December 30, 2011

Debbie Raphael  
Director  
Department of Toxic Substances Control  
Sacramento, CA 95812

Re: California Safer Consumer Product Informal Draft Regulations (October 31, 2011)

Dear Director Raphael:

I write as a member of the Green Ribbon Science Panel who has participated in DTSC’s efforts to develop a set of regulations to implement AB 1879 and SB 509 for the past three years. I appreciate the opportunity to provide these comments on my own behalf on the new draft green chemistry regulations.

I congratulate DTSC on developing the draft regulations and am highly supportive of several features. I support identification of several thousand COC’s by relying on existing authoritative body listings – all responsible entities must already be aware that all of these chemicals are problematic. I support DTSC’s intent to not further rank prioritize these COC’s or Priority Products – that impossible task would doom the program to paralysis by analysis on a grand scale. I also support DTSC’s intent to begin with a relatively small number of Priority Product/COC combinations, although DTSC should choose combinations that have both broader market significance and sufficient economic importance to their manufacturers to encourage them to participate in the program rather than abandon the products in California. Finally, while I understand the reasons for DTSC’s obvious conservative interpretation of its authority under AB 1879, I urge DTSC to acknowledge to the legislature that one consequence of this decision is that DTSC will need additional authority to fully implement an effective Green Chemistry Initiative.

I remain, however, deeply concerned that this program will not enjoy public confidence in the decisions that result from it, nor drive the market strongly toward green chemistry. The causes of these two problems are the lack of transparency that is all but certain to result from trade secret claims, the continued pervasive data gaps, and the lack of resources for DTSC to implement and oversee the program on any reasonable scale. Many far-reaching proposals have been made to address these problems over the last three years, and more will be undoubtedly be made in comments on these draft regulations and in the future. Comprehensive solutions have not been adopted in these draft regulations in part due to the limitations of AB
1879 and in part due to practical and other considerations. My instant comments do not offer additional comprehensive solutions, though I support any effort to address these problems seriously.

These concerns inform many of my comments, though my specific suggestions are relatively narrowly targeted. The following detailed recommendations for improvements in the draft regulations are all well within DTSC’s authority under AB 1879. They are intended to make the program stronger, more effective and more closely aligned with the intent of that statute. I hope the Department will consider them.

1. **The Regulations Should Articulate An Explicit Legal Standard For Regulatory Responses**

§69506.6(a) of the draft regulations provides that DTSC will determine whether a regulatory response is “necessary to limit potential exposures.” But this does not articulate a legal standard for what exposures are unacceptable and therefore “necessary” to limit. The draft regulations as a whole lack any such legal standard.

AB 1879 provides limited explicit guidance on this critical question. HSC §25253(a) directs DTSC to determine “how best to limit exposure or to reduce the level of hazard posed by a chemical of concern,” but unfortunately does not articulate a clear legal standard for how conflicts between the interests in environmental health and economic factors are to be “best” balanced.

Inevitably, DTSC is going to have to confront this issue in deciding what regulatory responses to impose. Moreover, AA assessors will have to know how DTSC is going to approach this issue when they decide which alternative to choose because the consequent regulatory responses could affect that decision. Without an articulated standard, there is no hope of DTSC decisions or AA Report decisions being transparent, consistent or accountable to the public.

Accordingly, DTSC should be forthright about this issue and articulate a transparent legal standard that both the Department and AA assessors can apply consistently and that the public can hold DTSC and industry accountable to.

Fortunately, I believe a solution to this problem is clear from the background and intent of AB 1879. Clearly, DTSC should not adopt the standard currently contained in the Toxic Substances Control Act. That statute places the burden of proof on the Administrator of U.S. EPA to make a number of showings before regulating a chemical, including demonstrating that the chemical presents an “unreasonable risk,” as evaluated under a cost-benefit test. The difficulty EPA has had in carrying this burden of proof is the essential source of the “safety gap” that the Green Chemistry Initiative is intended to confront, as identified in the 2006 Wilson et al.
and 2008 Schwarzman et al. Reports from U.C. Berkeley to the Legislature and DTSC, respectively.

