UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 5 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Chris Bryant
Managing Director
Chemical Products and Technology Division
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209

Dear Mr. Bryant:

The Assistant Administrator for EPA's Office of Prevention, Pesticides and Toxic Substances, Jim Gulliford, asked me to respond to your letter of July 17, 2008, in which you proposed a conceptual research plan on behalf of the Brominated Flame Retardants Industry Panel (BFRIP) to address data needs identified by EPA for decabromodiphenyl ether (DecaBDE, CAS No. 1163-19-5). The data needs identified in the Voluntary Children's Chemical Evaluation Program (VCCEP) were biodegradation in sludge and sediments and indoor photolysis, which are needed to better understand DecaBDE's fate and exposure. You also proposed to prepare a VCCEP Tier 3 submission by September 30, 2010, using existing data, integrating the results of the three Tier 2 studies, developmental neurotoxicity study data, and new human health or exposure data available to BFRIP.

EPA appreciates your interest in developing additional data for DecaBDE. Because you have proposed to provide the identified needed data, EPA is willing, subject to the conditions identified in the next paragraph, to temporarily suspend its plan to develop a test rule and work with you to prepare an enforceable consent agreement (ECA) as the means to develop that data. ECAs (and the process for their development) differ from research plans in that they, for example, have specific time limits for negotiations, have specific deadlines, and are enforceable. An example of an ECA is included as Attachment 1.

Although your proposal contains a number of elements that may form the basis for an ECA, EPA's interest in pursuing an ECA is conditioned on the following:

- You proposed to use OECD test guidelines 308 and 314 to evaluate biodegradation in aquatic sediments and sludge, respectively. OPPT, however, does not use OECD guidelines for enforceable data collection actions, such as ECAs and test rules. Accordingly, instead of OECD test guideline 308, EPA is willing to pursue an ECA that requires the use of OPPTS test guideline 835.4400 or 835.3180, as described in

Attachment 2 entitled "Anaerobic Debromination of Decabromodiphenyl Ether in Aquatic Sediments." Likewise, instead of OECD 314, EPA is willing to pursue an ECA that requires the use of OPPTS 835.3280, as described in Attachment 3 entitled "Anaerobic Debromination of Decabromodiphenyl Ether in Digester Sludge." The three 835 guidelines are also included as Attachments 5, 6, and 7. Before ECA discussions are initiated, biodegradation in aquatic sediments and sludge study methods based on Attachments 2 and 3 need to be developed. EPA will need to receive a draft method from you before entering ECA discussions. EPA will review the method before approving its use in the ECA.

- EPA scientists have reviewed the 835.2310 guideline which you proposed for the photolysis study and believe that a better choice would be the two tests described in Attachment 4 entitled "Photodegradation of Decabromodiphenyl Ether in the Indoor Environment." Before ECA discussions are initiated, a photolysis study method based on these two tests needs to be developed. EPA will need to receive a draft method from you before entering ECA discussions. EPA will review the method before approving its use in the ECA.

If you wish to pursue an ECA, please respond to this letter within ten business days stating that you agree to the testing approaches described above. The letter should also state that you agree to these preconditions to developing an ECA. For an ECA to be a timely mechanism for data development, a draft ECA with attached 835 guidelines and your draft method for a photolysis study will need to be received by EPA within six weeks of the date of this letter. EPA will review the draft ECA and respond within four weeks after receiving it. If these conditions can be met, EPA will announce in the Federal Register that the public will have an opportunity to participate in the public meeting to resolve any remaining differences and, unless new information or objections are received during this public participation process, EPA expects that the ECA would be concluded within the two to four-hour time frame of the public meeting.

I hope this letter clarifies EPA's expectations in offering the ECA option to BFRIP. Unfortunately, your offer to prepare a VCCEP Tier 3 submission is beyond the scope of the current identified data needs that the ECA will address and not consistent with DecaBDE's terminated status in VCCEP. However, if the ECA process is productive, the Agency may reconsider DecaBDE's VCCEP status; the Agency would welcome any additional data on DecaBDE that BFRIP can provide. Please contact Ward Penberthy of the Chemical Control Division at (202) 564-8171 if you have questions.

Sincerely,

Charles M. Auer, Director
Office of Pollution Prevention and Toxics

Attachments (7)

1. Enforceable Consent Agreement for Ethylene Dichloride (EDC), May 15, 2003.

2. Anaerobic Debromination of Decabromodiphenyl Ether in Aquatic Sediments. Testing, Analysis, Guidelines/ Standards.

3. Anaerobic Debromination of Decabromodiphenyl Ether in Digester Sludge. Testing, Analysis, Guidelines/ Standards.

4. Photodegradation of Decabromodiphenyl Ether in the Indoor Environment. Testing, Analysis, Guidelines/standards.

5. OPPTS 835.4400. Anaerobic Aquatic Metabolism. June 2008.

6. OPPTS 835.3180. Sediment/ Water Microcosm Biodegradation Test. January 1998.

7. OPPTS 835.3280. Simulation Tests to Assess the Primary and Ultimate Biodegradability of Chemicals Discharged to Wastewater. April 2008.

cc:

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