

US EPA ARCHIVE DOCUMENT

OPP 21st Century Activities



**PRESENTATION TO THE PPDC
NOVEMBER 30, 2012**

OPP 21st Century Vision



- **OPP Vision**

- Integrative (Tiered)
- Hypothesis-driven
- Efficient & effective

- **Transition Strategy**

- Based on sound science and risk management needs
- Research in concert with regulatory dialogue
- Incremental application to decision making
- Expert peer review and stakeholder involvement

**Focus
resources
on risks of
greatest
concern**



<http://www.epa.gov/opp00001/science/testing-assessment.html>

Genetic Toxicology Policy



- **OPP commitments**
 - use current state-of-the-science methods to enable a more effective and efficient testing and assessment paradigm for chemical risk management.
 - reduce the number of animals used in testing while still producing a reliable safety assessment of pesticide chemicals.
- Recent advances in the area of genetic toxicity testing would reduce animal usage and still provide the necessary information for an assessment of the genotoxic potential of substances.
- Policy on website <http://www.epa.gov/pesticides/science/policies.htm>, EPA encourages new, scientifically credible approaches to address pesticide genetic toxicology data requirements.

Non-Animal Testing Approach for Eye Irritation: Labeling Antimicrobial Products with Cleaning Claims



- 2009 – voluntary pilot program to evaluate a non-animal testing approach for eye irritation for labeling antimicrobial products with cleaning claims.
 - Pilot based on an ICCVAM review of *in vitro* and *in vivo* data on antimicrobial cleaning products.
 - Purpose: to determine the usefulness of this approach for precautionary labeling, and to ensure appropriate hazard labeling.
- The strategy uses three testing protocols because no single test has the range of sensitivity to identify all four toxicity categories
 - Bovine Corneal Opacity Test (BCOP) is an *ex vivo* assay
 - EpiOcular Assay (EO) is an *in vitro* assay
 - Cytosensor Microphysiometer (CM) is an *in vitro* assay
- The Agency has received and reviewed studies; study results have been successfully used for labeling decisions for eye irritation classification.
- AD is working towards establishing the approach as an OPP policy

OPP Guidance for Waiving or Bridging of Mammalian Acute Toxicity Tests



- **March 2012 - OPP Waiving/Bridging Guidance: Acute Oral, Acute Dermal, Acute Inhalation, Primary Eye, Primary Dermal, and Dermal Sensitization**
- **The purpose of this document is to consolidate information from multiple previous agency documents and provide a single reference source for acute toxicity waiver guidance as well as criteria for bridging of acute toxicity data.**
- **Covers all pesticides – biochemical, microbial, antimicrobial, conventional**

Open Literature Guidance



- Two guidance documents for staff to assist in their evaluation of open literature studies of pesticides specific to ecological and human health risk assessments:
 - [Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment](#)
 - [Evaluation Guidelines for Ecological Toxicity Data in the Open Literature](#)
- OPP considers multiple sources of information when conducting risk assessments for pesticides, not just studies conducted specifically to support pesticide registration.
- Guidances describe how OPP searches the literature and evaluates the quality and utility of open literature studies to identify data that are pertinent for risk assessment and regulatory decision making.
- Also make transparent to the public how we identify, select, and ensure that the data we use in pesticide risk assessments is of sufficient scientific quality. The studies that are the most relevant and informative to risk assessment are those that clearly and fully describe study design, conduct and methods, as well as providing access to the underlying data.
- The principles articulated in these documents are consistent with agency policy
 - 2002 Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency - policy and procedural guidance for ensuring and maximizing the quality of information
 - Risk Characterization Policy - describes a philosophy of transparency, clarity, consistency, and reasonableness.