DTSC should instead adopt a standard that will implement the intent of the Green Chemistry Initiative to close the safety gap. As the U.C. Berkeley Reports to the legislature and DTSC make clear, what is needed to close the safety gap is a legal standard that (1) is grounded in protection of human health and the environment (rather than cost-benefit tradeoffs between economic and health interests) and (2) allocates the burden of proof onto industry rather than government. Several significant laws, including REACH in Europe and some pollution laws in the United States, implement one or both of these goals.

I recommend the legal standard set forth in the Safer Chemicals Act of 2011, a proposed law for reforming the Toxic Substances Control Act. Under S.847, the bill introduced in 2011 into the U.S. Senate, all chemicals in commerce, including both new chemicals and existing chemicals, would be subjected to the requirement that the Administrator must find that “there is a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance.” Safe Chemicals Act of 2011, S.847 (2011), at Section 6(b)(1)(C)(ii)(II)(bb), see p. 66.

Significantly, this standard is already present in U.S. law. The U.S. Congress adopted this "reasonable certainty of no harm" test in the Food Quality Protection Act (FQPA), which amended FIFRA, the federal pesticides law. In the FQPA, that test is interpreted to mean a one per million risk for cancer or 1000-fold less than a reference dose [often referred to as a "safe" dose] for other effects.

DTSC should follow this lead and ensure that this legal standard is adopted as the Department’s goals for its Regulatory Responses. It constitutes the most reasonable way to “best” limit exposure to COC’s in consumer products. Implementing this standard will require carefully embedding it into several places in the regulation. I have not undertaken to do this, but will assist the Department in doing so if it requests my assistance.

2. The Burden Of Proof For DTSC On The Issue Of Causation Is Too High, And Not Warranted By AB 1879

The draft regulations consistently impose on DTSC a high burden of proof to show that chemicals and products cause harm to human health and environment. AB 1879 does not require this. Ideally, DTSC should place the burden of proof on industry to provide information and demonstrate that consumer products are safe. At an absolute minimum, DTSC should reduce the burden of proof on the issue of causation that it must carry throughout the regulations.
The allocation of the burden of proof (to either industry or DTSC) defines the law’s default position in the event available information is deficient. For example, if DTSC carries the burden of proving harm conclusively, then inconclusive evidence of harm disables it from regulating even where a chemical is likely to be harmful. The modern reality of the impact of toxic chemicals on the environment and human health is that often the best proof available is that a chemical may contribute, along with other chemicals and other environmental factors, to adverse effects on human health and the environment. Even the question of whether a chemical actually exhibits a particular hazard trait can almost always be disputed, and such disputes can only be resolved by defining how much evidence is required to meet a given legal standard – it is ultimately a definitional and legal question, not a scientific one. Given this reality, a requirement for DTSC to have more information than is commonly available (such as a requirement to prove actual harm or that a chemical indisputably demonstrates a hazard trait) has a deregulatory function – since the absence of the required heightened evidence means no regulation is possible.

Reducing the existing burdens of proof on government is one of the central goals of chemicals policy reform as articulated by the Green Chemistry Initiative and the national efforts to reform TSCA. The regulations should enable DTSC to act on the type of evidence that is reasonably available and to act on early warnings of harm. There is no other way to proactively protect human health and the environment from harm. Indeed, the authoritative bodies being relied on by DTSC in this draft proposed regulation often employ a lower burden of proof than these regulations impose on DTSC.

Accordingly, the draft regulations should be amended so as to eliminate various requirements that DTSC demonstrate actual harm, actual existence of hazard traits, etc. Instead they should empower DTSC to identify COC’s and Priority Products, as well as implement Regulatory Responses, based on evidence that exposure to a toxic chemical creates a threat of, or may contribute to, adverse effects on human health and the environment. These recommendations should be employed throughout the document so consistency is maintained. Changes are needed in draft regulations relating to definitions, identification of chemicals of concern and priority products, de minimis exemption and regulatory responses. Several examples of these changes are as follows:

Definitions

§69501.2(a)(5), p. 6, should read:
““Adverse public health impacts” means any of the adverse toxicological effects on public health listed in articles 2 and 3 of chapter 54.”

