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

**Re: Exclusion of Food-Contact Materials from the Scope of Regulations
Implementing California's Green Chemistry Initiative**

Dear Director Movassaghi:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the scope of its proposed regulations to implement the new sections of the California Health and Safety Code added by AB 1879 (Feuer) and SB 509 (Simitian). We refer to these new requirements in this letter as the Green Chemistry Initiative (GCI). These comments are being submitted on behalf of a number of trade associations that collectively represent the majority of food-contact materials suppliers in the United States, as well as trade associations that represent the food industry, which has a critical interest in the availability of safe and effective materials for packaging, holding, storing, and transporting food products.¹

In its draft Straw Proposal for Safer Alternatives Regulation, DTSC has included food packaging and other food-contact materials within the scope of the consumer products that are intended to be covered by the regulation.² While our members realize that the Straw Proposal represents only DTSC's initial thoughts on the regulations that will implement the GCI, it is our position that food-contact materials are fully regulated by the U.S. Food and Drug

¹ Specifically, these comments are being submitted on behalf of the Grocery Manufacturers Association, the Society of the Plastics Industry, Inc., the American Forest and Paper Association, the Can Manufacturers Institute, the North American Metal Packaging Alliance, the Foodservice Packaging Institute, and the Flexible Packaging Association.

² Straw Proposal for Safer Alternative Regulations (October 1, 2009).

Administration (FDA) and that the regulation of these materials is not legally permitted under the GCI because of the proscription of Section 25257.1(c) of the California Health and Safety Code, which restricts DTSC from adopting regulations under the GCI that duplicate or conflict with existing or pending regulations of other Agencies that are consistent with the purposes of the GCI. In addition, we do not believe that the inclusion of food-contact materials within the scope of the GCI will further the goals of the legislation and that this action could possibly have the unintended consequence of inhibiting the development of new food packaging materials that ensure the safety of food and prevent food waste due to spoilage. The remainder of this letter provides a detailed discussion of these issues.

I. GCI's Regulation of Food-Contact Materials Would Duplicate Consistent Regulations at the Federal Level

As stated above, Section 25257.1(c) of the Health and Safety Code restricts DTSC from adopting regulations under the GCI that duplicate or conflict with existing or pending regulations of other Agencies that are consistent with the purposes of the GCI.³

In Section 6xxxx.1(a), the Straw Proposal identifies the consumer products that fall within the scope of the regulations, including in paragraph (8) those “[p]roducts designed to store or dispense food products or designated for food preparation including, but not limited to, bags or containers, flatware, eating and cooking utensils, and pots and pans.” The language of paragraph (8) covers food packaging as well as those materials that would be used in contact with food. We respectfully submit that all materials used in contact with food are subject to strict and comprehensive regulations existing at the federal level that address their safety when used by the consumer, as well as the environmental impact of such usage, consistent with the goals of the GCI. The regulation of these materials under the GCI would duplicate FDA’s regulatory scheme for these materials and is prohibited by Section 25257.1(c).

³ Section 25257.1(c) states, “The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.”

A. Premarket Clearance by FDA

Food-contact materials are unique among the consumer products that are proposed to be regulated under the GCI in that these materials are already regulated under a comprehensive system administered by the FDA and explicitly mandated by the Federal Food, Drug, and Cosmetic Act (FFDCA).⁴ The regulation of food-contact materials was established by Congress as part of the 1958 Food Additives Amendments.⁵ These amendments require FDA to regulate food-contact materials as food to the extent that there is any migration or exposure to the components of the packaging (or other materials used in contact with food). More specifically, Section 201(f) of the FFDCA defines food to mean “articles used for food or drink for man or other animals,” including “articles used for components of any such article” (*i.e.*, food additives). The FFDCA further defines a “food additive,” in Section 201(s), as a substance that is reasonably expected to become a component of food under the intended conditions of use, with certain statutory exceptions.⁶ Thus, to the extent that there is any migration, FDA regulates a food-contact material in the same manner as any substance that is directly and intentionally added to food. Food additives, including food-contact materials, are subject to premarket authorization by FDA before they can be marketed, unless the use of the substance qualifies for one of the limited exceptions provided under the FFDCA. Accordingly, unless an exemption applies, a person intending to market a new food-contact material must first seek clearance from the FDA.

Like substances directly added to food, FDA regulates components of food packaging materials by the promulgation of food additives regulations, which set forth the conditions under which a particular substance may be used. FDA’s food additive regulations may be found in Title 21 of the Code of Federal Regulations, Parts 170-189. Each of the clearances in these regulations for a food-contact substance indicates that FDA has conducted a detailed review of the substance’s safety. In addition, as part of its promulgation of a new food additive regulation, FDA (as required by the National Environmental Policy Act⁷) conducts an environmental assessment of the proposed applications to determine if there would be any environmental

⁴ 21 U.S.C. §§ 301 *et seq.*

⁵ Pub. L. No. 85-929, 72 Stat. 1784 (1958).

⁶ As detailed below, examples of substances that are exempt from the definition of food additive are substances that are generally recognized as safe (GRAS) or prior-sanctioned for their intended use by FDA before January 1, 1958.

⁷ 42 U.S.C. §§ 4321 *et seq.*

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impact from the manufacture and use of a new substance or whether the use and disposal of the new product would adversely affect the recycling of post consumer materials.^{8,9}

Congress provided FDA with authorization to use a new regulatory procedure for the review of new food-contact substances and new uses of food-contact substances when it enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA).¹⁰ FDAMA added Section 409(h) to the FFDCFA authorizing the Food Contact Notification (FCN) program. The FCN program has been operational at FDA since 2000, and now FDA reviews the overwhelming majority of food-contact substances under this program. Under the FCN program, manufacturers must submit information on the identity and use of the food-contact substance, along with information supporting the conclusion that the substance is safe for the intended use. While the system does not result in the promulgation of a new food additive regulation, the safety and environmental evaluation standards are the same as they were for the food additive petition process. (Arguably, FDA's evaluation of food-contact substances under the FCN program is even stricter than it was before the FCN program was available, as the Agency added additional chemistry and toxicity data requirements when it established guidelines for the new program.) If FDA does not object to a manufacturer's FCN, the proposed substance, along with the terms and conditions under which it may be used, is published on FDA's website along with the identity of

⁸ FDA has published guidance documents discussing the information and data that must be included for its environmental review. *See* FDA, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" (May 2006) at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081049.htm> and "Environmental Assessment Technical Assistance Handbook" at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm084224.htm>.

⁹ An article describing FDA's food additive approval process and safety evaluation was recently published by the former director of FDA's Center for Food Safety and Applied Nutrition and the former Director of the Office of Food Additive Safety. While the article focuses on food ingredients, *per se*, FDA regulates the safety of food-contact materials in a similar manner, thus, the article is instructive of the Agency's safety assessment. *See* "FDA's food ingredient approval process – Safety assurance based on scientific assessment" A.M. Rulis and J.A. Levitt, *Regulatory Toxicology and Pharmacology* 53 (2009) 20-31.

¹⁰ Public Law No. 105-115, 105th Congress (Nov. 21, 1997).

the notifier.¹¹ FCNs are proprietary to the notifier and may only be relied upon by the notifier and its customers. Manufacturers who produce the same material must submit their own notification to FDA.¹²

Once a material is cleared by FDA, FDA continues to monitor public information and safety that may question whether the use of the material continues to be safe. Under the FCN, notifiers are required to submit to FDA any new toxicological data or other information that may come to their attention that could affect FDA's decision that the use of the substance is safe.

1. Data Required for FDA's Review

To evaluate the safety and environmental aspects of the use of a new food-contact substance, FDA requires a manufacturer to submit extensive data to the Agency. FDA reviews these data in the Division of Food Contact Notifications within the Office of Food Additive Safety, which has a staff of approximately 35 officials. FDA has published guidance documents regarding its requirements for the data and information that must be included in a food additive petition or FCN.¹³ These data include:

- (1) a full chemical description of the food-contact substance, its impurity profile, and details regarding its manufacture;
- (2) data demonstrating the amount of the substance that may migrate from the article to food;

¹¹ Effective notifications are published on FDA's website at <http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm>.

¹² Additional information on the FCN process and FDA's regulation of food-contact materials can be found in a recent chapter in a book published by the Food and Drug Law Institute. See D.W. Hill and R.A. Bond, "Chapter 4: Food and Drug Packaging," in the Food and Drug Law Institute's *Food and Drug Law and Regulation*.

¹³ FDA, "Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations" (Sept. 1999, updated Apr. 2002), at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081825.htm> and "Preparation of Food Contact Notifications for Food Contact Substances: Chemistry Recommendations" (Apr. 2002, updated Dec. 2007) at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081818.htm>.

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- (3) calculations of the estimated dietary exposure to the substance and its impurities based on its anticipated use;
- (4) all available toxicological data that the notifier has in its possession or that is publicly available must be provided for the substance and its impurities;
- (5) certain minimum toxicological data, the volume of which depends on the estimated dietary exposure from the proposed use; FDA's tiered requirements for toxicological data for substances with a potential dietary exposure between 0.5 parts per billion (ppb) and 50 ppb mandate two *in vitro* genotoxicity studies demonstrating that the substance is not mutagenic or genotoxic; for substances with dietary exposures above 50 ppb, FDA requires a third genotoxicity study in the form of an *in vivo* chromosomal aberration study, and two subchronic feeding studies, generally one in a rodent species and one in a non-rodent species. For substances with exposures above one part per million in the diet, FDA requires a full panoply of toxicological data, including the data identified above as well as from a chronic two-year bioassay, a one-year feeding study in a non-rodent species, and multigenerational reproductive and developmental toxicity studies. Of course, if any of these studies indicate a hazard trait or toxicological endpoint of concern, FDA may require additional studies to demonstrate that the proposed use will be safe,¹⁴
- (6) data that allow FDA to consider the potential environmental impact that may result from the clearance of a new food-contact material;¹⁵ unless the proposed use of the food-contact substance qualifies for an exemption, petitioners and notifiers must submit information that the proposed manufacture of the food-contact substance will not affect compliance with any federal and state environmental laws related to any discharge to the environment, such as air and water emissions.

¹⁴ Id.

¹⁵ FDA's categorical exclusions are set forth at 21 C.F.R. §§ 25.30-34. The Agency set forth its rationale for why certain applications are exempt from the need for an environmental assessment in the Federal Register notice promulgating this rule. *See* 62 Fed. Reg. 40569-40600 (July 29, 1997). *See also* FDA, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" (May 2006) at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081049.htm>

Further, we note that information also must be submitted on the environmental fate resulting from the use and disposal of the food-contact substance demonstrating that it will not affect the environment. In particular, information must be submitted that evaluates any potential environmental impact when the substance is disposed, such as landfill leachate, incineration and the potential air emission and ash disposal from incineration. Any environmental impact that may result from manufacture, use, or disposal, such as aquatic toxicity or toxicity to terrestrial organisms, must be addressed.

FDA pays particular concern to any impacts that the proposed use of the substance may have on the ability to recycle post consumer packaging materials. If there is a concern that the new substance may create problems with the recycling processes currently being used, FDA will require further data and information or limitations to ensure that the proposed use will not create an adverse economical or technical impact on the ability to recycle food packaging materials.

In sum, FDA has in place a comprehensive and robust system of regulation for food-contact materials that establishes a large margin of safety. The regulations proposed by DTSC to implement the GCI would duplicate this system. FDA's regulatory scheme is consistent with the purposes of the GCI. Thus, the inclusion of these products in the California's Safer Alternatives Regulations would contravene the limitations proscribed by Section 25257.1(c) of the Health and Safety Code and would not promote the safety or environmental goals of the GCI.

B. Exceptions from Premarket Review

As noted above, there are limited exceptions to the need to obtain a food additive regulation or an effective FCN for the proposed use of a new food-contact substance. First, FDA may exempt a material from the need for a regulation of FCN under its Threshold of Regulation exemption procedure. FDA's Threshold of Regulation procedure, which is codified at 21 C.F.R. § 170.39, allows the Agency to exempt a substance from the need for a regulation or FCN if the proposed use of the substance meets certain criteria:

- (1) the substance must not be a carcinogen and may not contain any carcinogenic impurities with a TD_{50} (*i.e.*, median toxic dose) value less than 6.25 mg/kg body weight per day;¹⁶

¹⁶ The TD_{50} is the chronic dose level that would induce tumors in half the test animals at the end of a standard lifetime for the species.

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- (2) the proposed use of the substance must not result in a dietary exposure exceeding 0.5 ppb or, if the substance is currently regulated for direct use in food, the proposed increase in the dietary exposure must be less than one percent of the established acceptable dietary intake (ADI) for the substance;
- (3) the substance has no technical effect in the food; and
- (4) the proposed use of the substance may not have a significant impact on the environment.

FDA adopted the Threshold of Regulation procedure after reviewing a large number of published studies indicating that there was little toxicological concern from the exposure to noncarcinogenic substances at levels below 0.5 ppb in the diet.¹⁷ FDA reserves the right to determine if substances qualify for the exemption and provides response to companies submitting such a request.

The FFDCA also provides certain exceptions to the definition of a food additive that also apply to food-contact materials. Specifically, the Act excepts those materials that are considered to be generally recognized as safe (GRAS) or that were sanctioned by either FDA or the United States Department of Agriculture (USDA) prior to the adoption of the Food Additives Amendment in 1958. Food additives, as well as food-contact materials that qualify under these exemptions, are not technically subject to premarket review by FDA, although in many cases companies request FDA's review.

The FFDCA exception for GRAS substances as provided in Section 201(s) states that such a determination requires a general recognition "among experts qualified by scientific training and experience to evaluate [the additive's] safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use." FDA has promulgated regulations setting forth the criteria that the Agency regards as necessary to establish that the use of substance is GRAS. These eligibility requirements provide that (a) general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance

¹⁷ 60 Fed. Reg. 36595, July 17, 1995. A full report and all of the individual papers written as part of a study examining this issue were published in the August 1990 issue of *Regulatory Toxicology and Pharmacology*. See Munro, "Safety Assessment Procedures for Indirect Food Additives: An Overview," 12 *Regulatory Toxicology and Pharmacology* 2 (August 1990).

