

US EPA ARCHIVE DOCUMENT



# Common Themes Heard

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- Applying New Approaches/Tools to Address Risk Assessment Issues
  - What is included in approaches and tools?  
How are we going to implement the approaches and tools?
  - How are we going to communicate?
  - How does a chemical move from tier to tier?

- Validation concerns
  - how confident are we that the assays can detect effects, or negate effects?
  - false negatives and false positives
  - relevance to human physiology and disease
- Need to characterize exposure/dose better
- Defining meaning of biological perturbation

## Advantages

- understanding of MOA
  - characterizing interspecies and intraspecies variability
- refine NOAEL/LOAEL, UFs
- effects at molecular level help inform pathways to disease
- predictive toxicology; set priorities
- mixtures testing
- potential to be more cost effective
- reduce animal testing & improve efficiency of testing

- Challenges...
  - in vivo dose: ADME, point of entry, volatility
  - adverse vs. adaptive versus reversible?
  - mixtures
  - human variability/complicated disease states/windows of susceptibility
  - data management and public access to data
  - funding
  - regulatory and stakeholder communication and acceptance when standards are set
  - interpretation of the data, reproducibility

- Solutions...
  - more complex in vitro systems to better model in vivo cell relationships
  - involve risk assessors and risk managers (translation)
  - improve through iterative process
  - align with U.S. competitiveness initiatives
  - continue the stakeholder engagement

- For what kinds of environmental challenges would these approaches be useful?
  - Improve occupational risk assessment, herbal supplements
  - Characterize soil sampling
  - Emergency response
  - mixtures
  - technology transfer to streamline R&D to build better chemicals

- Communication suggestions
  - decide what the message is and keep on it
    - “vision” versus “actual advancements”
    - carefully convey uncertainty; keep in mind the public may be fearful of uncertainty
  - lessons learned from other similar attempts
  - who are the target audiences? (get specific)
    - convey benefits and limitations/pros and cons
    - help the media get the message right
    - how do they need it organized (e.g., reporters need to find the information within 3 clicks)

- Communication suggestions
  - be clear about inter-agency coordination/consistent communications
  - active communication
  - education (all levels)
  - train communities (e.g., promoters, primary care physicians)
  - best methods of communication will depend on audience you want to reach