



April 23, 2009

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

Re: Green Chemistry Initiative, AB 1879, SB 509

Dear Director Movassaghi:

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

First, we congratulate you on the conduct of the Green Chemistry Initiative and the public workshops in during the last few months, after completion of the Green Chemistry Initiative Final Report last December. We have appreciated the many opportunities you have provided during this Initiative for us to express our views on chemicals policy reform.

At the April 21, 2009 Workshop in Berkeley DTSC proposed a “Draft Straw Proposal” for the implementation of AB 1879 and SB 509. While members of CHANGE have regularly attended the DTSC public workshops including the most recent one in Berkeley and have offered comments during those workshops, we would like to offer these written comments on the “Draft Straw Proposal.” We also stand ready to assist the Department in developing actual regulatory language once the structure and objectives of this Proposal are more clearly decided. In the meantime, please consider these comments on DTSC’s Proposal.

I. SECTION 3 PROCESS TO IDENTIFY CHEMICALS OF CONCERN

a. Any chemical that may threaten human health or the environment should be considered a chemical of concern

Under AB 1879 and SB 509, DTSC is intended to develop a comprehensive chemicals policy, and any such policy should respond to any and all threats posed by chemicals in commerce to human health or the environment. We believe that a chemical posing any kind of threat to human health or the environment, either alone or in combination with other factors, should be considered a chemical of concern. There is no reason for the regulations to exclude any particular kind of hazard from potential regulation by the State.

We also believe that the threshold of evidence required for determining that a chemical may pose a threat should be low enough to constitute an early warning of harm. That is, a small amount of evidence or even equivocal evidence should be sufficient for a chemical to be designated as being of concern and therefore to potentially warrant further scrutiny.

This means that many of the chemicals in commerce will become designated chemicals of concern. We encourage this. Because these chemicals will be acted on only if prioritized, many chemicals of concern will not be acted on by DTSC. Nevertheless, the mere designation of chemicals as being of concern should motivate consumers and industry to avoid them in favor of those that are not. This would clearly be warranted and would further the market-oriented goals of the program.

b. DTSC should not limit the regulations to conventional consumer products

SB 509 and AB 1879 have been argued by industry representatives to be limited to consumer products (with some specific exceptions set forth in Section 25251(e)). We believe such a limitation would be unwarranted. The definition provided by the statute clearly includes all chemicals that are bought by any person for any purpose. Thus, essentially all chemicals in commerce should be subject to a new, comprehensive chemicals policy.

This is important because many chemicals are purchased by industry for use in manufacturing or otherwise in the workplace, and can harm workers and/or the environment without being what are typically considered consumer products. Workers in particular often bear the brunt of chemical exposures because of their close proximity to large volumes of chemicals in the workplace. They also often inadvertently function as a vehicle for exposure of family members and neighbors to chemicals they are exposed to in the workplace. The current frequent discrepancies between many workplace standards and environmental or other standards are not justifiable and are improper. Accordingly, we urge DTSC to take workplace exposures seriously and to consider workers as a potentially highly exposed population.

Products containing nano materials, though they seem to be evading TSCA, are specifically included within the ambit of the legislation. Specific classes of chemicals such as pharmaceuticals and pesticides should be excluded only if they are already subject to adequate regulatory programs.

c. DTSC should establish a “no data, no market” requirement by establishing a required data set to identify chemicals of concern

As the Green Chemistry reports by U.C. Berkeley have demonstrated, many chemicals on the market are likely to be hazardous even though we have little or no chemical safety information about them. Such chemicals present hazards to human health and the environment even though the hazards are unrecognized. Indeed, one might say they are of greater concern than chemicals for which we have hazard data because people have no way of avoiding hazards that they cannot recognize. As DTSC begins to take action on known hazardous chemicals under this Green Chemistry Initiative, there is a high likelihood that such chemicals will be replaced by alternatives posing unrecognized hazards, thereby resulting in little or no real improvement in public health and the environment. Such perverse consequences should be avoided by a comprehensive chemicals policy.

