Hazard, Risk and Eco-efficiency Assessments: Advantages/Disadvantages & Greener Chemicals and Processes Information Standard

July 26, 2010

Teresa L McGrath
NSF International
Tmcgrath@nsf.org
651-493-4247

Outline

- **Hazard Assessment**
- **Risk Assessment**
- **Life Cycle Assessment**
- **NSF/GCI 355**

Hazard Assessment

- **Definition:** Identification of a potential source of harm
- **Examples**
  - Used by DTSC to Identify Chemicals of Concern (COC)
  - EPA Design for the Environment (DfE) Program Ingredient Reviews
  - CleanGredientsTM Ingredient Reviews
  - Clean Production Action's Green Screen
  - Restricted Substances Lists
  - European Risk Phrases
- **Pros**
  - Allows for chemical screening outside of a finished product
  - Relatively quick screening process
  - Removing hazards, can lead to reduced risk
- **Cons**
  - Does not address exposure/risk of alternatives
  - Does not address the life cycle impacts of alternatives
    - Concentrates
    - Wash in cold water

Hazard X Exposure = Risk

- **Definition:** Identification of the probability of adverse effects resulting from exposure to an environmental agent or mixture of agents.

- **Examples**
  - Used by DTSC to identify Priority Products
  - Used by EPA in setting regulatory and guidance (IRIS) levels for chemical contaminants
  - Used by FDA, the EU, and WHO in setting acceptable/tolerable daily intake levels for direct and indirect food additives
  - NSF performs risk assessments for non-regulated substances detected in water or food

NSF Risk Assessment Process:

Step 1: Non-regulated substance is identified as a Direct/indirect drinking water or food additive

↓

Step 2: Evaluation
- Hazard
- Exposure
- Dose response
- Risk Characterization

↓

Step 4: Internal Peer review

↓

Step 5: External Peer review

↓

Step 6: Publication of Risk Values & Documents ITER & NSF Bookstore

External Peer Review:

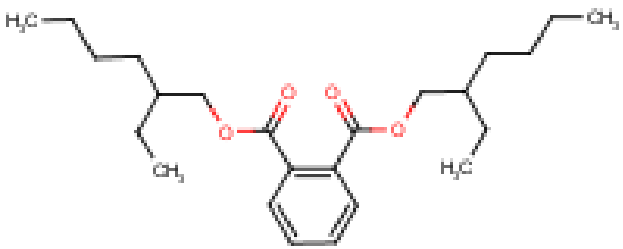
The NSF Health Advisory Board

- Edward Ohanian, U.S. EPA, Chair
- Michael Dourson, TERA, Vice-Chair
- David Blakey, Health Canada
- Steven Bursian, Michigan State University
- Craig Farr, Consultant
- Robert Hinderer, The Lubrizol Corporation
- Gene McConnell, ToxPath, Inc.
- Jennifer Orme-Zavaleta, U.S. EPA
- Calvin Willhite, State of California

Risk Assessment Example 1: Plasticizer

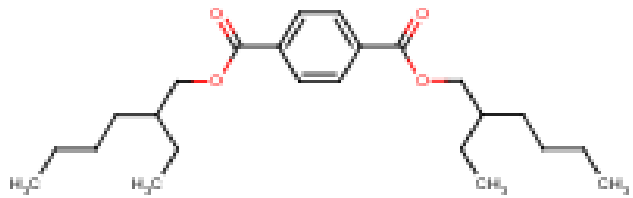
- **Di-2-ethylhexyl phthalate (DEHP)**
  - Commonly used phthalate with reproductive toxicity effects at 5mg/kg.
- **Uses**
  - Toys (DEHP use is restricted, or banned)
  - Food contact materials
    - Wrap, containers, tubing, connectors
  - Medical devices
    - Tubing, blood bags, and other medical devices
  - Water contact materials
    - Flexible tubing
- **Potential Alternatives**
  - DEHT
  - DPHP
  - DINCH

DEHP is regulated in drinking water by the U.S. EPA, MCL = 0.006 mg/L.



