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March 6, 2001

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Re: Request For Immediate Governmental Action/Regulation Relating To DuPont's C-8 Releases In Wood County, West Virginia And Notice Of Intent To Sue Under The Federal Clean Water Act, Toxic Substances Control Act, And Resource Conservation And Recovery Act - NOTE: For Inclusion In USEPA Docket No. OPPTS-50639A

Ladies and Gentlemen:

Our law firm represents Wilbur Earl Tennant and Sandra K. Tennant (Route 3, Box 17, Washington, WV 26181, (304) 863-8787), James David Tennant and Della Marie Tennant (Route 3, Box 372, Parkersburg, WV 26101, (304) 863-5428), and Erwin Jackson Tennant (Route 3, Box 17A, Washington, WV 26181, (304) 863-6977) (collectively, the "Tennants") in connection with a lawsuit that is currently pending against E.I. duPont de Nemours & Co., Inc. ("DuPont") in Federal Court in Parkersburg, West Virginia, styled *Tennant v. E.I. duPont de Nemours & Co., Inc.*, Civil Action No. 6:99-0488 (S.D. W.Va.). The Tennants have sued DuPont in connection with the release of various pollutants and contaminants from DuPont's Dry Run Landfill in Wood County, West Virginia. (See Exhibit 133.) The Tennants believe that

such releases have resulted in and continue to result in personal injury and property damage to the Tennants, including the death of several hundred head of the Tennants' cattle and serious health problems for the Tennants.

During the course of the litigation, we have confirmed that the chemicals and pollutants released into the environment by DuPont at its Dry Run Landfill and other nearby DuPont-owned facilities may pose an imminent and substantial threat to health or the environment. More specifically, information currently available to the Tennants confirms that DuPont has been releasing and continues to release into the air, land, and water, including human drinking water supplies, an essentially unregulated, confirmed animal carcinogen known as ammonium perfluorooctanoate (a/k/a C-8/FC-143/APFO/PFOA) (CAS No. 3825-26-1) (hereinafter "C-8").[1] Hundreds of head of cattle, along with numerous deer, fish, frogs, and other animals, have died in the area affected by the C-8 releases, and area residents exposed to the C-8 releases have been suffering ill health effects that are believed to be associated with C-8 exposure. For example, one of our clients, Wilbur Earl Tennant, has been in and out of the hospital repeatedly over the last few years suffering from respiratory problems, chemical burns, and other health problems after exposure to materials from the Dry Run Landfill.

For the reasons discussed in more detail below, the Tennants hereby request that each of your agencies intervene in the Tennants' pending lawsuit and order the immediate investigation, assessment, containment, removal, and remediation of DuPont's C-8 releases into the environment from the Dry Run Landfill, including an order that DuPont immediately cease and desist all C-8 releases and that appropriate medical care/testing/evaluation be provided to the Tennants. The Tennants also request that DuPont's permit to operate the Dry Run Landfill be immediately revoked and that all operations at that landfill be suspended until adequate scientific demonstrations are made to prove that the C-8 releases have been abated and will not recur.

In addition, the Tennants specifically request that USEPA exercise its authority under TSCA to order DuPont to immediately cease all manufacturing activities involving C-8 until DuPont can prove through appropriate scientific testing and research that its usage of C-8 does not pose an unreasonable risk of injury to health or the environment. In the meantime, the Tennants request that your agencies take those steps necessary to begin regulating C-8 releases into the environment. In that regard, the Tennants request that, at a minimum, USEPA include C-8 among the chemicals that it proposed in October of 2000 to regulate under TSCA on the grounds that the chemicals "may be hazardous to human health and the environment." (See Exhibit 123.) The Tennants believe that the information recently obtained from DuPont regarding C-8's potential threat to human health, (see e.g., Exhibits 71, 125, and 126), warrants regulation of C-8 at least as aggressively as the related perflourinated chemicals manufactured by 3M.

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[1] Currently available information also indicates unusual levels of iodide/iodine, along with Triton in Dry Run Creek. (See Exhibit 91.)

This letter also constitutes notice on behalf of the Tennants and a class of other individuals similarly situated of their intent to bring citizen suit claims against DuPont in connection with DuPont's C-8 releases into air, land, and water from DuPont's Washington Works facility in Wood County, West Virginia under the Federal Clean Water Act ("CWA"), Toxic Substances Control Act ("TSCA"), and Resource Conservation and Recovery Act ("RCRA").[2] The factual and legal basis of such citizen suit claims is explained in detail below.

Additional documentation in support of the basic facts summarized below is available at our offices in Cincinnati, including a chronologically-organized database of the over 110,000 pages of documents produced to date by DuPont on this topic.

I. DuPont Has Used C-8 Primarily At Its Washington Works Plant In Wood County, West Virginia.

C-8 is a perfluorinated detergent/surfactant manufactured in the United States by 3M Company that DuPont uses in connection with its manufacture of Teflon®-related products. (See Exhibits 1 and 118.)[3] DuPont has used C-8 as a reaction aid in its production of polytetrafluoroethylene (PTFE) and tetrafluoroethylene (TFE) co-polymers at its Washington Works facility outside Parkersburg, West Virginia since the early 1950s. (See Exhibit 118.) Wastes from the Washington Works' C-8 processes are either vented to the air following incineration, dumped into the Ohio River, sent to DuPont's Chambers Works facility in Deepwater, New Jersey for treatment and discharge, or disposed of at landfills. (See id.) The polymer product manufactured at the Washington Works is either sold directly to DuPont's customers (in the United States and abroad) or transferred to DuPont's Spruance Plant in Richmond, Virginia for use in the production of Teflon® and PTFE-coated fibers or transferred to DuPont's Parlin Plant in Parlin, New Jersey for use in the production of Teflon® finishes, some of which is then used in consumer cookware. (See id.) C-8 may remain in some of the products sold from DuPont's Washington Works, Spruance Plant, and Parlin Plant. (See id.) Some of DuPont's Teflon® materials have been used in medical implants that are inserted directly into the human body. (See Exhibit 132.)

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2 Please note that, although the Tennants already have filed claims against DuPont under the CWA and RCRA, these pending claims relate only to releases from DuPont's Dry Run Landfill. This letter provides notice of the Tennants' intention to also bring separate claims against DuPont under the CWA, TSCA, and RCRA with respect to releases from DuPont's nearby Washington Works plant in Wood County, West Virginia, on behalf of themselves and a class of others similarly situated.

3 ®DuPont's registered trademark.

II. DuPont Has Known That Excessive Exposure To C-8 Causes Adverse Effects.

DuPont has worked closely with 3M since at least the 1970s to investigate the toxic and carcinogenic effects of C-8 on animal and human health. (See id. and Exhibits 2, 24, and 49.) Through such company-sponsored studies, DuPont acquired knowledge by at least the early 1980s that C-8 was toxic and carcinogenic to animals, whether through inhalation, direct skin contact, or ingestion. (See Exhibits 12, 49, and 71.) Around the same time, DuPont also became aware that C-8 is biopersistent/bioaccumulative in animals and humans. (See Exhibits 30, 49 and 71.)[4]

In response to the mounting toxicity data on C-8, and because C-8 was essentially an unregulated chemical that, according to USEPA, had simply "sail[ed] under the agency regulatory radar screen" for decades, (see Exhibit 114), DuPont established in the 1980s its own internal standards for what it considered to be acceptable C-8 exposure levels for humans. For exposure to C-8 via air emissions/inhalation routes, DuPont determined that an "acceptable exposure limit" (AEL) for humans is 0.01 mg/m^3 (skin), with an acceptable "community exposure guideline" (CEG) for airborne emissions of 0.0003 mg/m^3. (See Exhibits 2-4, and 9.) For human exposure to C-8 through contaminated water, DuPont established a CEG of 1 ppb. (See id.) DuPont also began routine monitoring of the levels of C-8 in the blood of its own employees, including employees at Washington Works, as early as 1981, (see Exhibit 118), and began looking for alternatives to C-8. By 1993, DuPont believed it may have found a viable, less toxic alternative to C-8, (see Exhibit 42), but decided to keep using C-8 anyway.

Later in 1993, a study conducted by the University of Minnesota linked C-8 exposure with increased prostate cancer among human males. (See Exhibits 47 and 51.) By 1996, DuPont also had been informed that new tests were linking C-8 to DNA damage. (See Exhibit 60.) In response, DuPont, 3M, and others commissioned studies to further assess the potential effects of C-8 on humans through tests on monkeys. (See Exhibits 77, 84, 93, and 105.) By November of 1998, DuPont knew that one of the monkeys in the study receiving a 30 mg/kg dose of C-8 was suffering severe health effects. (See Exhibit 90.) By February of 1999, DuPont knew that one of the monkeys involved in the C-8 testing receiving the lowest dose of C-8 (3 mg/kg) had suffered such severe health effects that it had to be sacrificed. (See Exhibit 94.) By May of 1999, DuPont knew that a second monkey in the study had also suffered such severe health effects that it had to be sacrificed. (See Exhibits 103, 105, 107, 108 and 125.) The preliminary monkey study results also confirmed adverse liver effects among all of the monkeys in the study, regardless of exposure levels. (See id. and Exhibits 125 and 126.) Thus, because even exposure to the lowest

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[4] DuPont also became aware of evidence as early as 1981 that at least two children born to its Washington Works employees who worked with C-8 while pregnant appeared to have been born with birth defects similar to those observed among rats exposed to high levels of C-8. (See Exhibit 13.)

dose of C-8 during the studies (3 mg/kg) produced adverse observable effects, a "no observable effects level" (NOEL) could not be found for C-8 in primates. (See Exhibits 105, 126.)

3M eventually notified USEPA of the preliminary results of the monkey study in a filing under TSCA, Section 8(e) during November of 1999. (See Exhibit 111.) Within only a few months, USEPA notified 3M that it intended to pursue more rigorous regulation of the perfluorinated chemicals manufactured by 3M. (See Exhibits 113 and 120.) Soon thereafter, 3M publicly announced that it would "voluntarily" withdraw from the market all of its perfluorinated chemical products, including the C-8 that it sells to DuPont for use in DuPont's Teflon® products, and the chemicals 3M uses to make its Scotchguard® products. (See Exhibits 113 and 114.)[5]

After learning that DuPont was one of the principal users of 3M's C-8 product, USEPA's TSCA Division requested in April of 2000 that DuPont supply information regarding DuPont's usage and release of C-8 within the United States. (See Exhibit 112.) DuPont produced some C-8 research data to USEPA on May 25, 2000, (see Exhibit 115), followed by preliminary usage and release information in a letter dated June 23, 2000. (See Exhibit 118.) In its C-8 disclosure letter to USEPA, DuPont confirmed that it has used C-8 primarily at its Washington Works site and that it had released C-8 into the air, water, and land at the Washington Works, into water at its Parlin Plant, Spruance Plant, and Chambers Works, into soils at the Chambers Works, and into soil and water at the "Local," Letart, and Dry Run Landfills owned and operated by DuPont near the Washington Works in West Virginia. (See id.) DuPont did not, however, reference any of the results of the C-8 monkey studies. (See id.) On October 18, 2000, USEPA proposed to begin regulating most of 3M's perfluorinated chemicals under TSCA on the grounds that the chemicals "may be hazardous to human health and the environment." (See Exhibit 123 (65 Fed. Reg. 62319-33 (Oct. 18, 2000)).) USEPA deferred, however, regulation of C-8, pending further review of the information being obtained from 3M and DuPont. After receiving a draft of this letter in November of 2000, DuPont sent revised C-8 usage and release information to USEPA in a letter dated January 25, 2001. (See Exhibit 136.) As of today's date, however, the Tennants are not aware of the results of the C-8 monkey studies having been "finalized" or published.

III. DuPont Promised Not To Dispose Of Toxins Like C-8 In Its Dry Run Landfill.

In the early 1980s, DuPont approached the Tennants seeking to buy several hundred acres of the Tennants' property for the purposes of constructing a landfill near the base of Dry Run Creek in Wood County, West Virginia. (See Exhibit 14.) In response to initial resistance from the Tennants to the idea of selling any portion of their land for a landfill, DuPont promised the Tennants that no hazardous materials would ever be disposed of in the landfill. (See Exhibit 14.) After receiving DuPont's verbal and written assurances that no harmful chemicals would ever be disposed of in the proposed landfill and that the Tennants would be permitted to graze their

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[5] ®3M's registered trademark.

cattle along the adjacent Dry Run Creek,[6] the Tennants eventually agreed to sell a portion of their property to DuPont for construction of the "non-hazardous" landfill. DuPont received a permit to operate the Dry Run Landfill as an unlined, non-hazardous, solid waste landfill in 1982, and began actual landfilling operations at the Landfill in 1984. (See Exhibit 5.)

IV. DuPont Has Dumped Thousands Of Tons Of C-8 Wastes Into The Dry Run Landfill.

Soon after DuPont began operating the Dry Run Landfill in 1984, DuPont received the results of internal sampling confirming that C-8 was leaching into groundwater beneath three old, unlined anaerobic digestion ponds at the Washington Works that DuPont previously had used for the disposal of thousands of tons of C-8-soaked sludges. (See Exhibits 9, 17, 20, and 31.) DuPont's internal sampling indicated that, not only was C-8 getting into the groundwater that DuPont used for the Washington Works' drinking water, but C-8 also was migrating through the groundwater under the Washington Works and into the Lubeck Public Service District's ("Lubeck PSD's") immediately-adjacent public drinking water wells. (See Exhibits 17, 18, 20, and 31.) Internal DuPont sampling confirmed C-8 in the Lubeck PSD community drinking water supply as high as 1.5 ppb in 1984, (see Exhibits 17, 18, and 20), increasing to as high as 1.9 ppb in 1987, (see Exhibits 19 and 20), and further increasing to as high as 2.2 ppb in 1988 (see Exhibits 27 and 28. See also Exhibit 33.) All of these levels exceed DuPont's own 1 ppb CEG for community drinking water. (See Exhibits 2-4, and 9.)

Upon receipt of those results, DuPont decided to try to remove the source of the C-8 in the public and company drinking water supplies by digging up and removing the sludges from Washington Works' three anaerobic digestion ponds and dumping the tons of C-8-contaminated sludge[7] into the Dry Run Landfill. (See Exhibits 20, 21, 22, 23, and 26.) After DuPont submitted data to the West Virginia Division for Environmental Protection ("WVDEP") asserting that the sludges were "non-hazardous" under RCRA, WVDEP granted DuPont permission to dispose of approximately 7,100 tons of the sludge in the unlined Dry Run Landfill. (See Exhibits 21, 23, and 25.) DuPont completed the sludge disposal in 1988. (See Exhibit 6.)

Rather than abate the presence of DuPont's C-8 in the public drinking water supply, DuPont simply purchased the Lubeck PSD well property and the wells were moved approximately two miles further down-gradient from the Washington Works. (See Exhibits 9, 30, 31, and 97.) DuPont then notified its employees to immediately cease all sampling of the

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[6] DuPont even agreed to lease back to the Tennants for cattle pasture significant portions of the landfill property along the Dry Run Creek. Those leases remained in effect until the Tennants began complaining about the Dry Run Landfill to USEPA. (See Exhibit 5.)

[7] DuPont confirmed C-8 levels as high as 610 ppm in the sludge taken from the three ponds. (See Exhibit 9.)

former Lubeck PSD wells and to destroy all previously-drawn, unanalyzed Lubeck PSD well samples. (See Exhibit 29.)

Also in 1989, WVDEP informed DuPont that new landfill regulations had gone into effect in the State of West Virginia requiring existing, unlined landfills to be upgraded with more rigorous waste containment mechanisms, including liners and more extensive groundwater monitoring well systems. (See Exhibit 32.) In response, DuPont installed a series of new groundwater monitoring wells at its Dry Run Landfill and at its nearby, unlined Letart Landfill in Mason County, West Virginia where DuPont had been disposing of most of its Teflon® and other C-8 wastes from the Washington Works as non-hazardous solid waste since the 1960s. (See Exhibit 121.) After DuPont's initial groundwater sampling at the Letart Landfill confirmed the presence of C-8 at 0.7 ppm, (see Exhibit 9), DuPont began investigating whether any C-8 also was leaching out of the waste at the Dry Run Landfill. (See Exhibit 6.) By April of 1990, DuPont had confirmed that C-8 was, in fact, leaching from the Dry Run Landfill and discharging directly into the Dry Run Creek at levels as high as 1.6 ppm – more than 100 times DuPont's own internal standard for drinking water of 1 ppb. (See Exhibits 9, 35, 37, 41, and 136.) Soon thereafter, DuPont abandoned its efforts to seek a new permit for the Letart Landfill, and notified WVDEP that it had decided, instead, to simply close that landfill "for economic reasons." (See Exhibits 74 and 121.)[8] DuPont proceeded, however, with its efforts to get a revised permit for the Dry Run Landfill that would allow DuPont to continue to operate the landfill without having to install a liner. (See Exhibit 50.)

