• 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
  - CleanGredients™ 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
**Risk Assessment**

**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
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
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
<table>
<thead>
<tr>
<th>Effects in Rats</th>
<th>DEHP</th>
<th>Alternatives</th>
<th>DEHT</th>
<th>DPHP</th>
<th>DINCH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute LD$_{50}$</strong></td>
<td>&gt;5,000 mg/kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Subchronic</strong></td>
<td>3.7 (liver, testes)</td>
<td>277 (slight anemia)</td>
<td>181 (pituitary &amp; thyroid)</td>
<td>100 (kidney)</td>
<td></td>
</tr>
<tr>
<td><strong>Reproduction</strong></td>
<td>5 (testes-parents &amp; offspring)</td>
<td>447</td>
<td>600</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>Developmental</strong></td>
<td>747</td>
<td>200</td>
<td>1,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Genetic</strong></td>
<td>genetic toxicity assays were predominantly negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td>29 (kidney)</td>
<td>54$^1$ general/ocular toxicity</td>
<td>No chronic study</td>
<td>40 (thyroid)</td>
<td></td>
</tr>
<tr>
<td><strong>Cancer</strong></td>
<td>liver tumors</td>
<td>negative</td>
<td></td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

$^1$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 (BPA)  
Polycarbonate monomer

Terephthalic acid (TPA)  
Polyethylene terephthalate monomer
<table>
<thead>
<tr>
<th>Effects in Rats</th>
<th>NOAEL (mg/kg-day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BPA</td>
</tr>
<tr>
<td><strong>Acute LD$_{50}$ (mg/kg)</strong></td>
<td>&gt; 3,000</td>
</tr>
<tr>
<td><strong>Subchronic</strong></td>
<td>70 (body weight)</td>
</tr>
<tr>
<td><strong>Reproduction</strong></td>
<td>5 (general toxicity)$^1$</td>
</tr>
<tr>
<td><strong>Developmental</strong></td>
<td>50 (general toxicity)$^1$</td>
</tr>
<tr>
<td><strong>Genetic</strong></td>
<td>genetic toxicity assays predominantly negative</td>
</tr>
<tr>
<td><strong>Chronic/Cancer</strong></td>
<td>74 (general toxicity)</td>
</tr>
</tbody>
</table>

$^1$BMDL values for reproductive effects were higher than the NOAEL for general toxicity (reduced body weight)
• **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

- Social
- Economic
- Environmental

Eco-Efficiency Analysis
Life Cycle Assessment

Sustainability
Considers the Total Life Cycle

Extraction of Raw Materials

Processes

Products

Recycling

Disposal

Use of products
Development of Ecological Value

Parameters considered:
- Raw Materials
- Energy consumption
- Land Use
- Emissions
- Toxicity
- Risk potential

Ecological footprint:
- Energy Consumption
- Land Use
- Emissions
- Toxicity Potential
- Risk Potential

Ecological advantage:
- Relative environmental impact
  - High
  - BASF
  - Low
  - Product 2
  - Product 1
The Eco-efficiency Portfolio: Environmental & Cost Impacts

- **High eco-efficiency**
- **Low eco-efficiency**

Alternatives:
- **Alternative 1**
- **Alternative 2**
- **Alternative 3**
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
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 product's 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

Greener Chemical Product

Greener Chemical Ingredients

Hazard data
Process Impact data

Full Component Disclosure

NSF/GCI 355
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
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

A. Extraction

B. Molecular Transformation

C. Downstream Fabricators & Formulators

D. Consumer Chain

E. End of Life

Chemical & Process reported

Formulators will use reports to make informed decisions
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
• **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:
- 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
• **NSF/GCI 355:**
  – Mindy Costello, Standards Specialist, [MCostello@nsf.org](mailto: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](mailto:tmcgrath@nsf.org), 651-493-4247