

US EPA ARCHIVE DOCUMENT

# 21<sup>st</sup> Century Toxicology/New Integrated Strategies Work Group

## Metrics of Success Subgroup

Presentation to PPDC

October 14, 2009

# Metrics of Success Subgroup - Objectives

- To suggest specific metrics for EPA to communicate
  - *progress toward* implementation of integrative strategies
  - *successful implementation* of strategies
- To relate metrics to
  - tools matrix
  - EPA objectives

# Considerations for All Metrics

- Metrics must be
  - Measurable
  - Specific to the intended purpose and to what is being measured
  - Be useful and valuable in the communications goal
- Measures of progress versus measures of success
- Duration – i.e., during what period of time is the metric applicable

# Considerations continued

- How easy or difficult to measure (including resources required)
- Retrospective vs ongoing
- How specific is the measure to what is being accomplished by the integrative approach compared to other activities and actions
- What are we trying to communicate?

# Proposed Metrics of Progress

- Development and finalization of guidance documents for tools and other aspects of the new paradigm
- Development and finalization of new or revised testing guidelines
- Development and release of new tools for use by regulators and by industry
- Identification, validation and acceptance of specific toxicity pathways

# Proposed Metrics of Progress

- Each proposed metric of progress
  - Can be subdivided into multiple steps (e.g., for guidance: initiation within EPA, draft for public comment, review by FIFRA SAP, issuance of final document)
  - Can be clearly identified and described in terms of relation to implementation of the new paradigm
  - Can be easily measured: count and report how many documents reach each step during each fiscal year
  - Duration:
    - short term – guidance documents & testing guidelines (annual report)
    - medium to long term – new tools & toxicity pathways

# Metrics of Success

- Much more difficult to clearly identify and measure than measures of progress, particularly at this early stage in the overall process
- EPA's objectives for new paradigm:
  - Reduce animal testing
  - Evaluate more chemicals more quickly and for broader range of effects
  - Reduce testing and evaluation costs
  - Target testing toward effects of concern
  - Ability to assess risks of mixtures
  - Potential for improved diagnostic and surveillance methods to better manage risks
  - Enhance the quality and efficiency of risk assessment and risk management decisions

# Metrics of Success

- Considerations
  - If measurable, will the measure be truly meaningful for communication purposes
  - Will the resources to measure outweigh the value for communication
  - Are the measures actually specific to the integrative testing paradigm or are they related to other initiatives

# Proposed Metrics of Success

- Retrospective analysis of number of animals used in testing under old paradigm versus new
  - When to do? With introduction of each new tool, after several years of experience?
  - On what timeframe? For each application, for specific types of endpoints, for each risk assessment decision, for each registration review decision?
  - On what basis? Case studies versus more ongoing comparisons?

# Proposed Metrics of Success

- Faster testing/evaluation & Reduced testing/evaluation costs
  - What is the basis when different pesticides and different use patterns can present different times and costs even under the old paradigm?
  - If do retrospective case studies, will the resources needed be available and will the results be helpful in communication?
  - How does this relate to PRIA timelines?

# Proposed Metrics of Success

- Enhanced quality and efficiency of risk assessment and risk management decisions
  - Can decisions be made earlier in the process
  - Has uncertainty been reduced
  - Are decisions with new paradigm equally or more health protective than under the older approaches
  - Can the impact of the new paradigm be clearly separated from that of other initiatives

# Metrics of Success

- This is an area where input from the PPDC is particularly requested
  - How and when do you measure whether the new strategies and paradigm are “successful”?
  - How do you effectively communicate that success?