

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION**

<p>IN RE: AQUEOUS FILM-FORMING FOAMS PRODUCTS LIABILITY LITIGATION</p>	<p style="text-align:center">MDL No. 2:18-mn-2873-RMG</p> <p style="text-align:center">This Document relates to ALL CASES</p>
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**TELOMER MILSPEC AFFF MANUFACTURERS’ SUPPLEMENTAL FILING AFTER
AUGUST 19, 2022 ORAL ARGUMENT**

As the Court instructed at the August 19, 2022 oral argument, the Telomer MilSpec AFFF Manufacturers provide the accompanying documents (1) dated after the FFFC email of October 30, 2003 (Pl. Ex. 231) and before 2016 showing that the United States, including EPA, knew that telomer MilSpec AFFF could degrade to PFOA; and (2) demonstrating that DoD and its branches have been taking action since the 1980s to mitigate the impact of training with MilSpec AFFF. In accordance with the Court’s Order (ECF No. 2547), the Telomer MilSpec AFFF Manufacturers also respond to the exhibits Plaintiffs submitted on August 24, 2022.

I. Documents Showing Government Knowledge of PFOA from Telomer AFFF.

Along with numerous previously-submitted exhibits dating back to 2000,¹ the following additional documents address the Court’s question regarding the government’s, including EPA’s, knowledge between October 30, 2003 and EPA’s May 2016 Lifetime Health Advisory for PFOA that telomer MilSpec AFFF could degrade to form PFOA in the environment.²

- **TMM Ex. 67 at 5**: March 9, 2004 EPA presentation explaining that telomers are used as a “[s]urfactant in fire fighting foams” and that “PFOA may be formed in the environment via the biodegradation and metabolism of some telomers.”

¹ See, e.g., ECF Nos. 1965, 1969, 1971, 2141, 2348 (Def. Exs. 100, 109, 110, 112, 120, 122, 125, 126, 127, 136, 138, 139; TMM Exs. 2, 4, 5, 6).

² For the Court’s convenience, we have highlighted the relevant portions of the exhibits.

- **TMM Ex. 68 at 4:** [REDACTED]
- **TMM Ex. 69 at '363, '368:** [REDACTED]
- **TMM Ex. 70 at slide 8:** June 8, 2006 EPA presentation explaining that “PFOA may also be formed by degradation of telomers . . . not made with PFOA” and that “[r]esidual monomers in telomers can degrade.”
- **TMM Ex. 71 at 1–2:** December 12, 2006 summary of the “Aqueous Film Forming Foam (AFFF) Discharge Assessment Team” meeting, attended by, among others, EPA and the Navy, including Mr. Doug Barylski of NAVSEA. The summary states that Ms. Dominiak of EPA recommended that the group “identify classes of AFFF concentrate formulations by their carbon chain lengths” and that “[p]roducts classified as eight-carbon chain length are known to contain or degrade to PFOS, PFOA or other perfluorinated surfactants with eight or more linked carbons in a straight chain or in a branched set.”
- **TMM Ex. 72 at '101, '104–'105:** October 29, 2009 EPA internal draft of the “Existing Chemicals Action Plan of Long-Chain Perfluorinated Chemicals (PFCs)” explaining that “[s]ome fluorotelomer based products are . . . used as high performance surfactants in . . . fire-fighting foams” and “PFOA also can be produced unintentionally by the degradation of some fluorotelomers, which are not manufactured using PFOA but could degrade to PFOA.”

II. Documents Illustrating That DoD and Its Branches Have Been Taking Actions to Mitigate the Impact of AFFF Training Since the 1980s.

The documents that follow answer the Court’s question regarding actions DoD and its branches have been taking since the 1980s to mitigate the impact of training with AFFF.

- **Pl. Ex. 70 (Walker Dep.) at 115:2–116:5, 120:5–13:** Explanation by Mr. Frederick Walker, Chief Fire Protection Engineer for the Air Force from 1987 to 2014, that training exercises using unlined facilities “stopped” in the “mid-1980s” and the “use of AFFF went down dramatically.”
- **TMM Ex. 73 (Walker Dep.) at 835:8–836:2:** Confirmation by Mr. Walker that “from the early ‘90s on, most live fire training was done with propane,” with “water as the agent used to extinguish the fire as opposed to AFFF.”
- **Pl. Ex. 35 (Farley Dep.) at 173:25–176:3:** Explanation by Mr. John Farley of the NRL that Navy schools switched to propane-based fire training likely “in the ‘90s” and recalling in particular that a new propane trainer was built in Newport, Rhode Island while he was there in the 1990s.

- **Def. Ex. 100 at '774:** October 2000 memo by Mr. Doug Dierdorf, Air Force toxicologist, recommending that the Air Force “[e]liminate use of AFFF for firefighter training purposes,” “[s]ubstitute ‘training’ foam where AFFF is currently used,” and “convert remaining base training pits to propane.”
- **Def. Ex. 109 at 18, 21:** [REDACTED]
- **Def. Ex. 122 at 2:** 2011 DoD Chemical & Material Emerging Risk Alert for AFFF noting that, “[a]lthough not allowed for use today, DoD has used unlined earthen areas/basins at many installations to support live firefighting training activities.”
- **Def. Ex. 139 at E-3:** September 24, 2014 DoD Information Paper explaining that “[d]ue to environmental concerns, military firefighting training facilities use propane fires, which eliminates the use of Class A (combustible solid), pooled Class B (flammable liquid), and Class C (electrical) fuel sources,” and “[a]s a result, there is no need to use AFFF during firefighting training evolutions, water only or water with a foam simulant is used.” The Paper also notes that “all foam manufacturers market a foam simulant that is recommended for training.”

III. Plaintiffs’ Additional Exhibits.

At the August 19 hearing, Plaintiffs referred to exhibits that had not been included in their briefing of the GCD motion. Per the Court’s August 19 Order, the PEC filed those exhibits on August 24, 2022. The Telomer MilSpec AFFF Manufacturers provide the following responses.

A. Pl. Ex. 260 (DL1878).

At the hearing, Plaintiffs’ counsel showed (in a demonstrative aid) only a small excerpt from Plaintiffs’ Exhibit 260 (DL1878) and suggested to the Court that [REDACTED]

In fact, the email shows just the opposite. In the paragraph right after the one Plaintiffs excerpted at the hearing, the author states: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

██████████ Pl. Ex. 260 at '162. ██████████

██████████

Though Plaintiffs described this document as the centerpiece of their argument about government knowledge during the August 19 hearing and further characterized it as newly-produced in July 2022, Plaintiffs have now confirmed that this is incorrect, and the email was actually produced more than a year ago, in June 2021. *See* ECF No. 2560 at 2 n.2. The reason this document was never mentioned in Plaintiffs' GCD briefs is because it does not in any way support their argument.

Regardless, as noted above (*see* Section I), there is no dispute that DoD and its branches knew many years before this 2015 email (including after October 30, 2003) that telomer MilSpec AFFF could degrade to PFOA. Thus, even if ██████████
██████████ that would be immaterial to the Telomer MilSpec AFFF Manufacturers' summary judgment motion.

B. Pl. Ex. 262.

Plaintiffs' Exhibit 262, an EPA presentation dated April 2007, likewise demonstrates EPA's continuing knowledge that "PFOA may also be formed by degradation of telomers" and that "[r]esidual monomers in telomers can degrade." Pl. Ex. 262 at 3 (slide 6). Thus, this document also further reinforces the timeline set forth in Section I, above.

C. Plaintiffs' Demonstrative Aids (Pl. Exs. 265 to 268).

Although the Telomer MilSpec AFFF Manufacturers appreciate the PEC's courtesy in providing copies of its various demonstratives, the out-of-context quotations and other assertions contained in these demonstratives are not evidence. The actual documents, outlined above, answer the Court's questions regarding whether and when the government knew that telomer AFFF could degrade to PFOA.

Dated: August 26, 2022

Respectfully submitted,

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/s/ Jonathan I. Handler

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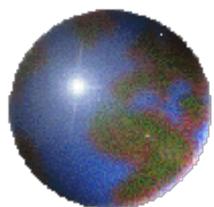
EXHIBIT LIST

<u>TMM EXHIBIT</u>	<u>DESCRIPTION</u>
67	Mary Dominiak (EPA), PFOS/PFOA: EPA Update on Perfluorinated Compounds, March 9, 2004 (FF_EPA011_00131796) (converted from native PowerPoint file)
68	NAVFAC, Alternative Environmentally Friendly Firefighting Foams, May 19, 2004 (FF_NAVY11_00068882)
69	Mary Dominiak (EPA) Email Correspondence regarding DELIBERATIVE: preliminary comments on Ohio physician factsheet on PFOA, and attached document, May 19, 2006 (FF_EPA011_00624363 & FF_EPA011_00624364)
70	EPA, Non-ECA PFOA Information Forum, June 8, 2006 (FF_EPA011_00851201) (converted from native PowerPoint file)
71	Aqueous Film Forming Foam (AFFF) Discharge Assessment Team, Draft Meeting Summary, Dec. 12, 2006 (PENNA-NAVY-020265)
72	EPA, Existing Chemicals Action Plan of Long-Chain Perfluorinated Chemicals (PFCs) (Draft), Oct. 29, 2009 (EPA003_00004101)
73	Deposition of Frederick K. Walker, Jr., May 21, 2021 (excerpt) ¹

¹ Excerpts of particularly long documents are provided for the Court's convenience; full length copies can be provided on request.

TMM EXHIBIT 67

Document Produced In Native Format



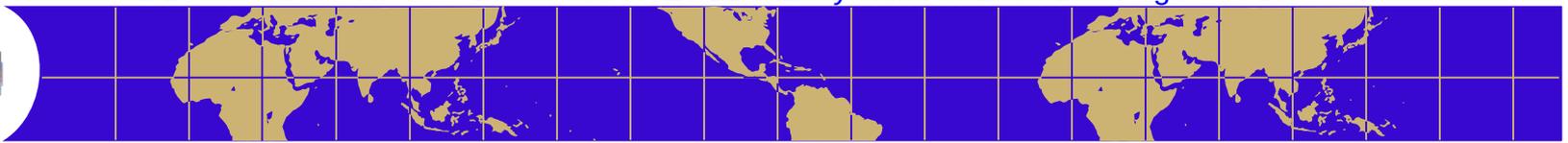
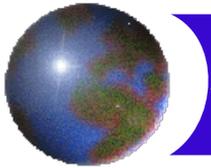
PFOS/PFOA: EPA Update on Perfluorinated Compounds

Mary F. Dominiak

U.S. Environmental Protection Agency

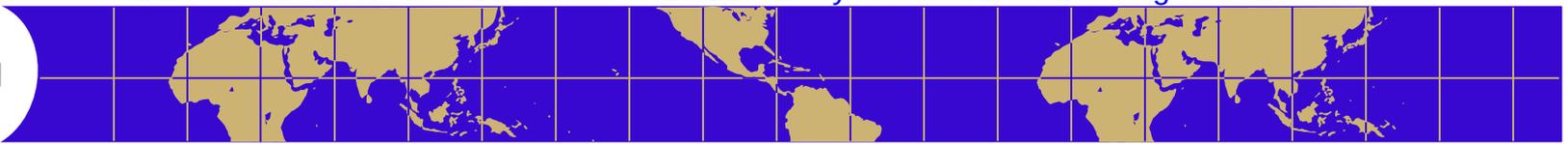
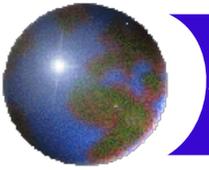
March 9, 2004

GCRC 2004



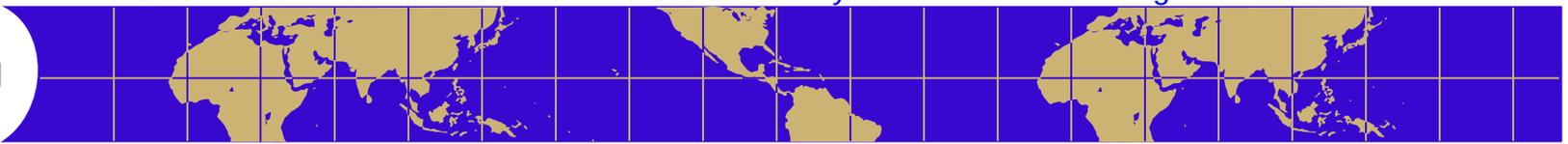
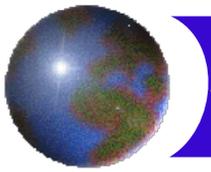
History: Initial EPA Focus

