

OPPT-2003-0071-0094



David.Menotti@shawpittman.com

03/02/04 04:53 PM

To: Rich Leukroth/DC/USEPA/US@EPA
cc: Robert J Giraud <Robert.J.Giraud@USA.dupont.com>, Gautam Srinivasan/DC/USEPA/US@EPA
Subject: Re: FYI... IP transmittal note

Rich;

I haven't done a line-by-line comparison between the QAPP section in this and the text in Robert's earlier email; I am assuming that it is the same, based on your cover note to me. Assuming that it is, it is fine with us. I would suggest that you delete the underlining in the two paragraphs stating our respective positions -- a suggestion I neglected to make in my earlier email. However, that is a suggestion, not a demand, and I am not conditioning our approval of this document on its acceptance. I have no comments on any of the other text in this document.

David

David E. Menotti
202-663-8675

Leukroth.Rich@epamail.epa.gov
david.menotti@shawpittman.com
<Robert.J.Giraud@USA.dupont.com>, 03/02/2004 04:44
Srinivasan.Gautam@epamail.epa.gov PM
transmittal note

To:
cc: Robert J Giraud
Subject: FYI... IP

Earlier today, in the transmittal e-mail that Robert included with the revised ECA Appendices, he noted that he changed some of the text in the description of the QAPP issue. In that e-mail he said that he was counting on me to touch base with you about his changes. Based on our conversations this morning EPA left the text description of the QAPP issue as per Roberts' changes.

So... attached FYI is a copy of the transmittal note that EPA is sending out to the Interested Parties regarding the IP review of the Final Draft Incineration ECAs.

(See attached file: IP Transmittal 3-2-04.pdf)

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

(See attached file: IP Transmittal 3-2-04.pdf)



IP Transmittal 3-2-04.pc

Dear Interested Parties:

Attached below, for your review and comment, you will find the Final Draft enforceable consent agreements (ECAs) for laboratory-scale incineration of fluorotelomer based polymers (file = ECA_TelomerIncin_Fdft3-2-04.pdf), fluoropolymers (file = ECA_FluoroIncin_Fdft3-2-04.pdf), and their shared appendices (file = Appendices B through G draft 2-27-04-revised-2.pdf). Pursuant to 40 CFR 790.22(b)(7), Interested Parties have four (4) weeks in which to submit written comments on or objections to the two Final Draft documents. All comments and/or objections must be sent to EPA Docket ID Number OPPT-2003-0012 and must be received no later than 4 p.m. Eastern Standard Time on March 30, 2004. It is the intent of the Drafting Committees to compile comments and objections for presentation to the Technical Workgroups on March 30 and 31, and to summarize Workgroup discussions and recommendations at the Plenary Session scheduled for April 1, 2004.

For your information in submitting comments we provide the following description that typically accompanies EPA Public notices.

How and To Whom Do I Submit Comments?

You may submit comments/objections electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number OPPT-2003-0012 and the title: "Interested Party Review of Final Draft PFOA Incineration ECAs" in the subject line on the first page of your comment/objection. Please ensure that your submission is completed within the specified comment period.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

a. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, select "Quick Search," and then key in OPPT-2003-0012. Click on the underlined docket number to open the docket that your search retrieves, and use the "Submit Comment" button to open a comment screen. Follow the instructions to submit your comment. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

b. *E-mail*. Comments may be sent by e-mail to oppt.ncic@epa.gov, Attention: Docket ID Number OPPT-2003-0012. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

c. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you convey by hand delivery or courier to the address identified at 3 below. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *By hand delivery or courier*. Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Building Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number OPPT-2003-0012. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930.

What Should I Consider as I Prepare My Comments /Objections ?

EPA invites interested parties to provide views on the Final Draft PFOA Incineration ECAs. As noted below, EPA is specifically asking for comments regarding the Quality Assurance Project Plan (QAPP) issue and incineration ECA Appendix F. You may find the following suggestions helpful in preparing your comments:

1. The Interested Parties are specifically asked to comment on a remaining issue regarding QAPP and ECA Appendix F (for background information see below "Description of Incineration ECAs QAPP Issue").
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the science.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response.
9. Explain your views as clearly as possible.

DESCRIPTION OF INCINERATION ECAs QAPP 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 the required contents of the QAPPs. In other words, something that is not required by Appendix F is not required in a QAPP. The companies believe that having to address items not specified in Appendix F would be 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 how to improve Appendix F.