



Implementing Alternatives Assessments at the U.S. EPA DfE Program

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Design for the Environment

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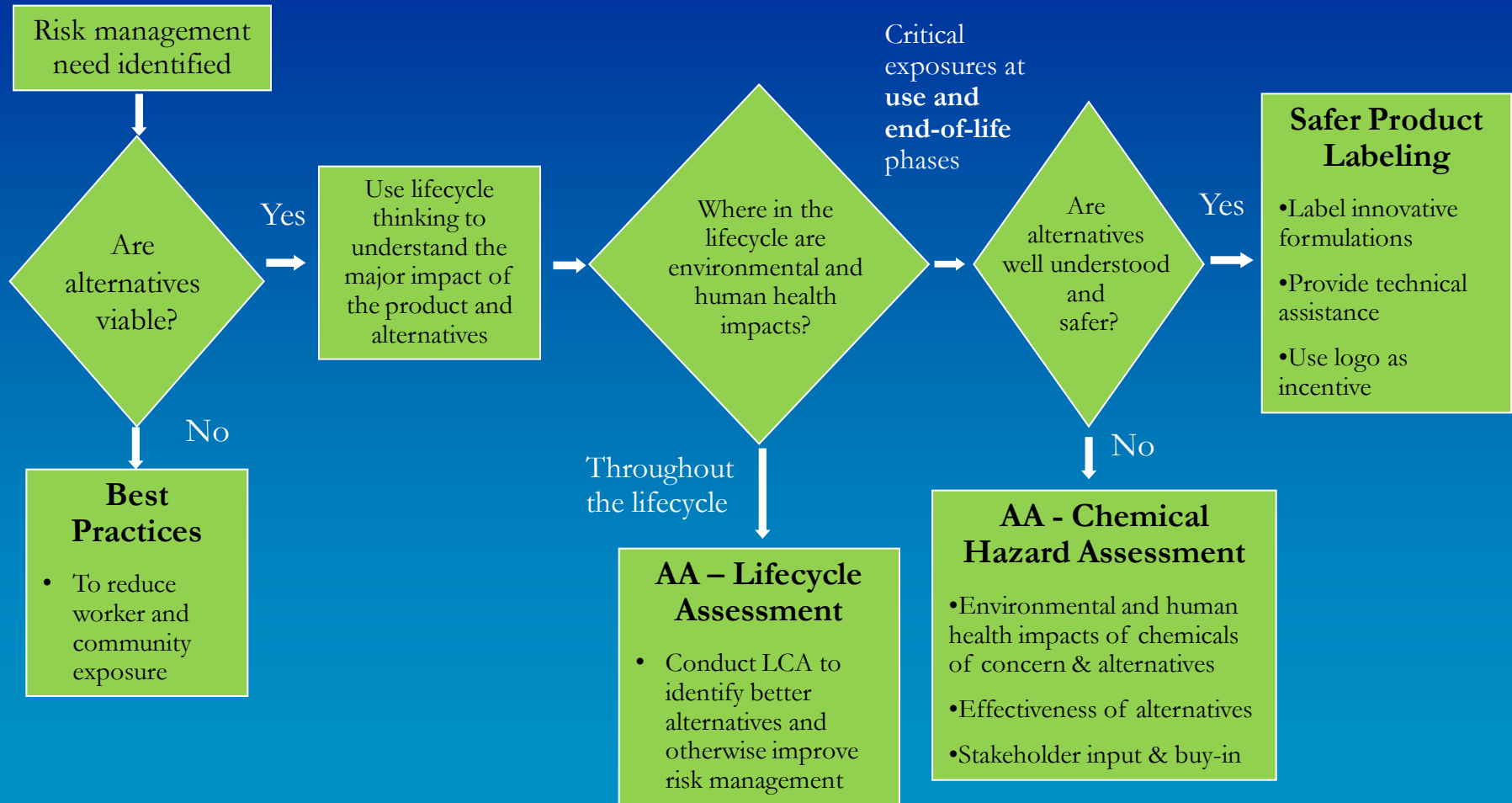
- Choosing a tool
- Alternatives assessments
 - Early examples
 - Methodologies
 - Current focus
- Lessons learned and next steps