- ❖ EPA began investigating perfluorinated compounds in late 1999, based on new data on perfluorooctyl sulfonate (PFOS)
 - ❖ Present in human blood and environment worldwide; human half-life of years
 - ❖ Persistent; does not further degrade
 - ❖ Developmental and systemic toxicity in animal testing



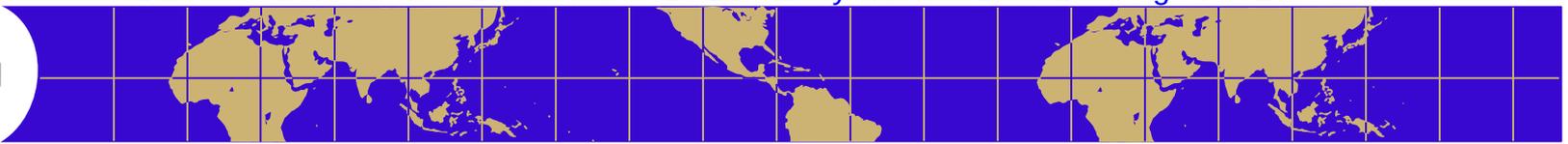
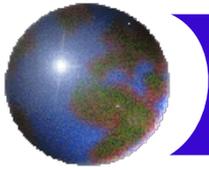
History: Initial EPA Focus

- ✚ EPA expanded investigation in 2000 to perfluorooctanoic acid (PFOA) and fluorinated telomers (small polymers)
 - ▣ PFOA also found in human blood in US, at lower concentrations than PFOS
 - ▣ PFOA is also persistent
 - ▣ PFOA toxicity in animal testing



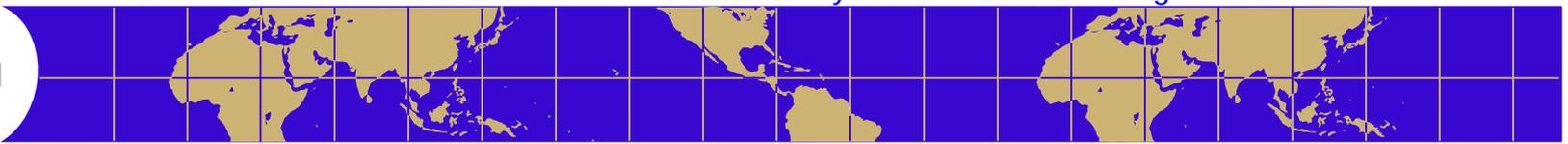
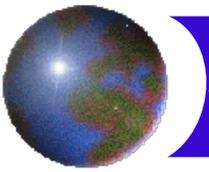
History: Definition and Source

- ✦ Perfluorooctanoic acid (PFOA) used only as an essential polymerization aid to make fluoropolymers
 - ✦ Enclosed process, controllable releases
 - ✦ PFOA not expected to be present in final fluoropolymer products except as trace contaminant; testing needed
- ✦ Fluoropolymers are widely used:
 - ✦ Industry uses in electrical/chemical/automotive/military/aerospace/medical/telecommunications/construction
 - ✦ Consumer uses in cookware coatings and breathable membranes for apparel, textiles



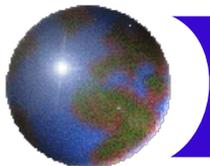
History: Definition and Source

- ❖ “Telomers” – small polymers not made with or incorporating PFOA – may be a source: PFOA may be formed in the environment via the biodegradation and metabolism of some telomers
- ❖ Telomers competed with and substitute for PFOS-based products:
 - ❑ Soil/stain/grease-resistant textile, carpet, paper coatings
 - ❑ Surfactant in fire fighting foams, cleaners



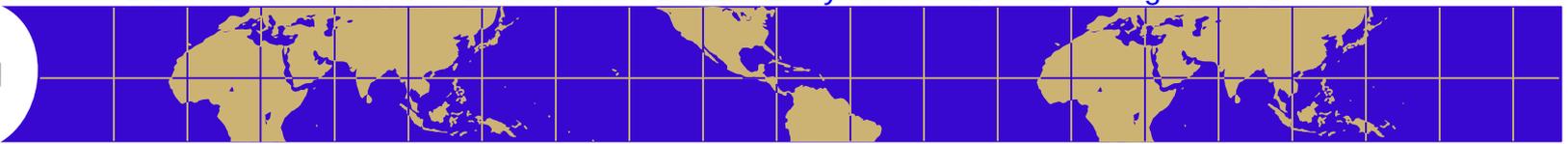
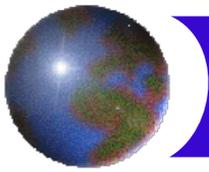
History: The Changing Picture

- ✚ 3M voluntarily began phase-out of PFOS in 2000, completed in 2002
- ✚ EPA published proposed and final Significant New Use Rules under the Toxic Substances Control Act in 2000 and 2002 to close out PFOS
- ✚ Industry began voluntary research on PFOA and telomers in 2000



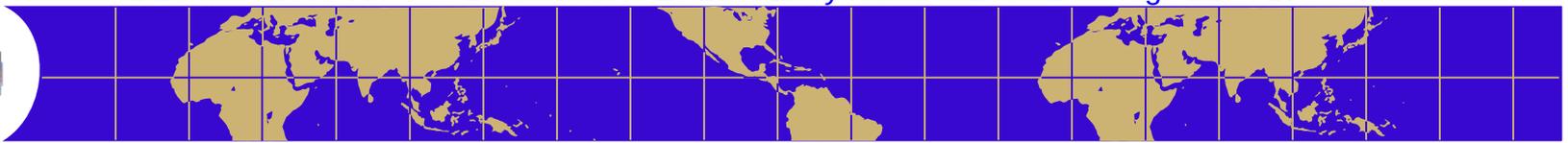
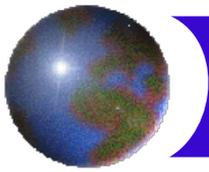
History: The Changing Picture

- ✚ Voluntary PFOA research produced additional concerns
 - ▣ Developmental effects in 2-generation rat study
- ✚ EPA released draft hazard assessments on PFOA in 9/02 and 11/02
- ✚ 3/03, Industry submitted Letters of Intent (LOI) outlining additional voluntary studies and other data generation efforts



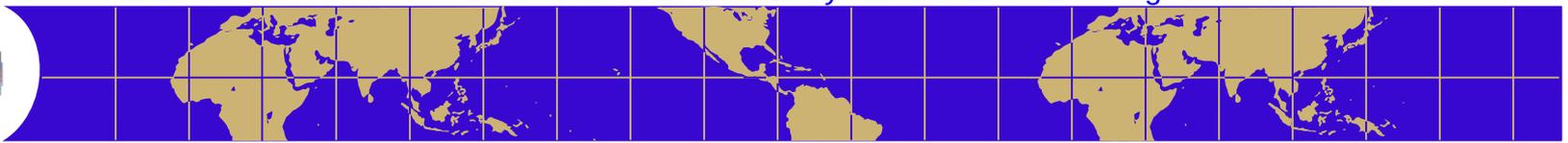
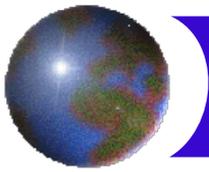
History: To The Present

- ✿ 4/03, EPA released Preliminary Draft Risk Assessment on developmental concerns, published FR notice soliciting parties for enforceable consent agreements (ECAs)
 - ❏ ECA focus is on understanding sources of PFOA in environment, pathways leading to human and environmental exposure
 - ❏ ECAs are an alternative to TSCA §4 test rulemaking: consent-based, published in FR



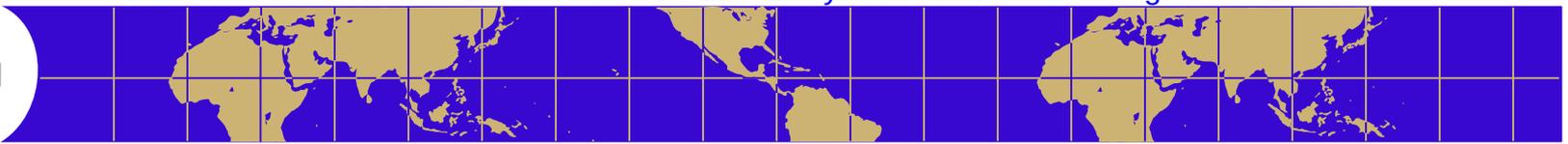
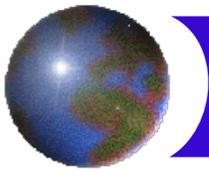
ECA Process

- ❖ Industry LOIs promise additional data:
 - ❖ Market and use information, p-chem data
 - ❖ Product and article contamination analysis
 - ❖ Monitoring/modeling for releases, mass balance
- ❖ ECAs seek to fill perceived data gaps
 - ❖ Incineration, degradation, article aging, environmental sampling and monitoring



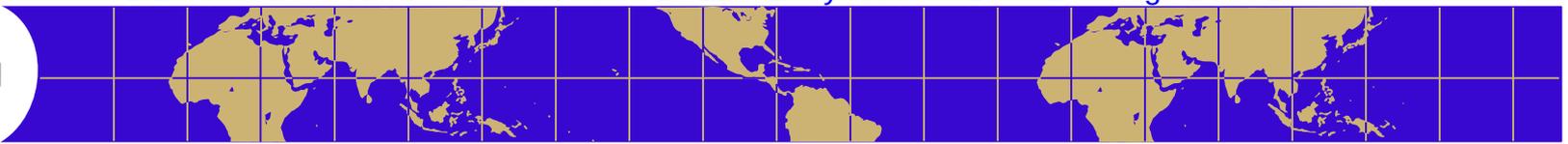
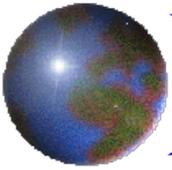
ECA Process

- ✿ Initial public meeting 6/03; 191 attendees, 50 registered Interested Parties
- ✿ Formed technical subgroups to pursue possible ECAs; meetings June 03-March 04
 - ✻ Fluoropolymer and telomer incineration
 - ✻ Telomer biodegradation
 - ✻ Fluoropolymer aged article analysis
 - ✻ Environmental sampling and monitoring



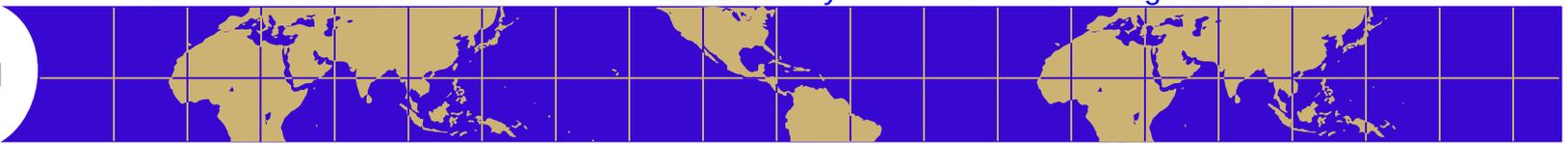
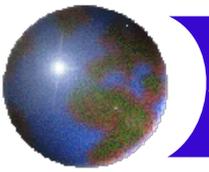
ECA Process

- ✦ Additional technical ECA meetings 3/30-31/04; next plenary session 4/1/04
- ✦ Goal: approve two incineration ECAs at 4/1/04 plenary; continue drafting committee technical work on telomer biodeg and fluoropolymer aged article testing ECAs
- ✦ 2/04: Fluoropolymer monitoring shifted into voluntary Memoranda of Understanding (MOUs) between 3M, DuPont, and EPA; MOUs being developed through public process
- ✦ ECA and MOU Process will continue into future



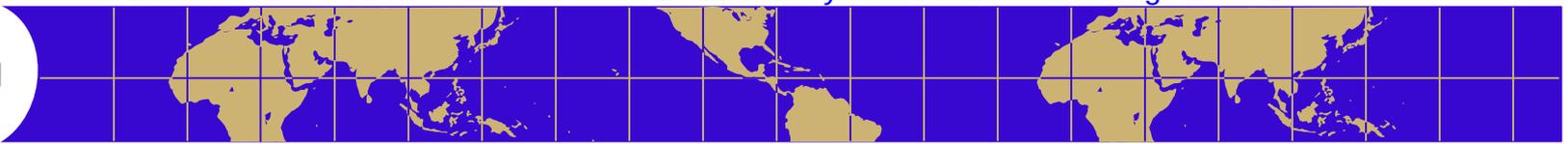
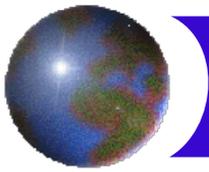
ECA Process

- ✚ ECA negotiation is public process, open to comment and participation
- ✚ Online docket: www.epa.gov/edocket/, use “Quick Search” to locate docket OPPT-2003-0012
- ✚ Extensive data repository in file AR-226: 14 CDs, electronic index available from oppt.ncic@epa.gov



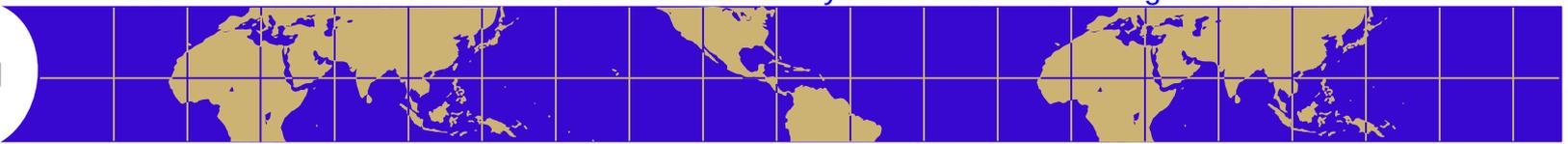
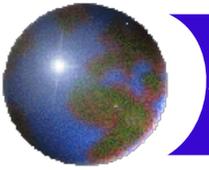
Additional Related Matters

- ❖ EPA proposed that CDC include PFOS, PFOA, and other perfluorinated chemicals in the next NHANES study
 - ❖ Provide baseline of human exposures to compare with current data and track future trends to assess release/exposure reductions
 - ❖ CDC included PFOS and PFOA as candidates in Class 1 list published September 30, 2003



Additional Related Matters

- ❖ EPA nominating to National Toxicology Program “class” study on perfluorochemicals
- ❖ EPA ORD engaging in additional research
- ❖ Spring 2004: EPA’s Science Advisory Board will review refined EPA risk assessment on PFOA addressing all hazard endpoints
- ❖ NIH grant for an Ohio PFOA community exposure assessment; schedule TBD



For Further Information ...

