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Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

- Alliance of Automobile Manufacturers
- American Chemistry Council
- American Electronics Association
- American Forest & Paper Association
- California Chamber of Commerce
- California League of Food Processors
- California Manufacturers & Technology Association
- California Paint Council
- California Restaurant Association
- California Retailers Association
- Can Manufacturers Institute
- Chemical Industry Council of California
- Citizens for Fire Safety Institute
- Consumer Specialty Products Association
- Grocery Manufacturers Association
- Industrial Environmental Association
- Metal Finishers Association
- National Paint and Coatings Association
- Personal Care Products Council
- Plumbing Manufacturers Association
- Soap & Detergent Association
- Toy Industry Association
- Western Plant Health Association
- Western States Petroleum Association

TO: Maziar Movassaghi

FROM: Green Chemistry Alliance (GCA)

DATE: March 19, 2009

RE: Green Chemistry "Wiki" Response

On behalf of the Green Chemistry Alliance, which is comprised of business organizations and associations committed to product sustainability in the global economy, please see our attached response to your original "Wiki" questions.

By way of background, our organization was founded on the following core principles:

1. *Use sound scientific methods of review recognized by other nations, governments, and authoritative bodies.*
2. *Avoid duplicative and conflicting regulatory and reporting requirements.*
3. *Ensure protection of Confidential Business Information (CBI).*
4. *Require all regulations to be cost-effective, sustainable, and technologically and commercially feasible.*
5. *Ensure regulations balance consideration of the unique applications, intended function, performance, product benefits, and useful life of the product in addition to other lifecycle factors required by statute.*
6. *Use a systematic approach in which uses of chemicals of concern and potential alternatives are first prioritized based on hazard and exposure to the chemical in specific applications.*
7. *Minimize compliance costs and administrative burdens, and protect California jobs and consumers.*

We commend the work your Department is doing on Green Chemistry and appreciate the opportunity to submit our comments. We look forward to being an active participant as you continue your workshops and rulemaking activities.

Should you have any questions, please contact Mike Rogge (mrogge@cmta.net) or Jason Schmelzer (jschmelzer@calchamber.com). Thank you.

DIRECTOR'S OFFICE
DEPT OF TOXIC SUBSTANCES CONTROL

MAR 24 2009

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**GREENCHEMISTRY
A L L I A N C E**

Committed to product sustainability in the global economy

DTSC WIKI RESPONSE

I. REGULATORY "TRIGGER": When is the Requirement to Do an Alternatives Analysis Triggered?

A. Chemical of Concern in a Product

California is required to develop a process to identify and prioritize "chemicals of concern" in consumer products in California.

- What factor(s) should be considered to identify a product sold in California containing a chemical of concern?

We need to first define chemicals of concern (COC), and then consider types of applications/uses of such products that pose highest potential risk, based upon characteristics of the use and the particular hazard trait(s) of concern for that chemical. For example, if there is no exposure potential for the particular trait of concern for a given product, it should not be considered. As an initial matter, if a COC is used in the manufacturing process, but is no longer in the actual product sold in California, the product should not be considered for inclusion.

In addition to consideration of chemical hazard data (TIC, etc.), the statute calls for consideration of "the potential for exposure to the chemical in a consumer product", i.e., the screening process must establish a plausible exposure pathway as a precondition of listing. For example, while biomonitoring data might establish exposure to a COC, unless there is evidence that the COC is likely to be released from the subject product during manufacturing, use, or end of life management (considering applicable exposure control technologies), there is no identifiable exposure pathway to the product and no basis for listing the product. Absent this determination, one can argue that most products containing chemicals for which hazard/toxicity data exists, and that are found in meaningful volumes in state commerce (a crude surrogate for potential exposure), should be listed. This approach would result in indiscriminant listings (analogous to Prop 65) that would quickly overwhelm DTSC's capacity to conduct the product

reviews required by AB 1879 – a setback for public health and environmental protection. Thus the goal of the screening criteria is to focus the regulatory review on particular products that are likely to pose significant human health and ecological risks.

The chemical of concern definition needs to take into consideration:

- Volume of a COC in a product.
 - Volume of sales of a product containing a COC.
 - Control technologies and physical methods in place to limit exposure to a COC.
 - Formulation of a product and factors that balance or negate toxicity and exposure concerns.
 - Designated use for a product.
 - Potential for exposure.
 - Protective equipment recommended or required for a products use.
 - Determination if a sensitive subpopulation comes in contact with a product and if so, how.
- Should the process allow for chemicals to be “nominated” by external parties for consideration?

