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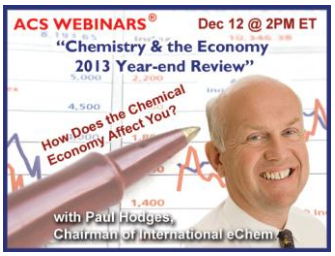

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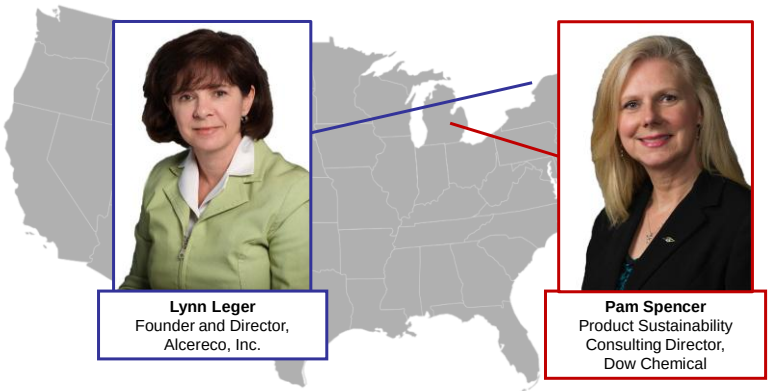
Alternative Assessments: Strategies for Sustainable Product Development



Lynn Leger
Founder and Director,
Alcereco, Inc.

Pam Spencer
Product Sustainability
Consulting Director,
Dow Chemical

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Challenges & Strategies in Identification of Sustainable Alternatives

Pam Spencer, Ph.D., D.A.B.T.
Product Sustainability Consulting Director
Toxicology Environmental Research & Consulting
The Dow Chemical Company
December 5, 2013

Outline

- **Why focus on alternative selection?**
- **Current guidance for alternative assessments**
- **Key challenges**
  - **Implementation**
  - **Decision making**
- **Recommendations**
- **Emerging needs**
- **Q&A**

Why do we care or need to look for alternatives?

- **Increasing pressures to find more sustainable, safer alternatives**

Regulatory drivers: Replace Chemicals of Concern

- REACH Authorization
- California Safer Consumer Products Regulation
- TSCA reform

Corporate Sustainability Initiatives

- Greenhouse gas reduction
- Energy conservation
- Raw material preservation
- Reduced hazard options

Customer/Consumer Drivers

- Banned lists of chemicals
- Ecolabel certifications

Alternative Assessment Can Guide Selection Process

- **Alternative Assessment (AA)**
  - A process used to identify and compare potential chemical and non-chemical alternatives that can replace chemicals or technologies of high concern.

Characteristics of AA

- AA frameworks have been developed to guide assessors through the process
- Typically addresses the general principles of the assessment but <u>does not</u> give detailed guidance on how to conduct comparisons and reach conclusions
- General principles can vary by framework but often place heavy emphasis on hazard traits
- Attributes often include:
  - Technical Performance/Feasibility
  - Cost
  - Hazards (human & environmental)
  - Exposure
  - Lifecycle Considerations
  - Social Justice

What is the reason for your interest in AA?

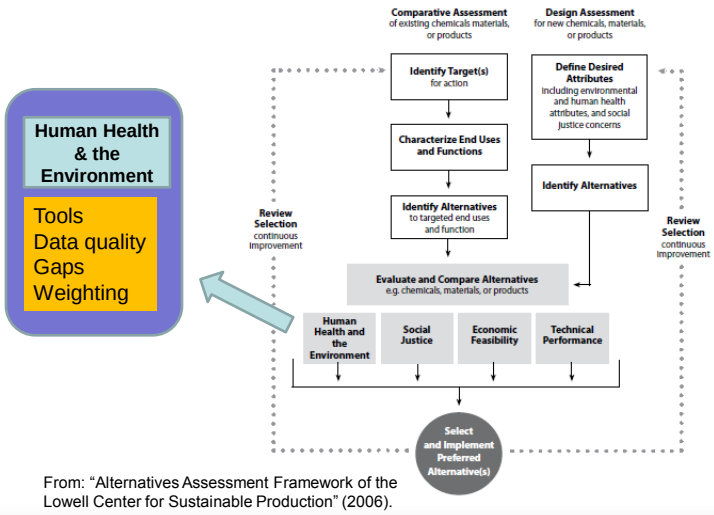
A. To meet sustainability objectives of my organization

