

US EPA ARCHIVE DOCUMENT

PPDC 21st Century Toxicology/ New Integrated Testing Strategies Workgroup



**PRESENTATION TO THE PPDC
NOVEMBER 30, 2012**

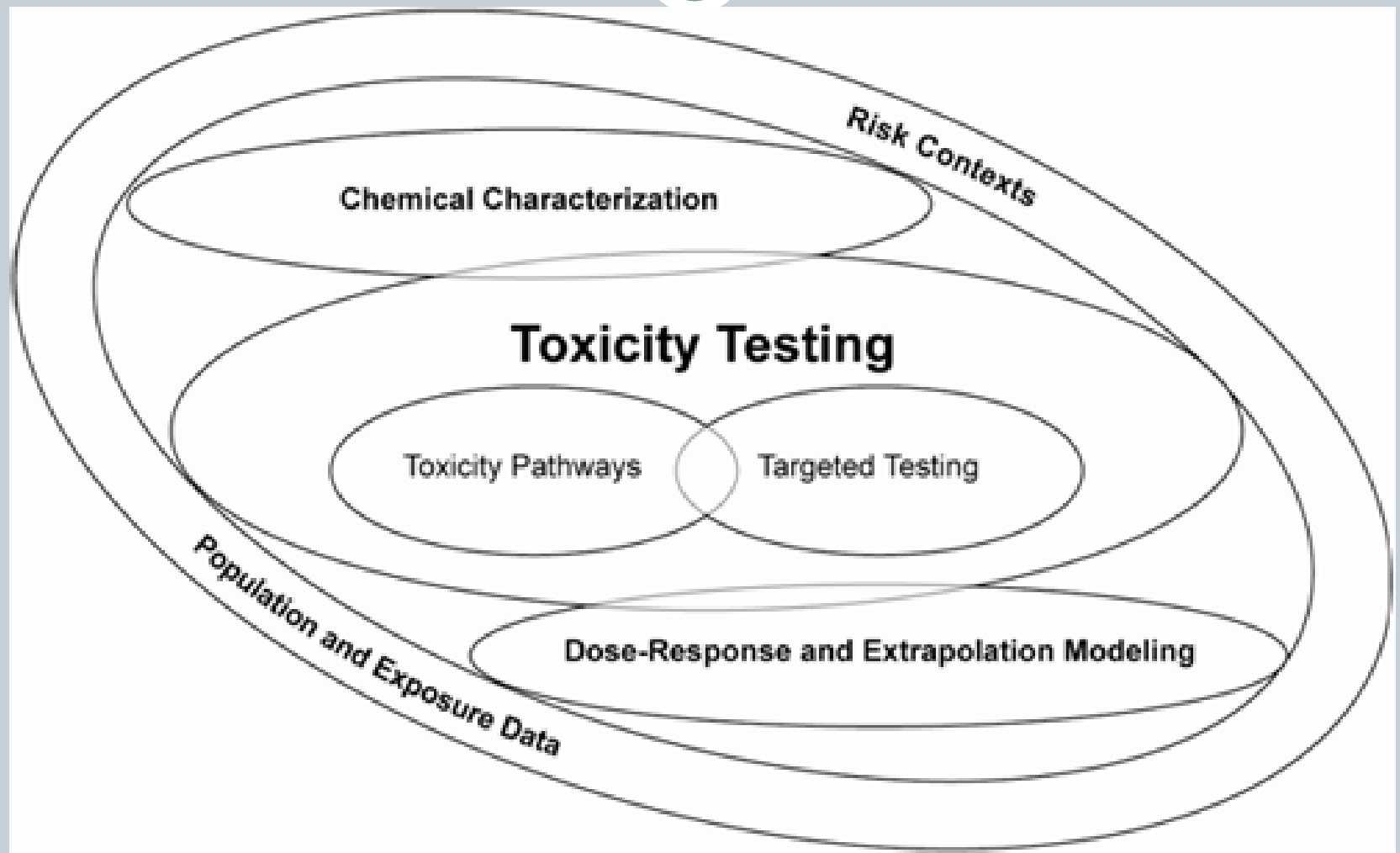
PPDC Workgroup: 21st Century Toxicology/New Integrated Testing Strategies (established 2008)

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- Objective: Focus on communication & transition issues as EPA phases in new molecular and computational tools

Key transition activities include: identifying other internal and external applications of this 'new' science (e.g., improving agency decision-making capability by harnessing new data streams and **developing new diagnostic tools and biomarkers**) and providing process recommendations to transition to the new testing paradigm.

21st Century Toxicity Testing



PPDC 21st Century Workgroup



- **FACA Stakeholder Workshops on Key Areas**
 - December 13, 2010 – OPP's Strategic Vision: Integrated Testing and Assessment Strategies: Transitioning Research to Regulatory Practice
 - October 11, 2011 - Diagnostic Tools & Biomarkers in Pesticide Medical Management, Exposure Surveillance, and Epidemiologic Research: State-of-the-Science, Challenges, and Opportunities

Outcome of Biomonitoring Workshop



- **Charge to the Workgroup**
 - 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
 - Create pesticide use case(s) to encourage funding for research on rapid diagnostic methods for pesticides to enable clinical trials and point-of-need diagnostics
 - Develop biomarker definitions
- **Progress of Expert Group for the Development of a Priority Pesticide List**
 - Expert group of scientists and public health professionals from industry, NGOs, academia, the medical community & EPA
 - Charge: Establish prioritization criteria & make recommendations on pesticides that should be the focus of further biomarker research and development

Biomarker Definitions



- OPP & ORD developed a set of biomarker definitions for the EPA website
- The goal of these definitions is to provide clarity on biomarker terminology
- Requested by PPDC after 2011 Biomarker Workshop
- Webpage will include definitions & examples of:
 - Biomarkers of Exposure
 - ✦ Chemical, metabolite & endogenous surrogate
 - Biomarkers of Effect
 - ✦ Bioindicator, undetermined consequence & exogenous surrogate
 - Biomarkers of Susceptibility

2013 Workshop on the Tox21 Toolbox & AOP's



- 1-Day mostly non-technical workshop to explore the regulatory application of Adverse Outcome Pathway (AOP) based tools
- Overview of Proposed Agenda
 - Understanding the Application of the AOP Framework
 - ✦ What is an AOP?
 - ✦ Case studies in AOP development and application
 - ✦ Application of AOP-derived knowledge
 - Benefits and Challenges to the Use of the Tox21 Toolbox
 - ✦ Case studies in implementation
 - Panel Discussion: Building Confidence in Regulatory Use of Alternative Testing Methods

Metrics Subgroup



- Subgroup is developing a proposal to establish & implement metrics for progress on *in vitro* testing & other alternative approaches
- Set goals for reduced animal testing & ways to measure progress within OPP
- Focus on acute hazard labeling studies

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QUESTIONS?