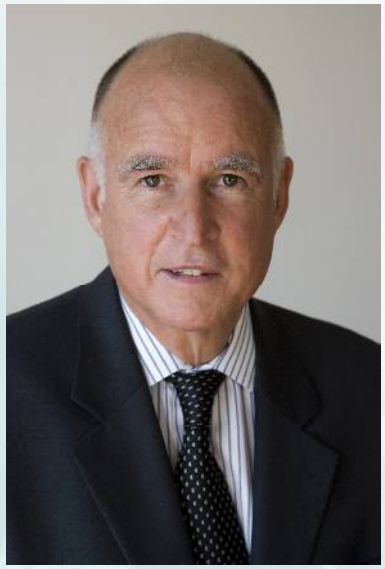
California's Safer Consumer Products Regulations

Debbie Raphael, Director

California Department of Toxic Substances Control

Japan MOE/Network for Strategic Response on International Chemical Management Meetings
Tokyo, Japan, May 2013

http://www.ci.berkeley.ca.us/ContentPrint.aspx?id=11244



Edmund G. Brown, Jr.
Governor of California

Secretary Matthew Rodriquez
California Environmental Protection Agency

Appreciate this opportunity !

Debbie Raphael, Director

California Department of Toxic Substances Control

Disclaimer

The policy approach of the California Green Chemistry Initiative & Safer Consumer Products Regulations is still evolving through stakeholder input and constant policy evolution.

Therefore, what you hear today may not represent the final position, policy or approach of the Administration.

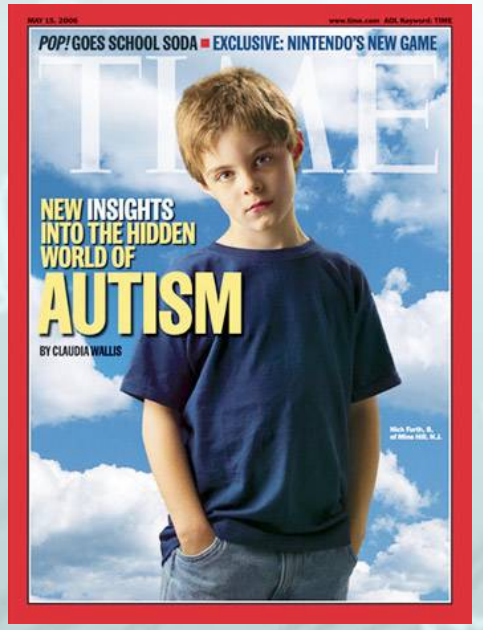
Speech Overview:

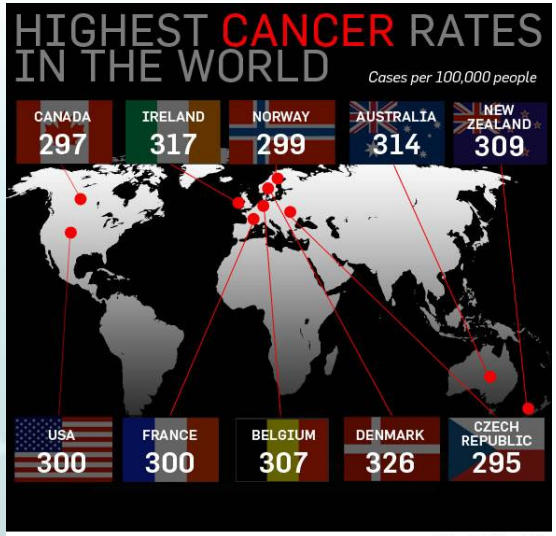
- I. California's Green Chemistry Initiative – Intent & History
- II. California's Safer Consumer Products Regulations (SCPR)
  - Steps in Process
  - Important Changes
- III. Stakeholder Comments
- IV. Comparison of SCPR with REACH & U.S. TSCA

Green CHEMISTRY

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Why are we here?





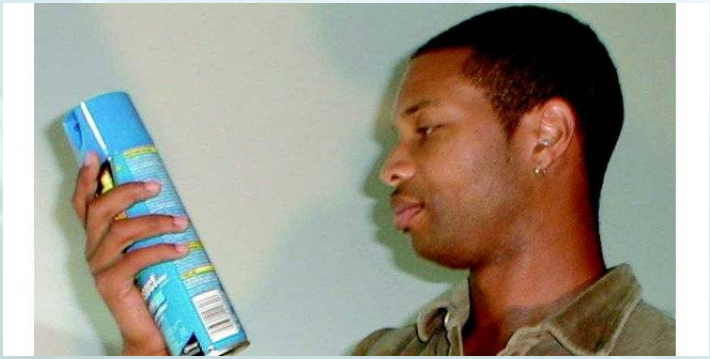
CDC

BIOMONITORING CALIFORNIA

I. California's Green Chemistry Initiative Intent & History

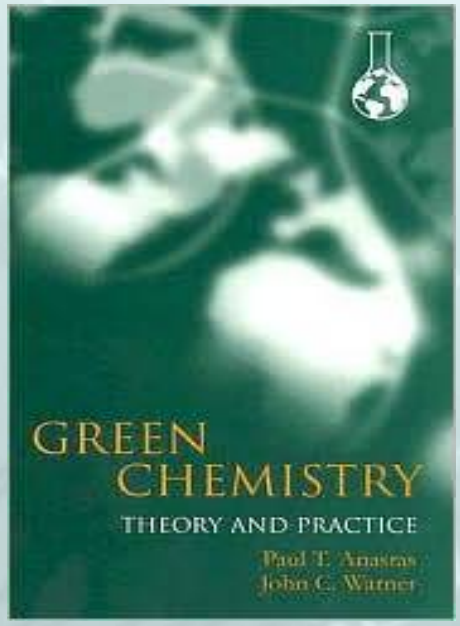
Concern over consumer products

Shouldn't require a PhD



Information needs to be in the marketplace

Response from Chemists:



1. Waste prevention
2. Atom Economy
3. Derivatives
4. Catalysis
5. Chemical Synthesis
6. Solvents and Auxiliaries
7. Degradation
8. Renewable Feed-stocks
9. Energy Efficiency
10. Inherently Safer

Response from Policy-makers:

ECHA

REACH

Canadian Environmental Protection Act

TSCA Reform

Response from NGOs:

Response from Companies:

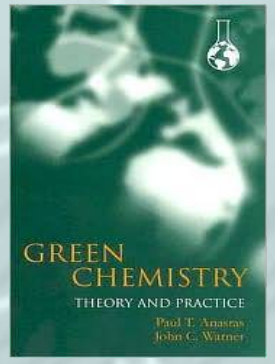
Historical Response of California Policy-makers:

Laws that focus on only one chemical.

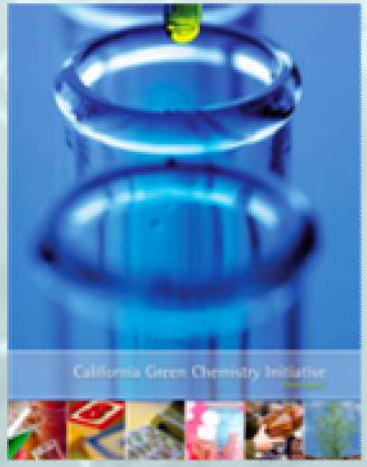
Green Chemistry Initiative

California Leadership in innovation, use, and manufacture of safer, ever more environmentally benign chemicals and products.

