Best Practices for Sustainable Alternative Chemical Substitutions

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ILSI Health and Environmental Sciences Institute

Outline

- Background about Alternatives Assessments and the HESI Sustainable Alternatives Subcommittee
- Workshop Held in February 2013
- Technical Progress of the Three Subgroups
- Next Steps
- Discussion

What is Alternative Chemical Assessment?

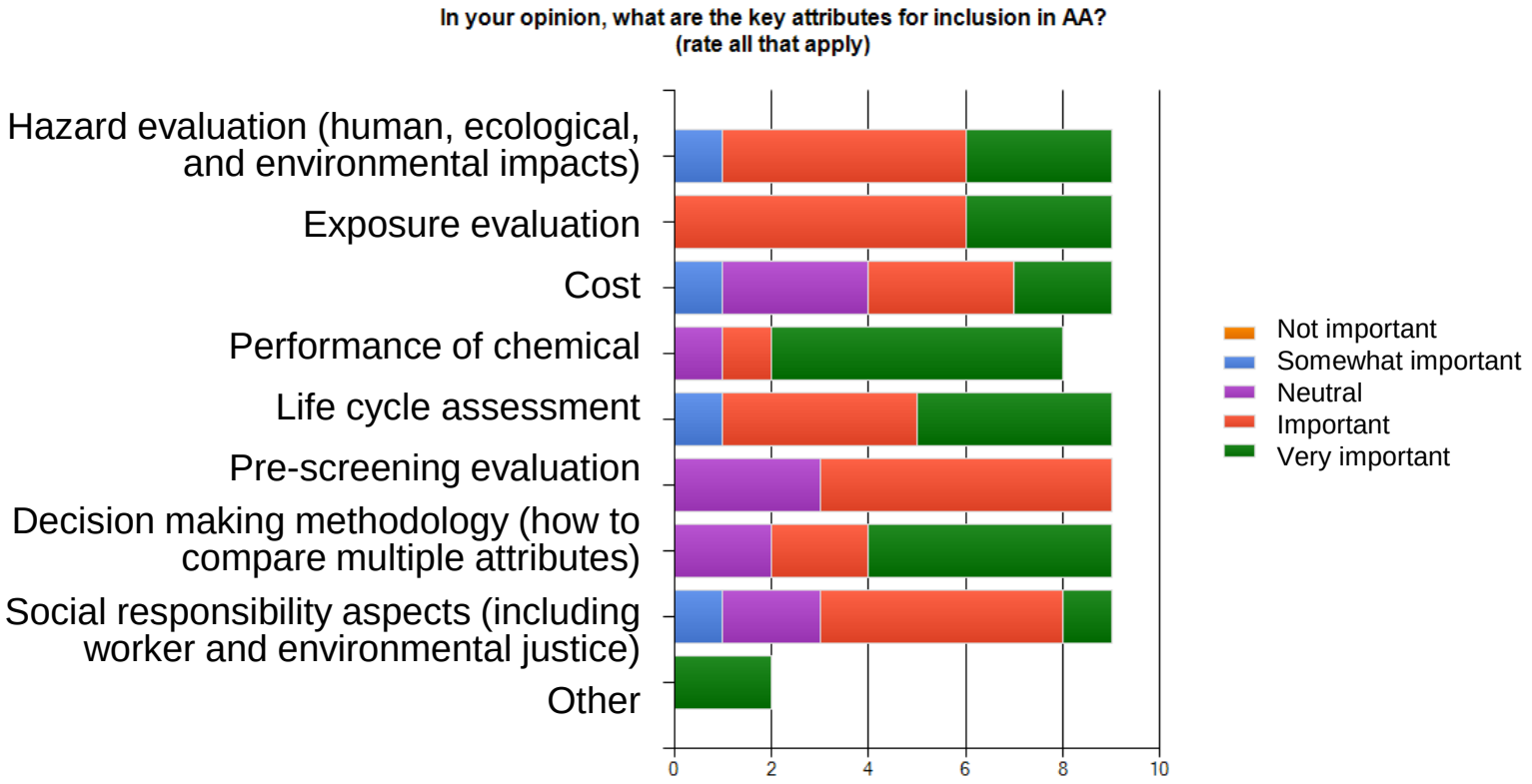
- Alternatives Assessment (AA) is a process for identifying and comparing potential chemical and non-chemical alternatives that can be used as substitutes to replace chemicals or technologies of high concern.*
  - Generally, AA compares human health and safety, environmental health, lifecycle thinking, as well as social, economic, and technical performance factors.
  - AA is NOT referring to animal alternatives.

