

**BEFORE THE ENVIRONMENTAL APPEALS BOARD  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C.**

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ENVIR. APPEALS BOARD

IN THE MATTER OF: )

E. I. du Pont de Nemours )  
and Company )

Wilmington, DE )

Respondent )

Washington Works Facility )  
Route 892 South DuPont Road )  
Washington, Wood County, WV )

Docket No. TSCA-HQ-2004-0016  
Docket No. RCRA-HQ-2004-0016  
Docket No. TSCA-HQ-2005-5001

**JOINT MOTION TO AMEND THE SETTLEMENT**  
**TO ALLOW A SECOND EXTENSION OF THE COMPLETION DATE**  
**FOR RESPONDENT'S BIODEGRADATION**  
**SUPPLEMENTAL ENVIRONMENTAL PROJECT (SEP)**

The United States Environmental Protection Agency ("EPA" or "Complainant") and E.I du Pont de Nemours and Company ("DuPont" or "Respondent") (referred to jointly as "the Parties") file this Joint Motion to Amend the Settlement to Allow a Second Extension of the Completion Date for Respondent's Biodegradation Supplemental Environmental Project (SEP) pursuant to 40 C.F.R. §§ 22.4(a) and 22.16 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Rules of Practice). In this Motion, the Parties respectfully request to modify Appendix A (also referred to as the Biodegradation

SEP, SEP, or SEP A) of the Consent Agreement and Final Order (CAFO) signed by the Environmental Appeals Board on December 21, 2005, as amended on January 8, 2009, to extend the Completion Date by two (2) years and three (3) months, to March 27, 2014, and to incorporate several other changes to facilitate implementation of the SEP. The Parties have inserted deadlines for certain deliverables, added greater flexibility for the duration of future pilot testing, and inserted a requirement that assures that either the levels of residuals in the test substance measured by the contracted characterization laboratory and the contracted biodegradation laboratory are substantially equivalent or that additional activities are performed in lieu of further testing. The Parties believe good cause exists to grant the relief because DuPont has been working in good faith on this project, major milestone activities have been completed under the SEP so that much of the start-up work has been performed, and additional time would provide an opportunity for completion of independent review of methods developed, performance of characterization testing and performance of biodegradation testing. The Parties believe that the remaining DuPont obligation (as of November 30, 2011) of \$2,265,237.00 (of the \$5 million required under the CAFO) would be best used on completion of the SEP. A proposed revised SEP dated December 22, 2011 (Appendix A without Attachments) is attached as Exhibit 1.

### **Objectives of the Biodegradation SEP**

The original CAFO required that DuPont “will use its best efforts to satisfactorily complete this Biodegradation SEP . . . no later than three (3) years from the date DuPont receives the signed Final Order of the Environmental Appeals Board (“SEP Completion Date”).” (Section II.B. of SEP A of the CAFO.) The Parties stipulate that DuPont received the signed Final Order on December 27, 2005, and that the initial SEP Completion Date was December 27, 2008. On January 8, 2009, the Environmental

Appeals Board granted the Parties' Motion to extend the SEP for an additional three (3) years from December 27, 2008 to December 27, 2011. The Parties now seek to extend the SEP Completion Date to March 27, 2014.

Under Appendix A, as amended in 2008, Semicontinuous Activated Sludge ("SCAS") Testing is to be conducted in order to determine if certain fluorotelomer based polymer test substances can biodegrade to perfluorooctanoic acid ("PFOA") or precursors of PFOA. Full and detailed characterization of the fluorotelomer based polymer test substances is necessary in order to distinguish whether any PFOA found after SCAS testing is residual material that had been bound to the polymers prior to testing or if PFOA was formed as a result of biodegradation during SCAS testing. The methods development for this testing has been challenging. Substantial time and expense have been invested in refining and validating methods for extracting and identifying residuals and biodegradation products. Because these polymers were designed to repel other chemicals and not to react with them, they are generally more difficult to analyze than most chemicals.

### **Progress on the SEP**

DuPont has performed many of the tasks required in the SEP since the prior extension of time was granted. DuPont purified nine (9) Fluorotelomer Products under a "Purification Procedure Agreement"<sup>1</sup> and shipped those Products to EPA by June 1, 2009 as required. DuPont sought requests for proposals to select laboratories to perform the characterization work and the biodegradation work. DuPont received the proposals, obtained EPA approval for the proposed work, selected the laboratories

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<sup>1</sup> The Purified Fluorotelomer Products and the Purification Procedure Agreement are defined in SEP A and are not repeated herein.

and entered into contracts to perform specified work. The laboratories under contract with DuPont developed analytical methods and protocols. DuPont initiated the SCAS pilot test by January 30, 2010, as required. DuPont completed the pilot test in September, 2010. DuPont established an independent peer consultation group through a Panel Administrator who sought panel nominations and selected panel members. The panel members held conference calls, toured the facility where the SCAS pilot testing was conducted and held a meeting to review results of the biodegradation portion of the pilot study. Although analytical methods require additional optimization and validation, the work continues at an acceptable pace given the unexpected complications encountered as part of characterization. A detailed timeline of the activities performed since the first amendment to the SEP is attached as Exhibit 2.

### **Future SEP Activities**

Proper characterization of the fluorotelomer based polymer test substances provides information about the residuals in the test substance prior to performing the biodegradation testing. Thus, only with a clear picture of the test substance at the start of the biodegradation testing can the change in the chemical due to biodegradation be interpreted. This characterization involves looking for eighteen (18) different analytes. When the DuPont contract laboratory started the characterization testing, a problem arose concerning the use of gas chromatography/mass spectrometry ("GC/MS") analysis. Similarly, GC/MS analysis at the contract laboratory for biodegradation testing became a problem. Both laboratories experienced signal enhancement of certain analytes on the instruments when performing GC/MS. This signal enhancement resulted in unreliable data through this GC/MS method and DuPont sought a modification to the method to correct for the problem. The inability to

characterize the test substance at the start of the SCAS pilot test also prevented the peer review panel from completing its report about the SCAS pilot test. DuPont consulted EPA on potential solutions to the dilemma and made multiple attempts to obtain reliable characterization data. These attempts have required much greater time and costs than was anticipated during the original settlement discussions. The Parties have decided to utilize liquid chromatography/mass spectrometry ("LC/MS") in lieu of the GC/MS method and are working through method validation for this work.

The Parties have established priorities for testing based on the cost information now available. The highest testing priorities are full characterization of at least one fluorotelomer based polymer test substance and completion of a definitive full scale SCAS test on the polymer test substance that has been fully characterized. Although the SEP funding may be exhausted in completing a definitive full scale SCAS test on one polymer test substance, it is also possible that funding could remain for additional testing. There are four families of polymers involved among the nine (9) SEP fluorotelomer based polymer test substances: urethane-based, acrylate-based, methacrylate-based, and phosphate salt-based. The Parties have agreed that if there are available SEP funds, one polymer test substance from each family should be tested. Of the four (4) variants of each fluorotelomer based polymer discussed in the SEP, the Purified Fluorotelomer Product variant and the Lab-scale Synthesized Fluorotelomer Product variant of each the four families will be given higher priority for testing. The prioritization takes into account the unexpected high start-up costs experienced in establishing validated test methods for these polymers. The priorities are adjusted as cost estimates become clearer and DuPont obtains better information about the testing.

The Parties believe that much of the preliminary work for performing biodegradation testing on the fluorotelomer based polymers has occurred. Although there have been numerous unexpected obstacles in the preliminary stages of this project, there has been significant effort devoted to overcoming those obstacles and setting the stage for important testing. If the Board grants this Joint Motion to Extend the SEP Completion Date, the Parties hope to be able to perform the tests that have been under development for several years.

#### **Trial Run to Assess Fluorotelomer Based Polymer Residuals Baseline Agreement**

Criteria have been added to the SEP that establishes that a minimum level of agreement must be met between the results of fluorotelomer based polymer test substance characterization by the characterization laboratory and the results from analysis of analytes in the polymer test substance as added to SCAS units in a trial run. This trial run is designed to obtain time zero samples ("trial run time zero samples") by the biodegradation testing laboratory before the full scale definitive SCAS test begins. The SEP now requires that DuPont demonstrate an understanding, via this trial run, of the residuals in the polymer test substance prior to the commencement of the full scale SCAS test. Identifying and quantifying the residuals in the trial run time zero samples is vital to obtaining accurate and reliable results concerning the extent of biodegradation, if any, at the conclusion of the SCAS test. The SEP also now requires that full scale SCAS testing should not be initiated if a comparison of (1) the sums of the molar concentrations of each analyte reported by the characterization laboratory for the polymer test sample to (2) the sums of the molar concentrations of each analyte reported by the biodegradation laboratory for the trial run time zero sample do not agree with a 95% molar equivalence, unless EPA determines upon review to accept a lesser level of agreement. This requirement is designed to help address a concern that the full scale SCAS testing could be run and the

data produced could be unreliable. If full scale SCAS testing does not commence due to the characterization results and the results from the trial run time zero samples not meeting the minimum data agreement of 95% molar equivalence, and if the EPA decides not to pursue full scale SCAS testing in light of that disagreement, and assuming SEP funding remains, then the revised SEP requires DuPont to perform certain additional activities to complete the SEP.

### **Additional Activities**

The proposed SEP incorporates a new section (Section VI) that requires DuPont to purchase research equipment and chemicals for universities or state labs approved by the EPA if full scale SCAS testing does not commence as described above. The cost of these items will not exceed one million five hundred thousand dollars (\$1,500,000). Any equipment purchase and donation will be made in accordance with the EPA's 1998 SEP Policy<sup>2</sup>. The items eligible for purchase are instruments or reference standards used in laboratories that relate to the PFOA substance at issue in the initial action. These items are restricted to research on the presence of PFOA in people or the environment and research on whether other chemicals degrade to form PFOA. These purchases may also occur if there is a full scale definitive SCAS study on a Purified Fluorotelomer Product and one of its Corresponding Polymers and the EPA determines that the remaining funds are not likely to be enough to complete a second full scale definitive SCAS test.

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<sup>2</sup> The EPA 1998 SEP Policy and related guidance is found at <http://cfpub.epa.gov/compliance/resources/policies/civil/seps/>

### **Flexibility Sought For SCAS Pilot Testing**

DuPont has performed an initial SCAS pilot test. The SCAS pilot test is a preliminary trial to make sure the instrumentation proposed in the validated method will work. The pilot test provides information primarily on the appropriateness of the hardware to be used in the full scale testing. Section II.J.3.a. of the Biodegradation SEP states, "The laboratory performing the biodegradation studies shall conduct one 14-day pilot test for SCAS on each of the Fluorotelomer Products that have been selected for pilot testing as identified in Attachment A, and shall conduct one 14-day pilot test for SCAS on each of the Corresponding Polymers that have been selected for pilot testing as identified in Attachment A, to develop test data that can inform protocol decisions . . . ." Because the polymer test substances being tested are all fluorotelomer products, they tend to share many of the same properties as the polymer test substance used in the initial 14-day pilot test. The initial 14-day pilot test has been performed and has informed the Parties about many of the protocol decisions. Because future test substances could be using test systems very similar to those used in the initial SCAS pilot test, the Parties believe that future pilot studies may only need to last a few days to inform the protocol decisions. The Parties have agreed that subsequent pilot tests shall be conducted for up to fourteen (14) days, with the exact number of days to be determined by EPA prior to the start of each pilot test. Such a change is expected to allow for more economical and time efficient pilot testing while also providing useful technical information.

### **Posting Reports on the Internet**

The original SEP designated an Administrative Record (AR-226) for posting documents concerning this SEP. The public could obtain documents from AR-226 by requesting copies that would be provided in hard copy or on disk. The internet site Regulations.gov allows the public to search for documents at any time without the need for EPA to respond to a request. A docket file identified as EPA-HQ-OPPT-2011-0991 has been created in Regulations.gov for this SEP and the requirement for posting to AR-226 is changed to this new docket file on Regulations.gov. In addition, other documents submitted to EPA, such as monthly reports and quarterly reports, will now be posted to this new web site. Posting documents to this web site allows greater public access.

### **Conclusion**

For the foregoing reasons, the parties request this Joint Motion to Amend the Settlement to Allow a Second Extension of the Completion Date for Respondent's Biodegradation Supplemental Environmental Project (SEP) be **GRANTED**.

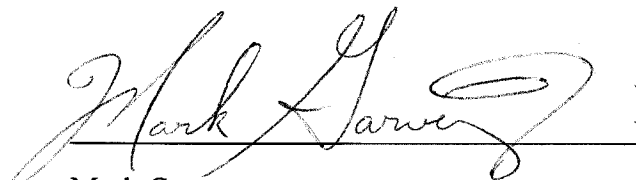
**Motion to Amend the Settlement to Allow a Second Extension of the Completion Date for  
Respondent's Biodegradation Supplemental Environmental Project (SEP)**

**Docket Nos. TSCA-HQ-2004-0016, RCRA-HQ-2004-0016, and TSCA-HQ-2005-5001**

Respectfully submitted,

12/22/11

Date



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## CERTIFICATE OF SERVICE

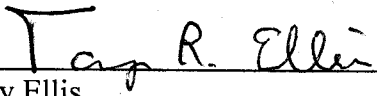
I certify that the original of the above joint Motion to Amend the Settlement to Allow a Second Extension of the Completion Date for Respondent's Biodegradation Supplemental Environmental Project (SEP) Docket Nos. TSCA-HQ-2004-0016, RCRA-HQ-2004-0016, and TSCA-HQ-2005-5001 were filed with the Environmental Appeals Board Hearing Clerk and that copies were sent:

Hand carried to:

Eurika Durr, Clerk of the Board  
U.S. Environmental Protection Agency  
Environmental Appeals Board  
Colorado Building  
1341 G Street, N.W., Suite 600  
Washington, D.C. 20005

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Date: 12/23/11

**APPENDIX A**  
**TO CONSENT AGREEMENT AND FINAL ORDER**

**FLUOROTELOMER-BASED PRODUCT BIODEGRADATION TESTING  
SUPPLEMENTAL ENVIRONMENTAL PROJECT**

# I. OVERVIEW OF FLUOROTELOMER-BASED POLYMER PRODUCT BIODEGRADATION TESTING SUPPLEMENTAL ENVIRONMENTAL PROJECT

A. This document, Appendix A, describes the Fluorotelomer-Based Product Biodegradation Testing Supplemental Environmental Project (“Biodegradation SEP”) that Respondent, E. I. du Pont de Nemours and Company (“DuPont”) has agreed to perform pursuant to Section III of the Consent Agreement and Final Order (“CAFO”) in TSCA-HQ-2004-0016, et al., entered into between DuPont and the United States Environmental Protection Agency (“EPA” or “Agency”) (collectively, “the parties”). This Appendix describes the SEP activities that DuPont will conduct to the extent that applicable funding allows.

