0007-2003-0071-0070



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Subject: Joint Incineration ECA development meeting for Telomers & Fluoropolymers

The next Incineration ECA development teleconference will be a joint call for both Telomer and Fluoropolymer. The call is scheduled for February 11th 8 a.m. - 10 a.m.

As per the 2/4/04 conference call I have compiled an abbreviated handout for the group to work from (see attached file = 2-11-04\_IncinConfCall.pdf). We will continue to refer back to the documents circulated at the January public meetings (i.e., Fluoropolymer Draft #7, Fluorotelomer Draft #2, and compiled Appendices B-E all dated 1/27-29/04).

## TENTATIVE AGENDA

- 1) Introductions
- 2) Update on information call-in for signature pages
- 3) Update on CBI disclosure with other government organizations
- 4) Update on GLP / QAAP
- 5) Update on Table 1 revisions and need for clarification of Phase II trigger text
- 6) Other discussions (to be determined by the group)
- 7) Next Steps

## **TELECONFERENCE CALL INFO:**

EPA has reserved the phone lines for this call. Note: You cannot call in earlier NOR stay on later than the scheduled end time as EPA Teleconferences are connected and disconnected automatically by the system.

Date: 2/11/04

Times Eastern: 8 a.m. -10:a.m.

Conference Name: Incineration ECAs (Telomer & Fluoropolymer)

Telephone #: (202)275-0170

Access Code: 7869#

If you are not calling from an EPA Headquarters phone then you must <u>dial 1 plus the</u> <u>area code (202) and the 7-digit telephone number</u>. At the prompt all participants must <u>enter</u> <u>the four-digit conference access code followed by the "#"sign</u>. If the code is not entered properly, the caller will be given two more changes. If it is still unsuccessful he or she will be placed in out "<u>Waiting Room</u>" until an operator can provide assistance. If you have difficulty accessing the conference call contact (202) 272-0168.

Please note that all EPA teleconferences are monitored for audio quality by EPA's

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telecommunications service contractors, therefore discussions of any sensitive or restricted information is prohibited.

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NOTE: Dear Incineration ECA Drafting Committees:

This is a working document containing excerpts of those sections of the Draft ECA document ("cover document") for which the Drafting Committee is continuing discussions to finalize text. Included are:

...)

1)	GLP / QAAP Discussions - Excerpt of Part IX and X (from the 1/21/04 draft)Pgs 1-2
2)	CBI Use By Other Government Organizations - Excerpt of Part XV (from the 1/21/04 draft)Pg 3
3)	Suggested clarification text for the Phase II triggerPg 4
4)	Revised Table I FluoroTelomer (based on 2/4/04 discussions)Pgs 6-8
5)	Revised Table I Fluoropolymer (based on 2/4/04 discussions)Pgs 9-11

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## IX. STANDARDS FOR CONDUCTING TESTING

A. Testing for the laboratory-scale incineration of the fluoropolymer test substance composites described in Part II of this ECA which contain the fluoropolymers listed in Appendix A.1 of this ECA must be conducted in accordance with the Test Standards listed in Table 1 and described in Appendices B.1 and C.1 - C.2 as annotated in Appendices D.1-D.3 to this ECA. Certain provisions of these Test Standards are considered to be mandatory and are referred to as "requirements." These requirements are identified by the use of the word "shall" in the text of the Test Standard. For the purpose of this ECA, the words "will" and "must," if they appear in the Test Standards, are considered equivalent to the word "shall" and therefore delineate a test requirement to be followed or met.

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

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

## \*\*\* FOLLOW-ON DISCUSSION POINT:

[SUMMARY: FMG maintains that the University of Dayton laboratory can not comply with GLPS requirements for testing under this ECA. In addition, FMG expresses concern about duplication between QAPjP and study plan requirements. EPA maintains that: 1) study plan(s) are required, 2) all studies must be conducted in accordance with GLPS and 3) separate QAPjP(s) must be submitted. EPA noted that cut and paste from ECA protocols etc. can be used to complete QAPjP and study plan submission requirements. On 12/6 and 12/10/03 FMG agreed to prepare a table listing GLPS requirements, whether laboratory compliance was impossible / possible at additional cost / possible at no additional cost, and whether the item is covered by the QAPjP / in conflict with QAPjP requirements / or not addressed by QAPjP requirements (Note: The table was not available for 1/13/04 Draft Committee discussions). On 1/21/04 EPA reiterated that adequate quality assurance for testing aimed at sorting out the environmental sources of PFOA and routes to human exposures is sufficient to compel the need for full compliance with these requirements.]

