The Association of Food, Beverage and Consumer Products Companies

March 10, 2009

Maureen F. Gorsen
Director
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: California's Green Chemistry Initiative - 'Wiki' Regulatory Outline

Dear Director Gorsen,

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of consumer packaged goods through scientific excellence. The GMA Board of Directors is comprised of chief executive officers from the Association's member companies. The $2.1 trillion consumer packaged goods industry employs 14 million workers and contributes over $1 trillion in added value to the nation's economy. GMA has appreciated the opportunity to participate in California's Green Chemistry Initiative, and submit this letter in response to questions raised on the Wiki regarding the development of regulations for AB 1879.

AB 1879 is a key aspect of California's Green Chemistry Initiative, establishing authority to identify and manage priority chemicals. The regulations should create an integrated, timely, transparent, stepwise and risk-based process in which the state can 1) identify priority chemicals: 2) identify what products containing those chemicals may present concerns for safety; 3) identify whether there are suitable alternatives and 4) make final determinations on regulatory risk management choices as identified in AB 1879.

In identifying priority chemicals the state should use a risk-based prioritization approach in which both hazard and use/exposure information are considered. AB 1879 suggests a few criteria, but additional criteria would benefit the overall Initiative. Focus should be indicators of high potential for hazard, e.g. CMR, PBT and on indicators of high potential for exposure, e.g. US EPA data on production level, found in drinking water, air, used in consumer products, especially those intended for children, emission/discharge data, and CDC biomonitoring information. In implementing the prioritization, the state should create an open and iterative process for involving the expertise and knowledge of stakeholders to contribute to the information used to make decisions. The process should also work to funnel or narrow the universe of chemicals from a large initial set to

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a final small set to concentrate on "the important few" versus the trivial many. This process will create a workable approach that produces highly evident results.

On alternatives analysis, the product research and development paradigm is an excellent analog. During R&D, improvement objectives are set, alternative approaches for achieving the improvement are identified, and alternatives are evaluated considering a number of factors. Alternatives must:

- Provide an improved profile for health and environmental issues;
- Be technologically feasible and commercially available in sufficient quantity;
- Deliver the same or better value in cost and performance;
- Be accepted by the consumer;
- Account for economic and social considerations; and
- Have potential to result in lasting change.

GMA believes that alternatives analysis must be done from a broad lifecycle perspective to avoid the potential for unintended consequences that can occur from a narrow or hazard-only approach. At the end of the day, it will always be the consumer who finally determines the performance, value and acceptance of a product and its ingredients.

In making final determinations on regulatory risk management choices, AB 1879 provides an appropriate range of potential responses, to be taken after a deliberate and risk-based process with appropriate opportunity for notice-and-comment by stakeholders.

- Not requiring any action.
- Imposing requirements to provide additional information needed to assess a priority chemical and its potential alternatives.
- Imposing requirements on the labeling or other type of information.
- Imposing a restriction on the use of the chemical.
- Prohibiting the use of the chemical in specific uses.
- Imposing requirements that control access to or limit exposure to the chemical.
- Imposing requirements to manage the chemical at the end of its useful life, including recycling or responsible disposal.
- Imposing a requirement to fund green chemistry challenge grants where no feasible alternative exists.
- Any other outcome the agency may determine.

As a first step, California should work with industry and other stakeholders on voluntary programs and consumer education. This can often prevent many issues and unexpected outcomes. In making the determination, California needs to consider other statutes and regulations that apply, e.g. whether the chemical is approved for certain uses by regulation.

The specifics of reformulation response in the case of a restriction or ban should not be mandated, but must be left to manufacturers. Each company should determine appropriate formulation changes for its products.

As to compliance with final regulatory determinations, there are many current examples of regulations, restrictions, prohibitions, and expectations for product manufacturers. GMA members obey the law in complying with those requirements, and will continue to do so with future requirements including those from the Green Chemistry Initiative. Many manufacturers currently disclose ingredients in their products and many more are moving to do so. This should eliminate the vast majority of concerns. In the case of a priority chemical being intentionally formulated into a product in which the use is regulated or restricted, non-disclosure could represent mis-branding. Thus, we believe that California should avoid any new burdensome and costly bureaucratic processes for compliance and reporting for these regulations.

GMA's detailed responses to the Wiki questions are enclosed. If you have any questions or comments, please feel free to contact us. We look forward to our continued work together on this important public policy initiative.