B. In compliance with, and in addition to, the requirements of the CAFO, DuPont, shall (1) comply with the requirements of this Appendix and Attachments A-H, and (2) require any entity that DuPont contracts with to fulfill DuPont's obligations under this SEP, to comply with the requirements of this Appendix and Attachments A-H.

C. ***Purpose and Background.*** The purpose of this Biodegradation SEP is to determine the degradation potential of the nine commercial fluorotelomer-based products identified in Attachment A to this Appendix (“the Fluorotelomer Products” or “Fluorotelomer Products”) as well as the degradation potential of corresponding synthesized or purified polymers equivalent to the Fluorotelomer Products with respect to the chemical composition that creates their fluorotelomer functionality (“Corresponding Polymers”). Eight of the nine

1 Fluorotelomer Products to be tested under this Biodegradation SEP are fluorotelomer-based  
2 polymers, while the ninth is a fluorotelomer-based phosphate ester. The Fluorotelomer  
3 Products are products that were sold by DuPont prior to the date DuPont signs the Consent  
4 Agreement, and that DuPont will provide as the chemical substances to be tested pursuant to  
5 this Biodegradation SEP. An understanding of the degradation potential of the Fluorotelomer  
6 Products will be developed by considering the results of semi-continuous activated sludge  
7 (SCAS) studies. Accordingly, this Biodegradation SEP is designed to provide information on  
8 the inherent biodegradation potential of the Fluorotelomer Products and their Corresponding  
9 Polymers using SCAS.

10 The modified SCAS test is an inherent biodegradability study in which the test  
11 substance is exposed to activated sludge microorganisms in an aerated, aqueous medium with  
12 periodic settling of the solids and renewal of the aqueous phase with fresh media and test  
13 substance. The laboratory will run the test for twelve (12) weeks and will measure analytes  
14 that are indicative of degradation by determining the amount and rate of formation of  
15 observed degradation product(s) in the aqueous, sludge, and gas phases. Performing SCAS  
16 on the Purified Fluorotelomer Products and then comparing the results to the same study  
17 performed on one or more of their Corresponding Polymers will enable a close look at the  
18 potential aerobic biodegradation of the Fluorotelomer Products.

19 D. *Use and Functionality of Fluorotelomer Products.* Fluorotelomer products are  
20 used widely in a range of commercial applications, including some that are directly released  
21 into the environment, such as fire fighting foams, as well as soil, stain, and grease resistant  
22 coatings on carpets, textiles, paper, and leather. Fluorotelomer products are aqueous  
23 dispersions. They originate from fluorotelomer iodides  $[F(CF_2CF_2)_n-I]$ ; where  $n= 3,4,5$

1 commonly] which are commercially made by reacting pentafluoroethyl iodide with  
2 tetrafluoroethylene to create even-number-carbon polyfluoroalkyl iodides. Although the  
3 telomerization process can be used to produce odd-number-carbon raw materials, those are not  
4 intentionally made or sold by DuPont.

5 Fluorotelomer iodides are functionalized to create a series of fluorotelomer raw  
6 materials [including other fluorotelomer iodides  $[F-(CF_2-CF_2)_n-CH_2-CH_2-I]$ ,  $n = 3,4,5$   
7 commonly] and fluorotelomer alcohols  $[F-(CF_2-CF_2)_n-CH_2-CH_2-OH]$ ,  $n = 2,3,4,5$  etc.] that are  
8 then appended to an organic or inorganic moiety that contains the fluorotelomer as a functional  
9 group. As an example, fluorotelomer acrylate monomers  $[F-(CF_2-CF_2)_n-CH_2-CH_2-O-C(O)-$   
10  $CH=CH_2]$ ,  $n = 3,4,5$  commonly] are copolymerized with one or more of a group of  
11 hydrocarbon monomers to create an acrylic polymer with fluorotelomer functionality. The  
12 most common fluorotelomer raw material used in DuPont's fluorotelomer products is the  
13 family of fluorotelomer alcohols. These alcohols are generally further transformed into  
14 polymeric and non-polymeric fluorotelomer-based products. This Biodegradation SEP  
15 involves the testing of polymeric and non-polymeric fluorotelomer products based on these  
16 common fluorotelomer intermediates; any reference in this Biodegradation SEP to DuPont's  
17 commercial Fluorotelomer Products and their Corresponding Polymers is a reference to both  
18 the polymeric and non-polymeric products.

19 DuPont generally manufactures product concentrates as aqueous dispersions of  
20 fluorotelomer products that are sold to industrial customers who dilute, formulate, and blend the  
21 fluorotelomer products. These customers then either apply these new formulations to finished  
22 articles or sell them to other customers who apply them to finished articles. In this way, the  
23 DuPont commercial Fluorotelomer Products being tested as part of this Biodegradation SEP

1 are thus analogous to paint concentrates and the finished articles to a cured paint surface.  
2 Evaluations of these biodegradation studies carried out on DuPont's Fluorotelomer Products  
3 for the purpose of attempting to assess the biodegradation potential of cured fluorotelomer-  
4 based polymer products would need to be carefully done given the differences between the  
5 cured and uncured fluorotelomer-based products. Substances made with fluorotelomer  
6 functionality should not be referred to as either "perfluorinated" or "fluoropolymers" as these  
7 terms describe other materials.

8 E. As part of this Biodegradation SEP, DuPont will:

9 1. Provide sufficient quantities, as described in Sections II.D-E below, of  
10 DuPont's nine Fluorotelomer Products, listed in Attachment A.

11 2. Prepare the following chemical substances (referred to collectively as  
12 "Corresponding Polymers").

13 a. A purified polymer that is prepared in accordance with this  
14 Appendix Attachment H – Purification Procedure Agreement (PPA) for each of the  
15 Fluorotelomer Products listed in Attachment A ("Purified Fluorotelomer Product"). DuPont  
16 and EPA have agreed on the procedure(s) that DuPont will use to purify the Fluorotelomer  
17 Products to produce the Purified Fluorotelomer Products, taking into consideration the need to  
18 optimize various factors, including the appropriate duration of extraction and redispersion  
19 processes, the desired purity of the Purified Fluorotelomer Products, the schedule for delivery  
20 of the Purified Fluorotelomer Products to the laboratories for characterization, testing and  
21 studies, and the overall schedule for completing this Biodegradation SEP. The PPA represents  
22 the agreement reached between EPA and DuPont concerning the procedure to be used to  
23 produce the Purified Fluorotelomer Products. Reporting on the production of the Purified

1 Fluorotelomer Products shall be in accordance with the reporting provisions of the PPA.

2 b. A synthesized fluorotelomer product containing a purified  
3 polymer, comparable to the Fluorotelomer Product for which it corresponds, that is prepared in  
4 the laboratory using production plant raw materials ("Synthesized Fluorotelomer Product").

5 c. A synthesized fluorotelomer product containing a purified  
6 polymer, comparable to the Purified Fluorotelomer Product for which it corresponds, that is  
7 prepared in the laboratory using high purity raw materials ("Lab-scale Synthesized  
8 Fluorotelomer Product").

9 3. *Timing of Test Substance Transfer.*

10 a. Within thirty (30) days of entering into a contract with (1) the  
11 laboratory performing biodegradation and (2) the laboratory performing characterization,  
12 DuPont shall transfer the sufficient quantities, as described in Sections II.D, below, of the nine  
13 Fluorotelomer Products to such laboratories.

14 b. Within thirty (30) days of entering into a contract with (1) the  
15 laboratory performing biodegradation and (2) the laboratory performing characterization,  
16 DuPont shall transfer the sufficient quantities, as described in Sections II.D of the  
17 Corresponding Polymers, identified on Attachment A for pilot testing, to such laboratories.

18 c. DuPont shall transfer sufficient quantities, as described in Sections  
19 II.D, of the Corresponding Polymers that EPA selects for biodegradation studies to such  
20 laboratories to timely commence characterization and the biodegradation studies as required in  
21 each laboratory's EPA-approved work plan.

22 d. The timing for transfer of test substances to EPA is set forth in  
23 Section II.E., below.

1                   4.     ***Third Party Laboratory Contract: Characterization.*** Contract with a  
2     Third Party Laboratory ("laboratory") to characterize the Fluorotelomer Products, their  
3     Corresponding Polymers identified in Attachment A for pilot testing, and any of their  
4     Corresponding Polymers selected by EPA for biodegradation studies according to Attachment B  
5     parameters to help inform the results of the biodegradation studies. The characterization of  
6     these Fluorotelomer Products and Corresponding Polymers, discussed in greater detail in  
7     Attachment B, will determine, using the most accurate instrumentation and procedures  
8     available as of the time of testing, and the best achievable precision, the amount of residual  
9     monomers and oligomers, other residuals, and the molecular weight distribution of polymeric  
10    material in the Fluorotelomer Products and Corresponding Polymers.

11                   a.     The Characterization Laboratory shall commit to the following  
12    timeline for characterization if the solvent selected is tetrahydrofuran (THF), for which a  
13    validation protocol was submitted to EPA in August 2011:

14                         1.     Report the results of method validation no later than forty-  
15    five (45) days after the validation protocol submitted to EPA in August 2011 has been approved  
16    by EPA.

17                         2.     Submit the final characterization protocol no later than five  
18    (5) days after the method validation results in subsection 4.a.1. above have been submitted.

19                         3.     Submit the final characterization report with the Certificate  
20    of Analysis no later than thirty-five (35) days after EPA approves the final characterization  
21    protocol in subsection 4.a.2. above.

22                   b.     The Characterization Laboratory shall commit to the following  
23    timeline for characterization if the solvent selected is methyl tert-butyl ether (MTBE):

1                               1.     Revise and submit to EPA the validation characterization  
2     protocol no later than three (3) days of EPA deciding MTBE should be used for  
3     characterization.

4                               2.     Report the results of method validation no later than  
5     twenty-one (21) days after EPA approves the validation characterization protocol of  
6     subsection 4.b.1. above.

7                               3.     Submit the final characterization protocol no later than five  
8     (5) days after the method validation results in subsection 4.b.2. above have been submitted.

9                               4.     Submit the final characterization report with the Certificate  
10    of Analysis no later than thirty-five (35) days after EPA approves the final characterization  
11    protocol in subsection 4.b.3. above.

12                           5.     ***Third Party Laboratory Contract: Biodegradation.*** Contract with a  
13    Third Party Laboratory ("laboratory") to:

14                           a.     Pilot test the Purified Fluorotelomer Products and Corresponding  
15    Polymers, as identified in Attachment A, following study guidelines for modified semi-  
16    continuous activated sludge (SCAS). SCAS pilot testing shall begin by the laboratory no later  
17    than January 31, 2010.

18                           b.     Submit the final SCAS analytical method development plan by  
19    January 20, 2012.

20                           c.     Submit the final SCAS analytical validation protocol no later than  
21    thirty (30) days after EPA approval of the results from implementation of the EPA-approved  
22    SCAS analytical method development plan of subsection 5.b. above. Within thirty (30) days  
23    after approval of the results from implementation of the EPA-approved SCAS analytical

validation protocol, the Biodegradation Laboratory shall measure analytes from two (2) replicate trial run time zero samples from each of three (3) separate test substance dosed SCAS units for a total of six (6) replicate samples for one or both variants as described in Section II.M., below, and submit results. Subsections 5.d.-5.g. below shall be implemented only if the EPA approves the trial run results.

d. Submit the final SCAS study protocol no later than fourteen (14) days after EPA approval of the trial run results of subsection 5.c. above.

e. Submit the SCAS QAPP no later than fourteen (14) days after EPA approval of the final SCAS study protocol of subsection 5.d. above.

f. Perform SCAS studies on the Purified Fluorotelomer Products and any Corresponding Polymers selected by EPA to be used in the biodegradation studies.

g. Subject to section II.M. below, the laboratory will conduct the SCAS studies on the Purified Fluorotelomer Products and any of their Corresponding Polymers in order to investigate the degradation potential of these Fluorotelomer Products to produce perfluorooctanoic acid (PFOA) or other analytes identified in Attachment C, and to determine the potential, if any, for their Corresponding Polymers to degrade to form PFOA or other analytes identified in Attachment C. The SCAS testing shall begin within thirty (30) days after the EPA approval of the final SCAS QAPP of subsection 5.e. above.

6. ***Panel Administrator Contract.*** Contract with an independent third party ("Panel Administrator") to implement and administer the Peer Consultation process under this Biodegradation SEP. As discussed in greater detail in Section V, a Peer Consultation Panel will be involved in this Biodegradation SEP at specified milestones.

F. ***Applicability of Results.*** Because this Biodegradation SEP is designed to

1 examine (1) the inherent biodegradation potential of the Fluorotelomer Products and their  
2 Corresponding Polymers and (2) the biodegradation potential and fate of the Fluorotelomer  
3 Products and their Corresponding Polymers under aerobic sewage treatment plant simulation  
4 conditions, it does not address the biodegradation potential of the Fluorotelomer Products or  
5 their Corresponding Polymers in soil, sediments, landfills, or aquatic or marine systems, nor  
6 does it address degradation under anaerobic conditions. Additionally, using the results of this  
7 Biodegradation SEP to attempt to assess the biodegradation potential of cured polymers would  
8 need to be carefully done given the differences between cured and uncured fluorotelomer-  
9 based products.

