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Rich Leukroth

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To: Robert.J.Giraud@USA.dupont.com, david.menotti@shawpittman.com,
Greg Fritz/DC/USEPA/US@EPA, John Blouin/DC/USEPA/US@EPA

cc:

Subject: Fluoropolymer ECA Drafting Committee

To: Fluoropolymer Incineration Drafting Committee

Attached for discussion at our November 17th 10 a.m. - noon fluoropolymer drafting committee teleconference is the draft document: ECA for Laboratory-Scale Incineration Testing of Fluoropolymers.



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Richard W. Leukroth, Jr.
Environmental Scientist / Toxicologist
Chemical Control Division
U.S. Environmental Protection Agency
Mail Stop 7405; Room 4328 S
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Phone: 202-564-8167
FAX: 202-564-4765
E-mail: leukroth.rich@epa.gov

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



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 11/6/03]
[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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I. INTRODUCTION

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

On April 16, 2003, EPA initiated a public process to negotiate enforceable consent agreements (ECAs) under section 4 of TSCA concerning perfluorooctanoic acid (PFOA) and fluorinated telomers to develop environmental fate and transport information, as well as relevant information to enhance understanding of the sources of PFOA in the environment and the pathways by which human exposure to PFOA is occurring (68 FR 18626; April 16, 2003). The goal of the ECAs resulting from these public discussions is to develop data relevant to identifying the pathway or pathways that result in exposures to PFOA by air, water, soil, or food; and to characterize how PFOA gets into those pathways (including the products or processes that are responsible for the presence of PFOA in the environment). EPA anticipates that the data to be developed under such ECAs will be beyond or supplemental to that of ongoing testing efforts described under industry letters of intent (LOIs) (Refs 1-4). ~~[OPPT-2003-0012-0007,0012,0013,0016]~~

In preparation for the June 6, 2003, public meeting, EPA developed a preliminary framework document outlining data needs that the Agency deemed appropriate to address the outstanding PFOA source and exposure questions identified in the *Federal Register* notice of April 16, 2003 (Ref 5) ~~[OPPT-2003-0012-0056]~~. The intent of EPA's preliminary framework document was to serve as a discussion guide for the June 6, 2003, public meeting and to aid in distinguishing between outstanding EPA data needs and industry LOI commitments. The preliminary framework document was not a predetermined list of information needs defining the outcome of the ECA process.

This ECA provides for a laboratory-scale incineration testing program of fluoropolymers, which is one of the data needs identified in EPA's preliminary framework document for PFOA. On June 6, 2003, the PFOA Plenary Group (consisting of EPA and all interested parties) acknowledged such a testing program as an opportunity for ECA development and tasked the Fluoropolymer Technical Workgroup to work out the details that could be incorporated into an ECA between test sponsors and EPA. On July 9, 2003, the Fluoropolymer Technical Workgroup received proposals from the Companies and EPA for incineration testing of fluoropolymers. Details of this testing program were developed by members of the Fluoropolymer Incineration Subgroup of the Fluoropolymer Technical Workgroup during subsequent meetings. On

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1 [Month/Date], 2003, the Fluoropolymer Technical Workgroup acknowledged that this testing
2 program had sufficient merit for consideration by the Plenary Group. On [Month/Date], 2003,
3 the Plenary Group discussed the merit of this testing program and recommended that EPA
4 consider entering into an ECA with test sponsors. The official record for developing this ECA,
5 including the public version, is established under EPA docket control number [OPPT-2003-
6 0012]. The procedures for ECA negotiations are described at 40 CFR 790.22(b). The official
7 record for the testing conducted under this ECA is Docket No. [OPPT-?YEAR-EDOCKET
8 NO. XXXX?]
9

10
11 **II. TEST SUBSTANCES**
12

13 The chemicals subject to this ECA are the fluoropolymers listed in Appendix A.1.¹ For
14 the purpose of testing under this ECA the chemicals listed in Appendix A.1 will be combined to
15 form four composites (see Appendix A.3 and A.4). These composites are representative of
16 fluoropolymer products manufactured by the Companies and are currently available in the
17 marketplace. The Companies will provide the fluoropolymers specified in Appendix A.1 for
18 incorporation into the composites that will be tested under this ECA. Criteria for the selection of
19 each composite to be tested under this ECA are described in Appendix A.2 of this ECA¹. The
20 four composites to be tested are defined for purposes of this ECA as:

