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11/21/03 02:45 PM

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cc:

Subject: text to review during 9 am November 24 fluoropolymer incin testing
DraftingComm. call

Colleagues,

As noted in Rich's 11/20/03 e-mail, one of the items on the tentative agenda is comments on EPA draft ECA text. In preparation for the discussion during this part of the agenda, David and I have marked up the 11/6/03 draft (previously shared by Rich) through the end of the Part titled "Rights of the Companies". Please see the attached and please note general comments below.

(See attached file:
ECA_Fluoropolymer_Incin_draft11_6_03-mark-up-11-21-03.pdf)

The 11/6/03 draft is marked up (in red color) using strike through for recommended deletions and underlining for recommended insertions.

David and I plan to address markups or comments on Table 1 and later parts of the 11/6/03 draft ECA text during subsequent drafting committee calls.

I have not yet gone through the chemical names and CAS numbers in Part II in detail to confirm they match up to substances that FMG has proposed.

Similar to Rich's use of "??" and "XXXX", I have used "YY" and "YYY" to refer to two additional yet-to-be prepared short appendices.

We understand that all deadline and related timing issues will be dealt with in Table 1 (including its footnotes).

The new reference to "calculations" in Part VI is to related to stoichiometry which involves calculations rather than testing.

The paging of the draft document has apparently changed in the course of my secretary's thankless job of converting the pdf file to a WORD document for David and I to work with as the basis for the attached pdf file. I have reviewed the document to assure that the text from the 11/6/03 draft has been preserved in the conversion. However, I have not tried to deal with page break and other formatting issues.

The Table of Contents has not yet been updated to reflect the recommended edits of the draft document.

As I mentioned to Rich, I will have to end the call at about 11:30 am on Monday in order to go to a parent-teacher conference. If we need further discussion time on Monday, I can be available a part 2 to the call from 3 pm to 5 pm the same day.

I look forward to our discussion on Monday.

Thank you.

Best Regards,

Robert Giraud

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ECA_Fluoropolymer_Incin_draft11_6_03-mark-up-11-21-



DRAFT TO PFOA ECA PROCESS DRAFTING COMMITTEE

**ENFORCEABLE CONSENT AGREEMENT
FOR
THE LABORATORY-SCALE INCINERATION
TESTING OF FLUOROPOLYMERS**

Docket No. OPPT - [YEAR] - [EDOCKET NO.]

**[DRAFT 11/21/03]
[Month Year]**

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ENFORCEABLE CONSENT AGREEMENT FOR THE LABORATORY SCALE
INCINERATION TESTING OF FLUOROPOLYMERS

Docket No. [OPPT-?YEAR-EDOCKET NO. XXXX?]

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XXI. RIGHTS OF THE COMPANIES.....13

XXII. IDENTITY OF THE COMPANIES.....14

XXIII. SIGNATURES.....15

Table 1. REQUIRED TESTING, TEST STANDARDS, REPORTING AND OTHER REQUIREMENTS FOR THE LABORATORY-SCALE INCINERATION TESTING OF FLUOROPOLYMERS.....20

APPENDICES

- A. Test Substances
 - A.1 List of Chemicals Subject to this ECA
 - A.2 Rationale for Selecting Composites to be Tested
 - A.3 Composition of Composites to be Tested
 - A.4 Preparation of Composites to be Tested
- B. Testing Standards with Annotations as Appropriate
 - B.1 ASTM D 3176
 - B.2 ASTM E 1868-02 Loss-On-Drying by Thermogravimetry
 - B.3 others.....
- C. Study Protocols as Test Standards
 - C.1 Transport Efficiency Testing
 - C.2 Incineration Testing
 - C.2.1 Elemental Analysis
 - C.2.2 Combustion Stoichiometry
 - C.2.3 Thermogravimetric Analysis
 - C.2.4 Combustion Testing
 - C.2.5 Sampling and Analysis
 - C.2.6 Study Reporting
- D. Attachments and Referenced Materials
 - D.1 Wickbold Torch Method
 - D.2 Waste Incineration and Operation Conditions
 - D.3 PFOA Analysis Method
- E. Outline for Release Assessment Report

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1 **I. INTRODUCTION**

2
3 Under the authority of section 4 of the Toxic Substances
4 Control Act (TSCA), 15 U.S.C. 2603, and 40 CFR Part 790 of the
5 Agency's implementing regulations, the United States
6 Environmental Protection Agency (EPA) and Asahi Glass
7 Fluoropolymers USA, Inc., Daikin America, Inc., Dyneon, LLC, and
8 E.I. du Pont de Nemours and Company (hereinafter collectively
9 "the Companies") enter into this enforceable consent agreement
10 (ECA). This ECA will take effect on the date of publication of
11 the notice in the Federal Register announcing the issuance of the
12 testing consent order (Order) that incorporates this ECA.

13
14 On April 16, 2003, EPA initiated a public process to
15 negotiate enforceable consent agreements (ECAs) under section 4
16 of TSCA concerning perfluorooctanoic acid (PFOA) and fluorinated
17 telomers to develop environmental fate and transport information,
18 as well as relevant information to enhance understanding of the
19 sources of PFOA in the environment and the pathways by which
20 human exposure to PFOA is occurring (68 FR 18626; April 16,
21 2003). The goal of the ECAs resulting from these public
22 discussions is to develop data relevant to identifying the
23 pathway or pathways that result in exposures to PFOA by air,
24 water, soil, or food; and to characterize how PFOA gets into
25 those pathways (including the products or processes that are
26 responsible for the presence of PFOA in the environment). EPA
27 anticipates that the data to be developed under such ECAs will be
28 beyond or supplemental to that of ongoing testing efforts
29 described under industry letters of intent (LOIs) (Refs 1-4).