- ✚ Consult online docket and AR-226 data
- ✚ To receive email notification updates on current status of ongoing efforts, email dominiak.mary@epa.gov

TMM EXHIBIT 68

Confidential Document Place Holder Sheet

Confidential Documents Contemporaneously Submitted
to the Court for In Camera Review in Compliance with
CMO No. 17

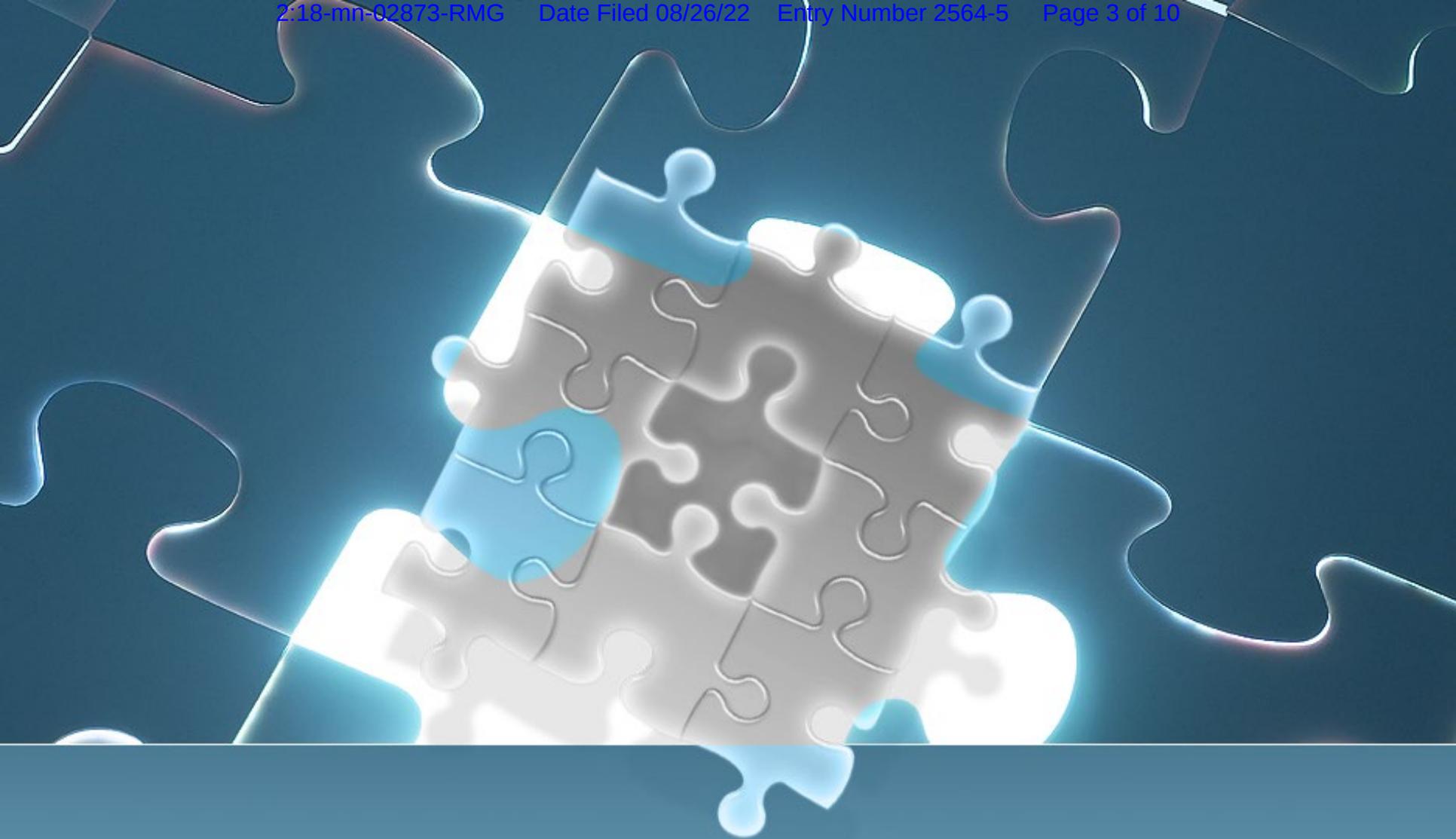
TMM EXHIBIT 69

Confidential Document Place Holder Sheet

Confidential Documents Contemporaneously Submitted
to the Court for In Camera Review in Compliance with
CMO No. 17

TMM EXHIBIT 70

Document Produced In Native Format



Non-ECA PFOA Information Forum

U.S. EPA, Washington, DC June 8, 2006



Non-ECA PFOA Information Forum

- Many activities are underway to help develop an understanding of PFOA and related chemicals
- Purpose of the Information Forum is to provide a summary of some of those activities; what types of information they may produce; when information may be available; and where information may be found as it is developed



Non-ECA PFOA Information Forum

- Program of Presentations
 - EPA: Background Information
 - EPA: Federal Government Activities
 - State of Minnesota
 - Environment Canada
 - Asahi
 - DuPont
 - Fluoropolymer Manufacturers Group



Background

- PFOA is perfluorooctanoic acid. EPA uses the “PFOA” acronym generally to describe both the acid and its salts
- The most commonly used of these chemicals is the ammonium salt, ammonium perfluorooctanoate, or APFO, also called C8
- APFO goes to PFOA in the environment. PFOA is persistent and does not break down



Background

- PFOA is of concern to EPA because:
 - PFOA is persistent in the environment
 - PFOA can bioaccumulate in living organisms
 - PFOA remains in the human body for years
 - PFOA is found at low levels in human blood and in the environment, even in remote places
 - Exposure to PFOA has caused adverse effects in laboratory studies in animals
 - Sources and pathways of PFOA exposure aren't understood, making reductions difficult



Background

- EPA has no information linking current levels of PFOA in the blood of the general public to any adverse health effects in people
- Additional study is still needed to understand these persistent chemicals
- While information is being developed, EPA is taking the prudent step of seeking to reduce possible sources now, to avoid potentially larger future problems



Background

- PFOA (as APFO) is used as polymerization aid in manufacture of fluoropolymers, which are used in many industries and consumer products
 - Non-stick cookware coatings; architectural coatings; chemical and fire-resistant cable; waterproof, breathable fabrics; etc.
- PFOA not expected to be found in most final fluoropolymer products except in trace amounts



Background

- PFOA may also be formed by degradation of telomers - small fluorinated polymers - not made with PFOA
 - Residual monomers in telomers can degrade
 - Whether polymer backbone degrades unknown
- Telomers are widely used in industrial and consumer products
 - Stain and water repellent surface coatings on carpets, textiles, paper; surfactant in cleaners, performance products, etc.

TMM EXHIBIT 71

**Aqueous Film Forming Foam (AFFF) Discharge Assessment Team
Draft Meeting Summary**

**12 December 2006
1330-1530**

Teleconference, AMSEC, Maritime Plaza

Participants

Jonathan Amson, EPA OWOW (via phone)	Dawn Schroeder, Navy, NSWCCD
Lisa Bacanskas, EPA-OPPT (via phone)	Rita Schuh, Navy, NSWCCD
Doug Barylski, NAVSEA 05P4 (via phone)	LCDR Jerry Slater, USCG (via phone)
Mary Dominiak, EPA-OPPT (via phone)	Gordon Smith, SEA 05M (via phone)
Virginia Fox-Norse, EPA-OWOW (via phone)	Michelle Aulson, Booz Allen Hamilton
Robert Neumann, Navy, NSWCCD	Debra DiCianna, AMSEC LLC (via phone)
Brian Rappoli, EPA-OWOW (via phone)	Matthew Worris, AMSEC LLC

Background

The purpose of the meeting was to review the Discharge Assessment Report (DAR) annotated outline, discuss the path forward for DAR completion, and discuss draft target language. During the meeting EPA, Navy, and Armed Forces representatives discussed EPA’s comments on the DAR annotated outline. Mr. Robert Neumann facilitated the meeting.

Review of DAR Annotated Outline

Mr. Neumann opened the meeting and asked Ms. Virginia Fox-Norse to discuss EPA’s comments on each section of the DAR annotated outline.

Section 1.0 – EPA representatives requested, and Navy concurred that the word “determination” should be replaced with “identification” when referring to the zero discharge MPCD. The intent of this change is to indicate that the zero discharge MPCD has been identified and not imply that the zero discharge standard has been established.

Section 2.0 – EPA representatives expressed concerns that the DAR does not adequately address discharge of AFFF discharges resulting from firefighting. Mr. Neumann explained that firefighting is not part of the AFFF discharge as defined by the UNDS regulation. Dr. Brian Rappoli stated that the scope of the UNDS regulation includes all discharges from Armed Forces vessels occurring within 12 nm; therefore, firefighting is still an issue and should be discussed in the DAR. Mr. Neumann clarified that UNDS regulation specifically states that only AFFF discharges resulting from training, testing, or maintenance operations are applicable; therefore, emergency discharges of AFFF, such as those that occur during firefighting, are not applicable. Ms. Dawn Schroeder proposed, and EPA representatives concurred, that the DAR should include a qualitative description of firefighting, as noted in the DAR annotated outline. EPA representatives requested the DAR not quote the exact Nature of Discharge (NOD) phrase that states there are no priority pollutants or bioaccumulators are known to be present in the AFFF discharge, because the statement does not accurately state current information about some AFFF products. Navy representatives concurred with summarizing the NOD’s findings and to provide an update based on current information.

Section 3.0 – Ms. Mary Dominiak requested that draft international standards and conventions relevant to AFFF constituents be incorporated into the DAR. Ms. Dominiak agreed to provide the references by 15 December. *[[UPDATE: Ms. Fox-Norse provided the references on 15 December 2006.]]*

Section 4.0 – Mr. Neumann restated that the vessels table had been moved to Appendix B and had been updated with an additional “vessel type” column, as previously requested by EPA. Ms. Rita Schuh reported that complete vessel descriptions will be included in the Technical Development Document (TDD) for Batch Two.

Section 5.0 – EPA representative requested that AFFF research efforts not be separated out in a text box but rather a subsection. Navy representatives concurred.

Section 6.0 – EPA representatives requested section 6.1, as previously discussed with Mr. Neumann and Ms. Schuh, include a list of suspected persistent, bioaccumulative, and toxic constituents (e.g., PFOS, PFAS, POSF). Navy representatives concurred.

Ms. Dominiak recommended that the DAR identify the classes of AFFF concentrate formulations by their carbon chain lengths rather than the manufacturing process that created them (i.e., eight-carbon chain vice ECF, six-carbon chain vice telomerization). The manufacturing process is not as materially related to environmental impact as the composition of the end product. Products classified as eight-carbon chain length are known to contain or degrade to PFOS, PFOA or other perfluorinated surfactants with eight or more linked carbons in a straight chain or in a branched set. Products classified as six-carbon chain contain perfluorinated surfactants primarily of chain lengths shorter than eight carbons. The tendency of this class of products to have environmental impacts comparable to that of PFOS or PFOA has not been determined. A third class of AFFF product that contains no perfluorinated surfactants of any chain length and may have adverse environmental impacts also needs to be discussed in the DAR. Navy representatives concurred.