10           Inherent biodegradability tests are designed to assess whether a substance has any  
11 potential for biodegradation. According to OECD Guidance on the Use of the Globally  
12 Harmonized System for the Classification of Chemicals which are Hazardous for the Aquatic  
13 Environment (April 2001), a positive result in an inherent biodegradation test indicates that the  
14 test substance will not persist indefinitely in the environment; however, rapid and complete  
15 biodegradation cannot be assumed. A negative result in an inherent biodegradation test does  
16 not definitively demonstrate that a chemical will not biodegrade under any conditions, but rather  
17 that the chemical will not biodegrade under the conditions of the test. Aerobic sewage  
18 treatment simulation tests are designed to yield information on the behavior of chemicals in  
19 aerobic sewage treatment plants. These tests permit the measurement of the rates of loss of the  
20 test chemical, formation and identification of degradation products, partitioning of these  
21 chemicals to sludge solids, and volatilization under conditions controlled to mimic those found  
22 in full-scale aerobic wastewater treatment systems. The results from these studies are indicative  
23 of how the test substance will behave in full-scale systems.

## **II. GENERAL OBLIGATIONS AND REQUIREMENTS**

A. **Total Cost.** DuPont must spend no less than five million dollars (\$5,000,000) in eligible SEP costs in performing activities under this Biodegradation SEP, but is not required to spend more than five million dollars (\$5,000,000) in eligible SEP costs.

B. **SEP Completion.** DuPont shall comply with the deadlines set forth in this Appendix and will use its best efforts to satisfactorily complete this Biodegradation SEP, within the meaning of Section IV.4 of the CAFO, no later than March 27, 2014 ("SEP Completion Date"). No later than sixty (60) days prior to the SEP Completion Date, if DuPont believes that it will be unable to satisfactorily complete the SEP within such time period, DuPont shall petition EPA to extend the SEP Completion Date based upon DuPont's assertion of good cause to extend such date. The Office of Civil Enforcement, in consultation with the Office of Pollution Prevention and Toxics, will review DuPont's petition and meet with DuPont to discuss its petition. The Office of Civil Enforcement, in consultation with the Office of Pollution Prevention and Toxics, shall determine whether DuPont has demonstrated that there is good cause to extend the SEP Completion Date and, if determining that DuPont has demonstrated good cause, determine how long to extend the SEP Completion Date.

C. **Good Laboratory Practices and Study Monitor.** For purposes of this Biodegradation SEP, with regard to characterization and biodegradation testing and studies, DuPont and its contractors shall be subject to, and must comply with, 40 C.F.R. Part 792. Each laboratory conducting research under this Biodegradation SEP shall designate a Study Director in accordance with 40 C.F.R. § 792.33. DuPont shall designate a Study Monitor that will serve as the point of contact for EPA and the laboratories.

D. **Supply of Test Substances to Laboratories.** DuPont shall provide the laboratory

1 that it contracts with to perform characterization and the laboratory that it contracts with to  
2 perform the biodegradation studies, sufficient quantities of the Fluorotelomer Products,  
3 identified in Attachment A, and any Corresponding Polymers, to perform all of the tests and  
4 studies discussed in this Biodegradation SEP for which such laboratory has been contracted to  
5 perform. Sufficient quantities of the Corresponding Polymers, identified in Attachment A for  
6 pilot testing, must include the quantities necessary to perform characterization, the pilot tests,  
7 and biodegradation studies, even if such Corresponding Polymers are not selected by EPA to  
8 be used in the biodegradation studies. Each Fluorotelomer Product and Purified Fluorotelomer  
9 Product that DuPont provides to the laboratory performing characterization must be from the  
10 same production batch as provided to the laboratory performing the biodegradation studies.  
11 Each Synthesized Fluorotelomer Product and Lab-scale Synthesized Fluorotelomer Product  
12 that DuPont provides to the laboratory performing characterization must be from the same  
13 laboratory batch as provided to the laboratory performing biodegradation testing.

14 E. ***Supply of Test Substances to EPA.*** EPA shall receive sufficient quantities of the  
15 Fluorotelomer Products identified in Attachment A, and Corresponding Polymers, to replicate  
16 the characterization and biodegradation studies (i.e., SCAS tests (including pilots)) performed  
17 under this Biodegradation SEP. DuPont shall fulfill this obligation as follows:

- 18 • Sufficient quantities for EPA of the Fluorotelomer Products identified in  
19 Attachment A, the nine Synthesized Fluorotelomer Products, and the nine Lab-scale  
20 Synthesized Fluorotelomer Products shall be shipped by DuPont to a laboratory identified by  
21 EPA (per SEP A Section II.H.) on or before November 18, 2008 and
- 22 • Sufficient quantities for EPA of the Purified Fluorotelomer Products

1 resulting from the PPA shall be shipped by DuPont no later than fourteen (14) days after  
2 sparging ceases for each such Product or by June 1, 2009, whichever occurs first. Further  
3 details on the quantities to be shipped, the specific timing for shipment, and shipment location  
4 are set forth in Section II.B.4. of the PPA.

5 All test substances shall be provided to EPA following the chain of custody  
6 procedures in Attachment D, except that quart jars acceptable under DOT regulations may be  
7 substituted for the 30 mL containers. DuPont shall develop appropriate holding procedures for  
8 the test substances to assure the chemical integrity of such substances. These appropriate  
9 holding procedures shall be provided to EPA three (3) days in advance of the date that DuPont  
10 ships the test substance to the EPA-identified laboratory.

11 F. ***Chain of Custody.*** Any instance in which, pursuant to this Biodegradation SEP,  
12 DuPont or a laboratory transfers either Fluorotelomer Products, Corresponding Polymers, or  
13 other chemicals to a laboratory or to EPA, DuPont and/or such laboratory(ies) are required to  
14 follow the chain of custody procedures in Attachment D of this Appendix.

15 G. ***EPA Review and Approval (or Acceptance) Process.*** EPA will review and  
16 either approve or, pursuant to Section II.G.3, below, accept all work plans, protocols, contracts,  
17 request for proposals/bids, confidentiality agreements, lists, material modifications, and any  
18 other submission other than a final report, progress report, preliminary report, or quarterly  
19 report, relating to performance of this Biodegradation SEP.

20 1. In providing comments to DuPont regarding such documents or  
21 submissions, EPA will include justification(s) and/or rationale(s) for the comments. EPA will  
22 provide such comments to DuPont within a reasonable amount of time, commensurate with  
23 the type and nature of the document or submission being reviewed.

1           2. All of EPA's comments, including requested changes, to a document or  
2 submission enumerated above must be incorporated by DuPont, and/or its contractors, and  
3 resubmitted to EPA for approval. With regard to contracts, request for proposals/bids, and  
4 confidentiality agreements, if DuPont believes that EPA's comments do not relate to the  
5 performance of the Biodegradation SEP, DuPont shall notify EPA within seven (7) business days  
6 of DuPont's receipt of such comments. In this notification to EPA, DuPont shall explain why it  
7 believes that EPA's comments do not relate to the performance of this Biodegradation SEP and  
8 that such comments are not required to be incorporated into the document. EPA shall consider  
9 DuPont's explanation before making a final decision regarding whether such comments relate  
10 to the performance of this Biodegradation SEP; provided, however, that EPA will not  
11 unreasonably require DuPont to modify or remove from any such contract or agreement any  
12 provision that requires the contractor to indemnify DuPont for stipulated penalties that DuPont  
13 pays under Section VII.4 of the CAFO as a result of the contractor's failure to perform work in  
14 accordance with a schedule to which the contractor has agreed.

15           3. In limited circumstances, EPA may, in its discretion, after reviewing a  
16 proposed contract, proposed confidentiality agreement, or proposed protocol opt to accept such  
17 a document without formally approving it. If EPA exercises this option, EPA will notify  
18 DuPont that the proposed contract or proposed confidentiality agreement has been accepted.

19           H. *Submission Procedures and Transfer of Test Substances to EPA.* All  
20 submissions by DuPont, a laboratory, or the Panel Administrator to EPA shall be submitted via  
21 first class mail, return receipt requested, or by commercial delivery service with documented  
22 delivery, to the person identified in Section V. of the CAFO. Such submissions shall be  
23 provided in electronic format on a compact disc (CD) and shall be accompanied by a cover

1 letter in hard copy that describes the contents of the CD and complies with any other  
2 requirements of the CAFO. In addition, as of January 1, 2012, the same submission shall also  
3 be submitted to EPA on a CD that is identified as containing documents for posting on the  
4 internet on [www.regulations.gov](http://www.regulations.gov) in the folder labeled EPA-HQ-OPPT-2011-0991. The  
5 submissions for internet posting shall include an electronic version of the hard copy cover  
6 letter that accompanied the submission to the person identified in Section V. of the CAFO.  
7 EPA will specify, in advance of the transfer of test substances addressed in Section II.E, above,  
8 where to transfer such divided samples.

9 I. ***Final Reports containing Confidential Business Information.*** All final reports  
10 provided to EPA containing Confidential Business Information ("CBI") must also be provided to  
11 EPA in a sanitized version within thirty (30) days of submission of the CBI version. Such final  
12 reports include final laboratory reports under 40 C.F.R. Part 792, final reports of the Peer  
13 Consultation Panel, and SEP Completion Reports submitted pursuant to Section IV of the  
14 CAFO and, as of January 1, 2012, sanitized Final Reports shall be submitted for posting by  
15 EPA on the internet on [www.regulations.gov](http://www.regulations.gov) in the folder labeled EPA-HQ-OPPT-2011-0991.  
16 Any claim of CBI must be substantiated pursuant to 40 C.F.R. Part 2, upon submission of the  
17 sanitized version. Note that this Section II.I governs over CAFO Section V.9. with respect to  
18 the timing for submittal of sanitized final laboratory reports, final Peer Consultation Panel  
19 reports, and the SEP Completion Report.

20 J. ***Manner in which Testing and Studies shall be Performed.*** The characterization  
21 and biodegradation studies must be performed in the following manner and in compliance with  
22 the following Attachments, unless DuPont or its contractor requests, and EPA approves, a  
23 change, or if EPA, after consultation with DuPont, determines that a change is appropriate:

1                   1.     DuPont shall use one laboratory to characterize the Purified Fluorotelomer  
2     Products, one or more Corresponding Polymers identified in Attachment A for pilot testing,  
3     and any Corresponding Polymers that EPA selects for biodegradation studies, in accordance  
4     with Attachment B.

5                   2.     DuPont shall use one laboratory to perform SCAS studies (alternatively  
6     referred to herein as the "biodegradation studies"), in accordance with Attachment C.

7                   a.     This laboratory shall perform the SCAS studies on the  
8     Fluorotelomer Products and any Corresponding Polymers that EPA selects for biodegradation  
9     studies, following both the sequence, and grouping (to maximize laboratory efficiency,  
10    capacity allowing) provided in Attachment A.

11                  b.     If, based on their submissions in response to the Request for  
12    Proposals ("RFP") and any further information that DuPont or EPA receives, none of the  
13    laboratories identified in Attachment G appears to be reasonably capable of, or if no laboratory  
14    is willing to contractually commit to, completing all of the biodegradation studies (including  
15    pilots) by no later than September 1, 2011 (or such longer time as EPA approves), the parties  
16    agree to implement the following approach, in the following order of preference:

17                  i.     DuPont shall use one laboratory identified in Attachment  
18    G to perform the biodegradation studies but not the analytical component of the studies, and  
19    DuPont shall use the laboratory that DuPont contracts with to perform characterization of the  
20    Fluorotelomer Products and any Corresponding Polymers under this Biodegradation SEP, as a  
21    subcontractor for the analytical component of the biodegradation studies; or

22                  ii.    DuPont shall propose two laboratories identified in  
23    Attachment G to perform the biodegradation studies and shall propose how to divide the

1 biodegradation work between the two laboratories, subject to EPA approval.

2 3. Pilot Testing

3 a. The laboratory performing the biodegradation studies shall conduct  
4 one pilot test for SCAS on each of the Fluorotelomer Products that have been selected for pilot  
5 testing as identified in Attachment A, and shall conduct a pilot test for SCAS on each of the  
6 Corresponding Polymers that have been selected for pilot testing as identified in Attachment A,  
7 to develop test data that can inform protocol decisions and to establish that these  
8 biodegradation studies can produce results that can be analyzed and quantified with regard to  
9 the biodegradation potential of the Fluorotelomer Products and any Corresponding Polymers.  
10 The first pilot test shall be for fourteen (14) days. Any subsequent pilot tests shall be  
11 conducted for up to fourteen (14) days, with the exact number of days to be determined by  
12 EPA prior to the start of each pilot test.

13 b. EPA reserves the right, after reviewing the results of the first pilot  
14 of the Fluorotelomer Products or first pilots of its Corresponding Polymers, to specify the use of  
15 the Corresponding Polymers for the pilot tests in the remaining groups.

16 c. The Peer Consultation Panel, described in Section V, below, shall  
17 review the results of such pilots, including the pilots' protocol and design, in conjunction with  
18 the characterization data. The Panel Administrator shall develop and forward to EPA and  
19 DuPont a final Panel report providing: (1) each participating Panel member's comments and  
20 recommendations on appropriate final protocols for the laboratory to use for the biodegradation  
21 studies and (2) comments and recommendations regarding which of the Corresponding Polymers  
22 should be used in the biodegradation studies. EPA will review the Panel report and any  
23 comments that DuPont has submitted to EPA pursuant to Section II.K, below. EPA will then

1 transmit its comments and judgments to DuPont and require DuPont to direct the laboratory to  
2 develop a final protocol, within a specified timeframe, to be submitted to EPA for approval.  
3 The final protocol that the laboratory develops shall consider the Panel report and EPA's  
4 comments and judgments. The laboratory shall not commence the biodegradation studies until  
5 it has received EPA's approval of the final protocol and EPA's determination regarding which  
6 of the Corresponding Polymers shall be used in the biodegradation studies.