30 **[OPPT-2003-0012-0007, 0012, 0013, 0016]**

31
32 In preparation for the June 6, 2003, public meeting, EPA
33 developed a preliminary framework document outlining data needs
34 that the Agency deemed appropriate to address the outstanding
35 PFOA source and exposure questions identified in the *Federal*
36 *Register* notice of April 16, 2003 (Ref 5) **[OPPT-2003-0012-00561]**.
37 The intent of EPA's preliminary framework document was to serve
38 as a discussion guide for the June 6, 2003, public meeting and to
39 aid in distinguishing between outstanding EPA data needs and
40 industry LOI commitments. The preliminary framework document was
41 not a predetermined list of information needs defining the
42 outcome of the ECA process.

43
44 This ECA provides for a laboratory-scale incineration
45 testing program of fluoropolymers, which is one of the data needs
46 identified in EPA's preliminary framework document for PFOA. On
47 June 6, 2003, the PFOA Plenary Group (consisting of EPA and all
48 interested parties) acknowledged such a testing program as an
49 opportunity for ECA development and tasked the Fluoropolymer

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1 Technical Workgroup to work out the details that could be
2 incorporated into an ECA between test sponsors and EPA. On July
3 9, 2003, the Fluoropolymer Technical Workgroup received proposals
4 from the Companies and EPA for incineration testing of
5 fluoropolymers. Details of this testing program were developed
6 by members of the Fluoropolymer Incineration Subgroup of the
7 Fluoropolymer Technical Workgroup during subsequent meetings. On
8 **[Month/Date]**, 2003, the Fluoropolymer Technical Workgroup
9 acknowledged that this testing program had sufficient merit for
10 consideration by the Plenary Group. On **[Month/Date]**, 2003, the
11 Plenary Group discussed the merit of this testing program and
12 recommended that EPA consider entering into an ECA with test
13 sponsors. The official record for ~~developing the development of~~
14 ~~this ECA, including the public version,~~ is established under EPA
15 docket control number [OPPT-2003-0012]. The procedures for ECA
16 negotiations are described at 40 CFR 790.22(b). The official
17 record for the testing conducted under this ECA is Docket No.
18 **[OPPT-?YEAR-EDOCKET NO. XXXX?]**
19
20

21 **II. TEST SUBSTANCES**

22
23 The chemicals subject to this ECA are the fluoropolymers
24 listed in Appendix A.1.[†] For the purpose of testing under this
25 ECA the chemicals listed in Appendix A.1 will be combined to form
26 four composites (see Appendix A.3 and A.4). These composites are
27 representative of fluoropolymer products manufactured by the
28 Companies ~~and that~~ are currently available in the marketplace.
29 The Companies will provide the fluoropolymers specified in
30 Appendix A.1 for incorporation into the composites that will be
31 tested under this ECA. Criteria for the selection of each
32 composite to be tested under this ECA are described in Appendix
33 A.2 of this ECA[†]. The four composites to be tested are defined
34 for purposes of this ECA as:
35

- 36 (A) Dry Non-Melt PTFE Homopolymer Resin/Gum
37 Composite: Ethene, tetrafluoro-,
38 homopolymer, CAS No. 9002-84-0,
39
40 (B) Dry Melt Fluoropolymer Resin Composite:
41 (containing: 1-Propene, 1,1,2,3,3,3-
42 hexafluoro-, polymer with tetrafluoroethene),

[†] ~~There is a Public and CBI version of Appendices A.1, A.2, A.3, and A.4 [To be determined] because the Companies have asserted that details describing the chemicals subject to this ECA are considered by them to be entitled to treatment as TSCA confidential business information (CBI) (see Part XV of this ECA regarding confidentiality of information).~~

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1 CAS No. 25067-11-2; Propane, 1,1,1,2,2,3,3-
2 heptafluoro-3-[(trifluoroethenyl)oxy]-,
3 polymer with tetrafluoroethene, CAS No.
4 26655-00-5; Ethene, tetrafluoro-, polymer
5 with trifluoro(pentafluoroethoxy)ethene, CAS
6 No. 31784-04-0; 1-Propene, 1,1,2,3,3,3-
7 hexafluoro-, polymer with 1,1-difluoroethene
8 and tetrafluoroethene, CAS No. 25190-89-0; 1-
9 Hexene, 3,3,4,4,5,5,6,6,6-nonafluoro-,
10 polymer with ethene and tetrafluoroethene,
11 CAS No. 68258-85-5; and, 1-Propene,
12 1,1,2,3,3,3-hexafluoro-, polymer with ethene
13 and tetrafluoroethene, CAS No. 35560-16-8),
14

15 (C) Dry Non-Melt Fluoroelastomer Resin/Gum
16 Composite: (containing: 1-Propene,
17 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-
18 difluoroethene, CAS No. 9011-17-0; 1-Propene,
19 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-
20 difluoroethene and tetrafluoroethene, CAS No.
21 25190-89-0; 1-Propene, polymer with 1,1-
22 difluoroethene and tetrafluoroethene, CAS No.
23 54675-89-7; 1-Propene, polymer with
24 tetrafluoroethene, CAS No. 27029-05-6;
25 Ethene, tetrafluoro-, polymer with
26 trifluoro(trifluoromethoxy) ethene, CAS No.
27 26425-79-6; and, Ethene, chlorotrifluoro-,
28 polymer with 1,1-difluoroethene, CAS No.
29 9010-75-7; and ??generic name??, **Accession**
30 **No. ??????1**, and
31

