

Topic #1 --- Chemical Identification and Prioritization
Topic #2 --- Product Identification and Prioritization

CRITERIA AND PROCESS FOR IDENTIFYING CHEMICAL/PRODUCT COMBINATIONS THAT WILL BE SUBJECT TO THE ALTERNATIVES ASSESSMENT AND REGULATORY RESPONSE PROVISIONS OF AB 1879:

- (i) IDENTIFYING (FROM THE UNIVERSE OF CHEMICALS THAT EXHIBIT A HAZARD TRAIT) “PRIORITY CHEMICALS”; AND
- (ii) IDENTIFYING (FROM THE UNIVERSE OF CONSUMER PRODUCTS THAT CONTAIN A PRIORITY CHEMICAL) “PRIORITY PRODUCTS”.

Many subcommittee members recommended that the evaluation and decision-making process for prioritizing chemicals be integrated with the process for prioritizing products. Attachment 1 presents a diagram that is intended to show one possible conceptual interaction between consideration of chemicals, products, and hazard and exposure factors. [Note that this diagram is *not* intended to reflect the full range of factors that might be considered for chemical/product prioritization (e.g., volume, concentration, potency, cumulative impacts, short-term v. long-term impacts, extent/severity of problem, intended uses, use frequency and duration, mode of application, relative contribution to problem, externalized cost impacts, availability of alternatives, weight of evidence, DTSC resources, other existing regulatory programs).]

Primary Decision Points

	<u>Page</u>
I. Chemical List Tiering and Sequencing	3
(1) “Chemicals of Concern” (COC) List	3
(2) “Priority Chemicals” (PC) List	4
II. Product List Tiering and Sequencing	5
(1) “Products under Consideration” (PUC) List	5
(2) “Priority Products” List	6
III. Prioritization Criteria	8
(1) Chemical Prioritization Criteria	8
(2) Product Prioritization Criteria	9
(3) Options for Using the Criteria to Prioritize Chemicals/Products	10
IV. Decision-Making Process	13

List of Attachments

- 1** --- Iterative / Interactive Consideration of Chemicals & Products and Hazard & Exposure Concerns
- 2** --- Example List of Authoritative Body Chemicals Lists
- 3** --- California Air Resources Board (CARB) Decision-Making Process for VOC Limit Regulations
- 4** --- Globally Harmonized System (GHS) Model
- 5** --- U.S. EPA Design for the Environment Alternatives Assessment Matrix
- 6** --- German Federal Environmental Agency's Five Step Evaluation Matrix
- 7** --- Washington State's Children's Safe Product Act Model
- 8** --- Scoring Matrix Example
- 9** --- Product Screening and Decision-Making Process Flowchart

NOTE: The options presented on the following pages (including Attachments 1 through 9) are intended to present DTSC's understanding of the primary suggestions offered by one or more members of GRSP Subcommittees #1 and #2. Many of the options presented are not mutually-exclusive. Members of the subcommittees or the GRSP may wish to offer variations on these options. These options do not represent DTSC's proposals or perspective on these issues.

SECTION I: CHEMICAL LIST TIERING AND SEQUENCING

Objective: To specify the procedural steps for developing the prioritized chemicals list(s).

(1) “CHEMICALS OF CONCERN” (COC) LIST

(If there are two lists, the COC list would be the larger list of which the smaller PC list is a subset.)

OPTION I(1) A --- The COC list could be defined in the regulations to include all chemicals that exhibit an OEHHA-identified hazard trait, and that meet one of the following criteria:

- (i) The chemical is listed on any of a list of authoritative bodies lists as of the effective date of the regulations. (See ***Attachment 2*** for a possible list of lists.)
- (ii) The chemical is not listed pursuant to (i) above, but “reliable information” shows that the chemical exhibits any of a list of hazard traits not covered by the list of lists. (Possible examples: neurotoxicants, developmental toxicants, astmagens, endocrine disruptors, environmental PBTs.)
- (iii) The chemical is not currently listed on any of the listed lists, but is subsequently added to one of the lists because it exhibits one of a list of hazard traits. (Possible examples: CMRs, PBTs, neurotoxicants, developmental toxicants, astmagens, endocrine disruptors, environmental PBTs.)

OPTION I(1) B --- The COCs could be specifically listed in the regulations, capturing the same chemicals that would be captured under definitional criteria (i) and (ii) described in Option I(1)A. *NOTE: This option would require the adoption of revised regulations every time the list is updated.*

OPTION I(1) C --- DTSC could develop the COC list using criteria and a process to be set forth in the regulations. [Refer to the options below (see pages 8-13) pertaining to listing criteria and decision-making process.]

If this option was chosen, the COC list could be developed using the same criteria as used for the smaller PC list, or using a subset of the PC criteria. Another possibility would be for the COC list to be developed using a purely narrative standard, and then use a more structured process to develop the smaller PC list.

OPTION I(1) D --- There could be no COC list --- only a PC list (see page 4 below) would be developed. In this case, criteria (i) and (ii) described in Option I(1)A could be used as an initial screening in the process of identifying chemicals for possible inclusion on the PC list.

SECTION I: CHEMICAL LIST TIERING AND SEQUENCING (con't)

(2) "PRIORITY CHEMICALS" (PC) LIST

(If there are two lists, the PC list would be developed as a subset of the larger COC list. The two lists could be developed concurrently or sequentially.)

OPTION I(2) A --- DTSC could develop the PC list using criteria and a process to be set forth in the regulations. *(The criteria for developing the chemical list(s), and the decision-making process for applying the criteria, are explored below on pages 8-13.)*

OPTION I(2) B --- The regulations, in addition to specifying the criteria and process for identifying PCs in the future through the listing process, could also identify as the initial list of PCs specific chemicals that meet the following criteria:

- (i) There is strong evidence that the chemical poses a potential for public health harm, harm for sensitive subpopulations, and/or environmental harm. This would include chemicals that have been identified for public health or environmental action by other government agencies based on their mandates; and
- (ii) Chemicals for which there are known safer chemical or design alternatives.

