

## California's Green Chemistry

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## Overview: What is Green Chemistry?



“Green chemistry is the design of chemical products and processes that reduce or eliminate the use or generation of hazardous substances. Green chemistry applies across the life cycle, including the design, manufacture, and use of a chemical product. Green chemistry is a highly effective approach to pollution prevention because it applies innovative scientific solutions to real-world environmental situations.”



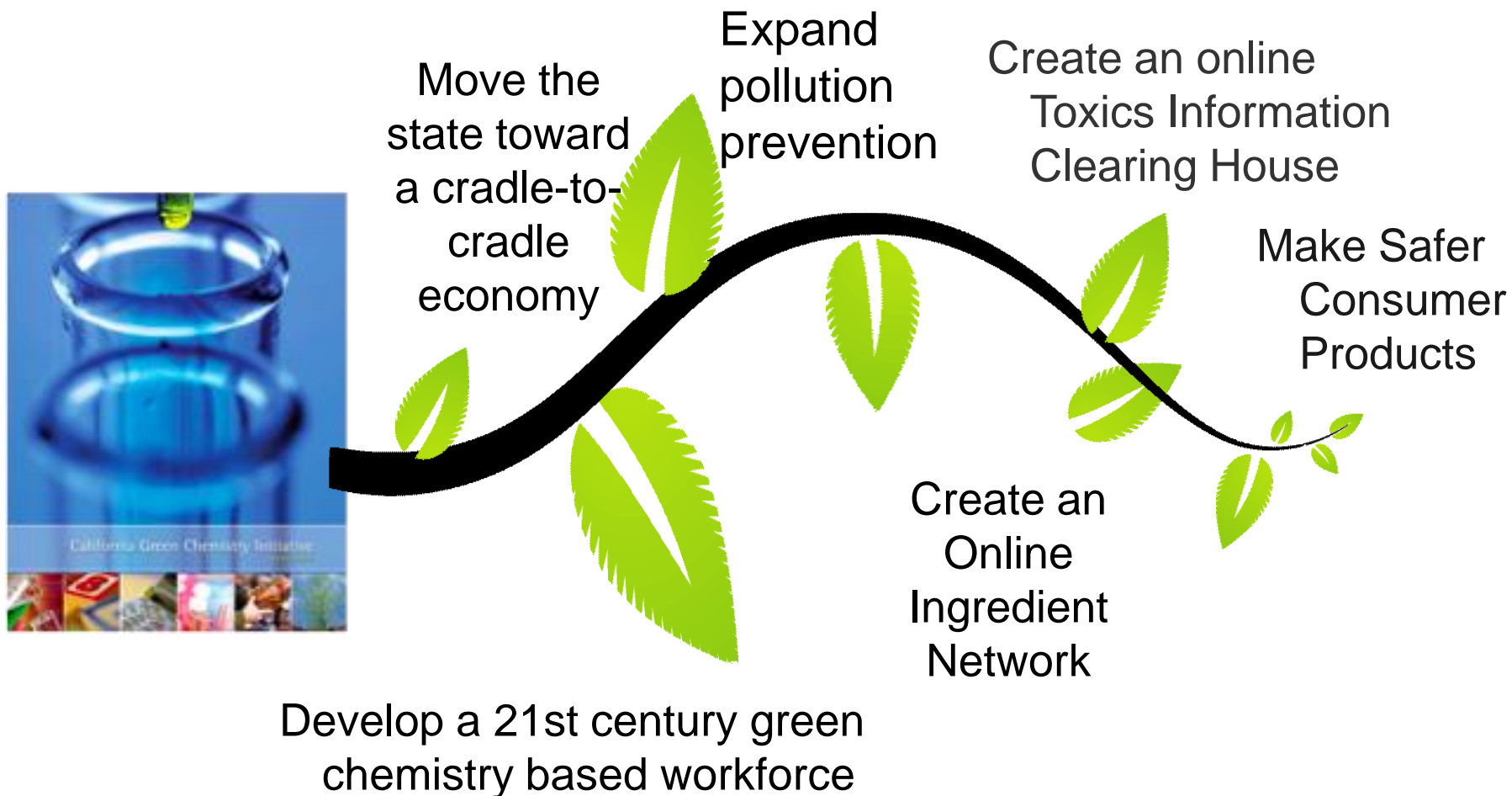
—California Department of Toxic Substances Control