Accordingly, DTSC should seek to identify all chemicals in commerce that are of concern, whether that concern is recognized today or not. DTSC should specify a required data set that must be provided by industry to the public for all chemicals in commerce, both new and existing. The information must be sufficient to permit a reasonable evaluation of the safety of the chemical for human health and the environment, including not just hazard information, but also product use (ingredient) and exposure information. The design of the required data set may be coordinated with, but not limited to, other chemical data collection programs, including REACH. Such required data sets should be provided for all chemicals in commerce within about ten years. DTSC should be able to request further information beyond the required data set if it would help the State in evaluating the chemical or as we learn more about chemical impacts on the environment.

There must be a regulatory penalty when the required data set is absent in order to motivate industry to produce the required information. At the very least, chemicals with insufficient data should be designated chemicals of concern and subject to some kind of regulatory response. We believe the appropriate response is that a mandatory data set should be required both for new chemicals before they are introduced into commerce and for all existing chemicals in commerce by a date certain as a condition for being permitted on the market. If it is not provided, chemicals should not have access to the market.

Also, industry should also be required to produce all health and safety information in its possession even if it is not part of the required data set. A required data set could be coordinated with and provide a basis for requests for further information under HSC § 25253(b).

Finally, DTSC should pay attention to the problem of identifying suitable information requirements for nanomaterials. These new materials clearly require different kinds of information to assess their impacts than traditional chemicals.

d. Trade secret protection should not be given to any information relating to the safety of products, including hazard data and product ingredient information

AB 1879 adds new Section 25257 of the Health and Safety Code relating to trade secret information. Despite Section 25257(f), this section arguably may permit submitters to claim trade

secret designation for some kinds of health and safety information as well as product ingredient information.

We believe that no information relating to the environmental health impacts of a chemical of concern should be withheld from the public through trade secret designation. This includes information about both the hazard properties of chemicals and the ingredients in products. Even if such information has competitive value, the public's need for that information in order to evaluate whether a chemical is a chemical of concern, to review the alternatives analyses done under these laws, and to choose safer chemicals and products, outweighs that competitive interest. The problem with trade secret designation for any information relating to the environmental health impacts of a product, including identification and amounts of its constituent ingredients, is that all evaluations of chemicals and products based on that information will also be removed from the public domain. In that event, all decisions about chemicals would be driven into a process in which only government and the affected industry can participate.

The public should have complete access to all decisions about chemicals of concern used in products, including public oversight of listings of chemicals of concern, regulatory decisions and alternatives analyses. Public access is required if this new chemicals policy expects to harness the ability of the consumer and industrial markets to respond to chemical safety information. These goals can only be accomplished if there is complete transparency for all chemical safety and product ingredient information for chemicals of concern.

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

Two ideas for accommodating the interests of industry in trade secret information have been suggested. One is to disclose only ranges of product ingredient concentrations. We do not support use of thresholds below which no information need be reported at all. But a reported range might be workable if the regulatory assumption that follows were that the maximum concentration (or most hazardous concentration) in the range were used in doing alternatives analyses and fashioning a regulatory response. A second possibility would be to find some way to recognize the value of trade secret information by granting some preferential regulatory use to those industries that produce the information, means of obtaining compensation from other industries or other such provisions. Once DTSC clearly determines that information relating to the environmental health impacts of a chemical of concern will not be designated as a trade secret, we would gladly participate in a discussion about these kinds of accommodations.

e. Animal tests should be phased out

In designing data requirements or in requesting chemical toxicity data about any chemical or alternative, DTSC should recognize that there is profound ethical concern with the continued use of animal tests. A growing body of alternative, faster, more reliable techniques is being developed. Animal tests are also expensive and time consuming. All these reasons have led the National Research Council and others to recommend replacing animal toxicity tests with better methods. They also led the EU to incorporate into REACH numerous provisions designed specifically to keep animal testing to a minimum. Accordingly, DTSC regulations should ensure that animal testing be kept to a minimum, that duplicative animal testing be prevented, and that animal testing will ultimately be phased out completely.

