

# **ECA FOR THE LABORATORY-SCALE INCINERATION TESTING OF FLUOROPOLYMERS**

Progress Report

December 9, 2003

# Status: Appendices & Attachments

Appendix / Title		% Completed
A 1-4	Test Substance	95 %
B 1-?	ASTM Stds	0 %
C 1-2	Study Protocols	90 %
D 1-3	Attachments	0 %
E	Outline: Release Assessment Rpt.	60 %
F “?”	QAPP Outline	10 %
G	EPA Order	95 %

# **Status: ECA Document**

- Accomplishments:
  - 11/6/03 EPA circulates Draft ECA to Drafting Committee
  - 11/24/03 EPA receives initial comments
- Additional Work Needed
  - Clarify “Boilerplate Language”
  - Differing views in some 7 important areas
  - Develop alternative language to:
    - Convey Test Sponsors concerns
    - Simplify without compromising clarity or intent
    - Reduce duplicative language, where appropriate

# **Schedule**

12/22/03 Compile draft ECA document with completed appendices & attachments

12/23/03 – 1/17/04 Interested Party comment period

1/20-23/04 EPA / Drafting Committee resolve comments

1/27-28/04 Technical Workgroup discussion

1/29/04 Workgroup recommends ECA to EPA

# **Revised Schedule**

12/10-1/14 Drafting Committee completes ECA document / Appendices / Attachments

1/16/04 Compiled ECA document distributed to Technical Workgroup

1/27-28/04 Technical Workgroup Discussion

1/29/04 Workgroup presents ECA at Plenary

2/1/04 ECA review process comment period begins

# **“Boilerplate Language” #1 & #2**

- Part III Obligation of the Companies and the FMG
  - #1 40 CFR 790.62(d) and 40 CFR 790.60(a)(4) requires that the principal test sponsor be identified in the ECA
  - #2 40 CFR 790.62(b)(10) Schedule of reasonable timeables and deadlines

# **“Boilerplate Language” #3 & #4**

- **Part VIII Standards for conducting Testing**
  - #3 Good Laboratory Practice Standards:**  
40 CFR 790.60(7) cross references to 40 CFR 792 and requires that ECA testing be conducted in accordance with EPA GLP regulations.
  - #4 Interim Status Reports: required under**  
40 CFR 790.62(d)

# Other Clarifications #5

- Part Part XXI Rights of the Companies
  - Proposed revisions to indicate that the Companies maintain their rights to comment upon or challenge any potential subsequent EPA action under TSCA section 4 regarding the subject testing of this ECA



# Other Clarifications #6

- Part Part IX Study Plans & QAPP
  - 40 CFR 790.62 requires the submission of a study plan for each study conducted under an ECA.

## Guidance for Quality Assurance Project Plans

- QAPPs can also be required in ECAs and settlement agreements.
- The QAPP documents the results of a project's technical planning process, providing in one place a clear, concise, and complete plan for obtaining the type and quality of data needed and expected.
- The study plan and QAPP communicate, to all parties, the specifications for project implementation and to help ensure that the quality objectives are achieved for the project.
- The study plan can be appended to or incorporated by reference into the QAPP to reduce QAPP preparation and review time and length.

# Other Clarifications #7

- Part VII Technical Consultations
  - Suggested revisions omit:
    - The specificity outlined in the original language
    - Opportunity for public process in the event of “major changes”
  - Further discussion and clarification is needed