32 (D) Aqueous Fluoropolymer Dispersions Composite:
33 (containing: Ethene, tetrafluoro-, polymer
34 with trifluoro(pentafluoroethoxy) ethene, CAS
35 No. 31784-04-0; Ethene, tetrafluoro-,
36 homopolymer, CAS No. 9002-84-0; 1-Propene,
37 1,1,2,3,3,3-hexafluoro-, polymer with
38 tetrafluoroethene), CAS No. 25067-11-2;
39 Propane, 1,1,1,2,2,3,3-heptafluoro-3-
40 [(trifluoroethenyl)oxy]-, polymer with
41 tetrafluoroethene, CAS No. 26655-00-5;
42 Ethene, tetrafluoro-, polymer with
43 trifluoro(pentafluoroethoxy)ethene, CAS No.
44 31784-04-0; and 1-Propene, 1,1,2,3,3,3-
45 hexafluoro-, polymer with 1,1-difluoroethene
46 and tetrafluoroethene, CAS No. 25190-89-0.
47

¹ See Part XXIII. company signature pages for CBI.

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1 The procedure for constructing each composite is described
2 in Appendix A.4 to this ECA[±]. Components of each fluoropolymer
3 composite to be tested ~~must be as pure as can be reasonably~~
4 ~~attained, and in any event must not be less than 97 percent pure.~~
5 ~~The polymer components will be unfilled first quality product~~
6 ~~polymer, substantially free of inorganic constituents. Each~~
7 ~~component of the four composites to be tested under this ECA will~~
8 ~~be accompanied by a certificate of analysis.~~
9

10
11 **III. OBLIGATION OF SIGNATORY COMPANIES AND ROLE OF THE**
12 **FLUOROPOLYMER MANUFACTURING GROUP**
13

14 A. Testing will be sponsored by the Companies, ~~which are~~
15 ~~responsible for complying with this ECA. Each company shall be~~
16 responsible for supplying the test substances it manufactures for
17 incorporation into the composites to be tested under this ECA, as
18 specified in Appendix A-2. Each company required to contribute
19 to a particular composite is obligated to complete the testing
20 required by this ECA for that composite when all companies have
21 fully satisfied their individual obligations to contribute test
22 substances to that composite, except as otherwise provided
23 herein. The Companies shall not be responsible for any failure
24 to perform an obligation under this ECA that is caused by
25 circumstances beyond their control, that the Companies could not
26 have prevented through the exercise of due diligence.
27

28 B. The Companies recognize that to implement this ECA, EPA
29 will issue an Order under section 4 of TSCA that incorporates the
30 terms of this ECA in the form set out in Appendix YY. The
31 Companies agree that all terms of this ECA will take effect on
32 the date of publication of the notice in the Federal Register
33 announcing the issuance of the Order that incorporates this ECA,
34 and all applicable time periods will be treated as beginning on
35 that publication date.
36

37 C. The Companies are members of the Fluoropolymer
38 Manufacturers Group (FMG) of the Society of the Plastics Industry
39 (SPI) which represents the manufacturers of the fluoropolymer
40 test substances described in Part II and listed in Appendix A.1
41 which are subject to this ECA. The companies, in their sole
42 discretion, may elect to use FMG to administer the test program
43 under this ECA, and to communicate will be responsible for
44 coordinating and administering testing under this ECA and
45 communicating with EPA about study plans, protocols, test
46 standards, and other aspects of the testing program. In
47 performing these functions, the FMG will be acting as the agent
48 of the Companies for purposes of communication with EPA. EPA and
49 the Companies recognize acknowledge that, except for its role as

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1 ~~agent as specified in this ECA,~~ the FMG has no legal respon-
2 sibility for complying with this ECA. Responsibility for
3 complying with the ECA rests at all times with the ~~individual~~
4 Companies.

5
6
7 **IV. PURPOSE OF THE TESTING PROGRAM**

8
9 The purpose of the testing program specified by this ECA is
10 to assess the potential for waste incineration of fluoropolymers
11 (see Part II and Appendix A.1 of this ECA) to emit PFOA, based on
12 quantitative determination of potential exhaust gas levels of
13 PFOA that may emanate from under-laboratory-scale incineration
14 combustion testing under conditions representative of typical
15 municipal waste combustor operations in the United States, and to
16 quantify potential emission levels of PFOA that may emanate from
17 laboratory scale combustion testing.

18
19 EPA believes that these incineration studies of
20 fluoropolymers will develop data needed by the Agency to
21 determine whether ~~municipal~~ waste incineration of fluoropolymers
22 is a potential source of PFOA that may contribute as a pathway to
23 environmental and human exposures. The data may also be used to
24 inform screening level human and environmental exposure
25 assessments. In addition, the data may also be used by other
26 Federal agencies (e.g., the Agency for Toxic Substances and
27 Disease Registry (ATSDR), the National Institute for Occupational
28 Safety and Health (NIOSH), the Occupational Safety and Health
29 Administration (OSHA), and the Consumer Product Safety Commission
30 (CPSC), the Food and Drug Administration (FDA)) in assessing
31 chemical risks and in taking appropriate actions within their
32 programs. It is intended that the data generated under this ECA
33 will identify whether the incineration of fluoropolymers
34 contributes to the sources and pathways of environmental and
35 human exposure to PFOA.

