

Jae Choi

Which exposure potential criteria should be used to identify and prioritize the products (chemicals in the products)?

1. Focus on exposure point of product chemical contamination
  - a. Drinking water
    - i. Contaminated from chemicals from disposal and landfill?
    - ii. Contaminated from pollutant in air dust?
  - b. Solid waste and waste water
  - c. Utilize existing and available data sources
    - i. Biomonitoring California Priorities Chemicals from the Designated Chemical List
    - ii. RoHS
    - iii. REACH/ECHA
    - iv. EPA
    - v. TSCA
    - vi. Etc.
2. Identify and determine if the chemical from the product has short- or long-term effect on public health (children, women of childbearing age) and environment
  - a. Determine levels of contaminants (by PPM and known/published suspect level)
  - b. Establish trend of effect by the product chemicals on public health and environment
3. Prioritize the High volume products by
  - a. How and where the products are disposed to
    - i. Landfill – contaminate soil and leach into water source
    - ii. Incineration – fumes in air, e.g., what is the by product chemical like hydrochloric acid and dioxin from PVC incineration
  - b. Require the manufacturer to manage the product lifecycle (to the end of its useful life)
    - i. Recycling
    - ii. Responsible disposal of the consumer product
4. Safe alternate chemical ingredient available?
  - a. Provide technical guidance to alternative source
  - b. Apply AB1879 – 25253
  - c. Apply Table of Standards from California Air Resources Board Consumer Products Program

Jae Choi

What criteria/ process should be used to include and prioritize products on the list?

This metrics is to demonstrate the simplicity, flexibility, and some clarity.

	Criteria	Score	Recommendation	Comments
Product Volume	>1000 lbs, 1000 gallons/month – 5  <999 lbs, 999 gallons/month - 1	5		
Use Frequency	Every day – 5  Monthly - 1	1		
Chemical banned by	RoHS, TSCA, REACH – 5  Not list but suspect – 3  Not listed - 1	3	Consider to find an alternative chemical	
Toxicity <sup>2</sup>	Oral – 5  Skin – 4  Respiratory - 3	3		May cause long-term health problem
		12/20	B <sup>1</sup>	

- 1) A – Required to remove from product and replace with alternative chemical(s)  
 B – Recommend to remove from product  
 C – No action is required
- 2) Toxicity can be as simpler or more complex than shown in this example

**From:** Michael Kirschner <mike@designchainassociates.com>  
**To:** 'Odette Madriago' <OMadriago@dtsc.ca.gov>  
**CC:** 'Kathy Barwick' <KBarwick.DTSCHQ.DTSCHQGW@dtsc.ca.gov>  
**Date:** 4/22/2011 9:08 AM  
**Subject:** RE: Subcommittee #2 Homework  
**Attachments:** product prioritization flowchart mgk.ppt

Hi Odette & Kathy,

See attached. Process steps are included on the first two slides in the notes section. I don't know enough about the regulatory system and requirements in California to know what problems this would create for you. It's based on Kelly Moran's thoughts (I found that when I drafted a rough process it matched almost exactly with what she had said at the start of the 4/19 call) to a great extent.

I think it's important to understand that this proposed process is meant to provide a level of screening and then a method of prioritizing what gets through. The screening criteria may not be right or may need to be tweaked; you don't want to overwhelm the prioritization process though with too many Candidate Priority Products.

Let me know if you have any questions.

Best Regards,  
Michael Kirschner  
President  
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Design Chain Associates, LLC - Design Chain Solutions for Competitive Advantage

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-----Original Message-----

From: Odette Madriago [mailto:OMadriago@dtsc.ca.gov]  
Sent: Wednesday, April 20, 2011 5:30 PM  
To: Jae Choi; Michael Wilson; Roger McFadden; hsm@cmu.edu; Michael Kirschner; Bruce Cords; Debbie Raphael; Kelly Moran; Julie Schoenung; Oladele Ogunseitan  
Cc: Kathy Barwick  
Subject: Subcommittee #2 Homework  
Importance: High

