Workshop on Acute Chemical Safety Testing: Advancing In Vitro Approaches and Humane Endpoints for Systemic Toxicity Evaluations

National Institutes of Health (NIH) Natcher Conference Center

February 6 – 7, 2008

Workshop Agenda and Topics

Day 1   Wednesday, February 6, 2008

0800   Registration

0830   Opening Session - Welcoming Remarks
    William Stokes, D.V.M., DACLAM, Director NICEATM, Executive Director, ICCVAM
    Marilyn Wind, Ph.D., CPSC, Chair, ICCVAM
    Thomas Hartung, M.D., Ph.D., Director, ECVAM
    Hajime Kojima, Ph.D., Director, JaCVAM

Workshop Objectives
    William Stokes, D.V.M., DACLAM

Session 1   Acute Systemic Toxicity: Public Health Significance and Regulatory Testing Needs
    Co-chairs:  William Stokes, D.V.M., DACLAM (NIEHS)
                Marilyn Wind, Ph.D. (CPSC)

    0900   Public Health Perspective of Acute Poisoning
            Daniel Cobaugh, PharmD., DABAT, Director of Research and Program Development, American Society of Health-System Pharmacists (ASHP)
            Research and Education Foundation, Silver Spring, MD

    0930   Regulatory Needs and Uses for Acute Systemic Toxicity Data
            Amy Rispin, Ph.D., Senior Scientist, Field and External Affairs Division, Office of Pesticide Programs, EPA

Session 2   Acute Systemic Toxicity: Human and Animal Assessments, Biomarkers, and Key Pathways
    Co-Chairs:  Debbie McCall (EPA)
                Thomas Hartung, M.D., Ph.D. (ECVAM)

    0950   Data Currently Collected During Acute Systemic Toxicity Tests
            Gary Wnorowski, B.A., M.B.A., LAT, President, Eurofins Product Safety Laboratories

    1010   Break


1030  **Quantifying Evident Toxicity for the Fixed Dose Procedure**
Robert Guest, B.Sc., Head of Alternative and Acute Toxicology, Safepharm Laboratories

1050  **Clinical Biomarkers Used to Diagnose and Treat Acute Poisoning in Humans**
Frank Paloucek, Pharm.D. DABAT, FASHP, Director of Residency Programs, College of Pharmacy, University of Illinois at Chicago

1120  **Clinical Biomarkers Used to Diagnose and Treat Acute Poisoning in Animals**
Steven Hansen, D.V.M., DABT, DABVT, Senior Vice President, ASPCA Animal Poison Control Center, University of Illinois at Urbana-Champaign

1150  Lunch

1250  **Methodologies for Collecting Clinical Biomarker Data in Laboratory Animals**
Karen Steinmetz, Ph.D., DABT, Director, Mammalian Toxicology Dept., Biosciences Division, SRI International

1310  **Non-Invasive and Minimally Invasive Techniques for Measuring Physiological Parameters in Laboratory Rodents**
Kathleen Murray, D.V.M., M.S., DACLAM, Senior Director, Animal Program Management, Charles River Laboratories

1335  Break

1350  **Concurrent Breakout Group Discussions**

a.  **Breakout Group 1: Key Pathways for Acute Systemic Toxicity**
Co-chairs: Daniel Acosta, Ph.D., Dean, College of Pharmacy, University of Cincinnati
Frank Paloucek, PharmD., DABAT, FASHP, Director of Residency Programs, College of Pharmacy, University of Illinois at Chicago
Recorders: David Allen, Ph.D., Integrated Laboratory Systems, Inc.
Raymond Tice, Ph.D., Deputy Director, NICEATM, NIEHS

b.  **Breakout Group 2: Current Acute Systemic Toxicity Injury and Toxicity Assessments**
Co-chairs: A. Wallace Hayes, Ph.D., DABT, FATS, Flbiol, Science Advisor and Visiting Scientist, Harvard School of Public Health
Daniel Marsman, D.V.M., Ph.D., DABT, Section Head, Animal Welfare and Alternatives, Procter & Gamble
Judy Strickland, Ph.D., DABT, Integrated Laboratory Systems, Inc.
1520    Break

1535    Concurrent Breakout Group Discussions (continued)

1700    Breakout Groups Adjourn

1715    Breakout Group Co-chairs meet with Organizing Committee

Close of Day 1
Day 2  Thursday, February 7, 2008

0800  Registration

0830  Plenary Session - Discussion of Conclusions and Recommendations Reached by Breakout Groups 1 & 2

Co-Chairs:  William Stokes, D.V.M., DACLAM, NIEHS/NICEATM
            Marilyn Wind, Ph.D., CPSC

