



November 9, 2009

Maziar Movassaghi, Acting Director
Department of Toxic Substances Control
Sacramento, California

RE: Straw Proposal for Safer Alternatives Regulation (10/1/09)

Dear Acting Director Movassaghi:

On behalf of the members of the Advanced Medical Technology Association, AdvaMed, I am writing regarding the potential impact on medical devices of some aspects of the Draft Straw Proposal. While the Green Chemistry law exempts medical devices, as well as their components and parts, we are concerned about ambiguous definitions regarding the scope of the proposal. Also, presentations around the Straw Proposal cause us great concern over the future availability of some critically needed raw materials.

Ambiguous Definitions

According to 2008 Senate Bill 509 (Chapter 560), the law applies to consumer products, but “does not include any of the following:

- (1) A dangerous drug or dangerous device as defined in Section 4022 of the Business and Professions Code.
- (2) Dental restorative materials as defined in subdivision (b) of Section 1648.20 of the Business and Professions Code.
- (3) A device as defined in Section 4023 of the Business and Professions Code.
- (4) A food as defined in subdivision (a) of Section 109935.
- (5) The packaging associated with any of the items specified in paragraph (1), (2), or (3).
- (6) A pesticide as defined in Section 12753...”

In Section 25251 of the California Health and Safety Code, The Green Chemistry law provides exclusions for “dangerous devices” and “devices” generally. The act references the definition of “device” in Section 4023 of the Business & Professions Code, which defines a device as:

“Any instrument, apparatus, machine, implant, in vitro agent, or contrivance, including its components, parts, products, or the byproducts of a device, and accessories.”



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However, in some DTSC documents, relating to the Straw Proposal, the term “durable medical goods” is used. Also, in some meetings, DTSC staff has referred to “durable medical appliances.” Use of these terms is confusing and much more limiting than the statutory definition. We do not see any rationale for using these more limiting terms. We also urge the Department to clarify that combination products that combine drugs and devices into one, such as drug-coated stents, and are generally regulated as medical devices should be exempt from the Green Chemistry proposal.

Further, the statutory definition of “dental restorative materials” in Section 1648.20 of the Business & Professions Code is broader than the “dental amalgam” term used in the DTSC conceptual flow chart. We recommend that the more inclusive “dental restorative materials” term be used.

Access to Raw Materials

Our understanding of the Draft Straw Proposal is that raw materials used to manufacture final products at California facilities would come under the scope of the Green Chemistry regulations. However, since medical devices, their components and parts are exempt then the raw materials used to manufacture these devices should also remain exempt. There was no intent in AB1879/SB509 to regulate raw materials as “consumer products.” Any restriction on raw materials used in manufacturing in California would put California companies at an extreme competitive disadvantage relative to non-California manufacturers. Finally, alternative replacement materials will require substantial evaluation to ensure device performance and safety requirements are met.

Therefore, to avoid ambiguity in the law’s implementation, we strongly urge you to ensure that terminology used during the regulatory stage is consistent with statutory language. In addition, we urge you to clarify that raw materials and components needed for the manufacture of medical devices are excluded from the law’s scope, at least as far as its’ medical applications.

We appreciate the opportunity to comment and would be glad to work with you through the rulemaking process to ensure that medical device manufacturers are able to continue to provide patients with life-saving and life-enhancing therapies.

Sincerely,

//original signed by//

Thomas E. Tremble
Associate Vice President, State Government Relations



November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxics Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806
Sent via e-mail: mmovassa@dtsc.ca.gov

RE: Straw Proposal for Safer Alternatives Regulation

Dear Director Movassaghi:

On behalf of the Alliance of Automobile Manufacturers (Alliance), I would like to convey our serious concerns with the Safer Alternatives Regulation Straw Proposal as currently drafted. Although Alliance 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).

The Alliance of Automobile Manufacturers is a trade association of 11 car and light truck manufacturers including BMW Group, Chrysler LLC, Ford Motor Company, General Motors, Jaguar Land Rover, Mazda, Mercedes-Benz USA, Mitsubishi Motors, Porsche, Toyota, and Volkswagen.

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.

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

**BMW Group • Chrysler Group LLC • Ford Motor Company • General Motors • Jaguar Land Rover
Mazda • Mercedes-Benz • Mitsubishi Motors • Porsche • Toyota • Volkswagen**

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.

The Alliance supports the GCA's approach, as set forth in the GCA's 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. Once this prioritization is complete, it calls for 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.

For these reasons, the Alliance of Automobile Manufacturers urges the Department to seriously consider the GCA proposal as a workable solution. If you have any questions regarding the Alliance's position on the current Straw Proposal, please contact me at (916) 447-7315. Thank you for your consideration

Sincerely,

//original signed by//

Steve Douglas
Senior Director of Environmental Affairs
Alliance of Automobile Manufacturers

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

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

Via Email: green.chemistry@dtsc.ca.gov

Re: DTSC October 1, 2009 Green Chemistry Initiative Straw Proposal

Dear Director Movassaghi:

On behalf of the American Apparel & Footwear Association (AAFA) – the national trade association of the apparel and footwear industries, and their suppliers – I am writing to offer these comments and observations in connection with the October 1, 2009 Green Chemistry Initiative Straw Proposal. I understand that the deadline for comments regarding the October 1 draft has been extended to November 9.

