CHANGE
Californians for a Healthy & Green Economy

COMMENTS ON THE
CALIFORNIA SAFER CONSUMER PRODUCTS
DRAFT REGULATIONS OF JULY 27, 2012

October 11, 2012

CHANGE Coalition
Californians for a Healthy and Green Economy

Californians for a Healthy and Green Economy (CHANGE) offers the following comments on DTSC's draft regulations to implement a Safer Consumer Products program under the authority of AB 1879. CHANGE is a statewide coalition of environmental and environmental justice groups, health organizations, labor advocates, community-based groups, parent organizations, faith groups, and others who are concerned with the impacts of toxic chemicals on human health and the environment.

We have closely tracked the development of the regulations by DTSC from the beginning. We appreciate that DTSC has provided CHANGE with the opportunity to provide the public interest perspective of our member organizations on this important effort.

Please let me know if you have any questions about these comments.

Sincerely,

Kathryn Alcántar

Kathryn Alcántar
CHANGE Campaign Director

CHANGE acknowledges that this is the first time a regulatory agency has set out to build a broad chemicals regulatory structure that has been mandated by statute to require analysis of alternatives to toxic chemicals. This is the first time an agency has attempted to regulate chemicals, and the products that contain them, by focusing first on intrinsic hazard traits of chemicals rather than exclusively relying on risk assessment. This is the first time chemical regulations are attempting to incorporate cumulative exposures, which are a key public health concern and as well as a long-standing demand from environmental justice communities. And this is the first time manufacturers of consumer products will be required to formally answer the question, "Is the use of this hazardous chemical necessary in my product?"

This approach constitutes a long-overdue paradigm shift in how society should manage chemicals, and represents an effort to generate a process of continuous movement towards a green economy, in which toxic chemicals can be replaced with non-toxic alternatives. Such an approach focuses on public, occupational, and environmental health, maintaining the essential concept of primary prevention.

Two components of the draft proposal are essential in our view and must be retained. The first is a large Chemicals of Concern (CoC) list that is unranked. The second is the requirement that the Department set science-based, case-by-case alternative analysis threshold levels. Detailed comments about these two issues are below.

However, as we have observed before, some portions of the draft regulations contain deep flaws that need to be fixed. In particular, there are two critical aspects to the program that require improvement: the standard of causation DTSC is requiring of itself to consider action; and the lack of transparency and oversight in the generation of Alternative Assessment reports. Our detailed comments about these issues also appear below.

Beyond these content issues, funding must be found so DTSC can carry out the program. There is consensus among all stakeholders that DTSC does not have the resources to undertake implementation in a sustained way. DTSC has said that only 2-5 product categories will be identified in the first round, and a final alternative analysis report will take three years if all goes smoothly. The pace of work outlined in the draft regulations will lead to very modest accomplishments. It would be impossible to argue that the program can generate any significant throughput without additional funding.

Providing DTSC with the means to implement this program should be a top priority for the Legislature. CHANGE intends to continue to communicate this priority to elected officials. However, as a first step, we urge DTSC to build permitting and licensing fees, which would not rely on legislative action, into the regulations.

Furthermore, a "no data, no market" requirement must be developed to close the pervasive data gaps about chemical information and to put all chemicals, both new and old, on a level playing field. DTSC's limited ability to create a requirement for a minimum data set for all chemicals in commerce under its existing authority is a critical shortcoming of the proposed program. Building a "no data, no market" mechanism into California's regulatory structure is a big job that remains to be undertaken. This is another key task for the Legislature: filling the data gaps outlined in the 2006 report *"Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation"* which was commissioned by the Legislature in 2004.

CHANGE's view of the draft regulations is that there are important improvements that still need to be made so they can be as effective as possible. But it is now time for DTSC to quickly bring this program online and see how it works in the real world.

A comprehensive Chemicals of Concern list is critical to the SCP program's success.

CHANGE strongly supports DTSC's plan to post a robust list of Chemicals of Concern (CoC) within 30 days of the effective date of the regulations that relies on the work of authoritative science bodies. The proposed list contains chemicals for which there is already sufficient cause for concern for human and environmental health. Relying on authoritative bodies, which have listed chemicals after comprehensive and peer-reviewed scientific processes, constitutes a thoughtful and reasonable process for the identification and prioritization of Chemicals of Concern.

The language of AB 1879 explicitly requires DTSC to identify chemicals of concern in Section 25252 (a). There is no mention in the statute of a category called "chemicals under consideration" and therefore CHANGE believes retaining the term "chemicals of concern" in the regulations is appropriate and legally required.

A large CoC list will support, encourage, and stimulate efforts by forward-thinking entrepreneurs and businesses to voluntarily act before subsequent regulation compels them to do so. This will create jobs for California's green economic development. The size of this list will, as DTSC intends, help reduce the problem of regrettable substitutions. A large CoC list will enable DTSC to use scarce resources for other important program activities.

While some may claim that the estimated 1,200 chemicals which will be listed is too large a number to be meaningful, in fact it represents only a small fraction of the more than 80,000 industrial chemicals currently registered for use in the U.S., most of which are not adequately tested for health and safety effects before reaching the market.

CHANGE also strongly supports DTSC's intent not to rank chemicals on the CoC list in what would be a misguided effort to identify and prioritize the "worst" chemicals. We believe such an effort is inherently impossible because of the pervasive data gaps and difficult judgments that would be required to compare and rank different kinds of harm. It would result in an endless paralysis by analysis and lead to fruitless litigation over the resulting prioritization. Moreover, such ranking is not required by AB 1879. An unranked list is consistent with the approach used by other states with similar programs. Chemicals on the list have made it through prioritization processes of a variety of reputable scientific bodies and legislative authorities. An unranked list also provides strong market signals so that manufacturers and others can begin looking for alternatives before products are prioritized.

DTSC should specify that when any lists it relies on are updated, the updated list becomes the version that DTSC uses in its own CoC list.

We support the addition of the Priority Chemicals list of the California Environmental Contaminant Biomonitoring Program.

The proposed CoC list needs some additions. DTSC should ensure that all hazard traits identified by OEHHA are captured in its CoC list, including neuro-developmental hazard traits.

DTSC should also augment the list with substances of particular relevance to workers and consumers: asthmagens, respiratory sensitizers, skin irritants/sensitizers. OEHHA lists these hazard traits already (e.g., Chapter 54, s. 69403.16 Respiratory Toxicity) and there are lists available from North America and Europe. The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) also includes these

hazard traits, which the US federal *Hazard Communication Standard* will require to be considered on "safety data sheets" in the next few years. California already plans to follow suit, adopting the federal changes at a minimum.

For asthmagens and other sensitizers:

- http://www.cdc.gov/niosh/topics/skin (NIOSH information about skin irritants and sensitizers);
- http://www.aoecdata.org/ExpCodeLookup.aspx (Association of Occupational and Environmental Clinics -- AOEC);
- http://esis.jrc.ec.europa.eu/index.php?PGM=cla (*European Chemical Substance Information System*. Table 3.1, searching for H317 Skin sensitizer Cat 1 -- may cause an allergic skin reaction -- and H334 Respiratory sensitizer Cat 1 -- may cause allergy or asthma symptoms or breathing difficulties if inhaled.);
  - http://www.cleanproduction.org/library/greenScreenv1-2/Green_Screen_v1-2_Supporting_Lists.pdf

Other lists CHANGE recommends including are the following:

- Washington State Department of Ecology *Reporting List of Chemicals of High Concern to Children* at http://www.ecy.wa.gov/programs/swfa/cspa/chcc.html;
- Minnesota's list of 1,700 chemicals of high concern in 2010 under the *Minnesota Toxic Free Kids Act*;
- Maine's list of 1,700 chemicals of high concern in 2009 under the Maine Toxic Chemicals in Children's Products Law;
- California's 303(d) list of impaired waterways: http://www.waterboards.ca.gov/water_issues/programs/tmdl/303d_lists2006_epa.shtml.
- The Skin Disease portion of the Haz-Map database from the U.S. National Library of Medicine, http://hazmap.nlm.nih.gov/types-of-diseases; and
- The Green Chemistry & Commerce Council's *an analysis of corporate restricted substance lists (RSLs) and their implications for green chemistry and design for environment*, November 2008 (chemicals listed in Appendix 1), http://www.greenchemistryandcommerce.org/publications.php

We are alarmed that the proposed list of CoCs does not include the 303(d) list of the federal Clean Water Act for contaminants impacting California waterways. This is the central list by which to identify water pollutants impairing the state's waters to the degree that they violate water quality standards as specified by the federal Clean Water Act and California's Porter Cologne. It is necessary to include the contaminants on the 303(d) list in order to ensure that water quality is given the priority it deserves when identifying CoC/Priority Product combinations. Without it, we do not see a pathway for DTSC to address water quality concerns. Furthermore, the regulations should indicate that Department will review the list each time it is updated by the California State Water Resources Control Board.

§ 69502.2(b)

In addition, it is important to provide a mechanism for additions to the CoC list that do not appear on existing authoritative body lists. New peer-reviewed science, for example, can point to health or environmental concerns before authoritative bodies can act. As written in the current draft, CHANGE supports DTSC having the authority to identify new CoCs based on their hazard traits or environmental or toxicological endpoints. This is an important avenue for new chemicals of concern to be identified as soon as possible, and it further distinguishes the Safer Consumer Products program as forward-looking.

