

**Topics #1 and #2 --- Alternatives Assessment Process**

**INTRODUCTION:**

AB 1879 (Health and Safety Code (HSC) section 25253) requires DTSC to adopt regulations that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. The statute further requires that this process include an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways. The alternatives assessment (AA) process is required to include life cycle assessment tools that (at a minimum) take into consideration 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

HSC section 25253(c) also requires DTSC, in developing the processes and regulations, to ensure that the tools available are in a form that allows for ease of use and transparency of application. DTSC is also required to make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers, and consumers can use to make consumer product manufacturing, sales, and purchase decisions.

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## **List of Attachments**

- 1** Statutory (AB 1879) Requirements for Alternatives Assessments (HSC section 25253)
- 2** Comparison of QCAT and GS<sup>TM</sup> Hazard Endpoints *(excerpt from Quick Chemical Assessment Tool 1.0 Beta Version, created by Alex Stone, Sc. D., Washington State Department of Ecology, draft, December 2010)*
- 3** Triaged AA Approach Flow Diagram *(Donald Versteeg, Ph.D., The Procter and Gamble Company)*
- 4** Tiered Alternatives Assessment Concept Model *(prepared by GRSP members Ann Blake, Ken Geiser and Kelly Moran --- April 2010)*

## NOTES:

- (1) Subcommittee member comments universally seemed to support some form of a “tiered” or “triaged” approach to the AA process. Many of the ideas offered by subcommittee members, and captured in this paper, preliminarily seem to meet the practical, meaningful and legally-defensible criteria. (Further analysis by DTSC will be needed to confirm this.)
- (2) At least until further experience with the AA process is gained (by DTSC, those engaged in conducting AAs, and other stakeholders), the initial regulations will likely need to avoid being overly specific or inflexible. As more experience is gained, the regulations can be revised in the future to reflect the knowledge gained through those experiences. This caution needs to be kept in mind when considering the conceptual options presented in this paper. The initial regulations could set forth one or more somewhat specific approaches that would be acceptable, but at the same time allow for other approaches to be proposed in AA work plans as long as those approaches met certain basic criteria as dictated by the statute.
- (3) In light of the dilemma described in (2) above, many subcommittee members have recommended that DTSC provide detailed guidance to assist manufacturers in performing AAs. DTSC does plan to work with partners to provide AA guidance documents. However, it is important to keep in mind that standards contained in guidance documents are recommendations only, not mandates, and such standards cannot be enforced. Only standards specified in the regulations themselves can be enforced as binding requirements.
- (4) Over the course of the subcommittee #1 and #2 discussion, the question arose as to what is meant by the term “LCA tools” referred to in HSC section 25253. There is no definition in the statute itself, and there is no commonly understood or accepted definition of this term. The best guidance for interpreting this term, therefore, seems to be the statutory requirement that (for purposes of HSC section 25253 AAs) the LCA tools developed and used: (i) allow for ease of use and transparency of application; and (ii) be simple and accessible tools that manufacturers, distributors, retailers, and consumers can use to make consumer product manufacturing, sales, and purchasing decisions.

***The options presented on the following pages 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: ALTERNATIVES ASSESSMENT PROCESS

### OPTION I-A --- “Tiered” AA Process

Option I-A attempts to consolidate a number of interrelated suggestions provided by various members of the subcommittee. This option, which is set forth as a series of sequenced steps, actually presents two approaches. **Steps 1-4** would be the same, with the two approaches diverging at **Step 5**.

**Step 1** requires an evaluation of the technical criteria for the priority product. **Step 2** is the identification of alternatives, and **Step 3** requires an initial screening of potential alternative chemicals. In **Step 4**, a qualitative assessment screen is used to identify any (A)-(M) factors (and associated exposure pathways, levels of hazard, and life cycle segments) that are relevant to the comparison of the priority product/COC and the potential alternatives.

**Step 5** offers two possible approaches as the next step after Step 4:

**Option 5(A)** calls next for the conduct of a robust comparative assessment (relying on quantitative data where available) using the relevant factors (and exposure pathways, levels of hazard, and life cycle segments) identified in Step 4. This assessment would be followed by the AA decision (a selected alternative or a decision to stay with the existing priority product) and the submission of the AA report to DTSC. At this point, DTSC would determine the appropriate regulatory responses.

**Option 5(B)** calls for an AA report to be submitted to DTSC after completion of only the qualitative assessment screen in Step 4. In this case the AA decision could be: (i) selection of an alternative, (ii) a decision to retain the existing product/chemical, or (iii) a decision to conduct a more robust comparative analysis before making a final decision. Under Option 5(B), DTSC would make a regulatory response determination based on the AA report resulting from the Step 4 qualitative assessment screen --- this could include (but not be limited to) a requirement for the more robust comparative assessment, which could ultimately lead to an adjustment of the final regulatory response(s).

