Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

May 27, 2010

Maziar Movassaghi
Acting Director
Department of Toxic Substances Control
California Environmental Protection Agency
1101 I Street, 25th Floor
Sacramento, CA 95814

Re: Safer Alternatives Regulation

Dear Director Movassaghi:

On behalf of the Green Chemistry Alliance (GCA), we respectfully submit the following comments relative to the development of the Safer Alternatives regulation, a draft of which is expected to be released in the coming weeks. The regulations, if crafted appropriately, will enable the Department of Toxic Substances Control (DTSC) to fully and successfully implement AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008), which will in turn enhance public health and environmental protection, promote innovation while still respecting confidential business information and intellectual property, and further the principles of sustainable development.

While the GCA and its members appreciate the complicated nature of drafting the Safer Alternatives Regulation, we remain concerned regarding certain important principles and issues in the regulatory outline. Although the impending draft regulation will be just that – a draft – the details are critical and could have sweeping ramifications on virtually all industry sectors which manufacture or sell consumer products in the state.

We are hopeful that the draft regulation will be a forward-looking approach to identify, prioritize, evaluate; and as appropriate, regulate the highest priority uses of chemicals of concern in priority products; promote truly safer alternatives on the basis of technically sound comparative multi-media life-cycle evaluation; consist of a comprehensive set of regulatory concepts that fully satisfy the substance and intent of legislation; allow for timely implementation in an orderly and economically responsible manner; and provide clarity regarding compliance, and enforcement.

The GCA has its roots in a group of business trade associations and companies that have long advocated for a science-based framework for chemicals management. As you know, a driving force behind the enacting legislation was a broad-based desire for state regulators, rather than the

legislators, to exercise their expert scientific and engineering judgment and experience when determining appropriate regulatory actions affecting chemicals of concern in consumer products.

In the wake of this groundbreaking legislation, the GCA was formalized for the purpose of constructively informing the implementation effort such that the promulgated regulations remain true to the objective and scientific ideals of the authorizing legislation.

In a proactive fashion and in response to the Department of Toxic Substances Control (DTSC) requests for comments, GCA members have invested countless hours over the last year and a half developing regulatory text and comments for implementing the regulation. This work has been the result of a focused and proactive effort by a broad array of individuals from coast to coast with science, engineering, toxicology, R&D, manufacturing, regulatory and legal backgrounds and possessing significant expertise in state, national and international chemical management policy.

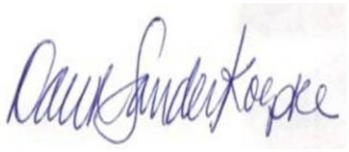
The task of chemicals management is a long-term endeavor driven by ever-changing developments in science. Regardless of the resources directed toward development of data, there will always be more questions to ask and more data to gather – it is after all the nature the scientific process. The issue is not whether there is a data gap, but rather what are the critical "data needs," and how can the state manage its finite resources to best identify and prioritize the uses of the chemicals of greatest concern in high priority consumer products? In the current and foreseeable economic climate, California must adopt balanced regulations that focus on the highest risk exposures to substances in consumer products sold or used in the state.

GCA and its members appreciate the work DTSC and other interested stakeholders have put into the process thus far. GCA is committed to continuing to work with all parties to finalize reasonable and effective regulations that reflect the intent and specific requirements of AB 1879 and SB 509 and, most importantly, provide for a program that will foster innovation rather than stifling it.

Based upon DTSC's earlier flowchart, detailed outline, presentations to the Green Ribbon Science Panel and our own discussions with the department, GCA respectfully submits the attached comments and positions regarding our expectations for the Safer Alternatives regulation package. For further information or questions regarding the Green Chemistry Alliance, its members, or the attached comments - please contact either John Ulrich (916) 989-9692 or Dawn Koepke (916) 930-1993. Thank you!

Sincerely,

John R. Ulrich
Co-Chair
Chemical Industry Council of California



Dawn Sanders Koepke
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Green Chemistry Alliance Signatories

