OPP 21st Century Activities: Guidance, Policies, and Rule

PPDC
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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

Alternate Testing Framework 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.
- Established the approach as an OPP policy in May 2013
  - Other pesticides evaluated on a case by case basis
- The strategy uses three testing protocols because no single test has the range of sensitivity to identify all four US 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
- http://www.epa.gov/pesticides/science/eye-irritation.html

Guidance for Neurotoxicity Battery, Subchronic Inhalation, Subchronic Dermal & Immunotoxicity Studies

- May 2013 – Guidance for OPP staff
- Provides guidance on
  - conducting a weight of the evidence-based evaluation to determine data needs or to review a waiver justification for these studies and
  - how to subsequently incorporate this determination in risk assessment.
- Covers all pesticides – biochemical, microbial, antimicrobial, conventional
- http://www.epa.gov/pesticides/regulating/part158-tox-data-requirement.pdf

Data Requirements for Antimicrobial Pesticides (158W)

- Title 40 of the US Code of Federal Regulations (CFR) part 158 subpart W (40CFR158W)
- Effective July 2013. Data requirements for pesticides used in agriculture and other pesticides were updated in 2007.
- Updates data requirements for antimicrobial pesticides to meet changes to the law and evolving science to ensure pesticide risk management decisions are founded on the best available sound science.
- Significant milestone toward the agency's longer term vision for a paradigm shift to 21st Century science and using integrated approaches to testing and assessment. http://www.epa.gov/pesticides/science/testing-assessment.html

OPP Guiding Principles for Data Requirements

- Guidance for OPP staff intended to help guide the identification of data needs , promote and optimize full use of existing knowledge, provide consistency in the data request process across all scientific disciplines and all OPP divisions, and focus on the data needed to allow for a scientifically sound and credible characterization of a specific pesticide's risk profile for the exposure scenarios of interest.
  - Registration of new pesticides and uses and re-evaluation of existing pesticide uses.
- The goal is to ensure there is sufficient information to reliably support registration decisions that are protective of public health and the environment while avoiding the generation and evaluation of data that does not materially influence the scientific certainty of a regulatory decision.
- Only require data that adequately inform regulatory decision making to avoid unnecessary use of time and resources, data generation costs, and animal testing.

- http://www.epa.gov/pesticides/regulating/data-require-guide-principle.pdf

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.