



Alliance of Automobile
Manufacturers

October 21, 2014

American Chemistry
Council

American Cleaning
Institute

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

Independent Lubricant
Manufacturers
Association

Industrial Environmental
Association

Metal Finishing
Associations of Northern
and Southern CA

National Paint and
Coatings Association

Natural Products
Association

Personal Care Products
Council

The Honorable Miriam Ingenito
Acting Director
Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814
(via [California Safer Products Information Management System \(CalSAFER\)](#))

Re: Draft Safer Consumer Products Regulation Priority Product 3-Year Work Plan

Dear Director Ingenito:

On behalf of the Green Chemistry Alliance (GCA) and its coalition members, we respectfully submit the following comments relative to the Department of Toxic Substances Control's (DTSC) draft Safer Consumer Products Priority Product 3-Year Work Plan (Work Plan) which was released for public review and comment on September 12, 2014.

GCA is a highly diverse coalition comprised of national and state trade associations and numerous large and small companies spanning the consumer market and global supply chain. Over the last five years and multiple iterations of the regulations, GCA and its coalition members have largely coalesced around major aspects of the process and continuously offered productive solutions to aid the smooth implementation of the regulation. However, going forward GCA will defer to individual companies or associations to provide detailed critiques of and proposed solutions to the category-specific issues affecting their products. DTSC must be mindful of the unique issues these industries have as they attempt to comply with the proposed regulatory program.

The business community has supported the goal of California's Green Chemistry Initiative to significantly reduce adverse impact to human health and the environment and many of our GCA founding members actively supported the 2008 enacting legislation. These members supported the legislation based on assurances that the subsequent regulatory framework would be anchored in strong science-based hazard and exposure evaluations and priority setting; that innovation would thrive; and trade secrets would be adequately protected. While GCA remains committed to the goals of the legislation, we are concerned that these high standards of scientific scrutiny and priority setting will not be met as a result of this draft Work Plan.

Timeline & Next Steps are Vague, at Best

First, we note the Work Plan does not provide any meaningful discussion of next steps or timing. Instead, the document merely provides a recap of the items discussed to date or that have been completed. The Work Plan does not appear to be a “Work Plan” in any traditional sense, as one would expect an operational work plan to layout not only the current state but also the upcoming events and timing for the program. Further, given this is a short-term, three year plan, it arguably should contain a level of specificity commensurate with that time horizon.

In its Work Plan, DTSC has identified seven Priority Product Categories. Many of the categories identified are quite broad, however, and could theoretically include literally thousands of products, thus covering a significant amount of products within the panoply of consumer products that exist in California’s stream of commerce. It is difficult to imagine what future implementation will look like and how the regulated community should adequately prepare when thousands of products may fall within the regulation’s reach in the short-term.

Additionally, the Candidate Chemicals list includes well over a thousand chemicals. DTSC has indicated it intends to select 5 to 10 Priority Products per year total from within the seven categories. GCA notes that this would represent potentially 15 to 30 Priority Products over the three-year time horizon for this Work Plan. Unfortunately, there is absolutely no discussion within the draft Work Plan to elucidate how DTSC intends to proceed to narrow the universe of products within the seven categories from thousands of potential products to only 15 to 30. In other words, what specific set of rubrics will DTSC rely upon during the next three years as the Department moves to select the next group(s) of proposed Priority Products from this incredibly large candidate pool? A traditional work plan would include such information, and hence DTSC’s draft Work Plan is seriously deficient in this regard.

Regulatory Duplication, Superseding of Authority

The statute is clear on the matter of regulatory duplication. Specifically, the regulation states that DTSC is not authorized to supersede the authority of other agencies and that the DTSC shall not duplicate or adopt conflicting regulations for products and chemicals already regulated or subject to pending regulation. (Health and Safety Code, §25257.1(b) and (c))

As currently drafted, however, the Work Plan exceeds DTSC’s legal authority by listing a number of currently regulated products and chemicals. During the development of the SCP regulation, GCA and its coalition members repeatedly expressed significant concerns with the broad discretion DTSC reserved to itself in listing and reviewing whether a product-chemical combination should be subject to the regulation. The Department appears to have ignored the direct statutory prohibition against superseding, conflicting with and duplicating the authority of any other state or federal agency and regulation. The enacting statute under SB 509 (Simitian, 2008; Health & Safety Code §25257.1(b) and (c), is clear on the matter, with two applicable provisions:

(b) This article does not authorize the department [DTSC] to supersede the regulatory authority of any other department or agency.