§ 69504.(a)

CHANGE supports the petition process whereby a person may petition DTSC to add or remove a chemical or the entirety of an existing chemical list to the SCP CoC list.

§ 69502.3(a)

DTSC needs to specify how often the CoC list will be formally updated. As currently written, DTSC will do

this "periodically." CHANGE urges that the CoC list be updated at least every two years.

§ 69502.3(c)
CHANGE supports the opportunity for formal public input on proposed revisions to the CoC list.

CHANGE strongly supports the removal of default alternative analysis (*de minimis)* threshold exemptions.

One of the most important improvements in the new proposed regulations is the removal of the alternative analysis threshold (AAT), or what was termed a "*de minimis*" level in previous drafts. CHANGE, along with many from the scientific community, members of the Green Ribbon Science Panel, a coalition of 44 wastewater agencies, and many other environmental and public health groups pointed out the serious problems inherent within the proposed default alternative analysis threshold. We are gratified to see that DTSC has addressed these serious concerns and eliminated default AAT thresholds from the proposed regulations.

While we recognize that the previously proposed default thresholds of 0.01 percent and 0.1 percent (depending on the health endpoint in question) was somewhat more protective than de minimis thresholds in other programs and was an improvement over the original proposed 0.1 percent threshold for all health endpoints, these default thresholds nevertheless lacked scientific justification and would have posed significant public health hazards.

For example, a consumer product could have contained 20 times more lead or arsenic, 100 times more cadmium, 200 times more benzene, and 500 times more mercury than what would be considered a hazardous waste under federal Environmental Protection Agency regulations, but be exempted *a priori* from undergoing alternative analysis under DTSC's previous proposed regulations. Given that DTSC is the California agency that enforces EPA hazardous waste regulations, this provision of the regulations was simply unsupportable.

We also know from peer-reviewed research that some chemicals, previously thought to be harmless, can in fact have adverse impacts at extremely low doses. For the endocrine disruptor bisphenol A, for instance, effects can be observed in the parts-per-trillion range. A threshold of 0.01 percent would have failed to be protective by several orders of magnitude. Endocrine disruptors in general would have been under-recognized within DTSC's proposed structure.

Moreover, the previously proposed AAT exemption would have created perverse incentives than ran counter to the intent of the program. For example, product manufacturers would have been motivated to continue to use chemicals of concern (and other dangerous chemicals) as long as they were below the AAT threshold. Manufacturers would also have been motivated to replace a chemical of concern used at levels above the threshold with multiple chemicals of concern each at levels below the threshold. These counter-productive incentives would have undermined the intent and central goal of AB 1879, to prompt a search for safer alternatives.

We commend DTSC for its decision to affirm scientific integrity and chemical-specific alternative analysis thresholds for each product category the agency prioritizes for review. This approach is vastly preferable to a one-size-fits-all approach that lacks scientific integrity and undermines the intent of the Safer Consumer Products program.

Illegal standard of causation language

The proposed regulations employ a burden of proof for causation that is higher than that specified by AB 1879. That burden should be conformed to the requirements of AB 1879.

We believe that DTSC has strayed so far from the clear provisions of AB 1879, the intent of the law and the Green Chemistry Initiative and the earlier drafts of the regulations that we request that DTSC provide a full written explanation of its decision on this issue, including answers to the six questions we pose below, at the end of this section.

This erroneous causation standard carries enormous consequences for the program. It will in practice disable the program from its goal of encouraging industry and society to begin to avoid early warnings of harm. It also causes the regulations to diverge from DTSC's goal of making them legally defensible. This destabilizes the program because not only may NGO's legal challenge the validity of the regulations, but one can expect an individual industry to do so as well whenever DTSC attempts to enforce the regulations or a regulatory response against that industry. Moreover, the erroneous causation standard destabilizes the initial COC list by potentially opening an avenue for removing chemicals from that list. For all of these reasons, we hope DTSC will take this issue very seriously.

AB 1879 explicitly requires DTSC to establish a process for identification of chemicals of concern that must include evaluation of the "potential" effects of a chemical on sensitive subpopulations, including infants and children, HSC § 25252 (a)(3), and evaluation of the "potential" for exposure to the chemical in a consumer product, HSC § 25252(a)(2). It requires DTSC to develop a process for evaluating alternatives to a COC that must include evaluation of all the "potential" hazards of the alternatives. HSC § 25253(a)(2); 25253 (a)(2)(K). Finally, AB 1879 instructs DTSC "to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern" in fashioning a regulatory response after the alternatives assessment process is complete. HSC §25253(a)(1). The requirement for DTSC to determine how best to limit exposure or reduce the level of hazard is consistent with the concept of reducing even potential exposures and hazards wherever reasonably possible.

Thus, AB 1879 requires DTSC to develop a process to evaluate the "potential" hazards of and "potential" exposures to chemicals when identifying them as COCs, and then a process to evaluate the "potential" hazards of any potential alternatives before DTSC may then fashion a regulatory response to best limit exposure or reduce the level of hazard.

In contrast to these unambiguous requirements of AB 1879, the objective of the current regulatory proposal is to evaluate and respond only to hazards that a chemical is shown to have the "ability" to cause or contribute to. The "potential" standard of earlier draft regulations has been replaced by the "ability" standard virtually throughout this version. As one example, §69502.2(H)(b)(1)(A) provides that in order to list a chemical as a chemical of concern, DTSC must consider the "ability of the chemical to contribute to or cause adverse public health and/or environmental effects." (This and similar standards of causation used at various places in the proposed regulations that recite or imply the word "ability" are referred to herein as "ability" standards of causation.) "Ability" rather than "potential" is now used in the provisions relating to whether a chemical can be identified as a COC (see, for example, p. 23, line 12; p. 23, line 23; p. 23, line 34; p. 23, line 40). It is used in the provisions relating to identification of a priority product (see, for example, p. 25, line 32; p. 26, line 2; p. 26, line 5; p. 26, line 17; p. 27, line 9; p. 27, line 27; p. 27, line 27). It is used or implied in the provisions relating to preparation of an alternatives analysis (see, for example, p. 42, lines 3-7; p. 42, lines 14-16; p. 43, lines 8-12). It is similarly implied in the very definition of a safer alternative (see p. 13, line 14). It is explicitly used in

some of the provisions relating to regulatory responses (see, for example, p. 55, line 13; p. 55, line 38) and effectively by implication in others (see, for example, p. 52, line 8; p. 52, line 12; p. 54, line 5).

In the paragraph above we have sometimes said that a provision uses the "ability" standard by implication. Let us explain that. Take, as an example, the regulatory response section §69506(a). That section provides that DTSC shall implement regulatory responses designed to protect public health and the environment and maximize use of alternatives of least concern. There is no explicit reference to the term "ability" (or "potential" or any other particular standard) in that section. But, if COC's and alternatives are identified and compared in AA's that consider solely evidence that meets the "ability" test, with any lesser evidence showing only "potential" adverse effects discarded from the analysis, then any regulatory response by DTSC could only protect public health from adverse effects from COC's or alternatives that can be shown to meet the "ability" test. DTSC will not be able to protect the public or environment from "potential" hazards because DTSC will have no evidence of any such potential hazards in the record for it to consider. Similarly, in maximizing use of alternatives of least concern, the only evidence DTSC will have before it in AA Reports will be any evidence that the COC and alternatives meet the "ability" test, with all lesser evidence of potential harm removed from its consideration. Thus, the "ability" test is impliedly employed in this section.

The same issue arises in §69506(b), which instructs DTSC to focus on "avoidance or reduction of adverse impact or exposure" by a COC in a product. Again, the section does not explicitly recite the "ability" test. But the only evidence of any adverse impact or exposure that will be present in the AA Report being considered by DTSC will be that rising to the level of meeting the "ability" test. Evidence not rising to that level will not be part of the record for DTSC to consider. Again, the "ability" test is impliedly employed in this section.

While the proposed regulations use the "ability" test explicitly in numerous places, the impact of that test is felt even more broadly and, indeed, infects every aspect of the proposed regulations. The pervasive use of the "ability" standard explicitly and by implication means that potential hazards cannot be considered by DTSC in identifying COCs, by alternatives assessors comparing alternatives to COC's, or ultimately by DTSC in fashioning a regulatory response. This approach, which contrasts with that mandated by AB 1879, would not fulfill the requirements of the law.

The bottom line: the use of the "ability" standard of causation in the proposed regulations is illegal under AB 1879.

One potential contradiction in the proposed regulations in particular should concern DTSC. That is that many of the authoritative bodies relied on for identification of the initial COC list very likely use a standard that is less stringent than the "ability" test of these proposed regulations. Does use of the "ability" standard in the regulations undermine DTSC's ability to rely on those authoritative bodies? Will it be used by industry to have COC's removed from the initial COC list where the evidence used by an authoritative body does not rise to the level of the "ability" test? How can DTSC justify these contradictions?

