Office of Environmental Health Hazard Assessment

Joan E. Denton, Ph.D., Director
Headquarters • 1001 I Street • Sacramento, California 95814
Mailing Address: P.O. Box 4010 • Sacramento, California 95812-4010
Oakland Office • Mailing Address: 1515 Clay Street, 16th Floor • Oakland, California 94612

Linda S. Adams
Secretary for Environmental Protection

Arnold Schwarzenegger
Governor

MEMORANDUM

TO: Peggy Harris
Assistant Deputy Director
Office of Legislative and Regulatory Policy
Department of Toxic Substances Control

FROM: Allan Hirsch
Chief Deputy Director
Office of Environmental Health Hazard Assessment

DATE: November 4, 2009

SUBJECT: DTSC STRAW PROPOSAL FOR SAFER ALTERNATIVE REGULATIONS (10/01/09 VERSION)

We understand that the Department of Toxic Substances Control (DTSC) has removed the latest straw proposal from your Green Chemistry web site and is actively working on a revised version. The Office of Environmental Health Hazard Assessment (OEHHA) staff reviewed the straw proposal. Given the extensive input you have recently received from the Green Ribbon Science Panel and the public on the straw proposal, we think it would be most effective for us to provide detailed comments on the revised version. Below we offer some overarching comments that we think are critical to consider in your next draft and point you to some of our earlier comments that are still relevant:

1. The state, not manufacturers of consumer products, is the appropriate entity to identify and prioritize chemicals of concern (COCs).
2. Casting a broad net for chemicals of concern by consulting established lists and/or applying criteria is consistent with stakeholder input, but this large pool of COCs must be prioritized.
3. The prioritized, interrelated framework of hazard traits that OEHHA is developing will be helpful as one element in prioritizing COCs.
4. The state could identify some very high priority chemicals for early action based on criteria set out in AB 1879.
5. Pilot studies on very high priority chemicals in specific products could be considered to develop alternatives assessment guidelines and evaluate implementation strategies for the regulation.

OEHHA provided comments on the chemicals of concern portion of DTSC's earlier version of the draft regulations (OEHHA, 2009a). Most of our previous comments still apply and we think it might be useful for you to consult them as you formulate the next draft. More recently, we sent by email some specific comments on the list of lists included in the draft regulation (OEHHA, 2009b). OEHHA also agrees with many of the recommendations recently provided by the Green Ribbon Science Panel on approaches to consider in revising the regulations.

We will be happy to review and provide comments on the revised version when it is released. If you have questions or would like to discuss this further, please feel free to contact me at 916-324-2831, or Sara Hoover at 510-622-3224.

References:

OEHHA (2009a). OEHHA Comments on DTSC's Draft Regulation on Identification and Prioritization of Chemicals and Chemical Ingredients of Concern in Consumer Products (version 6/17/09). Attachment to email dated 6/30/09 from Sara Hoover to Rob Brushia, Peggy Harris and other DTSC regulations team members.

OEHHA (2009b). Some technical points on list of lists. Email dated 10/13/09 from Sara Hoover to Rob Brushia and Peggy Harris.

cc: Odette Madriago
Acting Chief Deputy Director
Department of Toxic Substances Control

George Alexeeff, Ph.D.
Deputy Director for Scientific Affairs
Office of Environmental Health Hazard Assessment

Melanie Marty, Ph.D., Chief
Air Toxicology and Epidemiology Branch
Office of Environmental Health Hazard Assessment

Lauren Zeise, Ph.D., Chief
Reproductive and Cancer Hazard Assessment Branch
Office of Environmental Health Hazard Assessment

Sara Hoover, M.S., Chief
Safer Alternatives Assessment and Biomonitoring Section
Office of Environmental Health Hazard Assessment

President and
Chief Executive Officer

O·P·I

OPI PRODUCTS INC.

Direct (818) 759-2400
Fax (818) 759-5769
gschaeffer@opi.com

November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxics Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: Straw Proposal for Safer Alternatives Regulation (October 1, 2009)

Dear Director Movassaghi:

On behalf of OPI Products Inc. ("OPI"), I would like to convey our serious concerns with the Safer Alternatives Regulation Straw Proposal as currently drafted (this input is being provided consistent with the Green Chemistry Alliance's [GCA] comment extension deadline of November 9th). Although OPI understands the Straw Proposal is not a formal regulation at this time, the program described would have sweeping ramifications on virtually all industry sectors that manufacture or sell a consumer product in California and does not reflect the intent of the enacting legislation under AB 1879 (Feuer, 2008).

OPI is the leading manufacturer of professional nail care products worldwide and manufactures a broad range of products, including nail polishes, treatments and other items used by salon nail technicians. As part of its mission, OPI provides training, education and support for salon professionals and students in cosmetology schools.

OPI, a family-owned business, was founded over 25 years ago in North Hollywood. We are part of the larger fashion/entertainment/beauty complex in Southern California that includes many other salon brands including Wella, Sebastian, Joico, J.P. Mitchell, Nexxus, Graham Webb, Creative Nail Design, Orly, etc. OPI employs approximately 500 people and we sell our products in over 100 countries.

Our industry is one of the largest employers of single mothers with flexible work hours and is a great place for immigrants and those with limited capital or language skills to become independent business owners. There are approximately 100,000 nail technicians in California, over 30,000 salons, and over 100 beauty schools. Nationally, the industry represents $7 billion in revenues, nearly as large as a movie box office.

Under the framework laid out in the current proposal, manufacturers and importers of consumer products for sale in California would be required to identify whether their product contains a "chemical of concern" and, if so, would require a costly and onerous alternatives assessment process. If a consumer product manufacturer/importer could not identify or chose not to implement a safer alternative, the consumer product containing the chemical of concern would be banned in 2-20 years. Furthermore, if the manufacturer/importer chose to implement a safer alternative that, while incrementally better than the identified chemical of concern, has other specified hazard traits it too would be subjected to a ban in 2-20 years. The current Straw Proposal contains no consideration of potential or severity of exposure; rather, it would place roughly 10,000 chemicals on the path for eventual phase-out.

OPI is highly concerned the scope of the current proposal is overly broad and fails to focus on consumer products that present the greatest risk to human health and the environment. This is partially attributed to a very broad definition of "consumer product" that could conceivably include not only finished traditional consumer products, but individual chemicals and component parts as well. This is further complicated by the inclusion of four different pathways in to the process:

1. 11 consumer product categories that are not well defined;
2. 16 designated "chemicals of concern;"
3. Chemicals identified by 29 different state, federal and international sources; and
4. 13 hazard criteria.

The broad pathways would result in an infinite number of chemicals and products being covered and subject to a costly and onerous alternative assessment. Furthermore, it is not clear how we as manufacturers could establish compliance given the number of chemicals covered and ongoing changes to chemical lists and hazard data, with the potential outcome of having to defend their good faith efforts at compliance in the courts.

OPI supports the GCA's approach laid out in their regulatory proposal that was provided to the Department on June 24, 2009. The GCA proposal provides the Department an opportunity to implement Green Chemistry in an efficient, cost-effective and impactful manner by first prioritizing chemicals for review, evaluating how those chemicals are used in consumer products, assessing whether they pose a potential risk to public health, examining potential alternatives and instituting a regulatory action if necessary.

If the Department fails to implement an approach that is scientifically based and narrows the scope – at least at the outset of the program – it will surely collapse under its own weight. Furthermore, California's business community cannot afford to implement the current approach as laid out in the current Straw Proposal. The GCA proposal, as an alternative, is a thoughtful, workable proposal that should be given serious consideration.

For these reasons, OPI urges the Department to start over in their development of the Safer Alternatives Regulation and look to the GCA proposal as a workable solution. If you have any questions regarding OPI's position on the current Straw Proposal, please contact me at 818-759-5720. Thank you.

Sincerely,

//original signed by//

George Schaeffer
President & CEO

cc: Linda Adams, Secretary of CalEPA
Patty Zwarts, CalEPA
Cindy Tuck, CalEPA
John Moffatt, Office of the Governor
Victoria Bradshaw, Office of the Governor
The Honorable Sam Blakeslee, Assembly Republican Leader
The Honorable Mike Feuer, Member of the Assembly
The Honorable Joe Simitian, Member of the Senate

PERFORMANCE
Environmental Services, Inc.

30553 Wixom Road, Suite 500 • Wixom, Michigan 48393 • Voice: 248.926.3800 • Fax: 248.926.3838

November 3, 2009

TO: Michael O'Docharty
Safer Alternatives Comments
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95814

Dear Mr. O'Docharty,

Performance Environmental Services, Inc. (*Performance)* appreciates the opportunity to comment on the California Straw Proposal for Safer Alternative Regulations. *Performance* is submitting these comments on behalf of it clients who are auto manufactures and their suppliers focused on making positive environmental and economic impacts within the automotive supply chain.

Specific Comments to the CA Straw Proposal

SP members appreciate the comprehensive approach of the Straw proposal that the DTSC has developed and support conceptually a number of the aspects and intentions of the effort. We would, respectfully, make comments on several aspects of the proposal:

Data requirements and timing. The hazard characteristics identified, in many ways are appropriate; however, there are many common chemicals for which this comprehensive data set do not exist. These chemicals are also used in many consumer products. Therefore, it will be very redundant if every consumer manufacturer is required to generate the needed hazard data for these substances. It is suggested that California recognize the test data that is being generated through the EU REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) regulation, where extensive data sets are being compiled and will be generated when data gaps exist, from 2010 through 2018, based on production volume and hazard. It is also suggested that the timing that DTSC is proposing for generating the data be extended beyond 1 year. Many of the toxicology test methods required to generate the appropriate hazard data take longer than a year to complete. The utilization of the REACH data provide a much more realistic and practical timeframe and will allow for data sharing and reduced economic burden. Therefore, the 1 year timeframe should be for providing the plan for data generation, not for data submission. DTSC should also consider the initial focus to be on the chronic hazard characteristics - carcinogens, mutagens, reproductive hazards along with persistent and bio-accumulative toxics.

De minimus levels and "insignificance". The DTSC Straw Proposal makes no mention of de minimus levels for chemicals in consumer products. In order to better prioritize the effort, it is recommended that a de minimus level be established, so that if a chemical of concern is below this value, no additional

actions need be taken. SP also suggests that the focus be on substances that are intentionally added and not incidentally or naturally occurring constituents in a product. Additionally, DTSC should incorporate the concepts currently used in Proposition 65 that allows for "no significant risk levels" for carcinogens and "maximum allowable daily levels" for reproductive hazards. This should be incorporated into the exposure and priority setting process and if a substance in a consumer product falls below these levels, no further action would be required. Currently, DTSC allows for this in the Petition Process, however, it could significantly reduce the burden on both the manufacturers and the DTSC if this were allowed in the up-front prioritization process.

Alternatives assessment. SP recognizes that the alternatives assessment process is a cornerstone of the DTSC proposal. We believe, however, that this process needs to be prioritized, at least initially, to focus on the Priority 1 consumer products and high volume chemicals of concern. Priority 2 and 3 products could be considered at a later date, after the effectiveness, resources needed and cost can be evaluated.
Supply Chain communication and data gathering. As indicated above, the automotive supply chain is very complex with parts and suppliers coming from a broad global base. Because of this, it will be very difficult to obtain the required information from the non-California suppliers in the timeframe currently being proposed. It is again suggested that additional time be provided to assess and prioritize the chemicals of concern in consumer products and that the process begin with the REACH data being generated by the chemical manufacturers in a phased-in approach based on manufactured volume and potential hazard.

Confidential Business Information. SP is concerned with the provisions for maintaining confidential business information (CBI). As manufacturers of articles, we will be dependent on the chemical data and hazard information provided by the chemical manufactures and the data available in the public literature. Additionally, auto manufacturers are also concerned about protecting their own technologies from competitors and may need strong provisions that protect CBI while providing appropriate hazard information. DTSC will need to develop a robust hazard and exposure process that gives users of the information the confidence that the data are accurate, while providing meaningful information to allow for making material decisions up the supply chain while maintaining CBI.

Authoritative Bodies. DTSC has asked for comments regarding use of authoritative bodies and their chemical lists. It will be critical for DTSC to clearly define their criteria for including a chemical as a chemical of concern. The use of other Authoritative Bodies for identification of chemicals of concern may be appropriate if the criteria for selection are the same.

Performance appreciates the opportunity to comment on the California Straw Proposal for Safer Alternative Regulations. If you should have any questions contact me at (248) 926-3800.

Respectfully Submitted,
PERFORMANCE ENVIRONMENTAL SERVICES, INC.

//original signed by//

Douglas S. Andrews, CHMM, CSS
Regulatory Compliance Manager

Personal Care Products Council
Committed to Safety, Quality & Innovation

November 9, 2009

BY E-MAIL AND REGULAR FIRST-CLASS MAIL

Maziar Movassaghi
Acting Director
Department of Toxic Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: Revised DTSC Straw Proposal for Safer Alternatives Regulation

Dear Mr. Movassaghi:

The Personal Care Products Council (Council) is writing to convey our serious concerns with the Safer Alternatives Regulation Straw Proposal (straw proposal) that was publicly released by the Department of Toxic Substances Control (Department) on October 1, 2009. Although we understand the straw proposal is not a formal regulation at this time, the program prescribed therein would have sweeping ramifications for virtually all industry sectors that manufacture or sell a consumer product in California and does not reflect the intent of the enacting legislation under AB 1879 (Feuer, 2008).

The Council is the national trade association representing the personal care products industry. Founded in 1894, we represent approximately 600 members involved in the manufacture and distribution of cosmetics, toiletries and fragrances in California and throughout the United States. Approximately one half of our members are manufacturers or distributors of personal care products while the remaining members provide goods and services to those manufacturers and distributors. Many of these companies are based in California and/or have significant facilities in the State, and all are likely to be subject to the requirements of the green chemistry law and its implementing regulations.

Our member companies are committed to the broad goals outlined in California's green chemistry law. However, as a member of the Green Chemistry Alliance (GCA), we agree with GCA's basic observation that many of the requirements in the current straw proposal are simply not viable. As written, the straw proposal effectively stifles innovation with its overly expansive scope and unworkable morass of requirements, and ignores real-life exposure scenarios that, if considered properly in context with chemical hazards, would allow the Department to facilitate meaningful improvements in consumer and environmental protection. Moreover, the proposal ignores AB 1879's specific mandate to establish a meaningful prioritization process for chemicals of concern. Further, as noted during the Green Ribbon Science Panel meeting and the general public workshop, the cost and time required to conduct an alternatives assessment for even a single chemical is likely to be substantial – and possibly prohibitive for smaller to medium sized companies. In order for the program to be feasible, the scope of chemicals covered must be narrowed significantly, at least in the initial stages.

1101 17th Street, N.W., Suite 300 | Washington, D.C. 20036-4702 | 202.331.1770 | 202.331.1969 (fax) | www.personalcarecouncil.org

Specific Issues

Scope. The scope of the straw proposal should encompass only those ingredients in consumer products that are 1) intentionally added, and 2) above a de minimis level (to be determined for each chemical). This would facilitate the viability of the program. With respect to cosmetics and personal care products, the "intentionally-added" qualifier for ingredients would not only be consistent with the longstanding policy of the U.S. Food and Drug Administration (FDA), which excludes from the labeling requirement those incidental ingredients that do not provide a functional benefit in the finished product, see 21 C.F.R. § 701.3(l), but it would reflect the definition of "ingredient" in the California Safe Cosmetics Act, which deliberately excludes from the scope of the reporting requirement any incidental ingredient, as defined by FDA. Further, including de minimis levels for each chemical is a major component of "risk-based" hazard analysis, without which meaningful prioritization is impossible.

In addition, we are unaware what the Department seeks to accomplish by adding the product categories. Not only are the product categories ill-defined, they do not appear to add any discernible function in terms of shaping the scope of the program. The scope should focus on chemicals. If chemicals need to be evaluated in the context of their specific intended uses for purposes of the alternatives assessment, then perhaps product categories can be inserted for that purpose – but only if they are more specifically tailored than the existing ones.

Chemicals of Concern. There are 29 lists from which to draw chemicals of concern and no process for public review or challenge to the list. The lists are a random compilation, with variations in level of formality, different criteria for listing chemicals, and different processes for decisionmaking. Some of the lists are generated by bodies that would not meet the definition of "authorized body." Further, the list of lists may represent an unconstitutional delegation of power (to some of the listing sources) if CA adopts determinations made by outside bodies with no opportunity for the affected public to challenge or provide input on individually listed chemicals.

Hazards Evaluation. The proposal requires the compilation of a wide range of hazard information for anyone making a product that contains a chemical of concern. When determining the need for hazard information, exposure is a relevant consideration, and generation of the complete set of data required by the proposal is not always necessary. Further, the timing under which manufacturers are expected to produce the data is unworkable. Much of the data requested would take many years to generate and evaluate, and is not possible to accomplish in the one year proposed within the straw proposal. At a bare minimum, whatever the pertinent hazard data set ultimately determined to be necessary for an individual chemical, industry should be allowed to cross-reference hazard data already in existence and/or generated for purposes of other programs (e.g., REACH).

Prioritization. The priority criteria set forth in the straw proposal are not meaningful. The criteria for the first tier of priority are extraordinarily broad and will cover the vast majority of chemicals, each of which in turn would trigger the never-ending alternatives assessment. The Department should consider employing only one level of priority designation (rather than multi-tiered) that could be revised over

time as the more critical chemicals "go through the system" first. Such an approach would facilitate a program that is manageable in scope, and appropriate, given severely restricted state resources. As chemicals "exit" the system (either through a successful substitution, management measure, or other response), other chemicals could be phased into the system, in order of priority. In addition, there is no guidance on how to set priority when evaluating a chemical of concern against alternatives; for example if they have different hazard components, which one should take precedence?

Exposure Assessment. Exposure assessment is given cursory treatment with no procedure for incorporating it into the chemicals of concern identification process or alternatives assessment process. The Department should consider a chemical/exposure based evaluation that would lead to chemicals being "chemicals of concern" for specific exposure scenarios. This would also allow a chemical to be removed from consideration as a chemical of concern before getting into an alternative analysis if used in products where exposure is such that the chemical is not a safety concern. This is especially critical given the recommendation under the current straw proposal that any chemical that enters into an alternatives analysis scenario will be phased out of California in 2-20 years.

Information Dissemination. The current straw proposal contains extremely onerous information dissemination requirements that essentially require a manufacturer to convey to all downstream distributors of their products a range of hazard and exposure data for any priority chemicals of concern in its products. This is somewhat akin to the concept of a material safety data sheet that is required in the workplace for occupational health and safety purposes. The purpose of such a requirement is unclear in the commercial context. In the case of cosmetics and personal care products, ingredients are required to be on the product labeling; hence, downstream distributors through the end user are already notified as to the ingredients they contain and their routes of exposure. Additionally, it is the expectation of the straw proposal that each company's information is to be shared publicly with "transferees" and posted on the internet; however, the straw proposal lacks a provision for protection of confidential business information (CBI). AB 1879 specifically requires the Department to establish a process for CBI protection.

Cost. The cost of compliance with the current straw proposal would be enormous to both industry and the state of California. Industry would be responsible for generation of a massive amount of data on each product containing one or more of the identified chemicals of concern, and even more data if any of those chemicals were deemed a "priority chemical." This data generation would entail a prohibitive economic burden, especially under the current deadlines which are wholly unrealistic. Indeed, the cost of doing a single alternatives assessment alone can be staggering, as was noted at the both the Green Ribbon Science Panel meeting on October 14, and again at the public workshop on October 21.

* * * * *

In summary, we believe the issues noted above, among others, pose serious obstacles to the viability of the green chemistry program and its beneficial intent. While we appreciate that the Department faces a statutory deadline for issuing these regulations, we believe that it is critical that the Department

construct a program that is workable from the onset, with a narrowly drawn scope, clear procedures and criteria for prioritization, and requirements that are not cost-prohibitive. To that end, we urge the Department to give serious review and consideration to the GCA proposed regulations submitted earlier this summer as it prepares to craft its formal proposed regulations.

Sincerely,
//original signed by//

Frances K. Wu
Associate General Counsel

Cc: Lezlee Westine, President & CEO
Elizabeth Anderson, Executive Vice President – Legal and General Counsel

Cc (by regular first-class mail):

The Honorable Linda Adams
Secretary
California Environmental Protection Agency
P.O. Box 2815
Sacramento, CA 95812

Patty Zwarts
Deputy Secretary
California Environmental Protection Agency
P.O. Box 2815
Sacramento, CA 95812

Cindy Tuck
Undersecretary
California Environmental Protection Agency
P.O. Box 2815
Sacramento, CA 95812

John Moffatt
Legislative Affairs, Office of the Governor
State Capitol
Sacramento, CA 95814

Victoria Bradshaw
Cabinet Secretary & Deputy Chief of Staff
Office of the Governor
State Capitol
Sacramento, CA 95814

The Honorable Sam Blakeslee
Assembly Republican Leader
California State Assembly
State Capitol, Room 3104
Sacramento, CA 95814

The Honorable Mike Feuer
California State Assembly
State Capitol, Room 3146
Sacramento, CA 95814

The Honorable Joe Simitian
California State Senate
State Capitol, Room 2080
Sacramento, CA 95814
Fax: 916/323-4529
Email: senator.simitian@sen.ca.gov

November 4, 2009

Maziar Movassaghi
Director
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

RE: STRAW PROPOSAL FOR SAFER ALTERNATIVE REGULATIONS (10/1/09)

Dear Director Movassaghi:

The following comments are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, and the Humane Society of the United States, all of which are national non-profit organizations with significant numbers of members who reside in California. Our organizations are concerned about animal-based chemical testing methods and work to promote the minimization of, and alternatives to, the use of animals in chemical, pesticide, product, and drug safety testing on national, regional, and international levels.

While our members support increased protections for human health and the environment through modernized chemical regulations, they believe that these protections should not, and need not, come at the expense of animals killed in chemical tests. The following comments are offered with the intent to improve the draft Straw Proposal for Safer Alternative Regulations (the Proposal) by offering suggestions for how the Department of Toxic Substances Control (DTSC) can ensure these concerns are taken into account. Thus both the general and specific comments offered below are specifically applicable to Section 6xxxx.6 (Data Requirements) and 6xxxx.7 (Hazard Categories) of the Proposal, unless stated otherwise.