The process for identifying COC should use science-based criteria to select chemicals which should be reviewed and aired for public comment. Individual chemical selections must be open for public comment and an appeals process must be established. Those in the best position to identify and assess potential chemicals for inclusion in the process are state scientists, with the support of the advisory panel. This will ensure that the state's limited resources are wisely managed.

- Any person wishing review of a chemical or a product containing a chemical of concern may submit it for consideration by DTSC. What information should they be required to provide?

DTSC is delegated responsibility for implementing this program and , as stated above, is in the best position to identify and review chemicals. If a decision is made to allow individuals to submit chemicals or products for inclusion, the information package must be robust and vetted by a recognized expert (consultant). It should be like the “Whistle Blower” provision under OSHA and Prop 65.

- Which “endpoints” (toxicity, risk, hazard, other) or other attributes should trigger designation as a chemical of concern?

Exposure at any level does not automatically mean the chemical is of concern and a hazard does not automatically imply unacceptable risk. A full safety assessment of a chemical looking at the toxicity, exposure and ultimately the risk for a product's uses should be considered.

- What relationship should exist (if any) between this process and the Toxics Information Clearinghouse?

The State should be able to use information in the Toxic Information Clearinghouse as this data will have been vetted/approved for use.

- How should data gaps (absence of endpoint or other information) influence state action? What should the state do where uncertainty exists? How should "quality" of data affect this determination?

Data gaps with respect to defining Chemicals of Concern may be different than data gaps with respect to product containing that chemical. There needs to be a strong reason to suspect the "Chemical" may be of concern versus a specific trait, in order to justify spending resources to "fill the gap" (cannot fill all gaps for all chemicals). Filling data gaps needs to be prioritized by risk. Data gaps for the highest priority risks with greatest uncertainty should be addressed first, to optimize limited state resources.

Under AB 1879, the State clearly has the responsibility to fill the data gaps through their own research and data submitted by the manufacturer of the chemical. If sufficient data does not exist to satisfy the screening criteria in #2, DTSC should work cooperatively with affected manufacturers pursuant to H&SC 57019 (AB 289), to fill identified data gaps.

The State should develop surrogate measures or methods to extrapolate from known data points. For instance, if no information exists on a particular chemical, but information is available for similar chemicals, or similar structured chemicals, methods should be available to use the known information in the absence of chemical specific data. There are several well-validated Quantitative Structure Activity Relationship (QSAR) models available to maximize read-across data from structurally similar compounds. (See OECD and EPA models.)

The quality of data is paramount. It needs to be relevant and of the highest quality. The actions taken by DTSC can have severe economic impacts and should only be taken when the data is clear.

- Who should make the determination regarding a product containing a chemical of concern?

As stated above, the legislature delegated that responsibility to DTSC. DTSC is in the best position to evaluate and make decisions with respect to the risks associated with products containing chemicals of concern based on the best scientific knowledge available. DTSC scientists should make determinations through a safety-based assessment process with mandated consultation with product manufacturers.

- How frequently should products with a chemical of concern be reviewed, updated, or changed?

Not more than once every 5 years or even longer unless some there is a product reformulation or new, significant information comes out concerning either the trait in question or its use/exposure potential in the product.

- Can a chemical identified as a chemical of concern later be "de-selected" based on new or additional information or by filling data gaps?

Definitely YES. If the process is based on data, then data should dictate the selection or de-selection of a chemical of concern. It is not consistent to say that a chemical can be added based on objective criteria, but not removed based on the same criteria. Science is ever evolving and failure to consider significant new data, regardless whether it is positive or negative, would impact the integrity of the system.

- How should this process link to the evaluation of safer alternatives? (See II below.)

The presence of a chemical of concern should trigger the requirement for an alternatives analysis to be performed. This could be refined and narrowed by coupling the presence of the chemical with a factor related to the likelihood of exposure, release during use, or release at the end of life.

Actions should not be taken versus any product or application without at least an equivalent assessment of likely implications for alternatives and a sense of their potential impacts – sufficient to get at least a strong indication that we are not pulling another MTBE.

B. Factors for Prioritization

California is required to consider three explicit factors in prioritizing products containing chemicals of concern; they are: (i) the volume of a chemical in commerce in the state, (ii) the potential for exposure from use of a consumer product, and (iii) potential effects on sensitive subpopulations (including infants and children).

- How should the state consider these factors?

A background report should review existing government prioritization schemes to identify strengths, uncertainties and weaknesses of existing programs including (at a minimum) EPA's HPV program, Canada's Chemicals Management Plan and EU's REACH program.

