Lowell Center for Sustainable Production
UNIVERSITY OF MASSACHUSETTS LOWELL

Alternatives Assessment 107 Webinar:

The Role of Exposure Information in Alternatives Assessment Processes

OCTOBER 23, 2012

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** If you would like to ask a question or comment during this webinar please type your question in the question box located in the control panel.*

Goals

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- Continuing education and dialog
- *"To advance the practice of alternatives assessment for informed substitution across federal, state, and local agencies through networking, sharing of experiences, development of common approaches, tools, datasets and frameworks, and creation of a community of practice."*

Purpose of this call

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Defining what is a safer alternative is a nebulous concept. In some cases a safer chemical or product is defined by statute. In other cases it is defined by guidance. It can differ between regulatory and non-regulatory programs. The goal of the webinar is to engage a discussion on how "safer" is defined by different agencies.

Rather than focus on agreement of definitions, **it is important to understand differences in approaches, criteria, and whether commonalities exist.**

Speakers

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- Joel Ticker, Lowell Center for Sustainable Production, University of Massachusetts Lowell
- Cal Baier Anderson, Design for Environment Branch, US Environmental Protection Agency
- Hortensia Muniz-Ghazi, California Department of Toxic Substances Control

Discussion Questions

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- What are limitations exist around each agency's ability to define the term safer? Do we need to define "safe" or "unsafe"
- How does safer differ for regulatory versus discretionary policies?
- Are there some consistent definitions and/or criteria that could be developed – for certain endpoints etc. – that could help us identify safer chemicals or eliminate some chemicals as clearly less "safe"
- How can agencies work together in the future on this question?

Webinar Discussion Instructions

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- Due to the number of participants on the Webinar, all lines will be muted.

- If you wish to ask a question, please type your question in the question box located on the right side panel of your webinar control panel.

What do we mean by safer?

- **Safer Alternative**: An option, including the option of not continuing an activity, that is healthier for humans and the environment than the existing means of meeting that need. For example, safer alternatives to a particular chemical may include a chemical substitute or a re-design that eliminates the need for any chemical addition.
- **Safer Chemical**: A chemical that, due to its inherent chemical and physical properties, exhibits a lower propensity to persist in the environment, accumulate in organisms and induce adverse effects in toxicological studies. Synonyms: lower hazard, inherently low hazard; 'green' chemical

But it all depends on context…

- Regulatory vs. voluntary
- Type of product category
- The standard of judicial review
- How the courts and agencies interpret (guidance)
- Other statutes/burdens that must be considered when determining "unreasonableness of risk" such as economic feasibility, etc.
- Safe vs. unsafe vs. not unsafe

Example – OSH Act

- The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.
- OSH Act Section 6 (b)(5)

Early interpretation of significant risk

- The ultimate facts here in dispute are on the frontiers of scientific knowledge and though the factual finger points, it does not conclude. Under the command of OSHA, it remains the duty of the Secretary to protect the working-man, and to act even in circumstances where existing methodology or research is deficient.
- The Society of the Plastics Industry, Inc., v. Occupational Safety and Health Administration, 1975

Benzene – changes the definition

- It is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it.... while the Agency must support its findings that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations (and is not “a mathematical straightjacket”.
- Industrial Union Department vs. American Petroleum Institute (1980)

Example - TSCA

- Section 5e New Chemicals
- If the Administrator determines that—
  - (i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and
  - (ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, **may present an unreasonable risk of injury to health or the environment, or (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human**
  - **exposure to the substance**, the Administrator may issue a proposed order, to take effect on the expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities

Example - TSCA

- Section 6
- If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, **presents, or will present an unreasonable risk of injury to health or the environment**, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements

Interpreting unreasonable risk

- Unreasonable risk never defined by Congress but includes cost-benefit balancing and choosing least burdensome action.
- EPA and others attempted to determine range of approaches to determining when risks trigger TSCA action – significant risk vs. unreasonable risk
- Interpretation of may present and will present varies though there is some agency guidance on this.
- Fifth Circuit Court of Appeals (Corrosion Proof Fittings v. EPA 1991) in asbestos case found that the agency had not demonstrated a reasonable basis for regulatory action – "the EPA"s regulation cannot stand if there is any other regulation that would achieve an acceptable level of risk as mandated by TSCA".

Food Quality Protection Act

- Section 408 b(2) – Authority to issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food
- The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.
- "(ii) DETERMINATION OF SAFETY.—As used in this section, the term 'safe', with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

Determining reasonable certainty of no harm

- Starting point: Reference Dose, with focus on key endpoints of concern, pesticide breakdown products, and vulnerable populations, adding a 10x safety factor for children - “Population Adjusted Dose”
- Look at aggregate exposures to determine if tolerance is “safe”
- Similar safety standard approach in Lautenberg Safe Chemicals Act with PBT chemicals automatically unsafe (Priority 1) and some considered “safer” (priority 3) – “does not and would not, at any stage of the lifecycle of the chemical substance, pose any risk of adverse effects to human health or the environment under existing, pro posed, or anticipated levels of exposure to, or production or patterns of use of, that chemical substance.”

