NOTE TO DOCKET READER:

These pages are excerpted from the EPA Preliminary PFOA ECA Framework document and are specific for Fluoropolymer chemicals. The complete document, including the appendices, is available from EPA Docket No. OPPT-2003-0056. Incineration testing is identified as EPA data need number 8 in the accompanying table.

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/ 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/. 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. 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.

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

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

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 Determination of air/water partition coefficient/Henry's Law Constant (method to be determined) UV/visible absorption OPPTS 830.7050 Direct Photolysis in Water OPPTS 835.2210 Indirect Photolysis Screening Test OPPTS 835.5270
5.	Determination of PFOA FPA 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. 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 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). The range of chemical emissions from these products and articles can be estimated under laboratory conditions such as in test chambers or test houses. Sampling and testing standards to be determined.

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: 1. ASTM E1641: Decomposition Kinetics by Thermogravimetry. 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.