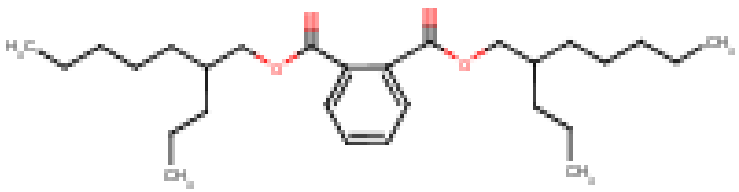
DEHT:

NSF Risk Assessment Performed



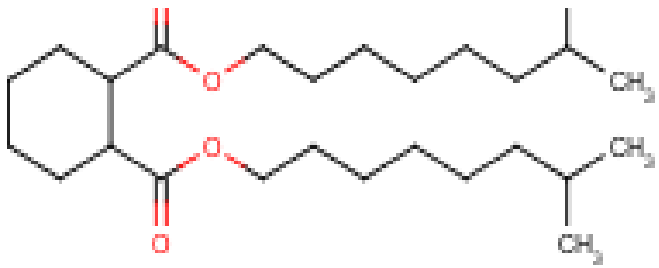
DPHP:

NSF Risk Assessment Performed



DINCH:

NSF Risk Assessment Performed



Effects in Rats	NOAEL (mg/kg-day) in rats			
	DEHP	Alternatives		
		DEHT	DPHP	DINCH
Acute LD_{50}	>5,000 mg/kg			
Subchronic	3.7 (liver, testes)	277 (slight anemia)	181 (pituitary & thyroid)	100 (kidney)
Reproduction	5 (testes-parents & offspring)	447	600	100
Developmental		747	200	1,000
Genetic	genetic toxicity assays were predominantly negative			
Chronic	29 (kidney)	54[1] general/ ocular toxicity	No chronic study	40 (thyroid)
Cancer	liver tumors	negative		negative

[1]BMDL (mg/kg-day)

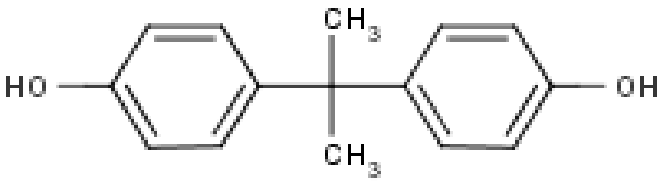
Risk Assessment Example 2: Plastic Bottles

- **Bisphenol A (BPA)**
  - Commonly used monomer with endocrine disruption concerns.
- **Uses**
  - Polycarbonate – major monomer bisphenol A
  - Bottles and can liners
  - Epoxy resins and coatings
- **Potential Alternative:**
  - Polyethylene terephthalate – major monomer terephthalic acid or dimethyl terephthalate

Bisphenol A and Terephthalic Acid

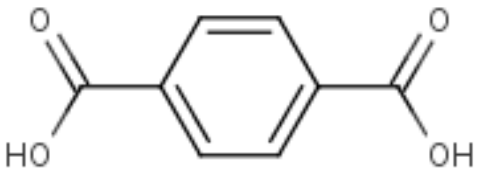
Bisphenol A (BPA)

Polycarbonate monomer



Terephthalic acid (TPA)

Polyethylene terephthalate monomer



Effects in Rats	NOAEL (mg/kg-day)	
	BPA	**TPA**
Acute LD_{50} (mg/kg)	> 3,000	> 5,000
Subchronic	70 (body weight)	≥ 500 (bladder stones & pathology)
Reproduction	5 (general toxicity)[1]	≥ 240 (pup viability)
Developmental	50 (general toxicity)[1]	250 (bladder stones in pups)
Genetic	genetic toxicity assays predominantly negative	
Chronic/Cancer	74 (general toxicity)	142 (bladder effects)

[1]BMDL values for reproductive effects were higher than the NOAEL for general toxicity (reduced body weight)

Risk Assessment Conclusion

- **Pros**
  - Integrate both hazard and exposure data allowing for more informed decisions
  - Data gaps and uncertainties in the data base are addressed
  - Baseline exposures are incorporated
- **Cons**
  - Risks above the defined acceptable exposure are not estimated
  - Does not take into account life cycle impacts of alternatives

