



Key Exposure Science Challenges Facing Regulators

***- Ensuring we have the exposure science to
deliver***

**Observation: “regulator” “scientist” divide –
need to break down that mindset; as we are all
trying to answer the same questions**



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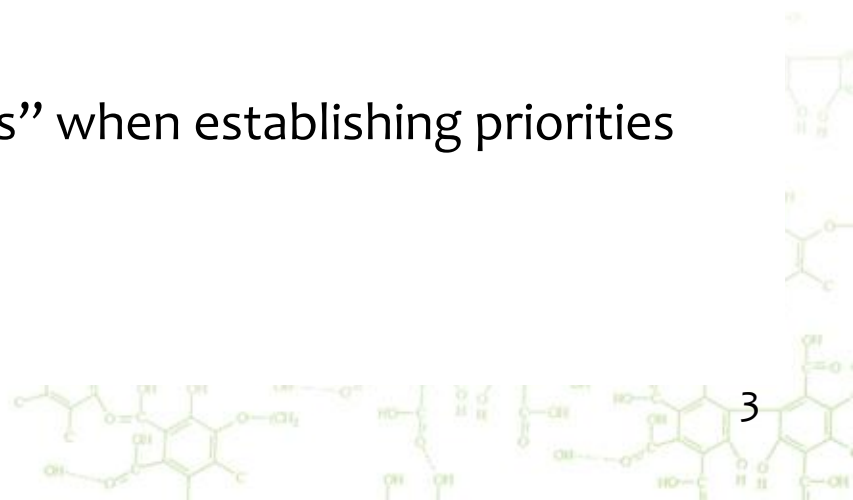
Moving Forward – Ensuring a Strong Exposure Science Foundation

- **Need:**
 - Refinements to existing models and default parameters, and development of higher tier models
- **Session Insights:**
 - “All models are wrong” “parsimonious” “scientific habit of mind” (Matt McLeod)
 - “already too many models” (Chris Money)
 - “Focus where the risk is” “focus on generic inputs” (Mary Mitchell)
 - Focus on key/sentinel exposures (Natalie von Gotz)
 - Mining market research data to improve emission estimates (Paul Mason)
 - Mine nontraditional sources of information (Chris Chaisson)
 - Need for foundational data; minimum data sets
- **Now What:**
 - Prioritize key needs and approach in a systematic manner



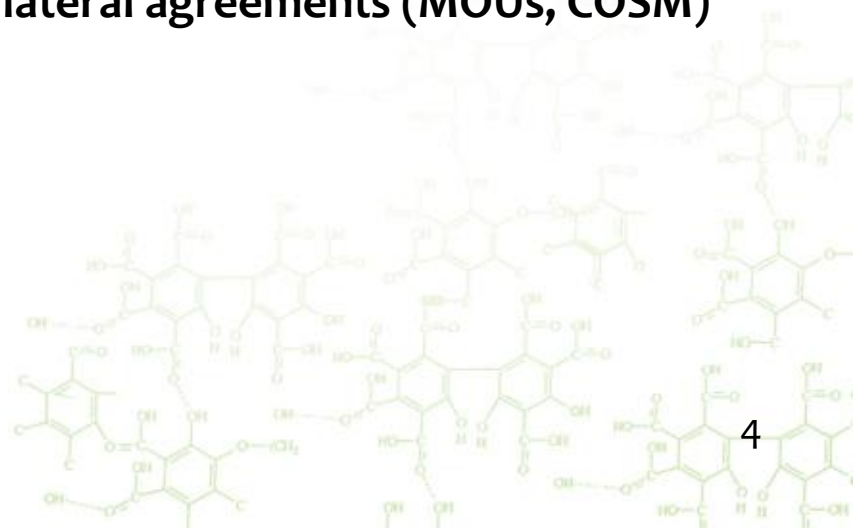
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- Need:
 - Continued development of approaches for assessment of mixtures
- Session Insights:
 - “chemical risk assessment normally ignores mixture effects”
“something from nothing” “Is there sufficient protection at exposures not exceeding ADIs or PNECSs?” (Andreas Kortenkamp)
 - “Mixture Exposure Patterns” “Hotspots – problematic chemicals or groups” ((Theo Traas).
- Now what:
 - Consider “Mixture Exposure Patterns” when establishing priorities moving forward.