Sincerely,

//original signed by//

Robert E. Brackett, Ph.D.
Senior Vice President
and Chief Science and Regulatory Affairs Officer

Enclosures

cc: Linda Adams, California EPA
Jeff Wong, DTSC
Rick Brausch, DTSC
Don Owen, DTSC
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DIRECTOR'S OFFICE
DEPT OF TOXIC SUBSTANCES CONTROL
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California Green Chemistry Initiative
GMA WIKI Comments—March 10, 2009

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.

OVERVIEW. There are several steps to accomplish the state's goal: 1) identifying "chemicals of concern": 2) identifying what products containing those chemicals may present concerns for safety; 3) identifying whether there are suitable alternatives and 4) making final determinations on risk management actions. Ideally this will be an integrated, stepwise risk-based process to look at chemicals with hazards of concern and at their uses in products that have exposure scenarios of concern to identify priorities for alternative analysis and then, where warranted, risk management action as identified in AB 1879.

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

   "Consumer products" are broadly defined under AB 1879 and SB 509, exempting only a few categories of products. This will help to maximize the potential for achieving the stated goals of the California Green Chemistry Initiative. The regulations should outline a reasonable, clearly defined approach for identifying, prioritizing, evaluating, and restricting chemicals where warranted in the whole of California commerce, not just a particular category of use. The following are important considerations:

   - The process needs to have an integrated way of considering chemicals with hazards in the context of their intended uses in products that have exposure scenarios of concern and to then identify priorities for action by California.
   - The priority setting process and risk management decisions need to consider factors which are frequently used to limit human exposure to chemical ingredients, e.g. the type and design of both products and packaging; directions for use and label warnings; protective equipment during product use, directions for disposal.
   - The process and outcome should be oriented to identifying real priorities of concern to public health and the environment—the important few, vs. the trivial many.
   - In moving from initial priorities to final determinations, DTSC should engage with producers and users of priority chemicals to acquire information and expertise that is available.
   - Also, in moving from initial priorities to final determinations, exposure assessments should be done to allow California to identify those products containing the priority chemicals that contribute significantly to exposure (based not only on concentration of the chemical in the product but also the intended use of a product and resulting routes of exposure including ingestion, inhalation, and dermal.)
   - In performing exposure assessment, these should focus on intentional ingredients looking at exposure pathways that result for intended use.

- Consideration needs to be given to whether a truly better alternative has been identified for use as a replacement for the priority chemical in that product for that particular use; i.e., the alternative must have undergone and met at least the same level of scrutiny and been held to the same standards prior to its identification as such (See Section II responses for more detail on Alternatives).

2. Should the process allow for chemicals to be "nominated" by external parties for consideration?

   California needs to operate a transparent and timely process for this effort that includes several opportunities for input by stakeholders. This input could lead to both additions and deletions from preliminary findings. California should undertake a first round in the process, then allow parties to comment with rationale for additions/deletions and level of priority. California can then consider and update its findings. The state could consider multiple iterations for this as was done in Canada, enabling very useful input from stakeholders. However, the process needs to be arranged in an efficient manner to ensure the overall process is timely and minimize the potential for diverting state resources such as a nomination process might do.

3. Which "endpoints" (toxicity, risk, hazard, other) or other attributes should trigger designation as a chemical of concern?

   The process should be risk-based prioritization considering both hazard and use/exposure information. To ensure that priority setting is focused on the "important few", the selection criteria should include 1) indicators of high potential for hazard, e.g. carcinogens, mutagens or reproductive toxicants (CMR), persistent, bioaccumulative and toxic (PBT) compounds and 2) indicators of high potential for exposure, e.g. production level, found in drinking water, air, used in consumer products, especially those intended for children, emission/discharge data, found in biomonitoring.

   In final determinations, on a weight-of-evidence approach comparing hazard level to anticipated exposure levels must be made, not simply considering the "presence" of a chemical in any given medium such as drinking water, air, or biomonitoring information.

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

   The TIC is intended to be a decentralized web-based system to collect, maintain, and distribute data on chemical hazard traits, environmental and toxicological endpoints. Its usefulness is partially dependent on timing. If the TIC is set up and has gathered substantial information on hazards, uses, exposures, priorities and risk management from other authoritative bodies it could provide useful resource in establishing priorities. However, it should not be the only source of information. As mentioned in A.2. above, there should be a notice and comment opportunity for stakeholders, which has great potential to contribute additional information from sources not already incorporated in the TIC.

