

IDENTIFYING AND PRIORITIZING CHEMICALS OF CONCERN IN CONSUMER PRODUCTS

*Informal Workshop
October 21, 2009
Sacramento*

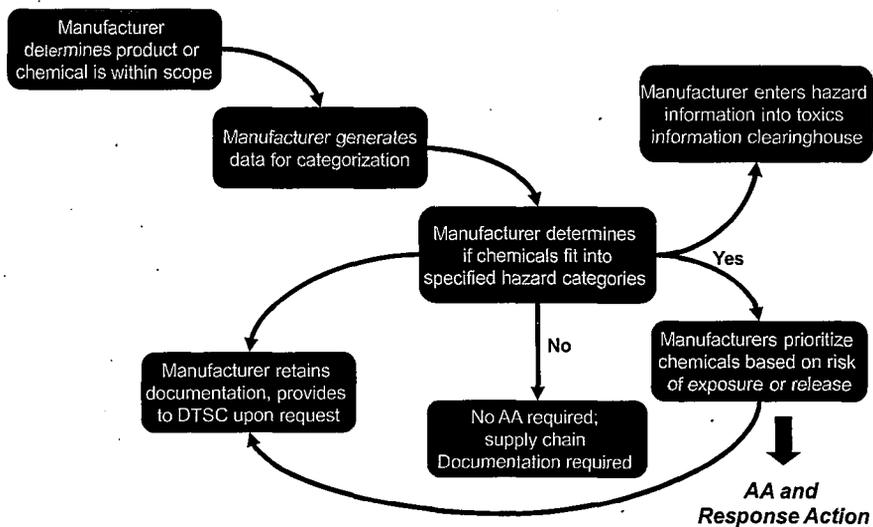
Key Terms

- *“Chemical”*
- *“Chemical ingredient”*
- *“Manufacturer”*
- *“Consumer product”*
- *“Chemical of concern”*

The Process: An Overview

1. **Manufacturers determine if their *product* or *chemical* is within scope (section 6xxx.1 & .2).**
 - a. Broad list of product categories.
 - b. Designated chemicals and list of chemicals.
2. **Manufacturers generate data to determine hazard categories (sections 6xxx.6 & .7).**
 - a. Manufacturers choose *appropriate* test methods.
 - b. Manufacturers generate data to determine if chemicals in their products fit into specified hazard categories.
3. **Manufacturers prioritize chemicals of concern. Prioritization is based on potential exposure or release (section 6xxx.8).**
4. **Manufacturers communicate hazard categorization information to the Clearinghouse and to the first link in the supply chain (sections 6xxx.7 and 6xxx.9, respectively).**

Flow diagram of the entire process



Applicability Summary

Three pathways for entry into the required processes:

- 1. Nine categories of consumer products;*
- 2. Designated chemicals of concern; and,*
- 3. Chemicals identified on various lists.*

Eleven Product Categories

1. Products designed for use by infants or children;
2. Products designed for use in K-12 schools;
3. Products designed for application directly in or to the human body;
4. Clothing, linens and textiles;
5. Furnishings including, but not limited to, mattresses, sofas, chairs, tables, etc.;
6. Cleaning products including, but not limited to, soaps and laundry detergents;
7. Products designed to release fragrance or scent during use;
8. Products designed to dispense, store, or prepare food;
9. Products designed, or reasonably anticipated, to release any chemicals during intended use by consumers or after disposal (e.g., automobile brake pads, automobile tires, fireplace logs, glues, adhesives, and solvents);
10. Any products that contain any of the chemicals specified in section 6xxx.2 of this Article; and
11. Any of the chemicals specified in section 6xxx.2 of this Article.

Two Separate Chemical Paths

**1. 16 designated chemicals of
concern**

[6xxx.2(a)]

OR

**2. Any chemicals identified on
specified lists [6xxx.2(b)].**

Question 1:

***What are the pros and cons of the nine (9)
consumer product categories?***

***What specific changes would you recommend
and why?***

Question 2:

What are the pros and cons of the sixteen (16) designated chemicals of concern?