Possible examples include: lead, mercury, chlorinated hydrocarbon solvents, formaldehyde, dibutyl phthalate, brominated flame retardants, and bisphenol A. If this approach is taken, consideration could be given to specifying in the regulations the deadline for adopting a more expansive list of PCs. *NOTE: This option, along with Options II(2)B and II(2)C, would provide a "fast track" for addressing already known problems, as has been recommended by various GRSP members.*

OPTION I(2) C --- The regulations could also specify a schedule for evaluating and making a listing determination for chemicals, grouped by classification or other factors. Examples of factors that could be used, singularly or in combination, to group chemicals for such a scheduling approach include:

- (i) Type of hazard trait (e.g., carcinogenicity, developmental toxicity, reproductive toxicity, endocrine toxicity, epigenetic toxicity, genotoxicity, dermatotoxicity, neurotoxicity, respiratory toxicity, bioaccumulation, environmental persistence, global warming potential),
- (ii) Presence of the chemical in human or environmental monitoring data,
- (iii) Presence of the chemical in indoor air or dust,
- (iii) Chemicals known to present particular concern for sensitive subpopulations or environmental receptors,
- (iv) Chemicals known to be widely and frequently used in products applied as an aerosol or directly to the human body,
- (v) Chemicals known to be widely used in products that sensitive subpopulations are likely to come in contact with,
- (vi) High volume chemicals,
- (vii) Chemicals for which there are known safer alternatives,
- (viii) Chemicals known to significantly contribute to externalized costs (e.g., government costs and public health costs), including chemicals that are the basis for products being banned from MSW landfills.

SECTION II: Product LIST TIERING AND SEQUENCING

Objective: To specify the procedural steps for developing the prioritized products list(s).

(1) “PRODUCTS UNDER CONSIDERATION” (PUC) LIST

(If there are two lists, the PUC list would be the larger list of which the smaller Priority Products list is a subset.)

OPTION II(1) A --- The PUC list could be defined in the regulations to include all consumer products in the California marketplace that contain a PC.

OPTION II(1) B --- DTSC could develop the PUC list using criteria and a process to be set forth in the regulations. [Refer to the options below (see pages 8-13) pertaining to listing criteria and decision-making process.]

If this option was chosen, the PUC list could be developed using the same criteria as used for the smaller Priority Products list, or using a subset of the Priority Products criteria. Another possibility would be for the PUC list to be developed using a purely narrative standard, and then use a more structured process to develop the smaller Priority Products list.

OPTION II(1) C --- There could be no PUC list --- only a Priority Products list (see page 6 below) would be developed.

NOTE: *While many subcommittee members have expressed support for having two chemicals lists (so as to provide “early notice” to manufacturers, consumers and others), it is not clear (based on discussions to date) if GRSP members see value in having two products lists.*

SECTION II: Product LIST TIERING AND SEQUENCING (con't)

(2) "PRIORITY PRODUCTS" LIST

(If there are two lists, the Priority Products list would be developed as a subset of the larger PUC list. The two lists could be developed concurrently or sequentially.)

OPTION II(2) A --- DTSC could develop the Priority Products list using criteria and a process to be set forth in the regulations. *(The criteria for developing the product list(s), and the decision-making process for applying the criteria, are explored below on pages 8-13.)*

OPTION II(2) B --- The regulations, in addition to specifying the criteria and process for identifying Priority Products in the future through the listing process, could also identify as the initial list of Priority Products specific products that meet the following criteria:

- (i) There is strong evidence that the PC in the product poses a potential for public health harm, harm for sensitive subpopulations, and/or environmental harm. This would include chemicals/products that have been identified for public health or environmental action by other government agencies based on their mandates; and
- (ii) Chemicals/products for which there are known safer chemical or design alternatives.

If this approach is taken, consideration could be given to specifying in the regulations the deadline for adopting a more expansive list of Priority Products. *NOTE: This option, along with Options I(2)B and II(2)C, would provide a "fast track" for addressing already known problems, as has been recommended by various GRSP members.*

OPTION II(2) C --- Concurrently with developing and adopting the PC list, DTSC may, on its own initiative or in response to a petition (with adequate supporting information), list as Priority Products specific products that contain a PC and that meet the following criteria:

- (i) There is strong evidence that the PC/product poses a potential for public health harm, harm for sensitive subpopulations, and/or environmental harm. This would include chemicals/products that have been identified for public health or environmental action by other government agencies based on their mandates; and
- (ii) Chemicals/products for which there are known safer chemical or design alternatives.

If this approach is taken, consideration could be given to specifying in the regulations the deadline for adopting a more expansive list of Priority Products. *NOTE: This option, along with Options I(2)B and II(2)B, would provide a "fast track" for addressing already known problems, as has been recommended by various GRSP members.*

SECTION II: Product LIST TIERING AND SEQUENCING (con't)

(2) "PRIORITY PRODUCTS" LIST (con't)

OPTION II(2) D --- Also concurrently with developing and adopting the PC list, DTSC may develop of list of product categories (encompassing products that contain a PC) and specify a schedule for evaluating products in each category for possible listing as a Priority Product. Examples of factors that could be used, singularly or in combination, to group products for such a scheduling approach include:

- (i) Relative significance of the product's contribution as a source of PC exposures,
- (ii) Presence of the PC in the product in human or environmental monitoring data,
- (iii) Presence of the PC in the product in indoor air or dust,
- (iv) Products containing PCs known to present particular concern for sensitive subpopulations or environmental receptors,
- (v) Relative concern associated with the wide and frequent application of the product, ranging from direct application to the human body to use as an aerosol to hard surface application with likelihood of runoff,
- (vi) Products that sensitive subpopulations are likely to come in contact with,
- (vii) Products/chemicals for which there are known safer alternatives,
- (viii) Products/chemicals known to significantly contribute to externalized costs (e.g., government costs and public health costs), including products containing banned from MSW landfills.

SECTION III: Prioritization Criteria

Objective: To identify the criteria/factors that will be used to identify and prioritize chemical and products for listing.

(1) CHEMICAL PRIORITIZATION CRITERIA

(The factors listed under each category are not listed in any particular order.)

Menu of Chemical Hazard-Related Factors:

- 1) Physical state of chemical
- 2) Type of hazard trait
- 3) Extent to which chemical exhibits one or more hazard traits
- 4) Toxicity
- 5) Potency
- 6) Affect on sensitive subpopulations and environmental receptors
- 7) Short-term v. long-term effects
- 8) Extent and severity of adverse human health impacts associated with chemical

Menu of Exposure-Related Factors:

- 1) Evidence of exposures to the chemical (e.g., human & environmental monitoring, indoor air & dust monitoring)
- 2) Types of products containing the chemical
- 3) Mode of application of products containing the chemical
- 4) Frequency and duration of use of products containing chemical
- 5) Concentration of chemical in products containing the chemical
- 6) Potential exposure scenarios and pathways for sensitive subpopulations (ingestion, inhalation, dermal absorption)
- 7) Potential exposure scenarios and pathways for sensitive environmental receptors
- 8) Potential for and extent of other human and environmental exposures
- 9) Volume of chemical in commerce (look at TSCA HPV list)
- 10) Likelihood of potential exposures
- 11) Magnitude/extent of potential exposures
- 12) Impact severity of potential exposures

Menu of Other Factors:

- 1) Strength / weight of evidence
- 2) Cumulative exposures / impacts (multiple chemicals with same mode of action in same products & same/similar chemical in multiple products)
- 3) Known viable alternatives for the chemical in uses of concern exist
- 4) Externalized costs on state & local governments, and public health care system

SECTION III: Prioritization Criteria (con't)

(2) PRODUCT PRIORITIZATION CRITERIA

(The factors listed under each category are not listed in any particular order.)

