PFOA ECA Telomer Technical Workgroup Meeting Summary 3/30/04

Forty-two participants: Attendance list and presentation materials in docket at OPPT-2003-0012-0521 through 0527.

The meeting included six sections:

- I. Telomer Incineration ECA Update
- II. Telomer Biodegradation ECA Subgroup Report
- III. Telomer User Site Monitoring Update
- IV. Telomer Product and Article Analysis Update on LOI Activities
- V. Briefing on Related EPA Studies
- VI. Identification of Workgroup Next Steps

I. Telomer Incineration ECA Update

ECA Drafting Committee Presentation

Richard Leukroth of EPA presented an update on behalf of the Incineration ECA Drafting Committee on progress made in development of an Enforceable Consent Agreement (ECA) for incineration testing of fluorotelomer-based polymers. The presentation included a summary of recent drafting committee activities, an update on public comments on the ECA, an update on the status of Appendix F, a report on the fulfillment of the request for chemical specific data, a report on the conclusion of the Drafting Committee's work, a proposed recommendation to the Plenary, and next steps. The presentation is in the docket at OPPT-2003-0012-0523.

Discussion

An interested party requested clarification on the changes to Appendix D regarding how data is submitted. Mr. Leukroth responded that non-detect values will now be reported and flagged as a non-detect.

An interested party raised questions regarding this ECA being reported under a new docket number. Mr. Leukroth explained that the formal ECA and Federal Register (FR) notice will trigger the opening of a new docket. This new docket will contain only the information pertinent to the individual ECA, but the new docket and the current docket containing information on this ECA effort (OPPT-2003-0012) will cross reference each other.

The workgroup agreed to recommend to the Plenary that the Final Draft ECA for the Laboratory-Scale Incineration Testing of Fluorotelomer Based Polymers be executed by EPA.

An interested party had some comments on the Final Draft ECA with regard to the Table in Appendix B.1. The first comment was that there needs to be clarification made to the

statement in this table referring to section 2.1 of the ASTM standard that says the University of Dayton standards may be used. Mr. Leukroth replied that this reference can be made more specific. The next comment was that the statement in the table that refers to section 4.1 of the ASTM standard needs further clarification. Mr. Leukroth replied that he will follow up on this.

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

II. Telomer Biodegradation ECA Subgroup Report

Subgroup Presentation

Cathy Fehrenbacher of EPA reported on progress with regard to the Telomer Biodegradation ECA. The presentation included a list of the Telomer Degradation Technical Expert Subgroup members, a summary of the ECA study protocol discussions, a summary of the preliminary discussions of the subgroup, key issues identified by the subgroup, an update of progress made by the subgroup since its initial meeting, and continuing work and discussions. The presentation is in the docket at OPPT-2003-0012-0524.

Discussion

EPA asked how pure the "pure polymer" being proposed as the test substance actually would be. The Telomer Research Program (TRP) responded that each company is still working on purifying and characterizing the polymer it will provide. EPA also asked if there would be a standard technique set for purification of the polymer. TRP replied that there would not be a standard technique; however, criteria will be set for the characterization of the purified polymer. Examples of these criteria could include having less than 10 parts per million (ppm) of residuals in the purified polymer and setting a molecular weight to make sure there has not been a significant change in the fundamental character of the polymer during the purification process. EPA expressed concerns that 10 ppm may not be low enough. The issue of maintaining integrity of the polymer while reducing residuals is being discussed by the subgroup. TRP stated that during the purification of the polymer it is important to avoid washing away some of the lower molecular weight polymer. EPA stressed that, if the intent of the testing is to determine specifically whether the polymer backbone itself will degrade (e.g., biodegradation of the polymer's ester linkages to give telomer alcohol, etc.), having a polymer that is purer than what is on the market is important to the testing, and if sufficient purity cannot be achieved, the product that is on the market might as well be tested.

