



# Endocrine Disrupting Chemicals (EDCs) and Informed Decision-Making: Expert Panel Session

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# Agenda

- Introduction
- Panel Presentations:
  - **Laura Vandenburg**, Associate Professor, School of Public Health and Health Sciences, Division of Environmental Health Sciences, UMASS-Amherst
  - **Meg Whittaker**, Managing Director and Chief Toxicologist, Tox Services
  - **Paul Ashford**, Managing Director, Anthesis-Caleb
- Live Polling/Small Discussion Groups
- Q/A with Panel



# Refining GreenScreen® Criteria for Endocrine Activity



- **Goal:** Clear, pragmatic and responsible way to determine hazard of chemicals in terms of endocrine activity that can be incorporated into GreenScreen.
- **Strategy:** Refine GreenScreen hazard criteria for Endocrine activity and/or Benchmark criteria and/or Benchmark data requirements.



# Impact of EDCs on Informed Decision-Making

- **Retailers/brands** – reduction of chemicals of concern to meet sustainability goals and consumer demands.
- **Government agencies** (global) - concern about endocrine disruption but lack of clear prioritization/classification process.
- **Advocacy organizations** – implementation of stronger public health protections requires prior knowledge of potential chemical hazard.



# Endocrine Activity- requirements within and across sectors

- Licensed GS Profilers: consistency in assessments
- Suppliers/regulatory agencies/NGOs: raw materials, polymers, additives, contaminants
- Specifiers/purchasers/brands/retailers: products, packaging materials, medical device material

# Desired Outcomes

- Understand the importance of endocrine activity in chemical selection, green chemistry, and avoiding regrettable substitutes
- Understand scientific challenges of evaluating endocrine activity
- Understand resource needs of decision-makers and assessors
- Understand how GreenScreen® addresses endocrine activity
- Understand regulatory landscape and how it relates to both challenges and resources
- Inspire more people to engage with the BizNGO HA WG to support the refining of GS criteria for endocrine activity



# Current Challenges of Assessing Endocrine Activity in GreenScreen®



## High bar to assign Low hazard

*Stringent data requirements despite low availability of data.*

### Impacts:

- *Pro:* drives needed research and data generation
- *Con:* many chemicals assigned 'Data Gap'
  - Chemicals that have no data or chemicals that have some negative data are all assigned a data gap for endocrine activity.
  - The highest Benchmark score most chemicals can achieve is Benchmark 3<sub>DG</sub> due to insufficient data to assign low hazard for endocrine activity.



# Current Challenges of Assessing Endocrine Activity in GreenScreen®



**Moderate Hazard classification encompasses wide range of evidence of endocrine activity.**

## Impacts:

- Chemicals that have a single *in vitro* study indicating endocrine activity are classified the same as chemicals that have a large number of both *in vivo* and *in vitro* studies demonstrating endocrine activity.
- Many chemicals end up as Benchmark 2
- Not a lot of differentiation for decision makers
- Problem of differentiation likely to increase over time, as classification of chemicals in low end of moderate likely to increase





# Current Challenges of Assessing Endocrine Activity in GreenScreen®



**Benchmark-2 is the highest score possible with Moderate, but Benchmark-3 is possible with Data Gap.**

## Impact:

- Common yet incorrect association between 'Data Gap' and 'hazard-free'.
  - Chemicals assigned a data gap for endocrine activity are viewed as better than those assigned a moderate for endocrine activity.

**Manufacturers are very sensitive to this.**

- Benchmark scoring algorithm is creating an incentive to NOT test chemicals for endocrine activity or to share the data that has already been generated.





# Current Challenges of Assessing Endocrine Activity in GreenScreen®



**Lack of consistency in data interpretation among GreenScreen Profilers for classification of endocrine activity endpoint**



# Revising Endocrine Activity Criteria: Potential Solutions



- 1) Enhance guidance for classification through alignment with existing EU regulatory guidance.
- 2) Grade data availability/gaps on a scale to indicate how many of the five required endocrine mediated pathways have some data available (i.e., 1, 2, 3, or 4).
- 3) Sub-divide **moderate hazard** into two levels to create greater distinction and guidance for decision-makers.
- 4) Have endocrine activity and endocrine disruption as two separate endpoints in GS or incorporate updated WHO definition of ED into GS classification of high hazard for endocrine activity and retain 3 current levels (high, mod, low) for single EA endpoint.



# LIVE POLL



**Q1:** What is your biggest reason for incorporating endocrine activity/disruption in your decision-making process?

<http://bit.ly/endopoll>

wifi pw: 617#Npc89!





# LIVE POLL



**Q2:** What is your biggest challenge in using endocrine activity information for decision-making?

<http://bit.ly/endopoll>

wifi pw: 617#Npc89!





# LIVE POLL



**Q3:** You have selected a chemical that is endocrine active to replace a known endocrine disruptor. Would you consider this a regrettable substitution or a positive step toward chemical optimization?

<http://bit.ly/endopoll>



## Case Study- How Valspar engaged stakeholders to solve the BPA dilemma



Valspar (now owned by Sherwin-Williams) is one of the largest provider of food and beverage can coatings. Brand / customer pressure to move out of BPA based coatings but best performing alternatives were still bisphenol- based epoxy coating.

- **Goal:** to design a molecule with the appropriate functionality of a bisphenol epoxy resin minus the undesirable biological activity associated with BPA.
- **Result:** tetramethyl bisphenol F (TMBPF) lacked estrogenicity, lacked genotoxicity, and will not migrate into food or beverages as BPA has been shown to do. Compared to BPA and BPA-based epoxy coatings the TMBPF monomer and TMBPF-based epoxy coatings have lower hazards and lower exposure.

### Valspar's innovative approach:

1. partnered with NGOs, endocrine-activity experts and toxicologists to design testing scheme
2. published **test results** on their website
3. published the **structure** on their website

