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

Submitted via Electronic Mail

Dear Director Movassaghi:

I am writing to provide comments on the Safer Consumer Product Alternatives Draft Outline for Regulations dated April 15, 2010. Unfortunately, due to a scheduling conflict, I was unable to attend the Green Ribbon Science Panel (GRSP) meeting held on May 11, 2010. I appreciate the opportunity to provide written comments. I apologize in advance if my comments and questions were addressed at the meeting.

First, I want to commend you and your staff on the significant progress you have made in developing the draft Safer Alternatives regulation and in improving upon some of the concepts presented in earlier straw proposals. Your consideration of input from the GRSP and diverse stakeholders on this important effort is evident in the current outline of the regulation.

I am submitting the following comments and questions to help ensure that California promulgates an effective safer alternatives regulation that protects public health and the environment to the maximum extent possible, and that there is a common and clear understanding of the requirements of the regulation among stakeholders.

I. Scope

A. Applicability

Comments/Questions:

Does the phrase “in California” mean that the consumer products have to be “sold, offered for sale, manufactured, imported, marketed, or distributed” in the state to be subject to the regulation? If so, it is not clear whether the regulation will apply to online purchases of COC-containing consumer products that are offered for sale by out of state companies. For example, aerosol cans of *LPS Instant Super Degreaser*®, which contain 90-95% 1-bromopropane, can be purchased online from Alexandria General located in Parlin, New Jersey (<http://www.alexgs.com/search.php?page=1&q=LPS+Super+Degreaser>). 1-Bromopropane is a Chemical of Concern due to its listing pursuant to H&S Code section 25249.8 as a male and female reproductive toxicant and a developmental toxicant. Similarly, *Spray Grease*®, which contains 40-50% methylene chloride, a

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listed carcinogen and Chemical of Concern, can be purchased online from Ruth Industries located in St. Louis, Missouri
(<http://www.ruthindustries.com/www.ruthindustries.com/products.html#aerosols>).
Recommend clarifying this issue and revising the language, if necessary.

B. Certificate of Compliance

Comments/Questions:

The regulation should specify an “end of sale” deadline for Priority Products that are not subject to the regulation due to the date they were manufactured or imported. DTSC should not allow these products to be sold indefinitely or until the supplies run out. Depending on the product and the amount available for sale, allowing sales to continue until supplies are depleted could have significant adverse public health and/or environmental consequences. The regulation does not appear to address this issue. If it does, it is not clear based on the outline.

D. Information Submittal Requirements

Comments/Questions:

- (1) DTSC should develop and use transparent criteria to determine when to request information from manufacturers. For example, public health concern (substantiated by evidence) by another government agency or members of the public could be a criterion for requesting information. Another criterion could be lack of available toxicological or environmental data on chemicals in consumer products that are structurally related to identified chemicals of concern. Transparent criteria or guidelines that are available to the public, even if they are general, will improve understanding and oversight of this aspect of the regulation.
- (2) Will DTSC evaluate the minimum data sets submitted by manufacturers? Are there sufficient resources and expertise to evaluate the submissions? Obtaining data on chemicals and products but not evaluating the data would be of limited value in assessing their potential impact on public health and/or the environment.
- (3) Will the minimum data sets be available to the public and to other government agencies? Providing access to the information is important for several reasons. It would help to inform the public about products and assist them in making informed decisions—one of the desired outcomes of the regulation. It also would help other government agencies carry out their public health mandates, such as providing early warnings of potential health hazards. In addition, it also could facilitate data sharing among manufacturers, which would reduce the cost of compliance with the regulation. This would be a substantial benefit, especially for small and/or newly established manufacturing firms.
- (4) The “chemical and consumer product marketing data” required by the regulation should be more clearly described. For example, will the regulation require information on potential uses of the chemicals and consumer products, the types of businesses to which the chemicals/products are sold, the names and locations of the businesses, and the amounts sold in a given time period?

