



MARK B HORTON, MD, MSPH
Director

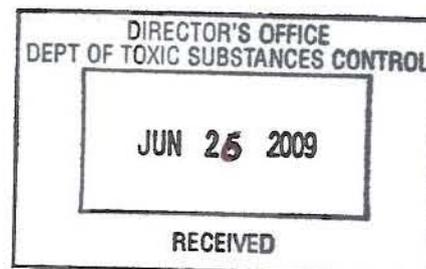
State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

June 22, 2009

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



Dear Mr. Movassaghi:

Staff from the California Department of Public Health (CDPH) have reviewed the Draft Straw Proposal, version 5.1 04-23-2009, and our comments are enclosed. We are pleased to be part of an effort to create a new framework for chemicals policy. This effort is complex and challenging, especially given the time requirements for promulgating new regulations, and you and your staff should be commended for the substantial progress that has been made in drafting the Straw Proposal.

Because CDPH is mandated to protect and preserve public health (including worker health) and has programs with specific mandates in consumer product protection, I have asked our Office of Legal Affairs to review the Straw Proposal specifically for overlapping mandates and conflicting authorities. Those comments will be sent separately. Also, I understand that the regulatory language will be changing as you receive comments from different stakeholders. I request that CDPH be given an opportunity to review future, near-final versions of the rules so that our substantial interests and broad experience can be reflected in the regulatory package.

The deadlines for drafting these regulations and obtaining appropriate review are very tight. My staff and I are committed to providing support to achieve these deadlines. However, it may become clear in the future that the aggressive timeline for promulgation of the regulation is unrealistic for allowing sufficient time to create sound regulations that achieve the desired goals. In such case, I hope the deadlines can be extended.

CDPH Comments on DTSC Version 5.1 4-23-09 Straw Proposal 6-15-09

This document contains California Department of Public Health (CDPH) comments on the Department of Toxic Substances Control (DTSC) Draft Straw Proposal. CDPH acknowledges that AB 1879 and SB 509 represent a significant shift in chemicals and consumer product policies in California that creates substantive challenges for development of new regulations. The Draft Straw Proposal is an important beginning and will be updated and changed as stakeholder comments are received and considered. CDPH anticipates reviewing and commenting on future versions before a final regulatory package is submitted.

General Comments

Timeline for promulgation of the regulatory package: CDPH has substantial interest in this regulatory package, in particular, the sections on prioritizing chemicals of concern and processes for identifying and evaluating alternatives. Because this straw proposal is already dated, CDPH review of the specific, detailed regulatory language will be critical. We request that adequate time be provided for a thoughtful response once the regulatory package becomes available. If it becomes clear that the aggressive timeline for promulgating the regulation is unrealistic, we recommend that the timeline be extended to allow sufficient time for a well thought out regulation that is most likely to accomplish the desired outcome of protecting health and the environment.

Increased interagency collaboration: Implementation of green chemistry (including the regulations pursuant to AB 1879 and SB 509) should fully utilize the expertise, knowledge, and experience of relevant programs across State agencies, and ensure that any overlaps or conflicts in regulatory authority are identified and addressed. DTSC should build into these regulatory processes appropriate points for consultation with other affected programs. Resources should be provided to agencies, such as CDPH, to ensure their meaningful participation, and specifically to allow for input from technical experts (i.e., not just the Leadership Council). The listing of programs on page 1 should be expanded to include all affected CDPH programs in both the CDPH Center for Chronic Disease Prevention and Health Promotion, and the Center for Environmental Health (complete listing available on request).

Potential impact on worker health: The "Safer Alternatives for Consumer Products" rule could greatly benefit worker health and safety since chemicals and chemical products are used by workers in many settings, often in much greater volume, duration, and frequency compared to the general public, thus resulting in worker exposures having greater health impact. As a non-regulatory public health program, CDPH's Occupational Health Branch (CDPH-OHB) has a mandate to recommend occupational standards to Cal/OSHA when it has been determined that a substance used in workplaces is potentially harmful to workers. As occupational health professionals, we have been trained that the most effective worker protection is elimination of hazards from the workplace, or substitution with less hazardous substances. CDPH-OHB has substantial interest in working with DTSC on green chemistry including identifying and prioritizing chemicals of concern, defining the processes for safer alternatives assessment, and considering appropriate regulatory responses. Two programs within CDPH-OHB are particularly relevant: 1) the Hazard Evaluation System and Information Service (HESIS) collects and evaluates toxicological, epidemiological, use data, and other information on toxic substances in the workplace and has conducted several significant projects to develop and promote the use of safer and effective alternatives; and 2) the California Safe Cosmetics Program is establishing a reporting system for cosmetic products (used by workers and/or

consumers) that contain carcinogens and/or reproductive hazards and has gained practical experience with the challenges of collecting and managing this kind of information.