* Dr. Ken Geiser of Lowell Center for Sustainable Production

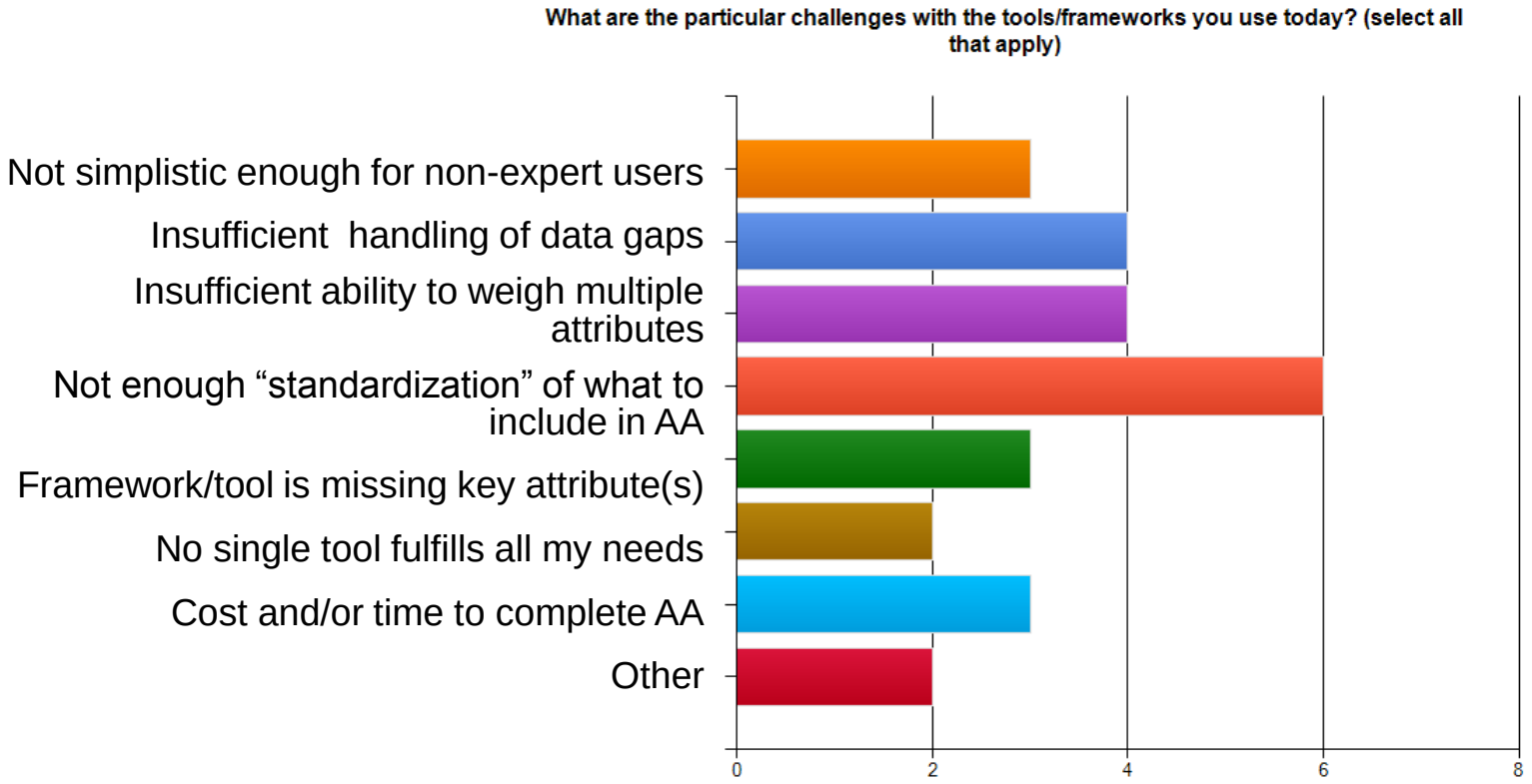
Why Guidance for Alternatives Assessment is Needed

- There are growing interest and demand for the use of alternative chemical assessment (regulatory, business, and consumer drivers)
- There is general agreement by stakeholders that:
  - Attributes beyond hazard are also important (i.e. LCA, risk/exposure, cost, performance, social responsibility)
  - Not one tool/method to meet all needs
  - Not enough standardization with current methodologies
  - Often insufficient handling of data gaps and insufficient ability to weigh multiple attributes
- There is a need to pool the expertise across academia, government, NGOs, and industry to develop guidance
  - ➢ HESI is uniquely positioned to do this

Survey Question to Steering Team: In your opinion, what are the key attributes for inclusion in AA?



Survey Question to Steering Team: What are the particular challenges with the tools/frameworks you use today?