- (5) The “chemical and consumer product marketing data” should be available to other government agencies to assist them in carrying out their public health mandates. For example, this information would be very useful to the Occupational Health Branch of CDPH to help in determining workers’ use/potential for exposure to chemicals of concern and in disseminating health hazard and safer alternatives information to affected workplaces.

II. Definitions

○ “Sensitive subpopulations”

Comments/Questions:

Workers should be listed in the regulation as a specific example of a sensitive subpopulation based on their unique fit to the definition of “sensitive subpopulations” on page 3, and the general perception that they are excluded from the regulation since it pertains to consumer products. Workers are a “meaningful portion of the general population” and “can be identified as being at greater risk of adverse health effects”. They routinely can be exposed to high levels of one or more chemicals of concern in several different consumer products during the course of their work. The report, “Occupational Health Hazard Risk Assessment Project for California: Identification of Chemicals of Concern, Possible Risk Assessment Methods and Examples of Health Protective Occupational Air Concentrations” (December 2007) prepared for the Hazard Evaluation System and Information Service, CDPH by the Office of Environmental Health Hazard Assessment, Cal/EPA (<http://www.cdph.ca.gov/programs/hesis/Pages/Publications.aspx>) documents that most of the carcinogens and reproductive and developmental toxicants listed pursuant to Health and Safety Code section 25249.8 that may be found in consumer products are not regulated to protect workers from these serious health effects.

III. Chemicals of Concern Prioritization Process

A. Applicability

Comments/Questions:

- (1) As written, this section does not address the fact that some Chemicals of Concern are sold directly as consumer products in addition to being contained in consumer products. For example, *Klean-Strip® Toluol or Toluene is sold in 1 and 5 gallon volumes at Home Depot, Wal-Mart, and local hardware and home maintenance supply stores* (<http://www.wmbarr.com/product.aspx?catid=21&prodid=106>). Recommend revising to read: *Applies to all consumer products that are listed Chemicals of Concern, or that contain a listed Chemical of Concern.*
- (2) “Public health threat” and “environmental threat” are not listed in Section II, Definitions. Is “threat” supposed to be synonymous with “impact” since “public health impact” and “environmental impact” are listed among the terms that will be

defined? It is important to use consistent terminology since the definitions of public health impact and environmental impact will determine whether the Safer Alternatives regulation applies to chemicals regulated by other government agencies.

- (3) Unless “public health threat” and environmental threat” are defined in Section II, I recommend changing #2 to read: *There are no exposure pathways by which the chemical might have a public health impact or an environmental impact.*

B. Chemicals Under Consideration

Comments/Questions:

- (1) This section should explain more clearly the process DTSC will use to develop the list of Chemicals Under Consideration. Understanding how chemicals get on the list will be a critical issue for most stakeholders. Providing a laundry list of “prioritization factors” that seem to be in random order without explaining how the factors will be used to prioritize chemicals, is not helpful and raises more questions than it answers. Will the prioritization factors be weighted differently or will they have equal weight? For example, will the volume of a chemical in commerce or its use in a consumer product be a major factor in determining whether chemicals with hazard traits as defined in Section II are put on the list? Will adverse impacts on sensitive subpopulations have greater weight than the volume of a chemical? Will chronic toxicity have greater weight than acute toxicity? Will chemicals that enter the body through skin absorption and inhalation be weighted differently than chemicals which enter the body primarily through inhalation?
- (2) The Department will have to use expert judgment to develop the list based on the hazard traits identified in Section II and on other key factors. As a result, it may clearer to state this directly rather than repeating many of the factors that will be identified as hazard traits, and labeling them “prioritization” factors. For example, the regulation could state: *the Department will develop the list of Chemicals Under Consideration based on assessments of a chemical’s potential to impact public health or the environment. In addition to the hazard traits defined in Section II, other factors, including the volume of the chemical in commerce and in consumer products, and the potential for exposure to the chemical or its release into the environment when contained in or sold as consumer products will be considered in the assessments. The specific factors considered in the assessments of the chemicals will be included in the Department’s rationale for listing each chemical.*
- (3) If the list of prioritization factors is retained in the regulation, it should be reviewed and revised to increase clarity. For example, are chemical “traits” the same as chemical “properties”? What is “public health toxicity”? What does “acute or chronic toxicity” mean? Will both types of toxicity trigger listing? Most chemicals are acute toxicants at some dose, so this may be casting an impractical and unnecessarily wide net. Will a developmental toxicant that is not

listed pursuant to H&S Code section 25249.8 be identified as CUC? This is inferred from 4d since H&S Code section 25249.8 is not specified. Does synergistic “potential” mean that synergism does not have to be an established property of the chemical?