## SECTION I: ALTERNATIVES ASSESSMENT PROCESS (con't)

### STEP 1: *PRODUCT TECHNICAL CRITERIA DETERMINATION*

- Identify technical criteria (e.g., functionality, cost, availability) for the Priority Product.
- Identify the function of the COC in meeting the products technical criteria.
- Is the COC or a substitute chemical necessary?
  - If “yes”, proceed to Step 2.
  - If “no”, are there any significant adverse impacts relative to the (A)-(M) factors if the COC is simply removed from the product? (See Steps 4 and 5 below.)

### STEP 2: *IDENTIFICATION OF ALTERNATIVES*

- Identify alternative chemicals to meet the product's technical criteria (or identify other design or manufacturing process change alternatives to eliminate the need for the either a COC or a substitute chemical).
- Is there already a known alternative?

### STEP 3: *INITIAL SCREENING OF ALTERNATIVE CHEMICALS*

- Screen out “problem chemicals” based on human health and environmental hazard concerns (e.g., CMRs, PBTs).
- Possible screening approaches (which can be used individually or in combination) include:
  - Screen out any chemicals that are listed as a COC or a Priority Chemical.
  - Application of the Quick Chemical Assessment Tool (created by Alex Stone of the Washington State Department of Ecology and/or Green Screen™. (**Attachment 2** shows the human health and environmental hazard endpoints examined by these screening tools.)
  - Elimination of any chemical that is not significantly safer than the COC with respect to the basis for the COC listing.

## **SECTION I: ALTERNATIVES ASSESSMENT PROCESS (con't)**

### **STEP 4: QUALITATIVE ASSESSMENT SCREEN**

- Conduct a qualitative assessment screen to compare the product/COC with the alternatives that passed the prior screens:
  - Consider critical exposure pathways, levels of hazard and all the (A)-(M) factors for each life cycle segment (LCS) (i.e., before use, during use, and after use).
  - Identify any (A)-(M) factors (and the associated critical exposure pathways, levels of hazard and LCSs) relevant to the comparison of the COC and the alternatives. A factor (and exposure pathway, level of hazard, and LCS) is “relevant” if it would constitute both:
    - A significant contribution to the impact of a given alternative, AND
    - A significant differential among the alternatives being compared.
  - Identify data gaps and uncertainties.
- DTSC would provide guidance for this qualitative assessment screen, including the criteria and questions to be asked for each factor and LCS. A template would be provided that combines a checklist with narrative explanations. In general, this screen would rely on qualitative information and analysis, but quantitative data could also be included if readily available.

## SECTION I: ALTERNATIVES ASSESSMENT PROCESS (con't)

### STEP 5: *IN-DEPTH ASSESSMENT OF RELEVANT FACTORS & LIFE CYCLE SEGMENTS*

The two approaches encompassed by Option I-A differ with respect to the process set forth in Step 5. One approach is described as Option 5(A) and the other as Option 5(B).

#### Option 5(A)

- A robust comparative assessment would next be conducted for the COC and the alternatives with respect to the factors (and associated critical exposure pathways, levels of hazard and LCSs) identified as “relevant” upon completion of the Step 4 qualitative assessment screen.
  - The relevant factors are evaluated using quantitative data available from existing literature and test results. Where such quantitative data is not available, an in-depth qualitative analysis can be substituted.
  - The depth of analysis for any given factor should be limited to that needed to capture the factor’s contribution to differential between the alternatives being compared.
  
- This assessment forms the basis for making an AA decision, which is then identified in an AA report submitted to DTSC. The report would include information on: AA process, data, data gaps, uncertainties, explanations of any (A)-(M) factors (and exposure pathways, levels of hazard and LCSs) determined not to be relevant based on the qualitative assessment screen performed in Step 4 (including the significance criteria used).
  
- DTSC determines the regulatory response for the AA decision, and for the existing product pending introduction of the new product into the marketplace. If there are data gaps identified with respect to relevant factors, DTSC may require the development of new scientific data and/or environmental models.

## SECTION I: ALTERNATIVES ASSESSMENT PROCESS (con't)

### Option 5(B)

- Following completion of the qualitative assessment screen in Step 4, an AA report would be submitted to DTSC (similar to the report described for Option 5(A)). The report would include the AA decision (and rationale), which could be any of the following:
  - Selection of an alternative (i.e., COC removal or substitution, of product redesign).
  - A decision not to replace the product with an alternative.
  - A decision to conduct a more robust comparative analysis (as described for Option 5(A)) before making an AA decision.
- Based on this report and the AA decision, DTSC would specify regulatory response(s) (i.e., labeling, measure to control access or limit exposure).
  - If an alternative has not been selected, DTSC would, at a minimum, require the completion of a more robust comparative analysis (as described for Option 5(A)).
  - DTSC might also require completion of a more robust comparative analysis if the decision has been made to replace the COC with another chemical, but there are relevant factor/LSC impacts needing more in-depth evaluation.
  - If DTSC disagrees with a determination that a particular factor (or exposure pathway, level of hazard or LCS) is not relevant, DTSC would require a more robust comparative analysis for the factor/LCS.
- If determined necessary by DTSC, an Option 5(A) comparative analysis would be conducted, an AA decision made, and an AA report submitted to DTSC.
- DTSC would adjust the previously determined regulatory response, as determined appropriate, based on the new AA decision and report.

