

California's Green Chemistry

Personal Care  Products Council

2011 Legal and Regulatory Conference

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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.”



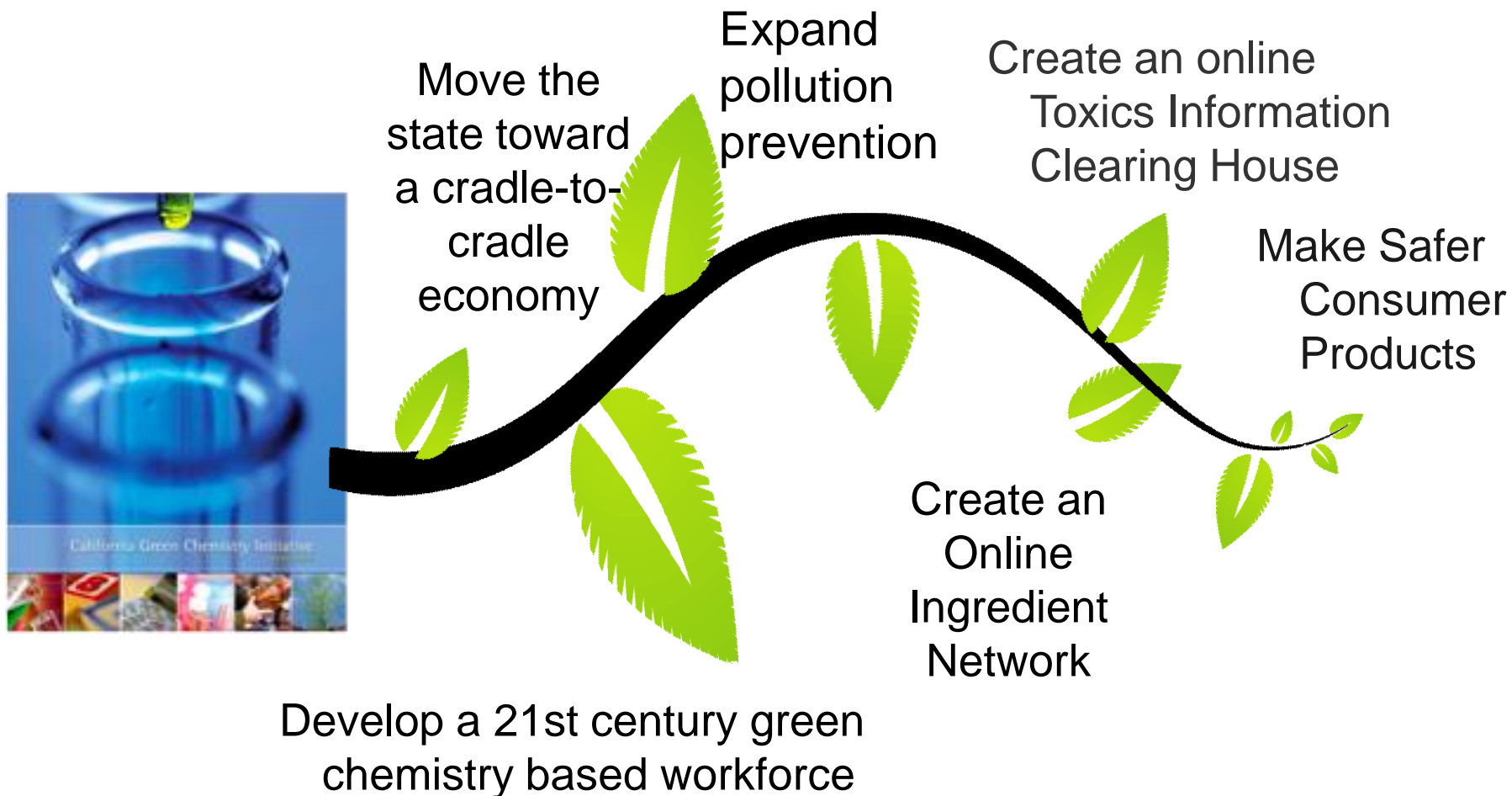
—California Department of Toxic Substances Control

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).

