



**Charles Auer**

Sent by: Sharon Clark

05/21/2003 04:25 PM

To: Mary Dominiak/DC/USEPA/US@EPA  
cc: (bcc: Mary Dominiak/DC/USEPA/US)  
Subject: OPPT-2003-0012: Materials for June 6, 2003 Meeting

May 21, 2003

To Interested Parties and Meeting Attendees:

Please find attached materials related to the upcoming public meeting, to be held June 6, 2003, on the enforceable consent agreement (ECA) development process for perfluorooctanoic acid (PFOA) and fluorinated telomers. These materials include:

- Draft Meeting Agenda
- Discussion guide: Preliminary Framework for ECA Data Development for PFOA and Telomers
- Background materials on the ECA process and expected outputs
- List of Interested Parties

Please note that due to the level of interest expressed by the public and interested parties, the meeting will begin one hour earlier (12:00 PM) than indicated in the Federal Register Notice (1:00 PM). The meeting will take place at EPA Headquarters in Room 1153 of the EPA East Building, 1201 Constitution Avenue, NW, Washington, DC 20460. For security purposes, participants will be required to pass through a metal detector, pass their belongings through an x-ray machine, and present a photo ID to gain entrance into the EPA building. No audio or video recording will be permitted.

The objective of this meeting is to initiate negotiations to develop one or more enforceable consent agreements. These agreements will identify environmental fate and transport information, as well as other relevant information to better understand the sources of PFOA in the environment and the pathways by which human exposure to PFOA is occurring. At this initial meeting, technical committees may be formed to address issues specific to individual ECAs, and the parties will establish the process and schedule(s) for further negotiation sessions and public meetings.

A verbatim transcript will be taken at the meeting and entered into the public docket, OPPT-2003-0012, at [www.epa.gov/edocket/](http://www.epa.gov/edocket/).

With respect to the draft meeting agenda, EPA is considering whether to attempt to set aside time at the beginning of the meeting to allow interested parties to make brief opening statements. This has generally been EPA's practice, but EPA is concerned that time constraints, combined with the large number of interested parties who have registered for this meeting, may render this infeasible. If you would be interested in making a brief opening statement, please notify EPA in advance, and we will make a determination as to the practicality of providing time for short verbal presentations based on the level of response to this request. Preferably, you could submit an opening statement in written form either at or before the meeting. EPA will make available at the meeting hard copies of written opening statements provided to EPA at least two days in advance of the meeting, and will place all opening statements in the docket along with the transcript of the meeting.

If you would like to request time to make an opening statement, or if you have questions concerning this meeting or any difficulty in opening the attached files, please contact Mary

Dominiak by phone at 202/564-8104, or by email at [dominiak.mary@epa.gov](mailto:dominiak.mary@epa.gov).

Sincerely,

Charles M. Auer /S/

Director

Office of Pollution Prevention and Toxics



Preliminary ECA Framework.fina ECA\_Process5\_20\_03.p Initial Interested Parties List.



6-6-2003 Draft Agenda.p

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Deliveries:  
EPA-East Building  
1201 Constitution Avenue, NW  
Room 3166A (7401M)  
Washington, DC 20004

**PUBLIC MEETING**  
**Enforceable Consent Agreement Development for**  
**Perfluorooctanoic acid (PFOA) and Fluorinated Telomers**

**Location:** Environmental Protection Agency (EPA), East Bldg. Rm. 1153  
1201 Constitution Ave., NW, Washington, DC 20460

**Date:** Friday, June 6, 2003; 12:00 PM - 5:00 PM

**Draft Agenda**

- |               |   |
|---------------|---|
| 12:00 - 12:30 | Introduction of Participants – Opening Remarks and ECA Process (EPA)<br>– Charles M. Auer, Director<br>Office of Pollution Prevention and Toxics (OPPT)   |
| 12:30 - 1:00  | Overview of EPA Preliminary Framework Document for ECA Data Development for PFOA and Telomers<br><br>I. Telomer Data Needs<br>II. Fluoropolymer Data Needs<br>III. Rationales for Proposed Fate Testing and Monitoring/Sampling |
| 1:00 - 2:00   | General Discussion of Testing Needs for Identifying Sources of PFOA in the Environment and Pathways of Exposure   |
| 2:00 - 2:10   | Break   |
| 2:10 - 4:00   | Identification and Discussion of ECA Opportunities and Approaches<br><br>I. ECA Topics Amenable to Quick Resolution<br>II. Telomer ECAs<br>III. Fluoropolymer ECAs<br>IV. Other Additional ECA Opportunities?                   |
| 4:00 - 4:20   | Next Steps  |
| 4:20 - 4:50   | Public Comment (Open mike: maximum time 3 minutes per speaker)  |
| 4:50 - 5:00   | OPPT Closing Remarks  |

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

### ***Background***

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

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

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

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

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

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

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

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

## ***Introduction***

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

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

**Telomer Data Needs**

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

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

*Fate, Biodegradation, and Incineration*

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

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

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

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

### *Monitoring*

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

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

### *Product Stewardship*

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

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

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

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

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



**Table I. Telomer Data Needs**

| Item | Data Need: Telomers  | Test Substances  | Suggested Test Methods   |
|------|--|--|--|
| 1.   | *Comprehensive telomer market information:<br>CAS numbers<br>Chemical names<br>Synthetic sequences<br>Production/import volumes<br>Uses/applications                                     | All telomers and polymers made from telomers.  | None required  |
| 2.   | P-chem properties to inform fate testing.<br>This information should be obtained prior to fate testing of representative test substances.<br>Unnecessary for certain polymeric materials | Examples:<br>telomer iodides<br>telomer alcohols<br>telomer esters of (meth)acrylates<br>telomer sulfonates  | The following, as appropriate:<br>*Water solubility OECD 105<br>*Vapor pressure OECD 104<br>*Soil and sludge adsorption/desorption isotherm OPPTS 835.1220<br>*UV/visible absorption OPPTS 830.7050<br>*Hydrolysis as a function of pH OPPTS 835.2130  |
| 3.   | Elucidation of degradation pathways and identification of degradation products   | Telomer products will be specified, and should be individual representative test substances with appropriate chain lengths representative of desired product information, and different classes of telomer-based polymers such as polyethers, polyurethanes, and polyacrylates<br><br>The choice of testing material should also be based on structure, production volume, use, and environmental exposures. | The following, as appropriate:<br>*Inherent Biodegradability Zahn-Wellens/EMPA Test 835.3200<br>*Activated sludge sorption isotherm OPPTS 835.1110<br>Aerobic and Anaerobic Transformations in Soil OECD 307<br>Aerobic and Anaerobic Transformations in Aquatic Sediment systems OECD 308<br>Direct Photolysis in Water OPPTS 835.2210<br>Indirect Photolysis Screening Test OPPTS 835.5270<br>*Determination of air/water partition coefficient/Henry's Law Constant (method to be determined)<br>Simulation test-Aerobic Sewage Treatment (Activated Sludge Units) OECD 303A<br>Anaerobic biodegradability of organic compounds in digested sludge: measurement of gas production, OECD 311 |