- Honor original Green Chemistry principles
- Producer Responsibility
- Create incentives in marketplace with information about products



California Green Chemistry Report: Six Recommendations



December 2008

Move toward a Cradle-to-Cradle Economy

Expand Pollution Prevention

Accelerate the Quest for Safer Products
-> Safer Consumer Product Regulations

Create On-line Product Ingredient Network

Develop a 21st Century Green Chemistry Workforce
-> University of California Berkeley Curriculum

Create an Online Toxics Information Clearinghouse
-> MOU with U.S. EPA

2007-2013: Green Chemistry to Safer Consumer Products Regulations

Green Chemistry Report
- Scientific Symposiums
- Science Advisory Panel
- Green Ribbon Science Panel

Green Chemistry Options
- Stakeholder Forums
- Web
- Outreach

Policy Thinking
- Stakeholder Input

AB 1879/ SB 509

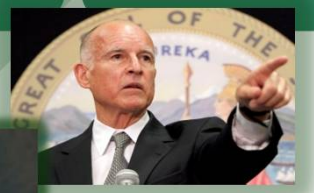
Statutory Authority

2010 Draft Regulations
- Stakeholder Input
- Statutory Date
- Administration Policy

2012 Draft Regulations
- Stakeholder Input
- Administration Support
- Expanded Use of Experts
- Scientific Peer Review

2013

Safer Consumer Products Regulations



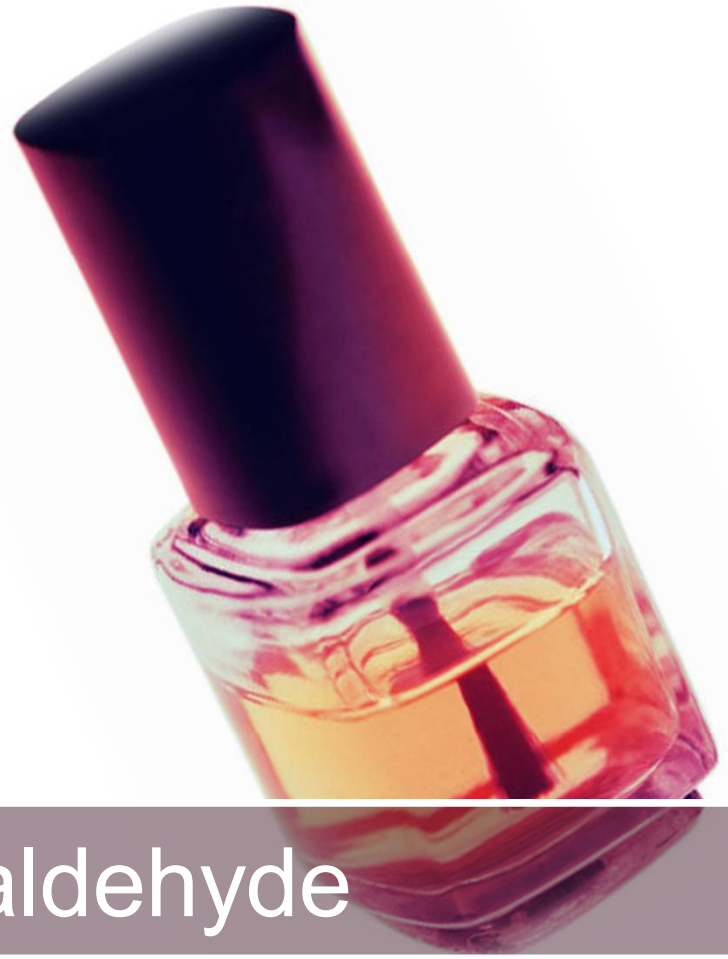
II. California's Safer Consumer Products Regulations

Statutory Authority granted by
Assembly Bill 1879

Safer Consumer Products Regulations will require product manufacturers to ask:

http://drbevmentalhealth.com/ask-a-question/

Is It Necessary?



Formaldehyde

Nonylphenol Ethoxylates

Brominated Flame Retardants

Safer Consumer Products Regulations

Mandates the question,
BUT
does not dictate the answer.

http://www.neurosciencemarketing.com/blog/wp-content/uploads/2011/02/choice.jpg

Responsibility for Compliance

One

The Manufacturer:

Who makes the product or who controls the manufacturing process or has the capacity to specify the chemicals in the product.

Two

The U.S. Importer:

Who imports the product into California.

Three

Retailers:

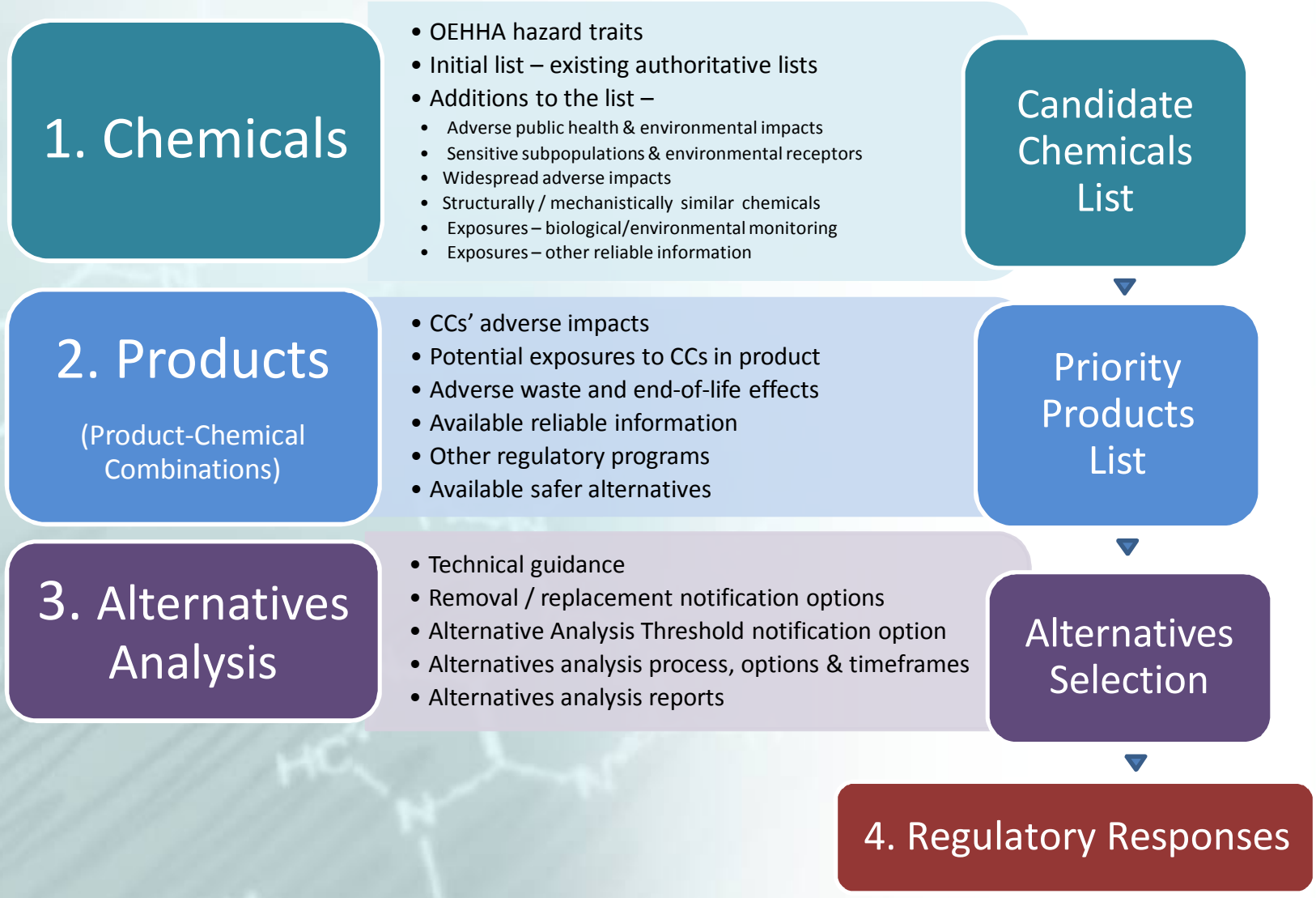
Who sell the product in California.

Assemblers:
Who assembles products containing Priority Product components

Products…sold, offered for sale, supplied, distributed, or manufactured in California.

