

# Role of Third Party Assessment in Alternative Analysis

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# Key Points

- Who/What/Where: Conformity Assessment and Third Parties
- Establishing Third Parties' Qualifications: The Challenge of Accrediting Alternatives Assessment Evaluators
- Examples of Third Party Alternatives Analysis of Safer/Greener Products
- Potential Role of Third Party Evaluators Facilitating DTSC's Alternative Analysis Program



# Conformity Assessment and the Role of Third Parties

- What is Conformity Assessment?
  - ISO/IEC 17000 defines conformity assessment as demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled
  - Conformity can be determined by a first-, second-, or third-party
  
- What are Third Parties?
  - A third party is a person or body that is independent of the person or organization that provides the object (e.g., testing, inspection), and of user interests in that object
  - Third parties differ from first or second parties:
    - First-party testing is a self-approval procedure where the responsible party (e.g. the manufacturer, supplier) determines that one or more characteristics of an object comply with the appropriate technical standards and requirements
    - Second-party testing is an approval procedure where a person or organization that has a user interest in an object (e.g. the procurer, purchaser or user) determines that one or more characteristics of an object comply with the appropriate technical standards and requirements

Sources: ANSI (2008), ISO (2010)



# Conformity Assessment and the Role of Third Parties

- In what instances is Third-Party evaluation preferable over first- or second-party evaluation?
  - The market demands or allows it
  - The risks associated with non-compliance are high
  - The first party and/or second party would like to provide users with an added level of confidence in the object of conformity assessment
  - It is required by U.S. regulations to fulfill the requirements for a suppliers' declaration of conformity
  
- Goal of Third-party evaluation
  - Provide independent, unbiased, and factual evaluation of conformity, thereby facilitating the exchange of goods and services

Sources: ANSI (2008), ISO (2010)



# How are Third Parties Accredited?

- Challenge to selecting qualified third party evaluators who are qualified to provide alternatives assessment for safer/greener chemicals
  - One man's meat is another man's poison, and one man's poison is another man's meat; what is rejected by one person may be valued very highly by another (Aesop's Fables, #57)
  - Impartiality, adherence to state of the science, and DTSC's pre-eminence to decide "safety" is paramount for third-party evaluator



# How Are Third-Parties Accredited?

- Accreditation:
  - is a statement from an Accreditation Body, an independent third-party entity, declaring that specified requirements related to Conformity Assessment Bodies have been met and that the accredited body is competent in its function.
- Accreditation Criteria:
  - For Testing Laboratories, ISO/IEC 17025
  - For Inspection Bodies, ISO/IEC 17020



# Proper Accreditation of Third-Party Alternatives Assessors

- Providing Third Party Alternatives Assessment support doesn't exactly fit into tasks specified in Standards 17025 or 17020
  - ISO 17025 is titled “*General requirements for the competence of testing and calibration laboratories*”
    - It specifies general requirements for the competence of testing and calibration laboratories
    - ISO 17025 sets out requirements for testing laboratories to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.
  - ISO 17020 is titled “*General criteria for the operation of various bodies performing inspection*”
    - Inspection bodies may typically inspect against a wide range of functions (e.g. products, services, materials, installations, plant processes, work processes, etc.) and parameters (e.g. quality, quantity, safety, fitness for use, etc.).



# Potential Third Party Evaluation In Support of AB 1879

- Both ISO 17020 and 17025 capture important concepts:
  - Including factors relevant to an organization's requirements and guidance for technical competency of staff; validity and appropriateness of methods
  - Management requirements on topics such as organization, management systems, document control, audits, and management reviews.
  - Specified need for policies relating to impartiality, and safeguards against conflicts of interest.
- DTSC could tailor requirements for Third Party evaluators based on criteria in ISO 17020 and 17025, as well as criteria of organizations such as U.S. EPA DfE