AAFA's members include numerous companies that design, manufacture, distribute, and sell apparel and footwear in California. Collectively, they employ thousands of people throughout California.

At the outset, we wish to stress our association's support for the broad goals of the green chemistry initiative to develop tools that will assist companies in their ongoing efforts to ensure that they make and market safe consumer products, and to ensure that consumers are aware of and have confidence in these efforts. Toward that end, we believe it is appropriate to identify, minimize, and eliminate (where possible) risks associated with substances that present documented health and safety hazards.

In this regard, AAFA maintains an active educational program to train companies on chemical management, restricted substances, and product safety throughout the United States, in Asia, and Latin America. As part of that program, AAFA publishes an updated restricted substances list (RSL) every 6 months to help textile, apparel, and footwear companies undertake effective chemical management activities. Through the RSL,¹ companies in our industry can understand the most restrictive global regulations for chemicals and other substances in the products. Many companies and organizations

¹ Made available free of charge on the AAFA website at <http://www.apparelndfootwear.org/Resources/RestrictedSubstances.asp>

have already adopted the AAFA RSL as the basis for their own chemical management programs.

Turning to the October 1 Straw Proposal, we make the following comments and observations.

Just as the Straw Proposal appears to be preliminary in nature (having been removed from your website two weeks ago), our comments are likewise preliminary. We intend to look very carefully at your next proposal and are hopeful that, because the final rule is not required until January of 2011, you will provide a wide window for substantial public input. It is important that the final regulation be predictable and practical and that it be the product of a thoughtful and transparent process.

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 be required to perform an 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 during a period of 2 to 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 during 2 to 20 years. The current Straw Proposal contains no consideration of potential or severity of exposure; rather, it would place roughly 10,000 chemicals, and consumer products that may contain those chemicals, equally on the path for eventual phase-out.

We appreciate that DTSC’s Straw Proposal is intended to apply to multiple industries, and, to this end, we urge DTSC to incorporate in its revised proposal the approach set forth by the Green Chemistry Alliance (GCA) in its June 24, 2009 comments to DTSC. We also draw your attention to the comments – which we adopt and incorporate as if fully set forth herein -- that are being submitted by GCA on November 9, 2009.

Collectively, both GCA comments emphasize risk-based determinations grounded in sound science, maintenance of business confidentiality, and the elimination of burdensome requirements. Such principles are consistent with the legislation which DTSC has been charged to implement and are crucial to generating business and consumer confidence in a predictable and sustainable regulatory environment.

While well-intentioned, the Straw Proposal strikes us as so complex and so sweeping in its breadth, that it is unworkable and cannot possibly achieve what the California state legislature has directed². Dow Chemical Company’s comment at the first October workshop, noting that the proposal could be construed as banning styrene needed to make medical gloves, is but one of a myriad of examples of problems that could arise if the current proposal is adopted.

² See, for example, the comments by members of the Green Ribbon Science Panel which recently studied this proposal.

Among other things, the Straw Proposal fails to focus on consumer products that present the greatest risk to human health and the environment. Rather, it treats a wide variety of consumer products – such as clothing or cleaning products – the same, regardless of the exposure risk associated with those products.

Similarly, the Straw Proposal incorporates by regulatory fiat a hodge-podge of often-inconsistent international standards (even extending, arguably, to local regulations on multiple continents). This approach will serve only to confuse companies' ongoing efforts to manufacture products which are safe and which are understood by their customers to be safe.

The Straw Proposal would impose an enormous cost through the myriad Life Cycle Analyses (LCAs), alternatives analyses, and other requirements imposed on an unrealistically broad sweep of companies. These new requirements extend to downstream companies that do not have the expertise of those companies that manufacture the chemicals.

Finally, it is not clear how manufacturers could establish compliance given the number of chemicals covered and ongoing changes to chemical lists and hazard data. We fear that, instead of a clear pathway to compliance, companies will have to (repeatedly) defend their good faith efforts in the courts – a sure sign that the underlying regulation is not functioning properly.

We raise these concerns drawing upon our recent experience with the implementation of two recent product safety and chemical management initiatives.

The recently approved REACH program in Europe is one such cautionary tale. At great cost, the REACH program requires the registration of at least 30,000 chemicals, even when such substances present no risk. The burden and confusion that has been imposed by the business community, with little no gain in public health or product safety, has been tremendous.

Likewise, the Consumer Product Safety Improvement Act (CPSIA), which was passed by overwhelming majorities to improve product safety laws, has created immense disruption and confusion. Poorly defined terms, retroactively applied rules, the absence of risk based standards, and an overly tight timetable has created problems for both the business community and the Consumer Product Safety Commission (CPSC). The result has been a black eye for product safety.

At any time, and particularly in the midst of a global recession, it is important that well-intentioned regulations not pose an unnecessary cost burden. Unfortunately, the inevitable effect of the October 1 Straw Proposal, and of any subsequent proposal which does not address these deficiencies, would be to raises costs, create uncertainty, and undermine confidence in public health and safety regulations.