## SECTION I: ALTERNATIVES ASSESSMENT PROCESS (con't)

### OPTION I-B --- "Triaged" AA Process

At the suggestion of one of the subcommittee members, DTSC staff contacted Donald Versteeg, Ph.D. of The Procter and Gamble Company's (P&G) Environmental Stewardship Organization, who provided the following suggestion modeled on the AA process used by P&G. **Attachment 3** provides a flow diagram for this option.

- In identifying alternatives for a COC, the first step should be to make sure the alternative is preferred from a human health and environmental hazard point-of-view (just the chemical itself, lifecycle not included yet). If it is, then it is a viable candidate and an exploratory LCA is conducted. This is done by a *green chemist* and forms the basis for a discussion with DTSC. This is a prioritization discussion that considers all (A)-(M) factors but focuses future analysis on the critical ones (could be all factors, could be only a few) so that targeted information can be provided.
- If volumes of the chemical are low, then economic impacts and resource use/impacts may be relatively low, thus, a qualitative assessment can be conducted (includes a *green chemist*, *financial expert*, and *toxicologist*). The qualitative assessment focuses on the (A)-(M) factors the *green chemist* and DTSC agreed upon, with most attention going to the high priority factors. Some of the factors may be assessed quantitatively (e.g., the economic analysis).
- If volumes of the chemical are high, economic impacts and resource use/impacts may be high, thus, more scrutiny will be needed throughout the process and a more intensive and quantitative assessment of the (A)-(M) factors is needed. Again, the analysis includes a *green chemist*, *financial expert*, and *toxicologist*. If a factor is not high priority, it would not receive a quantitative assessment, but would receive a qualitative assessment.
- (A)-(M) impact factors can be combined as follows:
  - Economic Impacts (A, B, M) --- *Financial Expert*
    - Analysis considers whether the product can be sold profitably by the company and includes AA impact on sales, performance and useful life relative to product with the COC.
  - Resources Used (C, D, G, H) --- *Green Chemist (GC)*
    - Importance of resource use proportional to the volume of the alternative chemical used (tons used in the state).
    - Analysis uses existing data and principles of green chemistry & engineering to compare COC & alternatives across all life cycles.
  - Resource Impacts (E, F, I, J, K, L) --- *GC, Toxicologist, Ecotoxicologist*
    - Importance of resource impacts proportional to the volume of the alternative chemical used (tons used in the state).
    - Analysis uses existing data and principles of green chemistry & engineering to compare COC & alternatives across all life cycles.

## SECTION I: ALTERNATIVES ASSESSMENT PROCESS (con't)

### OPTION I-C --- Grouping and Prioritization of (A)-(M) Factors

Several comments were received that suggested that the 13 factors listed in HSC section 25253 be *grouped* and/or *prioritized* in terms of importance:

(1) Factors could be grouped, **but not prioritized**, for analysis purposes as follows:

Assessment Criteria	AB 1879 Criteria
Human Health & Public Safety	<ul style="list-style-type: none"> <li>• Critical exposure pathways</li> <li>• Public health impacts (including sensitive subpopulation impacts) (K)</li> <li>• Air emissions (F)</li> </ul>
Environmental Impacts	<ul style="list-style-type: none"> <li>• Critical exposure pathways</li> <li>• Water quality impacts (E)</li> <li>• Greenhouse gas emissions (I)</li> <li>• Waste and end-of-life disposal (J)</li> <li>• Environmental impacts (L)</li> </ul>
Resource Impacts	<ul style="list-style-type: none"> <li>• Materials and resource consumption (C)</li> <li>• Water conservation (D)</li> <li>• Production, in-use, transportation energy inputs (G)</li> <li>• Environmental impacts (H)</li> </ul>
Technical Performance	<ul style="list-style-type: none"> <li>• Product function or performance (A)</li> </ul>
Cost	<ul style="list-style-type: none"> <li>• Economic impacts (M)</li> <li>• Useful life (B)</li> </ul>

(2) The stated purpose for the AA process, in HSC section 25253, is to determine how best to limit exposure or to reduce the level of hazard posed by a COC. Consistent with this stated purpose, the (A)-(M) factors could be grouped, **and prioritized**, for decision-making purposes as follows:

Priority One Factors	<ul style="list-style-type: none"> <li>• Water quality impacts (E)</li> <li>• Air emissions (F)</li> <li>• Greenhouse gas emissions (I)</li> <li>• Waste and end-of-life disposal (J)</li> <li>• Public health impacts (including sensitive subpopulation impacts) (K)</li> <li>• Environmental impacts (L)</li> </ul>
Priority Two Factors	<ul style="list-style-type: none"> <li>• Product function or performance (A)</li> <li>• Useful life (B)</li> <li>• Materials and resource consumption (C)</li> <li>• Water conservation (D)</li> <li>• Production, in-use, transportation energy inputs (G)</li> <li>• Environmental impacts (H)</li> <li>• Economic impacts (M)</li> </ul>

If an AA decision rejects an alternative that is safer than the existing product with respect to the priority one factors, DTSC may (in addition to other regulatory responses) require a more robust comparative analysis of one or more factors/LCSs. A green chemistry challenge grant may also be appropriate.

