

Asian Communities for  
Reproductive Justice

Bayview Hunters Point  
Community Advocates

Black Women for  
Wellness

Breast Cancer Action

Breast Cancer Fund

California Healthy Nail  
Salon Collaborative

California Pan-Ethnic  
Health Network

Californians for Pesticide  
Reform

Center for Environmental  
Health

Center for Race, Poverty  
and Environment

Clean Water Action

Coalition for Clean Air

Commonweal

Communities for a Better  
Environment

Environment California

Green Schools Initiative

Healthy 880 Communities

Healthy Child, Healthy  
World

Healthy Children  
Organizing Project

Just Transition Alliance

Movement Strategy  
Center

Pesticide Action Network  
North America

Physicians for Social  
Responsibility- LA

Science Environmental  
Health Network

Silicon Valley Toxics  
Coalition

United Steel Workers  
Local 675

Worksafe

October 19, 2009

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

**Re: DTSC October 1, 2009 Green Chemistry Initiative Straw Proposal**

Dear Director Movassaghi:

We write on behalf of CHANGE, Californians for a Healthy and Green Economy. CHANGE is a broad-based coalition of about 35 environmental and environmental justice groups, health organizations, labor advocates, community based groups, parent organizations, and others who seek to fundamentally transform how chemicals are managed in order to protect our workers, children, public health, environment, and the economy.

These comments are provided to the Department of Toxic Substances Control in response to its October 1, 2009 Straw Proposal for Safer Alternatives Regulations.

First, we appreciate the enormous effort DTSC has put in to creating this Straw Proposal. It constitutes a serious effort to make a concrete proposal for implementing AB 1879. We also continue to appreciate the opportunities DTSC has provided during this Initiative for us to express our views on chemicals policy reform.

These comments are divided into two sections. Section I relates to four overarching issues: (A) the delegation to manufacturers of value judgments that are essentially governmental in nature; (B) the lack of oversight over manufacturers' decision-making (i.e., limited public disclosures and excessive opportunities for CBI claims and waivers, and lack of penalties or enforcement provisions); (C) the allocation of the burden of proof to government rather than manufacturers; and (D) an inadequate no data, no market provision.

Section II refers to additional issues, organized by the Proposal's section number.

**I. FOUR OVERARCHING ISSUES**

**A. The Proposal delegates to manufacturers the responsibility for making value judgments that government itself should make.**

The proposed regulations require manufacturers to identify “significant impacts” of products and potential alternatives (Section 6xxxx.16(b)), and then to take Response Actions if a product or alternative to be implemented has a “significant impact” (Section 6xxxx.20(a)(1)). Similarly, the proposed regulations provide that DTSC may impose a response action if it finds there is a “significant risk” to human health or the environment (Section 6xxxx.20(a)(4)), and that it may grant a waiver if there is a “significant risk” (Section 6xxxx.21(b)). But the regulations nowhere define what a “significant impact” is or what a “significant risk” is. DTSC staff stated at the October 14, 2009 public meeting of the Green Ribbon Science Panel that the Proposal intends that manufacturers will determine for themselves what constitutes a “significant impact.”

This constitutes an excessive delegation to manufacturers of responsibility to protect the public health and environment. It is highly unlikely that manufacturers will do this voluntarily, as the Proposal essentially expects. Government should articulate standards that manufacturers must meet. Without clarity of standards, there will be no consistency of decisions from manufacturer to manufacturer, no ability to enforce the regulations and no means of oversight.

Moreover, AB 1879 provides guidance on this question. HSC Section 25252.5(g) provides that a multimedia life cycle evaluation means “the identification and evaluation of a significant adverse impact on public health or the environment . . .”

In these regulations, DTSC should define the terms “significant impact” and “significant risk” in the regulations, including for alternatives analyses, response actions and waivers. In the case of public health and environmental impacts, a “significant impact” or “significant risk” should be defined as “any adverse effect on human health or the environment,” with provisions to account for cumulative impacts, aggregate impacts and impacts on sensitive subpopulations. CHANGE has advised DTSC extensively on this question and can provide more specific language if DTSC desires it.

