



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

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OFFICE OF
AIR AND RADIATION

Mr. Robert M. Dineen
President and Chief Executive Office
Renewable Fuels Association
425 Third Street, S.W.
Washington, D.C. 20024

Mr. Tom Buis
Chief Executive Officer
Growth Energy
777 N. Capitol Street, N.E.
Suite 805
Washington, D.C. 20002

Dear Mr. Dineen and Mr. Buis:

This letter is in response to your submissions on February 18, 2011, October 19, 2011, and February 3, 2012. On those dates, the Renewable Fuels Association (RFA) and Growth Energy submitted Tier 1 and Tier 2 data and analyses which would, if approved by EPA, partially satisfy the requirements for a fuel or fuel additive manufacturer's registration of a fuel with more than 10 volume percent (vol%) and up to 15 vol% ethanol (E15) under 40 CFR Part 79 (hereinafter referred to as E15). For any potential registrant with over \$50 million in annual revenue, Tier 1 and Tier 2 requirements must be met before registering E15. Specifically, RFA and Growth Energy submitted Tier 1 emissions speciation testing and an analysis supporting their view that the Alternative Tier 2 testing for E10 and baseline gasoline conducted by the American Petroleum Industry (API) Section 211(b) Research Group should be sufficient to satisfy the Tier 2 health effects testing requirements for E15 under the registration regulations.

Under the testing requirements in the regulations, a fuel with more than 10 vol% and up to 15 vol% ethanol would generally require its own Tier 1 and Tier 2 testing. However, with regard to Tier 2 health effects testing for any fuel, the regulations recognize that, in certain cases, previous testing might provide results which would be reasonably comparable to the results that would be provided if testing of the new fuel were performed. The Agency has discretion to decide whether such previous testing can be used to satisfy the Tier 2 testing requirements for E15. This provision of the regulations is found at 40 CFR 79.53(d) and states that:

After submission of all information and testing, EPA in its judgment shall determine whether previously conducted tests relied upon in the registration submission are adequately performed and documented and provide information reasonably comparable to that which would be provided by the tests described herein. Manufacturers' submissions shall be sufficiently detailed to allow EPA to judge the adequacy of protocols, techniques, experimental design, statistical analyses, and conclusions. Studies shall be performed using generally accepted scientific principles, good laboratory techniques, and the testing guidelines specified in these regulations.

We have evaluated your submissions and have concluded that the data and analyses provided would be sufficient to satisfy these Tier 1 and Tier 2 requirements for E15 under the registration regulations at 40 CFR 79. Our evaluation is enclosed.

We also understand from your letter dated February 3, 2012, that RFA and Growth Energy will waive any right to proportional reimbursement of testing costs under 40 CFR Part 79.56(c). You have also asked us to waive the requirement that future users of this data provide evidence that they have notified you of their use of the data and have complied or intend to comply with the above-noted proportional reimbursement requirements. We do note, however, that since you are relying on the API Section 211(b) Research Group E10 data for your E15 Tier 2 testing requirements, potential registrants must comply with any proportional reimbursement requirements of the Research Group.

If I can be of any further assistance in this matter, please feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Byron Bunker", written over a horizontal line.

Byron Bunker
Acting Director, Compliance Division
Office of Transportation and Air Quality

cc: Kristy Moore, RFA
Erin Heupel, Growth Energy
Christopher Bliley, Growth Energy