Screen out those products where there is no potential for exposure.
Review the types of exposures and the risks from those exposures.

Note that the latter (iii) needs to account for the product and exposure potential, not just the potential effects of the chemical of concern in isolation. In a sense the "potential effects" should be considered as a surrogate for risk.

CSPA (from the Wiki): California should consider these three factors as part of a tiered screening process to identify chemicals of concern. The first tier should be screening based on human health (e.g. carcinogenicity, Mutagenicity, reproductive toxicity, etc.) and environmental (e.g. persistence, bioaccumulation, toxicity) factors; the human health screen could include effects on sensitive subpopulations. The second tier should be volume of a chemical in commerce. Finally, individual exposure scenarios should be developed for each chemical that is screened out to identify those uses with the highest exposure.

Volume should be considered in connection with routes of exposure. In relation to consumer products, in addition to volume and potential for exposure, DTSC must consider control technologies, product packages, and formulation attributes that limit exposure to chemicals of concern. DTSC must also consider label instructions and the intended use of a product when making prioritization decisions.

Initial prioritization should be performed in equal partnership among government, industry and academia with complete transparency.

Volume and potential exposure must be considered together and given equal weight. Sensitive populations must be more clearly defined in scientific terms and actual negative health responses in relation to a chemical in order for this consideration to be used for decisions.

116365.2. (a) In conducting the periodic review and revision of public health goals pursuant to paragraph (1) of subdivision (e) of Section **116365**, the Office of Environmental Health Hazard Assessment may give special consideration to those contaminants that, on the basis of currently available data or scientific evidence, cause or contribute to adverse health effects in members of subgroups that comprise a meaningful portion of the general population, including, but not limited to, infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subgroups that are identifiable as being at greater risk of adverse health effects than the general population when exposed to the contaminant in drinking water.

(b) In preparing and publishing risk assessments pursuant to subparagraph (C) of paragraph (1) of subdivision (c) of Section **116365** that involve infants and children, the office shall assess all of the following, to the extent information is available:

(1) Exposure patterns, including, but not limited to, patterns determined by relevant data, among bottle-fed infants and children that are likely to result in disproportionately high exposure to contaminants in comparison to the general population.

(2) Special susceptibility of infants and children to contaminants in comparison to the general population.

(3) The effects on infants and children of exposure to contaminants and other substances that have a common mechanism of toxicity.

(4) The interaction of multiple contaminants on infants and children.

- How should these be weighed or balanced?

Use volume as a filter first, then exposure—consecutive? Again, a main theme here should be to make the most efficient use of very, very limited resources. Cannot afford to grant everything an equal priority—need simple measures to at least triage.

Volume and potential exposure must be considered together and given equal weight. Sensitive populations must be defined scientifically for actual health impacts on a population for each product and chemical before they are considered.

After volume, screen chemicals in the following order:

- Receptors: sensitive subpopulations such as children should be focused upon first.
- Bioavailability: If a chemical does not physically reach receptors or the target organ, then it cannot exert effect.
- Biopersistence: Chemicals that bioaccumulate or are biomagnified in the environment and/or organisms should be considered first.
- Effect: Most serious effects should be prioritized first, e.g. cancer and reproductive/developmental toxicity.

Data from the Toxics Information Clearing House could inform the latter three screening steps (bioavailability, biopersistence and effect). The Clearinghouse should be a comprehensive repository of existing data gathered from other government agencies and the primary scientific literature, subject to data quality review. In addition, a chemical-specific data call-in could be announced with clearly defined data quality criteria, to capture most current information from any stakeholder. Data failing quality criteria would not be considered.

- What are sources of this type of information? How could this information be obtained?

The production volumes of some materials are already reported to various state agencies. Manufacturers are aware of their products intended uses and could supply exposure pathways and may have some data on these pathways.

All publically available information from authoritative governmental bodies should be considered. Also voluntary submissions from companies should be considered under CBI protections.

- What additional factors (if any) should be considered?

Nature of the hazard and risk. A high-dose only threshold effect should not be equated with an effect that could occur in real-world exposures.

Perhaps some sense of potential aggregate harm "threats of serious or irreversible damage".

In addition to volume and hazard the route of exposure and duration of exposure should be considered. Also, confidentiality of data needs to be addressed.

The control technologies and physical methods in place to limit exposure to a chemical of concern.

The formulation of a product and factors that balance or negate toxicity and exposure concerns
The designated use for a product.

Protective equipment recommended or required for a product's use.

- Should the state consider information—or the absence of information—about:

- a. Emission, effluent, discharge, release and waste stream data?