## SECTION I: ALTERNATIVES ASSESSMENT PROCESS (con't)

### OPTION I-C --- Grouping and Prioritization of (A)-(M) Factors (con't)

(3) Another suggested grouping, **and prioritization**, approach is as follows:

Priority One Factors	<ul style="list-style-type: none"><li>• Water quality impacts (E)</li><li>• Air emissions (F)</li><li>• Greenhouse gas emissions (I)</li><li>• Waste and end-of-life disposal (J)</li><li>• Public health impacts (including sensitive subpopulation impacts) (K)</li><li>• Environmental impacts (L)</li></ul>
Priority Two Factors	<ul style="list-style-type: none"><li>• Materials and resource consumption (C)</li><li>• Water conservation (D)</li><li>• Production, in-use, transportation energy inputs (G)</li><li>• Environmental impacts (H)</li></ul>
Priority Three Factors	<ul style="list-style-type: none"><li>• Product function or performance (A)</li><li>• Useful life (B)</li><li>• Economic impacts (M)</li></ul>

(4) The sequencing, grouping and prioritization of the (A)-(M) factors should be left to the person performing the AA.

### OTHER COMMENTS AND SUGGESTIONS ON THE AA PROCESS

The following represent some of the other key comments received from subcommittee members that can be considered in the context of the options outlined above:

- (1) The regulations need to allow for the AA process to be stepwise, iterative and flexible.
- (2) The use of proprietary “black box” LCA tools does not provide transparency as required by the statute.
- (3) Using the availability (location and quantity) of alternative chemicals as a consideration may stifle innovation.
- (4) The AA process should include consideration of occupational exposures and impacts.

## **SECTION II: Timeline for Alternatives Assessment Completion**

**OPTION II-A** --- The timeline for completing the AA should be worked out between DTSC and the manufacturer based upon the complexity of the proposed AA.

**OPTION II-B** --- DTSC should assign the timeline for the AA based on the complexity of the AA proposed in the work plan, with a provision allowing for extensions based on clearly defined criteria. Factors that might require a longer timeline include:

- The product contains multiple COCs,
- Evaluation of newly developed or conflicting hazard trait data on potential alternative chemicals,
- In-progress tests with projected completion dates that will provide critical information for conducting the AA,
- Awaiting information regarding the availability of a potential alternative that has passed the human health, environmental and exposure potential hazard screens.

**OPTION II-C** --- There should be a standardized timeline for all AAs for a specific product type.

**OPTION II-D** --- In the case of Option I-A 5(B), a standard timeline could be set for completing the qualitative assessment screen, but allow for DTSC to specify more customized timelines for the more robust comparative analyses.

## **SECTION III: Trade-Offs Among (A)-(M) Impacts**

This issue, while not initially raised by DTSC, was of interest to several of the subcommittee members, as well as DTSC. There was not sufficient time to discuss this issue during the subcommittee teleconferences, so it was agreed to raise this item for discussion during the meeting of the full GRSP.

**OPTION III-A** --- Leave the decision on how to address trade-offs to the manufacturer.

**OPTION III-B** --- Prioritize the (A)-(M) factors (see Option 1-C above) --- this would not completely address how to deal with trade-offs, but it would help to triage the trade-offs if they fall into different priority “pots”.

**OPTION III-C** --- If there are data gaps, require the development of new scientific data or environmental models if this may assist in further evaluation of trade-off issues.

**OTHER IDEAS?**

Statutory (AB 1879) Requirements for Alternatives Assessments

**Health and Safety Code section 25253**

**25253.** (a)(1) On or before January 1, 2011, the department shall adopt regulations pursuant to this section that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern, in accordance with the review process specified in Section 25252.5. The department shall adopt these regulations in consultation with all appropriate state agencies and after conducting one or more public workshops for which the department provides public notice and provides an opportunity for all interested parties to comment.

(2) The regulations adopted pursuant to this section shall establish a process that includes an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways. This process shall include life cycle assessment tools that 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.

(b) The regulations adopted pursuant to this section shall specify the range of regulatory responses that the department may take following the completion of the alternatives analysis, including, but not limited to, any of the following actions:

- (1) Not requiring any action.
- (2) Imposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives.
- (3) Imposing requirements on the labeling or other type of consumer product information.
- (4) Imposing a restriction on the use of the chemical of concern in the consumer product.
- (5) Prohibiting the use of the chemical of concern in the consumer product.
- (6) Imposing requirements that control access to or limit exposure to the chemical of concern in the consumer product.
- (7) Imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product.
- (8) Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists.
- (9) Any other outcome the department determines accomplishes the requirements of this article.