5. 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?

   The degree of uncertainty is a relevant factor in priority setting, however there needs to be some reason for suspected concern. For initial round of prioritization, the state should identify potential priorities and rationale, identify important data gaps and invite the public to provide information to fill gaps needed for final determination. This could then be repeated with the public release of updated information to allow for further input.

   The Canadian approach to chemical prioritization under the Canada Environmental Protection Act (CEPA) should be understood and considered by California. For example, in the initial data gathering, Canada used available data when possible, and inserted modeled data for persistence, bioaccumulation and aquatic toxicity when data was not available. During comment periods, stakeholders were invited to provide study data to replace model information.

   The state should employ data quality standards as developed by the Organization for Cooperative and Economic Development (OECD) based on the Klimisch method and use a weight of evidence approach when multiple studies are available. For final determinations, per the Canadian approach, the relative uncertainty of and degree of confidence in exposure and effects databases that serve as the basis for decision-making in the assessment of high intrinsic toxicity or the adequacy of margins of exposure including appropriate safety factors should be explicitly delineated and must be consistent across screening assessments. Consideration must be given to aspects such as:

   - interspecies and intraspecies variation,
   - nature of the critical effect,
   - dose spacing in the critical study,
   - steepness of the dose-response curve,
   - extent of the database as the basis for characterization of hazard for all effects including that considered critical,
   - degree of protection provided by the critical effect level, and whether or not estimates of exposure are based on, for example, environmental monitoring or modeled data or higher-confidence internal doses (e.g., levels in blood).

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

   A final determination of "high priority for risk management action" should be made by CalEPA/DTSC. As previously indicated, this should only occur after an iterative process and consultation with stakeholders and with the Green Ribbon Science Panel in arriving at final priority determinations.

   For effective resource management, it may be appropriate for California to make choices not only on what action to take, but when. In some cases the state may

put a 'hold' on action, pending further data collection, awaiting pending assessments/actions by other governments, etc.

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

   There should be a process with built-in steps to trigger review/re-evaluation when significant new data/information emerges which would alter the decision. In part, this depends on findings and the strength of evidence behind them. If the determination is a close call, there might be a shorter turnaround. If the determination indicates a large margin of safety and no action is taken, there should be long turnaround. The Clearinghouse should be updated on an ongoing basis as new data that meet reliability standards become available.

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

   Absolutely. Deselection for the list should be a potential outcome of the prioritization and assessment process. As directed in the legislation, if chemical ends up "not requiring any action" it should be delisted. Additionally, should future information indicate that listing/regulatory action was inappropriate, the actions should be reconsidered.

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

   Once a chemical and its use(s) have been determined to be high priority based on risk, the Alternative process should be triggered. No immediate risk management needs to be taken unless there is an "imminent risk".

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).

In identifying priority chemicals the state should use a risk-based priortization approach in which both hazard and use/exposure information are considered. AB 1879 suggests a few criteria, but additional criteria would benefit the overall Initiative. Focus should be indicators of high potential for hazard, e.g. CMR, PBT and on indicators of high potential for exposure, e.g. US EPA data on production level, found in drinking water, air, used in consumer products, especially those intended for children, emission/discharge data, and CDC biomonitoring information. In implementing the prioritization, the state should create an open and iterative process for involving the expertise and knowledge of stakeholders to contribute to the information used to make decisions. The process should also work to funnel or narrow the universe of chemicals from a large initial set to a final small set to concentrate on "the important few" versus the trivial many. This process will create a workable approach that produces highly evident results.

1. How should the state consider these factors?

   We support risk-based prioritization in which both hazard and use/exposure information are considered.

   Potential effects on sensitive subpopulations is an indication of potential hazard while volume and use in consumer products are indications of potential exposure. These are specifically stated in the law but there are other equally valuable factors that should be considered. The focus should be on indicators of high potential for hazard, e.g. CMR, PBT and on indicators of potential for exposure, e.g. production level, found in drinking water, air, used in consumer products, especially those intended for children, emission/discharge data, found in biomonitoring.

   Accurate volume information at a state level will be difficult to develop without a large and burdensome data-collection process. Production volume has limited use in human health assessments for most consumer products. It can be important for environmental safety assessments. There are several ways to approximate volume information with sufficient accuracy when appropriate for initial screening and priority setting, without the need for a burdensome data call-in.