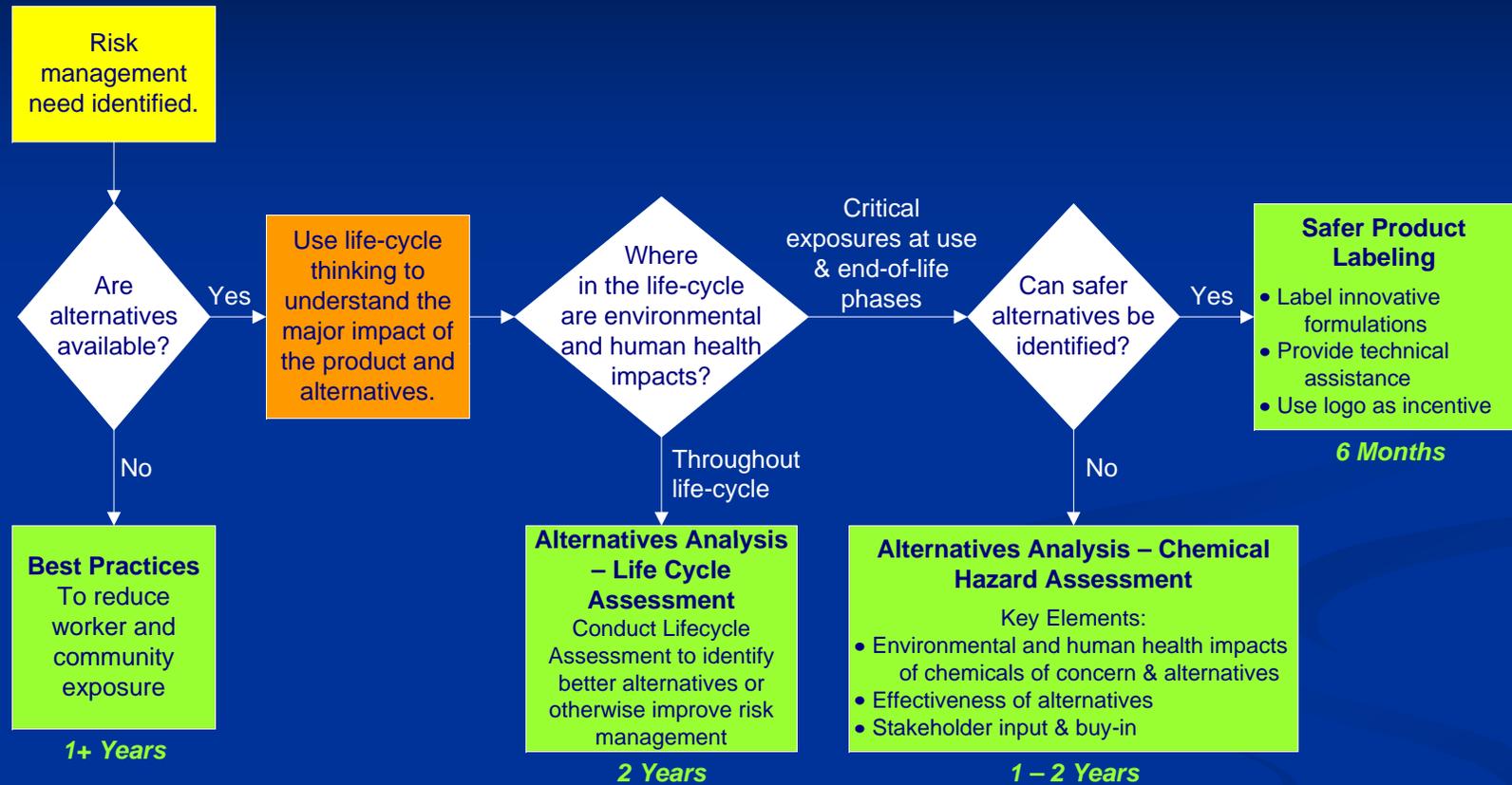
# U.S. EPA's Design for the Environment



- EPA's Design for the Environment (DfE) program works in partnership with industry, environmental groups and academia to reduce risk to human health and the environment.
  - Based on the premise of informed substitution
  - Industry partners replaced more than **500 million pounds** of chemicals of concern last year.
  - To date, more than 1700 products have been recognized by DfE