- (4) Prioritization factor #6 should be re-worded so that it is clear that the potential for worker exposure is also included. The word “public” could infer that worker exposure to chemicals in consumer products is not subject to the regulation. Recommend revising to read: *Potential for exposure to the chemical...*

C. Chemicals of Concern

Comments/Questions:

- (1) Will “public health threat” and “environmental threat” be defined in Section II or should “threat” be changed to “impact”?
- (2) The Department should develop, use, and make available to the public, the criteria/rationale/guidance it will use to determine what constitutes “greatest threat (or impact) to public health and the environment. The Department should work collaboratively with other government agencies with appropriate expertise and mandates in developing the criteria/rationale/guidance.
- (3) The Department should be required to disclose to the public when and how the availability of resources (or lack thereof) impacts development of the list.

D. Chemical Lists

Comments/Questions:

- (1) The Department should conduct outreach via community groups and labor groups, and use other means to ensure that diverse populations who may be exposed to COCs are aware of the lists and the regulation.
- (2) The supporting documentation for the lists should include information on uses of the chemicals, examples of the types of products they can be found in, and their health effects (cancer, reproductive/developmental toxicity, mutagenicity) and environmental effects (persistence, bioaccumulation). This information will help to provide a context for the chemicals and increase understanding of the relevance of the lists.
- (3) Comments submitted on the proposed lists and the Department’s responses to the comments should be posted on the DTSC website. This information is critical to the public’s understanding of the basis for any revisions to the proposed lists.

IV. Product Prioritization Process

A. Applicability

Comments/Questions:

- (1) Does the de minimis COC concentration of 0.1% in consumer products indicate that the hazard potential of the initial COC categories (carcinogens, reproductive and developmental toxicants, and mutagens) are considered equivalent in the regulation? Under the Hazard Communication Standard, the de minimis concentration of 0.1% applies only to carcinogens.
- (2) What criteria will the Department use to determine whether “regulation by other governmental regulations” adequately addresses public health and environmental threats posed by consumer products? With few exceptions, governmental agencies and departments work in “silos”. As a result, few existing toxic chemicals regulations have been developed with the goal of ensuring that the environment and the health of workers and community members are protected in an integrated manner.
- (3) See previous comments regarding distinguishing between public health and environmental “threats” and “impacts”.
- (4) Recommend revising #2 to read: *There are no exposure pathways by which the COC in the product might impact public health or the environment.*

B. Products Under Consideration

Comments/Questions:

- (1) How will the Department identify the universe of consumer products that contain COCs? Will it rely on self-reporting by affected manufacturers? Surveys? Other methods/sources? The method(s)/information sources the Department uses to develop the list of COC-containing consumer products should be made available to the public.
- (2) The Department should require submission of electronic copies of Material Safety Data Sheets for the listed products, and should ensure that the public has access to them.
- (3) The regulation should describe more clearly how the Department will determine which COC-containing products should be on the list of Products Under Consideration. It is not clear how the prioritization factors will be used to develop the list. Will the factors have equal weight or will they be weighted differently? For example, will the dispersive volume be a major factor in determining whether a product is listed or will the potential for sensitive subpopulations to be exposed to the product have equal or greater weight? Will the COC content of a product (percent volume by weight and/or the presence of more than one COC in a product) be considered in prioritizing the products since it is not listed as a prioritization factor?