Federal Food Drug and Cosmetics Act

- Cosmetics – adulterated standard
- A cosmetic shall be deemed to be adulterated—
- (a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye..,
- (b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.
- (c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
- (d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
- (e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

But…for color additives

- Section 379 e(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe (considering probable consumption/exposure, cumulative effects and safety factors)
- *Provided*, *however*, That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term "food additive" because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 321(s) of this title.

New Drugs – Safe and Effective

- Federal Food Drug and Cosmetic Act Section 355 **(d) Grounds for refusing application; approval of application**
- If the Secretary finds... that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof ...or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application.

California Draft Safer Consumer Products Regulations

- S. 69501.1 a62 “Safer alternative” means an alternative that, in comparison with the existing Priority Product, reduces, avoids, or eliminates the use of, and/or exposures to, one or more Chemical(s) of Concern, so as to reduce adverse public health and environmental impacts.

Defining Safer in Single Chemical Bills

- CA Toxin-Free Infants and Toddlers Act. S108941. (a) Manufacturers shall use the least toxic alternative when replacing bisphenol A in containers in accordance with this chapter. Alternatives cannot be reproductive toxicants or carcinogens
- City of San Francisco - Regulation Determining Acceptable Alternatives to Arsenic Treated Wood, Section 1302 No later than March 30, 2003, the Department shall identify, prepare and adopt, at a public meeting, a list of environmentally preferable alternatives to preservative-treated wood containing arsenic.

Maine – Act to Act to Clarify Maine's Phaseout of Polybrominated Diphenyl Ethers (2002)

- 14. Safer alternatives; policy. It is the policy of the State that the "deca" mixture of polybrominated diphenyl ethers be replaced with safer alternatives as soon as practicable.
- A. For the purposes of this subsection, "safer alternative" means a substitute process, product, material, chemical, strategy or any combination of these that:
- (1) When compared to the chemical to be replaced would reduce the potential for harm to human health or the environment or has not been shown to pose the same or greater potential for harm to human health or the environment as the chemical to be replaced;
- (2) Serves a functionally equivalent purpose that enables applicable fire safety standards, approvals and tests and relevant performance standards to be met;
- (3) Is commercially available on a national basis; and
- (4) Is not cost-prohibitive.

But lots of discretionary efforts

- Design for Environment
  - Safer Chemical Ingredient - Chemicals that meet the criteria of the Design for the Environment (DfE) Safer Product Labeling Program
- Pollution Prevention
  - Toxics Use Reduction - means in-plant changes in production processes or raw material that reduce, avoid, or eliminate the use of toxic or hazardous substances or generation of hazardous byproducts per unit of product, so as to reduce risks to the health of workers, consumers, or the environment, without shifting risks between workers, consumers, or parts of the environment.
- Green Chemistry
  - Wherever practicable, synthetic methods should be designed to use and generate substances that possess little or no toxicity to human health and the environment.

We do often determine safer - Chemical ranking, scoring and prioritization

- Dozens of different chemical ranking and scoring systems to either prioritize or categorize chemicals
- Some used to prioritize chemicals for risk assessment, some used to identify chemicals for substitution, some used to choose and evaluate chemicals
- Some purely based on hazard characteristics, some include exposure considerations
- Approach taken by several states in determining priority chemicals for action

Lessons learned

- Context matters
- Significant risk, safe and safer not well defined in many laws
- For laws with safety standards – little room for “shades of gray” – meets or doesn’t meet safety standard
- In some laws, safer alternative is just not having the hazard of concern or avoiding certain hazard endpoints
- Safer often not just a hazard comparison – may include many other factors
- Regulatory versus voluntary can look at this question very differently. Chemical categorization is common
- But…are there ways to have consistency in determining what is lower and higher hazard?

United States Environmental Protection Agency

Design for the Environment: Hazard Evaluation in Alternatives Assessment

Cal Baier-Anderson, PhD
Toxicologist
Design for the Environment Program

Office of Pollution Prevention and Toxics

Inspiration – Green Chemistry

- Prevent Waste
- Maximize Atom Economy
- Use Less Hazardous Chemical Syntheses
- Design Safer Chemicals
- Use Safer Solvents and Reaction Conditions
- Design for Energy Efficiency
- Use Renewable Feedstocks
- Avoid Chemical Derivatives
- Use Catalysis
- Design for Degradation
- Analyze in Real-time for P2
- Minimize Potential for Accidents

Motivation – Need for Hazard Information

- Every day, decisions are made about chemicals
  - Hazard information is not readily available
  - Alternatives not evaluated
- Use available information to understand and compare inherent hazard properties and potential environmental impacts
- Help stakeholders identify safer (less hazardous) functional chemicals
- Alternatively, recognize when safer alternatives are not available

What is Safer?