Life Cycle Assessment

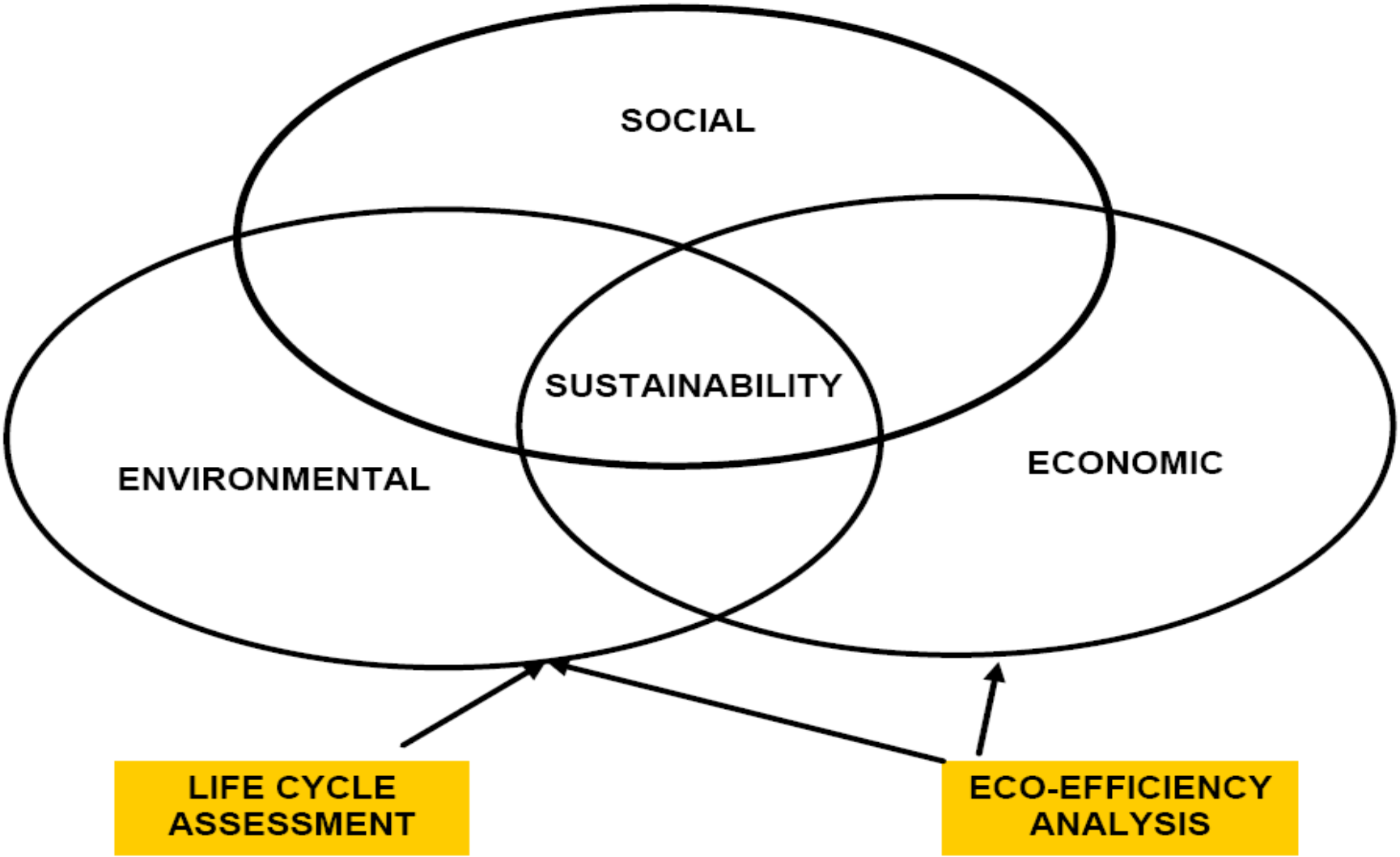
Life Cycle Assessment / Eco-Efficiency Analysis

- **Definition**
  - **Life Cycle Assessment (LCA):** An evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle.
- **Pros**
  - Considers entire life cycle of product
  - Comprehensive evaluation of impacts on human health and the environment
  - Allows direct comparison of two options based on functional unit
- **Cons**
  - No consensus on what impact categories should be included
  - Risk is not fully considered
  - Uncertainties are not considered
  - Results may not be conclusive
  - Resource intensive