(c) The department, in developing the processes and regulations pursuant to this section, shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers, and consumers can use to make consumer product manufacturing, sales, and purchase decisions.

## Attachment 2

The table below is an excerpt from:

### Ecology Quick Chemical Assessment Tool 1.0 Methodology Beta Version

Created by Alex Stone, Sc. D.  
Washington State Department of Ecology

(Draft --- December, 2010)

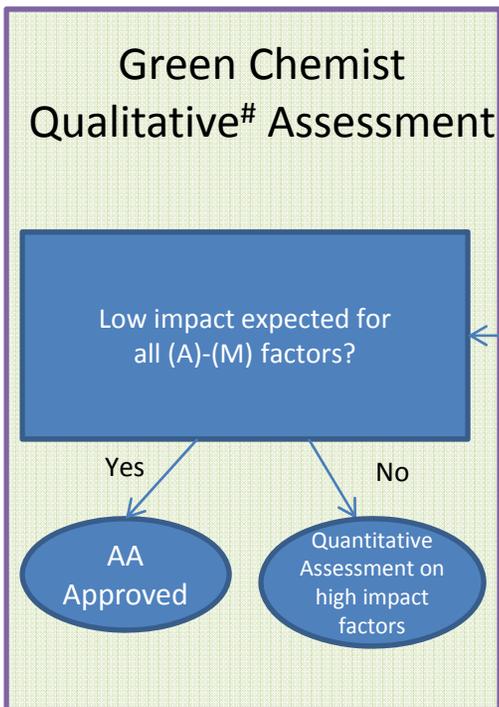
**Table 3: QCAT Hazard Endpoints Compared with the GS™**

	QCAT	GS™
<b>Human Health:</b>		
• Acute mammalian toxicity	X	X
• Carcinogenicity	X	X
• Reproductive/Developmental/Neuro-developmental toxicity	X	X
• Genotoxicity/Mutagenicity	X	X
• Endocrine disruption	X	X
• Neurotoxicity		X
• Respiratory sensitization		X
• Skin sensitization		X
• Corrosion & Irritation (skin)		X
• Corrosion & Irritation (eye)		X
• Systemic/organ effects toxicity including Immune System toxicity		X
<b>Ecological:</b>		
• Acute aquatic toxicity	X	X
• Chronic aquatic toxicity		X
<b>Environmental:</b>		
• Persistence	X <sup>1</sup>	X
• Bioaccumulation	X	X
<b>Physical:</b>		
▪ Reactivity		X
▪ Flammability		X

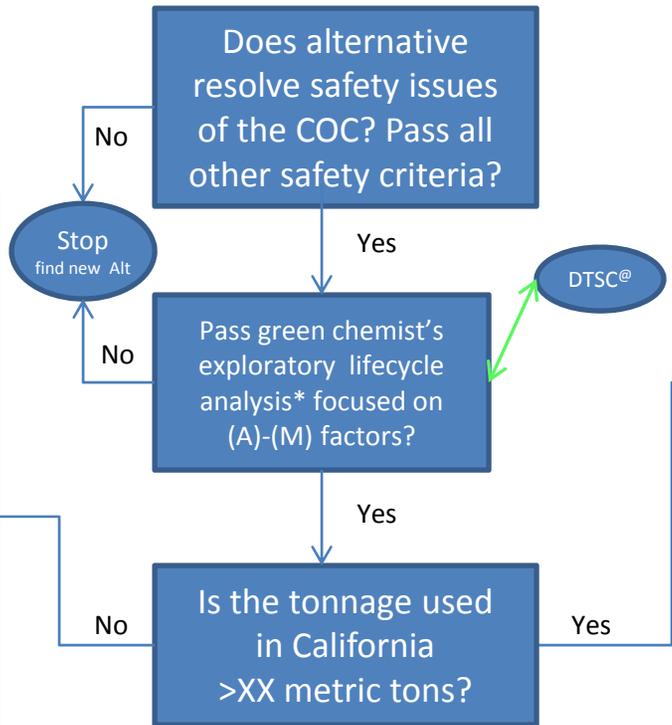
<sup>1</sup> Not needed if the assessment is done solely for metals as all metals are assumed to be persistent.