Only to the extent that it would help clarify potential exposure/risk (e.g. a chemical in a waste stream at a business does not necessarily mean that a nearby resident is exposed).

With a volume screen, you would likely get that via TRI reporting and, to the extent that it's relevant as a significant route of exposure for problem trait of problem chemical, yes.

For chemicals, DTSC should work with industry members to identify existing data and research needs. For specific consumer products, DTSC must work with industry members, under a CBI process, to determine proprietary data and research needs. In the absence of data, industry should be able to utilize consortium processes and collective data development agreements to provide information needed to help make individual product determinations.

- b. Biomonitoring data?

Don't see how they could not consider this data. Any consideration needs to consider levels detected and potential risk, not just yes/no on whether a measurable quantity was detected.

- c. Environmental monitoring data (water quality, air quality)

d. Disease registry data?

Yes, if relevant to the trait of concern for the chemical of concern.

e. Other information?

C. Available Information for Others

California is required to reference and use—to the maximum extent feasible—available information from other nations, governments, and authoritative bodies.

- Are there other models for identifying and prioritizing chemicals in consumer products that California could consider?

Other models include TSCA inventory registration as well as the Canadian Domestic Substances list. However, when looking at existing programs DTSC needs to take into account the programs strengths, uncertainties, and weaknesses. Additionally, DTSC also needs to taken into consideration programs and regulations that are currently in place for specific product categories such as the European Union's Restriction on Hazardous Substances Directive (RoHS).

- What are the limitations of these other models?

All existing models are limited by the data that is used to support the decisions. DTSC needs to continue to work with other governments to promote expanded research for toxicity and green chemistry.

Are there tools beyond the traditional toxicological risk management paradigm?

Need more input

Do these other models prompt the use of safer alternatives?

Need more input

Are there other approaches for assessing potential danger, weighing uncertainty, or determining priority or action regarding chemicals in consumer products used in other fields (such as workplace safety, medicine, food safety, finance, other) that California could consider?

Need more input

Where other institutions have acted (for instance, to allow, limit, restrict, or ban a chemical or chemicals in products)?

Need to discuss

II. ALTERNATIVES ANALYSIS: What must be included in this analysis? Who performs it? How quickly must it be performed?

A. Process for Alternatives Assessment

California is required to develop a process that provides for the evaluation of chemicals of concern and their potential alternatives in consumer products.

GENERAL QUESTIONS FROM GCA:

What is the definition of "consumer product"? Without a clear and concise definition, many of the answers to these questions cannot accurately be answered. Does the definition include chemicals of concern only when there is the potential for exposure to the end-user/consumer? During manufacture? End of life of the product? How does this mesh with Extended Producer Responsibility proposals?

How would this alternatives analysis apply to products under formulation, before the product is released into the market? How will confidential business information concerning a product under formulation be protected?

- What triggers the requirement to do an alternatives analysis?

An alternatives analysis should be conducted once a chemical of "potential" concern is designated as a chemical of concern in clearly-defined consumer products through manufacture, use and end of life of product, based on level of toxicity, volume of the product being used, potential for exposure and use of the product. Thus additional data has already been collected on the chemical of concern and a simplified life cycle analysis (LCA) has been conducted for its presence in consumer products and whether alternatives are or may be available.

There must be a clear demonstration of adverse impact on human health or the environment from exposure to a chemical in a product and use, and verified commercial information indicating alternatives may exist.

The presence of a chemical of concern should not necessarily trigger an alternatives analysis.

The nature of the product must pose a risk.

- Who should perform the analysis?

State Scientists should lead this effort in collaboration with manufacturers and academia using a state "facilitated" approach. Collaboration with industry is critical. The analysis should not be restricted to just chemical substitution or reformulation. The State may wish to consider the use of an independent third party to perform the analysis.

- What must be included in this analysis?

Alternatives should be assessed in the same way as chemicals of concern to ensure the comparison is apples to apples using the factors outlined in the law.

The analysis should also be consistent with ISO 14044 series standards. Importantly, the simplified LCA's should not be used as a basis of comparison or decision, but rather provide

some of the information needed to arrive at a decision. However, it may not be possible to complete and LCA for all of the factors in S. 25253 given existing technologies.

This process should not be used to eliminate product forms.

- What lifecycle based algorithms are available to be adapted for use in the analysis?

A simplified approach to Life Cycle Analysis (LCA) should be conducted. LCA is really designed for products, not individual chemicals.

- How does the state ensure that the alternatives which are evaluated include reformulation, safer chemical substitution, engineering alternatives (such as changing product fabrication to eliminate the chemical of concern) and other appropriate options?