- Risk is a function of hazard and exposure
  - Risk reduction can be achieved through both exposure controls and hazard reduction
    - Hazard reduction is an effective means of risk reduction
- Hazard can be ranked on a continuum
  - EPA Office of Pollution Prevention and Toxics
    - New Chemicals Program
    - Existing Chemicals Program
    - DfE Criteria for Safer Product Labeling and Alternatives Assessment
  - EPA Office of Pesticide Programs
  - European Union REACH Annex IV
  - Globally Harmonized System of Classification & Labeling

DfE Criteria for Safer Chemicals

- Human Health Traits:
  - Carcinogenicity
  - Mutagenicity/Genotoxicity
  - Acute mammalian toxicity
  - Respiratory & Skin Sensitization
  - Eye & Skin Irritation/Corrosivity
  - Reproductive and Developmental Toxicity
  - Repeated Dose Toxicity
  - Neurotoxicity
  - Immunotoxicity
  - Endocrine activity
- Environmental Traits
  - Acute aquatic toxicity
  - Chronic aquatic toxicity
  - Persistence
  - Bioaccumulation
  - Framework allows for additional criteria, when relevant and available:
    - Physical hazards
    - Ecosystem impacts

EPA Threshold-Based Criteria

Reproductive & Developmental Toxicity Criteria

Endpoint (LOAEL, NOAEL)	High	Moderate	Low	Very Low
Oral (mg/kg-bw/d)	<50	50-250	> 250-1000	>1000
Dermal (mg/kg-bw/d)	<100	100-500	>500-2000	>2000
Inhalation (vapor, mg/L/d)	<1	1-2.5	>2.5-20	>20
Inhalation (dust, mg/L/d)	<0.1	0.1-0.5	> 0.5-5	5

- Chemical potency
- Examples of threshold-based criteria
  - Acute toxicity
  - Acute aquatic toxicity
  - Bioaccumulation
  - Repeated dose toxicity
  - Reproductive & developmental toxicity

EPA Evidence-Based Criteria

- Strength of evidence linking a chemical to an effect
  - Endpoints that have no thresholds, e.g., Cancer, Mutagenicity
  - Use of expert judgment & structure-activity relationships
- Examples
  - HIGH CONCERN
    - Evidence of adverse effects in humans
    - Conclusive evidence of severe effects in animal studies
    - *Analog/Chemical class/Structural alert associated with significant toxicity*
  - MODERATE CONCERN
    - Suggestive animal studies for chemical or analogs
    - *Analog/Chemical class/Structural alert associated with some toxicity*
  - LOW CONCERN
    - No concern identified or only minor clinical signs of toxicity

Data Gaps

- No data, no problem?
  - Not necessarily!
- Tools for addressing data gaps
  - Analogs with measured data
  - (Q)SAR
    - Chemical category
    - Structural alerts
    - QSAR models
- Lower level of confidence in results

Identifying Safer Chemicals in DfE

Alternatives Assessment

- Applies uniform criteria to all chemicals
- Provides hazard information for each endpoint
- Emphasis on providing hazard information, identifying trade-offs

Safer Product labeling

- Criteria are tailored by functional use class
- Defines pass/fail criteria for select set of endpoints
- Acceptable trade-offs are incorporated into criteria

Example

DfE AA Criteria

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from estimation software and professional judgment.
◊ The highest hazard designation of a representative component of the oligomeric mixture with MWs <1,000.
‡ The highest hazard designation of any of the oligomers with MW <1,000§ Based on analogy to experimental data for a structurally similar compound.

Human Health Effects											Aquatic Toxicity		Environ. Fate	
Acute Toxicity	Carcinogenicity	Mutagenicity/ Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitizer	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
L	L	L	L	L	*L*	L	*L*		*M*	H	H	H	L	VL

Surfactant Criteria

Acute Aquatic Toxicity	Rate of Biodegradation	Evaluation	Pass/Fail?
≤ 1 ppm	May be acceptable if biodegradation occurs		PASS
> 1 ppm and ≤ 10 ppm	Biodegradation occurs within a 10-day window without products of concern	X	
> 10 ppm	Biodegradation occurs within a 10-day window without products of concern		

Alternatives to BPA in Thermal Paper (Draft 2012)

This table only contains information regarding the inherent hazards of the chemicals evaluated. Evaluation of risk considers both the hazard and exposure. The caveats listed in the legend and footnote sections must be taken into account when interpreting the hazard information in the table below.