Alliance of Automobile Manufacturers
American Apparel & Footwear Association
American Chemistry Council
American Forest & Paper Association
American Honda Motor Company, Inc.
Amway
Association of Home Appliance Manufacturers
Association of International Automobile Manufacturers
BASF
The Boeing Company
California Aerospace Technology Association
California Chamber Commerce
California Grocers Association
California Healthcare Institute
California League of Food Processors
California Manufacturers & Technology Assoc
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California Retailers Association
Can Manufacturers Institute
Chemical Industry Council of California
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Florida Chemical Company, Inc.
Fragrance Materials Association
Goodrich Corporation
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Honeywell
Hyundai-Kia America
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International Sleep Products Association
Johnson & Johnson
Kern Oil & Refining Company
Koch Industries
Metal Finishing Associations of Northern & Southern California
National Aerosol Association
National Paint & Coatings Association
Northrop Grumman
OPI Products Inc.
Personal Care Products Council
Phoenix Brands
Plumbing Manufacturers Institute
Procter & Gamble
Reckitt Benckiser
Soap & Detergent Association
Solar Turbines
TechAmerica
Toy Industry Association
Travel Goods Association
United Technologies
Western Growers
Western Plant Health Association
Western States Petroleum Association
Western Wood Preservers Institute

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CC: The Honorable Linda Adams, Secretary, CalEPA
Cindy Tuck, Undersecretary, CalEPA
Patty Zwarts, Deputy Secretary, CalEPA
John Moffatt, Legislative Affairs, Office of the Governor
Scott Reid, Cabinet Secretary, Office of the Governor
The Honorable Joe Simitian, California State Senate
The Honorable Mike Feuer, California State Assembly

Scope & Prioritization of Chemicals and Products

The mandate of AB 1879 is to identify those chemicals present in consumer products which pose a threat to human health and the environment and thus warrant additional regulation. The Legislature concluded that a meaningful prioritization was necessary to achieve this objective to "address the worst first". The Legislature also sought to avoid duplicative regulation in light of limited state resources.

The first step of the regulation implementing AB 1879 and SB 509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute, however, GCA is firm in its belief that the prioritization and evaluation process be based on ***exposure*** as well as hazard, and that it avoid duplication and conflicting regulatory requirements.

GCA anticipates the DTSC is intent on crafting a manageable process beginning with chemicals which exhibit the greatest hazards. In this regard, GCA expects DTSC will begin with substances known or presumed to cause cancer or developmental or reproductive harm (CMR) as provided for under Proposition 65; and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA. These chemicals would be identified as “chemicals for consideration,” subject to further review and study based on the severity of the risks associated with the chemical. At this stage DTSC would be able to request information regarding such chemicals and make its determination relative to elevating some of these chemicals to the category of “chemicals of concern.” In making its determination, DTSC will evaluate the potential exposure to the chemical, its volume in commerce within California, its potential effects on sensitive subpopulations, and its potential for adverse impacts on the environment. GCA supports this two step approach, i.e., “chemicals of consideration” and “chemicals of concern.”

To foster transparency and encourage public input, GCA supports public comment and appeal opportunities relative to a chemical under consideration as a chemical of concern prior to being officially listed as such.

Upon identifying chemicals as chemicals of concern, the department may immediately begin to evaluate consumer products containing these chemicals, taking into consideration data from various authoritative bodies and industry trade associations or consortia. The consumer products containing a chemical(s) of concern would be assessed for the concentration of the chemical of concern in the consumer product; ***reasonable and foreseeable*** exposure potential to the chemical of concern from the product; the volume of the product for sale in California; the use of the consumer product by sensitive subpopulations; design features and instructions for use and disposal of the consumer product; and environmental impacts from releases and exposures of the chemical of concern in the consumer product. GCA once again emphasizes the fundamental importance of a process to select priority products to undergo the alternatives assessment. The prioritization process should focus on evaluations of consumer exposure, especially for products targeted toward sensitive populations rather than solely on the properties of the individual chemicals in the consumer product, since exposure and risk vary depending on the product, and on how and by whom that product is used.

GCA is adamant that exposure is an upfront consideration in the prioritization process. AB 1879 specifically directs that the prioritization process include "The potential for exposure to the chemical in a consumer product." If there is no "reasonable and foreseeable" exposure pathway, an exemption should be provided in a manner consistent with provisions under Proposition 65

Additionally, the statute under SB 509 unequivocally states that DTSC is not permitted to "supersede the regulatory authority of any other department or agency" nor may it "duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation." It is essential that any applicability of the Safer Alternatives regulation abide by this mandate so as to not conflict with, impede or frustrate other regulatory schemes or systems by which products are currently identified and reviewed.

GCA has consistently advocated that the regulations should only apply to intentionally added ingredients that serve a functional purpose at or above 0.1%, consistent with other state, federal and international systems by which manufacturers are currently regulated. Unintentional constituents cannot be included if this is to become a feasible program focused on important safety concerns. Failure to recognize this will result in excessive and needless testing and wasted resources. Furthermore, requiring manufacturers to evaluate and find alternatives to chemicals that may have an incidental presence in the consumer products will not result in the significant improvements that are anticipated by the Act.