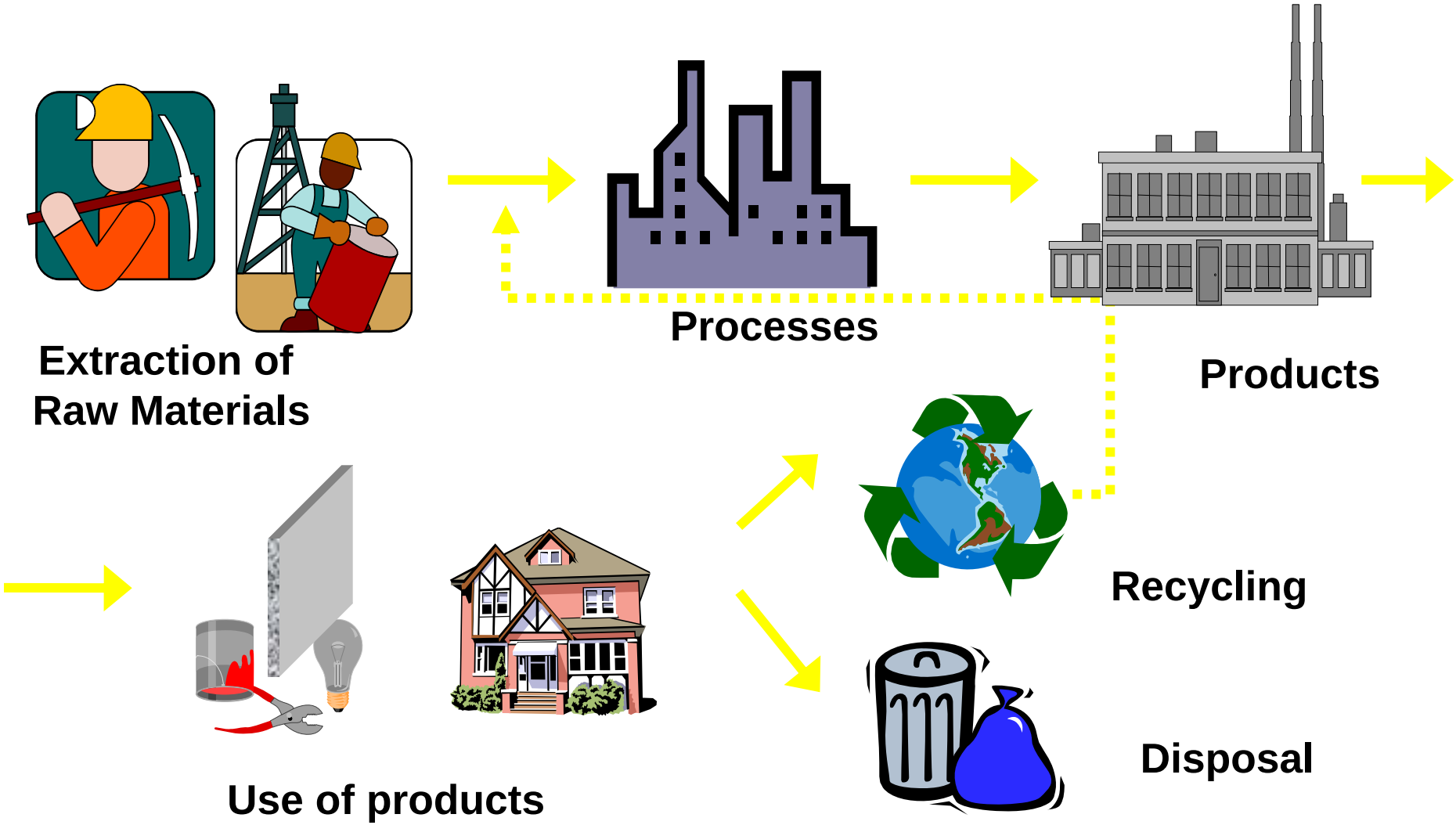
Eco-efficiency Analysis

- Eco-efficiency analysis (EEA): A tool used to quantify and evaluate the sustainability of product and process alternatives by evaluating its environmental burdens and economic costs through its anticipated life cycle.(NSF P352)
- BASF developed an EEA tool to help drive towards and measure sustainability
- Over 260 projects completed globally
- To help provide independent, third-party reviews of EEA analyses, NSF International developed NSF Protocol P352: Validation and Verification of Eco-Efficiency Analyses.