{original text}

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

## {12/22/03 Revised EPA placeholder text with supplemental text in red}

{11/24/03 FMG proposed revisions}

C. All testing required by this ECA must be conducted in accordance with <u>the EP4</u> Good Laboratory Practice Standards (GLPS) found at 40 CFR part 792. a Quality Assurance Project Plan prepared in accordance with Appendix YYY.

## X. STUDY PLAN(S) AND QUALITY ASSURANCE PROJECT PLAN(S) (QAPP)

The Companies will submit a study plan to EPA for each test 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 plan(s) 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 plan(s) submitted to EPA will comply with 40 CFR 790.62(b). This ECA and/or its appendices satisfy the applicable requirements of 40 CFR 790.62(b)(2), (8), (9), and (10). A study plan may cross reference the applicable provisions of the ECA and/or its appendices to satisfy these requirements. Also <u>pursuant to Part IX. (C) of for this</u> ECA, the Companies must submit Quality Assurance Project Plan(s) (QAPP) prepared in accordance with EPA guidance.<sup>1</sup> Modifications to the study plan(s) under this part of the ECA will be governed by the procedures of 40 CFR 790.62(c) (2) and (3) will be 45 day time periods. All study plan(s) will become part of the official record (Docket Control Number [OPPT-2003-0071).

<sup>&</sup>lt;sup>1</sup> Guidance for developing Quality Assurance Project Plans can be found in the EPA document EPA QA/R-5: EPA Requirements for Quality Assurance Project Plans, prepared by: Office of Environmental Information, EPA, March 2001. This is also available from the EPA website at http://epa.GOV/Quality/qs-docs.

## XV. PUBLICATION AND DISCLOSURE OF TEST RESULTS

#### **\*\*\* FOLLOW-ON DISCUSSION POINT**

[Summary - FMG proposed 11/24/03 additional text to clarify conditions under which EPA can share a CBI Document with another government agency. EPA struck this addition on 12/22/03 citing laws governing such distribution adequately addressed FMG concerns. During further discussion, it became clear that additional clarification could be provided to meet FMG's needs. On 1/6/04 EPA excerpt text from the OPPTS CBI manual to FMG and alternative language is suggested in red. On 1/13/04 discussions concluded that the EPA CBI manual adequately covered in-house sharing but questions remained about external sharing. EPA provided additional CBI manual excerpts to further clarify. FMG will consider this and discuss at the 1/21/04 meeting.]

All results of testing conducted pursuant to this ECA will be announced to the public by EPA in accordance with the procedures specified in section 4(d) of TSCA, 15 U.S.C. 2603(d). Disclosure by EPA of data generated by such testing to the public or other government agencies will be governed by section 14(b) of TSCA, 15 U.S.C. 2613(b), and 40 CFR part 2. The <u>CBI</u> version of a document will only be provided to another U.S. government organization in compliance with the procedures described in the OPPTS\_TSCA\_CBI Procedure Manual.

{FMG 11/24/03 proposed additional text / struck by EPA 12/22/03} <u>The CBI version of a document will not be provided to another government agency unless that</u> <u>agency has certified that it affords equivalent protection.</u>

NOTE to Drafting Committee: During the 2/4/04 conference call David Menotti corrected what is now the text of Table 1, footnote # 8 regarding the trigger language that leads to Phase II. After making these corrections to the footnote, EPA staff went back into the text of Part VII and Part VIII of the ECA document to check for consistency. As a result EPA recommends the following changes to improve clarity.

Suggested text changes to the following three (3) sections in the ECA are in red/strikeout.

