

7 pages

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03/26/04 01:30 PM

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Subject: Re: Incineration ECA Table 1 footnotes

Colleagues:

At Rich's request, I have tried my hand at drafting revisions to Table 1 which would put a sharper edge on the concept that the duty to perform both Phase I and Phase II testing is conditional on EPA having approved QAPPs.

The footnotes that are in play regarding these issues are footnotes 4 and 8. No changes are needed in Footnote 4 in the current drafts of the two ECAs (i.e., the IP Comment drafts, dated 3/2/04), because this footnote already includes the concept in question. In the attachment, I have included a draft revision to footnote 8 which would address the issue. Note that I have used exactly the same language as the language that is already in footnote 4. I have also suggested a revision to footnote 7. This revision is not a substantive change; rather, it conforms the language in footnote 8 to the language in the other two footnotes, so that we are using the same language to make the same point, all three times that we make it.

I look forward to discussing these proposed changes with all of you on Monday morning, as we continue our efforts to finalize these packages.

David

(See attached

file: DEM draft Table 1 Revisions 3-26-04.PDF)

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03/25/2004 11:17

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Subject: Re: Incineration ECA

Table 1 footnotes

David:

In my e-mail of March 19th I asked if you would put some language together for the suggested footnote fix to Table 1 for the incineration ECAs. As I recall this would be the addition of a phrase or some word changes into footnotes No 4 and No 7 that would place the obligation on the approval of the Phase I and Phase II QAPPs. It is my understanding that, with this change, there would no longer be a need for Appendix F. My e-mail asked you to circulate your suggested text addition(s) on or before March 25 so the Drafting Committee(s) will have time to reflect on the logic. Please send me an e-mail by noon tomorrow (Friday, March 26th) to let me know where you are on this. Thanks.

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03/19/2004 04:42 PM

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Subject: Re: Next calls/ incineration ECA drafting committee

David, thanks for arranging the phone lines to permit teleconferencing on booth March 29 and April 1. (see details below in e-mail from David Menotti)

The purpose of this e-mail is to follow-up on our March 10th Incineration ECA discussions.

1) I hope you agree that we made progress on the QAPP issue during the March 10th discussions. While I won't attempt to capture the numerous options that you proposed at the beginning of the call, I think that a path forward on this point will be to do the footnote fix in Table 1 (i.e., place the obligation on the approval of the Phase I and Phase II QAPP approvals). Could you put some language together that we can discuss during

the March 29th conference call? As I recall this would be the addition of a phrase into footnotes No 4 and No 7. It would be helpful to circulate your suggested text addition(s) on or before March 25th so the Drafting Committee will have time to reflect on the logic.

I understand that Barbara Leczenski has scheduled meeting to discuss Robert's concerns with EPA OECA folks. She will be able to report back on this during the March 29th phone call.

2) Although you may not remember, I have been working to obtained approvals to provide Robert with an example QAPP. I believe that the attached QAPP, prepared by the folks at Midwest Research Institute, should provide Robert with useful information as he goes about developing materials for the incineration ECAs. We do ask that you not quote or distribute the attached document (see below pdf file = MRI8-25-2000-QAPP) beyond the workgroup.

We have also identified an e-training course on preparing QAPPs. The following HTML address takes the reader to the QAPP self training course ([http://www.epa.gov/quality/trcourse.html#intro\\_qapps](http://www.epa.gov/quality/trcourse.html#intro_qapps)).

3) As you know I will be away on travel during the week of March 22nd. When I return, I will summarize comments received on the Incineration ECAs and be prepared to discuss this during the March 29th teleconference. If time permits, and if there are substantive comments, I will do my level best to send an e-mail out shortly before the Monday morning call so we will have something to work from.

Attachment: MRI QAPP example.....

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03/11/04 01:15 PM

To:Rich Leukroth/DC/USEPA/US@EPAcc:Subject:Re: Next calls/ incineration ECA drafting committee

Rich:

As you will recall, we scheduled conference calls for March 29 and April 1. Both calls are starting at 8 am EST, and are expected to run for

approximately an hour.

The call-in numbers are:

800-490-7515 (domestic)

334-323-3031 (international)

access code: \*5929163\* (don't forget the "\*" at each end!)

Please pass this information along to the usual suspects.

As you know, Robert and I were available for a call or calls on the week of the 22nd. We regret that it was not possible from your side of the table to schedule something during that week, but we understand the circumstances.

We look forward to working with you to resolve the remaining issues.

David

David E. Menotti

202-663-8675 (See attached file: MRI8-25-2000-QAPP.pdf)



DEM draft Table 1 Revisions 3-26-04.PI MRI8-25-2000-QAPP.pd

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Table 1 REQUIRED TESTING, TEST STANDARDS, REPORTING AND OTHER REQUIREMENTS FOR THE LABORATORY-SCALE INCINERATION TESTING OF FLUOROTELOMER BASED POLYMERS

Phase I PFOA Transport Testing	Test Standard	Deadline (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(s)	Appendix F 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>1</sup> A month is thirty calendar days, starting with the day following the event starting the time period in question. 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).

<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 of total fluorine (as determined by the formulas in Appendix C.1) are both individually less than 70% then the Companies will initiate a Technical Consultation with EPA. 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(s) 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(s), 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).

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Phase II Fluorotelomer Incineration Testing	Test Standard	Deadline (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(s)	Appendix F of the ECA	6 <sup>3</sup>
Receipt of components by designated facility(ies)	Part XXIV and Appendix A.3 of the ECA	3 <sup>7</sup>
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 <sup>8</sup>
Release assessment report	Appendix E.2 of the ECA	24 <sup>9</sup>

<sup>6</sup> 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 <sup>and</sup> for the approval of the Phase II QAPP(s) ~~whichever is later~~, that the Companies must meet their individual obligations to provide the designated facility(ies) with the components for each composite to be tested under this ECA (see Part III. B. of the ECA). If Phase II Testing is required by Technical Consultation agreement (see footnote 2), the deadline shall be as agreed in the Technical Consultation.

Number of months from the submission of a Phase I letter report signifying that Phase II testing can proceed when the report is due, if all components of each composite are received, or EPA determines that testing shall proceed with a partial composite(s) (see Part III. B. of this ECA). If the study plan(s) and QAPP(s) are not approved within 2 months of submission the Phase II QAPP(s), 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 shall be as agreed in the Technical Consultation.

In the event that Phase II laboratory-scale incineration testing identifies measurable levels of PFOA resulting (continued...)

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, and the approval of Study Plan(s) and QAPP(s) for Phase II testing

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<sup>9</sup> (...continued)

from the incineration testing for any or all of the fluorotelomer based polymer composites tested under this ECA, as defined in Appendix C.2.5.5, 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).