After confirming elevated C-8 levels in the water at Dry Run, DuPont began investigating how to get rid of the approximately 7,100 tons of C-8-contaminated sludge that it dumped into the landfill in 1988, which DuPont assumed was a source of the C-8 being detected in Dry Run Creek. (See Exhibits 7, 8 and 38.) Although DuPont initially notified WVDEP that it would remove the C-8-contaminated sludges from the Dry Run Landfill and dispose of the material at its Letart Landfill, (see Exhibits 36 and 39), DuPont simply moved the sludges to another location within the Dry Run Landfill in 1991. (See Exhibits 5 and 6.)

By the summer of 1993, WVDEP inspectors noticed increasingly excessive amounts of sediment and discoloration building up in the leachate collection ponds at the Dry Run Landfill. (See Exhibit 44.) In response, DuPont, despite knowledge that the leachate contained high levels of C-8 and despite knowledge that the Tennants' cattle were drinking the water in Dry Run Creek, ordered the drains on its leachate collection ponds opened for more than two weeks (after monthly sampling had been completed (see Exhibit 45)), so that the leachate could flow out of

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[8] After DuPont finally shut down its unlined, "non-hazardous" Letart Landfill in 1996, it began paying to dispose of its C-8-contaminated wastes at a RCRA hazardous waste facility in Alabama. (See Exhibit 121.)

the ponds and directly into the Dry Run Creek. (See Exhibits 46 and 86.)[9] Although WVDEP requested that DuPont submit acute toxicity sampling results for the leachate being discharged out of the sedimentation ponds, (see Exhibit 44), DuPont successfully avoided taking any such samples until four months after the original leachate had drained into the creek. (See Exhibit 48.) The acute toxicity results that DuPont did eventually submit to WVDEP confirmed a 15% mortality, even among neonates exposed to the water four months later. (See id.) In the meantime, dozens of the Tennants' cattle were dying along the Dry Run Creek bed and the Tennants and their family and friends were exposed to C-8.

By the fall of 1994, DuPont had adopted a corporate plan to start routinely dumping C-8 wastes into the Dry Run Landfill, in anticipation of the upcoming closure of its Letart Landfill. (See Exhibit 130.) Thus, in furtherance of this corporate plan, but without any authorization or approval of any kind from WVDEP, DuPont began dumping its C-8-contaminated biocake wastes into the Dry Run Landfill that Fall. (See Exhibits 5 and 86.) According to DuPont's own analyses, the biocake contained 930 ppb of C-8. (See Exhibits 6, 58, 85, and 87.) By the spring of 1995, discolored, foul-smelling water was observed being discharged out of the Dry Run Landfill sedimentation ponds into Dry Run Creek, with almost knee-high suds and foam present along the Dry Run Creek bed, which DuPont assumed contained C-8. (See Exhibits 5, 53, 54, 56, 88 and 91.) At the same time, even more of the Tennants' cattle were dying.

In response to repeated pleas from the Tennants that WVDEP force DuPont to take action to address the black odorous water and foam being discharged into the Dry Run Creek where their cattle were drinking and dying, WVDEP notified DuPont that it would need to start taking steps to address its improper discharges into Dry Run Creek and to upgrade the Dry Run Landfill. (See Exhibits 5 and 57.) After it became evident that little progress was being made by DuPont in response to WVDEP's requests,[10] the Tennants notified USEPA of the problem and provided copies of videotapes showing the discolored foaming water and dead animals along the Dry Run Creek bed. (See Exhibit 61.) Around the same time, the West Virginia Department of Natural Resources contacted DuPont in response to recent reports of numerous deer killed or dying in the area of the Dry Run Creek. (See Exhibit 59.) Despite such complaints, DuPont did nothing to disclose to the Tennants that C-8 was in the Dry Run Creek, nor did DuPont suggest in any way to the Tennants that their cattle should not be drinking the water in the Creek. (See Exhibit 74.) Instead, DuPont kept silent on the C-8 issue and took the position with the public and the regulatory agencies that all of the problems with the creek were simply the result of some high

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9 DuPont also ordered the landfill drain opened in 1989 and again in 1995 so that the contents of the sedimentation pond could flow directly into Dry Run Creek, without any apparent notice to or permission from WVDEP. (See Exhibits 34 and 55.)

10 Discolored, foaming water continued in Dry Run Creek throughout the remainder of 1995, 1996, 1997, 1998, and into 1999.) (See Exhibits 62, 63, 89, and 92.)

iron sulfide levels that had been fully addressed and completely resolved. (See Exhibits 5, 74, and 78.)[11]

In October of 1996, USEPA contacted DuPont and informed the company that it would be initiating an inspection of the Dry Run Landfill in response to the recent reports of hundreds of dead cattle and deer in the area of the Dry Run Creek. (See Exhibits 5, 64, and 68.) On the exact same day that DuPont learned of USEPA's pending inspection, Eli McCoy (with WVDEP's Water Division) forwarded to DuPont a draft complaint to aid DuPont in diffusing any potential enforcement action by USEPA relating to the discharge problems at the Dry Run Landfill. (See Exhibits 5 and 65.) Within a matter of weeks, DuPont completed its negotiations with the State and entered a consent decree to bar further governmental enforcement action in exchange for DuPont's payment to WVDEP of a $200,000 penalty. (See Exhibits 5, 67, and 69.) Soon thereafter Mr. McCoy left WVDEP and began working for the same DuPont consultant that would assist DuPont in complying with the consent decree - Potesta & Associates. (See Exhibit 73.)

As part of the December 1996 settlement with WVDEP, DuPont finally agreed to begin implementing upgrades to the Dry Run Landfill, such as installation of the type of liner that was required under the State's landfill regulations since 1988, and construction of a leachate collection system. (See Exhibits 66 and 69.) DuPont also finally agreed to cease the disposal of its biocake wastes at the Dry Run Landfill. (See id.) Thus, by the time USEPA actually commenced its ecological risk assessment activities in the Dry Run Landfill area in 1997, DuPont allegedly had stopped disposing of its C-8-contaminated biocake sludge at the Dry Run Landfill and had allegedly begun collecting C-8-contaminated leachate from the Landfill for transport to the Washington Works for treatment and discharge directly into the Ohio River. (See Exhibits 5, 70, and 72.)

By the end of 1997, USEPA released to DuPont a draft of its Ecological Risk Assessment Report for the Dry Run Landfill. (See Exhibit 75.) USEPA's report indicated that, although adverse impacts were clearly evident among numerous animals, plants, and other wildlife in the area of the Dry Run Creek, USEPA had not been able to identify any particular known, regulated chemical as the clear cause of the observed problems. (See id. at 52) USEPA, therefore, recommended further assessment and identification of numerous "tentatively identified compounds" that had been detected in various environmental media in the area of Dry Run Creek that might be contributing to the problems. (See id.) In response to the suggestion of further governmental investigation, DuPont immediately requested and USEPA agreed to discuss a "collaborative" effort to further investigate conditions in the area of Dry Run Creek. (See

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[11] DuPont's practices with respect to making public the company's knowledge of the toxicity of its products was addressed in detail in In re E.I. duPont de Nemours & Co., 918 F. Supp. 1524 (M.D. Ga. 1995) (court imposed over $100 million in sanctions against DuPont).

Exhibits 79 and 83.) Part of that collaborative effort included DuPont's agreement that it would disclose more fully the precise identities of each of the various types of chemicals it had dumped into the Dry Run Landfill that DuPont had not previously identified for USEPA. (See Exhibit 83.) Although DuPont had been monitoring C-8 levels in Dry Run Creek for years and had confirmed C-8 in the water each time, DuPont eventually identified C-8 as being only "possibly" present in the Dry Run Landfill in a list of dozens of chemicals that it sent to USEPA in late 1998 - almost a year after the USEPA had completed its draft Risk Assessment Report. (See Exhibit 83.)[12]

Because of USEPA's persistent concerns that something in the Dry Run Creek was killing hundreds of head of the Tennants' cattle, (see Exhibit 78),[13] DuPont also agreed to jointly fund an investigation into the health of the Tennants' cattle. Specifically, DuPont agreed in the Spring of 1999 to create a "Cattle Team" to "independently" investigate such issues. By that time, however, less than a few dozen of the Tennants' cattle were even still alive. The Cattle Team was comprised of three veterinarians selected by DuPont, including Greg Sykes, a DuPont employee who had been involved in DuPont's internal investigations into the effects of C-8 on animals for many years, (see Exhibit 24), and three veterinarians selected by USEPA. (See Exhibit 95.) Despite DuPont's knowledge that C-8 was a toxic animal carcinogen (as reenforced to DuPont by the recent C-8 monkey study results (see, e.g., Exhibits 87 and 166)), that the Tennants' cows were drinking out of Dry Run Creek, the information currently available to the Tennants does not indicate that anyone from DuPont ever disclosed such facts to the other members of the Cattle Team during the course of the Cattle Team's investigation. (See Exhibit 93.) Consequently, there is no evidence that the Cattle Team even considered the potential impact of C-8 on the Tennants' cattle, despite the release of the C-8 monkey study results to DuPont well before the final Cattle Team Report was released in December of 1999. (See Exhibit 109.) Again, DuPont kept completely silent on the C-8 issue and sat back and let the Cattle Team "independently" investigate the health of the Tennants' cattle, even though the USEPA-appointed Cattle Team members would never have any reason even to think to look at C-8.

Over the last several years, while DuPont was working with USEPA on their "collaborative" effort to address environmental problems in the area of Dry Run Creek, several of the Tennants have been in and out of the hospital suffering from respiratory problems, chemical

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12 At around the same time, DuPont, again, ordered the Dry Run Landfill sedimentation pond drain opened, so that the foul-smelling contents could discharge directly into the Dry Run Creek where the few remaining head of the Tennants' "[c]attle were wallowing in the stream just beyond the fence." (See Exhibits 81 and 82.)

13 At least two other local residents, including at least one current DuPont employee, also have complained that their cattle appear to have been harmed by something in Dry Run Creek. (See Exhibits 54 and 117.)

burns, and other health problems after having been exposed to fugitive air emissions and liquid discharge from DuPont's Dry Run Landfill. Moreover, despite installation several years ago of a leachate collection system that was supposed to prevent contaminants from the Dry Run Landfill from getting into the Dry Run Creek, DuPont's own monitoring reports confirm that C-8 is still getting into the Dry Run Creek with results as high as 87 ppb in the creek, as recently as the Summer of 1999, and as high as 27.6 ppb during the Fall of 2000 – readings more than twenty times DuPont's CEG for C-8 in water. (See Exhibit 134.) Thus, DuPont's own monitoring reports confirm that, despite installation of a purported leachate collection system, there is a continuing, ongoing discharge of high levels of C-8 from the Dry Run Landfill into Dry Run Creek.

V. DuPont Has Known That Its C-8 Wastes Have Leached Into Drinking Water.

In addition to DuPont's failure to disclose to the Tennants or the USEPA-appointed Cattle Team members the full extent of its knowledge regarding the nature, extent, and likely effects upon wildlife of the C-8 it has been releasing and continues to release into Dry Run Creek, the information currently available to the Tennants indicates that DuPont also has not fully disclosed to USEPA, WVDEP, local governmental entities, its neighbors, or the public its knowledge of the full extent of the impact of its C-8 wastes on local drinking water.

As part of its efforts to complete its RCRA Facility Investigation Report ("RFI Report") for the Washington Works, DuPont was required to investigate whether any of its former solid waste management units, including the three anaerobic digestion ponds that were closed in 1988, are contributing to any release of wastes onto neighboring properties and whether any wastes are exposing any persons to unreasonable health risks. (See Exhibits 98 and 99.) In connection with its RFI efforts, DuPont took more samples of the groundwater under the Washington Works site that it uses for drinking water at the Plant. (See Exhibits 10, 11, 76, and 99.) DuPont also arranged for the sampling of groundwater under the neighboring GE Plastics Plant that GE uses for its own plant drinking water. (See Exhibits 10 and 11.) Sampling confirmed C-8 in the Washington Works' drinking water as high as 3.3 ppb[14] and as high as 0.71 ppb in the neighboring GE Plastics drinking water supply. (See Exhibits 10, 11, 43, 76, 96, 99, 102, 104,

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[14] It is noted that, although DuPont had been sampling three drinking water wells at the Washington Works (wells 331, 332, and 336), when it came time to actually report the results to USEPA in its RFI Report, Dupont was careful to sample only the drinking water well that had previously yielded C-8 results less than 1 ppb (well 336), and conveniently did not even sample the wells that traditionally had yielded the higher C-8 results, nor did DuPont report these higher results in its RFI Report. (See Exhibits 76, 96, 99). Yet, when even the well with the C-8 readings traditionally below 1 ppb yielded a result of 1.9 ppb, DuPont fabricated a new 3.0 ppb "screening level" for C-8 to avoid having to reference any drinking water results exceeding DuPont's own 1 ppb CEG in its own plant drinking water. (See Exhibit 99).

106, 110 and 129.) DuPont even found C-8 as high as 0.8 ppb in the new Lubeck PSD drinking water wells, which are now located approximately two miles farther away from the Washington Works site. (See Exhibits 10-11, 40, and 41.)[15] Recent sampling of the private drinking water wells on the Tennants' property down-gradient from the Dry Run Landfill also has now confirmed C-8 in those drinking water wells. (See Exhibit 131.) DuPont has even investigated what C-8 levels might be present at various cities along the Ohio River, based upon DuPont's on-going releases of C-8 into the River from the Washington Works facility. (See Exhibits 40, 100, and 118.)[16] Approximately 24,000 pounds of C-8 also is discharged directly into the air every year from the Washington Works Site, although it is not clear that C-8 is actually permitted for such air discharge by DuPont. (See Exhibits 101 and 118.)

Thus, it is evident that the residents living in at least the area near DuPont's Washington Works facility, Letart Landfill, and Dry Run Landfill (the "DuPont Sites") may have been and may continue to be exposed to DuPont's C-8 through DuPont's on-going and continuous releases of C-8 into the air, land, and water at and/or around those Sites, (see Exhibit 80), including direct ingestion of C-8 in the C-8-contaminated drinking water extracted from wells at the Washington Works Plant, the neighboring GE Plastics Plant, the Lubeck PSD well fields, and private residential and agricultural properties near DuPont's Sites.[17] Local wildlife and the environment may be similarly exposed. Despite DuPont's knowledge for years of the nature, extent, and effect of these C-8 releases on human health and the environment, including the

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15 Sampling results from 1991 confirmed C-8 at 2.4 ppb in the new Lubeck wells with C-8 levels as high as 3.9 ppb in the tap water of several local, Lubeck-area homes. (See Exhibit 128.) Sampling in August of 2000 confirmed C-8 still present in the new Lubeck PSD wells at levels as high as 0.59 ppb. (See Exhibit 119.)

16 DuPont has been evaluating the levels of C-8 in the Ohio River, which is a source of drinking water for numerous communities, since at least 1982. (See Exhibit 15.)

17 In August of 2000, after the Tennants had made it known to DuPont that they had become aware of the C-8 in the Lubeck PSD wells, DuPont drafted a letter for the Lubeck PSD to send to its water customers to "disclose" the existence of the C-8. (See Exhibit 124.) In that letter, however, DuPont was very careful to refer only to the current C-8 levels in the current Lubeck PSD wells, and avoided any mention whatsoever of the earlier C-8 readings that were substantially above DuPont's 1 ppb CEG. (See id.) DuPont again was careful to avoid any public disclosure of its knowledge of earlier C-8 drinking water results that were well-above DuPont's 1 ppb CEG in recent statements provided to local Parkersburg newspapers, even though DuPont had received in November a draft of this letter referencing the higher C-8 levels. (See Exhibit 135.)

bioaccumulative/biopersistent nature of the material,[18] it appears that DuPont has allowed and continues to allow these releases to occur unabated for fear of not being able to continue to make its Teflon® products, if it cannot use C-8. This situation is particularly disturbing, given that DuPont apparently has known of ways to remediate C-8-laden soils since the early 1990s but because of the expense, chose to do nothing "pending further actions that may be dictated by the EPA for remediation of the Washington Works site." (See Exhibit 122.) Even more disturbing is the fact that DuPont has known for years that C-8 levels in the Washington Works and old Lubeck PSD drinking water wells far exceeded its own 1 ppb CEG but has done absolutely nothing in response. DuPont has chosen, instead, to focus either on current, somewhat lower C-8 levels, or to simply fabricate a totally new drinking water "screening level" of 3 ppb for the Washington Works Plant when faced with having to disclose to USEPA in its RFI report for the Washington Works the existence of C-8 in the Plant's drinking water at levels well above 1 ppb. (See Exhibits 99 and 124.)

VI. DuPont Should Be Ordered To Remediate Its C-8 Releases And To Immediately Shut Down Its Manufacturing Processes Involving C-8 Until Adequate Demonstrations Are Made That There Is No Unreasonable Risk To Health Or The Environment.