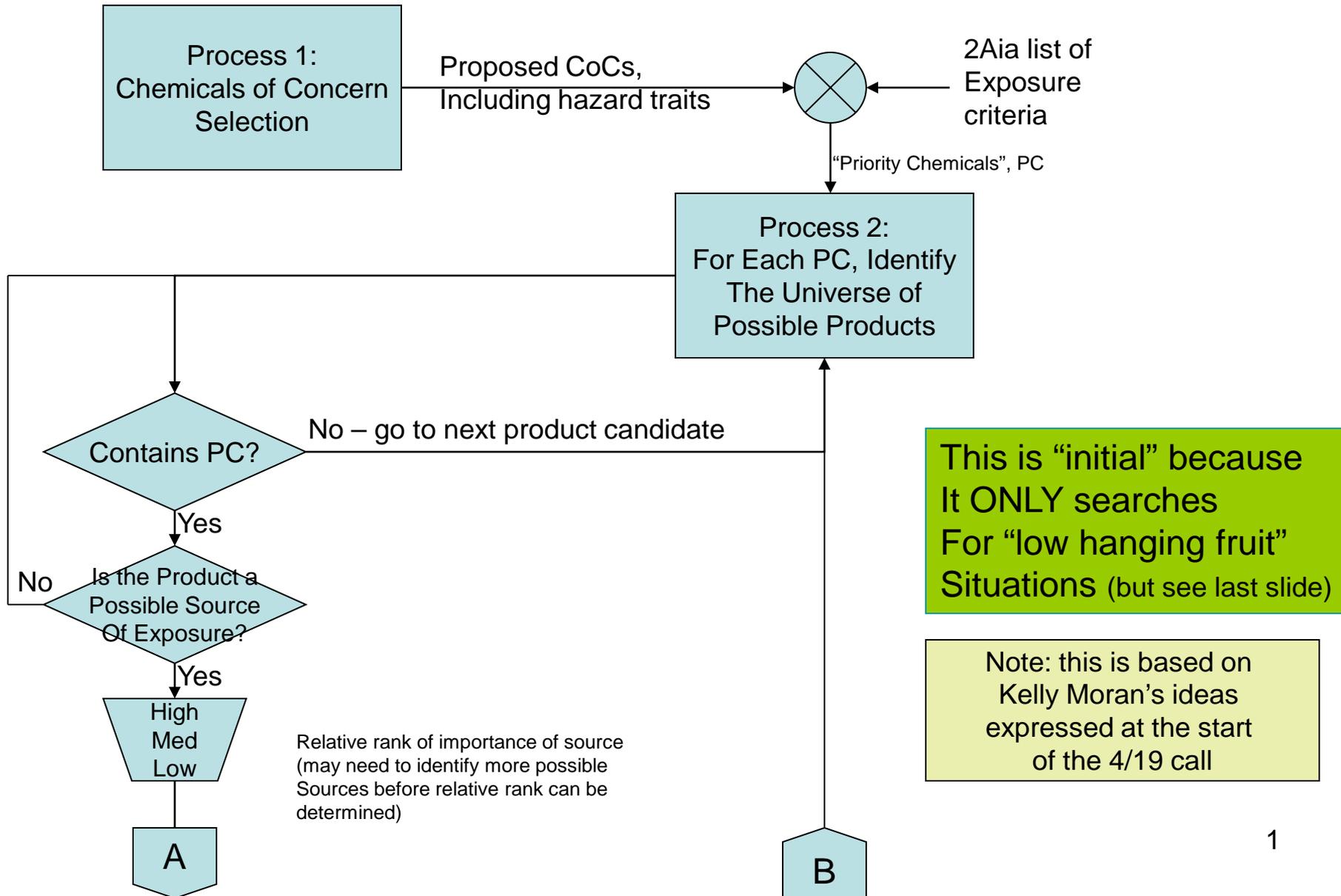
\*\* High Priority \*\*

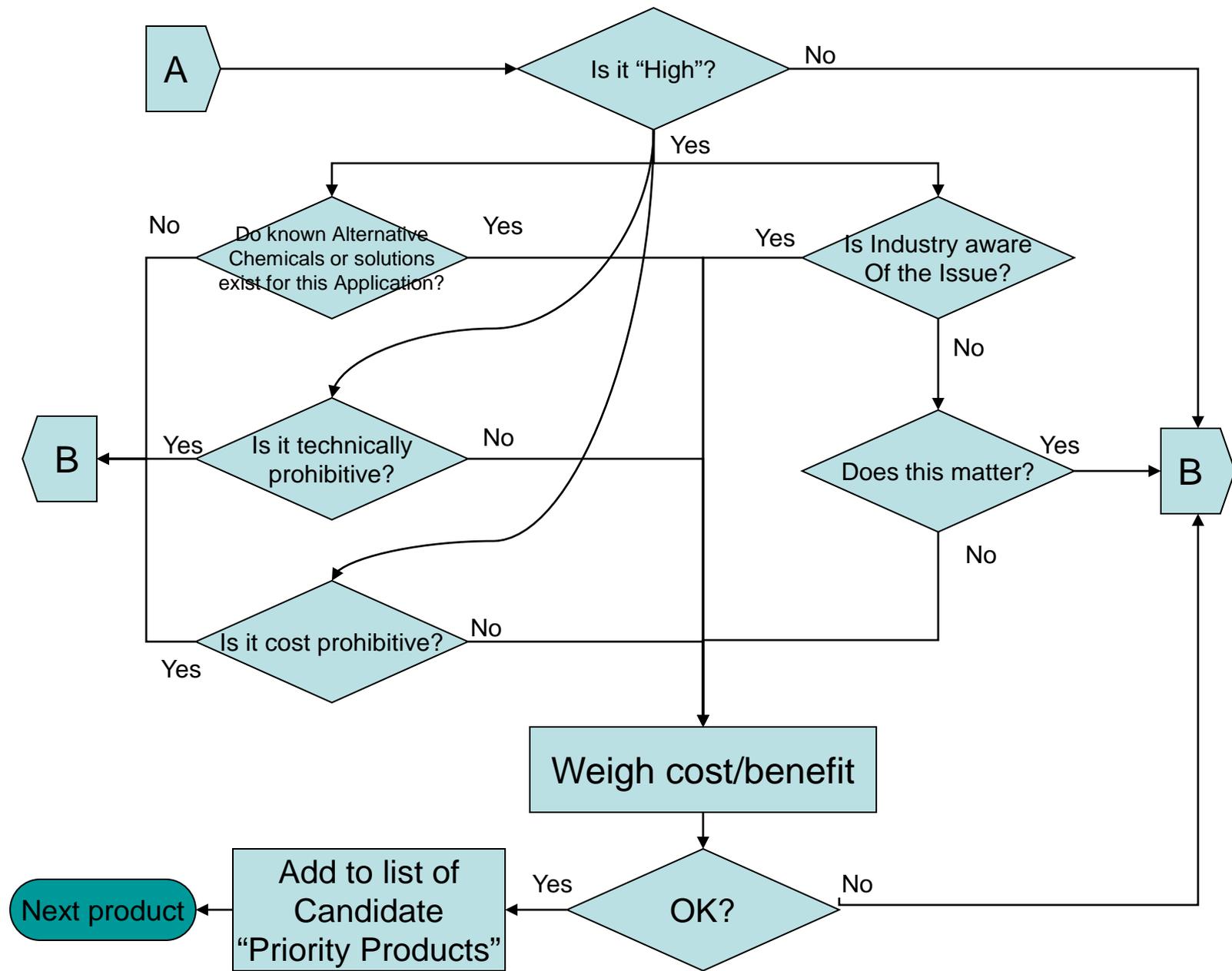
This is a friendly reminder to please email your written individual recommendations to Kathy (with a cc to me) by this Friday at the latest.

Thanks,  
Odette



# An approach for an INITIAL Priority Products List





# Notes

- Determining how significant a source of pollution a product is may require industry and use information
- Not all of the items on page 2 may be done simultaneously, based on situation
- Industry Awareness of either the issue or availability of alternatives may or may not matter depending on severity of the pollution, and solution cost/time.
- Industry will be the likely source of assessing technical viability of a solution
  - And cost viability

# Where to use AHP or Other Rating/Ranking Methods?

- Candidate “Priority Products” Prioritization Process
  - Compare the following criteria for each identified product/product class

Cost to industry, CA Gov't (\$)	Time to Solution	Benefit to CA (\$)	Industry Support
Extent of Pollution	Severity of Pollution	Cost to healthcare or ecosystem (\$)	Etc.