The focus should be on problem products, with the aim to find alternative formulations. In most cases the manufacturer may not be able to provide such information. This process must be a collaborative one with State scientists, product manufacturers and chemical/alternative chemical manufacturers.

- What factors should be considered in assessing performance of an alternative?

There are five key factors that should be considered when assessing the performance of an alternative. The alternative should:

1. Be technologically feasible.
2. Deliver equivalent or better value in cost and performance.
3. Provide an improved profile for health and environmental issues.
4. Account for economic and social considerations; and
5. Have potential to result in lasting change.

Market considerations and performance are key considerations. Products must should perform at the same or equivalent level as the original. All claims of equal performance must be carefully substantiated, and the State should require the source of all claims to be identified, and require the company making the claims to validate those claims. The State should be careful not to allow those making claims to gain market share without validating claims.

Other factors to be considered are:

- Product applications and exposure patterns
- Recommended user precautions and other risk management for the chemical use
- Environmental exposure pathways
- Environmental fate
- Whether it is used in combination with other chemicals that reduce its risk
- Commercial availability of alternatives
- Cost factors
- Adaptability of chemical for intended use
- Formulation interaction considerations
- Unintended consequences to human health, impact on the environment, noise, and resource utilization, including whether substantially more product must be used to achieve the same performance of the original product negating any benefits.

The State should also consider current State requirements for California's environmentally preferable purchasing (EPP) program. Section 12400 requires the Department of General Services, in consultation with CalEPA, to take into account a range of factors in making procurement decisions, including "the needs of the purchaser". Consumer preferences and demands must be considered in evaluating the efficacy of alternatives. Section 12400 reads as follows:

12400. For purposes of this chapter, "environmentally preferable purchasing" means the procurement or acquisition of goods and services that have a lesser or reduced effect on human health and the environment when compared with competing goods or services that serve the same purpose. This comparison shall take into consideration, to the extent feasible, raw materials acquisition, production, manufacturing, packaging, distribution, reuse, operation, maintenance, disposal energy efficiency, product performance, durability, safety, the needs of the purchaser, and cost.

Alternatives analysis must include performance testing. If a substitute chemical or technology fails to meet product specifications (e.g. ASTM), then it should not be considered further regardless of other attributes.

The alternatives analysis and factors needed to assess alternatives also will vary from product to product. Is the chemical the active ingredient? Does it perform a specific function as a carrier for the active ingredients? What properties cause companies/consumers to choose it or reject it?

- How should "necessity" be assessed or weighted in the analysis?

The concept of "weighting" factors is not in the statute. This should not be an issue. Necessity is a subjective term; demand is dictated by the market not the government.

- How are possible hazards, risks, or exposure pathways of any alternative evaluated?

These factors, again, should be evaluated for alternative the same way they would be evaluated for chemicals of concern.

- What other considerations should inform the alternatives analysis?

Products should be evaluated fully for their positive impacts on public health, human quality of life, beneficial use, economic benefit, etc. The analysis must fully consider the negative impact of chemical restrictions on the ability to produce a technologically and commercially viable product. The analysis must also consider what behaviors/practices consumers might use to substitute if a product is eliminated from the market or becomes so ineffective that it is no longer valuable in the market place (i.e. the use of gasoline to replace less effective solvent products).

- Should the state adopt a formula to balance or weigh the mandatory and other factors? If so, what would that formula look like?

As previously stated, the statute does not require balancing or weighing of factors. This should not be part of the alternatives analysis.

In addition, the State should use the factors specifically identified in the statute to ensure that manufacturers have certainty as to what factors products and alternatives will be required to address.

Any formulas developed would most likely not be able to work for all products as products, and categories of products, will be impacted differently by the factors.

- What data is available or should be required and how would that data be used in evaluating:
(a. through m.)?

Company data should be accepted for all elements and utilized as the primary sources of information.

B. Process for Lifecycle Analysis

California is required to use lifecycle assessment tools in its alternatives analysis process. The law sets forth thirteen required elements.

1. What models or examples of lifecycle analysis are currently being used?

A LCA generally extends from the creation of raw materials to final disposal of the product or service residuals, and takes into account environmental emissions to air, water, and land. In 2000, the International Standards Organization (ISO) completed work on a series of standards that have become the general benchmark for the technique, which usually includes four stages:

- Defining the goal, scope and boundaries of the assessment.
- "Life Cycle inventory" (LCI) - a database of energy/materials use and emissions, relative to some "functional unit" (e.g., for a detergent, emissions per 1000 loads of laundry washed; for an automobile, emissions per 1000 person-kilometers traveled).
- "Life Cycle impact assessment" (LCIA) - translation of inventory data into potential impacts on the environment.
- "Interpretation" - sensitivity and uncertainty analyses. Only if a chemical receives the COC designation should this third piece be conducted.