Over the years, DuPont has successfully avoided fully disclosing the nature and extent of the C-8 problem at its Dry Run Landfill by characterizing C-8 as an unregulated "non-hazardous" waste and/or substance under applicable law. Consequently, when the Federal and State agencies have asked questions about the nature and quantity of toxic wastes handled by DuPont at the Dry Run Landfill, DuPont has omitted any comprehensive discussion of C-8 on the grounds that it is not a "hazardous waste," "hazardous substance," or otherwise listed or regulated waste under current laws. DuPont shrewdly avoided any permit limits on its C-8 emissions and/or dumping at its Washington Works facility and Dry Run Landfill through similar corporate strategies. Thus, although DuPont has known for years that C-8 is an animal carcinogen and bioaccumulative/biopersistent substance, it has continued to knowingly dump thousands of tons of the waste into the environment at unlined, uncontrolled landfills and has allowed the waste to be disposed directly into the air, Ohio River, and local drinking water supplies, arguing that there has not been any improper disposal and/or release of any regulated material.

In addition, DuPont has been careful to refer to the chemical in conflicting, inconsistent ways in its filings with regulatory agencies - sometimes calling it "C-8," sometimes calling it "FC-143," sometimes calling it "PFOA," sometimes calling it "APFO," and sometimes calling it by its full chemical name - "ammonium perfluorooctanoate" - thereby making it difficult for the agencies to understand how all the information interrelates. As confirmed by USEPA's recent

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[18] DuPont's own employees even raised concerns about Teflon® customer exposure to C-8 as early as 1983. (See Exhibits 16 and 52.)

proposal to begin regulating 3M's previously-unregulated perfluorinated chemicals, DuPont's past corporate strategy for diverting regulatory attention away from C-8 should stop now.

Based upon the foregoing facts, the Tennants hereby respectfully request that your agencies intervene in the Tennants' pending Federal Court litigation and order the immediate investigation, assessment, containment, removal, and remediation of DuPont's on-going C-8 releases into the environment by virtue of the authority granted to your agencies under at least the following laws and their implementing regulations:

- The Toxic Substances Control Act, as amended, 15 U.S.C. §§ 2601-2692;
- The Federal Clean Water Act, as amended, 33 U.S.C. §§ 1251-1387;
- The Safe Drinking Water Act, as amended, 42 U.S.C. §§ 300f-300j-26;
- The Federal Clean Air Act, as amended, 42 U.S.C. §§ 7401-7671q;
- The Resource Conservation and Recovery Act, as amended, 42 U.S.C. §§ 6901-6992k;
- The Comprehensive Environmental Response, Compensation and Liability Act, as amended, 42 U.S.C. §§ 9601-9675;
- The West Virginia Air Pollution Control Act, W.Va. Code §§ 22-5-1 through 22-5-18;.
- The West Virginia Water Pollution Control Act, W.Va. Code §§ 22-11-1 through 22-11-28;
- The West Virginia Groundwater Protection Act, W.Va. Code §§ 22-12-1 through 22-12-14;
- The West Virginia Natural Streams Preservation Act, W.Va. Code §§ 22-13-1 through 22-13-15;
- The West Virginia Solid Waste Management Act, W.Va. Code §§ 22-15-1 through 22-15-21;
- The West Virginia Hazardous Waste Management Act, W.Va. Code §§ 22-18-1 through 22-18-25; and

- The West Virginia Hazardous Waste Emergency Response Fund Laws, W.Va. Code §§ 22-19-1 through 22-19-6.

The Tennants also request that your agencies exercise their respective authority under the referenced laws to order DuPont to **immediately** cease and desist its C-8 releases into the environment, as addressed in this letter and to provide for immediate, appropriate medical care/testing/evaluation of the Tennants. The Tennants further request that DuPont's permit to operate the Dry Run Landfill be **immediately** revoked until adequate scientific demonstrations are made to prove that the C-8 releases have been abated, will not recur, and pose no unreasonable risk to human or animal health or the environment.

With respect to minimizing harm to the public health and the environment from future C-8 releases, the Tennants hereby specifically request that USEPA exercise its authority under the Toxic Substances Control Act to order DuPont to immediately cease all manufacturing activities using C-8, including DuPont's Teflon® manufacturing operations, until DuPont either confirms that it has stopped its usage of C-8 entirely or has made adequate scientific demonstrations to prove that its continued usage of C-8 (whether from 3M or any other source) does not pose an unreasonable risk of injury to health or the environment. In the meantime, the Tennants request that your agencies take these steps necessary to regulate C-8 emissions/releases to the environment. As mentioned above, the Tennants believe that such steps should include, at a minimum, including C-8 among the list of perfluorinated chemicals that USEPA proposed in October of this year to begin regulating under TSCA on the basis that the chemicals "may be hazardous to human health and the environment." (See Exhibit 123.)

VII. The Tennants Intend To Bring Citizen Suit Claims Against DuPont Under The CWA, TSCA, And RCRA If Appropriate Action Is Not Taken Immediately To Abate And Remediate DuPont's C-8 Releases From Its Washington Works Facility.

As explained above, DuPont has been and continues to discharge C-8 from its Washington Works Facility in Wood County, West Virginia into the air, groundwater, and Ohio River. Moreover, the C-8 discharged by DuPont has been contaminating and continues to contaminate the land, air, and human and animal drinking water supplies.

A. DuPont Is Violating The CWA.

Section 505(a)(1) of the Clean Water Act ("CWA") permits citizens to commence a civil action against "any person ... who is alleged to be in violation of (A) an effluent standard or limitation under this chapter." 33 U.S.C. §1365(a)(1). "Effluent standard or limitation" is defined under the CWA to include, among other things, "a permit or condition thereof issued under Section 1342 of this title," such as state-issued but federally-enforceable NPDES discharge permits. Id. at §1365(F). Based upon information currently-available to the Tennants, DuPont's NPDES permit for its Washington Works facility specifies that DuPont shall not discharge any

effluent in violation of applicable Water Quality Standards. (See, e.g., WV/NPDES Permit No. WV0001279, Conditions A.1 - A.10, C.12, and H.2). The West Virginia Water Quality Standards prohibit DuPont from discharging into surface or groundwaters any "materials in concentrations which are harmful, hazardous, or toxic to man, animal, or aquatic life." W. Va. Code St. R. tit. 46, §46-1-3.2 (2000). Based upon currently-available information, as described above, DuPont has been discharging and continues to discharge C-8 into surface and groundwaters in concentrations exceeding DuPont's own CEG for human drinking water and at concentrations that are otherwise harmful, hazardous, or toxic to man, animal, or aquatic life, constituting a continuing violation of the West Virginia Water Quality Standards, and thereby constituting a continuing violation of DuPont's NPDES permit terms and the CWA. See, e.g., 33 U.S.C. §§1311(a), 1342. Notice is, therefore, hereby provided that the Tennants, on behalf of themselves and a class of others similarly situated, intend to file suit against DuPont, pursuant to Section 505(a)(1) of the CWA, within sixty (60) days of this notice to obtain appropriate relief for the violations of the CWA referenced herein.

B. DuPont Is Violating TSCA.

Section 20(a)(1) of the Toxic Substances Control Act ("TSCA") permits citizens to commence a civil action against "any person . . . who is alleged to be in violation of [TSCA] or any rule promulgated under Sections 2603, 2604, or 2605 of [TSCA], or Subchapters II or IV of [TSCA]." 15 U.S.C. § 2619(a)(1). TSCA requires 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" to "immediately" inform USEPA of "such information, unless such person has actual knowledge that" USEPA has been adequately informed of such information. Id. at § 2607(e). TSCA also requires each person who manufactures or processes a chemical substance to comply with the regulations adopted by USEPA under TSCA governing the reporting to USEPA of certain research and adverse health effects information relating to such chemical substances. See id. at § 2607(a), (c), (d); 40 C.F.R. Parts 716 and 717. Failure to comply with such TSCA requirements constitutes a violation of TSCA. See 15 U.S.C. § 2614. As indicated above, the information currently available to the Tennants indicates that DuPont has not reported to USEPA all information within DuPont's possession regarding C-8 that is required to be reported to USEPA under Section 8(a), (c), (d), and (e) of TSCA, 15 U.S.C. § 2607 (a), (c), (d), and (e), such as the results of the C-8 monkey studies and the Tennants' allegations of adverse health effects among themselves, their cattle, and area wildlife arising from exposure to DuPont's C-8. Notice is, therefore, hereby provided that the Tennants, on behalf of themselves and a class of others similarly situated, intend to file suit against DuPont, pursuant to Section 20(a)(1) of TSCA, within sixty (60) days of this notice to obtain appropriate relief for the violations of TSCA referenced herein.

C. DuPont's C-8 Releases From Its Washington Works Facility May Present An Imminent And Substantial Endangerment To Health Or The Environment Under RCRA.

Section 7002(a)(1)(B) of the Resource Conservation and Recovery Act ("RCRA") permits citizens to commence a civil action against:

> [a]ny person ..., including any past or present generator, past or present transporter, or past or present owner or operator of a treatment, storage, or disposal facility, who has contributed or who is contributing to the past or present handling, storage, treatment, transportation, or disposal of any solid or hazardous waste which may present an imminent and substantial endangerment to health or the environment.

42 U.S.C. § 6972(a)(1)(B). As discussed above, DuPont's past and on-going disposal of C-8 into soil, water, and air from DuPont's Washington Works Facility has resulted in C-8 in soil, water, and air at and/or around the Washington Works Facility in amounts, levels, and/or concentrations which, based upon the currently-available information, may present an imminent and substantial endangerment to health or the environment. Notice is, therefore, hereby provided that the Tennants , on behalf of themselves and a class of others similarly situated, intend to file suit against DuPont, pursuant to Section 7002(a)(1)(B) or RCRA, within ninety (90) days of this notice to obtain appropriate relief for the imminent and substantial endangerment referenced herein.

Please confirm as soon as possible how your respective agencies plan to address our request for your involvement in this important public health and environmental matter. In that regard, please let us know if you will intervene in the Tennants' Federal Court proceedings or if

you would like to review any of the additional backup documentation maintained here at our Cincinnati offices. We would be happy to meet with you at your offices to discuss this matter in more detail. Thank you.

On behalf of the Tennants,

Robert A. Bilott

RAB/mdm
Enclosures
cc: Larry A. Winter, Esq. (West Virginia Counsel for the Tennants) (w/o encls.)
Paula Durst Gillis, Esq. (Counsel for DuPont) (w/ encls.)
(by **CERTIFIED MAIL NO: 70000600002406963531, RETURN RECEIPT REQUESTED & REGISTERED MAIL NO: R410009299, RETURN RECEIPT REQUESTED)**
Registered Agent for E.I. duPont de Nemours & Co., Inc. (w/o encls.)
(CT Corporation System, 707 Virginia Street, East, Charleston, WV 25301
by **CERTIFIED MAIL NO: 70000600002406963500)**

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Perfluorooctanoic Acid (PFOA), Fluorinated Telomers; Request for Comment, Solicitation of Interested Parties for Enforceable Consent Agreement Development, and Notice of Public Meeting

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ENVIRONMENTAL PROTECTION AGENCY
[OPPT-2003-0012; FRL-7303-8]

Perfluorooctanoic Acid (PFOA), Fluorinated Telomers; Request for Comment, Solicitation of Interested Parties for Enforceable Consent Agreement Development, and Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: EPA has identified potential human health concerns from exposure to perfluorooctanoic acid (PFOA) and its salts, although there remains considerable scientific uncertainty regarding potential risks. EPA is requesting public comment on pertinent topics of interest, as discussed in this document, and the submission of additional data concerning these chemicals. EPA is also soliciting the identification of interested parties who want to monitor or participate in negotiations on one or more enforceable consent agreements (ECAs) under section 4 of the Toxic Substances Control Act (TSCA) concerning PFOA and fluorinated telomers which may metabolize or degrade to PFOA, and is announcing the first public meeting for these ECA negotiations.

INFORMATION CONTACT.

E. What Should I Consider as I Prepare My Comments for EPA?

We invite you to provide your views on the various options we propose, new approaches we have not considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider during the development of the final action. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

EPA has prepared a preliminary risk assessment (Ref. 1) on perfluorooctanoic acid (PFOA) (Octanoic acid, pentadecafluoro-; Chemical Abstracts Service Registry Number (CAS No.) 335-67-1) and its salts, predominantly ammonium perfluorooctanoate (APFO) (Octanoic acid, pentadecafluoro-, ammonium salt (CAS No. 3825-26-1)). This preliminary assessment indicates potential nationwide human exposure to low levels of PFOA. Based on certain animal studies, there could be a potential risk of developmental and other adverse effects associated with these exposures in humans. However, this assessment also reflects substantial uncertainty about the interpretation of the risk. EPA has identified areas where additional information could be very helpful in allowing the Agency to develop a more accurate assessment of the potential risks posed by PFOA and the other compounds addressed in this notice, and to identify what voluntary or regulatory mitigation or other actions, if any, would be appropriate. EPA is making this preliminary assessment public in order to identify the Agency's concerns, to indicate areas where additional information or investigation would be useful, and to request the submission of data addressing these issues.

EPA is also soliciting the identification of parties who would be interested in monitoring or participating in negotiations for the development of one or more ECAs under section 4 of TSCA on PFOA and on fluorinated telomers (hereafter ``telomers'') which may metabolize or degrade to PFOA. The intent of the ECAs would be to develop additional information, particularly environmental fate and transport information, to enhance understanding of the sources of PFOA in the environment and the pathways by which human exposure to PFOA is occurring.

III. Background

In 1999, EPA began an investigation after receiving data on perfluorooctyl sulfonate (PFOS) indicating that PFOS was persistent, unexpectedly toxic, and bioaccumulative. These data also showed that PFOS had been found in very low concentrations in the blood of the general population and in wildlife around the world. 3M Company (3M), the sole manufacturer of PFOS in the United States and the principal manufacturer worldwide, announced in May 2000 that it was discontinuing its perfluorooctanyl chemistries, including PFOS. EPA followed the voluntary 3M phaseout with regulatory action under TSCA section 5 to limit any future manufacture or importation of PFOS before EPA has had an opportunity to review activities and risks associated with the proposed manufacture or importation (Ref. 2).

In June 2000, EPA indicated that it was expanding its investigation of PFOS to encompass other fluorochemicals, including PFOA, in order to determine whether these other fluorochemicals might present concerns similar to those found with PFOS. EPA was concerned in part because 3M had also found PFOA in human blood during the studies on PFOS (Ref. 3).

In September 2002, the Director of OPPT initiated a priority review on PFOA because the developmental toxicity data, the carcinogenicity data, and the blood monitoring data presented in an interim revised hazard assessment raised the possibility that PFOA might meet the criteria for consideration under TSCA section 4(f) (Refs. 4 and 5). When the priority review commenced, EPA anticipated completing the review within a few months. However, as explained in this notice, there remain substantial uncertainties associated with the preliminary risk assessment. EPA believes these uncertainties may be reduced through acquisition of the information described in this notice. EPA is therefore continuing the priority review in order to acquire this information and better inform the Agency's decisionmaking.

A. PFOA Sources and Uses

PFOA and its salts are fully fluorinated organic compounds that can be produced synthetically and formed through the degradation or metabolism of certain other manmade fluorochemical products. PFOA is a synthetic chemical and is not naturally occurring. Consequently, all PFOA in the environment is attributable to human activity.

PFOA is used primarily to produce its salts, which are used as essential processing aids in the production of fluoropolymers and fluoroelastomers. Although they are made using PFOA, finished fluoropolymer and fluoroelastomer products are not expected to contain PFOA. In recent years, less than 600 metric tons per year of PFOA and its salts have been manufactured or imported in the United States (Ref. 6). The major fluoropolymers manufactured using PFOA salts are polytetrafluoroethylene (PTFE) and polyvinylidine fluoride (PVDF). PTFE has hundreds of uses in many industrial and consumer products, including soil, stain, grease, and water resistant coatings on textiles and carpet; uses in the automotive, mechanical, aerospace, chemical, electrical, medical, and building/construction industries; personal care products; and non-stick coatings on cookware. PVDF is used primarily in three major industrial sectors: Electrical/electronics,

the environment, such as fire fighting foams, as well as soil, stain, and grease resistant coatings on carpets, textiles, paper, and leather. The extent to which these telomer-containing products might degrade to release PFOA is unknown. However, anecdotal evidence of the atmospheric presence of telomer alcohols in a multi-city North American survey suggests that telomers may be one source of environmental PFOA (Ref. 10). Additional fate information is necessary to determine whether and the extent to which telomer product degradation may be a source of PFOA.

EPA is not currently aware of any other potential sources of PFOA in the environment. EPA specifically requests comment on this issue, and the submission of any data identifying or characterizing PFOA sources. EPA is especially interested in the thermal stability and oxidative degradation products of materials containing PFOA or telomer chemicals which are incinerated.

B. Hazard and Exposure

EPA has conducted a detailed review of all available hazard and exposure information on PFOA. This review is available in the Agency's Revised Draft Hazard Assessment on PFOA and Its Salts (Ref. 11). This draft hazard assessment has not been formally peer reviewed, but has been reviewed internally by the EPA Office of Research and Development (ORD).

PFOA is persistent in the environment. It does not hydrolyze, photolyze, or biodegrade under environmental conditions. Based on recent human biomonitoring data provided by industry, which found PFOA in the blood of workers and the general population in all geographic regions of the United States, exposure to PFOA is potentially nationwide, although the routes of exposure for the general population are unknown.

