Legal Lookout: Evaluating Chemicals: EPA Rolls Out Its Plan

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A new EPA document may improve risk-bases evaluations. This is a must-read for environmental professionals.

On March 25, 2009, EPA announced the availability of a document entitled The U.S. Environmental Protection Agency's Strategic Plan for Evaluating the Toxicity of Chemicals. According to the agency, the purpose of the plan is to serve as a blueprint for the agency in incorporating advances in molecular biology and computational sciences into toxicity testing and risk assessment practices across the agency. This is an important document as it sets forth the agency's game plan for conducting chemical and risk assessments.

Background

The strategic plan is centered on three interrelated components: (1) toxicity pathways identification and use of this information in screening and prioritization of chemicals for further testing; (2) the use of toxicity pathways information in risk assessment; and (3) the institutional transition necessary to implement such practices across the agency. EPA stated in the document: "This strategic plan describes an ambitious and substantive change in the process by which chemicals are evaluated for their toxicity." A workgroup of the agency's Science Policy Council oversaw the development of the strategic plan, incorporating input obtained from an external peer review. The plan is available at www.epa.gov/osa/spc/toxicitytesting/docs/toxtest_strategy_032309.pdf.

According to the agency, the plan "provides a framework for EPA to comprehensively move forward to incorporate this new scientific paradigm into future toxicity testing and risk assessment practices." The agency states that the new paradigm has the potential to address complex issues in evaluating environmental contaminants for risks to human health and the environment. EPA believes that the paradigm will create more efficient and cost-effective means to screen and prioritize for further assessment the many chemicals that are already found in the environment. The new paradigm also is expected to facilitate evaluating the susceptibility of different groups of human populations, life-stages and genetic variations in the population, understanding the mechanisms by which toxicity occurs, and considering the risks of cumulative exposure to multiple chemicals, while also reducing reliance on animal testing for assessing human risk. Diminished animal testing has long been a key agency priority.

Implications

The rapid advance of molecular biology and computational sciences in toxicity testing will continue to change materially traditional risk assessment practices. To the environmental professional, it is important to be aware of how these advances will translate into regulatory measures and broad-reaching governance policies. The greater speed of testing afforded by

computational sciences will likely identify adverse effects more rapidly and perhaps correlate these effects with specific chemical substances. How these adverse effects might specifically impact an identified human subgroup or population demographic will have very significant implications for product labeling, product liability, adverse effects reporting, risk assessment, and other legal, medical and science policy matters. While this may sound futuristic and not especially relevant now, think again. Some over-the-counter bio-monitoring products are marketed now that allow consumers to test whether they have a particular susceptibility to a particular chemical substance or class of substances.

If a person or company produces, distributes, processes or otherwise manages a particular substance that is identified with a particular effect to which a well-defined demographic is believed to be more susceptible, this is important information that needs to be understood early and accounted for in business planning. Environmental, health and safety professionals are urged to review this strategic plan and carefully consider its implications. PE

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