May opt-out by ceasing to order Priority Product

How It Works: The Safer Consumer Products Regulations



Step 1: Identify Chemicals

- Initial Candidate Chemicals List within 30 days of Regulations taking effect
- List drawn from 23 authoritative body lists
- Chemicals Can Be Added or Deleted - > Petition Process

Step 2: Identify Priority Products

- Initial products -> up to 5 consumer products
- Propose initial products within 180 days of effective date. Public input before final.
- For future Priority Products: Workplan within 1 year of effective date
- Manufacturers Notify DTSC within 60 days of final listing of initial Priority Products

Step 3: Alternative Analyses

- **First Stage AA:** Preliminary AAs are due 180 days after product is listed.
- **Second Stage AA:** Final AAs due to DTSC one year after notice of compliance for Preliminary AA. Public comment on Final Aas.
- **Alternative Process AAs**

Step 4: Regulatory Response

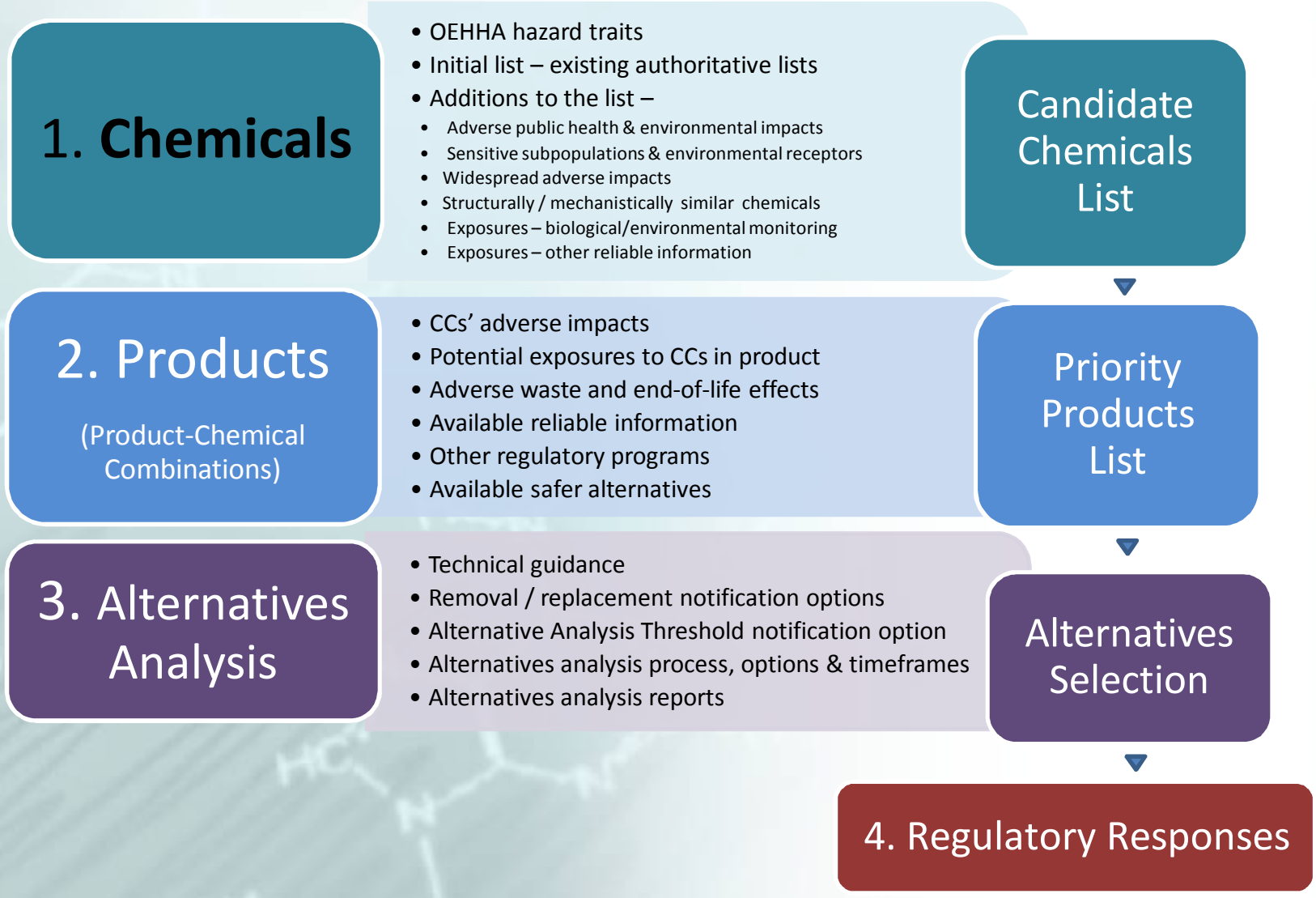
- Within 90 Days of Notice of Compliance or Disapproval of Final AA -> DTSC issues **Notice of Proposed Determination**

- Range of Responses

A Closer Look at the SCPR

from http://www.bard.edu

How It Works: The Safer Consumer Products Regulations



Step 1:
Identify Chemicals -
Candidate Chemicals

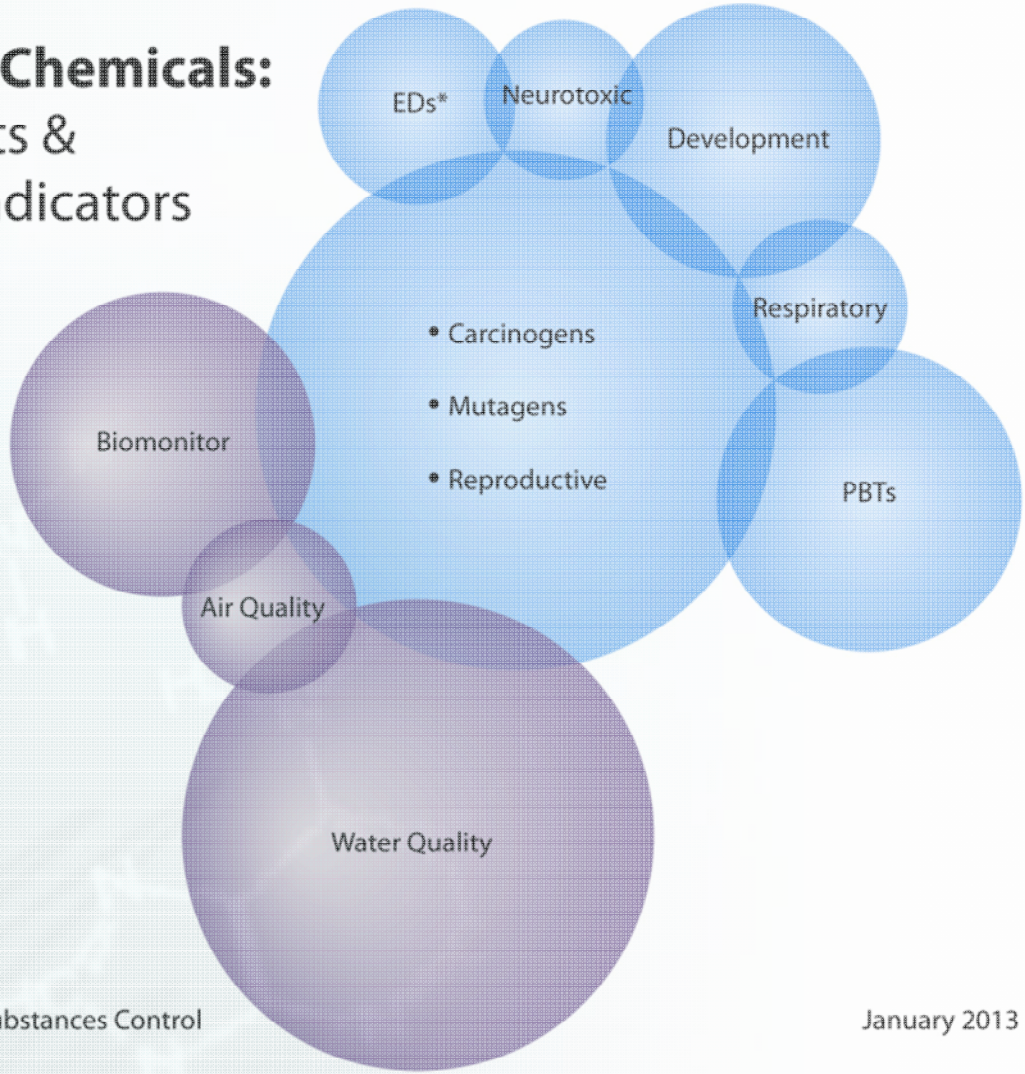
http://www.planet-science.com/umbraco/imagegen.ashx?image=%2Fmedia%2F122048%2Fthinking+children.jpg&width=600

Candidate Chemicals

WHY?