Several epidemiological studies on the effects of PFOA in humans have been conducted on workers. An association with PFOA exposure and prostate cancer was reported in one study; however, this result was not observed in an update to the study in which the exposure categories were modified. A non-statistically significant increase in the levels of the hormone estradiol in workers with high serum PFOA levels (>30 parts per million (ppm)) was also reported, but none of the other hormone levels analyzed indicated any adverse effects.

APFO is the most widely used salt of PFOA, and most animal toxicity studies have been conducted with APFO. An extensive array of animal toxicity studies have been conducted in rodents and monkeys. These studies have shown that APFO exposure can result in a variety of toxic effects in animals including liver toxicity, developmental toxicity, and immunotoxicity. In addition, rodent bioassays have shown that chronic APFO exposure is associated with a variety of tumor types. The mechanisms of APFO tumorigenesis are not clearly understood. At this time, EPA is evaluating the scientific evidence and has not reached any conclusions on the potential significance to humans of the rodent cancer data.

There are marked gender differences in the elimination of PFOA in rats. In addition, there are substantial differences in the half-life of PFOA in rats, monkeys, and humans. The gender and species differences are not completely understood and therefore the extent of

potential risks to humans is uncertain.

C. Preliminary Risk Assessment

Because TSCA section 4(f) is focused narrowly on the specific toxicity endpoints of cancer, birth defects, and gene mutation, the preliminary risk assessment prepared as part of this priority review focused on the potential risks for developmental toxicity in humans. EPA did not include cancer risk in this preliminary assessment due to questions concerning the potential significance to humans of the rodent cancer data. Because data indicate that PFOA is not mutagenic, concern for gene mutation was not an issue for this preliminary assessment.

The preliminary risk assessment used a margin of exposure (MOE) approach (Ref. 1). For many risk assessments, the MOE is calculated as the ratio of the administered dose from the animal toxicology study to the estimated human exposure level. The human exposure is estimated from a variety of potential exposure scenarios, each of which requires a variety of assumptions.

A more accurate estimate of the MOE can be derived if measures of internal dose are available for humans and the animal model. In this preliminary risk assessment, serum levels of PFOA, which are a measure of internal dose, were available for some administered dose levels in the rat 2-generation reproductive toxicology study and from human biomonitoring studies. Thus, internal dose was used for the

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calculation of MOEs in this assessment. The actual values of the MOEs derived must be viewed with caution, however, due to the differences in kinetics between humans and rodents. The range of MOEs in the preliminary assessment encompasses some values that would indicate potential concern and other values that would indicate a low level of concern. Due to the uncertainties in the assessment, and the possibility that the additional information discussed in this notice might reduce those uncertainties, the Agency has not attempted further interpretation of these MOEs at this time. The interpretation of the significance of the MOEs for ascertaining potential levels of concern will necessitate a better understanding of the appropriate dose metric in rats, and the relationship of the dose metric to the human serum levels.

As this priority review of PFOA progresses, EPA will continue to develop the characterization of hazard and potential risk associated with exposure to PFOA. Because the scientific interpretation issues in this case are particularly complex, given the unusual properties and behavior of PFOA and the absence of data on exposure pathways and levels, EPA anticipates that a more comprehensive risk analysis will be taken to the Agency's Science Advisory Board for review and comment in fall 2003. The preliminary risk assessment described in this notice has not been formally peer reviewed, but has gone through internal review by multiple EPA offices, including ORD, the Office of Science Coordination and Policy (OSCP), the Office of Pesticide Programs (OPP), and the Office of Policy, Economics, and Innovation (OPEI). The preliminary risk assessment has also been the subject of an external letter peer review.

D. Uncertainties and Data Needs

Although EPA has concerns with respect to the potential nationwide presence of PFOA in blood and with the potential for developmental and other effects suggested by animal studies, there are significant uncertainties in the Agency's quantitative assessment of the risks of PFOA. In addition, the uncertainties discussed in this unit with respect to the identification of the pathway or pathways that result in human exposure to PFOA (air, water, food, etc.), and the uncertainties associated with how PFOA gets into those pathways (including the products or processes that are responsible for the presence of PFOA in the environment) make it difficult to determine what, if any, particular risk mitigation measures would be appropriate. The Agency believes that the additional information identified in this notice would better inform this priority review and Agency decisionmaking with respect to PFOA.

The sources of PFOA in the environment, as described in Unit II.A., are not fully defined or understood. Historically, direct PFOA releases during the manufacture of PFOA and its use in the manufacture and processing of fluoropolymers and fluoroelastomers have been quantified at some sites. Industry has identified and implemented voluntary control technologies to reduce releases, as well as to improve PFOA recovery for recycling or destruction, as described in Unit II.E. The effectiveness of these programs could be assessed, possibly through the ECA process described in Unit V., by monitoring PFOA levels at the respective facilities and determining if the release reduction and waste management programs are reducing the PFOA levels in the media surrounding the affected facilities. PFOA exposures and releases to the environment may also come from the distribution of PFOA in aqueous dispersions of fluoropolymers used by processors to apply coatings to metals and textiles, a topic which industry is also attempting to resolve.

In addition, the question of the potential contribution to PFOA levels from telomer manufacture and from telomer product degradation remains. The universe of specific telomer chemicals that may ultimately degrade or metabolize to PFOA has not been fully defined. Preliminary data suggest that only higher perfluorinated homologues (chemicals with carbon chain lengths of eight and higher) would be converted into PFOA via normal environmental pathways. The 8-2 telomer alcohol has been shown to biodegrade and metabolize to form PFOA, but other telomer chemicals, including telomer iodides and telomer-derived polymers, have not yet been tested. Determining possible telomer product sources of PFOA may be particularly difficult because these fluorochemicals are typically used in products in very low concentrations, indicating that any individual source contribution by specific products could be very small, widely distributed, and difficult to detect. For example, products contaminated with volatile, unreacted telomer alcohol residuals could potentially release those residuals into the environment where they could be subject to biodegradation.

The exposure routes leading to the presence of PFOA in human blood are not known. The nationwide presence of PFOA in human blood, contrasted with the limited geographic locations of fluorochemical plants making or using the chemical, suggests that there must be

additional sources of PFOA in the environment, and exposures beyond those attributable to direct releases from industrial facilities. But whether these exposures are due to PFOA in the air, the water, on dusts or sediments, in dietary sources, or through some combination of routes is currently unknown. Data evaluating the environmental presence of PFOA in water are very limited and site-specific. Data on the presence of PFOA in air or soil are not currently available. Data on the presence of PFOA in wildlife suggest that animals are not as likely as humans to have PFOA in their blood, and that PFOA is not found as widely in animals as PFOS. Whether these differences may be due to different exposure pathways or to differences in how the chemicals are processed or retained by animals and humans is unknown. The technical difficulties of detecting and accurately measuring the chemical in all these various media, particularly in the low concentrations that EPA would anticipate, are considerable.

The preliminary risk assessment on potential developmental toxicity was based on a comparison of serum levels in the 2-generation rat reproductive study with those found in the human population. However, there are considerable species differences in the kinetics of PFOA. Interpretation of the significance of the MOEs for ascertaining potential levels of concern will necessitate a better understanding of the appropriate dose metric in rats, and the relationship of the dose metric to the human serum levels.

Finally, there are some uncertainties regarding the use of the human biomonitoring data. Although the available data include a range of populations with various demographics in many States and all geographic areas of the country, there may be some populations that are not represented. Because it is unknown how the human exposures are occurring, proximity to a manufacturing facility may or may not be a factor in exposure. However, populations living near these facilities were not sampled. Therefore, it is possible that PFOA serum levels may be underestimated for certain portions of the U.S. population. The children's sample was derived from blood collected in 1994/1995; therefore, it may not reflect the current status of PFOA in children's blood.

Voluntary activities by industry are underway as described in Unit II.E. to help address some of these uncertainties

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and data gaps. For example, pharmacokinetics studies examining the biological processing of PFOA in rats are expected to be completed in the summer and fall of 2003. These studies may help to reduce the uncertainty in the estimation of risk to humans. In addition, EPA has submitted a nomination to the Centers for Disease Control and Prevention (CDC) to include PFOS, PFOA, and certain related fluorochemicals in the next National Health and Nutrition Examination Survey (NHANES). This would provide a national baseline of PFOA exposure, both to indicate whether current data are representative of the U.S. population and to offer a gauge with which to measure the effectiveness of actions to reduce exposures.

EPA will continue to develop and clarify issues relating to hazard, exposure, and risk as the priority review continues and the Agency receives additional information that allows further resolution of the

uncertainties identified in this unit.

Additional data beyond EPA's current activities and the voluntary efforts undertaken by the industry may be necessary to resolve the existing uncertainties and fill remaining data gaps, including gaps not yet identified. EPA requests comment on these issues, and particularly requests that comments include the submission of any additional data that may help to fill these gaps. Certain specific information requests are identified in Unit IV.

E. Ongoing Voluntary Activities

In 2000, EPA opened a non-regulatory public docket file, Administrative Record AR-226, for information on PFOS, PFOA, telomers, and related fluorinated chemicals, and began to express its concerns to the global fluorochemical industry (Ref. 3). In response, the industry began providing information to the Agency, all of which has been placed into AR-226. Two industry groups, the Fluoropolymer Manufacturing Group (FMG) and the Telomer Research Program (TRP), formed and began pursuing voluntary collective actions to address issues associated with PFOA and the telomers. 3M continued its ongoing research efforts despite having discontinued the manufacture of both PFOS and PFOA. Much of the information reflected in the EPA's revised draft hazard assessment and preliminary risk assessment on PFOA was provided through these voluntary activities on the part of industry.

In March 2003, EPA received letters from 3M, FMG, and TRP documenting their ongoing voluntary programs and outlining their plans for continuing research and product stewardship activities (Refs. 7, 12, and 13). These letters have been placed in the public docket for this notice and can be accessed as described in Unit I.B.2. The letters contain substantial additional information concerning the specifics of the voluntary industry actions beyond what is presented in this notice.

In its letter, 3M indicated that it would not resume the manufacture of PFOA for commercial sale; that it would continue its medical monitoring efforts for workers and provide biannual reports to EPA and update its epidemiological study reports to EPA every 5 years; and that it will continue monitoring groundwater, surface water, and other environmental media and provide a summary report to EPA within 2 years. 3M also stated that it would work with other members of industry to conduct additional validation of PFOA analytical methods and sampling protocols and to participate in human health and environmental fate and effects studies of PFOA. 3M also indicated that the facilities and employees of its subsidiary, Dyneon LLC, would continue to be part of the 3M monitoring program.

The members of the FMG--Asahi Glass Fluoropolymers USA, Inc.; Daikin America, Inc.; E.I. duPont de Nemours & Company; and Dyneon LLC--indicated that they and their parent companies represent most of the known use of APFO for the production of fluoropolymers both in the United States and worldwide. Their letter includes commitments to reduce emissions of APFO from fluoropolymer and APFO manufacturing facilities on a global, individual company-wide basis by a minimum of 50% by 2006; to conduct studies on both finished polymers and finished products from these polymers to determine if any exposure to the general population can be related to the fluoropolymer industry; to conduct studies on emissions from fluoropolymer processing facilities

to determine the level of current emissions; and to develop additional toxicological data on APFO. The companies noted that they are participating in activities through the Association of Plastics Manufacturers in Europe (APME) to conduct pharmacokinetics studies in rats and develop a pharmacokinetic model, and would share those data with EPA as they are developed, beginning in spring 2003. The companies indicated that they would continue to follow principles of product stewardship similar to those described in the Responsible Care[reg] programs of the American Chemistry Council and the Synthetic Organic Chemical Manufacturers Association in their efforts to support toxicological research, control occupational exposures in their own facilities, monitor employee health, assist customers in protecting their employees, and meet the general commitment to reduce emissions to the environment. The companies stated that they will continue to use appropriate criteria, including such standards as the interim air and water screening levels and water quality guidelines recently adopted in West Virginia, to evaluate operations and emissions (Refs. 14 and 15). The letter includes a schedule for the completion of various studies already underway.

The members of the TRP--AGA Chemicals (Asahi Glass); Clariant GmbH; Daikin America, Inc.; and E.I. duPont de Nemours & Company--indicated that they comprise the major telomer producers, and that they are evaluating telomer products sold in the United States to determine whether they contribute to significant human or environmental exposure to PFOA. They noted that their evaluation has six key components: Analysis of products and articles; analysis of ``aged'' products and ``in use'' articles; characterization of potential release of PFOA from telomer-based product manufacture; characterization of potential release of PFOA from telomer-treated article manufacture; analysis of possible biodegradation of telomer-based polymeric products; and evaluation of the ultimate fate and disposal routes for telomer-treated articles in the United States. The letter includes lists and schedules for these various evaluation components, as well as for the submission of additional information to the Agency.

EPA appreciates the industry response to the Agency's concerns regarding PFOA and the telomers, and looks forward to continued cooperation on assessment and management activities. EPA invites the participation of additional interested persons in these efforts. EPA considers that the timely submission of the information which industry has already committed to provide will be essential to developing a better and more complete understanding of the potential risks of PFOA. However, in light of the concerns identified to date, the Agency will continue its ongoing expeditious review.

While the voluntary industry activities as described in the letters will provide substantial additional information, EPA considers it likely that

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issues will remain even after these activities are complete, and that the results of some of these programs may well identify additional questions that will need to be answered. EPA requests comment on these issues.

IV. Specific Requests for Comments, Data, and Information

EPA specifically requests comments, data, and information on the following topics.

A. Use and Production Volume Information

What are the specific chemical identities (by Ninth Collective Index name and CAS No., if available) of the telomer chemicals, including polymers derived from these telomers, and of the fluoropolymers and fluoroelastomers made with PFOA or related chemicals, currently in commerce? In what volumes and at what locations are these chemicals manufactured or imported? How and in what volumes are these chemicals used? What are the benefits of these chemicals and products in their specific uses, and what alternatives to these chemicals may be available for specific uses?

B. Exposure Information

How are products containing the chemicals identified in Unit IV.A. used? How are these products disposed of? What environmental releases occur at manufacturing and processing facilities where these chemicals are used? What data are available on worker exposures to these chemicals? What data are available on exposures to the general population? What data are available on measured levels of these chemicals in humans and the environment, in all environmental media? What data are available on the biodegradation of these chemicals, on releases of these chemicals from consumer and industrial products, and on their breakdown during product biodegradation, incineration, and other disposal practices?

C. Monitoring and Related Information

EPA specifically requests that any persons who have in their possession existing human or environmental monitoring data indicating or assessing the presence of PFOA and related fluorochemicals in humans, in wildlife, or in any environmental media, including studies conducted in other countries, provide those data to the Agency in response to the publication of this notice to enhance the understanding of PFOA presence in the environment and of the pathways leading to exposures. EPA includes in this request any existing data not otherwise provided to EPA concerning the toxicity, pharmacokinetics, and half-life of PFOA in organisms.

D. Additional Data

Are there other pieces of information not addressed in Unit IV. A., B., and C., that would help EPA more accurately assess the risks of these chemicals and determine appropriate further action, if warranted?

V. Enforceable Consent Agreement Development

EPA is interested in developing one or more ECAs under TSCA section 4 and 40 CFR part 790 for PFOA and telomers that focus on identifying

environmental fate and transport information, as well as other relevant information to enhance understanding of the sources of PFOA in the environment and the pathways by which human exposure to PFOA is occurring. The objective of the ECA process is to conclude one or more ECAs that will set in place an industry-sponsored testing program that will address a number of EPA's current data needs for PFOA and telomers. EPA expects that industry will meet the voluntary testing commitments made in their letters of intent, as discussed in Unit III.E. Therefore, EPA anticipates that the ECA process will focus generally on testing issues beyond or supplemental to those contained in the industry letters of intent.

A. Solicitation of Interested Parties

EPA is soliciting interested parties to monitor or participate in negotiations on ECAs for PFOA and telomers. As discussed in Unit III.E., 3M; AGA Chemicals; Asahi Glass Fluoropolymers USA, Inc.; Clariant GmbH; Daikin America, Inc.; Dyneon LLC; and E.I. duPont de Nemours & Company, have been pursuing voluntary collective actions to address issues associated with PFOA and telomers and have been keeping EPA informed of these activities. Any person who desires treatment as an ``interested party'' during the development of the ECAs must respond in writing to this notice on or before May 16, 2003 following the instructions in Unit I., and must specifically request that they be given ``interested party'' status. These interested parties will not incur any obligations by being so designated. Negotiations will be conducted in one or more meetings, all of which will be open to the public. EPA will contact all interested parties who have expressed a desire to participate in or monitor the ECA negotiations and advise them of all meeting dates. EPA will also notify the public of such meeting dates in the electronic public docket for this action. The negotiation time schedule for PFOA and telomers will be established at the first negotiation meeting. It is EPA's current intent to move quickly to attempt to finalize any ECAs, if possible. If an ECA is not established in principle within a reasonable time-frame, negotiations will be terminated, and any unmet data needs may be pursued via a test rule promulgated under TSCA section 4. If the data generated from the ECA do not meet the Agency's needs, EPA reserves the right to proceed with rulemaking to obtain the needed data. EPA also reserves the right to announce and convene subsequent ECA negotiations for additional data, if the testing from voluntary activities, the initial ECA, or from a test rule identify additional data gaps which must be filled.