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| 4. | Determination of p-chem, fate and transport properties of major degradation products  | Synthesis and testing of standards for known degradants (e.g., Rf-acetate and Rf-acrylate)   | P-Chem properties/Fate/Transport in 2 & 3 above<br>Determination of air/water partition coefficient/<br>Henry's Law Constant (method to be determined).<br>UV/visible absorption OPPTS 830.7050.<br>Direct Photolysis in Water OPPTS 835.2210.<br>Indirect Photolysis Screening Test OPPTS 835.5270. |
| 5. | Determination of incineration byproducts of telomers and telomer treated products and articles  | Representative telomers and telomer treated products and articles (paper, textile and carpet products, fire-fighting foams) from manufacturers and importers           | "Laboratory" Burn Test Protocol:<br>1. ASTM E1641: Decomposition Kinetics by Thermogravimetry.<br>2. Laboratory-Scale Thermal Degradation via GC/MS yielding the temperature for 99% destruction efficiency @ 2.0 second residence time & excess oxygen.   |
| 6. | Determination of p-chem, fate and transport properties of incineration byproducts   | Representative telomer incineration byproducts (direct release of PFAC / Rf acetate)<br><br>Potential olefins from incineration oxidation / conversion to acids        | To be determined based on incineration test results.<br><br>[half life gas phase HO. Reactivity]   |
| 7. | *Presence/quantification of PFOA, telomer alcohol or other PFOA precursors in telomer chemical products                                   | Representative telomers from manufacturers and importers   | Draft Study Plan received from TRP; however, Plan does not contemplate identifying PFOA precursors.<br><br>Sampling and testing standards to be determined.  |
| 8. | *Presence/quantification of PFOA, telomer alcohol or other PFOA precursors in telomer-treated or telomer-containing products and articles | Representative telomer-treated or telomer-containing products and articles (paper, textile and carpet products, fire-fighting foams), from manufacturers and importers | Draft Study Plan received from TRP; however, Plan does not contemplate identifying PFOA precursors or addressing fire fighting foams.<br><br>Sampling and testing standards to be determined.  |

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| 9.  | *Presence of PFOA, telomer alcohol or other PFOA precursors emitted from telomer treated products and articles as they age during use     | Representative telomers and telomer treated products and articles from manufacturers and importers in indoor air adjacent to – and dust from or adjacent to – carpet, textile, and paper products. | <p>Draft Study Plan received from TRP; however, Plan does not contemplate identifying PFOA precursors or performing air or dust analysis.</p> <p>Sample before, during, and after such activities as chemical re-treatment of carpet and apparel, carpet vacuuming, steam cleaning, and laundry washing and drying (apparel).</p> <p>The range of chemical emissions from these products and articles can be estimated under laboratory conditions such as in test chambers or test houses.</p> |
| 10. | Release and exposure assessments for PFOA and PFOA precursors adjacent to telomer manufacturing and use facilities; also of control areas | Representative telomers and related compounds in air, stream and quiet surface waters (surface film and subsurface), groundwater, sediment, surface soil, and biota.                               | Sampling and testing standards to be determined. 3M (OPPT-2003-0012-0035) and DuPont (Exygen) (OPPT-2003-0012-0040) PFOA methods may serve as initial point for water, but they lack differentiation for surface film. Mabury (as described in OPPT-2003-0012-0010) may provide air starting point.   |
| 11. | Release and exposure assessment for PFOA and PFOA precursors from use of fire-fighting foam   | Representative telomers and related compounds in soil, groundwater, surface water runoff, and air during and after fire-fighting foam use  | Sampling and testing standards to be determined. 3M (OPPT-2003-0012-0035) and DuPont (Exygen) (OPPT-2003-0012-0040) PFOA methods may serve as initial point for water, but they lack differentiation for surface film. Mabury (as described in OPPT-2003-0012-0010) may provide air starting point.   |
| 12. | Product stewardship information concerning telomer products and articles  | Telomer products and articles  | None required.  |

\* Denotes that the TRP has committed to provide some, but not necessarily all, information concerning this particular data need or endpoint for one or more chemicals. Analytical methods are to be determined, and data quality requirements need to be reviewed to determine appropriateness and acceptability in the context of this ECA. To the extent that chemicals beyond those being covered under the LOI are identified as possible test candidates, the need for such testing will be considered in the context of the ECA process.

Test methods may be amended and adapted through the ECA process, and where test methods have not been identified, they may be developed during the ECA process.

**Fluoropolymer Data Needs**

The fluoropolymers of concern to the Agency are those for which PFOA (generally in the form of ammonium perfluorooctanoate, APFO) is used as a polymerization aid. Information currently available suggests that these fluoropolymers would not break down to form PFOA as a degradation product. The industry has indicated that PFOA is not expected to be present in fluoropolymer products manufactured using PFOA as a fluoropolymer processing aid, and has proposed in their LOI (OPPT-2003-0012-0012) to test products for the presence of PFOA. Such information may be helpful in constructing an understanding of PFOA's mass balance in these processes. Questions remain concerning potential releases of PFOA from the incineration of fluoropolymer products. EPA's concern is for potential releases of PFOA from fluoropolymer and PFOA manufacturing processes, and from any potential presence of residual PFOA in fluoropolymer products or resulting from the incineration of such products.

EPA requested clarification of certain of 3M's and FMG's LOI commitments on April 30, 2003 (OPPT-2003-0012-0028 and 0029, respectively). 3M responded on May 7, 2003 (OPPT-2003-0012-0035), and FMG and DuPont responded on May 5 and May 7, 2003 (OPPT-2003-0012-0036 through 0044).