36
37
38 **V. SCOPE OF THE TESTING PROGRAM**

39
40 ~~The Companies, through the FMG, will jointly conduct or~~
41 ~~provide for the performance of the testing program specified in~~
42 ~~this ECA. This testing program will consist of: 1) conducting~~
43 ~~the testing listed in Table 1 in accordance with the test~~
44 ~~standards specified in Table 1 and described in Appendices B.??~~
45 ~~and C1 - C2.6 as annotated by Appendix D.?? to this ECA ("Test~~
46 ~~Standards"), and 2) submitting the reports and documents~~
47 ~~specified in Table 1 in accordance with the deadlines set forth~~
48 ~~in Table 1.~~

1
2 **VI. DESCRIPTION OF THE TESTING PROGRAM**
3

4 The testing program has two segments as follows: Phase I
5 PFOA Transport Testing and Phase II Fluoropolymer Incineration
6 Testing.
7

8 A. Phase I PFOA Transport Testing: Phase I will consist
9 of quantitative transport efficiency testing for PFOA. Phase I
10 testing for PFOA transport efficiency is specified in the Phase I
11 PFOA Transport Testing segment of Table 1 and described in
12 Appendix C.1 as annotated by Appendixes ~~B.??~~ and ~~D.??~~. At the
13 conclusion of Phase I testing, the Companies, ~~through the FMG,~~
14 will provide EPA with a letter ~~/~~ report summarizing the results.
15 In the event that the transport efficiency of PFOA or ~~total~~
16 ~~fluorine (as expressed as total stoichiometric fluorine content~~
17 ~~of PFOA and/or total fluorine)~~ is equal to or greater than 70%,
18 testing will proceed to Phase II Fluoropolymer Incineration
19 Testing. In the event the transport efficiency of PFOA or ~~total~~
20 ~~Total fluorine Fluorine (as expressed as total stoichiometric~~
21 ~~fluorine content of PFOA and/or total fluorine)~~ is less than 70%,
22 the Companies, ~~through the FMG,~~ will initiate a technical
23 consultation with EPA (see Part VI. ~~B.~~ and Part VII of this ECA).
24

25 ~~B. Phase I Technical Consultation: At the conclusion of~~
26 ~~Phase I PFOA Transport Testing, the Companies, through the FMG,~~
27 ~~will initiate a technical consultation with EPA if the transport~~
28 ~~efficiency of PFOA or total fluorine (as expressed as total~~
29 ~~stoichiometric fluorine content of PFOA and/or total fluorine)~~ is
30 ~~less than 70%. The purpose of this technical consultation will~~
31 ~~be to review the outcomes of the Phase I PFOA Transport~~
32 ~~Efficiency Testing, to discuss the feasibility of proceeding with~~
33 ~~Phase II Testing as described in this ECA, and to determine~~
34 ~~whether additional modifications are needed to the test standards~~
35 ~~and/or protocols described in Appendices B, C and D for Phase I~~
36 ~~PFOA Transport Testing and/or Phase II Fluoropolymer Incineration~~
37 ~~Testing.~~

38
39 ~~Specifically, the technical consultation will determine:~~
40 ~~(1) whether the data from the Phase I PFOA Transport Testing~~
41 ~~segment provide a sufficient basis for conducting the laboratory-~~
42 ~~scale incineration testing specified in the Phase II~~
43 ~~Fluoropolymer Incineration Testing segment; (2) the nature and~~
44 ~~scope of any additional Phase I work that may be required prior~~
45 ~~to the commencement of Phase II Testing and reporting (e.g.,~~
46 ~~modifications to the Advanced Thermal Reactor System) as~~
47 ~~described in Part VII. B. of this ECA), and/or (3) the nature and~~
48 ~~scope of modifications to the protocols and test standards for~~

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1 ~~Phase I and/or Phase II testing that may be needed to complete~~
2 ~~the testing under this ECA.~~

3
4 ~~— In the event that significant changes are made to the~~
5 ~~testing program as a result of the technical consultation, an~~
6 ~~opportunity for public participation will be provided. EPA will~~
7 ~~publish a request for public comments and/or announce a public~~
8 ~~meeting in the Federal Register. Following the technical~~
9 ~~consultation, EPA will place in the record for this action a~~
10 ~~summary of the Technical Consultation, a copy of comments~~
11 ~~received, and a copy of the letter sent to the Companies, through~~
12 ~~the FMG, explaining decisions and outcomes from the technical~~
13 ~~consultation and documenting modifications, if any, to this ECA~~
14 ~~testing program.~~

15
16 EB. Phase II Fluoropolymer Incineration Testing: This
17 testing, specified in the Phase II Fluoropolymer Incineration
18 Testing segment of Table 1 and described in Appendix C2.1 - C2.6
19 as annotated by Appendices B.?? and D.?? will include the
20 following ~~endpoint testing or calculations~~ for each fluoropolymer
21 composite to be tested under this ECA: 1) elemental analysis,
22 2) combustion stoichiometry, 3) thermogravimetric analysis, 4)
23 laboratory-scale combustion testing, and, 5) if ~~triggered~~required
24 under this ECA,² release assessment reporting.

25
26
27 **VII. PHASE I TECHNICAL CONSULTATION OUTCOMES**

28
29 A. Following completion of Phase I and prior to the
30 initiation of Phase II, the Companies will submit a letter report
31 to EPA with the results for the recovery across the laboratory-
32 scale thermal reactor system, as determined from Phase I testing.

33
34 B. If the recovery for either PFOA or Total Fluorine is
35 greater than or equal to 70%, the Companies will proceed to Phase
36 II testing.