In short, the analysis should be consistent with ISO 14044 series standards. Importantly, the simplified LCA's should not be used as a basis of comparison or decision, but rather provide some of the information needed to arrive at a decision.

2. Who should perform the lifecycle analysis?

An ISO certified lab. In addition, all affected stakeholders should be able to submit recommendations, information, and data throughout the process.

3. What should be the scope of the analysis, and should there be any limitations on the scope of the analysis?

a. full lifecycle of the product from extraction of raw materials through use of the product and then disposal or reuse?

b. the product lifecycle from design and manufacture (production) to retail sale and use?

c. other?

LCAs must be comparative from product-to-product within a category. LCA must balance available and reliable data for product life-cycle stages versus a desire to know impacts at every stage. Each product category under consideration should form a consensus as to the life-cycle stages evaluated and acceptable data.

Life Cycle Assessment has several limitations:

- It is not a substitute for safety or risk assessment, since it cannot produce specific data that relates directly to human or ecological exposure, or toxicity (Owens, 1997a).
- Life Cycle data can be incomplete, and assumptions (for example, about boundaries) can be unclear. This makes it difficult to compare products, especially using results from different studies. Furthermore, in comparing products, Life Cycle Assessment will typically identify trade-offs, not overall "winners and losers."
- There are often uncertainties about the reliability of results, or a lack of understanding about the sensitivity of different lifecycle stages to change.
- Life Cycle Assessment does not provide a direct measure of impacts on the environment due to the aggregation of emissions across different phases of a product's lifecycle. Instead it provides, at best, a measure of potential impacts (Owens, 1997b).

Given these limitations, we believe that all users of Life Cycle Assessment, especially for public purposes (e.g., to support environmental claims in the marketplace, or policy making), should follow similar principles:

- Life Cycle Assessment should be used as a decision support tool and not as a decision making tool.
- Methods should be based on the ISO 14040 standards. These procedures are internationally recognized, and agreed by numerous experts in the field.
- Analyses should be publicly available and fully transparent, including the underlying assumptions, data sources, results, and conclusions.
- Life Cycle Assessments should be peer reviewed (as recommended by ISO) and undergo a thorough sensitivity analysis.
- There should be a thorough discussion whether identified differences between products or activities are really meaningful, relative to other human activities.
- In situations where Life Cycle Assessment is to be used for setting public policy, all stakeholders (including industry) should be involved in the design, execution, and interpretation of lifecycle studies.

4. What are the essential components of the lifecycle analysis?

In 2000, the International Standards Organization (ISO) completed work on a series of standards that have become the general benchmark for the technique, which usually includes four stages:

- Defining the goal, scope and boundaries of the assessment.
- "Life Cycle inventory" (LCI) - a database of energy/materials use and emissions, relative to some "functional unit" (e.g., for a detergent, emissions per 1000 loads of laundry washed; for an automobile, emissions per 1000 person-kilometers traveled).
- "Life Cycle impact assessment" (LCIA) - translation of inventory data into potential impacts on the environment.
- "Interpretation" - sensitivity and uncertainty analyses.

Efficiency of use should be considered, both shelf life of product prior to first use and after consumer purchases it. (i.e., if all of the product can be used before "going bad").

5. Should the assessment have a specified time limitation?

This will depend on each product category. The economic impacts associated with the length of the analysis (i.e., manufacturing, sales, etc.) must be included in making this determination.

6. How should criteria—such product useful life, in-use energy consumption, public health effects, greenhouse gas emissions, etc.—be balanced or weighed against each other?

This will depend on each product category.

7. How should the analysis address and include both internal and external costs?

Internal costs to a company should be considered first as these can be more easily identified. External costs should be included when reliable and validated data can be used to provide reasonable external costs. If such data, however, includes production and marketing costs information for the product, the State needs to recognize that such data may be competitively sensitive and that DTSC may be required to protect that data as confidential business information.

8. Are there implications of conducting lifecycle analysis of particular chemicals versus specific consumer product categories (i.e., specific chemical uses)? If so, what are these? How should the state address these?

(LCA for a consumer product derived from chemicals will be exponentially more involved if a LCA is required to assign costs to each chemical's life-cycle included in products.