We look forward to working with you as this process develops to ensure that any future regulations achieve the proper balance.

Thank you for your consideration of these comments. Should you require additional information, please contact Steve Lamar at slamar@apparelandfootwear.org or at 703.797.9041.

Respectfully,

//original signed by//

Kevin M. Burke
President and CEO

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



MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

November 9, 2009

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

Dear Acting Director Movassaghi:

The American Chemistry Council (ACC) appreciates the opportunity to provide comments on the second straw proposal to implement AB 1879 (Feuer). ACC is an active member of the Green Chemistry Alliance (GCA), and we fully support GCA's comments on the second straw proposal. We are offering additional comments here that highlight our views on the straw proposal and the state's Green Chemistry Initiative more broadly.

The Department of Toxic Substances Control (DTSC) has a unique opportunity to design a regulatory program under AB 1879 to leverage coming changes in the federal chemical management system. ACC and the U.S. Environmental Protection Agency (EPA) have released sets of principles to guide changes to the federal system. A copy of ACC's principles is attached. While there are some differences between the ACC and EPA approaches, there are many common elements as well. ACC urges DTSC to design an AB 1879 implementation program that can capitalize on emerging approaches to enhance key elements of a modernized federal chemical management system, with particular attention to three central issues: prioritization, safe use, and risk management measures. Doing so will allow DTSC to achieve more efficiently and effectively the Green Chemistry Initiative's goal of promoting innovative technologies that are more environmentally benign and protective of human health.

Prioritization. ACC and EPA recognize the need to prioritize chemicals in commerce to identify those of potential concern. In the absence of prioritization, everything (or nothing) is a priority, and the system quickly becomes unmanageable.

The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$689 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.



ACC believes that a robust prioritization process should utilize specific hazard and use/exposure criteria so that both governmental and industry resources are directed toward the greatest potential risks. Such a process should also allow for the re-examination of priorities as new information becomes available.

AB 1879 provides clear guidance on the types of information that should be considered in a prioritization process. The statute also directs DTSC to leverage the process and results of other “nations, governments, and authoritative bodies” that have conducted similar prioritization exercises. DTSC should develop a prioritization process that uses the criteria in AB 1879 and clearly leverages work by other bodies in a way that creates an organized and predictable program. A robust prioritization process would be an important step in addressing widespread feedback that the scope of the program as envisioned by both the initial and the most recent DTSC straw proposals is too expansive and likely unmanageable.

Safe Use. In both the ACC and EPA principles for modernizing the federal chemical regulatory process, there is a foundational role for the federal government to make decisions on chemical safety. ACC specifically calls for these determinations to focus on the most significant uses, and thus the most potentially significant routes of exposure, of high priority chemicals. Such determinations would combine information on both hazard and exposure to reach risk-based conclusions. The second straw proposal considers the mere presence of a chemical, without any demonstration of risk to human health or the environment, as sufficient reason for a ban. That result is incongruent with AB 1879.

The concept of a safe use is instructive for DTSC’s implementation of AB 1879. Following prioritization of chemicals in consumer products, DTSC should prioritize uses of chemicals of concern in consumer products. Use prioritization could include factors clearly articulated in AB 1879, such as the potential for exposure of sensitive subpopulations during reasonable intended use and the potential for environmental release during use and/or disposal. ACC also urges DTSC to incorporate a *de minimis* concentration below which a consumer product containing a chemical of concern is exempt from the law’s alternatives analysis process. Such an approach would avoid a never-ending chase for trace levels of detectable contaminants (for instance, in the public water supplies consumer product manufacturers depend on for their manufacturing processes, even if those water supplies are declared safe under federal and state maximum contaminant level standards). Also, setting a *de minimis* threshold bounds the program to what regulated entities can reasonably expect to control.

Risk Management Measures. ACC and EPA agree that the Agency should have the authority to employ a range of measures to manage potential risks. This notion is consistent with AB 1879, which clearly gives DTSC authority to utilize a range of risk management options to “limit exposure or to reduce the level of hazard posed by a chemical of concern” based on the findings of the alternatives analysis.

ACC believes that DTSC should implement AB 1879 in a way that utilizes the full range of risk management measures made available to it in AB 1879. Doing so allows for application of risk management measures proportional to the potential risk posed by the use of a chemical of concern in a consumer product. Currently, DTSC appears to be leaning toward a “one size fits

all” approach that ultimately results in banning the use of chemicals of concern in consumer products, or the chemicals themselves should they qualify as consumer products. Instead, DTSC should focus on ways to assess potential risks and manage exposure so that chemicals can be used safely and effectively. Even the most hazardous chemicals can be used safely when appropriate risk management measures are implemented. ACC believes that such an approach can help avoid widespread disruption in the state’s economy while achieving the state’s overarching goals of enhancing public health and environmental protection.

In closing, ACC urges DTSC to incorporate prioritization, safe use, and flexible risk management measures as necessary elements of the forthcoming draft regulation. These elements are clearly called for in the statute, and they are necessary to ensure the efficient use of both public and private resources while advancing California’s goal of enhanced public health and environmental protection. More importantly, we believe an approach that incorporates these elements has significant advantages over a regulatory process that relies on chemical bans as its primary risk management tool. We also call DTSC’s consideration to the many issues identified in the GCA’s comments, including appropriate protections for confidential business information in supply chain communication, avoiding duplicative and conflicting regulations, exclusion of feedstocks and intermediates used by in-state manufacturing facilities, and others.