- 21
22 (A) Dry Non-Melt PTFE Homopolymer Resin/Gum Composite:
23 Ethene, tetrafluoro-, homopolymer, CAS No. 9002-84-0,
24
25 (B) Dry Melt Fluoropolymer Resin Composite: (containing: 1-
26 Propene, 1,1,2,3,3,3-hexafluoro-, polymer with tetrafluoroethene),
27 CAS No. 25067-11-2; Propane, 1,1,1,2,2,3,3-heptafluoro-3-
28 [(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene, CAS No.
29 26655-00-5; Ethene, tetrafluoro-, polymer with
30 trifluoro(pentafluoroethoxy)ethene, CAS No. 31784-04-0; 1-
31 Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene
32 and tetrafluoroethene, CAS No. 25190-89-0; 1-Hexene,
33 3,3,4,4,5,5,6,6,6-nonafluoro-, polymer with ethene and
34 tetrafluoroethene, CAS No. 68258-85-5; and, 1-Propene,

¹ 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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1,1,2,3,3,3-hexafluoro-, polymer with ethene and tetrafluoroethene, CAS No. 35560-16-8),

(C) Dry Non-Melt Fluoroelastomer Resin/Gum Composite:
(containing: 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene, CAS No. 9011-17-0; 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and tetrafluoroethene, CAS No. 25190-89-0; 1-Propene, polymer with 1,1-difluoroethene and tetrafluoroethene, CAS No. 54675-89-7; 1-Propene, polymer with tetrafluoroethene, CAS No. 27029-05-6; Ethene, tetrafluoro-, polymer with trifluoro(trifluoromethoxy) ethene, CAS No. 26425-79-6; and, Ethene, chlorotrifluoro-, polymer with 1,1-difluoroethene, CAS No. 9010-75-7; and ??generic name??, **Accession No. ??????**, and

(D) Aqueous Fluoropolymer Dispersions Composite: (containing: Ethene, tetrafluoro-, polymer with trifluoro(pentafluoroethoxy) ethene, CAS No. 31784-04-0; Ethene, tetrafluoro-, homopolymer, CAS No. 9002-84-0; 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with tetrafluoroethene), CAS No. 25067-11-2; Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene, CAS No. 26655-00-5; Ethene, tetrafluoro-, polymer with trifluoro(pentafluoroethoxy)ethene, CAS No. 31784-04-0; and 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and tetrafluoroethene, CAS No. 25190-89-0.

The procedure for constructing each composite is described in Appendix A.4 to this ECA¹. Components of each fluoropolymer composite to be tested must be as pure as can be reasonably attained, and in any event must not be less than 97 percent pure. The polymer components will be unfilled first quality product polymer, substantially free of inorganic constituents. Each component of the four composites to be tested under this ECA will be accompanied by a certificate of analysis.

III. OBLIGATION OF SIGNATORY COMPANIES AND ROLE OF THE FLUOROPOLYMER MANUFACTURING GROUP

A. Testing will be sponsored by the Companies, which are responsible for complying with this ECA.

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1 B. The Companies recognize that to implement this ECA, EPA will issue an Order under
2 section 4 of TSCA that incorporates the terms of this ECA. The Companies agree that all terms
3 of this ECA will take effect on the date of publication of the notice in the Federal Register
4 announcing the issuance of the Order that incorporates this ECA, and all applicable time periods
5 will be treated as beginning on that publication date.
6

7 C. The Companies are members of the Fluoropolymer Manufacturers Group (FMG) of
8 the Society of the Plastics Industry (SPI) which represents the manufacturers of the
9 fluoropolymer test substances described in Part II and listed in Appendix A.1 which are subject
10 to this ECA. The FMG will be responsible for coordinating and administering testing under this
11 ECA and communicating with EPA about study plans, protocols, test standards, and other
12 aspects of the testing program. In performing these functions, the FMG will be acting as the
13 agent of the Companies for purposes of communication with EPA. EPA and the Companies
14 recognize that, except for its role as agent as specified in this ECA, the FMG has no legal respon-
15 sibility for complying with this ECA. Responsibility for complying with the ECA rests at all
16 times with the individual Companies.
17

18
19 **IV. PURPOSE OF THE TESTING PROGRAM**
20

21 The purpose of the testing program specified by this ECA is to assess the potential for
22 fluoropolymers (see Part II and Appendix A.1 of this ECA) to emit PFOA under laboratory-scale
23 incineration conditions representative of municipal waste combustor operations in the United
24 States and to quantify potential emission levels of PFOA that may emanate from laboratory-scale
25 combustion testing.
26

27 EPA believes that these incineration studies of fluoropolymers will develop data needed
28 by the Agency to determine whether municipal waste incineration of fluoropolymers is a
29 potential source of PFOA that may contribute as a pathway to environmental and human
30 exposures. The data may also be used to inform screening level human and environmental
31 exposure assessments. In addition, the data may also be used by other Federal agencies (e.g., the
32 Agency for Toxic Substances and Disease Registry (ATSDR), the National Institute for
33 Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration
34 (OSHA), and the Consumer Product Safety Commission (CPSC), the Food and Drug
35 Administration (FDA)) in assessing chemical risks and in taking appropriate actions within their
36 programs. It is intended that the data generated under this ECA will identify whether the
37 incineration of fluoropolymers contributes to the sources and pathways of environmental and
38 human exposure to PFOA.
39
40
41

