



# Collaboration between Monitoring Authorities (MA), Regulatory Authorities (RA) and Test Facilities (TF) on GLP Principles – (An Example of a Focused Collaborative Effort that Paid Off)

Betsy Grim, Director of Quality Assurance, Office of Pesticide Programs

Thomas Steeger, PhD Senior Science Advisor, Environmental Fate and Effects Division, Office of Pesticide Programs

USEPA. Washington DC, USA

[Grim.betsy@epa.gov](mailto:Grim.betsy@epa.gov)

[Steeger.thomas@epa.gov](mailto:Steeger.thomas@epa.gov)



- Thomas Steeger, PhD, Senior Science Advisor
- John Helm, PhD (Office of Enforcement and Compliance Assurance)
- Stephanie Irene, PhD, Senior Science Advisor (Environmental Fate and Effects Division)
- Lora Johnson, Director of Quality Assurance (Office of Research and Development)



# Legal Authority



- Federal Insecticide Fungicide Rodenticide Act (FIFRA)  
Food Drug and Cosmetic Act (FDCA) (authority to regulate pesticides)
- US Code of Regulations 40 (CFR) Part 158 (regulations on Data Requirements for Registration of Pesticides)
- 40 CFR Part 160 (Good Laboratory Practices)



# *Evaluating Pesticide Safety*



- Transparency
- Objectivity
- Consistent with Scientific Information
- Scientifically Sound



# *Evaluating Pesticide Safety*



- Guidelines
- Good Laboratory Practice (GLP)
- Laboratory Monitoring Authority (OECA)



# *FIFRA GLP Program*



- OECA conducts inspections of facilities
- OPP may request inspections
- Special requests for highly influential scientific assessments



# Atrazine



- One of the most studied pesticides
- 6,000 studies in EPA files
- Preliminary Risk Assessment 2001
- Revised Risk Assessment 2002
- Interim reregistration Eligibility Decision 2003



# *Uncertainty*



- Does atrazine affect frog gonadal development?
- Reviewed 17 laboratory and field studies
- Information scientifically flawed
- Studies not conducted in accordance with standard protocols
- No firm conclusions



# *FIFRA Scientific Advisory Panel (SAP)*



- Scientific Peer Review
- Significant Scientific Uncertainty
- Source of Controversy
- Advised EPA to require new research



# Tiered Study Approach



- African clawed frogs (*Xenopus laevis*)
- Tier 1-laboratory studies to determine whether atrazine affects amphibian gonadal development
- GLP compliant protocol



# *Inspections*



- **Leibniz Institute for Freshwater Ecology and Inland Fisheries (Berlin, Germany) (June 27 - July 1, 2005)-- in-life portion of study.**
- Thomas Steeger, PhD, Senior Science Advisor (OPP Environmental Fate and Effects Division)
- John Helm, Ph.D. (OECA)
- German GLP Federal Bureau, Institute for Risk Assessment



# *Inspections*



- **Wildlife International Limited, Easton, Md. (July 11 - 14, 2004)-- in-life portion of study.**
- Thomas Steeger, PhD (EFED)
- Stephanie Irene, PhD, Senior Science Advisor (EFED)
- John Helm, PhD (OECA)



# *Inspections*



- **Experimental Pathology Laboratory (August 17 - 18, 2006)-- histological analyses of tissues.**
- John Helm, PhD (OECA)
- Lora Johnson, (ORD NERL)
- Thomas Steeger, PhD (EFED).



# *Inspections*



- Intended to identify potential methodological issues in advance
- Mutual goal of quality science
- No GLP violations



# *Benefits of Collaboration*



- Understand logistical constraints
- Fostered level of trust
- Identified problems early
- Became familiar with methods



# *Additional Benefits for Registrant*



- Comments improved quality of studies
- Rigor of review applied to FIFRA GLP studies
- Increased level of detail and accountability