Menu of Exposure-Related Factors:

- 1) Evidence of exposures to the chemical in product (e.g., human & environmental monitoring, indoor air & dust monitoring)
- 2) Product's mode of application (e.g., direct body application, aerosol, hard surface application likely to run off)
- 3) Product frequency and duration of use
- 4) Concentration of chemical in product
- 5) Potential exposure scenarios and pathways (for the chemical in the product) for sensitive subpopulations (ingestion, inhalation, dermal absorption)
- 6) Potential exposure scenarios and pathways (for the chemical in the product) for sensitive environmental receptors
- 7) Potential for and extent of other human and environmental exposures (to the chemical in the product)
- 8) Volume of chemical/product in commerce (for chemicals, look at TSCA HPV list)
- 9) Product's relative contribution to the concerns related to the chemical in the product (e.g., human and environmental exposures, externalized costs)

Menu of Other Factors:

- 1) Hazard-related factors pertaining to the chemical in the product (see list of factors on page 6).
- 2) Strength / weight of evidence
- 3) Cumulative exposures / impacts (multiple chemicals with same mode of action in same products & same/similar chemical in multiple products)
- 4) Known viable alternatives for the chemical/product exist
- 5) Externalized costs to state & local governments, and public health care system

SECTION III: Prioritization Criteria (con't)

(3) OPTIONS FOR USING THE CRITERIA TO PRIORITIZE CHEMICALS/PRODUCTS

OPTION III(3) A

Priority 1 Products

The product meets all of the following criteria:

- There is “credible evidence” that the product contains a PC;
- The PC in the product has been detected in California drinking water, surface water, cord blood, or breast milk;
- The product is intended or is likely to be applied directly to the human body, or applied as an aerosol;
- The product is intended or is likely to be used by, or marketed in California to, sensitive subpopulations; and
- There are readily available safer functionally equivalent alternatives.

Priority 2 Products

The product does not meet the Priority 1 criteria, but does meet all of the following criteria:

- There is “credible evidence” that the product contains a PC;
- The PC has been detected in California drinking water, surface water, cord blood, breast milk, or indoor air or dust; and
- The product has been banned from MSW landfill disposal, or the product is applied to hard surfaces with the likelihood of run off.

OPTION III(3) B

Give highest priority to products meeting the following criteria:

- Products that contain PCs identified as PBTs, including carcinogens; PCs potentially of concern for children’s health because of reproductive or developmental effects; and PCs found in human biomonitoring programs;
- Sensitive subpopulations are likely to use or be exposed to the PC in the product;
- Products that contain the highest concentrations of the PC, and have the highest frequency of use;
- Products that have the highest volume of production and contain the highest concentration of the PC; and
- Products for which there are readily available safer functionally equivalent alternatives.

SECTION III: Prioritization Criteria (con't)

OPTION III(3) C

Use the following factors to prioritize products:

- Threat to human health and the environment, considering both hazard and exposure:
 - Extent to which the chemical exhibits one or more hazard traits
 - Potential for and extent of human or environmental exposure
 - Volume of the chemical in California commerce
 - Potential effects on sensitive subpopulations, environmental habitats or species
- Extent of externalized costs:
 - Health care costs
 - Disposal costs
 - Cleanup and abatement costs for release of the PC
 - Costs for treatment to remove PC pollutants from wastewaters or urban runoff
- Availability of safer alternatives for the PC or the product
- Information received from the public:
 - Sense of urgency
 - Time needed to implement alternatives
 - Reformulation costs
 - Barriers to reformulation
 - Public interest
 - Actions by other regulatory agencies

OPTION III(3) D

Give highest priority to products meeting the following criteria:

- Products that contain PCs above a specified concentration;
- Products that are sold above a specified volume per year in California;
- Products that contain PCs that have been “designated” under California’s Biomonitoring Program;
- Formulated products that are intended to be dispersed from the container as an aerosol, applied directly to the human body, or applied to hard surfaces with the likelihood of run off;
- Products that are widely and frequently used;
- Products for which there is information to suggest that the PC would likely come in contact with sensitive subpopulations or environmental receptors; and
- A safer alternative is reasonably available.

SECTION III: Prioritization Criteria (con't)

OPTION III(3) E

Give highest priority to products meeting the following criteria:

- The product is a “high” contributor to the human health or environmental concern associated by the PC in the product;
- The product is a “high” contributor to the externalized costs associated by the PC in the product; and
- There is a readily available safer functionally equivalent alternative that is technologically and economical feasible.

OPTION III(3) F

Give highest priority to chemicals exhibiting hazard traits meeting the following criteria:

- Endpoints that pertain to sensitive subpopulations;
- Endpoints that are severe and delayed;
- There is evidence of widespread exposure to substances that have the hazard trait; and
- There is no or a low threshold for toxicity (carcinogenicity, developmental toxicity, reproductive toxicity, endocrine toxicity, epigenetic toxicity, genotoxicity, bioaccumulation, environmental persistence)

SECTION IV. DECISION-MAKING PROCESS

Objective: To determine that process that will be used to prioritize and list chemicals and products using the criteria addressed in Section III.

NOTE: It is possible that different approaches (such as those listed below) could be used for each of the two chemicals lists and two products lists.

OPTION IV A --- Use a “narrative” prioritization standard, for example:

- DTSC shall give highest priority to chemicals/products meeting the following criteria ... OR
- DTSC shall prioritize chemicals/products based on consideration of the following factors ...

For other examples, see Options III(3) (A)-(F) on pages 10-12, and **Attachment 3** which summarizes the decision-making process used by the California Air Resources Board for its VOC limit regulations.

OPTION IV B --- Use thresholds to prioritize chemicals and/or products. Possible examples include:

- Setting thresholds based on the attributes of available safer alternatives.
- Using the Globally Harmonized System (GHS) model (see **Attachment 4**) to apply thresholds to group chemicals/products into priority “bins”.
- Using an approach similar to the U.S. EPA’s Design for the Environment model (see **Attachment 5**).