(c) The department [DTSC] shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.

As currently drafted, the Work Plan contains a number of examples within its Potential Candidate Chemicals where a state or federal regulatory program already exists and addresses these same chemicals and products. The California Air Resources Board (ARB) for example, has an aggressive program to eliminate volatile organic compounds from chemically formulated consumer products including cleaning products. Additionally, FDA is currently in the process of a rigorous review of triclosan as an antimicrobial agent in various products. Further, triclosan used in products as an antimicrobial agent is regulated by FDA as an over-the-counter consumer antiseptic drug product for some products and by USEPA as a pesticide for other products. FDA's and USEPA's authority in the above example provide a level of public health consideration that is equivalent to or greater than the protection that would potentially be provided if the product were listed as a Priority Product by DTSC. GCA and its coalition members do not believe the Department should attempt to conflict with or duplicate the activities of ARB, FDA, USEPA and others in these areas. Indeed, our position on this matter is premised not only policy beliefs, but on strict legal grounds. Further, we believe the Safer Consumer Products program does not apply to any such products under § 69501(a)(3)(A) of the regulations.

GCA calls upon the DTSC to focus the Work Plan on those product categories, products and chemicals for which there is a regulatory gap resulting in an inadequate level of public health or environmental protection.

Prioritization Process Lacks Clarity

During the regulatory drafting process, GCA and coalition members provided numerous recommendations regarding the prioritization process that would enable DTSC to make quantitative comparisons of hazard and exposure thereby facilitating accurate priority setting with focus on those chemical/ product combinations exhibiting the greatest likelihood for serious and widespread human health and or environmental exposure. GCA remains firm in its belief that DTSC must employ a rigorous, reproducible, and transparent scientific process for selecting Priority Products.

Health and Safety Code Section 25253, subsection (c), makes it expressly clear that in developing the processes and regulations, the Department must do the following:

“[E]nsure that the tools available are in a form that allows for ease of use and transparency of application. The Department [DTSC] shall also make every feasible effort 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”

- Health and Safety Code Section 25253

Instead, DTSC envisions a “narrative standard” that will allow for the subjective regulatory selection of a chemical-product combination based on perception rather than a combination that truly poses the greatest potential for harm. This was not the intent of the enacting statutes or that of the Legislature in passing the measures. The Legislature concluded that a meaningful prioritization was necessary to achieve this objective to “address the worst first,” and yet the Work Plan’s lack of a defined prioritization process seems to reflect a subjective, non-scientific approach. This is further borne out by the fact that the seven

chosen product categories were listed without clarifying how or why these seven were chosen.

DTSC's Priority Products prioritization process should be clear and transparent to the regulated community and broad public while sending discernible market signals. More specifically, an objective, step-by-step process should be constructed, based on credible, scientifically valid criteria that clearly outline the process by which DTSC will identify priority products. GCA has repeatedly held that the use of a highly subjective selection process based on a narrative standard is not acceptable from a scientific or public policy standpoint – it will only serve to politicize the process that was originally intended to rely on science-based decision making.

As noted by DTSC, the Work Plan is “intended to provide a higher level of predictability regarding potential future regulatory actions by DTSC” (Work Plan, page 4). DTSC is anticipating that manufacturers will examine the list of Priority Product Categories and Candidate Chemicals and proactively begin the process of developing safer alternatives in advance of their possible selection. However, each of the categories provided by DTSC includes potentially thousands of products, not just a product that will be evaluated for potential future action. There is no possibility for manufacturers to predict or gather information based on what DTSC has provided. The broad categories only serve to confuse and frustrate. DTSC instead indicates which industries might be impacted, and in doing so fails to focus on what products might have a greater likelihood of being subject of further DTSC review.