**B. The Proposal sets forth a “self-implementing” structure that comprises insufficient oversight of industry decision-making, excessive opportunity for claims of confidential business information and waivers, and a lack of enforcement and penalty provisions.**

The proposed regulations are what DTSC refers to as “self-implementing,” meaning that they rely on decisions by manufacturers, rather than independent third parties, with government oversight that is minimal and occasional rather than comprehensive and systematic. This structure is not required by AB 1879. While this regulatory approach may save government resources (at least in the short run), it also puts manufacturers in a position that inherently carries a conflict of interests. They have a vested interest in their own products, and yet are being asked to evaluate them and alter them or take response actions in the public interest.

Such a self-implementing structure is very unlikely to be effective unless it includes substantial mechanisms to motivate and enforce compliance. Four features of this Proposal undermine compliance and will be discussed in turn: (i) it comprises insufficient oversight of industry decision-making, (ii) it includes excessive opportunity

for claims of confidential business information, (iii) it includes excessive opportunity for waivers, and (iv) it comprises too few enforcement and penalty provisions.

1. The need for public oversight. In the absence of independent third party decision-making or government oversight, the only source of meaningful oversight is the public. To this end, if any information relevant to ingredients in products, assessments of hazards, alternatives assessments and evaluations of significant impact or significant risk is not made publicly available, then the regulations will provide no means of (1) obtaining public oversight of decisions by manufacturers (2) building public confidence that products are safe or (3) permitting consumers and industrial users of chemicals to choose safer alternatives – which is a key goal of a market-driven regulatory strategy. The regulations should be explicit that all data and analyses generated under these regulations will be publicly available.

One source of public availability of information stems from Section 6xxxx.7(a)(3), which requires documentation of the hazard criteria determinations of Section 6xxxx.7(a)(2) to be made available “on the internet.” However, it is not clear that this will include all information that is relevant to whether each chemical and chemical ingredient exhibits each hazard criteria, including the identity of each chemical. Indeed, DTSC staff seemed to indicate at the October 14, 2009 meeting of the Green Ribbon Science Panel that they do not intend the identity of product ingredients to be publicly disclosed in connection with disclosures under Section 6xxxx.7(a)(3). Moreover, it is not clear how easily the public will be able to use such widely-dispersed information.

Another source of public availability of information stems from Section 6xxxx.18(a), which requires that the alternatives analyses findings report generated under Section 6xxxx.17 will be publicly available. But, alternatives analyses will be performed only for products manufacturers determine contain priority CoC’s, not all CoC’s, and it is not clear that these reports will provide all the information the public needs to assess the safety of consumer products.

The importance of transparency articulated in Section 6xxxx.14(a)(5) applies to many aspects of these regulations, not just the alternatives analyses. The regulations should provide in all relevant sections, including the following sections, that besides providing information to DTSC on request, all data and analyses relevant to product safety, including ingredient information, shall be made publicly available:

6xxxx.6(f)  
6xxxx.7(a)(3)  
6xxxx.8  
6xxxx.9(a)(5), 6xxxx.9(b), (c), (d), (f)  
6xxxx.12(b)(3), 6xxxx.13(b)(2)(C) and 6xxxx.16(g)(2) to the extent not disclosed under Section 6xxxx.18(a)  
6xxxx.20 (many sections)

2. Confidential Business Information/Trade Secrets. Section 6xxxx.18(d) allows manufacturers to claim CBI and/or trade secret status for information (though not chemical hazard information under HSC Section 25257(f)) in all submissions they make to DTSC or to the public. This may permit designation of substantial information, including exposure information and ingredient information (and perhaps even product identification), as CBI/trade secrets even in the disclosures they are required to make to the public. This will remove critical information from the public domain and prevent meaningful public oversight.

“Chemical hazard information” under HRC 25257(f) should be interpreted to apply to all information that is relevant to whether a chemical in a consumer product is safe for human health and the environment. Accordingly, Section 6xxxx.18(d) should not permit designation as CBI/trade secret any information that relevant to the environmental health and safety analyses conducted pursuant to these regulations.

Moreover, if any CBI/trade secret designations are to be permitted, these must be policed by the Department and the public. Unscrutinized claims of CBI/trade secret status serve to withdraw needed information from the public domain and are a form of abuse of the system that happens all too often under TSCA.

