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1999 APR -2 AM 11:48

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**AIHC SUPPORTS USE OF MODE-OF-ACTION APPROACH
WHEN COMPLETE, MECHANISTIC DATA ARE LACKING**

"Use of mode-of-action information should always take precedence over use of a default assumption," states the American Industrial Health Council (AIHC) in a new publication titled *Determining Modes of Action for Biologically Based Risk Assessments*. The brochure describes what a mode of action is, how it differs from a mechanism of action, and what its role is in the development of biologically based risk assessments.

According to AIHC, a "mode of action" is a category or class of toxic mechanisms for which the major (but not all) biochemical steps are understood. Identifying a mode of action requires solid scientific information and inference, but requires less scientific data and is considerably more feasible than having detailed knowledge and understanding of the full set of biological mechanisms by which a toxic agent exerts its effect. If mode-of-action information is available, the shape of the exposure-response relationship at low doses can be inferred, thus reducing the need to rely on default assumptions.

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The AIHC publication notes EPA's growing acceptance of the mode-of-action concept, exemplified in the Agency's inclusion of the approach in its recent revisions to the Proposed Guidelines for Carcinogen Risk Assessment. The brochure also demonstrates how specific approaches to low-dose extrapolation can be guided by mode-of-action research, thus promoting harmonization of cancer and noncancer risk assessment practices.

AIHC emphasizes that establishing a mode of action involves logic, inference, and good judgment. By encouraging the use of biologically based approaches that rely on mode-of-action information, incentives will be created for developing new scientific data that ultimately improve and refine regulations.

AIHC is a multi-industry trade association that represents manufacturers of consumer products, pharmaceuticals, petroleum, paper, chemicals, motor vehicles, foods and beverages, high technology and aerospace products. Our mission is to promote the sound use of scientific principles and procedures in public policy for the assessment and regulation of risks associated with human health effects and ecological effects. A copy of AIHC's brochure, *Determining Modes of Action for Biologically Based Risk Assessments*, is attached. For additional copies, call Kathleen Leary, AIHC Program Coordinator, at (202) 833-2131, ext. 3019.

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