- (4) The Department will have to use expert judgment to develop the list of Products Under Consideration. The expert judgment will have to be based primarily on the potential for the consumer products to impact public health or the environment as a result of exposure to COCs contained in the products or their release into the environment. The Department will use the factors outlined in this section to assess the potential for COC exposure and release, and the potential impacts of the products on public health or the environment. Given this, it may be clearer to describe, in general, the process for developing the list of Products Under Consideration rather than providing a list of prioritization factors, which probably will be revised over time, and without explaining how the factors will be used. For example, the regulation could state: *The Department will develop the list of Products Under Consideration by assessing the products' potential to impact public health or the environment through exposure to COCs contained in the products or release of COCs from the products into the environment. A number of factors, including the dispersive volume of the product, containment of COCs in the product, potential of the COCs to migrate or distribute across environmental media, and the types and extent of consumer uses, will be considered in the assessments. The specific factors considered in the assessment of each listed product will be included in the Department's rationale for listing the product.*
- (5) The language in #1 should be revised to ensure understanding that the regulation applies to occupational use of consumer products. The word “public” is often interpreted as excluding workers. Recommend revising to read: *Potential for exposure to the COCs in the product, ...*
- (6) What does 1a, “Controlled access to the product”, mean? This term should be defined in Section II. It may be referring to use of consumer products in workplaces where “controls” are presumed to be in place to limit worker access and exposure to COC-containing consumer products. If so, I recommend revising 1a to read: *Controlled access to the product that has been demonstrated to be effective.* The outbreak of peripheral neuropathy cases among mechanics who used consumer product brake cleaners newly formulated with n-hexane (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5045a3.htm>) is one of many demonstrations that “controlled access” to toxic chemicals in workplaces, although required, is often deficient or non-existent.
- (7) Prioritization factor 1d, “Frequency and duration of exposure for each use scenario and end of life scenario”, is particularly relevant for occupational exposures to consumer products. Similar to the cases of nerve damage referred to above, in which some mechanics used up to nine cans of consumer product brake cleaners a day, workers typically use consumer products in much larger quantities and for much longer periods compared to consumers who use the same products in non-occupational settings. Examples of COC-containing consumer products that workers are likely to use in larger quantities compared to the general public include: *Goof Off Graffiti Remover* (N-methylpyrrolidone); *Outdoor Project Adhesive* (toluene, silica, n-hexane); *Strip X* (methylene chloride); *RSVP High Speed Floor Finish* (dibutyl phthalate); and *Renew White* (trichloroethylene).

- (8) “Controlled distribution systems” should be defined in Section II. What criteria will the Department use to verify that the systems are controlled?
- (9) As written, prioritization factor #3, “Types and extent of consumer uses that could result in public exposure to the COC in the product...”, is not clear. The goal appears to be to prioritize the products based on the severity and magnitude of the potential health impacts they may cause. Based on the various factors listed, the Department apparently will assess who uses the products, how and where they are used, and the extent to which they are used. For example, the use of products by sensitive subpopulations could be expected to increase the severity of potential COC-induced health impacts. Using products in settings where large numbers of people can be exposed (such as nail salons and other service sector businesses) would increase the magnitude of the potential health impacts. Improper disposal of household products containing COCs could lead to environmental contamination, which may also increase the number of people exposed or the magnitude of any potential health impacts. Products used in places frequented by large numbers of sensitive subpopulations (e.g., schools, hospitals, etc.) could affect both the severity and magnitude of potential health impacts that result from COC exposures. If this is the overall goal of the prioritization factor #3, then I recommend revising it to communicate this more clearly.
- (10) Factors 5c and 5d appear to overlap with prioritization factor #1. It is not clear how or if these two factors provide a different basis for prioritizing products, or how they will be used to augment or to expand upon the basis for prioritizing products described in #1.
- (11) Factor 5e is not an appropriate basis for prioritizing products for listing as Products Under Consideration, and should not be used by the Department for this purpose. There is an underlying and incorrect assumption in 5e that workers, customers, clients, and members of the public who come into contact with consumer products or releases from consumer products in workplaces, have equivalent exposures to COCs. By extension, 5e also infers that the health impacts of the COC exposures on these four groups are equivalent. As noted in earlier comments, workers, including furniture strippers, painters, construction workers, plumbers, nail technicians, and auto repair workers, use a variety of COC-containing consumer products. In contrast to customers, clients, and members of the public who are may be exposed for short periods of time to low concentrations of consumer products when they are in workplaces on an infrequent basis, workers who use the products are typically exposed to much larger quantities, on a daily basis, for years. Based on the magnitude, frequency, and duration of their exposures and their greater health risks, and on their unique fit to the regulatory definition in Section II, workers should be identified as a sensitive subpopulation in the regulation.