# Decision Logic for DfE Approaches

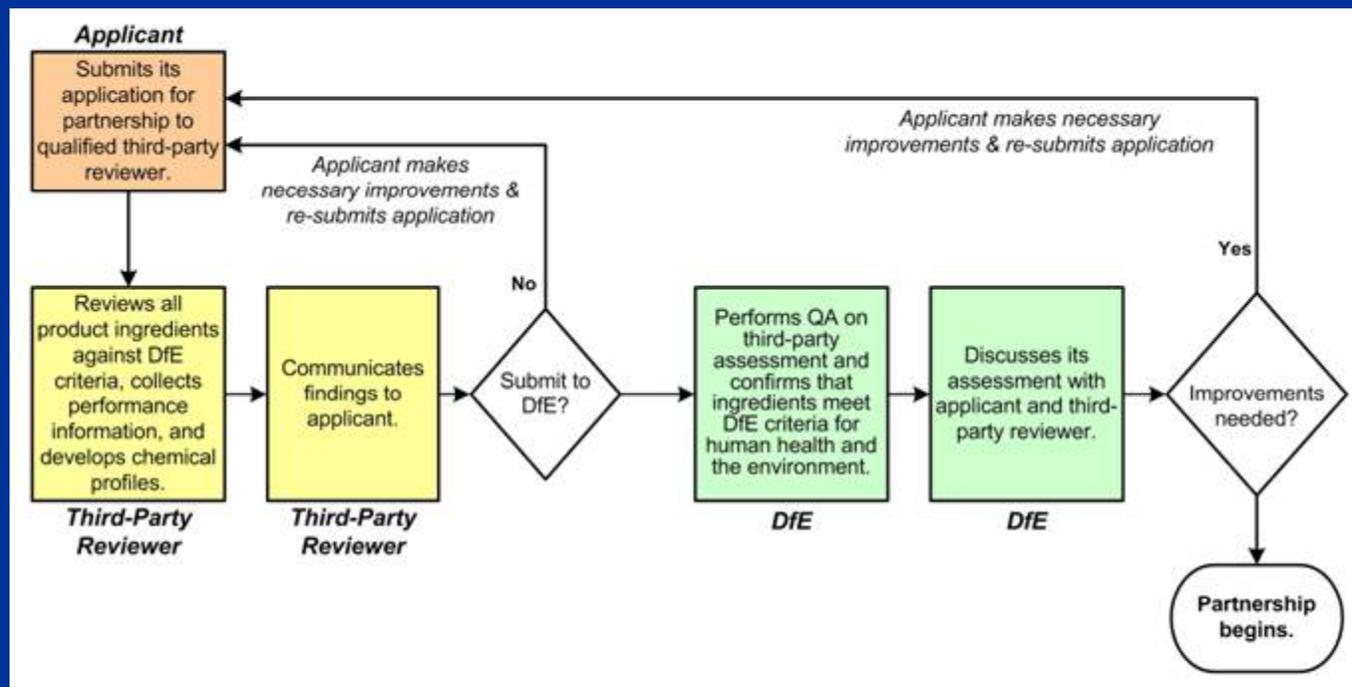


Source: DfE (2010)



# Third Party Support: U.S. DfE

- Two Third-party evaluators provide technical assistance to U.S. EPA's DfE Safer Product Labeling Program
  - Involvement is at all stages of the process



# Third Party Support: U.S. DfE

- Third-party evaluator competes for opportunity to evaluate client's product for DfE recognition
- Third-party evaluator:
  - Adheres to CBI throughout all stages of review, coordinates contact with manufacturer and suppliers
  - Evaluates each chemical above 0.01% in formulation for compliance with applicable DfE criteria
  - Prepares individual chemical screens and synthesized product report
    - Screens are 6-12 pages long and address:
      - Acute Mammalian toxicity
      - Carcinogenicity
      - Genetic Toxicity
      - Neurotoxicity
      - Repeat Dose Toxicity
      - Reproductive and Developmental Toxicity
      - Respiratory and Skin Sensitization
      - Environmental Toxicity and Fate
    - Data for all available route of exposure are evaluated
    - Many of the DfE tools are those advocated by EPA's Sustainable Futures program (<http://www.epa.gov/oppt/sf/>)
  - Presents screens and reports to DfE, where DfE expert panels "vote" upon third party's recommendations contained in reports and screens