## Goals of California Green Chemistry Program



- ***“Benign by Design”***
  - The Green Chemistry mantra
- Reduce or eliminate toxic chemicals in consumer products sold in California
- Upfront multimedia life-cycle evaluation vs. regulation of end points
  - e.g., air pollution, hazardous waste, sewer discharge
- Intended to fill gaps in existing laws, including federal TSCA

## Cal/EPA's Six Recommendations (October 2008)



## Diverse Perspectives in California



- **Legislature's View:** Not equipped to decide complex scientific issues. Green Chemistry legislation of 2008 requires DTSC to adopt regulations no later than January 1, 2011.



- **Environmentalists' View:** State should have greater authority to regulate chemicals in consumer products.



- **Industry View:** Need a better process that values science, and promotes a level playing field between existing products and alternatives.

## Why Green Chemistry in California?

- Past legislation proposing chemical bans based more on politics and perceived risk, rather than science.
- The Governor signed only one controversial chemical ban since 2007 (AB 1108, banning phthalates in children's products).



*“I do not believe that addressing this type of concern in the Legislature on a chemical by chemical, product by product basis is the best or most effective way to make chemical policy in California.”*

—Governor Arnold Schwarzenegger, Signing Message, AB 1108

# Green Chemistry Regulations

## ■ September 2010 Draft for Public Comment



### **NGOs:**

- Businesses given too much responsibility for implementation
- List of target chemicals and products incomplete
- Protections for trade secrets will hamper transparency



### **Industry:**

- Too complex
- Expensive and time-consuming
- May lead to regulatory gridlock
- Could impede technological innovation
- Could drive product development out of California



# Green Chemistry Regulations

## ■ November 2010 Revised Draft

- Clarified, simplified
- Added transparency and more oversight
- Focus on three categories of products through 2016:

- Children's products
- Personal care products
- Household cleaning products



- Major NGOs and sponsors of the legislation withdrew support
  - NGO view: November draft is too pro-industry
  - Industry view: Better but still complex and burdensome