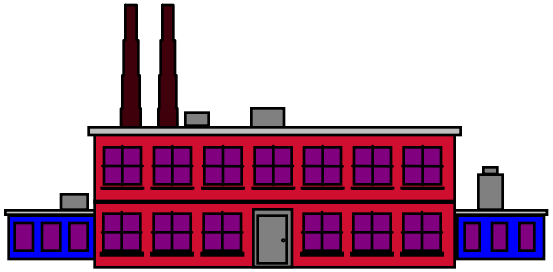


Why Guidance is Important… Moving Beyond Hazard

For example:

- Assessment of chemical performance
- Assessment of exposure
- Basis of comparison/assessment
- Data gaps/assessment of data poor chemical substances
- Lifecycle

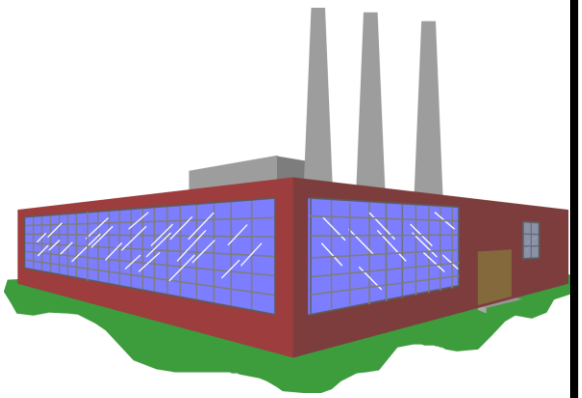
Why Guidance is Important . . .
To avoid *unintended* consequences of replacement throughout the lifecycle



Manufacturing Facility

Retail Outlet

Consumer Products



Customer Formulator

Confirm:

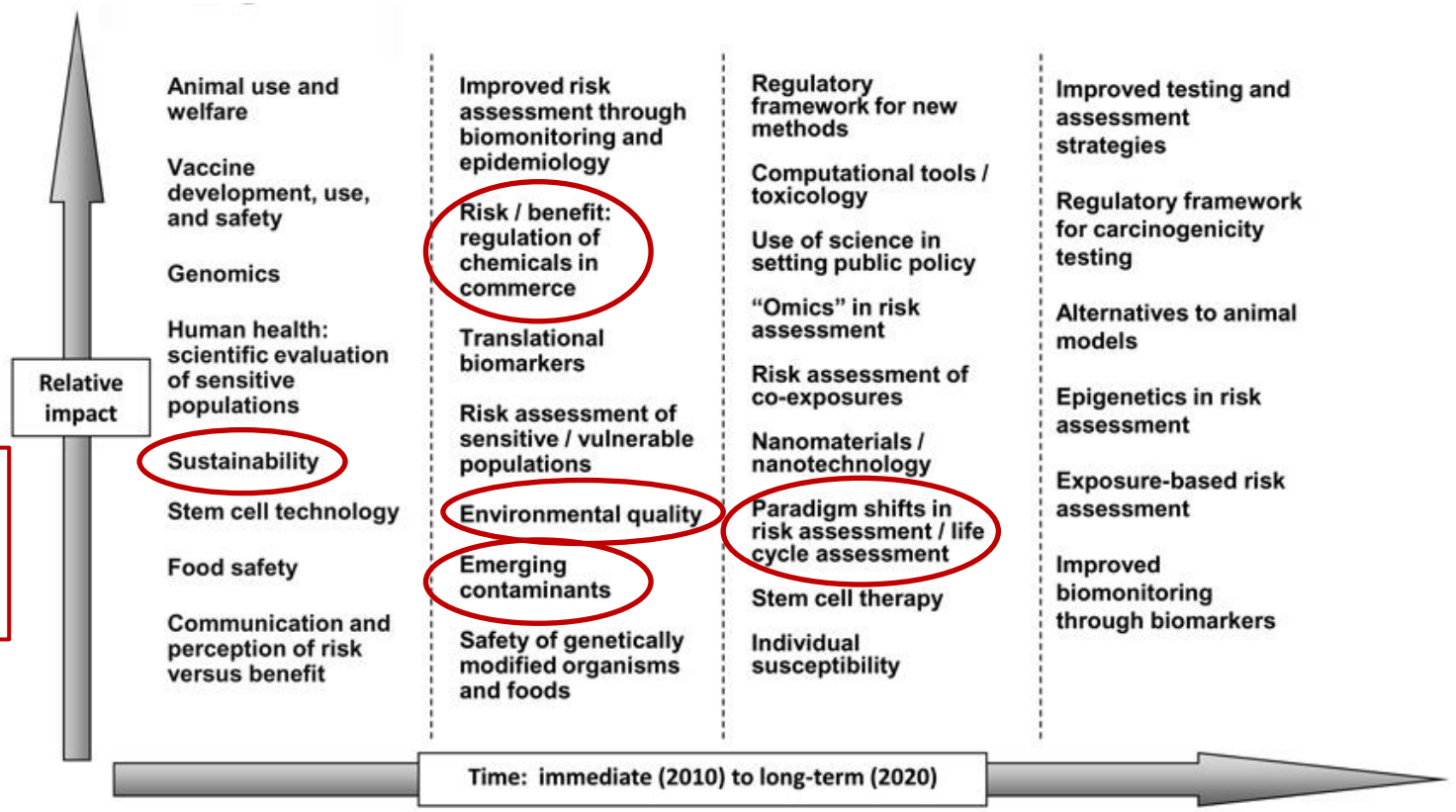
- **substitutes do not have greater/unknown toxicity or exposure potential.**
- **risk is not transferred to different point in value chain**