² In the event that Phase II Fluoropolymer Incineration Testing identifies measurable levels of PFOA (where measurable PFOA is defined to be at or above the limit of detection quantitation (LODLOQ) and, where LOD is identified to be 10 ppt under standard temperature and pressure (see also as defined in Appendix D.3)) resulting from the incineration testing for any or all of the fluoropolymer composites tested under this ECA (see Part II and Appendix A.1 - A.4 to this ECA), the Companies, ~~through the FMG,~~ will prepare a release assessment report (see Table 1 and Appendix E to this ECA) to place in perspective the relevance of the such measurable levels in the laboratory-scale incineration testing data results with respect to full-scale municipal waste combustor operations in the United States.

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1
2 C. If the recovery for both PFOA and Total Fluorine is less
3 than 70%, a Technical Consultation will be held. The objective
4 of the Technical Consultation will be to reach agreement o how to
5 proceed. Possible outcomes of the Technical Consultation
6 include, but are not limited to, the following:

7
8 1. An agreement to conduct additional Phase I testing
9 and the schedule and standards for such testing to
10 inform whether and under what condictions to conduct
11 Phase II testing.

12
13 2. An agreement to proceed into Phase II testing with
14 or without agreed-to modifications to plans, test
15 standards and schedule for Phase II testing.

16
17 3. No agreement on a path forward, in which case the
18 Companies' obligations to conduct testing or reporting
19 beyond Phase I PFOA Transport Testing as described in
20 this ECA are terminated.

21
22 D. EPA shall place in the record for this action a summary
23 of any Technical Consultation that is held under this paragraph.
24 Modifications to this ECA reflecting any agreements reached
25 during a Technical Consultation will be made according to the
26 procedures contained in 40 CFR 790.68 (see Part X of this ECA).

27
28 ~~For the testing program described by this ECA, technical~~
29 ~~consultation between the Companies, through the FMG, and EPA at~~
30 ~~the conclusion of Phase I PFOA Transport Testing can result in~~
31 ~~several possible outcomes, as described below.~~

32
33 ~~A. Phase I Testing Data are Acceptable: EPA and the~~
34 ~~Companies, through the FMG, may determine that the Phase I~~
35 ~~Testing data can be used to inform and support Phase II Testing~~
36 ~~for the laboratory scale incineration testing. In such an~~
37 ~~instance, EPA and the Companies, through the FMG, agree that~~
38 ~~Phase II endpoint testing and reporting must be conducted as~~
39 ~~specified in Table 1 and Part VI.C. of this ECA.~~

40
41 ~~B. EPA and/or the Companies Identifies Limitations in the~~
42 ~~Phase I Testing Data: EPA and/or the Companies, through the~~
43 ~~FMG, may determine that additional Phase I Testing is needed~~
44 ~~before the Phase II endpoint testing and reporting that are~~
45 ~~specified in Table 1 and Part VI. C can be conducted. In such an~~
46 ~~instance, EPA and the Companies, through the FMG, will continue~~
47 ~~technical discussions on this matter.~~

48

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1 ~~(1) Agreement on Additional Phase I Testing: If EPA and~~
2 ~~the Companies, through the FMG, agree to the additional testing~~
3 ~~and/or modifications to the relevant Test Standards specified in~~
4 ~~the Phase I Testing section of Table 1 and described in the~~
5 ~~associated appendices for the relevant Test Standards will be~~
6 ~~made according to the procedures contained in 40 CFR 790.68 (see~~
7 ~~Part X of this ECA). The additional Phase I Testing will be~~
8 ~~conducted in accordance with these modifications. The data~~
9 ~~resulting from this additional testing will be reviewed to~~
10 ~~determine if such data meet EPA needs. This review may include~~
11 ~~one or more Technical Consultations between the Companies,~~
12 ~~through the FMG, and EPA and/or may impact modifications to Phase~~
13 ~~II Test Standards as described in the associated appendices. In~~
14 ~~the event that significant changes are made to the Phase II~~
15 ~~testing program, opportunity for public participation will be~~
16 ~~provided either by a request for written comments and/or through~~
17 ~~an announcement of a public meeting. Following such announcement~~
18 ~~or Public Meeting, EPA will place in the record for this action a~~
19 ~~summary of the Public Meeting and summaries of any Technical~~
20 ~~Consultations along with a copy of the comments received.~~

21
22 ~~(a) Additional Phase I Testing Meets Data Needs: If~~
23 ~~and when the Phase I Testing data are determined to be acceptable~~
24 ~~to EPA, EPA will inform the Companies, through the FMG, by~~
25 ~~certified letter or Federal Register notice, that the data from~~
26 ~~the Phase I Testing can be used as a basis to inform and support~~
27 ~~Phase II Testing, and that Phase II Testing can proceed as~~
28 ~~specified in Table 1 and described in Part VI. C. of this ECA. A~~
29 ~~copy of the letter or notice will be placed in the record for~~
30 ~~this action.~~

31
32 ~~(b) Additional Phase I Testing Does Not Meet Data~~
33 ~~Needs Requiring Changes to Phase II Testing Standards: EPA and~~
34 ~~the Companies, through the FMG, may determine that the expected~~
35 ~~transport efficiency as specified Appendix C.1 for PFOA is not~~
36 ~~feasible and that a different value, to be mutually agreed upon,~~
37 ~~would be acceptable for the purpose of Phase II endpoint testing.~~
38 ~~In this instance, EPA will inform the Companies, through the~~
39 ~~FMG, by certified letter or Federal Register notice, that Phase~~
40 ~~II testing can proceed as modified above along with details of~~
41 ~~the specific modification(s). Modifications to this ECA will be~~
42 ~~made according to the procedures contained in 40 CFR 790.68 (see~~
43 ~~Part X. of this ECA). A copy of the letter or notice and summary~~
44 ~~of any Technical Consultations will be placed in the record for~~
45 ~~this action.~~