Chemical Categories/Listings Too Broad

With regard to the chemical categories listed in the Work Plan, we note a number of inaccuracies and mischaracterizations associated with the examples in the tables regarding Potential Candidate Chemicals. Some such examples include, but are not limited to, the following:

- Fish and angling equipment, the Work Plan states “[p]roducts in this category contain a variety of chemicals that appear on the Candidate Chemicals List, including metals such as lead, zinc and copper.” However, the Potential Candidate Chemicals table (Table 6) states “Metals”. The table should be revised to specify copper, lead and/or zinc or any other metal which may be a Potential Candidate Chemical.
- Aldehydes – this is too large of a chemical/chemical category. DTSC should be more specific on the intended category. The functions are not obvious for the intended scope. They should try to align as best as possible with the INCI dictionary functions. GCA coalition members do not see the functions “modifier” or “cross-linking” agent in the INCI dictionary for aldehydes.
- Formaldehyde – is not an ingredient in personal care products. With the inclusion of “preservative” as a function, it is more likely DTSC is referring to formaldehyde releasers; however, it is important to note that formaldehyde releasers have a different hazard profile than formaldehyde. As such, the Work Plan needs to clarify the intent and scope associated with this chemical/chemical category. Additionally, the Cosmetic Ingredient Review (CIR), which assesses the safety of cosmetic ingredients, concluded that formaldehyde and methylene glycol were unsafe to use in hair straighteners, and consequently most companies have formulated away from

its use. In the extreme case of Brazilian Blowout, which is referenced in the Work Plan, the company failed to disclose high levels of formaldehyde contained in the product. Regardless, formaldehyde is not an endorsed ingredient in personal care and beauty products.

- Dyes – for personal care products, manufacturers can only use FDA-approved colors. As such, any regulations on dyes could directly conflict with federal regulation which is not authorized by statute.
- Coal tars – the reference is vague and needs clarification. Pharmaceutical coal tar, for example, is a drug active that is already regulated by the FDA and further action for this specific chemical category would be unauthorized.
- Phthalates – the reference is too broad.

DTSC should correct inaccurate chemical listings associated with various products/product categories and clarify its intent regarding the scope of chemicals/chemical classes to be considered as part of the Work Plan.

Timelines, Data Call-Ins

In section “5.0 Conclusions,” DTSC states the following:

“Priority Products will be identified from these categories only after stakeholder engagement, information exchange with industry experts, and robust scientific review. Public workshops, data call-ins and extensive research will be used to identify potential Priority Products.”

GCA is greatly concerned with the lack of detail associated with the timelines and data call-in expectations associated with the Work Plan. Given the three-year timeline associated with this Plan, it would seem that the Department should be better prepared to clarify its next steps, associated timeline, and other process oriented issues. To achieve meaningful and timely engagement with the regulated community and to move forward with DTSC’s intended 5-10 Priority Products in the first year of the Work Plan, DTSC should provide the regulated community with specifics on these next steps. By identifying the seven Priority Product Categories, DTSC states it is providing some predictability for the manufacturers and the regulated community. True predictability will come from knowing not only what will be looked at but also who, when and how.

Conclusion

To ensure a meaningful Work Plan it is imperative to avoid regulatory duplication and superseding of authority; provide clarity regarding DTSC’s prioritization process; ensure correct characterization and listing of chemicals/chemical categories; and provide clarity regarding the next steps, timeline, data call-in process and more.

Further, the Work Plan indicates DTSC will engage and continue to seek feedback from the NGO community, but may seek feedback from and engage industry. The Work Plan should not suggest that DTSC might elicit feedback, but instead make the promise and commitment to industry that it will engage with the relevant industry stakeholders in a productive and proactive dialogue. This will allow DTSC to make more informed decisions

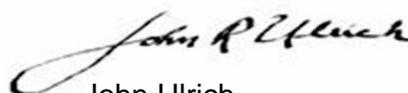
and avoid making costly mistakes related to how products are already regulated, or what the industry has already undertaken to reduce or eliminate certain chemicals in products. Proactive dialogue with product manufactures will allow DTSC the opportunity to better understand why certain chemicals are used and what potential alternatives have already been evaluated. In some cases, alternatives that have been identified are in fact a greater concern and would fall into the category of "regrettable substitutions," a situation DTSC has repeatedly stated it seeks to avoid. As this process unfolds DTSC should consider the regulated community a knowledgeable and indispensable resource.

GCA and its coalition members appreciate your consideration of our comments. For further information or questions regarding the Green Chemistry Alliance, its members, or our comments contact Dawn Koepke (916) 930-1993 or John Ulrich (916) 989-9692. Thank you!

Sincerely,



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Cc: Meredith Williams, Deputy Director, Safer Consumer Products Branch, DTSC
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