U.S. EPA Design for the Environment Program

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Presentation Outline

- Overview
  - Priorities
  - Operating principles
- Safer Product Labeling Program
  - Product review
  - Criteria
- Developing Transparent Criteria

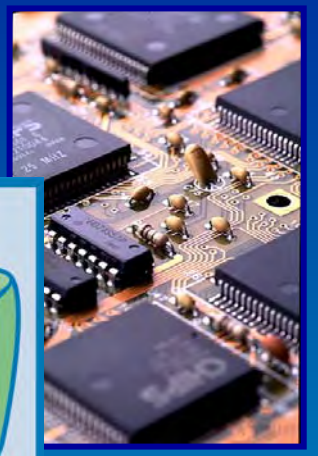
Overview of DfE Program

- Focus
  - Chemicals of concern
  - Informed Substitution
  - OPPT technical tools and expertise
- Considerations
  - Business client
  - Multi-stakeholder participation
  - Business realities
  - Potential benefits for industry and the environment

- Results
  - Partners reduced more than 335 million pounds of chemicals of concern last year

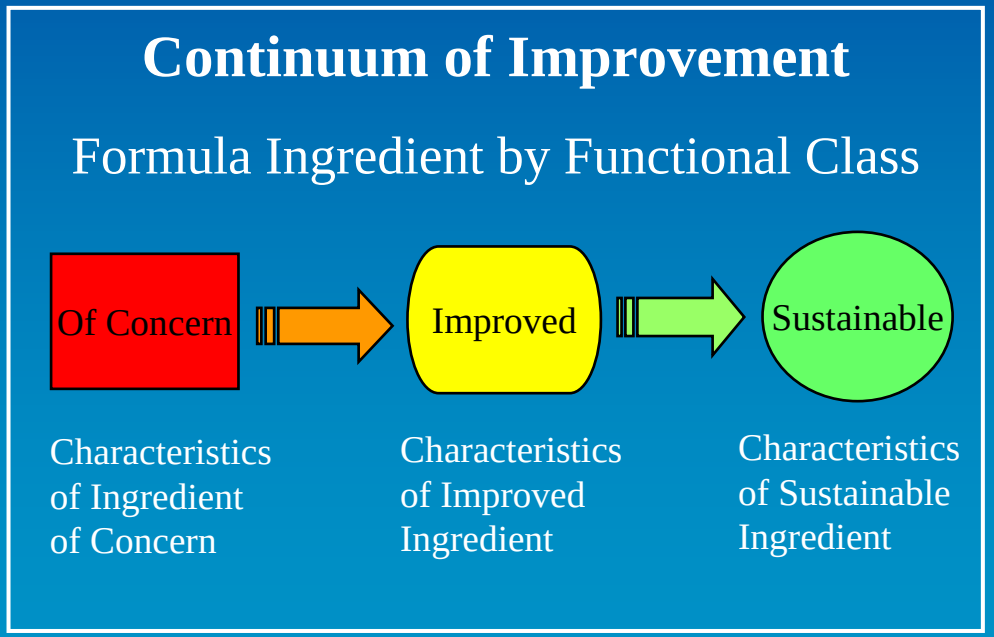
DfE: Informing Substitution to Safer Chemicals

- **Alternatives Assessments**
  - Flame Retardants
    - Furniture Foam
    - Printed Circuit Boards
  - Lead-Free Solder
- **Auto Refinishing Best Practices**
- **DfE Safer Product Labeling Program**
  - Product Recognition
  - Safer Ingredients (CleanGredients™ database)
- **Safer Detergents Stewardship Initiative (SDSI)**



DfE Safer Product Labeling

- **Hazard Focus**
- **Continuous Improvement**
  - Driven by Green Chemistry – *As Innovation Occurs Continua May Shift*
  - Acknowledges Business Realities



DfE Safer Product Labeling Program

Steps to Partnership – From the Formulator's point of view

1. Contact EPA DfE to discuss product submissions.
2. Request 3rd-party ingredient profiling.
3. 3rd party Submit ingredient profiles to EPA DfE.
4. Review ingredient profiles – EPA technical workgroup.
5. Post-assessment discussion with submitter.
6. Sign partnership agreement.
   - 3-year agreement between formulator and EPA

DfE Review – 3 Basic Components

1) Review <u>every</u> ingredient by functional use class
   - To promote green chemistry
   - To understand toxicity
     - Literature
     - Analogous chemicals – SAR
2) Review formulation as a whole
   - Synergistic effects
   - pH
   - Performance testing
3) Partnership Agreement

Data in DfE

- Sources
  - Literature Search
  - Data from internal sources
    - PMN submissions
    - TSCA Section 8(e)
    - RED documents
  - Data from manufacturers
- Preferences
  - Measured data
  - Estimated data
  - Authoritative lists

DfE Screens for Safer Chemicals

- Overarching "General Screen"
  - Environmental and Human Health Endpoints
  - Can be refined for "functional use" component classes
- Endpoints with thresholds corresponding to New Chemicals Program criteria for low concern
  - Acute mammalian toxicity
  - Carcinogenicity
  - Environmental toxicity and fate
  - Genetic toxicity
  - Neurotoxicity
  - Repeated dose toxicity
  - Reproductive and developmental toxicity
  - Respiratory sensitization
  - Skin sensitization

DfE General Screen:
Thresholds for acceptable chemicals - Examples

Carcinogenicity

- Listed on IARC, NTP, EPA, or EU CMR
  - Carcinogenic in humans
  - Probably carcinogenic to humans
  - Possibly carcinogenic to humans
- Chemicals not listed
  - Consider data and apply GHS criteria
  - Evaluate structural activity relationships (SAR) and run OncoLogic™ (If no measured data)

Acute Mammalian Toxicity

- Criteria

Route of Exposure	Median Lethal Dose
Oral LD50	>2000 (mg/kg)
Dermal LD50	>2000 (mg/kg)
Inhalation LC50 (gas)	>5000 (ppm)
Inhalation LC50 (vapor)	>20 (mg/L)
Inhalation LC50 (dust/mist)	>5 (mg/L)

- SAR and application of GHS (If no measured data)

DfE General Screen:
Thresholds for acceptable chemicals - Examples

Environmental Fate and Toxicity

Acute Aquatic Toxicity Value (L/E/IC50)1,2	**Persistence** (Measured in terms of rate of biodegradation)	**Bioaccumulation Potential**
If ≤1 ppm…	**…then** may be acceptable if biodegradation occurs within a 10-day window …	**…and** BCF <1000
If >1 ppm and **≤**10 ppm…	**…then** biodegradation must occur within a 10-day window…	
If >10 ppm and <100 ppm…	**…then** biodegradation must occur within 28 days without products of concern …	
If ≥100 ppm…	**…then** biodegradation need not occur within 28 days if there are no products of concern and half-life <180 days…	

Building a Transparent Screen

Objective: For a given "functional use" component class: Differentiate chemicals at the safer end of the environmental and human health continuum

- Convene a multi-stakeholder group (with NGOs)
- Establish the scope of the functional use class
- Develop list of representative chemicals for the class – across the continuum
  - Human health and environmental data
  - Efficacy information
- Information evaluated by EPA and presented to all stakeholders
  - Proprietary information is protected
  - Environmental and human health data is displayed in a user-friendly format
- Establish key distinguishing endpoints & thresholds to differentiate safer ingredients

Contact Information

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