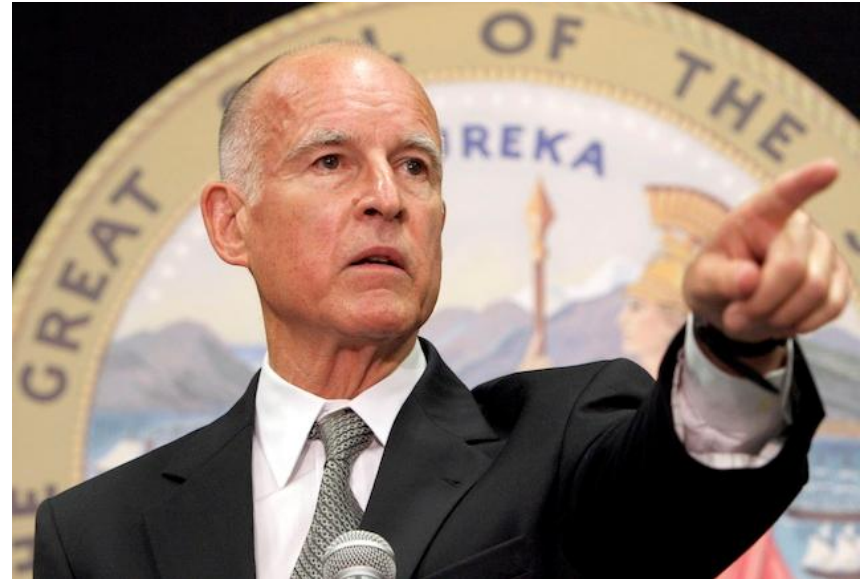


“I do not believe that addressing this type of concern in the Legislature on a chemical by chemical, product by product basis is the best or most effective way to make chemical policy in California.”

—Governor Arnold Schwarzenegger, Signing Message, AB 1108

What Will the Brown Administration Do with Green Chemistry?

- *“Protecting the environment is essential to our long-term prosperity. I have long recognized that environmental protection and economic development go hand in hand and will continue to promote both as Governor.”*



New Director of DTSC: Deborah Raphael



- Appointed May 2, 2011
- Former Program Manager for the City & County of San Francisco's Toxics Reduction and Green Building Programs
- MA, Plant Physiological Ecology, UCLA
- Member of the Green Ribbon Science Panel
- *"Science driven pragmatic reformer with excellent leadership skills, strong budget and managerial experience."* – Governor's press release
- Developed broad coalitions including business leaders, industry representatives, community activists, government agencies, and local commissions to create groundbreaking environmental initiatives.
- Spent the last 15 years working within local government to design and implement programs around the reduction of hazardous chemicals used in city operations and consumer products.
- A strong advocate for public and environmental health—meaning she'll work to ensure tougher regulations and promote legislation that protects environmental health.
- While at SF Environment, she worked on many environmental health projects, including the city's green purchasing initiative, ultimately resulting in the SFApproved website (<http://www.sfapproved.org/>).
- Helped craft and implement San Francisco's Precautionary Principle Ordinance.