Section 6.1.2.1 –EPA representatives requested clarification of the annotated outline section 6.1.2.1, "Explains that the AFFF discharge was not sampled, therefore, precise quantification of overboard discharges (e.g., constituent concentration) not possible." Mr. Smith recommended that the DAR include a qualitative analysis of shipboard releases of AFFF, including instances in which AFFF waste is containerized for shore disposal. Process knowledge is useful for this analysis and may provide sufficient results for the analysis. EPA representatives concurred.

Section 6.1.2.1 –EPA representatives requested clarification of annotated outline section 6.1.2.1 "Additional constituents in the AFFF discharge from outside sources are considered under other UNDS discharges (i.e., firemain, bilge, deck runoff)." Mr. Neumann explained that the AFFF DAR will not contain detailed discussions of other discharges but will identify and summarize functional interrelationships between shipboard systems and other discharges related to the AFFF discharge. This DAR issue covers two topics: the first topic will note that firemain constituents occur in AFFF discharge and will specifically identify constituents of concern, priority pollutants and bioaccumulators based on Phase I analysis of the firemain. The second topic will note that AFFF may be a constituent of other discharges, such as bilge and deck run off, and will indicate that a zero discharge standard for AFFF is not intended to

apply to residual amounts of AFFF inadvertently directed overboard from other shipboard systems within 12 nm.

Section 6.2 –EPA representatives expressed concern with Navy addressing collection and disposal costs and costs of updating directives addressing shipboard discharge of AFFF in the feasibility section. Navy representatives agreed to continue discussion at a later date.

[[UPDATE: During a conversation on 13 December 2006, Mr. Neumann, Ms. Schuh, and Ms. Fox-Norse concurred that updating the MRC cards and other guidance documents would not be a Phase II cost. This will be a Phase III, implementation cost. Navy and EPA also concurred there should not be any cost associated with not discharging inside 12 nm, because this is our current practice.]]

Section 6.3 –EPA representatives requested the DAR deviate from the normal UNDS environmental effects analysis (EEA) format. Additionally, the EEA section should address specific concerns with the environmental impacts of discharging AFFF beyond 12nm. EPA representatives recommended that the EEA section include a general discussion on environmental effects of AFFF constituents. EPA representatives explained that the intent is to reflect the fact that some AFFF constituents are both persistent and bioaccumulative. Navy representatives agreed to provide a discussion on general concerns and the transportation routes and fate of AFFF in the worldwide environment. EPA representatives recommended that the DAR include a discussion that the zero discharge within 12 nm MPCD does not necessarily mean zero environmental impact within 12 nm. Navy representatives concurred. Navy representatives recommended that the DAR not provide specific figures on environmental impacts such as Appendix D of the DAR annotated outline. EPA representatives concurred that the DAR describe what limited water quality criteria are available, but provide a qualitative discussion on the environmental impacts of PFOS and PFOA.

At the close of the DAT meeting some agenda items still needed discussion. Mr. Neumann and Ms. Fox-Norse agreed to discuss the remaining sections of the DAR annotated outline during a teleconference on 13 December. Mr. Neumann will continue drafting version 2 of the DAR, based on comments received at the DAT meeting.

New Action Items

1. EPA (Ms. Dominiak) to provide the relevant sources for section 3.0 (***Complete: 12/15/06***).
2. Navy (Mr. Neumann) and EPA (Ms. Fox-Norse) to hold further discussions as the Navy drafts version 2 of the DAR (*Due Date: ongoing*).
3. Navy (Mr. Neumann) to drafting version 2 of the DAR, based on comments received at the 12/12/06 DAT meeting (*Due Date: TBD*).
4. Navy (Mr. Neumann) and EPA (Ms. Fox-Norse) to schedule the next DAT meeting (*Due Date: TBD*).

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Final Action Plan due to OD on November 10, 2009

**Existing Chemicals Action Plan of
Long-Chain Perfluorinated Chemicals (PFCs)¹**

**Perfluoroalkyl Sulfonate (PFAS) Chemicals and
Perfluoroalkyl Carboxylate (PFAC) Chemicals**

I. Action Decision

The PFAS and PFAC are found world wide in the environment, wildlife, and humans. They are persistent in the environment, wildlife, and humans. They are bioaccumulative in wildlife and humans. They are toxic to laboratory animals and wildlife. Fortunately, to date, significant adverse effects have not been shown in humans. This is presumably due to the fact that body burdens have not yet reached critical levels. However, given the long half-life of these chemicals in humans (years), it can reasonably be anticipated that continued exposure could increase body burdens to levels that will result in adverse outcomes.

To expand the reach of the 2010/15 PFOA Stewardship Program (PFOA SP) achievements beyond the eight participating companies and further address the concerns for potential PFAC exposure through the use and disposal of fluorotelomer-treated articles, OPPT is considering developing regulation under TSCA § 6 to ban or severely restrict the use of PFAC in articles (including imports). Such a rule could be targeted to enter into force at the conclusion of the PFOA SP (i.e., January 1, 2016) and could also contain provisions to prevent any domestic resumption of activities covered by the PFOA SP. Because the U.S. is a major user of products containing fluorotelomers, such an action in the U.S. would likely exert a major influence on the global marketplace.

To expand the reach of SNURs on PFAS chemicals, OPPT is considering developing further regulation under § 5(a)(2) or § 6 to ban or severely restrict the use of PFAS chemicals in articles (including imports). Such a rule would be targeted to enter into force before 2015.

Commented [tk1]: TBD : This will change based on management decisions.

II. Introduction

Action plans comprise initial evaluations of the potential risks presented by chemicals based on EPA's review of available hazard, exposure, and use informationⁱⁱ and consideration of potential

ⁱ The term PFCs in this document refers only to chemicals described in the chemical identity section including certain polymers that contain perfluorinated moieties; but does not include other PFCs, particularly those having shorter chain lengths. The same hold for PFAS and PFAC chemicals.

ⁱⁱ Information sources customarily employed include Inventory Update Reporting (IUR) submissions; Toxic Release Inventory (TRI) reporting; data submitted to the HPV Challenge Program; existing hazard and risk assessments performed by domestic and international authorities including but not limited to U.S. Federal government agencies,

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actions that EPA could initiate under the Toxic Substances Control Actiii (TSCA) to address those risks. Action plans do not constitute either final Agency determinations as to risk or final determinations as to whether sufficient data are available to characterize risk for the purpose of making statutory findings. Proceedings initiated to address the recommendations in these action plans to further assess, characterize, and manage risk will include opportunities for public and stakeholder comment as well as the evaluation of additional information.

Commented [tk2]: This is draft language still under development, intended to be uniform.

The information used by EPA for this Action Plan includes the OECD assessments of PFOS (Ref. 1) and PFOA (Ref. 2), OPPT's draft risk assessment of PFOA (Ref. 3), Environment Canada's assessment (Ref. 4), the assessment of PFOS by Stockholm Convention on Persistent Organic Pollutants (Ref. 5), and other sources. The summary of the toxicity information is based on these previous assessments, and where appropriate additional information on lower and higher chain lengths is provided. OPPT is currently working with the Office of Water to update the PFOS and PFOA assessments which is scheduled to be completed in late 2010 or early 2011.

III. Scope of Review

The PFC chemicals included in this review are considered a category represented by the similar chemical structure as required under 15 USC 2625(c)(2)(A). The two related PFC sub-categories are perfluoroalkyl sulfonate (PFAS) chemicals and perfluoroalkyl carboxylate (PFAC) chemicals.

Continuing contributions of PFAS/PFAC to the environmental/human reservoir need to be addressed using a category approach because all the chemicals are PBT chemicals or degrade to PBT chemicals, and because a chemical-by-chemical analysis would be impractical.

The PFAS/PFAC precursors may be polymers that are coated on a specific substrate. This action is only considering the contribution of precursors as a source of PFAS/PFAC and not the inherent toxic effects of the polymer or exposure to dust that contains fluorinated polymers.

PFAS sub-category

The PFAS sub-category includes perfluorohexane sulfonic acid (PFHxS) and perfluorooctane sulfonic acid (PFOS)^{iv}, and other higher homologues. The category also includes the acid salts and precursors.

[EMBED Visio.Drawing.11]

The similarity within the PFAS sub-category can be established when reviewing representative structures of the different category member compounds:

the Organization for Economic Cooperation and Development, the Stockholm Convention on Persistent Organic Pollutants, Health and Environment Canada, the European Union; and others. Action plans will reference specific sources used.

ⁱⁱⁱ 15 U.S.C. §2601 *et seq.*

^{iv} CF₃-(CF₂)₅-SO₃H and CF₃-(CF₂)₇-SO₃H; CAS RN: [355-46-4] and CAS RN: [1763-23-1], respectively.

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a. $\text{CF}_3(\text{CF}_2)_n\text{-SO}_3\text{M}$ where $\text{M} = \text{H}^+$ or any other group where a formal dissociation can be made; and

b. $\text{CF}_3(\text{CF}_2)_n\text{-S(=O)}_y\text{-X}$ where $y = 0 - 2$ and X is any chemical moiety.

where $n > 4$.

PFAC sub-category

The PFAC sub-category includes perfluorooctanoic acid (PFOA)^v, and other higher homologs. The category also includes the acid salts and precursors.

[EMBED Visio.Drawing.11]

These similarities within the PFAC sub-category can be established by reviewing representative structures of the different category member compounds:

a. $\text{CF}_3(\text{CF}_2)_n\text{-COO}\cdot\text{M}$ where $\text{M} = \text{H}^+$ or any other group where a formal dissociation can be made;

b. $\text{CF}_3(\text{CF}_2)_n\text{-CH=CH}_2$;

c. $\text{CF}_3(\text{CF}_2)_n\text{-C(=O)-X}$ where X is any chemical moiety;

d. $\text{CF}_3(\text{CF}_2)_m\text{-CH}_2\text{-X}$ where X is any chemical moiety; and

e. $\text{CF}_3(\text{CF}_2)_m\text{-Y-X}$ where Y = non-S, non-N hetero atom and where X is any chemical moiety.

where $n > 5$ or $m > 6$.

IV. Market Characterization Summary

Production Volume

Worldwide production of fluorotelomers was estimated at 20 million pounds in 2006. The United States accounts for more than 50 percent of worldwide fluorotelomer production. Textiles and apparel account for approximately 50 percent of the volume, with carpet and carpet care products accounting for the next largest share in consumer product uses. Coatings, including those for paper products, are the third largest category of consumer product uses. To prevent double counting, a simple manufacturing sequence needs to be considered:

Manufacture of Monomers → Manufacture of Polymers → Processing and Use → Product Life

^v $\text{CF}_3\text{-(CF}_2)_8\text{-COOH}$; (CAS RN: [335-67-1]).

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The manufacture of non-polymeric chemicals (surfactants, wetting agents, cleansers, etc.) is included in the manufacture of monomers. Companies reporting under PFOA SP differentiate between the amounts of PFAC or precursors residuals and the amount present in the polymer, even though it was all manufactured from the same R_f source feedstock. The R_f amount remains constant during the processing, use, and life cycle of the product. It's availability from the residuals is only a small fraction of the total potential release from the polymeric material which is several orders of magnitude larger.

A worse case exposure scenario would be where all PFAC precursors used to manufacture polymers associated with commercial products would eventually become available for exposure purposes. This scenario could be avoided only if the final products containing the polymers were destroyed, and the PFAC precursors were mineralized via incineration at temperatures that could cleave the corresponding C-F bonds. Potentially all monomers, not just the small amounts released at each of the four steps in the sequence above, could be PFAC precursors; a quantity 1000's of times greater than the residual releases.

Global Issues

Commercial production of PFAS chemicals began over half a century ago. Total production from 1970 to 2002 was estimated to be about 100,000 t (Ref. 6). By 2003, PFAS chemicals were no longer manufactured by 3M, the principal U.S. producer. However, production of PFOS-related chemicals is still ongoing in other countries, though to a much smaller extent than before 2003 (Ref. 7). As PFOS-based products became more strictly regulated in developed countries, production shifted to other countries. For example, manufacturers in China began large scale production in 2003 at the advent of 3M's 2002 global PFOS phase out. China had an annual production in 2004 of less than 50 tons, but has increased production dramatically in recent years, with an estimated production of more than 200 tons in 2006. Approximately 100 tons of that amount is designated for export. (Ref. 8)

As fluorinated telomers are increasingly used as substitutes for PFAS compounds, the annual global market is likely to continue to grow. Global production already has doubled from approximately 5,000 to 6,000 metric tons in 2000-2002 to 10,000 metric tons in 2006 (Ref. 9).

