

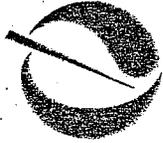
# Office of Environmental Health Hazard Assessment

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## MEMORANDUM

**TO:** Rick Brausch  
Legislative Director  
Office of Legislative and Regulatory Policy  
Department of Toxic Substances Control

**FROM:** Allan Hirsch *all h*  
Chief Deputy Director  
Office of Environmental Health Hazard Assessment

**DATE:** May 18, 2009

**SUBJECT:** OEHHA Comments on DTSC Draft Straw Proposal

Attached are the Office of Environmental Health Hazard Assessment's (OEHHA) comments on the Draft Straw Proposal that the Department of Toxic Substances Control (DTSC) developed to describe the "Safer Alternatives for Consumer Products" Rule in plain English. We congratulate DTSC on an excellent start to this complex rule. We understand that DTSC is already moving to revise this proposal, based on comments received from stakeholders and the Green Ribbon Science Panel. OEHHA would be happy to assist with the revision as well as provide additional comments on the revised proposal. Please feel free to forward these comments to the appropriate DTSC staff. If you have any questions about these comments, please contact Sara Hoover of our staff at (510) 622-3224.

Attachment

cc: Sara Hoover, M.S.  
OEHHA

California Environmental Protection Agency

*The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption.*

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## OEHHA Comments on DTSC's Draft Straw Proposal, Version 5.1, 4-23-2009: Plain English Outline of "Safer Alternatives for Consumer Products" Rule

In this document, OEHHA provides comments on DTSC's Draft Straw Proposal (Version 5.1, 04-23-2009 15:00), which was released to the public and provided to the Green Ribbon Science Panel (GRSP) for review and discussion. We understand that DTSC staff have already been updating the proposal based on input from stakeholders and the GRSP. We'll be happy to provide additional comments when the revised proposal is completed.

### General Comments

The straw proposal is an excellent first step in outlining some of the key elements in the implementation of AB 1879. OEHHA suggests that DTSC consider the following general issues in preparing the next draft:

*Increased interagency collaboration:* The proposal does not fully describe the extent of collaboration that would be necessary and would benefit the green chemistry program. We suggest that consultation with OEHHA and other appropriate state agencies be built into the proposal. Areas where input from other agencies would be particularly helpful are provided in the "Specific Comments" section below.

*Definition of chemicals of concern:* We suggest candidate chemicals of concern and chemicals of concern be defined using general criteria and that any lists that meet these criteria be specifically incorporated into the regulation by reference. In that way, DTSC can quickly move forward on known bad actors. We also suggest that the language in the proposal regarding candidate chemicals of concern, chemicals of concern, high priority chemicals of concern, prioritized chemicals of concern, etc., be explained and made consistent throughout the proposal, so the interlinking aspects of the proposal are clear. We realize that there is already a new proposal and flow chart about chemicals of concern, so appropriate definitions can be developed to fit the new proposal.

*Poorly studied chemicals:* DTSC is taking a very innovative approach by highlighting chemicals lacking sufficient hazard and exposure data as being of concern. OEHHA supports this approach, as do many stakeholders. As one option for addressing these chemicals, we suggest that requirements for generating toxicity data be considered as a regulatory response. This will need to be carefully constructed because any such requirements will be closely scrutinized by stakeholders. OEHHA would be happy to assist with developing regulatory options for addressing poorly studied chemicals.

*Importance of hazard trait data:* We suggest that some additional details be included in the proposal regarding the role of hazard trait data (including human health and environmental toxicity data) in the process for evaluating chemicals of concern and their alternatives. These criteria should reference the hazard traits, toxicological and environmental endpoints, and other relevant data evaluated and specified by OEHHA. OEHHA would be happy to assist DTSC with developing this language.

*Development of guidelines for alternatives analysis:* We suggest that DTSC, in consultation with OEHHA and other appropriate state agencies, develop guidelines for conducting an alternatives analysis. OEHHA's initial experience with the Hot Spots Program was that consultants were conducting risk

assessments following varying, non-standard approaches. Once risk assessment guidelines were developed, consultants had a road map to use and the risk assessments became more standardized and more acceptable. DTSC could include the requirement for guidelines development in the regulatory language. OEHHA would be happy to assist DTSC with the development of these guidelines.