No other definition of adverse impacts refers to “causation” and there is no logical need for such a reference in this section or the others.
Identification of Chemicals of Concern

§69502.2(a) (p. 24, line 15) should read:
“... Chemical of Concern if it may exhibit a hazard trait...”

§69502.2(a)(1) (p. 24, line 17) should read:
“The chemical is identified as potentially exhibiting a hazard trait...”

§69502.2(b) (p. 25, lines 21-22) should read:
“... the Department may identify chemicals that potentially exhibit one or more hazard traits...”

§69502.2(b)(1)(A) (p. 25, line 25) should read:
“The potential for the chemical to contribute to adverse public health...”

§69502.2(b)(1)(B) (p. 25, line 37) should read:
“... the chemical associated with or contributing to the adverse impact(s)...”

§69502.2(b)(2) (p. 26, line 3) should read:
“... quantities that may contribute to adverse impacts...”

Prioritization of Products

§69503.2(a)(1) (p. 27, lines 34-36) should read:
“The Department shall consider the potential of the Chemical of Concern in a product to contribute to adverse public health and environmental impacts due to potential exposures during the...”

§69503.2(a)(1)(A)(1) (p. 27, line 40) should read:
“... in a product to contribute to adverse public...”

§69503.2(a)(1)(B) (p. 28, line 17) should read:
“... quantities that may contribute to adverse impacts on human health and the environment, considering:”

§69503.2(b)(1) (p. 29, line 17) should read:
“The Chemical(s) of Concern in the product exhibit(s) a significant potential to contribute to adverse public health...”

§69503.2(b)(3) (p. 29, line 121) should read:
“... in quantities that may contribute to adverse public health...”

§69503.2(b)(4) (p. 29, lines 24-25) should read:
“... in quantities that may contribute to adverse public health...”
De Minimis

§69503.4(b)(1) (p. 31, line 21) should read:
“... and that may exhibit...”

§69503.4(b)(2) (p. 31, line 26) should read:
“... and that may exhibit...”

§69503.4(c)(2)(A) (p. 31, line 37-39) should read:
“... there is the potential for exposures to the Chemical of Concern, or releases of the Chemical of Concern, to contribute to adverse impacts to human health and the environment, due to one or more of the following:”

§69503.4(c)(2)(B) (p.32, lines 2-3) should read:
“... the Chemical of Concern may contribute to adverse impacts on human health and the environment in concentrations...”

§69503.5(b) (p. 33, line 12) should read:
“... and is unlikely to contribute to an adverse public health or environmental impact.”

Regulatory Response

§69506.2(b) (p. 48, lines 16-17) should read:
“No regulatory response is necessary to limit potential exposures or reduce the level of potential adverse public health or environmental impacts posed by the selected alternative.”

NOTE: this language is intended to track and impose the same test as in §69506.6(a) where DTSC’s regulatory response power and obligation is articulated. Industry should not be able to establish that no regulatory response is warranted on a test that differs from DTSC’s obligation and power to require such a response.

3. DTSC’s Approach To Cumulative Impacts Should Be Strengthened

I strongly support DTSC’s efforts to account for cumulative impacts in evaluating chemicals in consumer products. This is, admittedly, a challenge for decision-makers. But it is a long overdue response to a longstanding and legitimate concern of environmental justice communities and others. 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.
Moreover, DTSC’s approach is consistent with Cal/EPA’s ongoing process for studying methods of evaluating and responding to cumulative impacts (OEHHA’s Cumulative Impacts and Precautionary Approaches Workgroup, which I am an appointed member of). While more tools for evaluating cumulative impacts clearly need to be developed, tools are never developed unless they are needed, and so I encourage DTSC to maintain its commitment to this issue and perhaps even to work with OEHHA on developing the needed tools.