- Sends immediate signals to the marketplace
- Flexible palette for future action
- Deters regrettable substitutions
- Similar in size to existing industry lists

Candidate Chemicals:
Hazard Traits & Exposure Indicators
(~1,200)

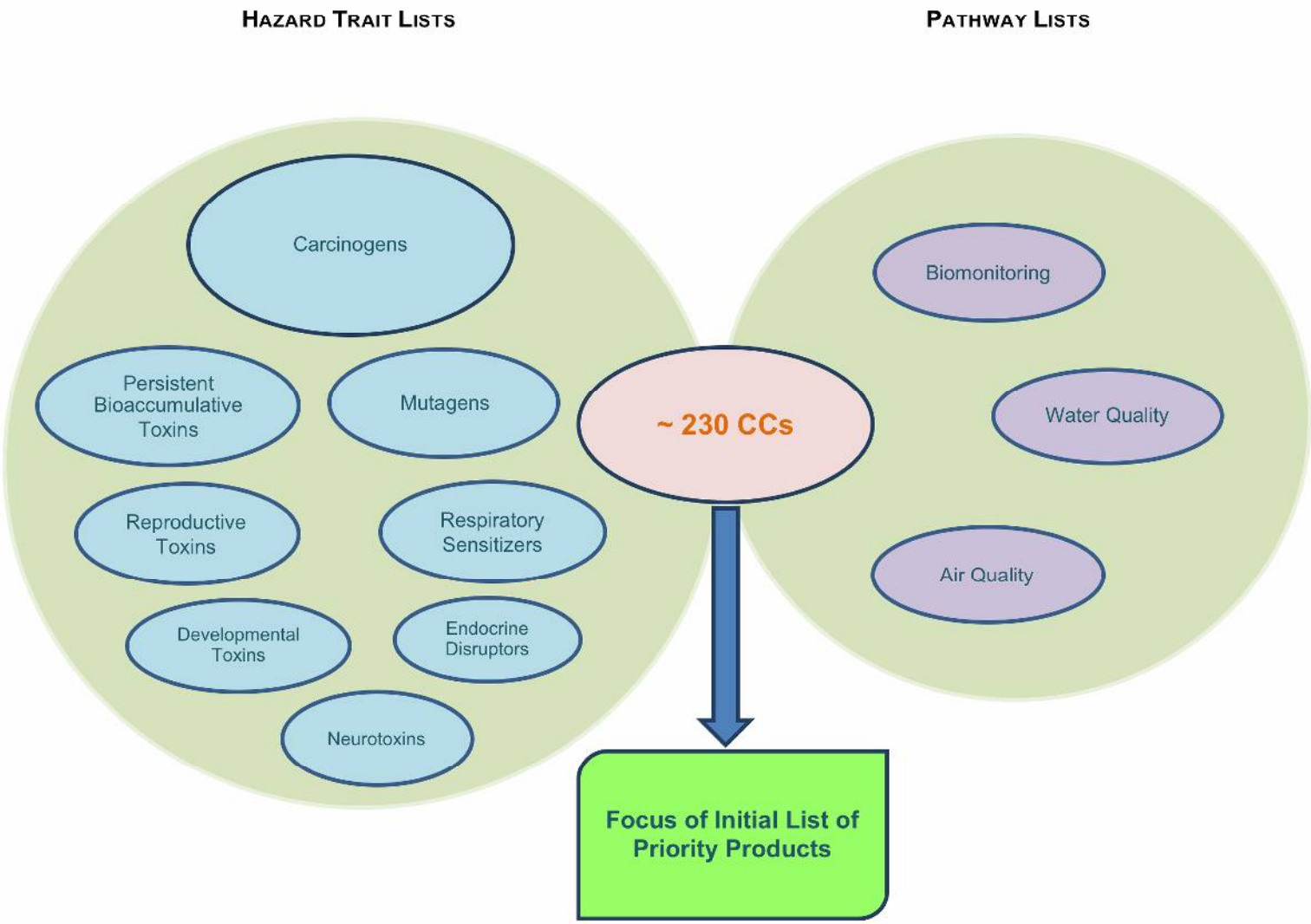


* Endocrine Disrupting

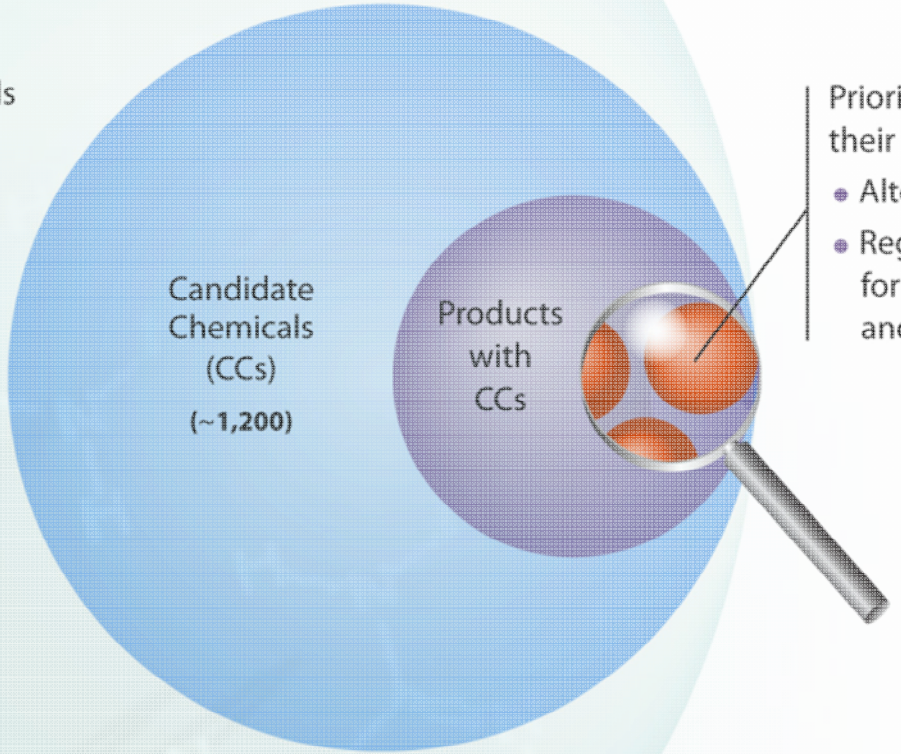
Department of Toxic Substances Control

January 2013

INITIAL LIST OF CANDIDATE CHEMICALS
~1,200



Overview: The Safer Consumer Products Regulations

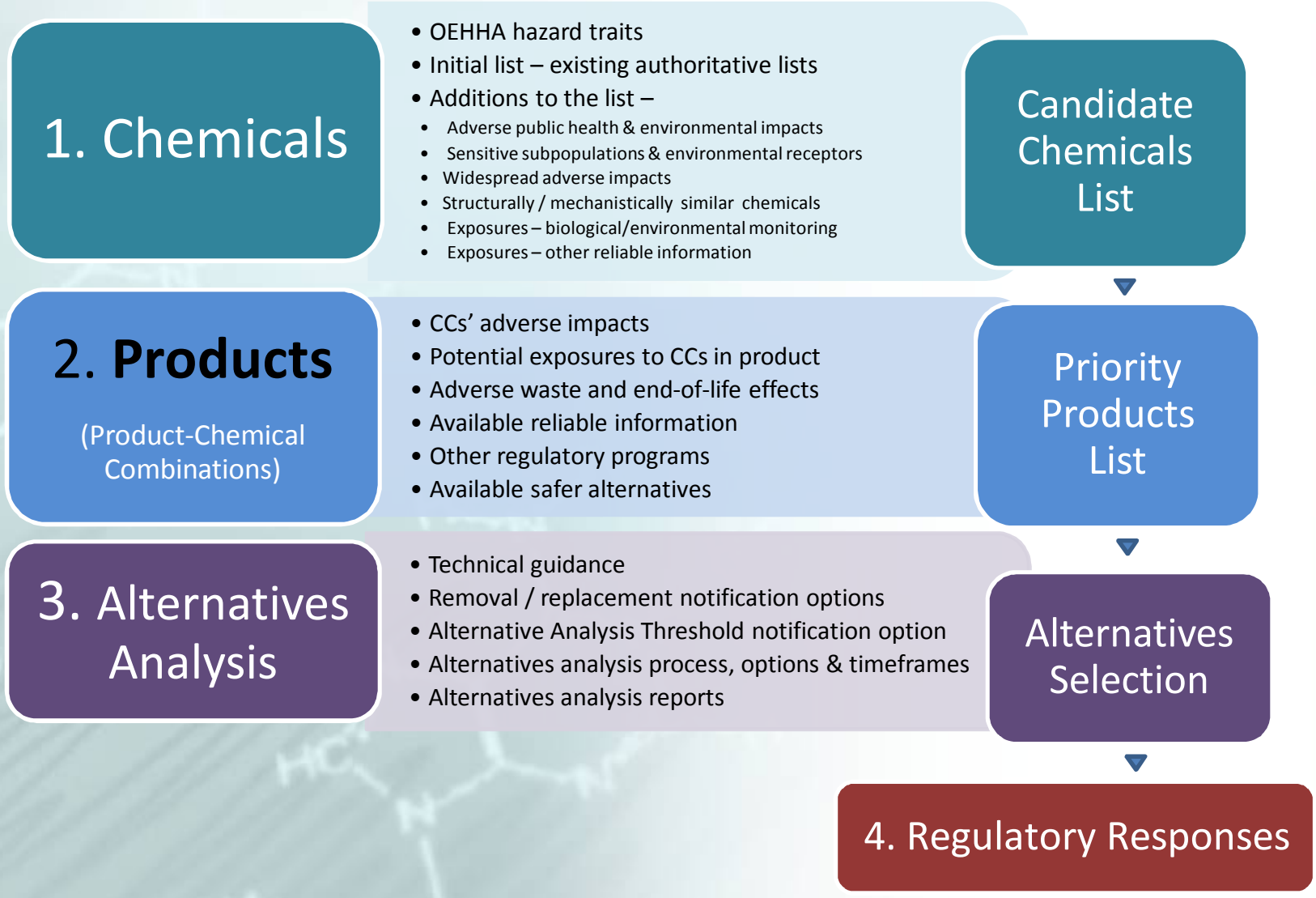


- A **Candidate Chemical (CC)** is a chemical that is a candidate for designation as a **Chemical of Concern.**
- Each **Candidate Chemical** exhibits one or more hazard traits and/or environmental or toxicological endpoints.
- The **Candidate Chemicals** that will be evaluated for development of the first Priority Products List will be ~230 chemicals that have both listed hazard traits and listed exposure concerns.
- A **Chemical of Concern (COC)** is a Candidate Chemical that is the basis for a product-chemical combination being listed as a Priority Product.

Department of Toxic Substances Control

January 2013

How It Works: The Safer Consumer Products Regulations



http://www.microbiology.columbia.edu/wolfprize/images/selection.jpg

Step 2: Identify Priority Products with Chemicals of Concern

Safer Consumer Products Regulations

http://www.businessinsider.com/when-to-buy-generic-vs-brand-name-goods-at-the-grocery-store-2011-10?op=1

What products?

Prioritization Factors for Priority Products

http://www.nsta.org/sciencematters/images/index_13.jpg

Adverse Impacts and Exposures:

- ✓ Potential Hazards posed by chemicals in the products
- ✓ Potential Exposure with special focus on:
  - ✓ Sensitive Subpopulations
  - ✓ Environmentally Sensitive Habitats
  - ✓ Endangered and Threatened Species
  - ✓ Impaired Environments - designated by California

Prioritization Factors for Priority Products (continued)

- Adverse Waste and End-of-Life Effects
- Availability of Information