1. Regulations Should Remain Flexible

As many California EPA staff are aware, the field of toxicology is undergoing a fundamental paradigm shift, in concert with, and perhaps driven in part by, calls for increased scrutiny of chemicals in consumer products and the environment. This has resulted in the National Academy of Sciences 2007 report *Toxicity Testing in the 21st Century: A Vision and Strategy* and prompted activities by US government agencies and US and International bodies such as the Society of Toxicology, the OECD, and the European Commission. In short we are already seeing changes to the way chemicals are assessed for hazards, and those changes are very likely to increase in pace and nature in the near future. It is very important that the final DTSC regulation takes this reality into account, and avoids specifying test guidelines or test systems (i.e. “animal test”) in association with individual data requirements in the interests of promoting

maximum flexibility and limiting the rate at which provisions within the final regulation become obsolete.

The current Proposal does provide some measure of flexibility; for example, subsection (d) allows for tests to be performed according to any acceptable, standardized test method. The appropriate balance must be struck to ensure that data generated by such methods are accepted by the DTSC (avoiding duplicative testing), while avoiding such prescriptive language that advances in toxicity testing methods require revision of the regulations.

Flexible data requirements are in line with recent moves in the pesticide sector to move away from a rigid check-list approach to a more chemical-specific, integrated testing approach. Such schemes often involve graduated or tiered testing and the use of a weight-of-evidence (WoE) approach to determine true hazards of concern, instead of requiring a minimum data set up front. The European Commission, because of its responsibilities under REACH, has embraced this approach and is investing in a new project, termed OSIRIS, to create guidelines for WoE determinations and using “test” data alongside “non-test” data (e.g. QSAR results or epidemiological data). We encourage DTSC to become familiar with the work of the OSIRIS project: http://www.osiris.ufz.de/index.php?en=15009.

Specific comments:

- Section 6xxxx.6(b)(1): The Proposal has wisely sought to gain from the chemical regulation programs of other regions, such as Canada’s Domestic Substances List and REACH, for chemicals that have already been classified. However, for non-classified chemicals, this section states that data must be provided within one year. We recommend amending this section to allow manufacturers to use data from planned testing requirements under REACH if such plans are being made, since REACH regulations are more specific.

- Section 6xxxx.6(d): The definition of “authoritative body” as set out in Section 6xxxx.3 should be clarified to include all bodies that publish or determine validity of test methods such as the US FDA, the Interagency Coordinating Committee for the Validation of Alternative Methods, the Organization for Economic Co-operation and Development, the European Center for the Validation of Alternative Methods, or other similar bodies, which do not “characterize chemicals” per se but would be examples of bodies responsible for setting out test methods and/or protocols, are included.

- Section 6xxxx.6(e): The role of (Q)SAR models in hazard and risk assessment is increasing as models improve, and these models are seen as an essential piece of the chemical assessment puzzle within REACH implementation--for demonstrating hazard or lack thereof. We commend the DTSC for allowing the

use of QSAR models with appropriate scientific validity and documentation, and find the guidelines given to be appropriate, except for part (3); restricting the use of (Q)SAR to “risk assessment” is inappropriate here, especially since the intent is to gather hazard information for chemicals for classification purposes. We recommend striking part (3). Regarding the use of adequate documentation for (Q)SAR models, we encourage DTSC to learn from the current activities of the European Chemicals Agency and European Commission with regard to REACH implementation and apply model acceptance and documentation practices to this regulation as appropriate.

- Section 6xxx.7(a)(1) (Hazard Identification): The requirement to “evaluate each chemical with respect to each of the hazard criteria listed in subsection (b)” is unnecessarily prescriptive and inflexible, and does not permit the use of widely accepted approaches such as chemical grouping into scientifically-supported clusters, tiered testing, and weight-of-evidence assessment. We also have a number of comments regarding the proposed test battery, which are discussed below.

- Section 6xxxx.7(b) (Hazard Criteria): The proposed hazard criteria are, by and large, consistent with the United Nations’ Globally Harmonized System of Classification and Labeling (GHS). However, we caution against exclusive use of in vivo endpoint/physiological descriptors, which limit the flexibility with which the criteria may be applied as the science of safety testing evolves. A case in point would be the descriptors provided for eye irritant classifications, which completely ignore validated non-animal alternatives currently available for eye corrosion and irritation, as well as recommended testing strategies from the US EPA, OECD, ECVAM, and ICCVAM. While it may be reasonable to expect that many chemicals will have data from Draize tests already available, new ocular irritancy assessments should not default to the Draize test. We provide the links below to help DTSC determine new criteria for the classification of chemicals that may cause eye damage that are amenable to data derived from animal and nonanimal test methods.

  http://ecvam.jrc.it/
  http://iccvam.niehs.nih.gov/methods/ocutox/ivocutox.htm
  http://www.epa.gov/oppfead1/cb/csb_page/updates/2009/eye-study.html
  www.iivs.org
  www.alttox.org
  www.mattek.org
  http://titania.sourceoecd.org/vl=1092779/cl=23/nw=1/rpsv/cw/vhosts/oecdjournals/1607310x/v1n4/contp1-1.htm (TGs 405, 437, 438)

- Section 6xxx.7(b)(7 and 8): These sections specifically list classifying criteria as results from an “appropriate animal” test, and do not mention criteria that would

result from the use of other, non-animal methods. For skin sensitization especially, a cell-based strategy has begun the validation process at ECVAM. Information that might help DTSC determine criteria for skin sensitization classification can be found here: http://www.sens-it-iv.eu/.

Section 6xxx.7(b)(10) (Acute aquatic toxicity): This section is another example of how intelligent approaches to testing and flexible regulations can minimize laboratory testing and maintain desired protections. The "Upper Threshold Concentration (UTC) Step Down Approach" first described by Hutschinson et al.[1] and later evaluated on a larger data base by ECVAM and European Chemicals Bureau[2] is a straightforward strategy making use of the fact that in acute aquatic toxicity tests fish are in many cases less sensitive than algae and daphnia. The chemical is tested in one group of fish at the level of known acute toxicity values for algae and/or daphnia. If no toxicity is seen, the chemical can be classified. If toxicity is seen, the test can proceed from there depending on the results. More information about this approach can be found on the ECVAM web site (http://ecvam.jrc.it/; *Statement on the scientific validity of the upper threshold concentration (UTC) step-down approach--a new testing strategy to reduce the use of fish in acute aquatic toxicity testing*), and a draft OECD guidance document can be found here: http://www.oecd.org/dataoecd/49/3/43226061.pdf. Following such a tiered approach could result in a reduction of 65% to 72% of fish in toxicity tests, and the regulations describe the potential for following such an approach.

- Section 6xxx.15 (methodological approach for assessment of hazards): As previously stated, the requirement to "evaluate each chemical with respect to each of the hazard criteria listed in subsection (b)" is unnecessarily prescriptive and inflexible, and does not permit the use of widely accepted approaches such as chemical grouping into scientifically-supported clusters, tiered testing, and weight-of-evidence assessment. In regard to the second point, we strongly recommend that data requirements be divided among tiers, beginning with endpoint data that can be considered necessary in all cases (e.g. acute studies for worker protection labeling, in vitro and other non-animal studies), followed by studies that would only be triggered on the basis of particular findings in preliminary hazard and exposure assessments (e.g. carcinogenicity and reproductive toxicity). Designating each of the 13 endpoint categories as a "tier 1" requirement is insupportable on scientific, practical, and animal welfare grounds.

  (1) Acute toxicity: Median lethal dose-type studies and their contemporary equivalents are perhaps the most cruel, yet least informative, studies carried out

[1] Hutchinson, T.H., *et al.* (2003). A strategy to reduce the numbers of fish used in acute ecotoxicity testing of pharmaceuticals. *Environ. Toxicol. Chem.* 22, 3031-3036.
[2] Jeram, S., *et al.* (2005). A strategy to reduce the number of fish in acute ecotoxicity testing of new chemical substances notified in the European Union. *Reg. Tox. Pharm.* 42, 218-224.

in toxicology. Derivation of a precise LD50 value is not necessary for classification and labeling, which is the primary purpose for the conduct of such studies. Instead, we propose that this data requirement be deleted and that classification decisions regarding toxicity concomitant to single, acute exposures be based upon the data requirement specified in point (2) in this section.

(2) Specific target organ toxicity (single exposure): The title of this data requirement is ambiguous and should be rewritten to convey a clear understanding of the intended study design and rationale (e.g. acute reference dose / neurotoxicity / immunotoxicity study?)

(3) Target organ toxicity (repeated exposure): Repeated dose general toxicity studies range in duration from 14 days to 2 years, depending upon anticipated conditions of human exposure. Clarification is required as to the appropriate route of exposure, criteria for when longer-term studies may be triggered, and the potential for combining endpoints (e.g. genetic toxicity, reproductive toxicity, immunotoxicity, etc.) as an alternative to carrying out separate studies. See OECD TG 407 or 428 for examples: http://oberon.sourceoecd.org/vl=2159212/cl=12/nw=1/rpsv/cw/vhosts/oecdjournals/1607310x/v1n4/contp1-1.htm.

(4) Adverse eye effects: Guidance should be provided regarding appropriate tiered and weight-of-evidence testing strategies using in vitro methods for evaluating eye irritation potential, as articulated above.

(5) Mutagenicity and genetic toxicity: Guidance should be provided regarding appropriate tiered testing strategies, as well as the potential for endpoint combining (e.g. carrying out an in vivo micronucleus study in the context of a repeated-dose general toxicity study).

(6) Reproductive toxicity: Reproductive and developmental toxicity studies range from screening studies to definitive multigenerational breeding studies. Given the low prevalence of reproductive toxicants within the universe of industrial chemicals,[3] we question the appropriateness of including these studies as a “tier 1” requirement, particularly if mechanistic endocrine screening studies are contemplated.

(7) Carcinogenicity: Carcinogenicity testing should be conducted only after WoE-determinations have been conducted for a chemical’s analogs and its potential for genotoxicity has been established, as this can preclude the conduct of a 2-year, animal-intensive bioassay and allow protective classification. (Q)SAR

[3] Bremer S et al. (2007) The development of new concepts for assessing reproductive toxicity applicable to large-scale toxicological programmes. Current Pharmaceutical Design 13: 3047-58.

models can be especially helpful here for some classes of substances.

(8) Endocrine disruption: This data requirement fails to distinguish between a mechanistic interaction with an aspect of the endocrine system (e.g. estrogen receptor binding) and an endocrine-mediated adverse effect (e.g. reproductive toxicity, which is addressed as a separate data requirement). Protective classification of chemicals that interact with the endocrine system can be accomplished with a suite of in vitro tests, (Q)SAR models, and data available from longer-term toxicity tests addressed in other hazard endpoints.

(9) Respiratory sensitization: To our knowledge there is no harmonized and/or validated test method to determine respiratory sensitization. Therefore, the Regulations should not recommend additional testing for this endpoint.

(10) Skin sensitization: The endpoint can be assessed using a number of animal-based and in vitro tests. Please see comment 2 below for a specific discussion and recommendation to require the Reduced Local Lymph Node Assay (rLLNA), until such time as an in vitro test system is available.

(11) Bioaccumulation: A WoE determination can render empirical data unnecessary, such as when direct aquatic exposure is unlikely and/or log Kow < 3 and/or there is minimal Potential to cross biological membranes

(12) Aquatic toxicity: (Q)SAR models can be especially helpful in classifying chemicals for this endpoint. Empirical data gathered from animal testing is unnecessary when direct aquatic exposure is unlikely. Additionally, the UTC approach can be relied upon to categorize most chemicals according to their potential for aquatic hazard.

2. Nonanimal Methods Should be Required Where Available

The State of California and its citizens have an interest in ensuring that the fewest number of animals are killed in chemical testing laboratories. To this end we would recommend the addition of an over-arching principle: where a nonanimal test method exists and is reasonably and practicably available, new testing to fulfill the information requirements of this regulation should always use such a method unless prevented for scientific reasons. Furthermore, where there is a choice between two animal-based test methods, the method that uses the fewest number of animals and can still accomplish the requirements of the regulations should be used. Skin sensitization provides a good example. Classic tests for skin sensitization (i.e., the Guinea Pig Maximization and Buehler tests) consume at least 30 guinea pigs and involve multiple, stressful injections. In contrast, the mouse LLNA reduces animal use to 16 per test, and is significantly less invasive. A limit dose version of the LLNA —using only a negative control group and the equivalent of the high-dose group from the conventional LLNA— has recently been

proposed by a number of regulatory bodies including ICCVAM (http://iccvam.niehs.nih.gov/methods/immunotox/rLLNA.htm), ECVAM (http://ecvam.jrc.it/), and the OECD (http://www.oecd.org/document/55/0,3343,en_2649_34377_2349687_1_1_1_1,00.html #Draft_TG_for_Comment). This protocol is sufficient to distinguish between sensitizers and non-sensitizers, which would fulfill the criteria for the DTSC regulations, and uses ½ the number of mice as the traditional LLNA.

Although not inclusive of all scientifically appropriate non-animal methods, information on validated methods and methods approved for regulatory use can be found on the ICCVAM, ECVAM and OECD web sites.

We know from experience that despite some advantages, such as lower cost and time commitments in many cases, the decision to spare animals is not always made at the manufacturer level, and so we would encourage DTSC to include this concept in its final regulations.

3. Cooperation During Data Collection Should be Heavily Incentivized

Chemicals and products should be grouped into clusters of like chemicals where possible, and manufacturers at all levels of the supply chain should be given stronger incentives for form consortia in order to share existing data and data collection responsibilities. Current language in the Proposal states persons or entities “may collaborate” (6xxxx.7(g))--stronger incentives are needed. This strategy--scientifically grouping similar chemicals and using data from some chemicals to identify hazard properties of other chemicals and the category of chemicals as a whole--was responsible for the largest reductions in animal use in the EPA’s HPV Program, and is being referred to as the only way to ensure REACH accomplishes its goals.[4] The OECD has provided guidance for grouping chemicals: http://www.oecd.org/LongAbstract/0,3425,en_2649_34379_39404999_119829_1_1_37407,00.html.

4. Hazard Category Prioritization

As mentioned above, the hazard categories listed in this Proposal are not prioritized in any way; however, prioritization is fundamental to efficacy of the program. Initial characterization of hazard should mandate the collection and evaluation of all existing information, including physico-chemical properties, on it and any analogous chemicals. It may be possible to classify a chemical based on existing and physico-chemical properties before conducting any testing. Using a tiered approach, initial characterization is followed by short-term tests that identify primary toxicity and chemicals of concern, which are subsequently characterized using longer, more

[4] Schaafsma et al. (2009) REACH, non-testing approaches and the urgent need for a change in mind set. Reg Tox Pharm 53:70-80.

definitive tests, only if considered necessary for a regulatory decision. Manufacturers should be given the option to classify their chemical as a carcinogen, for example, based on unequivocal positive genotoxicity data. For regulatory purposes, a data gap is not a data need and testing should be focused accordingly. The draft Proposal should articulate such a tiered approach, as delays to gather data for all of the endpoints listed could be quite significant—a minimum of 2-10 years.

Other Comments:

- The definitions for “Primary data” and “Secondary data”, on page 24 of the Proposal apply a value judgment to information gathered from “secondary" sources such as a publicly available database or the literature. This is inappropriate--data gathered from external databases can be as good or better than data from newly-conducted laboratory studies. Weight should be given to data based on its quality rather than where the information is stored.

- Table XX: This table lists some likely exposure scenarios for the three main routes of exposure. In the case where it can be shown that exposure will not take place by one or more of these routes, a provision allowing waiving of testing should remain in place so that new testing will not be performed. Changing circumstances could allow for a reassessment, and available data could also be collected and posted for purposes of transparency.

  The Threshold of Toxicological Concern (TTC) approach can also be used to quantify considerations for waiving of testing for low exposure substances. TTC is a “weight of evidence” risk assessment approach used extensively by the Food and Drug Administration and other regulatory authorities worldwide for the safety assessment of food additives, some cosmetic products, and other substances of unknown toxicity but with demonstrably low human exposure (i.e. on the level of parts-per-billion per day). When combined with known structural information and predicted metabolism or other behavior, the approach bins chemicals into classes, each of which has its own acceptable human exposure limits. If exposure is below these very low levels, toxicity testing may be avoided.

  Certain chemicals may also be exempted from the testing process for other reasons. For example, testing may not be feasible due to handling concerns for explosive chemicals. Testing of known corrosive chemicals in systemic tests represents a significant animal welfare problem and should not be undertaken. Finally testing for some endpoints can be waived, for example, if it can be shown that the chemical does not present an effective internal dose (i.e. lack of skin absorption or potential for inhalation due to physicochemical properties of the chemical).

While some of these are incorporated into Section 6XXXX.21, we mention them here to support their inclusion.

We understand based on presentations from OEHHA staff that additional work will be completed on hazard traits and categories in 2010, and we look forward to participating in those deliberations.

Please feel free to contact the undersigned with any questions.

Sincerely,

Kristie Sullivan, MPH
Scientific and Policy Advisor
Physicians Committee for Responsible Medicine
ksullivan@pcrm.org

Troy Seidle
Senior Director for Research & Toxicology
The Humane Society of the United States
tseidle@humanesociety.org

Catherine Willett, PhD
Science Policy Advisor
People for the Ethical Treatment of Animals
katew@peta.org

CC: Kathy Barwick

Procter & Gamble Plaza (C-6)
The Procter & Gamble Company
NA Regulatory & Technical Relations
One Procter & Gamble Plaza
Cincinnati, OH 45202
www.pg.com

November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxic Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806
Email: MMovassa@dtsc.ca.gov

Re: Comments on the Straw Proposal for Safer Alternative Regulations

Dear Director Movassaghi:

The Procter & Gamble Company welcomes this opportunity to provide comments on the Straw Proposal for Safer Alternative Regulations, published by the Department on October 1, 2009.

The Procter & Gamble Company is the world's leading consumer products company operating in more than 80 countries worldwide. Our portfolio of recognized brands includes numerous household, industrial and personal care products. Procter & Gamble is fully committed to helping solve sustainability challenges, which is embedded in our Company Purpose "to improve the lives of the world's consumers, now and for generations to come." We believe the California Green Chemistry Initiative is intended to accelerate and promote sustainable innovation while making meaningful improvements in the protection of the environment and health of California consumers, workers and children.

Procter & Gamble supports the California Department of Toxic Substances Control's (DTSC) efforts to fully implement the Green Chemistry Initiative and is committed to providing constructive direction to help shape the regulatory development.

Overall Recommendation

Green Chemistry implementation is an opportunity to drive the California market toward quality consumer products that are protective of human health and the environment while advancing innovative technology that improves consumers' lives and are less impactful to the environment. To leverage this primary opportunity, the Straw Proposal needs to outline a practical and workable regulatory framework that establishes a process for identification and prioritization of Chemicals of Concern. This process will focus safer alternative assessment on areas that will result in meaningful improvements to consumer and environmental protection. A regulation framed in this manner will accelerate and promote sustainable innovation and align with the spirit and letter of the enabling legislation of AB1879 and SB509 to create an effective Green Chemistry program for California.

We believe that the October 1, 2009, Straw Proposal does not adequately meet the objectives discussed above and needs to incorporate the following recommendations:

Legislative Requirement: Identification and Prioritization of Chemicals of Concern

The enabling legislation of AB1879 (H&S Code Section 25252.a) requires the Department to "adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a Chemical of Concern." The Straw Proposal recognizes 4 pathways by which chemicals can enter the Safer Alternatives process as "Chemicals of Concern": 1) presence in 11 undefined consumer product categories (section 6XXXX.1); 2) any of the 16 designated chemicals (section 6XXXX.2a); 3) presence on any of 29 domestic and international chemical lists (section 6XXXX.2b); and 4) hazard characteristics outlined in section 6XXXX.7. These pathways would result in approximately 10,000 chemicals that would require an individual alternatives assessment according to the Straw Proposal. This presents an enormous compliance responsibility for consumer product manufacturers, with no clear indication that full compliance could be adequately achieved considering the countless combinations of these chemicals and their consumer product applications that would be subject to alternatives assessment. The sheer breadth of this scope makes this an un-workable program with no focus for consumer product manufacturers or State resources on true priorities.

To establish a credible program, the Department needs to provide scientifically defensible, consistent, transparent criteria that best identify those Chemicals of Concern that present the greatest risk to public health. These criteria do not exist for the list of 16 designated Chemicals of Concern in the Straw Proposal, and are not evident for the selected 29 domestic and international chemical lists. Based on these observations, we believe the Department has failed to satisfy the legislative requirement of AB1879 to establish a process to identify Chemicals of Concern. Furthermore, the Straw Proposal does not include an effective prioritization process for Chemicals of Concern, as required by legislation. Thus, the Straw Proposal is inconsistent with legislative requirements and does not provide an efficient mechanism for focusing on priority Chemicals of Concern that, when assessed in both a hazard and use/exposure context and managed appropriately, will result in meaningful improvements to consumer health and environmental protection.

Identification Process

We urge the Department to support a regulatory approach that considers both hazard and use/exposure to identify and prioritize chemicals warranting further assessment under the Safer Alternatives program. This process will sort a large universe of chemicals into priority tiers of chemicals to allow for a workable and manageable program. Using this approach, work will begin on the highest priority chemicals and proceed (as needed) to lower tiered chemicals to deliver a program that produces results.

We believe the appropriate first step is for DTSC to identify criteria for focusing on those chemicals with the greatest and most severe health and environmental hazard traits – substances known or presumed to cause cancer or developmental or reproductive harm (CMR), or substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by Authoritative Bodies.

Prioritization Process

As stated earlier, the current Straw Proposal will encompass approximately 10,000 chemicals. This provides no real focus for the Department, no indication of priorities, and will stymie breakthrough, innovative technology by forcing consumer product manufacturers to redirect company scientists from R&D activities to compliance activities, including alternative assessments on numerous chemicals in thousands of finished products that have already been evaluated for safety.

Once the chemicals with the most severe hazard traits are identified, DTSC can next prioritize this collection of chemicals by considering their volume in California commerce (as required by AB1879 H&S Code Section 25252.a). This can be achieved by comparing the CMR-PBT chemicals against the U.S. EPA's 2006 Inventory Update Rule (IUR), which reports use volume data on high and medium production volume chemicals in the US. The 2006 IUR data indicate which reported chemicals are used in consumer products intended for use by children to assist DTSC account during prioritization for the "potential effects on sensitive subpopulations," as required by AB1879 H&S Code Section 25252.a. DTSC should also consider during prioritization any chemicals on the US Centers for Disease Control and Prevention's biomonitoring program. By focusing Department and Industry resources on these highly hazardous chemicals with significant *potential* for exposure during an initial, 5-year implementation phase of the Safer Alternative Regulations, DTSC will maximize results. Risk mitigation approaches applied to these highest priority chemicals will produce meaningful improvements to the safety and environmental impact of consumer products in the California marketplace. A second, 5-year phase of the program can then focus on mid-tier chemical priorities and incorporate practical learnings from the initial implementation phase.

