November 13, 2001

Dr. William S. Stokes
Director, NICEATM, NIEHS
MD-EC-17
PO Box 12233
Research Triangle Park, NC 27709

Re: NIH Publication 01-4499, "Report of the International Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity"

Dear Dr. Stokes:

In Defense of Animals appreciates the opportunity to offer comments on the International Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity conducted in October 2001. IDA is a national, non-profit organization dedicated to promoting the welfare of animals. We speak on behalf of our 75,000 U.S. members and the millions of animals used in toxicity testing.

IDA applauds the International Workshop conducted by NIEHS as yet another step to reduce the current reliance on animal tests to assess chemical toxicity in humans. In the quest to validate non-animal methods of toxicity testing, it is important to note that the original animal methods were never formally validated.

Indeed, toxicity tests on rodents and other animals have been widely criticized by large numbers of scientists and doctors for yielding results that are misleading or erroneous to humans.

Nearly a decade ago, in March 1993, the New York Times reported:
"So much evidence has accumulated that chemicals frequently have wholly different effects in animals and humans that officials throughout government and industry often do not act on the studies' findings." (Brinkley, Joel, "Many say lab-animal tests fail to measure human risk," New York Times, March 23, 1993).

The article continues: ".many of the assumptions driving the rat and mouse research 'do not appear to be valid.' The experts particularly questioned the practice of feeding rodents the 'maximum tolerated' dose of the chemical being tested, the MTD, as it is called."

Philip H. Abelson who, as Deputy Editor of Science magazine reviews a great deal of data in his role, wrote of the MTD:
"The rodent MTD test that labels plant chemicals as cancer-causing in humans is misleading. The test is likewise of limited value for synthetic chemicals. The standard carcinogen tests that use rodents are an obsolescent relic of the ignorance of past decades." (Science, vol. 249, p1357, 1990).

A group of scientists at Carnegie-Mellon University in Pittsburgh summed it up thus:

"For almost all of the chemicals tested to date, rodent bioassays have not been cost-effective. They give limited and uncertain information on carcinogenicity, generally give no indication of mechanism of action, and require years to complete. [They are] rarely the best approach for deciding whether to classify a chemical as a human carcinogen." (Lave, Dr. Lester, Nature: vol. 336, p631, 1988).

Only when animals are removed from the laboratory and replaced with accurate, cost-effective and cutting-edge technologies we will truly be able to ensure human safety. It is time to bring toxicity testing into the twenty-first century and end reliance on animal models, for both the benefit of humans and animals.

Respectfully,
Barbara Stagno, RN
Director of Programs and Communications
In Defense of Animals