f. Providing updated information on uses, productions volumes and patterns, and health and environmental impacts

The Draft Straw Proposal, on page 5 at the end of Section 3, sets forth specific information that should regularly be provided by industry for newly introduced chemicals as they become incorporated into commerce. We believe this same data should be provided for existing chemicals. 92% of the 3,000 High Production Volume chemicals in commerce today were in commerce in 1979, and their uses have continued to proliferate and grow since then. Accordingly, the need to continually evaluate chemicals as they spread throughout commerce relates not just to new chemicals but to existing ones as well.

g. Conducting and paying for assessments and evaluations

Both the data and the various analyses that are produced under AB 1879 and SB 509 must be reliable and credible. We also believe that the financial burden for producing the data and analyses should be borne by industry. We recognize that there are advantages in having industry create chemical information and perform analyses, but we also recognize the inevitable impact of self-interest on the conduct of these activities. DTSC should collect funds from industry to have independent third parties perform these activities under supervision of DTSC. DTSC should develop mechanisms designed to ensure that industry bears the financial costs of data production and assessment, that the assessment process is transparent, and that government and the public have oversight and review capability to ensure the credibility and reliability of chemicals management.

II. SECTION IV PROCESS TO PRIORITIZE CHEMICALS OF CONCERN

a. Categories of chemicals of concern that should considered high priority for stronger regulatory responses

Several classes of chemicals are of higher concern than others, and DTSC should prioritize these for rapid review, restriction and possibly elimination. We recognize that the following classes of chemicals should be defined more precisely, and we are prepared to assist the Department in developing such definitions.

Some chemicals of concern that DTSC should prioritize because of their hazardous nature include:

- (1) Carcinogens, mutagens and reproductive and developmental toxins (CMR's) are of such high priority because they cause devastating diseases and often have the capacity to affect future generations;
- (2) Persistent, bioaccumulative and toxic chemicals (PBT's) are of high priority because they accumulate in the environment, persist, often for long periods of time, and often concentrate in the environment and in species higher on the food chain, including humans;
- (3) Very persistent, very bioaccumulative chemicals (vPvB's) are of concern even if not known to be toxic because of their persistence and tendency to concentrate in the environment and in people; and
- (4) Other hazardous properties of equivalent concern include endocrine disruptors.

Some chemicals of concern that DTSC should prioritize because of the likelihood that many people are exposed to them, including:

- (5) Chemicals sold or used in high volumes in the state;
- (6) Chemicals that are widespread in the environment or chemicals (or their metabolites) that are found in tissues of people in the State through biomonitoring; and
- (7) Chemicals that vulnerable subpopulations are likely to be exposed to, including workers, pregnant women and children.

We agree with DTSC's suggestion that any chemical for which an adverse environmental impact is detected should be prioritized.

We also agree that any chemical for which a minimum data set is not available should be prioritized for provision of the missing data or phase out.

III. SECTION 5 PROCESS TO EVALUATE POTENTIAL ALTERNATIVES

a. Avoidance of paralysis by analysis, use of life-cycle "thinking"

Conflicting data, lack of information and competing priorities can all lead to unduly lengthy analytical processes. AB 1879 refers in several places to the use of "life-cycle analysis" in reaching chemical decisions. As both the GCI Final Report and the May 2008 Science Advisory Panel's Report made clear however, many of the important concepts and values implicit in considering the full life-cycle impacts of chemical production, use and disposal can be considered more efficiently under the

rubric of "life-cycle thinking." See May 2008 SAP Report at pp. 5-6; GCI Final Report at pp. 13-14, 30-32, 34-36. We urge DTSC to follow this insight and take a life-cycle thinking approach to implementing AB 1879, and to establish specific, short time frames for conducting them.