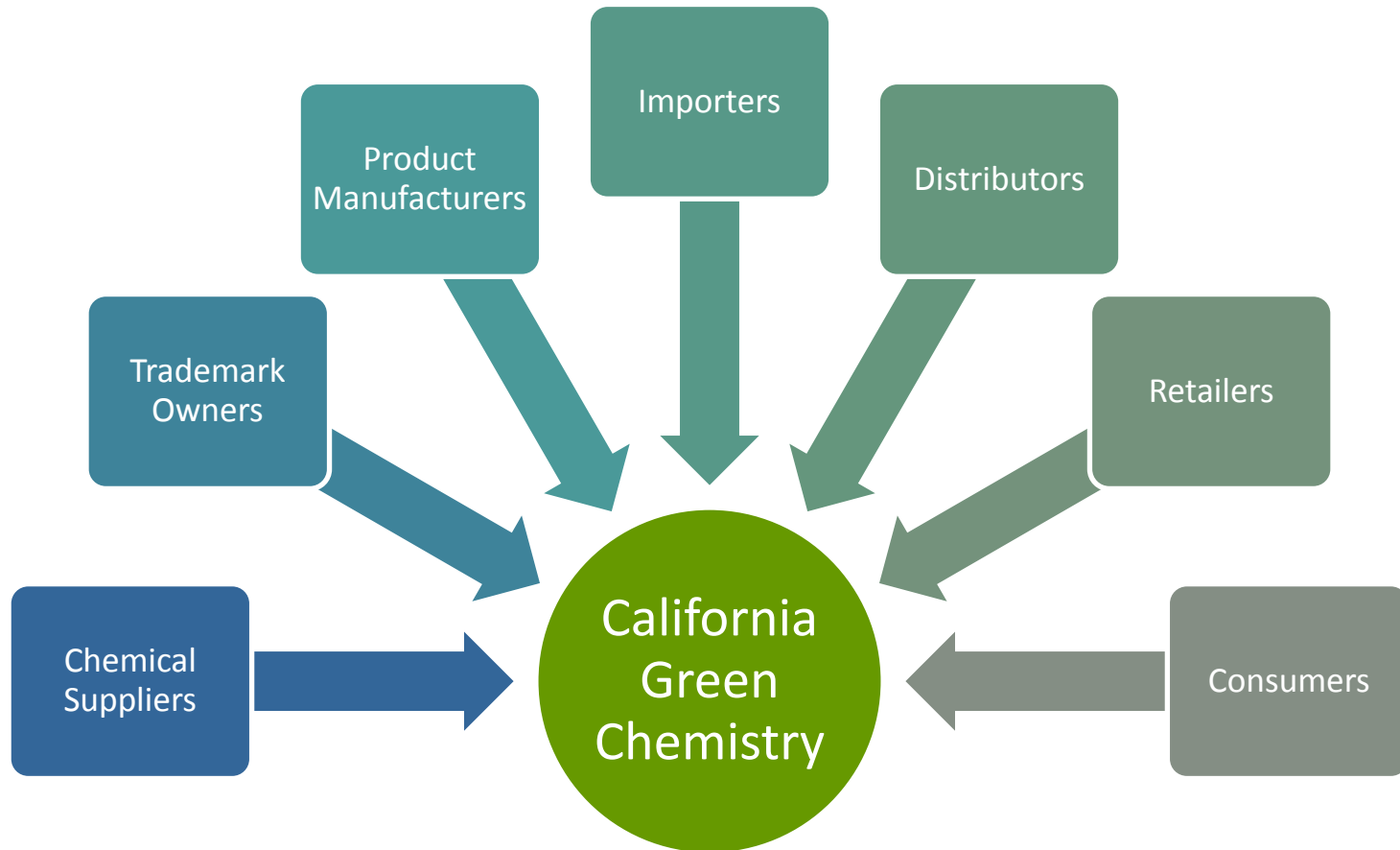


## Green Chemistry Regulations

- **January 1, 2011 Statutory Deadline Allowed to Pass**
  - Head of Cal/EPA asked DTSC to withdraw November draft, and issue a new draft in 2011 after Governor Brown takes office



## Green Chemistry: Who Are the Stakeholders?



## What is Regulated? Consumer Products

- November 2010 Draft Applies To:
  - “All products that contain a Chemical of Concern, and that are reasonably expected to be placed into the **stream of commerce** as a **consumer product** in California”, and
  - “All **chemicals** that exhibit a hazard trait and are reasonably expected to be contained **in products** placed into the stream of commerce in California.”



## What Consumer Products are Exempt?

- Easier to define what is **not** a consumer product:
  - Prescription drugs and devices (and packaging)
  - Dental restorative materials (and packaging)
  - Medical devices (and packaging)
  - Food
  - Pesticides
  - Mercury-containing light bulbs (only through Dec. 31, 2011)