Additional consumer product safety mandates: The Straw Proposal also could benefit from other CDPH programs like our Food and Drug Branch, Drinking Water Program, and Child Lead Poisoning Prevention Branch that are mandated to deal with the interaction between and health impacts on people of all ages and the various consumer products that fall within the definitions of the Draft Straw Proposal. The CDPH legal office will be providing additional comments on the Straw Proposal in the near future.

Confidential business information: It is essential that all information collected by DTSC through new regulations, such as locations and volume of chemical use, toxicity information, formulations, alternatives assessments, etc., including confidential business information, is made freely available to all State programs with mandates for preventing harm to health and the environment due to toxic chemicals. Information sharing agreements should be put in place with legal consultation.

Section 1. Purpose scope and intergovernmental coordination

Specify that consideration of alternatives should result in actions that do not lead to adverse consequences *to workers, the general public, or the environment*. Most often, poor decisions about alternatives have been identified after workers have become ill from exposure to untested and/or unregulated chemicals (including chemicals where industry-sponsored toxicity testing results were not provided promptly to government). There is now a new term to describe this phenomenon, the "regrettable substitution." An important goal of green chemistry is to prevent further regrettable substitutions.

Moving beyond limitations of the existing risk assessment system should include the notion of incorporating new knowledge in continuous alternative assessment and product improvement.

Market-based compliance measures should only be used when the degree of hazard does not indicate the need for immediate exposure reduction.

Intergovernmental coordination should reference CDPH's programs in occupational and environmental health, including biomonitoring, environmental health tracking, child lead poisoning prevention, and drinking water in addition to consumer product safety and cosmetics.

Section 2. Definitions

CDPH will want to closely evaluate this section once definitions to key terms are provided.

In addition to repeating the "consumer product" definition from the statute, it should be clearly specified that DTSC's authority includes regulatory oversight of the use of these products in the workplace. We do not believe this poses a conflict with Cal/OSHA regulation of the workplace, since Cal/OSHA rules typically are exposure limits rather than the type of far-reaching regulatory responses DTSC may implement. Green chemistry offers the opportunity to provide far greater worker protection than that afforded by Cal/OSHA Permissible Exposure Limits, since DTSC would have the authority to ban or restrict use of chemicals/chemical products, which Cal/OSHA typically does not do.

(c) "chemical" this definition may not encompass materials that are "on the surface of" and not "in" consumer products and substances that may occur from interactions with atmospheric oxygen, even when the product is not being used.

Section 3. Process to identify chemicals of concern

The list of hazard endpoints for the minimum data set should explicitly include carcinogenicity.

"Any chemical meeting one or more of the following criteria may be placed on the candidate list." It's not clear how this "candidate" list will differ from the chemicals of concern referred to in the statute. If they are the same, then placement on this list should be nondiscretionary – i.e., "shall be placed on the candidate list."

The listing of chemical lists to be considered for candidate chemicals should explicitly include relevant worker health listings, such as chemicals with Cal/OSHA Permissible Exposure Limits; Threshold Limit Values (TLVs) established by the American Conference of Governmental Industrial Hygienists, Recommended Exposure Limits (RELs) established by the National Institute for Occupational Safety and Health, etc. The Association of Occupational and Environmental Clinics also maintains a list of recognized asthmagens.

We object to the statement on page 3, "DTSC would have the sole discretion to make this determination." OEHHA, which has the State's greatest concentration of toxicological expertise, is the more appropriate program to assess chemicals for placement on the candidate list from a toxicological standpoint. Other programs may have the greatest expertise in other areas such as ecotoxicity. The fact that green chemistry requires input from many disciplines should be recognized and provided for throughout the regulatory proposal.

The statement on page 4, "Any chemical to which humans have been shown to be exposed through the California Environmental Contaminant Biomonitoring Program..." suggests that a reason for listing a chemical should simply be measurable exposure. This will assure a very broad list of candidate chemicals of concern; but provides little basis for their prioritization.

"New" chemicals- DTSC needs to specify clearly what "adequate hazard characterization data" will consist of. This is not spelled out in the criteria listed on the preceding pages, but it appears from p. 7 that DTSC means the OECD criteria from 1998. If that's the case, this is clearly insufficient. The OECD criteria do not specifically include genotoxicity (except for mutagenicity), carcinogenicity, endocrine disruption (specifically referring to estrogenic or anti-estrogenic, androgenic or anti-androgenic, and thyroid hormone effects, at least), epigenetic effects, biopersistence, or bioaccumulation. The OECD list is 11 years old and does not reflect the current state of toxicology or hazard assessment. The National Research Council produced a report on new approaches for toxicity testing last year that could be incorporated into this proposal. In addition, this section states that data on identity and proposed uses of "new" chemicals (including use of existing chemicals in a new use application) would be submitted to the Toxics Information Clearinghouse. The Clearinghouse, though not yet established, is clearly under-resourced for the mandates outlined in SB 509. It is not clear how the Clearinghouse would incorporate this additional information. Also, there is currently no repository for data on the uses of all existing chemicals in consumer products, a problem that is far from being solved to date.

