

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

**Summary of April 1, 2004 Public Plenary Meeting**

Seventy-six people attended the fifth public enforceable consent agreement (ECA) Plenary session on PFOA and fluorinated telomers at EPA Headquarters in Washington, DC on Thursday April 1, 2004 from 1:00 PM to 4:00 PM. The meeting participants represented registered interested parties, observers, and EPA staff. Copies of the attendance list, the meeting agenda, and the summary presentations made by the PFOA ECA Technical Workgroups can be found in the electronic docket at OPPT-2003-0012-0537 through 0543. Workgroup presentations are reports given on behalf of the entire workgroup and not the individuals presenting the reports. The next Plenary meeting was scheduled for June 24, 2004, in Washington, DC.

**I. Introduction**

EPA welcomed the participants to the Plenary session and reiterated the goal of the process as obtaining agreements for development of data to identify the sources of PFOA in the environment and the pathways of human and environmental exposures.

**II. Update on Developing Incineration ECAs**

Rich Leukroth of EPA presented an update on behalf of the Incineration ECA Drafting Committee on progress made in development of an ECA for incineration testing of fluorotelomer based polymers and fluoropolymers. The presentation included a list of the Incineration ECA Drafting Committee members, a summary of recent drafting committee activities, an update on public comments on the ECAs, an update on the status of Appendix F, a report on the status of the submission of requested data for the samples to be tested, workgroup recommendations, and next steps. It was the recommendation of both the Fluoropolymer and Telomer Technical Workgroups that the ECAs be executed by EPA. The presentation is in the docket at OPPT-2003-0012-0539.

Discussion/Questions: None

Conclusions:

- The Plenary group accepted the Workgroup recommendations and directed that the necessary steps be taken to sign and execute the ECAs and to publish notice of the ECAs in the *Federal Register*.
- The members of the Plenary congratulated the Incineration Drafting Committees on their success and pointed out that their resolution of many issues will help move future ECAs to conclusion.
- EPA noted that the steps that must be taken to preserve confidential business information (CBI) will affect the signature process, and indicated that the signature process and *Federal Register* notice publication would likely be complete in June 2004.

The companies that have not yet submitted complete information on the chemicals to be tested were directed to submit that information.

### III. Telomer Technical Workgroup Reports

#### *Telomer Degradation ECA Subgroup Report*

Speaking on behalf of the Telomer Degradation Technical Expert Subgroup, Cathy Fehrenbacher of EPA reported on progress pertaining to telomer degradation ECA testing. The presentation included identification of the Telomer Degradation Technical Expert Subgroup members; summary of telomer degradation ECA study protocol discussions; preliminary discussions of the subgroup; examples of key issues; progress since the initial meeting of the subgroup; continuing work and discussions; EPA proposed architecture and triggers; Telomer Research Program (TRP) proposed alternative approach; and proposed next steps. The presentation is in the docket at OPPT-2003-0012-0540.

#### Discussion/Questions:

EPA noted that it considers that the detection of any PFOA under conditions of the Modified SCAS Test (OPPTS 835.5045) would have to trigger the Aerobic Sewage Treatment Simulation Test (OECD 303A), and accordingly reaffirmed its position that including a Limit of Detection trigger for conducting the 303A test was necessary. EPA also restated its position that Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD 308) and Anaerobic Biodegradability of Organic Compounds in Digested Sludge (OECD 311) testing are necessary and independent of the SCAS and 303A findings.

TRP indicated that it was not prepared to discuss EPA's proposed architecture options until significant technical issues are resolved. One of these issues is how to interpret data. TRP also stated that it would be willing to discuss other tests at a later time once technical issues are resolved, but stated that it is industry's position that this ECA is only for SCAS and OECD 307, and would not include 303A, 308, or 311.

EPA also noted that, while it understands that the proposed ECA involves testing only pure polymers, EPA continues to maintain that to provide an adequate understanding of this critical issue, it will be necessary to conduct complementary degradation testing on actual commercial products and surfactants to determine potential real-world impacts.

#### Conclusions:

- The Plenary acknowledged the efforts made by the subgroup to address biodegradation testing scientific issues. The Plenary also stated that an adequate understanding of biodegradation as a source of PFOA in the environment remains elusive, and that it is essential to come to agreement concerning how to deal with this issue.