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



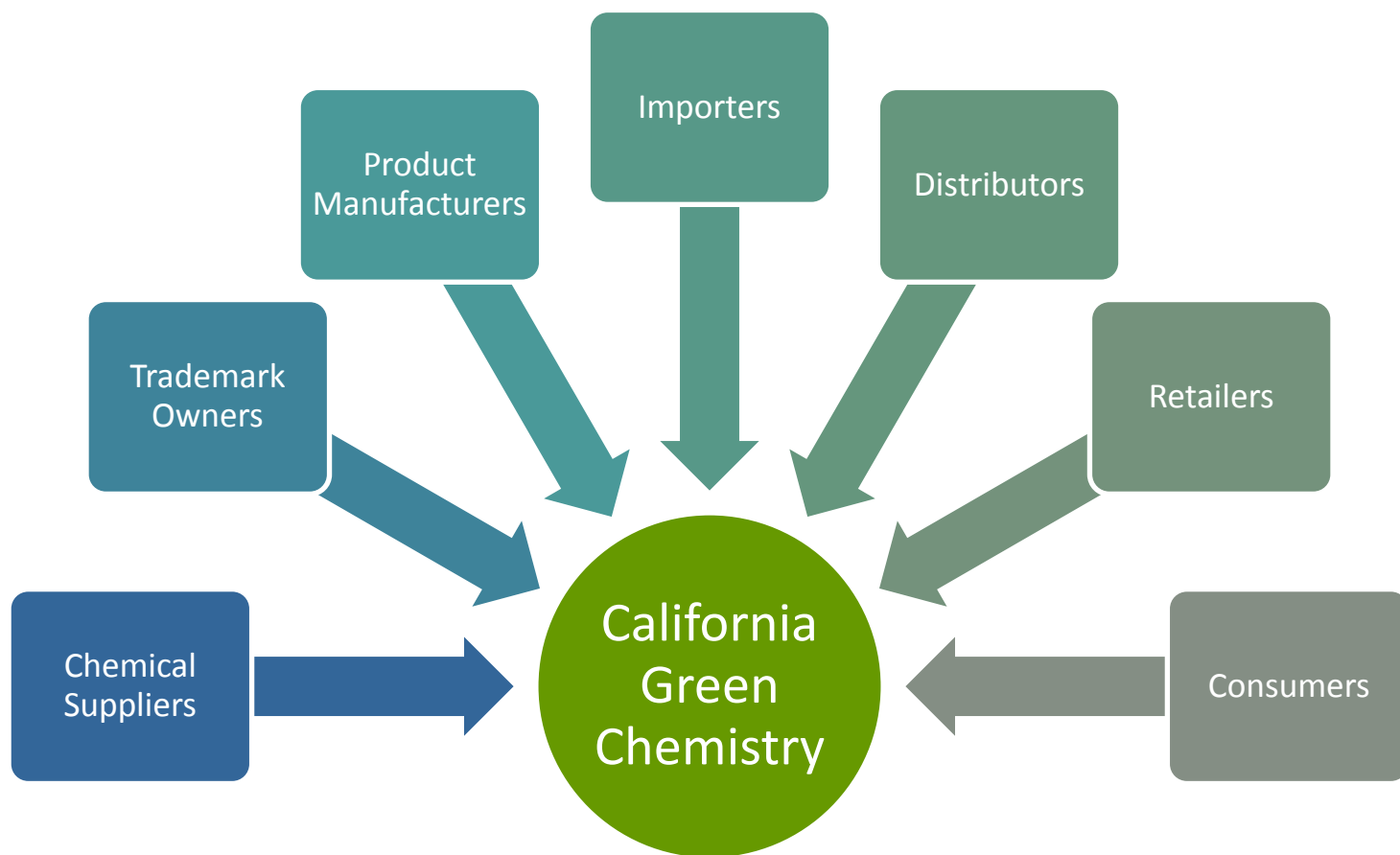
- Major NGOs and sponsors of the legislation withdrew support
 - NGO view: November draft is too pro-industry
 - Industry view: Better but still complex and burdensome

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)