***Fate, Biodegradation, and Incineration***

EPA has identified some questions with respect to the potential for fluoropolymer degradation, and with the fate and degradation of the products of fluoropolymer incineration. Accordingly, EPA is suggesting certain physical/chemical property, fate, and incineration testing, as shown on the following table.

***Monitoring***

With respect to characterizing releases from PFOA manufacture, from fluoropolymer manufacture, and from the use of fluoropolymer dispersions in treating articles, EPA believes that screening-level environmental monitoring in the immediate vicinity of all PFOA and fluoropolymer manufacturing facilities, as well as a selection of facilities from different industries that utilize fluoropolymer dispersions to coat or treat other manufactured articles, are appropriate. Accordingly, EPA is suggesting potential sampling and monitoring activities addressing the potential presence of PFOA in air, water, soils, sediments, and biota at PFOA and fluoropolymer manufacturing facilities, and at facilities utilizing fluoropolymer dispersions. EPA is also suggesting the sampling and testing of fluoropolymer products and fluoropolymer-treated articles to determine the potential residual presence of PFOA or the release of PFOA during use and aging.

Information concerning blood levels in workers may further help to identify and characterize the sources and pathways of exposure, and may be contemplated in the future

depending upon the results of monitoring for PFOA in the vicinity of fluoropolymer and PFOA manufacturing and use facilities, and other information available to EPA. EPA will not pursue blood monitoring as part of this ECA process.

### *Product Stewardship*

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

EPA has identified potential data needs for PFOA and fluoropolymers in Table II. Some of these needs appear to be met in whole or in part under the 3M and FMG LOIs, and are identified in the following table with an asterisk (\*). This ECA process offers the opportunity to further refine and develop related testing and approaches to address needs or to generate data that go beyond those expressed in the existing 3M and FMG LOI commitments.

**Table II. Fluoropolymer Data Needs**

| <b>Item</b> | <b>Data Need or Issue: Fluoropolymers</b>  | <b>Test Substances</b>  | <b>Suggested Test Methods</b>   |
|-------------|--|---|---|
| <b>1.</b>   | Comprehensive fluoropolymer market information:<br>CAS numbers<br>Chemical names<br>Production/import volumes<br>Uses/applications | All fluoropolymers made using PFOA as fluoropolymer polymerization aid (FPA).   | None required.  |
| <b>2.</b>   | P-chem properties to inform fate testing   | Representative fluoropolymers   | The following, as appropriate:<br>Soil adsorption/desorption isotherm OPPTS 835.1220<br>Hydrolysis as a function of pH OPPTS 835.2130<br>UV/visible absorption OPPTS 830.7050   |
| <b>3.</b>   | Elucidation of degradation pathways and identification of degradation products   | Representative fluoropolymers<br><br>The choice of testing material will be targeted based on structure, production volume, uses and environmental exposures. | The following, as appropriate:<br>Inherent Biodegradability Zahn-Wellens/EMPA Test 835.3200<br>Activated sludge sorption isotherm OPPTS 835.1110<br>Aerobic and Anaerobic Transformations in Soil OECD 307<br>Aerobic and Anaerobic Transformations in Aquatic Sediment systems OECD 308<br>Direct Photolysis in Water OPPTS 835.2210<br>Indirect Photolysis Screening Test OPPTS 835.5270<br>Determination of air/water partition coefficient/Henry's Law Constant (method to be determined)<br>Simulation test-Aerobic Sewage Treatment (Activated Sludge Units) OECD 303A<br>Anaerobic biodegradability of organic compounds in digested sludge: measurement of gas production, OECD 311 |

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| 4. | Determination of p-chem, fate and transport properties of major degradation products  | To be determined based on test results   | P-Chem properties/Fate/Transport in 2 & 3 above<br>Determination of air/water partition coefficient/Henry's Law Constant (method to be determined)<br>UV/visible absorption OPPTS 830.7050<br>Direct Photolysis in Water OPPTS 835.2210<br>Indirect Photolysis Screening Test OPPTS 835.5270   |
| 5. | Determination of PFOA EPA contamination of processed fluoropolymer (solid), including a detailed material balance focusing on interstage transfers and releases to environmental compartments | Analysis of processed fluoropolymer products : PTFE homopolymers, copolymers, fluoroelastomers. Validation of engineering models with analytical data. Documentation of PFOA removal/destruction (asserted in AR226-1000). | To be determined based on granular vs fine powder solids.<br><br>The TRP proposed method for detecting PFOA impurity in carpet/textile/paper may serve as a starting point   |
| 6. | *Presence of PFOA in fluoropolymer and fluoropolymer treated products and articles  | Representative fluoropolymers and representative fluoropolymer treated products and articles (paper, textile and carpet products, PTFE cookware, engine oil with PTFE) from manufacturers and importers.                   | Sampling and testing standards to be determined<br>Stability of products during melt processing or molding /extrusion procedures.  |
| 7. | Presence of PFOA emitted from fluoropolymer treated products and articles as they age during use  | Representative fluoropolymers from manufacturers and importers in indoor air adjacent to – and dust from or adjacent to – carpet, textile, and paper.  | Sample before, during, and after such activities as chemical re-treatment of carpet and apparel, carpet vacuuming, steam cleaning, and laundry washing and drying (apparel).<br><br>The range of chemical emissions from these products and articles can be estimated under laboratory conditions such as in test chambers or test houses.<br><br>Sampling and testing standards to be determined. |

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| 8.  | Determination of incineration byproducts of fluoropolymer and fluoropolymer treated products and articles                    | Representative fluoropolymers and fluoropolymer treated products and articles (paper, textile and carpet products, engine oil with PTFE) from manufacturers and importers.             | “Laboratory” Burn Test Protocol:<br>1. ASTM E1641: Decomposition Kinetics by Thermogravimetry.<br>2. Laboratory-Scale Thermal Degradation via GC/MS yielding the temperature for 99%destruction efficiency @ 2.0 second residence time & excess oxygen.   |
| 9.  | Determination of p-chem, fate and transport properties of incineration products  | Representative incineration products from 8 above.   | To be determined based on incineration test results   |
| 10. | *Release and exposure assessments adjacent to PFOA and fluoropolymer manufacturing and use facilities; also of control areas | Fluoropolymer polymerization aids (FPAs) and related compounds in air, stream and quiet surface waters (surface film and subsurface), groundwater, sediments, surface soil, and biota. | Sampling and testing standards to be determined. 3M (OPPT-2003-0012-0035) and DuPont (Exygen) (OPPT-2003-0012-0040) PFOA methods in docket may serve as initial point for water, but they lack differentiation for surface film. Mabury (as described in OPPT-2003-0012-0010) may provide air starting point. |
| 11. | Product stewardship information concerning PFOA and fluoropolymer product and article manufacturing, use, and disposal       | PFOA and fluoropolymer products and articles   | None  |

\* Denotes that 3M and/or FMG have committed to provide some, but not necessarily all, information concerning this particular data need or endpoint for one or more chemicals. Analytical methods are to be determined, and data quality requirements need to be reviewed to determine appropriateness and acceptability in the context of this ECA. To the extent that chemicals beyond those being covered under the LOIs are identified as possible test candidates, the need for such testing will be considered in the context of the ECA process.