The European Classification, Labeling and Packaging (CLP) directive applies to both chemicals and product mixtures and includes a default 0.1% *de minimis* threshold for CMRs and PBTs. One refinement GCA recommends is that for some chemicals on a case-by-case basis, a lower or higher concentration may be identified by authorities based on a risk assessment, not unlike the approach to develop Proposition 65 chemical specific exposure thresholds in no significant risk levels (NSRL). If a chemical of concern in a product meets both criteria (intentionally added and at or above 0.1%), a company would be required to conduct an exposure evaluation and develop a work plan (presuming no disqualification because of duplicative or conflicting regulation). If the above criteria are not satisfied, then the product would be in compliance and nothing more would be required. However, if DTSC fails to implement a science-based approach to screening out products with low likelihood of harm, the program will surely collapse under its own weight.

GCA again supports and urges the inclusion of an opportunity for public comment and appeal relative to the uses of the chemicals of concern in consumer products being considered and listed as higher priorities.

Chemical Data Issues / Resources

There has been much discussion among stakeholders regarding the need for DTSC to require manufacturers and others to fill a perceived "data gap" of chemical health and safety information. Some have even alleged that little is known about chemicals in commerce yet such broad, sweeping claims about the lack of publicly available information on chemicals are inaccurate.

GCA urges DTSC to ensure that the Safer Alternatives regulations anticipate and fully leverage the wealth of quality information on chemicals in commerce from government agencies and inter-governmental bodies around the world as AB 1879 specifically requires. These resources capture information including, but not limited to, physical properties, human and environmental toxicology, and national and regional hazard classifications according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

The claim that DTSC cannot proceed with prioritization under AB 1879 until it has complete and comprehensive information on every chemical in commerce is unrealistic, contradicts the spirit of the statute, and will lead to paralysis. GCA offers the following:

1. Such claims ignore the fact that numerous national and state chemical programs have prioritized tens of thousands of chemicals based on existing information and/or by creating opportunities for government and industry to share information and talk about safety in specific uses.
2. There is more than enough information for DTSC to proceed with prioritization (especially on a subset of chemicals like CMRs and PBTs) and to identify targeted data needs that may emerge during that process.
3. The tremendous amount of information available through REACH will provide a significant resource for DTSC beginning with over 4400 high production volume and high hazard chemicals to be submitted in November 2010.
4 Any effort that forces DTSC to administer and manage a massive, unfocused data gathering exercise will detract from the implementation of AB 1879 and the Green Chemistry Initiative more broadly.
5 DTSC should establish a process that allows industry to respond to *specific* data needs that emerge after prioritizing based on available data.

DTSC must ensure that it fully appreciates the difference between a chemical “data gap” and a “data need.” Data gaps are any pieces of information on a chemical that are unavailable. The list of potential “data gaps” is arguably endless, thereby making “data gaps” an impractical basis for a conversation on prioritizing and characterizing chemicals in a priority consumer product. On the other hand, the important subset of “data gaps” required to characterize potential risks associated with a chemical in a consumer product are referred to as “data needs”. “Data needs” are targeted and specific and are often linked to how a chemical is used and the associated potential exposures (i.e., a closed system intermediate versus a substance in a children's product).

Sound scientific priority-setting and decision-making does not hinge upon a rigid check-the-box approach that would result in enormous amounts of unnecessary animal testing and further burden public and private resources with the obligation to generate, review, and interpret data that are not needed. GCA urges DTSC to ensure the regulations are crafted in a manner that utilizes both public and private resources efficiently and effectively.

Alternative Assessment – BEST PRACTICES

The Alternatives Assessment provisions of the regulation need to be considered in light of the mandate of AB 1879, which calls for a process for evaluating chemicals of

concern in consumer products and their potential alternatives, *to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern*. AB 1879 further mandates that the process must include an evaluation of the *availability of potential alternatives* and *potential hazards* posed by those alternatives, as well as an evaluation of *critical exposure pathways*. AB 1879 also requires the evaluation to include life cycle assessment tools that take into consideration thirteen (13) economic and scientific parameters listed in the statute.