Authoritative Body

We recommend that the Department recognize an "Authoritative Body" (for consideration in the identification and prioritization process) as a government agency or formalized scientific organization that characterizes chemicals with a deliberative, scientific process open to public stakeholder input. An "Authoritative Body" needs to satisfy all of the following criteria:

1. It characterizes chemicals pursuant to an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.

2. It is widely perceived to be objective, scientifically based, and does not engage in advocacy.

3. It bases its characterization of chemicals on a weight-of-evidence approach. To the extent available, it considers multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and gives full consideration to mode of action, confounding factors, maternal toxicity, historical controls and any other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.

4. It publishes its characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications.

Focus on Meaningful Exposure Potential

When a chemical meets the scientific criteria for a "Chemical of Concern" and is prioritized as a high priority, there is a need to further differentiate between the *theoretical hazard* of the Chemical of Concern due to presence in a consumer product and the *potential hazard* due to anticipated exposure. Sophisticated analytical techniques are capable of detecting trace levels of chemicals in consumer products to extremely low levels. Presence of a Chemical of Concern in a consumer product at ppb or ppt levels is often below normal background, environmental levels and does nothing to jeopardize the safety of the finished product to consumers and the environment. Ultimately, the Safer Alternative Regulations will have productive impact by focusing priority attention on Chemicals of Concern that are *intentionally-added* to consumer products at levels above a de minimis of 0.1%.

Focus on “intentionally-added” ingredients is consistent with the scope and definitional text of “ingredient” as found in the California Safe Cosmetics Act and the Food, Drug & Cosmetic Act regulatory provisions for cosmetic labeling found in 21 CFR 701.3(l), which specifically exclude incidental ingredients that do not provide a functional benefit in the finished product. P&G believes the recommended de minimis level of 0.1% is appropriate given DTSC’s reliance on hazard traits used for classification and labeling of chemical substances and mixtures under the EU’s Globally Harmonized System (GHS). EU GHS applies concentration cutoffs that apply to chemical substances in mixtures, ranging from 0.1% to 10% depending on the type of hazard and the hazard category. If DTSC intends to use the EU GHS hazard criteria, we contend that the Department must also acknowledge the concentration cutoffs in determining whether a consumer product containing a Chemical of Concern is subject to further assessment under the regulation.

Intentional use of a Chemical of Concern above 0.1% in the finished formulation are the appropriate criteria for DTSC to use to target the purposeful introduction of hazardous chemicals into consumer products at levels that could result in significant exposure to consumers and the environment. These are the true priority Chemicals of Concern for which alternative assessments are needed to find improved ways of ensuring consumer product safety for the California marketplace, and represent a reasonable and effective allocation of Industry and State resources and focus.

Safety Assessment

We believe DTSC needs to specifically identify in the California Regulatory Notice Register the prioritized Chemicals of Concern to focus the regulated community’s compliance efforts. For a high priority Chemical of Concern intentionally present in a consumer product, manufacturers (or consortia) should have the opportunity to demonstrate to DTSC the safety of the consumer product before commencing the massive alternatives analysis that requires examination of all “functionally equivalent potential alternatives.” By following the recommended process discussed earlier, DTSC will identify and prioritize Chemicals of Concern using available data that place a heavy emphasis on hazard with consideration of indicators of exposure. A chemical’s hazard profile and realistic and probable human and environmental exposure must be equally evaluated to assess the safety of its use in a consumer product, considering both the intended use of the product by consumers and end-of-life management. Consumer product manufacturers are in the unique position of possessing realistic exposure information needed to properly assess for safety. Therefore, P&G strongly encourages DTSC to allow manufacturers the opportunity to demonstrate safe use of Chemicals of Concern before proceeding to a costly and resource-intensive alternatives assessment.

Responsible consumer product manufacturers already employ a comprehensive product safety management system that assesses and ensures the safety of consumer products prior to and during marketing. Such product safety management systems employ rigorous control of production; compliance with all product safety, labeling, and regulatory requirements; constant post-market surveillance and rapid response to identified concerns; and ongoing innovation to improve product sustainability and performance to ensure product safety right from the start. Consumer product manufacturers (or consortia) need an opportunity in the regulatory framework to demonstrate to DTSC, through submission of a safety assessment summary and description of applied control measures, that there is insignificant human and environmental exposure to Chemicals of Concern during foreseeable consumer product use and end-of-life disposal and/or recycling.

Examples of effective control measures consumer product manufacturers already employ to limit exposure to Chemicals of Concern include the following:

- Robust precautionary product labeling in compliance with requirements of the Federal Hazardous Substances Act or the Food, Drug & Cosmetic Act
- Packaging control features, such as child-resistant closures required by the Poison Prevention and Packaging Act
- Protective equipment required when using the product
- Manufacturing controls and storage/disposal product labeling to limit unintended releases to the environment

Upon review of the safety assessment summary, DTSC may conclude that additional control measures will effectively mitigate exposure to a Chemical of Concern in lieu of a resource-intensive alternatives assessment. In this situation, DTSC could require manufacturers to apply additional control measures to manage consumer product uses of Chemicals of Concern, which may include:

- Development of additional data for specific characteristics of a priority Chemical of Concern
- Additional product labeling instructions or warnings
- Additional packaging control features
- Additional protective equipment when using the product
- Reduced use of the priority Chemical of Concern in the consumer product formulation
- Enhanced storage/disposal requirements to better manage the product at the end of its useful life

If the safety assessment summary and/or control measures demonstrate that human health and the environment are not adversely impacted by the consumer product use of a Chemical of Concern, DTSC need not require an alternatives assessment. DTSC review of a consumer product manufacturer's (or consortia's) safety assessment summary and description of applied control measures is yet one more way to narrow the focus of this program to the true, high priority Chemicals of Concern most in need of alternatives assessment and risk management.

Alternatives Assessment

DTSC should require a consumer product manufacturer to conduct an alternatives assessment only when control measures are ineffective or the safety assessment summary demonstrates an adverse impact on human health or the environment from consumer product use of a prioritized Chemical of Concern. The alternatives assessment should apply to both the identified consumer product use of a Chemical of Concern and to functionally equivalent potential alternatives for effective comparison.

The alternative assessment should be a holistic analysis involving life cycle assessment (LCA) and evaluation of commercial and technological feasibility of the proposed alternatives. The Straw Proposal requires assessment of *all* functionally equivalent potential alternatives, yet provides no guidance on what is meant by this term. P&G recommends that functionally equivalent potential alternatives meet the following criteria:

- Technologically feasible with same or better product performance
- Commercially available and in volumes needed to address the current use of the priority chemical in the consumer product
- Account for economic and social considerations
- Provide an improved profile for health and environmental issues
- Have a history of safe use under current risk management measures
- Have an equivalent amount of safety data to the Chemical of Concern
- Have a potential to result in lasting change

The alternatives assessment process outlined in DTSC's Straw Proposal is not practical because of the unrealistic, rapid timing to complete and update the assessments and the lack of inclusion or reference to substantive, existing methodologies for assessments. The compliance timelines of 1 year to develop new hazard data, 1 year to complete the alternatives assessment and 2 years to update that assessment fail to recognize time needed to complete a quality life cycle analysis/alternatives assessment. LCAs are very costly and can take several years to complete, even with the availability of dedicated resources/personnel. The generation of toxicity data alone to fill an indentified hazard gap for the LCA may exceed 1 year. The process to identify alternative chemicals may be a multi-year process and may not quickly reveal acceptable candidates. DTSC's expedited timing for alternatives assessment presents an impossible compliance obligation for manufacturers (especially small and medium enterprises). Forcing manufacturers to complete this alternatives assessment cycle for the approximate 10,000 Chemicals of Concern identified in the 4 pathways of the Straw Proposal would grind innovation to a halt. We encourage the Department to require alternatives assessments only after effective chemical prioritization, and to be open to tailoring deadlines on a case-by-case basis following a pre-consultation meeting with a manufacturer or consortia. Flexible timelines will likely be needed to address circumstances and data needs unique to individual products.

The alternatives assessment process included in the final regulation will need to be supported by technical guidance to identify existing methodologies for assessment and their proper application. A technical guidance document can be updated more quickly than regulation to keep pace with emerging science. This technical guidance is needed to ensure alternatives assessments are conducted consistently across Industry, with robust analysis and attention to reproducibility.

This discussion on alternatives assessment is not complete without acknowledgement of P&G's sincere belief that California will miss opportunities for new technologies that create real environmental improvements if the Safer Alternative Regulations focuses squarely on chemical substitutions. R&D resources will be increasingly deployed to the discovery of less hazardous chemicals to human health through the alternatives assessment process, and diverted away from cutting edge research. As previously discussed, presence of a chemical hazard in a consumer product must be evaluated in an exposure context to make any sort of meaningful conclusions about safety. Alternatives assessment, which is the keystone of the proposed Safer Alternative Regulations, fails to drive improvements to the overall quality, safety and environmental benefit of consumer products in the California marketplace by limiting focus to mere presence of "toxic" chemicals in consumer products. This short-term focus on chemical substitutions misses the longer-term incentive of real environmental change that can be achieved when a holistic analysis of hazard and use/exposure is applied to a consumer product to make conclusions on overall benefit to society.

DTSC Response Actions

Upon review of the results of an alternatives assessment, DTSC should determine appropriate response actions and enforcement measures. DTSC outlines in the Straw Proposal a timeline of 2-20 years over which consumer products containing Chemicals of Concern must stop sale in California and substitute with a safer alternative. This inevitable prohibition fails to acknowledge that other enforcement measures may be successful at limiting exposure to a Chemical of Concern below a level that poses no significant risk. If there is no risk of significant exposure, there is no need to prohibit use of a Chemical of Concern in consumer products. The threat of inescapable prohibition may force some manufacturers from marketing products in California; therefore, needlessly limiting market selection rather than encouraging innovation. We believe chemical prohibitions should be enforced as a last resort only after first applying other measures to limit

exposure to a Chemical of Concern below levels that pose no significant risk. Such enforcement measures may include the following:

- No action needed
- Require consumer product manufacturers to develop additional data for specific characteristics of Chemicals of Concern to more fully assess the chemical in the consumer product and its potential alternatives
- Additional product labeling instructions or warnings
- Additional packaging control features
- Additional protective equipment when using the product
- Reduced use of the Chemical of Concern in the consumer product formulation
- Enhanced storage/disposal requirements to better manage the product at the end of its useful life

In fact, AB1879 (H&S Code Section 25253.b) provides 9 regulatory response options the Department can implement following an alternatives analysis; however, the Straw Proposal only focuses on prohibition. The aforementioned enforcement measures may be quite effective at adequately limiting exposure to a Chemical of Concern. Only when it is evident that other existing enforcement measures are not successful and the alternatives assessment reveals a functionally equivalent and available alternative, then prohibition of the use of the Chemical of Concern in a specific consumer product application is reasonable. Any proposed enforcement action should include a plan for a transition period to allow manufacturers to procure alternative materials, equip manufacturing plants, complete sell-through of existing inventories and manufacture new inventories.

Variance Petitions

Section 6xxxx.21 of the Straw Proposal outlines a process by which manufacturers may petition DTSC to waive compliance provisions of the regulation. The Department identifies several criteria that, when properly demonstrated, will result in a successful variance. These criteria include demonstration of insignificant exposure to the Chemical of Concern below a no significant risk level and an assertion that the consumer product is already regulated by another governmental agency that provides equivalent protection to human health and the environment. We believe this type of information should be included in the safety assessment conducted prior to an alternatives assessment rather than after its completion. This type of information could effectively demonstrate early in the process that an alternatives assessment is not needed.

Supply Chain Information Dissemination Requirements

The Straw Proposal requires consumer product manufacturers to communicate absence or presence of Chemicals of Concern; the associated hazard categories; status and final content of an alternatives assessment; and a response action plan and other information to “transferees” throughout the supply chain and to the public via the Internet. This documentation requirement presents a massive administrative burden for manufacturers who have complex distribution paths for delivering product from manufacturing plants to consumers. Manufacturers will have to supply distributors, warehouse and distribution centers, and retailers, ranging from large retail outlets to online vendors to small corner stores in California, with this documentation and provide new updates on a two year cycle as alternatives are re-assessed. We believe the Straw Proposal has exceeded legislative authority in Section 6XXXX.9 since the statute provides no authority to DTSC to require such information dissemination throughout the supply chain. We believe it is inappropriate for private supply-chain relationships to be responsible for monitoring and potentially enforcement of a statutory mandate in California law.

The Straw Proposal has failed to incorporate a procedure for protection of confidential business information (CBI), which is specifically required of DTSC in AB1879 (H&S Code Section 25257). Providing this extent of information to retailers will make extremely sensitive and proprietary information available to our competitors, as many retailers manufacture and market private label products that directly compete with our own branded products. We believe manufacturers should communicate directly with DTSC (as the regulating authority) on safety assessment summaries, alternatives assessment findings, and resulting action plans to avoid loss of CBI protections. Disclosure of such highly sensitive information to retail competitors is a clear conflict of interest for manufacturers.

Concerning CBI protections, we also reject the requirement in the Straw Proposal that manufacturers populate the Toxics Information Clearinghouse with toxicity data for certain endpoints used in product assessment without an established process for CBI protection and quality control of information. We believe DTSC could rely on the wealth of existing data/information from the US and OECD HPV programs to populate the Toxics Information Clearinghouse and add new data/information as they become available in REACH registrations. The data/information captured in the Toxics Information Clearinghouse needs to represent the best available science for endpoint assessments, including read-across, SAR, modeling and information that provides mechanistic understanding.

* * * * *

In summary, we entreat the Department to re-shape the Straw Proposal to outline a practical and workable regulatory framework that establishes a process for identification and prioritization of Chemicals of Concern. This process will focus safer alternative assessment on areas that will result in meaningful improvements to consumer and environmental protection and better align with the spirit and letter of the enabling legislation. We remain committed to advancing the implementation of a California Green Chemistry program that is designed to accelerate and promote sustainable innovation while protecting the environment and health of California citizens.

The Procter & Gamble Company appreciates the opportunity to provide recommendations for the development of the California Safer Alternative Regulations. Should you have any questions about these comments, please contact me at (513) 983-2531 or froelicher.jm@pg.com

Sincerely,

Julie Froelicher
NA Regulatory & Technical Relations Manager
The Procter & Gamble Company
One Procter & Gamble Plaza
Cincinnati, OH 45202
(513) 983-2531
froelicher.jm@pg.com

cc:

The Honorable Linda Adams
Secretary
California Environmental Protection Agency

P.O. Box 2815
Sacramento, CA 95812
Email: LAdams@calepa.ca.gov

Patty Zwarts
Deputy Secretary
California Environmental Protection Agency
P.O. Box 2815
Sacramento, CA 95812
Email: pattyz@calepa.ca.gov

Cindy Tuck
Undersecretary
California Environmental Protection Agency
P.O. Box 2815
Sacramento, CA 95812
Email: ctuck@calepa.ca.gov

John Moffatt
Legislative Affairs, Office of the Governor
State Capitol
Sacramento, CA 95814
Email: john.moffatt@gov.ca.gov

Victoria Bradshaw
Cabinet Secretary & Deputy Chief of Staff
Office of the Governor
State Capitol
Sacramento, CA 95814
Email: vickie.bradshaw@gov.ca.gov

The Honorable Sam Blakeslee
Assembly Republican Leader
California State Assembly
State Capitol, Room 3104
Sacramento, CA 95814
Email: assemblymember.blakeslee@asm.ca.gov

The Honorable Mike Feuer
California State Assembly
State Capitol, Room 3146
Sacramento, CA 95814
Email: assemblymember.feuer@asm.ca.gov

The Honorable Joe Simitian
California State Senate
State Capitol, Room 2080
Sacramento, CA 95814
Email: senator.simitian@sen.ca.gov

SAFER AND GREENER AMERICA, INC.

P.O. Box 265
Gardnerville, NV 89410
(775) 636-6578
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DIRECTOR'S OFFICE
DEPT OF TOXIC SUBSTANCES CONTROL
NOV -4 2009
RECEIVED

November 2, 2009

Director Maziar Movassaghi
California Dept of Toxic Substances Control
1001 I Street, 25th Floor; Box 806
Sacramento, CA 95812-0806

RE: Forcing Removal of Chrome 6 from the Workplace and the Environment

Dear Director Movassaghi

Summary

The health, safety and well-being of every man, woman, child and living creature in the United States are being put at serious risk every day as the result of exposure to dangerous levels of the cancer-causing chemical called hexavalent chromium (commonly known as "Chrome 6"). Made infamous by the movie *"Erin Brockovich"*, Chrome 6 is a highly toxic, hazardous carcinogen, regulated in the workplace by OSHA. Chrome 6 is widely used for corrosion resistance and as a bonding agent for paint on thousand of household items and industrial applications. Tens of thousands of workers in the metal finishing industry are exposed to Chrome 6 daily at their workplaces and all Americans are subjected to serious, life-long illnesses and death from lung cancer constantly because Chrome 6 can be a ground water contaminant.

Chrome 6 is Extensively Used

While most people have heard of or seen the movie *"Erin Brockovich"* and may be familiar with the term "Chrome 6" or "Hexavalent Chromium", the vast majority of Americans are not aware of its irreversible hazards to their health and the environment. *"Erin Brockovich"* is the 1996 story of Hinkley, CA v. Pacific Gas and Electric (PG&E) which resulted in a $333 million dollar settlement, the largest settlement ever paid in a direct action lawsuit. PG&E also settled a similar lawsuit with 1,200 Plaintiff's in Kettleman Hills, CA for $335 million ten years later, in 2006.

Chrome 6 is not an obscure chemical that is only applied in a limited number of heavy industrial applications in a few rural areas such as Hinkley, California (population of 1,915). Chrome 6 is one of the most widely used chemicals for corrosion protection, bonding and paint adhesion. It is applied virtually every second, minute and hour of every single day 24/7 to products in the U.S. It is used as an undercoating or as a topcoat on thousands of metal finished parts and components in every-day products found throughout our homes and on about 7,000 automobile parts. It is also the undercoat for common household appliances, computers, televisions, electronic equipment, cell phones and golf clubs. Most tools in our garages have Chrome 6 underneath the nickel, zinc, brass or chrome plating. For over 60 years, it has been used by industry on aircraft, boats, trains, building materials, bridges and pipelines-even though Chrome 6 is a known carcinogen and extremely hazardous to workers' health and harmful to the environment.

OSHA's, the EPA's and the Individual States' Failures

OSHA issued Chrome 6 regulations called PEL (Permissible Exposure Limit) on February 28, 2006. OSHA's issuance was not voluntarily, but rather the result of litigation and judicial mandate. The OSHA PEL contains no penalties or fines for non-compliance. Now, 3 years later, metal finishers are allowed to delay the removal of Chrome 6 from the workplace with impunity because of the BAT (Best Available Technology) loop hole in OSHA's PEL. BAT gives metal finishers until the year 2010 to identify, test and validate the "best available technology". Industry experts estimate that fewer than 25% of American metal finishers are complying with OSHA's PEL regulations. The metal finishing industry's failure to adhere to the OSHA PEL is directly aided by OSHA, the EPA and state and federal agencies' unwillingness to force timely, full compliance with OSHA's PEL. Full compliance would effectively ban Chrome 6 from the workplace and as a ground water contaminant.

NIOSH (National Institute for Occupational Safety and Health), OSHA's technical research and advisory counterpart is currently proposing to lower the recommended exposure limit (REL) for Chrome 6 to twenty-five times lower than OSHA's 2006 PEL. OSHA has not adopted the new NIOSH recommendation or responded to it. This is shameful and unacceptable because while OSHA does nothing regarding Chrome 6, American metal finishing workers are getting serious illnesses and dying of cancer and the environment is being exposed to ground water contamination.

By contrast, in the last several years, the European Union has adopted and implemented many laws banning Chrome 6, including: RoHS (Restriction on Hazardous Substances), WEEE (Waste Electronic and Electrical Equipment), ELV (End of Life Vehicles) and as recent as June, 2007, REACH (Regulation, Evaluation, Authorization and Restriction of Chemicals). These regulations require total removal of Chrome 6 from the workplace and ban the importation of products in which Chrome 6 was used in the manufacturing process.

The Navy's Green Replacement ("TCP") for Chrome 6

The U.S. Navy recognized the dangers of Chrome 6 over 10 years ago and the need for a safe similar performing replacement chemical. NAVAIR (Naval Air Systems Command), Patuxent River, Maryland, together with R&D partners, decided to develop an environmentally friendly, non-carcinogenic replacement for Chrome 6. From 1998 until 2000 this group developed, formulated and tested a drop-in replacement called Trivalent Chromium Process ("TCP"). NAVAIR extensively tested TCP on the exterior framework of an Army amphibious assault vehicle and on the wings of F-16 and F-18 jet strike fighters. The Navy's "green" replacement chemical proved to be effective for corrosion resistance and provided superior bonding characteristics compared to Chrome 6. Most important of all, TCP is safe for workers and the environment. NAVAIR patented TCP (Patent Numbers *6,375,726, 6,511,532, 6,521,029 and 6,527,841)* and made TCP commercially available in 2004/05 by licensing TCP to four U.S. companies: Henkel, Luster-On, Metalast and SurTec, to manufacture and sell.

Since then, many large, well-respected manufacturers such as Alcoa, BAE Systems, Boeing, GE, General Dynamics, Honeywell, Lockheed Martin, Pratt & Whitney, Raytheon, Tyco, Westinghouse and others have independently tested and validated TCP or the versions formulated by the licensees. In addition to these companies, many corrosion technology firms, NADCAP-certified chemical labs, hundreds of other companies and universities also independently tested TCP. All of them have validated TCP as a replacement for Chrome 6. As a result of their own extensive testing, many Fortune 500 companies in the aerospace, defense, electronics, medical equipment, computer and other industries have stopped using Chrome 6 and switched to TCP.

Jeopardizing Worker Safety and Causing Ground Water Contamination

Most manufacturers and the vast majority of job shops still use Chrome 6 today. The majority of metal finishers and manufacturing plants have not switched to TCP-- in large part because of OSHA's lack of enforcement of its 2006 PEL and OSHA's allowing them to delay compliance until 2010. These job shops and manufacturers continue to jeopardize the health and safety of their employees and are not protecting the surrounding population from possible ground water contamination. It is not just the potential for ground water contamination at the Chrome 6 processors' facilities. Once Chrome 6 is applied, no one knows how many homes, office buildings, backyards, playgrounds, school buses, restaurants or public buildings will be the final dumping ground for these products or where a Chrome 6-contaminated object will end up. We can only pray that it will not be near a water supply.