*Quality control for alternatives analysis:* If manufacturers are responsible for conducting the alternatives analysis, it will be important for there to be a quality control mechanism. There are a number of possible approaches to achieve quality control, such as requiring the alternatives analyses to be conducted by third-party assessors who are trained and certified by the state and requiring audits of the analyses by the state.

*References to federal programs:* In several places, the straw proposal references approaches used by U.S. EPA in implementing TSCA and in ChAMP. Throughout the green chemistry initiative (GCI), stakeholders have submitted well-supported criticisms of both TSCA and ChAMP. California's GCI is going beyond these approaches to improve chemicals policy in the state. We suggest that the proposal reference innovative approaches as models for moving forward, instead of past approaches that have been unsuccessful.

*Toxics Information Clearinghouse:* The proposal mentions the Clearinghouse in several places as accepting submitted data and making submitted data publicly available. OEHHA's understanding based on discussions with DTSC is that there is no funding for such an undertaking and that the Clearinghouse will be a portal to existing Internet sites. If this concept has changed and a more ambitious database is planned for the Clearinghouse, OEHHA would like to have input to the new proposed approach. We suggest that DTSC and OEHHA work closely together in planning the structure of the Clearinghouse. The hazard traits, endpoints and other relevant data evaluated and specified by OEHHA will be important to consider in designing the structure of and data sources for the Clearinghouse.

## **Specific Comments**

### Section 1. Purpose and Scope

*Intergovernmental Coordination:* Below are some suggestions for additional programs that may be relevant (along with one edit, shown in italic underline).

- ARB *and OEHHA* Consumer Products
- DPH, OEHHA, DTSC California Environmental Contaminant Biomonitoring Program
- OEHHA Proposition 65
- ARB and OEHHA SB 25 Children's Health Protection Act
- ARB and OEHHA AB 998 Perchloroethylene Alternatives

### Section 2. Definitions

Certain important definitions are still under development by DTSC (e.g., alternatives analysis, candidate list, chemical of concern, potential alternative). When these are developed, we suggest that they be circulated widely to relevant agencies for comment.

We suggest that additional definitions be included:

- "Alternative" - this is a term used in the statute and is relevant in addition to "potential alternative"
- "Office" means Office of Environmental Health Hazard Assessment

### Section 3. Process to Identify Chemicals of Concern

We suggest that this section be renamed to accurately reflect the content: "Process to Identify Candidate Chemicals of Concern." We understand that a different approach may be taken, so the "candidate list" may not be relevant in the new approach.

We suggest that DTSC obtain legal advice from the DTSC, ARB, and OEHHA legal departments on the feasibility of the following in a regulatory context: "Criteria would be clearly laid out in regulation, but the list itself will not be in regulation, and will be dynamic."

We agree with the approach that DTSC has taken of casting a very broad net for the candidate chemical of concern list. This concept was repeatedly emphasized by stakeholders. Instead of having a long list of bullets, it might be simpler to define a few general criteria for a "candidate chemical of concern." Lists of chemicals developed by any state, national, or international body that meet these criteria could be identified and explicitly incorporated into the regulation. For example, below are some possible broad definitions for *candidate* chemicals of concern, adapted from some of the bullets in the proposal:

- Any chemical with any of the hazard traits or environmental or toxicological endpoints evaluated and specified by OEHHA pursuant to Section 25256.1
- Any manufactured chemical, industrial byproduct, or metabolite or breakdown product of a manufactured chemical or industrial byproduct that is detected in people, wildlife or the environment
- Any new or existing chemical for which a minimum data set [to be specified by DTSC in regulation] is not available

Similar kinds of broad criteria could be developed for "chemical of concern." For example: "Any chemical on the candidate chemical of concern list that is found in a consumer product sold, bought or used in California."

We suggest that DTSC indicate that the identification of candidate chemicals, chemicals of concern, etc. would be ongoing and that lists (including those incorporated by reference) would be regularly updated.

Regarding the bullet: "Any chemical which appears on any 'list' published by any government authoritative body, or nongovernmental organizations, and that are deemed by DTSC to be potential chemicals of concern... (DTSC would have sole discretion to make this determination.)" This statement appears to mean that a chemical of concern (COC) is anything DTSC determines, however no criteria are given. Stakeholders may object to this. We suggest that DTSC develop general criteria for what constitutes a COC (or candidate chemical), as noted above. We also suggest that DTSC incorporate

consultation with OEHHA and other appropriate state agencies as part of the process for identifying COCs. Input from other state agencies would help DTSC demonstrate a thoughtful process to stakeholders and assist DTSC in effectively implementing the law.