Final Consumer

About Sustainable Alternatives Subcommittee

- Initiated in 2011 when selected as HESI's Emerging Issue
  - First sustainability project for HESI
  - Named "Frameworks for Alternative Chemical Assessment and Selection of Safer, Sustainable Alternatives"
- Began as 13 member Steering Team to develop initial scope of subcommittee
- Membership expanded in 2012 to multidisciplinary team of over 25 who refined objectives and organized workshop

HESI Combined Challenges Map 2010-2020



Sustainability related topics

Participating Organizations in 2012

- California EPA
- Celanese
- Chemical Compliance Systems
- Dow AgroSciences LLC
- Dow Corning
- DuPont
- EFSA liaison officer at FDA**
- Environment Canada*
- ExxonMobil*
- George Washington University*
- ICL-Ip America, Inc.
- London School of Economics
- Merck
- NIEHS*
- Novozymes
- NSF International*
- Research Institute for Fragrance Materials
- Sanofi
- SciVera*
- Shell Chemicals*
- Sustainability Foresights LLC
- The Dow Chemical Company*
- The Procter & Gamble Company*
- UCLA
- University of Illinois
- University of Michigan*
- US Department of Commerce
- US EPA*

Current Leadership

- Co-chairs
  - Derek Muir (Environment Canada)
  - Pam Spencer (The Dow Chemical Company)
- Subgroup Leaders
  - Subgroup 1: Satinder Sarang (Shell International)
  - Subgroup 2: Royce Francis (GWU)
  - Subgroup 3: David Constable (ACS Green Chemistry Institute)
  - Additional leadership for workshop and manuscript: Darlene Dixon (NIEHS)
- HESI Staff
  - Jennifer Young Tanir; Brianna Farr

Mission of Subcommittee

- To evaluate and identify key elements/criteria and tools to help trigger and guide the selection of safer, sustainable alternatives while minimizing the likelihood of regrettable substitutions.