Test methods may be amended and adapted through the ECA process, and where test methods have not been identified, they may be developed during the ECA process.



## APPENDIX A

### ***Rationales For Proposed Fate Testing and Monitoring and Sampling Activities***

This Appendix presents additional information explaining why certain testing may be proposed, and discussing proposed test standards and methodologies. The information in this Appendix applies to both the telomer and fluoropolymer tables in the Preliminary Framework Document.

#### **Testing: chemical properties**

Objective: Obtain fundamental chemical property data on subject telomers and fluoropolymers.

Tests: Water solubility; vapor pressure; soil adsorption/desorption isotherm; UV-Visible absorption spectrum; hydrolysis.

Rationale: These data are prerequisites to and inform subsequent fate testing. OECD guidelines 307, 308, and 303A (respectively soil; sediment; activated sludge tests) all state that information on water solubility, vapor pressure, soil adsorption/desorption isotherm and hydrolysis should be available before additional testing is done. Information on these endpoints is required to ensure the correct design of fate protocols for sediment, soil and sludge, so that they accomplish their objectives. UV-Visible absorption spectrum is also easily determined in the laboratory and indicates whether the test substance absorbs light in the visible range. If it does, the possibility exists that direct photolysis may be a significant fate process, and a more definitive test to quantify this process should then be performed. In addition, water solubility and vapor pressure together (as the vapor pressure/solubility ratio) provide an estimate of the Henry's Law constant ( $H_c$ ), which is an important indicator of volatility from water. If a test substance has an estimated Henry's Law constant within a certain range (to be decided), the substance should then be subject to more definitive testing to determine  $H_c$  experimentally.

#### **Testing: environmental transformation**

Objective: Identify the most important environmental transformation (degradation) processes for subject telomers and fluoropolymers. Elucidate degradation pathways and identify and quantify major degradation products to the extent possible.

Tests: Inherent biodegradability: Zahn/Wellens/EMPA test (OPPTS 835.3200 or OECD 302B); Activated Sludge Sorption Isotherm (OPPTS 835.1110); Aerobic and anaerobic transformation in aquatic sediment, OECD 308; Aerobic and anaerobic transformation in soil, OECD 307; Simulation test-aerobic sewage treatment, OECD 303(A: Activated sludge test); direct and indirect photolysis in water; Anaerobic biodegradability of organic compounds in digested sludge: measurement of gas production, OECD 311. Because of the unique properties of these perfluorinated chemicals, the analytical methods themselves may need to be tailored to attain valid results.

Rationale: See below.

*Zahn-Wellens/EMPA test. OPPTS 835.3200* The inherent biodegradability of a test substance is an important fundamental characteristic. In concert with supplemental analytical techniques the Zahn-Wellens test can allow the identification of important biodegradation products and pathways under conditions conducive to aerobic biodegradation in an activated sludge medium. The test also gives an indication of the potential for removal of the test substance via sorption to the activated sludge inoculum.

*Aerobic and anaerobic transformation in aquatic sediment, OECD 308.* Test substances may enter shallow or deep surface waters by a variety of routes, including industrial or domestic effluents, waste disposal and atmospheric deposition. The subject guideline is capable of yielding quantitative information on a substance's fate in aquatic sediment samples collected from the environment and brought into the laboratory for study. The guideline is written so as to accommodate a variety of specific objectives which include multiple sampling locations (thus sediments with a variety of characteristics); identification and quantification of major degradation products; and specification of test conditions (e.g. duration, temperature) as appropriate. Transformation rates and half-lives can also be determined for subsequent use in environmental fate and exposure modeling (e.g. EXAMS II) if that is done.

*Aerobic and anaerobic transformation in soil, OECD 307.* Test substances may enter soils by a variety of routes, including land application of biosolids, waste disposal (landfilling) and atmospheric deposition. The subject guideline is capable of yielding quantitative information on a substance's fate in soil samples collected from the environment and brought into the laboratory for study. The guideline is written so as to accommodate a variety of specific objectives which include multiple sampling locations (thus soils with a variety of characteristics); identification and quantification of major degradation products; and specification of test conditions (e.g. duration, temperature, pressure) as appropriate. Transformation rates and half-lives can also be determined for subsequent use in environmental fate and exposure modeling if that is done.

*Simulation test-aerobic sewage treatment: OECD 303A, Activated sludge test.* Aqueous wastes from manufacture, processing and use of telomers and fluoropolymers may be disposed in a variety of ways. Activated sludge secondary treatment is the chief removal process in publicly owned treatment works (POTWs) and also in many if not most industrial wastewater treatment systems. OECD 303A is a simulation test for activated sludge treatment and as such, assuming proper conduct of the test, optimum selection of test conditions, etc., can yield information on removal that can be used in subsequent modeling and exposure assessment. Primary objectives would be to:

- (1) Identify the most important transformation (degradation) processes for subject telomers and fluoropolymers. Elucidate degradation pathways and identify and quantify major degradation products (if any) to the extent possible;

(2) Obtain measured values and standard deviations for overall removal rates for the test substances and any degradation products that are also determined in the studies;

(3) Measure and quantify test substances and degradation products in the three main “waste” streams from such treatment; namely effluent, waste sludge and aeration off-gases.

If such testing yields negative results, defined as no formation of biotransformation products greater than xx % relative to starting material, then additional testing for this endpoint may be unnecessary. An exception may occur because any fate test can only yield a snapshot of likely environmental processes. It is always possible that the snapshot may turn out to be unrepresentative of some specific treatment plants(s) of interest, which might not even be identified at the time the test is done. Positive results could trigger further investigation of a specific removal process (e.g., volatilization, sorption).