# Getting to a Complete Solution

- Once “High” sources of pollution are dealt with, go to “Med” then “Low” (see step 8)
  - This is the “Pareto Principle”
- Where alternatives don’t yet exist, require manufacturer to develop alternatives. Then run this process once the alternative is developed.
- Technical or Cost prohibitive: industry challenge
- Eventually open up 2Aia and (methodically/slowly) broaden it to go beyond known exposure towards pure hazard

***Response to DTSC questions by Roger McFadden, California Green Ribbon Science Panel Member***

***April 22, 2011***

**Question 2A: How should products be identified and classified?**

**Priority 1 Products**

Where there is credible evidence that a product contains a priority chemical of concern;

And when that priority chemical of concern has been intentionally added to the product;

And when that priority chemical of concern has been detected in California drinking water, surface water, cord blood, or mother's breast milk;

And when the product containing the priority chemical of concern is intended or likely to be applied directly to the human body,

And when the product containing the priority chemical of concern is intended or likely to be used by or marketed in California to sensitive populations including children, women of childbearing age or the elderly,

And when there are readily available safer alternatives that are functionally equivalent to current product.

**Priority 2 Products**

Where there is credible evidence that a product contains a priority chemical of concern;

And when that priority chemical of concern has been intentionally added to the product;

And when that priority chemical of concern has been detected in California drinking water, surface water, cord blood, mother's breast milk, indoor air, indoor dust, or banned from MSW disposal.

And when the product containing the priority chemical of concern is intended or likely to be applied directly to the human body, applied as a spray or aerosol into the air, or applied to hard surface where there is likelihood that they would run off or enter streams, waterways, storm drains or sewers,

And when the product containing the priority chemical of concern is intended for use or likely to be used or marketed in California.

**Priority 3 Products**

Where there is credible evidence that a product contains a priority chemical of concern;

And when that priority chemical of concern has been intentionally added to the product;

And when the product containing the priority chemical of concern is marketed in California!

**Question 2B: What criteria and/or process should be used to include and prioritize products on the list?**

**(i) What exposure potential factors should be used to prioritize products?**

**Priority 1 – Products that contain chemicals identified as persistent, bioaccumulative, and toxic including but not limited to carcinogens, chemicals potentially of concern for children’s health because of reproductive or developmental effects and chemicals found in human biomonitoring programs.**

**Priority 2 -- Who uses or is likely to be exposed to the product and priority chemical of concern?**

Sensitive populations including children, women of childbearing age, elderly and people with compromised immune systems should have priority.

**Priority 2 – How is the product used? And what is the frequency of use by those that use or are likely to be exposed to the product and priority chemical of concern?**

Priority should be given to products that contain the highest concentration of the priority chemical of concern and have the highest frequency of use.

**Priority 3 – What products account for the highest volume of production of the priority chemical of concern?**

Priority should be given to products that have the highest volume of production and contain the highest concentration of the priority chemical of concern.

**(ii) a. In assessing a product’s threat of adverse impact associated with each identified exposure potential factor should there be a threshold established for each factor – is so, how should the thresholds be determined?**

**Yes. Thresholds should be established based on safer alternative attributes. de minimus levels based on existing thresholds are acceptable except in the cases where credible evidence exists that indicates the priority chemical of concern may have adverse effects at low dose levels.**

**b. Should the prioritization evaluation be based on the product’s individual threat of adverse impact, or the product’s contribution to cumulative adverse impacts?**

**Both. It is important to consider the adverse impact of the product and its priority chemicals of concern first, but understanding what percentage of the priority chemical of concern is used in this type of product can be useful information when attempting to distinguish product priority.**

c. Should a ranking formula be used to apply the identified prioritization factors? If so do we weight different factors?

Yes. More weight should be placed on toxicity, persistence and bioaccumulation; use and exposure to sensitive populations and if readily available and credible safer alternatives exist.

#### Question 2C: Size and changes to the product lists?

(i) Do we list specific “products” and explain how additional ones get added or do we just set up a process?

List specific products or product categories based on your ingredient and product prioritization scheme as well as developing a process for adding additional ones. Selecting products that contain priority chemicals of concern and where functionally equivalent safer alternatives already exist may be where you want to begin. And then your process could be to add products and product categories as viable safer alternatives emerge.