B. ECA Process and Public Participation in Negotiations

EPA will provide the public with an opportunity to comment on and participate in the development of any ECAs on PFOA and telomers to ensure that the views of interested parties are taken into account during the ECA process. This process is described generally in this unit, and is more fully addressed in 40 CFR part 790.

Individuals and groups who respond to this notice by May 16, 2003 and request treatment as interested parties will have the status of interested parties. All negotiating meetings for the development of this ECA will be open to the public and minutes of each meeting will be

prepared by EPA and placed in the official public docket for this action. The Agency will advise interested parties and the public of meeting dates and make available meeting minutes, testing proposals, background documents, and other relevant materials exchanged at or prepared for negotiating meetings. Where tentative agreement is reached on an acceptable testing program, a draft ECA will be made available for comment by interested parties and, if necessary, EPA will hold a public meeting to discuss any comments that have been received and determine whether revisions to the ECA are appropriate. EPA will not reimburse costs incurred by non-EPA participants in this ECA negotiation process.

Enforceable consent agreements will only be concluded where an agreement can be obtained, which is satisfactory to the Agency, manufacturers or processors who are potential test sponsors, and other interested parties, concerning the need for and scope of testing. In the

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absence of an ECA, EPA reserves the right to proceed with rulemaking.

More specifically, EPA will not enter into an ECA if either the Agency and affected manufacturers or processors cannot reach an agreement on the provisions of the ECA, or the draft ECA is considered inadequate by other interested parties who have submitted timely objections to the draft ECA. However, EPA may reject these objections if the Agency concludes that:

1. They are not made in good faith;
2. They are untimely;
3. They are not related to the adequacy of the proposed testing program or other features of the ECA that may affect EPA's ability to fulfill the goals and purposes of TSCA; or
4. They are not accompanied by a specific explanation of the grounds on which the draft ECA is considered objectionable.

EPA will prepare an explanation of the basis for each ECA. That document will summarize the agreement (including the needed data development), explain the objectives of the data collection/development activity, and outline the chemicals' use and exposure characteristics. That document, which will also announce the availability of the final ECA, will be published in the Federal Register. Upon the successful completion of an ECA, export notification under TSCA section 12(b) would be required for all signatories to the ECA who export or intend to export the chemicals subject to the ECA. A separate action would be published in the Federal Register following the announcement of the ECA to apply the export notification requirement to others by adding the ECA chemicals to the list of chemicals subject to testing consent orders at 40 CFR 799.5000.

VI. References

These references have been placed in the official docket that was established under docket ID number OPPT-2003-0012 for this action as indicated in Unit I.B.2. Reference documents identified with an Administrative Record number (AR226-XXXX) are available in the public version of the official docket maintained in the OPPT Docket. Copies of

C

Donald K. Duncan
President

The
Plastics
Industry
Trade
Association

March 14, 2003

The Honorable Stephen L. Johnson
Assistant Administrator
The United States Environmental Protection Agency, Headquarters
Office of Prevention, Pesticides and Toxic Substances
1200 Pennsylvania Avenue
Room 7101M
Washington, DC 20460

Dear Mr. Johnson:

On behalf of the Asahi Glass Fluoropolymers USA, Inc.; Daikin America, Inc.; Dyneon LLC; and E. I. du Pont de Nemours and Company, we are transmitting a Letter of Intent describing the initiatives that these companies have taken to assist EPA in its assessment of perfluorooctanoic acid and its salts. This Letter describes in some detail the activities underway to develop information and data needed to assure the continued safe use of ammonium perfluorooctanoate in the manufacture, processing, and use of fluoropolymers

If you have any questions about the Letter of Intent, please contact Lynne R. Harris, of The Society of the Plastics Industry, Inc. (SPI) at 202-974-5233.

Respectfully submitted,

Don Duncan

Enclosure

cc: Charles M. Auer
Margaret N. Schneider

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March 14, 2003

Regular Mail

The Honorable Stephen L. Johnson
Assistant Administrator
The United States Environmental Protection Agency, Headquarters
Office of Prevention, Pesticides and Toxic Substances
1200 Pennsylvania Avenue
Room 7101M
Washington, DC 20460

Re: **Voluntary Actions to Evaluate and Control Emissions of Ammonium Perfluorooctanoate (APFO)**

Dear Mr. Johnson:

Asahi Glass Fluoropolymers USA, Inc.; Daikin America, Inc. (Daikin); E. I. du Pont de Nemours and Company (du Pont), and Dyneon LLC (Dyneon) (the "APFO Users") each use ammonium perfluorooctanoate (APFO)[1] to produce fluoropolymers and fluoroelastomers in the U.S. Fluoropolymers are plastic products while fluoroelastomers are rubber-like products, both of which provide highly desirable and unique properties that make the end-use products created from them useful. All of these companies are members of The Society of the Plastics Industry, Inc. (SPI) Fluoropolymers Manufacturers Group (FMG) and its Fluoropolymers Division (FPD). Together, they and/or their parent companies represent, both globally and in the U.S., most of known use of APFO for production of fluoropolymers.

APFO is essential in making certain fluoropolymers,[2] which, in turn, are used in many high-performance applications in critical industries such as defense, aerospace, semiconductors, telecommunications, and pollution control. A list of commercial fluoropolymers is provided in Addendum I to this document. Many grades of these fluoropolymers can be made *only* with APFO.

The APFO Users share the goal of the U.S. Environmental Protection Agency (EPA) to understand and assess the toxicity of and exposures to the APFO used by the fluoropolymer industry, and to safeguard human health and the environment. To that end, the APFO Users have made specific commitments to provide additional information and research to EPA. These

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1 The APFO Users use a commercially available form of the compound, technically known as octanoic acid, pentadecafluoro-, ammonium salt, CAS 3825-26-1.

2 For purposes of this letter, we will use fluoropolymers to include fluoroelastomers, unless there is a distinction that needs to be made.

commitments are: (1) to reduce emissions of APFO from fluoropolymer and APFO manufacturing facilities; (2) to conduct studies on both finished resins and finished products made from these resins to determine if any exposure to the general population can be related to the fluoropolymer industry; (3) to conduct studies on emissions from fluoropolymer processing facilities to determine the level of current emissions; and (4) to develop additional toxicological data on APFO.

This Letter of Intent includes timetables for completion of various studies and research, including additional studies on the toxicity and environmental fate of the substance. The timetables are the best estimates available at this time. The APFO Users will promptly provide EPA with the information as it is developed so that it can be made available to the public generally.

Addendum II describes the history of APFO use in the fluoropolymer industry, the reasons for the recent interest in APFO, and the extensive activities that the APFO Users in the industry have completed, and continue to conduct, to protect human health and the environment while society retains the substantial benefits of fluoropolymers.

Current Activities of Fluoropolymer Manufacturers

The APFO Users believe that fluoropolymers and products made from them are safe for their intended use. Nevertheless, the companies are examining the use of APFO more closely. Initially, the APFO Users, in conjunction with the FMG, determined that they needed to find out how much APFO was used and how much was emitted to the environment, as well as to re-examine work practices in their own plants. Thus, the FMG prepared a global materials balance including APFO used in manufacturing fluoropolymers.

The information developed from the materials balance was provided to EPA in 2001; it was updated in 2002, and will be revised in the future as described below. The global materials balance was and is based on the best available evidence that the companies have regarding the use of APFO in making fluoropolymers and the fate of these substances in the fluoropolymer industry.

Based on these estimates and the method used, the companies have accounted for essentially all the APFO used in the fluoropolymer manufacturing industry.

As responsible manufacturers, the APFO Users are committed to reducing APFO emissions. Based on that global materials balance, and as described below, FMG members have voluntarily begun to modify their processes to reduce AFPO emissions, on a global, individual company-wide basis, by a minimum of 50% for calendar year 2006. This reduction will be compared to baseline data submitted to EPA in September 2002. This initial commitment was based on the best information available to the companies at the time of the decision and what the companies believed could be achieved, even with some difficulty, given the available technology, the characteristics and uses of the surfactants and the nature of processes involved.

Using data collected from the materials balance and such environmental monitoring and other studies as they become available, the companies will continue to use appropriate criteria, including such standards, limits or parameters as the West Virginia air and water screening levels and water quality guidelines, to evaluate operations and emissions.[3]

To facilitate the commitment to reduce emissions, du Pont has provided, and will continue to provide to FMG companies where needed, its "capture for destruction" technology, license-free. In addition, Dyneon and du Pont each have offered to license their respective company's "capture for recycle" technologies. All of the companies are evaluating the applicability of available technologies to their processes and continue to track APFO emissions. Because of the differences in the manufacturing processes and the kinds of products manufactured, it is not possible to know whether these technologies will be effective, or if they are, what the final reductions will be. Nevertheless, the companies are committed to the minimum 50% reduction and to taking additional steps as described below.

The APFO Users, through the FMG, also continue to support research on the toxicology, ecotoxicology, and environmental fate of APFO, as such research relates to the safe use of APFO as surfactants in the manufacture and use of fluoropolymers. Collectively and individually, the FMG members have worked with customers to help them safely manage the processing of fluoropolymer products, and to help them adopt practices and procedures to control employee exposures. These activities are essential parts of long-standing product stewardship programs and are ongoing, as described below.

In addition, the APFO Users have, and are, committed to working to identify the possible routes, related to the manufacture, processing, and use of fluoropolymers, by which the general population could be exposed to APFO. The APFO Users have begun to examine their products, embarking on the difficult analytical process of determining any residual levels. The first step in this effort was to evaluate methods for analysis of APFO. The method evaluation work is under way, which is necessary to meet EPA's QA/QC criteria and is difficult and time-consuming. As part of that effort, the FMG published in January 2003 *Detecting and Quantifying Low Levels of Fluoropolymer Polymerization Aids – A Guidance Document.* A copy of this document was provided to EPA's technical staff for inclusion in the docket under separate cover.

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[3] The toxicologists and scientists who participated in the assessment included representatives from government, independent third party experts, and industry. The organizations represented included: West Virginia Department of Environmental Protection; Toxicology Excellence for Risk Assessment, Cincinnati, Ohio; U.S. Environmental Protection Agency, Region III; U.S. Agency for Toxic Substances and Disease Registry; EPA National office in Washington; and EPA's Cincinnati Laboratory.

Further Industry Commitments

A. General Commitment to Product Stewardship Principles and Practices

The APFO Users will continue to follow the principles of product stewardship similar to those described by American Chemistry Council's (ACC) or Synthetic Organic Chemical Manufacturers Association's (SOCMA) Responsible Care® programs in their efforts to support the toxicological research, control occupational exposures in their own facilities, monitor employee health, assist customers in protecting their employees, and meet the general commitment to reduce emissions to the environment.

For example, as has been done in the past, through the semi-annual SPI FPD meetings, an update on information about APFO, including the results of toxicology studies, coordination efforts with EPA, and other activities, will be provided to processor members of the fluoropolymer industry. High on the list of topics will be an emphasis for fluoropolymer users on the need for care in handling and processing the raw fluoropolymer products, and the need to follow recommended procedures to protect their employees. Special attention will be given to address the practices and procedures of those who use dispersions and coatings made from dispersions on the safe handling of products that contain APFO. In addition, as part of their workplace product stewardship efforts described below, the APFO Users, working with the FMG, will continue to update and distribute the manuals and information documents described.

Further industry efforts on product stewardship programs directed to customers will focus on technical support and assistance to fluoropolymer processors to help them keep their occupational safety and health programs current. While APFO Users recognize their responsibilities as suppliers of fluoropolymers, each processor and customer, as an employer, has an independent and non-delegable duty to take reasonable steps to comply with OSHA standards, and where there is a recognized hazard that is not addressed by specific OSHA standards, to assure that their employees are protected from safety and health hazards. Accordingly, the fluoropolymer manufacturer's product stewardship role is to provide the necessary information, assist in the understanding of it and provide support to processors using the fluoropolymers so they can meet their statutory obligations. Specific steps and studies are described below that demonstrate how the APFO Users will meet their obligations under product stewardship principles.

The APFO Users generally will submit information to and work with EPA through the SPI FMG. Such information and studies may be conducted under the auspices of industry groups such as the Association of Plastics Manufacturers in Europe (APME). The APFO Users will share the information we develop with EPA. As described below, the FMG continues to work on additional studies that will provide useful information to assess any potential environmental and health effects of APFO used in fluoropolymers. APFO Users are supportive of EPA's efforts and intend to assure that EPA has adequate information to understand the benefits, and any risks, of APFO use in fluoropolymers.

B. Data Quality

APFO Users recognize the importance of assuring good data quality. EPA's recently issued QA/QC Guidelines[4] describe EPA's efforts to maximize the quality of environmental information made available to the public in terms of quality, integrity, reliability and validity of the data disseminated. APFO Users will incorporate the guidance contained in EPA's QA/QC guidelines into their research and monitoring programs to assure that sound scientific information is available to EPA and the public.

C. Specific Commitments

1. Supporting EPA Efforts to Involve CDC in Testing Programs

The APFO Users support adding APFO to the CDC NHANES process. To facilitate that step, work is underway to confirm the validity of the analytical method and sampling protocol for analyzing human blood for the presence of APFO, and the results will be shared with CDC. Efforts will be made to have the analytical methodology published in a peer-reviewed journal so it will be widely available. In addition, and in the further interest of adding transparency to the process, there will be support and assistance for one or more independent laboratories to become qualified to perform the validated method.

2. Toxicology Research

Under the auspices of the APME, the following additional studies will be completed on the schedule noted:

Study Description	Anticipated Report Date[5]
Acute toxicity in daphnia	May 2003
Acute toxicity in trout	May 2003
Algal growth	July 2003
Chronic toxicity in daphnia	June 2003
Chronic toxicity in trout	November 2003
Adsorption/desorption soil studies	June 2003
ADE mass balance in rats	June 2003
Protein binding; rat/human	August 2003

[4] "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," announced in 67 F.R. 63657, October 15, 2002. *Quality Assurance for Data Collection*; 5360.1/A2 May 2000.

[5] Based on commitments from contracting laboratories, we believe these dates can be met. EPA will be advised of any changes in the reporting schedule.

Study Description	Anticipated Report Date[5]
Physiologically based kinetic modeling	October 2003
Mechanistic studies of pancreatic tumor induction in rats.	October 2003

Industry plans to conduct an additional study to determine parameters for route-to-route extrapolation (oral to inhalation), and the protocol was discussed with EPA scientists. Timing for the anticipated report date will be communicated when the final bid for the project is accepted.

Copies of the final reports for these studies will be submitted to EPA promptly upon receipt. EPA will be apprised immediately if any substantially new and unanticipated information develops as a result of the research programs consistent with current requirements; the above schedule does not, of course, supersede any statutory reporting obligations.

Following EPA's QA/QC guidelines, the reports will include documentation to allow EPA to evaluate the validity of the studies. This validation will enable EPA to assure that the information provided by the companies can be disseminated to the public consistent with EPA's data quality guidelines. Through the FMG, the APFO Users will promptly submit final reports of these studies to EPA and consult with EPA on what additional studies would be beneficial.

3. Understanding Routes of Exposure

Although there is no known evidence of adverse human health or environmental effects to date related to APFO, the APFO Users agree with EPA that it is useful to examine the potential for human and environmental exposure to APFO to determine where potential exposures may have occurred or currently occur. Such research will include, but may not be limited to (a) sites where APFO is manufactured; (b) sites that use APFO to make fluoropolymers; (c) sites that use fluoropolymer dispersions containing APFO; and (d) articles of commerce containing fluoropolymers, including dry fluoropolymer products and dispersion coated products, that might lead to general population exposure related to the fluoropolymer industry.

D. Specific Product Stewardship Activities by Site

1. Product Stewardship at Sites Where APFO Is Manufactured in the U.S.

Consistent with the principles of Responsible Care®, any APFO User who decides to manufacture APFO for commercial use in the United States (including current manufacturers) will first notify EPA and will review its product stewardship program with EPA covering the provisions listed in Addendum III to this letter, which applies only to APFO manufacturing.

As of the date of this letter, only one company has decided to manufacture APFO in the United States for use in fluoropolymer manufacturing. That company is du Pont, which already has committed to adopting the steps in Addendum III as part of its operating practices. Because

of antitrust considerations, APFO Users are legally barred from seeking to enforce any kind of group sanction against a future U.S. manufacturer that does not adopt Addendum III as part of its operating practices. They also cannot take any steps that might be construed by the U.S. antitrust enforcement agencies as anti-competitive. However, EPA would appear to have adequate authority to assure that future U.S. manufacturers of APFO, if any, follow the provisions outlined in Addendum III and commit to adequate product stewardship.

