

## **CONCEPT REVIEW – November 21, 2008**

**Contract Title:** Production and Characterization of Molds for NTP Toxicology Studies

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### **I. Purpose**

The purpose of the proposed contract is to provide bulk quantities of well-characterized specific molds and mold mixtures for use in planned NTP toxicology studies. Through this contract, the NTP seeks to develop the capability to produce individual fungi and mold mixtures that can be used in toxicological studies that will explore the relationships between mold exposure and disease, and to characterize the hazard that mold exposure may represent to human health. At this time, the NTP anticipates the production and characterization of 4 individual fungal strains and 2 mixtures.

### **II. Background**

The National Toxicology Program (NTP) was established as a cooperative effort within the Department of Health and Human Services to coordinate and manage toxicology testing efforts and provide the scientific information about environmental exposures needed by health and regulatory agencies for sound public health decision-making. The NTP is headquartered at the National Institute of Environmental Health Sciences (NIEHS), but also includes the relevant activities at the National Institute for Occupational Safety and Health and the National Center for Toxicological Research. The NIEHS as part of the National Institutes of Health (NIH), has a mission is “to reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease.”

Molds were nominated to the NTP in 2004, and the NTP Board of Scientific Counselors and the Executive Committee endorsed the study of molds. In 2007, an information group was convened by the NTP to discuss organisms and study design. The group identified several key areas, including growing conditions, life-stage, and physical and chemical properties of molds as having a direct bearing on study design and potential study outcomes. Key recommendations of the information group were: 1) the use of single organisms as well as mold mixtures cultured on different building materials; 2) production of a sufficient quantity of each mold, or mold mixture that were harvested at a particular growth stage and dried for use in the entire study; and 3) characterization of molds with respect to mycotoxins, glucans allergens, particle size, protease activity, colony forming units and spores.

### **III. Objectives**

The overall objective of the NTP Mold Production contract is to establish a mechanism to acquire bulk quantities of specific molds and mold mixtures for use in toxicology studies. More specific objectives include:

- Grow individual organisms and mold mixtures on relevant building materials as fresh isolates from specific samples and/or colonies provided by the NTP.
- Obtain samples from NTP-specified fungal colonies, sites or sources.
- Microscopically characterize the fungi and mold mixtures produced.
- Chemically characterize the fungi and mold mixtures with respect to specific substances of interest, such as mycotoxins, glucans, allergens, protease activity and endotoxins.
- Confirm the viability and life-stage characteristics of the materials produced.
- Provide bulk quantities of these fungal materials in dry form to the NTP or an NTP designated contractor for use in toxicology studies.
- Provide guidelines for the safe handling of the fungal materials produced.
- Provide detailed information on the procedures used in production and characterization of the material, as well as instructions for reconstituting the dried fungal material into a viable, growing colony.

### **IV. Priority**

This support contract is considered a high priority because it would support the NIEHS and NTP efforts in assessing the potential health effects of mold exposures. There is a strong need for well characterized fungal materials to perform an assessment of mold toxicity which will provide scientific information to protect public health.