# Triaged AA Approach

Don Versteeg, Ph.D.  
The Procter and Gamble Company

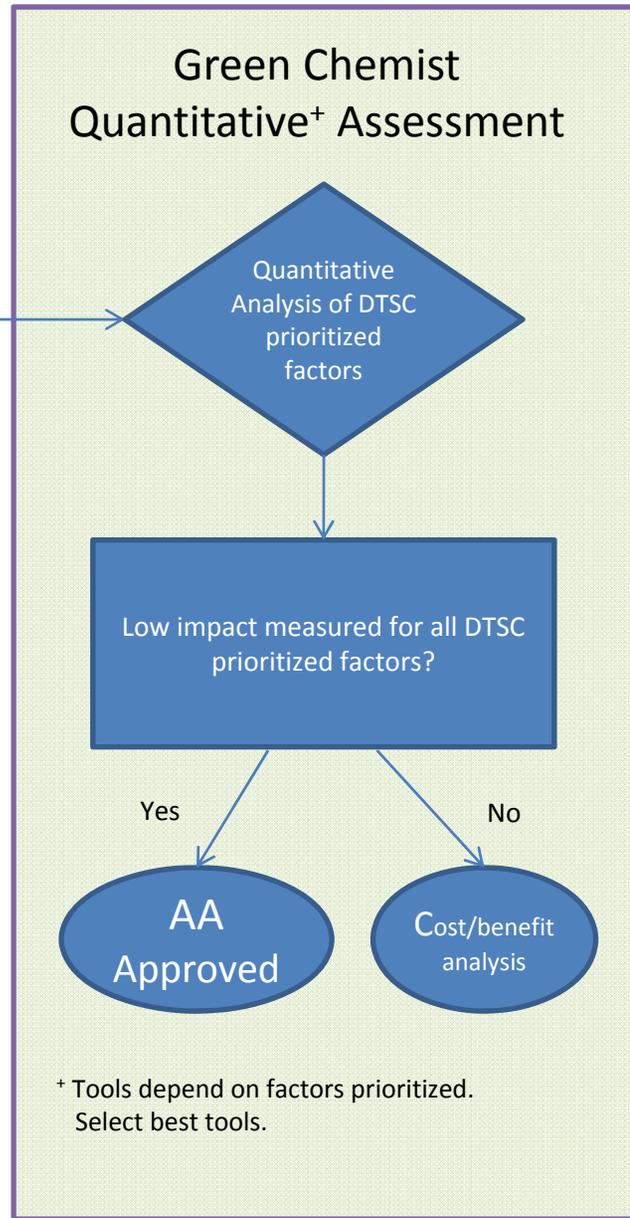


# Low volume, thus, resource use and impact, and waste may be low for all factors.



\*Financial Analysis  
California & Company  
Resource Use Assessment  
Consider all lifecycle phases  
Resource Impact Assessments  
Consider all lifecycle phases  
Waste Assessment

@Meeting between green chemist and DTSC prioritizes impact areas to identify priorities for quantitative analysis. Quantitative analysis compares data on COC and alternative.



+ Tools depend on factors prioritized. Select best tools.

This relatively simple flow diagram is supported by P&G's history of successfully bringing new, safe products & ingredients to market in a sustainable manner.

**California Green Chemistry Initiative  
Alternatives Assessment Process  
Tiered Concept Model**

**Draft: April 6, 2010**

The Department of Toxic Substances Control (DTSC) shall establish a tiered approach to the alternatives assessment required under AB 1879. A manufacturer may conduct an alternatives assessment in order to a) identify preferred alternatives to a priority chemical of concern or b) to demonstrate that no preferred alternatives exist.

The DTSC shall establish three performance tiers for manufacturers who wish to sell products in California containing priority chemicals of concern as determined by DTSC. The DTSC shall produce a guidance document describing the three performance tiers as follows:

- For Tier 1, DTSC provides a simple guidance and requires qualitative responses to the list of questions
- For Tier 2, DTSC provides a specific guidance, requires an inventory of impacts over a product's life cycle using existing literature and test results, and establishes an expectation for quantitative assessment
- For Tier 3, DTSC may provide additional specific guidance. A Tier 3 assessment is required when a Tier 2 assessment or DTSC's evaluation of a Tier 2 assessment identifies the need for an assessment of impacts over a product's life cycle where such assessments may require development of new scientific data and/or running of environmental models. Tier 3 assessments may be focused (i.e., omit more detailed analysis of topic areas where all alternatives are essentially equal and where no problems were identified in Tier 2.)

The DTSC guidance document will clarify the conditions necessary to determine which tier of an alternatives assessment must be conducted.

Where a manufacturer uses an alternatives assessment to identify preferred alternatives, the DTSC guidance document shall encourage the use of a simple Tier 1 assessment if the manufacturer soon thereafter adopts one of the preferred alternatives. However, DTSC shall require a higher order tier assessment where preferred alternatives are more difficult to identify or require complex trade-offs among hazard traits or environmental or human health values.

Where a manufacturer uses an alternatives assessment in order to demonstrate the absence of an acceptable alternative, DTSC may require a Tier 1 assessment where the expected state response will be to require product labeling or further research to develop preferred alternatives. However, where DTSC determines that the use of a priority chemical of concern may be conditioned, restricted or

banned, the manufacturer shall be required to conduct Tier 2 or 3 assessments in order to demonstrate that there are no preferred alternatives.

### **Selection of alternatives**

Alternatives include alternative chemicals, materials, parts, or approaches that provide a functionally equivalent purpose in the product. [More info]

### **Assessment of Alternatives**

An alternative assessment is a process for identifying acceptable alternatives to the use of a priority chemical in a product. For each alternative, complete the list of questions below. [Goal – thought out individual answers, rather than simple +/- comparisons.]