C. Priority Products

Comments/Questions

- (1) The Department should define “greatest threat or impact”. The Department also should develop and use transparent criteria to identify products that fit this descriptor. The criteria should be available to the public.
- (2) The COC content (type, concentration, and the number of COCs) of the Products Under Consideration should be a factor in identifying the Priority Products. The COC content can be helpful in comparing potential health impacts of products. The concentration of COCs in consumer products (when available on MSDSs) can range from de minimis levels of 0.1% to 100%, and many products can contain more than one COC. COCs that are mutagens should have a lower priority than COCs that are carcinogens and reproductive/developmental toxicants.
 - (a) Examples of consumer products with varying levels of COCs
 - *Super Thoroseal® Waterproof Coating* contains 35% silica. It is available online in 35 lb pails from Ace Hardware stores (<http://www.acehardware.com/search/index.jsp?kwCatId=&kw=thoroseal%20waterproofing%20paint&origkw=Thoroseal%20Waterproofing%20paint&sr=1>).
 - *Latex-ite 5 Gallon Ultra Shield No-Stir Driveway Treatment* contains an undisclosed amount of silica. It is available from Home Depot stores (http://www.homedepot.com/Building-Materials-Concrete-Cement-Masonry-Driveway-Products/h_d1/N-5yc1vZ1xglZarom/R-100508445/h_d2/ProductDisplay?langId=-1&storeId=10051&catalogId=10053).
 - *Klean-Strip Toluol* is 100% toluene.
 - *Goof Off Cleaner VOC Compliant* contains 0.-0.1% toluene.
 - *PL 500 Outdoor Adhesive* contains 5-10% toluene.
 - (b) Examples of consumer products that contain more than one COC
 - *Strip X* contains methylene chloride (30-50% and toluene (1-10%;
 - *Klean Strip Deep Down Stain Stripper* contains methylene chloride (<60% and ethylbenzene (<12%).
- (3) The availability of safer alternatives should also be a factor in identifying Priority Products. Many manufacturers sell safer alternatives to those that will be listed as Products Under Consideration. Some manufacturers sell both COC-containing consumer products and “green” or safer alternatives to the products. It is critical, however, to review MSDSs to determine that the “green” or safer alternatives do not contain COCs. Examples are below:
 - (a) *Möstenböcker’s Lift Off #4* (graffiti remover), available at Home Depot, is a water-based and biodegradable product that contains <10% acetone as the only hazardous ingredient. It is a safer substitute for: (1) *Klean-Strip Graffiti Remover*, which contains 40-60% N-methylpyrrolidone; (2) *Vandal Marker Remover (VMR)*, which contains 15-25% toluene and

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2-5% N-methylpyrrolidone, (3) *Sprayway Gel Vandal Mark Remover 880*, which contains 20-30% toluene and (4) *Taginator Biodegradable Graffiti Removal*, which contains an unspecified concentration of N-methylpyrrolidone.

- (b) Klean-Strip sells a “green” line of products (www.kleanstripgreen.com) in addition to products that contain toxic solvents, including solvents that are COCs (www.kleanstrip.com). *Klean-Strip Green Natural Multi-Purpose Solvent*, which contains >99.0% ethyl lactate (a non-hazardous ingredient), is a safer substitute for the following Klean-Strip products that contain COCs: (1) *Klean-Strip Toluol* (100% toluene); (2) *Klean-Strip Lacquer Thinner* (5-60% toluene); (3) *Klean Strip Lacquer Thinner Supreme* (70-80% toluene); *Klean-Strip General Purpose Automotive Lacquer Thinner* (30-60% toluene).

