

US EPA ARCHIVE DOCUMENT

September 20, 2012
PPDC 21st Century Toxicology/New Integrated Testing Strategies Workgroup
Meeting Minutes

Time: 1:00 – 3:00 PM (EST)

Summary

On September 20, 2012, the PPDC 21st Century Toxicology / New Integrated Testing Strategies Workgroup met for the group's bi-monthly meeting. During the meeting the workgroup discussed the development of metrics for *in vitro* testing, the proposed agenda for a 21st Century Toxicology workshop in Spring 2013, biomarker definitions and the next steps for the development of a priority pesticide list. At our last meeting the metrics subgroup presented a proposal to revisit, augment and implement metrics for progress on *in vitro* testing by setting specific goals and measuring progress to achieve these goals in the context of acute hazard labeling studies. At this meeting EPA presented baseline data on the number of *in vitro* and *in vivo* acute toxicity tests submitted to the Agency in FY 2008 - FY 2012 leading to a conversation on the implications of these numbers and the incentives for both industry and the EPA to pursue *in vitro* testing. Next, the workgroup discussed the most recent draft of the proposed agenda for a 2-day workshop in Spring 2013 addressing Tox21 tools currently being utilized and/or considered by EPA and case studies on those tool. Both of these subgroup will meet before the next workgroup meeting to finalize the information to be presented to the general PPDC at the November meeting.

As a result of the October 2011 biomarker workshop and questions from the PPDC, OPP worked with ORD to develop a set of biomarker definitions for the workgroup's webpage. The goal of these definitions is to provide clarity on biomarker terminology. At the workgroup meeting, EPA presented the draft definitions for considerations. EPA hopes to receive input on the definitions from the workgroup in the near future so that they can be presented to the PPDC in November. Next, the workgroup discussed progress on the creation of a subject matter expert group for development of a priority pesticide list. The workgroup hopes to hold the first meeting in October. Lastly, the group discussed the current internal use of *in vitro* testing in industry and how information on this testing, although not able to be used by the Agency at this time, could possibly be shared to help educate Agency scientists.

Attendees

Non-EPA: Patricia Bishop, Peter Chan, Caroline Cox, Erik Janus, Thomas Kellner, Amy Liebman, Tim Pastoor, Gary Patterson, Pat Quinn, Virginia Ruiz, Kristie Sullivan, Dave Tamayo, Catherine Willett

EPA: Jennifer McLain, Elaine Cohen-Hubal, Stephen Edwards, Aaron Niman, Cecilia Tan, Rebecca von dem Hagen

Notable Issues/Actions/Commitments

OPP Charge to Subgroups on Biomonitoring:

1. Develop priority list of candidate pesticides for developing human health pesticide biomarkers for research and clinical applications. Convene expert group and agree upon criteria for developing list.
 - a. OPP will work with subgroup to identify and contact experts.
 - b. OPP will coordinate calls with expanded subgroup.
2. Create pesticide use case(s) for submission to DARPA as well as other research programs (e.g., NIEHS, EPA ORD) to encourage funding for research on rapid diagnostic methods for pesticides to enable clinical trials and point-of-need diagnostics.
 - a. OPP will work with subgroup to develop use case(s) i.e., pesticide exposure scenarios (background on the DARPA project attached below; see also email from Erik J 5/21/2012).
 - Consider priority exposure and clinical diagnostic scenarios associated with chemicals on the priority pesticide list.
3. Identify existing data relevant to diagnosing overexposure to pesticides
 - a. OPP will inquire with EU/EFSA regarding availability of biofluid analytical methods and criteria EU uses to determine when biofluid methods are necessary.
 - b. Subgroup will determine if information on existing biofluid analytical methods should be incorporated into pesticide use case(s).
 - c. Review WHO guidance “Triage and clinical management of patients with acute pesticide self-poisoning presenting to small rural hospitals”.
4. Subgroup will identify whether information on existing data relevant to diagnosing overexposure to pesticides and/or information from the WHO guidance should be included in future versions of Physician’s Handbook.

Subgroups:

- Biomonitoring: Develop a priority list of pesticides for biomarker research. Identify how existing data relevant to diagnosing overexposure to pesticides can be made more accessible and explore opportunities for additional information.
 Lead = Jimmy Roberts & Cheryl Cleveland
 Members = Matt Kiefer, Amy Liebman, Erik Janus, Caroline Cox, Valentin Sanchez, Virginia Ruiz and Cindy Baker Smith
- Future FACA: Develop and plan future workshop to support OPP's communication on and transition to 21st C science.
 Lead = Erik Janus
 Members = Kristie Sullivan, Kate Willett, Tim Pastoor
- Metrics: Create a proposal to OPP for measuring progress on *in vitro* testing.
 Leads = Kristie Sullivan, Kate Willett

Members = Pat Bishop, Cheryl Cleveland, Caroline Cox, Jennifer McLain, Joel Patterson, Pat Quinn, Tom Kellner

Next Meeting

The regular, bi-monthly meeting scheduled for November 15th will be cancelled and replaced by a lunch meeting during the 1st day of the general PPDC meeting on November 29, 2012. A call-in number will be provided for those who are unable to attend in person.