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1 **V. SCOPE OF THE TESTING PROGRAM**

2
3 The Companies, through the FMG, will jointly conduct or provide for the performance of
4 the testing program specified in this ECA. This testing program will consist of: 1) conducting
5 the testing listed in Table 1 in accordance with the test standards specified in Table 1 and
6 described in Appendices B.?? and C1 - C2.6 as annotated by Appendix D.?? to this ECA ("Test
7 Standards"), and 2) submitting the reports and documents specified in Table 1 in accordance with
8 the deadlines set forth in Table 1.
9

10 **VI. DESCRIPTION OF THE TESTING PROGRAM**

11
12 The testing program has two segments as follows: Phase I PFOA Transport Testing and
13 Phase II Fluoropolymer Incineration Testing.
14

15 A. Phase I PFOA Transport Testing: Phase I will consist of quantitative transport
16 efficiency testing for PFOA. Phase I testing for PFOA transport efficiency is specified in the
17 Phase I PFOA Transport Testing segment of Table 1 and described in Appendix C.1 as annotated
18 by Appendices B.?? and D.???. At the conclusion of Phase I testing, the Companies, through the
19 FMG, will provide EPA with a letter/report summarizing the results. In the event that the
20 transport efficiency of PFOA or total fluorine (as expressed as total stoichiometric fluorine
21 content of PFOA and/or total fluorine) is equal to or greater than 70%, testing will proceed to
22 Phase II Fluoropolymer Incineration Testing. In the event the transport efficiency of PFOA or
23 total fluorine (as expressed as total stoichiometric fluorine content of PFOA and/or total fluorine)
24 is less than 70%, the Companies, through the FMG, will initiate a technical consultation with
25 EPA (see Part VI. B. and Part VII of this ECA).
26

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

37 Specifically, the technical consultation will determine: (1) whether the data from the
38 Phase I PFOA Transport Testing segment provide a sufficient basis for conducting the
39 laboratory-scale incineration testing specified in the Phase II Fluoropolymer Incineration Testing
40 segment; (2) the nature and scope of any additional Phase I work that may be required prior to the
41 commencement of Phase II Testing and reporting (e.g., modifications to the Advanced Thermal

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1 Reactor System) as described in Part VII. B. of this ECA), and/or (3) the nature and scope of
2 modifications to the protocols and test standards for Phase I and/or Phase II testing that may be
3 needed to complete the testing under this ECA.
4

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

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

20
21 **VII. PHASE I TECHNICAL CONSULTATION OUTCOMES**
22

23 For the testing program described by this ECA, technical consultation between the
24 Companies, through the FMG, and EPA at the conclusion of Phase I PFOA Transport Testing
25 can result in several possible outcomes, as described below.
26

27 A. Phase I Testing Data are Acceptable: EPA and the Companies, through the
28 FMG, may determine that the Phase I Testing data can be used to inform and support Phase II
29 Testing for the laboratory-scale incineration testing. In such an instance, EPA and the

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 (LOD) and, where LOD is identified to be 10 ppt under standard temperature and pressure (see also 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 laboratory-scale incineration testing data with respect to municipal waste combustor operations in the United States.

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1 Companies, through the FMG, agree that Phase II endpoint testing and reporting must be
2 conducted as specified in Table 1 and Part VI.C. of this ECA.

3
4 B. EPA and/or the Companies Identifies Limitations in the Phase I Testing Data:
5 EPA and/or the Companies, through the FMG, may determine that additional Phase I Testing is
6 needed before the Phase II endpoint testing and reporting that are specified in Table 1 and Part
7 VI. C can be conducted. In such an instance, EPA and the Companies, through the FMG, will
8 continue technical discussions on this matter.

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

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

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

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1 (c) Additional Phase I Testing Does Not Meet Data Needs: If, at any point,
2 EPA determines that the Phase I Testing data, as supplemented by the additional Phase I Testing
3 data, cannot be used to inform and support Phase II incineration testing as specified in Table 1
4 and Part VI. C. of this ECA, then the outcome described in Part VII. C. below will apply to these
5 endpoints.

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

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

22
23 D. Other Possible Outcomes: If the technical consultation between EPA and the
24 Companies, through the FMG, do not result in any of the outcomes described above, EPA and
25 the Companies, through the FMG, may modify this ECA according to the procedures contained
26 in 40 CFR 790.68 (see Part X. of this ECA).

27
28
29 **VIII. STANDARDS FOR CONDUCTING TESTING**

30
31 A. Testing for the incineration of the fluoropolymers described in Part II and listed in
32 Appendix A.1 of this ECA must be conducted in accordance with the Test Standards listed in
33 Table 1 and described in Appendices B.?? and C.1 - C.2 as annotated in Appendix D.?? to this
34 ECA. Certain provisions of these Test Standards are considered to be mandatory and are referred
35 to as "requirements." These requirements are identified by the use of the word "shall" in the text
36 of the Test Standard. For the purpose of this ECA, the words "will" and "must," if they appear in
37 the Test Standards, are considered equivalent to the word "shall" and therefore delineate a test
38 requirement to be followed or met.