My Own Investigation

I was formerly involved in the specialty chemical business and metal finishing industry. I am familiar with the issues and problems relating to removal of Chrome 6 from the workplace. During my 6 month investigation and as a part of an in-depth search on the Internet, together with discussions I have had with job shops and manufacturers, many of the people I have spoken with concluded that some of the non-hexavalent chromium products are not only a suitable replacement for Chrome 6, but in many cases (in particular Metalast TCP-HF) actually produced superior performance. Thus, I believe that it has been clearly established, independently validated and is undisputed that the Navy's TCP based chemical is a proven technology as a replacement for Chrome 6. Yet thousands of American workers in job shops and manufacturing plants around the country that are working on metal finishing process lines which still use Chrome 6 baths. The vast majority (about 75%) of these owners choose not to switch over to green alternative chemicals such as TCP. They continue to process products and parts 24/7 with Chrome 6, even though the costs are the same as TCP and TCP does not cause health problems or death.

The Solution: Enforce OSHA PEL or Ban Chrome 6

Chrome 6 must be banned from use in the metal finishing industry immediately, before more innocent workers are subjected to injurious health risks or the environment is further exposed to ground water contamination. OSHA, the EPA and local, state and Federal agencies and the Centers for Disease Control and Prevention acknowledge the dangers of Chrome 6. However, those responsible for regulation, oversight and compliance have not banned or required immediate and full compliance with the 2006 OSHA PEL regulation. OSHA, itself, undermines its own PEL regulation concerning Chrome 6 because it has no penalties or fines for non-compliance, does not compel compliance, but instead grants extensions for compliance.

The Mission

We must work together to immediately:

- **Pressure OSHA to enforce its PEL and compel employers to stop using Chrome** 6 **in the workplace**
- **Force OSHA to protect workers' health and the safety of the environment**
- **Urge individual states to ban Chrome** 6 **from the workplace**

Call to Action

I urge you to use your legislative or administrative authority to compel OSHA to enforce its PEL and for the EPA and individual states to ban Chrome 6 from the workplace and the environment. I request that you take swift and decisive action to protect the lives of the general public, workers and the environment. I ask you to apply pressure to OSHA and other governmental agencies responsible for compelling employers to comply with existing and new regulations and to force them to switch to non-Chrome 6 green products. We must sup President Obama and his plan and commitment to make the United States a green nation with a healthy environment so that our future generations may enjoy a better quality of life. Please demand the removal of Chrome 6 from industry. This Erin Brockovich real life drama must not be allowed to continue. I am certain that no American wishes to be a part of a sequel.

Thank you for your concern and your prompt action.

Sincerely,

Safer And Greener America, Inc.
//original signed by//

James L. Hillman
President

DIRECTOR'S OFFICE
DEPT OF TOXIC SUBSTANCES CONTROL
NOV - 4 2009
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For additional information, please see:

1. OSHA Fact Sheet (July, 2006); Health Effects of Hexavalent Chromium; Hexavalent chromium is a toxic form of the element chromium.

   *www.osha.gov/OshDoc/data_General_Facts/**hexavalent_chromium**.pdf*

2. OSHA Hazard Recognition, Hexavalent Chromium (May, 2008).

   *www.osha.gov/SLTC/**hexavalentchromium**/recognition.html*

3. NIOSH/CDC Discussion of OSHA final rule on Hexavalent Chromium.

   *www.cdc.gov/niosh/topics/**hexchrom**/*

4. Acute Toxic Effects from Chromium Compounds and Hexavalent Chromium; Toxicological Review of Hexavalent Chromium.

   *www.epa.gov/ttn/atw/hlthef/**chromium**.html*

5. Thorough Study of Hexavalent Chromium; Health Effects of Hexavalent Chromium; Danger to workers; Ground water contamination; Hinkley, California-the basis for the Erin Brockovich story*. Article entitled: "Reflections on Hexavalent Chromium: Health Hazards of an Industrial Heavyweight Hexavalent Chromium" (September, 2000).

   www.ehponline.org/docs/2000/108-9/focus.html

6. Website of Safer And Greener America, Inc.

   *www.SAGA**chrome6**.com*

Safer Building Solutions
P.O. Box 168 Clarksburg, CA 95612
916-698-6862
bill@saferbuilding.us www.saferbuildingsolutions.com

November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxics Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: Straw Proposal for Safer Alternatives Regulation (October 1, 2009)

Dear Director Movassaghi:

On behalf of Safer Building Solutions (SBS) I would like to convey our serious concerns with the Safer Alternatives Regulation Straw Proposal as currently drafted (this input is being provided consistent with the Green Chemistry Alliance's [GCA] comment extension deadline of November 9th). Although SBS understands the Straw Proposal is not a formal regulation at this time, the program described would have sweeping ramifications on virtually all industry sectors that manufacture or sell a consumer product in California and does not reflect the intent of the enacting legislation under AB 1879 (Feuer, 2008).

Safer Building Solutions does product development and regulatory work in California for companies with fire retardant building products. The costs associated with having to resubmit chemical changes to a product every 2 years and having to have it re-tested are going to be passed on to the consumer, making the products even more expensive. Given the current state of the economy and that more regulations are being enacted, it is no wonder our state is experiencing difficulties. More regulations mean more companies moving and taking their work force and California's tax base with them. In the fire safety industry we will be forced to cut back on the products available to prevent home ignition in the Wildland Urban Interface. Most products in this category meet the federal standards for Green Chemistry, but under the new California Green Chemistry regulations these products will have to go through evaluations every 2 years. Let's keep California Green and safe, and consider some of the federal standards that are currently in use. We don't need to make products more expensive or lose any more companies to other states or countries.

Under the framework laid out in the current proposal, manufacturers and importers of consumer products for sale in California would be required to identify whether their product contains a "chemical of concern" and, if so, would require a costly and onerous alternatives assessment process. If a consumer product manufacturer/importer could not identify or chose not to implement a safer alternative, the consumer product containing the chemical of concern would be banned in 2-20 years. Furthermore, if the manufacturer/importer chose to implement a safer alternative that, while incrementally better than the identified chemical of concern, has other specified hazard traits it too would be subjected to a ban in 2-20 years. The current Straw Proposal contains no consideration of potential or severity of exposure; rather, it would place roughly 10,000 chemicals on the path for eventual phase-out.

SBS is highly concerned the scope of the current proposal is overly broad and fails to focus on consumer products that present the greatest risk to human health and the environment. This is partially attributed to a very broad definition of "consumer product" that could conceivably include not only finished traditional consumer products, but individual chemicals and component parts as well. This is further complicated by the inclusion of four different pathways in to the process:

1. 11 consumer product categories that are not well defined;
2. 16 designated "chemicals of concern;"
3. Chemicals identified by 29 different state, federal and international sources; and
4. 13 hazard criteria.

The broad pathways would result in an infinite number of chemicals and products being covered and subject to a costly and onerous alternative assessment. Furthermore, it is not clear how we as manufacturers could establish compliance given the number of chemicals covered and ongoing changes to chemical lists and hazard data, with the potential outcome of having to defend their good faith efforts at compliance in the courts.

SBS supports the GCA's approach laid out in their regulatory proposal that was provided to the Department on June 24, 2009. The GCA proposal provides the Department an opportunity to implement Green Chemistry in an efficient, cost-effective and impactful manner by first prioritizing chemicals for review, evaluating how those chemicals are used in consumer products, assessing whether they pose a potential risk to public health, examining potential alternatives and instituting a regulatory action if necessary.

If the Department fails to implement an approach that is scientifically based and narrows the scope – at least at the outset of the program – it will surely collapse under its own weight. Furthermore, California's business community cannot afford to implement the current approach as laid out in the current Straw Proposal. The GCA proposal, as an alternative, is a thoughtful, workable proposal that should be given serious consideration.

For these reasons, SBS urges the Department to start over in their development of the Safer Alternatives Regulation and look to the GCA proposal as a workable solution. If you have any questions regarding SBS's position on the current Straw Proposal, please contact me at 916-698-6862. Thank you!

Sincerely,

//original signed by//

William Hendricks
Owner
Safer Building Solutions

cc: Cindy Tuck, Undersecretary, California Environmental Protection Agency
Dan Pellissier, Deputy Cabinet Secretary, Office of the Governor
Peggy Harris, Chief of Intergovernmental Policy, DTSC

SEM PRODUCTS, INC.
1685 Overview Road
Rock Hill, SC
8032078225

November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxics Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: Straw Proposal for Safer Alternatives Regulation (October 1, 2009)

Dear Director Movassaghi:

On behalf of SEM Products, Inc., I would like to convey our serious concerns with the Safer Alternatives Regulation Straw Proposal. Although SEM understands the Straw Proposal is not a formal regulation at this time, the program described would have sweeping ramifications on virtually all industry sectors that manufacture or sell a consumer product in California and does not reflect the intent of the enacting legislation under AB 1879 (Feuer, 2008).

SEM Products, Inc. manufactures primarily automotive aftermarket products for use automotive repair facilities. We have continually tried to provide products that fully meet requirements of environmental regulations set in place in the numerous AQMDs in California, and find it increasingly resource-intensive to meet those requirements.

Under the framework laid out in the current proposal, manufacturers and importers of consumer products for sale in California would be required to identify whether their product contains a “chemical of concern” and, if so, would require a costly and onerous alternatives assessment process. If a consumer product manufacturer/importer could not identify or chose not to implement a safer alternative, the consumer product containing the chemical of concern would be banned in 2-20 years. Furthermore, if the manufacturer/importer chose to implement a safer alternative that, while incrementally better than the identified chemical of concern, has other specified hazard traits it too would be subjected to a ban in 2-20 years. The current Straw Proposal contains no consideration of potential or severity of exposure; rather, it would place roughly 10,000 chemicals on the path for eventual phase-out.

SEM is highly concerned the scope of the current proposal is overly broad and fails to focus on chemicals that present the greatest risk to human health and the environment. This is further complicated by the inclusion of four different pathways in to the process:

1. 11 consumer product categories that are not well defined;
2. 16 designated “chemicals of concern;”
3. Chemicals identified by 29 different state, federal and international sources; and

4. 13 hazard criteria.

The broad pathways would result in an infinite number of chemicals and products being covered and subject to a costly and onerous alternative assessment. Furthermore, it is not clear how we as manufacturers could establish compliance given the number of chemicals covered and ongoing changes to chemical lists and hazard data, with the potential outcome of having to defend their good faith efforts at compliance in the courts.

SEM supports the Green Chemistry Alliance (GCA) approach laid out in their regulatory proposal that was provided to the Department on June 24, 2009. The GCA proposal provides the Department an opportunity to implement Green Chemistry in an efficient, cost-effective and impactful manner by first prioritizing chemicals for review, evaluating how those chemicals are used in consumer products, assessing whether they pose a potential risk to public health, examining potential alternatives and instituting a regulatory action if necessary.

If the Department fails to implement an approach that is scientifically based and narrows the scope – at least at the outset of the program – it will surely collapse under its own weight. Furthermore, California's business community cannot afford to implement the current approach as laid out in the current Straw Proposal. The GCA proposal, as an alternative, is a thoughtful, workable proposal that should be given serious consideration.

For these reasons, SEM urges the Department to start over in their development of the Safer Alternatives Regulation and look to the GCA proposal as a workable solution. If you have any questions regarding SEM's position on the current Straw Proposal, please contact me. Thank you!

Sincerely,

Steve Gaver
Technical Director,
SEM Products, Inc.
(803) 207 8225
sgaver@semproducts.com

Cc: Linda Adams, Secretary of CalEPA
Patty Zwarts, CalEPA
Cindy Tuck, CalEPA
John Moffatt, Office of the Governor
Victoria Bradshaw, Office of the Governor
The Honorable Sam Blakeslee, Assembly Republican Leader
The Honorable Mike Feuer, Member of the Assembly
The Honorable Joe Simitian, Member of the Senate
Steve Fussy, Presidents, SEM Products, Inc.

The Soap and Detergent Association

November 9, 2009

Maziar Movassaghi
Acting Director
California Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95814
(via e-mail: green.chemistry@dtsc.ca.gov)

Re: SDA comments on DTSC Straw Proposal for Regulation on AB 1879

Dear Mr. Movassaghi:

The Soap and Detergent Association (SDA) appreciates this opportunity to provide comments on the *Straw Proposal for Safer Alternatives Regulations* released on October 1, 2009 by the California Department of Toxic Substances Control for the implementation of AB 1879. These comments also relate to presentations and comments made by DTSC staff and other stakeholders at the October 14, 2009 meeting of the Green Ribbon Science Panel (GRSP) and the October 21, 2009 stakeholders' workshop in Sacramento.

SDA is a trade association representing the $30 billion U.S. cleaning products market. SDA members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. As a trade association for a particular consumer product sector (cleaning products) we are acutely aware of the public's concern for the safety of the products they purchase both in their homes during use and in the environment following disposal. There are numerous chemical management initiatives around the world taking place at the local, regional, federal and international levels in which we participate.

SDA has been participating directly in the California Green Chemistry Initiative and through the industry coalition know as the Green Chemistry Alliance over the past two and a half years. SDA appreciates the tremendous effort by your staff to develop a complete set of regulations and to present them at these two recent meetings. However, we are greatly disappointed that SDA's interactions with DTSC, the input of our individual members to DTSC and the suggestions of the Green Chemistry Alliance have been largely ignored. Likewise, SDA was surprised by your opening remarks at the GRSP meeting where you stated that DTSC had not received much in the way of proposed regulatory language from stakeholders. The Green Chemistry Alliance presented a complete set of regulations to the Department in June that would fulfill the requirements, as well as meet the intent and spirit of AB 1879; I am enclosing a copy of that submission for your further consideration. In addition, we offer the following comments on the straw proposal.

Identification and Prioritization of Chemicals of Concern in Consumer Products (Article X)

Identification of Chemicals of Concern in Consumer Products
The DTSC straw proposal does not "establish a process to identify… chemicals of concern" (COCs) in consumer products contrary to Section 25252(a) of the subject statute (AB 1879). The designated product category applicability in Section 6xxxx.1 is arbitrary, and in some cases vague and in conflict with the specific exemptions cited in the statute. Product Categories (1) through (7) are expansive and not tightly focused. For instance, Category (1), "products designed for use by infants or children" is overly broad and does not identify or prioritize product classes that would be of highest concern. Such vagueness here and elsewhere in the proposal unnecessarily burdens companies who do not have the expertise to make such determinations. The scope of products captured by Category (2), "products designed for use in K-12 schools," is potentially endless, extends well beyond US EPA's definition of age 14 for "children", and fails to focus on what DTSC believes to be the most important sources of exposure in schools. Category (3) would include a number of over-the-counter drugs which are regulated by the US FDA for safety and efficacy. Category (8) targets food contact products, which would be duplicative and in direct conflict with existing FDA regulation. Category (9) targets products designed, or reasonably anticipated, to release any chemicals during intended use and disposal. Considering current analytical capabilities to detect trace chemicals in migration studies, the term "reasonably anticipated" has the potential to greatly expand covered products to virtually everything. Category (10) covers "Any products that contain" chemicals of concern, essentially sweeping in 100% of commerce in California. Category (11) covers every chemical triggered as a COC, essentially setting up direct chemical bans for over 10,000 chemicals in California. These bans would also affect reactive bulk chemicals that are transformed in California into innocuous products within manufacturing facilities. This would not only ban raw chemical use in covered products and categories, but also ban use in the manufacture of exempted product categories in California—pharmaceuticals, medical devices, food, dental restoratives, etc. All affected manufacturers would have to move their operations to another state or offshore.

The designated list of COCs in Section 6xxxx.2(a) of the proposal, the "List of Lists" in Section 6xxxx.2(b) and the Hazard Traits in Section 6xxxx.7(b) are arbitrary. The Department should identify criteria for establishing hazard traits that would serve as the initial tool for identifying candidate chemicals of concern. The severest human health hazard traits such as cancer, or other developmental or reproductive harm (CMR), and persistence, bioaccumulation and toxicity (PBT) as inclusive characteristics for environmental concern would be consensus selections.

The process for identification of candidate chemicals of concern should be a dynamic, on-going process with the most severe hazards being considered first and additional hazards considered based on resources available to DTSC and related agencies over time.

Prioritization of Chemicals of Concern in Consumer Products
The proposal does not "establish a process to… prioritize… chemicals of concern" (COCs) in consumer products contrary to Section 25252(a) of AB 1879 (not withstanding Section 6xxxx.8 which does not really constitute prioritization). The proposal does not consider "the volume of the chemical in commerce in the state" or "the potential for exposure to the chemical in a

consumer product" when identifying and prioritizing chemicals of concern, contrary to Sections 25252(a)(1) and (2) of the Statute, respectively.

Proposed Activities beyond the Scope of the Statute
AB 1879 does not authorize DTSC to require the generation of data to assess hazard traits of all chemicals in commerce and consumer products as part of the identification and prioritization process (Section 25252) contrary to the provisions proposed in 6xxxx.6 *Data Requirements*. In Section 25253, the Department is authorized to require additional data following completion of the alternatives analysis as a regulatory response.

AB 1879 does not provide the authority for DTSC to require manufacturers to populate the Toxics Information Clearinghouse (Section 6xxxx.7(a)(4)). Moreover, the proposal misses the intent of the statute authorizing the Clearinghouse (SB 509) which is to develop a web-based portal that can be used to collect hazard data on chemicals that exists in the public domain (i.e., a Google-like tool).

AB 1879 does not provide the authority for DTSC to require supply chain information dissemination of information (Section 6xxxx.9); and those proposed requirements are in conflict with the trade secret provisions of the statute (Section 25257).

Alternatives Analysis (Article XX)

DTSC has proposed that the manufacturer (each manufacturer) of a subject product would conduct an alternatives assessment on the product. However, the statute (AB 1879) does not give DTSC the authority to require manufacturers to conduct the alternatives assessment. In fact, it would be counterproductive for many manufacturers to be conducting separate analysis. In addition, manufacturers of current products may not be well suited to conduct an alternatives assessment on their own. They may not use an alternative technology and the information on performance and safety would likely be in the hands of suppliers who they may not work with and who might also be a competitor. Since the alternatives assessments will be use-specific for a particular chemical, it would be more efficient and effective if a single assessment was conducted with broad stakeholder participation including participants from manufacturers of conventional products as well as alternatives.

The proposed process envisions a clear "safer" alternative being identified as a result of the analysis. This may occur in some instances, but it is more likely that there will be substantial variability and uncertainty in the various parameters evaluated such that the results are inconclusive. In those instances where a safer alternative is identified, there may be numerous legitimate business reasons why a company does not select the "safer" alternative due to circumstances beyond its control; e.g., there is not sufficient supply in the market place to reliably replace the subject chemical, consumers may not accept the performance of the alternative product, a reformulated/re-engineered product cannot be produced profitably, etc. It would be more efficient for the state to examine those cases where "safer" alternatives are not selected and assist in bringing them to market if the social and environmental benefits justify it. Consequently, the alternatives assessment process should not be arbitrarily repeated every two years if the "safer" alternative is not selected. In addition, the statute does not authorize the

requirement of a justification of the continued use of the consumer product containing the Chemical of Concern.

The Department has proposed a one year timeline for completing the Alternatives Assessment. The Department should have evidence that such an analysis can be successfully completed within a year before moving forward on this proposal. The proposal fails to acknowledge the time it takes for chemical suppliers and product manufacturers to educate one another about the needs, benefits, and applications with regard to a new technology. Furthermore, product development and consumer testing, supply chain development and roll-out of a new product can be very time consuming for a number of industries, some of whom work on cycles of multiple years. So consideration and implementation of what may be considered a feasible alternative could take several years on its own. Such realities of market substitutions must be considered.

Response Actions (Article XXX)

Contrary to the proposal, the statute does not authorize manufacturers to take response actions following the completion of an alternatives analysis. In fact, the statute is clear and unambiguous that the regulatory responses shall be taken by the department (Section 25233(b)). As such, manufacturers should not be required to prepare a Response Action Implementation Plan.

Under Section (a)(4)(B), the proposal states that "if the Department determines… the continued availability in California of the consumer product… would pose a significant risk to human health or the environment, the Department may impose response actions…." The statute does not authorize the Department to conduct safety assessments of the products or the alternatives, nor does DTSC describe how they would conduct such assessments.

Under Section (c)(3), the Department has proposed that a consumer product <u>containing</u> one or more of the proposed <u>thousands</u> of Chemicals of Concern would be prohibited from being made available for use in California within 20 years, regardless of the safety of that product, the use of the product, the content of the chemical and the exposure to the chemical. This is completely unacceptable and counterproductive since there will be little incentive to participate in the Alternatives Assessment process if your product is subject to elimination at the outset.

The statute authorizes regulatory responses and specifies nine responses including a "no action" option and "any other option the department determines accomplishes the requirement of this article;" the article in question is Section 25253 of the Health and Safety Code. That distinction is important because the context is the alternatives assessment process found in the same article, and the ultimate goal of the process also is specified. That is, "to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern." Therefore, all response actions should be taken in the context of reducing exposure or reducing hazard, and those actions should result in material benefit (i.e. material reduction in exposure or material reduction in hazard). Based on the requirements of the statute, if a chemical is identified and prioritized as a chemical of concern based on a hazard trait that has an exposure threshold, and the use of that chemical in a consumer product leads to exposures less than that threshold level (e.g. acceptable daily intake (ADI)), then no action should be necessary.

Required Agency Resources

It is imperative that the Department clearly delineate those responsibilities and burdens that will be borne by it. Likewise, it must understand its current capabilities in those areas and the capabilities that need to be established in order to successfully implement the regulation. The Department could not hope to meet the requirements of the straw proposal which would only lead to a widespread lack of compliance.

Possible Solutions

Identification and Prioritization of Chemicals of Concern
SDA and its industry partners in the Green Chemistry Alliance proposed a simple process for identifying candidate chemicals of concern at the outset (see enclosure). DTSC should identify those chemicals of the highest hazard, particularly those known to cause cancer, or reproductive or developmental harm (CMR) and those chemicals which are persistent, bioaccumulative and toxic (PBTs). Using data from authoritative bodies around the world, you will find over 2,000 chemicals identified. Next DTSC should consider the volume of those chemicals in commerce in the state by comparing the 2,000 CMR-PBT chemicals against the U.S. EPA's 2006 Inventory Update Rule (IUR) which reports use volume data on high and medium production volume chemicals in the U.S.; there is no reason to believe use patterns in California are largely different from use patterns across the U.S. You will find approximately 650 CMR-PBT chemicals on the 2006 IUR. In order to consider the "potential effects on sensitive subpopulations" as specified in AB 1879, DTSC should look closely at those chemicals identified specifically in the 2006 IUR as being used in children's products, and also any chemicals on the CDC's biomonitoring program as CDC has made such considerations in selecting chemicals for analysis. In addition, DTSC should utilize adverse event report information collected by the US EPA under TSCA and FIFRA, and by the US FDA under FFDCA to assist them in prioritizing Chemicals of Concern.