*Anaerobic biodegradability of organic compounds in digested sludge: measurement of gas production, OECD 311.* In wastewater treatment a principal disposition of many chemical substances is to partition to the solids phase. Chemical properties are a driving force in this process, wherein partitioning to solids is favored for the less water-soluble substances. In typical treatment plants, especially those using activated sludge secondary treatment, excess sludge is generated during treatment and normally is sent to an adjacent anaerobic digester to reduce volume and organic load prior to ultimate disposal. Conditions are not identical to those of a full-scale digester, but results of the test should provide a good indication of the potential for degradation at full scale. Important test conditions--e.g. temperature, duration, etc.--can be selected so as to mimic actual digestors (although the test is not regarded as a simulation test). The test is intended to measure ultimate anaerobic degradation via total gas production (a standard method), but it can be modified to incorporate substance-specific analysis.

This test can be triggered by “significant” presence of test substances in the sludge, as determined in the activated sludge simulation test (OECD 303A), above). Assuming optimum selection of test conditions, test duration, analytical methods, etc., it should be possible to obtain sufficient data to develop a picture of the most probable anaerobic biotransformation pathway(s) and products (if any). Quantitative data on removal of test substances and removal/formation of degradation products (if any) can be used in subsequent exposure modeling, to adjust the amount of the given substance calculated to be sent later to landfill, spread on land surfaces, etc. If such testing yields negative results, defined as no formation of biotransformation products greater than xx % relative to starting material, then additional testing should be unnecessary.

*Activated Sludge Sorption Isotherm, OPPTS 835.1110.* The sorption of chemical compounds to activated sludge biomass in biological wastewater treatment systems is an important process that affects the distribution of the compounds between solid, aqueous, and vapor phases. If a chemical compound is sorbed to sludge biomass, it may be removed from the

system along with other solids by clarification. If a compound is not sorbed, it will remain in the aqueous phase where it is subject to removal via biodegradation, chemical interactions, and/or volatilization. A non-sorbing, non-biodegradable, non-interacting, nonvolatile compound will pass through a biological treatment system unaffected. Information on sorption potential is needed to assess the possibility for the removal of chemical compounds in biological wastewater treatment systems. While the focus of the Activated Sludge Sorption Isotherm test is the measurement of *sorption* of the test chemical to sludge, it can be modified to assess the potential for *desorption* of the test chemical as well. This modification would permit the assessment of the potential for a chemical sorbed to sludge to be leached from sludge. The additional information would be useful in examining the potential for migration of the test chemical from sludge as a result of sludge land application.

### **Exposure Monitoring and Modeling**

Accurate estimation of total human and environmental exposures requires extensive knowledge of chemical behavior (fate), routes and location of exposure, and human activity patterns that lead to exposure. For a diverse set of chemicals in widespread use, a complex mix of information must be tailored for well-designed monitoring tests or meaningful modeling. Insufficient information, poorly designed and/or incomplete tests or models will defeat the reasonable estimation of exposures.

### **Testing: Monitoring of environmental, general population and consumer exposure**

Chemical monitoring in the outdoor environment is usually tailored to the known or estimated behavior (fate) of the chemical(s), e.g., if it is known that a chemical partitions to water, monitoring can focus on the water pathway. Because neither all the chemicals' identities nor their fate are known, the monitoring suggested here must be considered as subject to change as more information becomes available. Given these limitations, the initial monitoring proposal is based on the fate known for PFOA, as follows:

For facilities that have manufactured or used the chemical(s), measure appropriate chemicals in air, water, soil, sediments, and biota. Similar facility samplings should be done at sites with no expected sources of exposure – control sites. All samplings should be designed to find significant differences between sampling locations (control and expected), and sampling times, e.g., before, during, and after emissions.

Facility air, water, soil, sediments, and biota samples should be taken before, during, and after emissions to those respective media. Since PFOA may partition to water surfaces, both surface and subsurface water samples should be gathered, from appropriate stream and quiet water sites. Since PFOA may partition to airborne particulates, surface soil samples should be gathered, from areas that air monitoring or modeling indicate are probable for particulate deposition.

Exposures to chemical emissions from products should be estimated from appropriate studies of product use/activities in chamber or test houses. These should include testing the indoor air and dust on samples before, during, and after such activities as chemical re-treatment of carpet and apparel, carpet vacuuming, steam cleaning, and laundry washing and drying (apparel).

### **Monitoring Uncertainties**

As in the fate rationale presented above, exposure monitoring may constitute no more than a snapshot of a rapidly changing situation and so not be adequately representative. This is especially true for media that the chemical moves through but doesn't partition to. Conversely, media that act as sinks where the chemical can accumulate can obscure the source(s) and pathway(s) of exposure, e.g., PFOA in biota. Repeating samplings over time may address these concerns, as changes measured over time in the pathways and in biota may correlate with observed changes in environmental concentrations. More certain correlation of pathway exposure and corresponding environmental levels can be investigated with carefully planned radioisotope studies, which, if in sufficient concentration to be detected, can be tracked from release through exposure.

### **Testing: Modeling of environmental, general population and consumer exposure**

An attempt to model correlations between environmental concentrations and human blood levels of PFOA was made by DuPont (Hinderliter and Jepson, 2001). More chemical fate and PBPK information would be needed to validate/improve this model. EPA is aware that additional PBPK studies in rats are underway in Europe.

## APPENDIX B

### *Determination of Test Substances*

This Appendix provides examples and explanations of how specific test substances, which are only identified generally in the tables in the Preliminary Framework Document, may be determined during the ECA process.

#### **Telomers**

The telomer chemicals of greatest interest to the EPA are those currently in commerce. EPA is aware that the specific identities of many of the telomer chemicals currently produced are claimed as confidential business information (CBI) under the Toxic Substances Control Act (TSCA), and are thus not subject to public disclosure. Accordingly, EPA would expect that certain of the identities of specific telomer test substances to be used in this ECA process would also be claimed as CBI, although the test results would be publicly available.