39
40 Provisions that are not mandatory, and are therefore only recommended, are identified by
41 the use of "should" statements. In the event such "should" provisions are not followed, the

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1 Companies will not be deemed by EPA to be in violation of this ECA and will not be subject to
2 penalties or other enforcement actions, as described in Part XI. of this ECA. However, in such
3 cases, EPA will use its professional judgement to determine the scientific adequacy of the test
4 results and any repeat testing that is determined by EPA to be necessary will be required either
5 under a separate ECA or pursuant to a rule promulgated under section 4(a) of TSCA, 15 U.S.C.
6 2603(a).

7
8 B. The Companies, through the FMG, and EPA will consult in a good faith effort to
9 consider the need for Test Standard modifications if either EPA or the Companies desire such
10 modifications. Modifications to this ECA will be governed by 40 CFR 790.68 (see Part X. of
11 this ECA).

12
13 C. All testing required by this ECA must be conducted in accordance with the EPA
14 Good Laboratory Practice Standards (GLPS) found at 40 CFR part 792.

15
16 D. All final reports must be submitted by the Companies, through the FMG, to EPA
17 by the dates specified in Table 1 unless otherwise authorized by EPA pursuant to 40 CFR 790.68.
18 Interim status reports describing the status of all studies to be performed under this ECA testing
19 program must be submitted by the Companies, through the FMG, to EPA every six months
20 beginning six months from the effective date of this ECA and until the end of the ECA testing
21 program described in Table 1 of this ECA. These interim reports should contain information
22 such as a summary of the status of each study being performed under this ECA testing program, a
23 description of significant activities and/or difficulties experienced during the interim, and an
24 explanation of the actions taken in response to such difficulties. See Part XIII. of this ECA
25 regarding submissions to EPA.

26
27
28 **IX. STUDY PLANS**

29
30 The Companies, through the FMG, will submit a study plan to EPA for each test
31 conducted pursuant to this ECA prior to the initiation of testing in accordance with 40 CFR
32 790.62. (For this ECA, EPA will not require the study plans to be submitted “no later than 45
33 days prior to the initiation of testing,” as specified at 40 CFR 790.62(a)). The content of the
34 study plans submitted to EPA will comply with 40 CFR 790.62(b) and must include submission
35 of Quality Assurance Project Plans (QAPjP).³ Modifications to the study plans will be governed

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

(continued...)

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1 by the procedures of 40 CFR 790.62(c). All study plans will become part of the official record
2 (Docket Control Number [OPPT-YEAR-EDOCKET NO. ?? XXXX ??]).
3
4

5 **X. MODIFICATIONS TO THIS ENFORCEABLE CONSENT AGREEMENT**
6

7 Except as provided in this agreement, modifications to this ECA, if any, will be made
8 according to the procedures contained in 40 CFR 790.68.
9

10
11 **XI. FAILURE TO COMPLY WITH THE ENFORCEABLE CONSENT AGREEMENT**
12

13 The Companies acknowledge that a violation of the requirements of this ECA will
14 constitute a "prohibited act" under section 15(1) of TSCA, 15 U.S.C. 2614(1), and will trigger all
15 provisions applicable to a section 15 violation. In addition, the Companies acknowledge that
16 noncompliance with any term of this ECA by any Company will constitute conduct "in violation
17 of this Act" under section 20(a)(1) of TSCA, 15 U.S.C. 2619(a)(1), and could result in a citizen's
18 civil action.
19

20 Under the penalty provisions of section 16 of TSCA, 15 U.S.C. 2615, and the Federal
21 Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, as amended by the Debt
22 Collection Improvement Act of 1996, 31 U.S.C. 3701 note, as implemented by 61 FR 69360
23 (December 31, 1996), a non-complying Company could be subject to a civil penalty of up to
24 \$27,500 per violation, with each day in violation potentially constituting a separate violation
25 under section 15. Knowing or willful violations may lead to the imposition of criminal penalties,
26 or a fine of not more than \$27,500 for each day of violation, or imprisonment for not more than
27 one year, or both. In addition, EPA could enforce this ECA pursuant to section 17 of TSCA, 15
28 U.S.C. 2616, by seeking an injunction to compel adherence to the requirements of this ECA.
29
30

31 **XII. EPA MONITORING OF ENFORCEABLE CONSENT AGREEMENT TESTING**
32

33 EPA may conduct monitoring activities of the testing conducted under this ECA such as
34 laboratory inspections and study audits, as permitted under section 11 of TSCA, 15 U.S.C. 2610.
35
36
37

³ (...continued)
at <http://epa.GOV/Quality/qs-docs>.

