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VIA FEDERAL EXPRESS AND ELECTRONIC MAIL

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Re: USEPA and ATSDR Activities Related To PFOA: For AR-226/EPA-HQ-OPPT-2003-0012/EPA-HQ-OW-2007-1189/TSCA 8(e) Public Files/Dockets

Dear Directors Johnson and Frumkin and Regional Administrators Mathur, Welsh and Werner:

Recently, information has been released suggesting that certain 'industry sources'¹ or other "political" sources² have been trying to persuade USEPA to

¹ See *InsideEPA's* "Superfund Report" for 11/19/07, at 24-25.

² See, e.g., U.S. Government Accountability Office, "Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information

discontinue or delay its efforts to pursue further toxicity and exposure research on perfluorooctanoic acid ("PFOA"). In a February 21, 2008, *Federal Register* Notice, USEPA confirmed that it does not now plan to complete its PFOA risk assessment work "for several years, as a number of important studies are underway." 73 *Fed. Reg.* 9629, at 9652 (Feb. 21, 2008). On behalf of our clients who continue to be exposed to this poison in their residential drinking water on a daily basis, we write to express our strong opposition to such continued delay and to express our support for prompt completion of all work necessary to allow USEPA to complete its assessment and full public disclosure of human health risks associated with exposure to PFOA. We also write to express our support for ATSDR promptly completing and releasing its report regarding human exposure to PFOA in the West Virginia and Ohio communities with PFOA drinking water contamination and its report on health concerns associated with the presence of PFOA in human breast milk. We also support inclusion of PFOA on USEPA's Contaminant Candidate List 3 and support formal regulation of PFOA as a drinking water contaminant.

We first wrote to USEPA seeking the Agency's assistance in a prompt investigation of PFOA human health risks more than seven years ago.³ At that time, we notified USEPA that we had uncovered information confirming that E.I. du Pont de Nemours and Company ("DuPont") had known since at least 1984 that PFOA released from its Washington Works Plant along the Ohio River near Parkersburg, West Virginia, was contaminating the public drinking water supplies of tens of thousands of Ohio and West Virginia residents but had not reported that information to USEPA or the surrounding communities. We also noted that the level of PFOA in the public drinking water had been exceeding DuPont's own internal safety limit for PFOA in public drinking water for over a decade and that there were internal toxicity and health studies, including a 1981 study of birth defects among babies born to DuPont's Washington Works employees, that also had not been reported. We asked USEPA in 2001 to take immediate action to investigate and respond to the issue.

Over the next several years, we submitted numerous letters and information packages to the Agency highlighting the ever-increasing scope of contamination of residential drinking water supplies with PFOA, as such contamination was revealed in Ohio, West Virginia, and New Jersey communities near DuPont's manufacturing plants and in the Minnesota and Alabama communities near manufacturing facilities operated by the 3M Company. Our letters included some of the only data available confirming elevated levels of PFOA and other perfluorochemicals found in the blood of residents, including children, exposed to the contaminated drinking water in Ohio, West Virginia, New Jersey, and Minnesota. Although USEPA cited to information we provided through such letters as support for the enforcement lawsuit USEPA brought against DuPont in

System" (GAO-08-440) (March 2008); Union of Concerned Scientists, "Interference at the EPA: Science and Politics at the U.S. Environmental protection Agency" (April 2008).

³ See March 6, 2001, Letter from Robert A. Bilott (USEPA-AR-226-1246) (extra copy of letter attached at Exhibit A).

2004 for failure to report PFOA drinking water contamination and human health data,⁴ it appears that many of the letters we sent providing that information are no longer readily available to the public. In particular, it appears that much of the information we provided to the public TSCA 8(e) docket is no longer available on USEPA's on-line TSCA 8(e) web page⁵ and that the on-line webpage has not been updated for many months.

In the meantime, the state agencies faced with having to respond to the contaminated residential water supplies have been requesting guidance from USEPA and ATSDR on the safety of PFOA in residential drinking water and resulting contamination of human blood and breast milk. Although USEPA has released several draft hazard assessments and risk assessments for PFOA since 2001, none have been finalized. In addition, although USEPA has taken steps to initiate the process for evaluating PFOA through the IRIS process, USEPA has not publicly released any draft of any such assessment.⁶ Although it was publicly-stated years ago that ATSDR was working on an evaluation of health risks, including risks arising from PFOA contamination of human breast milk, arising from PFOA-contaminated drinking water in Ohio and West Virginia,⁷ ATSDR also has not yet released a draft of any such report and has not clarified if or when it intends to do so.