We suggest that DTSC obtain legal advice from DTSC, ARB and OEHHA legal departments on whether chemicals of concern identified as part of OEHHA's evaluation and specification of hazard traits, environmental and toxicological endpoints, and other relevant data for the Clearinghouse can be incorporated into the regulation by reference.

The "list of lists" is impressively comprehensive. There are other lists that could be considered as meeting general criteria for candidate chemicals of concern. Examples are noted below.

- Most carcinogens will be captured by the Proposition 65 list. We suggest including the following additional lists of known or potential carcinogens:
  - IARC 2A and 2B carcinogens (instead of only category 1)
  - Chemicals identified in the NTP Report on Carcinogens to be "known to be a human carcinogen" or "reasonably anticipated to be a human carcinogen"
  - Chemicals identified by U.S. EPA as "carcinogenic to humans" and "likely to be carcinogenic to humans"
- Canada's priority lists developed pursuant to the Canadian Environmental Protection Act (CEPA)
- Oregon's Priority Persistent Pollutant List
- Chemicals identified as reproductive or developmental toxicants by NTP under the Center for Evaluation of Risks to Human Reproduction (CERHR) program.
- Chemicals identified as being hazardous to workers. Consider the following sources:
  - California Department of Occupational Safety and Health ("Cal/OSHA") lists (e.g., "Hazardous Substances List")
  - NIOSH Pocket Guide and other NIOSH documents
  - ACGIH Threshold Limit Values (and documentation)

The paragraph discussing how the proposed regulation will address "new" chemicals seems out of place in this candidate chemical section and has elements that too closely mirror the TSCA approach. The proposal text seems to indicate that lack of adequate hazard characterization would place a "new" chemical on the "high priority chemical of concern list," but the manufacturer would only be required to provide information on "the identity and proposed or anticipated use of that chemical to the Toxics Information Clearinghouse." The section goes on to say that the manufacturer would "have to submit the new [not defined] data to the Toxics Information Clearinghouse prior to initiating a planned or foreseeable change in the use of a chemical." We suggest that the data be submitted to DTSC as the regulatory body. It is not clear if it will be practical to structure the Clearinghouse to accept data submissions. In addition, the approach described is essentially identical to TSCA, which has not been adequate in identifying and regulating chemicals of concern. We suggest that DTSC delineate requirements for the manufacturer to submit and/or generate the necessary hazard data.

#### Section 4. Process to Prioritize Chemicals of Concern

We suggest that DTSC clarify which list will be prioritized – e.g., chemicals on the candidate list that are found in consumer products in California? Or some other screened sub-set of the candidate list?

We suggest that some general details be provided on how the prioritization approach might work, such as what data will be used to define each factor (e.g., volume), how those data will be reviewed and evaluated, and how the different factors will be weighed to come up with priorities. This would allow stakeholders to understand the process and provide input. Addressing how exposure/use information will be combined with hazard/toxicity information to prioritize chemicals will be important. We also suggest that DTSC outline possible methods that will be used to prioritize chemicals of concern in the absence of adequate hazard data. However, we think DTSC should have flexibility in implementing the law, so any details given should allow for that flexibility. OEHHA would be happy to assist DTSC with developing some details on the prioritization approach.

The requirement that manufacturers submit use data is an excellent approach to obtaining the information the state needs to determine potential chemicals of concern from the candidate list. There does not appear to be a comparable requirement for submission of the necessary hazard data to identify and evaluate chemicals of concern. Use and exposure information in the absence of a toxicity/hazard evaluation will not be sufficient for prioritizing chemicals of concern.

We suggest that OEHHA be consulted on the identification and evaluation of “potential effects on sensitive subpopulations, including infants and children.” We have specific mandates and extensive experience in this area.

It is not clear what the term “human experience” means. This seems to imply exclusion of animal evidence, but a later bullet is much broader and would appear to incorporate animal evidence as well (i.e., “any evidence that otherwise suggests that there are ‘reasonable grounds for concern’ regarding the potential adverse impacts of the chemical”).

We suggest that DTSC remove any reference to the U.S. EPA ChAMP program. This program is seriously flawed and has been widely criticized. We suggest that DTSC provide general definitions as to what is meant by a “high” or “low” priority chemical in the California program.