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used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.”¹⁸ Moreover, FDA has clarified that “scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation.”¹⁹ The main toxicological data and other information that support a GRAS determination must be published, generally in peer-reviewed scientific journals.

FDA has a procedure to review and sanction GRAS determinations through a GRAS Notification process.²⁰ In addition, the Agency has listed or affirmed some materials as GRAS in Parts 182, 184, and 186 of the food additive regulations. A determination may be made without FDA review that a substance is GRAS, provided that sufficient published toxicological data exist that establish a general scientific recognition that a substance’s use is GRAS. The standards for such a self-determined GRAS assessment are robust. As stated by two former FDA officials, Drs. Alan Rulis and Joseph Levitt, “many people mistakenly associate GRAS with a sort of “second” tier of safety protection based on a less-than rigorous standard compared to petitioned food additives. This is not true. In fact, the safety standard applicable to GRAS food ingredients is the *same* as for food additives; namely reasonable certainty of no harm.”²¹ The former directors went on to say that “[i]n fact, the GRAS criteria are in some ways more difficult to satisfy than the food additive criteria because of the additional requirement of public availability of the data and general recognition and acceptance of a safety conclusion based on those data.”

The FFDCA also expressly exempts those materials that were sanctioned by USDA or FDA in letters issued by these Agencies before the passage of the Food Additive Amendments in 1958. In the experience of our members, the substances covered by prior sanctions and still used in commerce are limited and many of the substances were subsequently petitioned or notified to

¹⁸ 21 C.F.R. § 170.30(a)(2).

¹⁹ 21 C.F.R. § 170.30(b).

²⁰ See FDA, GRAS Notification Program, at <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASNotificationProgram/default.htm>.

²¹ See A.M. Rulis and J. Levitt, p. 26.

the FDA. FDA very strictly interprets prior sanction letters previously issued, and limits the scope of the exclusion by construing prior sanctions as narrowly as possible.²²

Substances also may be used without express premarket approval from FDA if they can additionally be shown to not migrate from the food-contact article. The standard for this assumption is strictly interpreted by both the Agency and industry. In general, a showing of no migration must be based on an analytical sensitivity demonstrating that there would be no migration at a level equivalent to 50 parts per billion and often lower in some situations.²³ The basis of the exclusion from premarket clearance is that, given the very low migration of the substance to food, the resulting dietary exposure among consumers will be negligible.

In sum, the exemptions from premarket approval for food-contact materials are strictly limited by the FFDCA. Only those materials that are subject to published toxicological data and generally accepted by the scientific community as safe may be considered to be GRAS and used without FDA review. Those substances covered by prior sanctions are limited, and the substances used in food-contact materials that do not migrate to food result in no exposure to consumers. In addition, these substances when used in food-contact articles are still subject to FDA regulation under Section 402 of the FFDCA.²⁴ Under no circumstances may any substance cause a health or safety concern when used as intended and may not affect the taste or odor of the food. Thus, it is our opinion that the substances that qualify for these limited exceptions do not result in exposures of concern and, therefore, subjecting them to the scope of the GCI would not promote the purposes of the statute. Including such materials within the scope of the GCI will duplicate the existing regulatory scheme which Congress and FDA have established.

C. The Current Regulation and Evaluation of Food-Contact Materials Is Consistent with the Hazard Category Endpoints That Are Described in DTSC's Straw Proposal

The Straw Proposal published by DTSC has established a series of hazard categories under Section 6xxxx.7. Under the proposal, the manufacturer of a consumer product covered by the GCI must evaluate the chemicals of concern that are present in these products according to

²² See 456 F. Supp. 207, 209 (d. Neb. 1978), *aff'd sub nom.* United States v. Nielsen (8th Cir. 1979), cert. denied 444 U.S. 832 (1979). See also, 21 C.F.R. § 170.38(d).

²³ The resulting dietary exposure for most food-contact substances, even if there were some migration below the level of detection, would be less than 0.5 ppb, a level below FDA's threshold of toxicological concern.

²⁴ 21 U.S.C. § 342(a)

the hazard criteria identified in paragraph (b) of this section. These criteria are: (1) acute toxicity, (2) eye irritation, (3) genetic toxicity and mutagenicity, (4) reproductive toxicity, (5) carcinogenicity, (6) endocrine disruption, (7) respiratory sensitization, (8) skin sensitization, (9) bioaccumulation, (10) acute aquatic toxicity, and (11) hazards to the ozone layer.

(1) Acute Toxicity, Eye Irritation, Skin Sensitization, Respiratory Sensitization

The acute exposure endpoints identified in the hazard criteria are not relevant endpoints for exposures from food packaging materials. Substances used in food-contact materials are generally of low acute toxicity and are trapped within a matrix (*e.g.*, a polymer, coating or paper) that prevents their migration and limits exposure to levels that are not relevant for acute exposures. While FDA requires the submission of acute toxicity data when available, the Agency generally is not concerned with acute, single-dose toxicity data and, rather, is more concerned with potential carcinogenicity effects or other endpoints from repeated-dose studies.

(2) Genetic Toxicity and Mutagenicity

FDA requires genetic toxicity and mutagenicity testing for any chemical substance with a potential dietary exposure above 0.5 ppb. In addition, if structural alerts suggest that a substance may have genetic or mutagenic attributes, FDA may request that additional data be provided. Any GRAS determination must consider these toxicological endpoints, as well. In the case of materials that do not migrate, there would be no exposure, although the level of analytical sensitivity to determine whether the “no migration” threshold should be lower than 50 ppb also is based on these genotoxicity concerns. In our experience, if a substance is determined to be mutagenic or genotoxic in screening tests, FDA will require (a) data demonstrating whether these effects are likely to be observed *in vivo*, (b) a cancer bioassay to resolve whether the material is a carcinogen, or (c) proof that potential dietary exposure will be insignificant even if the material is later determined to be a carcinogen; generally, this would be at a level that would not exceed 50 parts per trillion, 0.05 ppb, in the diet.

(3) Reproductive Toxicity

FDA requires that reproductive and developmental toxicity data be submitted for substances when the dietary exposure may be significant for these toxicological endpoints. In addition, if structurally similar compounds suggest that a compound may exhibit a concern for reproductive or developmental toxicity, the Agency may request additional data. As with genotoxicity data, any GRAS determination must consider these toxicological endpoints as well.

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In the case of materials that do not migrate, there would be no exposure, and generally this toxicological endpoint is not relevant when the exposures are below 0.5 ppb in the diet.²⁵

²⁵ In a 1999 paper, Dr. Ian Munro and colleagues established a safety evaluation procedure for use by the Joint Food and Agricultural Organization/World Health Organization of the United Nations (FAO/WHO) for flavoring substances implementing a threshold of toxicological concern approach involving a number of toxicological endpoints.²⁵ The study authors concluded that “toxicity endpoints, such as developmental toxicity, neurotoxicity, and immunotoxicity demonstrate considerably higher human exposure thresholds than the threshold value [established using carcinogenicity data], making it highly unlikely that these non-cancer endpoints are a relevant concern in applying the threshold concept.” See also, Kroes, R., Galli, C., Munro, I., Schiltwe, B., Tran, L.-A., Walker, R., and Würtzen, G. (2000) “Threshold of Toxicological Concern for Chemical Substances Present in the Diet: A Practical Tool for Assessing the Need for Toxicity Testing,” *Food and Chem Toxicol*; 38: 255-312. The Kroes study reviewed an expanded databases to establish if additional toxicological endpoints were more sensitive than the carcinogenic endpoints of a variety of chemical substances. The report indicates that none of the specific non-cancer endpoints (*i.e.*, developmental toxicity, developmental neurotoxicity, and immunotoxicity) was more sensitive than cancer endpoints for the same substances. The results of a more recent analysis were published by Kroes and colleagues in 2004. The authors conclude that, based on their examination of metabolism and accumulation, structural alerts, endocrine disrupting chemicals and specific toxicological endpoints, including neurotoxicity, teratogenicity, developmental toxicity, and immunotoxicity, carcinogenicity is the most sensitive toxicological endpoint. See Kroes, R., Renwick, A.G., Cheeseman, M., Kleiner, J., Mangelsdorf, I., Piersma, A., Schilter, B., Schlatter, J., van Schothorst, F., Vos, J.G., and Würtzen, G. (2004) “Structure-Based Thresholds of Toxicological Concern (TTC): Guidance for Application to Substances Present at Low Levels in the Diet,” *Food and Chem Toxicol*; 42: 65-83.

(4) Carcinogenicity

The FFDCFA prohibits the use of carcinogenic food additives, including substances used in food-contact materials that become components of food. Specifically, Section 409(c)(3)(A) of the Act (also known as the “Delaney Clause”) states that no food additive shall be deemed by FDA to be safe if the additive is found “to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of safety of [the additive], to induce cancer in man or animal.”²⁶ Thus, it is not possible to use a substance considered to be a carcinogen that would be a food additive when used in food-contact materials.

The Agency has established standards for the presence of any carcinogenic impurities that may be present in food-contact materials. The standard that FDA has established for these materials is known as the “constituents policy.”²⁷ FDA sets an extremely strict standard for carcinogenic impurities. The Agency uses data from animal carcinogenicity studies, together with extrapolation procedures, to calculate the potential risk from the estimated daily exposure to the carcinogenic impurities as a result of the particular use. In order to determine that there is a reasonable certainty of no harm, FDA requires that the dietary exposure to a carcinogenic impurity must not exceed the calculated upper-bound lifetime risk from all sources of exposure and be lower than a risk of 1 in 1 million.²⁸

(5) Endocrine Disruption

The proper assessment of the endocrine disrupting potential of a particular chemical is a topic of much current discussion. Whether the *in vitro* endocrine disrupting effect exhibited by a chemical at the extremely low doses of oral exposure associated with food packaging actually translates to an adverse physiological effect is in our opinion, at best, very controversial. Moreover, the health effects of chemicals acting through an endocrine mode of action should generally be captured by traditional toxicological tests, which are designed to detect adverse health effects acting through any means, including interaction with the endocrine system.

²⁶ FFDCFA § 409(c)(3)(A); 21 U.S.C. § 348(c)(3)(A).

²⁷ 47 Fed. Reg. 14,464 (Apr. 2, 1982). Although this Advanced Notice of a Proposed Rulemaking was withdrawn by the agency in a November 26, 2004 Federal Register notice (69 Fed. Reg. 68,831, 68,831), the impetus of the withdrawal was administrative only, and FDA has since made clear that the constituents policy remains a valid means by which it evaluates minor carcinogenic impurities of food additives.

²⁸ *Id.* at 14,468.

FDA and other bodies around the world that regulate food-contact materials are monitoring current scientific information on this subject. At this time, however, no regulatory body in the world that is responsible for food safety has established separate endocrine disruption data requirements for food-contact materials. Instead these regulatory bodies rely on information from reproductive, developmental and other well established, validated toxicology studies to understand the potential health effect of chemical regardless of their mode of action. While industry and government continue to monitor this issue, it is our opinion that there is not sufficient scientific information or agreement on the data at the present time to establish endocrine disruption as a regulatory criterion.

(6) Bioaccumulation

FDA considers the biopersistence and bioaccumulation of a proposed food-contact substance as part of its evaluation of food additive petitions and FCNs. If a substance is suspected of being bioaccumulative, the Agency requires further data on its absorption, distribution, metabolism and elimination to determine the potential bioaccumulation in the body. Any GRAS evaluation of a substance would also take this outcome into account. With regard to the other materials that may not be subject to FDA's review, the Agency considers that a daily exposure of 0.5 ppb in the diet is an insignificant addition to the diet from a cumulative exposure standpoint (except for carcinogens). If a substance is present at levels below 0.5 ppb, its bioaccumulation potential is considered to be insignificant.

(7) Acute Aquatic Toxicity and Hazards to the Ozone Layer

As stated above, FDA requires in its review of food-contact materials that the substance not have an adverse environmental impact during its manufacture, use, and disposal. In addition, the manufacture of food-contact materials—like any other consumer product—is subject to federal, state, and local environmental laws that govern discharges to the air and water (*e.g.*, the laws administered by the California Air Board and Office of Environmental Health Hazard Assessment). Most importantly, because of their inert design there is not likely to be any exposure from a food-contact material that could have an effect on aquatic toxicity or the ozone layer at any level of concern. The possible levels of migration of a substance from a food-contact article are very low, generally in the part per million range or lower, and these toxicological endpoints are simply not relevant to packaging or other food-contact articles.

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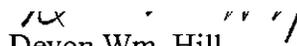
II. Conclusion

Food packaging is important to ensure the safety and quality of food. Modern packaging is designed to be inert and not transfer its components or have an effect on food. It is also carefully designed to preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf-life of products to reduce food waste. FDA, under federal law, has established a comprehensive regulatory scheme to ensure the safety of food-contact materials, which provides a large margin of safety. This regulatory scheme is consistent with the goals and purposes of the GCI. In the opinion of our members, a separate duplicative regulate scheme would inhibit technological innovation and development that is important to ensure the safety of food and provide consumers with even safer and more environmentally friendly food packaging materials. Thus, the further regulation of food-contact materials under the GCI is prohibited by Section 25257.1(c) of the Health and Safety Code.

For the reasons set forth above, we respectfully request that the DTSC exclude food-contact materials and substances used as components of food-contact materials from the scope of any regulations promulgated to implement the provisions of AB1879 or SB509.

Sincerely,

//original signed by//


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Re: Draft Straw Proposal for Safer Alternatives Regulation – Food Packaging Materials

Dear Director Movassaghi:

On behalf of the Food Packaging Coalition, we appreciate your efforts and the ongoing, open stakeholder process that the Department of Toxic Substances Control (DTSC) has conducted relative to the development of the Green Chemistry Initiative (GCI) and in particular the straw proposal for conforming regulations for legislative companion bills AB 1879 (Feuer) and SB 509 (Simitian), which were signed into law by Governor Schwarzenegger on September 29, 2008.