The process for completing USEPA's risk assessment for PFOA already has stretched over many years. USEPA first released a draft risk assessment in 2003. Over the next several years, USEPA indicated that it could not finalize its risk assessment for PFOA until it had been reviewed and approved by USEPA's Science Advisory Board's ("SAB's") independent PFOA Review Panel. Initiation and completion of that additional review process was repeatedly delayed, but eventually resulted in a final report and recommendation that USEPA revise the risk assessment in May of 2006. In particular, the PFOA review Panel told USEPA that it had underestimated the potential risk of cancer⁸ and other health effects from PFOA and advised USEPA to

⁴ USEPA later settled that case against DuPont for \$16.5 Million – the largest administrative civil penalty in the Agency's history. The United States also initiated a criminal investigation into DuPont's involvement with PFOA in 2005, which was inexplicably and suddenly dropped last year.

⁵ One of the other sources for our submissions, USEPA's Administrative Record 226 ("AR-226") also still remains unavailable online. Our most recent submissions to the public docket established under the PFOA TSCA ECA program (OPPT-2003-0012) also do not appear to have been made available yet. We strongly support making all of this information readily available on-line or at least updating the existing dockets, including the TSCA 8(e) docket.

⁶ Although it appears USEPA prepared a draft IRIS assessment for a related perfluorochemical, PFOS, more than five years ago and discussed the draft with the 3M Company, it does not appear that the draft was ever released for public comment or shared at the time with any of the State agencies looking for guidance on PFOS in residential drinking water after 3M's comments were received. See Exhibit B.

⁷ See ATSDR/Ohio Dept. Health, "2006 C-8 Physician Reference" (July 1, 2006) (ATSDR "is currently writing a public health consultation document to address the [C-8] contaminated water and infant formula/food question in further detail.")

⁸ The potential cancer risk was recently highlighted by the University of Minnesota study 3M submitted to USEPA's AR-226 docket February 20, 2008, confirming elevated rates of death from prostate cancer and cerebrovascular disease among 3M workers exposed to PFOA. Recent research also suggests that an important cancer mechanism may have been missed in USEPA's prior PFOA assessments. See Tilton, et al., "Genomic Profiling Reveals an Alternative Mechanism for Hepatic Tumor Promotion by

perform a risk assessment more thoroughly addressing such risks to humans.⁹ Although it has now been almost two years since that report and recommendation was submitted to USEPA, USEPA has not released any revised risk assessment or IRIS review for PFOA and has now confirmed that it does not intend to do so for at least "several years." Consequently, no further formal guidance has been forthcoming from USEPA to the States as to appropriate safety levels for PFOA in residential drinking water.

Thus, as the presence of PFOA contamination of residential drinking water has spread into an ever-increasing number of communities over the last several years, some state agencies have moved forward on their own to address the immediate public health threat to their residents. For example, in 2007, the States of Minnesota, New Jersey, and North Carolina took steps to establish their own guidelines and standards for PFOA in residential drinking water. Minnesota also took the lead in preparing an ATSDR Public Health Assessment for PFOA contamination in Minnesota released for public comment in March 2008. Other state agencies, including those in West Virginia and Ohio, continue to claim to have insufficient resources and/or staffing to undertake such efforts on their own and continue to wait for additional guidance from USEPA and ATSDR to help them establish appropriate safe drinking water and breast milk/infant formula standards for PFOA. USEPA, however, continues to state publicly that some undefined additional research and data are necessary before it can release any additional advice.¹⁰ ATSDR has not said when or if it will release any additional guidance on the issue.

Yet, it appears that USEPA agreed to enter an agreement with DuPont in November 2006 when DuPont wanted to address these same issues. In 2005, DuPont had agreed to pay for the design, installation and operation of water treatment systems for public and private water supplies in Ohio and West Virginia where PFOA had been detected above the then-existing "quantification level" (at or above 0.05 parts per billion ("ppb")) for PFOA in drinking water. That agreement was secured under a settlement of a class action lawsuit (the "Leach Case") that had been brought by our clients against DuPont on behalf of the tens of thousands of residents who were drinking PFOA-contaminated water in West Virginia and Ohio. In the Spring of 2006, only months after the final settlement in the Leach Case, PFOA was reported for the first time to have been found at levels above 0.05 ppb in the water supply of the City of Parkersburg, West Virginia (near DuPont's Washington Works Plant along the Ohio River) and in water supplies near DuPont's Chambers Works Plant in New Jersey, and two new lawsuits were filed seeking the same type of water treatment benefits that DuPont had just agreed to provide to similarly-impacted communities under the Leach Case settlement. Yet DuPont, rather than simply agree to extend the same water treatment

Perfluorooctanoic Acid in Rainbow Trout," EHPonline, doi:10.1289/ehp.1190 (<http://dx.doi.org/>) (May 9, 2008).