   In making final determinations, the state must compare hazard data on the chemical with estimates of exposure from the use(s) to identify concern. An exposure assessment would estimate various exposure scenarios (e.g., ingestion, inhalation, dermal) based on expected use(s) of the chemical to establish what action the margins of exposure warrant on the potential risks of the priority chemical in its product uses.

2. How should these be weighed or balanced?

   This might best be done in several iterative rounds as the Canadian CEPA system had done. A first round would be to order, via available data chemicals/uses according to an initial binning from high to low. Following public comments, a second round, focusing on the highest group, priorities could be refined and more detailed data needs established for finalizing high priority chemicals/uses.

   As discussed in I.B.1.4, in making final determinations, the state should follow a scientific weight-of-evidence approach based on the entirety of available data to include:

   - The intrinsic toxicity; AND
   - The margin of exposure - is the margin of exposure sufficient to protect even the most sensitive subpopulations (e.g., infants, occupational, etc.); AND
   - The relative uncertainty – based on the available dataset.
   - This same prioritization process must be applied to any potential alternative as well;

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

   For hazard information there are many sources: US HPV and OECD HPV databases; NTP Report on Carcinogens and NTP_CERHR data; IARC monographs; US EPA IRIS database; Health and Environment Canada categorization databases; EU Annex 1 and ESIS databases; variety of online and published chemical hazard databases; producer GHS information; Proposition 65 data; REACH data when it becomes available.

   For volume information the best source is US production level information and partial California information via US EPA's 2006 IUR. There are also commercial databases for many chemicals and producer marketing information and websites.

   For Use and Exposure information: US EPA's 2006 IUR (use categories and use in products intended for children; EPA's air and water (NCOD) monitoring databases; EPA's TRI databases; CDC's Biomonitoring data; sector trade associations; Economic surveys; producer marketing information/websites. In addition there are a number of sources to assist with developing exposure information. Some examples: US EPA's Exposure Factors Handbook, EPA's recently released exposure factors handbook for children, the Soap and Detergent Association's Exposure and Risk Screening Methods for Consumer Product Ingredients.

4. What additional factors (if any) should be considered?

   This should be risk-based prioritization using both hazard and exposure considerations. Focus should be indicators of high potential for hazard, e.g. CMR, PBT and on indicators of high potential for exposure, e.g. production level, found in drinking water, air, used in consumer products, especially those intended for children, emission/discharge data, biomonitoring indicates potential exposure. See also I.A.3. and I.B.1-4 above.

   See I.A.1.3, consideration of risk management in place as a result of type and design of product and packaging.

5. Should the state consider information—or the absence of information—about:

   Where information important to an identified potential concern or priority decision is absent, California should have a process and capability to request it. In some cases, California could also choose to use tools such as EPA models to develop estimates, to more timely move the priority process along towards determinations.

   a. Emission, effluent, discharge, release, and waste stream data?
   These can all be relevant to assessment of environmental risk and sometimes for human risk and may be useful in certain situations. Both Federal and California sources can contribute information to this. If available and of adequate quality, they should be used.

b. Biomonitoring data?
Biomonitoring data are point-in-time measurements that can potentially indicate an aggregate exposure. Given that adequate and sufficient information exist to interpret biomonitoring data (to link the detection to an exposure) biomonitoring can be useful in prioritization and in risk assessment. Biomonitoring data can be considered for use in priority setting based on clearly understood strengths and limitations of the data for a particular chemical; i.e., on a case-by-case basis. Final priority determinations and resulting risk management actions should not be taken based on presence alone, but based on a chemical's potential for bioaccumulation, persistence, toxicity and the likelihood of harm. If available and of adequate quality, biomonitoring data should be used.
c. Environmental monitoring data (water quality, air quality)
These can be relevant to assessment of environmental and human risk and may be useful in certain situations. If available and of adequate quality, they should be used.
d. Disease registry data?
Disease registry data can be used as another source of information to be considered in the context of all available information and weighted according to the quality of the data. They may be useful to the extent that the disease can be causally connected to exposure to/use of the particular chemical following accepted epidemiology scientific practice.
e. Other information?
AB 1879 contains significant provisions on Confidential Business Information. The Wiki outline does not cover the topic at all. This will be an important area to address in regulations.