When the concentration of a chemical of concern in a high priority consumer product exceeds the *de minimis* criteria, and is not otherwise excluded on the basis of pre-existing regulatory requirements, an Alternatives Assessment (AA) must be conducted. GCA urges that the regulations provide the option for manufacturers to conduct the AA of the chemical in question. GCA strongly supports the provisions in AB 1879 regarding protection for confidential business information and is alarmed by proposals that would otherwise erode those protections. Much of the information required to conduct an AA would be considered proprietary, necessitating the evaluation to be done by the manufacturer in order to protect CBI and intellectual property.

Under the AA the proposed alternative(s) would be evaluated based on four major components: 1) performance; 2) hazard screening; 3) life cycle assessment / thinking (LCA); and 4) economic impacts and feasibility. To conduct an Alternative Assessment, the manufacturer must evaluate appropriate alternatives for their impact on a) product quality and performance; b) human health or the environment; c) acceptance as defined by consumer preference; and d) economic impacts.

As described in publicly available information from the department, the hazard screening portion of the alternatives plan would have consumer product manufacturers report on at least 15 different toxicological elements. These requirements go *well* beyond any established regulatory program in existence and need to be modified or at the very least prioritized in a manner consistent with well-accepted and institutionalized principles of tiered toxicity testing. Some elements, such as “epigenetic effects,” “endocrine disruption” and “synergistic potential” are areas of current exploratory scientific research. It is not reasonable or appropriate to require manufacturers to report on these elements when the scientific community is not yet in agreement about proper methods or interpretive protocols. GCA recommends the department modify and clarify this list in order for the alternatives assessment process to reflect what is truly needed for robust comparative analyses and what is reasonable to expect from the regulated community.

Over the course of the green chemistry discussion, the LCA component of the alternatives assessment has been described by DTSC as simple and inexpensive. However, it is widely recognized the LCAs can be costly and time-consuming. On the other hand, GCA is concerned that too “simple” may create subjective and inconsistent results within and among consumer product categories. Consequently, GCA urges a realistic LCA program, which would evaluate the key LCA components that are most relevant to that particular use at a level of detail sufficient to allow both manufacturers and the department to make comparisons among potential alternatives. Such an approach should include major relevant sustainability impact indicators that will allow for the use of reliable LCA database information and LCA methods, such as use of materials (including water), energy consumed, and end-of-life. This approach creates

efficiency in an otherwise onerous process and still provides both transparency and consistency of key life cycle considerations in the evaluation.

GCA supports a regulation that provides for public engagement in identifying alternatives to a particular use of a chemical of concern in a consumer product; however, it would be incumbent upon the stakeholders suggesting alternatives to conduct the Alternatives Assessment based on guidance materials developed by the department. Unless otherwise provided for in a mutually agreed upon work plan, in no case should a manufacturer of a consumer product be compelled by regulation to conduct an assessment of an alternative put forward by a member of the public or a competitor.

Private Label / Responsible Entity

GCA recommends that in lieu of a definition of manufacturer, DTSC refer to the FTC Fair Packaging and Labeling (FPLA) Act definition for Responsible Entity to provide uniformity of laws (CARB, CPSC, etc.). Additionally, we recommend inclusion of permissive language stating that retailers and original manufacturers shall retain their rights to make contractual agreements regarding their respective responsibilities for conducting any Alternatives Assessment that may be required. This will address concerns regarding who is responsible for conducting assessments, particularly for private label products.

Manufacturer and Thrd Party Certification

While GCA is not opposed to a third party certification process, we are insistent that it be an option for manufacturers – not a mandate. Furthermore, the concept of certifying employees of manufacturers to conduct Alternatives Assessments is also of concern. Companies may need to certify more than one person due to different business groups and different product lines. Also due to the breadth of an AA, it is probable that no single individual has the skills and knowledge to perform the AA. Further, because the AA involves market acceptability and consumer preferences, a consultant may not have the necessary expertise to provide judgment on all critical aspects of the process.

Requiring several people to be California certified will be an unnecessary added cost. From a company perspective, a state specific certification requirement will be time consuming, expensive and complex. Furthermore, DTSC's obligation to certify companies and third parties to a yet to be determined standard will be time consuming, expensive and complex. Currently, no standard certification exists for alternatives assessments. For DTSC to develop and mandate its own state-specific certification standard will only serve to increase the overall costs of compliance without corollary benefit – i.e., identifying safer alternatives for chemicals of concern in priority products.

Other programs in California requiring third party certification for manufacturers have suffered from delays, expensive training/certification, and complexity. In the no-lead plumbing act and the composite wood requirements, manufacturers have been confused with the standard that must be met, found delays in getting products certified due to a lack of testing facilities, and were faced with expensive testing fees. Additionally, the lack of certification of the third party testing labs in other countries under the Air Resources Board (ARB) program hindered the ability of some manufacturers to keep products on the market.