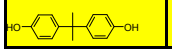
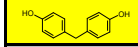
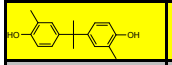
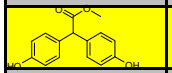
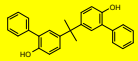
VL = Very low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very high hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data.

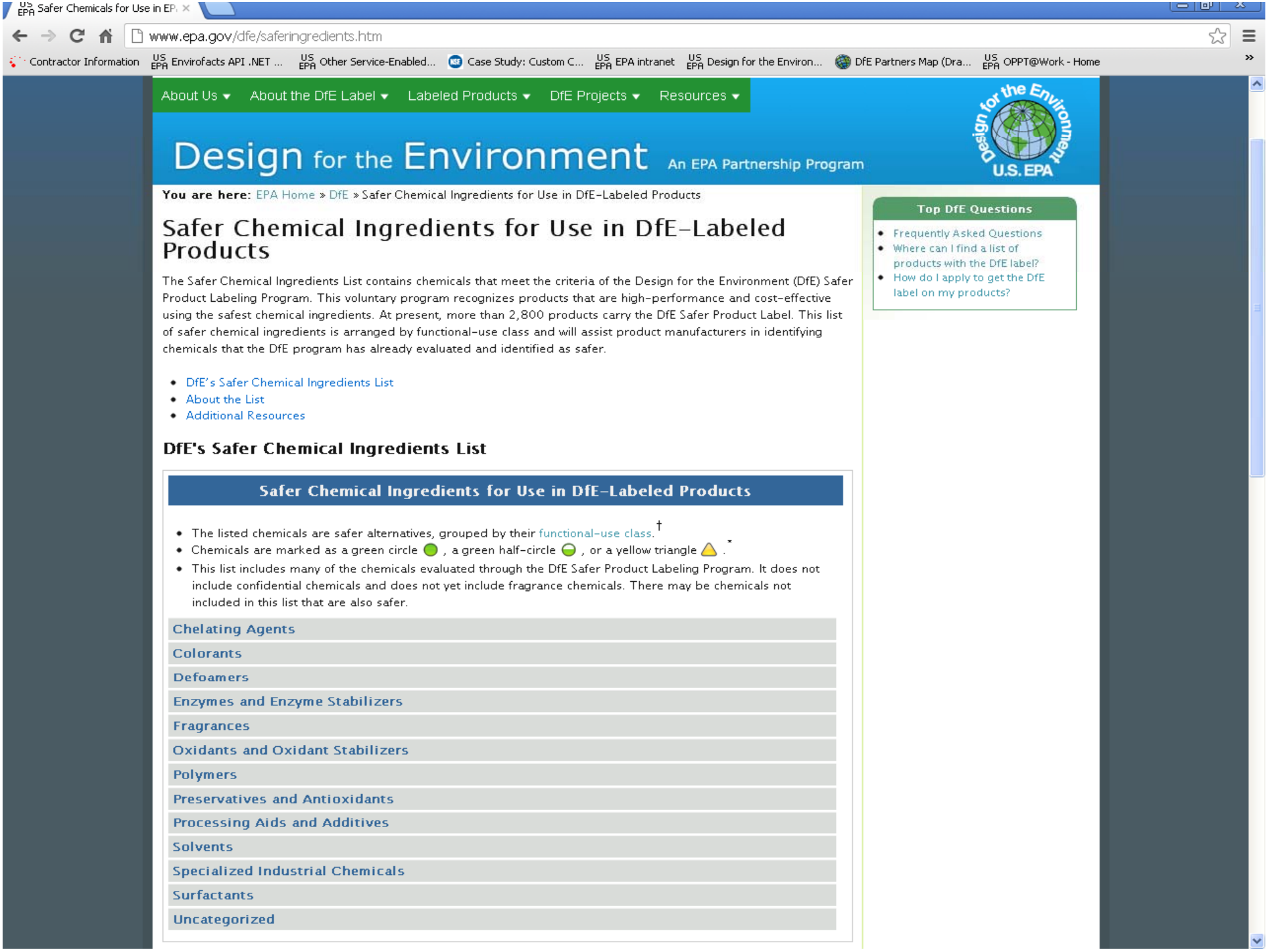
Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from estimation software and professional judgment [(Quantitative) Structure Activity Relationships "(Q)SAR"].

◊ For representative component, most predominant oligomer, of mixture (MW <1,000).

‡ Based on highest concern oligomer with a MW <1,000

§ Based on analogy to experimental data for a structurally similar compound.