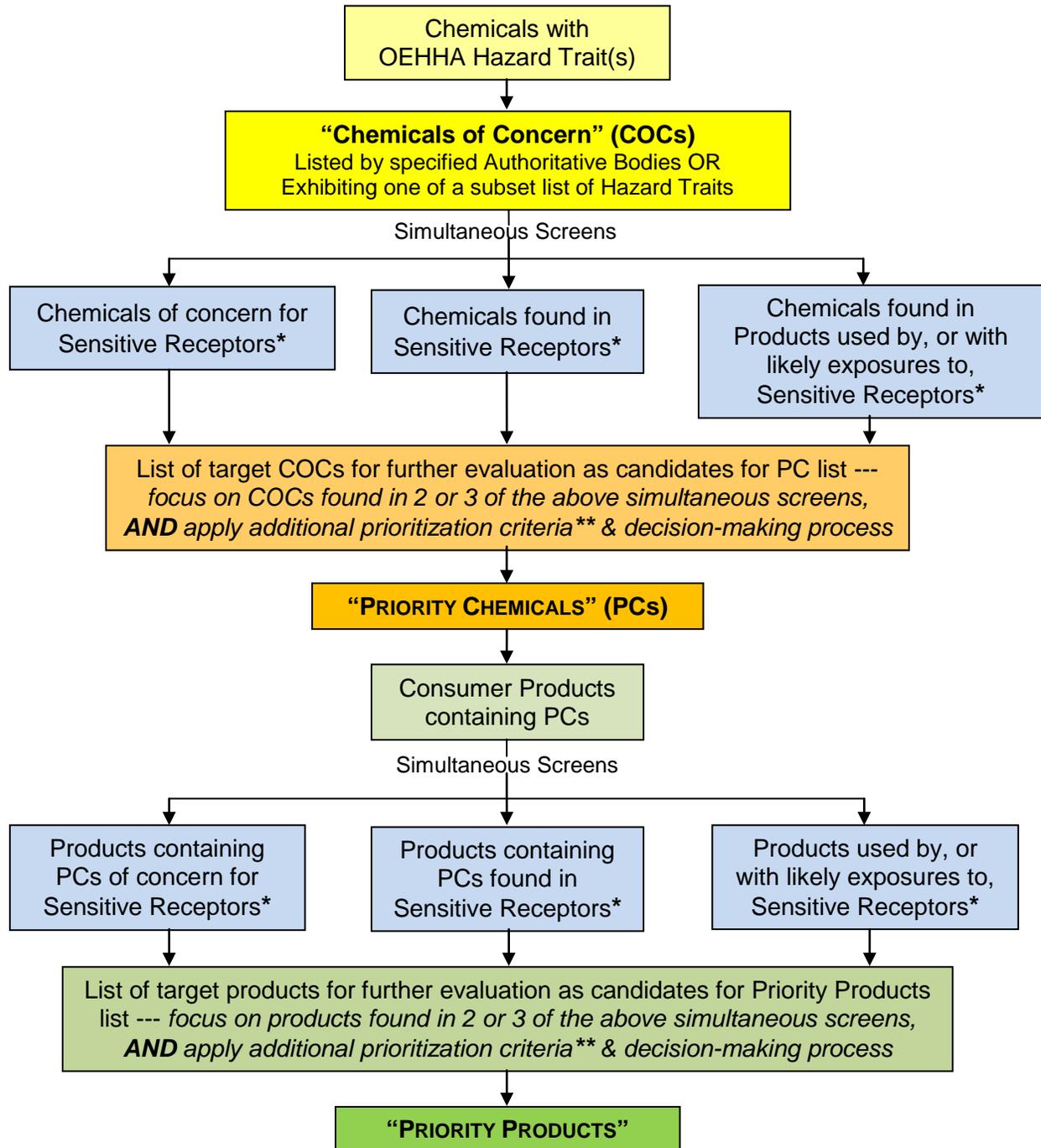
OPTION IV C --- Use a matrix or other structured approach. Possible examples include:

- A “sieving” process, such as the following example, to prioritize chemicals (something similar could be designed for products):
 - 1) Start by looking only at chemicals that exhibit CMRs, PBTs, and perhaps other specified hazard traits.
 - 2) Select from the list created in step 1), only “high” potency chemicals.
 - 3) Finally, apply exposure potential factors to the list created in step 2).
- The German Federal Environmental Agency’s Five-Step Evaluation Matrix (see **Attachment 6**) to prioritize chemicals
- A system based on Washington State’s Children’s Safe Product Act model (see **Attachment 7**)
- A “scoring” chart such as the example provided in **Attachment 8**.
- A screening and decision-making process such as the example provided in **Attachment 9**.

Attachment 1 ---Conceptual Diagram

(Not intended to represent a DTSC proposal or perspective)

Iterative / Interactive Consideration of Chemicals & Products and Hazard & Exposure Concerns



* "Sensitive Receptors" include: sensitive subpopulations, environmental habitats & species. After the program has addressed most/all sensitive receptor concerns, the screens and other criteria would be broadened to address chemicals/products of concern for other receptors.

** This diagram is only intended to show one possible conceptual interaction between consideration of chemicals, products, and hazard and exposure factors. It is *not* intended to reflect the full range of factors that might be considered for chemical/product prioritization (e.g., volume, concentration, potency, cumulative impacts, short-term v. long-term impacts, extent/severity of problem, intended uses, use frequency and duration, mode of application, relative contribution to problem, externalized cost impacts, availability of alternatives, weight of evidence, DTSC resources, other existing regulatory programs).

Attachment 2

Example List of Authoritative Body Chemicals Lists

- 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

**Overview of the Decision-Making Process Used by CARB
to Develop the List of Consumer Products for the VOC Limit Regulations**

(1) *The Product's Contribution to VOC Emissions*

The California Air Resources Board's (CARB) prioritization process is driven by data from its emissions inventory database, stakeholder surveys, and staff research and data analysis. This information is used to help CARB identify the largest sources of VOC emissions, evaluate reformulation options, and determine if there are existing low VOC alternatives. Specifically, the surveys and information include information about:

- Formulations of consumer products, including complete speciation of VOCs, low vapor pressure VOC (LVP-VOC) solvents, and key exempt ingredients.
- Total volumes of inorganic and other compounds.
- Information on sales, product form, customer types, and company size and economics.