## VII. DESCRIPTION OF THE TESTING PROGRAM

A. <u>Phase I PFOA Transport Testing</u>: Phase I will consist of quantitative transport efficiency testing for PFOA. Phase I testing for PFOA transport efficiency is specified in the Phase I PFOA Transport Testing segment of Table 1 and described in Appendix C.1 as annotated by Appendix D.1 and D.2. At the conclusion of Phase I testing, the Companies, will provide EPA with a letter report summarizing the results. In the event that the transport efficiency of PFOA or total fluorine (as determined by the formulas in Appendix C.1) is equal to or greater than 70%, testing will proceed to Phase II Fluorotelomer Based Polymers Incineration Testing. In the event the transport efficiency of PFOA or **or and** total fluorine (as determined by the formulas in Appendix C.1) is are both individually less than 70%, the Companies will initiate a technical consultation with EPA (see Part VII. B. and Part VIII of this ECA)

#### VIII. PHASE I TECHNICAL CONSULTATION

B. If the **analysis of the** recovery **fluids** for either PFOA or total fluorine (as determined by the formulas in Appendix C.1) is greater than or equal to 70%, the Companies will proceed to Phase II testing.

C. If the **analysis of the** recovery **fluids** for both PFOA and total fluorine (as determined by the formulas in Appendix C.1) is are both individually less than 70%, a Technical Consultation will be held between the Companies and EPA.

#### **Table 1** (footnote #2 as discussed 2/4/04)

At the conclusion of Phase I PFOA transport efficiency testing, and prior to initiation of Phase II, the Companies, will provide a letter/report to EPA summarizing the results of Phase I testing (see Part VII. A. of the ECA). In the event that the transport efficiency of PFOA or of total fluorine (as determined by the formulas in Appendix C.1) is greater than or equal to 70% then the Companies will proceed to Phase II Incineration Testing. In the event that the transport efficiency of PFOA and or of total fluorine (as determined by the formulas in Appendix C.1) is greater than the transport efficiency of PFOA and or of total fluorine (as determined by the formulas in Appendix C.1) is **are both individually** less then 70% then the Companies 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 VIII of this ECA.

**NOTE To Drafting Committee:** The following pages incorporate revisions discussed on 2/4/04.

In addition, we need to develop the schedule for Phase II fluoropolymer incineration testing which will be sequenced to begin following the fluorotelomer incineration testing.

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# Table 1REQUIRED TESTING, TEST STANDARDS, REPORTING AND OTHERREQUIREMENTS FOR THE LABORATORY-SCALE INCINERATION TESTING OFFLUOROTELOMER BASED POLYMERS

Phase I PFOA Transport Testing	Test Standard	Deadline for Final Report (Months) <sup>1</sup>
Phase I Study Plan(s)	40 CFR 790.62 (b) as annotated by Part X of the ECA	2 <sup>3</sup>
Phase I QAPP	Appendix G of the ECA	3 <sup>3</sup>
Quantitative PFOA transport testing <sup>2</sup>	Appendix C.1 of the ECA	8 <sup>4 5</sup>

<sup>2</sup> At the conclusion of Phase I PFOA transport efficiency testing, and prior to initiation of Phase II, the Companies, will provide a letter/report to EPA summarizing the results of Phase I testing (see Part VII. A. of the ECA). In the event that the transport efficiency of PFOA or of total fluorine (as determined by the formulas in Appendix C.1) is greater than or equal to 70% then the Companies will proceed to Phase II Incineration Testing. In the event that the transport efficiency of PFOA and <del>or</del> of total fluorine (as determined by the formulas in Appendix C.1) is less then 70% then the Companies will initiate a Technical Consultation with EPA. to determine under what eonditions Phase II testing can proceed. The outcomes of the Technical Consultation are described in Part VIII of this ECA:

<sup>3</sup> Number of months after the effective date of this ECA when submission is due.

<sup>4</sup> Number of months after EPA approval of the Study Plan(s) and QAPP for Phase I testing when a letter report describing transport efficiency test result(s) and what contingency testing was performed is due to EPA (see Part VII. A. and Appendix C.1.3 of the ECA). If the Study Plan(s) and QAPP(s) are not approved within 2 months of submission of the Phase I QAPP, then this deadline is extended by 6 months to accommodate re-scheduling with the thermal reactor system laboratory.