Uses

PFOA is a synthetic chemical that does not occur naturally in the environment. PFOA is manufactured for use primarily as an aqueous dispersion agent [as the ammonium salt] in the manufacture of fluoropolymers, which are substances with special properties that have thousands of important manufacturing and industrial applications.

PFOA also can be produced unintentionally by the degradation of some fluorotelomers, which are not manufactured using PFOA but could degrade to PFOA. Fluorotelomers are used to make polymers that impart soil, stain, grease, and water resistance to coated articles. Some fluorotelomer based products are also used as high performance surfactants in products where an even flow is essential, such as paints, coatings, cleaning products, and fire-fighting foams for use

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on liquid fuel fires. Fluorotelomer-based products can be applied to articles both at the factory and by consumers and commercial applicators in after-market uses such as carpet treatments and water repellent sprays for apparel and footwear.

PFOS is a synthetic chemical that does not occur naturally in the environment. PFAS chemicals are no longer manufactured in United States. However, there is a limited set of existing uses for which alternatives are not yet available.

The existing uses, which are characterized by low volume, low exposure potential, and low releases, include the following:

- Use as an anti-erosion additive in fire-resistant phosphate ester aviation hydraulic fluids.
- Use as a component of a photoresist substance, including a photo acid generator or surfactant, or as a component of an anti-reflective coating, used in a photomicroolithography process to produce semiconductors or similar components of electronic or other miniaturized devices.
- Use in a surface tension and static discharge control coating on films, papers and printing plates, or as a surfactant or defoamer in solutions used to process films and papers, in traditional and laser medical imaging and in industrial and consumer film products.
- Use as an intermediate only to produce other chemical substances to be used solely for allowed uses.
- Seven chemicals allowed for use as an etchant, and one chemical allowed for metal plating and finishing uses.

The SNUR regulations do not affect the continued use of existing stocks of the listed chemicals that had been manufactured or imported into the United States prior to the effective date of the SNURs. Existing products and formulations already in the United States containing these chemicals – for example, PFOS-based fire fighting foams produced before the rules took effect in 2002 – can also still be used. Because the PFAS SNURs exempt articles, it is possible for articles, including imports, to contain PFOS.

Fluoropolymers, such as polytetrafluoroethylene (PTFE), which may contain some PFAC contamination, or that use PFOA as an emulsion stabilizer in aqueous dispersions, have a large US market. The wire and cable industry is one of the largest segments of the fluoropolymer markets, accounting for more than 35 percent of total U.S. fluoropolymer use. Apparel makes up about 10 percent of total fluoropolymer use, based on total reported production volume. Fluoropolymers are used in a wide variety of mechanical and industrial components, such as plastic gears, gaskets and sealants, pipes and tubing, O-rings, and many other products. Total U.S. demand for fluoropolymers in 2004 was between 50,000 and 100,000 metric tons. The United States accounted for < 25 percent of the world consumption of PTFE in 2007, and between 25 and 50 percent of the world consumption of other fluoropolymers. PTFE is the most commonly used fluoropolymer, and the United States consumed < 50,000 metric tons of PTFE in 2008.

Substitutes

EPA is reviewing substitutes for PFOA, PFOS and other long-chain perfluorinated substances

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under the New Chemicals Program. EPA established the program under Section 5 of TSCA to help manage the potential risk from chemicals new to the marketplace.

EPA's review of alternatives to perfluorinated chemical substances has been ongoing since 2000 and is consistent with the approaches to alternatives encouraged under the PFOA SP. Through October 2009, EPA has received and reviewed over 150 perfluorinated alternatives of various types. EPA reviews the new substances against the range of toxicity, fate and bioaccumulation issues that have caused past concerns with perfluorinated substances, as well as any issues that may be raised by new chemistries (Ref.10).

V. PFAS and PFAC are ubiquitous in humans and the environment, and are persistent, toxic, and bioaccumulative.

World-wide Distribution of PFAS and PFAC

Presence in Humans

PFAS and PFAC have been detected in human blood samples throughout the world. Blood samples have been collected in countries worldwide including the United States, Japan, Canada, Peru, Colombia, Brazil, Italy, Poland, Germany, Belgium, Sweden, India, Malaysia, Korea, China, and Australia. In addition, PFAS and PFAC have been detected in breast milk, liver, umbilical cord blood and seminal plasma. In most cases, the analytes most often detected in human matrices, and usually in the highest concentrations, were PFOS, PFOA, and PFHxS. Other PFAS and PFAC detected in human tissue include perfluorooctane sulfonamide (PFOSA), 2-(N-methyl-perfluorooctane sulfonamido) acetic acid (Me-PFOSA-AcOH), 2-(N-ethylperfluorooctane sulfonamido) acetic acid (Et-PFOSA-AcOH or PFOSAA), perfluoroheptanoic acid (PFHpA), perfluorononanoate (PFNA), perfluorodecanoic acid (PFDeA or PFDA), perfluoroundecanoic acid (PFUA), perfluorododecanoic acid (PFDoA), perfluoropentanoic acid (PFPeA), perfluorohexanoic acid (PFHxA), and perfluorobutane sulfonate (PFBS).

National health and Nutrition Examination Survey (NHANES) data show that mean levels of PFOS, PFOA and PFHxS in the general U.S. population older than 12 years declined between the sampling period of 1999-2000 and 2003-2004 ([Calafat et al., 2007 Ref. 11](#)). In addition, 3M reported a decline of the same chemicals from 2000 to 2006 in a group of 600 adult American Red Cross (ARC) blood donors ([Olsen et al 2008 Ref. 12](#)). The biggest drop reported in both surveys was in PFOS (~30% in NHANES and ~60% in the ARC study). Both reported ~25% decline in PFOA. NHANES reported a 10% decrease in PFHxS while the ARC study reported a 30% drop. Conversely, PFNA increased by approximately 50% over 4 years in NHANES and by 100% over 6 years in the ARC study. 3M also reported a 100% increase in PFDeA, while the increase in NHANES was 60%. 3M reported an 80% increase in PFUA.

It appears that most of PFAS and PFAC do not vary much across adolescents participating in NHANES; however, pooled data from 2001-2002 indicate that most of the levels of perfluorinated compounds are higher in children ages 3-11 years compared to adults (individual

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samples 2001-2002), especially for PFHxS (Kato et al., 2009 Ref. 13). More recent data on children are not available.

It is clear that there are individuals who have been exposed to perfluorinated compounds at levels much higher than the majority of the population. Recent data indicate that individuals living near a U.S. facility that uses PFOA may have much higher PFOA serum concentrations than those currently reported for the general population (Ref. 14, 15 Calafat et al., 2007; Emmett et al., 2006a).

Presence in the Environment and Wildlife

Water

Log K_{ow} values for PFOA, PFOS and other commercially available ammonium salts range from -0.52 to > 6.8 (Tomlin 2005; De Silva 2008 Ref. 16, 17) and have water solubilities that range from 0.10 to > 500,000 (Kissa 2001; Hekster et al. 2003 Ref. 18, 19). Long-chain PFAC have been measured in surface waters of remote areas such as the north shore of Lake Superior, the Hudson Bay region of Northeastern Canada, tributaries of the Pearl River in Guangzhou, China and the Yangtze River. Ice surface samples in the Canadian Arctic (Northwest Territories and Nunavut) had levels of that ranged from 5-246 pg/L for C9-C11 compounds.

Multiple studies have reported a global distribution of PFAC and PFAS that have been reported in wildlife liver and blood samples. PFAS have also been found in a variety of aquatic organisms. Most recently, Delinsky et al. (2009) found four perfluorinated analytes (PFOS and PFAS: C10, C11, and C12) were found in fillets from bluegill in selected rivers in Minnesota and North Carolina (Ref. 20). In general, the highest concentrations in wildlife have been found in the livers of fish-eating animals close to industrialized areas.

Soil and Sediment

PFOA and PFOS are considered to be resistant to degradation in soil. Levels of C9-C11 PFAC have been found in remote Arctic region sediment ranging from 0.68 $\mu\text{g}/\text{kg}$ – 2.58 $\mu\text{g}/\text{kg}$. PFAC are known to increase over time in sediment as observed in a 22-year study (1980-2002) of the Niagara River discharge. Sediment dwelling invertebrates such as amphipods, zebra mussels, and crayfish have also been found to have PFOA concentrations ranging from 2.5 – 90 ng/g ww in the Raisin, St. Clair, and Calumet Rivers (MI) (Kannan et al. 2005 Ref. 21). At the 3M Decatur, AL. site, PFOA concentrations in Asiatic clams ranged from 0.51 ng/g to 1.01 ng/g. Mussels and oysters in Tokyo Bay were found to contain PFOA concentrations 0.660 ng/g ww and worms from the Ariake Sea in western Japan had concentrations of PFOA of 82 ng/g ww.

PFAS and PFAC are Persistent, Bioaccumulative and Toxic

Persistence and Bioaccumulation in Humans and Laboratory Animals

Animal studies of the straight-chain PFAS and PFAC have shown that these compounds are well absorbed orally, but poorly eliminated; they are not metabolized, and they undergo extensive

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uptake from enterohepatic circulation. Studies of PFOS and PFOA have shown that these compounds are distributed mainly to the serum, kidney, and liver, with liver concentrations being several times higher than serum concentrations; the distribution is mainly extracellular. Both compounds have a high affinity for binding to B-lipoproteins, albumin, and liver fatty acid-binding protein. Studies have reported PFOS, PFOA and several other PFAS and PFAC in umbilical cord blood indicating these chemicals cross the placenta.

The elimination half-lives of several PFAS and PFAC are summarized in Table 1. In general, the rate of elimination decreases with increasing chain length, although the half-life of PFHxS (C6) is longer than the half-life of PFOS (C8) in humans. There is a tremendous species difference in elimination, and elimination is greatly reduced in humans. Thus, the half-life of PFOS is 7 days in rats, 150 days in monkeys, and 5.4 years in humans. There is a gender difference in the elimination of PFOA and other PFAC in laboratory animals. Studies of PFOA in rats have shown that the gender difference is developmentally regulated, and the adult pattern is achieved by sexual maturation. The reason for the species and gender differences in elimination are not well understood. These differences are hormonally controlled, and may also be due to the actions of organic anion transporters. A gender difference has not been found in humans, although uncertainty exists due to the small sample size.

Table 1. Comparative Rates of Elimination*

Serum Half-life	PFHxS (C6)	PFOS (C8)	PFOA (C8)	PFNA (C9)	PFDA (C10)
Rat		7 days	2-4 hours 6-7 days	2 days 31 days	59 days 40 days
Mouse			16 days 22 days	41 days 64 days	
Monkey	87 days 141 days	150 days	30 days 21 days		
Human	8.5 years	5.4 years	2.3-3.8 years		

*Red – females; blue - males

Regardless of chain length, it is critical to note that the half-lives of these compounds are measured in hours to days to months in rats, mice and monkeys, but years in humans. This means that these compounds will persist and bioaccumulate in humans, and comparatively low exposures can result in large body burdens. The gender and species differences in elimination also indicate that comparisons of toxicological effects must utilize some measure of body burden rather than administered dose.

Persistence and Bioaccumulation in the Environment

PFOS and longer chain PFAC (> C8) bioaccumulate and persist in protein-rich compartments of fish, birds, and marine mammals such as carcass, blood, and liver (Conder et al. 2008 Ref. 22). Studies have found fish bioconcentration factor (BCF) values for C9-C8 to C14 PFAC ranging from 39.4 – 40,000 in rainbow trout (Ref. 23). Fish BCF values for C8-C11 PFAS are relatively lower (4-4900). There are no two BCF studies results to date for long chain PFAC with BCF

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values from 4,7000 to 4,800 for perfluorohexadecanic acid (C16) in carp and BCF values from 320 to 430 for perfluorooctadecanoic acid (C18) in carp (Ref. 24) (greater than C14); however Available there is evidence shows that the likely potential for bioaccumulation or biomagnifications in marine or terrestrial species is likely. This is due to conformational changes into a helical structure in the molecule resulting in a smaller cross-sectional diameter as chain length increases which can lead to the ability to accumulate in organisms (Wang et al. 1999 Ref. 25). Additional evidence that C14 and C15 PFAC bioaccumulate and are bioavailable is their presence in fish, invertebrates, and polar bears. The bioaccumulation of PFOS and PFAC (C8 through C14) in air-breathing animals (e.g., birds and mammals) is thought to represent biomagnification due to high gastrointestinal uptake and slow respiratory elimination (Ref. 26, 27). In addition, Conder et al. (2008) state that the bioaccumulation and bioconcentration potential of PFAC are directly related to the length of the perfluorinated chain; and PFAS are more bioaccumulative than PFAC of the same chain length (Ref. 28).