The purpose of our letter is to provide comments, which are attached, on the scope of DTSC's straw proposal and, specifically, on the inclusion of food packaging and other food-contact materials as referenced in the scope of consumer products. The Food Packaging Coalition is a group of trade associations representing food and beverage manufacturers, food and beverage packaging manufacturers, and their associated supply chains. Our members have a critical interest in the availability of safe and effective materials for manufacturing, packaging, distributing and serving food products.

It is our position that, as food packaging materials are currently and fully regulated by the U.S. Food and Drug Administration (FDA), further regulation of these materials in the straw proposal would be duplicative and conflict with the federal regulatory scheme that presently exists to ensure the human and environmental health and safety of these materials. Additionally, language found in SB 509 speaks to the issue of duplication or conflicting regulations for product categories already regulated.

Food packaging and other food contact materials are essential to ensure the safety and quality of food. Modern packaging is designed to be inert and not transfer its components or have an effect on food. It is also carefully designed to preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf life of products, preventing food waste. FDA's regulatory scheme is consistent with the goals and purposes of the GCI.

Food Packaging Coalition
November 5, 2009
Page 2

The inclusion of food-contact materials within the scope of California's GCI will not further the goals of the green chemistry statutes and may actually impede our industry's development of new food packaging materials that can improve the safety and environmental profile of these materials, as well as the safety, quality, and availability of the food supply while reducing food waste due to spoilage.

We thank you for your efforts and consideration of our views and look forward to further dialogue and collaboration as this process moves forward. If we can provide you with additional information or clarification, please contact Caroline Silveira at (916) 447-9425 or csilveira@gmaonline.org.

Sincerely,

Members of The Food Packaging Coalition:

American Forest and Paper Association	Grocery Manufacturers Association
Can Manufacturers Institute	North American Metal Packaging Alliance, Inc.
Flexible Packaging Association	Society of the Plastics Industry, Inc.
Foodservice Packaging Institute	

Attachment

cc: Linda Adams, Secretary of CalEPA
Cindy Tuck, Undersecretary, CalEPA
Patty Zwarts, Deputy Secretary, CalEPA
Victoria Bradshaw, Cabinet Secretary, Office of the Governor
John Moffatt, Deputy Legislative Secretary, Office of the Governor



Fragrance Materials Association of the United States

1620 I Street NW, Suite 925
Washington, DC 20006
Phone (202) 293-5800 Fax (202) 463-8998
www.fmafragrance.org

November 9, 2009

Acting Director Maziar Movassaghi
Department of Toxic 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 Fragrance Materials Association (FMA), I am writing to express the fragrance industry's concerns with the Safer Alternatives Regulation Straw Proposal as currently drafted. Although the FMA 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, in our opinion, does not reflect the intent of the enacting legislation under AB 1879 (Feuer, 2008).

Based on the fragrance industry's calculations, at least 400-500 fragrance ingredients, or roughly 1/6 of all fragrance materials currently in use, could be impacted under the proposal and labeled "chemicals of concern." In addition, many substances used by the industry are naturally occurring (i.e. essential oils) and could have an unanticipated impact on supplier industries within the state of California.

As you may know, representatives from FMA were joined by the Research Institute for Fragrance Materials (RIFM) in a meeting on April 27, 2009 with Dr. Jeff Wong and other staff scientists at DTSC. At this meeting, RIFM, the international scientific authority for the safe use of fragrance materials, made a presentation detailing their extensive study of fragrance materials for human health and environmental effects. We stressed that the fragrance materials industry is quite unique in that we work closely not only with RIFM, but also the International Fragrance Association (IFRA), which promotes safe usage of fragrance ingredients through its strong alliance with RIFM. Since its formation in 1966, RIFM has conducted ingredient testing and acted as a repository for all human health and environmental safety data generated by its member companies, while IFRA communicates the results of that testing and evaluation to the industry at large.

As noted in April's meeting, the global fragrance industry has instituted a regulatory process that is administered through IFRA. Both environmental and human safety of fragrance materials is assessed by RIFM's Expert Panel consisting of internationally recognized academic experts in toxicology, environmental science, dermatology, and medicine, who use the latest approaches to independently review and assess safety of the industry's materials. The IFRA

Code of Practice is based on the conclusions of the Panel and is periodically re-evaluated and updated to ensure that current safety considerations are incorporated. There are currently 153 IFRA Standards, covering more than 200 fragrance materials. Of the 153 Standards, 73 prohibit specific materials, 69 restrict individual materials or groups of materials and 11 specify purity criteria for certain materials. As an IFRA member association, FMA bylaws require its member companies to abide by the IFRA Code of Practice.

As a representative of an industry with a robust safety program based on sound science, the FMA is particularly concerned with the inclusion of a number of the reference lists, many of which lack definition, and we feel it is critical for DTSC to apply the necessary rigor and scrutiny to understand and communicate the purpose of lists cited, particularly when proposing to regulate based on them. We call your attention to the following:

- Most importantly, “(21) chemicals classified by Canada as inherently toxic to aquatic organisms” would potentially impact over 400 fragrance materials including terpenes, a class of hydrocarbons produced primarily by a wide variety of plants, and which are the primary constituents of many essential oils. One terpene in particular, limonene, is present in most consumer products with a citrus scent and has been tested for its safety in the context of fragranced materials. Following a strict reading of the proposal, phasing out these naturally occurring compounds could have a devastating impact on the agricultural industry of California, especially the orange growers. It is also worth mentioning that the Canadian regulatory authorities never intended to regulate chemicals based solely on inherent toxicity.
- Another reference list, “(20) Chemicals identified by the Association of Occupational and Environmental Clinics as occupational asthmagens,” was also clearly never intended for use in a regulatory framework. The AOEC website states as much: “[This list] is not an official document of any governmental agency nor is it intended to be considered the final authority...”¹
- Several of the lists (ex. 7, 9, 27 and 28) lack the applicable region or regulatory body for identification of appropriate criteria.
- Lastly, reference list (18) Japan International Center for Occupational Safety and health List of mutagenic Chemicals refers to the list of a Center that has been closed since 2008.² We question whether the list is still valid and relevant under these circumstances.

Like the members of the Green Chemistry Alliance, the FMA is highly concerned that the scope of the current proposal is far reaching and fails to focus on materials 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 and 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.

¹ <http://www.aoec.org/tools.htm>

² <http://www.jniosh.go.jp/icpro/jicosh-old/english/topics/mutagenicchemicals/mutagenicchemicals.html>

The broad pathways would result in an infinite number of chemicals and products being covered and subject to a costly and onerous alternatives 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 FMA supports the GCA's approach as laid out in their June 24, 2009 proposal. 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. Likewise, as previously stated, FMA cannot support a proposal which has not applied the necessary list integrity or taken into consideration the extensive safety evaluations that already exist on our materials.

For these reasons, FMA urges the Department to reassess the methodology underpinning the Safer Alternatives Regulation and to consider the GCA framework in developing a workable solution. If you have any questions regarding the FMA's position on the current Straw Proposal, please contact Sarah Mechum, FMA's Assistant Director of Government Relations at (202) 331-2463.

Sincerely,

//original signed by//

Jennifer Abrill
Executive Director

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

Dear Director Movassaghi:

On behalf of Funrise Toy Corporation, 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 Funrise Toy Corp. 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).

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.

Funrise Toy Corp. is highly concerned the scope of the current proposal is overly broad and fails to focus on the greatest risks to human health and the environment. As drafted the proposal would result in an infinite number of chemicals and products being impacted 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 included in the

proposal, with the potential outcome of having to defend our good faith efforts at compliance in the courts.

Funrise Toy Corp. supports the Green Chemistry Alliance'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:

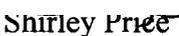
1. Prioritizing chemicals for review,
2. Evaluating how those chemicals are used in consumer products,
3. Assessing whether they pose a potential risk to public health,
4. Examining potential alternatives, and
5. Instituting a regulatory action if necessary.

Funrise Toy Corp. strongly believes, any action by the Department should be scientifically based and narrow in the scope of chemicals addressed; otherwise, 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, Funrise Toy Corp. 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 Funrise's position on the current Straw Proposal, please contact Arnie Rubin at (818) 883-2400. Thank you!

Sincerely,

//original signed by//


Chief Operating Officer

Cc: Linda Adams, Secretary of CalEPA



Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

Alliance of Automobile
Manufacturers

American Chemistry Council

American Forest & Paper
Association

California Chamber
of Commerce

California League of Food
Processors

California Manufacturers
& Technology Association

California Paint Council

California Restaurant
Association

California Retailers
Association

Can Manufacturers
Institute

Chemical Industry Council
of California

Citizens for Fire Safety
Institute

Consumer Healthcare
Products Association

Consumer Specialty
Products Association

Grocery Manufacturers
Association

Industrial Environmental
Association

Metal Finishing
Associations of Northern
and Southern CA

National Paint and
Coatings Association

Personal Care Products
Council

Plumbing Manufacturers
Institute

Soap & Detergent
Association

TechAmerica

Toy Industry Association

Western Plant Health
Association

Western States Petroleum
Association

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 numerous trade associations and individual companies which comprise the Green Chemistry Alliance (GCA), we respectfully submit the following comments regarding the Safer Alternatives Regulation Straw Proposal (~~Straw Proposal~~). While the GCA and its members appreciate the complicated nature of drafting the Safer Alternative Regulation (~~Regulation~~), we are extremely concerned with the framework under the Straw Proposal. In a proactive fashion and per the Department of Toxic Substances Control (DTSC) request, GCA members put countless hours into developing regulatory text and comments for implementing the Regulation. The GCA comments, none of which are reflected in the Straw Proposal, were submitted to DTSC on June 24, 2009. Although the Straw Proposal is not a formal draft regulation at this time, the proposed program, if it were to be implemented, would have sweeping adverse ramifications on virtually all industry sectors which manufacture or sell consumer products in the state. The Straw Proposal simply does not reflect the intent or the statutory authorities of the enacting legislation. In fact, the current Straw Proposal exceeds, in many aspects, the authority delegated to DTSC to develop Green Chemistry regulations. See Appendix 1.

The GCA is an alliance composed of business trade associations and companies which lobbied effectively during the closing weeks, days and hours of the 2008 California legislative session in support of bi-partisan measures to create a new, science-based framework for managing chemicals of concern in consumer products under the Green Chemistry Initiative. The driving force behind the legislation was a broad based desire for state regulators, rather than the legislators, to exercise their expert scientific and engineering judgment and experience when evaluating potential threats to human health or the environment and to determine appropriate regulatory actions.

In the wake of this groundbreaking legislation, the GCA was formalized for the purpose of constructively informing the implementation effort such that the promulgated regulations remain true to the objective and scientific ideals of the authorizing legislation. The GCA and its members appreciate the work DTSC and other interested stakeholders have put into the process thus far and the GCA is committed to working with all parties to craft reasonable and effective regulations that reflect the intent and specific requirements of Assembly Bill (AB) 1879 (Feuer) and Senate Bill (SB) 509 (Simitian).

While the Straw Proposal of October 1, 2009 has been characterized by DTSC as a catalyst for further discussion and not as a formal regulatory proposal the extreme breadth and complexity of this proposal defies any reasonable interpretation of the enacting legislation. As written, the proposal is entirely unworkable.

The proposal is so seriously flawed that GCA sees no merit in editing or refining the current document in a manner that it might be used as a starting point for further rule development. Instead, GCA is compelled to point out some of what we view as major deficiencies.

Scope of the Straw Proposal

The scope of the current proposal is overly broad and fails to focus on consumer products that may potentially present significant threats to human health or the environment. This is partially attributed to a very broad definition of "consumer product" that could conceivably include both traditional consumer end products and raw materials and chemicals used throughout commerce. Although food, pesticides, prescription drugs, durable medical equipment, dental amalgams and mercury lighting are specifically exempted under AB 1879, the upstream feedstocks and intermediates used in the manufacture of the final consumer products have been interpreted by DTSC (DTSC Workshop on 10/21) to fall within the definition of a consumer product thereby subjecting the basic chemical building blocks to the same Safer Alternatives regulation as an end use consumer product.. The whole notion of including California manufacturers' feedstocks and upstream manufacturing intermediates as "consumer products" has serious consequences. Conceivably it would result in the untimely elimination of those feedstocks, intermediates and associated manufacturing from the California market place.

Additionally, despite specific statutory direction prohibiting DTSC from enacting regulations that conflict with, or are duplicative of, other regulations (See SB 509, H&S Code Section 25257.1), the breadth of the current proposal will result in duplicative and potentially conflicting regulation for many products subject to the authority of other federal and state agencies.. This problem is further complicated by the inclusion of four distinct pathways into the regulatory process:

- a. Eleven (11) consumer product categories that are not well defined;
- b. Sixteen (16) pre-designated "chemicals of concern" that lack any coherent foundation;
- c. Chemicals identified by twenty-nine (29) different state, federal and international sources; and
- e. Thirteen (13) hazard criteria, applicable to every detectable chemical in the product;

These pathways would result in roughly 10,000 chemicals and hundreds of thousands of products being subjected to alternatives analysis and resultant bans within two to twenty years. This extreme approach seems to defy the fundamental reality that potentially toxic effects are related to chemical reactivity. In that context, blanket chemical prohibitions risk denying society the very utility and value inherent in the reactivity of the chemical. The key to societal benefit and value is not to prohibit chemical use because of hazard, but to ensure that the reactivity associated with that hazard is harnessed safely, the key to which is consideration of exposure. By mandating sweeping phase-outs of vast numbers of chemicals and products based solely on considerations of hazard as called for in the Straw Proposal, the department would effectively preclude Californians from realizing the benefit from those chemicals and products.