46
47 ~~(c) Additional Phase I Testing Does Not Meet Data~~
48 ~~Needs: If, at any point, EPA determines that the Phase I~~
49 ~~Testing data, as supplemented by the additional Phase I Testing~~

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1 ~~data, cannot be used to inform and support Phase II incineration~~
2 ~~testing as specified in Table 1 and Part VI. C. of this ECA, then~~
3 ~~the outcome described in Part VII. C. below will apply to these~~
4 ~~endpoints.~~

5
6 ~~(2) Failure to Agree on Additional Needed Phase I Testing:~~
7 ~~If the Companies, through the FMG, and EPA do not agree to the~~
8 ~~additional Phase I Testing that EPA has determined to be needed,~~
9 ~~the outcome described in Part VII. C. below will apply to these~~
10 ~~endpoints.~~

11
12 ~~C. EPA Determines that the Approach to Incineration~~
13 ~~Testing of Fluoropolymers is Not Feasible.~~ EPA may determine
14 that the approach to incineration testing of fluoropolymers set
15 forth in this ECA, for the Phase I PFOA Testing as applied to the
16 Phase II Fluoropolymer Incineration Testing, is not feasible. In
17 such an instance, EPA will notify the Companies, through the FMG,
18 by certified letter or Federal Register notice. The notification
19 will include the reason(s) for the determination and will be
20 placed in the record for this action. If EPA issues such a
21 notification for any endpoint(s), the Companies' obligations to
22 conduct testing or reporting beyond Phase I PFOA Transport
23 Testing as described under this ECA are terminated. EPA may
24 pursue testing for Phase II Fluoropolymer Incineration Testing
25 via development of a separate ECA or TSCA rulemaking for the
26 purpose of obtaining the needed data, as appropriate.

27
28 ~~D. Other Possible Outcomes:~~ If the technical
29 consultation between EPA and the Companies, through the FMG, do
30 not result in any of the outcomes described above, EPA and the
31 Companies, through the FMG, may modify this ECA according to the
32 procedures contained in 40 CFR 790.68 (see Part X. of this ECA).

33
34 **VIII. STANDARDS FOR CONDUCTING TESTING**

35
36 A. Testing for the laboratory-scale incineration of the
37 fluoropolymers described in Part II and listed in Appendix A.1 of
38 this ECA must be conducted in accordance with the Test Standards
39 listed in Table 1 and described in Appendices B.?? and C.1 - C.2
40 as annotated in Appendix D.?? to this ECA. Certain provisions of
41 these Test Standards are considered to be mandatory and are
42 referred to as "requirements." These requirements are identified
43 by the use of the word "shall" in the text of the Test Standard.
44 -For the purpose of this ECA, the words "will" and "must," if
45 they appear in the Test Standards, are considered equivalent to
46 the word "shall" and therefore delineate a test requirement to be
47 followed or met.

48

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1 Provisions that are not mandatory, and are therefore only
2 recommended, are identified by the use of "should" statements.
3 In the event such "should" provisions are not followed, the
4 Companies will not be deemed by EPA to be in violation of this
5 ECA and will not be subject to penalties or other enforcement
6 actions, as described in Part XI. of this ECA. However, in such
7 cases, EPA will use its professional judgement to determine the
8 scientific adequacy of the test results and any repeat testing
9 that is determined by EPA to be necessary will be required either
10 under a separate ECA or pursuant to a rule promulgated under
11 section 4(a) of TSCA, 15 U.S.C. 2603(a).
12

13 B. The Companies, ~~through the FMG,~~ and EPA will consult in
14 a good faith effort to consider the need for Test Standard
15 modifications if either EPA or the Companies desire such
16 modifications. Modifications to this ECA will be governed by 40
17 CFR 790.68 (see Part X. of this ECA).
18

19 C. All testing required by this ECA must be conducted in
20 accordance with ~~the EPA Good Laboratory Practice Standards (GLPS)~~
21 found at 40 CFR part 792a Quality Assurance Project Plan prepared
22 in accordance with Appendix YYY.³
23

24 D. All final reports must be submitted by the Companies,
25 ~~through the FMG,~~ to EPA by the dates specified in Table 1 unless
26 otherwise authorized by EPA pursuant to 40 CFR 790.68 except as
27 otherwise provided herein. ~~Interim status reports describing the~~
28 ~~status of all studies to be performed under this ECA testing~~
29 ~~program must be submitted by the Companies, through the FMG, to~~
30 ~~EPA every six months beginning six months from the effective date~~
31 ~~of this ECA and until the end of the ECA testing program~~
32 ~~described in Table 1 of this ECA. These interim reports should~~
33 ~~contain information such as a summary of the status of each study~~
34 ~~being performed under this ECA testing program, a description of~~
35 ~~significant activities and/or difficulties experienced during the~~
36 ~~interim, and an explanation of the actions taken in response to~~
37 ~~such difficulties. See Part XIII. of this ECA regarding~~
38 ~~submissions to EPA.~~
39
40

³ Guidance for developing Quality Assurance Project Plans can be found in the EPA document EPA QA/G-5: *Guidance for Quality Assurance Project Plans*, prepared by: Office of Environmental Information, EPA, December 2002. This is also available from the EPA website at <http://epa.GOV/Quality/qs-docs>.

