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EPA Office of Pesticide Program's Stakeholder Workshop on 21st Century Science and Integrated Testing and Assessment Strategies: Transitioning Research to Regulatory Practice

Workshop Synopsis

Overview: On December 13, 2010, the Office of Pesticide Programs (OPP) hosted a day long public workshop in Arlington, Virginia to broaden and strengthen stakeholder dialogue on OPP's strategic vision and application of 21st Century science to inform chemical management decisions for human health and ecological risks. This public workshop provided a unique opportunity for stakeholder to provide input into OPP's strategic direction and offer suggestions on how the Agency should proceed. (Also visit: [Strategic Direction for New Pesticide Testing and Assessment Approaches](#)).

Since the publication of the 2007 National Research Council (NRC) of the National Academy of Sciences (NAS) report on [Toxicology Testing in the 21st Century](#) there has been a great deal of focus within the scientific community to develop and evaluate new technologies in molecular, *in vitro*, and computational sciences to supplement or replace more traditional methods of toxicity testing and risk assessment. Over the next several years, we in EPA's Pesticide Program will be evaluating and transitioning these new technologies to improve and transform our approach to pesticide risk assessment and risk management in a manner that allows us to evaluate the safety of chemicals with increasing efficiency and effectiveness while using fewer resources and experimental animals.

The Pesticide Program Dialogue Committee (PPDC) workgroup on "Integrated Testing Strategies/21st Century Toxicology" was established in 2008 to inform and engage stakeholders early in OPP's efforts to implement the NRC recommendations. The key objective of this workgroup is to advise the Pesticide Program on communication and transition issues as we move forward. The planning of this workshop was a direct outcome of the PPDC workgroup. (Also visit: [Pesticide Program Dialogue Committee 21st Century Toxicology/New Integrated Testing Strategies Workgroup](#)).

The workshop objectives included:

- Communicate EPA's Pesticide Program Strategic Vision for Integrated Approaches to Testing and Assessment through the application of case studies
- Increase common understanding of new 21st Century science tools and how they might be applied
- Understand stakeholder perspectives, priorities, and expectations
- Build an Effective Transparent Communication Strategy

Perspectives on the Strategic Vision:

The meeting opened with a series of speakers from the Agency discussing the context of OPP's vision. The speakers highlighted the benefits and challenges of achieving the vision. See (link) for presentations.

Stephen Owens, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, opened the meeting with comments on why new approaches are critical to evaluating chemical safety with increasing speed and accuracy and the importance of building a transparent process and coherent strategy to inform the public what are we doing, why we are doing it, and how it affects them. (Also visit [The Future of Chemical Toxicity Testing in the US](#)).

Dr. Robert Kavlock, National Program Director for the Chemical Safety for Sustainability research program (CSS) and Director of the National Center for Computational Toxicology, Office of Research and Development (ORD), provided an overview of ORD's efforts to develop the scientific basis and tools to transform the nature of information used in managing chemical risks through the new ORD research program, Safer Products for a Sustainable World (currently titled the Chemical Safety for Sustainability research program) (Also visit: [Chemical Safety for Sustainability: EPA Research to Meet 21st-Century Needs](#)).

Dr. Steven Bradbury, Director of EPA's Office of Pesticide Programs, explained OPP's "Strategic Vision for Integrated Approaches to Testing and Assessment." This strategy lays a path for human health and environmental risk assessment/risk management that moves away from a testing and assessment paradigm that relies heavily on animal studies to generate information on all possible outcomes, to one that is less reliant on animal testing and takes full advantage of new knowledge and new *in vitro* and computer based technologies to efficiently focus on chemicals of concern. (Also visit [Strategic Direction for New Pesticide Testing and Assessment Approaches](#)). Bradbury discussed EPA's partnerships, including efforts on the international stage related to Integrated Approaches to Testing and Assessment (IATA) and Adverse Outcome Pathways (AOPs)). (Also visit [A Strategic Vision for a 21st Century Testing & Assessment Paradigm](#)).

Several EPA staff provided case studies to illustrate the different aspects of the vision presented by Dr. Bradbury. (See [Pesticide Program Dialogue Committee 21st Century Toxicology/New Integrated Testing Strategies Workgroup](#)). These presentations started with an illustration of where the Agency would like to be over the long term (15 Years) with respect to "Moving From Data Requirements to Knowledge Requirements to Inform Risk Assessment & Regulatory Decisions: Using knowledge from relational databases on chemical characteristics and biological

properties of chemicals to predict the toxicological potential of untested chemicals”. (See [Moving From Data Requirements to Knowledge Requirements](#)). Case examples of initial milestones over the next 1 to 3 years were presented including:

- The first application of new *in vitro* and computer based approaches to enable faster and more effective prioritization of chemicals for tiered based screening and testing in the Agency’s Endocrine Disruptor Screening Program. (See [Priority Setting: Using new predictive computer models and in vitro tools \(PDF\)](#)).
- The Agency’s efforts to capture legacy data that will be critical to developing these new predictive methods and to efficiently and effectively leverage existing information across chemical classes as exemplified by MetaPath. MetaPath (Metabolism Pathway) is a database that is designed to store summary information on pesticide metabolism and environmental degradation products. (See [Using Searchable Databases and Predictive Systems: MetaPath \(PDF\)](#)).
- A case example on targeted testing which illustrated the components of an integrated testing strategy that incorporates computer and *in vitro* technologies, and smarter *in vivo* study designs to minimize use of animals in testing. (See [Integrated Approach to Testing and Assessment to Inform Regulatory Decisions](#)).