2. Product Stewardship at Sites in the U.S. That Use APFO To Make Fluoropolymers

As noted above, the APFO Users early on made a specific and substantial voluntary Emissions Reduction Commitment regarding the amounts of APFO emitted from their manufacturing facilities. Based on the baseline data from global materials balance submitted to EPA in September 2002, as described above, APFO Users, as FMG members, have committed to modifying their processes to reduce AFPO emissions, on a global, individual company-wide basis, by a minimum of 50% for calendar year 2006. This reduction will be achieved by reducing the use, recycling a greater proportion, or by capturing and destroying it. In addition, at each of the fluoropolymer manufacturing sites listed below, the APFO Users will:

1) Develop site-specific plans to assess or model levels of APFO in air and water around their manufacturing sites; development of the plans will begin not later than 30 days after the date of this letter;
2) Conduct site-specific air dispersion modeling, using the EPA approved Industrial Source Complex Short Term 3 (ISCSTS) model, as described in EPA's Guideline on Air Quality Models (40 C.F.R. Part 51, Appendix W),[6] and assess the results using the air screening levels established in West Virginia;
3) As necessary to implement a site-specific plan, conduct ground and surface water analysis, and assess the results using the water screening levels established in West Virginia; and
4) Use the West Virginia screening levels to determine what additional actions, if any, may need to be taken, after reviewing the information with EPA.

These commitments will be undertaken at the following sites:

[6] http://www.epa.gov/scram001/guidance/guide/appw_01.pdf

a) du Pont
Washington Works Plant
Rt. 892 South
Washington, WV 26181

b) Dyneon
1400 State Docks Road
Decatur Alabama
35609-2206

c) Daikin
905 State Docks Road
Decatur, AL 35601

Six months after this Letter is signed, reports will be submitted by each company for each site on progress made with regard to environmental assessments.

In addition, the APFO Users will:

1) Within 30 days of this letter, provide a list of each site in the United States where APFO is used to make fluoropolymers and which fluoropolymers, including CAS numbers, are produced at that site;
2) For each listed site, beginning in 2004 for the 2003 calendar year and continuing through the 2008 calendar year, provide EPA with a biennial report, describing total emissions of APFO at each site, on a calendar year basis. The reports will be submitted to EPA within 180 days of the end of each reporting period and will include CAS numbers for the substances reported;
3) For each listed site that uses APFO, continue to conduct industrial hygiene monitoring in the workplace of their employees, measuring exposure to APFO and providing results to exposed employees. The results will be used to assure that employee exposures are controlled and to protect employees' health. The companies, as they have in the past, will assure that appropriate protective equipment and proper handling practices are used. They also will continue to provide employees with training on any hazards to which they are exposed, the signs and symptoms of overexposure and methods of proper handling, updating as new information becomes available, as part of their ongoing employee Occupational Safety and Health Administration Hazard Communication Standard programs.

As further evidence of their ongoing commitment, the APFO Users will provide EPA with timely reports of their collective progress in reducing emissions and meeting the target goals so that the information can be made part of the public record. The reports will be based on estimates of annual emissions, derived from available sampling data and supplemented by best estimates when actual data are not available, compared to the original estimates provided to EPA.

The APFO Users long have followed American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) recommendations in assessing their occupational exposures to APFO, and they will continue to do so. As other recommendations become available, the APFO Users will incorporate them into their programs and, as they have in the past, work to ensure that their employees are adequately protected based on the best available scientific evidence.

The APFO Users can provide EPA with details about their individual occupational safety and health and environmental compliance programs. If asked, each APFO User will review its environmental and occupational health data and will describe and provide the rationale of its monitoring programs going forward.

3. Product Stewardship at Sites in the U.S. That Use Fluoropolymer Dispersions Containing APFO

The APFO Users are committed to continuing their Product Stewardship programs for their customers. To assist in assessing the potential routes of exposure at selected sites of their customers, the APFO Users, under the auspices of the FMG, will:

1) Engage a third-party consultant to develop a representative material balance for the fate of APFO contained in these dispersions. Similar to the information provided to EPA on fluoropolymer manufacturing, address in the representative material balance how the dispersion is used at the customer site and potential emissions of APFO to the environment;
2) Submit the material balance to EPA and work cooperatively to identify and recommend appropriate product stewardship elements to control emissions at customer sites.
3) Target completion of the material balance by the end of 2003.

This project is under way and the contractor is being selected. We expect that the results of the materials balance will suggest what actual monitoring may be necessary. After the initial survey is complete, the companies will review the information to determine if further research or monitoring is required, and, if so, will work through SPI to help customers conduct their necessary studies. Among the tasks that need to be completed are: validating air sampling methods applied to customer sites; providing analytical methods; and identifying consultants and laboratories with experience in collecting and analyzing workplace air samples for APFO. The APFO Users will discuss plans for additional work in this area with EPA.

Finally, consistent with the product stewardship principles to which APFO Users firmly adhere and which are discussed above, the APFO Users will continue to update information provided to customers and users of fluoropolymers, make the information widely available and work with customers to assure that the information is disseminated downstream as appropriate. Industry meetings such as the semi-annual FPD meeting and other venues where fluoropolymer

users participate will be used to communicate the need to be knowledgeable about fluoropolymers and APFO, and the need to take the recommended steps to reduce emissions from processor facilities and minimize potential processor employee exposures.

4. Product Stewardship for Articles of Commerce Made with Fluoropolymers

Fluoropolymer products made with APFO are sold in either a dry resin form or as a liquid dispersion. It is the intent of the APFO Users that APFO not be carried through the manufacturing and processing of articles of commerce. To document that this is the case, the APFO Users, under the auspices of the FMG, will:

1) Analyze representative articles of commerce containing or made with dry fluoropolymer resins for the presence of APFO and report the results to EPA.
2) For products coated or manufactured with liquid dispersions, analyze representative articles of commerce for the presence of APFO and report the results to EPA.
3) As appropriate, develop and disseminate information along with recommendations to processors for reducing the potential for exposure to APFO from articles of commerce.
4) Target completion of the analysis of articles of commerce by the end of 2003.

These studies will be conducted by contract laboratories or in company laboratories using validated methods. The products selected for analysis will be: (1) those most likely to have widespread consumer use; and (2) a representative sampling of industrial and commercial products.

The articles of commerce being tested will be selected from products made with fluoropolymers supplied by APFO Users. There are some articles of commerce made from imported fluoropolymers that are not produced by APFO Users and also some articles of commerce made outside the U.S. from fluoropolymers not supplied by APFO Users.

Based on preliminary data obtained using preliminary methods, it is our expectation that articles of commerce made from dry fluoropolymers will have no significant amounts of APFO present, and that most coated products will show similar results. An example can be found in the recent submission by du Pont to EPA showing that cookware coated with products made with fluoropolymer resins demonstrated no detectable level of APFO with current methods accepted by the U.S. Food and Drug Administration for analysis of food contact products.

Based on these analyses, the APFO Users will provide EPA with potential exposure source and route information for public dissemination as it is developed. These data will be used to determine whether those sources contribute to potential exposure to the general population and to develop appropriate practices, methods, and measures to reduce and control the emissions of APFO. Again, these will be discussed with EPA as they are being developed.

* * * * *

The APFO Users appreciate the opportunity to work with EPA on this matter and agree that close coordination of our efforts and sharing of information is important. Accordingly, we will continue to communicate with EPA as important relevant information arises and would appreciate similar consideration. As new information becomes available, the APFO Users are committed to work with EPA to take appropriate further actions in light of the information that is developed.

In closing, we would like to emphasize that the fluoropolymer industry is committed to the continued safe manufacture, processing and use of fluoropolymers and to working with EPA.

Respectfully Submitted,

APFO Users, attached

Attachments
Addendum I: Fluoropolymers and Fluoroelastomers That May Be Made With APFO
Addendum II: Background and Voluntary Activities
Appendix I: Partial List of Studies on APFO in EPA's Docket
Addendum III: Manufacture of APFO

Name: Richard J. Angiullo
Title: Vice President & General Manager
E. I. du Pont de Nemours and Company

Addendum I

Fluoropolymers and Fluoroelastomers Which May Be Made With APFO		
Polymer family	**CAS Number**	**Monomers**
Fluoropolymers		
PTFE	9002-84-0	TFE
FEP	25067-11-2	TFE, HFP
PFA	26655-00-5	TFE, PPVE
THV	25190-89-0	TFE, HFP, VDF
ETFE	68258-85-5	TFE, E
THE	35560-16-8	TFE, HFP, E
Fluoroelastomers		
Copolymers	9011-17-0	VDF, HFP
Terpolymers	25190-89-0	TFE, HFP, VDF
Base resistant elastomers	54675-89-7, 27029-05-6	TFE, VDF, P TFE, P
Perfluoroelastomers	26425-79-6	TFE, PPVE
CTFE elastomers	9010-75-7	CTFE, VFD
Low temperature elastomers	26425-79-6	TFE, PMVE

Monomers Used in Fluoropolymers		
Acronym	**Monomer name**	**CAS Number**
CTFE	Chlorotrifluoroethylene	79-38-9
TFE	Tetrafluoroethylene	116-14-3
HFP	Hexafluoropropylene	116-15-4
VDF	Vinylidene fluoride	75-38-7
PMVE	Perfluoromethyl vinyl ether	1187-93-5
PPVE	Perfluoropropyl vinyl ether	1623-05-8
E	Ethylene	74-85-1
P	Propylene	115-07-1

Addendum II
Background and Voluntary Activities

Background

A. APFO Use in Fluoropolymers

Ammonium perfluorooctanoate, or APFO, is a surfactant that acts as a polymerization aid to make certain base fluoropolymer resins. APFO is currently the most widely used surfactant for fluoropolymer manufacture and is essential in these processes. APFO typically is used in low concentrations (less than 1%) in the fluoropolymer manufacturing process and in a few, very limited industrial applications. Because of its use as a polymerization aid, it is substantially removed in finishing steps in dry fluoropolymer manufacturing. In water-borne dispersions, which are used to make various coatings, it allows application of the dispersion, but it is not intended to be part of the fluoropolymer or the finished, end-use product.

It is critical to understand the role of APFO in the fluoropolymer industry. The surfactant properties of APFO facilitate the *manufacture* of fluoropolymers and fluoroelastomers, but it does not contribute to the performance of the end-use product. Therefore, it is not intended to be – or needed – in the end-use products made with it.

In fact, most of the products made from fluoropolymers require heat treatment that removes or destroys the majority of the APFO in the fluoropolymer resin before the products made with fluoropolymers leave the manufacturing facility or are used. Therefore, fluoropolymer products do not normally present a route of exposure to APFO once they leave the hands of the end-use product manufacturer.

Further, APFO Users have long recognized their obligation to responsible use of chemicals such as APFO in their processes and products and long ago voluntarily committed themselves to establishing and supporting responsible health and environmental practices in the manufacture and use of fluoropolymers. This has been done to minimize the potential effect, if any, these activities have on human health and the environment, and to support the continued safe manufacture and use of fluoropolymers made using APFO. Those commitments continue today, and are exemplified by the additional commitments the APFO Users describe in this letter.

Also important to understand is that, despite more than 30 years of intensive research into alternatives, none has been found, as was presented by du Pont representatives on behalf of The Society of the Plastics Industry, Inc. (SPI) Fluoropolymers Manufacturing Group to the U.S. Environmental Protection Agency (EPA) on April 23, 2001. Driving the research were considerations regarding persistence, the existence of only one supplier, and the need for more effective, cheaper alternatives. Indeed, fluoropolymer manufacturers have tested literally dozens of compounds, and all have been rejected due to technical problems or potential safety concerns that made them unsuitable for such use.

B. The Role of Fluoropolymers in Society

Fluoropolymers are essential to a variety of technologies and products that enhance human life and promote environmental improvements. Ranging from power generation to emission controls on vehicles, to semiconductor chip manufacturing and aerospace applications, fluoropolymers provide superior performance in products that contribute to increased safety in our offices, homes, businesses, and communities.

Fluoropolymers provide unique and critical performance properties in "system critical" applications that protect and benefit people and the environment. Fluoropolymers are among the few plastic materials that can withstand the temperatures inside the engine compartments of aircraft. They also have high resistance to a broad range of fuels, solvents and corrosive chemicals, as well as excellent electrical insulating properties. These unique properties provide critical performance characteristics needed to prevent fire, fluid emission, electrical overloading or similar emergencies in many high-performance applications. And, for virtually all these applications, fluoropolymers are the only materials that meet system performance needs in high temperatures and harsh chemical environments.

C. 50 Years of Experience of Safe APFO Use

APFO has been used safely and without apparent adverse effects on human health for more than 50 years, in part because of the workplace safety programs the APFO Users had in place. This conclusion is supported by epidemiology and other human health studies (contained in EPA's public record and published in the scientific literature) on employees both at APFO production and fluoropolymer manufacturing facilities.

Multiple studies, the first of which was published in 1980, have examined the health-related experience of employees in the APFO manufacturing process. These studies looked for health effects similar to the effects observed in animal studies. This effort continues even now. No studies of the employees who have direct exposure showed any unusual or unexpected pattern of illnesses or deaths from any disease, including cancer.

Based on this experience, and the ongoing health and safety research they have supported and that has been published over the years, APFO Users do not believe that current levels of exposure to APFO cause adverse effects to human health or the environment.

D. Recent Events Triggering Interest in APFO

In May 2000, 3M announced that it would be "phasing out of the perfluorooctanyl chemistry used to produce certain repellents and surfactant products." Subsequent to the 3M announcement, EPA broadened their interest in a series of fluorochemicals that they considered to be persistent in the environment. This interest has been heightened recently by the discovery that certain of these fluorochemicals are found at trace levels in the blood of the US population.

Voluntary Activities of APFO Users and Manufacturers

The users and manufacturers of APFO have, both individually and collectively, supported research into the potential effects on human health and the environment, and have adopted in their own workplaces health and safety practices to minimize employee exposure. They have funded research on the toxicology, both for animal and environmental effects and, as noted above, conducted epidemiology studies to be sure that human health has not been affected by the use of APFO. In addition, they have developed control recommendations for the safe use and handling of fluoropolymers and, specifically, for dispersions containing APFO. These recommendations have been disseminated to customers through publications and meetings of the SPI Fluoropolymers Division and the Association of Plastics Manufacturers in Europe (APME), in addition to the information provided individually by the APFO Users through Material Safety Data Sheets (MSDS) and other technical information sources.

The studies the APFO Users and manufacturers have funded were conducted on APFO and a related chemical, perfluorooctanoic acid (PFOA).[7] These studies are among those that 3M and du Pont have submitted to EPA. The number of research studies on APFO included in EPA's docket is large. A brief list of some of the studies, including studies on human health assessments, is included in Appendix 1 of this Addendum.

To coordinate their efforts to assess and respond to EPA's concerns, the manufacturers of fluoropolymer resins, who are also members of SPI's Fluoropolymers Division, formed the FMG. The mission of the FMG is to promote the continued safe manufacture and use of fluoropolymers made using fluoropolymer polymerization aids such as APFO while establishing and supporting responsible use of fluoropolymer products and promoting environmental stewardship. The APFO Users, working with others in the FMG, will continue to support the safe use of APFO, will work with EPA to understand the information that exists and to develop research programs to fill in the gaps.

The APFO Users, as members of the FMG, first presented information about the FMG's work to EPA in September 2000. Since then, the APFO Users, through the FMG and the APME, have continued to provide information on manufacturing, distribution and use of APFO, as well as the available data on systemic toxicity and environmental fate of APFO. APFO Users have reviewed EPA's preliminary assessment of the potential hazards to human health and the environment associated with exposure to APFO, entitled "Revised Draft Hazard Assessment of Perfluorooctanoic Acid and its Salts," dated November 4, 2002. The FMG has also provided

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[7] While APFO is the product used in fluoropolymers, PFOA is the substance that has been found in some, but not all, the environmental and blood samples that have been tested. PFOA is also the chemical that has usually been tested in animal studies, because APFO dissociates in water into PFOA and ammonium ions. EPA has assigned OPPTS Docket Number AR226 for all submissions on perfluorinated substances. AR226 also contains documents pertaining to other perfluorinated chemical substances. The APFO Users believe that the matters concerning APFO are different from those associated with the other chemical substances included in EPA OPPTS Docket Number AR226.

EPA with a number of new documents and information about the use of APFO in fluoropolymers.

A. Fluoropolymer Manufacturers' Product Stewardship Commitment

The APFO Users specifically concur with and subscribe to the product stewardship principles similar to those described by American Chemistry Council's (ACC) and Synthetic Organic Chemical Manufacturers Association's (SOCMA) Responsible Care® programs. The APFO Users' product stewardship programs incorporate provisions (1) addressing the development and dissemination of health, safety, and environmental information; (2) adopting safe practices to limit risks to the community, customers, and employees from manufacturing and processing of fluoropolymer-based products; (3) establishing proper practices for effective health and safety management; and (4) instituting risk management approaches. These ongoing programs represent a substantial commitment of resources and efforts, and the activities described below are evidence of that commitment.