⁹ It appears that no transcript was made of any of the PFOA Review Panel or SAB proceedings on this matter, despite significant public interest in the discussions.

¹⁰ See, e.g., 73 *Fed. Reg.*, at 9652 (Feb. 21, 2008).

benefits it had just agreed to in the Leach Case, appears to have been able to persuade USEPA to set a "site specific" threshold for providing clean water in the area around its West Virginia Plant that would be significantly higher than the 0.05 ppb level DuPont already had just agreed to under the Leach Case settlement and higher than the levels being found in the water in Parkersburg and New Jersey. Although the negotiations between USEPA and DuPont were not open to the public, documents obtained through pending litigation with DuPont suggest that EPA agreed to DuPont's request to set a threshold for providing clean water or water treatment at 0.5 ppb, ten times higher than the level DuPont already had just agreed to under the Leach Case settlement, and agreed to memorialize the deal in a Consent Order announced publicly on November 22, 2006.¹¹

Since the 0.5 ppb number for short-term drinking water exposure was announced by USEPA for use around DuPont's West Virginia plant,¹² DuPont has refused to provide clean water or water treatment for the residents of Parkersburg or New Jersey with PFOA-contaminated drinking water. USEPA's announcement of the 0.5 ppb number agreed to with DuPont also apparently influenced the Minnesota Department of Health to initially adopt the same 0.5 ppb number as its official State Health Risk Limit for PFOA in drinking water, although MDH has since indicated that it intends to reduce that number.¹³ DuPont also has since referred to the USEPA's involvement with selection of the 0.5 ppb number in its efforts to try to persuade New Jersey's Department of Environmental Protection ("NJDEP") to replace its current, more appropriate 0.04 ppb guideline for PFOA in drinking water¹⁴ with the 0.5 ppb number preferred by DuPont or an even higher number.

It has now been approximately a decade since USEPA first learned of the existence of PFOA (and related perfluorochemicals) in the environment and in human blood. More than seven years have passed since we first reported to USEPA the presence of excessive levels of PFOA in residential drinking water supplies, and more than five years have passed since USEPA first announced the commencement of its formal investigation into the sources and effects of PFOA in the environment and

¹¹ Although it is not clear why USEPA agreed to DuPont's requests in this regard, documents recently obtained in ongoing litigation with DuPont confirm that there have been a number of high-level communications between DuPont and USEPA during the late 2005 to late 2006 time frame in which DuPont has sought and obtained USEPA's assistance in publicly supporting DuPont's views on the "safety" of PFOA and related products. See Exhibit C (non-confidential deposition transcript of Michael McCabe and non-confidential exhibits) (although several of the exhibits to the transcript are marked "confidential," DuPont has since withdrawn its confidentiality claims over the ones attached).

¹² The DuPont/USEPA 11/06 Consent Order indicates that the 0.5 ppb number is "site specific" and solely for use by the parties to the Order for the purposes of that Order around that West Virginia plant site.

¹³ As indicated in public comments filed with USEPA last week by Minnesota State Senator Katie Sieben, there is concern in Minnesota that the PFOA levels set in that State may now be too high, given more recent health/toxicology data. See Exhibit D.

¹⁴ NJDEP also filed public comments with USEPA last week indicating that NJDEP believes that more current health/toxicology data indicates that even NJDEP's 0.04 ppb guideline for PFOA in drinking water may be too high to protect human health. See Exhibit E. Other environmental organizations agree that USEPA should act quickly to regulate PFOA in human drinking water. See Exhibit F.

humans. It has likewise been more than five years since USEPA released its draft risk assessment for PFOA, and almost two years since the SAB recommended important revisions to that risk assessment, including consideration of important cancer risks. It has also been almost two years since it was publicly reported that ATSDR would be releasing additional guidance on the issue of PFOA in human breast milk and drinking water.