What DfE is About

- Goals
 - Safer chemical ingredients is focus
 - Life cycle impacts are considered
 - Protecting Consumers – Especially Children
- Central Elements
 - OPPT technical tools and expertise
 - Multi-stakeholder participation
- Approaches
 - Alternatives assessments (AAs)
 - Safer Product Labeling Program
 - Best practices
- Results
 - Industry partners reduced more than 750 million pounds of chemicals of potential concern each year

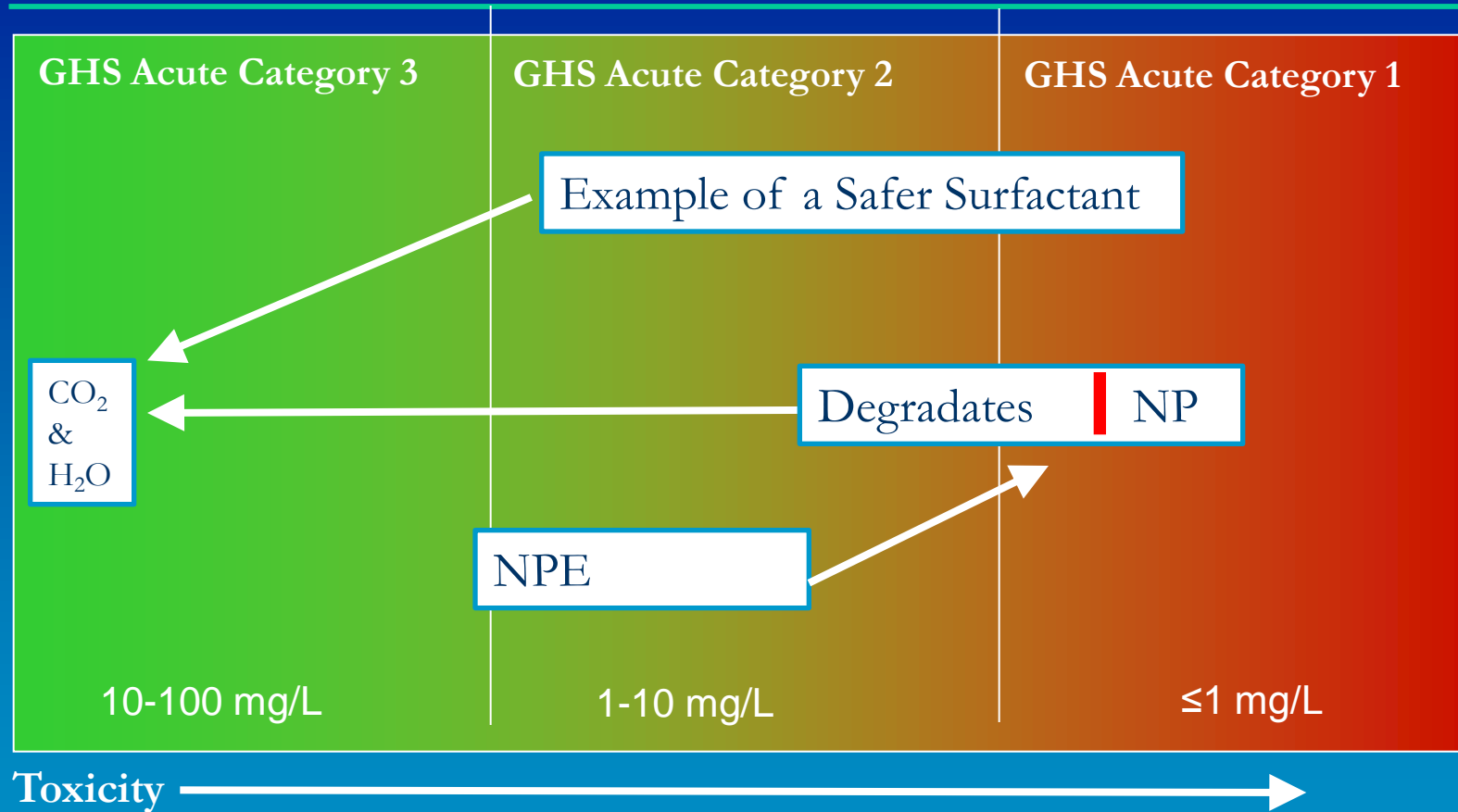


Decision Logic in DfE: Choosing a Tool



Early Examples

Surfactant of Potential Concern



Toxicity categories from the Globally Harmonized System (GHS)

Alternatives to NPEs / Safer Surfactants

- International activity concerning NPE use
- US EPA took a hybrid approach
 - Ambient water quality criteria (AWQC) for NP
 - Voluntary approaches
 - Definition of safer surfactant
 - Safer Detergents Stewardship Initiative
 - Safer Product Labeling: 2,500+ safer products
 - CleanGredients: 200+ safer surfactants
- Drivers included:
 - Demand from institutional purchasers
 - Wal-Mart
 - Governments

Furniture Example

- Predominant flame retardant (pentaBDE) for low-density flexible polyurethane foam
- Found increasingly in human tissue, breast milk and the environment
- Report guided switch to safer alternatives
- Drivers included:
 - Voluntary phase-out paired with regulatory backstop
 - Industry concern over public perception



Lessons from Early Partnerships

- Substitution outcomes depend on functional use challenges
- Drivers for substitution
 - Works well as a complement to regulatory activities (penta)
 - Demand pull is critical
 - Wal-Mart and institutional purchaser demand for NPE-free products
 - Furniture manufacturer demand for penta-free products
- Transparent approach was needed

Transparency for Alternatives Assessments

1. Methodology on DfE website; published in ES&T
2. Toxicological criteria; published for public comment

