



## **AMERICAN INDUSTRIAL HEALTH COUNCIL:**

### **SIGNIFICANT ACCOMPLISHMENTS IN 1986**

- AIHC's comments were instrumental in convincing the Council on Environmental Quality to rescind a rule requiring federal agencies to prepare a "worst case" analysis for environmental impact statements. The rule now requires agencies to evaluate "reasonably foreseeable adverse impacts."
- AIHC, in cooperation with the Environmental Protection Agency (EPA) and the National Academy of Sciences, co-sponsored a two-day workshop in October 1986 on the use of pharmacokinetics in the risk assessment process. AIHC advocates the use of pharmacokinetic data to determine the dose of a carcinogen affecting target tissues and organs.
- AIHC co-sponsored a three-day National Risk Assessment Workshop in March 1986 in San Antonio. The purpose of the workshop was to provide state health and environmental professionals with a better understanding of risk assessment techniques as they apply to problems of environmental contamination.
- AIHC has identified neurotoxicology as one of the most critical areas for incorporation into the risk assessment process. Consequently we have formed a Neurotoxicology Subcommittee to focus on consolidating industry efforts in the neurosciences. The new Subcommittee will assist in the development of neurotoxicity test methods, test guidelines and risk assessment procedures which accurately reflect the implications of neurotoxicology (or effectively incorporate neurotoxicology data).
- AIHC Board members met with high-level government officials including Secretary of Health and Human Services, Dr. Otis Bowen, and Office of Management and Budget Director of Regulatory Affairs, Dr. Wendy Gramm. Dr. Bowen believes in the need for a "common sense" approach to risk analysis and the importance of accurately and effectively communicating with the public about risk. The meeting with Dr. Gramm gave us an opportunity to stress the importance of sound science in making regulatory policy.
- AIHC sponsored a review and evaluation of the literature to examine the biological basis for risk assessment for chemicals causing developmental abnormalities. A "white paper" is being prepared for publication.
- AIHC was successful in convincing the Environmental Protection Agency to hold a workshop to review the scientific basis for the generic mutagenicity testing approach under the Toxic Substances Control Act. AIHC believes that a positive result in a single assay should not trigger a two-year oncogenicity study.
- AIHC submitted comments to the Food and Drug Administration (FDA) on three different proposed regulations:  
**Sensitivity of the Method (SOM):** AIHC encouraged FDA to incorporate the Statement of Principles from the White House Office of Science and Technology Policy (OSTP) report "Chemical Carcinogens: A Review of the Science and its Related Principles" and the Department of Health and Human Services Committee to Coordinate Environmental and Related Programs

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report entitled "Risk Assessment and Risk Management of Toxic Substances" as the basis for identification, evaluation and management of potential human carcinogenic risks. AIHC called for the elimination of "multiple conservatism" assumptions from scientific evaluations and urged the incorporation of the best estimate of risk unbiased by the social criteria that are evaluated in risk management decisions. AIHC also urged FDA to eliminate the use of pre-selected statistical models for estimating risk. AIHC supports the OSTP Principles which provide the basis for the selection of models and the incorporation of pharmacokinetic and mechanistic data.

**De Minimis Doctrine:** AIHC filed two sets of comments supporting the use of the *de minimis* doctrine and recommending additional scientific evaluation to provide most reasonable estimates of risk. FDA's proposals on vinyl chloride and methylene chloride gave us the opportunity to stress the importance of these concepts in the development of sound standards and regulations.

- AIHC joined with the Association of Government Toxicologists and the Society of Toxicology to co-sponsor a workshop in October 1986 on improved risk assessment procedures.
- In response to Congressional criticism of EPA, AIHC prepared detailed comments stressing the importance of using scientific data as the basis for hazardous waste regulations banning land disposal of wastes under the 1984 Resource Conservation and Recovery Act amendments. Our comments supported EPA's approach and were directed to key Congressional leaders.
- AIHC provided input to the National Toxicology Program and the International Agency for Research on Cancer concerning the interpretation of experimental data for purposes of classifying chemicals for carcinogenic potential.
- AIHC sponsored the Banbury Conference to review the scientific understanding of how cancer develops as a result of chemical exposure. AIHC is also funding a review of the scientific literature on promotion in chemical carcinogenesis.
- AIHC continues to be a strong advocate of using peer review in evaluating the scientific information upon which regulatory decisions are based. The Science Advisory Board of the Environmental Protection Agency responded positively to AIHC's recommendations on peer review and is now conducting such reviews. AIHC is working to establish a peer review mechanism in the Occupational Safety and Health Administration and throughout the Department of Health and Human Services, including the Agency for Toxic Substances Disease Registry.
- AIHC filed comments with EPA on two chemical testing rules. AIHC's comments concerned the following: (1) the need for more refined applications of structure-activity analysis before extensive testing is required; (2) the use of a "weight of the evidence technique" when determining that a substance is a neurotoxin; (3) the use of a tiered-testing approach to determine neurotoxicity; and (4) the use of alternate neurotoxicity and behavioral testing methodologies which will meet the objective of the test rule.



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