(2) *Availability of Viable Alternatives*

Once initial product categories are identified, CARB evaluates alternatives for reformulation. This analysis includes:

- Evaluating the range of VOC content in a given product category. Products with lower VOC content that have reasonable market share may serve as an initial basis for determining feasible VOC limits.
- If all products reported have similar VOC content, CARB determines if there are technologies that can be used to lower VOC content. This effort relies in part on stakeholders presenting potential reformulation options.
- CARB also sets "future second tier effective limits" as well as "near term effective limits" on VOC content. This approach is used when CARB determines there is the possibility for technology transfer within a given timeframe in the future from another source category or an emerging technology requiring further development.

(3) Other Considerations

- Generally, CARB seeks to regulate product categories for which it is determined, based on available information, that the setting of VOC limits would achieve significant emission reductions and that such limits are commercially and technologically feasible.
- Additionally, early in the program, CARB identified high priority product categories where: they could make a data-supported argument; there was general stakeholder support for regulating the product category; and there were known reformulation options or technology under development that would be commercialized in a predictable timeframe.
- As reductions needed to meet SIP commitments become more difficult to achieve, product categories that do not necessarily have the highest VOC emissions, but for which there are identified options for reformulation, are also selected.

Overview of 10 Human Health Endpoints

GHS Health Hazard Classes

GHS Hazard Category¹

<u>1 Acute Toxicity, Oral</u>	1	2	3	4	5
<u>1 Acute Toxicity, Dermal</u>	1	2	3	4	
<u>1 Acute Toxicity, Inhalation</u>	1	2	3	4	
<u>2 Skin Corrosion/Irritation</u>	1A	1B	1C	2	3
<u>3 Serious Eye Damage/Eye Irritation</u>	1	2a	2b		
<u>4 Respiratory Sensitization</u>	1				
<u>4 Skin Sensitization</u>	1				
<u>5 Germ Cell Mutagenicity</u>	1A	1B	2		
<u>6 Carcinogenicity</u>	1A	1B	2		
<u>7 Reproductive Toxicity</u>	1A	1B	2		Effects via Lactation
<u>8 STOT Single Exposure</u>	1	2	3		
<u>9 STOT Repeated Exposure</u>	1	2			
<u>10 Aspiration Hazard</u>	1	2			

¹ Categories are based on concentration limits in mixtures.

Overview of 16 Physical-Chemical Endpoints

GHS Hazard Class

GHS Hazard Category ¹

Explosives

Unstable Explosives	Div 1.1	Div 1.2	Div 1.3	Div 1.4	Div 1.5	Div 1.6
1	2					
1	2					
1						

Flammable Gases

Flammable Aerosols

Oxidizing Gases

Pressurized Gases

Compressed Gases

Liquefied Gases

Refrigerated Liquefied Gases

Dissolved Gases

Flammable Liquids

Flammable Solids

Self-reactive Substances & Mixtures

Pyrophoric Liquids

Pyrophoric Solids

Self-heating Substances & Mixtures

Water Reactive → Flammable Gases

Oxidizing Liquids

Oxidizing Solids

Organic Peroxides

Corrosive to Metals

1												
1												
1												
1												
1	2		3									
1	2											
Type A	Type B	Type C	Type D	Type E	Type F	Type G						
1												
1												
1	2											
1	2		3									
1	2		3									
1	2		3									
Type A	Type B	Type C	Type D	Type E	Type F	Type G						
1												

¹ Categories based on concentration limits in mixtures

6. Appendix

Table A1. Alternatives Assessment Criteria Quick Reference

Human Health Effects					
Acute Mammalian Toxicity	Very High	High	Moderate	Low	
Oral LD50 (mg/kg)	≤ 50	> 50 - 300	> 300 - 2000	> 2000	
Dermal LD50 (mg/kg)	≤ 200	> 200 - 1000	> 1000 - 2000	> 2000	
Inhalation LC50 (vapor/gas) (mg/L)	≤ 2	> 2 - 10	> 10 - 20	> 20	
Inhalation LC50 (dust/mist/fume) (mg/L)	≤ 0.5	> 0.5 - 1.0	> 1.0 - 5	> 5	
Carcinogenicity		High	Moderate	Low	
		Positive results	Equivocal results	Negative studies and no structural alerts	
Mutagenicity/Genotoxicity		High	Moderate	Low	
		Positive results	Equivocal results	Negative for chromosomal aberrations and gene mutations, and no structural alerts. Adequate data available.	
Reproductive and Developmental Toxicity		High	Moderate	Low	
Oral (mg/kg/day)		< 50	50 - 250	> 250	
Dermal (mg/kg/day)		< 100	100 - 500	> 500	
Inhalation (vapor, gas, mg/L/day)		< 1	1 - 2.5	> 2.5	
Inhalation (dust/mist/fume, mg/L/day)		< 0.1	0.1 - 0.5	> 0.5	
Neurotoxicity		High	Moderate	Low	
Oral (mg/kg-bw/day)		< 10	10 - 100	> 100	
Dermal (mg/kg-bw/day)		< 20	20 - 200	> 200	
Inhalation (vapor/gas) (mg/L/6h/day)		< 0.2	0.2 - 1.0	> 1.0	
Inhalation (dust/mist/fume) (mg/L/6h/day)		< 0.02	0.02 - 0.2	> 0.2	
Repeated Dose Toxicity		High	Moderate	Low	
Oral (mg/kg-bw/day)		< 10	10 - 100	> 100	
Dermal (mg/kg-bw/day)		< 20	20 - 200	> 200	
Inhalation (vapor/gas) (mg/L/6h/day)		< 0.2	0.2 - 1.0	> 1.0	
Inhalation (dust/mist/fume) (mg/L/6h/day)		< 0.02	0.02 - 0.2	> 0.2	
Sensitization		High	Moderate	Low	
Skin sensitization		High frequency of sensitization in humans and/or high potency in animals (GHS Cat. 1A)	Low to moderate frequency of sensitization in human and/or low to moderate potency in animals (GHS Cat. 1B)	Adequate data available and not GHS Cat. 1A or 1B	
Respiratory Sensitization	For this endpoint, High/Moderate/Low etc. characterizations will not apply. A qualitative assessment of available data will be prepared.				
Irritation/Corrosivity	Very High	High	Moderate	Low	Very Low
Eye Irritation/Corrosivity	Irritation persists for > 21 days or corrosive	Cleaning in 8-21 days, severely irritating	Cleaning in 7 days or less, moderately irritating	Cleaning in less than 24 hrs, mildly irritating	Not irritating
Skin Irritation/Corrosivity	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours	Not irritating
Endocrine Activity	For this endpoint, High/Moderate/Low etc. characterizations will not apply. A qualitative assessment of available data will be prepared.				
Environmental Toxicity and Fate					
Aquatic Toxicity	Very High	High	Moderate	Low	
Acute Aquatic Toxicity (LC50 or EC50) (mg/L)	< 1.0	1 - 10	> 10 - 100	> 100	
Chronic Aquatic Toxicity (LOEC) (mg/L)	< 0.1	0.1 - 1	> 1 - 10	> 10	
Environmental Persistence	Very High	High	Moderate	Low	Very Low
Persistence in water, soil or sediment	Half-life > 180 days or recalcitrant	Half life of 60 - 180 days	Half-life < 60 but ≥ 16 days	Half-life < 16 days OR passes Ready Biodegradability test not including the 10-day window. No degradation products of concern.	Passes Ready Biodegradability test with 10-day window. No degradation products of concern.
Persistence in air (half-life days)	For this endpoint, High/Moderate/Low etc. characterizations will not apply. A qualitative assessment of available data will be prepared.				
Bioaccumulation (BAF / BCF)	Very High	High	Moderate	Low	
	> 100,000	100,000 - 1,000	1,000 - 100	< 100	