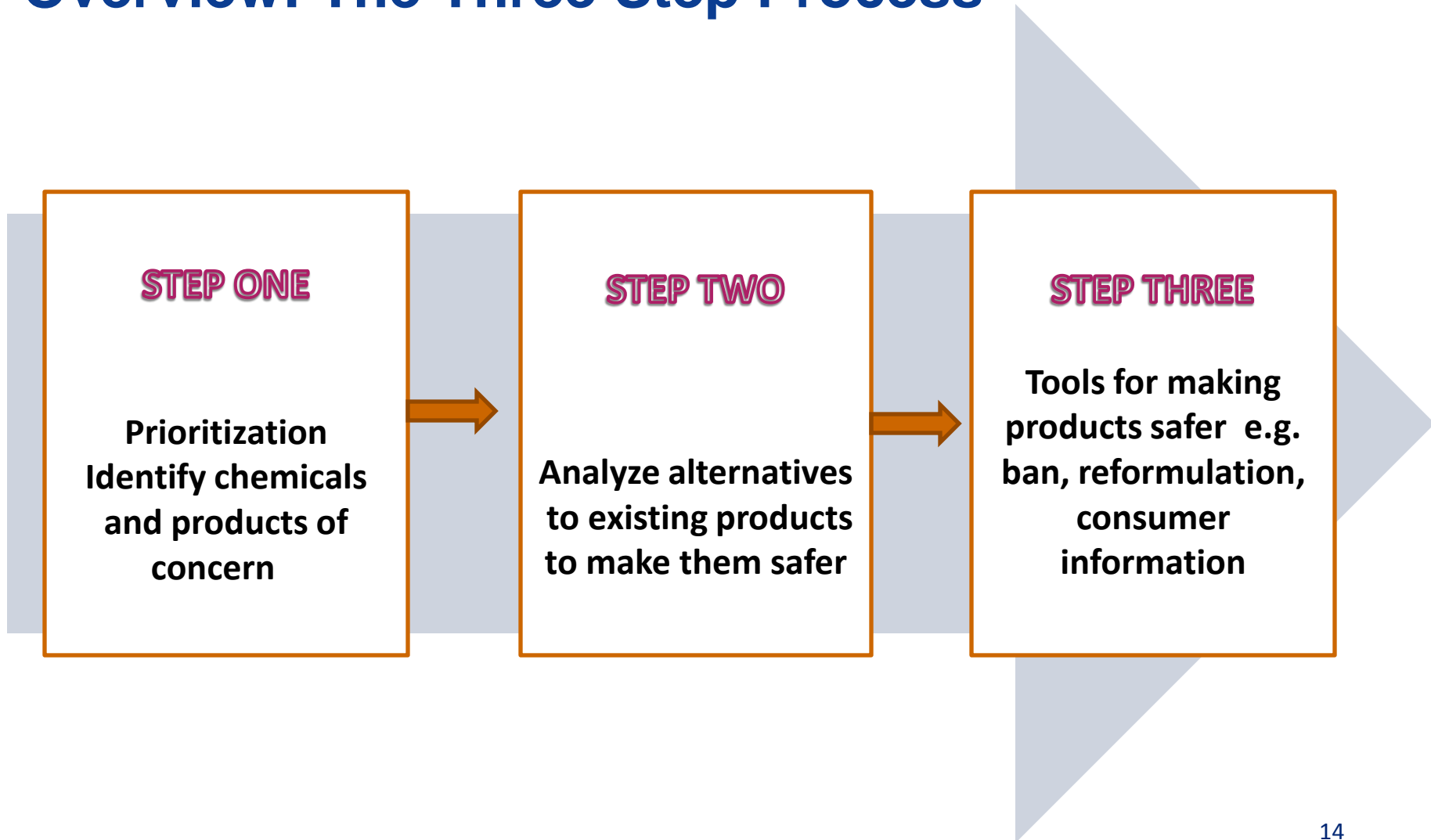


## Three Targets for Initial Regulatory Focus

- **November 2010 Draft**
- DTSC proposes to focus initially on 3 categories
  - Children's Products
  - Personal Care Products
  - Household Cleaning Products



## Overview: The Three Step Process



## Overview: The Three Step Process – Sept. 2010

### Prioritization

Chemicals Under Consideration



Chemicals of Concern



Products Under Consideration  
(Contain Priority Chemical)



Priority Products

### Alternatives Assessment For Priority Products

Alternatives Assessment  
(AA)



