

EPA OFFICE OF PESTICIDE PROGRAMS' STAKEHOLDER WORKSHOP ON 21ST CENTURY TOXICOLOGY AND EXPOSURE SCIENCE Diagnostic Tools and Biomarkers in Pesticide Medical Management, Exposure Surveillance, and Epidemiologic Research: State-of-the-Science, Challenges, and Opportunities

October 11, 2011

EPA's Potomac Yards South Building, First Floor Conference Room 2777 S. Crystal Drive, Arlington, VA 22202 Conducted under the auspices of the Pesticide Program Dialogue Committee

Goal: Diagnostic tools and biomarkers are valuable in public health practice and are envisioned to play an important role in the model for 21 st century toxicology and exposure science. The goals of the stakeholder meeting are (1) to discuss the value of diagnostic tools and biomarkers in medical management, surveillance and epidemiologic research, (2) to understand the state-of-the-science on analytical tools and methods, and (3) to explore challenges, opportunities, and policy approaches to advance the development of diagnostic tools and biomarkers in order to help realize the new model of 21 st century toxicology and exposure science.	
8:30-8:50	Welcome / Setting the Stage <u>Presenter:</u> Steven Bradbury, PhD, Director, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, USEPA
8:50-10:00 8:50-9:25	Critical Scientific Issues for Tool Development and Interpretation of Monitoring Results Pharmacokinetic Considerations <u>Presenter:</u> Lesa L. Aylward, PhD, Principal, Summit Toxicology, LLP
9:25-10:00	Evaluating Exposure <u>Presenter:</u> Dana Barr, PhD, Emory University
10:00-10:20	Break (20 minutes)
10:20-12:05	Tools for Diagnosis and Biomarkers of Pesticide Exposure: The Need and Role What is the role of diagnostic tools and biomarkers in the new model of 21 st Century Toxicology? What is the importance of diagnostic tools and biomarkers in public health practice? More specifically, how can diagnostic tools and biomarkers improve (i) identification and medical management of overexposure and (ii) surveillance and epidemiologic research? How can diagnostic tool and biomarkers help protect vulnerable populations?
10:20- 10:55	Diagnostic Tools in Identification and Management of Pesticide Overexposure <u>Presenter:</u> James R. Roberts, MD, MPH, Associate Professor of Pediatrics, Medical University of South Carolina
10:55-11:30	Biomarkers in Surveillance and Epidemiologic Research: Applications in Surveillance and Epidemiologic Research <u>Presenter:</u> Lynn Goldman, MD, Dean, School of Public Health, George Washington University
11:30-12:05	 Biomarkers in Surveillance and Epidemiologic Research: Applications for Environmental Justice; Research on Vulnerable Populations <u>Presenter:</u> Asa Bradman, PhD, Associate Director, Center for the Health Assessment of Mothers and Children of Salinas, University of California, Berkeley

12:10 - 1:15	Lunch (65 minutes)
1:15- 1:50	Tools for Diagnosis and Biomarkers of Pesticide Exposure: The Need and Role (cont.) Case Study - Washington State Cholinesterase Monitoring <u>Presenter</u> : Matthew C. Keifer, MD, MPH, Dean Emanuel Endowed Chair, National Farm Medicine Center, Marshfield Clinic Research Foundation, and Co Director, Upper Midwest Agricultural health and Safety Center
1:50-3:35	Biomonitoring: The State of the Art What is the current state-of-the-science on medical diagnostic tools and biomarkers in surveillance and epidemiologic research? What are the strengths and limitations of these current tools? How have they improved the public health community's ability to monitor exposure and evaluate health effects? What critical scientific issues must be addressed when developing tools and interpreting their results?
1:50-2:25	Medical Diagnostic Tools <u>Presenter</u> : Dean Jones, PhD, Professor, Emory University
2:25-3:00	Tools of Surveillance and Epidemiologic Research <u>Presenter</u> : Michael Alavanja, PhD, National Institutes of Health / National Cancer Institute, Senior Investigator
3:00-3:35	Promising Analytical Tools <u>Presenter</u> : David Balshaw, PhD, National Institutes of Health / National Institute of Environmental Health Sciences
3:35-3:45	Break / Time Allowance (10 minutes)
3:45-5:15	Advancing Diagnostic Tools and Biomarkers: Challenges, Opportunities, and Next Stepsfor SolutionsWhat regulatory approaches and policies are needed to fully implement the new model of 21^{st} century toxicology? What are the regulatory challenges and solutions to offeringhuman biomarkers or diagnostic tests for pesticides to establish overexposure to particularchemicals? What can we learn from other Federal Agencies? What regulatory approachesare needed to assure the new model of 21^{st} century toxicology helps protect vulnerablepopulations?
	 Panel Discussion Facilitated by Bill Jordan, Senior Policy Advisor, Office of Pesticide Programs, USEPA <u>Panel Members</u>: <u>Carol J. Burns</u>, PhD, MPH, The Dow Chemical Company <u>Suzanne C. Fitzpatrick</u>, PhD, DABT, Senior Science Advisor, Office of the Commissioner, Office of FDA Chief Scientist, USFDA <u>Erik R. Janus</u>, Technical & Regulatory Analyst, Steptoe & Johnson LLP <u>Matthew C. Keifer</u>, MD, MPH, Dean Emanuel Endowed Chair, National Farm Medicine Center, Marshfield Clinic Research Foundation, and Co Director, Upper Midwest Agricultural health and Safety Center <u>Amy K. Liebman</u>, MPA, Director of Environmental and Occupational Health, Migrant Clinicians Network <u>Marylou Verder-Carlos</u>, PhD, DVM, MPVM Assistant Director, Department of Pesticide Regulation Sacramento, California
5:15-5:30	Public Comment
5:30-5:45	Closing Remarks

Population and Exposure Data A Critical Component of the National Research Council

"At each step, population-base and human exposure data are considered."

Toxicity Testing in the 21st Century: A Vision and a Strategy (NAS, 2007)

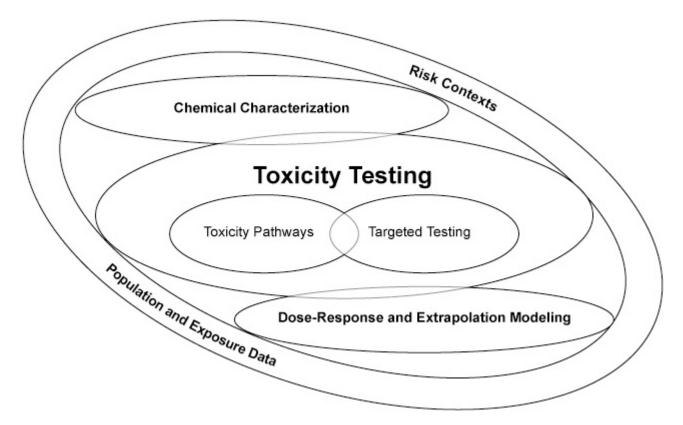


Figure 1 The committee's vision for toxicity testing is a process that can include chemical characterization, toxicity testing, and dose-response and extrapolation modeling. At each step, population-based and human exposure data are considered, as is the question of what data are needed for decision making.