B. To meet the requests of my customers

C. To meet current or future anticipated regulations (incl. local/state/region/international)

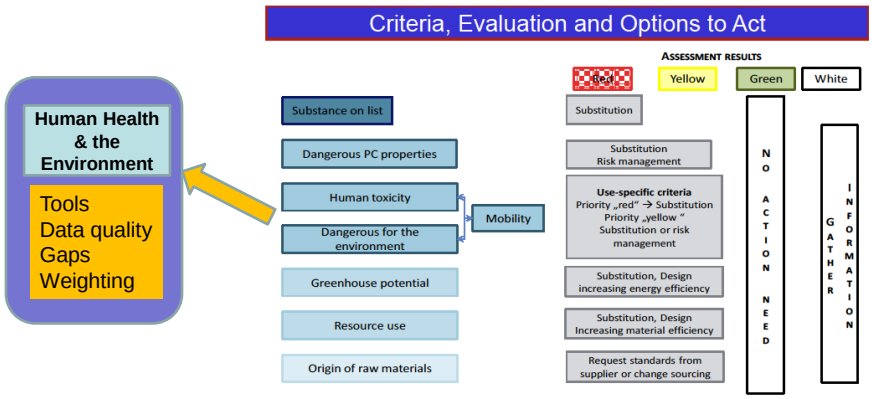
D. To stay ahead in the marketplace

Example: Lowell AA Framework



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

Example: UBA--Guide on Sustainable Chemicals



Comparing Alternatives is Complex

- Requires expertise across different disciplines & across the product lifecycle
  - Technical performance
  - Manufacturing
  - Toxicology
  - Environmental Chemistry
  - Exposure Assessment
  - LCA
  - Economics
- Requires different tools
- Integrated assessment and balance of trade-offs

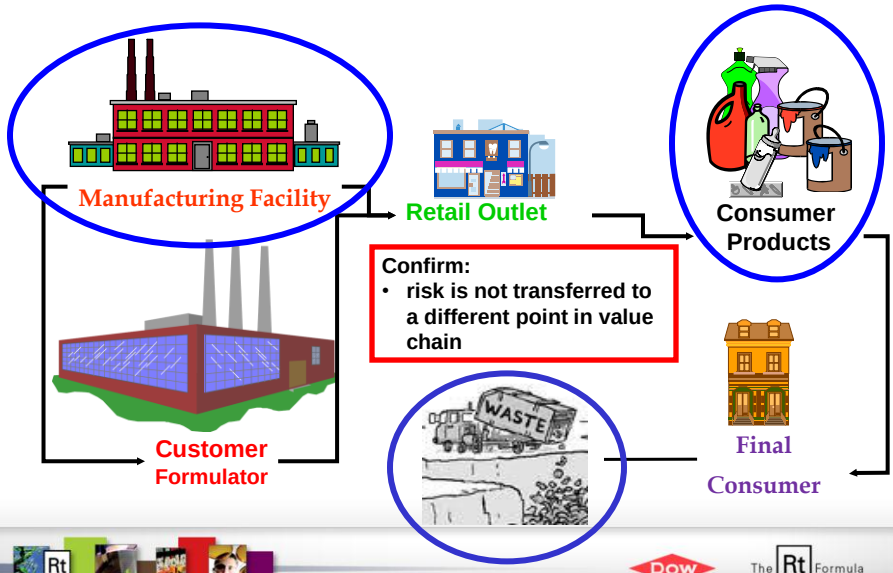
Devil is in the Details!

- How do you determine and compare what's most appropriate for the AA?
- Weighing one chemical against another?
  - Alternatives often have less information or profile is different compared to established products
- Minimum base data set?
  - Need the information that will discriminate between two options.
  - Are there scenarios where you can eliminate the need for certain data?

Devil is in the Details!