For the purpose of defining the types of telomer chemicals which would be of interest to the EPA in the context of this ECA process, EPA conducted a search of the public TSCA Inventory to identify telomer chemicals that reflect the scope of the Agency's interest. These chemicals are listed below. This list is not comprehensive, nor do the chemicals on this list necessarily represent chemicals that the Agency would propose as test substances for this ECA process. This list is offered to illustrate and provide examples of the generic descriptive terms used in the tables in this preliminary framework document.

**Example Telomer Chemicals and Polymers***C4-C18 alcohols, .gamma.-.omega.*

- CAS 54949-76-5: 1-Butanol, 3,3,4,4,4-pentafluoro-
- CAS 2043-47-2: 1-Hexanol, 3,3,4,4,5,5,6,6,6-nonafluoro-
- CAS 647-42-7: 1-Octanol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-
- CAS 678-39-7: 1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-
- CAS 865-86-1: 1-Dodecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafuoro-
- CAS 39239-77-5: 1-Tetradecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-pentacosafuoro-
- CAS 60699-51-6: 1-Hexadecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafuoro-
- CAS 65104-67-8: 1-Octadecanol,  
3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,17,17,18,18,18-tritriacontafuoro-

*C4-C20 alcohols, .gamma.-.omega.-perfluoro (meth)acrylates*

- CAS 52591-27-2: 2-Propenoic acid, 3,3,4,4,5,5,6,6,6-nonafluorohexyl ester
- CAS 17527-29-6: 2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester
- CAS 27905-45-9: 2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester
- CAS 17741-60-5: 2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafuorododecyl ester

|                 |   |
|-----------------|---|
| CAS 34395-24-9: | 2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-pentacosafuorotetradecyl ester   |
| CAS 34362-49-7: | 2-Propenoic acid,<br>3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafuorohexadecyl ester  |
| CAS 2144-53-8:  | 2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester   |
| CAS 2144-54-9:  | 2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafuorododecyl ester   |
| CAS 6014-75-1:  | 2-Propenoic acid, 2-methyl-,<br>3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-pentacosafuorotetradecyl ester                                       |
| CAS 4980-53-4:  | 2-Propenoic acid, 2-methyl-,<br>3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafuorohexadecyl ester                             |
| CAS 59778-97-1: | 2-Propenoic acid, 2-methyl-,<br>3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,17,17,18,18,18-tritriacontafuorooctadecyl ester             |
| CAS 65104-66-7: | 2-Propenoic acid, 2-methyl-,<br>3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,17,17,18,18,19,19,20,20,20-heptatriacontafuoroeicosyl ester |

*Other (meth)acrylates*

|                 |  |
|-----------------|--|
| CAS 49859-70-3: | 2-Propenoic acid, 2-[methyl[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulfonyl]amino]ethyl ester               |
| CAS 48077-95-8: | 2-Propenoic acid, 2-[[[(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl)sulfonyl]methylamino]ethyl ester |



*Phosphates*

- CAS 148240-85-1: 1,3-Propanediol, 2,2-bis[[[g-w-perfluoro-C4-10-alkyl]thio]methyl] derivs., phosphates, ammonium salts
- CAS 148240-87-3: 1,3-Propanediol, 2,2-bis[[[g-w-perfluoro-C6-12-alkyl]thio]methyl] derivs., phosphates, ammonium salts
- CAS 148240-89-5: 1,3-Propanediol, 2,2-bis[[[g-w-perfluoro-C10-20-alkyl]thio]methyl] derivs., phosphates, ammonium salts

*Other Class 1/2 Compounds*

- CAS 54950-05-9: Butanedioic acid, sulfo-, 1,4-bis(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) ester, sodium salt
- CAS 70983-60-7: 1-Propanaminium, 2-hydroxy-N,N,N-trimethyl-, 3-[[[g-w-perfluoro-C6-20-alkyl]thio] derivs., chlorides
- CAS 71608-61-2: Pentanoic acid, 4,4-bis[[[g-w-perfluoro-C8-20-alkyl]thio] derivs., compds. with diethanolamine
- CAS 82199-07-3: Carbamic acid, [2-(sulfothio)ethyl]-, C-(3,3,4,4,5,5,6,6,7,7,8,8,8- tridecafluorooctyl) ester, monosodium salt

*POLYMERS*

*Polyethers*

- CAS 68784-73-6: 2-Propenoic acid, 2-methyl-, 2-[methyl[[[g-w-perfluoro-C8-14- alkyl)sulfonyl]amino]ethyl esters, reaction products with polyethylene glycol bis(mercaptoacetate)
- CAS 72480-32-1: 2-Propenoic acid, 2-(methylamino)ethyl ester, N-[[[g-w-perfluoro-C8-14-alkyl)sulfonyl] derivs., reaction products with polyethylene glycol bis(thioglycolate)
- CAS 183146-60-3: Oxirane, methyl-, polymer with oxirane, mono[2-hydroxy-3-[[[g-w-perfluoro-C8-20-alkyl]thio]propyl] ethers
- CAS 70983-59-4: Poly(oxy-1,2-ethanediyl), a-methyl-w-hydroxy-, 2-hydroxy-3-[[[g-w-perfluoro-C6-20-alkyl]thio]propyl ethers

- CAS 68784-73-6: 2-Propenoic acid, 2-methyl-, 2-[methyl[(g-w-perfluoro-C8-14-alkyl)sulfonyl]amino]ethyl esters, reaction products with polyethylene glycol bis(mercaptoacetate)
- CAS 72480-32-1: 2-Propenoic acid, 2-(methylamino)ethyl ester, N-[(g-w-perfluoro-C8-14-alkyl)sulfonyl] derivs., reaction products with polyethylene glycol bis(thioglycolate)

*Poly(meth)acrylate (meth)acrylamide*

- CAS 70969-47-0: Thiols, C8-20, g-w-perfluoro, telomers with acrylamide
- CAS 65636-35-3: Ethanaminium, N,N-diethyl-N-methyl-2-[(2-methyl-1-oxo-2-propenyl)oxy]-, methyl sulfate, polymer with 2-ethylhexyl 2-methyl-2-propenoate, a-fluoro-w-[2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl]poly(difluoromethylene), 2-hydroxyethyl 2-methyl-2-propenoate and N-(hydroxymethyl)-2-propenamide
- CAS 68239-43-0: 2-Propenoic acid, 2-methyl-, 2-ethylhexyl ester, polymer with a-fluoro-w-[2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl]poly(difluoromethylene), 2-hydroxyethyl 2-methyl-2-propenoate and N-(hydroxymethyl)-2-propenamide
- CAS 196316-34-4: 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymers with g-w-perfluoro-C10-16-alkyl acrylate and vinyl acetate, acetates
- CAS 186397-57-9: 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymers with g-w-perfluoro-C10-16-alkyl acrylate and vinyl acetate
- CAS 174125-96-3: 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymers with d-w-perfluoro-C10-16-alkyl acrylate and vinyl acetate