AA Work Plan



AA Report

### Early Chemical Substitution

AA Notification +  
Tier I AA Report

### Regulatory Response

No action

Reformulation + Recall

Product Info

Labeling

End-of-life  
management

Use restrictions

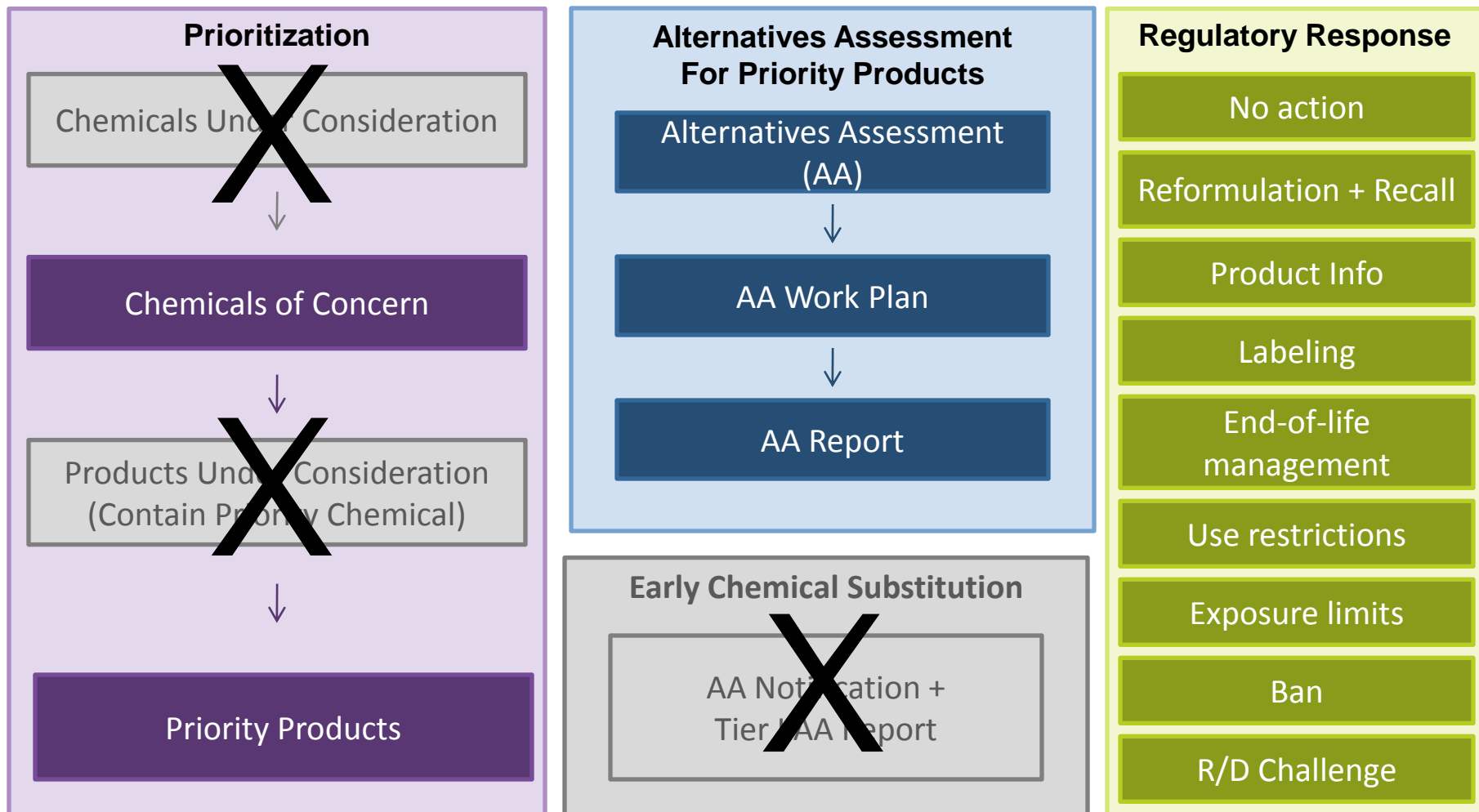
Exposure limits

Ban

R/D Challenge



## Overview: The Three Step Process – Nov. 2010



## Who is the "Responsible Entity"? (September 2010)

- ***"Responsible Entity"*** means:
    - **Manufacturer**, i.e. Owner or licensee of brand name or trademark
    - **California importer**
    - **California distributor**
    - **Retailer**
    - ***Any party to a contractual agreement*** with a California importer, exporter or retailer ***concerning a consumer product***
- (Even the consumer?  
Probably overbroad.)*



# Who is Responsible for Compliance? (September 2010)

- *Multiple responsible entities*
- *Only one responsible entity needs to comply*
- *DTSC can enforce against all if no one responds*
- **Contracts** will play a role
  - They may have indemnities/ reps and warranties
- **Criticized as unfair and overly complex**



## Who is the "Responsible Entity"? (November 2010)

- "***Responsible Entity***" means either:
  - ***Manufacturer*** or
  - ***Retailer – responsible only if manufacturer declines***
- ***Manufacturers*** or ***trade associations*** may respond in a group or consortium



# Key Duties of Responsible Entities

## – Data Call-in

- Submit chemical/product data (new and existing) to DTSC when requested.

## – Priority Product Notification

- Notify DTSC 60 days after DTSC lists a Priority Product.

## – Alternatives Assessment (AA)

- Prepare alternatives assessment for Priority Products.

## – Regulatory Response

- Comply with regulatory responses.



## Some Off-Ramps: Safe Harbors

- **Automatic Exemptions**
- **Exemptions By Filing of Notice with DTSC**
- **Exemptions By Petition to DTSC**



## Some Off-Ramps: Safe Harbors

- **Automatic Exemptions**
  - Expressly Exempt Products
    - Prescription drugs and devices/packaging
    - Dental restorative materials/packaging
    - Medical devices/ packaging
    - Food
    - Pesticides