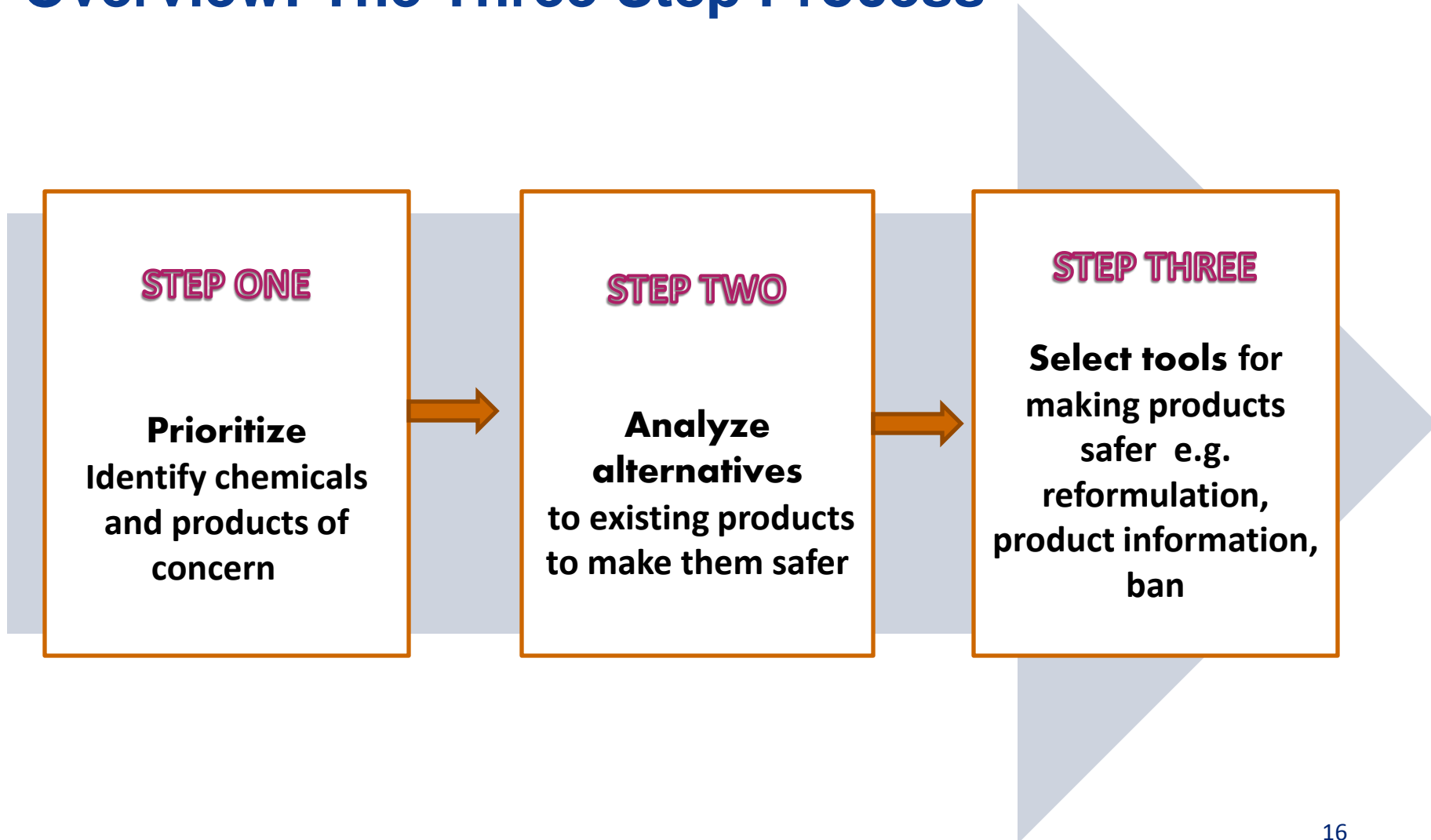


Three Targets for Initial Regulatory Focus

- **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

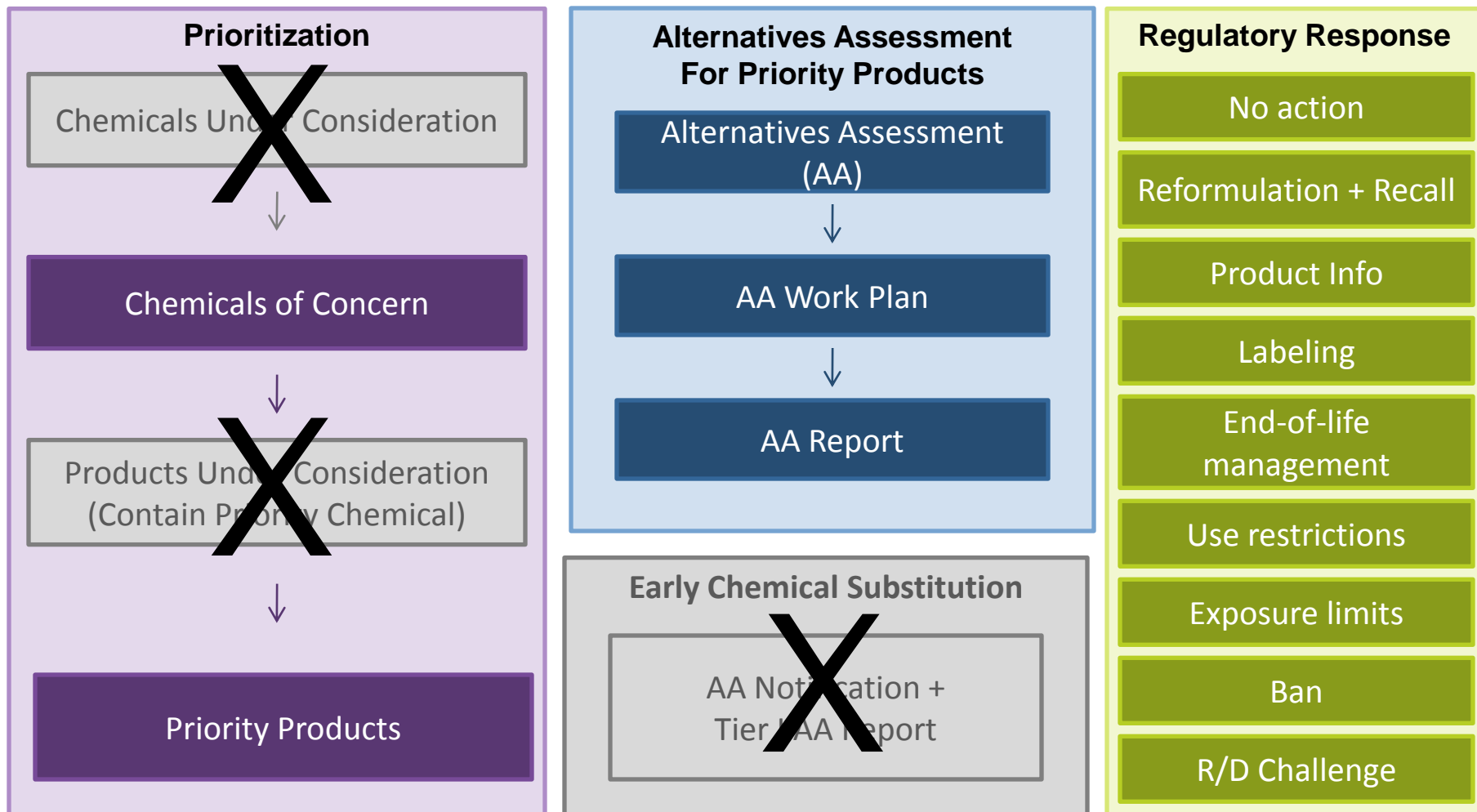
Use restrictions

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 commercial customer? 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*
- 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 of Chemical Removal