b. Alternatives analyses and life-cycle assessments should be broad in scope

All potential adverse effects on both human health, including workers, and the environment should be considered. Long term effects and cumulative effects should be considered. Economic impacts tend to preference the existing economic actors and this should be avoided, but if economic impacts are to be considered, then entire life cycle costs must be considered.

c. New chemicals should be assessed as well as chemicals already on the market

New chemicals should be assessed before marketing based on a required data set. Any data gaps should be specifically identified and action taken to close them. Otherwise, industry will continue to introduce new chemicals of concern, with their hazards are unrecognized, into the market.

d. Alternatives analyses should be made public

The alternatives analyses should be made public, including all information that is necessary to the analyses. Trade secrecy claims should be strictly limited so as not to prevent full public access to the analyses. There should be opportunity for the public and industry to comment on alternatives assessments and an obligation for those conducting them to respond and incorporate comments in revised assessments.

e. Non-chemical solutions

Options for replacing a chemical with a non-chemical solution should be part of alternatives analyses. Such options may include change in feedstock, change in production or change in basic material.

f. Safer alternatives may need to be regulated to protect human health and the environment

If a safer alternative is identified to a chemical of concern, but that safer alternative still presents a hazard to human health or the environment, then regulatory steps should be taken to restrict and condition any permitted uses of the alternative as well. Just being a safer alternative should not guarantee access to the market for a chemical of concern.

g. Alternatives assessments should be paid for but not be conducted by industry

Alternatives assessments must be credible and reliable if the public is to rely on them. They should be paid for by industry, but conducted by an independent third party with oversight by Cal/EPA to ensure quality control. We recommend a fund that product and chemical manufacturers pay into that can be used with DTSC oversight to fund assessments. DTSC should exert strong oversight over all assessments.

h. Alternatives assessments should be revisited periodically

It is important for alternatives assessments of prioritized chemicals of concern to be revisited and revised if necessary. This type of continuous process is critical to open up opportunities for new, safer chemicals to be recognized and be able to penetrate the market.

i. There must be a duty to investigate both whether products contain chemicals of concern and the properties of those chemicals

The Draft Straw Proposal provides that responsibility for performing alternatives assessments (or providing information to a third party assessor under our recommendation) will fall on the party responsible for introducing the product into commerce in California. This will often be retailers or product assemblers who have not themselves manufactured the products or constituent parts and who therefore are unlikely to know the composition of the products they introduce into commerce. These parties must be placed under a specific duty to investigate and demand information from their suppliers, to certify they have taken the required steps and provide the results. Unless all elements of the supply chain, including elements from beyond the state, are required to divulge the contents of products eventually sold in the state, effective alternative analyses will not be possible.

IV. SECTION 6 REGULATORY RESPONSES

a. DTSC should develop a mandatory regulatory program

DTSC should develop, implement, and enforce a program of regulatory responses that are mandatory, and not just voluntary. Voluntary programs have proved to be unable to protect public health and the environment.

b. DTSC should take immediate action to restrict or eliminate the use of high priority chemicals of concern independently of any alternatives analysis

High priority chemicals of concern, as we have defined them above, should be substantially restricted or removed from the market based on presenting a threat to human health and the environment, regardless of whether there is a safer alternative and independently of the program of alternatives analyses.