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IX. STUDY PLANS

The Companies, ~~through the FMG,~~ will submit a study plan to EPA for ~~each the~~ testing conducted pursuant to this ECA prior to the initiation of testing in accordance with 40 CFR 790.62. (For this ECA, EPA will not require the study plans under this Part of the ECA to be submitted "no later than 45 days prior to the initiation of testing," as specified at 40 CFR 790.62(a)). The content of the study plans submitted to EPA will comply with 40 CFR 790.62(b). Since Table 1 and the Appendices to this ECA meet the requirements of 40 CFR 790.62(b)(2), (8), (9), and (10), the study plan submission will address only 40 CFR 790.62(b)(1), (3), (4), (5), (6), and (7). Also, pursuant to Part VIII.(C) of this ECA, the Companies and must include submission of a Quality Assurance Project Plans (QAPP) prepared in accordance with Appendix YYY. Modifications to the study plans under this Part of this ECA will be governed by the procedures of 40 CFR 790.62(-c), except that the 15 day time periods in 40 CFR 790.62(c)(2) and (3) will be 45 day time periods. All study plans will become part of the official record (Docket Control Number [OPPT-YEAR-EDOCKET NO. ?? XXXX ??]).

X. MODIFICATIONS TO THIS ENFORCEABLE CONSENT AGREEMENT

Except as provided in this agreement, modifications to this ECA, if any, will be made according to the procedures contained in 40 CFR 790.68.

XI. FAILURE TO COMPLY WITH THE ENFORCEABLE CONSENT AGREEMENT

The Companies acknowledge that a violation of the requirements of this ECA will constitute a "prohibited act" under section 15(1) of TSCA, 15 U.S.C. 2614(1), and will trigger all provisions applicable to a section 15 violation. In addition, the Companies acknowledge that noncompliance with any term of this ECA by any Company will constitute conduct "in violation of this Act" under section 20(a)(1) of TSCA, 15 U.S.C. 2619(a)(1), and could result in a citizen's civil action.

Under the penalty provisions of section 16 of TSCA, 15 U.S.C. 2615, and the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996, 31 U.S.C. 3701 note, as implemented by 61 FR 69360 (December 31, 1996), a non-complying Company could be subject to a civil penalty of up to \$27,500 per violation, with each day in violation potentially constituting a separate violation under section 15. Knowing or willful

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1 violations may lead to the imposition of criminal penalties, or a
2 fine of not more than \$27,500 for each day of violation, or
3 imprisonment for not more than one year, or both. In addition,
4 EPA could enforce this ECA pursuant to section 17 of TSCA, 15
5 U.S.C. 2616, by seeking an injunction to compel adherence to the
6 requirements of this ECA.

7
8
9 **XII. EPA MONITORING OF ENFORCEABLE CONSENT AGREEMENT TESTING**

10
11 EPA may conduct monitoring activities of the testing
12 conducted under this ECA such as laboratory inspections and study
13 audits, as permitted under section 11 of TSCA, 15 U.S.C. 2610.

14
15
16 **XIII. SUBMISSIONS TO EPA**

17
18 All ~~data and other information~~ documents submitted to EPA
19 under this ECA will be identified by the Docket Number: **[OPPT-**
20 **YEAR-EDOCKET NO. ?? XXXX ??]** and the name: ECA on Laboratory-
21 Scale Incineration Testing of Fluoropolymers. Submissions made
22 by mail should be sent to: Document Control Office (7407M),
23 Office of Pollution Prevention and Toxics (OPPT), Environmental
24 Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC
25 20460-0001. -Submissions made by hand delivery or courier should
26 be delivered to: OPPT Document Control Office (DCO) in the EPA
27 East Building, Room 6428, 1201 Constitution Avenue, NW,
28 Washington, DC and marked Attention: Docket ID Number **OPPT- Year**
29 **- ??XXXX??**. The DCO is open from 8 a.m. to 4 p.m., Monday
30 through Friday, excluding legal holidays. The telephone number
31 for the DCO is (202) 564-8930.

32
33 Any ~~data and other information~~ document submitted to EPA for
34 which the ~~a Companies~~ Company makes a claim of confidentiality
35 (see Part XV of this ECA), must be submitted as two separate
36 versions. One version must be complete, with the information
37 being claimed as confidential marked in the manner described
38 under 40 CFR 790.7. The other, public version must have all of
39 the information claimed as confidential excised. EPA will place
40 the public version in the Agency's docket. The complete version
41 will be treated in accordance with EPA confidentiality
42 regulations in 40 CFR part 2 and 40 CFR 790.7.

43
44 ~~Do not electronically submit data~~ Data or other information
45 that are considered to be CBI must not be submitted through EPA's
46 electronic public docket or by e-mail. Any part or all of data
47 or other information claimed as CBI must be so marked. If the
48 CBI submission is on diskette or CD ROM, mark the outside of the
49 diskette or CD ROM as CBI and then identify electronically within

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1 the diskette or CD ROM the specific information that is CBI.
2 Information marked as CBI will not be disclosed except in
3 accordance with procedures set forth in 40 CFR part 2 (see Part
4 XV of this ECA).

5
6 ~~The Companies, through the FMG must submit six One (61)~~
7 ~~paper copies copy~~ of each version (Public and CBI) for all
8 reports described in Table 1 and Part VI A. and C. of this ECA
9 must be submitted. In addition, an electronic file of all
10 documents submitted submissions under this ECA (marked as CBI
11 where appropriate and in text-searchable, PDF format) will be
12 provided to EPA.