SDA acknowledges that particular human health or environmental issues that might warrant early attention but might not be captured by a broad screen. DSTC should establish a process by which citizens can petition for consideration of particular chemicals and their uses. However, more to the point, DTSC should have a process whereby they can seek out the expertise within their agency or sister agencies to address pointed particular questions.

Once DTSC has narrowed the universe of candidate chemicals of concern in consumer products, it should work with stakeholder groups including the chemical suppliers and the consumer product manufacturers to better understand the uses of the candidate chemicals in consumer products and to select the high priority Chemicals of Concern that would be the subject of an Alternatives Assessment.

Alternatives Assessment
The Alternatives Assessment portion of the regulations should be sufficiently broad and flexible, and the details of the process should be outlined in guidance issued by the Department in 2011 or beyond as it gains more expertise with the activity. The Department should pilot test the framework to determine the feasibility of the approach and the resources needed to successfully complete an assessment. It would be useful if such a pilot test was conducted on materials and uses that have already been studied such as those evaluated by the Massachusetts Toxics Use Reduction Institute's *Five Chemicals Alternatives Assessment Study* or under EPA's Design for

the Environment Program. The notion of pilot testing was broadly echoed during the Green Ribbon Science Panel meeting.

In order for the Department to consider the full range of regulatory responses within the goal of the statute to best "limit exposure or to reduce the level of hazard posed by a chemical of concern" it must have a complete hazard assessment and exposure assessment for each prioritized chemical of concern in a consumer product. This information should be developed as part of the Alternatives Assessment. Complete assessments will bring to light the opportunities to reduce hazard or exposure. It is important to note that the statute specifies that "the department shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes" and that the REACH regulation in Europe will result in chemical safety assessments for the highest volume, and other highly environmentally hazardous chemicals next year. This will greatly facilitate the development of hazard and exposure assessments for chemicals that would be considered under the AB 1879 process.

Regulatory Responses and Compliance
There are a number of hypothetical compliance issues that could arise, but the primary response that might need to be enforced would occur when the Department places a restriction on the permitted concentration of a chemical of concern in a consumer product, or prohibits it entirely. It is likely that such a provision would be the exception rather than the rule. Also, it is likely that there would be strong industry incentive to assist in enforcing those kinds of regulatory responses especially when those not respecting the restriction could have a competitive business advantage over those in compliance.

For many products, especially formulated products, it will be relatively easy to enforce any restriction in presence or concentration since more and more formulated product manufacturers are informing consumers of their ingredients. Those who choose to identify ingredients are subject to the Fair Labeling and Packaging Act so their labeling must be truthful.

Summary

The regulations developed by DTSC for the implementation of AB 1879 should carry out the three basic charges of the statute: developing a process for identification and prioritization of chemical of concern in consumer products, developing a process for evaluating chemicals of concern in consumer products and their alternatives (in order to determine how best to limit exposure or reduce the level of hazard posed), and specification of the range of regulatory responses the department may take following the completion of the alternatives analysis.

In meeting the challenges of those charges, DTSC must also satisfy the provision of the statute for "reference and use, to the maximum extent feasible, [of] available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes." There are extensive bodies of public information currently available through the US EPA, Environment Canada and Health Canada, the OECD and the European Union, and California may also be able to access information which is not otherwise publicly available. In addition, vast amounts of data on chemicals will be available beginning next year through the EU's REACH program.

Finally, DTSC's regulation should be a catalyst for the advancement of Green Chemistry and further consumer product innovation. As currently proposed, the regulations would serve merely as a burden that would force businesses to leave the market in California and manufacturers in the state to move out.

SDA would like to express once again its appreciation in being able to comment on the straw proposal and the DTSC staff presentations. SDA would be happy to further assist DTSC in your development of regulations for the implementation of AB 1879 and SB 509 by sharing our expertise and the expertise of our members. If you have any question regarding our submission, please feel free to contact me by phone at 202-662-2516 or by e-mail at pdeleo@sdahq.org.

Sincerely,

//original signed by//

Paul C. DeLeo, Ph.D.
Director, Environmental Safety

Enclosure

cc: Michael O'Docharty, DTSC
The Honorable Linda Adams, Secretary, CalEPA
Cindy Tuck, Undersecretary, CalEPA
Patty Zwarts, Deputy Secretary, CalEPA
John Moffatt, Legislative Affairs, Office of the Governor
Victoria Bradshaw, Cabinet Secretary, Office of the Governor
The Honorable Joe Simitian, California State Senate
The Honorable Sam Blakeslee, Assembly Republican Leader
The Honorable Mike Feuer, California State Assembly

November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxics Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: Straw Proposal for Safer Alternatives Regulation (October 1, 2009)

Dear Director Movassaghi:

Stoner Incorporated appreciates the opportunity to comment on the Safer Alternatives Regulation as currently drafted. Our understanding is that the Straw Proposal is not a formal regulation at this time, and this program, as currently described, will have a significant effect on our products and our ability to continue to do business in California. This draft does not reflect the intent of the legislation under AB 1879.

Stoner Incorporated manufactures specialized cleaners, lubricants, and coatings for industrial, commercial, and consumer applications. Founded 60 years ago by Paul Stoner, the company has enjoyed a history of innovation and accomplishment often against difficult odds. Today, Stoner's team pursues a mission to help customers save time, increase productivity, and improve the quality of their work.

The current draft proposal requires manufacturers of consumer products to identify whether their products contain a "chemical of concern" and, if so, will require a costly and burdensome alternative assessment process. In addition, little criteria are found in the draft to perform this assessment. Furthermore, there is not a description to determine a safer alternative chemical ingredient. This draft proposal places nearly 10,000 chemicals as chemicals of concern, and will phase out all of these chemicals within twenty years.

The scope of this current proposal is overly broad and fails to focus on the chemical exposure that presents the greatest risk to human health and the environment. The focus of this proposal needs to be narrowed starting with reducing the four different pathways into the process:

1. 11 consumer product categories that are not well defined;
2. 16 designated "chemicals of concern;"
3. Chemicals identified by 29 different state, federal and international sources; and
4. 13 hazard criteria.

It is not clear how a manufacturer such as Stoner can be compliant given the significant amount of work evaluating the lists against our products and then performing the assessments. Additionally, there will be difficulty trying to monitor the changes to the chemical lists and hazard data.

Stoner Incorporated supports the GCA's approach laid out in their regulatory proposal that was provided to the Department on June 24, 2009. The GCA proposal provides the Department with the opportunity to implement Green Chemistry in an efficient, cost-effective and impactful manner by first prioritizing chemicals for review, evaluating how those chemicals are used in consumer products, assessing whether they pose a potential risk to public health, examining potential alternatives and instituting a regulatory action if necessary.

In summary, the current proposal as written is overly broad, very costly and extremely burdensome for the manufacturer. This proposal needs to be changed significantly. Stoner urges the Department to consider these comments, and we look forward to working closely with the Department on a workable solution. If you have any questions regarding our comments, please contact our consultant Doug Raymond at 440-474-4999 or at djraymond@reg-resources.com.

Sincerely,

Harry Zechman
Chief Operating Officer

Cc: Linda Adams, Secretary of CalEPA
Patty Zwarts, CalEPA
Cindy Tuck, CalEPA
John Moffatt, Office of the Governor
Victoria Bradshaw, Office of the Governor
The Honorable Sam Blakeslee, Assembly Republican Leader
The Honorable Mike Feuer, Member of the Assembly
The Honorable Joe Simitian, Member of the Seante
Laurie Nelson, Randlett Nelson Madden
Doug Raymond, Raymond Regulatory Resources (3R)

SUPPLIERS PARTNERSHIP
FOR THE ENVIRONMENT™

November 4, 2009

Mr. Maziar Movassaghi
Director
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: DTSC's September 28, 2009 Draft "Straw Proposal for Safer Alternative Regulations

Dear Director Movassaghi,

The Suppliers Partnership for the Environment (SP) (www.supplierspartnership.org) appreciates the opportunity to comment on the California Straw Proposal for Safer Alternative Regulations.

SP is an innovative partnership between automobile original equipment manufacturers and their suppliers that work to improve the environment while providing value throughout the automobile supply chain. SP provides a forum for small, mid-sized and large automotive and vehicle suppliers to work together, learn from each other and share environmental best practices through various Work Groups addressing specific issues that have been identified by the SP membership.

The following specific comments on several aspects of the Straw Proposal have been developed by the Chemical Issues Work Group of SP and those comments include:

Data Requirements and Timing: The hazard characteristics identified, in many ways are appropriate; however, there are many common chemicals for which this comprehensive data set do not exist. These chemicals are also used in many consumer products. Therefore, it will be redundant if every consumer manufacturer is required to generate the needed hazard data for these substances. It is suggested that California consider recognizing the test data that is being generated through the EPA High Production Volume (HPV) program and the EU REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) regulation, where extensive data sets are being compiled and will be generated when data gaps exist, now through 2018, based on production volume and hazard. It is also suggested that the timing that DTSC is proposing for generating the data be extended beyond 1 year. Many of the toxicology test methods required to generate the appropriate hazard data take longer than a year to complete.

1155 Fifteenth Street, NW, Suite 500, Washington, DC 20005
Tel: (202) 530-0096 • Fax: (202) 530-0659 • www.supplierspartnership.org

The utilization of the HPV and REACH data provide a much more realistic and practical timeframe and will allow for data sharing and reduced economic burden. Therefore, the 1 year timeframe should be extended. DTSC should also consider the initial focus to be on the chronic hazard characteristics - carcinogens, mutagens, reproductive hazards along with persistent and bio-accumulative toxics.

De minimus Levels and "Insignificance": The DTSC Straw Proposal makes no mention of de minimus levels for chemicals in consumer products. In order to better prioritize the effort, it is recommended that a de minimus level be established, so that if a chemical of concern is below this value, no additional actions need be taken. SP also suggests that the focus be on substances that are intentionally added and not incidentally or naturally occurring constituents in a product. Additionally, DTSC should incorporate the concepts currently used in Proposition 65 that allows for "no significant risk levels" for carcinogens and "maximum allowable daily levels" for reproductive hazards. This should be incorporated into the exposure and priority setting process and if a substance in a consumer product falls below these levels, no further action would be required. Currently, DTSC allows for this in the Petition Process, however, it could significantly reduce the burden on both the manufacturers and the DTSC if this were allowed in the up-front prioritization process.

Alternatives Assessment: SP recognizes that the alternatives assessment process is a cornerstone of the DTSC straw proposal. We believe, however, that this process needs to be prioritized, at least initially, to focus on the Priority 1 consumer products and high volume chemicals of concern. Priority 2 and 3 products could be considered at a later date, after the effectiveness, resources needed and cost can be evaluated. DTSC will also need to define a process for determining potential safer alternatives and place responsibility for generating the necessary data on that substance manufacturer.

Supply Chain Communication and Data Gathering: The automotive supply chain is very complex with parts and suppliers coming from a broad global base. Because of this, it will be very difficult to obtain the required information from the non-California suppliers in the timeframe currently being proposed. It is again suggested that additional time be provided to assess and prioritize the chemicals of concern in consumer products and that the process begin with the HPV and REACH data being generated by the chemical manufacturers in a phased-in approach based on manufactured volume and potential hazard.

Confidential Business Information. SP is concerned with the provisions for maintaining confidential business information (CBI). As manufacturers of articles, SP members will be dependent on the chemical data and hazard information provided by the chemical manufactures and the data available in the public literature. Additionally, auto manufacturers are also concerned about protecting their own technologies from competitors and may need strong

provisions that protect CBI while providing appropriate hazard information. DTSC will need to develop a robust hazard and exposure process that gives users of the information the confidence that the data are accurate, while providing meaningful information to allow for making material decisions up the supply chain while maintaining CBI.

Authoritative Bodies. DTSC has asked for comments regarding use of authoritative bodies and their chemical lists. It will be critical for DTSC to clearly define their criteria for including a chemical as a chemical of concern. The use of other Authoritative Bodies for identification of chemicals of concern may be appropriate if the criteria for selection are the same.

We thank you for the opportunity to provide some of our specific comments on the CA Safer Alternative Straw Proposal.

Sincerely,
//original signed by//

Steven B. Hellem
Executive Director
Suppliers Partnership for the Environment

TechAmerica and ITI Comments:
DTSC Straw Proposal for Safer Alternative Regulations
(Version 10/1/09)

TechAmerica and ITI are pleased to provide the high-tech industry's comments on the Draft Straw Proposal for Safer Alternative Regulations. We greatly appreciate the Department's willingness to consider our comments during the development of this important rulemaking and we look forward to working with the Department as the regulations are refined and finalized.

The On-Going Environmental Improvements of the Electronics Industry

Together, TechAmerica and ITI represent more than 1,600 members of the global electronics industry. These companies represent the entire spectrum of the electronics industry – from small component suppliers to large multi-national consumer electronics corporations. The high tech industry is unique in that, due to technological improvements, its products continue to become more functional, energy efficient, and less expensive.

Due to industry-specific market and regulatory requirements, the electronics industry actively works to continually improve the environmental performance of our products, including reducing chemicals of concern that may be present contained in products. The electronics industry has been subject to the European Union's Restriction on the use of Hazardous Substances ("RoHS") Directive since 2006. The Directive restricts the use of lead, mercury, cadmium, hexavalent chromium and certain brominated flame retardants in the vast majority of electrical and electronic equipment sold in the European Union. Due to the size of the EU market, most global producers make RoHS compliant products available in <u>all</u> global markets in order to avoid the need for dual production lines, inventory and supply chain controls. The RoHS Directive is currently under regulatory revision to determine whether additional substances should be restricted in electronic applications. In addition to complying with EU RoHS, the electronics industry is also subject to the European Union's Restriction, Evaluation, Authorization and restriction of Chemicals (REACH) Regulation's requirements for substances in articles.

Because the market for consumer electronic products is extremely competitive, market forces will continue to play a strong role in the further "greening" of consumer electronics - even without additional regulation. Environmental performance scorecards, retailer programs, and federal procurement requirements continually motivate the industry to voluntarily improve the environmental performance of electronic products. Electronic producers voluntarily compete with one another to produce the most environmentally sound products. The "greening" of electronic products will continue to occur as technology evolves and the market demands environmental improvement.

As part of these ongoing efforts, the electronics industry has voluntarily developed an international supply chain reporting standard called the "Joint Industry Guide" that tracks regulated substances at their regulated threshold levels in all components and parts used in the global supply chain. The industry works with its supply chain to report regulated substances contained in products. This voluntary reporting framework has been recognized by the EU and other countries as part of a valid compliance assurance system.

The experience of the high tech industry in complying with the EU RoHS Directive is especially pertinent. Unlike the current approach in the current Straw Proposal, the EU RoHS Directive took a very controlled approach to regulating substances, restricting just six substances in electronics above a *de minimis* threshold level. The European Union included *de minimis* threshold limits because it recognized that 1) "a total avoidance (of lead) is impossible to achieve" and 2) that level was considered to "ensure a high level of protection."[1] The EU also recognized the need to grant exemptions where there are no technically feasible or environmentally preferable substitutes. While industry is continuing to analyze alternatives, it has not been possible to identify a viable alternative in all cases, and today, most, if not all, electronic devices manufactured today contain component parts that rely on one or more of the exemptions granted by the EU Technical Adaptation Committee. However, it has been expensive, challenging, and time-consuming for the electronics supply chain to obtain information on, and invest in the research and development of alternatives for, just these six substances. It is estimated that the industry spent 32.7 billion US Dollars to achieve compliance to the EU RoHS Directive.[2] Based on the industry's experience with the RoHS Directive, having to obtain information regarding the presence of thousands of chemicals (without even getting to the alternatives assessment) as proposed in the October 1 DTSC proposal would take years. The complexity of electronic articles, with many parts, makes the process of collecting and analyzing chemical information, and making changes to products without damaging functionality much more complicated.

When developing its regulations, the high-tech industry encourages the DTSC to recognize the fact that not all consumer products are similarly situated. Some industries, like the electronics industry, are already subject to significant regulatory and market requirements that have resulted, and will continue to result, in products with increased environmental performance. The DTSC and the California public would be well-served by ensuring that the Green Chemistry Initiative focuses on chemicals that are used in specific consumer applications where the exposure risks are highest to sensitive populations, and where existing regulatory incentives to switch to alternative chemistries with lower exposure risks are not as prominent.

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[1] See EU Commission Decision 18 August 2005 amending Directive 2002/95/EC.

[2] Technology Forecasters, Inc. "Economic Impact of the European Union RoHSDirective on the Electronics Industry." Presentation to Consumer Electronics Association (CEA), January 21, 2008.

A Meaningful Prioritization Process Must be Established

When enacting AB 1879/SB 509, the California legislature directed the California Department of Toxic Substances Control to identify *and prioritize* chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern.

Unfortunately, the Straw Proposal does not propose a system that would result in meaningful prioritization as mandated in AB1879/SB509. Instead, the Proposal identifies four broadly encompassing pathways for inclusion into the required processes. First, the Proposal lists 11 extremely broad categories of products that would be covered by the regulation, without any evaluation as to whether the use of chemicals in those applications would result in likely consumer exposure. Second, the Proposal identifies 16 chemicals of concern and follows with a "list of lists" that collectively contains over 10,000 chemicals. These lists would govern the determination of whether a substance is a "designated chemical of concern" without any DTSC assessment as to whether the lists overlap, differ in their regulatory thresholds, or are based on unfounded scientific principles. Finally, 13 hazardous criteria are identified, which are applicable to many chemicals, and likely overlap the other chemical criteria listed.

Overall, the lack of a workable scheme to prioritize uses of chemicals in consumer products that are of concern threatens to undermine one of the most important innovations of the CA Green Chemistry Initiative, namely recognition of the need to formally include an alternatives assessment process. At the October 14 Green Ribbon Science Panel meeting, DTSC rightly called out the creation of a "robust, innovative and implementable alternative assessment model" as California's unique contribution to the area of chemicals management. Without meaningful prioritization, almost any product and chemical will be subject to an alternatives assessment, without considering whether the product/chemical being assessed is a priority or not. While TechAmerica and ITI appreciate the goals set forth by the California Green Chemistry Initiative, we believe the current proposal is neither robust, nor innovative, nor implementable.

Recommendations for Meaningful & Effective Prioritization Process

As a preliminary matter, TechAmerica and ITI encourage DTSC to focus on chemicals that are actually contained in the final consumer product. In this regard, we prefer the approach set forth in the initial DTSC Straw Proposal (July 2009). In that draft, the first level priority was given to those chemicals or chemical products that are in consumer products sold or offered for sale in California. Chemicals or chemical ingredients that do not actually end up in consumer products were explicitly excluded. This is consistent with the mandate given in AB1879, "to establish a process to identify and prioritize those <u>chemicals or chemical ingredients in consumer products</u> that may be considered a chemical of concern."

The scope of the current proposal is overly broad and fails to focus on true consumer products that potentially present significant threat to human health or the environment. DTSC's very broad interpretation of the definition of "consumer product" (as expressed in the October 21 Workshop) could conceivably include not only traditional consumer end products, but also raw chemicals and materials used in manufacturing operations. Although food, pesticides, prescription drugs, durable medical equipment, dental

amalgams and mercury lighting are specifically exempted under AB 1879, their feedstock and upstream manufacturing intermediates could potentially be interpreted by DTSC to come within the definition of a “consumer product” that can be regulated by the Safer Alternatives program. Regulating feedstock and manufacturing intermediates relied upon by manufacturers as "consumer products" could result in displacing those feed stock and intermediaries from the market place, forcing California-based industries to move elsewhere to be able to produce products. Further, there are federal and state regulations that currently address potential occupational health exposures and risks. It would be prudent for DTSC to avoid duplication and focus its resources on consumer products where regulatory controls may be lacking.

TechAmerica and ITI recommend a meaningful prioritization process that would include three key steps: (1) designation of specific chemicals for further consideration, (2) designation of specific consumer product categories for further consideration and (3) prioritization of the uses of the designated chemicals (identified in step one) in the specific consumer products (identified in step two) above a *de minimis* threshold. This prioritization would focus DTSC implementation to achieve the greatest reduction of chemical risk in the most expedient and effective manner. Please see figure 1 for further detail with specific suggestions below.

1. Designation of specific chemicals for further consideration:

   TechAmerica and ITI believe that an approach where DTSC designates specific chemicals for consideration will best allow DTSC to focus its limited resources on addressing priority concerns. The Green Ribbon Science Panel has been established to provide advice to DTSC and the Panel could play a role in identifying criteria for use in determining a manageable list of priority chemicals. In general, we would suggest that when identifying chemicals, DTSC should focus on those chemicals that scientific evidence shows pose a substantial risk to human health and the environment. Key criteria could include chemicals that cause cancer, mutagenic effects, development harm or reproductive harm in humans and chemicals that persist in the environment, bioaccumulate and are very toxic.

   On the other hand, we are concerned that the “list of lists” approach will overwhelm the process rather than focus it. We are also concerned with the approach contained in the October 1 proposal that would require evaluation of each chemical contained in a covered product against 13 hazard traits, regardless of the chemical’s use in the product and potential for exposure. More generally, we note that the Straw Proposal proposes to address all consumer product applications in the same manner – regardless of whether the product is a chemical formulation that contains relatively few chemicals or a finished consumer good that could potentially contain hundreds of parts and thousands of chemicals and where there is limited potential for consumer exposure to the chemicals because of the way they are “contained” in the finished goods. This approach could lead to an outcome where a single product may need to undergo hundreds or thousands of individual alternative assessments. TechAmerica and ITI recommend that the DTSC consider approaches to address chemical formulations and “articles” differently. This is consistent with the European Union’s REACH Regulation where there are different requirements for chemicals, chemical formulations, articles with “intended releases”, and substances in articles. This reflects the fact that finished

goods ("articles") typically do not result in chemical exposures and, therefore, typically represent a lower risk than many formulated chemical products. This is also consistent with the OSHA hazard communication rules where articles do not require an MSDS (see 29 CFR 1910.1200(g)(2)(i)(C)(1) - determining which ingredients to include on the MSDS; 29 CFR 1910.1200(b)(6)(v) - exclusion of articles; and 29 CFR 1910.1200(c) - article definition).