There is an enormous difference between a chemical that presents a "potential" hazard and one that has the "ability" to contribute to cause an adverse effect. The scientific reality of the impact of toxic chemicals on the environment and human health is that often the best evidence available is that a chemical may contribute, along with other chemicals and other environmental factors, to adverse effects on human health and the environment. The difference between the standards is that between acting on early warnings of harm and waiting for proof of harm before acting. The former is the goal of all modern chemical policy reform efforts, including the Green Chemistry Initiative. The latter represents the discredited approach urged and sought by the chemicals industry as it seeks to externalize the damage from its chemicals onto society. As compared to a "potential" standard,

because it would remove early warnings of harm from consideration under the regulations, the "ability" standard disables DSTC from acting on early warnings of harm and therefore is essentially deregulatory in effect.

There was a time in the not too distant past when DTSC clearly understood this issue and the requirements of the law. Draft proposed regulations as recent as the October 31, 2011 version, after 3 years of drafts and regulatory development, were directed to "potential" adverse effects. It is only recently under the Brown administration that DTSC has lost its way on this issue.

We understand there to be several reasons offered for adopting the "ability" standard. One is that the "potential" standard could allegedly be met by any chemical, even those for which there is no data at all. We disagree. Establishing that a chemical has the "potential" to exhibit a hazard trait requires a body of reliable information. In our view, words other than "potential" can carry the same meaning, such as the word "may," as in the "may present" standard of TSCA Sections 4 and 5. In the case of TSCA, no one has ever suggested that TSCA's "may present" standard can be satisfied in the complete absence of evidence.

DTSC should be clear that use of the "potential" standard is not the same as switching the burden of proof onto industry (which would mean that chemicals are assumed hazardous until proved otherwise). A complete absence of information cannot establish that a chemical is potentially hazardous. The "potential" standard is a lower, but not a switched, burden of proof.

To remove any confusion about this issue, if that is the problem, we suggest DTSC provide a simple definition of "potential" to exhibit a hazard trait and clarify that any finding of a "potential" hazard requires reliable information to substantiate the finding.

A second reason suggested is that the term "ability" is allegedly "less ambiguous" than the term "potential." We emphatically disagree. There is nothing inherently more ambiguous about the term "potential" than about any other term defining a burden of proof. Even TSCA contains legal standards such as whether a chemical "may" present an unreasonable risk. See TSCA, Sections 4, 5. Standards such as "may present" or "potential" are not vague as compared to more stringent standards such as "ability" or "beyond a reasonable doubt"; they establish lower burdens of proof but are not more vague. Whatever standard is chosen, whether "ability" or "potential," there will undoubtedly be disputes over its precise meaning until some content is given to it through experience or a clear definition is provided. But there is nothing inherently more vague about "potential" as compared to "ability."

Indeed, just the opposite. Substantial confusion has emerged as to exactly what is meant by the "ability" standard. If anything, it is the vaguer term. Does it mean that a chemical must be proved to be able to cause adverse effects under any circumstances, regardless of whether those circumstances exist in the real world (such as through high dose tests)? Or does it mean that a chemical must be shown to be able to cause adverse effects as it is used in practice? In law, this is the distinction between specific and general causation – which is meant by the "ability" standard? DTSC should ask itself and answer the questions: has BPA been shown to have the "ability" to contribute to or cause an adverse effect? Have brominated fire retardants? Has mercury? Is DTSC going to be able to regulate any chemical hazard under this standard?

For all these reasons, CHANGE believes that the "ability" causation standard is illegal under AB 1879, and is also bad policy that flies in the face of the purpose of the California Green Chemistry Initiative. The regulations should be reoriented toward "potential" hazards by pervasive substitution of the "potential" standard for the "ability" standard in at least the places identified above.

In the event that DTSC does not reorient the regulations to the "potential" standard, then CHANGE requests that the Department explain in writing the following:

a. Why does AB 1879 not require the regulations to employ the "potential" standard?

b. What standard does AB 1879 authorize and what is the evidence for that?

c. If the Department insists on adopting the "ability" standard, what is the legal basis for adopting that standard rather than some other standard that would provide more public health protection than the "ability" standard, such as a "reasonable likelihood" standard, "likely" standard or "probable" standard?

d. If the Department chooses to retain the "ability" standard, what is the policy basis for adopting it, including an explanation of (1) the balance the Department is seeking to strike between protecting public health / environment and vested commercial interests and (2) the reason it must be applied throughout the regulations rather than in some places but not others?

e. If the Department chooses to retain the "ability" standard, what exactly does it mean? Does it refer to the inherent ability of a chemical to cause an adverse effect, or to proof that the chemical does cause such effects as used in the real world, or to something else?

f. Do all of the chemicals on the initial COC list all meet the "ability" standard of causation, and if they do not, must they be removed from the COC list; and why or why not?

Minimize regrettable substitutions by prioritizing classes of chemicals.

The draft regulations may result in regrettable substitutions as companies switch out of chemicals of concern before their product is designated as a priority product. Past proposals for implementing regulations have included: (1) a no data, no market requirement for all or most chemicals in commerce; or (2) detailed, admittedly cumbersome reporting requirements anytime a CoC is altered in any product. The current regulations do not address this, although the large number of CoCs may help somewhat with this problem.

Prioritizing classes or groups of chemicals or products, rather than taking them up individually or relying on authoritative body listings, would minimize regrettable substitutions. DTSC should consider building in a mechanism to do this when appropriate.

We suggest that at the very least, DTSC should try to collect information about the extent of this problem to inform the design of future elements of the GCI. In these regulations, DTSC could and should develop regulatory provisions to help accumulate information as to whether and how often companies switch out of CoCs prior to entering the formal AA process. For example, companies could be required to report to DTSC if they switch out or reduce the amount of a CoC in any product once the CoC list is finalized. A simple, non-burdensome program could provide information of great value in the further development of the regulations.

Cumulative exposures/impacts is an important component of the program.

CHANGE strongly supports DTSC's efforts to build in cumulative exposure. Addressing this regulatory challenge is long overdue and is a fundamental concern for many environmental justice communities and public health experts. It is important and appropriate because emerging science shows that many of our environmental and public health problems stem from the cumulative impact of many diverse stressors, often including, but not limited to, numerous chemicals. The European Commission, for example, has recognized that multiple exposures from combinations of chemicals have note been adequately addressed in existing regulatory structures and has taken steps to develop new approaches – see http://ec.europa.eu/environment/chemicals/effects.htm .

California EPA is engaged in an ongoing process that is studying cumulative impacts (OEHHA's Cumulative Impacts and Precautionary Approaches Workgroup). As OEHHA continues its work to develop tools to address this, we encourage DTSC to maintain its commitment to this issue.

What is important to consider is the impact of chemicals as they accumulate with other broadly defined environmental factors, not just "other chemicals with the same or similar hazard traits." Therefore, as before, we recommend that the regulations include language that commits DTSC to examining cumulative effects not just with other chemicals but "with other environmental factors" which include, but are not limited to nutrition, the built environment, and socioeconomic status.

We recognize that cumulative impacts are difficult to quantify, and yet it is also important to not restrict the scope of inquiry. Qualitative or semi-quantitative analysis of the real scope of impacts is more likely to be useful than greater quantitative analysis of a small portion of impacts.

§ 69502.2(b)(1)(A)(3) Page 23 line 16
Current language: The chemical's cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints.

Suggested language: The chemical's cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints, **as well as with other environmental factors**.

§ 69503.2(a)(1)(A)(1)(c) Page 25 line 38
Current language: The Chemical(s) of Concern cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints.

Suggested language: The Chemical(s) of Concern cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints, **as well as with other environmental factors**.

§ 69503.5 (d) Page 32 line 26
CHANGE strongly supports this section so that if multiple Chemicals of Concern exhibit the same hazard trait and/or environmental or toxicological endpoint(s) that have been identified as the basis for the products being listed as a Priority Product, DTSC may specify a single alternatives analysis threshold that applies to the total concentration in the Priority Product of all such CoCs.

Environmental impacts are neglected in the first round selection of Priority Products and should be included.

CHANGE has consistently advocated that environmental endpoints be prioritized along with human health impacts when establishing both a Chemicals of Concern (CoC) list and choosing Priority Products. Our concern has been that environmental issues are often not as readily apparent or seen as urgent as hazard traits such as carcinogenicity or the known ability of a chemical to cause reproductive harm. However, environmental protection is critical for a variety of reasons:

- A healthy environment is essential to the overall well being of society and is in and of itself worthy of protection.
- Environmental impacts, such as those to wildlife and ecosystems, are often first indicators or early warnings of adverse impacts on human health and safety.
- Human exposure, including those that can result in serious health impacts, is often due to environmental exposure (as opposed to exposure by direct use of or contact with a product), such as through the air, drinking water, and contaminated food sources.
- Continued introduction of chemicals into the environment places heavy technical, regulatory, legal, and financial burdens on local communities and agencies that must meet certain environmental standards or be in violation of the law. For instance, investing in higher levels of wastewater treatment to remove the many toxic substances from today's consumer products would cost California's more than 300 treatment plants hundreds of billions of dollars and, in the end, may not be technologically feasible.