Within the PFAC and PFAS categories, the perfluorinated carboxylic and sulfonic acids (R_f from C5 to C20) are persistent chemicals that are resistant to degradation under environmental conditions other than by reaction with hydroxyl radicals in the atmosphere. PFOA, PFOS and other PFAS and PFAC are expected to be stable in the environment. They are considered to be resistant to degradation in soil and do not degrade in water and are therefore available to fresh water and marine fishes and mammals. Evidence of the persistence of these compounds in aquatic environments is related to their presence in aquatic organisms ranging from unicellular algae to marine and freshwater mammals.

Toxicity in Humans

Until recently, epidemiological and medical surveillance studies have been conducted primarily in the United States on workers occupationally exposed to POSF-based fluorochemicals. These studies specifically examined PFOS or PFOA exposures and possible adverse outcomes. One occupational study of exposures to a PFNA surfactant blend was undertaken. The studies on PFOS and PFOA include mortality and cancer incidence studies, a study examining potential endocrine effects, an “episodes-of-care” study evaluating worker insurance claims data, and worker surveillance studies examining associations between primarily PFOS and/or PFOA serum concentrations and hematology, hormonal and clinical chemistry parameters. The PFNA study examined liver enzymes and blood lipid levels. In general, no consistent association between serum fluorochemical levels and adverse health effects has been observed.

Toxicity in Laboratory Animals

PFOA

The toxicity of PFOA has been extensively studied. Repeated-dose studies in rats have shown reduced body weight, hepatotoxicity, reduced cholesterol, and a steep dose-response curve for mortality. Due to gender differences in elimination, adult male rats exhibit effects at lower administered doses than adult female rats. Thus, dietary exposure for 90 days resulted in significant increases in liver weight and hepatocellular hypertrophy in female rats at 1000 ppm (76.5 mg/kg-day) and in male rats at doses as low as 100 ppm (5 mg/kg-day). Studies in

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nonhuman primates have shown similar effects at doses as low as 3 mg/kg-day, although the reduction in cholesterol has not been observed.

The carcinogenic potential of PFOA has been investigated in two dietary carcinogenicity studies in Sprague-Dawley rats, and has been shown to induce hepatocellular adenomas, Leydig cell tumors, and pancreatic acinar tumors. It has not been shown to be mutagenic in a variety of assays. There is sufficient evidence to indicate that PFOA is a PPAR α -agonist and that the liver carcinogenicity (and toxicity) of PFOA is mediated by PPAR α in the liver in rats. There is no evidence that the liver toxicity in nonhuman primates is due to PPAR α -agonism. There is controversy over the relevance of this particular mode of action for humans. The mode of action for the Leydig cell tumors and pancreatic acinar tumors has not been established, and therefore these are assumed to be relevant for humans.

Several studies have shown that PFOA is immunotoxic in mice. PFOA causes thymic and splenic atrophy, and has been shown to be immunosuppressive in both *in vivo* and *ex vivo* systems. Studies using transgenic mice showed that the PPAR α was involved in causing the adverse effects to the immune system.

Standard prenatal developmental toxicity studies in rats and rabbits in which pregnant animals are exposed only during gestation and sacrificed prior to the birth of the pups have not shown many effects. Thus, there was no evidence of developmental toxicity after exposure to doses as high as 150 mg/kg-day in an oral [SEQ CHAPTER \h \r 1] prenatal developmental toxicity study in rats. In a rat inhalation prenatal developmental toxicity study, the NOAEL and LOAEL for developmental toxicity were 10 and 25 mg/m³, respectively. In a rabbit oral prenatal developmental toxicity study there was a significant increase in skeletal variations after exposure to 5 mg/kg-day, and the NOAEL was 1.5 mg/kg-day.

However, the potential developmental toxicity of PFOA is evident when the pups are evaluated during the postnatal period. Thus, a two-generation reproductive toxicity study in rats showed a reduction in F1 pup mean body weight during lactation at 30 mg/kg-day group and during the post-weaning period at 10 mg/kg-day. In addition, there was a significant increase in mortality mainly during the first few days after weaning, and a significant delay in the timing of sexual maturation for F1 male and female pups at 30 mg/kg-day.

Due to the rapid elimination of PFOA in female rats, many researchers have examined the developmental toxicity of PFOA in mice. These studies have shown a pattern of developmental effects similar to those observed with PFOS. Full litter resorptions were noted at 40 mg/kg-day and the percent of live fetuses and fetal body weight were reduced at 20 mg/kg-day. The most notable effect of prenatal exposure to PFOA was the severe compromise of postnatal survival at doses as low as 5 mg/kg-day, and the postnatal growth impairment and developmental delays noted among the survivors; the BMD₅ and BMDL₅ for neonatal survival were estimated at 2.84 and 1.09 mg/kg-day, respectively. Additional studies in mice have shown that PFOA exposure causes a significant reduction in mammary gland differentiation in the dams and stunted mammary gland development in the female pups.

Several studies have examined the mode of action for the developmental effects. These have

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shown that exposure to a dose of 20 mg/kg-day for 2 days late in gestation is sufficient to cause the neonatal mortality in mice. Studies with PPAR α knockout mice have shown that the PPAR α is required for the neonatal mortality and expression of one copy of this gene is sufficient. This is in contrast to the studies showing that PPAR α is not involved in the neonatal mortality associated with PFOS exposure. Although there is controversy over the human relevance of the PPAR α -agonist hepatotoxicity observed in rodents, the role of PPAR α in development and particularly in the PFOA-induced neonatal mortality observed in mice is unknown; therefore this mode of action is assumed to be relevant for humans.

Other PFAC

Although there is an extensive database for PFOA, few studies have examined the toxicity of the shorter or longer chained PFAC. However, the data suggest that the toxicity profile is quite similar to that of PFOA, albeit at different dose levels presumably due to the differences in elimination half-life.

Although standard repeated-dose toxicity studies have not been conducted on the PFAC with chain lengths greater than PFOA, many studies have been conducted examining the potential for hepatomegaly and peroxisome proliferation (a marker for the activation of PPAR α). Kudo et al. (2000) found that PFOA, PFNA, and PFDA induced the activity of peroxisomal B-oxidation in male rats. Kudo et al. (2006) showed that all PFAC with six- to nine-carbon length chains induced hepatomegaly and peroxisomal B-oxidase activity in mice, and the potency was in the order of PFNA > PFOA > perfluoroheptanoic acid. Permadi et al. (1993) also showed that PFDA induces hepatomegaly and hepatic peroxisomal palmitoyl-CoA oxidase. Thus, these studies indicate that the PFAC with a carbon chain length of eight and greater activate PPAR α . The differences in potency probably reflect the differences in the half-life of the varying chain lengths. Despite the lack of traditional toxicity studies, it is likely that these compounds would produce similar effects as those observed with PFOA.

With respect to the potential developmental effects of PFAC with carbon chain lengths greater than C8, Lau et al. (personal communication) are completing a developmental toxicity study of PFNA in mice. Maternal body weight gain was reduced at 3 mg/kg-day, and severe toxicity was observed at 10 mg/kg-day. Neonatal survival was compromised at 5 mg/kg-day, and significant lags in neonatal growth were observed at 3 mg/kg-day. Thus, this study shows a pattern of effects very similar to those observed with PFOA. It is likely that PFAC with carbon chain lengths greater than nine would also result in similar effects, and that the potency would be dependent on the half-life of the compound.

PFOS

The toxicity of PFOS has also been extensively studied. Repeated-dose studies in rats and nonhuman primates have shown reduced body weight, hepatotoxicity, reduced cholesterol, and a steep dose-response curve for mortality. These effects occur in nonhuman primates at doses as low as 0.75 mg/kg-day, and in rats at 2 mg/kg-day.

The carcinogenic potential of PFOS has been investigated in a dietary carcinogenicity study in

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Sprague-Dawley rats, and has been shown to induce hepatocellular adenomas at 20 ppm. In addition, thyroid follicular cell adenomas were observed in male rats that had been allowed to “recover” for a year following treatment for one year; the reason for this is unclear. However, thyroid follicular tumors have also been observed in rats exposed to N-EtFOSE, a major precursor of PFOS. PFOS has not been shown to be mutagenic in a variety of assays. Although PFOS can activate PPAR α , the data are not sufficient to establish a PPAR α -agonist mode of action for the liver tumors.

A standard prenatal developmental toxicity study in rats has shown a significant decrease in fetal body weight and significant increase in external and visceral anomalies, delayed ossification, and skeletal variations; a NOAEL of 1 mg/kg-day and a LOAEL of 5 mg/kg-day for developmental toxicity were indicated. In rabbits, significant reductions in fetal body weight and significant increases in delayed ossification were observed; a NOAEL of 1.0 mg/kg-day and a LOAEL of 2.5 mg/kg-day for developmental toxicity were indicated.

A two-generation reproductive toxicity study in rats showed neonatal mortality. All F1 pups at the highest dose of 3.2 mg/kg-day died within a day after birth, while close to 30% of the F1 pups at 1.6 mg/kg-day died within 4 days after birth. As a result of the pup mortality in the two top dose groups, only the two lowest dose groups, 0.1 and 0.4 mg/kg-day, were continued into the second generation. The NOAEL and LOAEL for the F2 pups were 0.1 mg/kg-day and 0.4 mg/kg-day, respectively, based on reductions in pup body weight.

The results of this study prompted additional research. Studies in which pregnant rats and mice were dosed during gestation and the pups were followed postnatally provided a BMD₅ and BMDL₅ for neonatal survival of 1.07 and 0.58 mg/kg-day in rats, respectively, and 7.02 and 3.88 mg/kg-day in mice, respectively. Studies have shown that the critical period of exposure is during late gestation. Mode of action studies initially focused on the lung and found significant histological and morphometric differences in the lungs of pups treated with PFOS. However, subsequent studies did not find any effect on lung phospholipids and rescuing agents failed to mitigate the neonatal mortality. Thus, the mortality does not appear to be related to lung immaturity. In contrast to PFOA, studies with PPAR α knockout mice have shown that the PPAR α is not involved in the neonatal mortality. Current research is focusing on the possibility that the physical properties of PFOS may interfere with the normal function of pulmonary surfactant, leading to neonatal mortality.

Other PFAS

A combined reproductive/developmental toxicity study of PFHxS has been conducted in rats. In the parental males there was a significant reduction in cholesterol at doses as low as 0.3 mg/kg-day, and hepatotoxicity at doses as low as 3 mg/kg-day. There was no evidence of developmental or reproductive toxicity at doses as high as 10 mg/kg-day.

Toxicity to Wildlife

Adverse effects on exposed populations of organisms have been observed with exposure to perfluorinated compounds in the parts per million range. Studies have shown a reduction in

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hatchability of chickens when they were exposed *in ovo* to PFOS, and a reduction in survival in 14-day old Northern bobwhite quail from hens exposed to 10 ppm of PFOS in the diet. In addition, a delay in growth and metamorphosis in the Northern leopard frog exposed to 3 mg/L of PFOS has been reported, as well as reduced cumulative fecundity and fertility effects in fathead minnows exposed to 0.1 mg/L PFOS. Further evidence of potential reproductive effects has been observed with exposure to C9-C11 PFAC. A significant induction of vitellogenin in rainbow trout was observed in a dose-dependent manner at concentrations of C10 PFAC 0.0256-2000 µg/g in the diet as well as a weak affinity demonstrated for the hepatic estrogen receptor from C9-C12 PFAC.

Mortality in sediment dwelling organisms such as the nematode, *Caenorhabditis elegans* has been observed with concentrations of C9 up to 0.66 mM and subsequent effects in offspring generations were found at concentrations up to 1nM as evidence by a 70 % decline in fecundity.

VI. Fate of PFAC and PFAS in the Environment

The PFAS and PFAC acids are strong acids that exist in equilibrium between the neutral form and the anionic form. Both the anionic and neutral forms of PFOA are soluble in water. While the Henry's law constant values suggests partitioning to air for the neutral, protonated form, predicting the amount that partitions into air is complicated because there is uncertainty over the degree to which carboxylic and sulfonic acids partition from the water to atmosphere. The uncertainty arises with regard to the value of the acid dissociation constant (i.e., pK_a), or the fraction of the acid form present at environmentally relevant pH. PFAC and PFAS have been detected in air, water, and soil samples collected throughout the world. The oceans have been suggested as the final sink and route of transport for perfluorinated carboxylic and sulfonic acids, where they have been detected on the surface and at depths > 1,000 meters. (Ref. 29)

Some PFAS/PFAC have the potential for long-range transport. They are transported over long distances (i.e., long-range transport) by a combination of dissolved-phase ocean and gas-phase atmospheric transport; however, determining which is the predominant transport pathway is complicated by the uncertainty over water to atmosphere partitioning. Furthermore, there is evidence that transport and subsequent oxidation of volatile alcohol PFAS/PFAC precursors may contribute to the levels of PFAS / PFAC in the environment.