7       **K. DuPont Comments.** At any time during the performance of this Biodegradation  
8 SEP, DuPont may provide comments to EPA regarding the following technical documents:  
9 protocols, test methods, analytical methods (and any modifications of such technical  
10 documents), and the Panel report addressing the charge set forth in Section V.A.2.b. To be  
11 eligible for consideration by EPA, DuPont must submit such comments to EPA within seven  
12 (7) business days of DuPont's receipt of the technical document. EPA reserves the right to  
13 directly seek input from the appropriate laboratory regarding DuPont's comments. The  
14 extension of deadlines in Section II.L, below, does not apply to this Section II.K. A request for  
15 an extension of this deadline shall be subject to EPA's discretion, and granted for good cause  
16 shown.

17       **L. Extensions of deadlines other than the SEP Completion Date.**

18           1. **First Extensions.** For an extension of a deadline specified in this  
19 Appendix or in a work plan or other submission implementing this Biodegradation SEP, other  
20 than the SEP Completion Date, DuPont shall be entitled to a first extension as a matter of right,  
21 provided that DuPont submits a written notice to EPA that it is exercising this provision, no  
22 later than one business day prior to the deadline.

23           a. For deadlines of thirty (30) days or less, DuPont shall

1 automatically receive an extension equal to the number of days initially provided in this  
2 Appendix.

3 b. For deadlines greater than thirty (30) days, DuPont shall  
4 automatically receive a 30-day extension unless DuPont requests, and EPA approves, an  
5 extension greater than thirty (30) days, for good cause shown.

6 c. For deadlines that are not stated in terms of number of days after a  
7 preceding event but are stated as specific dates, DuPont shall automatically receive a 30-day  
8 extension unless DuPont requests, and EPA approves, an extension greater than thirty (30) days,  
9 for good cause shown.

10 2. ***Second Extension (for Third Party Work only).*** For an extension of a  
11 deadline other than the SEP Completion Date involving work that DuPont has contracted with  
12 a third party to perform, if, after exercising its right to an automatic extension provided in  
13 Section II.L.1, above, DuPont requests a second extension of the same deadline, such extension  
14 shall be granted provided that DuPont's Study Monitor sent a written notice to the third party  
15 no later than five (5) business days before the deadline, and DuPont requests an extension no  
16 later than one (1) business day prior to the deadline. In exercising this provision, DuPont shall  
17 furnish EPA with the written notice that it sent to the third party.

18 a. For deadlines of thirty (30) days or less, DuPont shall receive an  
19 extension equal to the number of days initially provided in this Appendix.

20 b. For deadlines greater than thirty (30) days, DuPont shall receive a  
21 30-day extension unless DuPont requests, and EPA approves, an extension greater than thirty  
22 (30) days, for good cause shown.

23 3. ***Additional Extensions.*** DuPont's request for an extension other than the

1 SEP Completion Date for which there is either: (a) a second request for an extension of a  
2 deadline that does not involve work that DuPont has contracted with a third party to perform,  
3 or (b) a third request for an extension of a deadline that does involve work that DuPont has  
4 contracted with a third party to perform, or (c) subsequent requests for extensions of deadlines  
5 addressed in Sections II.L.3.a-b, such requests are subject to EPA's discretion, and granted for  
6 good cause shown. In granting a request for an extension under Section II.L.3, EPA may grant  
7 an extension of time different from the amount of time requested by DuPont.

8           4.     *Delays resulting from EPA Review.* If DuPont is delayed in performing  
9 a required action prescribed in an EPA-approved work plan and the delay is caused only  
10 because of EPA's review and approval of a submission that DuPont provided to EPA  
11 sufficiently in advance of the deadline so as to allow EPA a reasonable amount of time to  
12 review and approve the submission, commensurate with the type and nature of the submission,  
13 DuPont will be entitled to an extension to perform the required action. The extension shall be  
14 equal to the number of days of EPA's review and approval of the submission and shall be  
15 calculated from the date that EPA received such submission through the date that EPA  
16 transmitted its approval of the submission to DuPont. If, during its review and prior to its  
17 approval, EPA requests that DuPont make changes to the submission, in calculating the  
18 extension, the parties shall not include the amount of time for DuPont to make such changes  
19 and resubmit the document to EPA for approval. Such time excluded from the extension shall  
20 start from the date that EPA transmits the requested changes to DuPont through the date that  
21 EPA receives the amended submission, incorporating the requested changes. But, such time  
22 excluded from the extension shall not include time during which EPA is still reviewing a  
23 portion of the submission for which EPA has also requested changes. If an extension is granted

1 under this provision, DuPont may still request an extension of the extended deadline under  
2 Sections II.L.1-3, above.

3 5. To the extent that this Section II.L governs requests for extensions of  
4 deadlines under this Biodegradation SEP, it shall supersede any provisions in the CAFO  
5 concerning the extension of deadlines.

6 **M. Trial Run to Assess Fluorotelomer Based Polymer Residuals Baseline**  
7 **Agreement.** Prior to the commencement of any full scale determinative SCAS testing,  
8 DuPont shall assess whether the residual levels in a SCAS trial run time zero sample of the  
9 polymer test substance reported by the Biodegradation Laboratory substantially agree with the  
10 residual levels of the polymer test substance as reported in the Certificate of Analysis from the  
11 Characterization Laboratory. For this section, the following two variants of the test substances  
12 shall be used: (1) the Purified Fluorotelomer Product and (2) the Lab-scale Synthesized  
13 Fluorotelomer Product. The chemical characterization conducted by the Characterization  
14 Laboratory is designed to identify and quantify the residuals (also referred to as analytes) listed  
15 in Attachment C. Knowing that residual levels can be accurately quantified before full scale  
16 SCAS testing begins assures a basis upon which the residuals at the conclusion of SCAS  
17 testing can be identified and quantified with accuracy. Although some variation may be  
18 anticipated and some residuals may have less impact on the study results, to assure that the  
19 SEP provides quality data, DuPont will proceed with full scale definitive SCAS testing on a  
20 given test substance only if the "substantially equivalent residual levels" requirements of either  
21 section M.1.i or M.1.ii are satisfied.

22 1. "Substantially equivalent residual levels" will be satisfied for the purposes  
23 of this SEP by meeting either the requirements of section M.1.i. to achieve a 95% molar

1 equivalence or by EPA's approval as described in M.1.ii.

2                   *i.*       "Substantial equivalence by meeting a 95% molar equivalence" is  
3 achieved where the sums of the molar concentrations of each analyte reported by the  
4 Characterization Laboratory for the polymer test samples compared to the sums of the molar  
5 concentrations of each analyte reported by the Biodegradation Laboratory for the trial run time  
6 zero sample agree with a 95% molar equivalence. The Characterization Laboratory shall  
7 measure analytes of interest from six (6) replicate samples of the polymer test substances (i.e.,  
8 the variants identified above). The Biodegradation Laboratory shall measure analytes from  
9 two (2) replicate trial run time zero samples from each of three (3) separate test substance  
10 dosed SCAS units for a total of six (6) replicate samples for one or both variants. The  
11 Biodegradation Laboratory shall also measure "Background" by measuring analytes from two  
12 (2) replicate trial run time zero samples from each of three (3) separate SCAS units to which  
13 test substance has not been dosed for a total of six (6) replicate samples. Trial run time zero  
14 samples will be collected from all six (6) SCAS units subsequent to the draw and fill procedure  
15 after a minimum of two (2) minutes after aeration has started to allow for uniform distribution  
16 of test substance in the SCAS units.

17                   *ii.*       If agreement with the 95% molar equivalence of section M.1.i. is  
18 not achieved, then EPA shall review the data associated with the residual levels to determine  
19 whether there is sufficient confidence to begin the full scale SCAS testing.

20                   2.       If it is necessary for EPA to review the residual levels from the time zero  
21 trial run with the residual levels reported by the Characterization Laboratory, and if EPA  
22 determines that the differences between the residual levels determined for the time zero trial  
23 run and the residual levels reported by the Characterization Laboratory are too great to allow

1 conclusions to be drawn on whether biodegradation of the test substance(s) in the definitive  
2 SCAS test occurs, then full scale SCAS testing shall not be initiated and DuPont shall perform  
3 the activities listed in Section VI below.

### 4 **III. SELECTION OF THIRD PARTY LABORATORIES**

5 A. *Development of Confidentiality Agreement.* Within forty-five (45) days from the  
6 date DuPont signs the Consent Agreement, DuPont shall submit to EPA the confidentiality  
7 agreement that DuPont intends to use with any laboratory. Within seven (7) business days of  
8 receipt of EPA's approval (or acceptance) of the confidentiality agreement, DuPont must provide  
9 the laboratories listed in Attachment G with a confidentiality agreement and request that such  
10 confidentiality agreement be signed and returned by a date certain consistent with the deadlines  
11 established in this Appendix.

12 B. *Development of Request for Proposals.* By February 1, 2006, DuPont shall  
13 submit to EPA one or more draft Requests for Proposals (RFPs) to be sent to all of the  
14 laboratories identified in Attachment G to solicit proposals for (1) characterizing the  
15 Fluorotelomer Products and any Corresponding Polymers, and (2) conducting the SCAS  
16 studies on the Fluorotelomer Products and any Corresponding Polymers (including pilot  
17 testing).

18 The proposed RFPs must at least include the following elements:

19 1. The laboratory's obligation, if selected, to follow 40 C.F.R. Part 792, and  
20 prepare (or subcontract for preparation of) and comply with, a QAPP, provided in Attachment E  
21 of this Appendix.

22 2. All existing information that would be reasonably relevant to assisting  
23 the laboratory to develop a firm cost estimate, with pricing, for the work that the laboratory is

1 solicited to perform, which must include such information as the identity, structure, and  
2 compositional analysis of the Fluorotelomer Products. The laboratory's proposal may be  
3 based upon not-to-exceed estimates for the proposed work or any other method that provides,  
4 to the extent feasible, a firm cost estimate for the work.

5 a. Laboratories receiving the RFP for characterization of the  
6 Fluorotelomer Products and Corresponding Polymers must provide cost estimates for  
7 characterizing all of the Fluorotelomer Products and their Corresponding Polymers.

8 b. Laboratories receiving the RFP for the biodegradation work must  
9 include cost estimates for conducting 14-day pilot tests for SCAS on the Fluorotelomer  
10 Products and the Corresponding Polymers, as identified in Attachment A, and for performing  
11 SCAS studies on all Fluorotelomer Products and their Corresponding Polymers.

12 3. The laboratory's cost proposal should include the identification of any  
13 analytical methods that the laboratory anticipates needing to develop in order to perform any of  
14 the required analytical work associated with the characterization or biodegradation studies  
15 required under this Biodegradation SEP.

16 4. For the laboratories receiving the RFP for the biodegradation work,  
17 DuPont shall provide the guidelines for SCAS, included in Attachment C of this Appendix.

18 5. A requirement that the recipient identify in its proposal a general schedule  
19 and budget for completion of the proposed work identified in the RFP in accordance with the  
20 deadlines and criteria set forth in this Appendix.

21 6. A copy of Section II.L, above, and the terms and conditions  
22 identified in Section III.F.2, below.

23 7. Notice that failure to submit a proposal meeting all of the criteria in the

1 RFP to DuPont within thirty (30) days of the laboratory's receipt of the RFP may render the  
2 laboratory ineligible for selection.

3 C. Within seven (7) days of receipt of the approved RFP, DuPont shall provide the  
4 EPA-approved RFPs to all laboratories listed in Attachment G that have submitted to DuPont a  
5 signed confidentiality agreement. If DuPont has not received a signed confidentiality  
6 agreement from a laboratory by the date that DuPont is required to provide the RFP, DuPont  
7 shall notify EPA why it cannot send the RFP to such laboratory. EPA reserves the right to  
8 contact such laboratory to inquire why it has not returned the confidentiality agreement and, if  
9 such laboratory agrees within seven (7) business days of contact by EPA to sign and submit the  
10 confidentiality agreement to DuPont, DuPont shall then provide the RFP to the laboratory.

11 D. **Laboratory Eligibility.** Within forty-five (45) days of EPA's approval of the  
12 RFPs, or such longer time as EPA has approved in accordance with Section III.D.2, below,  
13 DuPont must receive a firm proposal back from a laboratory receiving an RFP in order for that  
14 laboratory to be eligible to perform work under this Biodegradation SEP.

15 1. DuPont shall require the recipients to submit one duplicate copy of its  
16 proposal to EPA concurrent with its submission to DuPont.

17 2. If a laboratory that received the RFP does not submit a proposal to DuPont  
18 within thirty (30) days of receipt of the RFP, EPA reserves the right to contact such laboratory  
19 to inquire why it has not submitted a proposal to DuPont. If the laboratory indicates that it  
20 wants to submit a proposal, the laboratory must do so by a date to be specified by EPA, which  
21 shall not be longer than fourteen (14) days after contact by EPA, unless the parties agree to a  
22 longer time period.

23 E. **Selection of Laboratories.** No later than fourteen (14) days after receipt of the

1 last bid that DuPont received within the applicable period for submission under III.D, DuPont  
2 must propose to EPA the laboratory that DuPont would like to use to perform the  
3 characterization of the Fluorotelomer Products and Corresponding Polymers, and the laboratory  
4 that DuPont would like to use to perform the biodegradation studies of the Fluorotelomer  
5 Products and Corresponding Polymers.

6 1. DuPont must provide EPA with a detailed rationale describing why  
7 DuPont has selected such laboratories to perform the work and why it has not selected the  
8 other laboratories that submitted a proposal to perform such work.

9 2. DuPont shall contract with only one laboratory to perform the modified  
10 SCAS studies on the Fluorotelomer Products and Corresponding Polymers. DuPont shall  
11 contract with only one laboratory to characterize the Fluorotelomer Products and  
12 Corresponding Polymers.

13 3. If, after proposal submission, EPA rejects either the laboratory for  
14 characterization and/or the laboratory for biodegradation testing, EPA will provide DuPont with  
15 a written rationale for the rejection and require DuPont to propose a different laboratory from  
16 which DuPont has received a proposal. The parties will continue this process until EPA agrees  
17 to DuPont's laboratory selection.