Accordingly, regulations implementing HSC Section 25257(f) should provide the following: No information relating to the health and safety of a chemical, including the chemical's identity and product ingredient information needed to assess safety, should be granted trade secret protection. A party seeking trade secret designation for any information should assert each basis for such designation in writing when the information is submitted to DTSC. DTSC should make a case-by-case determination as to whether the party has established that such designation is appropriate. The submitting party should provide DTSC with a redacted, public version of each filing in order to relieve DTSC of the burden of preparing such documents. Each grant of trade secret protection should be time limited, subject to renewal upon application by the submitter. The public should be notified of all trade secret designations approved by DTSC and provided sufficient information to challenge that designation.

3. Waivers. Section 6xxxx.21(a) allows manufacturers to seek waivers or modification of the regulations, but it contains no standard for when DTSC will grant a waiver. This grants DTSC unlimited discretion as to when to grant a waiver, but also ensures that manufacturers will apply for waivers, and the ensuing delay in compliance, whenever they see fit. This is a recipe for extensive noncompliance with the law. DTSC should amend this section by specifying the particular bases it believes are legitimate grounds for a waiver.

Section 6xxxx.21(b) specifies a number of findings that relate to whether a product presents a significant impact or significant risk despite containing a CoC. Are these findings intended as bases for granting a waiver? If so, the identified issues would be better handled in the context of defining whether there should be a response action, not granting waivers to the regulations. Also, this section introduces a plethora of new terms that would all need to be defined. If any of these findings are retained, manufacturers rather than DTSC should have to establish by clear evidence they are entitled to the specified findings.

Similarly, Section 6xxxx.21(c) contains no standard for when DTSC will allow continued use despite the requirements for response actions under Section 6xxxx.20(c)(3). This grants DTSC unlimited discretion as to when to allow continued use, but also ensures that manufacturers will apply for continued use, and the ensuing delay in compliance, whenever they desire to avoid the prescribed response action. DTSC should specify the particular bases it believes are legitimate grounds for continued use despite the determination under the regulations that a response action is appropriate.

4. Enforcement. The regulations contain no provisions designed to assist DTSC in enforcing the regulations. There are no provisions for penalties for non-compliance. There is a requirement that manufacturers may not maintain a product on the market without complying with Sections 6xxxx.6 – 6xxxx.9 (see Section 6xxxx.4). But lack of compliance is very hard to detect, so that manufacturers who don't comply will be able to keep their products on the market until they are caught, and then it seems likely that they will be able to negotiate some

compliance schedule – the problem is that removal of a product from the market is a heavy handed tool that is not susceptible to calibrated application.

Many of the nation’s environmental laws contain penalty provisions and citizen suit provisions that increase the enforceability of those laws. These regulations should establish penalty provisions and a citizen suit provision to increase the likelihood of compliance with this “self-implementing” regulation.

**C. Decision-making when there is scientific uncertainty (i.e., allocation of the burden of proof) is at times very unclear and at other times places the burden of proof on government rather than industry.**

(i) Section 6xxxx.7 This section should place the burden of proof on industry to identify each chemical and chemical ingredient in their products and demonstrate that they are not chemicals of concern. Specifically it should require for each covered consumer product that:

- a. The manufacturer shall identify every chemical and chemical ingredient in the product.
- b. The manufacturer shall compile all information that is relevant to whether each chemical or chemical ingredient possesses each hazard criteria (not just information the manufacturer selects).
- c. The manufacturer shall demonstrate that the complete body of available information establishes clear and convincing evidence that the chemical or chemical ingredient does not exhibit each hazard criteria.
- d. If a manufacturer cannot make the showing of subsection (c), the chemical or chemical ingredient shall be designated a chemical of concern.

(ii) Section 6xxxx.16 This section calls for identification of “significant impacts” of products and potential alternatives. But “significant impact” is not defined and the burden of proof is not assigned.

This section should provide that all products that contain a chemical of concern are presumed to have a significant impact on human health and/or the environment. A manufacturer may establish no significant impact if it can demonstrate that all the relevant evidence constitutes clear and convincing evidence that the product will not present a threat to human health or the environment, taking into account cumulative impacts, aggregate impacts and impacts on sensitive populations.

(iii) Section 6xxxx.20 Section 6xxxx.20(a)(1)(A) requires manufacturers to take a response action if consumer product contains priority chemical of concern or “has a significant impact pursuant to section 6xxxx.17.” A response action should be required for all products containing any CoC, not just priority CoC’s. Also, “significant impact” should be presumed for all products containing a CoC, unless a manufacturer can demonstrate that all the relevant evidence constitutes clear and convincing evidence that the product will not present a threat to human health or the environment, taking into account cumulative impacts, aggregate impacts and impacts on sensitive populations.

