National Institute of Environmental Health Sciences
National Toxicology Program
Interagency Agreements

NIH/NIEHS/DNTP and FDA/NCTR

In December 1992, the NIEHS and FDA established a formal interagency agreement (IAG). The IAG established a mechanism where the NTP would support toxicology studies on FDA-regulated agents that were nominated to the NTP, and conduct the studies at the NCTR. These studies are designed to provide the FDA and other regulatory agencies with hazard identification and dose-response data to support risk assessment and risk management decisions that could affect public health.

This IAG has supported studies in the following program areas: endocrine active agents, dietary supplements, food contaminants, AIDS therapeutics, pediatric medicines, electromagnetic radiation, cosmetics, and nanoscale materials. Studies in these program areas have produced around 16 published NTP Technical Reports and over 200 peer-reviewed journal publications. Some of the data from the IAG-supported studies have led to increased understanding of the pharmacokinetics, mechanism of action, or dose-response of a substance. Other data have led to refinement of risk assessment models.

NIH/NIEHS/DNTP and CDC/NIOSH

The NIEHS/DNTP and CDC/NIOSH have two IAGs. One IAG was established in the early 1990s in general response to increased efforts to study non-cancer endpoints by the NTP. NIOSH and NTP have conducted studies to assess the potential toxicity of exposures to substances such as fungi, mycotoxins, volatile organics, lead, latex, nickel, isocyanates, and beryllium. Studies included workers that are exposed to mixtures of chemicals such as miners, farmers, health care workers, autoworkers, and firefighters. There have also been a number of studies examining how genetic variability in immune-inflammatory-antioxidant responses contributes to the development and severity of inflammatory and allergic disease in people of different occupations.

The second IAG involves multiple projects. NTP and NIOSH worked to establish methodologies to assess complex mixtures such as asphalt fume, welding fume, and tungsten fibers. NIOSH and NTP are jointly supporting two large initiatives that evaluate emerging issues in nanotechnology. One project focuses on identifying workplaces engaged in the development, production, and use of engineered nanomaterials and characterizing the potential for worker exposure to selected engineered nanoparticles. A second facet focuses on evaluating potential toxicity from workplace exposures to engineered nanomaterials. A study with similar purpose and design is evaluating occupational exposure to bisphenol A.

Many studies performed under these IAGs are published in the peer-reviewed literature and have been used for hazard identification, regulatory, and intervention purposes as appropriate.

NIH/NIEHS/DNTP and CDC/DLS

The NIEHS/DNTP and CDC/Division of Laboratory Sciences (DLS) are participating in a pilot study to characterize exposure profiles in a subset of 50 Danish women who will be enrolled in a larger study of 500 women designed to assess whether exposure to several common endocrine disrupting chemicals (EDCs) is related to reproductive health problems (fertility, risk of miscarriage, and low birth weight) and childhood obesity and potentially other health outcomes in the children. EDCs from the organotins and phthalates classes will be evaluated. Blood and urine samples will be collected three times from each woman, once prior to pregnancy and twice during pregnancy. This collaboration between NIEHS/DNTP and CDC/DLS facilitates common goals in understanding individual exposure profiles for multiple chemicals in woman of reproductive age.

NIH/NIEHS/DNTP and NIH/NCATS/DPI

This IAG supports on-going and anticipated studies to be conducted at the Division of Pre-Clinical Innovation (DPI) on the evaluation of high-throughput and high-content screening (HTS/HCS) assays in support of Tox21. Tox21 is an ongoing collaboration among Federal agencies to characterize the potential toxicity of chemicals by using cells and isolated molecular targets instead of laboratory animals. The collaboration between NTP and DPI will produce data for substances that lack needed toxicological information. Data from HTS/HCS assays can be used to prioritize substances for further studies, including toxicological evaluation, mechanisms of actions investigation, and development of predictive modeling for biological response. The use of HTS/HCS assays should greatly increase the number of substances tested and decrease the cost of testing.