(ii) Do we initially create a short list and then a timeline for adding the next category to send signals to the market?

List specific products or product categories to give those companies and/or industries that make those products an opportunity to begin to move towards safer alternatives with an objective of meeting a pre-determined timeline much like CARB VOC Regulations did when they identified products and product categories and the date by which they must comply with the targets. It is important for DTSC to use a phased focus and approach no matter what priority chemicals or products are selected. You will want to give businesses appropriate time to respond and make the transition and/or transformation to the safer alternatives.

**From:** Kelly Moran <kmoran@tdcenvironmental.com>  
**To:** Kathy Barwick <KBarwick@dtsc.ca.gov>, Odette Madriago <OMadriago@dtsc.ca...>  
**Date:** 4/22/2011 3:05 PM  
**Subject:** Criteria for selection of chemicals of concern and products for near-term regulatory action  
**Attachments:** Possible Criteria\_04-11.doc; Part.002

Odette & Kathy,

In my experience, the most effective regulatory processes serving the state's environmental programs--the ones that best serve the state's needs over a long time period--have been based on narrative criteria that balance scientific information with economic, social, and engineering (practical) considerations. For this reason, I recommend that DTSC use a set of narrative standards to prioritize chemicals and products under the Safer Consumer Product Regulations.

On the basis of the informative discussions of Green Ribbon Science Panel Subcommittee #2 during our two recent meetings, I have assembled the attached recommended narrative criteria for DTSC's consideration. The attachment also contains several general notes for the selection process. These also grew out of subcommittee conversations.

Thank you again for your hard work to tackle the challenge of developing these regulations!

Kelly D. Moran, Ph.D.  
TDC Environmental

# Potential Criteria for Identification of Chemicals of Concern and Prioritization of Consumer Product Categories for Regulation

## **Screening Criteria (statutory requirements)**

- (a) A Chemical or Chemical Ingredient may only be designated as a Chemical of Concern if it exhibits a hazard trait as defined by [cite code sections for regulations adopted by OEHHA assuming these are adopted first].
- (b) A consumer product category may not be designated for DTSC regulatory action under Health & Safety Code Section 25253 if DTSC makes a finding that regulation of the Chemical of Concern in that product category under this article would duplicate or conflict with existing or pending regulation that is consistent with the purposes of H&S Code Section 25253.

## **Selection Criteria to determine Chemicals of Concern and to identify product/chemical combinations for near-term DTSC regulatory action under Health & Safety Code Section 25253**

### (1) Threat to human health and the environment, considering both hazard and exposure.

- (a) Extent to which the chemical or chemical ingredient exhibits one or more hazard traits
- (b) Potential for and extent of human or environmental exposure
- (c) Exposure trends
- (d) Statutorily required consideration:
  - The volume of the chemical in commerce in this state.

Statewide exposure is unnecessary for listings. The Department may list on the basis of:

- a. Potential effects on sensitive subpopulations.
- b. Potential effects on sensitive environmental habitats or sensitive species
- c. Exposures that occur regionally (rather than statewide)

Definition: Sensitive subpopulations are human populations or ecosystems or environmentally or economically important species that may be harmed by a chemical of concern even though the general population or other ecosystems or species may not be harmed.

*Explanatory note: Examples of sensitive human subpopulations include infants, children, elderly, pregnant women, and people with cardiovascular disease. Examples of environmentally or economically important species are threatened and endangered species, a keystone species in a particular habitat, and livestock.*

### (2) Extent of Externalized Costs

Definition: Externalized costs are costs associated with the lifecycle of a consumer product that are not included in the price of the consumer product

*Explanatory note: Examples of externalized costs are healthcare costs, disposal costs, costs for cleanup and abatement for products that are dispersed into the environment, and costs for treatment to remove product-related pollution from wastewater and/or urban runoff.*

(3) Availability of viable safer alternative chemicals, chemical ingredients, or consumer products

(4) Information received from the public

*Explanatory note: Examples of the types of information from the public that may inform prioritization (other than information regarding the first three criteria) are urgency, timeframes for implementation of changes to the product, manufacturer plans (e.g., commitment to product reformulation or product withdrawal), reformulation costs, barriers to reformulation, opportunities for coordination with actions by others, schedules for related activities, demonstrated public interest, and ongoing or anticipated actions by other regulatory programs.*

**General notes**

It is not scientifically feasible to develop a quantitative prioritization system that compares differing environmental hazards, exposures, endpoints, and the other considerations listed above, because the nature of available information for chemicals, chemical ingredients, and products will be different depending on the history of the chemical, the use pattern of the chemical, and the relevant exposure endpoints. For this reason, decisions should be made on the basis of a weight-of-evidence assessment rather than a quantitative prioritization system.