# Third Party Support: U.S. DfE Audits

DfE Desk Audits v. On-Site Audits	
DESK AUDITS	ON-SITE AUDITS
<i>How Often?</i>	
Annually	Triennially
<i>Primary Focus?</i>	
Product ingredients and all claims made by client to ensure that recognized products comply with the DfE Partnership Agreement	The manufacturing process and procedures in place to ensure that recognized products comply with the DfE Partnership Agreement
<i>What Will Be Looked At?</i>	
<ul style="list-style-type: none"> <li>✓ <b>Product Information</b> provided by client including annual production, pH, use, packaging type, fragrance(s) used, performance testing, concentration, Hazardous Material Identification System Rating</li> <li>✓ <b>Product Formulation</b> ingredients listed with respective CAS number, chemical and trade name, supplier, function/ingredient class, and % composition</li> <li>✓ <b>DfE Partnership Agreement</b> ensuring the formulation is identical to the formulation recognized by DfE</li> <li>✓ <b>DfE Logo Use</b> focusing on label examples bearing the DfE logo</li> <li>✓ <b>Continuous Improvement Efforts</b></li> <li>✓ <b>Education Offered</b> to end-user</li> </ul>	<ul style="list-style-type: none"> <li>✓ <b>Product Information</b> provided by client including annual production, pH, use, packaging type, fragrance(s) used, performance testing, concentration, Hazardous Material Identification System Rating</li> <li>✓ <b>Product Formulation</b> including ingredient verification with batch tickets and records, acceptability of ingredients and suppliers, test data from suppliers, reports on ongoing efforts to improve the health and environmental performance of product</li> <li>✓ <b>DfE Recognition</b> focusing primarily on proper use and advertising of the DfE logo, and promotional DfE materials</li> <li>✓ <b>Good Manufacturing Practices</b> including a production walk-through, minimization of contamination review, records for manufacturing equipment, supplier qualification records, maintenance of product containers and vessels</li> <li>✓ <b>Product Packaging</b></li> <li>✓ <b>Customer Complaints and End-User Training</b></li> <li>✓ <b>Measures of Success</b> including influence on the market, formulation bills, and production volume</li> </ul>
*Adapted from U.S. EPA's DfE Standard for Safer Cleaning Products	

# Green Screen for Safer Chemicals

- The Green Screen was developed by Clean Production Action
  - Green Screen is a quantitative comparative chemical hazard assessment tool
  - Builds on U.S. EPA's DfE alternatives assessment approach
  - Uses criteria based on national and international precedents (GHS, OECD, EPA)
- Examines at human health and environmental hazards and assigns an overall chemical benchmark score
  - Version 1: Scores range from 1 to 4 Benchmark (1: Don't use chemical to 4: Use chemical)

<http://www.cleanproduction.org/Greenscreen.php>



# Green Screen for Safer Chemicals

- Incorporates life-cycle thinking with a focus on use and end-of-life phases in product life-cycle
- Open source, transparent and publicly accessible
- Can be applied to chemicals in products and processes as well as adapted to materials



# Third-Party Support to CPA

- ToxServices is a third-party Green Screen assessor
  - Chemicals as well as materials are evaluated under the Green Screen
  - Services provided are similar to those provided to DfE
    - Currently, there is not an external review of Green Screens
  - Utility of Green Screen is that it provides manufacturers with a quantitative number that they can use for comparative hazard selection:
    - Choosing a less hazardous material (e.g., PVC alternative for use in cables, or less hazardous flame retardant)
    - Ensuring that sources materials or chemicals meet a minimum Green Screen score