AB 1879 and SB 509 refer to several potential bases for regulating chemicals, including alternatives analysis (see HRC Section 25253(a)(2)) and "determining how best to limit exposure or reduce the level of hazard posed by a chemical of concern" (see HRC Section 25253(a)(1)). We interpret this to mean that if a safer alternative exists to a particular chemical, DTSC must take steps to restrict or phase out use of that chemical in order to protect environmental health and to promote use of the alternative. But we believe it also means that even where there is no safer alternative, industry should not be permitted to place or maintain a chemical on the market unless it can demonstrate with a reasonable certainty that the chemical is safe.

c. High priority chemicals that are found in cord-blood should be rapidly phased out

We believe that high priority chemicals of concern, such as CMR's, PBT's and vPvB's, that are found in human cord blood present such an unreasonable threat that they should be immediately phased out of commerce.

d. High priority chemicals of concern should be required to pass a safety test

Though an open-ended requirement for proof of safety would admittedly be difficult to satisfy, we believe that a safety test can and should be satisfied with respect to a data set that is required by the state pursuant to mandatory data requirements (plus any additional information that is requested by the state or otherwise becomes available). Where the state determines that a manufacturer has failed to make this showing, either because of the results of the data, or by failing to fulfill mandatory data requirements, chemicals should not be permitted to remain on or be introduced into the market.

We believe this safety standard should focus on whether the chemical presents an intrinsic hazard, and not on risk assessment or on balancing safety with economic or other countervailing considerations. Specifically, a legal test structured like that of the federal Toxic Substances Control Act, which permits use of monetized cost benefit analysis in which economic factors are weighed against human health or the environment, should not be part of any regulatory program under which the state seeks to better manage chemical hazards.

Moreover, in determining whether manufacturers have demonstrated the safety of their products, the state should ensure that manufacturers account for the importance of low doses, background exposures, synergistic effects, and the timing of exposures during the life cycle; account for the effects of cumulative exposures and differences in genetic responses to chemical exposure; and evaluate the hazards to the most vulnerable populations, most fragile ecosystems, and most susceptible life stages.

e. Industry should bear the burden of proof

The Draft Straw Proposal is not clear about who bears the burden of proof before regulatory action can be taken. For example, Sections (4) "Restrictions" and (5) "Prohibitions" both indicate that regulatory responses will be taken if "the data indicates a risk" or "data . . . indicates an impact." The question is, who has to make establish these facts? If DTSC is not careful, it will end up in the same straightjacket that EPA is now in under TSCA – EPA carries the burden of proof to show a chemical meets the required legal tests. As a consequence, all data gaps and uncertainties in the data militate against regulation, rather than for it.

In this case, high priority chemicals of concern should not be presumed safe with government bearing the responsibility to demonstrate that a chemical is unsafe or has a safer alternative in order for it to be regulated. Such a legal structure undermines producer responsibility, motivates manufacturers and commercial users to resist generating public information about the safety of their products, and makes it unreasonably difficult for government to take steps necessary to protect the public and the environment.

Allocating the burden of proof to industry rather than DTSC is a critical element of creating a system that will enable DTSC to protect public health and the environment and that will encourage rather than discourage the production of information. Several models exist for placing the responsibility on industry to demonstrate the safety of their products or lack of safer alternatives. These models include the European REACH legislation for authorization of industrial chemicals and the proposed "Kids Safe Chemicals Act of 2008" in the U.S., as well as models outside the field of industrial chemicals, such as the regulation of pharmaceuticals under the Federal Food, Drug and Cosmetics Act. DTSC should build on these models in structuring its regulatory program.

For example, it may be appropriate for DTSC to make an initial determination that a chemical is a chemical of concern. Then, the regulations could require that industry must show to a reasonable certainty that a chemical of concern does not present a threat of harm to humans or the environment and that there is no safer alternative for each particular use.

d. DTSC should not be required to restrict or eliminate high priority chemicals through lengthy formal rulemaking

DTSC should be empowered to act promptly to protect human health and the environment without protracted delay. In such cases, DTSC should act by order of the Director. DTSC must avoid allowing "paralysis by analysis" to prevent timely decisions about such chemicals. In particular, lack of complete information must not be used as a justification for further delay. While we support development of complete information and thorough analyses of chemicals, we also believe that DTSC can and should make timely decisions about many chemicals known to be hazardous based on already-existing information.