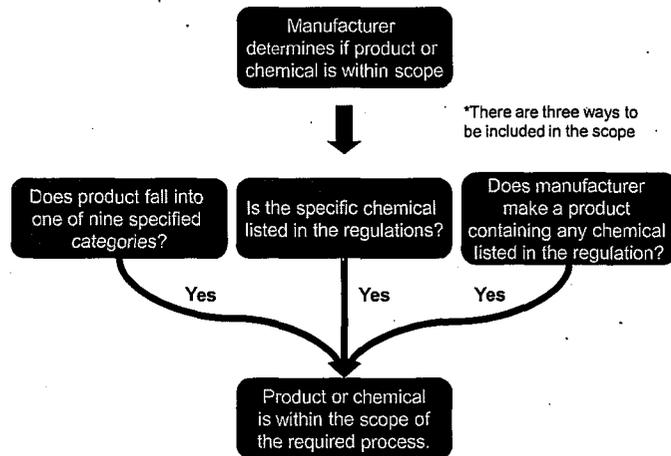
What specific changes would you recommend and why?

Question 3:

What are the pros and cons of those chemicals identified on various lists?

What specific changes would you recommend and why?

Product or Chemical within the scope?



Question 4:

What are the pros and cons of including a possible exemption for a chemical or chemical ingredient in a consumer product which presents:

- an insignificant level of hazard?***
- for which exposure is adequately controlled through product design and manufacture?***

Authoritative Bodies

The statute instructs DTSC to reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes, so as to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state's economy.

Authoritative Bodies

In the straw, "authoritative body" is defined as:

"any government agency, foreign or domestic, that meets"... two specific requirements:

- 1. It characterizes chemicals pursuant to a process in which stakeholders are able to participate and communicate through written and oral comments.*
- 2. It publishes its characterization of chemicals via web postings, press releases, government regulations, periodic reports, monographs, or similar publications*

Question 5:

What are the pros and cons of the definition of "authoritative bodies"? What specific changes, if any, would you recommend?

How and where should authoritative bodies be used?

Data Requirements

Manufacturers have one year to generate data or collect documentation sufficient to determine if the chemicals or chemical ingredients in their products fit into any of the hazard categories specified in 6xxx.7.

*Manufacturers have the discretion to select suitable testing methodology, and may rely on peer reviewed journals or determinations made by authoritative bodies, or may rely on QSARS under certain circumstances.
(Section 6xxx.6)*

Question 6:

Is one year an adequate amount of time to complete the required testing?

Question 7:

What additional data requirements might be required?

Should the testing methodology be specified? If so, which methodologies?

Hazard Categories

The following hazard categories are listed in the regulation (section 6xxx.7):

1. **Toxicity**
 - Acute
 - Target Organ, single exposure
 - Target Organ, repeat exposure
 - Acute Aquatic
2. **Serious eye damage**
3. **Germ cell mutagenicity, genetic toxicity**
4. **Reproductive toxicity**
5. **Carcinogenicity**
6. **Endocrine Disruption**
7. **Respiratory Sensitization**
8. **Skin Sensitization**
9. **Bioaccumulation**
10. **Hazardous to the Stratospheric Ozone Layer**

Hazard Categories

The hazard categories listed on the previous slide are from the United Nation's Globally Harmonized System for Classification and Labeling of Chemicals, and are incorporated into REGULATION (EC) No 1272/2008 of the European Parliament and The Council of 16 December 2008 on the classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Question 8:

Should additional or different hazard categories be considered?

If so, which categories and why?

Question 9:

If a chemical has not been analyzed and no data exists (i.e., completely unknown), what are the costs to conduct such testing and analysis?

Prioritization

After a manufacturer determines if any of the chemicals or chemical ingredients in their products fit into any of the specified hazard categories, they must prioritize based on the following (section 6xxxx.8):

Priority 1: Anticipated to be released during use or disposal, or to which humans are being exposed.

Priority 2: Will not be released during use, but may be released after disposal.

Priority 3: Will not be released during use or disposal.

Question 10:

The straw proposal requires the manufacturer to notify the supply chain regarding the identification and prioritization.

How can this information be shared most effectively and efficiently?

***How should these terms
be defined?***

- *“Chemical”*
- *“Chemical ingredient”*
- *“Manufacturer”*
- *“Consumer product”*
- *“Chemical of concern”*

Thank you.