Consideration needs to be given to the possibility that a priority chemical (or its metabolite) may already be endogenously produced in humans as part of the normal physiological process in addition to exogenous sources. A priority chemical may also be produced from natural sources. These situations must be considered in determining the likelihood of harm in the priority setting process, in the alternatives process and in the risk management process,

C. Available Information from Others

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

Available information from other nations, governments and authoritative bodies should be an important emphasis given limited resources. California needs some way to bring in other successful approaches, to evaluate and adapt them for the state's situation. California should use the Green Ribbon Panel to review and comment on CalEPA insights from these sources.

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

   To date, Canada has established the most efficient and effective process for doing this despite resource and information limitations. The clear focus of their legislation, single minded approach of the agencies, open and iterative process for involving stakeholders, prompt and timely capability of Canada's data call-in

process and high elected leadership support for the program have contributed to this success. There has been a very high focus to concentrate on "the important few" versus the trivial many and has led to a very workable approach producing highly evident results.

A process that emerged from a Canada/Mexico/US meeting in Montebello, the EPA Chemical Assessment and Management Program (ChAMP) program, holds a lot of promise, given strong support from agency leadership, EPA's technical capability, more available US information and effective assessment tools. But this has been underway for just a short time, its priority in the new administration is not clear, it is voluntary and is hampered by EPA's challenges in promptly getting adequate data for decisions.

In the 1990's, Europe had a prioritization process but it operated very slowly with very few decisions and actions over a decade of effort. Frustration with that led directly to the development for and advocacy on REACH.

2. What are the limitations of these other models?

   See above.

3. Are there tools beyond the traditional toxicological risk management paradigm?

   AB 1879 is focused on prioritizing, making decisions and taking control actions on priority chemicals to improve public health and the environment. There are no alternative science-based tools for accomplishing this purpose.

   There are some approaches which only focus on the one-dimensional aspect of considering hazard in making decisions. These can be very short sighted in not also considering performance, cost, availability and long term sustainability. And, unless exposure is also considered, California resources will almost certainly be misdirected to chemicals that do not pose any risk.

4. Do these other models prompt the use of safer alternatives?

   As noted above, approaches that focus only on reducing hazard are insufficient.

5. 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?
6. Where other institutions have acted (for instance, to allow, limit, restrict, or ban a chemical or chemicals in products)?

   Actions by other states or countries may be useful to California's consideration generally in understanding the objectives and criteria for decisions. For specific cases of chemicals and uses, California should consider bringing the relevant information from other jurisdictions into consideration, but follow the process that the state sets up so that the determinations are relevant to California.

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.

The product research and development paradigm is an excellent analog for the alternatives process. During R&D, improvement objectives are set, alternative approaches for achieving the improvement are identified, and alternatives are evaluated considering a number of factors—alternatives must:

- Provide an improved profile for health and environmental issues;
- Be technologically feasible and commercially available in sufficient quantity;
- Deliver the same or better value in cost and performance;
- Be accepted by the consumer
- Account for economic and social considerations; and
- Have potential to result in lasting change.

GMA believes that alternatives analysis must be done from a broad lifecycle perspective to avoid the potential for unintended consequences that can occur from a narrow or hazard-only approach. The Green Chemistry Science Advisory Panel made many useful suggestions on the Alternatives question that should be considered in this process. One caution that must be noted: even under the most rigorous and detailed execution of lifecycle analysis, relatively large margins of error are typical due to assumptions and lack of precision in the input data. Additionally, different models may give different results. Thus, an analysis which suggests a 10% or even 20% improvement may in fact, not be meaningful,

1. What triggers the requirement to do an alternatives analysis?

   Determinations by the state that a chemical and its use(s) are a risk to public health and/or the environment as an outcome of the priority chemical process.

2. Who should perform the analysis?

   CalEPA should facilitate but the process must include experts from the particular value chain—chemical producers and consumer product manufacturers and potentially trade associations with relevant expertise. This needs to be set up in a way to avoid anti-trust concerns and protect trade secrets.

   US EPA's Design for the Environment approach has been very constructive in providing a science-based approach to gaining insights on potential benefits and risks of competing alternatives for priority chemicals.

3. What must be included in this analysis?

   Much of the public discussion and debate on alternatives focuses solely on reducing the hazard posed by a priority chemical. To be successful in achieving

the goals of the Green Chemistry Initiative, the state must take a much broader approach. Of course, an acceptable alternative must provide an improved profile for health and/or the environment. However, it must also be technologically feasible and commercially available in sufficient quantity; deliver the same or better value in cost and performance; be accepted by the consumer; account for economic and social considerations; and, have the potential to result in lasting change.