    - Mercury-containing light bulbs (only through Dec. 31, 2011)





## Some Off-Ramps: Safe Harbors

- **Automatic Exemptions**
  - Unintentionally Added Chemicals
    - November 2010 draft dropped hard to prove requirement that chemical's presence be “unknown” after “due diligence”





## More Off Ramps: Notice to DTSC Chemical Removal

| September Draft                                                                                                                                                                                                                        | November Draft                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Chemical Removal Notice</b> <ul style="list-style-type: none"><li>• Applies to <i>two</i> lists of chemicals:<ul style="list-style-type: none"><li>• Chemicals under Consideration</li><li>• Priority Chemicals</li></ul></li></ul> | <b>Chemical Removal Notice</b> <ul style="list-style-type: none"><li>• Applies to smaller universe of chemicals<ul style="list-style-type: none"><li>• Chemicals of Concern</li></ul></li><li>• Due 180 days after product is listed</li></ul> |

## More Off Ramps: Petition or Notice De Minimis Amounts



### September Draft

#### ***De Minimis* Concentration**

Manufacturer may **petition** for exemption for *de minimis* concentration of Priority Chemical within 60 days after listing as a Priority Product

### November Draft

#### ***De Minimis* Concentration**

No longer requires **petition**, just **notice**.

- Notice must state that chemical of concern is present only at de minimis levels (**<.1%**)
- Exemption streamlined
- **De Minimis Exemption Notification**
  - Due 180 days after product is listed
  - Must state chemical concentration and describe data used to substantiate concentration
  - Must notify DTSC of changes to concentration within 30 days

## More Off Ramps: Petition to DTSC Comprehensive Regulation



### September Draft

#### Comprehensively Regulated

- Manufacturer may **petition** to show hazards are adequately addressed in other regulatory programs
  - For each life cycle segment
- No “significant gaps” between Green Chemistry and other regulations
- Responsible entity has burden of proof.