The list of Chemicals of Concern may include chemicals or chemical ingredients that are not among those in the list of products identified for near-term regulation under H&S Code Section 25253. For example, DTSC could list all PBTs and CMRs as chemicals of concern even if it only selects a few products containing these chemicals for initial regulation under H&S Code Section 25253. In this manner, DTSC can signal the market that these chemicals may be topics for future product-specific regulatory actions and that they may be the focus of data collection activity.

The Chemicals of Concern selection process (including petitions and other public information solicitation and interagency consultations) should not be separated from the product prioritization process. This ensures that:

- the selection of Chemicals of Concern is grounded by the real-world context of consumer product design and use patterns
- DTSC has the ability to address all types of pollution problems
- widespread, costly problems caused by pollutants that are not particularly toxic to humans (e.g., copper in vehicle brake pads) and products that cause significant local hazards (e.g., certain mobile home toilet deodorizer chemicals that cause septic system operational failure) can be tackled in a timely manner
- when common chemicals (e.g., copper) are listed due to a pollution problem from a specific class of products, manufacturers and retailers can have confidence that other products containing a chemical (e.g., copper pipe and wiring) are unlikely to be subject to regulation



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April 25, 2011

Green Ribbon Science Panel  
Subgroup 2: Products of Concern  
Implementation of AB 1879 (Feuer, D-LA)

Prepared by Mike Wilson, PhD, MPH  
Associate Director for Integrative Sciences  
Berkeley Center for Green Chemistry  
Center for Occupational and Environmental Health

This note represents the views of panel member Mike Wilson as an individual and as a research scientist employed by the University of California. These views do not necessarily reflect the views of the Center for Occupational and Environmental Health, the Berkeley Center for Green Chemistry, the UC Berkeley School of Public Health, the University of California, Berkeley, or the Regents of the University of California.

\* \* \* \* \*

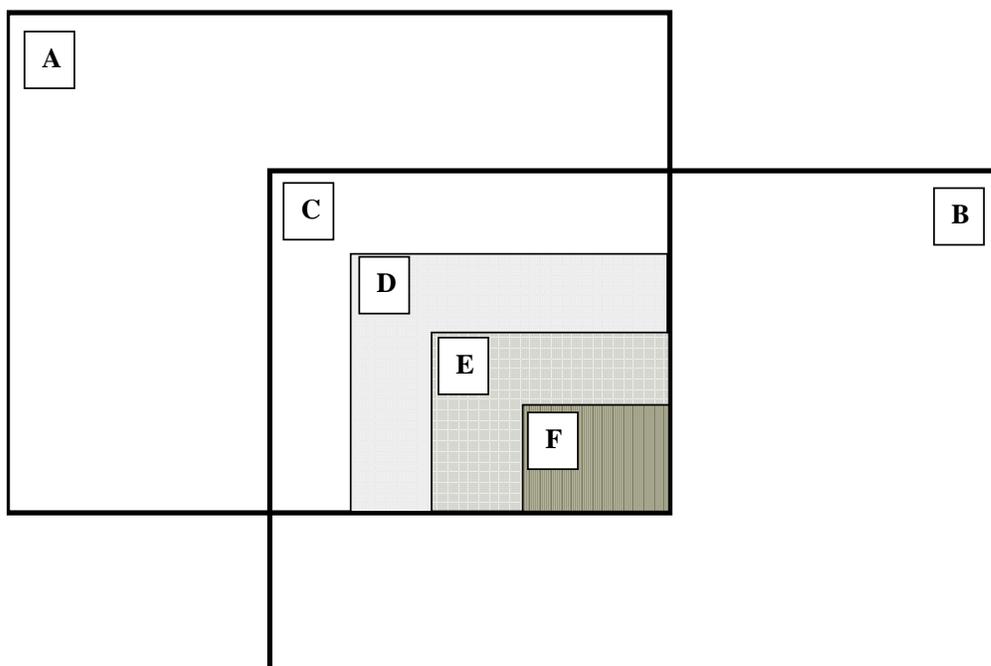
This note proposes that California will need two Paths to effectively implement AB 1879. The goal of these two *paths* is to establish an effective *process* for identifying, prioritizing, and taking action on chemicals and products of concern:

- Path 1
  - This Path is to catalog, prioritize and take action on products and pollutants for which there is sufficient information today and which pose a recognized health or environmental threat.
  - The highest priority products in Path 1 would be those for which safer alternatives exist. Copper-containing brake pads are a good example of products for high priority action under Path 1.
- Path 2
  - This Path is to identify, prioritize and take action on products for which there is poor hazard and exposure information; for example, we don't know if the product is sold in California, we don't know the identity of ingredients in the product, and if we did know, we do not have a system for classifying those ingredients and products into risk classes. Most products on the market fall into this Path 2.

The note focuses on Path 2. Other Subgroup 2 members have proposed elements of Path 1. These recommendations are not comprehensive, but they provide a means of getting started, based on the best available information that companies could readily provide. This information should be requested by DTSC as a *proactive* action by companies selling products in California; that is, it would not be manageable for DTSC to make individual contact with companies selling products in California as a means of gathering basic information.

Path 2 is illustrated in Figure 1. Boxes A through F are described in this note.

*Figure 1. Schematic of (A) chemicals in commerce, (B) products in commerce, (C) products of concern, which contain chemicals of concern, (D) products of concern sold in California, (E) priority products sold in California, (F) high priority products sold in California.*



### **Box A**

*Title:* Chemicals in commerce.

This square represents the TSCA inventory of 82,000 chemicals that are registered for commerce in the U.S. Of these, 8,282 are produced or imported at 10,000 pounds or more per year, and 2,943 are produced or imported at more than one million pounds per year (See Table 1). Some of these chemicals are present in finished products, some are used only in industrial processes. These figures are dated but are the most recently compiled by EPA in this format.

*Key Problem:* Due to the TSCA Data Gap, DTSC does not have information on the hazardous properties, use profiles, or exposure potential of most chemicals in the TSCA inventory.

*Recommendation:*

- To start, designate the substances listed in Table 2 as “California Chemicals of Concern.” This list of substances will be cataloged in a searchable database known as the Berkeley Public Library of Materials (Plum) beginning in the summer 2011. This database will consist of about 3,000 chemicals.
- Defer to OEHHA in identifying the most important chemical substances within these lists.

- In subsequent steps, DTSC should defer to OEHHA’s hazard traits database (developed under SB 509) to more comprehensively identify both new and existing chemicals of concern.

Table 1. Distribution of chemicals produced or imported in the U.S. in 2001, as reported under the 2002 TSCA Inventory Update Rule.\*

Distribution of chemicals produced or imported in the U.S.			
	U.S. production & import range, lbs	Number of chemicals in the production range	Percentage of chemicals in the production range
<b>Non-HPV</b>	10K to 500K	4,670	56%
	>500K to 1M	669	8%
	>1M to 10M	1,548	19%
	>10M to 50M	577	7%
<b>HPV</b>	>50M to 100M	153	2%
	>100M to 500M	273	3%
	>500M to 1B	77	9%
	>1B	315	4%
Total pounds reported		15,208,921,689,779	
Total HPV pounds		15,207,877,185,511	
HPV as percent of total		99.99%	

\* Chemicals produced or imported at less than 10,000 pounds per year are not subject to reporting under the Inventory Update Rule except under certain conditions, such as an order under Section 5(e). HPV chemicals constitute about 35% of the *number* of chemicals produced or imported at 10,000 pounds or more per year, but over 99% by *volume*, according to Inventory Update Rule reporting data.