Five Step Evaluation Matrix

The German Federal Environmental Agency has developed the Five Step Evaluation Matrix to assist businesses whose production processes may contribute to the contamination of water ecosystems because of the releases of persistence substances.¹⁰ Users can array hazard information and compare alternatives. The tool is similar to the Column Model in that it also defines five risk levels for different hazards as well as use patterns (see Table 3). Users of the Five Step Evaluation Matrix can review the disaggregated data by column and compare alternatives. In addition, the data can be aggregated by weighting the hazards to create a risk index, as follows:

A weighting can be assigned to various contributions to the risk (e.g. persistence = very important = 0.3 = 30% of the total risk). The extent of the risk can be scaled by number from 1-5. Summing up the weighted numbers results in the risk index of a certain substance in a specific application.¹¹

A risk index can be developed for each alternative and these aggregated indices can be compared. It is important to note, however, that transparency is lost when these data are aggregated; therefore, assumptions and decisions made using these indices must be clearly articulated.

Table 3 - Five Step Evaluation Matrix (developed by Ökopol and Fraunhofer for the German Federal Environmental Agency)

Extent of Risk Contribution	Substance Properties					Use Pattern			Risk Index
	Persistence	Bioaccumulation	Aquatic Toxicity	Chronic Toxicity	Mobility	Amt.	Mobilizing Conditions	Indirect Releases	
Very High									
High									
Medium									
Low									
Very Low									
Weighting									

Chemical Assessment and Ranking System (CARS)

The Zero Waste Alliance (ZWA) based in Portland, Oregon developed CARS as a decision support tool for assessing chemicals and planning for elimination or substitution of hazardous materials and processes. The CARS database¹² contains chemicals on State and Federal regulatory lists and other substances known to exhibit characteristics such as carcinogenicity, aquatic toxicity, persistence, bioaccumulation and ecotoxicity. To use the tool, the chemical constituents and associated CAS numbers are identified for products being assessed. Material Safety Data Sheets are utilized to determine hazard properties. The resulting chemical inventory is screened in the CARS database. Chemicals that are associated with any well-documented hazard will be flagged. The user is then

¹⁰ Rossi et al, "Chemical Hazard Assessment: Selecting and Designing for Safer Chemicals", p.6.

¹¹Ahrens, Andreas, Eberhard Bohm, Kerstin Heitmann, and Thomas Hillenbrand, *Guidance for the use of environmentally sound substances*, Ökopol Institute for Environmental Strategies and Fraunhofer Institute for Systems and Innovation Research, project commissioned by the German Federal Environmental Agency, 2003.

¹² CARS can only be accessed through the consulting services of Zero Waste Alliance.

Children's Safe Product Act

Washington Legislation Passed in April 2007

- Limited concentrations of lead, cadmium and phthalates in children's products
- Required identification of chemicals of high concern to children
- Included process on how to identify these chemicals

'High Priority Chemicals' (HPCs):

(From legislation)

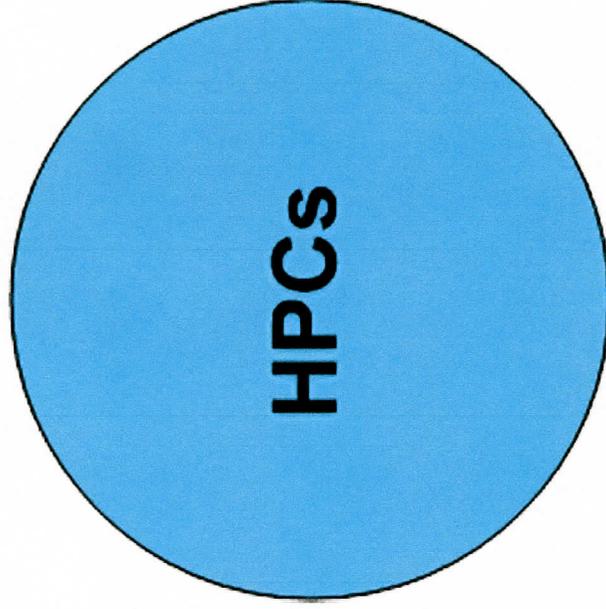
Section 2: Definitions

'High priority chemical' as identified by:

- State agency
- Federal agency
- Accredited research university
- Other scientific evidence deemed authoritative

One or more of the following criteria:

- a) Developmental toxin
- b) Cause:
 - Cancer
 - Genetic damage
 - Reproductive harm
 - Endocrine disruptor
- c) Damage:
 - Nervous system
 - Immune system
 - Organs
 - Other systemic toxicity
- d) PBT
- e) vPvB (very persistent & very bioaccumulative)



HPC Sources:

United States: Federal

EPA TRI PBT Chemicals

EPA VCCEP

Nat. Waste Min. Prg. Priority Chem.