§ 69501.1 (19)(A)2. and **§69503.2(a)(1)(A)h.** In earlier comments to DTSC, CHANGE offered suggestions to ensure and strengthen the consideration of environmental endpoints for the CoC and Priority Products lists. We support the addition of "degradates, metabolites, and reaction products" in the definition of a chemical, and consideration of a CoC's ability to degrade, form reaction products, or metabolize into another CoC or chemical that exhibits one or more hazard traits and/or environmental or toxicological endpoints.

As already stated, CHANGE is deeply concerned by the omission of California's 303(d) list of impaired waterways and related contaminants. Other concerns regarding environmental endpoints include the following:

§ 69503.3 (g) CHANGE strongly opposes the language in this section and urges that it be stricken. There is no reason to restrict the universe of CoCs to be considered in the first round of the Priority Products categories as the program gets underway. In fact, by requiring that chemicals in consumer products on the initial Priority Product list(s) (those prior to 2016) meet criteria described in BOTH sections §69502.2 (a)(1) and (2), DTSC effectively ensures that water pollutants will not be included because there are no ecotoxicity lists that are equivalent to the human PBT and CMR lists described in section §69502.2(a)(1). Consequently, pollutants on the 303(d) list, solvents, metals such as copper or zinc, and other common surface water and groundwater contaminants will be omitted. If a chemical appears on the CoC list, this should be sufficient for a consumer product containing that chemical to be considered for prioritization.

What DTSC does in the first few years that these regulations are implemented will be critical to setting the stage for their future effectiveness and that of the Green Chemistry Initiative as a whole. For this reason, limiting the Priority Product list in this way is both inappropriate and sets a troublesome precedent for decision-making by future DTSC staff and leadership. It also substantiates concerns that many in the water community – public advocates and water agency personnel – have expressed over the years, namely that environmental concerns will not be addressed with adequate vigor. For these reasons, CHANGE strenuously urges DTSC to strike §69503.3(g).

§ 69501.1(a)(3)
It should be made explicitly clear that the definition of "adverse air quality impacts" includes both indoor and outdoor air quality impacts.

Occupational health and worker protection of workers must be more consistently incorporated into the regulations.

§ 69501(b)(2), Page 4, lines 17-21
This section of the draft exempts products placed into the stream of commerce "solely for the manufacture" of a consumer product exempted from AB 1879. There is no reason a product used to make an exempted product should not be subject to the regulation – the statute excludes certain exempt products, not all chemicals used in their manufacture. This is an example where workers, who should be granted equal protection in the regulations, would be exposed to CoCs that others would not. We strongly object to this section and recommend that it be deleted.

§ 69501 (b)(3) Page 4, lines 22 – 23
Workers in California face hazards related to the manufacture, storage, or transport of products in the state, regardless of where those products are eventually sold. Hence, the regulations must apply to all products manufactured, stored, or transported in California, whether they are sold here or not.

The ISOR argues that the regulations are meant to design "consumers" from harmful chemicals in products. But consumers are not only individuals – businesses are consumers as well, buying chemicals and other products for manufacturing purposes in the state.

CHANGE has consistently objected to this section that exempts products that are manufactured or transported in California, but not sold here. This will expose workers who make the products and communities through which the products are transported to hazards that the regulations are meant to prevent. Workers and fenceline communities are members of the public and entitled to equal protection from harmful substances.

Any product that is manufactured here, whether it is sold here or not, will have an impact on the environment and public health. This section as drafted subverts the statute's goal of incorporating life cycle thinking. Life cycle is defined in 69501.1 (a)(39) to include manufacture, transport and distribution. In 69503.2 (a)(1)(B)4.a., "manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices" as Product Prioritization Factors.

We support the earlier comments from GRSP member Julia Quint, who has pointed out the unethical nature of excluding a consumer product that is "passing through" California. She wrote: "In contrast to customers, clients and members of the public who 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."

§ 69501.1(a)(6), Page 6, lines 4-5
CHANGE supports the language that states, "Public health includes occupational health." This is consistent with the definition, understanding, and practices of public health.

§ 69501.1 (a)(22)(A), Page 8, line 32

DTSC should ensure that the definition of "Consumer Product" makes clear that chemicals and products used in the workplace, including bulk purchases, are included.

Add language under a new 69501.1(a)(22)(A)4. to read: Chemicals and products used in the workplace, including bulk purchases.

§ 69501.1(a)(53)(A)2., Page 12, lines 14-15
We support this section where "reliable information demonstrating the occurrence of exposures to a chemical" includes monitoring data that shows the chemical to be "present in, or released from, products used in or present in the home of places of employment."

§ 69501.5 (entire section) Pages 18 – 20)
We support this section that will make information available on DTSC's website, which will enhance workers' right to know about the hazards of products they use, and the Injury and Illness Prevention Programs (IIPPs) their employers must prepare.

Unfortunately, the information only will be available in English. This does little for the many people in the state with literacy issues in that language. We recommend that the list of chemicals of concern and priority products should be available at least in Spanish. Other government agencies do this (e.g., Cal/OSHA, DLSE).

§ 69505.5 (f)(2)(B)
This section requires a description of how safeguards provided by other federal or state regulations were considered in AAs. DTSC should add language here that does not permit AAs to rely on outdated and inadequate occupational exposure limits in the development of a safer alternative chemical or product.

§ 69506.4, Page 54
Product information for consumers, as specified in this section, also needs to be made available to workplaces. "Consumer products" are used in workplaces and by workers every day. They have as much right to know about hazardous chemicals and products as others, including other consumers.

Workers are appropriately included in the definition of "sensitive sub-populations" .

§ 69501.1(a)(58) Page 13 lines 19-25
CHANGE supports the inclusion of language in this definition that identifies workers as a sensitive sub-population when they experience greater chemical exposures due to the nature of their occupation. It recognizes that occupational hazards often lead to greater and longer exposures than those encountered in other settings (e.g., someone cleaning their own home). The exposures can be both higher and more frequent, making the hazard significant.

The wording in this section could and should be improved, however because workers face increased hazards not only because of the "nature of their occupation" but also because of the specific tasks or activities they perform at work. For example, studies show that female cleaners and parks workers face different ergonomic and chemical hazards than their male counterparts, even when they have the same job title. It's what they actually do that matters.

Accordingly, CHANGE recommends changing the last sentence of the definition of sensitive sub-population (page 13, lines 23-25) as follows:

Current language: "Sensitive populations" also includes persons at greater risk of adverse health effects when exposed to chemicals, because they are either individuals with a history of serious illness or greater exposures or workers with greater exposures due to the nature of their occupation.

Suggested language: "Sensitive populations" also includes persons at greater risk of adverse health effects when exposed to chemicals, because they are either individuals with a history of serious illness or greater exposures, or workers with greater exposures **than the general population, due to the nature of their occupation and specific duties.**

The definition of "sensitive sub-populations" should be expanded to include women of reproductive age.

We also believe women of child-bearing age should be added as a sensitive sub-population. If we are concerned about exposure to chemicals at vulnerable windows of development (as we should be), then we must protect the woman who may become pregnant. The first weeks of gestation are a time of rapid development for the fetus and therefore also a time of critical vulnerability to harm. Consequently, many hazards to normal development threaten the fetus *in utero* early in pregnancy including before a woman may know she is pregnant. To protect the fetus, women of reproductive age must also be protected in addition to women who already know they are pregnant.

It should also be noted that children fathered by men who work in some occupations with high chemical hazards are at higher risk for birth defects. See Desrosiers, T.A.,, et al. (2012) "Paternal occupation and birth defects: findings from the National Birth Defects Prevention Study", *Occupational and Environmental Medicine*, 69(8): 534 – 542; and also Olshan, A.F., Teschke, K., & Baird, P.A. (1991) "Paternal occupation and congenital anomalies in offspring", *American Journal of Industrial Medicine*, 20(4):447 – 475.

DTSC actions, as well as innovation, will be hampered by dependence on "available information."

The draft regulations give preference to information that is already "available." Furthermore, prioritization and other decisions are influenced by, and are in fact dependent on, the current availability of safer alternatives. This sends the wrong signal to the marketplace and in fact runs counter to the goals of the SCP program by deterring innovation and the development of new alternatives. It could be interpreted to mean that no information implies a CoC is "safe." DTSC should not unnecessarily limit their decisions based on the availability of a safer alternative, especially in the regulatory response phase.

Much of what we are learning about potential harmful effects from chemical exposure is based on science that has emerged (and is emerging) quickly in recent years. New chemicals, and existing chemicals that have not been sufficiently studied, frequently lack the data sets that the definition of "safer alternative" could be interpreted to require.

There are many instances where DTSC's decisions and regulatory actions will be limited by the lack of available information. By giving preference to, and relying on, the current availability of chemical data, instead of exercising the Department's authority to request new information, DTSC will find itself promulgating the

data gap that continues to limit innovation or the development of green chemistry based alternatives. It also ensures that the burden of proof remains on the regulatory agency to demonstrate a chemical's hazards, not on the companies making the chemical or product containing the chemical to demonstrate it will not cause harm.

