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# AGRICULTURAL CHEMICAL SAFETY ASSESSMENT

## Opening Remarks

Neil G. Carmichael, PhD  
Bayer CropScience

November 16, 2005  
Nice, France



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## Why Reconsider the Agricultural Chemical Safety Assessment Process?

- Many assessment methodologies originated in the 1960s and 1970s.
- Knowledge of toxicology and testing capabilities increased dramatically in the last 40 years.
- More sophisticated and demanding potential health impact assessments are now required (e.g., intermittent exposure, susceptible populations, etc.)
- Multi-sector, international interest exists in determining whether the process can be made more efficient and accurate.



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## ACSA Project History

- **January 2000:** Concept is proposed at HESI Annual Meeting
- **June 2000:** First meeting held in HESI offices, Washington, DC
- **February 2001:** Steering Team is formed
- **April 2001:** Steering Team convenes scientific workshop
- **October 2002:** Committee forms Task Forces to develop elements of a tiered testing approach
- **2003-2004:** ADME, Life Stages, and Systemic Toxicity Task Forces develop detailed proposals
- **2005:** Manuscripts are prepared describing proposed ACSA tiered testing approach, and are submitted to a scientific peer-reviewed journal
- **2006:** ACSA Technical Committee is sunset



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# HESI ACSA Technical Committee

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## Committee Objective:

To provide a mechanism for reaching consensus across sectors (industry, government, and academia) 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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# Technical Committee Participation

- **Chair:** Dr. Neil Carmichael (Bayer CropScience)
- **Vice-Chair:** Dr. Tim Pastoor (Syngenta Crop Protection)
- **Private Sector:** 6 agchem/chemical companies  
BASF, Bayer CropScience, Dow AgroSciences, DuPont Crop Protection, Monsanto, Syngenta
- **Academia:** 9 institutions represented  
Imperial College London, Johns Hopkins University, Medical College of Wisconsin, Michigan State University, Mississippi State University, Università di Padua (Italy), University of California Riverside, University of Nottingham (UK), University of Southampton (UK)
- **US Government:** EPA (OPP, NHEERL, NCEA)
- **Non-US Government:** 6 institutions represented  
European Commission, European Food Safety Authority, German Federal Institute for Risk Assessment, Health Canada, OECD, Dutch RIVM



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# April 2001 Workshop: Developing Strategies for Agricultural Safety Evaluation

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Workshop recommendation:

*Develop a tiered approach to deciding what studies should be done (and in what order) for safety assessment. This approach should define a methodology which can be used to provide assurance that an agricultural chemical can be used without damaging human health, and which takes into account the toxicological properties and the use pattern of the chemicals.*



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## How Can Testing Be Improved?

- Introduce greater flexibility – science should drive the testing strategy.
- Incorporate the use of a tiered approach – develop a “basic” testing package (i.e., Tier 1), with subsequent tests (i.e., Tier 2) built on Tier 1 results.
- Emphasize the importance of reducing and refining animal usage.
- Integrate improved understanding of exposure.
- Consider broader applicability of the improved testing approach for other chemical classes and uses.



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# ACSA TASK FORCES

## ADME Task Force

Dr. Hugh Barton (EPA/NCCT)

Dr. Tim Pastoor (Syngenta Crop Protection)

## Systemic Toxicity Task Force

Dr. Alan Boobis (Imperial College London)

Dr. John Doe (Syngenta Ltd.)

## Life Stages Task Force

Dr. Ralph Cooper (EPA/NHEERL)

Dr. Jim Lamb (THE WEINBERG GROUP)





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# Publications

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A series of four scientific manuscripts (overview, ADME, systemic toxicity, and life stages) has been submitted to *Critical Reviews in Toxicology* for publication as a “special issue.”



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## 2003-2004 Outreach

### 2003:

- US EPA Science Policy Council Workgroup on Toxicity Testing
- US EPA Office of Pesticide Programs
- OECD Working Group on Pesticides (Paris)
- EuroTox meeting (Florence)
- Society for Risk Analysis Annual Meeting (Baltimore, MD)

### 2004:

- Society of Toxicology Annual Meeting (Baltimore MD)
- ILSI Brasil and ANDEF (a division of CropLife Latin America) (Brazil)
- NAS/NRC Committee on Toxicity Testing and Assessment of Environmental Agents (Washington, DC)
- American Bar Association Committee on Pesticides, Chemical Regulation and Right-to-Know (Washington, DC)



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## 2005 Outreach

- **January 2005:** OECD Side Meeting to Workshop on Advancing Worksharing of Agricultural Pesticide Reviews (Washington, DC)
- **May 2005:** US Environmental Protection Agency Science Forum (Washington, DC)
- **June 2005:** Life World Watch Center (Japan)
- **July 2005:** CropLife America Human Health and Risk Assessment Committee (Washington, DC)
- **September 2005:** EuroTox meeting (Krakow, Poland)
- **October 2005:** National Toxicology Program Laboratory of Experimental Pathology (Research Triangle Park, NC)
- **November 2005:** Twenty-Sixth Annual Meeting of the American College of Toxicology (Williamsburg, VA)
- **November 2005:** International Society of Regulatory Toxicology and Pharmacology Workshop (Baltimore, MD)
- **November 2005:** HESI Workshop on Framework Approaches to Risk Assessment (Nice, France)