- How will you get data or fill data gaps?
- Best practices, scientifically robust, vetted methods?
  - Utility of emerging tools/technologies
- How do you deal with trade-offs and conflicting results?
- Weighting – can come to different conclusions based on aspects deemed important in the assessment

Avoiding Regrettable Substitutions



Challenge

- Developing new molecules and replacing existing molecules is expensive.
- Alternatives must
  - Be technologically *feasible*
  - Deliver the *same or better value* in cost and performance
  - Provide an *improved* profile for health and environmental issues
  - Account for economic and social considerations
  - Have potential to result in *lasting* change. Want to avoid selecting alternatives that might be restricted in the future.

Case in Point:

Agricultural Product Development Fast Facts

- **Resource intensive**:
  - **10 years** and **$250 million** to research, develop and register new crop protection product
- **Tightly regulated**:
  - **1 in 139,000** chemicals successfully progresses from the lab to the field
  - A product undergoes **>100** regulatory studies to support the health, safety and environmental assessments required for registrations

Getting it right the first time save resources, time and money!!

Challenges with the tools/frameworks you use today?

A. Not simplistic or standardized enough for non-expert users

B. Insufficient handling of data gaps or ability to weigh attributes

C. Framework/tool is missing key attribute(s)

D. No single tool fulfills all my needs

E. Cost and/or time to complete AA

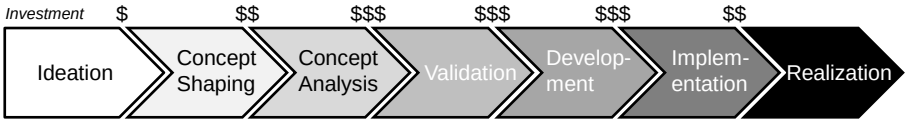
How do you identify BEST Alternative?

How do you avoid paralysis by analysis?

How can you use AA to drive innovation?!

Interface AA With Project Management

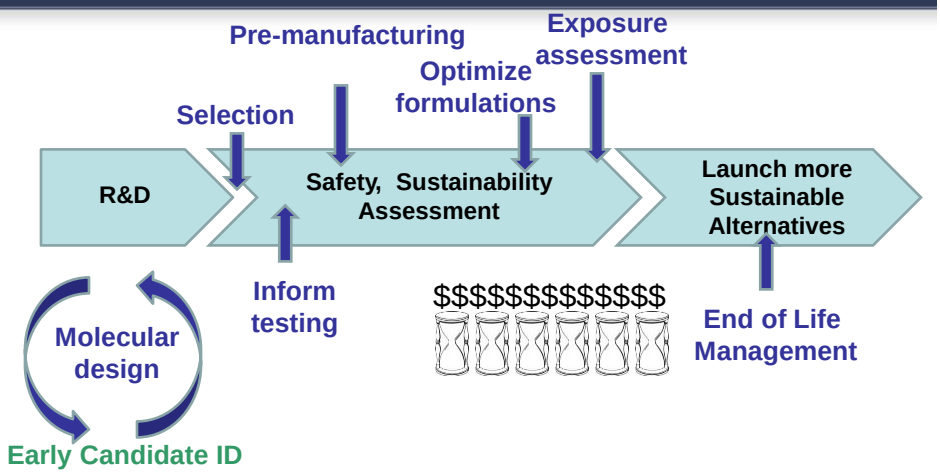
Stage Gate Concept



- Disciplined, but flexible "Stage Gate" process with well defined advancement criteria
- Front End Loading: Generate as much knowledge as early as possible while options are still open
- "Fail Fast / Succeed Early"
- Two-phases of R&D*
  1. Early → quickly eliminate poor candidates and absorb risk
  2. Late → increase probability of launch
- Alternate candidate: Equal performance, acceptable toxicity and environmental profiles, equivalent economics

*Bonabeau, E., Bodick, R., A More Rational Approach to New Product Development. *Harvard Business Review,* March 2008, 96-102

Use AA to Drive Decisions Early for Innovation



Value Proposition: Save time, resources and money!

GUIDANCE, GUIDANCE, GUIDANCE . . .

to create a clear, flexible and transparent process.

