuPont’s Corrective Action Permit provides:

\begin{quote}
The Permittee shall furnish, \textit{within the specified time}, any relevant information which the [EPA] Regional Administrator . . . may
\end{quote}


Furthermore, the EAB has noted that it would be “fundamentally absurd” to limit RCRA civil penalty enforcement actions o five years, despite a violator’s continuing violation of the law; such a limitation would allow a violator to “[b]e free to repeat its violations of the permitting requirements of RCRA indefinitely, safely beyond the reach of the law’s pecuniary sanctions.” \textit{Harmon}, 7 E.A.D. at 29-30 n.34.
request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit.

DuPont’s Corrective Action Permit, Part One, § I.7 (citing 40 C.F.R. § 270.30(h) (emphasis added)).

OCE argues that although Section I.7 of the Permit, at first blush, may seem to specify action within a particular time-frame, which would arguably make it akin to a one-time violation, other “key provisions” of the Permit mandate a continuous course of conduct rather than a discrete act. OCE’s Count III Reply at 5-6. For instance, OCE quotes Part One, Section I.1 of the Permit, which states, “The Permittee shall comply with all conditions of this Permit . . . .” Id. at 6. OCE contends that the word “comply” contemplates a continuous course of conduct rather than a discrete act, and that each day that DuPont was not in compliance with its Permit, DuPont was in violation of Section 3005(a) of RCRA, which requires a permitted treatment, storage, and disposal facility to operate in compliance with its permit. Id. Moreover, OCE contends that DuPont’s obligation to “comply” with its Permit is fundamentally akin to the obligation construed as being continuing in Harmon, that the owner or operator of a facility “have” a hazardous waste permit pursuant to Section 3005(a) of RCRA. Id. at 6-7 (citing Harmon, 7 E.A.D. at 24). OCE points out the EAB’s conclusion that the term “have” supported a continuing obligation giving rise to a continuing violation. Id. at 6 (citing Harmon, 7 E.A.D. at 24). Furthermore, OCE suggests that Section I.7 of the Permit carries no temporal limitation on DuPont’s obligation to submit information, but rather that the request for information within 30 days was, in essence, a beginning date for the obligation to provide the information. Oral Arg. Tr. at 100-01; OCE’s Count III Reply at 7-8.

OCE further contends that other Sections of DuPont’s Corrective Action Permit also establish that the obligation forming the basis for Count III is continuing in nature: Part One, Section I.14 (providing, “The Permittee shall report all other instances of noncompliance not otherwise required to be reported above, at the time monitoring reports are submitted”), and; Part One, Section I.15 (providing, “Whenever the Permittee becomes aware that it failed to submit any relevant facts in the permit application or in any report to [the EPA], the Permittee shall notify [the EPA] of such failure within 7 days. The Permittee shall submit the correct or additional information to [the EPA] no later than 14 days of becoming aware of the deficiency”). OCE’s Count III Reply at 7.

DuPont cites several non-RCRA cases in an effort to show that the violation alleged in Count III is not a continuing violation.59 DuPont’s Count III Response at 32. With regards to

59 DuPont cites: Toussie v. United States, 397 U.S. 112 (1970) (failure to register for the draft under the Universal Military Training and Service Act); United States v. Trident Seafoods Corp., 60 F.3d 556 (9th Cir. 1995) (Clean Air Act, failure to provide notice of asbestos removal); United States v. Del Percio, 870 F.2d 1090 (6th Cir. 1989) (Atomic Energy Act); New (continued...)
the Permit, DuPont challenges Sections I.14 and I.15 of the Permit as being inapposite to Count III. DuPont’s Post-Argument Br. at 28-29. For instance, DuPont contends, with regards to Section I.14, that it was not required to submit monitoring reports to the EPA. Id. at 28. With regards to Section I.15, DuPont suggests that it was not aware that the 1981 blood sample results should have been reported to the EPA. See id. at 29. The latter suggestion appears to tie in with DuPont’s arguments that the blood sampling information was not “toxicological information” or was not relevant to its corrective action permit. DuPont also contends that OCE is not alleging violations of these provisions of the Permit. Id. at 28-29.

