

# CSS/HHRA Breakout Group

- Elaine Faustman (Chair)
- Ed Carney (Rapporteur)
- Tom Burbacher
- George Daston
- Michael Dourson
- Lois Lehman-Mckeeman
- Eileen Murphy
- Dennis Paustenbach
- Gina Solomon
- Ponisseril (Som) Somasunderan
- Sheela Sathyanarayana
- John Vena

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- General themes
  - Overall, strong support for the programs
    - “program is on a path to revolutionize chemical safety assessment”
    - “cutting edge”, “leading the field”
    - “high quality science”
  - Clear evidence of integration throughout
  - Support for systems- and AOP-based approaches
  - New emphasis on communication, education and training is strongly encouraged
  - Extremely ambitious

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- General themes
  - Objectives exceed resources available to accomplish them
    - Prioritization is needed (StRAPs do not indicate priorities)
  - Time to focus on confidence building
    - Demonstration / evaluation projects identified by group are significant and represent critical and necessary activities
    - Collaboration between HHRA and CSS and other themes (i.e., water, air) to link new innovative tools with risk assessment, including exposures, is key
    - Collaborate with experienced risk assessors
    - Decision frameworks: be ready to deal with the possibility that predictive models may not always be predictive (especially for different susceptibilities at different life stages)
    - Better approaches to validation / qualification for specific purposes (how to bring in human data?) will likely be needed
    - Recommend an iterative process
  - Application of new methods
    - More clarity around how EPA intends to apply them
    - i.e., fit for *which* purposes?

# CSS/HHRA Charge Questions

- **2a.** How well will the research directions in each Early Draft StRAP (2016-2019) support EPA in achieving the relevant Agency objectives and cross-cutting strategies, as described in the EPA Strategic Plan (2014 -201 8)?
- *Excellent alignment with high level EPA goals*
- *High throughput bioprofiling and exposure assessment are game changers*
- *Novel approaches for assessing cumulative risk (chemical and non-chemical) – a potential new cross-cutting road map?*
  - *Support a systematic exposure-based approach*
- *Rapid tox assessment concept supported, although would like more clarity on how it would be used in decision making*

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- **2b.** What are the SAB/BOSC perspectives on the proposed research directions in each StRAP providing research to address environmental issues of 2020 and beyond?
- *Heading in the right direction*
- *More than enough research to last beyond 2020*
- *Research solutions need to be put in practice in 2016-2019 time frame in order to propel the programs to 2020 and beyond*
  - *But ... be careful not to force methods into use before they are ready*
  - *Identify achievable near-term applications*
- *Support emphasis on communication to grow understanding and stakeholder support.*
- *Committee noted that the efforts by CSS stakeholder input and evaluation were used as model.*

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- 2c. For each program, do the presentations and plans indicate that ORD is designing for integration, where appropriate, on topics that are relevant to other research programs?
- *Integration is clearly and deliberately emphasized*
- *Robust process in place at EPA*
- *ORD has come a long way in a relatively short period of time – fantastic!*
- *Extensive discussion of integration on multiple levels:*
  - *Across programs and cross-cutting road map areas*
  - *With other governmental agencies*
  - *Integration of human and ecological*
  - *International: WHO, EU (REACH; JRC), OECD, China – applaud TARGETED approach to international engagement*
    - *Recommend an ongoing “spreadsheet” of international activities*
    - *Focus on research not heavily pursued by other organizations [and borrow when necessary]*

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- 6a. Please comment on approaches the **HHRA** research program might target to better tailor its **exposure and response assessment** approaches to address fit-for-purpose characterizations (e.g., risk prioritization, risk screening, risk assessment).
- *Emphasis on exposure is game-changing and highly supported*
- *Timing of exposure (life stage) as linked to outcome is critical*
- *Holistic approach which considers chemical and non-chemical stressors is supported (albeit challenging)*
- *Support for incorporation of exposure into endocrine screening (and potentially other end points)*
- *Exposure data are necessary for the field to escape the issues of high dose testing*
- *Leverage the power of NHANES, new epidemiology data*

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- 6b. Please comment on approaches proposed by CSS and HHRA research programs to identify and integrate novel data streams to develop innovative fit-for-purpose assessment products.
- *Overall strong emphasis on incorporation of novel data streams*
- *Need more clarity around how novel data will be applied*
  - *e.g., What is the utility of novel HT data on the many REACH chemicals which will have in vivo 28-day and reprotox screening tests?*
  - *Can models be developed to predict longer term endpoints from these base studies?*
  - *Real time risk assessments (e.g., W VA spill)*
  - *Use of ToxCast + ExpoCast to increase the number of PPRTVs and increase the certainty of the ones already generated*
- *Rapid Tox as a new product line*
- *Incorporate human data from NIH, FDA, human disease literature*
- *Drive transition to AOP / MoA and systems biology approaches*

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- 6c. Are there other areas of fit-for-purpose characterizations (e.g., risk prioritization, risk screening, risk assessment) that are ripe for such collaboration/ integration?
- *Call out connections with Children's Health road map*
- *Many groups are working in this space...be sure you know all those activities*
- *Integration / collaboration with OECD, program offices, etc to generate new Integrated Testing strategies for different levels of assessment*
- *Incorporate 'omics technologies into ToxCast program*
- *Build confidence via demonstration / evaluation projects*
- *Cumulative risk projects were also notable and significant as they link to on going cross-cutting issues*

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## Miscellaneous comments

- Would like to hear more about systematic review
  - Is it on the right track?
- Develop metrics of success
- Life stages – don't forget about geriatric subpopulation
  
- *Thanks for the opportunity to comment!*