Thank you for the opportunity to provide these comments. We look forward to working with DTSC on the implementation of the Green Chemistry Initiative.

Sincerely,

//original signed by//

Michael P. Walls,
Vice President, Regulatory and Technical Affairs

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



10 Principles for Modernizing TSCA

The American Chemistry Council and its members support Congress' effort to modernize our nation's chemical management system. Such a system should place protecting the public health as its highest priority, and should include strict government oversight. It should also preserve America's role as the world's leading innovator and employer in the creation of safe and environmentally sound technologies and products of the business of chemistry.

The current chemical management law, the Toxic Substances Control Act (TSCA), is more than 30 years old. It should be modernized to keep pace with advances in science and technology. Moreover, the law must provide the Environmental Protection Agency with the resources and the authority to do its job effectively.

We have previously offered general concepts on which to base a modern chemical management system. This document expands upon those concepts and begins to provide more detail, which we hope will be useful to policy makers. We will continue to refine the details of our principles for modernizing TSCA and are committed to working with all stakeholders toward enactment of effective legislation.

1. Chemicals should be safe for their intended use.
 - Ensuring chemical safety is a shared responsibility of industry and EPA.
 - Industry should have the responsibility for providing sufficient information for EPA to make timely decisions about safety.
 - EPA should have the responsibility for making safe use determinations for high priority chemicals, focusing on their most significant uses and exposures.
 - Safe use determinations should integrate hazard, use, and exposure information, and incorporate appropriate safety factors.
 - Consideration of the benefits of chemicals being evaluated, the cost of methods to control their risks, and the benefits and costs of alternatives should be part of EPA's risk management decision-making, but should not be part of its safe use determinations.
 - Other agencies, such as FDA and CPSC, should continue to make safety decisions for products within their own jurisdictions.
2. EPA should systematically prioritize chemicals for purposes of safe use determinations.
 - Government and industry resources should be focused on chemicals of highest concern.

- The priorities should reflect considerations such as the volume of a chemical in commerce; its uses, including whether it is formulated in products for children; its detection in biomonitoring programs; its persistent or bioaccumulative properties; and the adequacy of available information.
3. EPA should act expeditiously and efficiently in making safe use determinations.
 - Since a chemical may have a variety of uses, resulting in different exposure potentials, EPA should consider the various uses and focus on those resulting in the most significant exposures.
 - EPA should complete safe use determinations within set timeframes.
 4. Companies that manufacture, import, process, distribute, or use chemicals should be required to provide EPA with relevant information to the extent necessary for EPA to make safe use determinations.
 - Companies throughout the chain of commerce should be responsible for providing necessary hazard, use, and exposure information.
 - EPA should be authorized to require companies, as appropriate, to generate relevant new data and information to the extent reasonably necessary to make safe use determinations without having to prove risk as a prerequisite or engaging in protracted rulemaking.
 - Testing of chemicals should progress to more complex and expensive tests through a tiered approach as needed to identify hazards and exposures of specific concern.
 - To minimize animal testing, existing data should be considered prior to new testing, and validated alternatives to animal testing should be used wherever feasible.
 - Existing data and information should be leveraged in EPA's safe use determinations, including data and information from other mandatory and voluntary programs such as REACH and the U.S. High Production Volume challenge.
 5. Potential risks faced by children should be an important factor in safe use determinations.
 - Safe use determinations should consider the effects of a chemical on children and their exposure to the chemical.
 - Safe use determinations should consider whether an extra margin of safety is needed to protect children.
 6. EPA should be empowered to impose a range of controls to ensure that chemicals are safe for their intended use.
 - The controls could range from actions such as labeling, handling instructions, exposure limits and engineering controls to use restrictions and product bans.

- The controls should be appropriate for managing the risk, taking into account alternatives, benefits, costs, and uncertainty.
7. Companies and EPA should work together to enhance public access to chemical health and safety information.
- EPA should make chemical hazard, use, and exposure information available to the public in electronic databases.
 - Other governments should have access to confidential information submitted under TSCA, subject to appropriate and reliable protections.
 - Companies claiming confidentiality in information submittals should have to justify those claims on a periodic basis.
 - Reasonable protections for confidential as well as proprietary information should be provided.
8. EPA should rely on scientifically valid data and information, regardless of its source, including data and information reflecting modern advances in science and technology.
- EPA should establish transparent and scientifically sound criteria for evaluating all of the information on which it makes decisions to ensure that it is valid, using a framework that addresses the strengths and limitations of the study design, the reliability of the test methods, and the quality of the data.
 - EPA should encourage use of good laboratory practices, peer review, standardized protocols, and other methods to ensure scientific quality.
9. EPA should have the staff, resources, and regulatory tools it needs to ensure the safety of chemicals.
- EPA's budget for TSCA activities should be commensurate with its chemical management responsibilities.
10. A modernized TSCA should encourage technological innovation and a globally competitive industry in the United States.
- A new chemical management system should preserve and enhance the jobs and innovative products and technologies contributed by the business of American chemistry.
 - Implementation of TSCA should encourage product and technology innovation by providing industry certainty about the use of chemicals.