However, the scope of cumulative effects contemplated by the regulations (that is, cumulative with “other chemicals of concern with similar modes of action”) is unduly limited and bears little relationship to the reason the concept is so important. “Other chemicals” are not the only source of impacts that accumulate. Also, the analytical burden for DTSC to determine “similar modes of action” is large but beside the main goal of cumulative impacts. What matters is for DTSC to consider the impact of chemicals along with other environmental factors, broadly defined. That is what OEHHA is doing in the CIPA Workgroup project. It is true that such cumulative impacts are sometimes difficult to quantify with precision. And yet it is important not to unduly restrict the scope of inquiry. Qualitative or semi-quantitative analyses of the real scope of cumulative impacts are more likely to be useful and accurate than more-precise quantitative analyses of only those discrete portions of a problem that happen to be more amenable to calculation.

Accordingly, I recommend that where “cumulative effects with other [factors]” is recited, this should refer to “other environmental factors,” not just other “Chemicals of Concern,” and should eliminate the phrase “mode of action.” These sections in particular should be amended:

§69502.2(b)(1)(A)(3) (p. 25, line 30) should read:
“The chemical’s cumulative effects with other environmental factors;”

§69503.2(a)(1)(A)(1)(c)(p. 28, line 2) should read:
“. . . cumulative effects with other environmental factors;”

4. **Trade Secret Claims Should Not Be Permitted For AA Methodologies Or Chemical Identity In Hazard Trait Submissions**

As I mentioned above, I am very concerned with the lack of transparency I anticipate to result from trade secret claims. This comment addresses just two elements of that problem that DTSC can solve without question.

a. **AA Methodologies.** As the regulations are written, trade secret provisions can apply to the process used to do the AA’s where the assessor chooses a process that differs from that specified by DTSC. If such processes are designated as trade secrets, public versions of AA Reports might have not just chemicals, alternatives and products redacted from AA Reports, they might even have the alternatives
analysis process redacted as well. This will make the AA process less transparent, less accountable and result in less influence on the market. Therefore the right to use an alternate AA process should be conditioned on full public disclosure that process.

Accordingly, §69505.2(b) should contain a new subsection that reads as follows:

“§60505.2(5) If a responsible entity uses an alternate AA process under this section, that alternate process may not be claimed as a trade secret or as otherwise entitled to immunity from disclosure to the public, and must be made available for full and complete public disclosure in the Preliminary and Final AA Report.”

b. Chemical Identity in Hazard Trait Submissions. §69510(f) provides that trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient. This section should be amended to clarify that this exclusion includes the chemical identity of the chemical or chemical ingredient. If it does not, then we know from experience with TSCA that chemical identity will often be claimed as a trade secret, thus disconnecting the public disclosure of hazard trait information from any particular chemical and making it useless to the public and the market.

§69510(f) should be amended to read:

“§69510(f) Trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient, which includes the chemical identity of the chemical or chemical ingredient.”

5. The Regulations Should More Clearly Reach Nanomaterials

The draft proposed regulations include a definition of “chemical” that apparently derives from TSCA and that may be interpreted so as not to permit adequate identification of nanomaterials as separate chemicals of concern that are distinct from their constituent chemicals. This is very important, because in some instances nanomaterials may be problematic where their constituent chemicals are not. The definitions of “chemical” and “chemical ingredient,” as well as the process for identifying new COC’s, should be amended to make clear that the properties of nanomaterials can form the basis for identifying substances as chemicals of concern. While essentially all nanomaterials should be “chemicals” or “chemical ingredients,” no regulatory implication whatsoever flows from that fact. Only when DTSC designates a particular material as a chemical of concern would any requirements or other regulatory implications attach to that material.

Accordingly, the following sections should be amended, as indicated:
§69501.2(16) “Chemical” means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or part, as a result of a chemical reaction or occurring in nature, or any element, ion or uncombined radical. The term ‘molecular identity’ means the physical and chemical characteristics of the substance, including its chemical structure and composition, size and size distribution, shape and surface structure, reactivity, and any other properties that may be relevant to whether the substance is a potential chemical of concern.

§ 69501.2(17) “Chemical ingredient” means a substance that comprises one or more chemicals.