Thus, information on product safety, performance, public health benefit, cost, commercial availability, quality, and feasibility, plus consumer acceptance and long term potential for use of the alternative must be analyzed in comparison with the priority chemical. The alternative must represent an improved profile for the hazard or risk concerns associated with the priority chemical while not introducing other concerns that could adversely shift the overall balance. An alternative must be workable, with means of adequate production to deliver an equal or better performing product at a competitive price and be accepted by consumers. Any alternatives that are seriously considered must have an expectation of being effective for a long period of time—industry should be able to make use of technologies for years, with later rounds of reformulation and capital investment beyond the immediate horizon.

Creating a consumer preferred formulation that performs well is complicated—simple "drop-in" alternatives are extremely unusual. Some factors to be considered are:

- Overall product characteristic and performance requirements;
- Physical properties of the alternative;
- Formulation interaction with other ingredients and packaging;
- Stability of the formula;
- Shelf-life preservation;
- Aroma;
- Appearance;
- Convenience and ease of product use and disposal.

Considerations for evaluating and improving product safety profile include:

- Product applications and human exposure patterns;
- Recommended packaging, user precautions and other risk management for use and disposal;
- Environmental fate and exposure pathways; and
- Whether it is used in combination with other chemicals that reduce its risk
- Unintended consequences to human health, impact on the environment, and resource utilization, including whether substantially more product must be used to achieve the same performance of the original product negating any benefits.

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

There are many models available which may or may not give different results. It is important that a consistent approach be used within each alternatives analysis.

5. 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?

   DTSC must establish expectations for the alternatives process and carry them out through facilitation of each alternative effort.

6. What factors should be considered in assessing performance of a chemical in a product?

   Performance of a chemical is product category and formulation specific. ASTM standards exist in some categories, and there may be guidance from trade and scientific organizations in certain product categories. This reinforces the need to have producers and users from affected value-chain engaged in the process.

   There are several generic factors to be considered. Characteristics that a chemical may impart to the overall performance of a product may include its compatibility with other chemicals, its contribution to increased shelf-life and stability, its function to modulate absorption of key ingredients, and others. However, these determinations must be made on a case-by-case basis depending on the intended function of the chemical.

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

   This question is not clear, but if the focus is socioeconomic value, it is difficult to assess this for many/most consumer products and the state should probably avoid it. If the use of an ingredient in a product is safe, there should not be a need for a risk-benefit analysis. Consumers should continue to be allowed to decide whether a product or individual chemical in products is necessary. Additionally, to be successful the California program must operate in a way that it is not vulnerable to legal challenges based on restraint-of-trade or interstate commerce concerns.

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

   Alternatives must be evaluated to the same extent as the chemical it is being proposed to replace to avoid any regrettable substitutions. The hazards, exposure pathways, uses, and lifecycle impacts should all be factored into the evaluation. California must consciously evaluate "what could go wrong" with the alternative as part of the analysis to ensure identification of potential problems

9. What other considerations should inform the alternatives analysis?

   At the end of the day, it will always be the consumer who finally determines the performance, value and acceptance of a product and its ingredients. Ideally,

there should be a consumer acceptance evaluation phase to an alternatives process.

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

    These will most likely be a case-by-case judgments, not adaptable to a "formula". Overall weight of evidence on priority chemicals/uses, their risks and a comparison with the available alternatives. The state's final determination should be on whether to restrict or ban the use of a priority chemical. It should never mandate the use of a specific alternative(s), but leave those decisions to the users.

11. What data is available or should be required for and how would that data be used in evaluating:

- 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?
- i. energy efficiency?
- j. waste and end-of-life disposal?
- k. public health impacts?
- l. environmental impacts? and,
- m. economic impacts?

These are excellent examples of lifecycle analysis factors. Lifecycle analyses have been done for some product categories but many have not been evaluated. Thus, availability of baseline lifecycle date and requirements can be vastly different per product category.

A simplifying approach in lifecycle analysis is to focus on what is changing and assess the impact of the change, vs assess the entire system. This can still be challenging and take significant effort, but can provide a practical approach for simplified analysis.

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.

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.

Who should perform the lifecycle analysis?

Undertaking the LCA should be the responsibility of the affected industry sector, facilitated and reviewed by CalEPA. An ISO certified lab should perform the analysis.

2. 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?

LCA's 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.