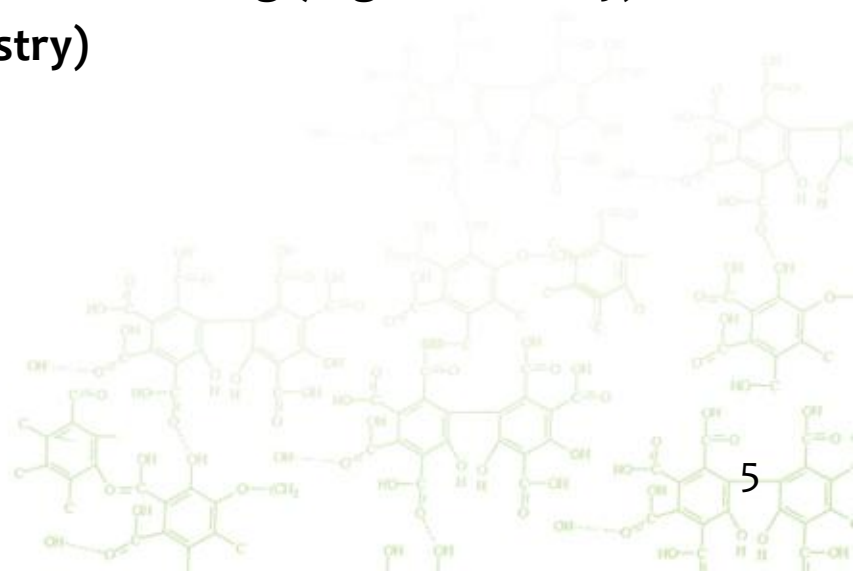
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- **Need:**
 - better coordination across regulatory jurisdictions
- **Session Insights:**
 - Successes in the pesticides/biocides world (Tim Leighton, Mary Mitchell)
 - “Pilots” effective means to move forward (Tim Leighton)
- **Next Steps:**
 - Use existing forum including OECD Exposure Assessment Task Force, ILSI initiatives (for methods/approaches), bilateral agreements (MOUs, COSM) for substance specific initiatives.
 - Other jurisdictions to pull in?



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- **Need:**
 - Structured sector-based use pattern information/overcome CBI challenges
- **Session Insights:**
- **Next Steps:**
 - Achieve better clarity on what we mean by “use pattern” – Ontology (Tom McKone) will aid that
 - Scope mechanisms for improved information sharing (reg community)
 - Pro-active voluntary engagement (industry)
 - Minimize duplication

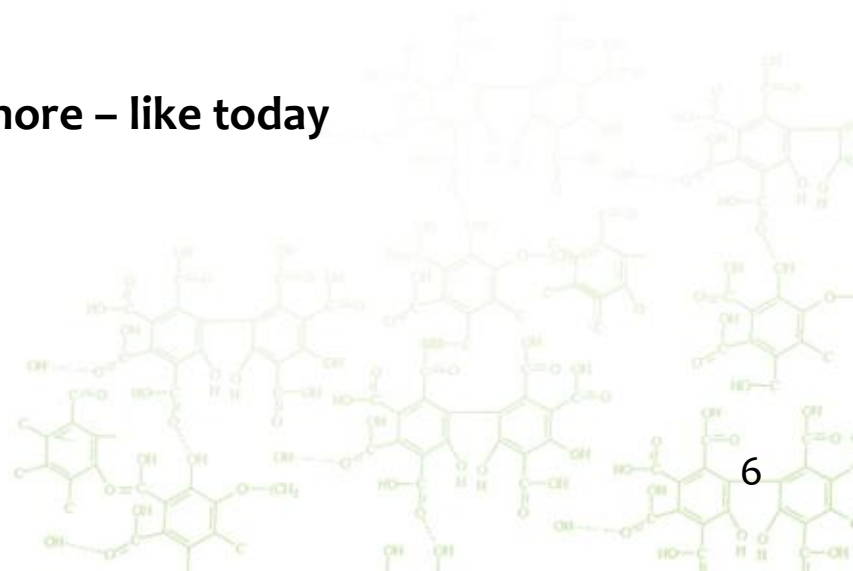


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- **Need:**
 - Better integration across disciplines
- **Session Insights:**
 - Use data-rich fields to inform data-poor (Mary Mitchell)
 - There is a common need to collect basic information about biological systems and how chemicals perturb them (Elaine Cohen-Hubal)

Next Steps:

- introspection and “extra-spection”
- Talk across human and eco disciplines more – like today



Moving Forward – Ensuring A Strong Exposure Science Foundation

- **Need:**
 - Role of exposure-based triggers
- **Session Insights:**
 - Use of triggers can focus resources on substances of concern (Beth Dederick)
 - A clear theme through discussions - TTC and Exposure-based waivers (Theo Vermeire)
 - Feasible to apply TTC concepts to both ecological and human health (Bob Safford)
- **Next Steps:**
 - Use existing fora such as ILSI to continue to scope out regulatory application and science issues associated with TTC
 - Integrate across human health and ecological domains moving forward