§69502.2(b) Additions to the Chemicals of Concern List. In addition to the chemicals and chemical ingredients identified as Chemicals of Concern pursuant to subsection (a), the Department may identify chemicals or chemical ingredients that exhibit one or more hazard traits or environmental or toxicological endpoints as Chemicals of Concern by considering the following factors for which information is available:
(1) Potential Chemical or Chemical Ingredient Adverse Impacts.
(A) The potential for the chemical or chemical ingredient to cause adverse public health and/or environmental impacts, considering:
1. The chemical or chemical ingredient’s hazard traits and environmental or toxicological endpoints, and modes of action;
2. The chemical or chemical ingredient’s aggregate effects;
3. The chemical or chemical ingredient’s cumulative effects with other Chemicals of Concern with similar modes of action;
4. The chemical or chemical ingredient’s physicochemical properties, including its chemical structure and composition, size, size distribution, shape, surface structure, reactivity and any other properties that may be relevant to whether it is a potential chemical of concern;
5. The chemical or chemical ingredient’s environmental fate properties; and
6. The populations and/or environmental receptors that are potentially adversely impacted by the chemical or chemical ingredient.

6. The Phrase “Chemical Or Chemical Ingredient” Should Be Used Throughout The Regulation Rather Than The Term “Chemical”

The draft regulations use the term “chemical” throughout, in dozens of places. But AB 1879 uses the phrase “chemical or chemical ingredient” in almost all instances throughout the statute, rather than just “chemical.” For example, AB 1879 provides:

“25252. (a) On or before January 1, 2011, the department shall adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern . . .”
Thus, under the statute, “chemicals” are distinct from “chemical ingredients” and the statute grants DTSC authority over both. Under AB 1879, DTSC has the authority to designate not just chemicals, but also chemical ingredients, as chemicals of concern. It may also designate as priority products those containing either chemicals or chemical ingredients. Thus, the use in the regulations only of the term “chemical” is an unwarranted restriction of DTSC’s statutory authority.

Accordingly, DTSC should employ the term “chemical or chemical ingredient,” or “chemical and chemical ingredient,” as appropriate throughout the regulation in place of the term “chemical,” in literally dozens of critical places. It should also define those two terms differently in the definitions; I have proposed distinct and appropriate definitions in these comments for those two terms in the context of ensuring the regulations will reach nanomaterials (see comment no. 5, above).

7. Reference to “Mode of Action” Should Be Eliminated From The De Minimis Exemption

I agree with those who argue there is no need for a default de minimis exemption (other than one defined by reasonable detection limits) in these regulations because there are so many other prioritization mechanisms, and that such an exemption is not required by and undermines the intent of AB 1879. But if DTSC is determined to implement such an exemption, then the exemption of the draft regulations should be amended.

The draft regulations provide that a de minimis exemption shall apply to a specified concentration applicable to all chemicals of concern that, inter alia, exhibit the same hazard trait or environmental or toxicological endpoint “and mode of action.” Applying the de minimis exemption to COC’s that exhibit the same endpoint is a solid approach to the problem of avoiding the de minimis exemption by incorporating more COC’s in smaller quantities but not reducing overall risk. But requiring the same “mode of action,” is not appropriate. It bears no relation to the reason for this provision of the de minimis exemption in the first place. It is also very difficult analytically to establish, which burden would fall on DTSC, since it is unlikely industry will seek to establish that COC’s use the same mode of action (and therefore must be subject to a combined de minimis level).

Accordingly, the regulations should eliminate the phrase “and mode of action” entirely from: §69503.4(b) (1) and (2) (p. 31, lines 22, 27) and §69506.2(a) (p. 48, line 14).
8. **The Draft Regulations Provide Insufficient Consideration of Adverse Effects to Workers**

Several provisions of AB 1879 explicitly require consideration of adverse effects on workers, but several provisions of the draft regulations unduly discount this concern. They should be amended as follows.

a. **Unwarranted exclusions from definition of “consumer product.”** The regulations state that they do not apply to “consumer products” that are:

   (i) used “solely for the manufacture” of a consumer product exempted from AB 1879. See §69501(b)(2). This is essentially a matter of priorities; there is no reason a product used to make an exempted product should not be subject to the regulation – the statute excludes the exempt products, not all chemicals used in their manufacture.