18 4. If no laboratories submit proposals to DuPont, or if none of the proposals  
19 submitted is acceptable to EPA, the Directors of the Office of Civil Enforcement and the  
20 Office of Pollution Prevention and Toxics shall meet with DuPont to discuss appropriate  
21 changes that can be made to this Biodegradation SEP to foster laboratory participation in the  
22 performance of this Biodegradation SEP. EPA and DuPont shall first implement the alternative  
23 approach set forth in Section II.J.2.b before EPA considers whether to expand the list of

1 potential laboratories identified in Attachment G to include foreign laboratories. If the parties  
2 cannot agree to any such appropriate changes, or if after agreeing to such appropriate changes,  
3 no laboratories submit a proposal, this Biodegradation SEP shall be deemed to have ceased  
4 prior to its completion, in which case, DuPont shall not be subject to Section VII.3 of the  
5 CAFO but DuPont shall be subject to Section VII.1 of the CAFO, and the parties may exercise  
6 Section VI of the CAFO even though this Biodegradation SEP is not deemed satisfactorily  
7 completed.

8       F.     ***Laboratory Contract Requirements.*** Within thirty (30) days of EPA's approval  
9 of the laboratories under Section III.E, DuPont must provide EPA with a final draft of the  
10 proposed contract that DuPont and the two laboratories have negotiated.

11             1.     No contract shall be executed by DuPont and a laboratory until EPA has  
12 reviewed and either approved or accepted the contract in accordance with Section II.G.2.

13             2.     The proposed contract must include the following terms and conditions in  
14 addition to the elements discussed in Section III.B, above:

15                 a.     The laboratory consents to inspection, for purposes of this  
16 Biodegradation SEP, at any reasonable time, as provided in 40 C.F.R. § 792.15.

17                 b.     All laboratory personnel must directly answer any questions from  
18 EPA pertaining to work the laboratory is performing under this Biodegradation SEP. Any  
19 request from EPA for written information from a laboratory pertaining to work it is  
20 performing under this Biodegradation SEP will be transmitted through DuPont's designated  
21 Study Monitor. DuPont's Study Monitor shall notify the laboratory of EPA's request for such  
22 information within three (3) business days of EPA's request, and the laboratory shall provide  
23 such information to EPA and DuPont within three (3) business days of DuPont's Study

1 Monitor's notice to the laboratory.

2 *i.* If, based upon oral or written information so obtained,  
3 EPA believes that a minor modification(s) to an approved or accepted test protocol or other  
4 analytical method must be made, EPA will inform DuPont of the modification and require  
5 DuPont to instruct the laboratory to implement the change immediately and continue running  
6 the test. DuPont may submit comments for EPA's consideration regarding such modification,  
7 in accordance with Section II.K, above.

8 *ii.* If, based upon oral or written information so obtained,  
9 EPA believes that a modification to an approved or accepted test protocol or other analytical  
10 method must be made that requires the laboratory to stop the test and start again, EPA will  
11 inform DuPont of the modification and require DuPont to instruct the laboratory to provide  
12 EPA and DuPont with all data generated up to that date and immediately terminate the test and  
13 re-run the test implementing the modification. DuPont may submit comments for EPA's  
14 consideration regarding such modification, in accordance with Section II.K, above.

15 *c.* EPA shall have the exclusive authority to approve all work plans,  
16 protocols, and test methods that the study sponsor would otherwise approve under 40 C.F.R. Part  
17 792 as well as any analytical methods not expressly enumerated in 40 C.F.R. Part 792, and the  
18 QAPPs. DuPont may submit comments for EPA's consideration regarding such technical  
19 documents, in accordance with Section II.K, above.

20 *d. **Material Modifications.*** Any proposed material modification that  
21 a laboratory or DuPont would like to make that involves work conducted under this  
22 Biodegradation SEP must be approved by EPA prior to implementation. For purposes of this  
23 Biodegradation SEP, a material modification is an adjustment to the work conducted under this

1 Biodegradation SEP made in the normal course of implementing such work that would result in a  
2 substantive alteration of the biodegradation studies or other activities conducted under this  
3 Biodegradation SEP.

4 e. EPA and DuPont shall receive written notification from the  
5 laboratory no later than five (5) business days before the laboratory makes any modification  
6 that involves work previously approved by EPA under this Biodegradation SEP, except as  
7 provided in Section III.F.2.f, below. If, based upon this notification, EPA believes that such  
8 modification is material, EPA will orally notify DuPont and the laboratory immediately, and  
9 require DuPont to instruct the laboratory to submit such proposed modification to EPA for  
10 approval within the timeframe that EPA establishes in the oral notice. DuPont may submit  
11 comments for EPA's consideration regarding such modification, in accordance with Section II.  
12 K, above.

13 f. ***Emergency Modifications.*** In the event of an emergency, the  
14 laboratory may make a modification that involves work previously approved by EPA under  
15 this Biodegradation SEP, to address an unforeseen circumstance or occurrence that will have  
16 an adverse affect on the test if not immediately implemented. The laboratory shall provide  
17 notice to EPA and DuPont within twenty-four (24) hours of such modification. If, based upon  
18 this modification, EPA believes that the laboratory must stop the test and start again or that the  
19 laboratory should implement an additional change, EPA will require DuPont to instruct the  
20 laboratory to provide EPA and DuPont with all data generated up to that date and either  
21 immediately terminate the test and re-run the test or immediately implement the additional  
22 change. DuPont may submit comments for EPA's consideration regarding such modification or  
23 additional change, in accordance with Section II.K, above.

1                   g.     **Progress Reports.** Within thirty (30) days of commencing the  
2 technical work, and by the first day of each month thereafter until the laboratory submits its  
3 last final report under Section IV.C, below, the laboratory shall provide EPA and DuPont with  
4 a progress report that describes the technical work performed, a copy of the raw data generated  
5 up to that date, and costs incurred.

6                   h.     **Information Exchange.** When the laboratory provides any  
7 information in written form to EPA or DuPont concerning the laboratory's work under this  
8 Biodegradation SEP, the laboratory shall provide such information to the other party as soon as  
9 practicable. The laboratory is not responsible for disseminating information that it receives in  
10 written form from DuPont; DuPont shall concurrently provide the information to EPA. When  
11 the laboratory provides information in oral form to EPA or DuPont concerning the laboratory's  
12 work under this Biodegradation SEP, the laboratory shall communicate such information to the  
13 other party as soon as practicable. The laboratory is not responsible for communicating  
14 information it receives in oral form from DuPont or EPA; each party shall communicate such  
15 information to the other party. However, when the laboratory receives an oral communication  
16 from DuPont or EPA, it shall notify both parties and provide a brief written description of such  
17 oral communication. To the extent practicable, the parties shall jointly communicate orally  
18 with the laboratory in light of the laboratory's obligation to prepare a written notification to the  
19 parties when it receives an oral communication, not jointly, from either party.

20                   i.     The laboratory shall allow Peer Consultation Panel members to  
21 visit the laboratory, as necessary, when the Peer Consultation Panel has a meeting(s) and/or  
22 deliberations relevant to the work that the laboratory is performing under this Biodegradation  
23 SEP.

1           G.     *Contract Execution.* Within five (5) business days of receipt of EPA's  
2 approval (or acceptance) of the proposed contract in accordance with Section II.G.2, DuPont  
3 must sign and forward the contract to the laboratory for execution.

4           a.     DuPont and the laboratory shall seek to execute the contract within thirty  
5 (30) days of receipt of EPA's approval (or acceptance) of the proposed contract. If DuPont  
6 and the laboratory have not executed the contract within thirty (30) days, DuPont must, inform  
7 EPA of the delay, explain the reason for the delay, provide a reasonable estimate as to when the  
8 contract will be executed, and exercise its right to an automatic extension in Section II.L,  
9 above. After exercising its right to an automatic extension in Section II.L, but before a second  
10 request for an extension under Section II.L, if DuPont believes that, notwithstanding its best  
11 efforts, the laboratory will not enter into the contract with DuPont, DuPont shall provide  
12 notice to EPA of the impasse. EPA reserves the right to contact such laboratory, upon receipt  
13 of such notice from DuPont, to inquire why the laboratory has not entered into the contract  
14 with DuPont. If DuPont and the laboratory have not entered into a contract within fourteen  
15 (14) days EPA's inquiry, unless DuPont and EPA agree to a longer time period, then the parties  
16 shall follow the approach set forth in Section III.H, below.

17           b.     Within five (5) business days from the date that DuPont and the  
18 laboratory execute the contract, DuPont must notify EPA that it has entered into the  
19 contract with the laboratory.

20           H.     If no laboratory enters into a contract with DuPont, the Directors of the Office of  
21 Civil Enforcement and the Office of Pollution Prevention and Toxics shall meet with DuPont  
22 to discuss appropriate changes that can be made to this Biodegradation SEP to foster laboratory  
23 participation in the performance of this Biodegradation SEP. If the parties cannot agree to any

1 such appropriate changes, or if after agreeing to such appropriate changes, no laboratories enter  
2 into a contract with DuPont, this Biodegradation SEP shall be deemed to have ceased prior to  
3 its completion, in which case, DuPont shall not be subject to Section VII.3 of the CAFO but  
4 DuPont shall be subject to Section VII.1 of the CAFO, and the parties may exercise Section VI  
5 of the CAFO even though this Biodegradation SEP is not deemed satisfactorily completed.

6 I. *Commencement of Work.* Within thirty (30) days from the date that DuPont and  
7 each laboratory execute the contract, the laboratory must commence the work it has agreed to  
8 perform under the contract, as described in Section IV, below.

9 **IV. TESTS TO BE PERFORMED ON DUPONT FLUOROTELOMER PRODUCTS**  
10 **AND CORRESPONDING POLYMERS**

11 A. Characterization of the Fluorotelomer Products and Corresponding Polymers

12 1. As provided in Section III.I, the laboratory shall commence the work  
13 identified in this Section IV.A, within thirty (30) days from the date that DuPont and the  
14 laboratory execute the contract to perform work under this Biodegradation SEP. The  
15 laboratory shall commence such work by submitting a work plan to EPA that describes the  
16 work the laboratory has been contracted to perform, addressing all requirements for such work  
17 under this Biodegradation SEP (including Attachment B), and a general schedule and budget  
18 for completion of the work. Within forty-five (45) days from the date that DuPont and the  
19 laboratory execute the contract to perform work under this Biodegradation SEP, the laboratory  
20 shall submit to EPA all relevant technical documents that require EPA's approval.

21 2. Within fourteen (14) business days of EPA's approval of the work plan  
22 and all relevant technical documents, the laboratory shall begin the implementation of the  
23 EPA-approved work plan.

1           3.       Within fourteen (14) business days of characterizing each Fluorotelomer  
2       Product and any Corresponding Polymers, the laboratory shall provide EPA and the Panel  
3       Administrator, a Certificate of Analysis, as provided in Attachment F, as well as the  
4       protocols and a copy of the raw data. The laboratory shall provide the QAPP to the Panel  
5       Administrator with the first Certificate of Analysis but need not provide the QAPP for the  
6       remaining eight Fluorotelomer Products and Corresponding Polymers.

7           B.       Biodegradation Studies: SCAS

8           1.       As provided in Section III.I, the laboratory shall commence the work  
9       identified in this Section IV.B, within thirty (30) days from the date that DuPont and the  
10      laboratory execute the contract to perform such work. The laboratory shall commence such  
11      work by submitting a work plan to EPA that describes the work the laboratory has been  
12      contracted to perform, addressing all requirements for such work under this Biodegradation  
13      SEP (including Attachment C), and a general schedule and budget for completion of the work.  
14      Within ninety (90) days from the date that DuPont and the laboratory execute the contract to  
15      perform work under this Biodegradation SEP, the laboratory shall submit to EPA all relevant  
16      technical documents that require EPA's approval.

17          2.       Within fourteen (14) business days of EPA's approval of the work plan  
18      and all relevant technical documents, the laboratory shall begin the implementation of the  
19      EPA-approved work plan.

20          a.       The laboratory shall run the SCAS test for twelve (12) weeks. The  
21      inoculum source shall be activated sludge mixed liquor from a municipal wastewater treatment  
22      plant operating in compliance with its National Pollutant Elimination Discharge System  
23      ("NPDES") permit. Settled domestic sewage from a municipal wastewater treatment plant

operating in compliance with its NPDES permit shall be used as feed. Daily samples of the aqueous phase, sludge solids, and off gas shall be collected, analyzed, and quantified for the analytes listed in Attachment C of this Biodegradation SEP. If at any time EPA determines, or if DuPont or the laboratory recommends and EPA determines, that daily sampling is not necessary, EPA will notify DuPont to instruct the laboratory of a change in the sampling schedule and establish a new timeframe for sampling. Analyses shall be conducted using the most accurate instrumentation and procedures available as of the time of testing. All analytical methods shall be approved by EPA prior to the start of the studies.

3. The laboratory shall conduct one 14-day pilot test for SCAS on the first Purified Fluorotelomer Product that has been selected for pilot testing as identified in Attachment A, and shall conduct one pilot test lasting up to 14 days, with the exact time to be determined, for SCAS on other Corresponding Polymers that have been selected for pilot testing as identified in Attachment A, to develop test data that can inform protocol decisions and to establish that these biodegradation studies can produce results that can be analyzed and quantified with regard to the biodegradation potential of the Fluorotelomer Products and Corresponding Polymers.

4. ***Pilot Preliminary Reports.*** No later than fourteen (14) days after the laboratory completes each pilot test, the laboratory shall provide EPA, DuPont, and the Panel Administrator with a preliminary report regarding the pilot test results. In providing the preliminary report, the laboratory shall summarize the pilot test results and provide the QAPP, the protocols, and a copy of the raw data.

5. Within fourteen (14) business days after EPA has approved the final design and protocols for the SCAS studies, the laboratory shall begin the biodegradation studies

1 following the sequence and groupings (capacity allowing) provided in Attachment A.

2 a. EPA reserves the right to omit any analyte identified in  
3 Attachment C for purposes of the biodegradation studies.

4 b. Upon consideration of the Panel's report addressing the charge in  
5 Section V.A.2.c, additional characterization data for any purified or synthesized Corresponding  
6 Polymers that had not been characterized prior to the Panel's report, and the amount of  
7 remaining eligible SEP dollars, EPA shall determine which of the Corresponding Polymers, if  
8 any, shall be used in the biodegradation studies.