Section 4. Process to prioritize chemicals of concern

The proposal states on page 6 that, "This initial screening evaluation will require use data"; however, volume and use information is not available for all chemicals that would likely be on a candidate list for chemicals of concern. There is also no indication how many chemicals would likely be on the candidate list, or how use data on these chemicals would be obtained from all relevant manufacturers. It would be important that "use data" include volume of use, what functional purposes the chemicals are used for, and what types of products they are contained in. Lacking this information, it is not clear how DTSC would proceed with prioritization.

It is proposed that manufacturers would submit use data to DTSC via the Toxics Information Clearinghouse; however, it is not clear how the Clearinghouse, mandated under SB 509 for a different purpose, would be modified to incorporate this information. It is also not clear that the State would have adequate resources to accomplish this task.

For simple consumer products produced by a single manufacturer, it may be possible to obtain reasonably complete information. For complex products assembled from components manufactured in facilities throughout the world, it may be impossible to elicit accurate information on the identities or amounts of chemicals in products that end up in California. It is not clear in this draft proposal how DTSC will identify or deal with products where the manufacturer, distributor or retailer does not know all the identities or quantities of product ingredients, or where there is incomplete reporting or falsification of information submitted regarding product ingredients.

It is likely that many hundreds, if not thousands, of chemicals will end up in the high priority list due to toxicity data gaps alone. There will need to be a way to prioritize the high priority list. Biomonitoring data could provide a partial basis for prioritizing the high priority chemicals. Structure-activity relationships, octanol-water partition coefficients, or other physicochemical characteristics may provide other approaches.

Given the enormous task of obtaining and managing information on chemical use, toxicity, and all the other criteria listed for consideration, and the lack of a described process for weighting different criteria, this section of the proposal cannot be evaluated at this time. It is also not clear how chemicals lacking key data on each of the criteria would be handled in the prioritization process. Nevertheless, CDPH has substantial interest in the prioritization of chemicals of concern and would expect to provide input at a later date once a complete proposal is available.

Section 5. Process to evaluate alternatives

CDPH questions the feasibility of simultaneously requiring a full lifecycle alternatives assessment for all consumer products that contain a chemical of concern. Although the proposal does not give any indication how many chemicals would be listed as chemicals of concern, even identifying and assessing all consumer products that contain a single known toxic chemical such as lead would be a daunting task. The regulatory package would need to estimate the number of alternatives assessments potentially required as part of its fiscal impact, as well as to ensure that adequate resources are available within DTSC to oversee this process, and within other appropriate agencies to provide input where applicable. Otherwise, who is going to check on the validity and accuracy of alternatives analyses submitted not only by American companies, but also by hundreds of foreign manufacturers?

There should be some way to move forward more quickly on the evaluation of alternatives to known hazards in known products, for example alternatives to perchloroethylene in dry cleaning, and ensure that the alternatives are carefully considered for the full range of criteria listed under the proposal and that the most appropriate regulatory response is selected.

We question the approach of having manufacturers perform their own alternatives assessments, due to potential conflict of interest inherent in the possible outcome of required changes in the formulation of their own products. Although we understand that the State could not take on the financial burden of performing the alternatives assessments, we would also want to be assured that the State had adequate resources for oversight and to ensure that alternatives assessments were prepared in a consistent and accurate manner. It is crucial that specific guidelines for conducting alternatives assessments be prepared by DTSC in consultation with other appropriate State agencies.

Establishing a process for certification of "alternatives assessors" would have to address where to find the full range of expertise necessary for full lifecycle evaluation, including disparate fields such as toxicology and ecology. Identifying available alternatives also would require professionals from fields such as chemistry and engineering that do not typically work with toxicologists and ecosystem experts.

Although the idea of making alternatives assessments available to the public is laudable, and necessary to ensure that assessments are accurate and the full range of alternatives is indeed evaluated, it is clear that the issue of confidential business information would severely constrain this aspect of the proposal. Alternatives assessments for products could not reasonably be evaluated without some knowledge of the formulations of the original product and the alternatives, particularly when it comes to the percentage of chemicals of concern in each product. DTSC has said it will collect CBI and keep it confidential, but DTSC will likely not have sufficient staff to evaluate the CBI claims or to ensure that alternatives assessments are accurate and include the full range of possible alternatives. As noted earlier, it is critical that any CBI collected by DTSC be made available to all other State programs with an interest in preventing harm to health or the environment due to toxic chemicals.

Like Section 4, this section is of substantial interest to CDPH, and we expect to provide additional input when a more complete proposal is available.

Section 6. Regulatory responses

When a chemical/chemical product reaches the point where regulatory responses are under consideration, CDPH would certainly expect to be consulted to provide input from relevant programs.

"Engineered safety measures" is an area where consultation with Cal/OSHA would be necessary, as occasionally Cal/OSHA regulations for specific chemicals have specific requirements for engineering controls.

Section 7. Enforcement

We would be happy to offer comments on this topic once a plan is put forward for enforcement.