The Agency also provided a presentation on the communication of science and policy that emphasized the important role of public perception. An understanding of changing science is critical to clear communication and bridging the gap between science and perception. The Agency must communicate early and often to gain the public’s trust.

Panel Discussions and Perspectives: There were two stakeholder panel discussions.

The first panel discussed “Stakeholder Perspectives of OPP’s Strategic Vision”. Five panel members discussed the concerns, issues, expectations, and benefits around OPP’s vision as well as highlighting the realities of shifting to a new paradigm in testing and risk assessment. Discussants included Dr. Michael Fry (Director of Conservation Advocacy and Chief Scientist, American Bird Conservancy), Dr. Susan Kegley (Consulting Scientist, Pesticide Action Network), Dr. Kate Willett (Science Policy Advisor, People for the Ethical Treatment of Animals), Cindy Baker (President, Exigent Company), and Dave Tamayo (Environmental Specialist, County of Sacramento Dept. of Water).

Summary: Panelists expressed support for OPP’s strategic direction toward evaluating chemicals with more reliability, relevancy, and efficiency while using fewer animals. The panelists had a number of recommendations and concerns for the Agency to consider. Some of the themes touched-upon by the speakers included the following:

- Understanding the biology resulting in toxicity and developing predictive tools with that knowledge will help improve the basis of safety assessment.

- The Agency has an obligation to minimize animal testing and reduce suffering.
- Societal benefits and science, not political influence, should be the drivers of the new approach.
- Feedback mechanisms and safeguards must be developed to ensure the integrity of human and ecological health protection. The Agency should establish systems to check new tools prospectively and retrospectively.
- The Agency should examine case studies to assess predictability and provide stakeholders with an understanding of the processes, decisions, and drivers of the conclusions.
- New environmental monitoring and exposure tools should be applied to discover environmental problems early.
- Incident data, biomarkers, and diagnostic tools are critical to identifying ecological and health problems, measuring impacts, and adjusting models.
 - Although many animals have the same fundamental processes, they are differentially affected in terms of endpoints and sensitivity. Incident reporting will ensure we understand the full range of effects caused by exposure to pesticides.
- Considerations for developing tools include:
 - New methodologies need to account for toxic effects in the whole organism across all species.
 - The ability to examine mixtures will be important.
 - The chemical diversity found in pesticides must be sufficiently understood in order to group them appropriately and must be reflected in the test methods used.
 - New methodologies must be able to discern the variation in how different species respond to chemicals and the genetic variability within populations.
 - Tools must be continually refined with new information and knowledge from related fields such as the pharmaceutical industry.
 - Tools should be developed with an integrated and interdisciplinary approach.
- Considerations for implementation include:
 - Concerns about potential false negatives should not be a barrier to adoption of new tools.
 - Evolving impacts on activities in progress will make the transition difficult.
 - The Agency must consider how this transition will affect processes. For example, risk assessment, risk management decisions, and harmonization efforts. The end result should be a clear, predictable process that is efficient and effective.
 - The transition should be open and transparent, tools and datasets must be publicly available.
 - Partnerships and collaborations will be critical to the success of the transition and will increase public confidence.

The final panel addressed the issue of “Ensuring Transparency and Building an Effective Communication Strategy”. The discussants, Dr. Tim Pastoor (Syngenta Crop Protection, Inc.) and Dr. Martin Stephens (The Humane Society of the United States) and the audience provided perspectives including:

- Dialogue is important. Involving the public and stakeholders in the process so they understand and support it will be critical.
- Three important issues in communication are openness, engagement, and trust.
- Terms of engagement must be easily understood by everyone, so keep it simple.
- Engagement must be global.
- Trust must be earned and we must do what we say we are doing to do.
- EPA must be decisive, scientific, and clear in its actions. The “ONE EPA” mindset is vital.
- Stakeholders must understand that there will be failure along the way. The approach will not be 100% predictive and successful.
- The internet is an important tool because it makes communication easy. Social media is an important communication tool because it is a two-way process rather than an announcement of a decision.
- A communications challenge is to keep people concerned with the issue in both the long and short term.
- Communication is a two-way street.

Contact: For more information about the PPDC workgroup on 21st Century Toxicology/New Integrated Testing Strategies, contact Dr. Vicki Dellarco (Dellarco.vicki@epa.gov) or Jennifer McLain (mclain.jennifer@epa.gov); or visit <http://www.epa.gov/pesticides/science/testing-assessment.html>.