		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

Example for Hazard ID: Cheminformatics in Early PD

Category	Currently Used Tools
QSAR	EPA Test ToxTree TOPKAT DEREK OECD Tool Box OASIS TIMES ECOSAR EpiSuite EpiWin
Analog ID	SciFinder; DSSTox; OECD Toolbox; Google; Experience
Data mining	Internal data ToxCast DSS Tox Acute Tox Other publically available data bases

PD= product development

Expanded list of search tools

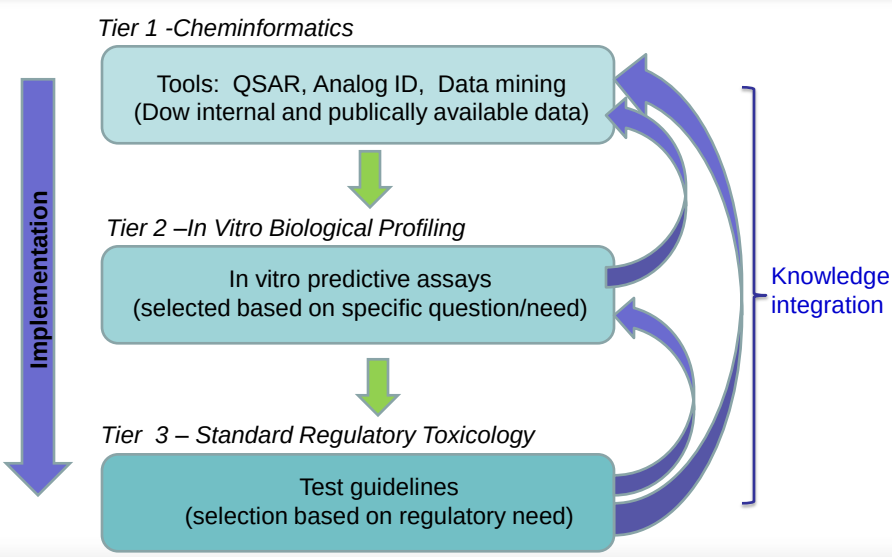
ACTOR	External Searching	Internal Databases	Data Mining Software
ToxRefDB	eChem Portal (Toxline, ECHA, IRIS, ACTOR)	TIC	Pipeline Pilot (Accelrys)
ToxCast DB	Google	Dow Registry (Chemcart)	Chem Axon
Chembl (Chebi)	RTECS	VISTA (DAS- SQL)	Tibco Spotfire
Pub Chem	MSDSs	One Stop (Access)	Open Eye
NTP	Technical Datasheets	SAP/TIME	Open Bable
ECHA	SciFinder	SAGE	EpiSuite
DSS TOX	QSAR Training Sets		OECD Toolbox
OECD SIDS	Ariel		Moe
ATSDR	Open Tox		
Golds Database			
ToxCast Dashboards			

Confirm Results of *In Silico* Assessments

- Focus on:
  - Endpoint aligned assays- i.e.- aligned to regulatory endpoint requirements. Practical applications for early decision making.
  - Endpoints with readily available assays

Toxicity Endpoints	Alternative assays	Traditional testing
Eye irritation	Neutral red release assay; EpiOcular 3D corneal	Rabbit
Skin corrosion/irritation	Corrositex; EpiDerm 3D human skin	Rabbit
Skin sensitization	KeratinoSens; Peptide Reactivity	Mouse or Guinea Pig
Acute toxicity to fish	Zebrafish embryo toxicity assay	Adult Fish
Developmental Toxicity	Zebrafish developmental toxicity assay	Rats and Rabbits
Endocrine Disruption	Estrogen and Androgen Receptor activation assays	Rats and Rabbits
Liver Toxicity	Nuclear receptor screen in primary liver cells	Mice and Rats