The SCP program should formally identify chemicals with little or no toxicity information as lacking adequate safety data. Furthermore, DTSC should use its call-in authority under AB 1879 to require the generation of new health and environmental data in order to accurately identify CoCs and safer alternatives and to make appropriate regulatory responses. DTSC should exercise this authority as early as possible in the program's implementation.

§ 69501.4(a)(3)
§ 69501.4(a)(4)
§ 69501.4(a)(3)(b)
Much of the information about chemicals that is needed by DTSC and the public is already known by manufacturers in-house, and should be required to be submitted to DTSC. While DTSC's effort to obtain existing or new information is laudable, the language should be strengthened so it is a requirement for responsible entities. Throughout these sections, "request" should be replaced with "require."

§ 69502.2(b)(3)
This is an example where DTSC could, instead of merely considering "the availability of reliable information to substantiate the potential adverse impacts and exposures," require responsible entities to provide or produce the needed data for additions to the CoC list. This would reverse the burden of proof and bring more information forward sooner.

§ 69503.2(a)(2)
Rather than rely on availability of information, DTSC should use this as an opportunity to require responsible entities to provide or produce information needed to make an informed decision.

§ 69506.2(a),(b)
CHANGE strongly supports the language in these two sections that gives DTSC authority to require the provision or development of needed additional information. This information would be even more useful earlier in the process.

The regulations are silent about how to treat chemicals for which we have insufficient or no information.

CHANGE continues to contend that chemicals for which there is little or no toxicity information can reasonably be considered CoCs under AB 1879, giving DTSC the authority to request further information so these chemicals can be assessed.

In the absence of such a minimum data requirement, the regulations should at the very least create a mechanism to identify these chemicals – a "yellow flag" that sends a message to the market and the public that they are under-studied and not necessarily "safe" or non-toxic.

The draft regulations rely too often on an over-reliance on simply reducing or containing chemical exposures instead of preventing their use.

We recognize that exposure data will be considered in the SCP implementation, but the innovative intent of AB 1879 is to base decisions on reducing hazards as the highest priority. That is, if a substance is dangerous, this is reason enough to act to restrict its use. Otherwise, it is far too easy to fall into a strategy of "containment" whereby exposures continue to be allowed based on a plan of containing a chemical to reduce or contain exposure. This approach unfortunately fails too often; for example, this can be easily seen in workplaces where workers still have to handle toxic chemicals and limiting harm is the most common solution, rather than eliminating a hazard. Moreover, safety standards are generally inadequate and often out-of-date.

Moreover, "containment" or "control" fails to drive the development and use of less toxic chemicals, one of the overarching goals of both the SCP regulations and California's broader Green Chemistry Initiative.

While CHANGE recognizes that restricting exposure by confining a chemical within a product may be an improvement and is in keeping with DTSC's approach of not prescribing how manufacturers address the CoCs in their products, CHANGE has consistently advocated that engineering safety measures or administrative controls be viewed as *interim actions*, not permanent solutions to reduce danger to the public and the environment while inherently less hazardous alternatives are developed.

§ 69506.7 (a) Page 57
CHANGE recommends that any engineered safety measures or administrative controls imposed by DTSC in in this section be considered ***an interim action*** until a more sustainable solution is found.

Current language for § 69506.7 (a)
The Department may, under subsection (b), impose requirements that control access to or limit exposure to Chemical(s) of Concern in a selected alternative product, or a Priority Product for which an alternative is not selected, to reduce the likelihood of adverse public health and/or environmental impacts.

Suggested language for § 69506.7 (a)
The Department may, under subsection (b), impose requirements that control access to or limit exposure to Chemical(s) of Concern in a selected alternative product, or a Priority Product for which an alternative is not selected, to reduce the likelihood of adverse public health and/or environmental impacts as an interim action while a solution to eliminate the hazard is found.

§ 69501 (a) Page 4, lines 8-12
Current language: This chapter specifies the process for identifying chemicals as Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying alternatives to consider for Priority Products to determine how best to limit exposure to, or the level of adverse impacts posed by, the Chemical of Concern in the product.

Suggested language: This chapter specifies the process for identifying chemicals as Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying alternatives to consider for Priority Products to determine how best to reduce the use of toxic chemicals, or the level of adverse impacts posed by the Chemical of Concern in the product.

§ 69501.1 (a)(11)(D) Page 7 line 24

Current language: Any other change to a Priority Product or a manufacturing process that reduces the adverse public health and/or environmental impacts or exposure associated with the Chemical(s) of Concern in the Priority Product.

Suggested language: If Removal, Reformulation, or Redesign is not feasible, a secondary strategy of another change to a Priority Product or a manufacturing process that reduces the adverse public health and/or environmental impacts or exposure associated with the Chemical(s) of Concern in the Priority Product.

§ 69505.3 (b)(2)(A)1 Page 41, lines 30-35

Current language: In addition to any alternative identified under paragraph (1)(C)2., the responsible entity shall identify alternatives that meet the definition of "alternative" under Section 69501(a)(11) and meet the requirements identified under paragraph (1)(A) for the Priority Product, and that eliminate or reduce the concentration of the Chemical(s) of Concern in the Priority Product and/or reduce or restrict exposures to the Chemical(s) of Concern in the Priority Product.

Suggested language: In addition to any alternative identified under paragraph (1)(C)2., the responsible entity shall identify alternatives that meet the definition of "alternative" under Section 69501(a)(11) and meet the requirements identified under paragraph (1)(A) for the Priority Product, and that eliminate or reduce the concentration of the Chemical(s) of Concern in the Priority Product. If a responsible entity concludes that eliminating or reducing the concentration of the Chemical(s) of Concern in the Priority Product is not immediately feasible, they should then seek to reduce or restrict the potential for release of the Chemical(s) of Concern, leading to human or environmental exposures, as an interim action until a less or non-hazardous alternative is developed.

Definition of "technically and economically feasible alternative"

We agree with others who have asked for greater clarification about the definition of "technically and economically feasible alternative," and that they should be defined and evaluated separately.

If something is technically possible, this should be the standard for whether it should be considered.

§ 69501.1 (a)(59) Page 13, Line 27-32

CHANGE strongly objects to the language in the definition of "technically and economically feasible alternative." Even if "significant reduction in a manufacturer's operating margin" and "meeting consumer demand" are defined, it requires numbers that can easily be manipulated to give an off-ramp to any responsible entity.

We urge § 69501.1 (a)(59)(B) be stricken: "The manufacturer's operating margin is not significantly reduced."

We urge the language in § 69501.1 (a)(59)(A) be amended by deleting "and to meet consumer demand after an appropriate phase-in period." Requiring a company to demonstrate consumer demand would limit timely options for alternatives especially if companies request delays to conduct consumer research.

Definition of "functionally acceptable"

This definition suffers from the same flaw as the definition of "technically and economically feasible alternative." The current draft would enable a responsible to cite its impacted operating margin as a reason to be exempted from pursuing safer products because "consumers have not been reasonably accepting of the alternative in the marketplace." This is a vague and undeterminable indicator that would be essentially impossible to define and measure. Who will judge what "consumers can be reasonably anticipated" to accept?

§ 69501.1(a)(31)(B) Page 9, Lines 35-36
We recommend the following language for the definition of "functionally acceptable": ***(B) "The product performs the functions of the original product sufficiently well that the product's goals are reasonably well attained."***

Definitions of "Chemical" and "Chemical Ingredient"

These important terms derive from AB1879. One goal in properly defining them is to ensure that they will reach complex nanomaterials in the event the Department identifies such materials as CoCs. Another is to ensure that the two statutory terms can both be used to identify chemicals of concern.

We appreciate the Department's response to our suggestions as to how to improve the definitions that were used in prior draft proposed regulations. The Department essentially has adopted CHANGE's recommendations, but with one discrepancy that can easily be fixed.

§ 69501.1(19)(A)(2)
The definitions currently provide that a chemical ingredient means "a substance comprising one or more of any **substance, element, ion, uncombined radical, degradate, metabolite, or reaction product**." The problem is that the terms in bold are now disconnected from the qualifiers that exist in the first part of the definition, and so are seemingly too broad and perhaps even essentially undefined.

We suggest that this can be easily fixed by amending the definition of chemical ingredient in §69501.1(19)(A)(2) to read:

"**a substance comprising one or more substances of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical, and any degradate, metabolite, or reaction product of a substance with a particular molecular identity."**

We believe this change, though minor, is important and that it will work. We appreciate the Department's attention to this important detail, and request that this suggestion be implemented.

CHANGE
Californians for a Healthy & Green Economy

Trade Secret Protection for Chemical Identify in Hazard Trait Submissions

CHANGE offers two comments on the proposed regulations in connection with trade secret protection for chemical identity in hazard trait submissions: one relating to the trade secret provisions and one relating to the definition of hazard trait submissions. Both of these comments are important to this issue.

a. Trade Secret Protection for Chemical Identity

§ 69510 (f)

The regulations provide in § 69510(f) that ". . . trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trait submission or any chemical identity information associated with a hazard trait submission." We believe this provision is not discretionary but is mandated by AB 1879, HSC § 25257(f), including as applied to chemical identity in hazard trait submission. The reason chemical identity should not be claimed as a trade secret in a hazard trait submission is that doing so would disconnect the remaining disclosure of health, safety or environmental information from any particular chemical and thereby render it meaningless, useless and immune from any oversight by the public or market. It would defeat the obvious intent of the law to make the health, safety and environmental information about particular chemicals contained in hazard trait submissions available to the public and the market. Accordingly, CHANGE strongly supports this provision.