Therefore, we urge the DTSC to adopt an approach that would prioritize specific chemicals for consideration, based on the application of scientific criteria, to best allow DTSC to focus its limited resources on addressing priority concerns.

2. Designation of specific consumer product categories for further consideration:

   Identifying a process to prioritize consumer products for consideration under the "Safer Alternatives Regulation" would also help to focus DTSC resources on the highest exposure risks. DTSC should assign a high priority level to consumer products that are intended for everyday household use and for consumer products used by sensitive populations. Protection of sensitive populations is one of the key purposes of the Green Chemistry Initiative and by focusing on products intended for everyday household use and for use by sensitive populations; DTSC can prioritize its resources on products where there are currently fewer protections. Products intended for industrial or commercial use should be designated as low priority as there are existing rules in place, as discussed above, to protect employees from workplace exposures. The Green Ribbon Science Panel has the expertise to help identify criteria for prioritizing consumer product categories. We also note that DTSC should ensure that the definitions of any identified product categories are sufficiently defined to give adequate certainty as to which products would be included within the regulatory scope of DTSC's proposals.

   As part of the process to prioritize specific consumer products for consideration under the "Safer Alternatives Regulation," we suggest that DTSC focus on those parts of the consumer product that a consumer is exposed to during the product's intended use. For example, the US Consumer Product Safety Improvement Act (CPSIA) has established limits on the use of the lead in children's products. These provisions provide for exclusions for component parts that are inaccessible to children during normal and foreseeable use and abuse of the product. The lead limits apply only to those parts of the product that a child may touch and where a child is potentially exposed to the substance of concern. We suggest that DTSC look to this CPSIA model and as part of its prioritization and include for further consideration only those products or parts of products that are accessible to a consumer during normal and foreseeable use and abuse of the product.

3. Prioritization of the uses of the designated chemicals in the designated consumer products:

   AB1879/SB509 directs the DTSC to identify those <u>chemicals or chemical ingredients in consumer products</u> that may be considered chemicals of concern. If a chemical is present in a low exposure risk or currently regulated application, that

application should be lower on the prioritization list than an application where the chemical poses a higher exposure risk. The DTSC should initially focus its efforts on consumer products where regulatory controls are weak or currently lacking and where sensitive populations face the greatest exposure risk. High priority uses of a chemical in the consumer product would trigger the alternatives assessment requirement, while low priority uses could be excluded from the alternatives assessment requirement and further consideration. The regulations can also allow for periodic re-evaluation of prioritizations so that there is no need to use "catch-all" language such as in the straw proposal released on October 1st. The suggestions below would help DTSC to achieve prioritization of chemicals of concern in consumer products.

First, a workable *de minimis* threshold must be established. In prioritizing uses of designated chemicals within the identified consumer product categories, chemicals that are not intentionally added and are contained in the product below a designated *de minimis* threshold level should be considered low priority and excluded from further evaluation and alternatives assessment. The electronics industry is currently regulated by many international substance restrictions, including the federal Consumer Product Safety Improvement Act, the European Union's REACH Regulation and the EU RoHS Directive. All of these restrictions contain a regulatory threshold that determines whether compliance obligations are triggered. Without these thresholds, it is very difficult for both producers and regulators to determine compliance. Trace amounts of chemicals can occur unintentionally through the use of raw materials or recycled feedstocks, and current testing, verification and compliance assurance systems cannot track materials down to the molecular level. Likewise, the inclusion of a regulatory threshold will ensure that DTSC is focusing its efforts on the highest risk applications of designated chemicals of concern and also provide industry with compliance certainty. TechAmerica and ITI urge the DTSC to choose a *de minimis* threshold that is consistent with current global chemical regulatory regimes. As a starting point, we recommend that DTSC look at the OSHA Hazard Communication Standards; 29 CFR 1910.1200(d)(5)(ii) and (iv) - determining the hazard of a mixture.

Second, uses where a consumer is not exposed to the chemical of concern during normal and foreseeable use and abuse of the product should be considered low priority. As a preliminary matter, TechAmerica and ITI recommend that DTSC focus its regulations on reducing consumer exposures to chemicals that may occur during normal use of the product. To the extent that the DTSC will consider possible exposures during disposal within the prioritization, TechAmerica and ITI recommend that the DTSC exclude this consideration where measures are in place to address disposal issues. For example, the disposal of electronic products is currently managed by the DTSC under the California Electronic Waste Recycling Act and the DTSC's Universal Waste Rules. Both regulatory regimes currently operate to achieve proper and resulting low-risk end-of-life management of electronic wastes. TechAmerica and ITI urge the DTSC to prioritize those high risk chemicals in high risk applications where exposure to sensitive subpopulations is likely during normal and foreseeable use of the product due to the lack of existing regulatory controls or other factors and to exclude disposal considerations.

Finally, uses of a designated chemical in a designated consumer product that are already regulated should be considered low priority. SB 509 states:

> "The department shall consult with other states, the federal government, and other nations to identify available data related to hazard traits and environmental and toxicological end-points, and to facilitate the development of regional, national and international data sharing arrangements…"

A DTSC focus on chemicals and applications where regulatory controls are currently lacking would avoid duplication and potential inconsistencies with existing measures and would also serve to focus DTSC resources on uses where existing controls in place to address potential exposures need improvement. Many products, such as electronic products, are designed for a global market. Any inconsistencies with existing requirements that address use of the chemicals in the design of the industry's products pose significant concerns for market access and the global flow of commerce. The California market is already receiving products from global industries, such as the electronic industry, that comply with chemical restrictions in other jurisdictions that meet the objectives of the "Safer Alternative Regulation." By deeming uses of chemicals in products that are already addressed under existing regulatory regimes or international standards as low priority, the DTSC will be able to focus limited resources on uses of chemicals in consumer products where measures are not currently in place. For cases where the use of the chemical in the designated product is regulated outside of California or measures are in international standards, a process could be established in the regulations where the impacted industry could apply for "exemption" from further consideration based on its currently regulated status.

The Initiative Must Allow for Exemptions

The Straw Proposal requires producers to phase out the use of chemicals of concern regardless of their performance, reliability, socio-economic impact, or even environmental benefits. It is important for the DTSC proposal to recognize that there may be future cases where chemical substitution may not result in the best public policy outcome for performance, reliability, and even health, safety and environmental reasons. In certain cases, exemptions may be warranted, for example, for mercury use in energy-efficient fluorescent lighting. Therefore, an exemption process must be established under the Green Chemistry Initiative. It is important to note that the "variance process" in the Proposal is not a substitute for useful exemptions and a process to identify future exemptions. In the proposed "variance" process, individual manufacturers must apply for single variances for specific applications. This is a very inefficient system for instances where an entire industry works the same way. For example, the EU RoHS Directive allows for exemptions that are used broadly across the entire industry where it is determined that there are no technically feasible or environmentally preferable substitutes for specific uses of the substances in electronic products. Most, if not all, electronic products rely on one or more of the 39 EU RoHS exemptions to comply with the restrictions on just six substances limited under this Directive. This experience from just one industry suggests that, given the complexity of what is set out in the October 1 DTSC proposal, an exemptions process must be included.

Confidential Business Information Must be Protected

The legislation that authorized this rulemaking process recognized that the two competing interests of the public's "right to know" about possible chemical exposures and industry's need to protect confidential business information ("CBI") must be balanced. TechAmerica and ITI are concerned that the current proposal does not provide sufficient protections for CBI.

Global Harmonization and Consistency is Critical

In his signing message for SB 509 and AB 1879 Governor Schwarzenegger said:

> "To ensure that the Green Chemistry Initiative is as visionary and efficient as possible, all administrative agencies involved in this process, including the Department of Toxic Substances Control as lead agency, should take into account programs in other states, countries and regions, such as the European Union, to build upon their experience, data and expertise."

TechAmerica and ITI believe it is critical that the DTSC learn from and adopt existing and evolving principles and implementation measures that are in use around the world. For global industries, such as the electronics industry, it is critical that chemical regulations make sense and work in coordination across jurisdictions. Most manufacturers of electronic products design, manufacture, distribute, and sell products on a global basis and do not develop separate products for sale in California or other jurisdictions. Inconsistencies across jurisdictions in terms of how substances in these products are regulated represent a serious concern for compliance, market access and the global flow of commerce. DTSC should look for consistency with existing regulations or international standards that are achieving the same goals. Similarly, DTSC should avoid duplication with existing regulations that are achieving the objectives of the "Safer Alternative Regulation." By doing so, the Department can better focus on the goals of the Act - protecting the public, especially sensitive populations, from the hazards of chemicals in everyday products.

Conclusion

TechAmerica and ITI greatly appreciate this opportunity to provide the high-tech industry's perspective on the Straw Proposal for Safer Alternative Regulations. As a global industry that is currently subject to numerous substance restrictions, TechAmerica and ITI urge the DTSC to consider and utilize wherever possible principles and implementation requirements that are currently being used by existing chemical regulation systems.

By building on existing programs, the DTSC can ensure that it is developing policy that is consistent with global requirements, which will minimize burdens and costs for regulated entities, but also ensure that California resources are focused in ways that address California's chemical safety needs. Examples of principles and implementation requirements that can be adopted without jeopardizing the intent of California's Green Chemistry Initiative include the adoption of a risk-based prioritization scheme, different regulatory requirements for formulated chemical products and finished consumer goods,

the allowance of exemptions, the use of threshold regulatory levels, the need to protect confidential business information, and the need to focus on products' "use as intended" risks.

TechAmerica and ITI member companies have long been leaders in innovation and sustainability, often taking measures to exceed regulatory requirements on environmental design, energy efficiency and product stewardship. TechAmerica and ITI look forward to working with the DTSC to develop a Green Chemistry Initiative that will drive improvements in environmental performance and also ensure California's continued leadership in technological innovation.

About TechAmerica

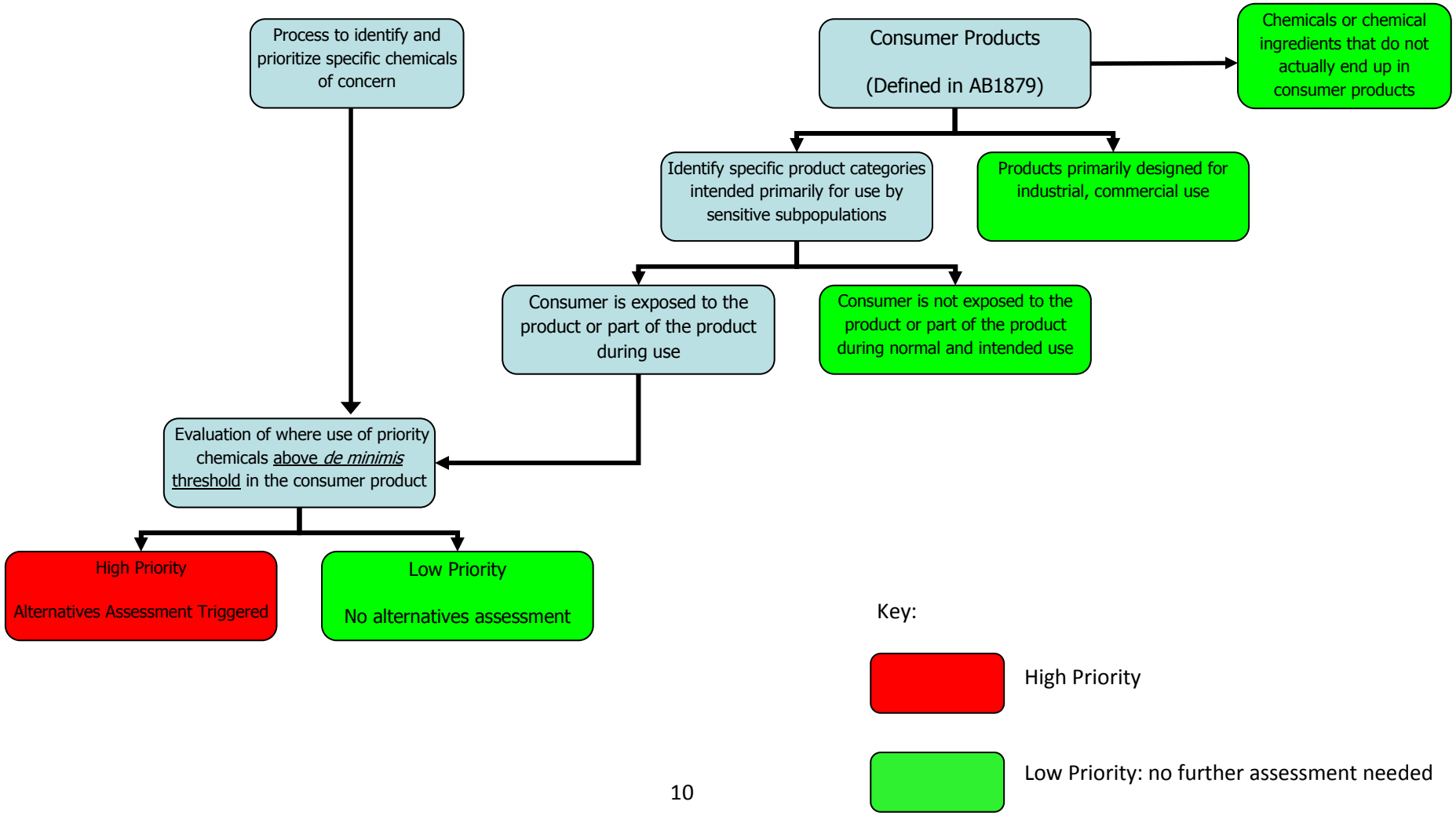
TechAmerica is the leading voice for the U.S. technology industry, which is the driving force behind productivity growth and jobs creation in the United States and the foundation of the global innovation economy. Representing approximately 1,500 member companies of all sizes from the public and commercial sectors of the economy, it is the industry's largest advocacy organization and is dedicated to helping members' top and bottom lines. It is also the technology industry's only grassroots-to-global advocacy network, with offices in state capitals around the United States, Washington, D.C., Europe (Brussels) and Asia (Beijing). TechAmerica was formed by the merger of AeA (formerly the American Electronics Association), the Cyber Security Industry Alliance (CSIA), the Information Technology Association of America (ITAA) and the Government Electronics & Information Technology Association (GEIA). Learn more at www.techamerica.org.

About ITI

The Information Technology Industry Council (ITI) represents the nation's leading high-tech companies and is recognized as one of the most effective advocacy organizations for the tech industry in Washington and internationally. ITI helps member companies achieve their policy objectives through building relationships with Members of Congress, Administration officials, and foreign governments; organizing industry-wide consensus on policy issues; and working to enact tech-friendly government policies. Learn more at www.itic.org.

Figure 1.

Prioritization of Uses of Chemicals of Concern Contained in Consumer Products



Elmer Rauckman, PhD, DABT
Toxicology and Regulatory Affairs Rauckman@Toxicsolutions.com

1201 Anise, Freeburg IL 62243 618-539-5280

04 November 2009

Michael O'Docharty
Safer Alternative Comments
Department of Toxic Substances Control
P.O. Box 806, Sacramento, CA 95814
green.chemistry@ dtsc.ca.gov

Sir;

As a former staff scientist at the National Toxicology Program (with the National Institute of Environmental Health Sciences of the National Institutes of Health), I managed government sponsored research programs on determining the toxicity of several chemicals used in consumer products. While I believe that the Green Chemistry Initiative is a step in the right direction for California's approach to chemical regulation, there are several factors that need to be taken into consideration upon implementation of the plan to prevent misidentification and miss categorization of materials. Errors of judgment in efforts such as these can have grave consequences on state economics, competitiveness and the health of Californians. We have learned a great deal from errors made in replacing tested chemicals with more hazardous but untested chemicals which appear safe but are not.

The Straw Proposal for the Safer Alternative Regulations puts a heavy emphasis in identifying priority chemicals of concern. In choosing criteria for the selection of priority chemicals, there are several factors the Department of Toxic Substances Control (DTSC) must take into consideration including the exposure level to humans and the intended use of the chemical in the consumer product.

The exposure pattern of a particular chemical should be taken into account when determining its potential for harm. Most environmental chemicals are tested for toxicity using laboratory studies on animals where lab rats are exposed to doses far above what humans are exposed to with everyday contact. The problem with using this type of test to draw conclusions is that everything (even water) can be toxic at high enough dose levels but that does not mean that water is dangerous and should be banned. It is far more important to look at realistic levels of exposure to the chemical through everyday use when determining its risk. The equation Hazard x Exposure = Risk is ultimately what determines adverse health effects. Banning a substance because it causes harm at extremely high doses could result in removal of low risk materials in favor of higher risk materials. Hopefully the days of "The sky is falling" hysteria are over and logic will prevail.

The panel should also take into account the intended use of the chemical when reviewing its hazard potential. While some chemicals can be dangerous in certain specific applications, we need to review the chemical for the use it was intended. For example, bleach does not pose a health risk when using recommended doses for laundry; however, there is risk in using open buckets of bleach for a cleaning agent. Bleach in both uses has the same hazard.

While it is important to review and regulate chemicals present in our environment, it is important to recognize the benefits these chemicals bring. We must weigh both the risk and the benefit of each chemical under review and also consider the safety of the alternative products. California has an economy that in large part was built on innovation. Sacrificing innovation will harm economic growth and stifle sustainable development – which relies on innovation. Everytime a chemical is removed from the marketplace, completeness is reduced. Admittedly, some chemicals should ultimately be removed but it needs to be by an evolutionary process where we take a step forward rather than back.

In gambling the old saying that scared money never wins is true and likewise we need to move forward with sustainable development from a position of knowledge and forge ahead not back. All chemicals are safe if there is no exposure, the driver to develop new technologies with less hazardous chemicals should be the expense and effort to prevent exposure by developing an improved technology and not by pulling innovation off the table.

We have the knowledge to do this so let's move forward with confidence and not throw up roadblocks to innovation.

Please feel free to contact me if you have any questions.

Sincerely,

//original signed by//

Elmer Rauckman PhD DABT
Consulting Toxicologist

Safety Evaluation Summary for Dry Erase Markers, Summary Table

#	Colors	Component	CASNO	Quantity (w/w %)	Toxicology	Regulatory Status See Notes	Approval and comments (see notes)
1	Orange	Pigment Yellow 139 With P Red 245 (below)	36888-99-0	5.8% 4.2%	Unknown No reports of sensitization (3)	TSCA = Y EINICS = Y DSL =Y OECD HPV AICS PubMed - ok	Regulatory ok US, EU, CAN Low concern
2	Red	Pigment Red 254	84632-65-5	10%	Reasonable data set Structure OK	TSCA = Y EINICS = NO (2) DSL =Y OECD HPV AICS FDA ADI IDA 178.3297 OECD HPV	Regulatory ok US, CAN No Concern
3	Blue	Pigment Blue 60	81-77-6	10	Good data set	TSCA = y EINICS =Y DSL =Y FDA eafus, INCI Inventory OECD HPV PubMed ok	Regulatory ok US, EU, CAN No concern
4	Green	Pigment Green 7	1328-53-6	10	Good supporting data, wide approvals.	TSCA = y EINICS =Y DSL =Y FDA eafus, INCI Inventory OECD HPV PubMed ok	Regulatory ok US, EU, CAN No Concern
5	Black	Carbon Black 7	1333-86-4	1.0	Sufficient data (4)	TSCA = y EINICS =Yk DSL =Y FDA eafus, IFA INCI Inventory OECD HPV	Regulatory ok US, EU, CAN No Concern
6	All	Ethanol	64-17-5	~45	Well known	No prohibitions known for use	Regulatory ok US, EU, CAN No Concern
7	All	Isopropyl alcohol	67-63-0	~35	Well known	No prohibitions known for use	Regulatory ok US, EU, CAN Low concern

#	Colors	Component	CASNO	Quantity (w/w %)	Toxicology	Regulatory Status See Notes	Approval and comments (see notes)
8	All	Isopropyl myristate	110-27-0	6-9	Good data set	TSCA = y EINICS =Y DSL =Y FDA eafus, INCI Inventory OECD HPV	Regulatory ok US, EU, CAN Low concern
9	All	Castor oil	8001-79-4	1.0	Sufficient data	TSCA = y EINICS =Y DSL =Y FDA eafus, IFA INCI Inventory OECD HPV	Regulatory ok US, EU, CAN Low concern
10	All	Hexaglyceryl tristearate	71185-87-0	0.5	No data	TSCA = Y EINICS = No DSL =Y INCI = Y	Regulatory ok US, CAN Low concern EU 1000kg limit
11	Most	Sucrose stearate	37318-31-3	1.0	No data found but structure indicated safety	TSCA = y EINICS =Y DSL =Y	Regulatory ok US, EU, CAN No concern
NOTES							
Approval and comments		The first item covers the Chemical Notification Requirements for the US, the EU and Canada, the concern level is a judgment on the possibility of the material causing adverse health effects in individuals. No or low concern indicated that enough information is available to have confidence that the material is safe. Impurities are not taken into consideration unless they are disclosed in the formulation information or any MSDS that may have been submitted.					
FDA eafus		US FDA Table titled "Everything Added to Food", DA = Direct food additive IDA or FC indirect food additive (food contact generally)					
INCI Inventory		International listing of acceptable components for cosmetics.					
TSCA		On TSCA Inventory					
EINICS		On EU Inventory					
DSL		Inventory Canada listed					
PubMed		An OK indicates that Pub Med was searched for any reports that the material had caused or was alleged to cause allergic reactions or skin sensitizations					
		Numbered notes					
		1	NTP: Salmonella Neg, , Chrom Abs, Neg, SCE, Positive- Insoluble in water and organic solvents Colorant is OECD HPV chemical Deleted from List of Undesirable substances Not AZO, not aniline Bit more data available but must be favorable or it would not have been deleted from List of Undesirable subs					

#	Colors	Component	CASNO	Quantity (w/w %)	Toxicology	Regulatory Status See Notes	Approval and comments (see notes)
		2	Not on EXpub List but is HPV and covered by other regs				
		3	The colorant is a yellow that is mixed with red to produce the desired orange shade. There were no data found in the open literature for this yellow colorant				
		4	The carbon black is certified free of Polycyclic aromatic hydrocarbons by Evonic in the MSDS for Printex 75 powder. This supplier and grade should be specified in the manufacturing contract				
			All colorants are "pigments" which are not soluble in water or have very limits water solubility. The consensus opinion is that they are not bioavailable because of their limited solubility. This factor alone reduces the level of concern relative to adverse health effects.				