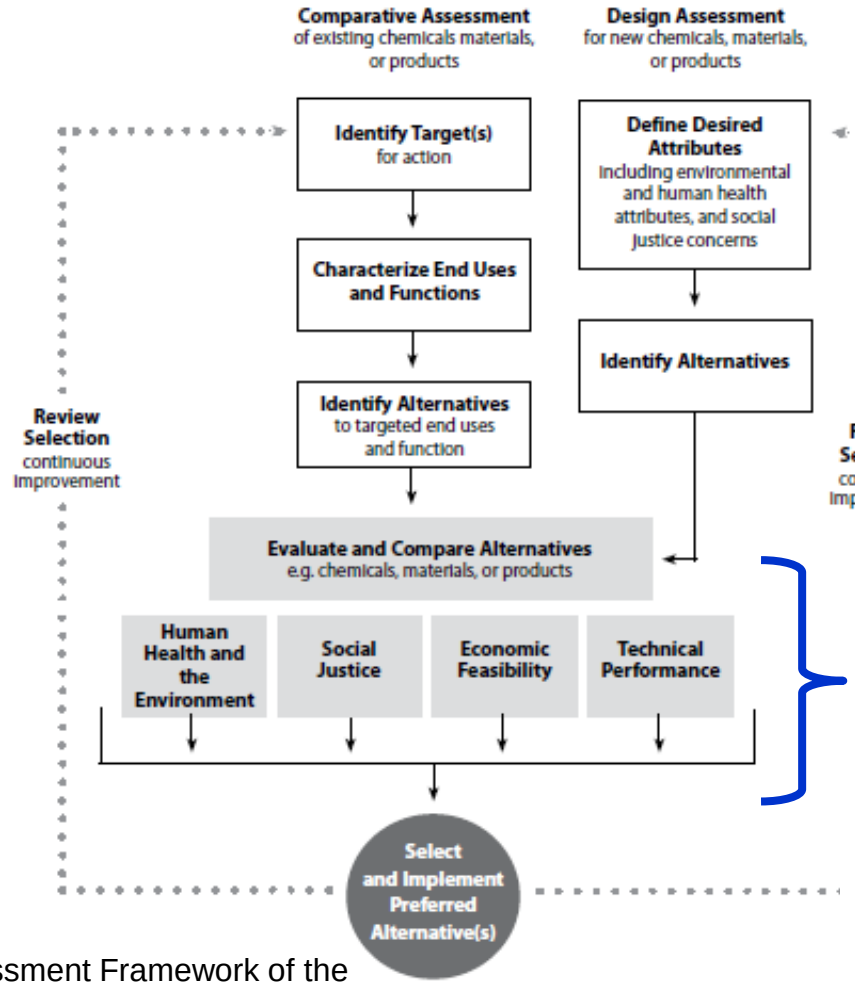
Project Objectives

- Build understanding of existing approaches used to select safer, sustainable alternatives.
- Identify strengths, weaknesses and gaps in current approaches.
- Develop a decision tree to guide key stakeholders through the alternatives assessment process.
- Identify emerging needs/challenges for the future.

Project Deliverables

- Hold a 2-day workshop during winter 2013 during which experts will discuss the key topics identified by the subcommittee.
- Publish recommendations aimed at guiding and improving the successful selection of safer, sustainable alternatives.

Alternatives Assessment Process



Our Focus:

- Attributes and new tools/models for prioritization/assessment
- Decision-making and weighing disparate attributes
- Data gaps/needs and solutions

From: "Alternatives Assessment Framework of the Lowell Center for Sustainable Production" (2006).

Focus of the Subgroups

Three inter-related topics which form basis for subgroups and workshop break-out discussions

1) Attributes and Tools

- **Attributes** beyond hazard that are also important, including life cycle assessment, exposure, risk, performance, cost and social responsibility
- New **tools** for prioritization and assessment of hazard, risk and other attributes

2) Decision-making and Weighing

- Making **decisions** with limited data and a minimum data set
- Best practices for **weighing** disparate attributes

3) Data gaps

- What are the **data gaps and data needs**
- What are **solutions** for missing data

Workshop Held in February

Purpose:

- Develop practical, problem driven guidance on the conduct of alternatives assessment
- Must address multi-stakeholder needs
- Must go beyond simple hazard assessment

35 Tripartite and Global Workshop Participants

Subcommittee Participants:

- ACS Green Chemistry Institute
- California EPA- Dept of Toxic Substances Control
- Celanese International
- Dow AgroSciences
- Dow Corning Corporation
- DuPont
- Environment Canada
- George Washington University
- ICL-Ip America, Inc.
- London School of Economics
- NIEHS
- Novozymes
- NSF International
- Procter & Gamble Co
- Shell International
- The Dow Chemical Company
- UCLA
- US Environmental Protection Agency

Other Invited Participants:

- American Cleaning Institute
- BASF Corporation
- Copper Alliance
- Eastman Chemical Co
- Environmental & Public Health Consulting
- PE International, Inc. & Five Winds Strategic Consulting
- RISS, AIST (Japan)
- Soleil Consulting
- Sumitomo Chemical America Inc.
- Toxics Use Reduction Institute
- UMASS Lowell
- Unilever
- University of California, Santa Barbara

Feedback from Workshop Survey

- “It's an important topic that needs to be aligned with (as much as possible) the many parallel activities already happening.”
- “I think the end product(s) will be valuable for a variety of stakeholders. I think that's the bottom line.”
- “Very good. Clear that thoughtful pre-work was done which formed basis for the workshop.”
- “Impressed that the committee would take on such a challenging task beyond the usual HESI scope.”

Technical Progress of the Three Subgroups

1) Attributes and new tools/models for prioritization/assessment
2) Decision-making and weighing disparate attributes
3) Data gaps/needs and solutions

Progress is summarized on the next slides.

Subgroup 1: Attributes and Tools/Models for Prioritization/Assessment

- **Attributes** beyond hazard that are also important, including life cycle assessment, exposure, risk, performance, cost and social responsibility
- New **tools** for prioritization and assessment of hazard, risk and other attributes

Subgroup 1: Outline of Discussions

- What is an AA
- What are the drivers behind an AA? What triggers an AA?
- What are the components of an AA? Key attributes to be considered?
- What tools are available to fulfill an AA? What are the advantages/dis-advantages of existing tools? Gaps in tools?
- What expertise is needed for an AA?
- What is a reasonable outcome (timing, implementation, cost, etc)?