§ 69510 (g)

Unfortunately, however, the regulations also set forth an exception to this bar on trade secret protection for chemical identity. § 69510(g) provides that trade secret protection may be available for chemical identity in hazard trait submissions in the case of new chemicals or new uses of existing chemicals. CHANGE believes this exception is legally invalid and also unwise policy, and that it should be eliminated.

The exception is illegal under AB 1879. In that statute, the legislature struck a balance between the competing interests of the commercial importance of the confidentiality of chemical information on the one hand, and the need of the public and the broader market to have access to such information on the other. The balance struck by the law is that trade secret protection is available for most such information, but not health and safety information in hazard trait submissions. The latter is particularly important for public disclosure, because it is the very information most necessary to evaluate the safety and health effects of chemicals and chemical ingredients. There is no basis anywhere in AB 1879 for the Department to disregard the law in the particular case of new chemicals or new uses of existing chemicals. The law requires disclosure of health and safety information in all hazard trait submissions without exception, which must include chemical identity if the disclosure is to have any meaning or utility.

Moreover, the law is just good policy. The public and the market need access to hazard trait information for new chemicals and new uses just as much as they do for existing chemicals and uses.

The exception of § 69510 (g) should be eliminated.

Should the Department nevertheless conclude that this exception is legal and wishes to maintain it as a policy matter, CHANGE recommends the following modifications designed to give greater force to the competing interest in disclosure:

1. The exception should apply not to all proposed alternatives to a CoC, but only to those not chosen as preferred to the CoC. If an alternative is chosen as preferred to a CoC and is therefore going to be marketed in a consumer product, the public and the market need to know the safety properties of that alternative. That need for a marketed chemical outweighs the private need for confidentiality. If the alternative is not chosen and there shall not be marketed, then the commercial interest in that new, but NOT SELECTED alternative would be protected under this proposal. Though we believe an important oversight function of disclosure would be foregone by following this proposal, it would protect both the public when it is exposed to a chemical and industry's interest in keeping confidential new chemicals and uses that are not yet marketed.

2. All trade secret claims made under this exception should be time limited and subject to revalidation periodically, for example every 5 years. Because the legislature has clearly expressed the view that hazard trait submissions should be publicly available, it is particularly important in this case that they not be withheld on the basis of trade secret claims that could grow stale.

3. § 69510 (g)(2) permits a party to provide the Department with selective information about the properties and toxicity of the alternative. CHANGE suggests that this section require that ALL available data about the alternative, not just the information that is selected by the party seeking trade secret protection, demonstrate health and safety to the Department's satisfaction.

b. Definition of Hazard Trait Submission

§ 69501.1 (a)(33)

This provision by its terms only applies if a study or datum indicates "that a chemical manifests any hazard trait." It does not apply if a study indicates that a chemical does NOT manifest a hazard trait. CHANGE believes that hazard trait submissions indicating that a chemical is non-toxic are just as important as those indicating a chemical presents hazards. The market and the public need to exercise oversight of study claims that a chemical is safe. They also need to know which chemicals are safer in order for the market to be able to select safer chemicals over more hazardous ones.

Current language: "When any study or datum indicates that a chemical manifests any hazard trait, chemical identity is part of any hazard trait submission."

Suggested language: "When any study or datum <u>provides information relating to whether a chemical manifests any hazard trait,</u> chemical identity is part of any hazard trait submission."

<u>Trade secret claims should be minimized.</u>

DTSC is not providing any broad new leadership on transparency and trade secrets in the informal draft regulations, but instead relies on existing law in this area. CHANGE believes this will impair the program's ability to be fully trusted by all stakeholders. Nevertheless, DSTC can take some steps to reduce the amount of trade secret claims that will be allowed under this program, and CHANGE urges it to do so. One of the most valuable contributions this program can make is to make more information about chemicals available to the public and the marketplace.

Trade secrets should not be allowed for any health and safety or product ingredient information, nor for a

chemical's identification in hazard trait submissions; nor for other kinds of information such as AA methodologies that AA assessors might choose. Transparency of this information is important for accountability, for public confidence in the program and for the ability of the program to affect the market. Simply put, consumers, workers and other downstream users of chemicals have a right to know about and avoid the hazards found in the chemicals and products they purchase. Recent tests by Women's Voices for the Earth found that popular cleaning brands had hidden ingredients linked to cancer, reproductive harm and allergies. Workers and employers have had similar experiences with inadequate and inaccurate Material Safety Data Sheets.

Importantly, DTSC should not see transparency provisions as an effort to satisfy NGO's. DTSC itself should have acute concern with both the credibility and effectiveness of this program. Without enough transparency for the public and industry to understand the results of the AA Reports, the program will simply not convince the public that it is being properly protected, and hopes for broad impacts of analysis of "sentinel product/CoCs" will be unrealized because no lessons will be understood by the market.

We support the requirement that responsible entities must provide adequate justification for trade secret claims. We believe these requirements will discourage trade secret claims that are not warranted or of little value to the responsible entity, and we urge DTSC to retain these requirements.

We propose the following specific amendments to the regulations to implement these suggestions.

§ 69501.1(a)(60) Page 13, line 34
The definition of "Trade Secret" should provide that "Trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient" as specified in 69510(f), Page 76, lines 32-34.

§ 69505.5. (a)(6)(A) Page 45, lines 38-41
CHANGE strongly supports the language that, if an AA Report contains information "claimed by the responsible entity to be a trade secret, a separate, publicly available AA Report shall be submitted to the Department that masks claimed trade secret information only to the extent necessary to protect its confidential nature." This would protect valid trade secret claims, but at the same time provide a useful range of data so the material basis for the decision is explained in some way. We believe many industries are already familiar with such masking strategies, such as preparing disclosures to comply with securities laws, or voluntarily describing confidential technology in initial approaches to prospective business partners, even under confidentiality agreements.

§ 69505.5(d),(e),(h)(2) beginning Page 46
CHANGE strongly supports the requirements that compel the responsible entity to provide information in their AA reports on the Supply Chain (d); Facility Description and Location (e); and the identification of unavailable reliable information (h)(2). This information will help the market operate more efficiently.

§ 69505.6(e) Page 51, lines 38-40.
All notices issued by the Department should also be posted on DTSC website.

§ 69508.3(e) Page 73, lines 21-22
CHANGE supports the inclusion of this provision, which reads: "An accreditation body may not claim trade secret protection for its general admission process, curriculum, and educational approach."

§ 69510 Page 75
Regarding the Assertion of a Claim of Trade Secret Protection, CHANGE supports the range of information DTSC will require to ensure that trade secret claims are in fact valid and are not made frivolously. We believe these requirements will discourage trade secret claims that are not warranted or are of little value to the responsible entity.

§ 69510 (a)(8) Page 75, lines 31-34
CHANGE strongly supports this requirement for trade secret justification: "The estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including for any chemical claimed as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering."

§ 69510(c)(2) Page 76, lines 18-20
CHANGE fully supports making a redacted copy of the documentation related to trade secret claims, excluding the information being submitted for trade secret protection, available to the public. This will allow the public, local agencies, employers, workers, and other end-users to gauge the degree to which information is being kept confidential and allow them to make better consumer, business, or regulatory decisions. Since no trade secret information will be included, CHANGE recommends that DTSC make the documentation available in all cases, rather than "at DTSC's discretion."

§ 69510(f) Page 76, lines 32-34
CHANGE strongly supports the provision that trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trait submission or any chemical identity information associated with a hazard trait submission. This explicit language is derived directly from the enabling statute, and reflects the importance of making this information publicly available.

§ 69510.1 Page 77
CHANGE recommends that DTSC add language here that the public shall be informed when companies' trade secret claims have been approved by DTSC so that the public knows that complete information about the chemical is not available.

A strong firewall is necessary between Responsible Entities and those who complete Alternative Assessments

The lack of transparency and oversight in the production and review of Alternative Assessment reports is breathtaking. Not only will DTSC permit responsible entities to claim substantial information about the chemicals in their products as confidential, shielding it from consumers, public researchers, and the marketplace, but the regulations will allow responsible entities to conduct their own AA reports with no public oversight or input. Instead, a cumbersome oversight structure is proposed for which DTSC does not have the resources.

Transparency in how the program is managed is important both for accountability of decision-making and for the ability of the program to correct the market failure caused by lack of publicly available information in the market. Moreover, without transparency, there is a substantial risk that the program won't be seen as credible by the people of California.

CHANGE has long maintained that Alternatives Assessments should not be conducted by the makers or users of toxic chemicals. Since AAs contain quantitative and qualitative data, the assessment can be easily "gamed" to arrive at a pre-determined outcome. We continue to believe that the best, unbiased way to conduct AAs would be for manufacturers to pay into a fund that is then administered by the department to hire one or more AA experts to conduct the AA, or for DTSC to conduct the AAs itself. This system would eliminate conflicts of interest and would provide DTSC with unbiased information prior to issuing a regulatory response. It would build expertise at the state in conducting AAs for following and developing best practices. And it would be more cost effective for DTSC to manage the program itself instead of the vast oversight responsibilities that will be needed under the current draft regulations.