It is not clear how manufacturers could ever 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, not to mention the likelihood of

different and perhaps conflicting interpretations among manufacturers encompassed in the Straw Proposal. Further, small manufacturers and retailers subject to this process will be hard pressed to pay for the sheer costs of compliance requirements envisioned under the program outlined in the Straw Proposal. In fact, the compliance cost burden (see *Cost Implications for California* below) for even largest manufacturers and retailers would be enormous and wasteful if the Straw Proposal was implemented.

GCA proposes that DTSC craft a more manageable approach that focuses initially on chemicals with the greatest hazards – 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. As discussed in greater detail in Appendix 2, this universe of substances should be further prioritized. Following a prioritization of chemicals, DTSC should then prioritize products containing intentionally added chemical ingredients in concentrations above applicable thresholds and products containing chemical ingredients which pose more than a *de minimis* exposure threat during use and at end of life. In this manner DTSC will have fulfilled the legislative mandate of AB 1879. However, if DTSC fails to implement a science-based approach to screening out products with low likelihood of harm, the program will surely collapse under its own weight.

Identification & Prioritization; Hazard Traits; Authoritative Bodies; Consumer Product Categories; Toxic Information Clearinghouse

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

The first step of the Regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. The Straw Proposal does not contain an objective, criteria-based process for identifying potential health and environmental threats from chemicals of concern in consumer products, nor does it establish a meaningful process for prioritization. In fact, it accomplishes just the opposite, encompassing over 10,000 chemicals—8,000 from the referenced lists and an estimated additional 2,000 from the hazard trait pathway. It also encompasses hundreds of thousands of products—virtually every consumer, commercial, construction, fertilizer and industrial product and chemical—sold in California commerce and used in California research. Since it focuses not on intentionally added chemical ingredients, but on 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.

According to the Straw Proposal identification, assessment and simultaneous supply chain communication must be completed in two (2) years and every two (2) years thereafter. This requirement would be unworkable even with a reasonable number of priority chemical/product combinations, but clearly impossible considering the size and scope of the proposed effort. Every detected chemical of concern triggers a ban from California commerce both of the products containing the chemical and the chemical itself within two to twenty years - in spite of the fact that the statute provides for eight (8) additional regulatory response actions. A ban would not necessarily be limited to the traditional products in commerce, but could also eliminate research involving the chemicals of concern or products containing the chemicals,

perversely prohibiting Green Chemistry advancements in California. Also, in some cases prior to the ban, an end of life management program must to be set up by the manufacturer.

This extremely burdensome process is triggered not as a result of the likelihood of harm, but merely resulting from the detectable presence of the chemical in a product, even if it is merely a trace chemical in the product's water source or other relatively benign intermediate(s) used in making the product.

Meanwhile, scientists at DTSC have no role in considering the safety of chemicals and their uses, and which uses of chemicals are a real concern for human health and the environment and thus should be subject to certain regulatory responses. Moreover, DTSC does not appear to have considered the myriad of other state and federal programs that also regulate chemicals and consumer products. Thus the breadth of the Straw Proposal results in duplicative regulation. The net effect is an overly broad, nonfunctional and infeasible scheme. The Green Ribbon Science Panel (October 14, 2009) and nearly all stakeholders raised these very concerns. Dr. Klaus Berend a European Commission Fellow at UC Berkeley, in comments to the Panel captured the views of many regarding this issue, stating, “. . .when everything is of concern, then nothing is of special concern.”¹ See Appendix 2 for detailed comments regarding this section.

Alternative Analysis and Life Cycle Assessment (LCA)

The Alternatives Analysis and Life Cycle Assessment need to be considered in light of the mandate of AB 1879, which calls for ~~a~~ process for evaluating chemicals of concern in consumer products and their potential alternatives, *to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.*” It mandates further that the process must ~~include~~ an evaluation of the *availability of potential alternatives and potential hazards* posed by those alternatives, as well as an evaluation of *critical exposure pathways.*” It is also required to ~~include~~ life cycle assessment tools that take into consideration” thirteen (13) economic and scientific parameters listed in the statute.

The alternatives analysis and related life cycle assessment mandate of the Straw Proposal imposes an incredible burden of data production, analysis and reporting that threatens to seriously compromise the use and availability of a very broad range of consumer products. By compelling every manufacturer in vast product categories to undertake these burdensome analyses for every single product in those categories, DTSC not only imposes an enormous economic burden, but it threatens to undermine the development and availability of new and improved products which is the very purpose of the Green Chemistry Initiative. See Appendix 3 for detailed comments regarding this section

¹ Dr. Berend is Head of Unit in the European Commission's Directorate-General Enterprise & Industry, Chemicals Unit, which among others, is responsible for the Community legislation concerning restrictions on the marketing and use of dangerous substances and preparations, the classification and labeling of dangerous preparations Good Laboratory Practices (GLP), detergents, fertilizers, and explosives. The unit also deals with the sustainability and competitiveness of the chemicals industry in the European Union.

Cost Implications for California

GCA believes that if implemented Straw Proposal would result in economic cost to industry and the State of California that are unsustainable. Absent the opportunity to do a thorough cost analysis, a rough comparison can be drawn to the cost estimate for the EU REACH program. The European Union (EU) Commission estimated cost of implementation at \$4.2 – 7.6 billion amortized over the eleven (11) year period of implementation. Since the pre-registration phase, estimates from other sources have suggested that this may be overly conservative.

REACH assumes that industry will consolidate data and perform data quality assessments in Substance Information Exchange Fora (SIEFs). Substance manufacturers are charged to perform these assessments with limited participation by downstream users. The most comprehensive evaluations and analyses are conducted on Substances of Very High Concern (SVHCs). To date, nineteen (19) chemicals have been formally identified as SVHC, although there have been calls by some stakeholders to increase that to approximately 400 chemicals. The proposed California program anticipates evaluation in one (1) year, so costs are not amortized as they are in the EU. Instead California's program will be substantially more costly to manufacturers. The program includes virtually all downstream chemical users, many of whom have never before been required to assemble and evaluate hazard data or to conduct alternative assessment and lifecycle analysis. The evaluation requires extensive evaluation of an estimated 10,000 chemicals, with no consideration given to data confidentiality or data quality concerns. Where EU requires consolidated substitution plans from SIEFS or manufacturers only after an authorization finding on SVHCs. California is anticipating substitution plans by consumer product manufacturers for all products containing detectable levels any of 10,000 chemical of concern.

GCA contends that manufacturer compliance with this program will lead to excessive economic impacts and substantial job loss, especially due to businesses that will be forced to move out of state. Furthermore, the application of the Straw Proposal would hinder the ability of out of state manufacturers to sell their products in California. The benefits of Green Chemistry can be achieved in a much more economical fashion than is provided in the Straw Proposal. The added burden described suggests that there is a multibillion dollar cost to implement this program with no opportunity to benefit from other chemical management program experience or data gathering/assessment.

If you have any questions regarding the Green Chemistry Alliance (GCA) and its members' position on these and other components of the Safer Alternatives Regulation Straw Proposal, please contact John Ulrich at (916) 989-9692 or Dawn Koepke at (916) 930-1993. Thank you!

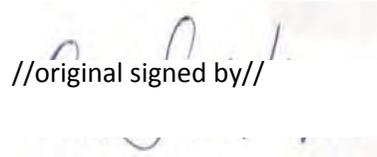
Sincerely,

//original signed by//



John Ulrich
Co-Chair
Chemical Industry Council of California

//original signed by//



Dawn Sanders Koepke
Co-Chair
McHugh & Associates

Green Chemistry Alliance Signatories

American Apparel & Footwear Association
American Chemistry Council
American Forest & Paper Association
American Honda Motor Corporation
Amway
Association of Home Appliance Manufacturers
Association of International Automobile
Manufacturers
BASF
The Boeing Company
BP
California Aerospace Technology Association
California Chamber Commerce
California Grocers Association
California Healthcare Institute
California League of Food Processors
California Manufacturers & Technology Assoc
California Paint Council
California Restaurant Association
California Retailers Association
Callaway Golf
Can Manufacturers Institute
Chemical Industry Council of California
Chevron
Citizens for Fire Safety Institute
Consumer Specialty Products Association
Dart Container Corporation
Defoamer Industry Trade Association
Del Monte
Dow Chemical Company
DuPont
Ecolab
Fashion Accessories Shippers Association
Florida Chemical Company, Inc.
Fragrance Materials Association
Grocery Manufacturers Association
Hyundai-Kia America
Industrial Environmental Association
Information Technology Industry Council
Johnson & Johnson
Kern Oil & Refining Company
Life Technologies Corporation
Metal Finishing Associations of Northern &
Southern California
National Aerosol Association
National Paint & Coatings Association
Northrop Grumman
Personal Care Products Council
Phoenix Brands
Plumbing Manufacturers Institute
Procter & Gamble
Reckitt Benckiser
Safeway
Soap & Detergent Association
Solar Turbines
TechAmerica
Toy Industry Association
Travel Goods Association
United Technologies
Western Growers
Western Plant Health Association
Western States Petroleum Association
Western Wood Preservers Institute

CC: 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

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The Straw Proposal is Arbitrary, Capricious & Lacks Evidentiary Support

California Code of Civil Procedure (CCP) Section 1085 allows persons to challenge regulations adopted by a state agency on the ground that they are arbitrary, capricious, or lacking in evidentiary support. The GCA submits that the Straw Proposal as a whole is arbitrary, capricious or lacking in evidentiary support. Section 6xxxx.2 fails to provide a process or the criteria that were used to establish the list of chemicals or the list of lists of chemical programs. The Straw Proposal discriminates against in-state California manufacturers by considering raw materials as consumer products despite the fact they are consumed in the manufacturing process and do not appear in the final consumer product. This will require in-state manufacturers to comply with the alternatives analysis, while a similar manufacturer of the same product out of state is exempt from this expensive and time consuming analysis. In addition to the unfair treatment of in-state manufacturers, the Straw Proposal poses an unbearable burden and cost on all manufacturers; the cost and resources are unreasonable for major manufactures, and even more impossible for small manufacturers.

The Straw Proposal's overly broad scope will require even those statutorily exempt product categories to evaluate the raw materials used in the manufacture of the consumer products and likely limit the availability of certain products in California. See H&S Code §25251(e)(1-10), §6xxxx.1 and §6xxxx.2. The automatic chemical prohibition included in Section 6xxxx.20(c)(3) sets up a process whereby innovation and continuous improvement cannot be achieved. This is because even where a manufacturer has taken the time to decrease the toxic profile by replacing a chemical of concern (CoC) with an alternative, that alternative may in turn be considered a CoC and will ultimately be banned under the Straw Proposal. See §6xxxx.20(c)(3). In addition, even if no alternative is identified, the Straw Proposal requires conducting an alternatives analysis every two years, whether there have been technical developments or any basis for believing that an alternative is available. See Section 6xxxx.13(b)(2)(D).

Furthermore, Section 6xxxx.9 establishes a supply chain information dissemination requirement that contemplates the disclosure of proprietary information to competitors, thereby violating the confidential business information protections established in H&S Code Section 25257. Overall, the Straw Proposal sets forth a scheme that establishes unbearable burdens and cost to manufacturers of consumer products sold in California. By failing to clearly define the processes or criteria relied upon and failing to consider the comments submitted by the industry in an effort to develop a workable process, DTSC has created a regulation that is open to challenge as being arbitrary, capricious and lacking in evidentiary support.

A Process Needs to be Developed for the Identification of Chemicals of Concern

Section 6xxxx.2 (a) establishes a list of chemicals that are chemicals of concern for purposes of the regulation. No criteria or process was identified describing how the list was developed. The statute clearly requires DTSC to develop a process to identify chemicals of concern and does not provide DTSC with the authority to designate a list of CoC. See H&S Code §25252(a). At a minimum, GCA submits that DTSC must establish a process for designating chemicals of concern subject to the regulation.

Additionally, the list of authoritative bodies is not consistent with the requirement that DTSC look at references that have undertaken "similar chemical prioritization processes." See H&S Code §25252(b)(2). Specifically, the statute requires DTSC to consider "(1) the volume of the

chemical in commerce in the state. (2) the potential for exposure to the chemical in a consumer product. (3) the potential effects on sensitive subpopulations, including infants and children." H&S Code §25252(a)(1-3). The statute goes on further to require DTSC to develop criteria by which chemicals and their alternatives may be evaluated including "the traits, characteristics and endpoints that are included in the clearinghouse data pursuant to Section 25256.1." See H&S Code §25252(b)(1). In order for lists to determine chemicals of concern, authoritative bodies should have gone through a "similar chemical prioritization process" for comparable regulatory purposes. GCA is not aware that all of the references listed have gone through such a similar process as required by the statute to identify chemicals as chemicals of concern. We strongly encourage DTSC to review the June 24, 2009 GCA Proposal which includes an initial screening of chemicals to determine if they exhibit one of the following characteristics: substances that cause cancer or developmental or reproductive harm (CMR), or substances that are persistent, bioaccumulative and toxic (PBT). Those chemicals displaying one or more of these characteristics would be identified as a chemical for consideration and would subsequently be evaluated based on potential exposures associated with use and the severity of its hazards prior to identifying the chemical as a CoC. GCA's proposed process complies with the requirements of and direction provided in Section 25252(a).

The statute requires chemicals to be identified and prioritized on the basis of "volume of the chemical in commerce in this state", their "potential for exposure" and "potential effects on sensitive subpopulations." H&S Code §§ 25252(a)(1)-(3). The potential end points and exposures associated with the use of chemicals in consumer products should be considered prior to including the chemicals in a list of CoC. Contrary to the statutory provision, the Straw Proposal includes no process for excluding from regulation products that contain chemicals of concern at *de minimis* levels or that result in virtually no exposure or pose no real likelihood of harm to humans or the environment. GCA has developed regulatory provisions with respect to these issues consistent with the statutory authority. See GCA Proposal June 24, 2009².

