Changes Coming to the IRIS Program

Toxic Tort and Environmental Law Update

May 2012 by Mari Spears

In response to mounting criticism, the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) program is implementing several new changes. IRIS is a human health assessment program and database that establishes safety factors for more than 550 chemicals. The EPA derives its IRIS values from available toxicological literature, including human and animal laboratory data. For each chemical in the IRIS database, there is an assessment that evaluates the toxicological or health effects of the chemical and one or more risk values, including cancer and non-cancer risk assessments. "The IRIS process consists of the development of a draft toxicological review for a chemical; internal and external scientific reviews of the draft document; the EPA's responses to review comments; and the development and posting of an IRIS summary and final toxicological review to the EPA's website." (www.epagov/iris/process.htm.) The IRIS assessments are important factors in determining Superfund and other contaminated site clean-up requirements, air quality limits, drinking water maximum contaminant levels, and other environmental quality regulations, policies, and rankings.

Last year, the National Academy of Sciences and the National Research Council released an independent committee's review of the EPA's June 2010 draft formaldehyde assessment for IRIS. The committee identified several flaws with the EPA's draft assessment. "In general, the committee found that the draft assessment was not prepared in a transparent, consistent fashion with clear linkages to an underlying framework." (National Research Council (2011); Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde 2011; Washington, DC: The National Academies Press.) The EPA's assessment did not include "sufficient documentation of methods and criteria for identifying

the epidemiologic and experimental evidence to be reviewed, for evaluating individual studies, for assessing weight of evidence, for selecting individual studies for derivation of toxicity and risk estimates, or for characterizing uncertainty and variability, according to the review." *Id.* The general problems that the committee identified were not unique to the draft IRIS assessment of formaldehyde. The committee noted that problems with clarity and transparency of the methods had been a problem for at least a decade.

In response to the review, Congress held a hearing in July 2011 regarding the IRIS program and its chemical risk assessment process. In September 2011, Sens. James Inhofe (R-Okla.) and David Vitter (R-La.) requested that controversial assessments cease until the flaws in the IRIS process were addressed.

The EPA has responded to the growing criticism with several anticipated changes to the IRIS process. First, there will be early public input on the scope of the review and the scientific information to be considered in the assessment. Second, the classification system for non-cancer effects will be analogous to the cancer weight-of-evidence classifications to create consistency. Third, there will be shorter documents with tables and links to enable greater comprehension. Fourth, there will be a standing scientific advisory board to review IRIS draft assessments promoting independent peer review.

In addition to the process changes, the EPA has decided not to rely on leukemia and lymphoma cancer data collected from the Ramazzini Institute (RI) in several of its upcoming IRIS assessments. The RI is a laboratory in Italy that conducts animal testing to evaluate the potential cancer-causing effects of chemicals. In April 2011, the EPA and National Institute of Environmental Health Sciences sponsored an independent group of scientists, Pathology Working Group (PWG), to review a large group of animal studies performed at the RI. The PWG found that the RI had recorded more than three times as many leukemias and lymphomas in test animals than could be identified by the PWG.

Finally, the EPA intends to hold a workshop this summer to discuss approaches to implementing weight-of-evidence guidelines to determine if a chemical poses a noncancer health hazard to humans.

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