Two other products that Klean-Strip sells as “green” products contain a COC. *Klean-Strip 1 Gal. Green Safer Paint Thinner* contains 30-50% N-methylpyrrolidone. *Klean-Strip Safer Paint & Varnish Remover* contains 30-50% N-methylpyrrolidone.

D. Product Lists

Comments/Questions:

- (1) The Department should conduct outreach via community groups and labor groups, and use other means to ensure that diverse populations who may use the products are aware of the lists and the regulation.
- (2) The supporting documentation for the lists should include information on uses of the products and the health effects (cancer, reproductive/developmental toxicity, mutagenicity) and environmental effects (persistence, bioaccumulation) of concern. This will help to increase understanding of the relevance of the lists and the importance of using safer substitutes.
- (3) Submitted comments regarding the proposed lists and the Department’s responses to the comments should be posted on the DTSC website. This information is critical to the public’s understanding of the basis for any revisions to the proposed lists.

V. **Opportunity to Petition for Inclusion of a Chemical and/or Product in Prioritization Process**

B. Timelines for Petition

Comment

The Department should document, and make available to the public, the impact that the availability of resources (or lack thereof) has on conducting technical reviews of the accepted petitions.

VI. Alternatives Assessments

A. General Requirements

Comments/Questions

- (1) In lieu of performing an alternatives assessment, will the manufacturer of a Priority Product be allowed to submit a signed, legal document indicating that the Priority Product will no longer be manufactured in California, sold, or offered for sale in California after the date specified in the regulation?
- (2) “Certified Assessor” and “Certified Green Products Assessment Entity” should be defined in Section II.
- (3) Will a manufacturer who obtains an Exemption Certificate based on small business status be able to sell the Priority Product in California?

B. Alternatives Assessment (AA) Work Plan Required Contents

Comments/Questions

- (1) Consistent with 4d, there are many existing products that could be substituted for Priority Products since they do not contain COCs. As a result, manufacturers will be able to get certificates of compliance to sell, offer for sale, manufacture, import, market, and distribute the products in California. However, there appears to be no incentive for manufacturers to identify these non-Priority products as alternatives, since they would be required to conduct comprehensive alternatives assessments on the products. It seems that it would be simpler for manufacturers to continue to sell the alternative products, but not advertise them as being compliant with the regulation. It would help purchasers of consumer products and others if they could readily identify products that do not contain COCs and that were safer alternatives to Priority Products. It also may stimulate the development of compliant products. There is a precedent for this. Due to the stringent air regulations in California and specific chemical bans (such as the chlorinated hydrocarbon solvents ban on auto repair products) many consumer products are specifically formulated to comply with the regulations, are labeled and marketed as such, and therefore are easy to identify.
- (2) The Proposed Methodology (#5) and the Product and Alternative(s) Analysis & Assessment (#6) methodology set a very high bar for identifying products that are safer alternatives to Priority Products. The goal of the Alternatives Assessment appears to be to identify products that conform to the principles of Green Chemistry. This is a noble goal and may be appropriate, but it is inconsistent with the much lower bar the regulation sets for identifying Priority Products that the alternatives would be replacing. The more stringent criteria for identifying safer alternatives is also inconsistent with many of the safer alternative consumer products that have been identified through pollution prevention projects, and with the emphasis of the Safe Cosmetics Act which, consistent with the Safer Alternatives regulation, focuses on COC-containing products.

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- (3) The assessment factors in 6c seem overly broad, and do not seem to be realistic in terms of assessing the health impacts of products and alternatives. The hazard traits that will be used to identify COCs should be incorporated into this section and used as the basis for assessing public health and environmental impacts.
- (4) “Occupational health impacts” are overtly mentioned only in this section of the regulation. Occupational health impacts should be assessed in identifying COCs and Priority Products. As a result, this language should be incorporated, as appropriate, into earlier sections of the regulation.

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