We suggest that OEHHA and other state agencies be consulted in a meaningful way before DTSC finalizes priority chemical lists.

#### Section 5. Process to Evaluate Alternatives

As noted in “General Comments” above, it will be important for DTSC to establish a standard procedure for alternative analyses or the submissions will be “potluck” and not comparable. We suggest this be accomplished through the development of detailed guidelines, with the assistance of OEHHA and input from other relevant agencies.

The third sentence in the second paragraph indicates that alternatives analysis will be required first for consumer products containing prioritized chemicals that "are intended for use by pregnant women and children under the age of six." U.S. EPA's Inventory Update Rule has utterly failed in getting relevant exposure data because of requesting information on chemicals "intended for use by children." Children and pregnant women live in places that get painted and cleaned, and are extensively exposed to products that are not necessarily "intended for use" by children. This phrase has so restricted any reporting to U.S. EPA that the information received is not very useful to determine potential exposures. Also, we know puberty is a time of increased susceptibility to some toxicants due to the rapid growth and differentiation of reproductive organs and the mammary gland, as well as structural changes in the brain. We suggest that the sensitive subpopulation of children be broader than children younger than six.

This section appears to tie the high priority chemicals of concern to those identified by ECHA (in paragraph 2). We suggest that the high priority chemicals of concern be those identified by California pursuant to Section 25252.

Regarding making certain elements of the alternatives analysis public, we agree that at a minimum a summary of the findings should be public. As discussed at the Green Ribbon Science Panel (GRSP) meeting on April 29-30, it will be important to determine which information is truly "confidential business information" (CBI) and not release that. It will likely not be possible to release the full alternatives analyses with all associated data for public review and comment, so a mechanism for public input that respects true CBI will be needed.

As noted in the statute, the criteria for evaluating chemicals and their alternatives must include at a minimum the "traits, characteristics and endpoints that are included in the clearinghouse data pursuant to Section 25256.1." We suggest that DTSC explicitly include this element of the law in the alternatives analysis section of the proposal and subsequent regulatory language.

DTSC's multi-stage approach to the alternatives analysis is an excellent framework. Comparing chemicals by first considering the critical attribute(s) associated with the chemical of concern is a great idea. We suggest that DTSC also establish a set of critical attributes that would also be reviewed in this first step, so it's clear what an "improvement" constitutes. For example, replacing a carcinogen with a reproductive toxin or a very persistent compound would not be considered an improvement. The second stage could then review the remaining human health and environmental impacts that are not in the "critical" set of attributes.

The multi-stage framework is also very useful in that it prioritizes health and environmental concerns before other issues, which will immediately begin to achieve the goals that DTSC laid out in the beginning of the proposal.

As suggested at the GRSP meeting, it would be helpful to hold workshops with companies who have successfully applied alternatives analysis and moved toward safer alternatives. DTSC might also pursue input from specific outside experts on life cycle assessment to assist with developing the semi-quantitative, practical approach that is being proposed. Section 6. Regulatory Responses

We understand from DTSC staff that the Regulatory Responses section is still under development, so we will provide more detailed comments on the next version of the proposal. Below we highlight a few issues.

The "Additional Information" section requires the manufacturer to comply with subsection (1); which is the "No further action" section, within 18 months. It's not clear how a manufacturer with inadequate information on a "prioritized chemical of concern" could comply with the "no further action" section in that time frame. It seems intended to compel a manufacturer to evaluate the chemical and its alternatives within 18 months, which is a good idea. However, it might be that all of the alternatives have limited data. The manufacturer could compare all of these alternatives, thereby complying with the alternatives analysis requirement, and so not need to generate adequate information to choose an environmentally preferred alternative. Some option to compel generation of a minimum data set on human health and environmental hazards for high priority chemicals seems important to include in the "Additional Information" regulatory response. This could be an opportunity to begin to fill key data gaps on high priority chemicals that are not well studied and have no preferred alternative.

The labeling ideas are excellent. DTSC may face difficulties in implementing this section, based on OEHHA's experiences with Proposition 65 labeling. There would also be a need to be more explicit in defining the levels of a "prioritized chemical of concern" in a product. For example, a Proposition 65 Safe Harbor number cannot be directly compared to a level in a product. Evaluating an exceedance of a Safe Harbor requires a detailed risk assessment.