- Through the Plenary chairman, EPA recognized that progress has been made and encouraged finalizing an ECA for the SCAS, soil, and appropriate OECD 303A testing as quickly as possible.
- Through the Plenary chairman, EPA asked that industry, EPA staff, and other interested parties engage as soon as possible in moving forward on what is needed to insure the inclusion of the OECD 308 and 311 testing protocol in an additional ECA.

#### ***Telomer User Site Monitoring Update***

Steve Korzeniowski of DuPont reported on the status of Telomer User Site Monitoring, which is not part of the ECA process, but represents a voluntary activity of the Telomer Research Program (TRP). He reported that TRP recently learned that the key contact with whom TRP had been working at the American Textile Manufacturers Institute (ATMI) had left the group. He noted that the community monitoring program originally proposed for the carpet industry in Dalton, GA had proven infeasible, and indicated that TRP and 3M would report back to EPA in 4 to 6 weeks on new action steps. He also described past actions and the path forward with regard to the paper industry, indicating that TRP, at the request of the American Forest & Paper Association (AF&PA) is waiting to hear from individual paper companies contacted by AF&PA to learn whether any companies may be willing to participate in a user-site monitoring program. The presentation is in the docket at OPPT-2003-0012-0541.

#### **Discussion/Questions:**

An interested party requested clarification regarding the status of textile and carpet industry monitoring. TRP responded that the original contact at ATMI had changed jobs and a new contact had not been identified. The interested party also asked if one of the options being considered for the carpet industry is individual site monitoring. TRP stated that volunteers would be needed and there have been none.

#### **Conclusions:**

- The Plenary expressed the importance of user site monitoring in understanding sources, pathways, and levels of exposure. The Plenary expressed concern regarding the status of carpet and textile industry monitoring.

#### **IV. Fluoropolymer Technical Workgroup Reports**

##### ***Fluoropolymer Aged Article ECA Subgroup Report***

On behalf of the Fluoropolymer Aged Article Technical Subgroup, referred to as the Equipment Design Team, Cathy Fehrenbacher of EPA reported on progress made with regard to the Fluoropolymer Aged Articles of Commerce (AAOC) ECA. Her presentation included information on the establishment and activities of the Equipment Design Team, a work flow

chart showing how input flows into the AAOC Equipment Design Team, articles of commerce to be tested, aged article use and test conditions, testing structure, extraction solvent selection, the path forward, and steps toward ECA drafting. The presentation is in the docket at OPPT-2003-0012-0542.

Discussion/Questions: None

Conclusions:

- The Plenary was pleased with the progress made by the Equipment Design Team and expressed the hope that an Aged Articles testing ECA could be concluded expeditiously.

***Summary of Development of Monitoring Memoranda of Understanding***

The Plenary session was placed into recess before the presentation and discussion of the agenda item concerning the status of the development of Fluoropolymer Monitoring Memoranda of Understanding (MOUs). During that recess, final edits were made to the presentation to be given to the Plenary to capture clarifications of the industry commitments reflected in the presentation.

Following the recess, Mary Ellen Weber of EPA, speaking on behalf of the Fluoropolymer Technical Workgroup, presented the status of the development of Fluoropolymer Monitoring MOUs. The presentation included a summary of progress made since the January 29, 2004 Plenary meeting, at which the MOU concept was first discussed and explained, and identified open issues and the path forward. The presentation is in the docket at OPPT-2003-0012-0543.

3M/Dyneon and DuPont each committed to submit by April 8, 2004, a revised draft MOU to EPA for distribution to and comment by the interested parties. These draft MOUs should include agreed-upon language for the charge to the peer consultation panel, an exposure assessment definition, and specific commitment to Phase III testing. EPA also asked that these next drafts of the MOUs include EPA's clarifying questions for the charge to the peer consultation panel. 3M/Dyneon committed to submit a draft Work Plan by April 6, 2004. The Fluoropolymer Monitoring Subgroup will meet on Wednesday, April 21, 2004 to discuss the DuPont Work Plan, which was provided in hard copy at the March 31, 2004 Fluoropolymer Workgroup meeting, and on Thursday, April 29, 2004 to discuss the revised draft MOUs and the 3M/Dyneon Work Plan.