**American
Forest & Paper
Association**

November 9, 2009

Mr. Maziar Movassaghi
Acting Director
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 Mr. Movassaghi:

On behalf of the American Forest & Paper Association (AF&PA), I am writing to convey our serious concerns with the Safer Alternatives Regulation Straw Proposal. Although AF&PA 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).

AF&PA is the national trade association of the forest products industry, representing pulp, paper, packaging and wood products manufacturers, and forest landowners. Our companies make products essential for everyday life from renewable and recyclable resources that sustain the environment. The forest products industry accounts for approximately 6 percent of the total U.S. manufacturing GDP, putting it on par with the automotive and plastics industries. Industry companies produce \$200 billion in products annually and employ almost 1 million people earning \$54 billion in annual payroll. The industry is among the top 10 manufacturing sector employers in 48 states. In California, our industry employs over 68 thousand people, owns and operates nearly 9 million acres of forestland, and manages more than 620 facilities.

Under the framework laid out in the Department's straw 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.

AF&PA 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 states, 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.

AF&PA supports 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 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.

California's business community cannot afford to implement the current approach as laid out in the straw proposal. We strongly encourage the Department to implement an approach that is scientifically based and is much narrower in scope. The GCA proposal, as an alternative, is a thoughtful, workable proposal that should be given serious consideration.

For these reasons, AF&PA 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 AF&PA's position on the current straw proposal, please contact me at (202) 463-2777.

Sincerely,

//original signed by//

Paul Noe
Vice President, Public Policy

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



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November 9, 2009

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Acting Director
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Via eMail: green.chemistry@dtsc.ca.gov
MMovassa@dtsc.ca.gov
(followed by US Postal delivery)

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

Dear Director Movassaghi:

Access Business Group (ABG) and Amway, members of the Alticor family of companies are providing the following comments to the *Straw Proposal for Safer Alternatives Regulations* released October 1, 2009 by the California Department of Toxic Substances Control pursuant to the implementation of California Legislature's AB 1879. ABG and Amway also support of the comments submitted by the Green Chemistry Alliance, the Soap and Detergent Association and the Personal Care Products Council submitted under separate cover.

ABG is the R&D, production and distribution entity that provides products to Amway that are in turn offered for sale by tens of thousands of small business entities within the state of California ("Amway" will identify all activities by both ABG and Amway). Alticor is an \$8+ Billion multinational corporation that has developed and manufactured a diverse product line including vitamin and food supplements that are manufactured in Southern California and sold globally under the Nutrilite brand name. Our products include household cleaners, laundry products, personal care and cosmetic products, household appliances and cookware. As such, we are within the scope of the proposed regulations and are representatives of California citizens affected by them. Amway participates in numerous chemical management initiatives globally, both those required by governmental regulation and voluntary programs implemented by industry.

Amway has been participating in the California Green Chemistry Initiative both directly and through the industry coalition know as the Green Chemistry Alliance. We acknowledge the significant effort by DTSC staff to develop a complete set of regulations and to provide them for public review and comment. Nevertheless, we are forced to conclude that DTSC has ignored industry input embodied in the Green Chemistry Alliance proposal. This is evident in the opening remarks at the

GRSP meeting stating that DTSC had not received much in the way of proposed regulatory language from stakeholders. The Green Chemistry Alliance June proposal to the Department gives regulatory structure that would fulfill the requirements stipulated in AB1879, meeting its intent and spirit. By contrast, Amway contends that the straw proposal exceeds the requirements of the legislation and in its overbroad language will, if implemented, impede the intent of the legislature to effectively implement alternatives without unduly disrupting the economy of the state.

Scope of the Straw Proposal

Although DTSC has characterized the Straw Proposal as a catalyst for further discussion, not as a formal regulatory proposal, the proposal is so broad as to ignore current supply chain considerations and to present an impossible, discontinuity with existing regulatory structures. Therefore, we see no basis of discussion in the proposal on which to build. If it were to be implemented as proposed, the program would adversely impact essentially all industry sectors. The complexity of this proposal would paralyze commerce by redirecting resources to toward activities that have questionable net benefit to human or environmental safety. The outcome exceeds any reasonable interpretation of the enacting legislation and can truly be called unsustainable in that it ignores significant negative social and economic impacts and considers only a limited environmental impact assessment.

