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EPA Announces Plan of Action to Address Four IRIS Assessments

WASHINGTON – The U.S. Environmental Protection Agency (EPA) announced today its plan to address the four draft Integrated Risk Information System (IRIS) assessments that were placed on hold in June 2010, pending a review of some of the underlying studies relied on in the assessments. EPA conducts IRIS assessments to determine the potential impact of specific chemicals on people's health. The four assessments are methanol, methyl tertiary-butyl ether (MTBE), ethyl tertiary-butyl ether (ETBE), and acrylonitrile. Methanol is used in paints, varnishes, wiper fluid and adhesives. MTBE and ETBE are gasoline additives and acrylonitrile is used in the manufacture of certain plastics.

EPA held the assessments because of a report written by the National Toxicology Program (NTP), a program administered by the National Institute of Environmental Health Sciences (NIEHS). The report outlined a review of research completed by the Ramazzini Institute, a lab in Italy that conducts animal testing to evaluate the potential cancer-causing effects of chemicals. The report discussed findings from an NTP assessment of an animal study on methanol and recommended that further pathology reviews be carried out to resolve differences of opinion between NTP scientists and the Ramazzini Institute in the diagnoses of certain cancers reported in the study.

Out of an abundance of caution and to ensure the agency's chemical assessments are grounded in the soundest possible science, EPA undertook a thorough review of all ongoing and previous chemical assessments to determine which, if any, relied substantially on cancer testing from the Ramazzini Institute. EPA found six assessments, four of which were in draft form and put on hold pending further review.

EPA and NIEHS decided to jointly sponsor an independent Pathology Working Group (PWG) review, in cooperation with the Ramazzini Institute, of selected studies, including the methanol cancer assessment study. The review has begun and will continue over the next several months. The results will be made public and the cancer assessment for methanol will remain on hold until its completion.

The non-cancer health effects resulting from exposure to methanol are not under review. Therefore, the draft assessment of methanol – IRIS Methanol Toxicological Review (Non-Cancer) – will be released shortly for public comment and peer review. (More information on the peer review of the non-cancer methanol assessment is available on the IRIS website.)

The Ramazzini Institute diagnosed leukemias and lymphomas in studies of MTBE and ETBE, and found other tumors in studies of acrylonitrile, MTBE and ETBE. The PWG review of these studies will inform the interpretation of the tumor findings for those three IRIS assessments; however, based on other available data, EPA has determined that reliance on Ramazzini Institute study results is not necessary to continue with assessment development for MTBE, ETBE and acrylonitrile, including an assessment of cancer risks. Therefore, work on the assessments for the three chemicals will continue during the PWG review.

When the four assessments – methanol, MTBE, ETBE, and acrylonitrile – were put on hold in June 2010, two completed and publicly posted assessments – vinyl chloride and 1,1-dichloroethylene – were also identified as relying substantially on Ramazzini data. EPA will evaluate the results of the PWG review to inform conclusions about Ramazzini Institute tumor findings for these two assessments.

More information on the non-cancer methanol assessment: <http://www.epa.gov/iris/>