Alternatives Analysis Consistency and Life Cycle Assessment Tools

Section 25253(a)(2) directs the Department to develop a process in its implementing regulations to evaluate the "availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways." That process shall include "life cycle assessment tools" that take into account several factors. See H&S Code § 25253(a)(2). The statute further requires DTSC to "ensure that the tools available are in a form that allows for ease of use and transparency of application." See H&S Code §25253(c). However, Section 6xxxx.16 does not identify available tools that should be used to evaluate the life cycle impacts. The nature of LCAs is such that different interpretations can be reasonably made by the evaluators. By failing to identify commonly accepted methodologies, the Straw Proposal creates an evaluation that is highly subjective and will result in inconsistent results. Without clearer and more explicit Alternative Analysis and LCA methodology, tools and guidance, the results will not be comparable, and DTSC's review of reports submitted for similar products will not be meaningful.

Regulatory Response Actions Must be Taken By the Department, Not Manufacturers

DTSC must take the regulatory response, not direct manufacturers to choose one or more of the regulatory responses contemplated by the statute. The statute provides the Department with

² —Comprehensive Proposal for the Implementation of AB 1879 (2008)," Green Chemistry Alliance, June 24, 2009, available on-line at http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/GC_Green_Chemistry_Alliance_Input3.pdf

discretion to take any one of several regulatory responses based on the alternatives analysis. See, H&S Code §25253(b). Further, Section 25253 (a)(1) mandates that the Department establish a process for evaluating chemicals of concern in consumer products and their potential alternatives, *to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.*” Neither of these implies a mandate to ban any product that merely contains a chemical of concern. Quite the contrary, the statute clearly anticipates discrimination based upon limitations in exposure and reduction in hazard. Unlike the Straw Proposal, the statute does not provide the Department with the authority to select just one of the numerous listed response actions as the only response action to which all manufacturers of all affected products will be ultimately subject. See, H&S Code §25253(b) and §6xxx.20(c)(3). The statute contemplates nine response actions that may be taken after the Department reviews the alternatives analysis; eight of these identified response actions do not ban the chemical in the product. See, H&S Code §25253(b)(1-9). The Straw Proposal’s Section 6xxx.20(c)(3), mandates that all chemicals of concern found in all consumer products will be banned in two to twenty years depending on prioritization. This arbitrary selection of one response action without having reviewed the completed alternatives analysis is contrary to DTSC’s statutory authority provided in Section 25253(b).

The GCA Proposal provides for the Department to adopt a regulation and to provide the basis for the specified regulatory actions. As suggested in the GCA Proposal, the Department’s regulations should articulate clearly the factors that the Department will consider when proposing regulatory response actions after the completion of alternative analysis. It is also possible for DTSC to take regulatory action; the Department’s regulatory proposal may undergo either a regulatory process or adjudicative process. To the extent the response action applies to multiple manufacturers, DTSC must proceed against each manufacturer in an adjudicative process or, if it is a rule of general application, DTSC must proceed via regulation. Delegation of DTSC’s responsibility to manufacturers to take regulatory responses based on the alternatives analysis is arbitrary and capricious and will create an “uneven playing field” and will cause confusion in the marketplace. Overall, manufacturers must have due process when faced with significant regulatory action, and due process is not contemplated under the existing Straw Proposal.

Supply Chain Information Disclosure and Data Generation Requirements Overstep DTSC Authority

The statute provides no authority to DTSC to require supply chain communication or dissemination of potentially proprietary information to competitors. Section 6xxx.9 directs manufacturers to provide the entire supply chain with potentially sensitive information. This information disclosure is not required by statute and is inconsistent with the confidential business information protections provided under Section 25257(a). GCA recommends deletion of the supply chain information dissemination section.

Furthermore, the statute does not authorize DTSC to require the generation of data to assess hazard traits of all chemicals and consumer products in commerce as part of the identification and prioritization process (H&S Code §25252) contrary to the provisions of the Straw Proposal. In Section 25253, the Department is authorized to require additional data following completion of the alternatives analysis as a regulatory response. GCA recommends the deletion of this data generation requirement in Section 6xxx.6, and recommends additional data generation be required only as necessary and appropriate after completion of an alternatives analysis.

Avoidance of Duplication of Existing Authority Needs to be Clarified

The statute provides that: "This article does not authorize the Department to supersede the regulatory authority of any other department or agency. The Department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article." See H&S Code §§25257.1(b)-(c). The Straw Proposal does not identify the Department's interpretation of these provisions of Section 25257.1. The regulation should clearly identify what is meant by Section 25257.1(b) and Section 25257.1 (c) to avoid confusion, duplication of, or superseding of existing requirements. The Safer Alternatives Regulation should not apply to products or chemical uses that are regulated by other agencies, however the Straw Proposal provides no guidance as to what would constitute an exclusion from the regulation. The proposed product categories (§6xxxx.1(a)) and listed chemicals (§6xxxx.2(a)-(b)) will result in direct duplication of many existing regulations for consumer products and chemicals. See H&S Code §25257.1(b)-(c).

Further, Section 6xxxx.7(a)(4) requires manufacturers to enter chemical information into the Toxic Information Clearinghouse. This information is duplicative of existing information available through numerous sources including: the US EPA, Health and Environment Canada, OECD's eChemPortal and the significant sources and that are being developed under the European REACH directive. Section 25257.1 is intended to prevent DTSC from frustrating the objectives of other governmental programs and avoid unnecessary costs and confusion to regulated entities by prohibiting DTSC from duplicating existing regulations. Section 6xxxx.7(a)(4) should be deleted as it is inconsistent with Section 25257.1, instead DTSC should use the existing data from other sources to populate the Toxic Information Clearinghouse.

In summary, the regulation should recognize existing laws and regulations that regulate the use of chemicals in consumer products to promote health and safety, and minimize impacts on the environment.

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Article X. Identification & Prioritization of Chemicals of Concern in Consumer Products

This section of the Straw Proposal attempts to identify and prioritize “product categories” subject to the regulation. DTSC has stated in public meetings that its selection criteria (which are not indicated in the Straw Proposal) were intended to identify products to which children and other vulnerable subpopulations may be exposed. While this has some basic logic, the 11 categories identified are overly broad and ambiguous in some cases and completely inappropriate in others. Instead of prioritizing the consumer products considered, the Straw Proposal would encompass hundreds of thousands of products. Even the few product categories exempted from the statute could be impacted by raw material bans. Of further concern, the key operative term used in the Straw Proposal focuses on chemicals “contained” in the subject products with no *de minimis* threshold concentration. Thus any detectible level of any chemical of concern, whether or not intentionally added, triggers regulation and, ultimately, a ban.

Section 6xxxx.1 - Applicability 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 and/or prioritize product classes that would be of highest concern. 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 (8) targets food contact products, which would be duplicative and in direct conflict with existing FDA regulation, and should be excluded. Category (9) targets products designed, or reasonably anticipated, to release any chemicals during intended use and disposal. This is also expansive and not tightly focused. Moreover, considering the capability to detect trace quantities in migration studies, the term “reasonably anticipated” has the potential to greatly expand covered products and must be dropped or more tightly defined to address exposures of real concern. Category (10) covers “Any products that contain” chemicals of concern, essentially sweeping in 100% of commerce in California. In its present format it must be deleted. Category (11) covers every chemical triggered as a concern by the Straw Proposal, essentially setting up direct chemical bans for over 10,000 chemicals in California. In its present format it too must be and dropped. These bans would also, as DTSC interprets the Straw Proposal, 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.

A final provision requires DTSC to evaluate potential additional product categories every two years. Even if the Straw Proposal had more tightly focused product categories, a workable number of chemicals with *de minimis* thresholds, a reasonable scope of evaluation, analysis and regulatory response in the balance of the Proposal, this should be increased to a five (5) year or longer cycle.

Identifying and Prioritizing Chemicals of Concern

The DTSC Straw Proposal does not “establish a process to identify... chemicals of concern” in consumer products contrary to Section 25252(a) of AB 1879. Chemicals identified via the designated list of 16 chemicals, the “List from Lists” and the Hazard Traits are arbitrary. Altogether, the designated chemicals, list from lists, and hazard trait approaches will generate

over 10,000 chemicals of concern.

The Department should identify criteria for focusing on a few of the most serious hazard traits. Such criteria would serve as the initial tool for identifying candidate chemicals of concern. The most severe human health hazard traits, such as chemicals known or presumed to cause cancer, or developmental or reproductive harm (CMR), and most severe environmental concerns, such as chemicals that are known to be persistent, bioaccumulative and toxic (PBT), would be consensus criteria. Severe and chronic hazards, where cause and effect are not easily identified, are clearly higher priority than acute hazards, which are readily noted and for which there are consumer protections and warnings. For severe and chronic hazards, chemicals categorized as known or presumed hazards should be prioritized higher than those categorized as "suspected". Chemicals with multiple severe hazards should be prioritized higher than those with single hazards.

The Proposal also does not establish a process to... prioritize... chemicals of concern" in consumer products contrary to Section 25252(a) of AB 1879 (notwithstanding Section 6xxx.8 which does not constitute a real 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, nor are the same factors applied to "identify" the chemicals of concern which should be included in the program in the first place.

Finally, the process for identification of candidate chemicals of concern should be a dynamic, on-going and iterative process with the most severe hazards being considered first and additional hazards considered in the future.

Section 6xxx.2 - Designated Chemicals of Concern (a) Specified Chemicals. As has been pointed out in both the October 14, 2009 Green Ribbon Science Panel and the October 21, 2009 public workshop by the Department itself, the sixteen (16) named chemicals were not selected in a systematic manner as a result of the application of scientific criteria. As written, the list appears more in line with the chemical-by-chemical ban approach that the Green Chemistry Initiative was intended to avoid. As noted earlier, mere designation of chemicals of concern programs products containing said chemicals for elimination. To take such an extreme action with no foundation of analysis or scientific consideration by the Department would seem to invite charges of arbitrary and capricious action. At the October 21 workshop, staff explained that these represented "placeholders" for uncertainty in science or disagreement among experts. The action taken by listing these chemicals not only fails to resolve or even inquire into that science, it abdicates any scientific consideration in favor of listing and therefore banning all consumer products that contain chemicals of concern as well as the chemicals themselves. This is completely contrary to the legislative premise under which AB 1879 and SB 509 were passed, the need to bring such science-based decisions into the hands of the state's scientists. In all likelihood, this approach merely transfers decision-making on these chemicals to the courts.

Section 6xxx.2 - Designated Chemicals of Concern (b) List from Lists The Straw Proposal identifies twenty-nine (29) reference lists from a broad set of sources that were developed for completely separate and independent objectives. While some of these lists are appropriate for DTSC to use in identifying chemicals for consideration and prioritization, none of the lists, on its own, is appropriate for declaring that a listed chemical and its uses should be banned in California without a deliberate and thorough scientific evaluation of the safety of those uses.

Section 6xxxx.3 - Definitions The definition section of the Straw Proposal poses a number of serious concerns, and need to be significantly reworked. For example:

- a) The definition for "Authoritative Body" is extremely broad. In selecting "authoritative body" references, DTSC should look to government agencies or formalized scientific organizations that satisfy all of the following requirements:
 - 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.
 - It is widely perceived to be objective, scientifically based, and does not engage in advocacy.
 - 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.
 - It publishes its characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications.
- b) The definition for "Chemical Ingredient" is extremely broad. The Straw Proposal defines "chemical ingredient" as any chemical in a consumer product that is necessary for the manufacturing process to produce a product that will function as intended. It should be more focused and changed to "chemical ingredient means any chemical intentionally added to a consumer product to serve a functional purpose in the final product."
- c) The definition for "Chemical of Concern" is indiscriminately broad. The Straw Proposal defines "chemical of concern" as any chemical which is designated, which is present on the list from lists, or which meets any of the hazard category criteria. The definition should be focused on chemicals which have undergone a process of prioritization using criteria for establishing hazard traits and targeting them on the most important threats to human health and the environment.
- d) The definition for "Manufacturer" is not sufficiently precise. The Straw Proposal defines "Manufacturer" as any person who imports, manufactures, assembles, produces, or which packages, repackages, or re-labels under their own brand name, a consumer product. Under the Federal Fair Packaging and Labeling Act, the responsible entity is required to be identified on the package and all consumer protections laws focus on that entity. The Safer Alternatives Regulations should follow that system as well.
- e) The Straw Proposal proposes definitions for existing chemicals and new chemicals, as well as existing uses and new uses of chemicals. These terms are already defined and used under the Federal Toxic Substances Control Act. Use of the terms with substantially different meanings in California will lead to confusion and difficulty with compliance.

The above are cited for example only.

Section 6xxxx.6 - Data Requirements AB 1879/SB509 do 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). In Section 25253, the Department is authorized to require additional data only following completion of the alternatives analysis as a regulatory response.

Section 6xxxx.7 - Hazard Categories The Straw Proposal requires manufacturers to populate the Toxics Information Clearinghouse. This method of creating a database would have no quality control or scientific synthesis. Moreover, the proposal misses the intent of SB 509, which is to develop a web-based portal that can be used to present chemical hazard data that exists in the public domain. There are many sources of such information, which will be expanded extensively in the next few years as REACH data come online from Europe. Over 90% of chemicals that are active in US commerce according to the 2006 Inventory Update Rule are pre-registered in REACH, and over 80% of those are scheduled for REACH submission in 2010. This information together with other existing sources should provide the vast majority of information needed.

Further, the hazard criteria described in this section demonstrate a misunderstanding and misapplication of the Globally Harmonized System (GHS) for Classification and Labeling. GHS was designed to communicate the hazard category of individual chemicals during transportation and handling. The system was neither intended to be used in an approach that provokes a ban on the use of those chemicals in consumer products, nor used to establish a ban on the chemical itself. As indicated earlier, the severity of the hazard traits vary widely and the Department further exacerbates the variation by expanding beyond the highest hazards as identified by GHS Category 1 for each trait.

In the European GHS, there is an application for using a chemical's hazard category in establishing hazard communication for mixtures. That approach recognizes *de minimis* concentration cutoffs that apply to the chemical within the mixture. These cutoffs range from 0.1% to 10% concentration in product depending on the type of hazard and the hazard category. The Department completely ignores this aspect of the GHS, even though the overwhelming majority of products potentially covered by the regulation are, in fact, mixtures of chemicals.