Toy Industry Association, Inc.
www.toyassociation.org

November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxics Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

Subject: Concerns with the California Department of Toxic Substances Control – Straw Proposal # 2 of Safer Alternatives Regulation

Dear Mr. Movassaghi:

Below please find a detailed discussion of key concerns and recommendations from the Toy Industry Association (TIA) on the Department of Toxic Substances Control (DTSC) Straw Proposal #2 for Safer Alternatives Regulation (Straw Proposal) under Assembly Bill 1879 and Senate Bill 509 (2008). TIA appreciates this opportunity to provide comments on this proposal and looks forward to working with you and DTSC in helping shape a proposal that accomplishes the objectives of the statute in protecting human health and the environment; while continuing to foster innovation and efficient commerce. However, we strongly feel that the current proposal is unworkable and significant new attempts must be made to prioritize the focus of the program to chemicals that are likely to cause harm to human health or the environment.

TIA is a not-for-profit trade association representing more than five-hundred (500) toy makers, marketers and distributors, large and small, located throughout North America. The Toy Industry Association and its members have long been leaders in toy safety. In this role, we develop safety standards for toys, working with industry, government, consumer organizations, and medical experts. The U.S.'s risk-based standards are widely used as models around the globe. We also serve to educate industry on these standards so that they comply and educate parents and caregivers on choosing appropriate toys and how to ensure safe play.

Product safety is a vital consideration for toy manufacturers. TIA's members perform rigorous safety-based assessments for all products prior to the marketing of a product and take into consideration potential impacts on a consumer, whether it be an adult or a child. In addition to meeting stringent internal product safety requirements, toys must also comply with numerous federal and international environmental and safety regulations under a variety of laws and regulations.

Below you will find general concerns, identification of specific elements of the Straw Proposal that are problematic, and recommendations on alternative solutions that will accomplish the

1115 Broadway | Suite 400 | New York | NY 10010 | Tel 212.675.1141 | Fax 212.633.1429 | info@toyassociation.org

goals of this proposal. TIA hopes that these comments are helpful as the straw proposal continues to be evaluated and revised.

General Concerns and Recommendations

Concerns:

- TIA is very concerned about the broad impact and extensive data and alternatives assessment burden imposed upon product manufacturers in the current DTSC straw proposal on Safer Alternatives Regulation.
- Focusing on broad product categories first diverts essential resources from those exposures to chemicals that are of most concern.
- Without streamlining the proposal, many product manufacturers, particularly smaller manufacturers, would likely not be able to continue to sell products in California, due to the sheer cost of compiling and maintaining data as well as the need to provide product certifications and conduct alternatives assessments.
- Including products in data development and alternatives assessment, simply because they may come into contact with children or a sensitive population is unjustified. There must first be some reasonable expectation of exposure to a chemical that has an adverse impact through the use of a product to warrant such data development and assessment. Existence of the chemical in a product is not sufficient to require action; there must be meaningful exposure potential.
- There is a lack of information provided regarding how chemicals were selected, coupled with a "list of lists" which appears to contain several thousands of chemicals. This option for inclusion in the scope of the regulation does not provide transparency or practical workability from an implementation standpoint and serves to undermine the credibility of the process.
- The alternatives assessment requires evaluation of extraneous data that are not relevant to hazard or exposure to the consumer; any extraneous analysis should be eliminated so that companies are not overwhelmed by the vast number of data points requested.
- The "Response Actions" criteria for prohibition of a chemical and timeframes for implementation are inappropriate given the breadth and number of chemicals impacted under the proposal.
- Including "end-of-life" management in the straw proposal is duplicative of extensive existing regulations under federal, state and local law.

Recommendations:

- The proposal must be amended to limit the scope through a process that prioritizes chemicals first and products second based upon reasonable evaluation of potential hazards and exposure, and taking into account reasonable and anticipated use of the consumer product containing the chemical.
- Prioritization should be of chemicals, not of broad product categories, as stated in the underlying statute.
- TIA supports a prioritized approach such as the Green Chemistry Alliance (GCA) proposal (6/24/09) that provides the Department an opportunity to implement Green Chemistry in an efficient, cost-effective and impactful manner by:

1. Prioritizing chemicals for review,
2. Evaluating how those chemicals are used in consumer products,
3. Assessing whether they pose a potential risk to public health,
4. Examining potential alternatives, and
5. Instituting a regulatory action if necessary.

- De minimis levels must be stipulated as DTSC moves forward with data and alternatives assessment requirements.
- All chemical selection decisions must be made through a public comment process and be scientifically justified by reasonable evaluation of potential hazards and exposure.
- The alternatives assessment process must be simplified and the data needs must be streamlined so that alternatives are evaluated in the same manner as the original chemicals of concern in the product. This evaluation must be, based upon hazards and potential exposure. This must occur so that true and useful comparisons can be made and so that companies are not overwhelmed by the vast data requirements.

Product Categories

TIA is very concerned about the broad scope and impact of the current straw proposal's product categories approach. The entirety of the product categorization section of the straw proposal should be reconsidered. First, the statute does not support prioritizing products; rather it specifically directs the department to prioritize "chemicals" or "chemicals of concern." Focusing on products first instead of prioritizing chemicals and exposures that cause harm diverts essential resources from those chemical issues of most concern. Second, the very general product categories threaten to overwhelm broad sectors of product manufacturers with requirements for hazard data development and analysis that will not contribute in a meaningful way to addressing the goals that DTSC seeks to achieve. Taking broad action on categories of products is unjustified and inequitable. The focus of the regulation must be to identify chemicals of concern that have an adverse impact on human health or the environment, based on a reasonable expectation of exposure. Although TIA objects to the categorization of products set forth in the straw proposal, TIA also objects specifically to each category as overbroad and unsupported by the underlying statute.

1. The categories of "Products designed for use by infants or children" and "designed for use in K-12 schools" are overly broad because they would result in mandating that all "toys," independent of composition, configuration or use, would require a hazard analysis and data submission, regardless of exposure circumstances and reasonable expectation of hazard arising from the use of a chemical in a product.

Suggestion: DTSC should prioritize chemicals of concern first (via the use of data from authoritative bodies) through a public process. Once the chemicals of concern are prioritized, the industry can then identify specific products that result in a reasonable expectation of exposure and resultant potential hazard to human health or the environment from those chemicals in order to comply with the notification and alternatives provisions for the identified chemicals. Exposure should be based on reasonable and anticipated use of the consumer product. The encapsulation or inaccessibility of a chemical of concern (such that

there is no exposure) should constitute an insignificant risk and not be subject to data development or alternatives assessment.

2. The inclusion of "products designed or anticipated to release any chemical(s) during use or end-of-life" in the hazard analysis requirements could capture virtually every consumer product ever made depending upon the use of the term "anticipated" and if it is intended to capture the release of any chemical or just chemicals of concern.

Suggestion: DTSC should eliminate this all-inclusive category. Regulating "end-of-life" release is already addressed extensively through existing federal, state, and local regulations. DTSC should look to leverage existing programs and initiatives with regard to this requirement.

3. The inclusion of "products that contain any of the chemicals specified in section 6xxxx.2" in the hazard data requirements could capture virtually every consumer product ever made due to trace contaminants and naturally occurring elements in product feedstock. It would be cost-prohibitively expensive and scientifically unjustified to require that the mere presence of a chemical in a product results in an obligation for extensive data development and alternatives analysis.

Suggestion: DTSC should eliminate this all-inclusive category. To the extent a product contains a priority chemical resulting in exposure above de minimis levels, resulting in a negative impact on human health, then such product may be identified by the manufacturer to be considered for alternatives assessment. An exposure determined to be cause an insignificant risk (e.g., inaccessible encapsulation of chemical in product) should not require an alternatives assessment.

Designated Chemicals of Concern

The proposal lists 16 specific chemicals of concern and provides a list of 29 authoritative body lists that range widely from the EU, Canada, US, International bodies, and California. Conservative estimates are that 6000-8000 chemicals could be included via this current structure. This universe of chemicals is overly broad and would paralyze commerce in constant chemicals analysis. Additionally, the 16 specified chemicals lack any scientific justification or cause to indicate why they are included in this proposal as "chemicals of concern". This broad conglomeration of lists, without proper critical technical review is almost certain to include inaccuracies, conflicting scientific bases, and inconsistencies.

This broad range of chemical designations without prioritization or designation of de minimis levels would require virtually every manufacturer of a product in commerce to be forced into an alternatives assessment pathway regardless of any potential exposure resulting in harm to human health or the environment. The legislature did not intend this result and interpretation in this way does not further the goals of the statute.

Suggestion: DTSC should not create a list that includes the universe of chemicals based on lists created by nations around the globe, without first evaluating the chemicals listed for

scientific accuracy, consistency and relevance. Instead of this broad, over reaching approach, DTSC should identify criteria for "chemicals of concern" and prioritize those chemicals (via a public process) that assesses the likelihood and potential severity of exposure of the chemicals of concern, based on reasonable and anticipated use of the consumer product, and using peer-reviewed sound science . It is essential that DTSC set reasonable de minimis limits (e.g., 0.1% of a product as a default value; as in EU REACH Article 7) for each priority chemical. "Zero" and "none" are not meaningful terms in these evaluations. Issues of detection limits and laboratory reproducibility place real constraints on the value of miniscule or highly variable analytical results.

Definitions

1. "Authoritative Body" does not indicate if the body uses a technical "weight-of-evidence" approach, or engage in advocacy regarding chemical listing.

Suggestion: The definition of "authoritative body" should ensure that the following factors apply to that "authoritative body":

a. It characterizes chemicals pursuant to an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.

b. It is widely perceived to be objective, scientifically based, and does not engage in advocacy for advocacy's sake.

c. It bases its characterization of chemicals on a weight-of-evidence approach. To the extent available, it considers multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and gives full consideration to factors such as mode of action, confounding factors, maternal toxicity, historical controls and any other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.

d. It publishes its characterizations of chemicals through publicly available governmental regulations, periodic reports, monographs or similar publications.

2. "Chemical Ingredient" does not address the distinction between intentional ingredients and unintentional ingredients in products (e.g., raw material contaminants, unrelated process introductions).

Suggestion: "Chemical ingredient" should mean any chemical intentionally added to a consumer product that is necessary for the functional use of a product. Other definitions are too speculative, variable and uncertain to be of practical value. De minimis levels should be accounted for.

Data Requirements

1. This proposal requires evaluation of every trace chemical *AND* chemical ingredient in every applicable product sold in California. First, it is infeasible to require manufacturers to develop and provide hazard data for every trace chemical and chemical ingredient in their products. Second (as discussed above) data needs should be prioritized by chemical based upon potential hazard and likely exposure. Third, supply chains for products (especially articles such as toys) are extremely complex. Thus, requiring the end-product manufacturer to be the sole entity responsible for submission of chemical hazard data would be unreasonable, cost-prohibitive, and scientifically infeasible. In addition, the process would be potentially compromised if various manufacturers of the same or similar products submit conflicting information, or have no access to information for components up the supply chain. Finally, requiring full hazard data for trace chemicals in a product is unwarranted and would have little to no demonstrable positive impact on human health or the environment.

Suggestion: DTSC should prioritize data needs to high priority substances (per above) and rely on publically available data resources.

2. The proposal requires that data used in a hazard evaluation must be entered into the Toxics Information Clearinghouse. Providing this highly sensitive information on a product-specific basis could be extremely detrimental to the protection of confidential business information, as well as being potentially conflicting/duplicative if data needs are not prioritized and all manufacturers are required to provide individual hazard data for all products. Additionally, it is not appropriate for product manufacturers to be the sole responsible party for populating the Toxic Information Clearinghouse, as this data may not be something they have the ability nor willingness to directly provide, for the practical reasons stated.

Suggestion: DTSC must set criteria that would prioritize data needs, to avoid such a broad-reaching mandate that cannot be implemented. The process should identify other mechanisms to populate the Toxic Information Clearinghouse that do not shift this burden solely and completely to end-product manufacturers.

Hazard Criteria

1. The proposal would require applicable consumer product manufacturers to develop hazard data for 13 end-points for **all** chemicals within their products, irrespective of the potential or likelihood for exposure and harm.

Suggestion: This is an unworkable mandate, particularly for articles that are assembled from various components and materials, at various locations, and possibly at various times. As stated above, data needs must be prioritized by chemical via criteria that consider potential for exposure and associated hazard, based on reasonable and anticipated use of the product. Then end-product manufacturers cannot be the sole entity charged with developing this hazard data. DTSC must be able to rely on a synthesis of publicly available, technically

reliable data from existing prioritization efforts in other jurisdictions, other authoritative bodies, or data provided by upstream suppliers.

2. The establishment of chemicals of concern via hazard criteria and uncritical acceptance of the decisions of worldwide authoritative bodies appears to be potentially conflicting and duplicative, unless a technical review process is applied to address potential inaccuracies, conflicting scientific bases, and inconsistencies.

Suggestion: One integrated approach to prioritizing chemical ingredients must be selected for consistency and to reduce duplicative data efforts. It is not sufficient to simply see which "authoritative bodies" have lists, and combine them in unspecified fashion to yield a DTSC list. DTSC should establish, through a public process, a set of criteria in advance for prioritizing chemicals based upon hazard traits and likely exposure. Then those product types that have exposure potential for a chemical of concern with the greatest potential impact on human health would be selected for alternatives assessment.

Prioritization of Chemicals of Concern

1. Prioritization of chemicals of concern first should be the focus of DTSC's straw proposal, as directed by the statute. Consumer products containing the prioritized chemicals of concern, above deminimis levels, and resulting in exposure causing harm to human health or the environment, should then be subject to the alternatives assessment.

Suggestion: Identification of products using chemicals of concern should occur <u>after</u> chemicals have first been prioritized, through a public process, as chemicals of concern which have the previously defined hazard characteristics of concern and which exhibit reasonable potential for exposure). Then, identification of products using chemicals of concern should be used so that only those products with the highest exposure (direct exposure during a product's normal use that is likely to cause harm) would be subject to an alternatives assessment. Products that do not result in reasonable or significant exposure to a chemical of concern should not be required to submit hazard data or perform an alternatives assessment. Products that may result in significant exposure to a chemical of concern should be considered for limited hazard data development and limited alternatives assessment, to be focused on determining alternatives or technologies to eliminate potential exposure, in a phased-in timeframe.

2. The release of a chemical of concern following end-of-life disposal of a product should not warrant a full alternatives assessment and/or subject specific products to chemical bans.

Suggestion: DTSC should eliminate the alternatives assessment triggered by a determination of theoretical release at end-of-use because such release is already extensively regulated under existing solid waste mechanisms for reuse or safe disposal.

3. The current biomonitoring programs do not take into account the exposure from any particular product and therefore cannot be used in the prioritization of a chemical of concern for a specific product.

Suggestion: DTSC should eliminate biomonitoring program element from the prioritization process for specific product categories, but instead might look at this data as a surrogate for exposure when determining chemicals for prioritization.

Supply Chain Information Dissemination Requirements

Information and data sharing requirements under this proposal would severely hinder or stop the flow of commerce and would jeopardize confidential business. The sheer volume of required data, certification elements, response action plans, and notifications that would be required under this proposal would overwhelm the supply chain that has no uniform mechanism to share this type of technical and proprietary information. Even if the universe of chemicals and products impacted by this proposal were significantly narrowed, there remains no mechanism to share this volume of data among supply-chain partners. This would be a particular burden for small and medium sized companies. Also, it is not the role of private supply chain relationships to serve as enforcement and reporting mechanisms for a public law.

As an example of the costly impact of supply-chain certification requirements, even a simpler supply-chain certification requirement, under the Consumer Product Safety Improvement Act (CPSIA) passed federally in 2007, resulted in a $2 billion negative impact (estimated retail value) on toy companies that have responded to TIA. Additionally, nearly $2 billion worth of inventory has been returned to manufacturers from retailers or was held in a producer's/importer's warehouse as non-salable or withheld for CPSIA verification before sale.

Suggestion: Any data provided or certification of product information should be provided directly to DTSC, not to retailers and other non-government entities. If supply chain entities require compliance information to comply with the public law, that information should be provided in conformance with trade secret protections. One submission of compliance by the manufacturer of the consumer product should be sufficient, accompanied by a label noting compliance, rather than requiring data submission at each step in the supply chain. Enforcement by DTSC would be limited to review of the submittal by the manufacturer, such that any product in the supply chain that is labeled in compliance will be available for sale.

Alternatives Analysis

1. Per previous comments, a full alternatives assessment for all the identified chemicals would likely impact hundreds of thousands of products in commerce under the current proposal. Thus, it is unworkable and not likely to provide any tangible benefit.

Suggestion: DTSC must first prioritize chemicals of concern (via a public process). Only those products using a chemical ingredient of concern which is present above a set de

minimis level, and that results in definite exposure should be mandated to perform an alternatives assessment.

2. Several of the factors that would need to be considered for an alternatives assessment would be difficult, if not impossible, for a product manufacturer to obtain for completion of a reasonable alternatives assessment. Specific relevant issues in the life-cycle evaluation include: raw materials, energy consumption, manufacturing, greenhouse gases generation and transportation, any of which could vary greatly from alternative to alternative and would be very difficult to quantify in any meaningful way for this analysis.

Suggestion: The alternative analysis should be streamlined to focus on issues of potential exposure and direct human health or environment impacts from the use of a specific chemical and its alternative. Cost and technological feasibility would be other important parameters. All other factors should only be considered if there is relevant data for all alternatives that is already publicly available and reasonably comparable.

3. The proposal automatically mandates that products containing chemicals of concern perform an alternatives assessment, regardless of whether there is reasonable potential for exposure in any phase of the product's life-cycle. This could place a tremendous and immediate burden on a wide spectrum of products, without solving problems that the legislation seeks to address.

Suggestion: The alternatives assessment process should be defined by pre-analysis chemical exposure prioritizations which would serve as the determinant of which products require an alternatives assessment. Those products that do not result in exposure concerns should not trigger an extensive alternatives assessment, regardless of their theoretical inherent toxic potential.

4. The proposal does not specifically consider physical safety with regard to evaluating potential alternatives. For example, glass might be an alternative to certain other bottling or encasement materials, but its use in toys would result in serious breakage risks and the obvious potential for injury from small parts.

Suggestion: Physical integrity and safety must be called out as considerations within the alternatives assessment process. Without this consideration the blind application of a complicated alternatives assessment process might lead to trade-offs that could pose greater physical safety risks than the use of chemicals or materials that have a higher physical safety profile.

Response Actions:

1. For those products requiring an alternative analysis, product manufacturers must submit an extensive Response Action Plan to the supply chain, to DTSC and place it on the internet within 90-days of completing the alternatives analysis. This requirement is

infeasible considering the range of issues that must be addressed, and compromises confidential business information that is necessary for internal company decisions.

Suggestion: The 90-day timeframe does not allow appropriate time to compile the extensive Response Action Plan elements. Additionally, these plans should not be submitted to the supply chain or to the public as they would include company-specific business planning decisions.

2. The prohibition timeframes outlined in the proposal are very aggressive and are predisposed to ban chemicals of concern even if there is no reasonable expectation of exposure.

Suggestion: Complete prohibition of a chemical should only occur only after it is determined that other appropriate control technologies, procedures, use directions, or precautions do not adequately control exposure to that chemical of concern. Additionally, for chemicals where there is no reasonable expectation of exposure, or for which there are no more desirable alternatives, a pre-determined prohibition date should not be assigned. Where there is no reasonable exposure to a chemical of concern there should be no prohibition. This is particularly important for inaccessible components in toys or other children's products. Inaccessibility of components is assured by strict testing and robust design of toys rendering access to internal parts is impossible for children. There is no exposure to these components and therefore no risk for children.

For example, in electronic toys all the electronic components are stored away in highly protected areas which are not accessible by children or adults without special tools and intellectual ability. Electrical components in toys are standard elements supplied by the electronics industry and the toy industry is a minute fraction of their global business; therefore, it is very difficult for toy manufacturers to impact the composition of these separate products. Finally, with regard to electrical components, under the Restriction of Hazardous Substances Directive or RoHS, electrical components are already regulated for hazardous substances. Therefore, any RoHS compliant component should also be deemed compliant under this DTSC program.

Additionally, where there is no technologically or commercially feasible alternative, any prohibition that is being considered must be evaluated on a case-by-case basis depending upon what alternatives might become available in the future.

3. The DTSC proposal provides for mandates that a manufacturer manage a product at the end of its life-cycle to address the possible release of chemicals of concern. It is neither feasible nor an appropriate use of resources for individual product sectors to establish independent product take-back systems and collection programs.

Suggestion: DTSC should eliminate this mandate and rely on existing federal, state and local laws regulating recycling, re-sale, and component reclamation; as well as traditional solid waste mechanisms address the end of a product's lifecycle.

Petition for a Variance:

1. The proposal allows for a manufacturer to petition the Department to modify or waive portions of this requirement if efforts to comply can be demonstrated. This process is useful and essential to any form of the regulation, given that hazard data and marketplaces for alternatives may be limited. However, without rational and systematic prioritization of chemicals earlier in the process, this mechanism will be overwhelmed by applications.

Suggestion: The variance process must be preserved, but prioritization of chemicals must occur before a product is forced to perform the process of hazard data development and alternatives assessment. This will minimize the likelihood that the process will be overwhelmed by problems associated with the current proposal, as outlined in previous suggestions.

Relationship to Existing Regulations

The Straw Proposal # 2 makes little provision for allowing consumer product categories to reference safety assessments performed under other regulatory programs as acceptable demonstration of compliance. Many of the safety goals of this proposal could be accomplished by referencing existing statutory compliance requirements as being acceptable to demonstrate compliance under this program.

Specifically, toys are regulated under various federal statutes, including: the Consumer Product Safety Act (CPSA), the Child Safety Protection Act (CSPA), the Federal Hazardous Substances Act (FHSA), the ASTM Safety Specification on Toys (and which was adopted as a federal standard on February 10, 2009). In addition, many provisions apply added under the comprehensive Consumer Product Safety Improvement Act (CPSIA) signed by Congress in 2008. Under this network of requirements, it is illegal to sell toys or children's products containing various substances known to be harmful to children and to which children might be exposed.

Therefore, information provided under those existing statutes and guidelines should be referenced under this program. Specifically, the certificates provided under the CPSIA, for toys, should be referenced as an acceptable baseline for ensuring that toys pose no significant risk to consumers and children. Only after new a chemical of concern has been designated under this program (that through reasonable and anticipated use of the consumer product results in an exposure that is likely to cause harm) would a product manufacturer be required to perform additional assessments.