As an alternative to a training and certification program, we recommend that DTSC require manufacturers or third parties conducting AA's to acknowledge that they have done the assessment in accordance with DTSC's AA Guidance. We believe this approach will provide DTSC and the public with a level of assurance regarding the process and procedures that each manufacturer is requested to follow should they decide to undertake the Alternatives Assessment in-house rather than use a third party. Preparing guidance rather than a full training program will lessen the economic impact and burdens on DTSC, manufacturers, and consumers. It will also require less time for DTSC to develop guidance than to develop a comprehensive training program. Guidance will also allow manufacturers to begin work rather than wait for one or more people within a company or a third party to complete the training.

Regulatory Response Actions & Enforcement

The regulatory enforcement provisions contained within the regulation should address those provided for under AB 1879 and provide for industry safeguards including a transition period, and a prohibition against chemical bans other than in the limited case of the use of a chemical of concern in a particular consumer product when risk is deemed otherwise unmanageable. Imposition of the most severe regulatory response actions should be accompanied by department findings for such action promulgated after notice and comment. GCA is concerned that without formal department action associated with the most severe of the regulatory responses, a level playing field will not emerge.

Additionally, the regulations need to provide flexibility in regulatory actions. Manufacturers need to have the ability to determine the most effective methods for customer notification, end-of-life management and other regulatory actions that may be necessary based on the outcomes of the analyses.

Certificates of Compliance

GCA is strongly opposed to certificates of compliance for all priority products whether in compliance or exempt from regulation. As an alternative, GCA recommends the development of a website, hosted by DTSC, which would list non-compliant products, and manufacturer of products that must have listserv capability. This allows the retailer to check the website and do so within a required timeframe (i.e., quarterly); at which point, the retailer shall have a reasonable cure / grace period (90 days) to remove a non-compliant product from sale.

Cost Implications for California

GCA notes that the estimated cost of the European Union (EU) REACH program is substantial. While the cost effectiveness of the program in terms of its actual impacts on health and environment is the subject of considerable debate, no one questions the fact that this enormous program will yield a tremendous amount of information and data.

GCA strongly recommends that the draft regulations be tailored to ensure that manufacturer compliance with this program does not lead to excessively burdensome economic impacts which might unintentionally result in perverse incentives for jobs to leave the state and for citizens to be deprived of safe and beneficial products that are

legally marketed throughout the rest of the US. It is ultimately DTSC's responsibility, as focal point for much of the activity surrounding the implementation of the proposed regulation to strike the proper balance between the scope of the program and the resources available for them in order to achieve success. A program that takes on more than it can achieve is unsustainable and will produce little to advance public health and environmental protection. GCA has and continues to support a balanced and scientifically based process for the discovery and advancement of safer alternatives.

Confidential Business Information Must Be Protected

GCA supports the Confidential Business Information (CBI) process set forth in AB 1879. No information needed by DTSC to conduct its regulatory role will be withheld; but once submitted - allowing manufacturers to identify information and intellectual property requiring protection is a reasonable approach and is consistent with numerous other regulatory programs.

Information contemplated by the flowchart and outline suggest that several type\s of sensitive information will be requested, such as market data, locations of facilities, alternatives under investigation, and process changes. GCA recommends that the work plan public summary report be limited to the following information:

1. Manufacturer's name;
2. NAICS Code identifying the general product category rather than the specific product;
3. Name of the chemical of concern that triggered the need for a work plan;
4. High level summary of the expertise of the manufacturer's employees conducting and involved in the alternatives assessment to the extent applicable;
5. Number of alternatives/approaches under review; and
6. Additional information voluntarily provided.

These recommendations for the work plan summary are based on general CBI principles. GCA further recommends that DTSC incorporate the following principles related to CBI: 1) Information requested by DTSC that has already been determined by another agency to be CBI must also be protected under the Safer Alternatives regulatory regime; 2) Protection from disclosure will be afforded to information that may lead to reverse engineering of products or processes.; and 3) Intellectual property is not compromised and competitive harm is not caused.

The ability to protect certain information from competitors is essential to defending the competitive position of companies in the marketplace. Protection of intellectual property (IP) is real and should not be judged as being hypothetical. Protection of IP is essential to every company's ability to remain competitive and sustainable.

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GCA respectfully requests that DTSC take all of the proceeding concerns seriously; and that it ensure strong CBI provisions are in-place to protect industry's continued ability to develop and market safe and innovative products.

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