The scope of the current proposal is unnecessarily broad because it fails to prioritize effort on consumer products by giving attention to highest potential threats to human health or the environment. The definition proposed for "consumer product" can conceivably be extended beyond accepted consumer products definitions to include raw chemicals and materials used throughout commerce. Although only food, pesticides, prescription drugs, durable medical equipment, dental amalgams and mercury lighting are specifically exempted under AB 1879, even their feedstock and upstream manufacturing intermediates have been interpreted by DTSC (DTSC Workshop on 10/21) as coming within the definition of a consumer product that can be regulated in the Safer Alternatives program. Including feedstock and upstream manufacturing intermediates relied upon by all California manufacturers as "consumer products" would advantage out of state producers so as to logically result in displacing those feed stock, intermediates and associated manufacturing from the California economy. In addition, DTSC seems to have ignored specific statutory direction prohibiting from enacting regulations that conflict with, or are duplicative of, other regulations. This proposal will result in duplicative and likely conflicting regulation of many products subject to the authority of other federal and state agencies. (See SB 509, H&S Code Section 25257.1)

The problem presented by the complexity and breadth of the Straw Proposal is exacerbated by the requirement that four distinct pathways be considered as

qualifiers for becoming regulated by the process. Each presents its own regulatory burdens.

1. Eleven consumer product categories which are not well defined;
2. Sixteen pre-designated "chemicals of concern" that are not justified by qualifications nor do they imply a uniform system of qualification;
3. Chemicals identified by 29 different state, federal and international sources; and
4. Thirteen health and environmental hazard criteria, applicable to every detectable chemical in the product;

By considering all of these pathways the chemicals of concern would easily number about 10,000 chemicals and countless products subject to complex alternatives assessment. This burden is out of proportion with the relatively good health of the general population of consumers, increasing longevity and the relative cost of this program versus other health and environmental interventions.

Manufacturers, particularly small and medium sized enterprises (SMEs), could never reliably establish compliance systems given the sheer number of chemicals and products covered and ongoing changes to referenced chemical lists, chemical hazard data, and analytical detection limits. Additionally, there is the distinct possibility of different and perhaps conflicting interpretations of many aspects of the regulation as proposed. For example, the Straw Proposal envisions chemicals identified by CAS Number and does not make special provision for natural materials. This would suggest that natural extracts that may consist of dozens of chemical species including the "may contain" constituents would be required to do complex analysis for each material. This would likely kill the natural products industry since has not demonstrated the expertise necessary and could not afford to develop it. There are also new competencies envisioned including moving toxicological and environmental assessments from chemical manufacturers to finished product formulators and sophisticated alternatives assessments that would have to come on line in a single year. These burdensome requirements are at odds with other chemical management programs; even the incredibly burdensome REACH requirements recognize supply chain efficiencies that come from chemical manufacturers performing hazard evaluations.

Finally, the straw proposal has dismissed the societal and economic benefits of the consumer products that would be adversely affected or banned. A more measured approach would secure the majority of the benefits of the program, allow for modification of the program in response to learning from the first tier priorities and minimize negative consequences unforeseen in the proposed massive implementation. The DTSC is placing a huge burden on industry to develop and manage data. There should be an opportunity for industry to demonstrate relative return on investment to focus on those efforts that will return net benefits to consumers.

Identification and Prioritization

The mandate given by AB1879 is to identify those chemicals present in consumer products that may pose a threat to human health and the environment that in turn warrant additional regulation. The legislature concluded that a meaningful prioritization was necessary to achieve this objective, to address the "worst first." The legislature specifically sought to avoid duplicative regulation in light of limited state resources.

As a reasonable first step towards implementing AB1879/SB509, DTSC must identify and prioritize chemicals of concern in consumer products. The Straw Proposal fails to accomplish this in a clear and objective manner. Instead some 10,000 chemicals—8,000 from the referenced lists and an estimated additional 2,000 from the hazard trait pathway are equally identified as chemicals of concern, many on an arbitrary and capricious basis. It also includes virtually every consumer, commercial, construction, fertilizer and industrial product and chemical sold in California commerce and used in California research. It addresses all chemicals that are "contained" in products with no *de minimis* threshold; any detectable level of any of the 10,000 in any product triggers every chemical/product combination directly—without evaluation of safety—into a massive alternative and lifecycle assessment as well as an extremely burdensome supply chain communication effort. This could conceivably result in giving maximum attention to replacing minor levels of ethanol included in a shampoo as a process aid for a surfactant (the intended ingredient) while ignoring beverage alcohol health effects. This could occur despite OEHHA identification of ingestion as the **only** meaningful route of exposure. Clearly, DTSC has forgotten the instruction on "how to eat an elephant" and has decided on the single gulp approach.

Chemicals of Concern in Consumer Products (Article X)

Identification of Chemicals of Concern in Consumer Products

The DTSC straw proposal fails to effectively "establish a process to identify... chemicals of concern" (COCs) in consumer products contrary to Section 25252(a) of AB 1879. 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) instead defers the identification of COCs to a variety of agencies and research review entities which do not themselves use consistent criteria. The result is an arbitrary listing that provides no stability to the proposed substitution process. To comply with the statute and give the necessary guidance to industry, the Department must identify criteria for establishing hazard traits that would serve as a screening tool for identifying candidate chemicals of concern. Ideally, the most severe human health hazard traits such as carcinogen, developmental or reproductive harm (CMR), and persistence, bioaccumulation and toxicity (PBT) as the most significant environmental characteristics of concern would, in our judgment, provide a focus on highest priority candidates while still giving a significant workload to both industry and the department considering the breadth of the proposed product use categories.