Subgroup 1: Example of Key Attributes for Comparing Alternatives

- Human Health Effects
  - Acute mammalian toxicity (oral, dermal, inhalation)
  - Carcinogenicity
  - Genetic toxicity
  - Neurotoxicity
  - Repeated dose toxicity (oral, dermal, inhalation)
  - Reproductive toxicity
  - Developmental toxicity
  - Respiratory sensitization
  - Skin sensitization
- Human Exposure
- Human Health Risk
- Environmental Toxicity and Fate
  - Aquatic toxicity
  - Persistence
  - Bioaccumulation
- Environmental Risk

Subgroup 1: Example of Key Attributes for Comparing Alternatives

- Lifecycle Data
  - Energy
  - Greenhouse gas emissions
  - Water use
  - Solid waste
  - Air toxics
  - Water toxics
  - Human health
  - Eutrophication
- Patent/IP (held by company)
- Social Sustainability
  - Child labor
  - Forced labor
  - Working conditions
- Regulatory (listed in all geographies?)
- Manufacturability
  - Supply sufficient?
  - Manufacture with existing equipment
  - Programs & systems available to handle?
  - Product stable?
- Consumer Acceptance
  - Aesthetics
  - Efficacy cost
  - Overall preference

Subgroup 1: Existing Tools and Frameworks Examined

1. BizNGO Chemical Alternatives Assessment Protocol (2011)
2. Industry Coalition's Principles of Alternatives Assessment (2012)
3. California EPA DTSC's Safer Consumer Products Proposed Regulations (2012)
4. California EPA DTSC's Alternatives Analysis Workshop, Hazard/Exposure Assessment Tools, Methods And Data Sources
5. EPA DfE Alternatives Assessment Criteria for Hazard Evaluation (2011)
6. GreenScreen (2011)
7. Lowell's Compendium of Chemical Hazards Reduction Methods and Tools (2011)
8. Lowell's Alternatives Assessment Framework (2006)
9. NSF-GCI-ANSI 355 Standard for Greener Chemicals and Processes Information (2011)
10. TURI's Alternatives Assessment for Toxics Use Reduction (2005)
11. UBA's Guide Sustainable Chemicals (2010)
12. UCLA's Developing Regulatory Alternatives Analysis Methodologies (2011)
13. UCSB's Safer Product Alternatives Analysis (2011)
14. Interstate Chemicals Clearinghouse (IC2)'s Alternatives Assessment Guidance (2012)

Subgroup 2: Decision-making and Weighing Disparate Attributes

- **Making decisions** with limited data and a **minimum data set**
- Best practices for **weighing** disparate attributes