This Hazard Trait section of the Straw Proposal creates its own pathway for identification of Chemicals of Concern that is not highlighted in DTSC presentations, a "Hazard Trait Pathway". In this section manufacturers are required to evaluate each chemical "contained" in a covered product against the hazard trait criteria. With no *de minimis*, this means anything that is detectable is encompassed. So, beyond the evaluation of actual chemical ingredients and over 8,000 chemicals in the list from lists, there may be an array of other traces that would be classified into the hazard traits. Beyond the over 8,000, this Hazard Trait Pathway could contribute over 2,000 additional chemicals of concern to the program.

6xxxx.8 - Prioritization of Chemicals of Concern This section purports to establish a prioritization process for the Safer Alternatives program, but has no practical effect other than to establish the date of the ban for the chemical and products containing it. The three criteria outlined in this section related to potential chemical releases, could play a role in distinguishing the potential for exposure from products and, together with other information, could be useful in prioritizing consumer products. However there are numerous additional considerations that should also be included in such an effort, such as the concentration in product, how the product is used, route of exposure, etc. Importantly, such an evaluation of use and exposure should be part of an upfront evaluation and prioritization that determines whether and when a

chemical/consumer product combination should be selected for alternatives analysis. This would result in actual prioritization in the program and ensure that it focuses on real threats to human health and the environment.

Biomonitoring is suggested as a priority setting tool. Biomonitoring is an indicator of exposure, not a marker of adverse health effects. Both the Centers for Disease Control and the National Research Council have been clear on this point.^{3,4} The Straw Proposal, however, makes the unscientific assumption that presence in the body automatically equals harm. Given the advanced state of analytical chemistry, virtually any chemical whether synthetic or naturally occurring, could be detected in trace amounts in body fluids or tissues. Under the program described by the Straw Proposal, any chemical found in biomonitoring and identified among the 10,000 chemicals of concern would be banned, regardless of the primary exposure scenario or, more importantly, whether the levels detected have any significance to health.

We also note that priority chemicals identified by the California Environmental Contaminant Biomonitoring Program's Scientific Guidance Panel (SGP) and consumer products that contain them are destined to be banned under the Straw Proposal. The purpose of the SGP list is only to narrow the scope of potential biomonitoring targets for the state, with the state making the ultimate determination of what is most important for understanding exposure. The SGP list is not the result of a rigorous weight-of-evidence analysis of potential harm to either human health or the environment. It merely identifies substances for further exposure characterization through biomonitoring. The Straw Proposal gives this source much more weight than is appropriate.

In addition to ensuring the appropriate use of biomonitoring information, there is a need to ensure that biomonitoring information considered in prioritization is of high scientific caliber. The Centers for Disease Control's biomonitoring program is an excellent benchmark for deliberate scientific methodology, and only data from CDC or other programs meeting the CDC benchmark should be used in prioritization.

One-Year Timeframe

The requirement of one year for manufacturers to identify, evaluate and prioritize is impossible to meet, considering the 10,000 chemicals covered by the Straw Proposal, the need to evaluate whether they are contained in hundreds of thousands of products and the absence of a *de minimis* concentration. The Department has an obligation to reach out directly to a range of consumer product manufacturers to learn more about realistic product development and analysis cycles. A one-size-fits-all approach that would apply equally to manufacturers of jet engine components and seasonal holiday decorations is neither reasonable nor workable.

Section 6xxxx.9 - Supply Chain Information Dissemination Requirements The Straw Proposal requires consumer product manufacturers to communicate the absence or presence of chemicals of concern contained in a product; the associated hazard categories; status and final

³ From the CDC Third National Report on Human Exposure to Environmental Chemicals: "Just because people have an environmental chemical in their blood or urine does not mean that the chemical causes disease."

⁴ The National Research Council said in its 2006 report *Human Biomonitoring for Environmental Chemicals* that "[r]esearchers are generating biomonitoring data whose relevance to human health is unclear in many cases." The Council's report also recognized that "[o]ur technical ability to generate new biomonitoring data has essentially exceeded our ability to interpret them."

conclusion of an alternatives analysis (if applicable); and a response action plan when needed to every transferee” throughout the supply chain and to the public via the Internet. This documentation requirement presents a massive administrative burden for manufacturers which have complex distribution paths for delivering product from manufacturing plants to consumers. Manufacturers will have to supply this documentation in California to an endless panoply of trucking, rail, and air delivery, distributors, warehouse and distribution centers, and retailers (ranging from large retail outlets to small corner stores to online and swap-meet sellers). Furthermore, the process would need to be repeated and new updates provided on a two-year cycle as alternatives are re-evaluated. Such data sharing requirements carry with them huge infrastructure costs to develop complex data tracking and notification systems. These types of data communication and development requirements would be cost-prohibitive for small and medium-size companies who do not have the resources or personnel to develop and maintain these systems. It is very likely this supply-chain communication mechanism would result in halting commerce for many industries and product sectors for long periods and with significant economic damage in the form of returned product shipments and halted product orders.

GCA also believes 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 the enforcement of a statutory mandate in California law.

The Straw Proposal has failed to incorporate a procedure for protection of confidential business information (CBI) as required of DTSC in AB 1879 (Section 25257) as information is transmitted along the supply chain. Such information dissemination will make extremely sensitive and proprietary information available to retailers, many of which manufacture and market private label products that directly compete with products produced by branded label manufacturers. The Safer Alternative Regulations should require consumer product manufacturers to submit all information related to regulatory compliance, alternative assessment results and response action plans directly to DTSC as the regulatory authority to avoid loss of CBI protections. Disclosure of such highly sensitive information to retail competitors is a clear conflict of interest for manufacturers.

Retailer Involvement & Associated Challenges

As the conduit between manufacturers and consumers, retailers are occasionally called upon to share important information in the marketplace. In fact they currently operate under a variety of requirements to do so in many areas of their operations. The draft Straw Proposal would impose onerous and overreaching requirements on retailers, distributors, warehouse, transporters and suppliers that are not supported by the underlying statutes. For example, the proposal requires all entities in the supply chain to maintain records documenting compliance with alternatives analysis requirements for a fixed number of years and to forward that documentation to additional parties in the supply chain. The Department was directed to make "feasible efforts to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers and consumers can use to make consumer product manufacturing, sales, and purchase decisions." See H&S Code Section 25253(c). The supply chain dissemination, data retention and management requirements are not simplified nor has DTSC developed an accessible tool. While it is clear that SB 509 authorizes the creation of a clearinghouse, it is also clear that neither AB 1879 nor SB 509 authorizes the DTSC to impose such far-reaching data retention and management requirements via regulation. Implementation and compliance issues should remain the responsibility of appropriate regulatory agencies working directly with affected manufacturers in any final regulations.

Additionally, the draft Straw Proposal does not recognize the complicated nature of California's existing consumer marketplace. Many consumer products are manufactured outside California and in fact outside the borders of the United States. Significant concerns exist regarding manufacturers located outside California that may be unable or unwilling to comply with the requirements of the proposed regulations. The draft seems to place retailers in an enforcement role by prohibiting sale of products when manufacturers are unable to document compliance with the regulations, or requiring them to conduct product analysis on behalf of manufacturers. This is an untenable position given that retailers generally are not knowledgeable or expert in product composition, safety assessment, alternative analysis or life cycle assessment.

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Article XX Alternative Analysis and Life Cycle Assessment (LCA)

The Alternatives Analysis and Life Cycle Assessment need to be considered in light of the mandate of AB 1879, which calls for ~~a~~ process for evaluating chemicals of concern in consumer products and their potential alternatives, *to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.*” It mandates further that the process must ~~include~~ an evaluation of the *availability of potential alternatives and potential hazards* posed by those alternatives, as well as an evaluation of *critical exposure pathways.*” It is also required to ~~include~~ life cycle assessment tools that take into consideration” thirteen (13) economic and scientific parameters listed in the statute.

The alternatives analysis and related life cycle assessment mandate of the Straw Proposal imposes an incredible burden of data production, analysis and reporting that threatens to seriously compromise the use and availability of a very broad range of consumer products. By compelling every manufacturer in vast product categories to undertake these burdensome analyses for every single product in those categories, DTSC not only imposes an enormous economic burden, but it threatens to undermine the development and availability of new and improved products which is the very purpose of the Green Chemistry Initiative.

Not only must each product in each category be assessed against each of the thousands of chemicals deemed ~~of concern~~” and every one of the thirteen (13) hazard criteria, but for every one of those hundreds of thousands of separate products, every manufacturer faces a mandate to identify every possible alternative and subject the original product plus each alternative to a comprehensive life cycle assessment spanning forty-six (46) separate considerations, each assessed against multiple stages of the life cycle. Because there are no provisions to encourage consolidation of these analyses for like-products (through trade associations, for example), the burden of these demands not only falls on each and every manufacturer, this could lead to duplicative and economically wasteful effort on a vast scale across vast stretches of the economy.

Complicating this further is the reality that neither guidance nor certification is provided by the Department on such crucial questions as the definition of ~~functionally-equivalent.~~” This creates the likelihood that any aggrieved party – be it a competitor or public interest – would be able to find some obscure product ~~alternative~~” or can challenge a judgment regarding life cycle assumptions and tie the product up in court, potentially for extended periods of time, during which the ultimate ban is approaching.

No provision is made to accommodate the reality that many products are manufactured by many different manufacturers, each of whom must make independent judgments regarding crucial variables, creating the potential both for different results or for being challenged legally, with little or no guidance and no ~~safe harbors~~” of validated compliance upon which to rely. Multiple conclusions are probable, even for essentially the same product, but none will have any sanction of ~~compliance~~” from the Department. Effectively, each and every manufacturer, no matter how large or how small, faces prospects of having to defend themselves and their interpretations of these very complex requirements in court if they choose to try to market in CA.

The most troublesome impact of the alternatives/LCA process is the chilling effect it will have on precisely what is sought by the Green Chemistry Initiative, namely the development and introduction of new, improved products. This is the result of 1) the very significant economic and time-to-market burden imposed by the analytic requirements for their product and every potentially competing product, 2) the uncertainties associated with the absence of any *de*

minimis level for any of the thousands of compounds that can be grounds for phase-out, and 3) prospects that no matter how diligent they are in pursuit of compliance, any effort to develop new products risks being tied up for indefinite time in litigation over questions of interpretation. All of this must enter the decision calculus regarding the initial R&D investment, where that investment is made, and whether it is worth entering the California market.

Section 6xxxx.12 - Identification of Potential Alternatives This section mandates evaluation of all functionally equivalent potential alternatives within one (1) year from the date a consumer product is prioritized (See Section 6xxxx.18 (a). It is unrealistic to expect any single manufacturer to have knowledge of all possible alternatives. It is also completely unreasonable to provide only one year for the myriad of products to be evaluated and compared to each other on the basis of meeting numerous complicated criteria, much of which may not be made available to the manufacturer.

This section imposes an onerous mandate to conduct a follow-up assessment within just two (2) years if no alternative(s) is found, which is particularly onerous and wasteful in those cases where no new data or technological information is available.

Section 6xxxx.13 - Hazard Categorization Comparison This section specifies that, if alternatives contain a chemical of concern of the same hazard category, they must be eliminated from consideration, unless it can be demonstrated that there will be “no relevant risk of exposure during reasonably foreseeable use of the product.” This standard of “no relevant risk” requires value judgment in the absence of any Department guidance – judgments that are open to legal challenge. Also, this effectively gives priority to the particular hazard category that gave rise to the review. There is no rationale for this *a priori* judgment. Indeed, this mandate could conceivably end up effectively eliminating products that may have very desirable considerations as alternatives.

This section also mandates a follow-up alternatives analysis every two (2) years.

Section 6xxxx.14 - General Requirements for Assessment of Hazards, Exposure and Life Cycle Impacts This section includes mandates to ensure the relevance, completeness, consistency, accuracy and transparency of any hazard, exposure and life cycle assessment, but provides no process, including the possibility of Department review and validation, by which to verify compliance with these mandates.

Section 6xxxx.15 - Methodological Approach for Assessment of Hazards & Exposure This section mandates collection of hazard and exposure information for each chemical of concern in each product evaluated. Given the very large number of chemicals deemed “of concern” by virtue of the “list from lists” approach taken, this will be enormously complicated, particularly for complex products. As stated above, the mandate for defining products of concern also extends to any product containing chemicals that meet any of the very extensive hazard criteria, with no *de minimis* level. This potentially draws in many products containing trace substances..

The hazard criteria iterated in this section add further to complexities of compliance with this mandate. The thirteen (13) hazard criteria upon which each and every product must focus are not universally accepted, in the first place. There is, for example, considerable scientific debate over the categorization of “endocrine disruption” as a “hazard category.” Despite those uncertainties, this section poses significant risk that a manufacturer could end up with their analysis and the market of their products being challenged not because of any chemical of concern used as an ingredient, but merely by detection of some obscure chemical contaminant at trace levels.

Section 6xxx.16 - Methodological Approach for Assessment of Life Cycle Impacts

The mandate reflected in this section is extraordinarily burdensome and arguably goes beyond the capability of contemporary life cycle assessment methods. Life cycle assessment has advanced considerably in the past decade and is employed widely within industry. However, life cycle assessment is done for products, not chemical substances. Hence, if a chemical substance is used in several very different products, then life cycle assessments would need to be run for all of them. Even similar products from different companies would have very different supply chains, materials used, and other factors that would affect life cycle assessment results.

In the end, even for one alternative analysis, we may be looking at multiple LCA studies. Life cycle assessment is best suited for use in very controlled comparisons with well defined boundaries, where all the variables are well understood and controlled. While the prescriptions of this section may be appropriate in such limited, controlled assessments, the breadth of applicability in the Straw Proposal renders this mandate overwhelming, even for large manufacturers. For small/medium enterprises this will undoubtedly impose impossible resource demands.