   (ii) “manufactured or stored in, or transported through California solely for use outside California.” See §69501(b)(3). This provision precludes DTSC or the AA assessors from considering threats to workers and the environment caused by manufacturing and transporting Priority Products containing COC’s within the state if they are to be used outside the state – but this provision has no basis in AB 1879 and subverts the statute’s goal of promoting life cycle reviews, including the risk of adverse effects to workers within the state.

   (iii) “bulk chemicals . . . not packaged for sale to . . . a retail customer.” See §69505.1(b)(2). This provision likewise has no basis in the statute and should be treated as a matter of DTSC priorities, not written as an exclusion in the regulation that deprives DTSC of statutory authority and would require new regulations before DTSC could ever consider a bulk product that creates risk to workers and the environment.

Accordingly, the regulations should eliminate §69501(b)(2), §69501(b)(3) and §69505.1(b)(2).

b. **Unwarranted restriction of Potential Adverse Impacts and Exposures.** §69503.2(a)(1) specifies that when prioritizing products DTSC shall consider potential exposures to COC’s “during the manufacture, useful life, and end-of-life disposal and management of the product.” This creates a permanent exclusion for adverse effects of COC’s that occur during the life cycle of the COC that precedes the manufacture of the product it is incorporated into, including the manufacture and transport of the COC itself. This limitation may also ultimately be incorporated into the AA process and perhaps the regulatory response process as well. This limitation has no basis in AB 1879 and undermines its focus on the full life cycle of COC’s.
Accordingly, §69503.2(a)(1) (page 27, lines 36-37) should be amended to read:

“... potential exposures during the manufacture and transport of the COC and during the manufacture, useful life, and end-of-life ...”

9. The Regulations Should Do More To Prevent Regrettable Substitutions

I expect these to occur on a large scale as the draft regulations create a loophole for manufacturers to avoid the regulations by switching out of chemicals of concern into any other chemicals. Past regulatory proposals sought to minimize this problem by including either (1) a no data, no market requirement for all or most chemicals in commerce or (2) a detailed, admittedly cumbersome reporting requirements anytime a COC is altered in any product.

The draft regulations contain no provision to address this, although the relatively large number of COC’s may help somewhat with this problem. I continue to believe that AB 1879 does provide support for a no data, no market requirement based on the authority it grants DTSC to identify COC’s. But in the absence of such a requirement, one strategy might be for DTSC to try to collect information as to the extent of this problem so as to inform the design of future elements of the GCI. For example, responsible entities could be asked or required to report to DTSC if they switch out of or reduce the amount of a COC in any product once the COC list is finalized. A simple, nonburdensome reporting program could provide information of great value to DTSC and the legislature as it considers the need to address the problem of regrettable substitutions.

10. The Provision For Stay Pending Dispute Resolution Process Needs Clarification

Article 7 of the draft regulations provides an administrative dispute resolution process. One of its provisions is that requirements pursuant this chapter shall be suspended “during the pendency of a dispute concerning the requirement.” §69507(c). I understand DTSC’s intent to be that requirements shall be suspended only during pendency of the administrative process, but that normal principles of administrative exhaustion of remedies and judicial review would apply if a petitioner were to seek judicial review of any requirements under this chapter, and that according to those principles a stay pending judicial review may or may not be appropriate. The current wording of § 69507(c) is not clear on this point.

Accordingly, §69507(c) (page 56, line 27) should be amended to read:

“... shall be stayed during pendency of the dispute resolution process under this article concerning the requirement.”
I am available to assist DTSC with these suggestions, including by answering questions, providing further information or assisting in drafting regulatory language. Please do not hesitate to call on me for further assistance.

Thank you for the opportunity to provide these comments.

Very truly yours,

Joseph H. Guth, Ph.D., J.D.
Member, Green Ribbon Science Panel
Science & Environmental Health Network
U.C. Berkeley Center for Green Chemistry

cc:
Odette Madriago, DTSC
Jeff Wong, DTSC
gcregs@dtsc.ca.gov