9 6. ***Study Preliminary Reports.*** Within seven (7) business days of the  
10 laboratory completing the biodegradation studies on the first Fluorotelomer Product and any of  
11 its Corresponding Polymers (or first group of Fluorotelomer Products and any of their  
12 Corresponding Polymers), the laboratory shall submit a preliminary report summarizing the  
13 study results to EPA, DuPont, and the Panel Administrator for distribution to the Peer  
14 Consultation Panel.

15 a. In providing the preliminary report, the laboratory shall also  
16 provide the protocols and a copy of the raw data. The laboratory shall only provide the QAPP  
17 to the Panel Administrator with the first Fluorotelomer Product and any of its Corresponding  
18 Polymers (or first group of Fluorotelomer Products and any of their Corresponding Polymers).

19 b. As the laboratory completes biodegradation studies on each  
20 Fluorotelomer Product and Corresponding Polymers (or group of Fluorotelomer Products and  
21 Corresponding Polymers), the laboratory shall submit preliminary reports and associated  
22 information described in Section IV.B.6.a, above, to EPA, DuPont, and to the Panel  
23 Administrator for distribution to the Peer Consultation Panel.

1 C. Reporting Test and Study Results

2 1. Each laboratory shall follow 40 C.F.R. Part 792, subpart J in preparing the  
3 final report for the tests that it performs.

4 2. Each laboratory must submit a final report to EPA, DuPont, and the Panel  
5 Administrator within thirty (30) days of completing all of the work identified in its contract  
6 with DuPont.

7 **V. PEER CONSULTATION FOR TESTS PERFORMED ON DUPONT**  
8 **FLUOROTELOMER PRODUCTS AND CORRESPONDING POLYMERS**

9 A. *Peer Consultation Panel and Charges.* As part of this Biodegradation SEP,  
10 DuPont shall contract with an independent third party to serve as a Panel Administrator to  
11 implement and administer the Peer Consultation process under this Biodegradation SEP.

12 1. The Panel Administrator shall select a Peer Consultation Panel ("Panel")  
13 that will address the charges set forth in Section V.A.2, below.

14 a. The Panel Administrator shall solicit potential Panel member  
15 nominations from the public, will allow self-nomination, and may nominate potential Panel  
16 members. The parties may submit Panel member nominations to the Panel Administrator.

17 b. After receiving Panel member nominations, the Panel  
18 Administrator shall develop a pool of potential Panel members that will be subject to comment  
19 by EPA, DuPont, and the public.

20 c. After considering all comments received regarding the Panel  
21 member pool, the Panel Administrator shall select a potential Panel and submit the potential  
22 Panel to EPA and DuPont for comment. The Panel Administrator has the exclusive authority to  
23 select the Panel. If both parties, independently, recommend to the Panel Administrator that a

1 particular potential Panel member would not be appropriate to serve on the Panel, the Panel  
2 Administrator shall remove such individual from the potential Panel and from the pool, select a  
3 new potential Panel from the pool of potential Panel members, and then submit a new potential  
4 Panel to EPA and DuPont for comment. The Panel Administrator shall follow this approach  
5 until it has selected a final Panel.

6 d. The Panel Administrator shall treat all comments received under  
7 Sections V.A.1.b and V.A.1.c as confidential.

8 2. The Panel is charged to:

9 a. Review the approved or accepted protocols that the laboratory used  
10 to characterize the Fluorotelomer Products and Corresponding Polymers for chemical  
11 characteristics, compositional analysis, oligomeric content, molecular weight distribution, and  
12 residual content as discussed in Attachment B of this Biodegradation SEP and determine:

13 i. whether the approved or accepted protocols were  
14 sufficiently robust to provide reliable characterization data, and

15 ii. whether the laboratory correctly followed the protocols.

16 b. Review the design and approved or accepted protocol that was  
17 used to run each pilot and results for each pilot to provide comments and recommendations for  
18 developing a final design and protocol for SCAS studies that will be approved by EPA prior to  
19 implementation by the laboratory.

20 c. Compare the pilot results and characterization data of each  
21 Fluorotelomer Product to the pilot results and characterization data of its Corresponding Polymer  
22 to advise EPA regarding the similarities and differences of the Corresponding Polymers as  
23 compared to the Fluorotelomer Products, and which, if any, of the Corresponding Polymers

1 should be used in the biodegradation studies.

2 *i.* If, based upon such comparison, the Panel can identify one  
3 Corresponding Polymer for each Fluorotelomer Product that should be used in the  
4 biodegradation studies, the Panel shall so state, and provide a detailed explanation as to why it is  
5 appropriate to use only this one Corresponding Polymer in the biodegradation studies.

6 *ii.* If, based upon such comparison, the Panel cannot identify  
7 one Corresponding Polymer for each Fluorotelomer Product but can identify two  
8 Corresponding Polymers for a particular Fluorotelomer Product, the Panel shall so state, and  
9 provide a detailed explanation as to why it is appropriate to use the two Corresponding  
10 Polymers in the biodegradation studies.

11 *iii.* If, based upon such comparison, the Panel cannot identify  
12 two Corresponding Polymers for each Fluorotelomer Product and recommends that all three  
13 Corresponding Polymers for a particular Fluorotelomer Product be used in the biodegradation  
14 studies, the Panel shall so state, and provide a detailed explanation as to why it is appropriate to  
15 use all three Corresponding Polymers in the biodegradation studies.

16 *iv.* If, based upon such comparison, the Panel cannot identify  
17 any Corresponding Polymers for a Fluorotelomer Product and recommends that no  
18 Corresponding Polymer be used in the biodegradation studies, the Panel shall so state, and  
19 provide a detailed explanation as to why it is not appropriate to use any Corresponding  
20 Polymers in the biodegradation studies.

21 *v.* The Panel shall also advise EPA as to whether the  
22 laboratory should run a 14-day pilot test for SCAS on each of the Corresponding Polymers that  
23 it recommends should be used in the biodegradation studies but which were not pilot tested by

1 the laboratory performing the biodegradation work.

2 d. Advise EPA regarding which analytes that were measured for in  
3 the pilot tests should also be measured for in the biodegradation studies.

4 e. Evaluate the results of the SCAS studies performed on the  
5 Fluorotelomer Products and any Corresponding Polymers, and advise EPA as to what the results  
6 mean, both for the individual substances and for the group of test substances as a whole.

7 f. Provide comment on whether 14C labeling or other methods would  
8 enhance the characterization of the test substances, measurement of the potential for  
9 biodegradation, and/or the evaluation of the biodegradation study results. If so, the Panel  
10 should describe how, and in what ways, the use of 14C-radiolabeled Lab-scale Synthesized  
11 Fluorotelomer Product would increase the usefulness of the results of the characterization and  
12 biodegradation studies.

13 3. EPA, after consultation with DuPont, may submit additional, timely  
14 charges to the Panel that relate to, and are consistent with, the purposes of this Biodegradation  
15 SEP.

16 4. The Panel Administrator may request a clarification from EPA regarding  
17 the charges set forth in Section V.A.2, above. Such request must be made in writing. The Panel  
18 Administrator will provide DuPont a copy of its written request and EPA will provide DuPont  
19 with a copy of its written response to the request, in accordance with Section V.E.8, below.

20 B. *Requirements of Panel Input.* The Panel will provide input to EPA on an  
21 advisory basis; such input will be provided by way of a summary document that reflects the  
22 individual opinions of the Panel members. The Panel Administrator may designate fewer than  
23 all members of the Panel to participate in providing advice on specific charges. Accordingly, at

1 different times during the Peer Consultation process, the Panel may be composed of different  
2 experts appropriate to the issue(s), but shall only be composed of the experts that have been  
3 selected by the Panel Administrator to serve as members of this Peer Consultation Panel. While  
4 consensus is not required, an accurate summary of all opinions expressed by the individual  
5 members must be submitted to EPA. The Panel will not operate under a consensus-based  
6 process but rather should identify areas of agreement and disagreement, and provide  
7 supporting scientific rationale. While EPA will consider the advice and recommendations it  
8 receives from the Panel, EPA is not bound by such advice or recommendations.

9 C. Qualifications and Requirements for Panel Members

10 1. The Panel must be composed of scientific experts who, collectively, have  
11 extensive and broad experience relevant to such areas as conducting and/or assessing  
12 biodegradation testing and environmental fate of polymers, and laboratory analysis and  
13 characterization of polymers and fluorochemicals. Specific knowledge of fluorotelomer  
14 chemistry is desirable.

15 2. Panel members must have sufficient technical expertise to make  
16 meaningful contributions to science-based evaluations.

17 3. Examples of the types of expertise that will be needed include, but are not  
18 limited to, conducting biodegradation testing, environmental fate, polymer chemistry,  
19 analytical chemistry under 40 C.F.R. Part 792, and/or fluorotelomer/ fluoropolymer chemistry.

20 D. General Requirements for the Peer Consultation Process

21 1. One Panel will be selected by the Panel Administrator and shall be  
22 composed of at least four (4) but no more than eight (8) members collectively meeting the  
23 qualifications stated in Section V.C.

1           2.     In selecting the Panel, the Panel Administrator shall use conflict of interest  
2 guidelines approved by EPA. DuPont shall have an opportunity to review and provide  
3 comments to EPA regarding the conflict of interest guidelines.

4           3.     The Panel Administrator shall submit information to Administrative  
5 Record (AR) 226 to ensure that the public has an opportunity to nominate panel members, access  
6 to the Panel's sanitized final reports, and access to all sanitized laboratory final reports. The  
7 Panel Administrator shall not disclose any information that would be Toxic Substances Control  
8 Act Confidential Business Information if submitted to EPA.

9           4.     Panel meetings and deliberations will not be open to the public but will be  
10 open to DuPont and EPA employees and/or contractors with Toxic Substances Control Act  
11 Confidential Business Information clearance. Such Panel meetings and/or deliberations may  
12 also be open to other individuals or entities that EPA would like to attend, subject to  
13 confidentiality agreements, and prior approval from DuPont.

14          5.     If practicable, Panel meetings and deliberations will be held at or near the  
15 facilities of the laboratory conducting work relevant to the charge or charges under consideration  
16 at such meetings and/or deliberations so that Panel members can visit the laboratory, as  
17 needed.

18          6.     EPA and DuPont may submit written comments to the Panel  
19 Administrator regarding technical documents developed by the laboratories under  
20 consideration by the Peer Consultation Panel. The Panel Administrator shall not provide such  
21 written comments to Panel members in advance of any Panel meetings or deliberations but  
22 only provide such comments to the Panel members at the time of the Panel meetings or  
23 deliberations so as not to bias the Panel members' premeeting consideration of any particular

1 issue under consideration.

2 E. Selection and Responsibilities of the Panel Administrator

3 1. By February 1, 2006, the parties will agree to the Panel Administrator.

4 2. By March 15, 2006, DuPont must provide EPA with a final draft of the  
5 proposed contract that DuPont and the Panel Administrator have negotiated. The contract shall  
6 not be executed by DuPont and the Panel Administrator until EPA has reviewed and either  
7 approved or accepted the contract. The contract shall provide for appropriate confidentiality  
8 provisions.

9 3. Within seven (7) business days from receipt of EPA's approval (or  
10 acceptance) of the proposed contract, DuPont must sign and forward the contract to the Panel  
11 Administrator for execution.

12 a. DuPont and the Panel Administrator shall seek to execute the  
13 contract within twenty-one (21) days of DuPont's receipt of EPA's approval (or acceptance) of  
14 the proposed contract. If DuPont and the Panel Administrator have not executed the contract  
15 within twenty-one (21) days of DuPont's receipt of EPA's approval (or acceptance) of the  
16 proposed contract in accordance with Section II.G.2, DuPont must inform EPA of the delay,  
17 explain the reason for the delay, provide a reasonable estimate as to when the contract will be  
18 executed, and exercise its right to an automatic extension provided in Section II.L, above.  
19 However, if DuPont believes that, notwithstanding its best efforts, the candidate Panel  
20 Administrator will not execute the contract with DuPont, DuPont shall provide notice to EPA of  
21 the impasse. EPA reserves the right to contact such candidate Panel Administrator, upon receipt  
22 of such notice from DuPont, to inquire why it has not entered into the contract with DuPont. If  
23 DuPont and the candidate Panel Administrator have not entered into a contract within fourteen

1 (14) days after EPA's inquiry, unless EPA and DuPont agree to a longer time period, then the  
2 parties shall follow the approach set forth in Section V.E.4, below.

3 b. Within five (5) business days from the date that DuPont and the  
4 Panel Administrator execute the contract, DuPont must notify EPA that it has entered into the  
5 contract with the Panel Administrator.

6 4. If no Panel Administrator enters into a contract with DuPont, the Directors  
7 of the Office of Civil Enforcement and the Office of Pollution Prevention and Toxics shall  
8 meet with DuPont to discuss appropriate changes that can be made to this Biodegradation SEP  
9 to foster Panel Administrator participation in the performance of this Biodegradation SEP. If  
10 the parties cannot agree to any such appropriate changes, or if after agreeing to such  
11 appropriate changes, no potential Panel Administrator enters into a contract with DuPont, this  
12 Biodegradation SEP shall be deemed to have ceased prior to its completion, in which case,  
13 DuPont shall not be subject to Section VII.3 of the CAFO but DuPont shall be subject to Section  
14 VII.1 of the CAFO, and the parties may exercise Section VI of the CAFO even though this  
15 Biodegradation SEP is not deemed satisfactorily completed.

16 5. ***Peer Consultation Process Work Plan.*** Within sixty (60) days of contract  
17 execution, the Panel Administrator must submit to EPA a proposed work plan (including all  
18 applicable attachments) that addresses the following:

19 a. The process, schedule, and budget for implementing and  
20 administering the Peer Consultation process under this Biodegradation SEP from the date the  
21 Panel Administrator executes the contract with DuPont through the date that the Panel  
22 Administrator submits to EPA and AR226 (or EPA-HQ-OPPT-2011-0991 at Regulations.Gov  
23 if submitted on or after January 1, 2012) the Panel's final report from the last Panel meeting.