# Green Screen Assessment

## Green Screen Hazard Endpoints and CMR Hazard Thresholds

Hazard	High (H)	Moderate (M)	Low (L)
Carcinogenicity <a href="#">See Test Methods</a>	<ul style="list-style-type: none"> <li>•GHS Category 1A (Known); OR</li> <li>•GHS Category 1B (Presumed); OR</li> <li>•On specified list(s)</li> </ul>	<ul style="list-style-type: none"> <li>•GHS Category 2 (Suspected); OR</li> <li>•On specified list(s)</li> </ul>	<ul style="list-style-type: none"> <li>•Meets USEPA DfE Master Criteria for Carcinogenicity</li> </ul>
Mutagenicity/ Genotoxicity <a href="#">See Test Methods</a>	<ul style="list-style-type: none"> <li>•GHS Category 1A (Known); OR</li> <li>•GHS Category 1B (Should be regarded as); OR</li> <li>•On specified list(s)</li> </ul>	<ul style="list-style-type: none"> <li>•GHS Category 2 (Possible); OR</li> <li>•On specified list(s)</li> </ul>	<ul style="list-style-type: none"> <li>•Meets USEPA DfE Master Criteria for Genetic Toxicity</li> </ul>
Reproductive & Developmental Toxicity (R/D) including Developmental Neurotoxicity (DNT) <a href="#">See Test Methods</a>	<ul style="list-style-type: none"> <li>•<b>Reproductive or developmental effect as defined in GHS (i.e. GHS Cat 1 or 2) or developmental neurotoxic effect as defined by the USEPA Risk Assessment Guidelines for the following guidance doses (LOAEL's):</b></li> <li>Oral &lt; 50 mg/kg-bw/d</li> <li>Dermal &lt; 100 mg/kg-bw/d</li> <li>Inhalation (vapor) &lt; 1.0 mg/L/d</li> <li>Inhalation (dust/mist/fume) &lt; 0.1 mg/L/d</li> <li>Inhalation (gas) &lt; 50 ppm/d; OR</li> <li>•<b>On specified list(s)</b></li> </ul>	<ul style="list-style-type: none"> <li>•<b>Reproductive or developmental effect as defined in GHS (i.e. GHS Cat 1 or 2) or developmental neurotoxic effect as defined by the USEPA Risk Assessment Guidelines for the following guidance doses (LOAEL's):</b></li> <li>Oral ≥ 50 - &lt; 250 mg/kg-bw/d</li> <li>Dermal ≥ 100 - &lt; 500 mg/kg-bw/d</li> <li>Inhalation (vapor) ≥ 1.0 - &lt; 2.5 mg/L/d</li> <li>Inhalation (dust/mist/fume) ≥ 0.1 - &lt; 0.5 mg/L/d</li> <li>Inhalation (gas) ≥ 50 - &lt; 250 ppm/d; OR</li> <li>•<b>On specified list(s)</b></li> </ul>	<ul style="list-style-type: none"> <li>•<b>Meets USEPA DfE Master Criteria for Reproductive and Developmental Toxicity</b></li> <li>•<b>No Reproductive or Developmental Effects (including Developmental Neurotoxic effects) i.e. not GHS Cat 1 or 2; OR</b></li> <li>•<b>Reproductive or developmental effect as defined in GHS (i.e. GHS Cat 1 or 2) or developmental neurotoxic effect as defined by the USEPA Risk Assessment Guidelines above the following guidance doses (LOAEL's):</b></li> <li>Oral ≥ 250mg/kg-bw/d</li> <li>Dermal ≥ 500 mg/kg-bw/d</li> <li>Inhalation (vapor) ≥ 2.5 mg/L/d</li> <li>Inhalation (dust/mist/fume) ≥ 0.5 mg/L/d</li> <li>Inhalation (gas) ≥ 250 ppm/d; OR</li> <li>•<b>On specified list(s)</b></li> </ul>

Environmental Fate	Environmental Toxicity	Human Health Priority Effects	Human Health Non-Priority Effects	Physical Properties
Persistence	Acute Aquatic Toxicity	Carcinogenicity	Acute Toxicity	Reactivity
Bioaccumulation	Chronic Aquatic Toxicity	Mutagenicity - Genotoxicity	Systemic or Organ Effects	Flammability
Evidence of long range transport		Reproductive toxicity	Immune System Effects	Particle size, form, (i.e. respirable)
Found in env and bio-monitoring studies		Developmental toxicity	Corrosion or Irritation of Skin/Eyes	Mobility (i.e. solubility)
		Endocrine Disruption	Sensitization of Skin/Respiratory System	Moieties; degrad products, metabolites
		Neurotoxicity/Neurodevel tox		



