ILSI Health and Environmental Sciences Institute

REDUCING ANIMAL USE IN TOXICITY TESTING

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TECHNICAL COMMITTEE ON AGRICULTURAL CHEMICAL SAFETY ASSESSMENT (ACSA)

The mission of the ACSA Technical Committee is to provide a mechanism for reaching consensus across sectors (government, academia, industry) on the development of scientifically credible and viable methods for assessing the safety of crop protection chemicals more efficiently, with fewer animals, and with fewer artifacts.

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ACSA Membership

MULTI-SECTOR, INTERNATIONAL PARTICIPATION

Government Participation: DG Health and Consumer Protection (Belgium), European Commission, European Food Safety Authority, Federal Institute for Risk Assessment (Berlin), INRA (France), OECD, PMRA (Health Canada), RIVM (Netherlands), US EPA

Academic Participation: Imperial College School of Medicine & Technology, Johns Hopkins SPH Center for Alternatives to Animal Testing, Medical College of Wisconsin, Michigan State University, Mississippi State University, University of California (Riverside), University of Nottingham, University of Padua, University of Southampton

Industry: BASF Corporation, Bayer CropScience, Dow AgroSciences, DuPont Crop Protection, Monsanto Company, Syngenta Ltd.

Other Participants: BBL Sciences, CIIT Centers for Health Research, Pacific Northwest National Laboratory, toXcel International Ltd., Tox Path Inc.

ACSA GOAL

Develop a flexible, tiered testing approach to evaluating agricultural chemical safety. This approach should provide assurance that the chemical can be used without damaging human health, and should take into account the toxicological properties and use patterns of the chemical.

ACSA TECHNICAL COMMITTEE OBJECTIVES

- Integrate metabolic and kinetic data into the safety assessment process (ADME Task Force).
- Develop a hierarchy of study types, endpoints, and triggers to cover vulnerable life stages (Life Stages Task Force).
- Develop a tiered testing framework for endpoints such as neurotoxicity, carcinogenicity, and chronic toxicity (Systemic Toxicity Task Force).
- Evaluate the range of relevant human exposure situations in the context of experimental study design.

Reduction in Animal Use (ACSA Project)

Each of these objectives includes a commitment to limit unnecessary or redundant testing, thus reducing the number of animals used in safety assessments.

How can the number of animals be reduced?

- ADME/PK data are collected early. These data inform dose-setting for definitive studies and assist in species selection.
- The first tier in life stages testing could be an "extended" one-generation study. This modified study provides valuable insight into the need (or lack thereof) for additional testing.
- Systemic toxicity testing could be initiated with a comprehensive 28-day study. This study identifies triggers (or lack thereof) for longer-term testing (e.g., carcinogenicity).

ACSA TIMING, NEXT STEPS

- The final tiered testing approach will be completed in early 2004. A scientific article summarizing the approach will be submitted for publication in the peer-reviewed literature.
- December 7-10, 2003, Society for Risk Analysis meeting (Baltimore) – symposium
- March 21-25, 2004, Society of Toxicology meeting (Baltimore) – workshop