21st Century Toxicology/New Integrated Testing Strategies PPDC Workgroup

Co-Chairs: Drs Vicki Dellarco & Jennifer Mclain

December 15, 2010
• Sponsored by EPA
• Recognized advancements in molecular in vitro, and computer sciences
• Use new technologies (e.g., cell-based assays, “omics”) to evaluate how chemicals perturb normal cellular functions and lead to adverse effects

Broader coverage of chemicals & endpoints
Reduce cost & time of testing
Use fewer animals
Increasing Effectiveness & Efficiency

Work toward transitioning new 21st century technologies, to increase the efficiency, effectiveness, & focus of risk management decisions for human health and the environment.

Long Term Goal

Better predictions of risk for regulatory endpoints
Focused in vivo testing
Less reliance on animal studies

Integrate data from new technologies

Structure
Molecular
Cellular
Organ
Individual
Population
PPDC Workgroup: 21st Century Toxicology/New Integrated Testing Strategies

• Objective
  – Focus on communication & transition issues as EPA phases in new molecular and computational tools
  – Provide input on key activities needed for successful communication and transition
  • e.g., identifying ways to improve understanding and communicate complex science to all stakeholders
Pesticides Program Dialogue Committee 21st Century Toxicology/New Integrated Testing Strategies Workgroup

August 2008

For more information contact Vera Au (au.vera@epa.gov).

Meeting dates scheduled for the remainder of 2009.

- November 18, 2009, 2:00 - 4:00 pm ET, One Potomac Yard South, Room N-4830
- December 9, 2009, 2:00 - 4:00 pm ET, One Potomac Yard South, Room N-4830

Previous Meetings
- October 19, 2009
  - Agenda
  - New Medical Management of Pesticide Poisoning: Why We Need Diagnostic Tools (PDF) (30 pp, 177.24K) by James J. Roberts, MD, MPH
  - New Why Do We Need Diagnostic Tests and Biomarkers for Pesticides? (PDF) (27 pp, 486.69K) by Matthew Keifer MD, MPH
- September 9, 2009
  - Agenda
  - Executive Summary (PDF) (1 p, 27.25K)
- July 8, 2009
  - Agenda
  - Metabolic Simulator presentation (PDF) (22 pp, 749K) by Dr. Patricia Schmieder
  - Executive Summary (PDF) (1 p, 21.71K)
- June 10, 2009
- May 20, 2009

http://epa.gov/pesticides/ppdc/testing/index.html
Workgroup Activities

- Education Seminars
- OPP Website

- Subgroups
  - Metrics of Success & Progress
  - Biomarkers
  - Issues

http://www.epa.gov/pesticides/science/testing-assessment.html
Workgroup Activities

EPA’s Pesticide Program’s Stakeholder Workshop on 21st Century Science & Integrated Testing & Assessment Strategies: Transitioning Research to Regulatory Practice

(CONDUCTED UNDER THE AUSPICES OF THE PESTICIDE PROGRAM DIALOGUE COMMITTEE)
FREE AND OPEN TO THE PUBLIC; NO REGISTRATION NEEDED.

MEETING DETAILS
December 13, 2010 9am – 5pm
2777 South Crystal Drive
PY South 1st floor conference room
Arlington, VA
For directions:
http://www.epa.gov/pesticides/contacts/officelocation.htm
Parking available on site (Fee).

PURPOSE & BACKGROUND
Through this workshop, EPA expects to broaden and strengthen stakeholder dialogue on our Pesticide Program’s strategic vision and application of 21st Century science in the context of integrated approaches for testing and assessment to better inform chemical risk management decisions. Visit:
http://www.epa.gov/pesticides/science/testing-assessment.html

Since the publication of the 2007 National Research Council (NRC) of the National Academy of Sciences (NAS) report on Toxicity Testing in the 21st Century, there

WORKSHOP OBJECTIVES
• Communicate, through the use of case studies, EPA’s Pesticide Program Strategic Vision for Integrated Approaches to Testing and Assessment
• Increase common understanding of new 21st Century science tools and how best to apply them now and in the future
• Understand stakeholder perspectives, priorities, and expectations within the context of EPA’s regulatory authority
• Build an effective, transparent communication strategy

PRELIMINARY AGENDA
Introductory Remarks
Stephen Owens, Assistant Administrator, Office of Chemical Safety and Pollution Prevention

Dr. Paul Anastas, Assistant Administrator, Office of Research and Development (invited)

Strategic Vision for Integrated Approaches to Testing
December 13th PPDC Stakeholder Workshop

• Stakeholder Panel Discussion
  – Perspectives of OPP’s Strategic Vision
    • concerns, issues, priorities, expectations, benefits of the vision

Panel Members:
- M. Fry, Conservation Advocacy and Chief Scientist, American Bird Conservancy
- S. Kegley, Pesticide Action Network
- K. Willett, People for the Ethical Treatment of Animals
- C. Baker, Exigent Company
- D. Tamayo, County of Sacramento Dept. of Water
December 13th PPDC Stakeholder Workshop

- Stakeholder Panel Discussion
  - Ensuring Transparency and Building an Effective Communication Strategy

Panel Members:
- T. Pastoor, Syngenta Crop Protection, Inc.
- M. Stevens, Human Society
Panel Discussion: Perspectives of OPP’s Strategic Vision

• General support for OPP’s strategic vision
  – The Agency needs to keep pace with technological advances and use best science

• Recognized several benefits
  – e.g., greater knowledge about chemical, ability to test more chemicals & a broader range of effects, reduction in animal usage

• Recognized it will be an evolving process of learning and adjusting
Panel Discussion: Perspectives of OPP’s Strategic Vision

• Key Feedback
  – Continue stakeholder engagement to build trust
    • Use case studies to ground truth and illustration how Agency will implement
    • Ensure transparency (including availability of tools, data, etc)
  – Need to build a process for how decisions will be made
Panel Discussion: Perspectives of OPP’s Strategic Vision

• Key Feedback
  – Need to build a system to evaluate accuracy & effectiveness of decisions
  • safe guards & feedback mechanisms to ensure new approach is working, e.g., biomonitoring
Panel Discussion: Communication

• Need to be broad in outreach but cognizant of having different audiences
• Need to do communication in such a way that it promotes a two-way interactive dialogue
• Need to recognize the difficulty in getting the public to pay attention to longer term objectives and highly technical subject matter
• Need to focus on common goals and shared values
• EPA needs to be clear and consistent about its vision and direction
Workgroup 2011 Activities

- Workshop on biomarkers
- Education seminars on progress and new advances
- Work on new ways to broaden outreach and dialogue