B. Toxicology Research

A number of the toxicology studies relevant to APFO that have been submitted to EPA, some of which were conducted in the early 1970s, were funded by fluoropolymer industry members, including the users and manufacturers of APFO. More recently, the studies conducted were organized and coordinated by the Toxicology Working Group of the Fluoropolymer Committee of APME. These studies, contained in AR226, examine acute and chronic health effects and include two carcinogenicity studies, a two-generation developmental and reproductive study, and studies of effects on tissues and organs, including in the liver, pancreas and reproductive organs, in laboratory animals.

Other studies have provided information on the physical and chemical characteristics of APFO and its potential effects in a variety of species, including fish, microorganisms and other species. The APFO Users' commitment to support EPA's efforts is demonstrated through the FMG and the APME research programs.

C. Workplace Product Stewardship Activities Directed Toward Protecting Fluoropolymer Manufacturing Employees

As a matter of good industrial hygiene practice, the APFO Users have occupational health and safety programs to protect their employees, including those who handle APFO in fluoropolymer manufacturing. Over the years, as more information has become available, 3M has provided information on APFO to the fluoropolymer manufacturers, along with recommendations for proper handling and use. Among the most significant changes in handling was the decision to sell the substance in a wet form to reduce dusting and thereby employee exposure. Additional precautions to prevent skin contact and otherwise limit exposure include the use of protective clothing, gloves, face shields, and respirators, disposable garments, installation of general mechanical and local exhaust ventilation systems, and other handling practices as recommended in the manufacturer's MSDS. These precautions, the effects of

APFO, and other important information are discussed with employees as part of ongoing Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS) programs and on MSDS and product labels.

All the companies adopted these various practices to keep employee exposures below the current American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of an eight-hour time-weighted-average (TWA) of 0.01 milligram per cubic meter (mg/m^3). The companies have used industrial hygiene monitoring to document the efficacy of control measures and employee exposures as needed. The companies remain committed to meeting the occupational standards and guidelines recommended by organizations such as ACGIH as they are updated.

D. Existing Product Stewardship Activities Directed Toward Customers

APFO Users have long-standing product stewardship programs that incorporate the principles and practices similar to those of the Responsible Care® program as it applies to obligations to customers. They have worked collectively and individually to provide health, safety and environmental information to customers and distributors. Commensurate with product risk, they select and periodically review customers and distributors to foster proper use, handling, recycling and disposal as well as the transmittal of appropriate information to downstream users. If improper practices involving a product are identified, the APFO Users work with the customer or distributor to improve those practices. Each of the companies evaluates its business relationships in light of these principles.

The APFO Users, with other FMG members, have worked for many years to assure that people who work with fluoropolymers have sufficient information to use them safely. As required under the OSHA HCS, the FMG companies have routinely included information about safe handling of their products on MSDS, including information about toxicity, protective equipment, and safe methods and practices. In addition, the companies have collectively worked to disseminate widely safety and health information using additional methods and documents, going beyond what current law requires.

One of the first collective efforts in this regard was the creation of a *Guide to the Safe Handling of Fluoropolymer Resins* (Safe Handling Guide) in 1992. A 3rd Edition was published in 1998, incorporating the recommendations from all the manufacturers of fluoropolymer resins, and a copy already has been provided to EPA. Those recommendations included chapters on Potential Health Effects, Regulations, Safety Measures, Waste Disposal, and Emergency Measures. Although focused on fluoropolymer resins, the Guide includes information on some ingredients, including surfactants, used in fluoropolymer resins. Health effects of some by-products also were included.

The Chapter on Safety Measures has extensive discussions of steps to take to avoid exposure to hazardous chemicals that might be present when processing fluoropolymers. Specific emphasis was placed on using local exhaust ventilation because of the by-products of thermal degradation, and information was provided on specific processing activities and their

unique associated hazards. Recommendations included required protective clothing and equipment, such as respirators and gloves, as well as other garments to prevent skin contact. Finally, an extensive education effort was conducted through SPI FPD's semi-annual meetings and seminars on the Safe Handling Guide and its updates.

The effort to update the Safe Handling Guide, now in its 3rd Edition, and other documents is an ongoing process that normally involves processor members of the FPD. Information on APFO will be included and highlighted.

In addition, the FMG prepared and published its *Guide to the Safe Handling of Fluoropolymer Dispersions* in October 2001 that describes APFO and related compounds and their use in fluoropolymer dispersions in detail. This document is currently being updated and a revised copy will be provided as soon as it is available.

Appendix 1

Partial List of Studies on APFO in EPA's Docket

Studies funded by APFO Users and manufacturers:

1) Fayerweather, "Liver Study of Washington Works Employees Exposed to C8: Results of Blood Biochemistry Testing," January 15, 1981;
2) Gortner, E.G. (1981). "Oral Teratology Study of T-2998CoC in Rats." Safety Evaluation Laboratory and Riker Laboratories, Inc. Experiment No. 0681TR0110, December 1981;
3) Gortner, E.G. (1982). "Oral Teratology Study of T-3141CoC in Rabbits." Safety Evaluation Laboratory and Riker Laboratories, Inc. Experiment No. 0681TB0398, February 1982;
4) Riker (1983). "Two-Year Oral (Diet) Toxicity/carcinogenicity Study of Fluorochemical FC-143 in Rats." Riker Laboratories, Inc., Experiment No. 0281CR0012, May 1983;
5) Staples, R.E., Burgess, B.A., and Kerns, W.D. (1984). "The embryo-fetal toxicity and teratogenic potential of ammonium perfluorooctanoate (PFOA) in the rat." *Fundamental and Applied Toxicology*, vol. 4, pp. 429-440;
6) York, R.G. (2002). "Oral (Gavage) Two-generation (One Litter per Generation) Reproduction Study of Ammonium Perfluorooctanoic Acid (PFOA) in Rats." Argus Research laboratories, Inc. Protocol Number 418-020, March 26, 2002;

Studies funded by APFO Manufacturers:

7) Gilliland, F.D. (1992). "Fluorocarbons and Human Health: Studies in an Occupational Cohort." Doctoral dissertation. Minneapolis (MN), University of Minnesota;
8) Gilliland, F.D. and Mandel, J.S. (1993). "Mortality among employees of a perfluorooctanoic acid production plant." Journal of Occupational Medicine, vol. 35, pp. 950-954;
9) Gilliland, F.D. and Mandel, J.S. (1996). "Serum perfluorooctanoic acid and hepatic enzymes, lipoproteins and cholesterol: a study of occupationally exposed men." American Journal of Industrial Medicine, vol. 29, pp. 560-568;
10) Olsen, G.W., Gilliland, F.D., Burlew, M.M., Burris, J.M., Mandel, J.S. and Mandel, J.H. (1998). "An epidemiologic investigation of reproductive hormones in men with occupational exposure to perfluorooctanoic acid." Journal of Occupational and Environmental Medicine, vol. 40, pp. 614-622;
11) Olsen, G.W., Burris, J.M., Burlew, M.M., and Mandel, J.H. (2000). "Plasma cholecystokinin and hepatic enzymes, cholesterol and lipoproteins in ammonium perfluorooctanoate production workers." Drug and Chemical Toxicology, vol. 23, pp. 603-620;
12) Alexander, B.H. (2001a). "Mortality Study of Workers Employed at the 3M Cottage Grove Facility." Minneapolis (MN), University of Minnesota;
13) Alexander, B.H. (2001b). "Mortality Study of Workers Employed at the 3M Decatur Facility." Minneapolis (MN), University of Minnesota;

14) Olsen, G.W., Logan, P.W., Simpson, C.A., Burris J.M., Burlew, M.M., Lundberg, J.K., and Mandel, J.H. (2001a). "Descriptive Summary of Serum Fluorochemical Levels among Employee Participants of the Year 2000 Decatur Fluorochemical Medical Surveillance Program." St. Paul (MN), 3M Company. U.S. EPA Docket AR-226-1030a020a;
15) Olsen, G.W., Burlew, M.M., Hocking, B.B., Skratt, J.C., Burris J.M., and Mandel, J.H. (2001b). "An Epidemiologic Analysis of Episodes of Care of 3M Decatur Chemical and Film Plant Employees," 1993-1998. St. Paul (MN), 3M Company. U.S. EPA Docket AR-226-1030a02;
16) Olsen, G.W., Burris, J.M., Burlew, M.M., and Mandel, J.H. (2003). "Epidemiologic assessment of worker serum perfluorooctanesulfonate (PFOS) and perfluorooctanoic acid (PFOA) concentrations and medical surveillance examinations." Journal of Occupational and Environmental Medicine, in press;

Recent toxicological reviews funded by APFO Users and APME:

17) An assessment prepared for the Association of Plastics Manufacturers in Europe and SPI entitled "Genotoxicity, Carcinogenicity, Developmental Effects and Reproductive Effects of Perfluorooctanoate: A Perspective from Available Animal and Human Studies," December 19, 2002; and
18) Environmental Health Research Foundation, "Summary and Analysis of Health Data on Perfluorooctanoic Acid (PFOA)," March 5, 2003.

Addendum III

Manufacture of APFO

Responsible manufacturing of APFO requires that the parties undertaking that manufacture meet certain environmental, health and safety standards. Accordingly, when manufacturing APFO for a commercial use in the United States, a responsible manufacturer will first notify EPA, and will review their product stewardship program with EPA covering the provisions listed below. For purposes of this addendum, manufacture means to make or produce for commercial use at a facility in the United States; importation of APFO for use in manufacturing or processing fluoropolymers is not included.

1) Limit total annual emissions in the US from each site where manufacturing of APFO occurs, using technology reasonably available that reduces APFO emissions to less than 500 pounds per year (a 99% reduction compared to prior manufacturing technology as reported in the documents contained in EPA's docket); and
2) Sell or resell APFO in accordance with ACC or SOCMA good product stewardship codes; and
3) Offer voluntary blood testing for employees, conduct industrial hygiene monitoring in the work areas where APFO is made or processed, and, based on the results, take steps to control the exposures to levels at least as low as the ACGIH TLV, by assuring that appropriate protective equipment and safe handling practices are used, and continue to provide and update employee training on safe handling; and
4) Monitor groundwater and surface water for APFO in the vicinity of the facility, conduct air modeling studies based on available technology for air monitoring for APFO at the facility; maintain off-site exposure below the West Virginia screening levels; and
5) Beginning in the year after production commences, and continuing for five consecutive years following, for the prior calendar year, report to EPA biennially, on a calendar year basis (unless otherwise provided in individual agreements with EPA and state regulatory agencies), within 180 days of the end of the reporting period, annual production volume of APFO, their emissions per facility (air, water, waste), summary reports on groundwater and surface water monitoring results, workplace industrial hygiene monitoring, and summary data on employee blood monitoring results (taking steps to preserve employee confidentiality).

D

Preliminary Framework for Enforceable Consent Agreement Data Development for PFOA and Telomers

Background

As indicated in the Agency's *Federal Register* notice (68 FR 18626; April 16, 2003) on perfluorooctanoic acid (PFOA) and fluorinated telomers, EPA is interested in developing enforceable consent agreements (ECAs) under section 4 of the Toxic Substances Control Act (TSCA) to identify environmental fate and transport information, as well as other relevant information to enhance understanding of the sources of PFOA in the environment and the pathways by which human exposure to PFOA is occurring.

EPA anticipates that the ECA process will focus on data needs issues beyond or supplemental to those contained in the industry letters of intent (LOIs) (3M, OPPT-2003-0012-0007; Fluoropolymer Manufacturers Group (FMG), OPPT-2003-0012-0012; Telomer Research Program (TRP), OPPT-2003-0012-0013; and all three groups jointly, OPPT-2003-0012-0016). All documents referenced in this Framework with OPPT-2003-0012 designation numbers can be found in the electronic docket on EPA's website at www.epa.gov/edocket/ by using the "Quick Search" feature to locate the specific document number.

EPA will not pursue additional health effects testing of PFOA through this ECA process. At this time, and for the purpose of this ECA process, EPA considers that the existing database of hazard information, as augmented by additional studies already underway, presents an adequate understanding of PFOA toxicity.

Independently of this ECA process, EPA has nominated a number of fluorochemicals for inclusion in the next National Health and Nutrition Examination Survey (NHANES) conducted by the Centers for Disease Control and Prevention (CDC). If the CDC includes these chemicals in the NHANES survey, the NHANES data would provide a national baseline for current general population exposures to these chemicals via human blood samples. If blood samples are analyzed for fluorochemicals over time, this would allow the tracking of trends to determine whether exposures are increasing or decreasing over time. Accordingly, EPA will not pursue human biomonitoring through these ECAs, although targeted sampling might be considered in the future if warranted by data produced through ECAs, voluntary activities, CDC studies, or other information available to EPA..

EPA anticipates that multiple ECAs may result from this process. For example, separate ECAs may be negotiated for telomer chemicals and products and for fluoropolymer chemicals and products, where the issues presented by these chemicals and products prove to be different and where test batteries differ. In addition, it may be possible to come rapidly to agreement and closure on certain data needs involving standard test protocols and screening-level data. In that instance, an ECA for the generation of screening-level data may be signed while negotiations continue on the need for other data to be developed by more advanced and/or new protocols. For example, biodegradation testing may be an area for which an ECA could be developed rapidly.

Similarly, ECA testing requirements may be tiered, providing that subsequent testing in certain areas would depend on the outcome of screening studies.

All data to be developed under this ECA process will be subject to the requirements of EPA's Quality Assurance Guidelines (EPA Order 5360./A2, May 2000), which can be found at www.epa.gov/quality/. These guidelines may require the preparation of a written Quality Assurance Project Plan (QAPP) describing the project design, the methods to be used, the project organization and responsibilities, and specific quality assurance and quality control activities that will be implemented to achieve specified data quality goals or requirements. Information on QAPPs and other quality management and quality assurance tools are available on EPA's website at www.epa.gov/quality/qatools.html. In addition, all testing required by a TSCA Section 4 ECA will be conducted in accordance with the EPA Good Laboratory Practice Standards (GLPS) found at 40 CFR part 792.

TSCA includes provisions which allow manufacturers, processors, and distributors to designate data which they believe are entitled to confidential treatment, making them exempt from public disclosure, and to submit those data separately from information which will be publicly accessible (15 USC 2613). EPA's regulations regarding confidential business information (CBI) are found at 40 CFR Part 2, Subpart B (see also, 5 USC 552). EPA anticipates that certain items referenced in this Preliminary Framework Document may be claimed as CBI, possibly including specific chemical identities, product formulations, and production volumes. No CBI information will be discussed or disclosed in public meetings or documents. Where CBI information is involved in this ECA process, EPA will work directly with the submitter to ensure both that CBI is protected and that the goals of this ECA process will be met.

Introduction

In this document, EPA presents for discussion a preliminary framework for the development of data that the Agency believes would be appropriate to address the outstanding PFOA source and exposure questions identified in the *Federal Register* notice. This document is intended as a discussion guide for the June 6, 2003 meeting, not as a predetermined list of information needs defining the outcome of the ECA process.

This document is presented in two parts, accompanied by two appendices. The two document sections, *Telomer Data Needs* and *Fluoropolymer Data Needs*, present brief identifications of overarching needs, with tables listing possible test substances and study protocols. Appendix A, *Rationales for Proposed Fate Testing and Monitoring and Sampling Activities*, provides more detailed explanations of and rationales for the specific tests and protocols identified in the tables in the first two sections. Appendix B, *Determination of Test Substances*, provides examples and explanations of how specific test substances, which are only identified generally in the tables in the Preliminary Framework Document, may be determined during the ECA process.

Telomer Data Needs

In their LOI (OPPT-2003-0012-0013), the member companies of the Telomer Research Program (TRP) announced their commitment to analyze products containing telomer chemicals and articles treated with telomer products, including "aged" products and "in use" articles, for the presence of PFOA; to characterize potential releases of PFOA from telomer-based product and article manufacture; to analyze possible biodegradation of telomer-based polymeric products; and to evaluate the fate and disposal routes for telomer-treated articles in the United States. The term "products" in this context generally refers to chemical formulations, including fire fighting foams and either dry or liquid coatings for factory applications, while the term "article" refers to an item of commerce to which a telomer product formulation has been applied, such as carpet or textiles. As described in the LOI, the focus of the TRP product, article, and manufacturing analysis is on the presence of PFOA in products, articles, the manufacturing workplace, and in manufacturing releases and waste streams.

EPA requested clarification of some of the TRP LOI commitments on April 30, 2003 (OPPT-2003-0012-0030). TRP responded on May 9, 2003. The TRP response and attachments can be found in the docket at OPPT-2003-0012-0049 through 0054.

Fate, Biodegradation, and Incineration

There is some evidence to suggest that the degradation of telomers to PFOA in the environment may be a stepwise process. To gain a better understanding of possible pathways, EPA believes that screening for the presence of precursors to PFOA formation, as well as for PFOA itself, is appropriate. Such precursors could include, for example, residual monomer telomer alcohols present in polymeric products.

