

January 21, 2014

Via E-Mail

Kenneth Olden, Ph.D.  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Mail Code: 8601P  
Washington, D.C. 20460

Re: ETBE IRIS Assessment

Dear Dr. Olden:

The Petroleum Industry Technology and Research Institute, Inc. of Japan (PITRI) submits this letter in anticipation of our meeting on January 23, 2014, with you and others on your team to discuss our serious concerns with the U.S. Environmental Protection Agency (EPA) decision to proceed with an Integrated Risk Information System (IRIS) assessment of ethyl-tert-butyl ether (ETBE). We urge EPA to re-evaluate its apparent decision to move forward with this assessment and believe, for the reasons noted below, that ETBE should never have been determined to meet the criteria for assessment. Given all the many priority assessments EPA is challenged to complete, we urge EPA to focus on substances of a higher priority and not direct its limited resources to a substance that is neither marketed in the United States nor for which there is need for an IRIS assessment.

**EPA Must Determine There Is a Need for an  
IRIS Assessment before Nominating Substances**

EPA states the following regarding its process for selecting substances for IRIS assessment:

EPA develops a list of substances for IRIS assessment development on an annual basis. The IRIS program submits queries to EPA Program Offices and Regions and the public for nominations for new assessments or updates of assessments currently on IRIS. Substances are selected based on one or more of the following factors: (1) potential public health impact; (2) EPA statutory, regulatory, or program-specific implementation needs; (3) availability of new scientific information or methodology that might significantly change the current IRIS information; (4) interest to other governmental agencies or the public; and (5)

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availability of other scientific assessment documents that could serve as a basis for an IRIS assessment. The decision to assess any given chemical substance depends on available Agency resources. Availability of risk assessment guidance, guidelines, and science policy decisions may also have an impact on the timing of EPA's decision to assess a chemical substance.<sup>1</sup>

The nominations process also must consider the purpose of an IRIS assessment itself, which is to provide information that government agencies or others can use to conduct exposure assessments and support risk management decisions.<sup>2</sup> If there is no need to conduct an exposure assessment, or if there are no risk management decisions to make, then the IRIS assessment itself would serve no purpose.

**ETBE Does Not Satisfy the Criteria for IRIS Review and  
Should Never Have Been Selected for an IRIS Assessment**

According to a 2013 Government Accountability Office (GAO) report, “the Office of Underground Storage Tanks, within the Office of Solid Waste and Emergency Response, submitted chemicals during the 2011 nomination period to support the requirement under Section 1505 of the Energy Policy Act of 2005 that the EPA Administrator conduct a study on the effects on public health of increased use of iso-octane and six other fuel additives as substitutes for methyl tertiary butyl ether (MTBE).”<sup>3</sup> The same GAO report also acknowledges, however, that: “The IRIS Program’s chemical nomination and selection process, which the

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<sup>1</sup> EPA, Integrated Risk Information System (IRIS), Site Help & Tools, Frequent Questions (updated Sept. 26, 2012), available at [http://www.epa.gov/iris/help\\_ques.htm#howsub](http://www.epa.gov/iris/help_ques.htm#howsub).

<sup>2</sup> 78 Fed. Reg. 48674 (Aug. 9, 2013) (“When supported by available data, IRIS provides health effects information and toxicity values for health effects (including cancer and effects other than cancer). Government and others combine IRIS toxicity values with exposure information to characterize public health risks of chemical substances; this information is then used to support risk management decisions designed to protect public health”).

<sup>3</sup> United States Government Accountability Office, Report to the Chairman, Committee on Environment and Public Works, U.S. Senate; Chemical Assessments: An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments, GAO-13-369 (May 2013) at 34 (GAO Report), available at <http://www.gao.gov/products/GAO-13-369>.

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agency uses to gauge interest in the IRIS Program from users inside and outside of EPA, may not accurately reflect current demand for IRIS toxicity assessments.”<sup>4</sup>

Current uses of ETBE in the United States are virtually non-existent. Manufacture of ETBE in the U.S. is predominantly for export only. Moreover, since MTBE has been banned for use as a gasoline oxygenate in at least 19 states, and the chemical and organoleptic properties for MTBE and ETBE are similar, there are no commercial opportunities for new uses now or in the future for ETBE.<sup>5</sup>

### **EPA Should Drop the ETBE IRIS Assessment to Focus on Higher Priority Substances**

The IRIS program has been under considerable scrutiny in recent years, including but not limited to issues that EPA’s chemical nomination and selection process does not reflect accurately the existing demands for assessments. The lack of public health or regulatory need for an ETBE IRIS assessment is supported by the EPA Drinking Water Contaminant Candidate List (CCL3) published in 2009 and the public nominations to the update that EPA expects to release in 2014 (CCL4).<sup>6</sup> A 2006 U.S. Geological Survey (USGS) report noted that ETBE was detected “infrequently” in sampled domestic and public drinking water wells, with a detection frequency well below 1% at an assessment level of 0.02 micrograms per liter.<sup>7</sup> PITRI appreciates EPA’s limited resources to conduct IRIS assessments and the need, considering those resources, to select substances for assessment that are particularly relevant to EPA or other agencies for the protection of public health through regulatory means.<sup>8</sup> ETBE does not meet these criteria and thus should be dropped from the IRIS program.

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<sup>4</sup> *Id.* at 15.

<sup>5</sup> *See, e.g.*, EPA, State Actions Banning MTBE (Statewide) (June 2004), available at <http://www.epa.gov/mtbe/420b04009.pdf>.

<sup>6</sup> *See* EPA-HQ-OW-2007-1189 (2009) and EPA-HQ-OW-2012-0217.

<sup>7</sup> USGS, The Quality of Our Nation’s Waters: Volatile Organic Compounds in the Nation’s Ground Water and Drinking-Water Supply Wells, Circular 1292 (Apr. 2006) at 50, available at <http://pubs.usgs.gov/circ/circ1292>.

<sup>8</sup> GAO Report at 26 (“With tens of thousands of chemicals listed with EPA for commercial use in the United States and about 1,000 new chemicals listed for commercial use each year, demand for IRIS toxicity assessments is potentially very high”).



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We look forward to visiting with you and others on January 23, 2014. Thank you for your consideration of this letter in advance of our meeting.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lynn L. Bergeson', with a long horizontal flourish extending to the right.

Lynn L. Bergeson