Data will need to be shared up and down the supply chain depending on the scope of the LCA in question. To limit the amount of data that would need to be developed and to ensure that LCAs are comparable, DTSC might consider setting limits to the beginning and ending life-cycle data development requirements in each product category under consideration. Peer-reviewed data will be essential in this process.

NOTE: Requirements for each product category LCA process must be reached through consensus.

9. How should the lifecycle analysis and the alternatives assessment evaluations account for limited or absent data? In other words, how should the assessments accommodate uncertainty?

Uncertainty cannot be used to negatively impact a LCA or Alternatives Assessment of a product or chemical. Data needs must be prioritized for the impact that they might have on understanding a chemical or product.

Uncertainty in a result is not the same as limited data. Uncertainty (used in this context) is assumed to mean variability in calculations or outcomes. An analysis that is highly variable may mean that the underlying data are highly variable, or factors have not been sufficiently determined; or that the answer is not, in fact, reliably obtained given the methods. Limited data, on the other hand, is a reflection of lack of study (e.g., the question has not been asked in the past). Hence, limited data cannot be used as a basis for any policy decision or conclusion relative to life-cycle analysis.

In either event, due to the significant consequences of state action in this area, the state should not act unless its the underlying data and analysis conducted by the DTSC meets all the applicable scientific and technical standards. In general, limited or less than reliable data cannot

be used as a basis for policy decisions given the wide-ranging consequences that these decisions might have.

III. REGULATORY RESPONSE: What are the appropriate regulatory outcomes based on the alternatives analysis?

The alternatives analysis, & subsequent regulatory actions, if any, should be focus on a clearly-defined consumer product(s) containing a specific chemical of concern. Transparency and public information is a key goal of CA's Green Chemistry program. Thus, consumers should be encouraged to make market decisions in lieu of state government regulatory actions.

1. What criteria should be considered to determine the appropriate regulatory response?

AB 1879 provides an appropriate range of potential responses in light of the possible range of outcomes. GCA has provided responses to questions in Section IIA above which specifically address criteria for evaluating possible alternatives to clearly defined consumer products containing specific chemicals of concern. Please refer to Section IIA responses for detailed information. Prior to taking regulatory action, DTSC should also consider other statutes and regulations that apply, e.g. is the chemical approved for certain uses by regulation?

2. At what point in the alternatives analysis or based on what information in the analysis is it appropriate for the State:

No regulatory action should be taken by DTSC until after the LCA has been completed as part of the alternatives analysis in accordance with HS 25253(a)(2), DTSC has submitted the LCA to the Council in accordance with HS 25252.5 (a), the Council has completed its review of the LCA in accordance with HS 25252.5(c), and DTSC has mitigated "significant adverse impacts" identified by the Council in accordance with HS 25252.5(d). Action taken by DTSC prior to ALL of these steps being taken would be inconsistent with the requirements of the statute.

A - to find a ban of the chemical of concern in the product is appropriate?

DTSC should only act to ban the use of a chemical of concern in a specific consumer product when consumers who use the product **as it is intended by the manufacturer** cannot be protected from unsafe levels of exposure to the subject chemical. If a ban is predicated on the basis of the existence of an alternative then the alternatives analysis must conclude the alternative provides a significant reduction in exposure to consumers, the alternative is available in commercial quantities, and that it preserves the performance and economic viability of the consumer product.

Any ban on the use of a chemical of concern in a specific consumer product must take into consideration the manufacturer's ability to respond in a timely manner and actually reformulate or redesign, or retool for the alternative. DTSC should be required to allow a sufficient period of time prior to the requirement taking effect and must NOT require a manufacturer to withhold products from the market that have previously been manufactured for sale in California.

B - to require labeling or other types of consumer product information?

When the alternatives assessment indicates that existing warnings and/or exposure mitigation measures are inadequate to provide consumers protection, additional product information measures may be necessary and appropriate. However, due to the multitude of consumers products in all shapes and sizes, manufacturers must be afforded flexibility when it comes to meeting the requirements for providing consumer product information. Labeling is but one means of providing

product information. The proliferation of labels is often more confusing than helpful to the consumers. Communication of information to consumers should be streamlined.

C – to place restrictions in use of the product?

The act of restricting the use of a product is a very serious matter and should not be entered into lightly. Any such action must be predicated on sound scientific evidence and its severity should be measured to address only the immediate issues of concern. Placing restrictions on a consumer product can result in a de facto ban. It can have the same effective impact as banning the use of a chemical of concern in a product, or banning the product outright. Placing restrictions on the use of a product should only be done when all other options have been exhausted.

D – to require end of life management such as extended producer responsibility?