The TRP LOI commitments include biodegradation studies on various telomer alcohols, telomer products, and telomer-treated articles. These biodegradation studies appear to be screening-level studies, predominantly involving 28-day ready or inherent biodegradation studies. The final report for a ready biodegradability test of 14C labeled 8-2 telomer B alcohol is expected May/June 2003. Protocols have been submitted for inherent biodegradation testing of telomer based polymeric products and polymeric products. These studies are expected to be conducted during the second and third quarter of 2003. Results indicating that these substances undergo biodegradation would trigger further fate testing on the biodegradation products. Negative results from these studies will be evaluated in the context of the study design and test conditions, including test duration, to make a determination as to how widely the results can be applied. One possible result is that EPA may request that the test duration be extended. Regardless of the outcome of these tests, EPA believes that longer term biodegradation studies, conducted under environmentally realistic conditions, may be necessary to provide confirmation that the data from the shorter-term studies accurately characterize the true long-term degradation potential of these chemicals. For the purposes of the ECA, EPA will seek to incorporate these

LOI screening-level data results into a more general decision process for testing beyond the screening level.

Many telomer-based products or telomer-treated articles may be subject to disposal by incineration, particularly in municipal incinerators, which operate at lower temperatures than hazardous waste incinerators. The strength of the carbon-fluorine bond suggests that very high heat would be needed to break the bond and destroy the fluorinated compound, and that lower-temperature incineration processes might instead release PFOA or PFOA precursors into the environment. EPA considers it important to develop an understanding of the incineration products of telomer chemicals, products, and treated articles.

Monitoring

With respect to characterizing releases from telomer-based product and article manufacture, EPA believes that screening-level environmental monitoring in the immediate vicinity of all telomer manufacturing facilities, as well as a selection of facilities from different industries that apply telomer products to end-use articles, is appropriate. In addition, it may be useful to characterize releases attributable to dispersive uses of telomer products that are associated with direct discharges into the environment, such as the use of fire fighting foams which contain telomer chemicals as fluorosurfactants. Accordingly, EPA is suggesting possible sampling and monitoring activities addressing the potential presence of PFOA and of PFOA precursors in air, water, soils, sediments, and biota at telomer manufacturing and use facilities, and at locations where fire fighting foams may be discharged into the environment.

Information concerning blood levels in workers may help to identify and characterize the sources and pathways of exposure, and may be contemplated in the future depending upon the results of monitoring for PFOA and PFOA precursors in the vicinity of telomer manufacturing and use facilities, and upon other information available to EPA. EPA will not pursue blood monitoring as part of this ECA process.

Product Stewardship

One additional area of information which EPA believes is necessary concerns an overall improved understanding of industry's product stewardship efforts with respect to the products and issues for which PFOA is a concern. Accordingly, EPA considers the reporting of specific product stewardship information as a data need which should be discussed during this ECA process. Product stewardship information may include, but is not limited to, descriptions of worker training and labeling and other hazard communication tools, descriptions of guidance provided to downstream users of products and articles (including, for example, specific processes to be used during factory applications of coatings), and steps to control and reduce exposures, releases, and wastes.

EPA has identified potential data needs for telomer chemicals, products, and treated articles in Table I. Some of these needs appear to be met in whole or in part under the TRP LOI commitments, and are identified in the following table with an asterisk (*). This ECA process offers the opportunity to further refine and develop related testing and approaches to address needs or to generate data that go beyond those expressed in the existing TRP LOI commitments.

EPA recognizes that the suggested test methods identified in the table may need to be modified in light of the unique properties of these fluorinated chemicals. EPA requests that available understanding of and experience with these chemicals and their unique properties be made available as part of this process to enable the identification and selection of appropriate representative test substances.

Where possible, example test substances or chemicals have been identified in the table or suggested in Appendix B, but the actual test substances will be determined during this ECA process. Test substances should be representative of products currently in commerce.

In some cases, for the purpose of the ECA process, telomer-treated or telomer-containing products are of interest, and general types of products have been identified for testing. In other cases, PFOA precursors in telomer chemical products have been identified as either potential test substances or as substances which should be the subject of screening and detection tests. In this latter case, a broad scan of telomer products, accompanied by appropriate speciation and quantitation, could assist in identifying the appropriate precursors for testing under an ECA.

E

Enforceable Consent Agreement Development for Perfluorooctanoic Acid (PFOA) and Fluorinated Telomers

Summary of June 6, 2003 Public Meeting

One hundred and ninety-one people attended the initial enforceable consent agreement (ECA) meeting on PFOA and the telomers at EPA Headquarters in Washington, DC on Friday, June 6, 2003, from noon to 5:00 PM. The meeting participants represented 49 registered interested parties, numerous observers, and EPA staff. Groups speaking at the meeting expressed support for EPA's actions and a willingness to work toward agreements on the data needs identified in EPA's Preliminary Framework document. Copies of the attendance list, the meeting agenda, and the four opening statements submitted in writing to the Agency can be found in the electronic docket, OPPT-2003-0012. A verbatim transcript of the proceedings will be placed in the docket within three weeks of the meeting. The next Plenary meeting will be held in Washington, DC on July 10, 2003.

Summary of Opening Statements

EPA and six interested parties made opening statements at the meeting.

- EPA welcomed the meeting participants, provided an overview of the ECA process, and noted that the goal of this process is to obtain agreements to develop data to clarify the sources of PFOA in the environment and the pathways leading to exposure. EPA reiterated statements made in the *Federal Register* notice and in the preparatory materials for the meeting that the Agency would not be pursuing additional PFOA toxicity testing or blood monitoring through this ECA process. EPA noted that pharmacokinetics studies are already underway in the private sector, and that EPA has nominated PFOA and related chemicals to the Centers for Disease Control and Prevention as candidates to include in the next National Health and Nutrition Examination Survey, which monitors chemicals in human blood. EPA stated that it saw no need to duplicate these activities in the ECA process. EPA also noted that it is continuing its efforts to refine a preliminary risk assessment on PFOA. EPA stated that a further developed, revised version of the preliminary risk assessment would be submitted to the EPA's Science Advisory Board for review later this year, in a public process that will allow for the consideration of issues specific to that assessment, and that the preliminary assessment would thus not be discussed in the context of these ECA proceedings.

- The Center for Regulatory Effectiveness indicated that all information disseminated by the Agency during the ECA process and with regard to the Agency's developing risk assessment on PFOA must meet the requirements of the Agency's information quality guidelines.

- The Little Hocking Water Association commented that its rural water system contains about 2 ppb of PFOA, and that its citizens are thus exposed to PFOA through their water supply. The Association requested that, during this ECA process, the EPA remember this local community and provide data and information in which these citizens can have confidence.

- The Environmental Working Group stated that any CBI claims with respect to PFOA toxicity or exposure data must be denied; that companies must submit to EPA all existing health and exposure data relating to PFOA and telomers; that the ECA process must include blood monitoring studies; and that the ECA process should include PFOA exposure from heated non-stick appliances.

- DuPont recognized that many questions have been raised by EPA and others about the potential risks associated with exposure to PFOA, and expressed its commitment to investigate past and current sources of exposure; to further reduce exposure pathways; and to provide information needed to allow for the development of an accurate, science-based assessment of risks. DuPont stated that there have been no known adverse human health effects associated with PFOA in the more than 50 years of PFOA use by DuPont and others.

- The Telomer Research Program (TRP) noted that questions have been raised about the potential for telomer products to transform to PFOA. TRP stated that it is actively working to identify the relevant routes by which telomer products may transform to PFOA and, if they do, to what degree these transformations take place and if there may be human or environmental exposure of consequence. TRP urged EPA to take a comprehensive and holistic approach to understanding environmental and human exposure to develop a risk assessment on PFOA and its salts that would include PFOA manufacture and use, the potential contribution by discontinued PFOS-based products, and telomers.

- The Fluoropolymer Manufacturers Group (FMG) of the Society of the Plastics Industry (SPI) stated that it is committed to working with the EPA to define the routes of exposure to the public and the environment; to characterize the health implications of that exposure; and to significantly reduce the potential exposure sources from the fluoropolymer industry. FMG also noted that fluoropolymers have many important uses in a wide variety of vital industries, and that PFOA is an indispensable polymerization aid in the manufacture of those products.

Discussion

EPA provided a brief overview of the Preliminary Framework document that was circulated to interested parties and placed in the docket on May 21, 2003 (OPPT-2003-0012-

0056). In the discussions that followed, agreement in principle was reached on most of the EPA data needs described in the Preliminary Framework, and it was agreed that further discussion of these data needs should occur in three technical workgroups. The technical workgroups were tasked to work out the technical details of testing and/or reporting programs for the agreed-upon data needs that can be developed into ECAs. The initial task set for each workgroup was to receive a detailed briefing from industry on the specifics of the commitments covered by the industry Letters of Intent (LOIs), and to determine what details beyond the terms of the LOIs should be negotiated through the workgroups as part of the ECA process. A fourth workgroup was tasked to develop a roadmap for addressing confidential business information (CBI) and proprietary information within the ECA discussions for PFOA and the telomers, as it relates to market information (data need number 1 in Tables I and II of the EPA Preliminary Framework), test substances, and article identity. Draft ECA products from the workgroups will be brought back to the Plenary Group for discussion and concurrence.

The four technical workgroups and their participants and focus are:

- ***Confidential Business Information (CBI) Workgroup***

  Participants: EPA, the Consumer Product Safety Commission (CPSC), 3M, the Environmental Working Group (EWG), the Fluoropolymer Manufacturers Group (FMG), the Telomer Research Program (TRP), and the Tuppers Plains-Chester Water District.

  Objective: Develop a roadmap to meaningfully communicate, within the PFOA ECA process, information regarding marketing data, test substance(s), and article identity in a way that preserves proprietary information and satisfies the needs of EPA and the interested parties.

- ***Environmental Monitoring Workgroup***

  Participants : EPA, 3M, EWG, FMG, TRP, the Little Hocking Water Association, environmental consultants Bennett & Williams, the WV Class Action Plaintiffs group, the National Center for Policy Research for Women and Families, consulting toxicologist Rich Purdy, and the Tuppers Plains-Chester Water District.

  Objective: To develop ECA proposal(s) for screening-level environmental monitoring of PFOA and PFOA precursors as identified by the Plenary Group. The initial focus will be for data needs identified in item 10 of Table I and item 10 of Table II of the EPA Preliminary Framework document, specifically addressing environmental sampling and monitoring in the vicinity of telomer and fluoropolymer manufacturing and use facilities. The interested parties were

supportive of using the existing 3M and DuPont analytical protocols and sampling methods as a starting place to develop analytical protocols and sampling methods specifically addressing PFOA data needs under the ECA. In addition, the Workgroup will develop considerations for site selection in monitoring studies.

- ***Fluoropolymer Workgroup***

  Participants: EPA, CPSC, 3M, FMG, EWG, and Bennett & Williams.

  Objective: To develop ECA proposal(s) for data needs identified in items 2, 7, 8, 9 and 11 of Table II in the EPA Preliminary Framework document, specifically addressing: (a) the physical/chemical (p-chem) properties of the fluoropolymers; (b) the presence of PFOA emitted from fluoropolymer-treated products and articles as they age during use for those products and articles not included in the LOI commitments; (c) determining the incineration byproducts of fluoropolymers and fluoropolymer-treated articles and determining the p-chem, fate, and transport properties of those byproducts; and (d) product stewardship information.

- ***Telomer Workgroup***

  Participants: EPA, CPSC, 3M, EWG, TRP, and Rich Purdy.

  Objective: To develop ECA proposal(s) for telomers and telomer-treated products as identified by the Plenary Group. The initial focus will be for the data needs identified in items 2, 3, 4, 5, 6, 7, 8, 9, and 12 of Table I of the Preliminary Framework document prepared by EPA, specifically addressing: (a) P-chem properties to inform fate testing for telomer chemicals not included in the industry-sponsored LOI; (b) elucidation of degradation pathways and identification of degradation products; (c) determination of p-chem, fate and transport properties of major degradation products; (d) determination of incineration byproducts of telomers and telomer-treated products and articles; (e) determination of p-chem, fate and transport properties of major incineration byproducts; (f) presence/quantification of PFOA precursors in telomer chemical products and in telomer-treated or telomer-containing products and articles; (g) presence of PFOA precursors emitted from telomer-treated products and articles as they age during use; and (h) product stewardship information.

Agreement in principle was not reached on several data needs identified in the EPA Preliminary Framework, and these will receive additional discussion in the Plenary. These include the need for data assessing the potential biodegradation products and pathways of fluoropolymers, and conducting a release and exposure assessment for PFOA and PFOA precursors from telomer-based fire fighting foams. With respect to the first set of issues, the

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Item 10. Release and exposure assessments adjacent to Telomer manufacturing and use facilities; also of control areas

EPA Monitoring Data Needs (DRAFT 9/21/03)

Data Need	LOI Commitment	Additional data need beyond LOI	EPA Proposal to Address Data Needs
Manufacturing			
Manufacturing Releases Information on releases of PFOA and PFOA precursors to air, water, wastewater, landfill leachate from manufacturing facilities	Data on PFOA and limited precursor releases to air, water, wastewater, landfill leachate. Continued monitoring of releases	Monitoring data on release of precursors	Analysis of discharge wastewater, air, solid wastes samples for known or suspected precursors (eg. 8-2 alcohol, carboxylic acid, olefinic acid)
Manufacturing Sites Concentration of PFOA and PFOA precursors in air, surface water, groundwater, soil, biota, wastewater, landfill leachate at manufacturing facilities	Surface water, groundwater, wastewater landfill leachate, data from manufacturing sites	Monitored concentrations of PFOA and PFOA precursors in air, soil, biota	Monitoring of PFOA and PFOA precursors in air, soil, biota (eg. plants, herbivores, avian terrestrial species, fish, aquatic species) at manufacturing facilities

Item 10. Release and exposure assessments adjacent to Telomer manufacturing and use facilities; also of control areas
EPA Monitoring Data Needs (DRAFT 9/21/03)

Data Need	LOI Commitment	Additional data need beyond LOI	EPA Proposal to Address Data Needs
Off Site from Manufacturing Concentration of PFOA and PFOA precursors in air, surface water, groundwater, soil, and biota, down gradient from manufacturing facilities	Surface water, groundwater data down gradient from manufacturing sites Limited biota data	Measured concentrations of PFOA and PFOA precursors in air, soil, additional biota	Monitoring of PFOA and PFOA precursors in air, soil, biota (plants, herbivores, avian terrestrial species) monitoring data at distance from manufacturing facilities. Data should be sufficient to allow screening level characterization of environmental concentration outside the manufacturing facility site, and to identify limit of environmental contamination

Item 10. Release and exposure assessments adjacent to Telomer manufacturing and use facilities; also of control areas

EPA Monitoring Data Needs (DRAFT 9/21/03)

Data Need	LOI Commitment	Additional data need beyond LOI	EPA Proposal to Address Data Needs
Use			
Use Releases Information on release of PFOA and PFOA precursors to air, water, wastewater, sludges from use facilities	Composite information on process releases from user facilities representing different use industries Modeling of releases from user facilities Pilot scale mill study	Monitored data on release of PFOA and PFOA precursors to air, water, wastewater, sludges from processing/use facilities sufficient to characterize concentrations and their variability	Monitoring of PFOA and PFOA precursors to air, water and wastewater at representative use sites to allow preliminary screening level assessment of releases associated with different use industries
Use Sites Concentration of PFOA and PFOA precursors in air, surface water, groundwater, soil, biota wastewater, landfill leachate at use facilities	Modeling of PFOA concentration in air, water, groundwater	Measured concentrations of PFOA and PFOA precursors in air, surface water, groundwater, wastewater, soil, sludges, biota at representative use facilities	Monitoring studies at facilities representative of different user industries. Initially 5-10 "worst case" sites associated with each use (carpet, paper, textiles). Monitoring should be designed to provide scoping baseline data to inform future site selection if needed, and to allow qualification efforts to reduce releases. Number of sites and locations dependant on information about number and location of user facilities Monitoring data should be collected sufficient for screening level characterization of PFOA and PFOA precursor concentrations in environmental media at the site and released from the site. Screening level study design is site/industry dependant, but may include 5-10 surface water samples upstream, at the site and downstream, 6-20 wells with quarterly groundwater sampling, 5-10 air samples, monthly wastewater sampling, quarterly sludge sampling if discharges go to POTW, 20-50 soil samples, 20-50 biota samples

Item 10. Release and exposure assessments adjacent to Telomer manufacturing and use facilities; also of control areas
EPA Monitoring Data Needs (DRAFT 9/21/03)

Data Need	LOI Commitment	Additional data need beyond LOI	EPA Proposal to Address Data Needs
Off site from use facilities Concentration of PFOA and PFOA precursors in air, surface water, groundwater, soil, and biota down gradient from use facilities	none	Measured concentrations of PFOA and PFOA precursors in air, surface water, groundwater, wastewater, soil, sludges biota down gradient from use facilities	Surface water, groundwater wastewater, air, soil, biota (plants, herbivores, avian terrestrial species) monitoring studies around use facilities Data sufficient for a screening level characterization of environmental concentration away from use site, and to identify spatial limit of environmental contamination Wastewater and sludges from POTW receiving discharge from use facilities should be included