Human Health Toxicity

- Acute mammalian toxicity
- Carcinogenicity
- Mutagenicity/
Genotoxicity
- Reproductive and Developmental Toxicity
- Neurotoxicity
- Repeated Dose Toxicity
- Respiratory and Skin Sensitization
- Eye and Skin Irritation/Corrosivity

Environmental Fate & Effects

- Aquatic toxicity
- Environmental persistence
- Bioaccumulation
-
- *Endocrine Activity*

www.epa.gov/dfe/alternative_assessments.html

EPA Priority Chemicals

- Chemicals for which action plans have been prepared:
 - Benzidine Dyes
 - Bisphenol A (BPA)
 - Hexabromocyclododecane (HBCD)
 - Methylene Diphenyl Diisocyanate (MDI)
 - Nonylphenol and Nonylphenol Ethoxylates
 - Perfluorinated chemicals (PFCs)
 - Penta, octa, and decabromodiphenyl ethers (PBDEs) in products
 - Phthalates
 - Short-chain chlorinated paraffins
 - Toluene Diisocyanate (TDI)

EPA Chemical Action Plans with DfE Component

- Decabromodiphenyl ether (decaBDE)
 - Assessing decaBDE and 30 alternatives; draft hazard assessment Summer 2011

- Bisphenol A (BPA)
 - Assessing BPA and 19 alternatives; draft hazard assessment Summer 2011

- HBCD
 - Will assess HBCD and alternatives; draft hazard assessment Winter 2012

- Phthalates
 - Will assess phthalates and alternatives; draft hazard assessment Summer 2012

- NP/NPEs
 - Draft report Summer 2011



Challenges and Next Steps

- **Broad stakeholder participation is important**
 - Account for the range of views
 - Improves communication among stakeholders
 - Understand viability of alternatives
 - Encourage implementation
- **Incomplete hazard data is a challenge**
 - Structure Activity and Models for missing data
 - Works well for EPA
 - Building technical capacity would be difficult many organizations (just collecting and interpreting this information where it is available is expensive)
 - Looking forward
 - Communicate needs to researchers
 - Use high-throughput screening when available