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1 **XIII. SUBMISSIONS TO EPA**

2
3 All data and other information submitted to EPA under this ECA will be identified by the
4 Docket Number: [OPPT-YEAR-EDOCKET NO. ?? XXXX ??] and the name: ECA on
5 Laboratory-Scale Incineration Testing of Fluoropolymers. Submissions made by mail should be
6 sent to: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT),
7 Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460-
8 0001. Submissions made by hand delivery or courier should be delivered to: OPPT Document
9 Control Office (DCO) in the EPA East Building, Room 6428, 1201 Constitution Avenue, NW,
10 Washington, DC and marked Attention: Docket ID Number **OPPT- Year - ??XXXX??**. The
11 DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The
12 telephone number for the DCO is (202) 564-8930.

13
14 Any data and other information submitted to EPA for which the Companies make a claim
15 of confidentiality (see Part XV of this ECA), must be submitted as two separate versions. One
16 version must be complete, with the information being claimed as confidential marked in the
17 manner described under 40 CFR 790.7. The other, public version must have all of the
18 information claimed as confidential excised. EPA will place the public version in the Agency's
19 docket. The complete version will be treated in accordance with EPA confidentiality regulations
20 in 40 CFR part 2 and 40 CFR 790.7.

21
22 Do not electronically submit data or other information that are considered to be CBI
23 through EPA's electronic public docket or by e-mail. Any part or all of data or other information
24 claimed as CBI must be so marked. If the CBI submission is on diskette or CD ROM, mark the
25 outside of the diskette or CD ROM as CBI and then identify electronically within the diskette or
26 CD ROM the specific information that is CBI. Information marked as CBI will not be disclosed
27 except in accordance with procedures set forth in 40 CFR part 2 (see Part XV of this ECA).

28
29 The Companies, through the FMG must submit six (6) paper copies of each version
30 (Public and CBI) for all reports described in Table 1 and Part VI A. and C. of this ECA. In
31 addition, an electronic file of all submissions under this ECA (marked as CBI where appropriate
32 and in text-searchable, PDF format) will be provided to EPA.

33
34
35 **XIV. PUBLICATION AND DISCLOSURE OF TEST RESULTS**

36
37 All results of testing conducted pursuant to this ECA will be announced to the public by
38 EPA in accordance with the procedures specified in section 4(d) of TSCA, 15 U.S.C. 2603(d).
39 Disclosure by EPA of data generated by such testing will be governed by section 14(b) of TSCA,
40 15 U.S.C. 2613(b), and 40 CFR part 2.

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1 **XV. CONFIDENTIALITY OF INFORMATION**

2
3 Any claims of confidentiality for information submitted under this ECA will be made
4 under the terms of 40 CFR 790.7. If no claim of confidentiality is made by the submitter of the
5 information at the time of submission, the information will be deemed by EPA, in accordance
6 with 40 CFR 790.7, to be public, and may be made available to the public without further notice
7 to the submitter. Information claimed as confidential will be treated in accordance with the
8 procedures in 40 CFR part 2 established pursuant to section 14 of TSCA, 15 U.S.C. 2613.
9

10
11 **XVI. RESPONSIBILITIES OF THE COMPANIES**

12
13 A. The Companies are bound by the terms of this ECA and the provisions of 40 CFR
14 790.62 and 790.65.

15
16 B. The Companies will comply with the notification requirements of section 12(b)(1)
17 of TSCA, 15 U.S.C. 2611(b)(1), and 40 CFR part 707, subpart D, if they export or intend to
18 export any of the fluoropolymer chemicals listed in Appendix A.1 to this ECA. Any other person
19 who exports or intends to export any of the fluoropolymer chemicals listed in Appendix A.1 to
20 this ECA is subject to the above cited export notification requirements
21

22 C. If any of the fluoropolymer chemicals listed in Appendix A.1 to this ECA become
23 subject to a rule promulgated under TSCA section 5(a)(2), 15 U.S.C. 2604(a)(2), governing
24 significant new uses of any of the fluoropolymer chemicals listed in Appendix A.1 to this ECA,
25 then the Companies will be subject to the data submission requirements imposed by section
26 5(b)(1)(A) of TSCA, 15 U.S.C. 2604(b)(1)(A), as if the testing under this ECA had been required
27 by a TSCA section 4 test rule.
28
29

30 **XVII. SEVERABILITY OF ENFORCEABLE CONSENT AGREEMENT PROVISIONS**

31
32 In the event that one or more provisions of this ECA are determined by a court decision to
33 be unenforceable, the remaining provisions of this ECA will not be presumed to be valid, and
34 EPA will either initiate a rulemaking proceeding to require testing or publish in the Federal
35 Register the reasons for not initiating such a proceeding.
36
37

38 **XVIII. FINAL AGENCY ACTION**

39
40 For purposes of 5 U.S.C. 704, publication of the FR notice announcing the issuance of the
41 Order incorporating this ECA constitutes final agency action..