# Green Screen Assessment

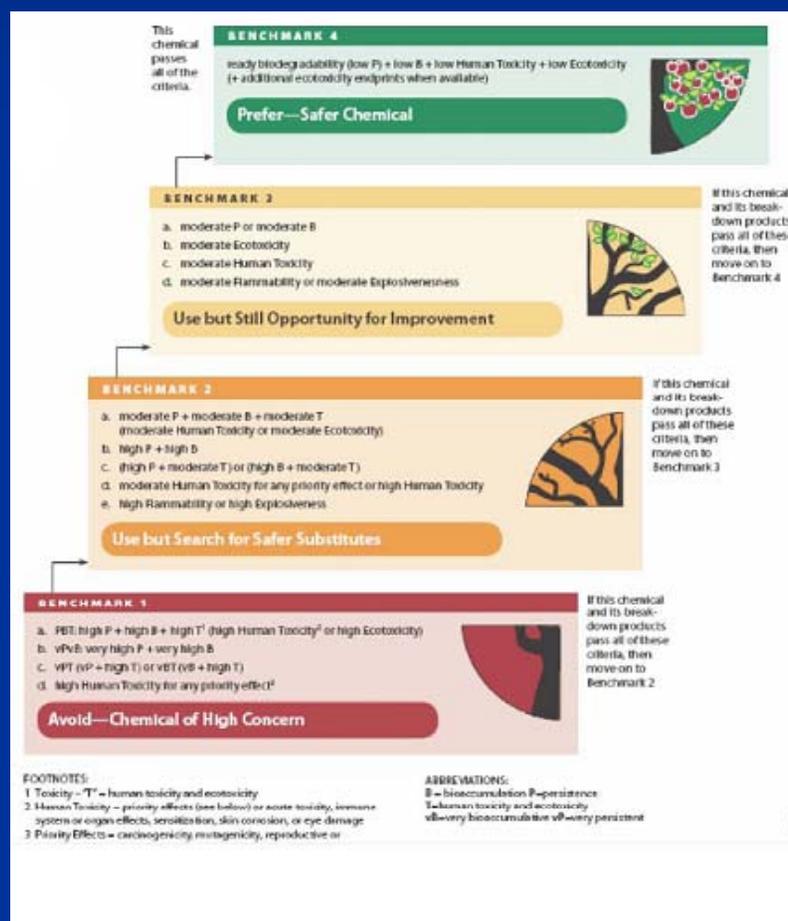
## Hazard Summary Table

Chemical	Chemical Abstract Services Registry Number (CAS#)	% in Formulation	Human Health Effects													Ecotox.		Fate		Breakdown Products	
			Priority Effects						Acute Toxicity	Systemic/Organ Effects	Sensitization (skin)	Sensitization (respiratory)	Irritation/Corrosion (skin)	Irritation/Corrosion (eyes)	Immune System Effects	Acute	Chronic	Persistence	Bioaccumulation	Metabolites	Degradation Products
			Carcinogenic	Mutagenic	Reproductive	Developmental	Endocrine Disruption	Neurological													
<b>Bisphenol A diphosphate (BPADP/BAPP) - CAS# 181028-79-5</b>																					
Phosphoric acid, (1-methylethylidene) di-4, 1-phenylene tetraphenyl ester	5945-33-5	~85	L	L	L	L	nd	L	L	M	L	nd	L	M	L	L	L	H	L	nd	phenol + bisphenol A
Phosphoric acid, bis[4-[1-[4-[(diphenoxyphosphanyl)oxy]phenyl]-1-methylethyl]phenyl] phenyl ester	83029-72-5	~11	L	L	L	L	nd	L	L	M	L	nd	L	M	L	L	L	vH	L	nd	phenol + bisphenol A
Triphenyl Phosphate	115-86-6	<3	L	L	L	L	nd	L	L	M	L	nd	L	M	L	H	H	L	M	nd	diphenyl phosphate + phenol
<b>Breakdown Products</b>																					
Bisphenol A: contaminant and degradation product	80-05-7		L	L	M	M	H	nd	L	M	M	M	L	H	M	M	M	L	L		
Phenol: contaminant and degradation product	108-95-2		L	M	L	L	L	M	M	H	L	L	H	H	M	M	M	L	L		
Diphenyl phosphate	838-85-7		<i>insufficient data for evaluation</i>																		



