

US EPA ARCHIVE DOCUMENT

ISSUES SUBGROUP (Q&A FORMAT)

**PPDC Work Group on 21st Century
Toxicology/New Integrated Testing
Strategies**

ISSUES SUBGROUP (Q&A FORMAT)

- Formed June 2009
- Members
 - Kristie Sullivan
 - James Roberts
 - Erik Janus
- CHARGE: Capture salient stakeholder issues related to new testing methods and strategies and present them in Q&A format

ISSUES SUBGROUP (Q&A FORMAT)

- Final product: Tool for EPA
 - Education
 - Research
 - Communication & Outreach
- Final product: document
 - Questions
 - “Points to consider” when creating response
 - Some questions may not be answerable yet

PROCESS-Q generation

- Brainstorming
- Quizzing constituents
- Listening
 - Full PPDC meetings
 - Workgroup meetings

PROCESS-Developing list

- Comments
 - Workgroup
 - Constituents
 - EPA
- Parity and Reorganization
- Check for duplication with web site
- Development of “points to consider” for EPA to use in formulating answers

STAKEHOLDER ISSUES (Q&A FORMAT)

- General questions
 - What is the timeline for this process?
- Technical questions
 - How will this new paradigm take human variability into account?
- Major themes
 - Benefits/drawbacks of paradigm shift
 - Maintaining environmental and health protection

Stakeholder Issues-General

~~WHAT?~~

- ~~• What changes are taking place?~~

~~WHY?~~

- ~~• Why is EPA, and OPP specifically, making efforts to implement these changes in toxicity testing and assessment?~~

Stakeholder Issues-General

~~WHEN?~~

- ~~• When does OPP plan to transition from the use of current methods to the use of new tools and ultimately implement the NRC Vision “paradigm shift”?~~
 - ~~– Suggest timeline linked with other workgroup products, like the Tools or Metrics Matrices~~
 - ~~– General view rather than hard and fast deadlines~~

Stakeholder Issues-General

HOW will these changes affect OPP's mission?

- How will the EPA ensure that the current level of protection of human health and the environment is **maintained or enhanced**?
- How will **decision-making be improved** by the use of molecular information?
- How will the new toxicity testing paradigm increase the **efficiency** of the pesticide regulation process? What are the expected resource savings for both regulators and the regulated community?

Stakeholder Issues-General

- How will this initiative be followed over time and upgraded and improved upon?
- How will EPA recognize the limitations and **uncertainties** associated with the use of the newer non-animal testing methods and take them into account during the risk assessment process?
 - What tools/checks are in place?

Stakeholder Issues-General

WHO?

- What are the opportunities for **public and other stakeholder input**? How can the public, academic, business and other federal agencies become engaged? How transparent will this process be?

Stakeholder Issues-Technical

- How can *in vitro* testing specifically predict the potential of a substance to cause adverse effects at **higher levels of biological complexity** (i.e. organ, system and organism level)?
 - Context: endpoints such as developmental tox
 - Translating data into risk management
- How will **inter-individual variations** in the human population (i.e. genetic and metabolic differences) be captured by *in vitro* and *in silico* methods?

Stakeholder Issues-Technical

- Sometimes during the implementation of new technologies or advances in science, methods that were originally considered to be replacements for current technologies become, for a number of reasons, additional requirements. What specific steps and actions is OPP and/or EPA taking to **ensure the regulatory acceptance of newer methods?**

Stakeholder Issues-Technical

- How will this new testing and assessment paradigm affect our ability to identify health outcomes from chemicals in worker or public populations? **Will EPA have a way to identify chemicals that may be contributing to an increased disease burden in the population?**

BACK TO YOU

- What have we missed?
- Check out the handout and web site and tell us what you DO and DON'T see!

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