The process for identification of candidate chemicals of concern can clearly be a dynamic process that foresees additional characteristics for identifying COCs. Also, there should be attention given to real health impacts by considering meaningful exposures as is done in the Proposition 65 listing rather than the proposed focus on chemicals "contained" in the subject products with no *de minimis* threshold concentration or route of exposure consideration. By constructing a tiered assessment, DTSC could assure Californians that resources are truly addressing the maximum impact chemicals and uses as intended in the statute, and that additional efforts would be forthcoming in a clear priority order.

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. 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. A prioritization system should clearly identify those activities that return best results for the citizens of California and encourage maximum effort on achieving health improvement impacts. By failing to prioritize, the DTSC has equated the highest volume use in the greatest exposure applications with the highest hazard to the least significant and demanded apportioning resources to replacing both equally. This approach flies in the face of the intended purpose for the legislation. As noted above, the plan could ultimately address the range of chemicals included in the Straw Proposal but in **prioritized** batches. This approach is working appropriately in the Canadian Chemical Management Plan which has rapidly focused on batches of chemicals and has already taken regulatory steps on a few while the EU REACH plan is still in preparation to gather data. The DTSC proposal fails to prioritize even as well as REACH, suggesting that the cost of such an extensive program may well exceed the anticipated **\$4 – 8 Billion estimated cost** of the EU program (See EU Commission estimates) or may simply eliminate promising technologies because of the economic burden.

Proposed Activities beyond the Scope of the Statute

Amway believes that DTSC has given too much attention to broadening the regulatory authority and has overstepped the letter and spirit of the underlying statute.

AB 1879 does not authorize DTSC to require the generation of data to assess hazard traits of all chemicals in commerce and consumer product as part of the identification and prioritization process (Section 25252) contrary to the provisions proposed in 6xxxx.6 *Data Requirements*. In that Section, the Department is authorized to require additional data **following completion of the alternatives analysis** as a regulatory response. The massive amount of data to be generated

is clearly beyond the mandate. Manufacturers are required to maintain data for all hazard categories for every ingredient, even those not identified as COCs. This could result in requiring such meaningless tests as those for ingredients that might be recognized as GRAS for ingestion as foods but used as botanical ingredients in cosmetics. The Straw allows for petitions of exception but both the testing and petition process demean the judgment of safety assessors who are actually qualified to declare the products "safe as used".

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 chemical hazard data that exists in the public domain rather than to deflect scientists into a box filling exercise.

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 when there could be a significant advantage for cooperation both in time expenditure and effectiveness of the substitution process. Including suppliers in the process would make alternative technology data, supply chain limitations and basic toxicology and environmental impact data available equally to participants. Data could be shared on a need to know basis and limit unnecessary disclosure of confidential data. Also, more novel approaches could be considered and evaluated quickly. This would not preclude individual actions by entrepreneurial companies. This type of collaborative process has been effectively used in the Consumer Product Working Group sponsored by the Air Resources Board in encouraging low VOC emissions technologies and products.

The proposed process envisions a clear "safer" alternative being identified as a result of the analysis. This may occur, but it is more likely that there will be substantial variability and uncertainty in results. When a clearly safer alternative is identified, there should be recognition by the state of barriers to implement the alternative, e.g., insufficient supply available to reliably replace the subject chemical, consumer acceptance of the alternative product, economics. Rather than letting product marketers muddle through individually, the state should encourage flexible approaches that encourage bringing meaningful alternatives to market based on sustainable benefits. Give some attention to the Innovative

Products Exemption, the Alternative Control Plan and other creative options included in the ARB regulation for Consumer Product VOC reduction.

Obviously, the alternatives assessment process should not be arbitrarily assigned to an inflexible one and two year cycle. This is the kind of command and control program that schedules the desired innovation as though it were a "fast food burger" with just as much likelihood of success in producing real "gourmet" green chemistry.

Response Actions (Article XXX)

In contrast to the DTSC proposal, the statute does not direct manufacturers to implement response to alternatives analysis. AB1879 clearly expects regulatory responses to be managed by the Department (Section 25233(b)). This requirement appropriately demands understanding and coordination of Green Chemistry by DTSC in collaboration with the manufacturers. Therefore, manufacturers should not be advisors in a process not authors of 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..." This certainly suggests a DTSC involvement beyond that in the statute. There is no defense of this authority nor are any criteria for departmental safety assessment of the products or the alternatives, nor is there a process for evaluating the appropriateness of such a ban or of the relative safety of the alternative. It would seem that DTSC is about to embark on a program of state product control as ambitious as Chairman Mao's famous five year economic plans, but in a shorter time frame.

Section (c)(3) proposes that any consumer product **containing** one or more of the **thousands** of Chemicals of Concern **at any concentration** would be prohibited in California within 20 years, regardless of the safety of the overall product, its utility, and the exposure risk to the public. This is actually counterproductive to the Alternatives Assessment process since it disincentivizes gradual demonstrable product improvement. The DTSC is taking this "all or nothing at all" not just with the highest concern chemicals but with every use of any CoC. This does not seem to be the best practice "to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern" as expected by the legislation. Instead, it is roughly the "Dirty Harry" approach with the Straw Proposal as the 44 Magnum asking industry and consumers "Do you feel lucky?"