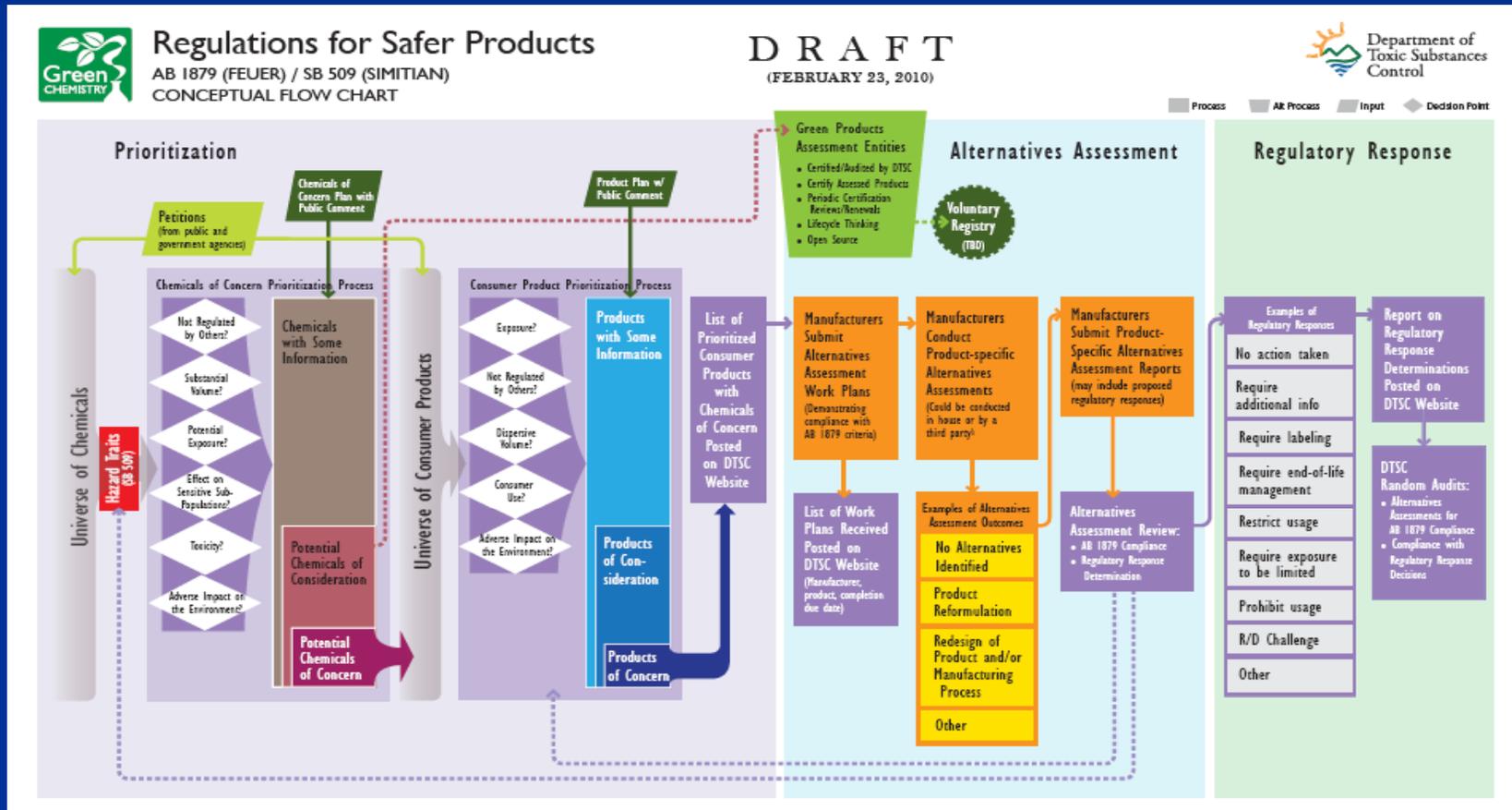
# Green Screen Assessment

## Applying the Benchmarks



# Third Party Assistance to DTSC

- Third party evaluators could assist DTSC at numerous steps in Alternatives Assessment process



# Summary

- In both instances of DfE and Green Screen, participation of third-party evaluators ensures:
  - Speed of evaluation
  - Confidentiality
  - Impartiality
  - Use of state of the science tools to evaluate human health and environmental hazards
  - Because there is competition to secure business, costs are kept to a minimum and time is of the essence
  - Data collection, scientific review, and auditing services
- Depending on needs of DTSC, all or some of these services could be provided to consumer products that will be regulated under AB 1879



Please contact me with Questions/Comments!!

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Thank you!!

#### References

ANSI (2008)

<http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/International%20Standardization/Regional/Standards%20Portal/US%20approaches.doc>

ISO (2010)

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