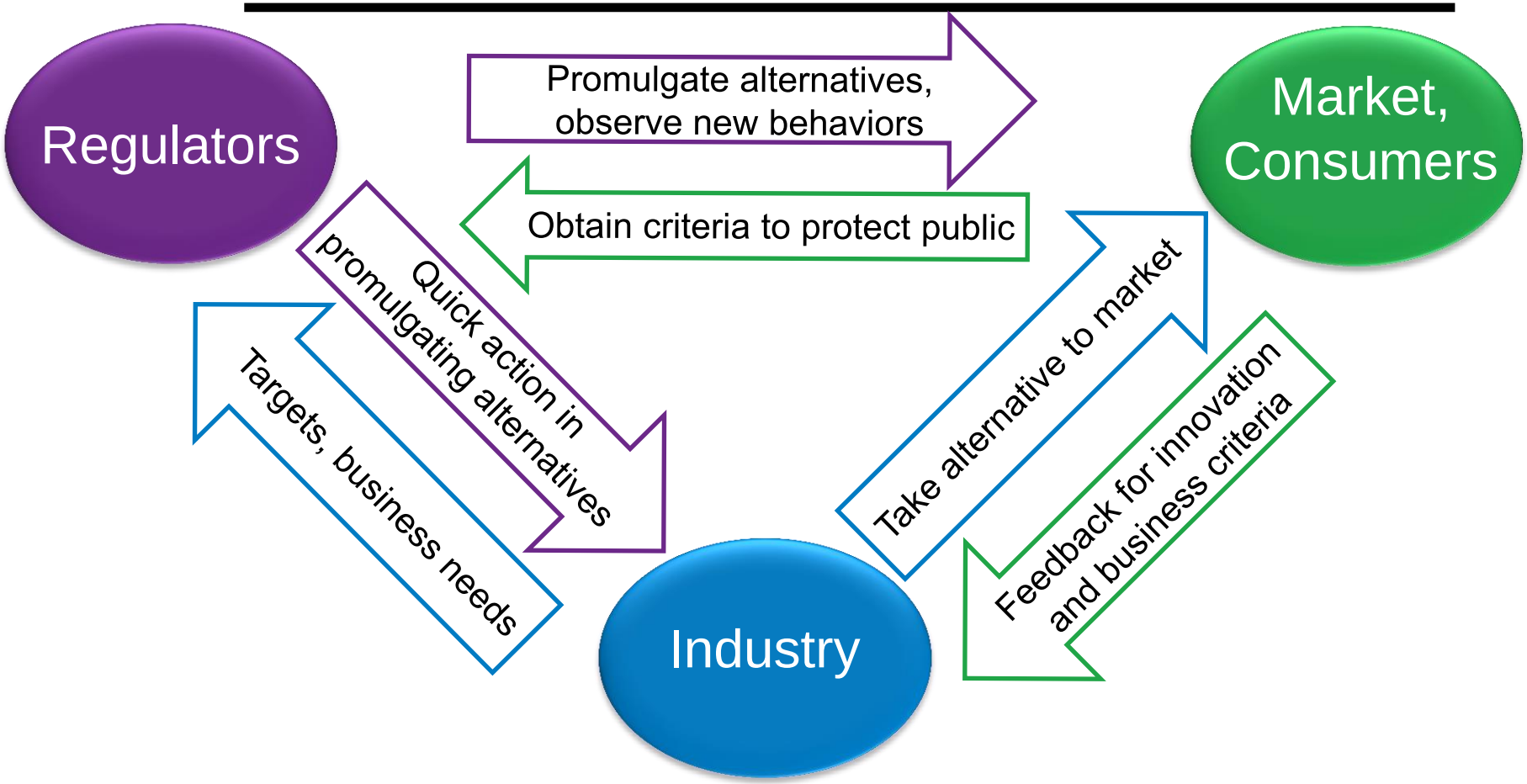
Subgroup 2: Outline of Discussions

- Alternatives Analysis as a generic decision-analytic process
- Lessons learned from AA decisions
  - Examples: Multi-Criteria Decision Analysis (MCDA), Hazard-based AA, Industrial AA (often stage-gate based)
- Interactions and synergies among stakeholders: regulatory, industrial, public
- Recommendations and continuing challenges

Subgroup 2: Generic Decision Processes in AA

1. Problem statement
2. Generation of alternatives
3. Identification of criteria
4. Data collection
5. Structuring elicited preferences/weighting
6. Screening of inferior alternatives
7. Ranking of non-eliminated alternatives
8. Recommendations

Subgroup 2: Interactions of Key Stakeholders



Subgroup 3: Data Gaps/Needs and Solutions

- What are the data gaps and data needs
- What are solutions for missing data
- This topic is also related to tools/models and decision-making

Subgroup 3: About Data Gaps

- Alternatives often have less information or a profile that is different compared to established chemicals or products.
- Chemical data can be hard to obtain and is generally not shared along the supply chain.
- Information is becoming publically available through legislation such as REACH, but significant data gaps exist for specific environmental, safety and health, life cycle and other end points of interest.
- Some data gaps will be filled through experimentation over time, but property prediction through the use of various tools and approaches is essential.
- Data quality will affect overall certainty of the assessment outcome and is a key concern.