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Alternatives Assessment with Life Cycle Thinking

Workshop
October 21, 2009

Alternatives Assessment

- Performed for consumer products that contain one or more prioritized chemical of concern
- Conducted by “manufacturer”
- Submit to DTSC electronically and post to website for public review and comment
- Ongoing updates

Alternatives Assessment

- Identify potential alternatives
 - Functionally equivalent
 - Specify performance factors
- Compare hazard categorization of product and potential alternatives
 - Identify & prioritize chemical of concern in each potential alternative

If No Alternatives

- Appropriate response action
- Documentation of findings
- Notification to DTSC
- Repeat alternatives analysis within two years

General Requirements for Alternatives Assessment

- *Relevance* – info sources, data & methods are appropriate to impacts
- *Completeness* – includes all inputs & outputs that provide material contribution
- *Consistency* – data & info provides meaningful comparison of results
- *Accuracy* – minimize bias & uncertainties
- *Transparency* – disclose sufficient info to allow validation & decision-making

Alternatives Assessment

- Hazard Criteria & values
 - Hazard categories from identification & prioritization of chemicals of concern
- Exposure Criteria & values
 - Potential dermal contact
 - Potential ingestion
 - Potential inhalation

Life Cycle Impacts

1. Determine scope and system boundaries
 - Functional unit
 - Life-cycle stages
 - Define "unit processes" or process description
2. Information collection
3. Assess ecological, human health, resource depletion and economic impacts
4. Document results and conclusions

Note: LCA principles and framework are standardized by the Organization for International Standardization's 14040 series of standards (ISO 14040)

Life Cycle Impacts

- §25253 (a) (2) ... life cycle assessment tools take into consideration, but shall not be limited to, all of the following:
 - (A) Product function or performance.
 - (B) Useful life.
 - (C) Materials and resource consumption.
 - (D) Water conservation.
 - (E) Water quality impacts.
 - (F) Air emissions.
 - (G) Production, in-use, and transportation energy inputs.
 - (H) Energy efficiency.
 - (I) Greenhouse gas emissions.
 - (J) Waste and end-of-life disposal.
 - (K) Public health impacts, including potential impacts to sensitive subpopulations, including infants and children.
 - (L) Environmental impacts.
 - (M) Economic impacts.

Compare & Select Alternative

Alternatives Analysis Summary Table (*partial*)

Impacts		Product	Alternative A	Alternative B
Hazard & Exposure Impacts	Acute Toxicity			
	Specific target organ toxicity (single exposure)			
	Target organ toxicity (repeated exposure)			
	<i>Etc.</i>			
Ecological Impacts	Global warming			
	Acidification			
	<i>Etc.</i>			
Resource Depletion Impacts	Energy consumption			
	Natural resource consumption			
	<i>Etc.</i>			
Economic Impacts	Direct corporate cost			
	Indirect corporate cost			
	<i>Etc.</i>			

Compare & Select Alternative

- Findings report
 - Justify determinations
 - Identify impacts
 - Describe decision process
 - Include implementation plan & schedule
- One year to complete
- Supply chain documentation
- Repeat within 2 years if no changes

Questions

1. Should the comparison of alternatives specify a preference for health and safety attributes over other attributes?

- How should trade-offs among attributes influence the selection of a preferred alternative?
- Should DTSC establish a weighting system for directing this decision? If so, how?

Questions

2. Are there specific suggestions to ensure accountability within the framework of a self-implementing alternatives assessment?

- What should we build into the process to ensure quality?
- Are there quality standards for alternatives assessment?

Questions

3. What should the process include to ensure that all potential alternatives are considered and evaluated?

- Are the provisions for transparency adequate to provide input for analyses?
- If not, what should be changed to improve transparency?

Questions

4. What are the costs that would be incurred to:

- Identify alternatives (per product)
- Determine hazard categorization for alternatives
- Evaluate lifecycle and other impacts (per product)
- Prepare a findings report
- Plan and implement an alternative

Questions

5. Have you already performed alternatives analysis for your product(s)?

Questions

6. How much do you think compliance with this regulation as a whole will cost per product?

Regulatory Response Actions

WORKSHOP PRESENTATION

October 21, 2009

AB 1879 requires the regulations to specify the range of regulatory responses following the completion of the alternatives analysis.