- Other Regulatory Programs
- Safer Alternative availability and feasibility

Initial Priority Products List

- ~230 Candidate Chemicals
- No more than 5 products with Chemicals of Concern
- Proposed list – 180 days

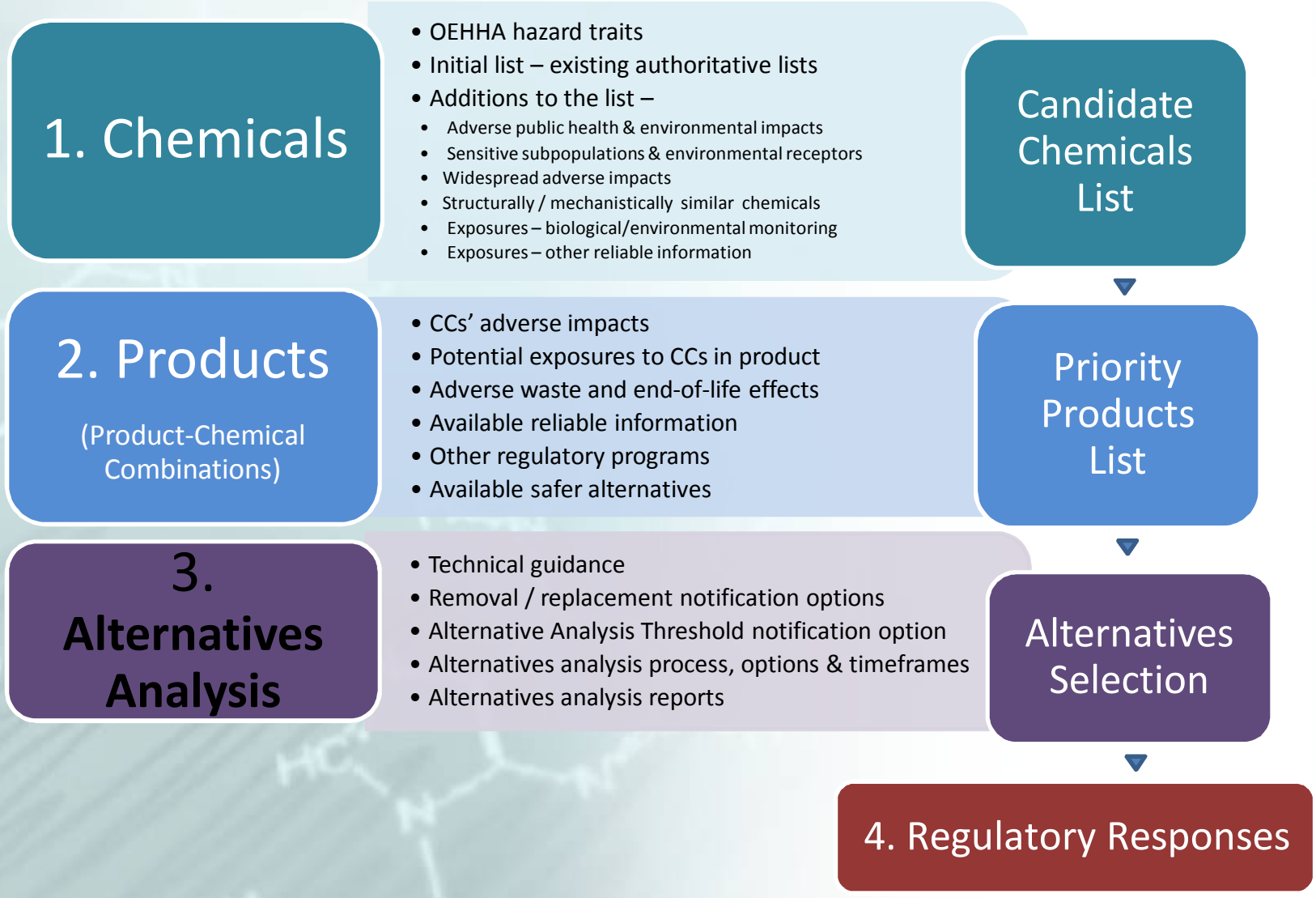
Priority Products Work Plan

- 3-year work plans
- Forecast product categories to be evaluated during the next 3-year cycle
- Public workshops prior to adoption of each work plan

Chemicals & Products
Petition Process

- Anyone may petition DTSC to add and/or remove a chemical, chemical list, or product
- High priority for petitions by federal and California regulatory programs

How It Works: The Safer Consumer Products Regulations



Step 3: Alternative Analyses

- **Phased process** – notification, preliminary report, final report
- **Flexibility** – format & timing
- **Notification options in lieu of AA** – chemical removal, product removal, product-chemical replacement, and alternatives analysis threshold exemption

Alternative Analyses Must Consider "A-M" Criteria

- A. Product function/performance
- B. Useful life
- C. Materials/Resource consumption
- D. Water conservation
- E. Water quality impacts
- F. Air emissions
- G. Prod., use, transp. energy inputs
- H. Energy efficiency
- I. Greenhouse gas emissions
- J. Waste and end-of-life disposal
- K. Public health impacts: sensitive sub-populations
- L. Environmental impacts
- M. Economic impacts

First Stage of Alternatives Analyses

Step 1 – ID Product Rqmts

- Function, performance, & legal
- Function of Candidate Chemical
- Is CC necessary?
- Is replacement chemical necessary?

Step 2 – ID Alternatives

- Meet product requirements
- Reduce / eliminate CC
- Reduce / eliminate exposure
- Look at existing alternatives

Step 3 – Screening Alternative Chemicals

- Info on adverse impacts
- Compare alternatives
- Eliminate replacement chems with greater adverse impacts

Step 4 – Next Steps

- **Preliminary AA report**
- Work plan for 2nd AA Stage

Step 2 should ID chemical substitutions AND other alternatives.