- CAS 150135-57-2: 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymers with Bu acrylate, g-w-perfluoro-C8-14-alkyl acrylate and polyethylene glycol monomethacrylate, 2,2'-azobis[2,4-dimethylpentanenitrile]-initiate
- CAS 68988-55-6: 2-Propenoic acid, 2-methyl-, C7-18-alkyl esters, polymers with 2-[methyl[(g-w-perfluoro-C8-14-alkyl)sulfonyl]amino]ethyl acrylate
- CAS 68988-54-5: 2-Propenoic acid, 2-methyl-, C7-8-alkyl esters, polymers with 2-[methyl[(g-w-perfluoro-C8-14-alkyl)sulfonyl]amino]ethyl acrylate
- CAS 68988-53-4: 2-Propenoic acid, 2-methyl-, C4-18-alkyl esters, polymers with 2-[methyl[(g-w-perfluoro-C8-14-alkyl)sulfonyl]amino]ethyl acrylate
- CAS 68988-52-3: 2-Propenoic acid, 2-methyl-, C4-8-alkyl esters, polymers with 2-[methyl[(g-w-perfluoro-C8-14-alkyl)sulfonyl]amino]ethyl acrylate

*Other Polymeric Compounds*

- CAS 68988-25-0: 1,4-Butanediol, 2,3-bis[(g-w-perfluoro-C4-18-alkyl)thio] derivs., polymers with 1,6-diisocyanato-2,2,4(or 2,4,4)-trimethylhexane and polyethylene-polypropylene glycol bis(2-aminomethylethyl) ether
- CAS 68037-23-0: 1,4-Butanediol, 2,3-bis[(g-w-perfluoro-C6-20-alkyl)thio] derivs., polymers with 1,6-diisocyanatotrimethylhexane and 2,2'-(methylimino)bis[ethanol]
- CAS 135228-60-3: Hexane, 1,6-diisocyanato-, homopolymer, g-w-perfluoro-C6-20-alc.-blocked
- CAS 71205-28-2: 1,4-Butanediol, polymers with 2,3-bis[(g-w-perfluoro-C6-20-alkyl)thio]-1,4-butanediol, C36-alkylene diisocyanate and 1,6-diisocyanato-2,2,4(or 2,4,4)-trimethylhexane
- CAS 68990-40-9: Fatty acids, C18-unsatd., dimers, diisocyanates, polymers with 2,3-bis(g-w-perfluoro-C4-18-alkyl)-1,4-butanediol, 1,6-diisocyanato-2,2,4(or 2,4,4)-trimethylhexane and 2,2'-(methylimino)bis[ethanol]

CAS 68037-22-9: 2-Butenedioic acid (2E)-, bis(g-w-perfluoro-C4-20-alkyl) esters, polymers with 1-(ethenyloxy)butanol, ethylene, 1,4-hexadiene and propene

CAS 170424-64-3: Siloxanes and Silicones, hydroxy Me, Me octyl, Me (g-w-perfluoro C8-14-alkyl)oxy, ethers with polyethylene glycol mono-Me ether

**Fluoropolymers**

The Fluoropolymer Manufacturers Group (FMG) identified in their LOI a list of fluoropolymers and fluoroelastomers which may be made with PFOA, and also identified monomers which are used in fluoropolymer manufacture. FMG subsequently submitted a slightly revised list correcting typographical errors (OPPT-2003-0012-0034). EPA anticipates that the fluoropolymer and fluoroelastomer test substances to be used for the purposes of this ECA process would be drawn from this list.

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

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

## **DEVELOPMENT OF ENFORCEABLE CONSENT AGREEMENTS (ECAs) UNDER SECTION 4 OF THE TOXIC SUBSTANCES CONTROL ACT (TSCA)**

### **I. Intent**

The intent of an ECA process under Section 4 of TSCA is to develop, using a voluntary and public procedure, a legally enforceable consent agreement to develop information needed to provide an adequate understanding of relevant aspects of the impact of the subject chemical(s) on health and the environment

### **II. Objective**

The objective of the ECA process is to conclude ECAs that will set in place an industry-sponsored program to develop the data EPA needs, usually through the conduct of specific tests. ECAs are an alternate vehicle for EPA to implement TSCA Section 4 authority.

### **III. Background**

Subsequent to identifying testing needs for TSCA-subject chemicals, EPA may invite the submission of proposals for conducting the needed testing via an ECA process. In the case of perfluorooctanoic acid (PFOA) and fluorinated telomers, EPA determined that an ECA Process could effectively develop other data needs for these chemicals that are not covered under existing industry-sponsored Letter of Intent (LOI) commitments.

The procedures for ECA negotiations are described at 40 CFR 790.22(b). These procedures provide the basis for EPA to: a) enter into a public process to negotiate testing programs to develop data on chemicals for which data needs have been identified; b) solicit interested parties to participate in the process; c) announce public meetings; and d) make negotiated products available for public comment prior to implementation by the Agency. EPA may enter into an ECA process for developing data for its own needs or in conjunction with other Federal Agencies (e.g., Agency for Toxic Substances and Disease Registry (ATSDR); National Institute for Occupational Safety and Health (NIOSH); Occupational Safety and Health Administration (OSHA); Consumer Product Safety Commission (CPSC)) that express or share the need for data that are critical for assessing chemical risks and for taking appropriate actions within their respective programs.

It is the goal of EPA to develop ECAs that would fulfill the identified data needs. While the Agency's objective of obtaining needed data could be accomplished by either rulemaking or establishing ECAs, EPA recognizes that the final testing program performed by test sponsors may differ depending on whether it is accomplished under a final TSCA Section 4 test rule or via the ECA process. This is because during the course of ECA negotiations, additional information

may be brought forward that could cause the Agency to reevaluate the nature of the testing requirements that need to be met. ECAs provide greater flexibility for the Agency to pursue state-of-the-science testing programs developed through iterative scientist-to-scientist discussions in developing the ECA. The resultant testing programs benefit EPA and the public by providing reliable test data relevant to the Agency's data needs for developing scientifically defensible environmental policies.