Conclusion:

In its current form, the Straw Proposal is unworkable in scope and data development requirements. TIA remains supportive of the Green Chemistry Alliance draft regulations (dated 6/24/09) and believes that elements from that GCA proposal would provide a more workable solution to these issues.

In order for this program to provide a workable framework TIA believes that first a prioritization of chemicals must take place, based upon reasonable evaluation of potential hazards and the product categories must be identified based upon exposure and taking into account reasonable and anticipated use of a consumer product. Additionally, the criteria for prioritizing these chemicals must be established in an open and transparent public process. Following the identification of chemicals that cause likely exposures of concern, then those products containing a chemical (above a de minimus level) and resulting in reasonable expectation of exposure will be required to perform an alternatives assessment and provision of documentation (work plan) to DTSC to demonstrate compliance.

This unless these steps are taken to prioritize and streamline this proposal, the resulting program would likely collapse from the sheer breath and volume of data that would need to be generated and submitted throughout it various steps. Additionally, commerce in many industries and retail areas would grind to a halt due to data needs and certification requirements.

Despite these concerns, TIA remains committed to working to ensure that this Safer Alternatives process provides a workable solution to chemicals management issues in California and looks forward to continuing to work with you on these outstanding issues. TIA thanks you and your staff again for this opportunity to comment on the Straw Proposal and looks forward to working with DTSC to reaching the very ambitious goals of this rulemaking. Please feel free to contact TIA directly via Andrew Hackman at: 646-520-4851 or ahackman@toyassociation.org if you have any questions or concerns about these comments or would like to discuss in more detail.

Respectfully,

//original signed by//

Andrew Hackman
Senior Director of State Government Affairs

CC: Linda Adams, Secretary of CalEPA
Patty Zwarts, CalEPA
Cindy Tuck, CalEPA
Peggy Harris, CalEPA
John Moffatt, Office of the Governor
Victoria Bradshaw, Office of the Governor
The Honorable Sam Blakeslee, Assembly Republican Leader
The Honorable Mike Feuer, Member of the Assembly
The Honorable Joe Simitian, Member of the Senate

Travel Goods Association
5 Vaughn Drive, Suite 105 | Princeton, NJ 08540
PH 609-720-1200 | FAX 609-720-0620 | www.travel-goods.org

November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxics Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: Straw Proposal for Safer Alternatives Regulation (October 1, 2009)

Dear Director Movassaghi:

On behalf of the Travel Goods Association (TGA) – the national association of the manufacturers, distributors and retailers of luggage, leather goods, business and travel accessories, business and computer cases, handbags and other products for people who travel – I would like to convey our serious concerns with the Safer Alternatives Regulation Straw Proposal as currently drafted (this input is being provided consistent with the Green Chemistry Alliance's (GCA) comment extension deadline of November 9th). Although the Travel Goods Association (TGA) understands the Straw Proposal is not a formal regulation at this time, the program described in the proposal would have sweeping ramifications on virtually all industry sectors that manufacture or sell a consumer products in California and does not reflect the intent of the enacting legislation under AB 1879 (Feuer, 2008).

Under the framework laid out in the current proposal, manufacturers and importers of consumer products for sale in California would be required to identify whether their product contains a "chemical of concern" and, if so, would require a costly and onerous alternatives assessment process. If a consumer product manufacturer/importer could not identify or chose not to implement a safer alternative, the consumer product containing the chemical of concern would be banned in 2-20 years. Furthermore, if the manufacturer/importer chose to implement a safer alternative that, while incrementally better than the identified chemical of concern, has other specified hazard traits, it too would be subjected to a ban in 2-20 years. The current Straw Proposal contains no consideration of the potential for or severity of exposure; rather, it would place roughly 10,000 chemicals on the path for eventual phase-out, regardless of the potential risk to California consumers.

We are highly concerned that the scope of the current proposal is overly broad and fails to focus on consumer products that present the greatest risk to human health and the environment. This is partially attributed to a very broad definition of "consumer product" that could conceivably include not only finished traditional consumer products, but individual chemicals and component parts as well. This is further complicated by the inclusion of four different pathways in to the process:

1. 11 consumer product categories that are not well defined;
2. 16 designated "chemicals of concern;"
3. Chemicals identified by 29 different state, federal and international sources; and
4. 13 hazard criteria.

The broad pathways would result in an infinite number of chemicals and products being covered and, in turn, being subject to a costly and onerous alternative assessment. Furthermore, it is not clear how we as manufacturers/importers could establish compliance given the number of chemicals covered and ongoing changes to chemical lists and hazard data, with the potential outcome of having to defend our good faith efforts at compliance in the courts.

We support the Green Chemistry Alliance's (GCA) approach laid out in their regulatory proposal that was provided to the Department on June 24, 2009. The GCA proposal provides the Department an opportunity to implement Green Chemistry in an efficient, cost-effective and impactful manner while also protecting California consumers and the environment by first prioritizing chemicals for review, evaluating how those chemicals are used in consumer products, assessing whether they pose a potential risk to public health, examining potential alternatives and instituting a regulatory action if necessary.

If the Department fails to implement an approach that is scientifically based or fails to narrow the scope of the program – at least at the outset of the program – the program will surely collapse under its own weight. Furthermore, California's business community cannot afford to implement the approach laid out in the current Straw Proposal. The GCA proposal, as an alternative, is a thoughtful, workable proposal that should be given serious consideration.

For these reasons, we urge the Department to start over in their development of the Safer Alternatives Regulation and look to the GCA proposal as a workable solution.

Thank you for your time and consideration in this matter. Please contact Nate Herman on my staff at 703-797-9062 or nate@travel-goods.org if you have any questions or would like additional information.

Sincerely,

//original signed by//

Michele Marini Pittenger
President

Cc: Linda Adams, Secretary of CalEPA
Patty Zwarts, CalEPA
Cindy Tuck, CalEPA
John Moffatt, Office of the Governor
Victoria Bradshaw, Office of the Governor
The Honorable Sam Blakeslee, Assembly Republican Leader
The Honorable Mike Feuer, Member of the Assembly
The Honorable Joe Simitian, Member of the Senate

November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxics Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: Straw Proposal for Safer Alternatives Regulation (October 1, 2009)

Dear Director Movassaghi:

We are contacting you with our comments on the Straw proposal for the Safer Alternatives regulation. There are significant changes which we would like to see incorporated into the regulation.

Over the past two years Unilever, a global consumer products company with manufacturing facilities in California in City of Industry, Sunnyvale, and Stockton, has been participating in the California Green Chemistry Initiative through our primary industry associations, including the industry coalition known as the Green Chemistry Alliance (GCA). We appreciate the tremendous effort by your staff to develop a complete set of regulations but are concerned that DTSC, in its current straw proposal, does not seem to have included the major points which the Green Chemistry Alliance presented in its submission to the Department on 24 June 2009. This proposal in this document would fulfill the regulatory requirements, as well as meet the intent and spirit of AB 1879. In addition to this document, we have other major concerns with the straw proposal.

The process for identification of candidate chemicals of concern should be a dynamic, on-going process with the most severe hazards being considered first and additional hazards considered based on resources available to DTSC and related agencies over time.

Under the framework laid out in the current proposal, manufacturers and importers of consumer products for sale in California would be required to identify whether their product contains a “chemical of concern” and, if so, would furthermore be required to develop a costly and onerous alternatives assessment process. If a consumer product manufacturer/importer could not identify or chose not to implement a safer alternative, the consumer product containing the chemical of concern would be banned in 2-20 years. Furthermore, if the manufacturer/importer chose to implement a safer alternative that, while incrementally better than the identified chemical of concern, has other specified hazard traits, it too would be subjected to a ban in 2-20 years. The current straw proposal contains no consideration of potential or severity of exposure; rather, it would place roughly 10,000 chemicals on the path for eventual phase-out. Chemical safety is not only a function of the hazard of the chemical but also the exposure of that chemical to the environment.

Unilever is highly concerned that the scope of the current proposal is overly broad and fails to focus on consumer products that present the greatest risk to human health and the environment. This is partially attributed to a very broad definition of “consumer product” that could conceivably include not only finished traditional consumer products, but individual chemicals and component parts as well.

The broad definition could result in an infinite number of chemicals and products being covered and subject to a costly and onerous alternative assessment. Furthermore, it is not clear how we as manufacturers could establish compliance given the number of chemicals covered and ongoing changes to chemical lists and hazard data, with the potential outcome of having to defend their good faith efforts at compliance in the courts.

Unilever supports the GCA’s approach laid out in their regulatory proposal that was provided to the Department on June 24, 2009. The GCA proposal provides the Department an opportunity to implement Green Chemistry in an efficient, cost-effective and impactful manner by first prioritizing chemicals for

review, evaluating how those chemicals are used in consumer products, assessing whether they pose a potential risk to public health, examining potential alternatives, and instituting a regulatory action if necessary. The Department must implement an approach that is scientifically based. Furthermore, California's business community cannot afford to implement the current approach as laid out in the current Straw Proposal. The GCA proposal, as an alternative, is a thoughtful, workable proposal that should be given serious consideration.

For these reasons, Unilever urges the Department to rework its Safer Alternatives Regulation by looking to the GCA proposal as a workable solution. Thank you.

Sincerely,

Dr. Jack Linard
Sr. Manager, Regulatory Affairs
Unilever Research and Development—Trumbull
40 Merritt Blvd.
Trumbull, CT 06611

Cc: Cindy Tuck, Undersecretary, California Environmental Protection Agency
Dan Pellissier, Deputy Cabinet Secretary, Office of the Governor
Peggy Harris, Chief of Intergovernmental Policy, DTSC
Patrizia Barone, Director Regulatory Affairs, Unilever
Tom Langan, Director Government Affairs, Unilever

WD-40 Company

November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxics Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: Straw Proposal for Safer Alternatives Regulation (October 1, 2009)

Dear Director Movassaghi:

The WD-40 Company appreciates the opportunity to comment on the Safer Alternatives Straw Proposal as currently drafted. WD-40 is a California Consumer Products Company based in San Diego. Our company has serious concerns with this draft proposal. Although we understand that the Straw Proposal is not a formal regulation at this time, the draft proposal as described would significantly effect our ability to continue business in California. WD-40 does not believe that this draft reflects the intent of the legislation under AB 1879.

The current draft proposal would require manufacturers of consumer products to identify whether their products contain a "chemical of concern" and if so, would require a lengthy, burdensome and costly alternative assessment process. If a safer alternative is not available or a manufacturer chooses not to implement a safer alternative, than the consumer product would be banned in 2 - 20 years regardless of the risk of exposure. The current proposal would place approximately 10,000 chemicals of concern in this phase out schedule.

The WD-40 Company is concerned that the scope of the current proposal is overly broad and fails to focus on chemicals that present the greatest risk to human health and the environment. The focus of this proposal needs to be narrowed, starting with reducing the four different pathways into the process:

1. 11 consumer product categories that are not well defined;
2. 16 designated "chemicals of concern;"
3. Chemicals identified by 29 different state, federal and international sources; and
4. 13 hazard criteria.

It is not clear how WD-40 could be compliant given the significant amount of work evaluating the lists against our products, then performing the assessments. This would be in addition to the difficulty in trying to monitor the changes to the chemical lists and hazard data.

WD-40 supports the Green Chemistry Alliance (GCA) approach laid out in their regulatory proposal that was provided to the Department on June 24, 2009. The GCA proposal provides the

Department an opportunity to implement Green Chemistry in an efficient, cost-effective and impactful manner by first prioritizing chemicals for review, evaluating how those chemicals are used in consumer products, assessing whether they pose a potential risk to public health, examining potential alternatives and instituting a regulatory action if necessary.

In summary, the current proposal as written is overly broad, very costly and extremely burdensome for the manufacturer. Given the economic conditions this proposal needs to be changed significantly. The WD-40 Company urges the Department to consider these comments and we look forward to working with the Department on a workable solution. Any questions regarding our comments please contact myself, Mike Freeman at 619-275-9328 or by e-mail at freeman@wd40.com.

Sincerely,

Mike Freeman
Division President - The Americas
WD-40 Company

Cc: Linda Adams, Secretary of CalEPA
Patty Zwarts, CalEPA
Cindy Tuck, CalEPA
John Moffatt, Office of the Governor
Victoria Bradshaw, Office of the Governor
The Honorable Sam Blakeslee, Assembly Republican Leader
The Honorable Mike Feuer, Member of the Assembly
The Honorable Joe Simitian, Member of the Senate
Doug Raymond, Raymond Regulatory Resources (3R)

Western States Petroleum Association
Credible Solutions • Responsive Service • Since 1907

Catherine H. Reheis-Boyd
Executive Vice-President and Chief Operating Officer

November 3, 2009

Via email: MMovassa@dtsc.ca.gov

Maziar Movassaghi
Interim Director
Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814

RE: WSPA Comments on the "Straw Proposal for Safer Alternative Regulations (10/1/09)

Dear Mr. Movassaghi:

The Western States Petroleum Association (WSPA) is a trade association representing twenty-seven companies that explore for, produce, refine, transport and market petroleum, petroleum products, natural gas and other energy products in six western states – California, Arizona, Nevada, Oregon, Washington and Hawaii.

WSPA member companies own and operate various types of facilities (e.g., oil and gas production properties, refineries, marketing terminals, retail gasoline outlets) in California that would be impacted by the Department of Toxic Substances Control's (DTSC) proposed regulation.

We are concerned that DTSC has only allowed a very limited time for WSPA and other stakeholders to review and analyze nearly 60 pages of new regulatory language (Straw II) released on October 1. The constrained time interval is grossly insufficient given the substantial impact this proposal will have on stakeholders and the public at large, and does not allow for the meaningful commentary necessary to evaluate the merits of this proposal.

WSPA remains committed to helping DTSC understand the core issues facing the manufacturing and commercial communities and in the interest of time has prepared the following brief general comments on the proposed regulation. We expect to submit more specific comments on subsequent iterations of the proposed regulation. We also urge the Department to carefully consider the comments prepared by the Green Chemistry Alliance.

Intent of AB 1879 and SB509

Historical consumer product legislation typically targeted a single chemical or family of chemicals to address the unique harm associated with potential exposures, with little consideration given to other

potential impacts. Indeed, prior to this legislation, action addressing chemicals in consumer products was developed ad-hoc in response to a specific event.

In an effort to create a program to improve the safety and environmental profile of consumer products and to address the problem of ad hoc approaches, the legislature enacted AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008). These bills delegated to DTSC the responsibility to develop and implement a rational, comprehensive, and uniform process for identifying chemicals in consumer products that could be of concern to the public. DTSC was to then prioritize these chemicals in such products for response actions to target the "worst first."

Subsequently, based on this prioritization, DTSC was to identify functionally viable alternatives to these chemicals in order to improve the safety and environmental profile of the product consistent with the practices and principles of green chemistry. Then, in a series of follow-up steps, DTSC would develop a continuum of regulatory response actions of increasing stringency in proportion to the risks posed by the chemical in the product.

At all steps of the process, it was intended that DTSC avoid creating duplicative regulation. *AB 1879 intended to use market forces, rather than generic regulatory prohibitions, to incentivize companies to develop and introduce better alternatives by creating a competitive advantage for products satisfying the green chemistry criteria*.

Problems with the Proposal

We share many of the concerns raised by members of the Green Ribbon Science Panel (GRSP) and other stakeholders that recognize the DTSC proposal is infeasible. Specifically, it is clear that the scope of the proposal is far too large considering the number of chemicals, products, and entities included.

Indeed, it is a hazard-based system that fails to account for de minimis levels, potential exposure, and differences in the type and magnitude of toxic endpoints. Thus, it does not provide a meaningful prioritization process.

The proposal also fails to identify the criteria, including their relative hierarchy, and the methodology for conducting the Alternative Analysis and Life-Cycle Assessment (AA/LCA). In addition, the scope of the data needed to satisfy the proposed regulations is also far too large.

In fact, DTSC does not appear to consider the practical impacts of the proposal. These impacts include requiring the development of new analytical techniques to measure thousands of chemicals of concern in hundreds of thousands of consumer products.

They also involve requiring regulated entities to undertake complex, time-consuming and costly research on the toxicology, environmental chemistry, green house gas contribution, socio-economic impacts, etc. on all chemicals of concern in their products and all possible alternatives.

The proposed regulatory actions include a mandatory ban of chemicals of concern present in consumer products irrespective of whether the chemical in the product can impact human health, safety, the environment, or any other endpoint.

Even alternative products that offer improved risk, exposure or environmental profiles would be subject to a ban simply by virtue of containing a "chemical of concern." This feature creates a strong disincentive to invest the considerable resources necessary to bring alternative products to market.

In addition, requirements placed upon entities within the supply chain, including thousands of small businesses, are unreasonably burdensome and infeasible. Lastly, the time constraints for compliance are infeasible as they fail to consider the time to identify, collect, generate and analyze all required data.

DTSC Proposal Frustrates Intent of AB 1879 and SB 509

The proposal is infeasible and will likely create significant and adverse unintended consequences that will frustrate the intent of creating an effective program that improves the safety and environmental profile of consumer products. More specifically, the broad scope of the proposal and lack of meaningful prioritization process frustrates the intent to identify and address the "worst first".

One stakeholder participating in the EU REACH program best expressed this deficiency in his comment at the GRSP workshop, *"that when everything is of concern, then nothing is of special concern*".

If the DTSC proposal is implemented, it is possible that a selected alternative could actually pose a greater potential risk to human health and/or the environment than the original product it was to replace, because of the proposal's hazard-based approach.

In addition, coupling the vast data needs inherent in the "no-data no-market" position espoused by some stakeholders with the uncertainty in the AA/LCA, the proposal has the unintended consequence of creating a substantial disincentive for developing alternatives.

WSPA believes the effect of the proposal is to deter the development of alternatives while slowly eliminating existing chemicals from consideration as alternatives. We believe that the proposal needs to be substantially revised in a manner consistent with a feasible and rational program that implements the intent of the legislation.

For these reasons, WSPA strongly recommends DTSC:

1) Withdraw the Proposed Regulation (Straw II);
2) Reconsider how to reconcile the regulatory approach with the intent of the Legislation;
3) Renew work with stakeholders to align DTSC's intent with the needs of commercial and manufacturing companies and the consuming public; and,
4) Issue revised regulations that include a feasible program that serves the public and the manufacturing community.

WSPA appreciates your consideration of our comments.

Sincerely,

//original signed by//

cc: Linda Adams, Secretary, Cal-EPA
Cindy Tuck, Undersecretary, Cal-EPA
Patty Zwarts, Deputy Secretary, Cal-EPA
Rick Brausch, Legislative Director, DTSC
Jeff Sickenger, KP
Peggy Harris, DTSC
John Moffat, Office of the Governor

Western Wood Preservers Institute

7017 N.E. Highway 99, Suite 108 Vancouver, WA 98665 360/693-9958 Fax 360/693-9967 E-Mail: info@wwpinstitute.org

November 3, 2009

California Green Chemistry Initiative
Department of Toxic Substances Control
1001 I Street
Sacramento, California 95814-2828

RE: Points of Concern - Straw Proposal on Safer Alternatives

The **Western Wood Preservers Institute (WWPI)** is pleased to have the opportunity to provide the following comments for consideration in development of revisions to the "Straw Proposal on Safer Alternatives for Consumer Products" Rule. **WWPI** is a non-profit trade association representing wood preservative companies, and small independently owned wood preserving manufacturers doing business in the western United States, including California. On behalf of our manufacturing members in California and other members offering products and services in California, we would like to offer the following specific comments on the revised "Safer Alternatives for Consumer Products" Rule.

- The process of chemical identification for inclusion on "the list" appears to lack a clear scientific basis for identification, prioritization, and inclusion. According to the proposal, the list of chemicals of concern (COC) will include chemicals known as carcinogens or reproductive toxicant; but also can include "any chemicals which appear on any list published by any government, authoritative body, or nongovernmental organization, and that are deemed by Department of Toxic Substances Control (DTSC) to be COCs." **WWPI** believes these criteria are too broad and will lead to chemical placement on the list without appropriate scientific justification.

- The proposal requires chemical manufacturers to provide data on potential risks including adverse health or environmental effects and exposure potential of the COC. Because of potential liability, we believe many manufacturers will be unwilling to, or will be advised by legal counsel not to, make claims about health or environmental effects of their products.

- The proposal states that DTSC can use any information deemed necessary to evaluate the potential health and safety and environmental impacts of a chemical; however, the criteria possibly is in conflict with other criteria requiring that decisions be based on a scientific approach.

- Significant costs will be required to perform alternatives analysis. As presently proposed, the alternatives analysis must be done by manufacturers, importers, suppliers, retailers and any other entities responsible for placing consumer products in commerce in California as it is the responsibility of the manufacturer to determine if the consumer product contains a COC. Placing the onus on the manufacturer, rather than an unbiased neutral entity, to evaluate

alternatives could result in unfair product cost differentiation between more reputable and less reputable manufacturers of competing products.

- **WWPI** is concerned that the guidance for performing an analysis of feasible alternatives will be flawed if it does not include an evaluation of the effectiveness of the alternative chemical in providing the performance that the consumer should expect from the product being purchased. Decisions on alternatives should only be made when effectiveness has been fully understood and considered in the decision process.

- Further, an evaluation of "feasible alternatives" would be incomplete if the full environmental life cycles of the original and alternative products are not compared. Such comparison, though important to making a science-based product decision, will be a further economic disadvantage to industry, particularly small businesses.

- The proposal also allows for a toxic chemical to remain in service where substitution of a prioritized COC is not feasible because the performance of the product would be "unreasonably compromised". The proposal should clarify how the manufacturer will prove the product has been "unreasonably compromised."

- **WWPI** is concerned about the requirement of manufacturers of COCs to provide financial guarantee for the management of products they produce. We also are concerned about the requirement that manufacturers provide collection, recycling, and reuse of the COC. How will this be accomplished? Are retailers willing to have recycle centers in the front of their stores? How will the retailer verify the product was purchased at that store? Who pays for the recycle center, the transport, and ultimately the final disposition?

- **WWPI** is concerned that the requirements of proposed rule place too much financial burden on the manufacturers. Many manufacturers and products will not be able to meet the financial demands of the criteria stated in the proposed rule, thus, leading to responsible businesses who are unable to operate or sell their products in the State of California.

WWPI appreciates the opportunity to provide these comments and concerns on behalf of its manufacturing members in California and other members offering products and services in California. Should you have any questions regarding these comments, please contact me by electronic mail at ted@wwpinstitute.com or by telephone at (360) 693-9958.

Sincerely,

//original signed by//

Ted LaDoux
Executive Director
Western Wood Preservers Institute