



# DfE Criteria for Safer Ingredients -

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BPA Alternatives in Thermal Paper Partnership

Kick-off Meeting

July 15<sup>th</sup>, 2010

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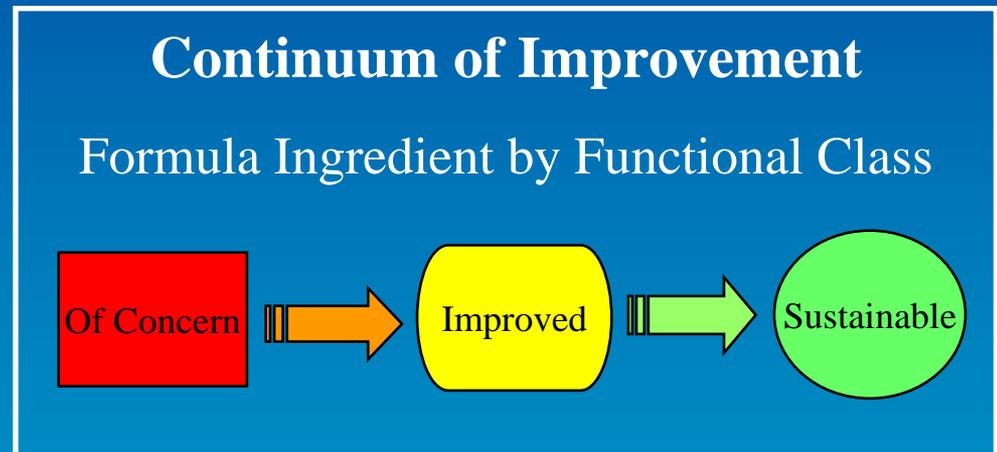
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- EPA DfE Criteria for Safer Ingredients
  - Why did DfE Develop the Criteria?
  - Summary of the Criteria
- Application for Alternatives Assessments
  - Criteria for High, Moderate, Low designations
  - Levels of Confidence in the designations

# EPA DfE Measures of Safer Chemistry

## Criteria for Safer Ingredients

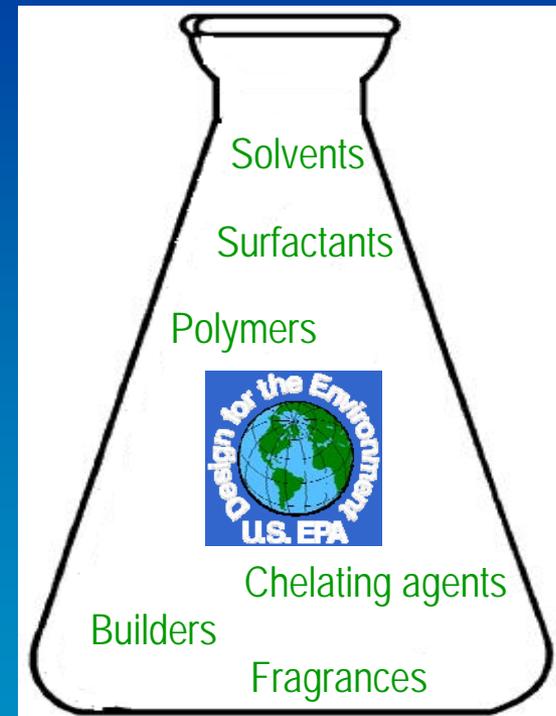
- Functional ingredient classes
  - Solvents
  - Surfactants
  - Fragrances
  - Chelating agents
  
- Master Criteria
  - Generally low hazard



# Why did DfE Develop Safer Chemicals Criteria?



- Treatment of New Chemicals under TSCA
- Leverage EPA toxicological tools and expertise
- Transparency
- Product formulators asked for a list of safer chemicals for product development



# DfE Criteria for Safer Ingredients

## Authoritative Lists

- International Agency for Research on Cancer (IARC)
- National Toxicology Program (NTP)
- EPA Carcinogens List
- EU CMR List
- EU Risk Phrases

## Evaluation of Experimental Data

- Globally Harmonized System (GHS)
- EPA New Chemicals Program
- EPA TSCA 8(e) reporting

# What is GHS?

- Harmonized criteria for the classification of chemical hazards
- Covers hazards to human health and environment
- GHS adopted by:
  - EU
  - OSHA
  - Japan
  - and others.