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1
2 **XIX. PUBLIC RECORD**
3

4 EPA has established a public record which will contain this ECA, the Order that
5 incorporates this ECA, the Federal Register notice announcing issuance of the Order
6 incorporating this ECA, and any and all relevant information, subject to the confidentiality
7 provisions of section 14(b) of TSCA and 40 CFR part 2. The official record for this ECA,
8 including the public version, which does not include any information claimed as CBI, has been
9 established under Docket Control Number [OPPT-YEAR-EDOCKET NO. ?? XXXX ?].
10

11 An electronic version of the public docket is available through EPA's electronic public
12 docket system, EPA Dockets. EPA Dockets may be accessed at <http://www.epa.gov/edocket/> to
13 access the index listing of the contents of the official public docket, and to access those
14 documents in the public docket that are available electronically. Although not all docket
15 materials may be available electronically, (for example the materials in the original dockets for
16 this action, [AR-226 and OPPTS-2003-0012], or materials under copyright), can be access any of
17 the publicly available docket materials through the EPA Docket Center, Rm. B102-Reading
18 Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. For materials available in
19 the electronic docket, once in the system, select "search," then key in the appropriate docket ID
20 number [(OPPT-YEAR-EDOCKET NO. XXXX).]
21

22
23 **XX. EFFECTIVENESS**
24

25 This ECA may be signed in separate counterparts. This ECA will not be effective unless
26 signed by each of the Companies and by EPA. This ECA will take effect on the date of
27 publication of the Federal Register notice announcing the issuance of the Order that incorporates
28 this ECA.
29

30
31 **XXI. RIGHTS OF THE COMPANIES**
32

33 By signing this ECA, the Companies waive their right to challenge EPA's authority to
34 assess penalties for violations of the terms of this ECA. This waiver does not affect any other
35 rights that the Companies may have under TSCA, including the right to dispute the amount of
36 any penalty or to dispute factually whether a violation of the terms of this ECA has occurred, or
37 to seek judicial review of any rule that may be adopted by EPA that imposes requirements to test
38 any of the fluoropolymer chemicals listed in Appendix A.1 to this ECA.
39
40
41

1 **XXII. IDENTITY OF THE COMPANIES**

2
3 The Companies subject to this ECA are:

4
5
6 Asahi Glass Fluoropolymers USA, Inc.
7 **[? ADDRESS ?]**

8
9
10 Daikin America, Inc.
11 **[? ADDRESS ?]**

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16 Dyneon, LLC
17 **[? ADDRESS ?]**

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19
20 E.I. du Pont de Nemours and Company
21 **[? ADDRESS ?]**

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1 **XXIII. SIGNATURE**

2
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4 **TEST SPONSOR**

5
6
7 **Asahi Glass Fluoropolymers USA, Inc.¹**

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ECA Subject Chemicals for Asahi Glass Fluoropolymers USA, Inc.		
CAS No.	Chemical Name	Composite(s)

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27 Date: _____

28 [? NAME ?]
29 [? TITLE ? e.g., Senior Vice President]
30 Asahi Glass Fluoropolymers USA, Inc.
31 [? ADDRESS ?]

¹ Data in the table listing the ECA subject chemicals for Asahi Glass Fluoropolymers USA, Inc. was provide to EPA by the Company. There may be both a Public and CBI version of this page in those instances where the Company has asserted that data in this table 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 **XXIII. SIGNATURE**

2
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4 **TEST SPONSOR**

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7 **Daikin America, Inc.¹**

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ECA Subject Chemicals for Daikin America, Inc.		
CAS No.	Chemical Name	Composite(s)

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27 Date: _____

28 **[? NAME ?]**
29 **[? TITLE ? e.g., Senior Vice President]**
30 Daikin America, Inc.
31 **[? ADDRESS ?]**

¹ Data in the table listing the ECA subject chemicals for Daikin America, Inc. was provide to EPA by the Company. There may be both a Public and CBI version of this page in those instances where the Company has asserted that data in this table 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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XXIII. SIGNATURE

TEST SPONSOR

Dyneon, LLC¹

ECA Subject Chemicals for Dyneon, LLC		
CAS No.	Chemical Name	Composite(s)

Date: _____

[? NAME ?]
[? TITLE ? e.g., Senior Vice President]
Dyneon, LLC
[? ADDRESS ?]

¹ Data in the table listing the ECA subject chemicals for Dyneon, LLC was provide to EPA by the Company. There may be both a Public and CBI version of this page in those instances where the Company has asserted that data in this table 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 **XXIII. SIGNATURE**

2
3 **TEST SPONSOR**

4
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7 **E.I. du Pont de Nemours and Company¹**

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ECA Subject Chemicals for E. I. du Pont de Nemours and Company		
CAS No.	Chemical Name	Composite(s)

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27 Date: _____

[? NAME ?]