Section 6xxxx.20(a)(4) allows DTSC to impose a response action, but DTSC retains the burden of proving that the product poses a “significant risk” to human health or the environment. Is “significant risk” different than “significant impact?” Is this a risk assessment, and if so, what risk is “significant”? To put the burden of proof

on manufacturers, DTSC should impose a response action for all products that contain a CoC unless the manufacturer shows by clear and convincing evidence that the product does not present a threat to human health or the environment, taking into account cumulative impacts, aggregate impacts and impacts on sensitive populations.

(iv) Section 6xxxx.21 Section 6xxxx.21(b) specifies a number of findings that relate to whether a product presents no significant impact or significant risk despite containing a CoC. This should be handled in the context of defining when there should be a response action, not granting waivers to the regulations. Also, this section introduces a plethora of new terms that would all need to be defined. It would be more straightforward to adhere to the terms “significant impact” or “significant risk,” which are already being used in the regulations.

Nevertheless, if waivers are retained, manufacturers and not DTSC should have to establish by clear and convincing evidence they are entitled to the specified findings.

**D. It is very unclear whether DTSC intends a mandatory data set to be produced for all chemicals in consumer products. Such a no data, no market requirement should be clarified.**

Section 6xxxx.6(a) and (b) require manufacturers to obtain only that information they judge “necessary to evaluate” chemicals according to the hazard criteria specified in section 6xxxx.7. But this would allow substantial discretion by manufacturers as to precisely what information is “necessary” to perform the required evaluations – perhaps even very little data. No standard for how much data is required, or policing or enforcement mechanisms, are provided. There is no clear requirement that manufacturers must provide a certain body of data, even if that means they must develop the data for the purpose of the regulation.

The regulations should clearly establish non-discretionary mandatory minimum data requirements, and define those required data.

**II. DISCRETE ISSUES, ORGANIZED BY SECTION NUMBER**

**1. Section 6xxxx.1**

6xxxx.1(9) should refer to products “reasonably likely” to release, not “reasonably “anticipated” to release (“reasonably anticipated” by whom?). It should also make clear that “consumers” refers to the broad definition of consumers used in AB 1879 and SB 509.

6xxxx.1 should include classes of consumer products that are used by workers in the workplace, such as barrels of solvent used in manufacturing. Substantial human and environmental exposures result from these products, which are clearly “consumer products” under AB 1879. We assume that the regulations require consideration of worker exposures that occur during the manufacture of the consumer products that are covered by the regulations. We assume that the regulations require consideration of worker exposures from covered consumer products that happen to be used in the workplace, including any product that contains a CoC listed under Section 6xxxx.2(a) or (b). But this still leaves unaddressed workplace and environmental exposures that occur from many other products that are not covered consumer products, such as a barrel of solvent that does not contain a designated CoC. This is a serious loophole in worker protection.

2. Section 6xxxx.2

6xxxx.2 should have an additional section 6xxxx.2(c) that identifies the following classes of chemicals as chemicals of concern: CMR's, PBT's, vPvB's, ED's. All consumer products containing such chemicals should be subject to these regulations. Definitions of each of these terms can be provided.

3. Section 6xxxx.3

In Section 6xxxx.3(d)(2), the phrase "that has any of the hazard characteristics listed in" should be replaced by "is identified as such pursuant to" so as to directly rely on the process set forth in that section for identifying a CoC.

4. Section 6xxxx.4

This section provides that consumer products may not be made available for use in California unless the provisions of Sections 6xxxx.6-9 are complied with. But it does not specify when such products should be withdrawn from the market or how DTSC will know these sections are not complied with or order products withdrawn. Since some products containing CoC's may remain on the market for 20 years under Section 6xxxx.20, one wonders how serious this provision is.

5. Section 6xxxx.6

Section 6xxxx.6(a) and (b), which require manufacturers to obtain all of the information "necessary to evaluate" chemicals according to section 6xxxx.7, is discussed in section I.C. above.

Section 6xxxx.6(d) makes data reliability requirements discretionary by using the word "may." Also, these criteria for reliability are too restrictive. They exclude data generated in the scientific literature by methods that are reliable even though not yet reduced to standardized tests. Criteria for reliability should permit use of data from peer-reviewed literature and perhaps other reliable sources.