EPA Presentation

Mary Ellen Weber of EPA presented proposed options for telomer degradation ECA architecture and triggers. The presentation is in the docket at OPPT-2003-0012-0525.

The architectures proposed by EPA were either: 1) two separate ECAs, one including SCAS and Soil (OECD 307) with a specific Limit of Detection trigger for the Sewage Treatment Plant test (OECD 303A), and a separate ECA with Peer Consultation to define conditions under which the Aquatic Sediment (OECD 308) and Sludge (OECD 311) tests would be conducted; or 2) a single ECA with SCAS, Soil, and a Peer Consultation to define conditions under which the OECD 303A, 308, and 311 tests would be conducted under a separate ECA to be negotiated in the future.

Discussion

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. EPA asked when the information on purification and characterization of the pure polymer would be available. TRP responded that it has asked the companies to provide an update on their progress by April 7, 2004. TRP stated that after April 7, it will have a better idea of when the purification and characterization information will be available. EPA expressed some surprise that TRP did not already have characterization information on the pure polymers, since TRP proposed the use of pure polymers as the test substances when the ECA negotiations began almost a year ago. TRP stated that unresolved technical issues have delayed the completion of characterization of the pure polymers.

EPA restated its position on the importance of all of the named degradation tests, including OECD 308 and 311, and noted that those tests provide important and different information than the SCAS, OECD 307, and 303A tests. For instance, the OECD 311 test is primarily associated with the activated sludge stage in wastewater treatment plans. The digestion process is an anaerobic process at an elevated temperature. The microbial population and conditions are different than the conditions used in any other tests. EPA stated this is a key piece of information to help understand the fate of these materials under the conditions in which they are treated and discharged. For OECD 308, wastewater treatment systems are not 100% efficient at solids removal, and solids may be discharged with the wastewater in the effluent and eventually partition to sediments where they may undergo further biodegradation under aerobic or anaerobic conditions. OECD 308 looks at both water column degradation and sediment degradation in the same test. This is important information not captured in any of the currently proposed degradation ECA tests.

TRP 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.

An interested party requested additional detail on the unresolved issues identified by the telomer degradation technical expert subgroup. EPA described the key issues and stated that the the Agency needs the detailed purification and characterization data in order to be able to assess

in detail the issue of attribution of sources of PFOA – whether PFOA may come from the polymer backbone itself, or from impurities present in the product. Regarding the issue of soils in the soil test, EPA noted that it has been asking clarifying questions to better understand what TRP has proposed. TRP proposed one soil for the test, and EPA noted that it has repeatedly stated that transformation rate data are needed and thus that four soils need to be tested, as required in the OECD protocols for derivation of transformation rates. EPA noted that these are scientific and technical issues that will be discussed at the next subgroup meeting. Regarding the Limit of Detection (LOD) vs Limit of Quantitation (LOQ) and analytical methods issues, EPA noted that these issues relate to how the results of testing are interpreted, how degradation is determined, and whether degradation can be attributed to the presence of residuals or to the breakdown of the backbone of the polymer. This concerns the attribution issue, and additional data are needed before this issue can be addressed.

III. Telomer User Site Monitoring Update

TRP Update

Steve Korzeniowski of DuPont reported on the progress of the TRP with regard to potential user-site monitoring for three telomer user industry groups (textiles, paper, and carpet). He reported that the original textiles contact from the American Textile Manufacturers Institute (ATMI) had left the organization and that TRP was attempting to determine the new contact.

He reported that the TRP has had multiple discussions with the Carpet and Rug Institute (CRI) and its members as well as with various Dalton area municipal authorities, specifically the Dalton publicly owned treatment works (POTW). He stated that TRP had several substantive conversations with the Dalton POTW authorities, but indicated that the POTW said they will not participate, and discussions have stopped at this time.