An alternative method to provide more assurances of an unbiased AA would be to require manufacturers to work with outside, certified AA experts who could conduct the AA. Yet another method would be to require independent third party verification of AA reports performed by industry. CHANGE has suggested that companies that conduct AAs with no trade secret claims and make the reports public could be exempt from third party oversight. Some BizNGO members have suggested a peer review panel to provide quality control on AAs. None of these suggestions is reflected in the formal draft regulations.

Rather, the department has decided that all AA reports may be done by manufacturers, so long as the person performing the AA meets certain requirements and has been certified by an accreditation body. While we understand that the Department hopes this certification will lead to unbiased outcomes, we disagree. Being certified by an independent body will not guarantee against mischief or even bias in AA reports. Moreover, the department does not have the resources required, nor the expertise, to fully review every AA report. The time and money required to do so will slow the pace of product prioritization and lead to consumer products containing CoCs remaining in the market for a longer period of time, increasing hazards for all Californians'. Requiring either independent AAs or third party review will allow the Department to spend its limited resources on prioritizing products and issuing the appropriate regulatory responses.

If DTSC proceeds with its proposed accreditation body model, CHANGE recommends the following changes:

§ 69508 (g)(1) Page 67, line 17

CHANGE supports the provision that a certified assessor may not be in responsible charge of conducting an AA and/or preparing a Preliminary or Final AA Report, or both, if the certified assessor has an ownership interest in the responsible entity whose product is the subject of the AA. We believe, however, that there should be no permissible equity stake as any amount would increase the chance of conflict of interest. Accordingly, the $10,000.00 threshold should be eliminated.

§ 69508.1 (b) and (c) Page 70, lines 4-8

CHANGE supports the provision that any entity that seeks designation as an accreditation body must be independent of, and may not hold any stock or ownership interest in, any consumer product manufacturing, importation, distribution, or retail business (except colleges, universities, or their subdivisions as noted).

§ 609508 (b)(2)(A) Page 66, lines 22-27

CHANGE supports the requirement for at least 20 hours of continuing education during each two-year accreditation period for assessors, including two hours each period in professional ethics.

§ 69508.1(a)(5)(D) Page 68, line 26-32

CHANGE supports the requirement that accreditation bodies demonstrate expertise in public health among other skill sets. But we believe that "pollution prevention" and "maternal and child health" should not have been deleted from the previous drafts and recommend that they be reinstated.

§ 69508.1(a)(5)(E) Page 68, line 33-42

CHANGE supports the requirement that accreditation bodies demonstrate expertise in professional ethics.

Transparency must be maximized in Alternatives Assessment Reports.

CHANGE is very concerned that responsible entities can do their own AAs. While the proposed accreditation process builds in some accountability, the fact remains that a responsible entity will have a vested interest in a specific outcome of an alternatives assessment, and DTSC may not have the resources to adequately audit the many AA reports that will be generated. Moreover, the expected prevalence of trade secret claims is very likely to result in AA Reports that cannot be meaningfully evaluated by the public or other parties. Under these circumstances, the public is unlikely to have confidence in the decisions made by the program.

CHANGE has long advocated for the public's right to know about chemicals in the products they use and the impacts of those chemicals on human and environmental health. We recognize businesses may need to claim information about the ultimate makeup or formulation of some of their products as a trade secret to maintain a competitive advantage in the marketplace and to attract investment in new, innovative chemicals and products. We further recognize that *the Safer Consumer Products Regulations* must conform to current legal trade secret protections.

However, given that AAs will be prepared by manufacturers with a vested interest in the AA's outcome, as well as DTSC's limited resources to review those AAs, the Department should rely on the public, as well as a manufacturer's competitors, to ensure that the AA is factual and represents a good faith effort to reduce the use of toxic chemicals. Without reasonable limits on the information that can be claimed as confidential in AA Reports, there is no way for the public to maintain its critical role as watchdog over this important part of the program.

CHANGE strongly supports the department's explicit language that health and safety information and chemical identity in relation to health and safety data may not be claimed as confidential. We also support the fact that a version of submitted AA reports will be made public and that trade secret information will be masked only to the extent necessary to protect its confidential nature as specified in 69505.5 (a)(6)(A).

However, the language in 69505.5 (a)(6)(A).is vague. It is not clear what information is subject to masking and what it means to ensure that the public has a substantive understanding of a company's workplan, the actual AA, and the ultimate conclusions of the AA. Furthermore, there are no clear steps that companies should take to ensure that they meet these provisions.

We therefore strongly recommend that the Department develop specific guidelines for masking strategies as part of the Alternative Assessment guidance published the adoption of these regulations. This guidance should clarify the types of information for which masking is acceptable and provide recommendations for compliance, including but not limited to using ranges to obscure specific formulations.

While a growing number of companies recognize that full public disclosure about their products actually creates competitive advantage, nothing in the regulations encourages this. Requiring companies to mask trade secret information in a way that promotes the public's understanding of AAs is a positive step. Still, DTSC should provide incentives for voluntary full public transparency. For example, manufactures could get a streamlined review process in exchange for forgoing all trade secrecy claims.

Importantly, since regulatory responses are based on the content of AA reports, it is essential that there be a mechanism for the public to register questions or objections to information in them. The Department should determine how the contents of AA Reports can be meaningfully shared with the public, and include a public comment period following the submission of AA Reports. A publicly available executive summary of both the Preliminary AA Report and Final AA report should be accompanied by a public comment period before DTSC accepts the findings of either document.

Ultimately, CHANGE believes that when it comes to potentially toxic chemicals in a consumer product, public, worker, and environmental health trumps an individual manufacturer's desire for confidentiality. We appreciate the Department's recognition of this and its attempts to facilitate a balance between the public good and legitimate business concerns. However, successful balance requires proper guidance, a variety of options, and public input, so that both businesses and the general public can have confidence in the program.

§ 69505.1. (g) Page 38, Lines 17-21.
CHANGE strongly supports the requirement of notification when a Chemical(s) of Concern is/are removed from a priority product, even when a responsible entity reformulates without adding or replacing a substitute chemical. This notification is necessary for the public and the Department to assess the program's overall success in achieving its goal to spur innovation and develop safer consumer products. Without receiving notification, neither the public nor the Department will be able to assess the true and complete impact of these regulations which may come under budgetary scrutiny or attack in the future.

§ 69505.1. (g)(2)(F) Page 38, Lines 35-36.
CHANGE supports the requirement for the responsible entity to submit notification of the measures it will take to "ensure the product that contained the Chemical(s) of Concern is no longer placed into the stream of commerce in California." This is an important protection for EJ communities since companies often dump old products into dollar or discount stores located in poorer communities. In fact, CHANGE strongly encourages the Department to institute fines to companies who continue to sell products containing Chemical(s) of Concern after notifying the department that they have been removed. Experience with California's Proposition 65 program has demonstrated that a combination of on-going surveillance and fines are needed to ensure companies comply with the law.

§ 69505.1. (g)(2)(G)2. Page 38, Lines 40-42.
CHANGE supports the requirement in the regulations that requires responsible entities to submit "laboratory analytical testing, quality control, and quality assurance protocols used to detect and measure the Chemicals(s) of Concern in the product that ensures the Chemical(s) of Concern have been removed."

§ 69505.3 (b)(1)(C)1. Page 41, Lines 21-23
CHANGE strongly supports the requirement that the responsible entity shall determine if the Chemical(s) of Concern or substitute chemical(s) is/are necessary to meet the Priority Product's requirements. This analysis should be explicitly required in the AA Reports.

§ 69505.5. (d) Page 46, line 19
CHANGE supports the inclusion of comprehensive supply chain information in AA Reports.

Some timelines can be shortened to avoid unnecessary delays in program implementation.

In places, the draft regulations are overly generous to responsible entities in the allowed timelines and the granting of extensions. In addition, the regulations allow all DTSC actions to be stayed during a dispute until resolved. We are concerned that allowing disputes at any stage can lead to frivolous delay tactics by those entities that are regulated. It is clear that DTSC will focus on chemical/product combinations that have enough evidence to suggest a high hazard to the public, and the public has a right to know which of these product/combinations are of sufficient concern to warrant DTSC's request for an AA.

§69503.4 (e) Page 30, Lines 35-38
Allowing 180 days to post the initial proposed list of Priority Products the effective date of the regulations is too long, especially since we have heard several times from DTSC that there will only be two to five product categories in the first round. CHANGE believes 90 days should be sufficient for the initial group of product categories to be identified and posted.

§69507.6 (d) Page 65, Lines 13-15
This section of the draft states: "The Department shall issue an order specifying its decision on the merits of the Request for Review within one hundred and eighty (180) days from the date it grants the Request for Review." CHANGE believes 180 days is much too long a time period for DTSC to make this kind of decision, especially since DTSC will have already had 60 days to consider whether to grant a Review or not. A total of 90 days should be more than adequate for DTSC to act.