Subgroup 3: Identifying and Filling Data Gaps

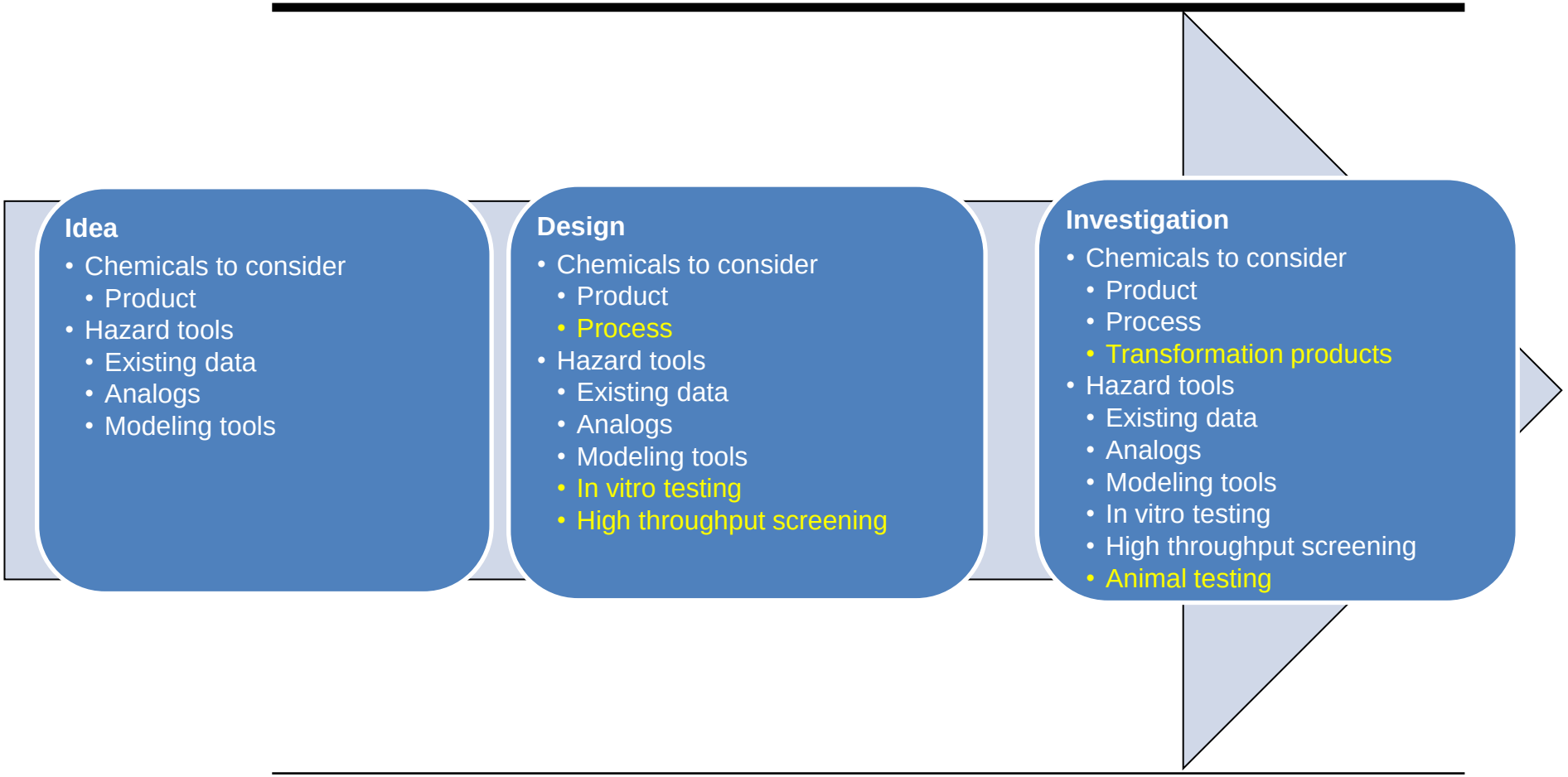
- A matrix was created consisting of data gap types (for different types of attributes, such as hazard, exposure, LCA, etc) and product life cycle stages, from idea generation through to end of life.
- At each life cycle stage, data gaps associated with the different types of attributes are usually filled utilizing different methods, tools (QSAR, Checklists, etc.) and laboratory experiments.
- The subgroup is developing guidance for how to fill data gaps for each stage of the life cycle.

Subgroup 3: Matrix of Data Gaps

		Type / Level of Assessment (Where data derived)							
Product Life Cycle Stage	**Functions Involved**	**Technical Performance**	**Hazard**	**Exposure**	**Risk**	**Life Cycle**	**Sustainability**		
							Economic	**Societal**	**Environmental**
Idea Generation	R&D	Desk	Desk	Desk	Desk		Desk	Desk	Desk
Design	R&D	Desk	Desk	Desk	Desk	Desk	Desk	Desk	Desk
Preliminary Investigation	R&D, Manufacturing, Corporate Staffs	Lab	Lab	Lab	Desk				
Detailed Investigation	R&D, Manufacturing, Corporate Staffs	Lab/Pilot	Lab/Pilot	Lab/Pilot	Desk	Desk	Desk	Desk	Desk
Development	R&D, Manufacturing, Corporate Staffs, Business Functions			Lab/Pilot	Desk	Desk			
Testing and Validation	R&D, Manufacturing, Corporate Staffs, Business Functions	Pilot / Manufacturing Trials		Pilot / Manufacturing Trials	Desk	Desk	Desk	Desk	Desk
Launch	Manufacturing, Corporate Staffs, Business Functions, Sales and Marketing	Field		Manufacturing / Field	Desk				
Distribution	Business Functions, Sales and Marketing, Corporate Staffs			Field	Desk				
Use	Business Functions, Corporate Functions	Field		Field / Customers	Desk		Desk	Desk	Desk
End-of-Life	Business Functions, Corporate Functions			Field / Customers	Desk		Desk	Desk	Desk

* Green indicated information has been collected

Subgroup 3: Information Behind the Matrix for Hazard Column



Next Steps

- Publish an Emerging Issue Review in Environmental Health Perspectives
- Publish three technical papers (one from each subgroup) in a targeted journal
- Outreach
  - Present progress at 17th Annual Green Chemistry & Engineering Conference (June 18-20, 2013)
  - Proposed symposia for SRA 2013 and SOT 2014
- Intend to petition to become a HESI Project Committee during Fall 2013

Discussion

- How do you see alternatives assessment taking place in your context?

Thank You!

Interested in Joining the Subcommittee?

- Contact **Jennifer Young Tanir** for more information or to join the subcommittee:

  jtanir@hesiglobal.org