#### **A. PRODUCT FUNCTION OR PERFORMANCE. Would the alternative:**

- 1) Adversely affect product function?
- 2) Reduce product quality in a manner that would affect customer satisfaction?
- 3) Meaningfully impede product performance?

#### Summary Comparison of Alternatives – Product Function or Performance

Original Product	Alternative A	Alternative B	Alternative C (etc.)
Are differences among alternatives meaningful?			
Are adverse changes meaningful?			

#### **B. USEFUL LIFE. Would the alternative:**

- 1) Meaningfully reduce the useful life of the product?
- 2) Substantially limit opportunities for reuse of a product that is currently reused?

#### **C. MATERIALS AND RESOURCE CONSUMPTION. Would the alternative:**

- 1) Generate a yield ratio of product material to process waste of more than 1:2
- 2) Consume non-renewable resources
- 3) Consume rare or endangered resources

#### **D. WATER CONSERVATION. Would the alternative:**

- 1) Require significant amounts of water in the product or the production process.
- 2) reduce the capacity to conserve water in the production process or during use or disposal.

**E. WATER QUALITY IMPACTS. Would the alternative:**

**Threshold question:** during manufacturing, use, or at end of life is the alternative substance or material exposed to rain or to water than flows into a sewer or septic system? IF SO, then complete this section.

- 1) Would sewer discharges violate any local wastewater discharge limit, have potential to interfere with treatment operations at a wastewater treatment plant, cause or contribute to effluent toxicity, pass through a treatment plant, or accumulate in biosolids (sewage sludge)?
- 2) Degrade the quality of urban runoff?
- 3) Have substantially greater aquatic toxicity?
- 4) Facilitate transport to the sewer, storm drain, or surface water of other product ingredients that are highly toxic to aquatic life?

[etc.....]

**F. AIR EMISSIONS. Would the alternative:**

**G. PRODUCTION, IN-USE, AND TRANSPORTATION ENERGY INPUTS. Would the alternative:**

**H. ENERGY EFFICIENCY. Would the alternative:**

**I. GREENHOUSE GAS EMISSIONS. Would the alternative:**

**J. WASTE AND END-OF-LIFE DISPOSAL. Would the alternative:**

**K. PUBLIC HEALTH IMPACTS, INCLUDING POTENTIAL IMPACTS TO SENSITIVE SUBPOPULATIONS, INCLUDING INFANTS AND CHILDREN. Would the alternative:**

- 1) Pose a meaningful human health hazard? This should be evaluated on the basis of hazard data, including data available from the Toxics Information Clearinghouse. Absence of data does not indicate absence of potential to cause harm.

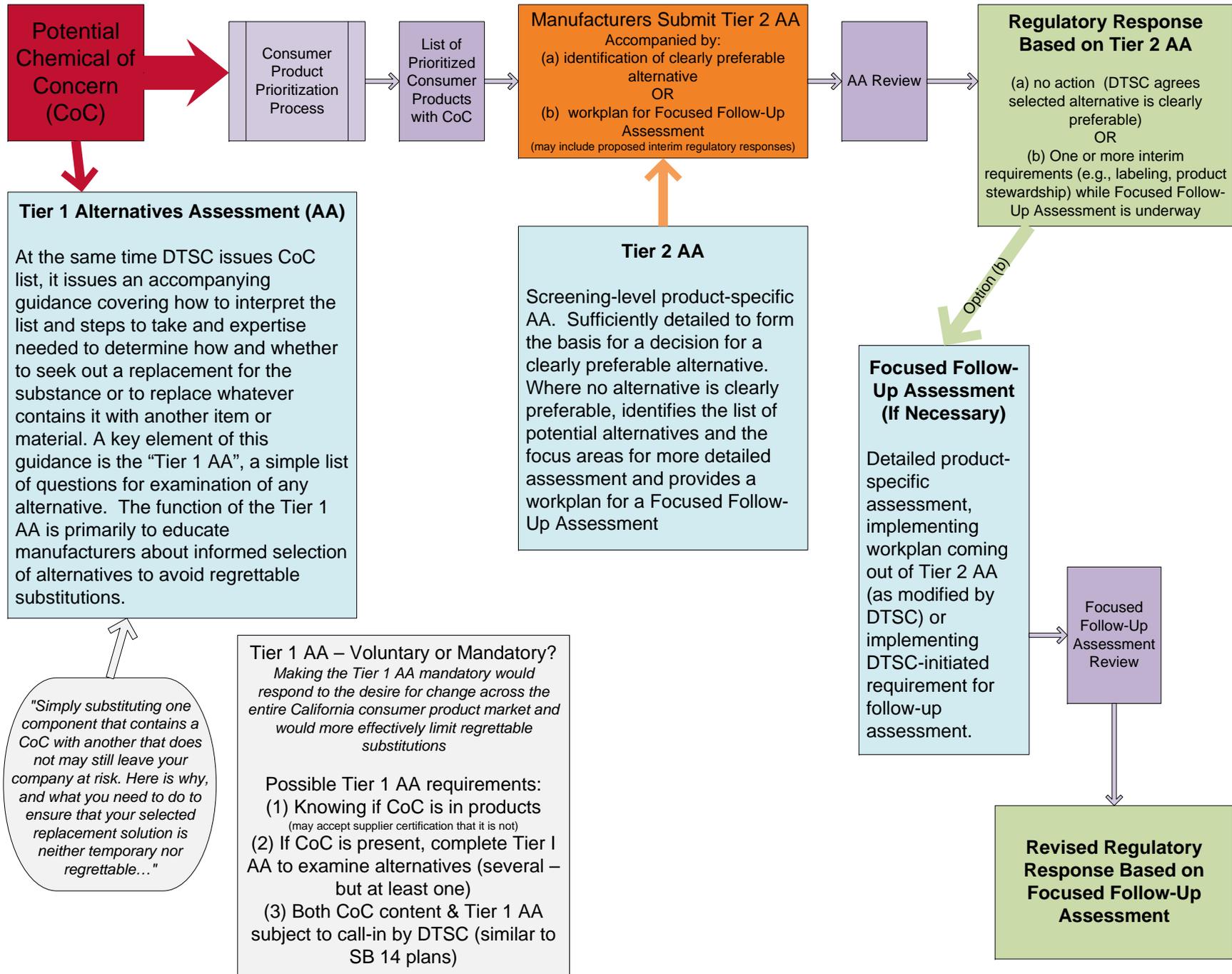
2) Involve use of a substance—or a substances with a metabolite—that has been found in humans? This should be evaluated on the basis of biomonitoring data, including data available through the Toxics Information Clearinghouse.