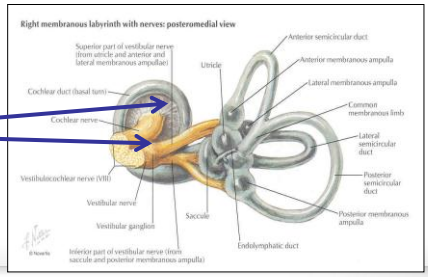
Tiered Assessment Approach



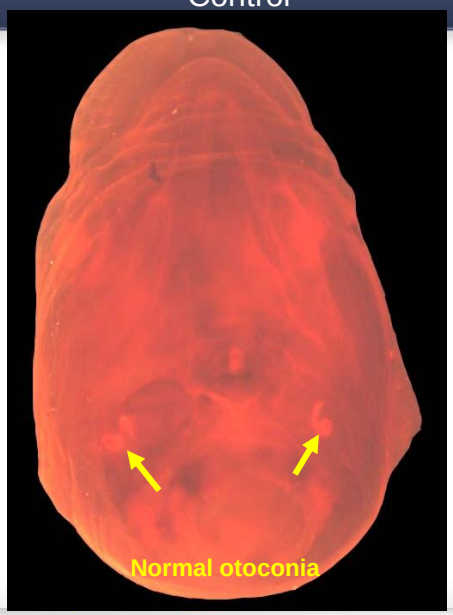
Success Story: Dinocap Substitution

- **Dinocap (Karathane®)** is a fungicide used on vineyards in Europe
- Teratogenic in rodents: cleft plate, torticollis (head tilt), circling behavior in swim test. NOEL=4 mg/kg/day in mice
- Torticollis and swimming behavior effects caused by otoconial agenesis
- Phase out of Dinocap; search for less hazardous substitute

Otoconia: $CaCO_3$ crystals
(“ear dust”)



Control | Dinocap



Dinocap Isomers as Substitution Candidates

- Dinocap composed of 6 isomers
- Evidence suggested that 2 isomers were NOT teratogenic (Rogers et al., 1987)
- R&D chemists discovered method for large scale isomer production
- Developed mouse teratogenesis screen to test isomers individually
- 6-MH isomer selected as lead candidate for substitution

- 6-MH isomer tested in mice:
  - No developmental toxicity
  - NOEL = 500 mg/kg/day (vs. 4 mg/kg/day for Dinocap)
- 6-MH not developmentally toxic in rats or rabbits
- 6-MH retained fungicidal efficacy
- Resulted in commercialization of a non-teratogenic replacement fungicide!

Emerging Needs

Guidance, guidance, guidance!

- There is general agreement that:
  - Attributes beyond hazard are also important for AA (i.e. LCA, risk/exposure, cost, performance, social responsibility)
  - More standardization needed with current methodologies
  - Clear process for handling data gaps and ability to weigh multiple attributes
  - Flexibility in tools/methods according to stage of product development

Increased collaboration across expertise

- A need to pool expertise across academia, government, NGOs, and industry
- HESI Sustainable Alternatives Subcommittee

Focus of HESI AA Subcommittee

1) Attributes, Tools & Data Gaps

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

2) Decision-making and Weighing

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

Interested in joining?
Contact Pam Spencer (pjspencer@dow.com) or
Jennifer Young-Tanir (jtanir@hesiglobal.org)

Summary

- There are growing interests and demands for the use of alternative chemical assessment (regulatory, business, and consumer drivers)
- Attributes beyond hazard are also important (i.e. LCA, risk/exposure, cost, performance, social responsibility) but more difficult to assess & compare
- Build on model for hazard ID - develop detailed processes/tools to inform assessment of alternatives throughout product lifecycle
  - Link to stage gate product development process
  - Exposure
  - Life cycle thinking
  - Economic
  - Societal
- Greater collaboration across areas of expertise

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QUESTIONS?

Available Tools and Frameworks

- **NGO**
  - BizNGO Chemical Alternatives Assessment Protocol (2011)
  - GreenScreen (2011)
  - Lowell's Compendium of Chemical Hazards Reduction Methods and Tools (2011)
  - Lowell's Alternatives Assessment Framework (2006)
  - NSF-GCI-ANSI 355 Standard for Greener Chemicals and Processes Information (2011)
  - TURI's Alternatives Assessment for Toxics Use Reduction (2005)