Second Stage of Alternatives Analyses

<u>Step 1</u> – ID Relevant Comparison Factors

- In conjunction with exposure pathways & lifecycle segments
- Quantitative / qualitative analysis
- Available information

<u>Step 2</u> – Compare Priority Product & Alternatives

- Quantitative / qualitative analysis
- Relevant factors
  - *exposure pathways*
  - *life cycle segments*
- Available information

<u>Step 3</u> – Alternatives Selection Decision

- **Final AA Report**
- Reason & justification for decision

Guidance for Alternative Analyses

Alternatives Analyses Guidance: California Approach

- Develop our own guidance.
- California collaborating with other States on additional guidance

California is Working with Other States

- ✓ IC2 Alternatives Analyses Guidance: U.S. States are collaborating to develop Alternatives Assessment Guidance
- ✓ States Involved: California, Connecticut, Minnesota, Massachusetts, Michigan, New York, Oregon

California SCP and IC2 AA Approaches Aim to:

1. Reduce risk by replacing toxic chemicals in products with inherently safer alternatives.
2. Prevent uninformed substitutions.
3. Define information requirements for credible alternatives assessment.
4. Continually improve product safety for human health and the environment.

How California SCP and IC2 AA Approaches are *Similar* *(continued)*

Guidance is intended to be:

1. Flexible and transparent to meet the needs of a wide range of users

2. Help users determine which AA components they need in *their AA.*

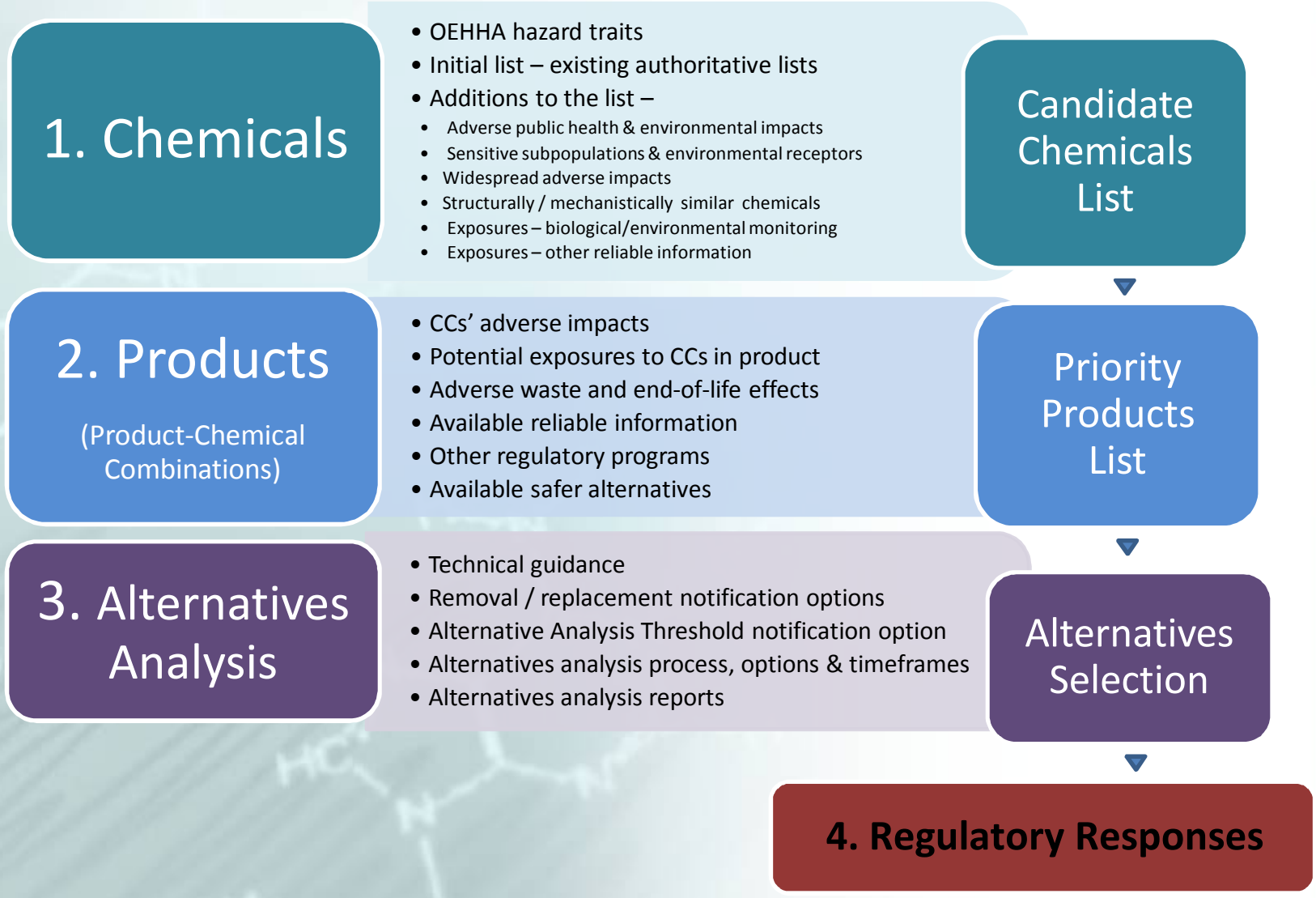
IC2 AA Guidance is Informing California

- ✓ IC2 Alternatives Assessment Guidance is Being Revised Based on Public Comment
- ✓ California is Learning from Participating in the process.
- ✓ Individual IC2 AA Modules may be suitable for California AA Guidance

IC2 is Revising Draft AA Guidance

- IC2 Guidance is being revised.
- California AA Guidance is not yet drafted, awaiting the final regulations.

How It Works: The Safer Consumer Products Regulations



Step 4:
Regulatory Response

Regulatory Response

- Additional information to DTSC
- Additional information to consumers
- Use restrictions
- Sales prohibitions
- Additional safety measures / controls
- End-of-life product stewardship
- Research funding

Important Changes

In

California's
Safer Consumer Products
Regulations

Exemptions

Upfront exemption *restored* for products regulated by other laws that provide equivalent or greater protections

Lower Priority Products

These are no longer automatic exemptions:

- Product is manufactured, stored, or transported in California solely for use outside of California
- Product is used in California solely for the manufacture of statutorily-exempted products

Chemical – Identification

- List of chemicals now called ***Candidate Chemicals*** list.

- A Candidate Chemical that is the basis for listing a product as a Priority Product is a ***Chemical of Concern*** with respect to that product.

Candidate Chemicals List

Includes two additional lists –

- Respiratory sensitizers.
- Clean Water Act section 303(c) ***and*** section 303(d) California pollutant chemicals.

"Potential"

- "Ability" replaced by "Potential".
- "Potential" – "the phenomenon described is reasonably foreseeable based on reliable information".

Eliminated Certified Assessors

Requirement for Alternatives Analyses to be performed by certified assessors has been eliminated.

AAs – Increased Stakeholder Participation

Public review and comment process added for Preliminary AA Reports.

Notifications instead of AA

- Chemical removal.
- Product removal.
- Product-chemical replacement.

✓ Intent notification followed by Confirmation notification within 90 days.

Alternatives Analysis Threshold (AAT) Exemption Notification

- Default AAT = PQL.
- Default applies only if COC is a contaminant.
- AAT for intentionally-added chemical – or a higher AAT for a contaminant – maybe set during Priority Product listing process.

AAs – Economic Impacts

- Compare public health & environmental costs, and costs to environmental protection agencies and nonprofits.
- If Priority Product is retained based on internal cost impacts – AA must compare internal cost impacts.

Regulatory Responses (RRs) Revision / Elimination of Unbounded RRs

- Limited to COCs and replacement CCs.
- Limited to situations specified in regulations.
- New AAs will not be required.
- Limited opportunity for DTSC to require information to fill data gaps.
- Limits on criteria & time frames for revising RRs.

Manufacture, Assemble, Assembler

- "Manufacture" definition excludes "assemble" activities – "bring together components to create a consumer product".

- "Assembler" – someone who assembles a product containing a component that is a Priority Product.