Section 6xxxx.6(e) appears to permit excessive use of QSARS. QSARS should only be used to generate hypotheses or perhaps indicate a chemical is harmful, but not to establish that a chemical does not possess a hazard trait.

6. Section 6xxxx.7

A process for place the burden of proof on manufacturers to identify each chemical and chemical ingredient in their products and demonstrate that they are not chemicals of concern is set forth in section I.B., above.

The hazard criteria should include additional environmental criteria. Aquatic toxicity is an insufficient indicator of environmental hazards.

Also, there should be a new hazard criteria (12) category intended to operate as a miscellaneous category that would allow DTSC to designate a hazard criteria that might apply to a given chemical if information demonstrates it presents a hazard to human health and the environment.

7. Section 6xxxx.8

Section 6xxxx.8 prioritizes chemicals based on how likely they are to be released into the environment. Some chemicals might not meet any of these criteria and therefore would not be a priority 1, 2 or 3 chemical. What CoC's are left out? For CoC's that are not priority 1, 2 or 3 chemicals, no supply chain information dissemination (6xxxx.9(a)) or alternatives analysis (6xxxx.10(a)) or response action (6xxxx.20(a)(1)(A)) will be required. While some chemicals should be prioritized for early action, the regulations should subject all consumer products containing a CoC to the requirements for supply chain information dissemination, alternatives analysis and response actions.

AB 1879 requires prioritization based on two additional bases: volume of the chemical in the state and potential effects on sensitive subpopulations. HSC 25252(a)(1) and (3).

In addition, certain classes of chemicals are inherently more dangerous and should be prioritized, including CMR's, PBT's, vPvB's and ED's. Chemicals meeting these criteria should be prioritized for early action.

With respect to the current language of 6xxxx.8:

In 6xxxx.8(a)(1)(a), change "reasonably anticipated" to "reasonably likely." ("anticipated" by whom?)

In 6xxxx.8(a)(2), is "encapsulation" requirement needed here?

In 6xxxx.8(a)(2), include releases during "use, reuse, before during and after disposal" language from (1)(a).

8. Section 6xxxx.9

6xxxx.9(a) only applies to products containing priority 1, 2 or 3 CoC's. Why not all products containing any CoC, not just those containing priority CoC's?

6xxxx.9 does not appear to authorize disclosures to the general public or ultimate consumers (only "direct consumers"). The disclosures required by this section should be publicly available.

9. Section 6xxxx.10

6xxxx.10(a) applies only to products containing priority CoC's. Why not all products containing a CoC?

10. Section 6xxxx.14

Section 6xxxx.14(a)(2) specifies use only of data that makes a "material contribution." This invites too much discretion. All "relevant" information should be considered.

11. Section 6xxxx.15

Section 6xxxx.15(c) relates only to human exposure, perhaps even to direct exposure to the product. This should also include environmental exposures.

12. Section 6xxxx.18

Several comments on Section 6xxxx.18(a) appear in Section I.A. above.

In addition, Section 6xxxx.18(a) provides that the provisions of Section 6xxxx.17 must be complied with. But, as discussed in Section I.B.4 above, this section does not specify what the consequences will be if they are not or provide penalties or citizen enforcement.

Section 6xxxx.18(c) requires a “statement of overriding socioeconomic benefit” when there is no safer alternative to the product. Three comments on this statement follow.

(i) There is no definition of what this means or assignment of the burden of proof. It sounds like a cost-benefit test in which harm to human health and the environment can be justified by economic value. Section 6xxxx.18(c)(2) should provide that any product containing a CoC is presumed to have a significant impact on human health and/or the environment. A manufacturer may establish no significant impact if all the relevant evidence constitutes clear and convincing evidence that the product will not present a threat to human health or the environment. The manufacturer should demonstrate that despite these impacts, the product provides a clear socioeconomic benefit.

(ii) The relevance of this statement is unclear. Response Actions will be required under Section 6xxxx.20 based on “significant risk,” so why does it matter whether there is a socioeconomic benefit?

(iii) If this analysis will be required, it should also be required for any alternative selected for substitution if it contains a CoC.

We thank you again for the chance to provide comment in an ongoing way to DTSC as you lead this important effort.

Sincerely, on behalf of the CHANGE coalition,

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