Available Tools and Frameworks

- **Government**
  - California EPA DTSC's Safer Consumer Products Proposed Regulations (2013)
  - EPA DfE Alternatives Assessment Criteria for Hazard Evaluation (2011)
  - Interstate Chemicals Clearinghouse (IC2)'s Alternatives Assessment Guidance (2012)
  - UBA's Guide Sustainable Chemicals (2010)
- **Industry**
  - Industry Coalition's Principles of Alternatives Assessment (2012)
- **Hybrid reviews**
  - UCLA's Developing Regulatory Alternatives Analysis Methodologies (2011)
  - UCSB's Safer Product Alternatives Analysis (2011)

References for LCA/LCT

- United Nations Environmental Programme, *Life Cycle Management: A Business Guide to Sustainability*, 2007, http://www.unep.fr/scp/publications/details.asp?id=DTI/0585/PA.
- United Nations Environmental Programme, *Towards a Life Cycle Sustainability Assessment*, http://www.unep.org/pdf/UNEP_LifecycleInit_Dec_FINAL.pdf, accessed 2/2013
- Institute for Environment and Sustainability, Life Cycle Thinking and Assessment, http://ies.jrc.ec.europa.eu/our-activities/support-for-eu-policies/life-cycle-thinking-and-assessment.html
- Interstate Chemicals Clearinghouse Guidance for Alternatives Assessment and Risk Reduction, http://www.newmoa.org/prevention/ic2/aaguidance.cfm
- USEPA http://www.epa.gov/nrmrl/std/lca/resources.html

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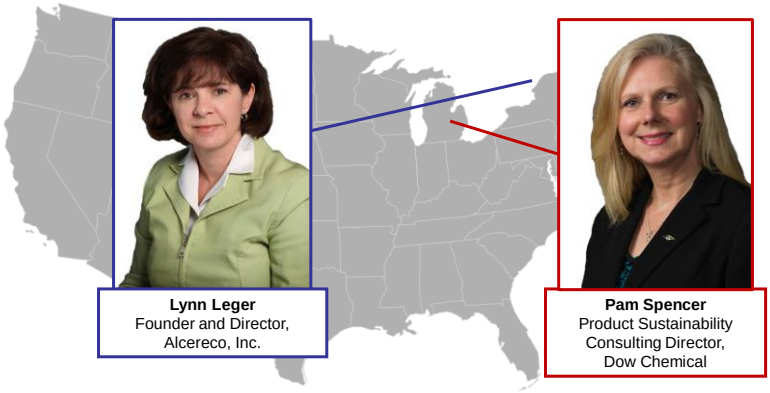

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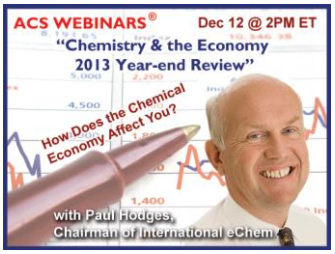

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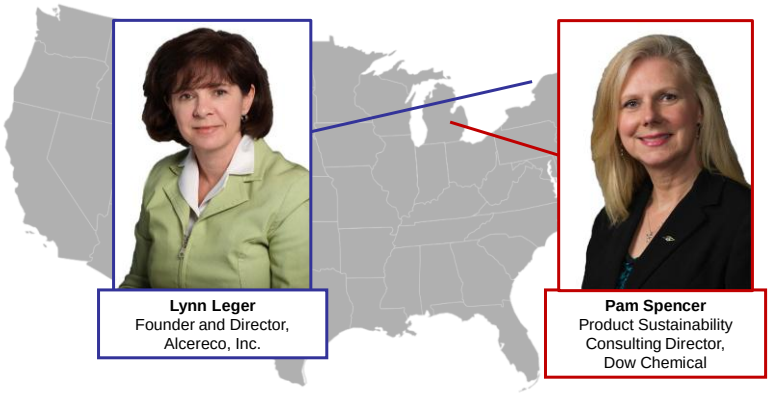

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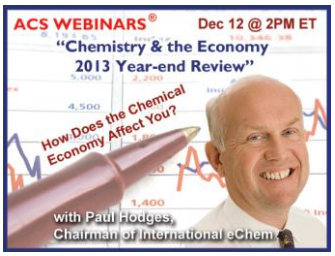

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