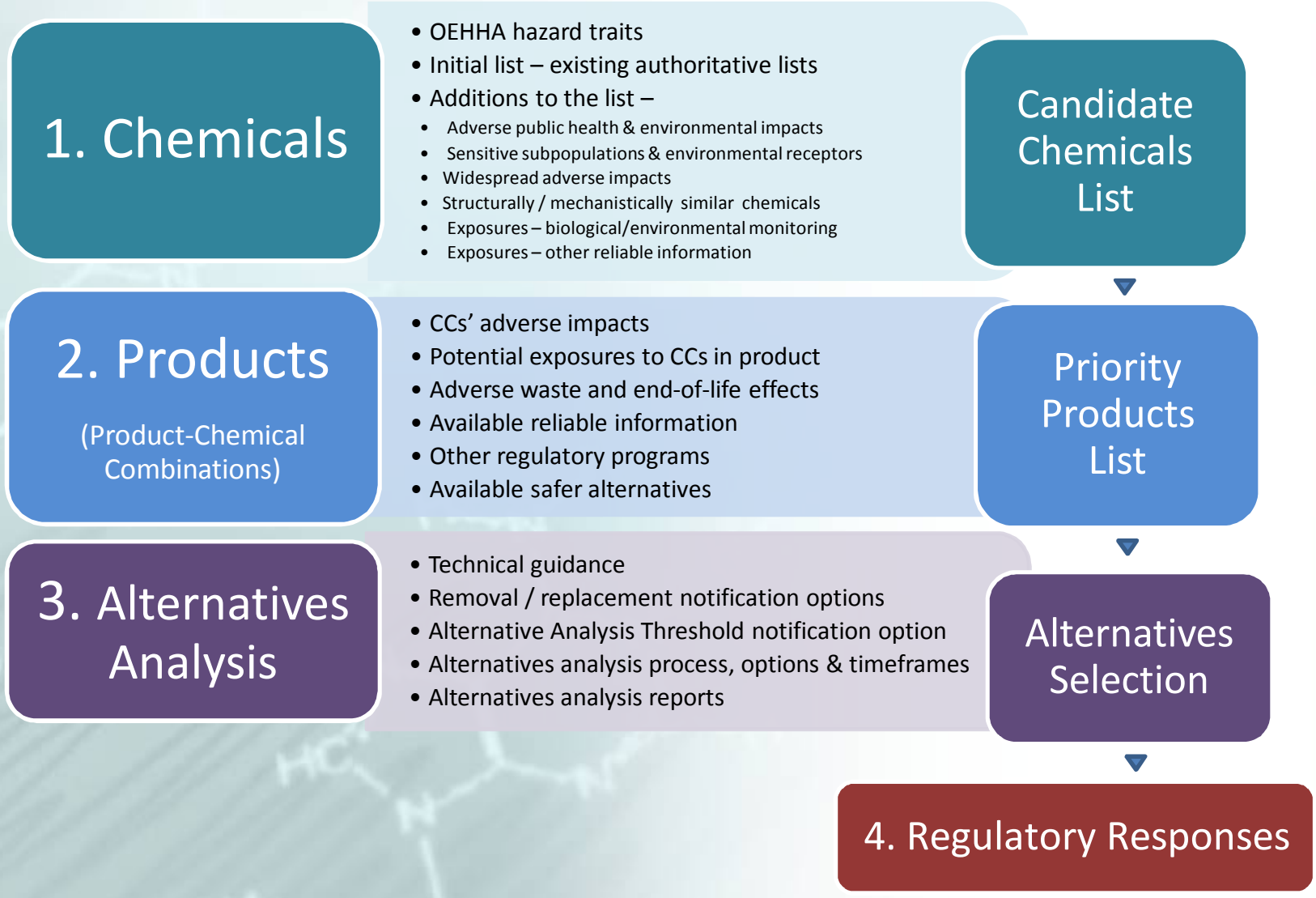
Reliable Information Definition

Expanded to provide appropriate criteria for determining the reliability of non-scientific information.

Trade Secret Protections

- Federal disclosure prohibitions & nondisclosure agreements accommodated.
- Chemical identity masking allowed while patent application is pending.

How It Works: The Safer Consumer Products Regulations



Remember the Goal of California's Safer Consumer Products Regulations

http://www.businessinsider.com/when-to-buy-generic-vs-brand-name-goods-at-the-grocery-store-2011-10?op=1

Creation of safer alternatives that protects public health & the environment.

Products are reformulated or redesigned.

Practical

+

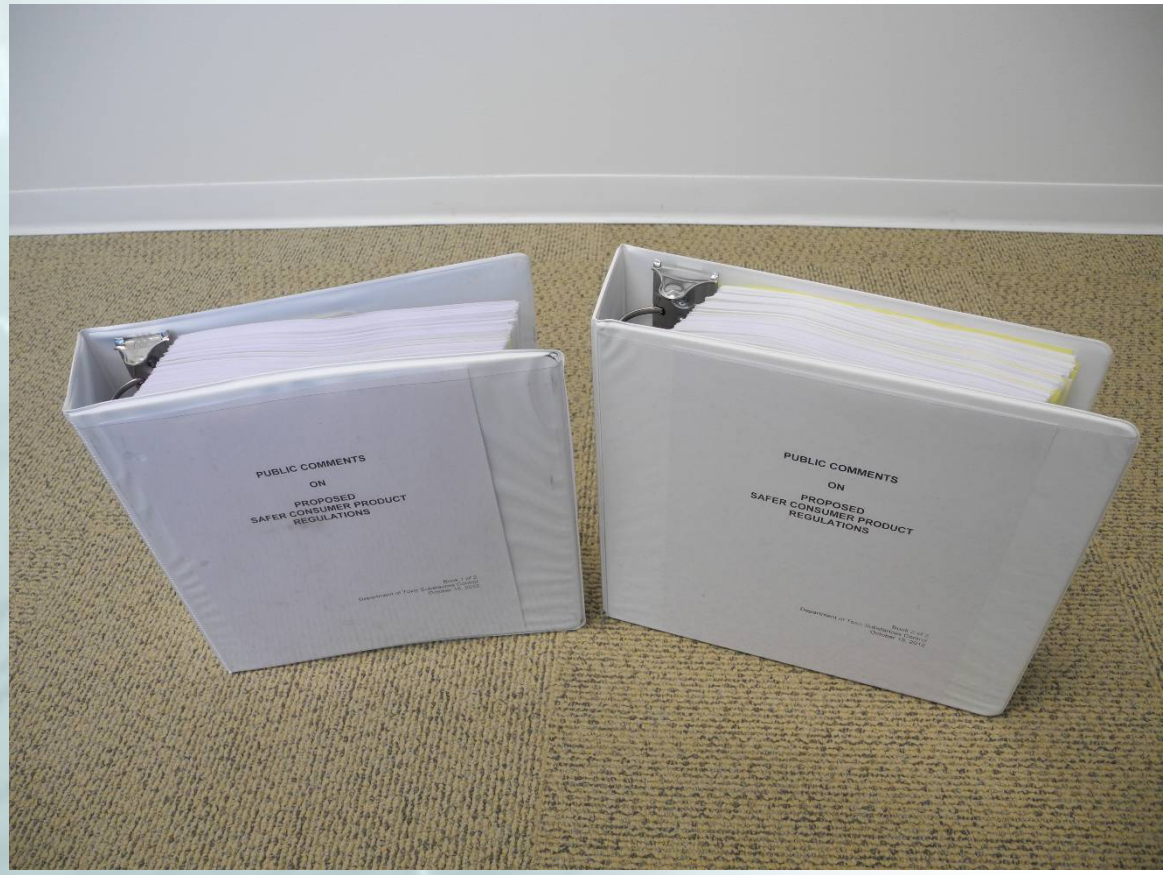
Meaningful

+

Legally Defensible

Voices of Our Stakeholders

http://karalyunets.blogspot.com/2011/02/blog-post.html



III. Comments from Japan

on

California's Safer Consumer Products Regulations

Comment Summary

- Concern over identification of priority product and the chemical of concern when product is covered under the Technical Barriers to Trade (TBT) notification.

- The difficulty in verifying the scientific evidence for risk tradeoff under the alternative analysis (AA). The AA will be time consuming with a large uncertainty regarding the benefit and cost analysis.

- The (1) validity and rationality of the draft regulation and (2) the benefit associated with the reduction of risk and expected cost of the regulation could not be evaluated without knowing designated subject product(s) and chemical(s) upfront.

- The regulation should take into consideration the impact on international stream of commerce and on the influence to the international community.

- California should conduct a regulatory impact assessment under Executive Order of the United States 12991.