Self Implementing

- Labeling
- Prohibiting of the Chemical of Concern
- Management at End-of-Life
- Additional Notifications

DTSC Authorized

- Additional information
- Restrictions on the use.
- Research & Development
- Funding Green Chemistry
- Any other outcomes

General Requirements

Applicability

- A consumer product that contains a priority chemical of concern; or
- The alternative to be implemented that contains a priority chemical of concern or has a significant impact

Exception:

If the manufacturer implements a safer alternative without a priority chemical or without a significant impact, the manufacturer complies with a notification and continues to comply with other articles.

General Requirements

Response Action Implementation Plan

- Part I: general information
- Part II: plan specific information.

Notification.

- An electronic notification (Part I) is sent to the Department
- Information is added to the supply chain documentation.

General Requirements

Department Imposed Response Actions

- Manufacturer has not taken response action
 - Continued availability of the consumer product poses a risk to human health or the environment.
- **Department Considerations**
 - Nature of the hazards and potential risk
 - Effectiveness of the response action
 - Consistency in response actions
 - Duplicative requirements

Response Actions & Criteria - Prohibition

Chemical Priority	Safer Alternative exists	Safer Alternative does not exist
1 with a Ban	2 years	5 years
1 w/o a Ban	5 years	10 years
Alternative - health impact	5 years	10 years
2	10 years	15 years
3	15 years	20 years

Response Actions & Criteria - Labeling

Product Has Attributes with Significant Impacts

- exposure risks (Restricted Use)
- end of life phase (End of Life Management)
- exposure risks to workers (Worker Protection)

Response Actions & Criteria - End of Life

Product Has Attributes with Significant Impacts for End-of-Life Phase

- End of Life Management

Response Actions & Criteria - Additional Notifications

Product Has Attributes with Significant Impacts

- **end of life management**
 - Notification to Integrated Waste Board
- **exposure risks to workers**
 - Notification to Department of Industrial Relations
- **greenhouse gas emissions or air quality**
 - Notification to the Air Resources Board
- **water quality impacts, or eutrophication**
 - Notification to the State Water Resources Control Board
- **ecotoxicity risk**
 - Notification to the Department of Fish and Game

DTSC Imposed Response Actions

- **Additional Data**
- **Restrictions**
- **Research and Development**
- **Green Chemistry Funding**
- **Other Response Actions**

Petition Process

Any manufacturer may petition the Department to modify or waive provisions of the regulations provided:

- efforts to comply with the requirements can be demonstrated; and
- a written narrative demonstrating the good faith efforts undertaken to comply is provided.

Petition Process

The Department determines one of the following findings:

- The chemical hazard is below
 - "no significant risk levels" for carcinogens or
 - "maximum allowable daily levels" for reproductive toxicity
- The chemical is an insignificant hazard
- The consumer product is an insignificant hazard
- The exposure during use is an insignificant hazard
- The consumer product is regulated by another governmental agency which provides protection

Petition Process

- **Petitions must be sent by certified mail**
- **Tentative petition decision:**
 - 45 day notice
 - available on website along with scientific support;
 - disclosed for written public comment;
 - considered and revised in response to comments;
- **The final decision will be published in the California Regulatory Notice Register and on the internet**

QUESTION 1: Additional Response Actions

- Are there any response actions, currently not included, that can be used to incentivize innovation?

QUESTION 2:

Modification of the prohibitions

- How should the schedule be adjusted to accommodate the hybrid approach that includes the list of chemicals and the list of lists?
- How should the schedule be adjusted to allow for depletion of inventories?

QUESTION 3

Variance

- Are there specific requirements, such as time-frames or minimum risk thresholds, which are more appropriately addressed by revising the regulatory language than by allowing a case by case variance petition?

QUESTION 4

Variance

- Should the regulations include a time limit for the duration of the variance?
- What should be the requirements for a manufacturer while a petition is being reviewed?

QUESTION 5

Cost Information

- What are the specific costs associated with the prohibition of a chemical in a consumer product?
- What are the specific costs associated with end of life management programs for specific consumer products?
- How much do you think compliance with this regulation as a whole will cost per product?

NOTE: Please include ranges for the costs and the product category

Questions or Comments?

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