"Economic Impacts" must capture all appropriate costs, including to public health, occupational health, and the environment.

DTSC should use consistent language about economic impacts throughout the document. When considering economic impacts, the regulations should ensure that all relevant impacts to public health, occupational health, and the environment are accounted for.

§ 69501.1 Page 4
We recommend re-inserting a definition of "Economic Impacts" using the following language: *"Economic Impacts means internalized and externalized costs to the public, families, the environment, public health, workers, government agencies, businesses, consumers, and the taxpayer."*

§ 69505.4(a)(2)(A) Page 43, Lines 8-17
Too often, extraction is left out of the considerations when talking about a life cycle analysis. "Extraction of raw materials" should be added to the life cycle impacts listed in 1.-7. This is an often significant life cycle impact that should not be ignored.

§ 69503.2 (a)(1)(B)4.a. Page 26, Lines 35-36

This is another example where "extraction of raw materials" should be added so this section reads: ***Extraction of raw materials****, manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices.*

§ 69505.4(a)(2)(C) Page 43, Lines 28-41
This section requires responsible entities, during the second stage of an AA, to "take into account all projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered."

Cost impacts need to explicitly include externalized costs related to public health, occupational health, and the environment which will be borne by society and the taxpayer stemming from the life cycle factors cited in § 69505.4(a)(2)(A). These cost factors should be listed in (C) so there is a complete understanding of the economic costs to retain a Priority Product despite the continuing presence of a CoC.

§ 69501 (b)(1) Page 4, Lines 15-16
DTSC should specify that being placed "in the stream of commerce in California" includes internet / online purchases.

§ 69501.1(a)(36) Page 10, Line 16
Add the words "or entity" to the definition of "Importer" so it reads: *"Importer means a person* ***or entity*** *who imports a consumer product into the United States."*

CHANGE is not convinced that regulation automatically leads to negative impacts on a responsible entity's balance sheet.

For example, Market Watch -- http://www.marketwatch.com/story/regulation-may-have-little-jobs-impact-2012-08-06?pagenumber=1 -- reported on August 6, 2012 that it is not clear that regulation hurt a business's bottom line or leads to a loss of jobs. It was noted that while there are clearly people who lose jobs from regulations in the U.S., there are also people who gain jobs as some regulations have created entire new industries such as catalytic converter manufacturing. Similarly, we should have every reason to expect the *Safer Consumer Products Regulations* will spawn a new industry of alternative analysis and assessment that leads to innovative products and processes in California.

In fact, Cary Coglianese, a regulation expert at the University of Pennsylvania Law School, says: "The net effects of regulations on employment are generally rather negligible." Some studies about environmental regulation show that, on balance, regulation has had little or positive impact on overall industry employment. Data from the U.S. Department of Labor indicate that employers cite government regulations and intervention as the reason for layoffs as employers cited governmental regulations/intervention as the reason for less than 1% of layoffs.

There also is important evidence that the anticipated costs of regulation generally are overestimated, often substantially. For example, see *"Not Too Costly, After All: An Examination of the Inflated Cost-Estimates of Health, Safety and Environmental Protections",* by Ruth Ruttenberg and Associates, Inc. for the Public Citizen Foundation, 2004.

Beyond this, it is not in society's best interest to preserve a job that has more negative impacts than positive ones. We don't want to produce something that is toxic just because it provides a job. Regulations are meant to promote overall social welfare which can include a variety of important societal benefits, not just employment. The potentially substantial health and worker productivity benefits associated with regulations which should be

factored into any cost-related analysis. The *Safer Consumer Product Regulations* are stimulating the development of better jobs, not less jobs.

A key principle driving Regulatory Responses by DTSC gives preference to responses providing the greatest level of inherent protection.

§ 69506 (b) Page 52, lines 10-14

"In selecting regulatory responses, the Department shall give preference to regulatory responses providing the greatest level of inherent protection."
CHANGE strongly supports this important principle that will guide DTSC regulatory responses. Preventing harm is easier, cheaper, and more effective than managing harm after it has occurred. This key language clarifies that the ultimate goal of the *Safer Consumer Product Regulations* is the elimination of toxic chemicals and the development of safer, green chemistry-based alternatives.

Enforcement must include significant penalties.

§ 69501.3 (a) – (c), Page 17, lines 1-21
We support these sections which require all information submitted to DTSC under the penalty of perjury to be signed by the person who prepared the information as well as the owner of the company or an official or authorized representative. It is an effective method to ensure the company's responsibilities under these regulations are integrated into the company's activities. This is consistent with requirements for California's workplace Injury and Illness Prevention Program rules and studies showing that programs are more effective with written management commitment that comes from the top.

In addition, CHANGE recommends that responsible entities be required to post a bond or otherwise provide proof of insurance regarding the information they submit to DTSC.

§ 69501.2(d)
If the most stringent or only punitive measure to address "Failure to Comply" is a DTSC website listing, this is inadequate to compel compliance by responsible entities. "Failure to Comply" and "Failure to Respond" should trigger more meaningful penalties, including significant fines.

Furthermore, warning responsible parties that they are not in compliance and will be so listed on DTSC's web site takes up Department resources and time. We would suggest that it is up to those parties to comply with the regulation and that not doing so should result in listing without warning, until they rectify the situation. In our view, this is not only fair, given that companies have the responsibility to be familiar with the law and heed it, but also appropriate given the current economic burden on public agencies and DTSC's limited funding and resources.

A robust end-of-life management program is important and will contribute to positive changes in the marketplace.

§ 69506.8(a)(2) Page 57, Lines 38-41
Concerning the End-of-Life Management Requirements in regulatory responses, CHANGE strongly supports the language that requires the responsible entity to "fund, establish, and maintain an end-of-life management program" including a detailed plan and financial guarantee mechanism, as well as compensation to retailers and other persons who agree to administer or participate in the collection program.

In addition, CHANGE believes responsible parties should also be required to estimate the lifetime of the applicable products they are managing and provide DTSC with a copy of their product stewardship plan.

§ 69506.8(d) Page 59, Lines 14-17
CHANGE objects to this provision which would permit a responsible entity to request an exemption from end-of-life management program requirements by demonstrating to DTSC that such end-of-life program "cannot be feasibly implemented for the product." Such an off-ramp will surely lead to claims that end-of-life programs are in fact not feasible. DTSC would then have the job of deciding if the responsible entity had adequately "demonstrated" its claim. An end-of-life management program should be required in all cases, with the responsible entity providing limitations and mitigating factors in the end-of-life management plan.

An inventory recall mechanism should be included in Regulatory Reponses.

§ 69506.6 Page 55
There is no provision for an inventory recall in the Product Sales Prohibition section. Additional language should be added here to ensure that phased-out products, with a consumer label or not, are not dumped into discount stores and low-income areas.

AA Report Supplemental Information Requirements

§ 69506.2 (a) and (b) Page 5, Lines 30-39
CHANGE supports these provisions allowing DTSC to require responsible entities to provide supplemental information or to take steps to fill data gaps.

Advancement of Green Chemistry and Green Engineering

§ 69506.9
CHANGE supports the draft regulations that give the Department the ability to require responsible entities to initiate a research /development project or fund a green chemistry challenge grant.

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Dispute Resolution

§ 69507(b) Page 62, Lines 33-36
CHANGE supports the language in the draft regulations that require responsible entities pursuing a dispute to follow the specified procedures or forfeit the right to further contest the dispute administratively.

CHANGE recommends that when a dispute is filed, DTSC make public the reason the dispute is being filed, as well as continue to inform the public as to where the matter stands. In other words, there should not be a blanket silence when a dispute is filed. Instead, there should be a summary of why the chemical/product combination was prioritized, and a current update about how the dispute is being resolved. Without provisions like this, companies will have a green light to pursue frivolous disputes, wasting scarce DTSC resources and undermining the public's confidence in the process.

Dispute processes should include short timelines to minimize costs to both sides. The current draft allows for far too much delay by the responsible entity for a straightforward task.

Priority Product Work Plan will limit DTSC's ability to respond to new hazards.

§ 69503.3 (f)
This new provision requires DTSC to develop and issue a Priority Product Work Plan by 1/1/14 that describes the product categories that the Department will evaluate to identify products to be added to the Priority Products list during the next six (6) years.

This provision has several serious flaws. First, it unnecessarily commits DTSC to a small number of consumer products, allowing the vast majority of products to continue to be marketed without any incentives to move away from CoCs. Second, it would prevent DTSC from responding to new science about CoCs and the products that contain them. Third, it is predicated on the current level of DTSC resources that may change over time. In the initial pilot stage, DTSC will identify no more than 5 priority products, in large measure because of resource constraints. If budget forecasts improve, DTSC should be able to ramp up the program as much as possible.

CHANGE opposes tying DTSC's hands with this restrictive requirement.

If a Priority Product Work Plan remains in the regulations, DTSC should not be limited in the number of possible priority products it will list. Rather, an open-ended list of potential products should be posted, allowing DTSC the flexibility to initiate the search for safer alternatives as circumstances and resources permit.

A DTSC Priority Product Work Plan must include an opportunity for public comment.

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