Table 2. Potential list of “Chemicals of Concern Known to California”

- US NIOSH Carcinogen List
- US NTP 11th Report on Carcinogens
- International Agency for Research on Cancer (IARC) Monographs - carcinogen classifications
- US EPA Integrated Risk Information System (IRIS) - carcinogen classifications
- California Proposition 65 List: Chemicals known to the state to cause cancer or reproductive toxicity
- European Commission Endocrine Disruptor Database
- Canada (CEPA) Domestic Substances List (Priority chemicals)
- ECHA Candidate List of Substances of Very High Concern for Authorisation under REACH
- US EPA PBT Chemical Program: Priority PBTs
- US EPA Toxic Release Inventory PBT Chemical List
- Washington State PBT List
- OSPAR Chemicals for Priority Action
- OSPAR Chemicals of Possible Concern
- UNEP Stockholm Convention on Persistent Organic Pollutants
- EC Joint Research Centre PBT List
- Grandjean & Landrigan, list of neurotoxins from “Developmental neurotoxicity of industrial chemicals”
- US NTP CERHR - neuro/developmental toxicant evaluations
- CDC Fourth National Report on Human Exposure to Chemicals (2009)
- Annex VI to Regulation (EC) No 1272/2008 - EU implementation of GHS Classifications
- Japan NITE GHS Classifications
- Canada (CEPA) Schedule 1 Toxic Substances List

- REACH Annex XVII: Restricted substances
- REACH Annex XIV: List of substances subject to authorisation
- Oregon Priority Persistent Pollutant List
- US EPA National Waste Minimization Program Priority Chemicals
- AOEC Exposure Code List - asthmagens
- International Chemical Secretariat SIN List 1.1, v 2.0 coming soon
- European Trade Union Confederation Priority List v 2.1

### **Box B**

*Title:* Products in commerce.

This box represents the millions of products on the market in the U.S.

### **Box C**

*Title:* Products of concern, which contain “California Chemicals of Concern.” These are products sold in the U.S. but not necessarily sold in California. DTSC would not gather information on these.

### **Box D**

*Title:* Products of concern sold in California. These are products that contain “California Chemicals of Concern” in x% and are sold in California.

*Key Problem:* DTSC does not currently have access to this information. Without this information, it is not possible to effectively implement AB 1879.

*Recommendation:*

- To start, require that companies that sell products in California that contain x% of “California Chemicals of Concern” report electronically to DTSC the following information:
  - Identity of the product by brand name
  - The identity and proportion of “California Chemical(s) of Concern” in the product
  - The number of units of product(s) intended for sale in California
  - The intended use(s) of the product(s)
  - The expected end-of-life disposition of the product

### **Box E**

*Title:* Priority products sold in California

*Key Problem:* DTSC does not currently have a means of identifying “priority products” sold in California. The information gathered under “Box D” would provide that information. With this information, DTSC could effectively identify and rank “priority products,” using the kinds of criteria listed here:

*Recommendation:*

- The definition of “priority products” should include one or more of the following, for example:
  - Products that contain >x% California Chemicals of Concern, in combination or as a single substance

- Products that contain >x% California Chemicals of Concern and are sold at >y pounds per year in California
- Products that contain >x% California Chemicals of Concern that have been “designated” under California’s Biomonitoring Program
- Formulated products that contain >x% California Chemicals of Concern and are intended to be dispersed from the container as an aerosol
- Products for which there is information to suggest that California Chemicals of Concern would likely come in contact with infants, children, or women of childbearing age.

DTSC should develop the criteria for designating “priority products” in consultation with OEHHA, other Boards, Departments, and Offices, and the GRSP. DTSC should address Confidential Business Information (CBI) issues by making some information inaccessible to the public. DTSC should place as much information into the public domain as possible. This process is similar to that of the Swedish Product Registry, which has been gathering this kind of information for several decades.

**Box F**

Title: “High priority products” sold in California

Key Problem: DTSC does not presently have a means of identifying “high priority products” sold in California. The information gathered under Box D would be necessary to take this step, but additional steps would be needed to determine whether or not safer alternatives exist.

Recommendation:

- The definition of “high priority products” should consist of “priority products” for which safer alternatives are reasonably available.
- The “high priority” classification might also include products that pose an imminent public or environmental health threat, regardless of the availability of safer alternatives. It might be necessary for DTSC to designate products as “high priority” in order to motivate investment in the alternative.
- These are products for which DTSC should take immediate action. The alternatives should be subject to the same reporting requirements as all products sold in California.

\* \* \* \* \*