	Chemical	CASRN	Human Health Effects										Aquatic Toxicity		Environmental Fate	
			Acute Toxicity	Carcinogenicity	Mutagenicity Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitizer	Respiratory Sensitizer	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
	Bisphenol A 2,2-bis(p-hydroxyphenyl)propane	80-05-7	L	M	L	H	H	*M*	M	M		M	M	H	H	VL	L
	Bisphenol F Bis(4-hydroxyphenyl)methane	620-92-8	L	*M*	L	*H*§	*H*§	*M*	H	L		VH	*M*§	M	*H*	L	L
	Bisphenol C 2,2'-Bis(4-hydroxy-3-methylphenyl)propane	79-97-0	*L*§	*M*	M	*H*§	*H*§	*M*	*M*§	*M*§		*H*§	*M*§	H	*H*	M	*M*
	MBHA Methyl bis(4-hydroxyphenyl)acetate	5129-00-0	*L*§	*M*	*L*§	*H*§	*H*§	*M*	*M*§	L		*M*§	*M*§	*H*	*H*	*M*	*L*
	BisOPP-A 4,4'-Isopropyllidenebis(2-phenylphenol)	2403 8-68-4	*L*§	*M*	*L*§	*H*§	*H*§	*M*	*M*§	*M*§		*M*§	*M*§	*L*	*H*	*H*	*M*


Safer Chemicals for Use in EP
www.epa.gov/dfe/saferingredients.htm
Contractor Information
Envirofacts API .NET ...
Other Service-Enabled...
Case Study: Custom C...
EPA intranet
Design for the Environ...
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Labeled Products
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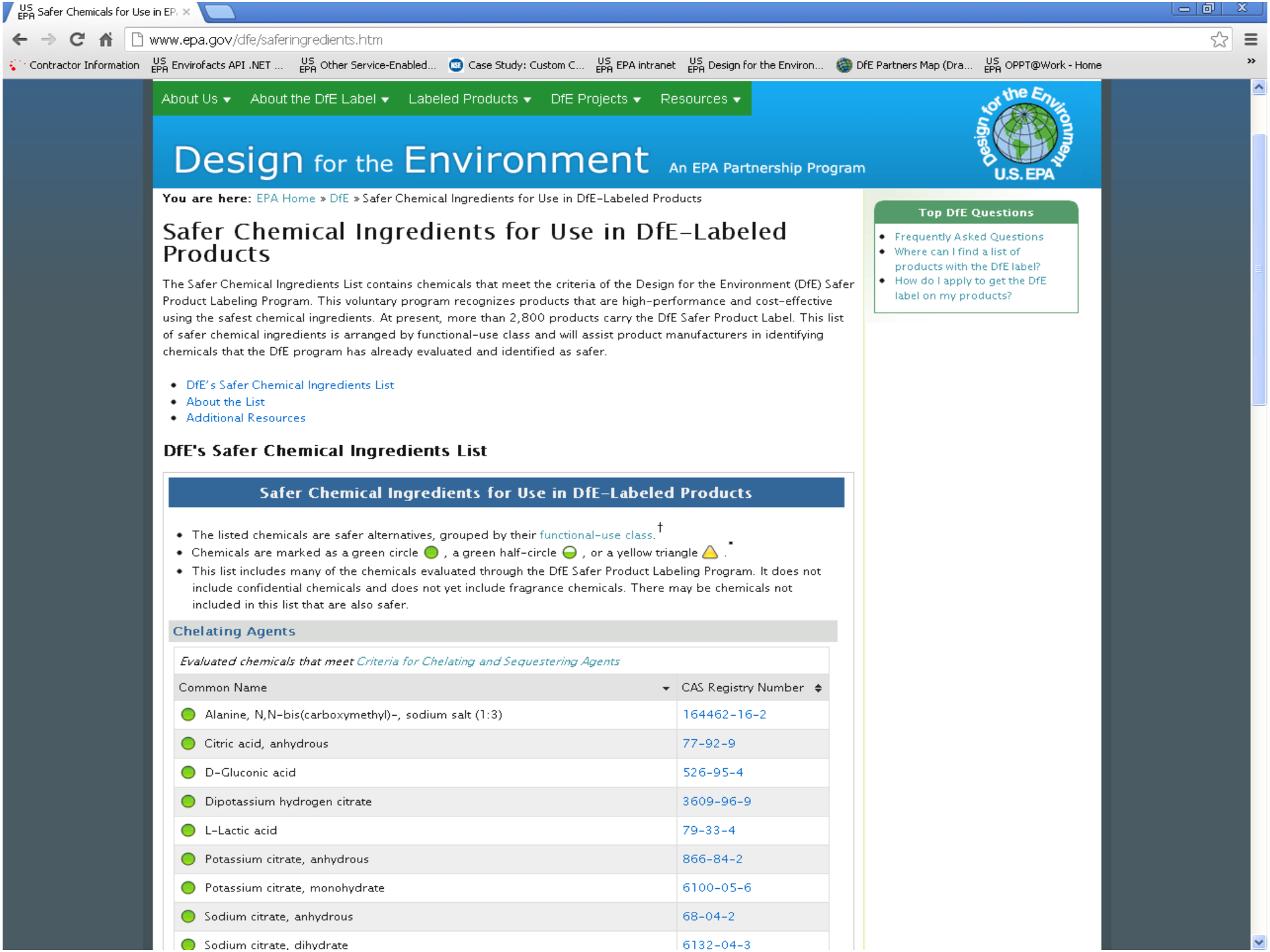
Safer Chemical Ingredients for Use in DfE-Labeled Products
The Safer Chemical Ingredients List contains chemicals that meet the criteria of the Design for the Environment (DfE) Safer Product Labeling Program. This voluntary program recognizes products that are high-performance and cost-effective using the safest chemical ingredients. At present, more than 2,800 products carry the DfE Safer Product Label. This list of safer chemical ingredients is arranged by functional-use class and will assist product manufacturers in identifying chemicals that the DfE program has already evaluated and identified as safer.
DfE's Safer Chemical Ingredients List
Safer Chemical Ingredients for Use in DfE-Labeled Products
The listed chemicals are safer alternatives, grouped by their functional-use class. †
Chemicals are marked as a green circle , a green half-circle , or a yellow triangle . *
This list includes many of the chemicals evaluated through the DfE Safer Product Labeling Program. It does not include confidential chemicals and does not yet include fragrance chemicals. There may be chemicals not included in this list that are also safer.
Chelating Agents
Colorants
Defoamers
Enzymes and Enzyme Stabilizers
Fragrances
Oxidants and Oxidant Stabilizers
Polymers
Preservatives and Antioxidants
Processing Aids and Additives
Solvents
Specialized Industrial Chemicals
Surfactants
Uncategorized
Top DfE Questions
Frequently Asked Questions
Where can I find a list of products with the DfE label?
How do I apply to get the DfE label on my products?


