

US EPA ARCHIVE DOCUMENT



Update: 21st Century Science Activities

Topics:

- PPDC Workgroup Activities
- May FIFRA Scientific Advisory Meeting
- Endocrine Screening Program

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

PPDC Workgroup: 21st Century Toxicology/New Integrated Testing Strategies

- ▶ December 13th PPDC FACA Stakeholder Workshop
- ▶ Workshop Synopsis is Available at <http://epa.gov/pesticides/ppdc/testing/index.html>
 - Agency Presentations on Vision and Case Studies
 - Panel Discussion 1 – Perspectives of OPP’s Strategic Vision (concerns, issues, priorities, expectations, benefits of the vision)
 - Panel Discussion 2 – Ensuring Transparency and Building an Effective Communication Strategy

PPDC Workgroup: 21st Century Toxicology/New Integrated Testing Strategies

- ▶ Planning a one day FACA workshop to be held in conjunction with October 2011 PPDC meeting
 - **Diagnostic Tools and Biomarkers in Pesticide Medical Management, Exposure Surveillance, and Epidemiologic Research**
 - **Topics**
 - **The Need and Role**
 - **Current State of the Science**
 - **Challenges, Opportunities, and Next Steps for Solutions**

FIFRA SAP Consultation on OPP's Strategic Vision/Direction

- ▶ May 24–26, 2011
- ▶ “Integrated Approaches to Testing and Assessment Strategies: Use of New Computational and Molecular Tools”
 - Presentations
 - From Agency: OPP Vision, ORD Research, Two case studies
 - From PPDC workgroup on science issues

Update on EPA's Endocrine Disruptor Screening Program (EDSP)

Background

- ▶ Statutory Authorities
 - 1996 Food Quality Protection Act (FQPA)
 - Amendments to the Safe Drinking Water Act (SDWA) Amendments
- ▶ Structure & Scope (based on 1996–1998 EDSTAC recommendations)
 - Estrogen, androgen, thyroid
 - Human health, fish , wildlife
 - Pesticides, environmental & commercial chemicals
- ▶ EDSP Program
 - Sorting & Prioritizing Chemicals, Tier 1 Screening, Tier 2 Testing, Hazard & Risk Assessment

USEPA Endocrine Disruptor Screening & Assessment Program

- ▶ **Sorting & Prioritizing Chemicals**
- ▶ **Tier 1 Screening**
 - Data to determine if a chemical has the potential to interact with the estrogen, androgen or thyroid systems
- ▶ **Tier 2 Testing**
 - Data to determine if endocrine-mediated adverse effects occur and quantify dose-response
- ▶ **Hazard & Risk Assessment**

Strategic Direction to Evolve EDSP: 21st Century Computational Toxicology Tools

- ▶ EDSTAC (1998)
 - recommended the use of measured or predicted receptor binding and/or transcriptional activation data derived through High Throughput Screening (HTS) and (Q)SARs
- ▶ SAB/SAP (1999)
 - concurred; but at the time concluded that HTS and (Q)SARs were not sufficiently developed at that time – encouraged continued research
- ▶ As part of USEPA's computational toxicology and endocrine disruptor research programs,
 - Office of Research and Development (ORD), in collaboration with OCSP has been developing High Through Put Systems (HTs) and (Q)SARs models

Strategic Direction to Evolve EDSP: 21st Century Computational Toxicology Tools

- ▶ Stepwise approach toward utilizing new rapid & mechanistically based 21st Century computational toxicology tools
- ▶ Benefits
 - Increase capacity to more efficiently screen chemicals for EDSP
 - Timely decisions
 - Effective allocation of resources where they are most needed
- ▶ Ensure transparency & build confidence in tools so they can be increasingly utilized in the EDSP

Strategic Direction to Evolve EDSP: 21st Century Computational Toxicology Tools

- ▶ **Near term goal**
 - **Chemical Prioritization**
 - Use Exposure and (Q)SAR & HTS predictions to focus chemical selection on those of greatest potential
 - **Targeted Screening**
 - As HTS/(Q)SAR models improve, use predictions to appropriately select subset of Tier 1 screening assays to focus on endocrine pathways of greatest concern
- ▶ Evaluation & peer review processes: follow prior to regulatory acceptance.
- ▶ Transparent process: opportunity for public comment

Strategic Direction to Evolve EDSP: 21st Century Computational Toxicology Tools

- ▶ Longer term goal
 - Continue to improve the assays systems for predicting endocrine pathways
 - Continue to evolve the EDSP to increase reliance on more rapid, effective, and mechanistically based non-animal screens for which there is confidence in their ability to predict in vivo adverse effects.

Other Updates

- ▶ Evaluation of Tier 1 Data
 - In 2012 EPA expects to begin the review of Tier 1 screening data from the List 1 chemicals
 - Determine which chemicals need no further testing
 - Determine which chemicals need Tier 2 tests and which tests to require
 - Analyze performance of the battery
- ▶ Weight-of-Evidence Guidance Document
 - Paper announced in Federal Register for the public to review and comment on 11/04/10
 - Public comment period closed in January 2011
 - Review of comments and revisions ongoing

Other Updates

- ▶ Standard Evaluation Procedures (SEPs) for Tier 1 assays
 - Templates under development & will be made available via EDSP website
- ▶ EDSP List 2 (FR 2010)
 - 134 Chemicals (SDWA priority chemicals & additional pesticides)
 - Reviewing public comments
- ▶ Amendment to ICR
 - Reviewing public comments
 - 2nd public comment period
 - OMB review
- ▶ Policies & Procedures related to SDWA orders
 - Reviewing public comments