1                   b.       A description of the process for nominating and selecting the Panel  
2 members, in accordance with Section V.A. 1, above, and the rationale to be used in determining  
3 how many experts to empanel to address the charges.

4                   c.       The schedule for the Panel to timely address the charges in Section  
5 V.A.2 to ensure the most efficient use of the Panel.

6                   i.       The Panel Administrator shall communicate with the  
7 laboratory performing the biodegradation testing to determine if it would be appropriate to  
8 have the Peer Consultation Panel review the results of the first pilot test for SCAS and, once the  
9 laboratory has begun the full biodegradation studies, the results of the SCAS studies for the  
10 first grouping of chemical substances identified in Attachment A, i.e., the three Fluorotelomer  
11 Products identified as the A group, and any Corresponding Polymers selected for testing, or  
12 any subsequent groupings identified in Attachment A, as appropriate. The Panel Administrator  
13 may seek a recommendation from the laboratory with regard to this issue and/or the Panel  
14 Administrator may make its own determination after reviewing the data as to whether it is  
15 appropriate to convene the Peer Consultation Panel to review such results or to delay the review  
16 until all pilot tests and all biodegradation studies are completed.

17                   ii.       Regardless of how Peer Consultation is handled with regard  
18 to reviewing the first pilot test results and biodegradation study results, all pilot tests and  
19 biodegradation studies shall be reviewed by the Peer Consultation Panel.

20                   d.       The proposed conflict of interest guidelines that will be used to  
21 screen potential Panel members. The Panel Administrator shall send the conflict of interest  
22 guidelines to DuPont concurrent with its submission to EPA. DuPont shall have fourteen (14)  
23 business days to provide comments to EPA regarding such conflict of interest guidelines.

e. The proposed contract for the Panel members, including the proposed honorarium to be paid to each Panel member.

f. The proposed confidentially agreements for the Panel members.

g. The process that the Panel Administrator will use to draft, on behalf of the Panel, the Panel's reports. The Panel Administrator must address the following:

i. The process and schedule for the Panel Administrator to compile comments from the Panel; and

ii. The process and schedule for the Panel Administrator to submit a draft of the document to the Panel members for their review and comment before such document becomes final.

h. The number and timing of the Panel's meetings to address the charges identified in Section V.A.2. If the Panel Administrator would like to arrange a Panel meeting or deliberation at a laboratory located outside of North America, the Panel Administrator shall seek prior approval from EPA before arranging such meeting.

i. A discussion of any other function(s) not expressly stated herein but that are necessary to implement and administer the Peer Consultation process under this Biodegradation SEP.

6. Within seven (7) days of receipt of EPA's approval of the work plan, the Panel Administrator must commence the Peer Consultation process, as described in the EPA-approved work plan.

7. The Panel Administrator is responsible for arranging Panel meetings and/or deliberations, and acting as facilitator during Panel meetings and/or deliberations; coordinating exchange of information to Panel members; submitting all Panel reports to EPA

1 and DuPont, with a copy of any such report and if there is CBI, a sanitized version of the  
2 report, submitted to AR 226 (if prior to January 1, 2012) or directed to EPA-HQ-OPPT-2011-  
3 0991 at regulations.gov (if on or after January 1, 2012) within thirty (30) days after submittal  
4 of a report to EPA and DuPont; and for carrying out all other functions necessary to implement  
5 and administer the Peer Consultation process under this Biodegradation SEP.

6           8.     ***Information Exchange.*** When the Panel Administrator provides any  
7 information in oral or written form to EPA or DuPont concerning the Peer Consultation  
8 process, the Panel Administrator shall provide such information to the other party in the same  
9 form as soon as practicable. The Panel Administrator is not responsible for sharing  
10 information it receives in oral or written form from EPA or DuPont; the party providing such  
11 information to the Panel Administrator shall concurrently provide the information in the same  
12 form to the other party. However, when the Panel Administrator receives a substantive oral or  
13 written communication from DuPont or EPA that impacts the Panel Administrator's  
14 implementation and/or administration of the Peer Consultation process, it shall notify both  
15 parties of the communication and provide a brief written description of the content of the  
16 communication.

17           9.     Recommendations, Advice, and Conclusions of the Panel

18               a.     ***Final Panel Reports submitted to the Parties.*** Within forty-five  
19 (45) days of each Panel meeting, the Panel Administrator shall submit a final written report, on  
20 behalf of the Panel, to EPA and DuPont, that addresses the charge or charges under  
21 consideration at such meeting.

22               b.     ***Final Panel Reports submitted, as of January 1, 2012, for posting***  
23 ***to EPA-HQ-OPPT-2011-0991.*** Within thirty (30) days after the Panel Administrator has

1 submitted a final written report to EPA and DuPont, such final written report and a sanitized  
2 version of such final written report shall be submitted to the person identified in Section V of  
3 the CAFO for posting on Regulations.gov at EPA-HQ-OPPT-2011-0991.

#### 4 **VI. ADDITIONAL ACTIVITIES**

5 A. If full scale SCAS testing is not initiated because of the "substantial equivalence"  
6 provisions of Section II.M. above, then DuPont shall spend up to \$1,500,000.00 (one million  
7 five hundred thousand dollars), without exceeding the total five million dollar cost of the SEP,  
8 on purchasing approved items referenced in Section VI.B. below, or other items as approved  
9 by EPA, for the purpose of assisting others to perform research on whether Fluorotelomer  
10 Products degrade to produce PFOA or assisting in the identification and quantification of PFOA  
11 in humans and/or the environment. These items shall be donated to universities, state, or local  
12 laboratories. The EPA, in its unreviewable discretion, must approve each item and recipient  
13 prior to any purchase in order for it to be considered an eligible SEP cost. Any equipment  
14 purchase and donation will be made in accordance with the EPA 1998 SEP Policy (signed  
15 April 10, 1998). If SEP funds are remaining after implementing this provision, refer to Section  
16 VII.1 of the CAFO.

17 1. **Timing and Manner of Initial Proposal.** Within ninety (90) days after  
18 EPA provides written notification to DuPont that full scale SCAS testing should not  
19 commence, DuPont shall propose in writing by email and via first class mail, return receipt  
20 requested, or by commercial delivery service with documented delivery, to the person  
21 identified in Section V of the CAFO, what items it intends to purchase, when the items will be  
22 bought, the name and address of the recipient of each item and a detailed cost estimate for the  
23 EPA to consider.

1                   2.     **Timing and Manner of Subsequent Proposals.** If EPA rejects an item  
2 or recipient in the initial proposal by DuPont, then any subsequent proposals shall be submitted  
3 in the same manner and to the same person as set forth above, except that subsequent proposals  
4 shall be submitted within forty-five (45) days of receiving written notice from EPA that a  
5 proposed item or recipient has not been approved.

6                   3.     **Timing of Purchase and Delivery of Approved Items.** An item shall be  
7 approved for purchase to the proposed recipient when DuPont receives written notice of such  
8 approval from EPA. DuPont shall order the approved item for shipment to the approved  
9 recipient within ninety (90) days of receiving EPA's written approval to make such a purchase.  
10 Delivery of the purchased items shall be set to occur within ninety (90) days after the purchase  
11 order is placed, unless EPA approves an extension.

12           B.     DuPont may purchase analytical instruments for the purpose of Gas  
13 Chromatography/Mass Spectrometry and Liquid Chromatography/Mass Spectrometry. DuPont  
14 may also purchase reference standards as described below, including but not limited to  
15 substances listed in SEP Appendix A Attachment B Table 1 Characterization of Fluorotelomer  
16 Products and Corresponding Polymers. Additional substances include: 10-2 Fluorotelomer  
17 Acrylate (10-2 FTAc), 12-2 Fluorotelomer Acrylate (12-2 FTAc), 8-2 Fluorotelomer Acetate  
18 (8-2 FTOH Acetate), 10-2 Fluorotelomer Acetate (10-2 FTOH Acetate), 12-2 Fluorotelomer  
19 Acetate, 8-2 Fluorotelomer Aldehyde (8-2 FTAL) and 8-2 Unsaturated fluorotelomer Aldehyde  
20 (FTUAL), Mass labeled fluorotelomer acids (e.g., M+2 , M+4 PFOA), Mass labeled  
21 fluorotelomer alcohols (e.g., M+4 6-2, 8-2, and 10-2 FTOH), Mass labeled fluorotelomer  
22 aldehydes (e.g. 8:2 FTAL and FTUAL)

23           C.     Upon EPA approval, DuPont may complete the SEP through the purchase of up to

1 \$1,500,000 (one million five hundred thousand dollars), without exceeding the total five  
2 million dollar cost of the SEP, of the approved items in this section VI.B. if it has completed  
3 one or more Purified Fluorotelomer Products and one or more of the Lab-scale Synthesized  
4 Fluorotelomer Products through full scale definitive SCAS testing. The EPA shall only  
5 approve such a request if it determines that additional SCAS testing is not feasible with the  
6 remaining budget or that the public interest is best served through the expenditure on the  
7 approved items instead of additional activities. Any equipment purchase and donation will be  
8 made in accordance with the SEP Policy. If SEP funds are remaining after implementing this  
9 provision, refer to Section VII.1 of the CAFO.

## 10 **VII. MISCELLANEOUS**

### 11 A. Eligible SEP Costs

12 1. The cost for providing sufficient quantities, as described in Sections II.D-  
13 E, above, of the Fluorotelomer Products for characterization, biodegradation pilot tests, and  
14 biodegradation studies shall not be an eligible SEP Cost.

15 2. The cost of preparing sufficient quantities, as described in Sections II.D-E,  
16 for characterization of Corresponding Polymers identified for pilot testing in Attachment A,  
17 and up to two additional Corresponding Polymers that the Panel recommends pursuant to  
18 charge V.A.2.c, shall not be an eligible SEP Cost.

19 3. The cost of preparing sufficient quantities, as described in Sections II.D-E,  
20 for biodegradation pilot tests of the Corresponding Polymers, as identified on Attachment A,  
21 shall not be an eligible SEP cost.

22 4. The cost of preparing sufficient quantities, as described in Sections II.D-E,  
23 for biodegradation studies of up to two of the Corresponding Polymers that the Panel identifies

1 pursuant to charge V.A.2.c, shall not be an eligible SEP cost.

2 B. The title, section headings, and sub-headings used in this Appendix A are  
3 intended by the parties to assist in reading the document and have no legal meaning or effect.

4 C. Unless otherwise indicated, the word "days" as used in this Appendix refers to  
5 calendar days.

6 D. Unless otherwise provided in this Appendix or its Attachments, terms shall have  
7 the same meaning as provided in 15 U.S.C §§ 2601 et seq. and 40 C.F.R. Parts 2 and 792.  
8 Terms not defined in 15 U.S.C §§ 2601 et seq. and 40 C.F.R. Parts 2 and 792, but that are  
9 defined in this Appendix or its Attachments, shall be given the meaning as defined in this  
10 Appendix or its Attachments.

11 E. Except as otherwise provided, all communications between the parties, including  
12 DuPont's third party contractors, shall be in writing.

## Exhibit 2

	Activity/Accomplishment	Time Period (month.year)
1	DuPont prepares to begin sparging experiments before SEP A is extended. Equipment ordered, personnel assigned, and procedures developed for conducting the experiments to produce the 9 Purified Fluorotelomers	12.08
2	DuPont extends Nondisclosure Agreements with the 6 laboratories designated in the SEP	1.09
3	DuPont and MPI develop protocols to validate GC/MS and LC/MS/MS methods to be followed in preparing the 9 Purified Fluorotelomers	1.09
4	DuPont develops and submits to EPA procedures for separating, preparing, holding, and shipping products from the pilot study to MPI for analysis	2.09
5	DuPont initiates method validation for pot control samples. LC/MS/MS method validated; problems encountered with GC/MS method validation; EPA notified of GC/MS method validation problems	2.09-3.09
6	DuPont begins sparging of 9 commercial Fluorotelomer Products	3.09
7	DuPont revises, due to modifications made to the SEP per the 1 <sup>st</sup> Extension, and re-submits to EPA the Biodegradation Laboratory and Characterization Laboratory Requests for Proposal (RFPs) submitted in January 2007	4.09
8	DuPont revises, due to modifications made to the SEP per the 1 <sup>st</sup> Extension, and re-submits to EPA the proposed Panel Administrator contract executed in February 2007	4.09
9	MPI completes validation for the LC/MS/MS method and the GC/MS method (both methods used for analyzing impurities in the 9 Purified Fluorotelomer Products)	4.09
10	MPI issues the final GC/MS and LC/MS/MS validation report	5.09
11	DuPont stops sparging, with approval of EPA, after 79 days of sparging	5.09
12	DuPont ships the 9 Purified Fluorotelomer products to EPA - total cost to produce these substances was \$722,449.00 (not an eligible SEP cost)	6.09
13	DuPont submits holding procedures and MSDSs for each test substance to EPA	6.09
14	DuPont submits final report and underlying raw data for the purification procedure to EPA	6.09
15	DuPont and the Panel Administrator execute a revised Panel Administrator contract modifications made to the SEP per the 1 <sup>st</sup> Extension, which was approved by EPA	6.09
16	Panel Administrator submits work plan to for approval; EPA approval granted	6.09-8.09
17	Panel Administrator establishes the on-line website for its work under the SEP and begins the nomination process for Panel members	9.09
18	EPA approves the Biodegradation Laboratory and Characterization Laboratory RFPs; DuPont submits the RFPs to the laboratories identified in the SEP	7.09-8.09
19	DuPont receives responses to RFPs; DuPont submits laboratory recommendation to EPA	9.09
20	Panel Administrator manages review of nominations to the SEP Panel by DuPont, EPA, and the public	10.09-1.10
21	EPA approves the recommended Biodegradation Laboratory(WLI) and Characterization Laboratory(MPI)	10.09