[? TITLE ? e.g., Senior Vice President]

E.I. du Pont de Nemours and Company

[? ADDRESS ?]

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¹ Data in the table listing the ECA subject chemicals for E. I. du Pont de Nemours and Company was provide to EPA by the Company. There may be both a Public and CBI version of this page in those instances where the Company has asserted that data in this table 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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XXIV. SIGNATURE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Date: _____

Stephen L. Johnson
Assistant Administrator
Office of Prevention, Pesticides, and Toxic Substances

Address:

U.S. Environmental Protection Agency
Office of Prevention, Pesticides, and Toxic Substances
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

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1
 2 Table 1 REQUIRED TESTING, TEST STANDARDS, REPORTING AND OTHER
 3 REQUIREMENTS FOR THE LABORATORY-SCALE INCINERATION TESTING OF
 4 LUOROPOLYMERS

Phase I PFOA Transport Testing	Test Standard	Deadline for Final Report (Months) ²
Quantitative PFOA transport analysis ³	See appendix C.1 as annotated in appendix D.?)	?TBD "4" ? ⁴

10

² Number of months after the effective date of the Order that incorporates this ECA when final report is due. Interim status reports, describing the status of all testing to be performed under this ECA, must be submitted by the Companies, through the FMG, to EPA every 6 months beginning six months from the effective date of this ECA until the end of the ECA testing program (see Part VIII. D. and Part XIII. of this ECA).

³ As described in Part VI. A. and B. of this ECA, at the conclusion of Phase I PFOA transport efficiency testing, and prior to initiation of Phase II, the Companies, through the FMG, will provide a letter/report to EPA summarizing the results of Phase I testing. In the event that the transport efficiency of PFOA or of total fluorine (as expressed as the total stoichiometric fluorine content of PFOA and/or as total fluorine) is greater than or equal to 70% then testing will proceed to Phase II Incineration Testing. In the event that the transport efficiency of PFOA or of total fluorine (as expressed as the total stoichiometric fluorine content of PFOA and/or as total fluorine) is less than 70% then the Companies, through the FMG, will initiate a Technical Consultation with EPA to determine under what conditions Phase II testing can proceed. The outcomes of the Technical Consultation are described in Part VII of this ECA.

⁴ In the event that the transport efficiency of PFOA or of total fluorine (as expressed as the total stoichiometric fluorine content of PFOA and/or as total fluorine) is less than 70% and the Technical Consultation concludes that testing can not proceed to Phase II, then the Companies, through the FMG, will submit a complete report for Phase I testing within 60 days following notification of the Technical Consultation outcome. In the event that the outcome of the Technical Consultation indicates that testing can proceed to Phase II Testing then the final report for Phase I will be incorporated into the final report for Phase II Testing.

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Phase II Fluoropolymer Incineration Testing	Test Standard	Deadline for Final Report (Months)⁵
Elemental analysis	ASTM D 3176 or equivalent (see Appendix B.? as annotated in Appendix C.2.1)	?TBD "4"?
Combustion stoichiometry	See Appendix C.2.2 as annotated in Appendix D.?	?TBD "4"?
Thermogravimetric analysis	ASTM E 1868-02 (see Appendix B.? as annotated in Appendix C.2.3)	?TBD "6"?
Laboratory-scale combustion testing	Appendix C.2.4 as annotated in Appendix D.?)	?TBD "18"?
Release assessment report ⁶	(see Appendix E)	?TBD "20"?

⁵ Number of months after initiation of Phase II testing when final report for this testing is due (see footnotes 2 and 3).

⁶ In the event that Phase II Testing identifies measurable levels of PFOA (where measurable PFOA is defined to be at or above the limit of detection (LOD) and, where LOD is identified to be 10 ppt under standard temperature and pressure (see also Appendix D.3)) resulting from the combustion testing for any or all of the fluoropolymer composites to be tested under this ECA, then the Companies, through the FMG, will prepare a release assessment report to put into perspective the relevance of the laboratory-scale incineration testing data with respect to municipal incineration operations in the United States (see Appendix E to this ECA).

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APPENDIX 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**

PUBLIC VERSION - CONTAINS NO CBI

APPENDIX A.1

LIST OF CHEMICALS SUBJECT TO THIS ECA¹

The following table lists the thirteen fluoropolymer chemicals that are the subject to this ECA.

The identities of the fluoropolymers subject to this ECA were provided to EPA as support documentation of the Companies' LOI commitments. Some of this documentation, including certain aspects related to the identity of the test substance as described in Part II of this ECA and the table below, may contain Confidential Business Information (CBI). In such instances EPA creates a comprehensive database for evaluation and comparison, and, when possible, provides a public version sanitized of CBI.