### November Draft

#### Comprehensively Regulated

- **No longer requires** (or provides for) **petition.**
- Instead, DTSC will consider during prioritization process.
- Expanded scope of exclusion to include exposure pathways.

## More Off Ramps: Petition to DTSC No Exposure Pathway



### September Draft

#### No Exposure Pathway

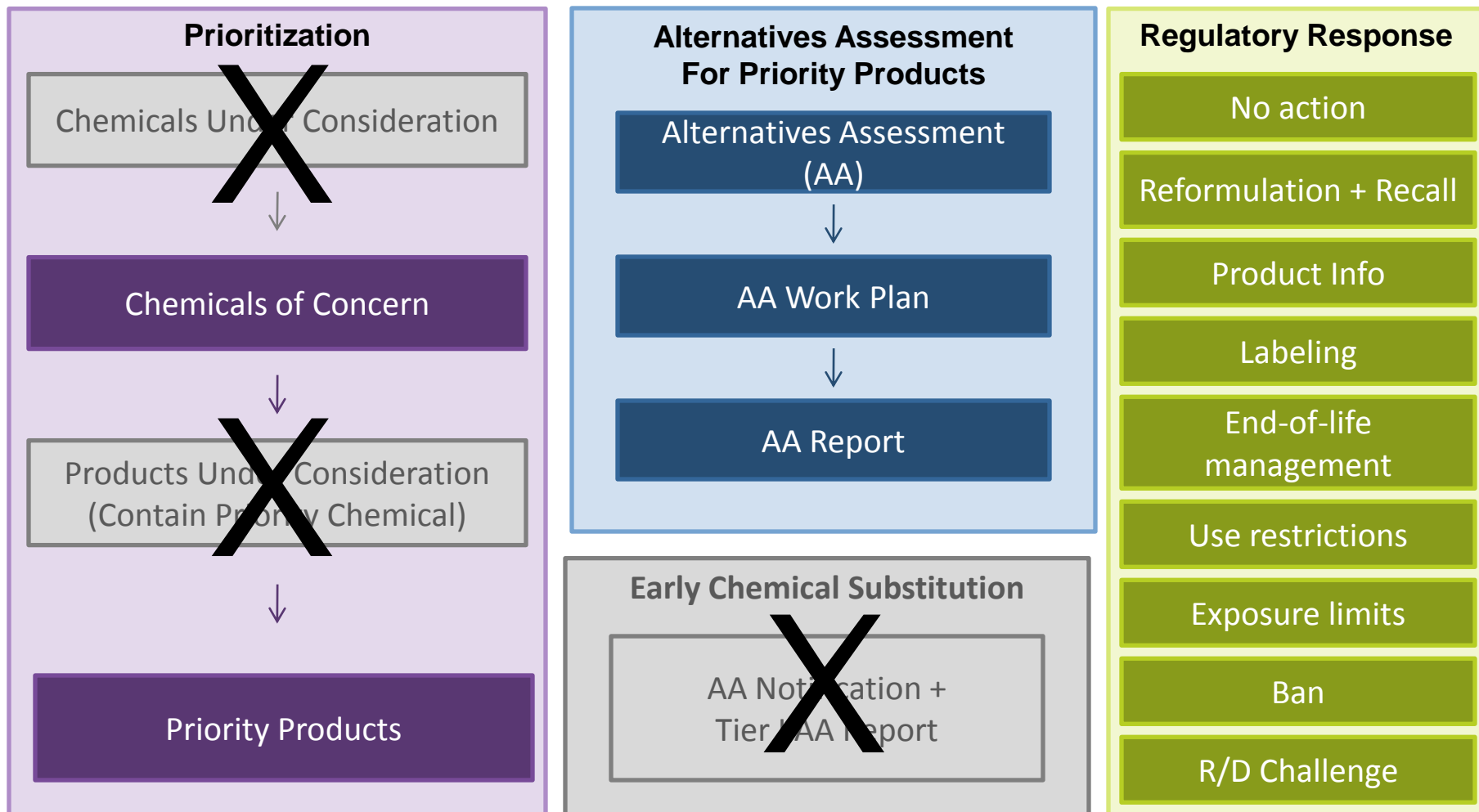
- Responsible entity must **petition**
- **Must show product has *no* exposure pathway to pose threat to human health or environment**
  - Hard to prove 'no' exposure
- Responsible entity has burden of proof

