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Subject: Text to IPs re: QAAP

Dear David,

Attached below is text EPA has drafted describing the unresolved issue with Appendix F. As discussed this would accompany the Final Draft ECA for the Interested Party review. We have done our best to represent both views in this text and would appreciate your comments to improve the clarity (especially regarding the Companies position). We trust you will get back to us with any comments by tomorrow.



2 Views on QAPP3.wpc

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DESCRIPTION OF INCINERATION ECAs QUALITY ASSURANCE ISSUE

The Incineration ECA Drafting Committee(s) have been unable to reach consensus on Appendix F. Appendix F is an effort supported by the Companies to list the required elements of the QAPP(s) and to address how these will be addressed in the QAPP. In discussions to date, EPA and the companies have reached a common understanding on several points. The QAPP(s) will be prepared in accordance with EPA document EPA QA/R5: EPA Requirements for Quality Assurance Project Plans ("QA/R5"). The QAPP(s), as described under Appendix F, would address the elements in QA/R5 in the order in which they appear in the EPA QA/R5 guidance document. The QAPP(s) and Appendix F would cover all activities under this ECA, including creation of the composite test substances that will be assembled at designated facility(ies). Finally, EPA and the companies agree that it should not be necessary to repeat in a QAPP information that appears elsewhere. EPA and the companies agree that QAPP elements may be satisfied by cross-referencing to applicable portions of the ECA agreement including any of the appendices as appropriate or to the GLP regulations at 40 CFR 792. While both groups agree that cross-referencing is appropriate where the QAPP elements overlap with the ECA, ECA appendices or GLP requirements, the level of specificity for cross-referencing that would be included in Appendix F is still under discussion.

EPA and the Companies have been unable to agree on the scope of Appendix F. The Companies believe Appendix F should be a definitive outline of requirements that the QAPP(s) will contain. In other words, if an element is not specifically described in Appendix F, then the Companies would have no obligation to include additional elements beyond those listed in the final QAPP(s) submitted to EPA. The Companies believe that having to address items not specified in Appendix F is equivalent to a renegotiation of the testing protocols that the Drafting Committee has compiled as appendices to the ECA.

While EPA and the Companies have been working since November to develop Appendix F, EPA believes that it is not feasible to develop anything more than an outline of what the QAPP could include and that this has already been accomplished. Up-front investment in developing study protocols and detailed procedures are a necessary part of the ECA development process to clarify the scope and intent of the testing program. Nevertheless, EPA believes this up-front effort should not be viewed as a means by which pre-approval of a QAPP(s) could be established. How Test Sponsors address data quality is unique to the characteristics of each laboratory or facility participating in the testing program, the equipment available at each facility, the nature of the testing, and the systems that the Test Sponsor establishes to collect, communicate, and report data across individual elements of the testing program. EPA believes that Appendix F could be acceptable as an outline for the QAPP(s) if the right hand column is deleted from the table in Appendix F; or, if the heading for the right hand column were changed from: "Required Content of QAPP(s) for the ECA Incineration Testing" to read: "Minimum Submission Requirements for QAPP(s)." A similar change would also be needed to the title of the appendix.

EPA and the Companies are specifically seeking input from interested parties on the appropriate scope of Appendix F. EPA and the Companies also welcome alternative approaches

that the interested parties may have regarding the need for and/or how to improve Appendix F.