dosimetric adjustments before extrapolation. Bronchoalveolar lavage fluid (BALF) analysis should be required in the chronic study. BALF analysis will not only enable the investigator to better select the exposure concentrations for the chronic studies but also to help in understanding the biochemical and cellular sequence of events of particle-induced toxicity and carcinogenicity. Impairment of clearance should be assessed via challenge with a tagged particle.

- A positive control need not be included in every study, but each new test system (including use of a different animal species or strain) should be validated with a positive control material.
- Neoplastic endpoints recorded should include epithelial hyperplasia, alveolar bronchiolization, metaplasia, adenomas, mesotheliomas, and carcinomas.

The workshop panel also concluded that no single assay or battery of short-term assays can predict the outcome of a chronic inhalation bioassay with respect to carcinogenic effects of fibers. However, it was suggested that appropriately designed Tier II (*in vitro*) and Tier III (short-term *in vivo*) studies – as defined in an earlier workshop sponored by the Chemical Industry Institute of Toxicology (McCllellan et al., 1992) – can provide useful information to assess the relative potential of fibrous materials to cause toxicity in the lung and associated tissues. Along with information on physicochemical properties, data from a battery of short-term *in vitro* solubility/durability and cell toxicity assays (Tier II), and short-term inhalation studies (Tier III) can be used to screen and set priorities for further chronic testing of fibers.

Summary

The EPA's current health effects test guidelines for carcinogenicity, and combined chronic toxicity and carcinogenicity are widely accepted by the scientific and regulatory communities for the testing of chemical substances (EPA, 1998). It is recognized, however, that these guidelines need to be modified to take into account testing issues which are unique to fibrous particles. On July 28, 1999, EPA proposed the combined chronic toxicity and carcinogenicity test guidelines for use in the testing of fibrous particles(EPA, 1999). The proposed guidelines were developed based on the comments and recommendations made by a workshop panel experts on a number of scientific issues related to fiber testing (EPA, 1996). Whereas no single assay or battery of short-term assays can predict the outcome of a chronic inhalation bioassay with respect to carcinogenic effects, data from a battery of *in vitro* and *in vivo* short-term studies can be used to screen and set priorities for chronic testing of fibers.

Disclaimer

This paper has been reviewed and approved by the Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency. Approval does not signify that the contents necessarily reflect the views and policies of the Agency.

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CONTINUING CHALLENGES OF FIBERS IN THE WORK ENVIRONMENT

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Abstract

The National Institute for Occupational Safety and Health (NIOSH) has been mandated by Congress to conduct occupational safety and health research and training, and provide recommendations for the prevention of work-related illnesses and injuries. Specifically, NIOSH has the responsibility to: enumerate hazards present in the workplace; identify the causes of work-related diseases and injuries; evaluate hazards of new technologies and work practices; create ways to control hazards; train safety and health professionals; and recommend occupational safety and health standards. Historically, NIOSH has played a major role in identifying occupational hazards, conducting field and laboratory research to elucidate the health risks, and developing intervention strategies that eliminated or greatly reduced the hazard to workers. Research regarding the potential health risks from occupational exposure to fibers has been an important objective of the Institute for the past 28-years. Throughout this period, NIOSH has conducted workplace assessments of workers exposed to asbestos and other mineral and synthetic fibers, that have included, medical and epidemiologic evaluations, sampling and analytical method development, and the development of recommendations for the prevention of disease. The advent of the commercial development of many synthetic, and organic and inorganic fibers for use in new products and different applications has heightened the awareness of the need for the ongoing health surveillance of exposed workers; a thorough characterization of the the fibers; and the assessment of workplace conditions under which exposures occur. NIOSH has initiated several efforts to elucidate the potential health concerns of exposure to fibers. These efforts have focused on the critical evaluation of data relevant to an understanding of fiber characteristics that cause disease and the development of a tiered research approach aimed at describing the mechanisms of toxicity. This paper outlines those efforts.

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