22	After receipt of cost estimates from the laboratories, EPA recommends prioritizing testing to 2 variants - the Purified Fluorotelomer Products and the Lab-scale Synthesized Fluorotelomer products, EPA forwards analytical methods (Washington et. al.) to DuPont for forwarding to the laboratories	11.09
23	DuPont submits the proposed Biodegradation Laboratory contract to EPA	12.09
24	Characterization Laboratory raises technical questions on analytical methods; consultation with DuPont and EPA for guidance and clarification	12.09
25	Panel Administrator selects the Panel members; non-disclosure agreements signed by Panel Members; initial Panel conference call hosted by the Panel Administrator	1.10-3.10
26	Biodegradation Laboratory contract revised, resubmitted to EPA, approved by EPA, and executed	1.10
27	Characterization Laboratory contract submitted to EPA, approved by EPA, and executed	1.10
28	Characterization Laboratory work plan submitted to EPA, reviewed, revised, and approved by EPA	2.10-3.10
29	Biodegradation Laboratory work plan submitted to EPA for review	3.10
30	DuPont ships SEP test substances to Biodegradation and Characterization Laboratories	1.10
31	Characterization Laboratory begins acquiring commercially available standards not in stock and identifying those which must be synthesized	2.10-3.10
32	Characterization Laboratory begins method development for instrument methods not currently established	2.10-3.10
33	Biodegradation Laboratory initiates work on SCAS pilot testing - assigns appropriate personnel begins design and fabrication of custom SCAS units	2.10-3.10
34	Biodegradation Laboratory acquires commercially available analytical standards and begins adapting EPA soil and sludge methodology to the SCAS matrices	2.10-3.10
35	Panel Administrator notified of prioritization of test substances for characterization and testing to two variants due to available funding and projected costs - asked to provide revised cost estimates for narrowed work scope	5.10
36	After further discussion and revision, EPA approves the Biodegradation Laboratory work plan which includes the pilot testing work plan and protocol, originally submitted in March 2010	5.10
37	Characterization Laboratory starts method development on the 18 analytes in the SEP; develops 4 instrumental methods (2 LC/MS/MS and 2 GC/MS) to complete characterization work; protocol for validation of methods reviewed by DuPont; weekly conference calls established to monitor progress and provide technical guidance	4.10-6.10
38	Monthly calls set with DuPont, EPA, and both laboratories to monitor progress and address technical issues; calls continued to present time	6.10-present
39	Panel Administrator hosts Panel conference call to plan for 2-day Panel meeting in December near the Biodegradation Laboratory	9.10
40	Panel Administrator informed by DuPont and EPA that a summary of the Panel's conclusions and recommendations is requested within a week after the December Panel meeting	9.09
41	Characterization Laboratory validates 2 LC/MS/MS methods and 2 GC/MS methods to allow characterization of SEP test substances; monthly calls continue with DuPont and EPA to address technical issues	7.10-9.10

42	EPA approves Characterization Laboratory method validation protocol amendments	8.10-9.10
43	Biodegradation Laboratory continues method development to adapt the EPA Athens soil and sludge methodologies to SCAS matrices and preparations for the initial pilot study; monthly calls continue with DuPont and EPA to address technical issues	7.10-9.10
44	Biodegradation Laboratory completes the acclimation phase of the initial pilot study	7.10-9.10
45	Biodegradation Laboratory completes the biological phase of the initial pilot study	7.10-9.10
46	Biodegradation Laboratory completes the method development trials specific for LC/MS/MS determination of the telomer acids in styrene-trapping media and completes the conduct of an analytical methods installation trial and the analytical processing of samples from the initial pilot study	7.10-9.10
47	Biodegradation Laboratory completes processing and determination of study analytes in the pilot study samples by GC/MS and LC/MS/MS	7.10-9.10
48	Biodegradation Laboratory submits 5 pilot study protocol amendments to EPA; EPA approves the amendments	8.10-9.10
49	Characterization Laboratory submits 3 method validation protocol amendments to EPA; EPA approves the amendments	8.10-9.10
50	Characterization Laboratory completes the analytical phase and data review for the validation of 4 methods used to determine fluorochemicals in the fluorotelomer test substances by LC/MS/MS and GC/MS	10.10-12.10
51	Characterization Laboratory prepares Quality Assurance Project Plan (QAPP), DuPont reviews it, QAPP submitted to EPA for approval	10.10-12.10
52	Characterization Laboratory develops a protocol for characterization of the test substance for the initial pilot study, DuPont reviews the protocol, EPA approves the protocol	10.10-11.10
53	Biodegradation laboratory prepares unaudited draft report for the initial pilot study and submits it to DuPont, EPA, and the Panel Administrator	10.10
54	Biodegradation Laboratory prepares a revised unaudited draft report for the initial pilot study and submits it to DuPont, EPA, and the Panel Administrator	11.10
55	Biodegradation Laboratory prepares an audited draft report for the initial pilot study and submits it, along with the raw data, to DuPont, EPA, and the Panel Administrator	12.10
56	Biodegradation Laboratory prepares and DuPont reviews a QAPP and an Analytical Method Validation Protocol; both documents submitted to EPA for approval	11.10-12.10
57	Panel Administrator convenes a conference call of the Panel to identify issues on the draft report submitted by the Biodegradation Laboratory on the initial pilot study, to identify key issues for discussion at the planned December 2010 Panel meeting, to develop the agenda and address logistics for the meeting and the plan and timeline for reporting by the Panel; questions from the Panel on the draft report forwarded to the Biodegradation Laboratory	11.10
58	Panel Administrator holds 2-day Panel meeting held at the Biodegradation Laboratory facilities; draft notes distributed to Panel members at the end of the meeting	12.10
59	Panel given tour of the laboratory where the initial pilot study was run (and where the 12.10 biodegradation studies will be run) and where the analyses of samples from the studies were performed	12.10

60	Panel Administrator issues to EPA and DuPont a draft report entitled "Preliminary Conclusions and Recommendations: Evaluation of the Biodegradation Pilot Studies by the Biodegradation SEP Panel"; EPA and DuPont agree that the report cannot be finalized until the analytical characterization data are received from the Characterization Laboratory; the report will be finalized 3 weeks after the Panel received the Final Report from the Characterization Laboratory	12.10
61	EPA accepts the Panel "Preliminary Report" referenced above to satisfy the Panel Final Report 12.10 requirement under the SEP on condition that the Preliminary Report IS revised after the characterization data becomes available	12.10
62	Panel Administrator leads Panel members in developing a plan to prepare its Final Report from the "Preliminary Report" - members assigned to draft sections of the Final Report – consolidated draft Final Report issued to Panel members	1.11-2.11
63	Panel completes as much as it can of the sections of the Report covering review of biodegradation pilot studies so that it can rapidly complete the Final Report once analytical protocols and data are received from the Characterization Laboratory	2.11-3.11
64	Panel combined Final Report on the biodegradation pilot studies and the analytical characterization results is on hold until the Characterization Laboratory analyzes test substances and submits results to the Panel	3.11-present
65	Characterization Laboratory receives EPA approval of the QAPP submitted in the 4 <sup>th</sup> quarter of 2010	1.11
66	Characterization Laboratory begins extraction/analysis of samples from the initial pilot study; DuPont is present at EPA request to observe extractions by MPI	1.11
67	Characterization Laboratory reports that the initial extractions it did following the approved protocol were not successful as aqueous and organic fractions did not separate	1.11
68	Characterization Laboratory, after consultation with EPA and DuPont and after protocol amendments were approved by EPA, starts extractions again - successful phase separation was achieved	1.11
69	Characterization Laboratory conducts extractions and analysis of the C4 fractions by LC/MS/MS and GC/MS methods; concentrations of analytes in MTBE extracts did not meet criteria in the protocol and the amount of MTBE recovered decreased with each extraction - findings reports to EPA by DuPont	1.11-2.11
70	DuPont submits a proposal to EPA for testing to determine how to best address issue described immediately above; EPA approves the proposed testing	2.11-3.11
71	Characterization Laboratory performs SEP-required molecular weight determination on the test sample and sends test samples and control to Lancaster Laboratories for SEP-required CHN analysis	1.11-3.11
72	Biodegradation Laboratory continues work on method refinements set forth in a submission made to EPA in November 2010; extensive discussions continue with DuPont, the Biodegradation Laboratory, and EPA to address technical issues on the SCAS method to be followed	1.11-3.11
73	Biodegradation Laboratory conducts 2 method development trials to investigate the low mass balance obtained for all volatile analytes upon fortifying and sampling SCAS activated sludge; a 3 <sup>rd</sup> method development trial was indicated after review of the 1 <sup>st</sup> 2 trials - the 3 <sup>rd</sup> trial was specifically focused on the effect of processing	1.11-3.11

	delay (time from fortification to initial MTBE addition) on volatile analyte mass balance data	
74	Characterization Laboratory submits a scope of work modification to EPA for review and approval as it is not realizing expected economies of scale due to a reduced scope of work and modifications required for the extraction procedure (and the effort associated with those modification)	3.11
75	Panel Administrator issues a revised draft of the SEP Panel's Final Report that incorporates comments from Panel members; Panel continues to wait for characterization data	4.11
76	Characterization Laboratory scope of work modification submitted in March 2011 is approved by EPA	6.11
77	Characterization Laboratory continues work on addressing issues with characterization of the initial pilot study test substance; submits proposals for additional development work involving (1) THF dissolutions of 2 pilot test samples (analyze only for PFOA by LC/MS/MS and 8-2 FTOH by LC/MS/MS) and (2) MTBE extractions of the 2 samples (analyze only for PFOA by LC/MS/MS and 8-2 FTOH by LC/MS/MS); EPA approves the proposals	5.11
78	Characterization Laboratory, DuPont, and EPA agree to proceed with evaluating the THF preparations described above rather than perform MTBE extractions - Characterization Laboratory presents data to EPA and DuPont; request made to include 6-2 and 10-2 FTOH compounds in the analysis; Characterization continues work on analyzing samples in THF	6.11
79	Characterization Laboratory asked to prepare a time-line and estimated costs for (1) LC/MS method development for 6-2, 8-2, and 10-2 FTOH, (2) validation protocol amendment and approval, (3) validation study, (4) new COA protocol or protocol amendment and revised QAPP and approvals, (5) perform study, (6) write draft report, (7) QA review and approvals	6.11
80	Biodegradation Laboratory conducts method installation trial to demonstrate quantitative acid analyte procedural recovery using the revised activated sludge mixed-liquor procedure	4.11-6.11
81	Biodegradation Laboratory revises draft method validation protocols and prepares a scope of work to evaluate the analysis of 6-2 FTOH, 8-2 FTOH, and 10-2 FTOH in MTBE extracts of an activated sludge matrix by LC/MS in the presence and absence of the Group A1 test substance	6.11
82	Biodegradation Laboratory requested by DuPont and EPA to outline an LC/MS/MS method (including cost and timing) to measure FTOH in the SCAS test MTBE extracts instead of using GC/MS as a result of the potential for polymer degradation in the GC inlet at elevated temperature	6.11
83	Biodegradation Laboratory final report for the initial pilot study still in draft - comments due from DuPont and EPA by June 17, 2011	6.11
84	Biodegradation Laboratory QAPP and draft Analytical Method Validation Protocol submitted to EPA in December 2010 still under review and technical discussion; issues such as number of replicates, frequency of draw and fill, analytical methods and validation need to be resolved prior to completing final protocol for QAPP; protocol revisions may be needed if all analysis to be used is LC/MS/MS instead of GC/MS on account of potential for polymer degradation in the GC inlet at elevated temperature	6.11

85	Biodegradation Laboratory requested by DuPont and EPA to outline (including cost and timing) a GC/MS method to measure FTOH in the SCAS test in MTBE extracts that have been centrifuged at high speed as a potential method change to overcome polymer degradation in the GC inlet at elevated temperature. The outline was subsequently approved and the lab conducted the work. Results demonstrate that centrifugation speed had no measurable effect on the potential for polymer degradation.	7.11-8.11
86	Biodegradation Laboratory develops and submits the draft definitive SCAS test protocol to EPA	7.11-9.11
87	Characterization Laboratory develops LC/MS/MS analytical conditions to analyze the 6-2 FTOH, 8-2 FTOH, and the 10-2 FTOH compounds and then perform dissolutions of the samples in the THF for analysis by LC/MS/MS; develops preliminary chromatographic and mass spec conditions for the 6-2FTOH, 8-2 FTOH, and the 10-2 FTOH compounds and performed preliminary analysis of the two pilot test samples; results discussed with EPA and DuPont; DuPont and MPI believe that the data showed that the LC/MSIMS platform would eliminate the problems experienced when using the GC/MS for the FTOH analyses	8.11
88	Characterization Laboratory submits to EPA for approval (1) modifications to the scope of 08.11 work, revised cost estimates, and timeline for the THF method validation and test substance characterization and (2) draft protocol and draft methods for THF based validations	8.11
89	Biodegradation Laboratory receives EPA approval on an amendment to the pilot study protocol submitted in August 2011 requesting that it need not include the COA from the Characterization Laboratory in the final report for the pilot study - as a result, the final pilot study report is expected to be issued shortly	9.11
90	EPA suggests that instead of changing to an LC/MS/MS platform for analysis of FTOI-I using THF dissolution, the test substance should be changed from a urethane to an acrylate. EPA believes changing the test substance would eliminate many of the obstacles encountered during test substance characterization.	9.11-10.11
91	The preference by DuPont to continue with the urethane is acknowledged by EPA since the cost to change the first test substance to an acrylate is substantial and DuPont seeks cost estimates for determining the appropriate solvent to use with the urethane.	10.11
92	Cost estimates for alternate analytical approaches and alternative test substances from MPI and WLI are provided to EPA	11.11
	<p>SEP funds remaining as of 11.30.11 are \$2,265,237.00</p> <p>Current in-progress items:</p> <ul style="list-style-type: none"> <li>• Characterization Laboratory - analytical work to generate the COA (Certificate of Analysis) for pilot test samples - method and protocol under review</li> <li>• SEP Panel - awaiting COA from Characterization Laboratory so that Final Report on the initial pilot study and characterization work can be issued</li> <li>• Biodegradation Laboratory - awaiting approval of SCAS method development and validation to finalize SCAS study protocol and then approval of QAPP</li> </ul>	