This should NOT be imposed because consumers are not disposing of products in the method required by law or recommended by the manufacturer. End of life management should only be imposed when there is a need that cannot be met by current municipal solid waste systems. The question itself is premature as there is no authority within the current legislation to initiate extended producer responsibility. Industry supports targeted voluntary actions over mandatory programs.

E – to require funding of research and development of potentially safer substitutes?

Business and industry are driven by market forces and competition to continuously invent and redesign products that are safer for public health and the environment, perform better, and are cost competitive. Research and development into safer alternatives is the lifeblood of successful business. The question itself is inappropriate as it fails to recognize the competitive nature of the market and the lack of authority within the current legislation to require such R&D.

F – to place technology-forcing regulations into place to phase out harmful ingredients and/or phase-in safer ingredients?

"Safer" is a relative concept. It should not be presumed because a product is deemed "safer" that it is without harm. Furthermore, because a party claims a new product is "safer" than another which it is intended to replace via substitution or as an alternative does not mean that the original product is itself harmful when used in accordance with the manufacturer's instructions.

Products that are not shown to be problematic should not be regulated or forced out of the market simply because of another company's marketing campaign and desire to increase market share.

However, if the state should impose a regulatory constraint because of a chemical of concern within that certain consumer product, it must be left to the product manufacturer(s) to determine how best to comply. The state is ill equipped to dictate a specific remedy or product formulation. Manufacturers must be afforded the opportunity to determine what modifications are needed for the product to comply with the regulation.

GCA believes that manufacturers should be favorably incentivized to develop and discover new products that are sustainable and whose lifecycle analysis demonstrates actual improvements and not simply marketing claims. DTSC should focus resources on validating claims and not on extraneous technology-forcing regulations which in themselves could impede real development.

3. What other regulatory responses are appropriate based on information in the alternatives analysis?

a) DTSC needs to develop a process by which manufacturers of consumer products that have been regulated can petition to have the regulatory requirements removed based on new information or

other factors. DTSC should also be required to review the petition and respond in a timely manner, i.e., 90 – 180 days

b) Other regulatory responses should strongly incentivize development of green chemistry alternatives, rather than obstruct manufacture within the state and commerce across its borders.

c) Banning the use of a chemical of concern in a specific consumer product could require significant investment on the part of the manufacturer, i.e., laboratory reformulation, physical plant equipment, product performance testing, customer qualification testing, advertizing and market acceptance. In consideration of this investment there needs to be a process by which the new product once fulfilling the requirements as an alternative is not subject to further regulation for a pre-determined period of time. Without such a provision, a product could be in a perpetual state of regulation and reformulation and the manufacturer would have no likelihood of recouping its investment.

IV. COMPLIANCE, AUDITING AND ENFORCEMENT: A means of ensuring compliance with the law's goal of moving toward safer alternatives for consumer products will be needed.

- Should testing be required by manufacturers to demonstrate compliance as a precondition for selling or offering for sale? If so, who would conduct laboratory analytical testing of consumer products? Under what conditions?

We believe that testing to demonstrate compliance as a precondition to selling a product in the state is outside the scope of AB 1879 and SB 509. The question is also unclear as to what testing would need to be done or what compliance would be demonstrated.

- Should reporting be required? If so, who should submit what information to whom, when, and for what purposes?

Reporting requirements are a regulatory action under the bill and only be imposed once the state meets all of the requirements necessary to move forward with regulatory actions.

- Should a manufacturer be required to provide a certification to a distributor or retail seller of their products?

It is best to keep supply chain out of regulatory reporting. Downstream users can put raw material specifications in place to their upstream suppliers. Those specs are CBI and not for public distribution. Arrangements between manufacturers and retailers should be similarly CBI. We are also unclear about what certification would achieve.

- Should review or auditing be required? If so, who should review submittals? What criteria should be applied to that review or audit?

Review and auditing requirements should avoid burdensome and costly bureaucratic processes and be targeted at specific regulatory actions undertaken by DTSC.

- Should other party standards-setting and validation be used? For instance, if manufacturers and producers were to conduct the lifecycle analysis and alternatives assessment, do standards exist to guide them? If so, what are these? If not, what would be required to be developed? By whom? How?

ISO Standards are available for LCA. California could hire a contractor to outline general approaches to be followed for CA application. Perhaps review contractor's proposal on how to apply in CA situation by Green Ribbon Panel.

See Section #2 of the Wiki Questions.

- What other considerations should inform the state's compliance and enforcement of this statute?

Compliance and enforcement efforts should be targeted based on the regulatory actions imposed by DTSC.