0830  a.  Breakout Group 1: Key Pathways for Acute Systemic Toxicity

Co-chairs:  Daniel Acosta, Ph.D.
            Frank Paloucek, PharmD. DABAT, FASHP

0850  b.  Breakout Group 2: Current Acute Systemic Toxicity Injury and Toxicity Assessments

Co-chairs:  A. Wallace Hayes, Ph.D., DABT, FATS, Flbiol
            Daniel Marsman, D.V.M., Ph.D., DABT

Session 3  Humane Endpoints

Co-Chairs:  Masih Hashim, Ph.D. (EPA)
            Cassandra Prioleau, Ph.D. (CPSC)

0910  The Concept of Humane Endpoints and Their Identification: Application for Acute Systemic Toxicity Testing

William Stokes, D.V.M., DACLAM, NIEHS, Director, NICEATM

0930  Opportunities for Detecting Pain and Distress Associated with Acute Systemic Toxicity

Steven Niemi, D.V.M., DACLAM, Director, Center for Comparative Medicine, Massachusetts General Hospital

1000  Break

Session 4  State of the Science: Using In Vitro Methods to Predict Acute Systemic Toxicity

Co-Chairs:  Steven Reynolds, Ph.D. (NIOSH)
            Hajime Kojima, Ph.D. (JaCVAM)

1015  The Future of Toxicology as a Predictive Science

Melvin Andersen, Ph.D., DABT, Director, Division of Computational Biology, The Hamner Institutes for Health Sciences

1045  Recommendations from the ICCVAM-NICEATM International Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity

A. Wallace Hayes, Ph.D., DABT, FATS, Flbiol, Science Advisor and Visiting Scientist, Harvard School of Public Health
Current ICCVAM Recommendations for the Use of In Vitro Test Methods to Estimate Acute Systemic Toxicity
Marilyn Wind, Ph.D., CPSC

The ACuteTox Project: Optimization and Prevalidation of an In Vitro Test Strategy for Predicting Human Toxicity
Thomas Hartung, M.D., Ph.D., Director, ECVAM

Using High Throughput Screening (HTS) to Identify Predictive In Vitro Biomarkers for Acute Systemic Toxicity
Raymond Tice, Ph.D., Deputy Director, NICEATM, NIEHS

Lunch

Concurrent Breakout Group Discussions

Co-chairs: Helen Diggs, D.V.M., M.Ed., SACATM member; Director, Office of Laboratory Animal Care, University of California, Berkeley
Steven Niemi, D.V.M., DACLAM, Director, Center for Comparative Medicine, Massachusetts General Hospital
Recorder: David Allen, Ph.D., Integrated Laboratory Systems, Inc.

b. Breakout Group 4: Application of In Vivo Mode of Action and Mechanistic Information to the Development and Validation of In Vitro Methods for Assessing Acute Systemic Toxicity
Co-chairs: Melvin Anderson, Ph.D., DABT, Director of the Division of Computational Biology, The Hamner Institutes for Health Sciences
Eugene Elmore, Ph.D., Project Scientist, Department of Radiation Oncology, University of California, Irvine

c. Breakout Group 5: Industry Involvement in Test Method Development, Validation, and Use
Co-chairs: Robert Scala, Ph.D., DABT, DATS, Consultant
William Stott, Ph.D., DABT, Senior Scientist, Toxicology and Environmental Research and Consulting, The Dow Chemical Company
Recorder: Judy Strickland, Ph.D., DABT, Integrated Laboratory Systems, Inc.
1420     Break

1435     Concurrent Breakout Group Discussions (continued)

1535     Break

1550     Plenary Session - Discussion of Conclusions and Recommendations Reached by the Breakout Groups
Co-Chairs:  William Stokes, D.V.M., DACLAM, NIEHS/NICEATM
            Marilyn Wind, Ph.D., CPSC

Co-chairs:  Helen Diggs, D.V.M., M.Ed.
            Steven Niemi, D.V.M., DACLAM

1610     b.  Breakout Group 4: Application of In Vivo Mode of Action and Mechanistic Information to the Development and Validation of In Vitro Methods for Assessing Acute Systemic Toxicity
Co-chairs:  Melvin Andersen, Ph.D., DABT
            Eugene Elmore, Ph.D.

1630     c.  Breakout Group 5: Industry Involvement in Test Method Development, Validation, and Use
Co-chairs:  Robert Scala, Ph.D., DABT, DATS
            William Stott, Ph.D., DABT

1650     Closing Comments
Marilyn Wind, Ph.D., CPSC, Chair, ICCVAM
William Stokes, D.V.M., DACLAM, Director NICEATM, Executive Director, ICCVAM

1700     End of Meeting