# DfE Criteria for Safer Ingredients

## Human Health Toxicity

- Acute mammalian toxicity
- Carcinogenicity
- Genetic toxicity
- Neurotoxicity
- Repeated dose toxicity
- Reproductive and developmental toxicity
- Respiratory sensitization
- Skin sensitization

## Environmental Fate & Effects

- Aquatic toxicity
- Bioaccumulation potential
- Biodegradation
- Eutrophication

# DfE Alternatives Assessments

Human Health  
Hazard Concern

Ecotoxicity  
Hazard Concern

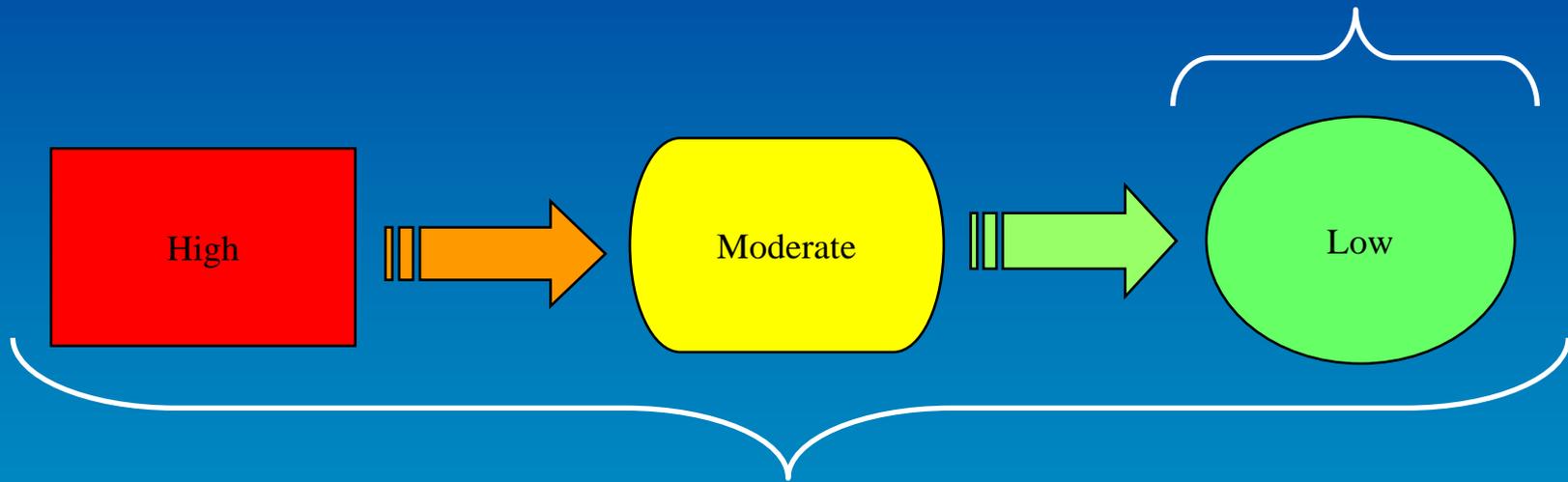
Environmental  
Hazard Concern



Company	Chemical	% in Formulation <sup>3</sup>	Human Health Effects							Ecotoxicity		Environmental		Potential Routes of Exposure							Reactive or Additive?			
			Cancer Hazard	Skin Sensitizer	Reproductive	Developmental	Neurological	Systemic	Genotoxicity	Acute	Chronic	Persistence	Bioaccumulation	Worker			General Population			Aquatic				
														Inhalation	Dermal	Ingestion	Inhalation	Dermal	Ingestion					
Albemarle	SAYTEX RZ-243																							
	Proprietary E Tetrabromophthalate diol diester		L	L	L*	L*	L	M*	L	L	H	L <sup>?</sup>	L	N	Y	Y	N	N	Y	Y				Additive
	Proprietary B Aryl phosphate		L	L	M*	M*	M	M*	L	H	H	L	M	N	Y	Y	N	Y	N	N				Additive
	Triphenyl Phosphate CAS # 115-86-6		L	L	L	L	L	M	L	H	H	L	L	Y	Y	Y	Y	Y	Y	Y				Additive
Ameribrom	FR513																							
	Tribromoneopentyl Alcohol CAS # 36483-57-5		M	L	M	M	M	M	M	M	M	L	L	Y	Y	Y	N	N	Y	Y				Reactive
Great Lakes	Firemaster 550																							
	Proprietary F Halogenated aryl ester		L	L	M	M	L	M	L	H	H	L <sup>?</sup>	L	N	Y	Y	N	Y	Y	Y				Additive
	Proprietary G Triaryl phosphate, isopropylated		L	L	M*	M*	M	M*	L	H	H	L	M	N	Y	Y	N	Y	N	N				Additive
	Triphenyl Phosphate CAS # 115-86-6		L	L	L	L	L	M	L	H	H	L	L	Y	Y	Y	Y	Y	Y	Y				Additive
	Proprietary H Halogenated aryl ester		L	L	M	M	L	M	L	H	H	L <sup>?</sup>	L	N	Y	Y	N	Y	Y	Y				Additive