Regarding paper, he reported that there have been multiple conversations with the American Forest & Paper Association (AF&PA) and its members. TRP was asked to provide contact names for its member companies to AF&PA and that information has been provided to allow individual members of AF&PA to contact companies and ask questions. AF&PA member companies are considering whether they will participate in a user-site monitoring program and they will contact TRP if additional information is needed or when a decision is made. The presentation is in the docket at OPPT-2003-0012-0526.

Discussion

EPA asked if TRP could still do a community monitoring program with the individual carpet companies even though the Dalton municipal POTW authority said it will not participate. TRP responded that its monitoring program was designed around the Dalton municipal POTW

authority and TRP has not pursued or had time to explore other options. EPA asked TRP to pursue other options for monitoring of carpet manufacturing facilities.

EPA asked if TRP could contact the AF&PA member companies. TRP said it has been asked by the Association not to contact the companies directly, but instead to let the companies choose whether they wish to contact the TRP members using the contact information that TRP has provided to AF&PA.

An interested party asked if there would be sampling at telomer manufacturing sites. TRP replied that this has been done under the TRP Letter of Intent (LOI) and that the results went into the docket in September 2003.

IV. Telomer Product and Article Analysis Update on LOI Activities

TRP Update

Steve Korzeniowski of DuPont reported on the progress of the TRP with regard to telomer product and article testing. This presentation included progress since the January 29, 2004 plenary session; information on the February 20, 2004 visit to Research Triangle Park (RTP) to gain information on the small chamber method; responses to EPA questions and comments; and next steps. The presentation is in the docket at OPPT-2003-0012-0527.

Discussion

TRP stated that the small chamber method is a mass balance approach but does not necessarily achieve a mass balance. EPA expressed a difference of opinion over how TRP had characterized difficulties with mass balance in their presentation, and reiterated the need for mass balance testing of telomer articles. TRP explained some possible limitations to the small chamber method. TRP indicated that it is willing to attempt to do mass balance, but stated that it may not be possible.

TRP stated there were significant difficulties encountered with the laboratory it used for products testing and that it is looking for a new laboratory. EPA asked if any data were received from the laboratory and whether anything had been learned from working with this laboratory. TRP stated the data from this laboratory were worthless and noted that, in future testing, it would be very important to be careful with packing materials and all other possible confounding factors to ensure achieving a background level of zero.

EPA asked what additional information TRP was waiting for from EPA on mass balance and the ASTM method. TRP responded that EPA had said they had technical information on mass balance. EPA previously provided the ASTM method to TRP. EPA noted that it has general information on key factors of aged articles testing that it can send to TRP. EPA also

indicated that it could provide TRP with information on the Jacksonville longitudinal study. It was agreed that EPA had provided TRP with the requested information on mass balance and the ASTM method.

EPA said it has received the solvent study report and has reviewed the study, and reported that EPA had several technical questions on the study and would be discussing this with Bill Buxton of DuPont and others at the upcoming Fluropolymers Aged Articles of Commerce (AAOC) ECA meeting.

EPA asked if there will be interim reports available during the carpet and textile testing. TRP stated that this program has changed over time due to issues that have been encountered. TRP has not had an opportunity to look at the possibility of interim reports but can consider it.

TRP explained that it is only looking at oral ingestion in its paper testing program because it is the most likely route of exposure from treated paper. TRP stated that FDA views this as the primary route. EPA pointed out that FDA is primarily concerned with potential ingestion from food contact with paper while EPA is concerned with all potential routes and pathways, including inhalation. EPA expressed interest in the inclusion of inhalation from microwaving as a possible route of exposure from fast food paper products. TRP said there are alternative technologies and that not all paper from fast food uses these chemicals. TRP noted that it is not planning on looking at microwaving or inhalation exposures.

EPA clarified for the parties that this testing is being done as a Letter of Intent (LOI) activity, and is not part of the ECA process. Interested parties may comment on LOI activities; however, there is no negotiation or endorsement. The ECA allows all parties to participate in negotiation.