In addition to perfluoro carboxylic acids and perfluoro sulfonates, a number of other chemicals with perfluorinated moieties have been and continue to be used in a wide variety of industrial and consumer applications. When these chemicals are released intentionally or unintentionally through manufacturing, use, and disposal, they can be degraded in the environment or be metabolized in organisms to form perfluoro carboxylic acids and perfluoro sulfonates. Limiting exposure to PFAC and PFAS will require limiting both the exposure to these precursors and the release of precursors that will form PFAC and PFAS in the environment.

Studies by industry and academic researchers have shown that fluorotelomer alcohols (FTOH) can be degraded by microorganisms and by abiotic processes. 8-2 FTOH and FTOH of other chain lengths, and related chemicals in mixed microbial cultures, activated sludge and soil

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systems have been shown to be easily degraded to form PFOA and related perfluorinated acids. These studies have also shown that $-CF_2-$ groups can be mineralized, forming shorter chain perfluoro acids. If FTOH are absorbed from ingestion, inhalation, dermal or ocular exposure or formed in vivo by from other compounds they can be metabolized by mammals and other organisms to form perfluorinated acids and other fluorinated compounds. FTOH can be degraded by abiotic processes in water and air to produce PFAC and various intermediates. FTOH are fairly volatile. Based on atmospheric half-lives determined in chamber studies, FTOH can be transported globally. Deposition or degradation in areas far from the source can result in PFAC contamination in high latitudes and other remote locations and contribute to global background levels of PFAC and PFAS.

Data submitted by industry and in the open literature show that perfluorooctane sulfonyl fluoride (POSF) and its derivatives can be degraded under environmental conditions to form perfluoroalkyl sulfonates and carboxylic acids. Reaction of POSF ($CF_3(CF_2)_n-SO_2F$) with methyl or ethyl amines is used to produce N-ethyl or N-methyl perfluorooctane sulfonamidoethanols (FOSE). Similar reactions are used to make shorter and longer chain analogs to POSF and POSF derivatives. FOSE compounds, (or $CF_3(CF_2)_n-SO_2N(R1)(R2)$, where R1 and R2 can be hydrogen, methyl or longer alcohols or other organic chains), such as N-methyl and N-ethyl FOSEs can be degraded through a series of intermediates to form both perfluoro carboxylic acids and perfluoroalkyl sulfonates. Data on the degradation of individual intermediates has been used to identify these pathways and has confirmed that these compounds can be degraded by a number of microbial and abiotic mechanisms. Reaction with other chemical intermediates produces other FOSA derivatives, including phosphate esters, fatty acids esters, silanes, carboxylates, and polymers with acrylate, urethane and other linkages. Longer and shorter chain perfluoro sulfonyl derivatives have also been produced intentionally and as unintended reaction products. Based on existing data from the open literature and CBI data, it is expected that that most, if not all, of these POSF and other chain length sulfonyl fluorides and their derivatives will be degraded to carboxylic acids and/or sulfonate over time. Most of these compounds will have environmental and metabolism half-lives of week to months. Some will be degraded faster and some will persist for longer, but all will eventually be degraded.

Very little data is available on the behavior of other perfluorochemicals in the environment and in vivo but the existing data suggest that they will also be degraded to form PFAC. For example, recent studies have shown that ingested mono and di polyfluoroalkyl phosphates (PAPs) can be degraded in rats to form PFOA and other PFAC in the body. They can also be degraded by microbial processes in soil and wastewater to form perfluorinated acids. (Ref. 30)

A limited number of studies on the degradation of fluorotelomer-based polymers have been submitted in support of PMN submissions and existing chemicals, and published in the open literature. Based on studies conducted using rigorous methods that are believed to have yielded valid data, fluorotelomer-based polymers are all subject to hydrolysis, photolysis and biodegradation to some extent. Studies have shown half-lives of a few days to hundreds of years. Some studies, which have been judged to be valid, have shown much slower degradation for some structures. Acrylate polymers have been shown to degrade with half-lives of decades or longer. A mixed acrylate was determined to be degraded within weeks. Urethane polymers have been shown to degrade faster. There is little data on methacrylates, but they are assumed to also

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~~degrade at similar rates.~~

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In addition, preliminary research on degradation of fluorotelomers has shown that some urethanes and acrylates biodegrade; however, half-lives and kinetics of the fluorotelomers are not yet well-defined. The ongoing ORD research is designed to generate high quality data that will help the Agency address some key uncertainties in pathways of exposure and potential risks from PFOA (Ref. 31).

These studies have shown that the perfluoro portion of the polymer is released as the polymer is degraded by microbial or abiotic processes to form telomer alcohols or other intermediates and that they eventually form PFAC. Polymers based on POSF and other chain length chemistries show similar degradation rates and release intermediates which further degrade to form perfluorinated acids and sulfonates. Studies have shown that some polymers can undergo indirect photolysis in soil and in aquatic systems and be degraded with half-lives of days to several years.

VII. Exposure Characterization Summary

The pattern of PFAS and PFAC contamination varies with location and among species, which suggests multiple sources of emission and patterns of migration into environmental media from the sources of emission. Major pathways that enable PFOA and PFOS to get into human blood in small quantities are not yet fully understood. Manufacturing releases are known to have contaminated local drinking water supplies in the immediate vicinity of some industrial plants, leading to localized elevated blood levels. The widespread presence of PFOA and PFOS precursors in human blood samples nationwide suggests other pathways of exposure, possibly including long range air transport, and the release of PFOA and PFOS from treated articles.

Summary of Exposure to Consumers and Children from PFCs in Indoor Environments

PFCs in Articles of Commerce

EPA's Office of Research and Development (ORD) has conducted research on 116 articles of commerce documenting that PFAC chemicals are contained in articles of commerce and have the potential to leave those articles. Articles tested and found to contain the highest levels of PFAC were carpet and carpet treatment products, various types of apparel, home textiles, thread sealant tape, floor wax and other sealants, and food contact paper and paper coatings. Carpet and carpet treatment products contained individual PFAC in levels from 0.04-14100 ng/g; food contact paper and paper coatings: 0.05-160,000 ng/g; thread sealant tape and apparel: ND (non-detect)-3488 ng/g and ND-4640ng/g respectively; floor wax and sealer: 0.03-3720 ng/g; and home textiles: ND-519 ng/g. Some of the more commonly found PFAC measured in these articles were PFHxA, PFHpA, PFNA, PFDA, PFUnDA, PFOA and PFOS. Inhalation levels of PFOA and total PFCs measured in carpet were 5385 pg/cm³ and 32500 pg/cm³ respectively. (Ref. 32)

Children are particularly susceptible to exposure from inhalation of PFC off-gassing from carpet and carpet protectants during their earliest years when they are lying, crawling and spending large amounts of time playing on the carpet. The significantly high levels of PFC found by ORD

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in carpet and carpet protectants pose an exposure concern for children through this pathway. Adults can also be exposed to PFCs in carpets through inhalation and dermal contact. Consumers and children may also be exposed to PFCs in apparel, home textiles, thread sealant tape, floor wax, contact paper and paper coatings. Some of these articles such as paper coatings for foods cannot be ruled out for the ingestion exposure pathways for children and adults depending upon how the PFCs in the paper contacts the food and subsequently humans.

PFCs in Indoor Air

Another source of PFCs to the indoor environment is dust containing not only PFAC and PFAS but also fluorotelomer alcohols. Maximum indoor dust air measurements of 6:2 FTOH were found at 804 ng/g in the eastern United States (Ref. 33). The PFAS (ET-FOSA, Et-FOSE, MeFOSE) chemicals were measured at 646 ng/g, 75440 ng/g, and 8860 ng/g respectively in indoor air in Canada (Ref. 34). PFOA was found at 3700 ng/g in Japanese household vacuum cleaner dust (Ref. 35).

Summary of Exposure to the General Population

PFCs in groundwater, freshwater, saltwater, and rainwater

PFAC and PFAS have been found in many countries as well as the US in untreated groundwater, rivers, streams, bays, estuaries, oceans and rain water. Levels of PFAC in groundwater near the 3M Cottage Grove, MN industrial site have been measured as high as 846,000 ng/l (PFOA) and in freshwater as high as 178,000 ng/l (PFBA) (Ref. 36). PFOS has been found near Cottage Grove, MN in groundwater at levels of 371,000 ng/l and in freshwater at 18,200 ng/l. PFAC in rainwater has been measured in the United States between 0.1 and 1006 ng/l (PFHpA) (Ref. 37).

Saltwater levels of PFOS have been measured in the Pacific Ocean at 57,700 ng/l and in precipitation from snow and rain in China at 545 ng/l (Ref. 38, 39). While the general population may not directly ingest these groundwater, freshwater and saltwater levels as drinking water, the ground water and freshwater containing PFCs may discharge to surface waters from which municipalities withdraw drinking water. The general population may also experience dermal, ingestion and inhalation exposures when coming into contact with freshwater containing PFCs. Rainwater containing PFCs may contribute PFCs to vegetables and fruits in home gardens, crops grown on commercial crop lands, drinking water reservoirs, and surface waters from which drinking water is withdrawn.

PFCs in Freshwater and Saltwater Fish

Freshwater fish have been found to contain levels of PFAS and PFAC. The highest levels of PFAS measured in the United States to date were near the 3M Cottage Grove, MN site (Ref. 40). Liver samples of bass, walleye and carp ranged from 130-6350 ng/g PFOS wet weight. Blood samples of these same fish ranged from PFOS levels of 136-29600 ng/ml in serum. Total PFCs for the blood of freshwater fish in the same area was measured at 32248 ng/ml serum. The highest levels of PFAC for freshwater fish were found near the 3M Cottage Grove, MN site and were measured for blood samples of bass, walleye, and carp in the range of 2.53-210 ng/ml

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serum. For comparison, saltwater fish in Danish seas had measured levels of PFOS up to 156 ng/g and saltwater fish in Charleston Harbor South Carolina were found with PFOS levels up to 101 ng/g (Ref. 41, 42).

PFCs in Environmental Media on and around PFC Manufacturing Facilities in the US (data from EPA's Memoranda of Understanding with 3M and DuPont at Decatur, AL and Parkersburg, WV PFC manufacturing facilities)

Residents living around the Parkersburg WV DuPont manufacturing facility have had measurable levels of PFCs in their municipal drinking water, groundwater and soils. There are also off-site PFCs in soils and groundwater, and surface water around the 3M, Decatur AL site. The 3M Cottage Grove, MN PFC manufacturing site similarly has levels of PFCs in groundwater, surface water, drinking water and soils on and around the site. The PFCs in these media may then be available for exposure to humans and environmental receptors through inhalation, ingestion and dermal contact depending upon the particular PFC and scenario of exposure. 3M's Decatur, AL facility and DuPont's Parkersburg, WV facility have identified drinking water exposures to date. Other types of exposures to humans may occur through food grown on local farms and in home gardens affected from off-site migration of PFCs. Ecological receptors are likely to have been affected by off-site migration of PFCs to nearby water and soils.

Uncertainties and Data Gaps

Information on the different routes of exposure to PFC is limited. Most of the PFC data measured in the ground water, surface water, soil and air is for PFOA and PFOS. More monitoring data are needed on the concentrations of PFAC, PFAS and as well as fluorotelomer alcohols in all environmental media, articles of commerce, all environmental media, near PFC manufacturing facilities, media on and around near wastewater treatment sludge application areas are in remote, rural, and urban areas. PFCs have been detected in drinking water, water, and it's. It is therefore important to monitor a greater number of drinking water sources in the most vulnerable areas near manufacturing plants, use plants and wastewater treatment plants.

Data for levels of PFCs in foods are very limited. It was noted that data are needed to determine the concentration in foods consumed by the general population and foods grown near manufacturing sites and sites where PFCs have been disposed in the past. Congener-specific data for food from plant products are needed. Because monitoring data indicate that a wide range of PFAC and PFAS are found in environmental media, it is critical to monitor for as complete a range of PFCs as possible whenever collecting samples of media or biota, especially higher trophic level organisms that may bioaccumulate PFCs.