**L. ENVIRONMENTAL IMPACTS. Would the alternative:**

[This is a large list of questions, recommend considering all of the CEQA topics.]

**M. ECONOMIC IMPACTS. Would the alternative:**

[More topics may be needed. Need also to figure out how to address big picture questions, like cumulative impacts.]



## Proposed Alternative Assessment Framework for AB 1879

Assessment Topic Area	AB 1879 Section 25253 (a) (2) criteria	Possible Data Points to Support AB 1879 Criteria	Data Sources	Regulatory Responses	Specific Triggers for Each Regulatory Response*	Other factors to be considered in selection of Regulatory Response
<b>Human Health &amp; Public Safety</b>	Potential hazards posed by those alternatives	<b>First Tier:</b> Carcinogenicity, Reproductive or Developmental Toxicity; Neurotoxicity, Endocrine Disruption (in vivo, in vitro, in silico); PBTs; <b>Second Tier:</b> Asthmagen, Respiratory/Skin/ Eye Irritant	Prop 65, (IARC, NTP), EU Risk Phrases; PBT/POPS lists, EPA PBT profiler, etc.	No action taken	Third party standard for environmentally preferable product or ingredient, certification	(1) Those used or designed for use by sensitive populations.
	Critical exposure pathways	Found in cord blood, or in blood/ urine of sensitive subpopulations; found in indoor/ outdoor air, drinking water, etc.	CDC, EPA, academic studies, etc.	Require additional info	Meets criteria for CoC for other regulatory bodies (Canada, EU, FDA, EP); missing data in First Tier health, multiple environmental endpoints	(2) Those most likely to expose individuals or the environment to one or more chemicals of concern.
	Public health impacts, including potential impacts to sensitive subpopulations, including infants and children	CDC Biomonitoring data on key chemicals, metabolites, subpopulations;	Peer-reviewed literature on health impacts	Require labeling	Red flags in First Tier human health, multiple environmental endpoints	(1) The cumulative exposure to one or more chemicals of concern through multiple products or from multiple sources, including multiple media.
	Air emissions	TRI		Require end-of-life management		(2) The synergistic effects of exposure to multiple chemicals of concern.

<b>Environmental Impacts</b>	Water quality impacts	TRI		Restrict usage	Demonstrated presence in cord blood and meets CMR, PBT criteria	
	Greenhouse gas emissions	TRI			Biomonitoring data in >75% of population or subgroup (children under 5, pubertal populations, women of child-bearing age, etc.)	
	Waste and end-of-life disposal	TRI		Require exposure to be limited	Demonstrated route of exposure and biomonitoring data in subpopulation (e.g. workers in manufacturing, end-of-life, fenceline communities, children, etc.)	
	Environmental impacts	??		Prohibit usage	(See above, with added health/ environmental criteria overlay, e.g. CMR or aquatic toxicity)	

<b>Resource Impacts</b>	Materials and resource consumption			R/D challenge	Some alternatives on the market, benefits/ performance/ cost not optimized	
	water conservation			Other		
	production, in-use and transportation energy inputs					
	energy efficiency				<b>*suggestions only....</b>	
<b>Technical Performance</b>	Product function or performance		Third party standards (e.g. GreenSeal, Responsible Purchasing Network, etc.), DfE "CleanGredients" model			
<b>Costs</b>	Economic impacts					
	Useful life					