<sup>5</sup> The final report for Phase I testing will be submitted to EPA within 60 days of the completion of the Technical Consultation if the consultation does not result in an agreement to conduct further testing. If the Technical Consultation results in an agreement to conduct further testing, the final report for Phase I testing will be included in the final report for such further testing, unless agreed otherwise in the Technical Consultation (see Part VIII of the ECA regarding Phase I Technical Consultation).

<sup>&</sup>lt;sup>1</sup> Interim progress reports must be submitted by the Companies 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 XIV and Appendix E.1 of the ECA).

Phase II Fluorotelomer Incineration Testing	Test Standard	Deadline for Final Report (Months) <sup>1</sup>
Phase II Study Plan(s)	40 CFR 790.62 (b) as annotated by Part X of the ECA	2 <sup>3</sup>
Phase II QAPP	Appendix G of the ECA	6 <sup>3</sup>
Receipt of components by designated facility(ies)	Part XXIV and Appendix A.3 of the ECA	3 7
Elemental Analysis <sup>6</sup>	Appendix C.2.1 of the ECA	24 <sup>8</sup>
Combustion Stoichiometry <sup>6</sup>	Appendix C.2.2 of the ECA	24 <sup>8</sup>
Thermogravimetric Analysis <sup>6</sup>	ASTM E1868, as modified in Appendix B.1 of the ECA	24 <sup>8</sup>
Laboratory-scale combustion Testing <sup>6</sup>	Appendices C.2.4 and C.2.5, as annotated / supplemented by Appendices D.1, D.2, D.3, and D.4 of the ECA	24 8
Release assessment report	Appendix E.2 of the ECA	24 - 9

 $^{6}$  The results of this testing will be provided in the final report for Phase II testing (see Appendix C.2.5 of the ECA).

<sup>7</sup> Number of months from the submission of a Phase I letter report signifying that Phase II testing can proceed; or, number of months following the completion of a Technical Consultation agreement to proceed with Phase II testing that the Companies must meet their individual obligations to provide the formulating laboratory(ies) with the components for each composite to be tested under this ECA (see Part III. B. of the ECA).

<sup>8</sup> Number of months from the submission of a Phase I letter report signifying that Phase II testing can proceed. ; <u>or, number of months following the completion of a Technical Consultation agreement to proceed with Phase II</u> testing that the final report for this testing is due to EPA. If the study plan(s) and QAPP are not approved within 2 months of submission the Phase II QAPP, then this deadline is extended by 6 months to accommodate re-scheduling with the thermal reactor system laboratory. If Phase II testing is required by Technical Consultation agreement (see footnote 2), the deadline for submission shall be as agreed in the technical consultation.

<sup>9</sup> In the event that Phase II laboratory-scale incineration testing identifies measurable levels of PFOA (where measurable PFOA is defined to be at or above the limit of quantitation (LOQ) as defined in Appendix D.2) resulting from the incineration testing for any or all of the fluorotelomer based polymer composites tested under this ECA, the

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Companies will prepare a release assessment report to place in perspective the relevance of such measurable levels in the laboratory-scale incineration testing results with respect to full-scale municipal and/or medical waste incinerator operations in the United States. If required, the Release Assessment Report will be submitted in conjunction with the Final Report for Phase II testing (see footnote 6 and 8).

Table 1REQUIRED TESTING, TESTSTANDARDS, REPORTING AND OTHERREQUIREMENTS FOR THE LABORATORY-SCALE INCINERATION TESTING OFFLUOROPOLYMERS

Phase I PFOA Transport Testing	Test Standard	Deadline for Final Report (Months) <sup>1</sup>
Phase I Study Plan(s)	40 CFR 790.62 (b) as annotated by Part X of the ECA	2 3
Phase I QAPP	Appendix G of the ECA	3 3
Quantitative PFOA transport testing <sup>2</sup>	Appendix C.1 of the ECA	8 4 5

<sup>2</sup> At the conclusion of Phase I PFOA transport efficiency testing, and prior to initiation of Phase II, the Companies, will provide a letter/report to EPA summarizing the results of Phase I testing (see Part VII. A. of the ECA). In the event that the transport efficiency of PFOA or of total fluorine (as determined by the formulas in Appendix C.1) is greater than or equal to 70% then the Companies will proceed to Phase II Incineration Testing. In the event that the transport efficiency of PFOA and or of total fluorine (as determined by the formulas in Appendix C.1) is less then 70% then the Companies 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 VIII of this ECA.