EEA Analyses vs. LCAs



Considers the Total Life Cycle

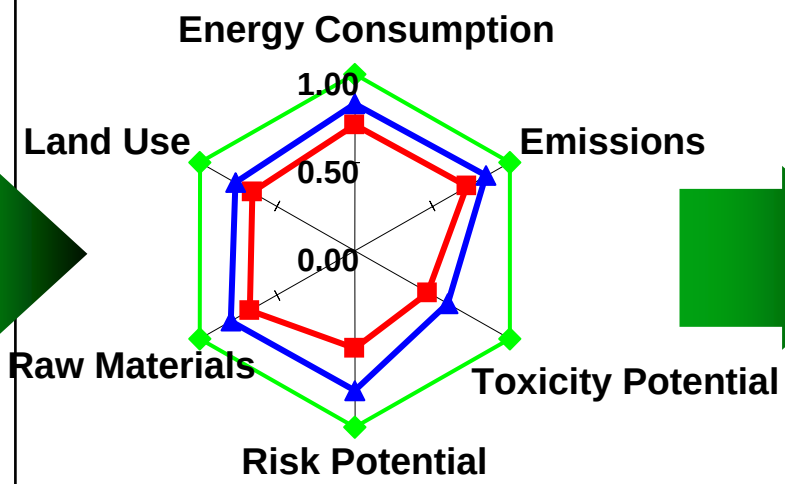


Development of Ecological Value

Parameters considered

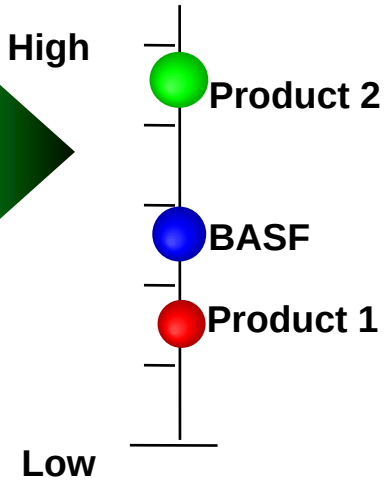
- Raw Materials
- Energy consumption
- Land Use
- Emissions
- Toxicity
- Risk potential