Children are likely exposed to PFCs through a number of routes and therefore should be the targets of extensive exposure monitoring in homes, schools, play areas, and other public places. The PFC data to date shows that indoor carpet, carpet protectant and indoor dust are all potentially significant sources of PFC exposure to children. Data are needed for children living near PFC manufacturing facilities, facilities where PFC has been disposed and wastewater treatment plant sludge areas known to contain PFC sludges.

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VIII. Risk Management Considerations

Current Risk Management Summary

PFAS Chemicals

Following the voluntary 3M phase-out of PFAS chemicals in the United States in 2002, EPA issued regulations to restrict the reintroduction of these chemicals into the U.S. market. Final rules were published on March 11, 2002 (Ref. 43) and December 9, 2002 (Ref. 44), to limit any future manufacture or importation of 88 PFAS chemicals specifically included in that phase-out. Furthermore, on October 9, 2007, EPA published another SNUR on 183 additional PFAS chemicals (Ref. 45). Those actions were necessary because data showed that certain alkyl chain lengths of the PFAS chemicals are toxic to human health, bioaccumulate, and are persistent in the environment. PFAS chemicals are no longer manufactured in United States. However, there is a limited set of existing uses which are excluded from SNURs because alternatives are not yet available.

Similar to the PFAS SNURs in United States, PFOS has also been restricted in the European Union, Canada, Australia and other countries, and has been nominated for inclusion in the Stockholm Convention and the Convention on Long-Range Transboundary Air Pollution (LRTAP) Persistent Organic Pollutants (POPs) protocol. At the fourth Conference of the Parties (COP) to the Stockholm Convention on POPs, held in May 2009, delegates agreed to add PFOS, its salts, and perfluorooctane sulfonyl fluoride (PFOSF) to Annex B, subjecting it to restrictions on production and use. Parties agreed that while the ultimate goal is the elimination of PFOS, production of the chemical may continue for limited purposes, including coatings for semiconductors, firefighting foam, photo imaging, aviation hydraulic fluids, metal plating, and certain medical devices. Countries must notify the Convention Secretariat whether they intend to continue production for acceptable purposes. Countries can also ask for specific exemptions allowing the production of PFOS for use in the production of chemical substances used in goods such as carpets, leather and apparel, textiles, paper and packaging, coatings, and rubber and plastics. (Ref. 46)

PFAC Chemicals

EPA's Office of Pollution Prevention and Toxics' (OPPT) core strategy for working towards the elimination of PFAC chemicals has been through the 2010/15 PFOA Stewardship Program (PFOA SP). Under the program, eight major companies operating in the United States committed to reduce global facility emissions and product content of PFAC chemicals by 95 percent by 2010, and to work toward eliminating emissions and product content by 2015 (Ref. 47). Companies provide annual progress reports, and most companies have reported significant progress in meeting program goals.

On March 7, 2006, EPA published a proposal to amend the polymer exemption rule to exclude from eligibility for the exemption polymers containing certain perfluoroalkyl moieties (Ref.48).

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Under this proposal, polymers containing these perfluoroalkyl moieties would need to go through the pre-manufacture notification (PMN) review process so that EPA can better evaluate these polymers for potential effects on human health and the environment. This change to the current regulation is necessary because, based on current information, EPA can no longer conclude that these polymers “will not present an unreasonable risk to human health or the environment” under the terms of the polymer exemption rule, which is the determination necessary to support an exemption under section 5(h)(4) of TSCA. This amendment to the polymer exemption rule is a necessary complement to the PFOA SP and will give EPA the necessary tools to review and control risk of PFC-based and related polymers, including those PFAS/ and PFAC containing polymers.

In January 2009, EPA’s Office of Water (OW) developed Provisional Health Advisory values for PFOA and PFOS to mitigate potential risk from exposure to these chemicals through drinking water (Ref. 49). Due to limited information on the toxicity of PFCs other than PFOA and PFOS, no attempt was made by OW at that time to develop Provisional Health Advisory values for the other PFCs. OPPT and OW are working together to determine whether revised health advisory values are needed for PFOA and PFOS.

EPA has taken the leadership role in raising the profile of PFCs at an international level stemming from Agency concerns about the role of long range transport in the environmental distribution of PFCs, and U.S. importation of products containing these chemicals (Ref. 50). As a result of these activities, in May 2009, during the International Conference on Chemicals Management (ICCM2), delegates to the Strategic Approach to International Chemicals Management (SAICM) agreed to consider the development of stewardship programs and regulatory approaches to reduce emissions and content of PFAC and PFAS chemicals in products and to work towards their elimination, where feasible (Ref. 51).

Remaining Issues and Concerns

PFAS Chemicals

PFAS chemicals are no longer manufactured in United States but continue to be manufactured outside of United States. Although the PFAS SNURs have effectively restricted the manufacture and import of the 271 PFAS chemicals listed in the SNURs to the point where they are no longer manufactured nor imported into United States, these chemicals may continue to be imported into United States in articles, such as carpets, leather and apparel, textiles, paper and packaging, coatings, and rubber and plastics. Recent research by EPA’s Office of Research and Development has shown that consumer articles could release PFCs, significantly increasing the magnitude and duration of exposure to humans and the environment to these chemicals (Ref. 52). Given that articles release PFAS chemicals listed in existing SNURs, EPA believes that action on articles containing PFAS chemicals is warranted.

PFAC Chemicals

Although the PFOA SP is expected to eliminate the production of C8-based fluorotelomers by the eight participating companies by 2015, the potential remains for continued environmental

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and human loading of PFAC in the United States. This is in part because companies not participating in the PFOA SP are expected to seize the market opportunity presented when the eight PFOA SP companies leave the PFAC market by 2015. This occurred with PFAS production in some Asian countries after the 2002 phase-out of PFAS chemicals in United States (Ref. 53).

If PFAC were to be added to the Stockholm Convention on POPs without major obstacles, the earliest addition of PFAC to the treaty would be five years after their nomination by a Party. This treaty is the most logical vehicle for the global phase out of persistent organic pollutants, as is being done with PFAS. Once added, it would still be several years before the provisions would become operative for all Parties. Hence, even without unforeseen delays, it is not likely that Stockholm provisions governing PFAC could be fully operative before around 2020.

Possible scenarios of concern:

- o Direct releases to the environment from U.S. facilities not participating in PFOA SP.
- o Direct releases to the environment from non-U.S. facilities not participating in PFOA SP, resulting in transboundary environmental transport to United States.
- o Articles, including imports, containing PFAC chemicals. These articles could release PFAC as a result of their residual content in fluorotelomer-based products and/or as the fluorotelomers-based polymers in articles biodegrade (Ref. 54).

Possible Additional Risk Management Options to Address Remaining Issues and Concerns

The remaining issues and concerns described above highlight the need for EPA to:

- o Take immediate regulatory action on PFAS containing articles, which continue to be a source of releases and exposure to PFAS chemicals.
- o Take regulatory action to make the gains from the PFOA SP permanent in order to preclude companies not participating in the PFOA SP (domestic and foreign) from manufacturing and importing PFAC chemicals once the eight companies transition away from PFAC manufacture in 2015.
- o Finalize the amendment to the Polymer Exemption Rule to exclude from eligibility polymers containing certain PFAC. Polymers containing these chemicals would then need to go through the PMN review process, and EPA could implement reviews of these PMNs in such a way as to result in the ultimate elimination of PFAC sources after 2015.
- o Develop a regulation to ban or severely restrict the use of PFAC, including fluorotelomers, in articles after 2015.

IX. Recommendation

Considering concerns about the toxicity, persistence and bioaccumulation potential of the PFAS and PFAC chemicals, it can reasonably be anticipated that continued exposure could increase body burdens to levels that will result in adverse outcomes. Consequently, EPA intends to further evaluate and if appropriate, control, exposures associated with these chemicals.

To expand the reach of the 2010/15 PFOA Stewardship Program (PFOA SP) achievements

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beyond the eight participating companies and further address the concerns for potential PFAC exposure through the use and disposal of fluorotelomer-treated articles, OPPT is considering developing regulation under TSCA § 6 to ban or severely restrict the use of PFAC in articles (including imports). Such a rule could be targeted to enter into force at the conclusion of the PFOA SP (i.e., January 1, 2016) and could also contain provisions to prevent any domestic resumption of activities covered by the PFOA SP. Because the U.S. is a major user of products containing fluorotelomers, such an action in the U.S. would likely exert a major influence on the global marketplace.

To expand the reach of SNURs on PFAS chemicals, OPPT is considering developing further regulation under § 5(a)(2) or § 6 to ban or severely restrict the use of PFAS chemicals in articles (including imports). Such a rule would be targeted to enter into force before 2015.

Commented [tk6]: TBD : This will change based on management decisions.

X. References

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TMM EXHIBIT 73

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: AQUEOUS)
FILM-FORMING FOAMS)
(AFFF) PRODUCTS) MDL NO.
LIABILITY LITIGATION) 2:18-mn-2873-RMG
_____)
THIS DOCUMENT RELATES)
TO ALL CASES)

FRIDAY, MAY 21, 2021
CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

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Remote videotaped deposition of
Frederick K. Walker, Jr., Volume III, held
remotely at the location of the witness in
Panama City, Florida, commencing at 9:41 a.m.
Eastern Time, on the above date, before
Carrie A. Campbell, Registered Diplomat
Reporter and Certified Realtime Reporter.

- - -

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deps@golkow.com

1 vehicle we have in the fleet, and it's about
2 how to maintain, repair and operate the ARFF
3 vehicles.

4 MR. NAPOLI: Okay. I don't
5 have further questions, and I would
6 just like to thank you for your
7 service, Mr. Walker.

8 THE WITNESS: Thank you.
9 Appreciate it.

10 MR. DOUGLAS: All right.
11 What's the plan, Joe?

12 MR. PETROSINELLI: Plaintiffs
13 are done?

14 MR. DOUGLAS: Yes.

15 MR. PETROSINELLI: No questions
16 from defense.

17 MR. DOUGLAS: Oh, you made my
18 day.

19 MR. COOK: Okay. I have one
20 follow-up question. Where is it.

21 RECROSS-EXAMINATION

22 QUESTIONS BY MR. COOK:

23 Q. Okay. Mr. Walker, are you
24 still there?

25 A. I'm still here.

1 Q. Okay. Great. Thank you for
2 your patience and endurance.

3 You were asked a question -- a
4 couple of questions, actually, a number or
5 so, about fire training and the adoption of
6 the double-liner design starting in the late
7 '80s, and here's what I wanted to ask you.

8 Is it true that from the early
9 '90s on, most live fire training was done
10 with propane, with an instructor-controlled
11 fire and water as the agent used to
12 extinguish the fire as opposed to AFFF? In
13 other words, water, not AFFF, to extinguish
14 the propane-based fire from the early '90s
15 on; is that correct?

16 A. That is correct. The fire is
17 actually controlled by -- by the instructor,
18 and he makes the fire respond to the
19 trainees' actions. If they're correct, then
20 the fire will go down and go out, and if they
21 aren't, the fire will continue to either grow
22 or at least remain the same. But it's an
23 instructor-controlled training event.

24 And so we -- we went there as
25 we developed and expanded our -- or in an

1 attempt to develop environmentally
2 responsible fire training.

3 MR. COOK: Okay. That's the
4 only question I have.

5 Are you finished as well?

6 MR. PETROSINELLI: Yeah. The
7 only thing I wanted to put on the
8 record is something I said off the
9 record.

10 I'm told from people who looked
11 at the realtime that some of my
12 objections were not recorded, I
13 think -- I think because with the
14 technology, when we speak over each
15 other, sometimes they don't get
16 captured.

17 So obviously we'll have to look
18 at the video and insert those
19 objections, but I just wanted to put
20 that on the record.

21 Mr. Walker, thank you.

22 MR. DOUGLAS: Thank you, sir --

23 MR. COOK: Gary, you're
24 breaking up a bit.

25 MR. DOUGLAS: -- these last

1 three days.

2 VIDEOGRAPHER: That's it?

3 MR. DOUGLAS: I was just
4 thanking you for your service,
5 Mr. Walker. We are indebted to you.
6 And thank you for your patience with
7 all us over the last three days.

8 VIDEOGRAPHER: The time --

9 MR. COOK: All parties are
10 done.

11 VIDEOGRAPHER: Let's go off
12 record. Sorry. The time is 3:55 p.m.
13 We are off the record.

14 (Deposition concluded at 3:55 p.m.)

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CERTIFICATE

I, CARRIE A. CAMPBELL, Registered Diplomate Reporter, Certified Realtime Reporter and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, Frederick Walker, was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.



CARRIE A. CAMPBELL,
NCRA Registered Diplomate Reporter
Certified Realtime Reporter
Notary Public

Dated: May 28, 2021