The process prescribed by the Straw Proposal requires evaluation of every product and every alternative against eleven (11) economic and thirteen (13) environmental parameters, mandating that information be collected for each process for each parameter. Further, it requires impact assessment against nine (9) ecological parameters, three (3) human health parameters, five (5) resource depletion parameters and five (5) economic parameters, one of which must be “societal externalities” (not defined and no guidance on interpretation). This mandate is stunning in its breadth and resource demands. As the Department heard during the Green Ribbon Science Panel discussion on October 14th, LCAs are very costly and can take several years to complete, even with the availability of dedicated resources/personnel, which many companies especially small “start-up” or “mom and pop” companies simply do not have and cannot afford. The time and costs would vary depending on data variability and availability. LCA results then become obsolete as soon as the product formulation changes.

A potentially serious concern with respect to the mandate for each individual manufacturer to conduct an alternatives analysis of every alternative is whether the manufacturer can adequately secure the information necessary to conduct the detailed analyses discussed above. Such an evaluation would require enough detailed information to enable assessment of chemical makeup and process inputs and outputs for every competitive product. This would necessarily require securing knowledge from competitors, much of which may be in the realm of confidential business information *i.e.*, information on innovating manufacturing processes. No provision is made for handling this circumstance, yet virtually every analysis of every product will confront the manufacturer with the challenge of securing information from competitors (and of course, with having to provide such information to competitors when they conduct a duplicative analysis). In fact, evaluation of life cycle impacts, prescribed by this section, is not limited to evaluation of alternatives known to the manufacturer of the subject consumer products. This obvious deficiency leaves the manufacturer vulnerable to lawsuit for not having thoroughly evaluated all potential alternatives.

The requirement of completing the alternative analysis, life cycle assessment and supply chain communication within one year is completely unreasonable, even for one chemical/product effort, and impossible considering the infinite number that would result from the Straw. There were several examples cited at the Green Ribbon Science Panel that indicated that alternative evaluations could take well over three (3) years. Even when a suitable alternative is identified,

implementation through purchasing, production and distribution into the market can be two (2) to seven (7) years depending on the product type, material sourcing, and R&D cycle.

Requiring this type of comprehensive analysis for every consumer product falling within this broad definition is unnecessary and unworkable practically and economically. It is unworkable practically because the mandated process including a life cycle impact assessment in this section is unclear, lumps in one tool different methodologies that need separate attention, lacks necessary information to be implemented with comparability and consistency in results, and is excessive in its uncoordinated listing of indicators and expansive in the scope of comparisons that are suggested [e.g. comparing plastic with glass, metal]. It is also unworkable economically since the cost of even a single LCA is very expensive and will be translated into substantially higher costs of consumer products in California, or it will lead to abandonment of the California market for those products.

In summary, the regulation should recognize existing laws and regulations that regulate the use of chemicals in consumer products to promote health, safety and minimize impacts on the environment.

* * * * *

APPENDIX 4

Other Issues

It is not the intent of the Green Chemistry Alliance to draft a detailed section-by-section review of the Straw Proposal, however, we are compelled to mention the remaining sections in order to avoid any misinterpretation our silence might otherwise imply.

Appendix 3 deals with alternatives analysis and life cycle assessment, and is replete with comments regarding what GCA views as deficiencies in Article XX of the Straw Proposal. These deficiencies would in many cases have a deleterious impact on consumer products manufacturers' ability to perform meaningful comparisons of all potential alternatives (Section 6xxx.17). While GAC believes it is properly the role of manufacturers to conduct the alternatives analyses and life cycle assessments GCA also believes the DTSC must have an active and determinative role regarding the adequacy and finality of alternatives analyses and LCAs respectively. GCA has observed that the Straw Proposal would establish such a broad and burdensome system with unrealistically short timelines that compliance (Section 6xxx.18) would be virtually impossible absent some type of regulatory relief. In an unconstrained and circular regulatory scheme as suggested in the Straw Proposal, compliance activities would totally eclipse manufacturers' ability to focus on innovation and the development of safer alternatives. Compliance and reducing one's exposure to enforcement action would likely become higher order priorities. See related comments Appendix 2, Section 6xxx.9 - *Supply Chain Information Dissemination Requirements /Retailer Involvement & Associated Challenges*.

Regarding Article XXX, Section 20 - Regulatory Response Actions - GCA believes DTSC, rather than manufacturers, is responsible for selecting scientifically-based regulatory response. The statute provides nine (9) possible response actions which the Department may select following its review of the alternatives analysis. Eight (8) of these response actions do not involve a ban on the chemical in the product, or the product itself. However, the Straw Proposal's Section 6xxx.20(c)(3), mandates that all chemicals of concern found in all consumer products will be banned in two to twenty years depending on prioritization. This arbitrary selection of one response action without having reviewed the completed alternatives analysis is contrary to DTSC's statutory authority provided in Section 25253(b). See Appendix 1 *Regulatory Response Actions Must be Taken By the Department, Not Manufacturers*

As noted above, compliance with the Straw Proposal would be nearly impossible without some sort of regulatory relief. DTSC proposes that the relief come in the form of a variance process (Article XXX, Section 6xxx.21). Given the tremendous burden on manufacturers resulting from alternatives analyses and life cycle assessments, as well as the unrealistic timeline to complete the analyses and assessments, one might think the variance procedure "~~too~~ little - too late." While it would arguably be but a band-aid on a mortally wounded business environment, one might prolong the inevitable by applying for as many band-aids as possible. The predictable result would be a total overload of DTSC's ability to receive and process variance applications in a timely manner. It is entirely unclear what the status would be of an otherwise timely application which DTSC was unable to approve or deny due to backlog. One cannot help but wonder aloud whether a reasonable, upfront, identification and prioritization process (first for chemicals of concern and subsequently chemicals of concern in consumer products) might eliminate the necessity for broad scale variance requests at the backend. A variance process is an important component of any regulatory scheme, but when the variance becomes the norm rather than the exception, one would have to question the validity of the underlying regulatory scheme. The Green Chemistry Alliance document entitled, "*Comprehensive Proposal for the Implementation of AB 1879 (2008)*" provides a sound science-based approach to identification and prioritization of chemicals of concern in consumer products. We recommend it anew for DTSC's consideration. END



November 6, 2009

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

Re: Comments on Draft Straw Proposal for Safer Alternatives Regulation

Dear Acting Director Movassaghi:

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of consumer packaged goods through scientific excellence. The GMA Board of Directors is comprised of chief executive officers from the Association's member companies. The \$2.1 trillion consumer packaged goods industry employs 14 million workers and contributes over \$1 trillion in added value to the nation's economy. GMA has appreciated the opportunity to participate in California's Green Chemistry Initiative, and submits this letter in response to DTSC's October 1, 2009 Safer Alternatives Regulatory Straw Proposal.

GMA supports California's Green Chemistry Initiative (GCI) and supported the passage of AB1879 and SB509 as key elements in establishing authority to identify, assess, and manage high priority chemicals and to establish a portal for chemical safety information.

Properly implemented, the regulations should create an integrated, timely, transparent, stepwise and risk-based process, focused on high priority chemicals of concern, in which the state can: 1) identify the high priority chemicals; 2) identify those products containing high priority chemicals that may pose a safety concern considering product use and exposure; 3) identify whether there are suitable alternatives; 4) make final determinations on regulatory risk management choices as identified in AB 1879; and, 5) establish a useful portal for chemical safety information.

Unfortunately, the Straw proposal accomplishes none of these. Instead, it seems to be trying to accomplish 40 years of green chemistry in 2 years. While the intent may be admirable, it will not work in practice. The Straw is breathtakingly expansive in scope, it

has no meaningful prioritization, and it would be impossible for any company to comply. If implemented, it would collapse under its own weight with no compliance and no Green Chemistry innovation.

Specifically, it would encompass hundreds of thousands of products and over 10,000 chemicals—over 8000 from the referenced lists and an estimated additional 2000 from the hazard trait pathway. Chemicals and products that are already strictly regulated and consistent with GCI's objectives would be unnecessarily subjected to the provisions of the Straw.

Since it does not focus on chemical ingredients or include a de minimis threshold, any detectable level of any of these 10,000 chemicals in a product would trigger a massive alternative and lifecycle assessment, and then an extremely burdensome supply chain communication effort. The identification and assessment must be completed in 2 years. Every detected chemical, if not eliminated within certain timeframes, triggers a ban from California commerce of all products containing the chemical and of the chemical itself. Prior to the ban, an end of life product management program has to be set up by the manufacturer in some cases, independent of any consideration of risk to human health and the environment. The Straw also requires populating the Toxics Information Clearinghouse (TIC) by having every chemical user supply all the data they have, which will not provide the quality control and scientific synthesis that is critical to the value of the clearinghouse for potential users. DTSC has no apparent significant role in regulating this process. Nor is there a role for the public—California consumers—in review and comment on evaluations and regulatory actions. Nor is there a role for the Green Ribbon Science Panel in providing ongoing review and comment as the Initiative proceeds.

Net, the Straw Proposal does not achieve the objective of the statutes to create a deliberate and focused program to drive real health and environmental improvements. Instead, it would create an unfocused and unworkable program doomed for failure. GMA member companies desire a credible, workable, and successful program that can achieve the Green Chemistry Initiative's objectives.

GMA is a member of the Green Chemistry Alliance and supports the Alliance's comments on the Straw proposal. Also, GMA is a member of the Food Packaging Coalition and supports the Coalition's comments on excluding food contact substances from the regulations. In the attachment to this letter, we offer specific comments on topics of particular interest to GMA members.

The Grocery Manufacturers Association remains committed to assisting the Department in developing a credible and workable Green Chemistry program that will not only achieve the Green Chemistry Initiative's objectives, but also be a model for the U.S. If you have any questions or comments, please feel free to contact us. We look forward to our continued work together on this important public policy initiative.

Sincerely,

//original signed by//

Caroline Silveira
Director, State Affairs
Grocery Manufacturers Association
1215 K Street, Suite 1500
Sacramento, CA 95814

Attachment

cc: Linda Adams, Secretary of CalEPA
Cindy Tuck, Undersecretary, CalEPA
Patty Zwarts, Deputy Secretary, CalEPA
Victoria Bradshaw, Cabinet Secretary, Office of the Governor
John Moffatt, Deputy Legislative Secretary, Office of the Governor

Attachment 1—Detailed Comments

PRIORITIZATION OF CHEMICALS AND PRODUCTS

Product Categories. The first section of the Straw identifies “product categories” subject to the regulation. While the logic of focusing on products intended for vulnerable populations is reasonable, the 11 categories identified are overly broad, unfocused and in some cases, completely inappropriate. Instead of prioritizing consumer products covered, the Straw would encompass hundreds of thousands of products. For instance, Category (1) (products designed for use by infants or children) is overly broad and does not identify and/or prioritize product classes that would be of highest concern. 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 (8) targets food contact products, which would be duplicative and in direct conflict with existing FDA regulation and should be dropped. Category (9) targets products designed, or reasonably anticipated, to release any chemicals during intended use and disposal. This is also expansive and not tightly focused. Moreover, considering the capability to detect trace quantities in migration studies, the term “reasonably anticipated” has the potential to greatly expand covered products and must be dropped or more tightly defined to address real exposures of concern. Category (10) covers “Any products that contain” chemicals of concern, essentially sweeping in 100% of physical commerce in California and must be dropped. Category (11) covers every chemical of concern, essentially setting up direct chemical bans for over 10,000 chemicals in California and must be dropped.

Of significant concern, the key operative term used in the straw focuses, not on chemical ingredients, but on chemicals “contained” in the subject products with no *de minimis* threshold concentration. Thus, any detectable level of any chemical of concern triggers regulation and ultimate ban of the product. There can be no workable Green Chemistry program without focusing on intentional chemical ingredients and the establishment of a *de minimis* threshold concentration as a key step in prioritization. The most meaningful health and environmental benefits will be achieved by targeting intentional addition of chemicals to products, and not by scrutiny of insignificant traces.

Chemicals of Concern. The Straw proposal has three pathways for identifying chemicals of concern—16 chemicals designated in the Straw, chemicals in a “list from lists” and chemicals detected in products that have certain hazard traits. Altogether, the designated chemicals, list from lists, and hazard trait approaches will generate over 10,000 chemicals of concern—an entirely arbitrary process. The Straw would ultimately ban all 10,000. These bans would affect reactive bulk chemicals that are transformed in California into innocuous products within manufacturing facilities. This would not only ban chemical use in all 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.

Chemicals should be prioritized with respect to the traits/characteristics they exhibit. The Department should identify criteria for establishing hazard traits that would serve as the initial tool for identifying candidate chemicals of concern. The most severe human health hazard traits, such as chemicals known or presumed to cause cancer, or developmental or reproductive

harm (CMR), and most severe environmental concerns, chemicals that are persistent, bioaccumulative and toxic (PBT), would be consensus criteria. Such severe and chronic hazards, where cause and effect are not easily identified, are clearly higher priority than acute hazards, which are readily noted and for which there are numerous consumer protections and warnings. Chemicals categorized as “known” or “presumed” (Category 1) hazards should be prioritized higher than those categorized as “suspected”. Chemicals with multiple severe hazards should be prioritized higher than those with single hazards.

To make the Green Chemistry Initiative workable, the process should target 25 to 50 high priority chemicals for first cycle, using the criteria discussed above. If only half of those selections come to successful resolution, California will be able to claim much more success than anywhere else on the globe. The process for identification of candidate chemicals of concern should be a dynamic, on-going and iterative process, with the most severe hazards being considered first and additional hazards considered in the future based on the success of the initial program.