A simplified approach to Life Cycle Analysis (LCA) should be conducted. LCA is really designed for products, not individual chemicals. Thus, a targeted approach focusing exclusively on the chemical under review is necessary to maintain scope.

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.

3. 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").

4. 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.

5. 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 is dependent on the product category being examined, thus must be considered on a case-by-case basis.

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

   Internal costs to should be considered first as these can be more easily identified. External costs should be included when reliable and validated data are available to provide reasonable external costs.

7. 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.

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

8. 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. There are always uncertainties in these analyses, which should be presented and explained. A useful way to present this can be with error bars to make the uncertainty more transparent.

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

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. In making a determination, California needs to consider other statutes and regulations that apply, e.g. whether the chemical is approved for certain uses by regulation.

The specifics of reformulation response in the case of a restriction or ban should not be mandated, but must be left to manufacturers. Each company should determine appropriate formulation changes for its products.

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

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

The risk assessment indicates that there are no levels for safe use (no margin of safety) for the priority chemical based on qualified assessments by experts.

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

The risk assessment indicates that warnings and/or risk management actions by the consumer provides adequate protection.

C – to place restrictions in use of the product?

The risk assessment shows that a restriction that could be to "maintain product concentration below a certain level that would be safe for the product category". It could also find that a product with a particular ingredient is not appropriate for use by children under a certain age, resulting in label warnings. Another example might be that a chemical would be restricted or banned from use in some product categories but allowed in others based on the assessment of hazard and exposure in those uses.

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

GMA opposes extended producer responsibility. Requiring extended producer responsibility for end of life management of products puts an undue burden on manufacturers, and is neither practical nor enforceable. Control of the ultimate disposal of a product is in the hands of the end-user. Additionally, end-of-life disposal options may vary according to municipal availability, such as for apartment complexes, which do not have multiple collection containers available. State and local consumer communications together with appropriate product labeling that suggest proper use, handling and disposal of a product are ways to support green habits for recycling, and composting, reusing or disposing spent products and their packaging.

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

When the risk assessment indicates a concern, but there are inadequate alternatives found in analysis.

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

This may be an action the state could consider for some of the scenarios in A – F and where an alternative is available meeting the criteria of the alternative analysis. However, the specifics of reformulation in response to a restriction or ban should not be mandated, but must be left to manufacturers. Each company should determine appropriate formulation changes for its products.

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

As a first step, California should work with industry and other stakeholders on voluntary programs and consumer education. This can often prevent many issues and unexpected outcomes. All potential outcomes identified in AB1879, taken after a deliberate and scientifically sound process with appropriate opportunity for notice-and-comment by stakeholders.

- Not requiring any action.
- Imposing requirements to provide additional information needed to assess a priority chemical and its potential alternatives.
- Imposing requirements on the labeling or other type of information.
- Imposing a restriction on the use of the chemical.
- Prohibiting the use of the chemical in specific uses.
- Imposing requirements that control access to or limit exposure to the chemical.
- Imposing requirements to manage the chemical at the end of its useful life, including recycling or responsible disposal.
- Imposing a requirement to fund green chemistry challenge grants where no feasible alternative exists.
- Any other outcome the agency may determine.

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.

1. 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?

Formulation testing is an unnecessary, costly and inefficient burden. Many manufacturers currently disclose ingredients in their products and many more are moving to do so. This should eliminate the vast majority of issues. In the case of a priority chemical being intentionally formulated into a product in which the use is regulated or restricted, non-disclosure could represent mis-branding.

There are many current examples of restrictions, prohibitions, and expectations for product manufacturers. GMA members obey the law in complying with those requirements, and will continue to do so with future requirements including those from the Green Chemistry Initiative. There are federal precautionary labeling

requirements and any additional needs to provide that kind of information to consumers would be covered by those laws. Consumer products in California and the US do not require pre-market registration and we would oppose any efforts to alter that.

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

   New reporting requirements should not be required. Ongoing ingredient disclosure should handle this need.

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

   It would be best to keep the supply chain out of regulatory reporting. As with all other regulatory compliance needs, downstream users can put raw material specifications in place to their upstream suppliers. Those specs are confidential business information and not for public distribution. Arrangements between manufacturers and retailers should be similarly CBI.

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

   California should avoid burdensome and costly bureaucratic processes. Ingredient disclosure should minimize any concerns.

5. 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. The contractor's proposal on how to apply LCA in the CA situation could be reviewed by the Green Ribbon Panel.

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

   The State could create additional market-based incentives for compliance.