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

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

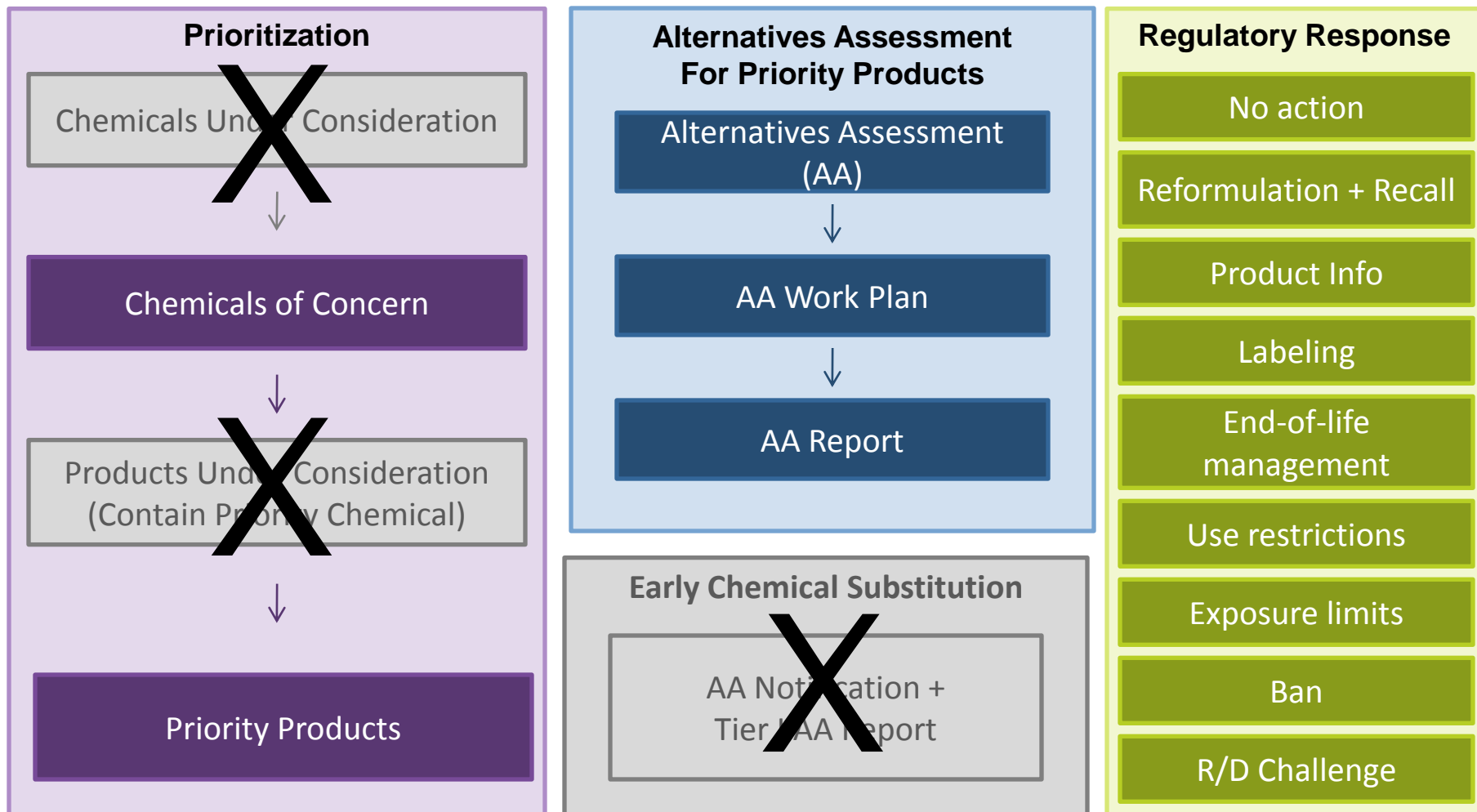
- Responsible entity must **petition**
- **Must show product has *no* exposure pathway to pose threat to human health or environment**
 - Hard to prove 'no' exposure
- Responsible entity has burden of proof

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

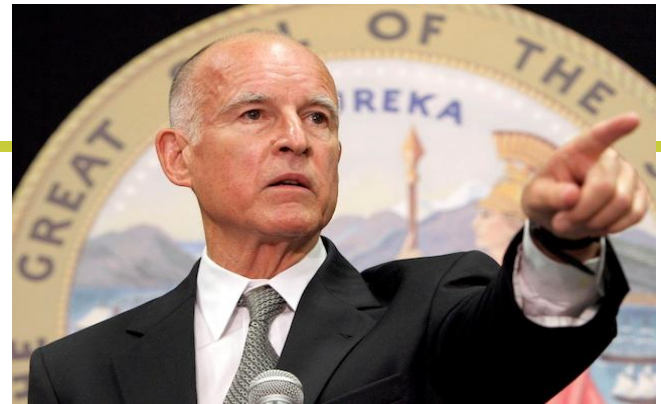
Recap: The (Simplified) Three Step Process



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?