US EPA Safer Chemicals for Use in EP
www.epa.gov/dfe/saferingredients.htm
Contractor Information
US EPA Envirofacts API .NET ...
US EPA Other Service-Enabled...
Case Study: Custom C...
US EPA EPA intranet
US EPA Design for the Environ...
DfE Partners Map (Dra...
US EPA OPPT@Work - Home
About Us
About the DfE Label
Labeled Products
DfE Projects
Resources
Design for the Environment
An EPA Partnership Program
Design for the Environment U.S. EPA
You are here: EPA Home » DfE » Safer Chemical Ingredients for Use in DfE-Labeled Products
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Chelating Agents
Evaluated chemicals that meet Criteria for Chelating and Sequestering Agents
Common Name
CAS Registry Number
Alanine, N,N-bis(carboxymethyl)-, sodium salt (1:3) 164462-16-2
Citric acid, anhydrous 77-92-9
D-Gluconic acid 526-95-4
Dipotassium hydrogen citrate 3609-96-9
L-Lactic acid 79-33-4
Potassium citrate, anhydrous 866-84-2
Potassium citrate, monohydrate 6100-05-6
Sodium citrate, anhydrous 68-04-2
Sodium citrate, dihydrate 6132-04-3
Top DfE Questions
Frequently Asked Questions
Where can I find a list of products with the DfE label?
How do I apply to get the DfE label on my products?

Limitations of Existing Criteria

- Criteria can be used to define chemical safety, but
  - Testing is expensive – cost, time, use of animals
  - Reliable computer models limited for human health endpoints
  - Existing test methods are limited aid to chemical design
    - Lack mechanistic data to understand structure-effect relationships
  - Data can be difficult to interpret
- Emerging endpoints (e.g., endocrine and epigenetic)
  - Most chemicals lack data
  - Absence of consensus on hazard ranking
- Strategy to integrate with LCA-type analyses evolving

Closing Thoughts

- DfE contributes to the process of alternatives assessment by focusing on comparative hazard
  - Stakeholders rely on additional information to inform substitution
  - DfE is engaged in dialogue to advance integration of hazard with other attributes
- As science advances “safer” continues to evolve
  - Opportunity for new thinking about criteria and evaluation
- Alternatives assessment will benefit from public access to hazard information

For more information:

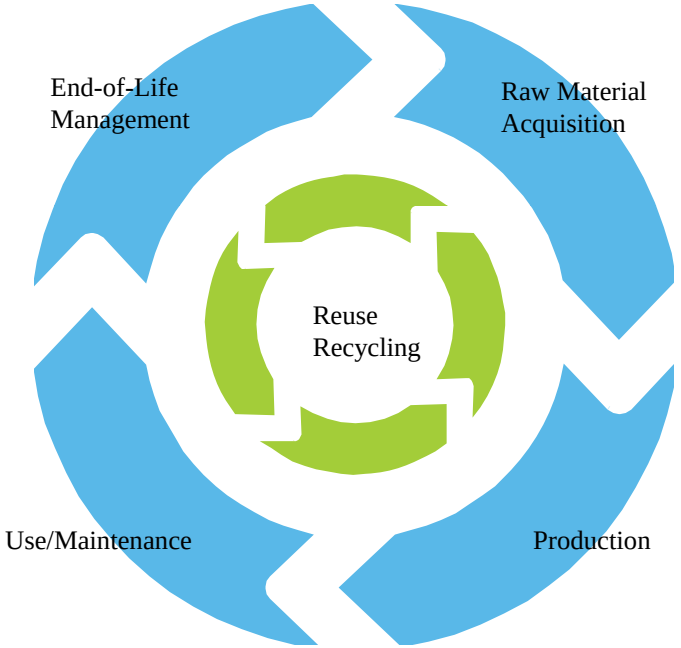
DfE: epa.gov/dfe

facebook.com/epadfe

baier-anderson.caroline@epa.gov

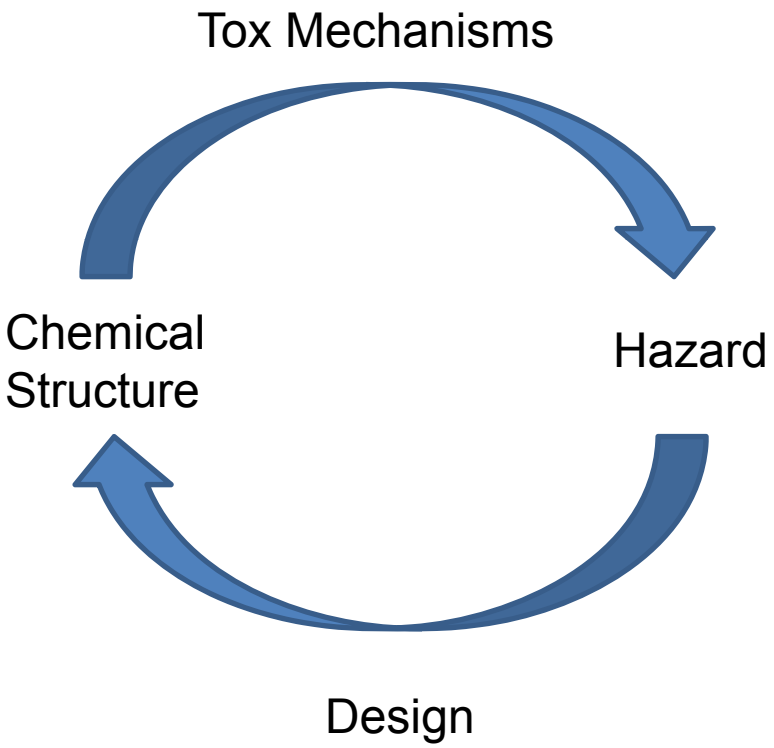
Integrating Life-Cycle Thinking

- Collaborative efforts to define integration
  - EPA ORD
  - BizNGO
  - Washington Department of Ecology
  - California DTSC
  - OECD
- Current direction:
  - Screen based on hazard, then evaluate potential life-cycle impacts of alternatives



Next Gen Criteria: Transparent, Predictive Toxicology

- Predictive toxicology
  - Incorporates structure-activity relationships & chemical categories, etc.
  - Integrates mechanistic toxicology that links toxicology to chemistry
  - Informs design-stage reduction/elimination of toxicity
- Hazard criteria that incorporates & reflects knowledge
- Translated into public database with transparent decision-logic options



Alternatives Assessment Program

- Chemical alternatives assessments:
  - Identify and evaluate ***potentially safer*** alternatives
  - DfE focus is on hazard component (comparative hazard assessment, CHA)
  - Involve stakeholders from across the spectrum of interested parties
- The outcome of an alternatives assessment:
  - Provides the best information on hazard from testing, analogs, and models
    - Based on EPA New Chemicals Program approaches
    - Does not rank (benchmark) chemicals
  - Helps minimize the potential for unintended consequences by reducing the likelihood of moving to alternatives that could pose a concern

Application: DfE Voluntary Partnership Programs

- **Safer Product Labeling:** Label innovative formulations made with lower hazard ingredients with the DfE logo as incentive.
- **Life-cycle Assessment:** Identify opportunities to improve sustainability.
- **Chemical Alternatives Assessment:** Characterize environmental and human health impacts of chemicals & alternatives; promote informed substitution.

California's Safer Consumer Products Regulations

Identifying safer alternatives, avoiding regrettable substitutes

Department of Toxic Substances Control

Green Chemistry

California Environmental Protection Agency

Alternatives Analysis Goals HSC 25253(a)

(1) …Establish a process by which chemicals of concern in products, and their potential alternatives, are evaluated to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.