With regards to the many non-RCRA cases DuPont cites, these cases are not dispositive to the extent they rely on non-RCRA statutes and regulations for their reasoning, because a determination of whether the nature of a violation is continuing first looks to the statutory language that serves as the basis for the specific violation at issue, and if necessary the legislative history, and then looks to language of the implementing regulation. Lazarus, 7 E.A.D. at 366-67; see Mayes, supra, slip op. at 16-27; Harmon, 7 E.A.D. at 22-40. OCE makes persuasive arguments with regards to the language used in Section 3005(a) of RCRA. I would add that RCRA’s “cradle to grave” permitting requirements are intended to impose continuing obligations on owners and operators in order to protect human health and the environment. Harmon, 7 E.A.D. at 29. I also note that the Permit’s duty to provide information requirement, at I.7, cites to 40 C.F.R. § 270.30(h), which requires information requested to be furnished “within a reasonable time.”

However, I recognize that DuPont challenges the relevancy of Sections I.14 and I.15 of the Permit, and that the specific language employed in Section I.7 of the Permit refers to compliance within a “specified time,” albeit when read in isolation from the statute, the regulation, the factual context of the request for information, and the remainder of the Permit. An evidentiary hearing is a more appropriate forum for resolving this matter. For instance, an

59(...continued)

60 DuPont submits that, in determining whether a violation is continuous in nature, the language of a requirement at issue must clearly state that there is a continuous duty, and it cites a Ninth Circuit case as authority. OCE’s Count III Response at 31 (citing Trident Seafoods Corp., 60 F.3d 556, 559 (9th Cir. 1995). Cases from the Ninth Circuit are not binding on the instant matter, which arises within West Virginia. See In re Bil-Dry Corp., RCRA (3008) Appeal No. 98-4, 9 E.A.D. 575, 590 (EAB 2001). Moreover, the specific holding in Trident was on whether a failure to provide notice under the Clean Air Act subjected the defendant to a per-day penalty (continued...)
evidentiary hearing will allow for a closer examination of the context in which the EPA made the request for information. At this time, I need not consider OCE’s two other defenses to the statute of limitations argument: fraudulent concealment and equitable tolling. However, I observe that the allegations of fraudulent concealment clearly raise a genuine issue of material fact requiring an evidentiary hearing. See, e.g., Oral Arg. at 50-52 (DuPont admitting that it responded to part of EPA’s 1997 request for “known toxicological information” regarding C-8, but contending that it did not furnish the 1981 blood sampling results because it was responding “voluntarily”).

III. Conclusion and Prehearing Schedule

For the reasons stated herein, I deny the parties’ motions for accelerated decision. However, I emphasize that an order denying accelerated decision, such as the instant order, does not decide the ultimate truth of the matter, but represents a threshold determination that an evidentiary hearing is necessary.

The parties shall conduct prehearing exchanges, as delineated in my Prehearing Order (Sept. 16, 2004) and my Order Clarifying Prehearing Order (Oct. 21, 2004), on Counts II and III and on the recently added Count IV (titled “Results of PFOA Serum Testing”), which shall be filed in seriatim manner, according to the following schedule:

- July 1, 2005 – Complainant’s Initial Prehearing Exchange
- August 1, 2005 – Respondent’s Prehearing Exchange, including any direct and/or rebuttal evidence
- August 15, 2005 – Complainant’s Rebuttal Prehearing Exchange (if necessary)

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60(...continued)

under the Clean Air Act. Trident, 60 F.3d at 559.

61 OCE has already filed its initial prehearing exchange on Count I. As specified in a previous order, DuPont’s prehearing exchange on Count I is due April 8, 2005, and OCE’s rebuttal prehearing exchange on Count I is due April 22, 2005.
I remind the parties that if they cannot settle this matter, an evidentiary hearing will be held in accordance with Section 556 of the Administrative Procedure Act, 5 U.S.C. § 556.

Finally, I instruct the parties that all future pleadings, including exhibits, shall be submitted in binders. Furthermore, I instruct the parties that all future briefs, memoranda, and motions greater than 15 pages in length (excluding attachments) shall contain a table of contents and a table of authorities with page references. 

So ordered.

Dated: March 29, 2005
Washington, D.C.

Barbara A. Gunning
Administrative Law Judge

See 40 C.F.R. § 22.4(c)(10).
OECD GUIDELINE FOR THE TESTING OF CHEMICALS
Simulation Test – Aerobic Sewage Treatment
303 A: Activated Sludge Units


To view a read-only copy of OECD Guideline 303, visit the EPA reading room located in EPA’s Docket Center, Rm. B102–Reading Room, EPA West Building, 1301 Constitution Ave., NW, Washington, DC. Request to view OPPT-2003-0012-0169.

The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566–0280.