Challenges and Next Steps

- **Green chemistry challenges could be used when safer alternatives are not available**
 - Traditional R&D (academic, industrial)
 - Crowd sourcing
 - Innocentive
 - Challenge.gov
 - Criteria to define a winner
 - DfE can develop criteria, but data on health, environment and performance are needed to differentiate a winner
- **Incentives for safer alternatives are growing**
 - Marketplace drivers
 - Green products
 - Corporate image
 - Chemical prioritization & regulatory drivers
 - DfE AAs works best as a complement to regulation
 - Regulation is resource intensive

Challenges and Next Steps

- **Leveraging for broad application of alternatives assessment**
 - Federal government has limited capacity
 - But can address highest-priority chemicals, develop methodologies and define qualifications
 - Others are conducting alternatives assessments / using DfE criteria
 - WA, MA, ME and other states
 - HP, Dow and others
 - Clean Production Action (CPA) Green Screen
 - CPA Green Screen may help facilitate AA use
 - Qualified third-party implementers could enable smaller firms to explore safer alternatives
 - Centers of excellence
 - Economies of scale
 - Overcome barrier of incomplete data
 - Focal point for GC needs





Thank you!

For more information:

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DfE: www.epa.gov/dfe

Action Plans: www.epa.gov/opptintr/existingchemicals/pubs/ecactionpln.html

Alternatives Assessments: http://www.epa.gov/dfe/alternative_assessments.html

ES&T Feature Article on CAA: <http://pubs.acs.org/doi/abs/10.1021/es1015789>

Seven Steps to Conducting an AA

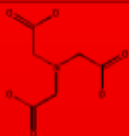
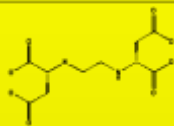
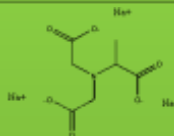
- 1) Determine need
- 2) Refine boundary conditions – through research and preliminary stakeholder consultation
- 3) Convene stakeholders
- 4) Identify viable alternatives
- 5) Conduct hazard assessment
- 6) Develop the report
- 7) Apply the information in decision making

DfE Criteria in Action



Chelating Agents Criteria

- Illustrates continuum of improvement
- All available data will be considered
- Evaluation of chelating agents is based on the following distinguishing endpoints:
 - ✓ Acute Mammalian Toxicity
 - ✓ Carcinogenicity
 - ✓ Repeated Dose Toxicity
 - ✓ Developmental Toxicity
 - ✓ Environmental Toxicity and Fate
 - ✓ Eutrophication

Chelating Agents Criteria	Nitriloacetic Acid (NTA) CAS# 139-13-9	(S,S)-ethylenediamine-N,N'-disuccinic acid (EDDS) CAS# 20846-91-7	Alanine, N,N-bis(carboxymethyl)-trisodium salt (MGDA) CAS# 164462-16-2
			
CHEMICAL STATUS	POTENTIAL CONCERN	IMPROVED	SAFER
Distinguishing Endpoints			
Acute Mammalian Toxicity	FAIL	PASS	PASS
Carcinogenicity	FAIL	No Data=FAIL	PASS
Repeated Dose Toxicity	FAIL	PASS	PASS
Reproductive Toxicity	Insufficient Data=FAIL	Insufficient Data = FAIL	PASS
Developmental Toxicity	Insufficient Data=FAIL	PASS	PASS
Environmental Toxicity and Fate †	PASS	PASS	PASS
Eutrophication	PASS	PASS	PASS
Additional Endpoints			
Genetic Toxicity	PASS	PASS	PASS
Neurotoxicity	No Data	No Data	No Data
Respiratory Sensitization	No Data	No Data	No Data
Skin Sensitization	PASS	PASS	PASS