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How does the Alternatives Analysis lead to Safer Alternatives?

- First Stage AA
  - Allows entities to scope and plan alternatives
  - Summarize early findings in Preliminary AA Report
- Second Stage AA
  - Gather additional information
  - Summarize findings in Final AA Report

What is an Alternative?

- Removal of a Chemical of Concern
- Reformulation or redesign of Priority Product (may contain less COCs)
- Redesign of product or manufacturing process
- Other change that reduces the potential for adverse impacts

What is Safer?

- Does not contain a Chemical of Concern or contains less.
- Does not pose “adverse impacts” or poses less
- Does not have significant ability to contribute or cause widespread impacts or poses less

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DTSC

A Safer Alternative must also:

- meet the function, performance, and legal requirements.
- be technically and economically feasible
- be evaluated for relevant factors, adverse impacts and other criteria.
- There will be trade-offs.

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DTSC

Impacts & Chemical Hazards

- Adverse environmental impacts;
- Adverse public health impacts;
- Adverse waste and end-of-life impacts;
- Environmental fate;
- Materials and resource consumption impacts;
- Physical chemical hazards; and
- Physicochemical properties.

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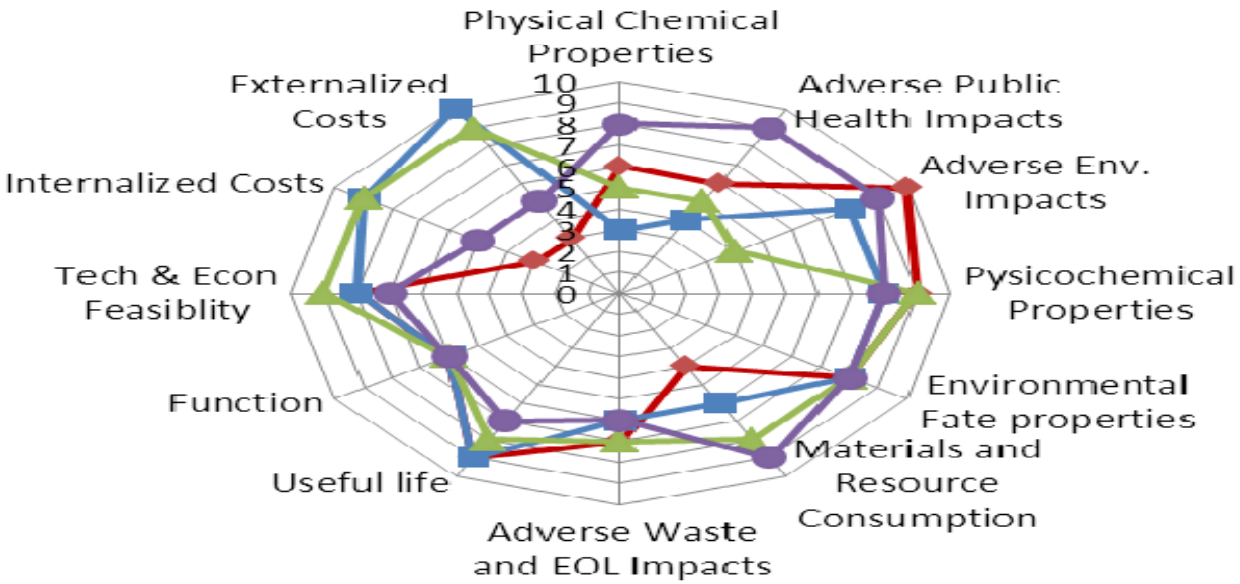
DTSC

How do relevant factors and impacts lead to Safer Alternatives ?



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Discussion Questions

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- What are limitations exist around each agency's ability to define the term safer? Do we need to define "safe" or "unsafe"
- How does safer differ for regulatory versus discretionary policies?
- Are there some consistent definitions and/or criteria that could be developed – for certain endpoints etc. – that could help us identify safer chemicals or eliminate some chemicals as clearly less "safe"
- How can agencies work together in the future on this question?

Next Webinars

Lowell Center for Sustainable Production
UNIVERSITY OF MASSACHUSETTS LOWELL

- Alternatives Assessment 108:Lifecycle Consideration in the Context of Alternatives Assessment
  - November 20, 2012 at 12pm Eastern/ 9am Pacific.
- Alternatives Assessment 109:Alternatives Assessment in Procurement
  - Fall 2012- Date and Time TBA

Webinar Audio & Slides

Lowell Center for Sustainable Production
UNIVERSITY OF MASSACHUSETTS LOWELL

The audio recording and slides shown during this presentation will be available at:

http://www.chemicalspolicy.org/alternativesassessment.webinarseries.php