e. There should be a regulatory response to the absence of a minimum data set

As we stated above, there must be a regulatory penalty when a minimum data set is absent or incomplete in order to motivate industry to produce the needed information. We believe a mandatory data set should be required for new chemicals before they are introduced into commerce and for all existing chemicals in commerce by a date certain as a condition for being permitted to remain on the market. If such data is not provided, then new chemicals should not be allowed on the market and existing chemicals should be removed from commerce.

f. Regulatory responses should be tied to certain outcomes of the alternatives assessments

If an alternatives assessment shows that there is a viable, safer alternative, DTSC should phase out the use of the chemical of concern for that particular use. If an alternatives assessment shows that there are not safer or viable alternatives, the department may then take any number of the actions listed in the legislation. In such cases, the department shall require a period of time in which the assessment should be conducted again in order to determine if viable safer alternatives exist.

g. Timelines and deadlines for assessments and regulatory decisions

AB 1879 and SB 509 do not generally specify deadlines for provision of required data, completion of alternatives assessments and safety assessments, or final promulgation of regulatory decisions. Such deadlines should be established so as to ensure that the public is provided safety information about chemicals in commerce as quickly as is reasonable, that review of the enormous number of chemicals already in commerce is completed within some reasonable time frame, and that regulatory decisions are made in a timely manner. Six to twelve months is a reasonable time for completing an alternatives assessment and a safety evaluation of a particular chemical based on currently existing data. One year is a reasonable time frame for making regulatory decisions. Three years is a reasonable time frame for providing a required data set for chemicals in commerce. Ten years is a reasonable time frame for completing review of all chemicals currently in commerce. Coordination of these deadlines with various programs that are underway internationally, such as REACH, may be reasonable in some instances.

h. The regulations should build in continuous improvement

As stated in the GCI Final Report, it is essential that any chemical evaluation process builds in mechanisms that encourage continuous improvement (see GCI Final Report at pp. 34-36). Since the knowledge base of chemical hazards, uses and alternatives will expand continually over time, DTSC should build into its regulations a process whereby decisions and recommendations may be revisited and revised based on newly arising information. Accordingly, DTSC should grant only time-limited approvals for uses of hazardous chemicals for which safer alternatives cannot be identified. The program should also require decisions to be revisited whenever material new information arises. Finally, DTSC should also consider various technology-forcing approaches that will drive continual adoption of safer alternatives as they are developed.

i. Sections (4) “Restrictions” and (5) “Prohibitions” should apply to a broader set of concerns

Section 6.5 currently provides for prohibitions when sensitive subpopulations are potentially affected. Prohibitions should also apply when industry cannot carry its burden of proof with respect to environment and human health generally, not just when sensitive subpopulations are threatened. Section 6.4 is broader than Section 6.5, but should also enable DTSC to respond to any threat to human health or the environment.

In conclusion, we support DTSC's effort to design a new, more effective regulatory program for chemicals in commerce. As the outlines of the program DTSC's program become better defined, we will participate in this process and offer specific suggestions and regulatory language to assist DTSC in this important work.

Sincerely,

Members of the CHANGE Coalition (partial list)

Ansje Miller
Center for Environmental Health

Gretchen Lee Salter
Breast Cancer Fund

Martha Arguello
Physicians for Social Responsibility-Los Angeles

Joe Guth
Science and Environmental Health Network

Jose Bravo
Just Transition Alliance

Pamela King Palitz
Environment California

Suzanne Murphy
WORKSAFE

Lauren Ornelas
Silicon Valley Toxics Coalition

Andria Ventura
Clean Water Action

Davis Baltz
Commonweal

cc: Peggy Harris
Kathy Barwick
Bob Boughton
Robert Brushia
Hortensia Muniz-Ghazi
Donald Owen
Karl Palmer
Claudia Polsky
Jeff Wong
Green Ribbon Science Panel