We support and commend USEPA's efforts over the last several years to work toward the elimination of PFOA production and use in commerce. Yet, we believe that it is equally if not even more important to address the present threats from "legacy issues" of the already-existing contaminated residential drinking water supplies, contaminated landfills, waste sites, rivers, streams, groundwater, soils, air, dust, and other existing PFOA waste, including contaminated human blood and breast milk. The existing, purely voluntary potential "phase out" of PFOA manufacturing use or releases years from now, while commendable for potentially reducing future exposures, will do nothing to address or remove the already-existing contamination. Even if PFOA were required to be completely eliminated from commerce tomorrow in some enforceable way, the biopersistent and bioaccumulative nature of the toxin guarantees that the PFOA already released and already existing out in the environment will remain indefinitely unless and until steps are taken to clean it up. As the years roll by, tens of thousands of people, including children and the elderly, continue to drink PFOA-contaminated water (or breast milk, in the case of infants) on a daily basis and the PFOA, due to its biopersistence, continues to accumulate in their bodies/blood and in the bodies/blood of their children.¹⁵ Unfortunately, the toxin appears to accumulate to the highest levels through drinking water exposure in some of the most sensitive/vulnerable subpopulations – the youngest children and the elderly.¹⁶

On behalf of our clients, we strongly oppose any position that USEPA or ATSDR further delay or suspend those activities necessary for the agencies to promptly complete their work on PFOA and to release appropriate public guidance and regulations for the toxin. We strongly support immediate completion of that work and public reporting of the results so that appropriate guidance can be delivered to the public agencies and citizens who are relying on USEPA and ATSDR for help on these issues. New studies and data will continue to be released, as is the case with essentially every other chemical. As USEPA and ATSDR have done in the past, the new studies should be evaluated to determine whether present agency conclusions warrant modification; but the present conclusions should not be held by the agencies

¹⁵ Under the "C-8 Health Project" we established under the Leach Case settlement, PFOA blood samples and health information were collected from approximately 70,000 people exposed to PFOA-contaminated drinking water supplies in West Virginia and Ohio. Some early, preliminary results from analysis of that have just been released suggesting significantly elevated PFOA blood levels, particularly in young children and the elderly, and potential effects on the liver, immune system, and thyroid, along with potentially increased cholesterol in children. See Exhibit G.

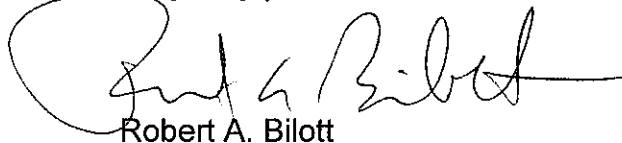
¹⁶ See, e.g., Emmett, et al., "Community Exposure to Perfluorooctanoate: Relationships Between Serum Concentrations and Exposure Sources," *J. Occup. & Environ. Med.* 48(8): 759-770 (2006). See also Exhibit G.

while researchers continue their work. Waiting yet another "several years" to complete the PFOA work¹⁷ in the hopes that some "better" or more "complete" data may come along is too long for those drinking the contaminated water (or breast milk) every day to continue to wait. This concept was recognized in a recent international conference through the Faroes Statement:

The accumulated research evidence suggests that prevention efforts against toxic exposures to environmental chemicals should focus on protecting the embryo, fetus and small child as highly vulnerable populations. Given the ubiquitous exposure to many environmental chemicals, there needs to be renewed efforts to prevent harm. Healthier solutions should be researched and proposed in future work. Prevention should not await definitive evidence of causality when delays in decision-making would lead to the propagation of toxic exposures and their long-term, harmful consequences.¹⁸

Our clients have worked hard over the last seven years to assist USEPA and ATSDR to evaluate all the necessary and available data so that the agencies can provide appropriate guidance on PFOA. We are committed to continuing to assist your agencies in this regard. Please let us know if there is anything we can do to help you complete these important activities in a timely manner.

Very truly yours,



Robert A. Bilott

RAB:mdm
Enclosures (by FedEx only)

¹⁷ With respect to some of the additional research USEPA is pursuing, it is unclear what conflict of interest process was followed by USEPA before it recently awarded a \$750,000 STAR ("Science to Achieve Results") grant for PFOA work to a group of investigators that includes at least one individual for whom public comments previously were submitted to USEPA (in connection with selection of the SAB PFOA Review Panel members) alleging "a distinct bias against USEPA guidelines for evaluating risk and precautionary approaches to environmental regulation." (See Exhibit H)

¹⁸ Grandjean, et al., "The Faroes Statement: Human Health Effects of Developmental Exposure to Chemicals in Our Environment," 102 Basic & Clin. Pharm. & Toxicol. 73-75 (2007).