Supply Chain Dislocation

The Straw Proposal has surprisingly little regard for the function of the current supply chain and its chemical management resources. As noted by every global chemical management process, hazard data are developed by chemical

manufacturers and are considered valuable intellectual property. The EU notes this in the REACH regulation by developing a Substance Information Exchange Forum (SIEF) structure for data sharing and by excusing Downstream Users from SIEF participation. Government agencies (EPA or Environment Canada, for instance) may choose to perform hazard assessment but often receive data from chemical manufacturers under confidential disclosure. The idea that data would be freely available to product formulators demonstrates a naiveté that would be quaint were it not so lethal to the industry. Trying to create data sharing mechanisms for high volume chemicals (as done under HPV programs) to generate a confidential submission to a government agency might seem possible. But generating data for **all** chemicals by CAS Number (considering that many commercial chemicals are multiple species) and dispersing to **all** user companies is a mathematical impossibility, rather like the Sultan's reward for the invention of chess (the inventor asked only for a grain of wheat on the first square, double on the second, double that on the third and so on for 64 squares...seemed reasonable until he did the math).

Required Agency Resources

This program will require significant regulatory and enforcement resources. It is imperative that the Department clearly delineate its responsibilities and the staffing needs. The Straw Proposal attempts to shuffle responsibility onto the consumer product industry but we have attempted to demonstrate the need for department oversight and coordination if the process is to be efficient and fair. Amway is deeply concerned that enacting a regulation similar to the Straw Proposal would result in insufficient resources and an uneven enforcement. The most irresponsible companies might be able to continue to offer product by paying lip service to the requirements or side stepping them with a "catch me if you can" mentality. Those companies who supported the legislation and desire to have a meaningful program instituted would be hamstrung by the rule and possibly forced out of the marketplace.

Possible Solutions

Identification and Prioritization of Chemicals of Concern

Amway recommends the Green Chemistry Alliance proposal for identifying candidate chemicals of concern at the outset. DTSC should identify those chemicals with criteria of highest health and environmental hazard, for instance those known to cause cancer, reproductive or developmental harm (CMRs) and those chemicals which are persistent, bioaccumulative and toxic (PBTs). Authoritative bodies have identified over 2,000 such chemicals. A commercial volume of each of those chemicals in the state could be ascertained by comparing the 2,000 CMR-PBT chemicals against the U.S. EPA's 2006 Inventory Update Rule (IUR) - reporting use volume data on high and medium production volume chemicals in the U.S. A reasonable surrogate for California volumes is 20% of that volume assuming relatively uniform use patterns across the U.S. Approximately 650 CMR-PBT chemicals are on the 2006 IUR. This should serve as a meaningful initial basis for assessing "potential effects on sensitive

subpopulations” as specified in AB 1879. The Department could focus on criteria to identify subsets of the CMR-PBT consumer uses by product type using the consumer product groups cited in the Straw Proposal with the goal of prioritizing by highest risk to target groups. Additional data such as appearance of target chemicals on CDC’s biomonitoring program as CDC could help in selecting chemicals for prioritization.

Recognizing that there may be community concerns about specific chemicals not on the CMR-PBT list, we recommend that DTSC establish a petition process similar to that used by OEHHA for Proposition 65 chemical nominations. Ultimately, this could serve as a continuing process and/or additional criteria for general addition could be added in phases. At all stages, DTSC can utilize a stakeholder process that includes the chemical suppliers, consumer product manufacturers, citizen advocates, environmental interest groups and other interested parties. They could all serve together or a break out consumer product group could advise on uses and exposures of candidate chemicals to inform the larger group. As noted above, this model is approximately that of the Consumer Product Working Group convened by ARB.

Alternatives Assessment

The Alternatives Assessment process demands flexibility and expertise. Amway sees this as a collaborative process between industry and DTSC. Manufacturers of the CoCs would have a high interest in assuring accuracy of the hazard and exposure data. The consumer product formulators and raw material manufacturers would have qualification to discuss alternatives assessment. Some consumer and environmental representatives may wish to observe the process. As discussion proceeds among stakeholders, the process for alternative assessment should become clearer and can be outlined as guidance by the Department at some future date.

Alternatives Assessment Study.

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. Cooperative assessments can produce the most effective opportunities to reduce hazard or exposure. Leveraging best practices from early efforts should create a standard of efficient “green chemical” substitution that can serve as a global prototype that will increase in power by increased participation.

Regulatory Responses and Compliance

Good faith participation by industry requires that DTSC enforce expectations uniformly among manufacturers. Larger manufacturers of chemicals and consumer products will expect assistance to SMEs but not at disproportionate

advantage. Importers should bear the same burdens and liabilities. This will require that the Department establish clear enforcement guidelines and provide some advantage to principle participants who help in developing uniquely effective "safe alternatives" strategies. It is likely that there would be strong industry incentive to assist in enforcing appropriate regulatory responses to assure that avoiding compliance would not have a competitive business advantage.

Compliance will require independence of the enforcement staff. However, there should be regular meetings with the regulated community to assure fairness and effectiveness of the enforcement program.

Respectfully submitted,

//original signed by//

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