#### **IV. ECA Process for Developing ECA(s) for Perfluorooctanoic Acid and Fluorinated Telomers**

Although the ECA process may vary slightly from one negotiation to another depending on the issues under discussion and the need for technical oversight, there are six (6) overarching steps in the development of an ECA.

- Step 1: EPA identifies data needs and is receptive to obtaining these data via an ECA process.
- Step 2: EPA initiates a notice in the Federal Register explaining the nature of the topic(s) and focus of the ECA discussions; solicits "interested parties" to participate in discussions to develop an ECA(s); and announces the date, time, and location for a public meeting.
- Step 3: A public meeting is held to identify the topics to include for ECA(s) development, to establish the structure for discussions to develop ECA(s) for the topics identified, and to establish a reasonable schedule to reach agreement in principle for the ECA(s).
- Step 4: After reaching agreement in principle for the ECA(s), EPA, potential test sponsors, and interested parties enter into "Technical Discussions" to develop the details of an acceptable testing program to meet EPA's data needs.
- Step 5: The acceptable testing program is incorporated into a draft ECA(s). The draft ECA is then distributed to interested parties for comment.
- Step 6: EPA considers comments and finalizes the ECA, which is announced in the Federal Register. The Federal Register notice establishes the schedule for testing and data reporting.



## **V. Identification of Interested Parties**

It is essential for all interested parties to recognize their responsibilities in the ECA development process. EPA solicits interested parties to monitor or participate in testing negotiations on all ECAs. To be designated an “interested party” for an ECA, one must respond in writing to EPA’s solicitations in the Federal Register. The address for this is specified in the Federal Register solicitation document. Individuals and groups who respond appropriately to the Federal Register solicitation will have the status of interested parties. Interested parties do not incur any obligations by being so designated. EPA will not reimburse costs incurred by non-EPA participants in this ECA negotiation process. The official notice soliciting for interested parties to participate in the development of ECA(s) for perfluorooctanoic acid (PFOA) and fluorinated telomers was published in the Federal Register of April 16, 2003 (68 FR18626).

## **VI. Public Participation in Negotiations**

The procedural rule for ECAs (40 CFR Part 790) contains provisions to ensure that the views of interested parties are taken into account during the ECA process. The public is provided with an opportunity to comment on and participate in the development of ECAs.

All negotiation meetings for the development of ECAs will be open to the public and a report on each meeting will be prepared by EPA and placed in the public docket. The Agency will advise interested parties of meeting dates and make available meeting minutes, testing proposals, background documents, and other materials exchanged at or prepared for the negotiation meetings. Where tentative agreement is reached on an acceptable testing program (“agreement in principle”), a draft ECA will be made available for comment by interested parties and, if necessary, EPA will hold a public meeting to discuss any comments that have been received and determine whether revisions to the draft ECA are appropriate.

## **VII. ECA Negotiation Outcomes**

ECA negotiations will be conducted in one or more meetings open to the public. The negotiation time schedule will be established at the first negotiation meeting. It is EPA’s goal that negotiations not last longer than 4 months. ECAs will only be concluded where an agreement can be obtained which is satisfactory to the Agency, to manufacturers or processors who are potential test sponsors, and to other interested parties, concerning the need for and scope of testing. If an ECA is not established in principle within this time frame and EPA does not choose to extend the negotiation time period, negotiations will be terminated. In the absence of an ECA, EPA reserves the right to proceed with rulemaking under section 4 of TSCA. Furthermore, if the testing from the ECA does not meet the Agency’s needs, EPA reserves the right to enter into rulemaking to obtain the needed data.

The Agency will not enter into an ECA if either:

- 1) EPA and affected manufacturers or processors cannot reach an agreement on the provisions of the ECA; or
- 2) The draft ECA is considered inadequate by other interested parties who have submitted timely written objections to the draft ECA.

EPA may reject these objections if the Agency concludes either that:

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

EPA will prepare an explanation of the basis for each ECA developed. The explanatory document will summarize the final agreement (including the required testing), explain the objectives of the testing, and outline the chemical's use and exposure characteristics. The document, which also announces the public availability of the ECA, will be published in the Federal Register and the FR publication date will establish the effective date for the ECA, which is the official starting date for the ECA Testing Program.

## OUTLINE FOR AN ENFORCEABLE CONSENT AGREEMENT

Docket No. OPPT -2003-????

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**List of "Interested Parties" for PFOA and Telomer ECA Negotiations**

As of this date, the following groups and/or individuals have requested status as "interested parties" for the purpose of monitoring or participating in ECA negotiations on PFOA and fluorinated telomers. Please be advised that, due to security delays in the processing of mail to Federal facilities, additional "interested party" registrations may be received between this date and the June 6, 2003 meeting. Updated lists will be provided as needed before the meeting. Additional parties may attend as observers without providing prior notice to the Agency.

3M

Advanced Polymer, Inc.

AGA Chemicals

American Council on Science and Health

American Chemistry Council

American Fiber Manufacturers Association, Inc.

Asahi Glass Co., Ltd.

Asahi Glass Fluoropolymers USA, Inc.

ATOFINA Chemicals, Inc.

Bennett & Williams (Environmental Consultants)

Chamber of Commerce of the Mid-Ohio Valley

Ciba Specialty Chemicals Corporation

Clariant GmbH

Daikin America

Department of the Navy

DuPont

DuPont Textiles and Interiors, Inc.

Dyneon

Fire Fighting Foam Coalition

Hughes Associates, Inc.

International Imaging Association

Little Hocking Water Association, Inc.

Miteni S.p.A.

Mitsubishi International Corporation

Ohio Environmental Protection Agency

Ohio River Valley Water Sanitation Commission

OMNOVA Solutions

Parkersburg-Wood County Area Development Corporation

Rich Purdy

Regenerative Products

Solvay Solexis, Inc.

Society of the Plastics Industry/Fluoropolymer Manufacturers Group

Telomer Research Program

The Carpet and Rug Institute

The Center for Regulatory Effectiveness

Tuppers Plains-Chester Water District

United Bank, West Virginia

University of Pennsylvania Medical Center

W.L. Gore & Associates, Inc.

Walki Wisa Ltd.

West Virginia Class Action Plaintiffs