<sup>3</sup> Number of months after the effective date of this ECA when submission is due.

<sup>4</sup> Number of months after EPA approval of the Study Plan(s) and QAPP for Phase I testing when a letter report describing transport efficiency test result(s) and what contingency testing was performed is due to EPA (see Part VII. A. and Appendix C.1.3 of the ECA). If the Study Plan(s) and QAPP(s) are not approved within 2 months of submission of the Phase I QAPP, then this deadline is extended by 6 months to accommodate re-scheduling with the thermal reactor system laboratory.

<sup>5</sup> The final report for Phase I testing will be submitted to EPA within 60 days of the completion of the Technical Consultation if the consultation does not result in an agreement to conduct further testing. If the Technical Consultation results in an agreement to conduct further testing, the final report for Phase I testing will be included in the final report for such further testing, unless agreed otherwise in the Technical Consultation (see Part VIII of the ECA regarding Phase I Technical Consultation).

<sup>&</sup>lt;sup>1</sup> Interim progress reports must be submitted by the Companies 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 XIV and Appendix E.1 of the ECA).

Phase II Fluoropolymer Incineration Testing	Test Standard	Deadline for Final Report (Months)
Phase II Study Plan(s)	40 CFR 790.62 (b) as annotated by Part X of the ECA	<u>? TBD ?</u> 3
Phase II QAPP	Appendix ?? G ?? of the ECA	<u>? TBD ?</u> 3
Receipt of components designated facility(ies)	Part XXIV and Appendix A.3 of the ECA	<u>? TBD ?</u> 7
Elemental Analysis <sup>6</sup>	Appendix C.2.1 of the ECA	<u> ? TBD ?</u> 8
Combustion Stoichiometry <sup>6</sup>	Appendix C.2.2 of the ECA	? <b>TBD</b> ? <sup>8</sup>
Thermogravimetric Analysis <sup>6</sup>	ASTM E1868, as modified in Appendix B.1 of the ECA	2. TBD 2 8
Laboratory-scale combustion Testing <sup>6</sup>	Appendices C.2.4 and C.2.5, as annotated / supplemented by Appendices D.1, D.2, D.3, and D.4 of the ECA	<u>?TBD 2</u> 8
Release assessment report	Appendix E.2 of the ECA	<u>? TBD ?</u> 8 9

 $^{6}$  The results of this testing will be provided in the final report for Phase II testing (see Appendix C.2.5 of the ECA).

<sup>7</sup> Number of months from the submission of a Phase I letter report signifying that Phase II testing can proceed; or, number of months following the completion of a Technical Consultation agreement to proceed with Phase II testing that the Companies must meet their individual obligations to provide the formulating laboratory(ies) with the components for each composite to be tested under this ECA (see Part III, B, of the ECA).

<sup>8</sup> Number of months from the submission of a Phase I letter report signifying that Phase II testing can proceed. ; or, number of months following the completion of a Technical Consultation agreement to proceed with Phase II testing that the final report for this testing is due to EPA. If the study plan(s) and QAPP are not approved within 2 months of submission the Phase II QAPP, then this deadline is extended by 6 months to accommodate re-scheduling with the thermal reactor system laboratory. If Phase II testing is required by Technical Consultation agreement (see footnote 2), the deadline for submission shall be as agreed in the technical consultation.

<sup>9</sup> In the event that Phase II laboratory-scale incineration testing identifies measurable levels of PFOA (where measurable PFOA is defined to be at or above the limit of quantitation (LOQ) as defined in Appendix D.2) resulting from the incineration testing for any or all of the fluorotelomer based polymer composites tested under this ECA, the

Companies will prepare a release assessment report to place in perspective the relevance of such measurable levels in the laboratory-scale incineration testing results with respect to full-scale municipal and/or medical waste incinerator operations in the United States. If required, the Release Assessment Report will be submitted in conjunction with the Final Report for Phase II testing (see footnote 6 and 8).