Nat. Tox Prg. Reproduction

Nat. Tox Prg. Carcinogens-Known

Nat. Tox Prg. Carcinogens-Suspected

IRIS Total

IRIS 1986 Category A (known)

IRIS 1986 Category B1 (probable-humans)

IRIS 1986 Category B2 (probable-animal)

IRIS 1986 Category C (possible)

IRIS 1996 Known/likely

IRIS 1999 Carcinogens

IRIS 2005 Suggestive Evidence

IRIS Oral RfD Critical Effects

Other

Grandjean Neurotoxins (developmental toxins)

United States: State

Prop 65-Total

Prop 65 Cancer

Prop 65 Developmental

Prop 65 Female

Prop 65 Male

WA PBTs

International

EU Endocrine Disruptors Cat 1

EU Endocrine Disruptors Cat 2

EU SVHC (Substances of Very High Concern)

EU PBTs

EU Chemicals identified for Risk Assessment

OSPAR Chemicals of Concern

OSPAR 1997 Chems for Priority Action

IARC Group 1 Known Carcinogens

IARC Group 2a Probable Carcinogens

IARC Group 2b Possible Carcinogens

Canadian PBiT list

High Priority Chemicals:

- From authoritative sources
- With specific toxicities

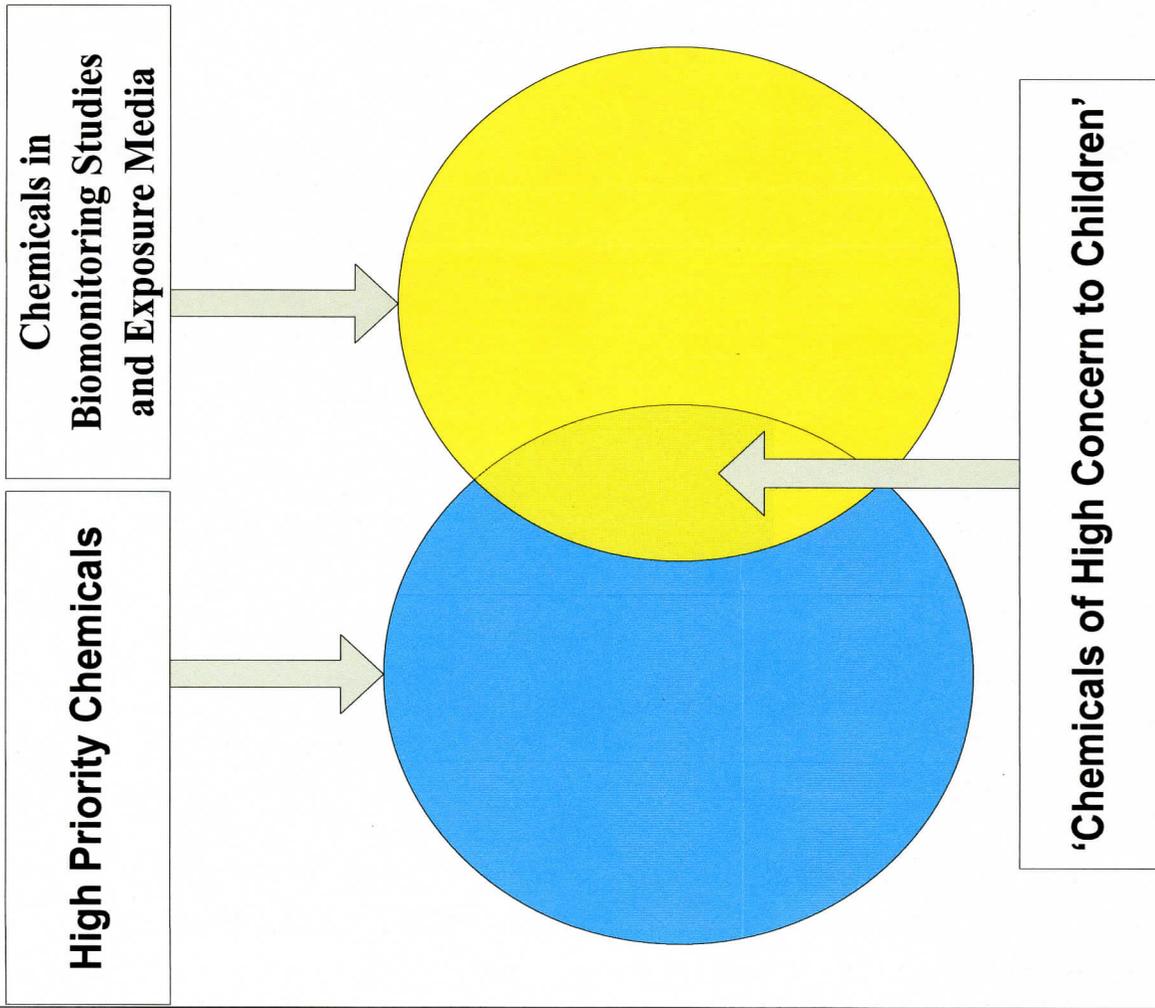
Biomonitoring & Potential Exposure Lists:

Chemicals found in:

- Humans
- Indoor Air and Dust
- Drinking Water
- Products

CHCCs:

- Intersection of two groups



Attachment 8

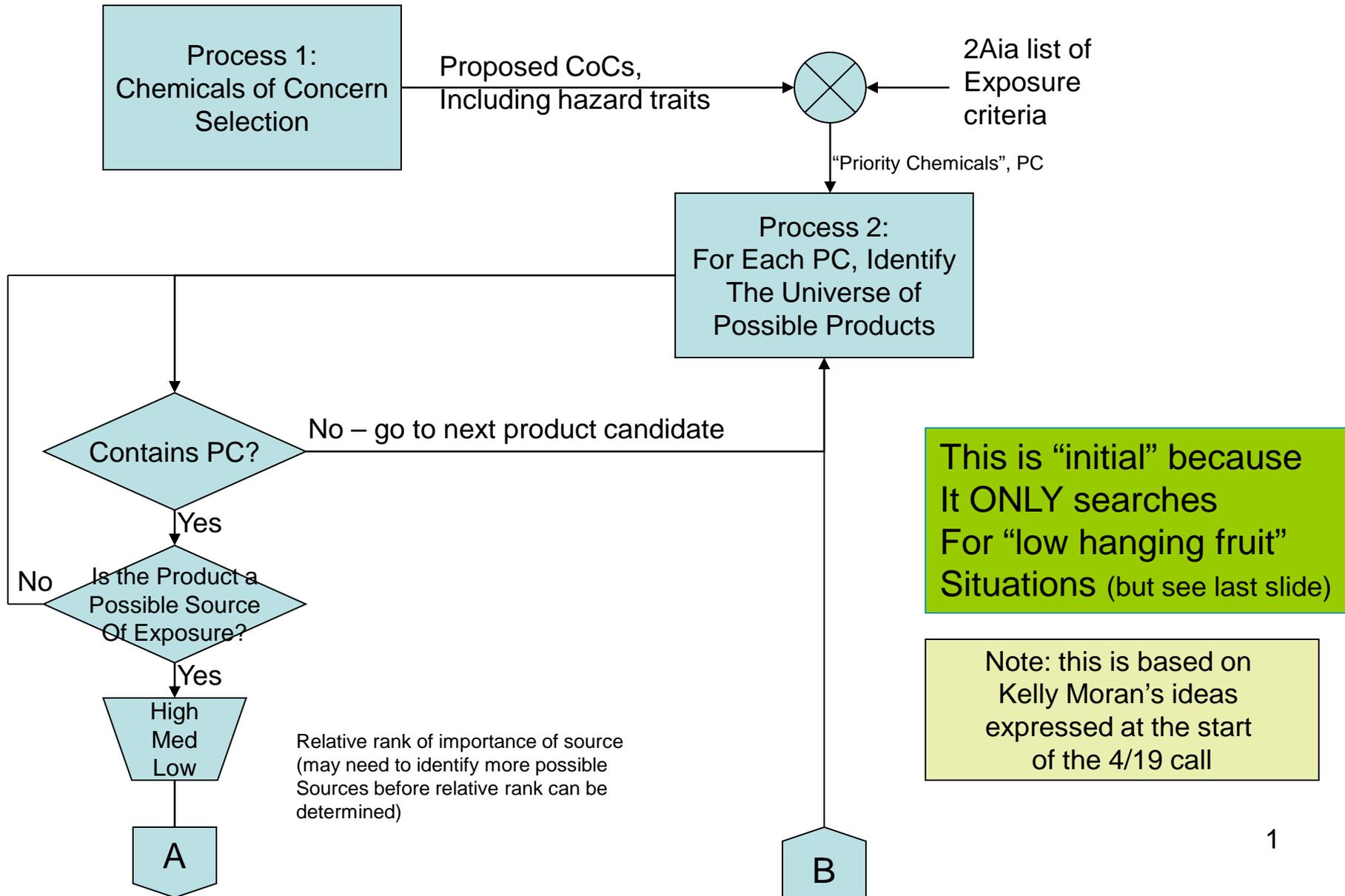
Conceptual Model --- Structured Prioritization Approach

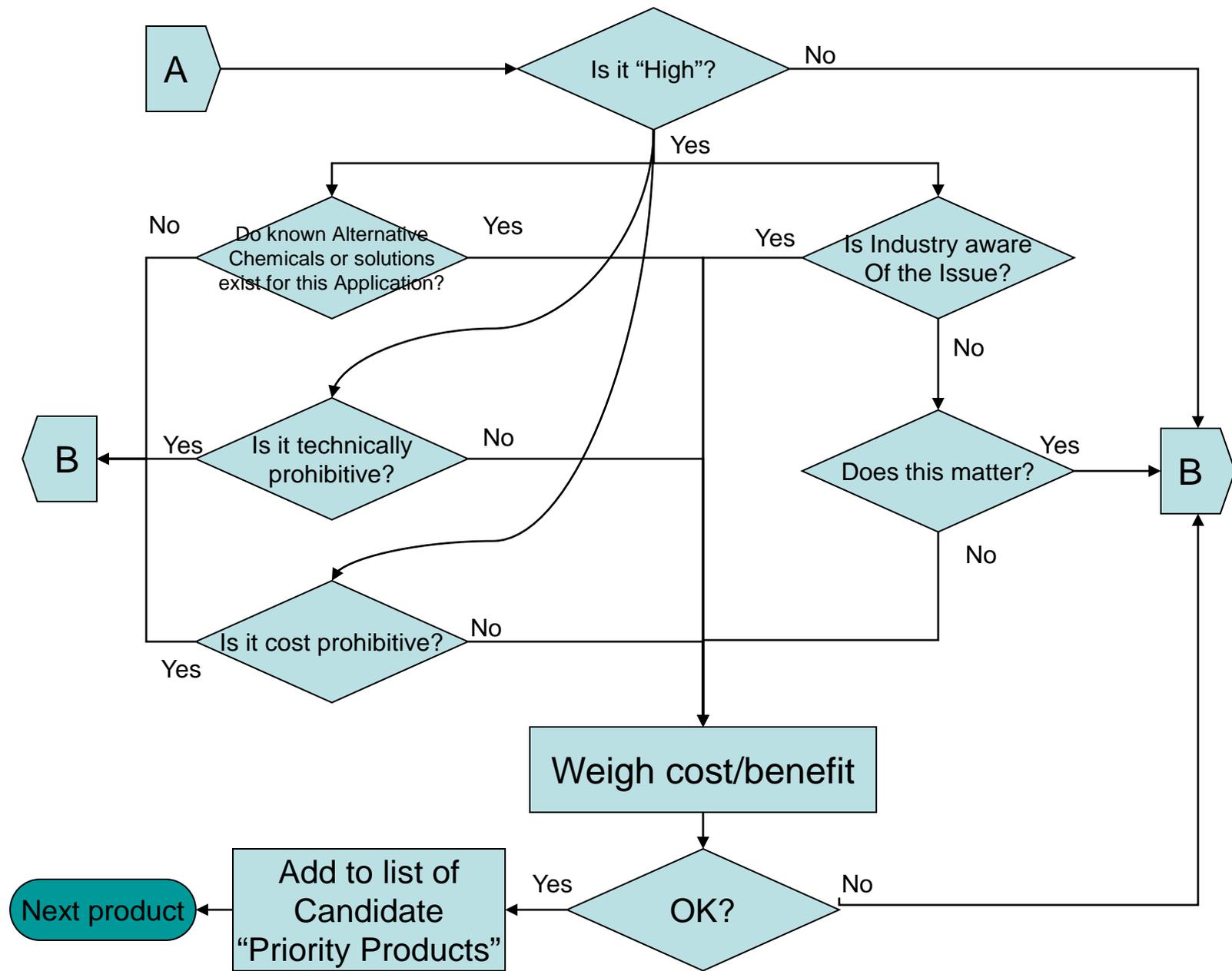
	Criteria	Score	Recommendation	Comments
Product Volume	>1000 lbs, 1000 gallons/month – 5 <999 lbs, 999 gallons/month - 1	5		
Use Frequency	Every day – 5 Monthly - 1	1		
Chemical banned by	RoHS, TSCA, REACH – 5 Not list but suspect – 3 Not listed - 1	3	Consider to find an alternative chemical	
Toxicity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

- 1) A – Require chemical in product to be removed or replaced with alternative chemical(s)
 B – Recommend to chemical be removed from product
 C – No action is required

- 2) Toxicity can be simpler or more complex than shown in this example

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