Ecological footprint

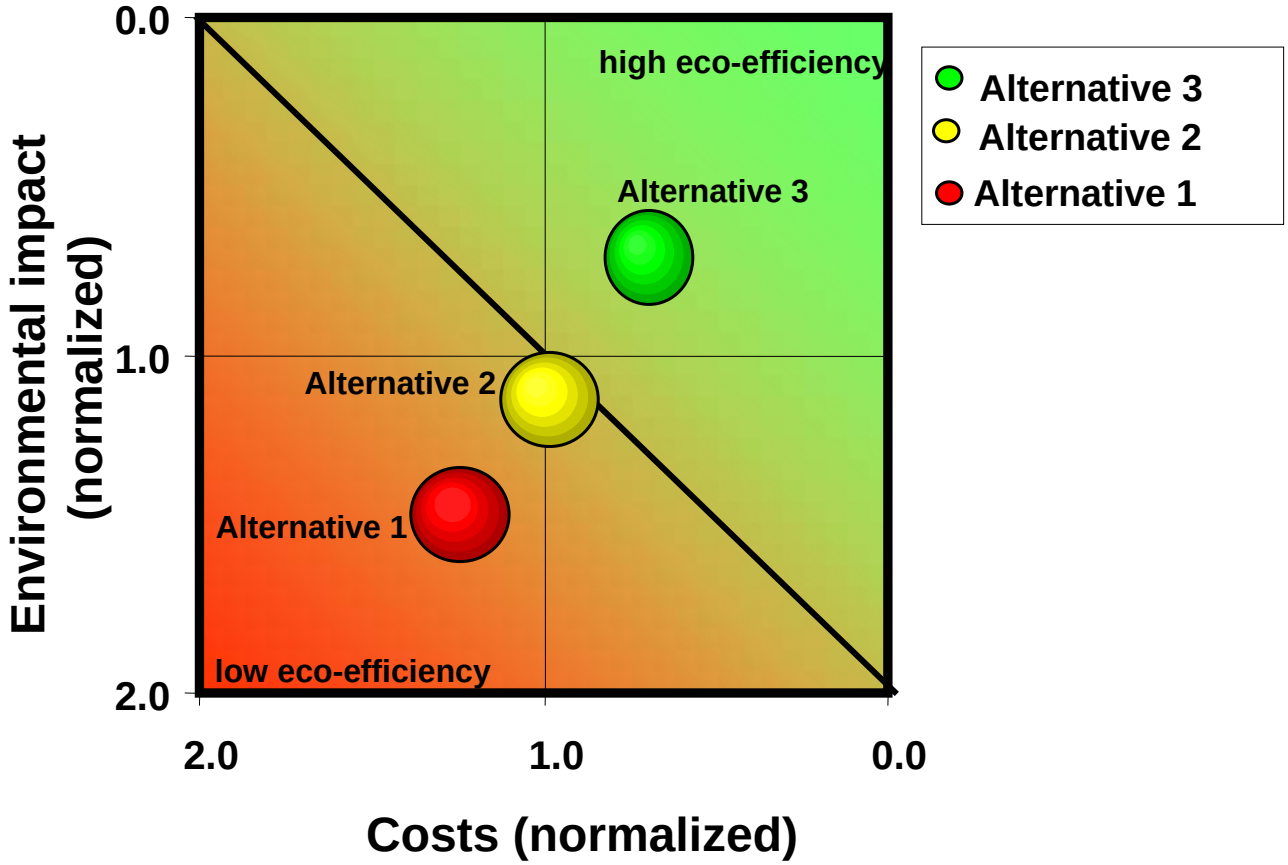


Ecological advantage

Relative environmental impact



The Eco-efficiency Portfolio: Environmental & Cost Impacts



Eco-Efficiency Analysis

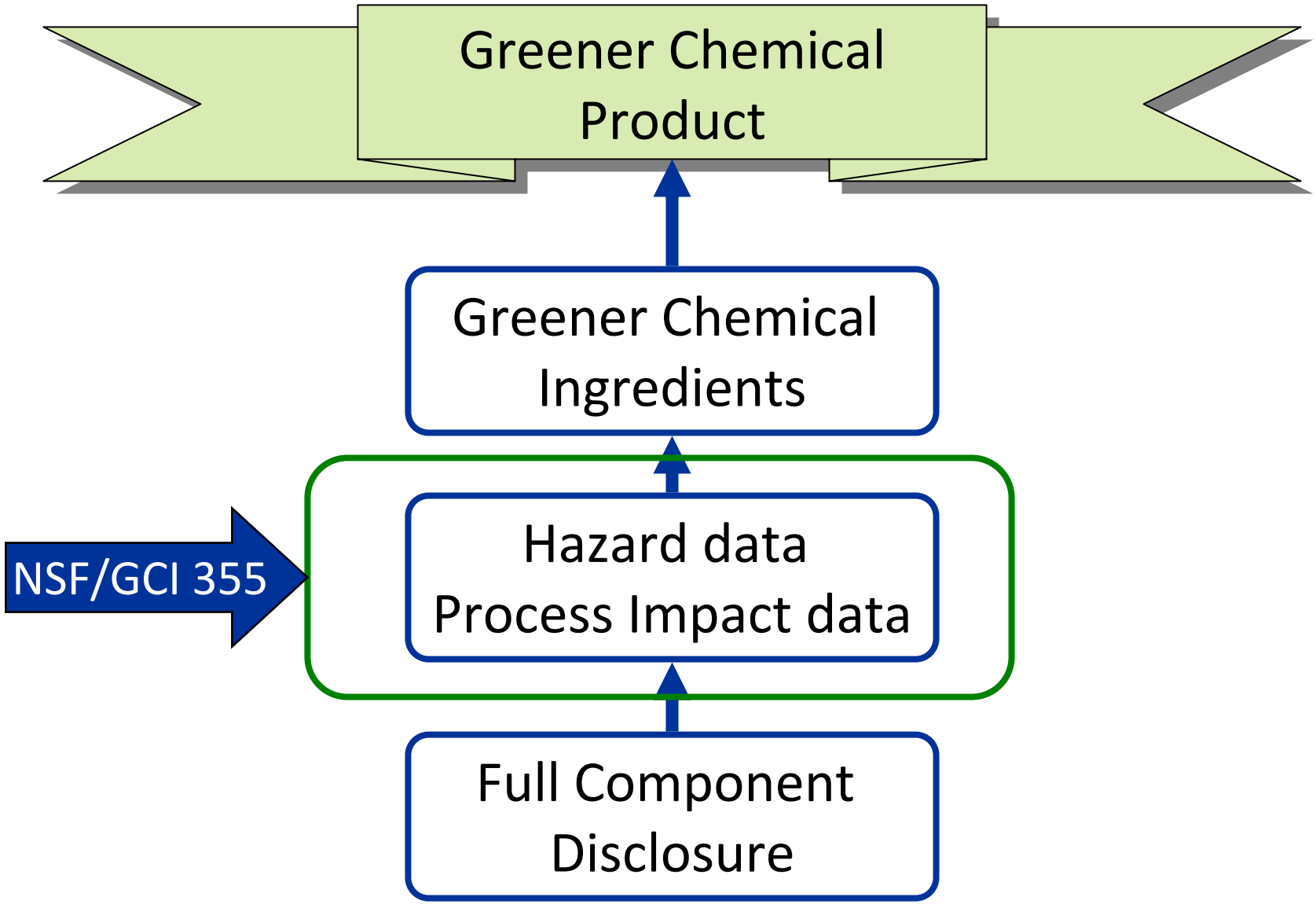
- **Pros**
  - Allows for Comparison of alternatives using both hazard assessment parameters and life cycle assessment parameters
  - Considers entire life cycle of product
  - Comprehensive evaluation of impacts on human health and the environment
  - Allows direct comparison of two options based on functional unit
- **Cons**
  - Does not incorporate risk characterization
  - Requires subjective weighting and normalization
  - Impacts from other chemicals in the functional unit or “Customer Benefit” may mask change in impacts associated with the COC and Functional Alternatives.
  - Resource Intensive

Conclusions

Risk Assessments are used to estimate the potential for a chemical to cause harm to humans or the environment during use or disposal.