13
14 A paper copy of a document shall be deemed submitted when it
15 is either postmarked or placed in the hands of a commercial
16 courier service for delivery to EPA at the appropriate address
17 specified above. Hand-delivered documents are deemed submitted
18 upon receipt. Electronically transmitted documents are deemed
19 delivered upon transmission.

20
21
22 **XIV. PUBLICATION AND DISCLOSURE OF TEST RESULTS**

23
24 All results of testing conducted pursuant to this ECA will
25 be announced to the public by EPA in accordance with the
26 procedures specified in section 4(d) of TSCA, 15 U.S.C. 2603(d).
27 Disclosure by EPA of data generated by such testing to the public
28 or other government agencies will be governed by section 14(b) of
29 TSCA, 15 U.S.C. 2613(b), and 40 CFR part 2. The CBI version of a
30 document will not be provided to another government agency unless
31 that agency has certified that it affords equivalent protection
32 for CBI.

33
34 **XV. CONFIDENTIALITY OF INFORMATION**

35
36 ~~Any claims of confidentiality for information submitted~~
37 ~~under this ECA will be made under the terms of 40 CFR 790.7. If~~
38 ~~no claim of confidentiality is made by the submitter of the~~
39 ~~information at the time of submission, the information will be~~
40 ~~deemed by EPA, in accordance with 40 CFR 790.7, to be public, and~~
41 ~~may be made available to the public without further notice to the~~
42 ~~submitter. Information claimed as confidential will be treated~~
43 ~~in accordance with the procedures in 40 CFR part 2 established~~
44 ~~pursuant to section 14 of TSCA, 15 U.S.C. 2613.~~

45
46
47 **XVI. OTHER RESPONSIBILITIES OF THE COMPANIES**

48

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1 ~~A. The Companies are bound by the terms of this ECA and~~
2 ~~the provisions of 40 CFR 790.62 and 790.65.~~

3
4 BA. The Companies will comply with the notification
5 requirements of section 12(b)(1) of TSCA, 15 U.S.C. 2611(b)(1)
6 and 40 CFR part 707, subpart D, if they export or intend to
7 export any of the fluoropolymer chemicals listed in Appendix A.1
8 to this ECA. Any other person who exports or intends to export
9 any of the fluoropolymer chemicals listed in Appendix A.1 to this
10 ECA is subject to the above cited export notification
11 requirements.

12
13 EB. If any of the fluoropolymer chemicals listed in
14 Appendix A.1 to this ECA become subject to a rule promulgated
15 under TSCA section 5(a)(2), 15 U.S.C. 2604(a)(2), governing
16 significant new uses of any of the fluoropolymer chemicals listed
17 in Appendix A.1 to this ECA, then the Companies will be subject
18 to the data submission requirements imposed by section 5(b)(1)(A)
19 of TSCA, 15 U.S.C. 2604(b)(1)(A), as if the testing under this
20 ECA had been required by a TSCA section 4 test rule.

21
22
23 **XVII. SEVERABILITY OF ENFORCEABLE CONSENT AGREEMENT PROVISIONS**

24
25 In the event that one or more provisions of this ECA are
26 determined by a court decision to be unenforceable, the remaining
27 provisions of this ECA will not be presumed to be valid, and EPA
28 will either initiate a rulemaking proceeding to require testing
29 or publish in the Federal Register the reasons for not initiating
30 such a proceeding.

31
32
33 **XVIII. FINAL AGENCY ACTION**

34
35 For purposes of 5 U.S.C. 704, publication of the FR notice
36 announcing the issuance of the Order incorporating this ECA
37 constitutes final agency action.
38
39

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XIXVIII. PUBLIC RECORD

EPA has established a public record which will contain this ECA, the Order that incorporates this ECA, the Federal Register notice announcing issuance of the Order incorporating this ECA, and any and all relevant information, subject to the confidentiality provisions of section 14(b) of TSCA and 40 CFR part 2. The official record for this ECA, including the public version, which does not include any information claimed as CBI, has been established under Docket Control Number [OPPT-YEAR-EDOCKET NO. ?? XXXX ??].

An electronic version of the public docket is available through EPA's electronic public docket system, EPA Dockets. EPA Dockets may be accessed at <http://www.epa.gov/edocket/> to access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, (for example the materials in the original dockets for this action, [AR-226 and OPPTS-2003-0012], or materials under copyright), can be access any of the publicly available docket materials through the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. For materials available in the electronic docket, once in the system, select "search," then key in the appropriate docket ID number [(OPPT-YEAR-EDOCKET NO. XXXX).]

XIX. EFFECTIVENESS

This ECA may be signed in separate counterparts. This ECA will not be effective unless signed by each of the Companies and by EPA. This ECA will take effect on the date of publication of the Federal Register notice announcing the issuance of the Order that incorporates this ECA.

XXI. RIGHTS OF THE COMPANIES

By signing this ECA, the Companies waive their right to challenge EPA's authority to assess penalties for violations of the terms of this ECA. This waiver does not affect any other rights that the Companies may have under TSCA, including the right to dispute the amount of any penalty or to dispute factually whether a violation of the terms of this ECA has occurred, or to seek judicial review of any rule that may be adopted by EPA that imposes requirements to test -any of the fluoropolymer chemicals listed in Appendix A.1 to this ECA.

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1 By signing this ECA, the Companies are not admitting that the
2 requirements of TSCA Section 4 have been satisfied for
3 promulgating a test rule to generate the data required by this
4 ECA.
5