EPA raised questions regarding studies to validate the testing methods proposed in the January 27, 2004 presentation. Industry replied that Jeff Driver provided references. EPA noted that some of these references are for pesticides or are general references. Industry said that they are similar for articles.

An interested party mentioned that popcorn bags had been discussed previously. Industry said that microwave use is small and is not part of this study, and that pet food and fast food grease-resistant packaging are the largest uses.

An interested party brought up that only PFOA was tested for at manufacturing sites and suggested industry look for the telomer 8-2 alcohol. Industry stated that it was not offering to do that.

V. Briefing on Related EPA Studies

EPA Presentation

Ross Highsmith of EPA provided an update on upcoming PFOA-related work to be undertaken by EPA's Office of Research and Development (ORD) and the Department of Housing and Urban Development (HUD). He noted that the focus of the EPA research is principally to understand children's health risks from exposures to pesticides. He observed that this upcoming research provided an opportunity to demonstrate applicability and usefulness of methods to characterize children's exposure to nontraditional environmental contaminants, including PFOA.

The first study is in Jacksonville, Florida and is a subsequent study to an aggregate pesticide study called Children's Total Exposure to Pesticides and Other Persistent Pollutants which was conducted by ORD from 2000 to 2003 in Ohio and North Carolina. Based on this study, it was found that a longitudinal study needed to be conducted to help understand the key factors influencing very young children's exposures to pesticides from birth to age two. EPA is developing the methods that can be used by other organizations, such as the National Children's Study, for assessing longitudinal lifetime exposure. The two-year longitudinal study in Jacksonville will start this year and will monitor children in the home over a two-year period. There will be two cohorts, one from birth to age two and the other from age one to age three. It was recommended that the study be expanded to include other things including PFOA. As a result, integrated samples of dust and air will be collected from selected residences and analyzed for PFOA.

The second study is being conducted by HUD. HUD periodically does national surveys to look at lead and allergens in homes. HUD is getting ready to do a national survey of both HUD and non-HUD residences. HUD will go to between 1,000 and 2,000 randomly selected houses. HUD asked EPA if they would like to participate. EPA noted that it would like to collect vacuum cleaner bags and dust samples and do laboratory analysis for PFOA, arsenic and other contaminants. This study will begin in approximately three months. This plan has not yet been officially approved and is still in draft form. EPA's first preference is to conduct a screening-level survey by testing approximately 100 samples for PFOA, taking samples that would be representative of the United States. Based on those results, additional analysis could be done if the screening results indicated that more work was warranted.

Discussion

EPA asked if blood was going to be tested as part of the Jacksonville longitudinal study. Ross Highsmith replied that there is an option in the study protocol to test blood on a volunteer basis.

An interested party asked what the population size is for the Jacksonville longitudinal study. Dr. Highsmith stated that it is 60 children over a 2-year period.

EPA asked if the study is going to look at treated carpet and clothing. Dr. Highsmith replied that there are questions that may be relevant but the study is not intended to address that.

Industry asked if the Jacksonville longitudinal study or the HUD study would look at any other perfluoro chemicals. Dr. Highsmith said that it was suggested that telomer 8-2 alcohol and PFOS be discussed as part of the longitudinal study. He also said that his focus had been on PFOA. Industry asked why PFOS would not be included in the HUD study and suggested EPA include it in both studies. Industry also asked if there is a formal way to comment on these studies. Dr. Highsmith said that comments on the HUD study can be sent to him and comments on the Jacksonville longitudinal study can be sent to the American Chemistry Council.

VI. Identification of Workgroup Next Steps

TRP

- 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.

EPA

- EPA will send general information on key factors of aged articles testing and information on the Jacksonville longitudinal study to TRP.
- Ross Highsmith will send a peer reviewed study design for the Jacksonville longitudinal study to Mary Dominiak for distribution to the workgroup.

Upcoming Meetings

• The next series of Technical Workgroup meetings combined with a Plenary session were 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. Information on the meetings will be provided as it becomes available.