Life Cycle Assessments are used to identify hot spots for environmental impacts throughout a products life cycle and compare two or more options to determine which is more environmentally friendly from a functional use perspective.

Pathway to Greener Chemical Products



NSF/GCI 355

- Why a Chemical Hazard Information & Chemical Process Information Standard?
- Current status of NSF/GCI 355
- Review status, schedule, & next steps
- Participate in the process

Purpose of NSF / GCI 355

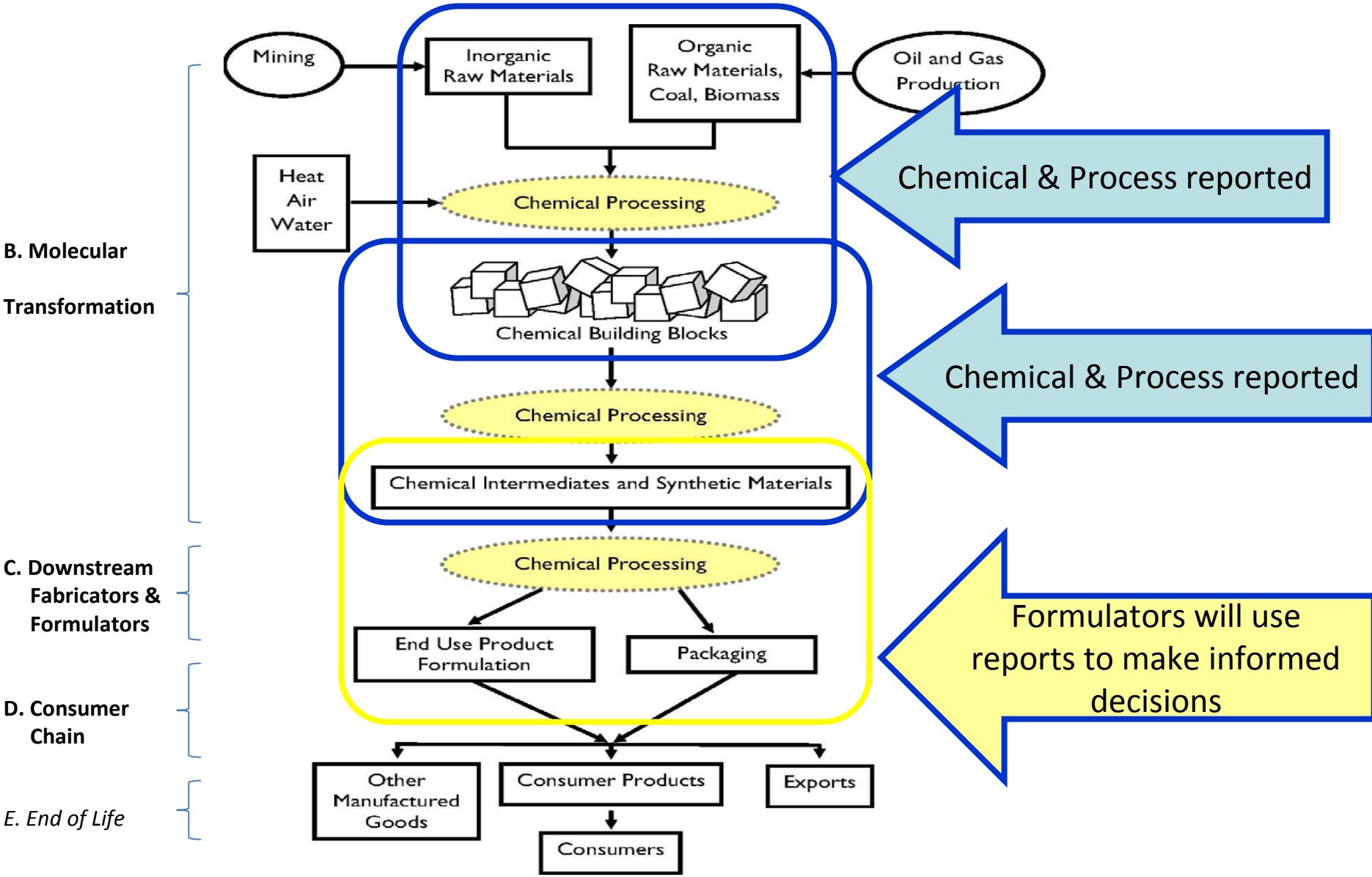
- **Provide the chemical enterprise with a voluntary and standardized way to define and report on:**
  - A chemical product's hazard profile
  - A chemical manufacturing process's impact
- **Clearly, consistently and transparently communicate this information to customers throughout the supply chain.**
- **Assist customers in evaluating the relative greenness of a chemical product and process over its life cycle.**
- **This standard was informed by:**
  - Green chemistry principles
  - Green engineering principles
  - ISO 14000
  - Global reporting initiatives
  - Many other existing programs

ACS Green Chemistry Institute®

Why Use 355?