Discussion/Questions:

An interested party asked what was meant by the exposure assessment definition referenced in the presentation. EPA noted that the exposure assessment definition and the charge language are considered as a package because when they are reviewed together they provide a

better interpretation of the scope of this activity. Comments have identified the need for additional clarifying questions and EPA has asked that these be added. The interested party asked if this was meant to reflect the issue discussed in the workgroup meeting regarding human exposure vs a broader exposure. The slide presented using the term "scope of the exposure assessment" was meant to reflect this issue.

An interested party asked if the MOUs would have some type of clarifying questions and if there would be a place to add additional clarifying questions. The response was that the MOUs will contain clarifying questions. Industry agreed to start with EPA's clarifying questions, and indicated that EPA and industry will then work to develop revised clarifying questions. Interested parties will have the opportunity to comment on the revised clarifying questions. The interested party also asked if there will be a data needs assessment. The response was yes.

One concept at issue concerned the nature of the commitment that the industry was making to Phase III monitoring. Following discussion, the industry emphasized that its statement is intended to reflect a commitment to Phase III that will fully meet the charge as informed by the peer consultation process, which includes public input.

Conclusions:

- The Plenary stressed the importance of the monitoring work as an essential element in providing a more developed and integrated understanding of the exposure potential presented by PFOA.
- EPA noted that it is important to provide an integrated understanding of the exposures that are occurring in the environment given the nature of PFOA (for example, persistence and long half life). Therefore, it is important to include appropriate sampling of environmental biota in this monitoring program to allow for a more integrated understanding of all of the exposures that would be occurring at production or use sites.
- EPA recognized that companies are already engaged in or have completed monitoring or sampling work to satisfy the needs of other parties, including State entities, the C8 Assessment of Toxicity Team (CATT), and the Groundwater Investigation Steering Team (GIST). EPA stressed that this work was not agreed to or endorsed by EPA, and made the point that the work to be done through the MOUs must be able to stand on its own and must be put in the context of meeting EPA's identified data needs.
- The Plenary noted that any scientific argument on whether or not to include an activity must be able to rise or fall on the merits of the argument itself, and that the genesis of any information as having been performed for CATT, GIST, or other entities is not relevant for purposes of developing these MOUs.

**V. Next Steps**

***Telomer Technical Workgroup***

- TRP will submit revised Appendices (except for Appendix D) for the Telomer Degradation ECA for review by the Telomer Degradation Technical Expert Subgroup on April 2, 2004.
- Companies that have not yet submitted complete information on the chemicals to be tested for the incineration ECA will submit that information.

***Fluoropolymer Technical Workgroup***

- By April 8, 2004, 3M/Dyneon and DuPont will each submit a revised draft Memorandum of Understanding (MOU) to EPA for distribution to and comment by the interested parties. These draft MOUs should include charge, exposure assessment definition, and commitment to Phase III testing. EPA also asked that these next drafts of the MOUs include EPA's clarifying questions.
- 3M/Dyneon will submit a draft Work Plan by April 6, 2004.
- Companies that have not yet submitted complete information on the chemicals to be tested for the incineration ECA will submit that information.

***Upcoming Meetings***

- The Fluoropolymer Monitoring Subgroup will meet on Wednesday, April 21, 2004 to discuss the DuPont Work Plan.
- The Fluoropolymer Monitoring Subgroup will meet on Thursday, April 29, 2004 to discuss the revised draft MOUs and the 3M/Dyneon Work Plan.
- June 22-24 was proposed for the next series of Technical Workgroup meetings and Plenary session. TRP said they would be without a chairman that week and would prefer alternative dates instead of using an alternative representative. June 15-17 was also suggested; however the Fluoropolymer Manufacturing Group (FMG) was not available during those dates. The next series of Technical Workgroup meetings combined with a Plenary session was scheduled for Tuesday through Thursday, June 22-24, 2004. The Plenary will be held on Thursday, June 24, 2004, from 1:00 to 4:00 PM in Room 1153 of the EPA East Building, 1201 Constitution Avenue, NW, Washington, DC. EPA indicated that complete scheduling information would be provided as it became available.

**VI. Closing Remarks**

EPA thanked the members of the Plenary session for their participation and attendance.