Message

From: Elizabeth Erwin [Erwin.ElizabethLNDU@usepa.onmicrosoft.com]
Sent: 3/12/2012 8:05:42 PM
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Subject: NEWS UPDATES: EPA Says It Will Not Use Italian Institute Data In IRIS Assessments of Gasoline Oxygenates (BNA)

EPA Says It Will Not Use Italian Institute Data In IRIS Assessments of Gasoline Oxygenates

By Pat Rizzuto

The Environmental Protection Agency announced it will not include data on leukemias and lymphomas from cancer studies conducted by the Ramazzini Institute as it completes Integrated Risk Information System (IRIS) assessments for three gasoline oxygenates.

In a March 8 announcement, EPA said it will not rely on the Italian institute's leukemia and lymphoma data it completes IRIS assessments for methanol, methyl-t-butyl-ether (MTBE), and ethyl-t-butyl-ether (ETBE). It cited differences in how pathologists from the Ramazzini Institute and those from a federally sponsored working group interpreted cancer study results.

Gregory Dolan, an executive director at the Methanol Institute, a trade association, told Bloomberg BNA that, without the Ramazzini Institute's study, he does not think there are sufficient data to support EPA's proposed finding in January 2010 that methanol is "likely to be carcinogenic to humans."

In June 2010, EPA placed IRIS assessments of these three chemicals on hold, along with an assessment of acrylonitrile, a hazardous air pollutant and industrial chemical, after pathologists from the National Toxicology Program raised questions about the assessments (114 DEN A-17, 6/16/10).

Summary of Inquiry Posted

The National Institute of Environmental Health Sciences, which manages NTP, and EPA have worked with the Ramazzini Institute since that time to address their divergent opinions, including sending an independent Pathology Working Group to Italy to review the data. NIEHS recently posted a summary of the working group's findings on its website.

EPA said that because of the differences in the interpretation of the data between the Italian institute and the Pathology Working Group regarding leukemias and lymphomas in several laboratory animal tests, "EPA has decided not to rely on data from the Ramazzini Institute on lymphomas and leukemias in IRIS assessments."

"This decision will impact IRIS assessments under development for methanol, MTBE, and ETBE. The draft assessment for acrylonitrile is not affected, as EPA relied on data from sources other than the Ramazzini Institute to complete the draft assessment," EPA said.

The agency did not reply to questions about how the absence of this data could affect the assessments or the timing of their release.

Dolan praised EPA and NIEHS for what he described as the due diligence they showed by sending the working group to review the data from the methanol and other studies.

The NIEHS summary shows the Pathology Working Group concluded that the rats in the methanol study had a respiratory infection that affected the results, he said, citing information from that summary.

64 Versus 4 Lymphomas, Leukemias

The summary said Ramazzini's pathologists diagnosed 64 lung lymphomas and leukemias in male and female rats in the methanol study compared with four such tumors being diagnosed by the independent Pathology Working Group.

Without the Ramazzini data, there are few studies available for EPA to analyze concerning the potential carcinogenicity of methanol, Dolan said. In his view, EPA should conclude the data are insufficient to assess methanol's carcinogenicity, Dolan said.

The American Chemistry Council also voiced its support for EPA's decision, but called for further IRIS reforms.

"We are encouraged that EPA recognizes the importance of making sure sound science is at the foundation for all chemical assessments under IRIS. This announcement provides further evidence that additional reforms are needed to ensure EPA establishes a transparent and consistent process for evaluating data and selecting studies," the chemistry council said.

Due to time differences, the Ramazzini Institute could not be reached March 9 for comment.

Studies Conducted Several Years Ago

Jennifer Sass, a senior scientist with the Natural Resources Defense Council, told Bloomberg BNA the Pathology Working Group investigation that led to EPA's decision should be put into perspective.

The studies reviewed by the Pathology Working Group were conducted many years ago, when respiratory infections were common among lab animals in labs all over the world, Sass said.

"Respiratory infections interfere with the ability of pathologists to interpret certain specific cancer endpoints (leukemia and lymphoma). All other cancer endpoints are reliable, and are not under review," Sass said.

"The Ramazzini Institute is a prestigious scientific institute, known and respected throughout the world. … I look forward to more high-caliber studies coming from the Ramazzini labs," Sass said.

"Although the chemical industry will try to blow this out of proportion to discredit all Ramazzini studies, the public should follow the scientific experts and ignore industry's attempts to attack the evidence that their products cause human diseases including cancer," she added.

For More Information

EPA's announcement is available at http://www.epa.gov/iris/ramazzini.htm.
NIEHS's summary of the Pathology Working Group's investigation and conclusions is available at http://tinyurl.com/7m3ko24.

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