- **Manufacturers of chemicals**
  - Develop one report to satisfy many requests
  - Form a normalized framework for business to business communication
- **Users of chemicals**
  - Receive a standardized set of information about chemical product and process
  - Use this information as a foundation for informed decision-making

Focus of standard: Molecular Transformation



Overview of Standard

Chemical Characteristics

- Human Health Effects
- Ecological Effects
- Physical Properties

Process Attributes

- Material chemical efficiency & waste prevention
- Water
- Energy

Corporate Attributes

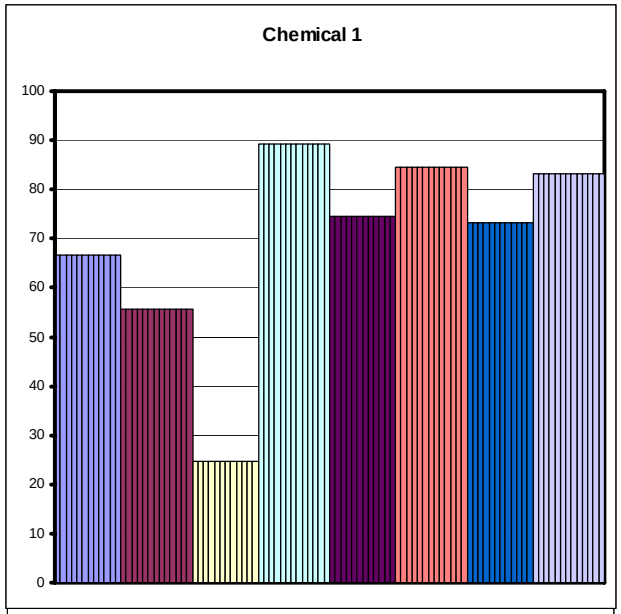
- Social Responsibility
- Chemical Process Safety Record

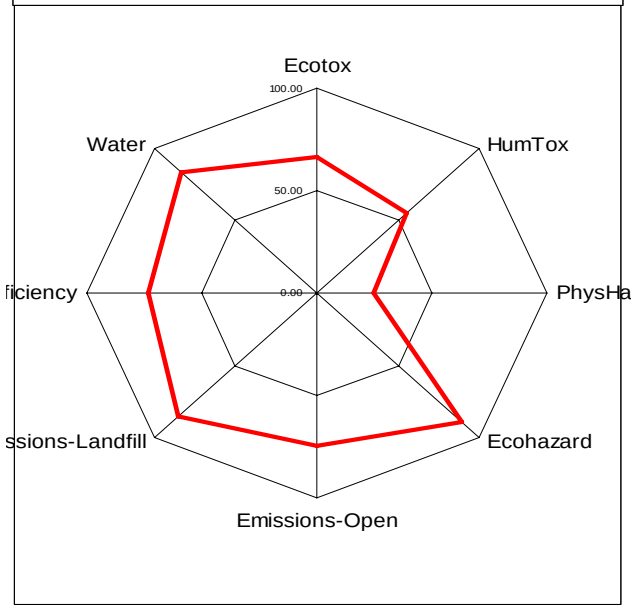
Not included

- Product performance
- Cost

Reporting Formats: TBD

- **Goals**
  - Standardized – easy to compare to make better choices
  - Simple
  - Flexible
  - Transparent
- **Possible formats**
  - Nutrition label
  - Spider Diagram
  - Bar charts





Your Role

You can help shape this standard every step of the way!

- **Check out the latest Draft of the Standard:**
  - ***http://standards.nsf.org/apps/group_public/workgroup.php?wg_abbrev=greener_chemical_prod_and_proc***
- **Participate in Committee meetings!**
  - Contact Mindy Costello: MCostello@nsf.org, 734-827-6819
- **Participate in Pilot**
  - Contact Mindy Costello: MCostello@nsf.org, 734-827-6819
- **Review Draft & Provide Comments before & during public comment period.**
  - Sign up for email updates at http://standards.nsf.org

Contact Us!

- **NSF/GCI 355:**
  - Mindy Costello, Standards Specialist, MCostello@nsf.org, 734-827-6819
- **Risk Assessments, EPA's Design for the Environment Program, CleanGredients Reviews or other product evaluation programs:**
  - Teresa McGrath, Supervising Toxicologist, Green Chemistry Programs, tmcgrath@nsf.org, 651-493-4247