



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

400 Seventh St., S.W.
Washington, D.C. 20590

MAY - 7 2003

Mr. Kenneth Olden, Ph.D.
Director
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709

Dear Mr. Olden:

Thank you for your letter to Secretary Mineta which forwarded toxicological test recommendations to the U.S. Department of Transportation (DOT) from the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The DOT was one of several Federal agencies that received the toxicological test recommendations for consideration. Your letter was referred to the Research and Special Programs Administration (RSPA), the agency within DOT responsible for regulations on the transportation of hazardous materials and participation in ICCVAM.

As requested, we reviewed the toxicological test recommendations. Based on ICCVAM's work, in March 2002 the Expert from the United States of America transmitted a proposal to the United Nations Economic and Social Council's Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labeling of Chemicals to amend the definition for acute oral toxicity in the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations). The proposal would allow the use of three alternative Organization for Economic Co-operation and Development (OECD) Test Guidelines (TGs) that have been developed and implemented to replace TG 401 (Acute Oral Toxicity). The three TGs are the Fixed Dose Procedure (FDP, TG 420), the Acute Toxic Class Method (ATCM, TG 423), and the Up-and-Down Procedure (UDP, TG 425).

The proposal was considered and adopted by the UN Committee. The amended definition for "LD50 for acute oral toxicity" will appear in the thirteenth revised edition of the UN Recommendations which is scheduled to be published later this year. Subsequently, the DOT will issue a notice of proposed rulemaking (NPRM) to propose amending the Hazardous Materials Regulations (HMR) to harmonize the HMR with the UN Recommendations. The NPRM will include a proposal to amend the definition for LD50 acute oral toxicity to reflect the ICCVAM recommendation.

I hope this information is useful. If we can be of further assistance in this matter, please contact Ms. Patricia Klinger, Director of External Communications, at (202) 366-4831.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Bonasso', with a long horizontal flourish extending to the right.

Samuel G. Bonasso
Acting Administrator