III A.
Japanese High Technology Companies

JEITA — Japan Electronics and Information Technology Industries Association

CIAJ — Communications and Information Network Association of Japan

JBMIA — Japan Business Machine and Information System Industries Association

JEMA — Japan Electrical Manufacturers' Association

General Comments

from

Japanese High Technology Companies

General Comment Group #1

The Draft Safer Consumer Products regulation regulates all consumer products & requires an Alternate Analysis.

There are no similar regulations around the world.

We share concerns of ACC, European Union and Japanese Government that the draft regulation appears inconsistent with TBT agreement represents an unreasonable trade barrier.

General Comment Group #2

The Alternative Analysis (AA) will require consideration of risk tradeoffs among available alternatives.

There will be difficulty with the verification of scientific data about safety and therefore uncertainty on the alternative.

The AA will be time consuming and a burden to perform with uncertain benefits.

General Comment Group #3

Since the draft regulation do not designate subject product(s) and chemical(s), **the benefits such as reduction of risk and the associated costs cannot be evaluated.**

At this point, potential result, validity and rationality of the draft regulation can not be evaluated.

Specific Issue Comments from Japanese High Technology Companies

Specific Comments

#1 Considering the international stream of commerce, the validity and rationality of the draft regulation should be verified, **harmonized and shared with stakeholders not only inside but also outside of the state of California.**

#2a Subject product(s) and chemical(s) should be clearly stated in the draft regulation.

#2b A regulatory impact assessment (RIA) under Executive Order of the United States 12991 should be done.

Specific Comment

#3 **Occupational health** should not be considered within the definition of "Public health."

#4 The **supply chain should be allowed sufficient time to eliminate inventory** in a reasonable manner.

Specific Comments

#5 DTSC is responsible for designating Candidate Chemicals. Scientific data supports such designation will vary and have different interpretation by different stakeholders. **DTSC needs to listen to all stakeholders and consider all evidence.**

#6 DTSC should consider the existence of and **harmonize with other regulations such as EU REACH.** It is burdensome for the industry to follow each of the regulations worldwide.

Specific Comment

#7 In Article 2 Section 69502.2, **some of the chemicals** are not explicitly hazardous, and some **do not have enough information to make such determination.**

#8 California's regulations should try to **harmonize the scope or the chemicals in the list with federal laws** and international agreements.

Specific Comment

#9 **We want guidance** on how to conduct an impact assessment on public health and environment etc. in the AA. We expect such assessment to be difficult and results to vary among assessors.

#10 We **want DTSC to consider establishing a body like EU SIEF** for AA activity either at Priority Product or Chemicals of Concern level.

Specific Comment

#11 Referring to the AA…in our industry, the selection of a potential alternative chemical will involve **long time between research and development time to actual start of mass-production.**

#12 Referring to **"trade secret,"** information about who is a part of the supply chain is confidential business information. From any point in the supply chain, the names of those further upstream or the downstream beyond the direct supplier or the customer is not known and therefore cannot be provided.

Specific Comment

#13 Many companies selling consumer products in California are headquartered outside of California. Due to distance and language problems the **45 days is too short to comment** and should be longer, such as 60 days.

#14 We are concerned with the possible confusion for consumers created by (c)(2) (A). **It is not practical for all labels on the product package to be changed over a night.** We suggest that website or POP (point of purchase) information should also be selected.

Specific Comment

#15 The regulations imply that each company has not only fund but establish and maintain a management system throughout the products life-cycle. **We believe such system is the responsibility of the government. We propose that EU WEEE method be studied.**

#16 The focus of **trade secrecy** appears to be upon technical, intellectual property and design issues. We consider operational information regarding supply chain or R&D strategies as confidential business information and should be included in the definition of "trade secret."

III B.
Comments from Japanese Chemical Companies

JAPAN CHEMICAL INDUSTRY ASSOCIATION JCIA

Japan Chemical Industry Association

Chemical of Concern/Candidate Chemical List

JCIA continues to be **concerned with the number of chemicals** to be included on the Candidate Chemical list. The initial list is much larger than comparable regulatory lists.

JCIA wants DTSC to provide disclaimer that a **Candidate Chemical is NOT a determination that a chemical is of concern** in a any particular product.

JCIA wants DTSC to develop a **rigorous prioritization transparent process** so stakeholders can understand DTSC's expectations.

Alternative Analysis (AA)

JCIA is concerned with the burden of having to perform a **potentially complex AA within the stated timeframe.**

Responsibility for Compliance with the Regulations

JCIA is concerned with the **apparent lack of the options for regulatory requirements to be fulfilled** by a consortium, trade association, or other entity acting on behalf of the manufacturer, importer, or retailer.

Revised Definition of Alternative Assessment Threshold (AAT)

JCIA does not support DTSC's approach to the AAT. This is not scientifically justified and could set thresholds lower than necessary for human health protection.

Voice of Other Stakeholders

Example - Article 2:

http://karalyunets.blogspot.com/2011/02/blog-post.html

- 1200 chemicals – too large,
  need a subset of chemicals
- Prioritization criteria: Weight of evidence approach
- CoC – should be used only for the highest priority subset, the larger 1200 chemicals should be called Chemicals under Consideration
- Adding chemicals – should be from Authoritative organizations only! Definition of reliable information is too loose.

IV. Comparison of California's Safer Consumer Products Regulations with REACH and TSCA

Comparison of California, REACH & EPA TSCA

	California SCPR	REACH	U.S. EPA TSCA	U.S. EPA Workplan
Scope	1200 Chemicals	30,000 chemicals	82,000 Chemicals on TSCA Inventory	83 Workplan Chemicals
Priority	3-5 consumer products initially	Chemicals > 1 million tons	1.Risk Assessments 2.Increasing Information 3.Safer Products	Conduct initial assessments on 23 chemicals
Chemical or Product Safety Focus	Both	Chemical Safety	Chemical Safety	Chemical Safety. Some Product Safety

How is CA's SCPR different from REACH?

California SCP

- **Product Focus**, based on chemical hazard and exposure
- **Scope**: To identify and accelerate the production of safer consumer products
- To expand business opportunities for product makers.

Europe's REACH

- **Chemical Focus**, not Products
- **Scope**: Earlier and better identification of the intrinsic properties of chemical substances.
- To enhance competitiveness of EU chemical industry

How is CA's SCPR different from TSCA?

EPA's TSCA

- **Chemical Focus** with most chemicals "grandfathered in"
- **Aim**: To require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures

EPA's Wkplan/DfE

- TSCA Workplans have a **chemical focus – 83 chemicals**
  - **2012: 7 chemicals**
  - **2013: 23 flame retardants**
- **Aim** of DfE (Design for Environment) focus on chemicals and products

Key Differences
California's SCPR vs. REACH & TSCA

- Wide Range - Number of Chemicals
  - California focusing on 230 chemicals out of 1200 initially
  - REACH addresses 30,000 chemicals
  - EPA TSCA addresses 82,000
  - EPA Workplan Chemicals: 83 with first 7 underway

Comparison of SCPR, REACH & EPA TSCA (cont'd)

	California SCPR	REACH	U.S. EPA TSCA	U.S. EPA Workplan
Alternative and/or Risk Assessments	Yes, AAs for products.	No for both	Yes, Risk Assessments	Both AA's and RA's
Who Provides Data	Business	Business	EPA collects available info. Limited testing authority.	EPA collects available info. Limited testing authority.
Info for Consumers	Yes.	Yes.	Limited. Info Portal soon.	Limited. Info Portal soon.
Regulatory Actions	Various	Various	Limited	Limited

Comparison of SCPR, REACH & EPA TSCA (cont'd)

	California	REACH	U.S. EPA TSCA	U.S. EPA Workplan
Enforcement Authority	Yes, various	Yes. Role of EU Member States	Limited	Limited
Confidential Business Information (CBI)	California reviews.	Fewer CBI protections than U.S.	Broader CBI though trend is increasing transparency & review of CBI claims.	Broader CBI though trend is increasing transparency & review of CBI claims.
Data Sharing By Companies	Yes	Yes	Yes	Yes
Changes Coming	Regs take effect 2013	New changes coming.	Seek reform of TSCA.	More workplan chemicals.

Japanese Insights & Lessons

- Japan is one of our largest trading partners. How can we work with Japanese Government to ensure good communication, coordination and collaboration?
- What lessons can California learn from Japan?
- Why is it challenging to meet the California's Safer Consumer Products Regulations timeframes?
- Opportunity for international cooperation and partnerships?
- Other thoughts?

We look forward to working together to protect public health and the environment !

Thank You

Japan MOE and to all of you in the audience!