Duplication. The Straw proposal would initiate duplication of regulation on many chemicals and products. This is prohibited under the statute, Section 25257.1(c), restricting DTSC from adopting regulations under the GCI that duplicate or conflict with existing or pending regulations of other Agencies that are consistent with the purposes of the GCI. There are several areas of duplication on which the state should not waste its limited resources and open itself up to legal challenges. Two examples:

- Food-contact materials are fully regulated by the U.S. Food and Drug Administration (FDA). Food packaging and other food contact materials are important to ensure the safety and quality of food. Modern packaging is designed to be inert and not transfer its components or have an effect on food. It is also carefully designed to preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf life of products, preventing food waste. FDA, under federal law, has established a comprehensive regulatory scheme to ensure the safety of food-contact materials, which provides a large margin of safety. This regulatory scheme is consistent with the goals and purposes of the GCI and must be dropped from the regulatory proposal.
- Hundreds of chemicals among the 10,000 that would ultimately be banned are safely used in the manufacturing of products that are exempted from the regulation including pharmaceuticals, medical devices, and food. Despite the exemption of these products, the bans would result in operations, manufacturing the products in California, having to move to other states or offshore.

UP FRONT EVALUATION AND WORKPLAN

The Straw proposes that a manufacturer, upon determining the existence of a chemical of concern in a covered product, must move directly into a very burdensome Alternative/Lifecycle Analysis and Supply Chain Communication process. The presumption is that the product is not safe for humans or the environment and must be changed or ultimately banned. A workable process should include an upfront evaluation step that looks at the likelihood of harm from chemicals of concern used as ingredients in consumer products. Europe’s REACH has an evaluation step, why not California Green Chemistry? Such a step would screen out low concerns and focus on real threats to health and the environment.

AUTHORITY/COMMUNICATION/TRANSPARENCY/STAKEHOLDER INVOLVEMENT

The Straw proposes that a significant and burdensome communication program be established for manufacturers to communicate the entire evaluation and analysis to their “supply chain” — literally tens of thousands of transportation, distribution, warehousing, retailing and other entities that exist between manufacturers of products and consumers of products. This puts the “supply chain” in the role of program oversight and enforcement, a role that it cannot fulfill. Nor is it an appropriate assignment. DTSC must be the focus for information, decisions, regulations and enforcement for this program. Manufacturers should communicate the results of their Evaluations to DTSC together with Workplans outlining further work. There should be an opportunity of public comment. This needs to include appropriate Confidential Business Information (CBI) provisions to protect trade secrets as mandated in the statute.

ALTERNATIVE ASSESSEMENT/LIFECYCLE ANALYSIS

The Straw proposes a very cumbersome and burdensome alternative assessment and lifecycle analysis process. This massive analysis is required for any Chemical of Concern found in a product beginning with identification of all “Functionally Equivalent Alternatives” including complete redesign of product form. This will be overwhelming even for a single chemical of concern in a single product and impossible with the scope of product categories and chemicals that the Straw proposes to be covered. It is unrealistic to expect any single manufacturer to have knowledge of all possible global alternatives. By placing this mandate, it effectively opens any analysis to legal challenge by anyone who can find an “alternative” anywhere in the world that was not included.

Moreover, the manufacturer must subject the original product plus each alternative to a comprehensive life cycle assessment spanning 46 separate considerations, each assessed against multiple stages of the life cycle. The mandate reflected in this section is extraordinarily burdensome and arguably goes beyond the capability of contemporary life cycle methods. Life cycle analysis has advanced considerably in the past decade and is employed widely within industry. It is best suited, however, for use in very controlled comparisons, where all the variables are well understood. While the prescriptions of this section may be appropriate in such limited, controlled assessments, the breadth of applicability here renders this mandate overwhelming, even for large manufacturers. For small/medium enterprises this may well impose impossible resource demands.

The Straw also imposes a mandate to conduct another assessment within 2 years if no alternatives are found, which is unreasonable.

The alternatives assessment and related life cycle analysis mandates of the Straw Proposal establishes an incredible burden of data production, analysis and reporting. By compelling every manufacturer in vast product categories to undertake these burdensome analyses for every single product in those categories, they not only impose an enormous economic burden, but they also threaten to undermine the development and availability of new, improved products that is the very aim of the Green Chemistry Initiative.

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

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

Alternative assessment and lifecycle analysis are not expertise areas for the department. This is an area that should be the subject of further workshops, bringing in experts to share their experiences, what does and does not work and what resources, scope and time are needed to create a successful program. Several Green Ribbon Panel members suggested establishing a “beta” test to try out a proposed program and to then build from that experience. Such an idea makes eminent sense when establishing an entirely new regulatory paradigm.

As discussed in the Evaluation/Workplan comments, Alternative Assessments should be submitted to DTSC and be given the opportunity for stakeholder comment. This needs to include appropriate CBI provisions to protect trade secrets as mandated in the statute.

REALISTIC TIMELINES

The Straw proposes extremely stringent timelines for manufacturer action—2 years for Evaluation, Supply Chain Communication and Alternative/Lifecycle analysis. This timing would be impossible even if a manufacturer were dealing with just one chemical of concern in one product, no less hundreds or thousands. There were several examples cited at the Green Ribbon Science Panel that indicated such evaluations and analyses could take well over 3 years. Even when a suitable alternative is identified, implementation through Purchasing, Production and Distribution into the market can be two to seven years depending on the product type, material sourcing, and R&D cycle. DTSC needs to set up a system that is realistic, considering these factors, and done in the context of the final regulations as they address the rest of the issues described in these comments.

RESPONSE ACTIONS

The Straw proposes to ban 100% of identified chemicals of concern and all of products containing them. This does not comply with the statutory direction that envisions nine (9) different regulatory responses. While the ban on a particular use of a chemical of concern might be appropriate in some cases, it was clearly not the legislative intent to automatically ban all uses, nor the intent to automatically ban the chemical itself. As indicated in the statute, a range of actions, including no action, are more appropriate in most cases. GCI regulations must better calibrate response actions with the level and likelihood of harm in a particular chemical use. In addition, regulatory responses should be directed by DTSC decision, with the opportunity for public comment and due process.

POPULATING THE TOXICS INFORMATION CLEARING HOUSE

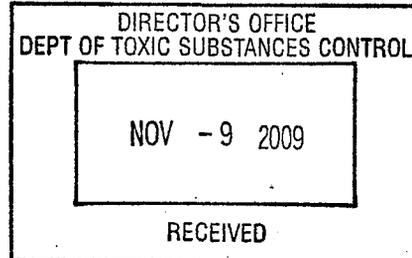
OEHHA and DTSC had initially indicated that the Clearinghouse would be populated by linking to and incorporating existing information—from the US, Canada, Europe and the Organisation for Economic and Cooperative Development (OECD), as directed in the statute to “facilitate the development of regional, national, and international data sharing arrangements to be included in the clearinghouse.” Earlier in the year, DTSC indicated that it was pursuing Memoranda of Understanding with governments to be able to accomplish the objective. We continue to believe that this is the soundest strategy. U.S. EPA has available data on thousands of chemicals. In Canada, the Health and Environment agencies developed data to screen the 23,000 chemicals in active inventory. In Europe, over 90% of the 2006 US IUR chemicals have been pre-registered in REACH and the vast majority of those are scheduled for submission by November 30, 2010. By following the original strategy, more useful and usable information can be made available to Californians much more quickly, with considerably less burden than the approach suggested in the Straw.

Cameron B. Smith Senior Director
Regulatory & Govt. Affairs & Intellectual Property

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November 6, 2009

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



By Telefax (916-324-3158)

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

Dear Director Movassaghi:

Herbalife International is a worldwide marketer of nutritional foods, dietary supplements, and topical personal-care products, with headquarters in southern California and operations in seventy-two countries. On behalf of Herbalife, I would like to convey serious concerns about the Safer Alternatives Regulation Straw Proposal. We believe the Straw Proposal to show a misreading of the purpose of the relevant legislation and to propose an unworkable process.

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. And 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. But absent from the Straw Proposal is any assessment of either the likelihood or severity of exposure to the chemicals. This is an unacceptable omission from a process that should be rooted in the science of risk analysis.

Further, 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 partly because of the very broad definition of "consumer product," which would include not only finished traditional consumer products, but individual chemicals and component parts as well. An infinite number of chemicals and products could be 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.

Herbalife supports the GCA's approach laid out in a regulatory proposal that provided to the Department on June 24, 2009. This proposal would allow a Green Chemistry initiative to be implemented in an efficient and cost-effective way by 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 only if warranted by risk to the public.



HERBALIFE.

Acting Director Maziar Movassaghi
Department of Toxics Substances Control
Page 2

California cannot afford to implement a plan that creates unnecessary burdens upon its businesses while serving no serious public-health concern. Herbalife urges the Department to jettison the Straw Proposal and use the GCA proposal as a workable model.

If you have any questions about Herbalife's position, please contact me. Thank you!

Sincerely,


//original signed by//

Cameron B. Smith
Senior Director, Regulatory & Government Affairs & Intellectual Property

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:

Hewlett-Packard appreciates the opportunity to provide comments and the Department's willingness to consider our input during the development of this important rulemaking. Hewlett-Packard is looking forward to working with the Department as the regulations are refined and finalized.

On behalf of Hewlett Packard, a California-based company, I would like to convey serious concerns with the Safer Alternatives Regulation Straw Proposal as drafted and reviewed at the October 21st 2009 workshop. Although Hewlett-Packard understands the Straw Proposal is not a formal regulation at this time, the program described would have significant implications on Hewlett-Packard doing business in the state of California. As currently drafted, the Straw Proposal does not utilize the harmonization/cost management options or reflect the original intent of the enacting legislation under AB1879 and SB509.

For the California Green Chemistry Initiative to be successful the regulations should;

Focus on key sub-populations and product categories

- Avoid catch-all definitions that will include every product sold in the state of California.
- Differentiate between formulated products versus manufactured articles.
- Utilize the Green Ribbon Science Panel to narrow down the sub-populations, products, and chemicals to regulate.

Select a manageable list of chemicals from recognized sources/regulations in high exposure products to regulate.

- For example the European Union RoHS banned substances and REACH candidate lists.
- Allow for minimum chemical trace limits that can occur unintentionally through impurities in raw or using recycled materials. Without minimum thresholds, it is impossible for producers to declare compliance.
- Allow for application exemptions/usage of a chemical similar to the European Union RoHS exemptions if an entire industry is using a chemical where a viable alternative does not exist.
- When a chemical is selected to be regulated, the regulatory requirements should be focused on the regulated chemical, not every other chemical in the product.
- When a chemical is selected to be regulated, there must be adequate Confidential Business Information protection in place for product content disclosures.

Utilize existing regulations to allow industry to harmonize globally and with California to cost effectively regulate chemicals of concern.

- Consumer Product Safety Improvement Act.
- European Union RoHS
- European Union REACH
- State mercury, lead and PBDE laws
- California Electronic Waste Recycling Act

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

Regards,

Bill Leong

Hewlett-Packard
Americas Region Environmental Compliance Manager

Email: bill.leong@hp.com
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INDEPENDENT LUBRICANT MANUFACTURERS ASSOCIATION

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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 Independent Lubricant Manufacturers Association (“ILMA”) has serious concerns with the “Safer Alternatives Regulation Straw Proposal” (“Straw Proposal”) as currently drafted. Although we understand the Straw Proposal is not a formal regulation, if the program described is formalized, it will have sweeping ramifications on virtually all industry sectors that manufacture or sell a consumer product in California and appears to outstrip the intent of the enacting legislation under AB 1879 (Feuer, 2008).

Introduction of ILMA

ILMA, established in 1948, is a national trade association of 135 manufacturing member companies, some of which are headquartered in California. As a group, ILMA member companies blend, compound and sell over 25 percent of the United States’ lubricant needs, including many private-brand label products, such as motor oils and automatic transmission fluids, that are sold in California in various outlets such as auto parts stores, discount stores and grocery stores, and over 75 percent of the metalworking fluids (“MWFs”) utilized in the machine shops across the country.

Independent lubricant manufacturers by definition are neither owned nor controlled by companies that explore for or refine crude oil to produce lubricant base stocks. Base oils are purchased from refiners, who are also competitors in the sale of finished products. Independent lubricant manufacturers succeed by manufacturing and marketing high-quality, often specialized, lubricants. Their success in this competitive market also is directly attributable to their tradition of providing excellent, individualized service to their customers.

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ILMA's Concerns with the Straw Proposal

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 alternative 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 to 20 years. Further, 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 to 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 current Straw 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 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.

The broad pathways would result in an enormous number of chemicals and products being covered and subject to a costly and onerous alternative assessment. Moreover, 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.

We support the Green Chemistry Alliance's ("GCA") approach laid out in its 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.

Lubricants usually contain greater than 90% highly refined mineral oil with the balance being various additives to provide the technical performance standards needed to ensure high fuel efficiency and protect advanced engines, transmissions and other devices from wear. These additives are contained at very low percentages. These products should be low on a priority list for review because of the low exposure to consumers and the environment. There are many products which consumers have potential exposure on a daily basis that should certainly be examined with a higher priority than lubricants. The Department should implement phase in and de minimis criteria that would be less

onerous to manufacturers of products that are intuitively low risk.

If the Department fails to implement an approach that is scientifically based and manageable in scope, we fear that the original (and commendable) policy objectives may very well be obscured and be placed out of reach. The GCA proposal, as an alternative, is a thoughtful, workable proposal that should be given serious consideration.

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

Sincerely,

//original signed by//

Celeste M. Powers, CAE
Executive Director

cc: Cindy Tuck, Undersecretary, California Environmental Protection Agency
Dan Pellissier, Deputy Cabinet Secretary, Office of the Governor
Peggy Harris, Chief of Intergovernmental Policy, DTSC
ILMA Board of Directors
ILMA SHERA Committee
Dr. Richard C. Kraska



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 Industrial Environmental Association (IEA), I would like to convey our serious concerns with the Safer Alternatives Regulation Straw Proposal as currently drafted.

IEA represents manufacturing, technology, biotech, pharmaceutical and research and development companies in the southern California area. We have closely monitored and participated in the development of California's Green Chemistry Initiative since the first workshops and legislative hearings in the Capitol.

Although the IEA 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).

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.

IEA 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 companies 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.

IEA 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.

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For these reasons, the IEA 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 the Industrial Environmental Association's position on the current Straw Proposal, please contact Patti Krebs at 619-544-9684.

Thank you for your consideration of our comments.

Sincerely,

//original signed by//

Patti Krebs
Executive Director