### November Draft

#### No Exposure Pathway

- Responsible entity must **petition**
- DTSC also considers in listing process
- **Must show no exposure pathway based on reasonably foreseeable uses, abuses and end-of-life management.**
- Responsible entity has burden of proof

## Recap: The (Simplified) Three Step Process

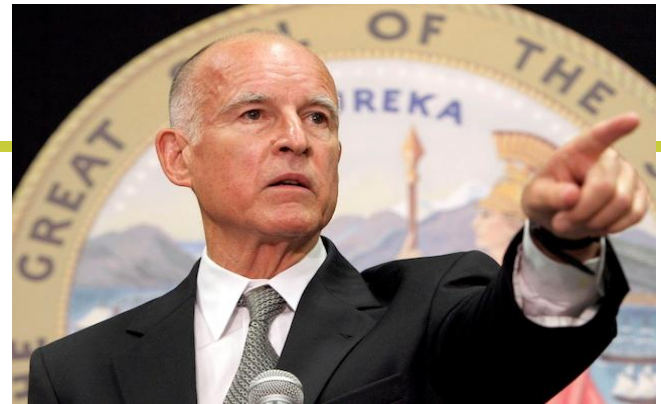


## What Happens if a Priority Product is Regulated?

- **Manufacturer must notify all retailers** who sell the ***Priority Product*** within 30 days
- **Manufacturer** required to **notify DTSC** upon completion of required Response Action and introduction of safer alternative
- **DTSC** must **post master list of Response Actions on its website** and update on a quarterly basis
- **If DTSC notifies** responsible entity that a **safer alternative** exists, responsible entity must **cease placement of the *Priority Product* into commerce** within 1 year and complete a **recall** within 3 years (2 years under the September draft)







## What's next?

We are  
here

**Jan.1, 2011:**  
Statutory  
deadline to  
adopt  
regulations

**Informal  
Meetings  
With Green  
Chemistry  
Experts**

**Green  
Ribbon  
Science Panel  
Getting More  
Engaged**

**DTSC  
Eventually  
Will Release  
New Draft  
Regulation**

**Expect  
Another  
Round of  
Public  
Comments**

**No Firm  
Timeline for  
Final  
Regulations**

## Stakeholder Issues: NGOs



NGOs\* (environmental groups, public health groups, labor) have concerns:

- Industry may dominate the process with little transparency and limited public participation
- The list of chemicals to be regulated is too limited
- The program may act too slowly in getting rid of known and bad actor chemicals and allow products with alarmingly high levels of hazardous chemicals to be considered safe



\*Source: Californians for a Healthy and Green Economy (CHANGE) letter to Governor, dated July 14, 2010.

## Stakeholder Issues: Business and Industry

- Process is far too complex, labor intensive, and prohibitively expensive
- Process may be overwhelmed by listings
- Listing may be based on theoretical risk to consumers rather than probable risk
- Innovation may be curtailed
- May lead to gridlock or litigation



**Green Chemistry Alliance**  
*Committed to Product Sustainability in the Global Economy*

## Concluding Thoughts

- Green Chemistry is a bold regulatory initiative
- Implementation will likely be by trial and error
- Product manufacturers have primary responsibility
  - Many may reformulate to avoid 'Alternatives Assessment' process
  - Will alternatives be safer?
- How will the program be funded given California's budget crisis?