Subsequent analysis of the list of fluoropolymers received by EPA supported the conclusion that the individual chemicals listed below are representative of all known fluoropolymer chemicals and the basic chemistries are represented by the four composite test substances that are subject to testing under this ECA (i.e., dry melt fluoropolymer resin, dry non-melt PTFE homopolymer resin/gum, dry non-melt fluoroelastomer resin/gum, aqueous fluoropolymer dispersions) (see ECA Appendix A.2 and A.3). The fluoropolymer structure is predominantly -(CF₂)_x- which is a potential source of PFOA. For all fluoropolymer products used in commerce, the -(CF₂)- moiety is common to all polymers and the composites to be tested under this ECA testing program (see Appendix A.2-A.4) are representative of the individual component and non-component fluorochemicals.

FLUOROPOLYMERS SUBJECT TO THIS ECA		
No.	CAS No.	Chemical Name
1	9002-84-0	Ethene, tetrafluoro-, homopolymer
2	25067-11-2	1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with tetrafluoroethene
3	26655-00-5	Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene
4	25190-89-0	1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and tetrafluoroethene
5	68258-85-5	1-Hexene, 3,3,4,4,5,5,6,6,6-nonafluoro-, polymer with ethene and tetrafluoroethene

¹ There is a Public and CBI version of Appendix A.1 because the Companies have asserted that details describing their chemical(s) 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).

PUBLIC VERSION - CONTAINS NO CBI

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6	35560-16-8	1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with ethene and tetrafluoroethene
7	9011-17-0	1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene
8	54675-89-7	1-Propene, polymer with 1,1-difluoroethene and tetrafluoroethene
9	27029-05-6	1-Propene, polymer with tetrafluoroethene
10	26425-79-6	Ethene, tetrafluoro-, polymer with trifluoro(trifluoroethoxy)ethene
11	9010-75-7	Ethene, chlorotrifluoro-, polymer with 1,1-difluoroethene
12	31784-04-0	Ethene, tetrafluoro-, polymer with trifluoro(pentafluoroethoxy)ethene
13	CBI Accession No. ????	??generic name ??

PUBLIC VERSION - CONTAINS NO CBI

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APPENDIX A.2

RATIONALE FOR SELECTING COMPOSITES TO BE TESTED

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APPENDIX A.3

COMPOSITION OF COMPOSITES TO BE TESTED¹

¹ There is a Public and CBI version of Appendix A.3 because the Companies have asserted that details describing their chemical(s) 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).

PUBLIC VERSION - CONTAINS NO CBI

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APPENDIX A.4

PREPARATION OF COMPOSITES TO BE TESTED¹

¹ There is a Public and CBI version of Appendix A.4 because the Companies have asserted that details describing their chemical(s) as a component of the composite(s) is 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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APPENDIX B

TEST STANDARDS

- B.1** ASTM D 3176
- B.2** ASTM E 18680-02 Loss-on-Drying by Thermogravimetry
- B.3** others.....?

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APPENDIX C

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**

* To be provided by the FMG

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APPENDIX D

ATTACHMENTS AND REFERENCED MATERIALS

- D.1 Wickbold Torch Method
- D.2 Waste Incineration and Operation Conditions
- D.3 PFOA Analysis Method
- D.4 Other.....

* To be provided by the FMG

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APPENDIX E

OUTLINE FOR THE RELEASE ASSESSMENT REPORT

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APPENDIX E
Outline for Release Assessment Report

As described in Part VI C., footnote 2 , and Table 1 footnote 5 of this document, if the results of Phase II Fluoropolymer Incineration Testing show that PFOA is quantitated at greater than the LOD (Limit of Detection), the Companies, through the FMG, will provide a release assessment report to put the data into perspective relevant to municipal waste incineration practices in the United States. The objective of this release report is to place the results of the laboratory-scale incineration test as described in Part VI C. and Table 1 of this ECA in context with the process of municipal waste incineration in the United States and to provide sufficient quality information to inform human and environmental exposure assessments. At a minimum, the report will follow the general outline described below and will state assumptions, verify the validity of the assumptions made, and evaluate and characterize the variability and uncertainty of calculated estimates:

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1.0 Introduction

- Statement of objective for combustion testing of fluoropolymers
- Applicability of the laboratory-scale combustion testing to municipal waste incinerators in the United States.

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2.0 Summary of study results

- A listing of compounds collected at the targeted temperature

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3.0 Discussion

- Description of the typical municipal incineration process being modeled including the rationale for selecting targeted temperatures, describe typical operational parameters, and potential occupational exposures.

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4.0 Extrapolation of laboratory test results to the typical municipal incinerator described in section 3.0 (above) for each composite.

- A description of the extrapolation
- A description of any assumptions used
- Any unique qualitative or quantitative descriptors of the test, the testing equipment, and the results deemed necessary for informative review of the test and test results.

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5.0 Sensitivity Analysis

- Assessment of the impact of variability/uncertainty (quantitative and qualitative) in each parameter on the modeling results.

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6.0 Conclusions

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7.0 References

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