# Application to Alternatives Assessment

Master Criteria – used in  
Safer Product Labeling



Expanded Master  
Criteria – to be used in  
Alternatives Assessment

# Example of Expanded Criteria – *Draft*

## Repeated Dose/Systemic Toxicity



**GHS Category 1**

Oral	10 mg/kg bw/d
Dermal	20 mg/kg bw/d
Inhalation	0.2 mg/L/6h/d

**GHS Category 2**

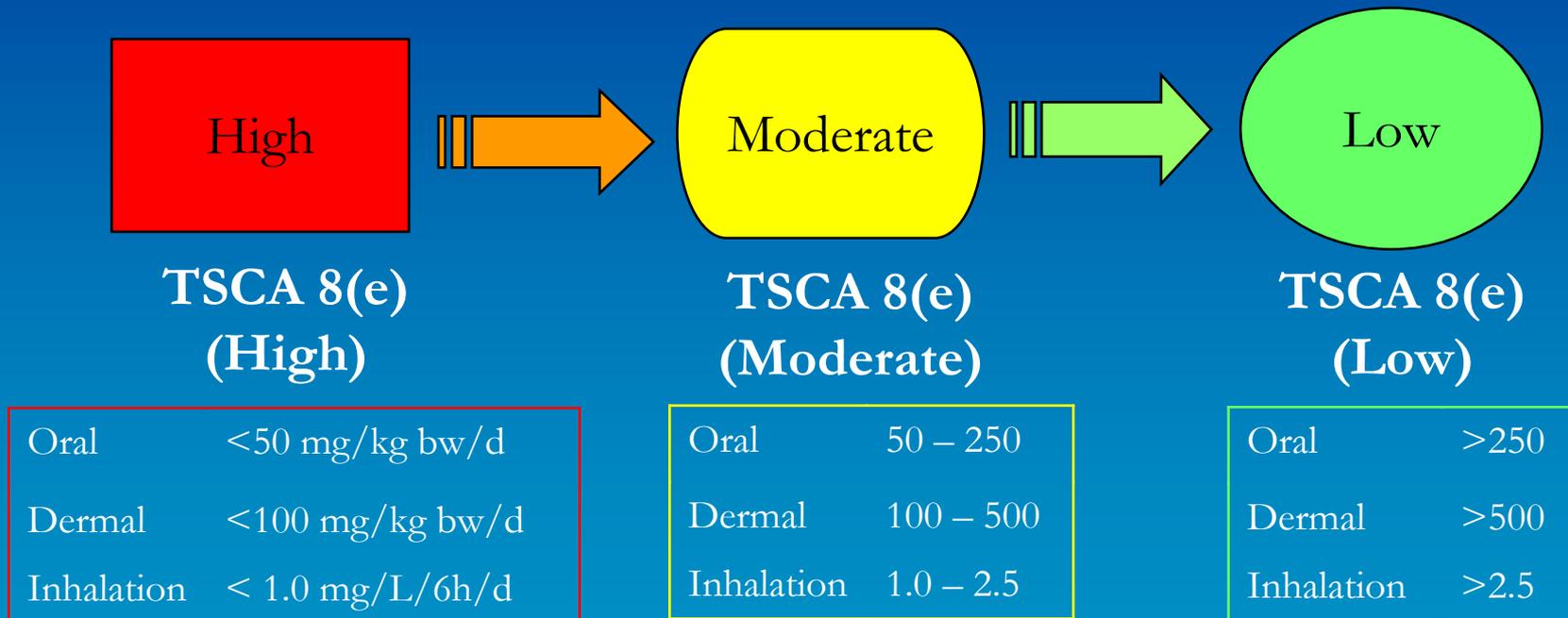
Oral	10 – 100
Dermal	20 – 200
Inhalation	0.2 – 1.0

**Not classified under GHS**

Oral	>100
Dermal	>200
Inhalation	>1.0

# Example of Expanded Criteria – *Draft*

## Reproductive & Developmental Toxicity





# Data Preferences

High Weight of  
Evidence



Low Weight of  
Evidence

- Experimental data
- Analogs
- Models

# Available EPA/OPPT Screening Level Models



- ECOSAR
- Oncologic<sup>®</sup>
- EPI Suite<sup>™</sup>
- OECD QSAR Toolbox
- ChemSTEER
- E-FAST
  
- Other detailed models are also used as needed

# OPPT Models and Methods Being Widely Used



- New Chemicals
  - PMN Reviews
  - Sustainable Futures
- Existing Chemicals
  - Design for the Environment
  - PBT Initiative
  - HPV Chemicals
- Office of Pesticide Programs
  - Inerts
  - Anitmicrobials
- Office of Air Quality Planning and Standards
  - Hazardous Air Pollutants
- Other Federal Agencies
  - Customs & Border Protection
  - Dept. of Defense
  - Food & Drug Admin.
  - Fed. Aviation Admin.
- International
  - European Union
  - Canada
  - The Netherlands

# Ongoing Model Development and Validation

- 25+ years of experience in the New Chemicals Program led to continual development and refinement of the EPA assessment methods
- This regulatory experience with SAR techniques inform EPA's understanding of proper application of the tools and model limitations

