Comments on November 15, 2010 Draft Regulations for Safer Consumer Products (AB 1879)

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by

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We respectfully submit the following comments to the Safer Consumer Product Alternatives Draft Regulations released by Department of Toxic Substances Control (DTSC) on November 15, 2010. As you know, STPP strongly supports the overall goals of SB 509 (Simitian, 2008) and AB 1879 (Feuer) to identify chemicals of concern in consumer products and promote the development and diffusion of safer substitutes whenever feasible. STPP's December 22, 2009 White Paper "Integrating Safer Alternatives into Chemical Policy: Developing a Regulatory Framework for AB 1879" outlined an approach we believed would lead to efficient and effective implementation of the legislation. We appreciate that a number of the recommendations suggested in the White Paper and in our later comments on various versions of draft regulations were addressed by DTSC. The comments below highlight a number of remaining problems with the current draft regulation which, if left to stand, would create significant barriers undermining the core goals of the legislation. For each problem, we provide practical solutions intended to resolve the underlying issue. Taken together, we believe that the recommended changes will result in a regulatory program that will efficiently and effectively drive the innovation and diffusion of safer alternatives.

These comments do not represent the opinion of the University of California or its Chancellors. Institutional affiliations are for identification purposes only and do not necessarily represent the views of the organization.

Comments

These comments are broken into general overarching comments which relate to a variety of sections and larger structural aspects of the draft regulations, followed by a series of section-specific comments that address more focused aspects of the draft.

General Comments

1. Listing and Prioritization: 69302.2 & 69302.3
    a. Despite ostensibly separating the actions of identifying the universe of chemicals of concern and prioritizing that list for action, Sections 69302.2 (Chemicals List) and 69302.3 (Chemicals of Concern Prioritization) functionally conflate these two distinct actions. This allows the list of chemicals of concern to be limited based upon the availability of DTSC resources for evaluation. Identification as a prioritized chemical of concern—even if department resources are not available for evaluation—can serve as an important signal for the market and lead to development of alternatives in its own right. The availability of DTSC resources, which is likely to be a significant constraint on the program, should be used only to guide the number of priority chemicals which move forward for evaluation rather than as a limit on whether such chemicals are identified and prioritized.

2. Third Party Verification: 69305.1(c)(1)
    a. The third party verification could be a valuable check of the rigor and legitimacy of the manufacturer-generated alternatives analysis. The proposed regulations retain an independence requirement and bright line rules for separation of financial interests. However, the regulations do not establish standards for expertise necessary to establish the credibility and legitimacy of the verifier. Given the emerging nature of the alternatives analysis methodology, it is difficult to identify existing standard training or certification programs. Nonetheless, the regulations should include a narrative standard requiring that the third party demonstrate appropriate training, experience and qualifications.

3. Screening/Exclusion of Alternatives: 69305.2(a)(4); 69305.3(a)(2)(D)
    a. The regulations provide for sequential decision-making, allowing responsible parties to screen out alternatives at multiple points during the analysis (i.e., in preparing the work plan, after the chemical hazards assessment and exposure potential assessment; and again after the multimedia life cycle evaluation). These decisions significantly impact the outcome, yet the regulations provide no standards for such decisions, nor do they require even a brief explanation of the choices until the AA Report—at the very end of

the process—see 69305.4(e)(i)). The regulations should incorporate conservative standards for exclusion of potential alternatives at these early stages, and require a justification for any such exclusions.

b. Similarly, the regulations provide for exclusion of life cycle segments and hazard/exposure criteria during work plan development, again without any standards or any requirement for explanation. 69305.2(a) (3)—(5).

4. Selection of Alternative: 69305.4(j)
    a. This section requires the responsible party to select an alternative or retain the original product, and provide a rationale for that decision. However, it provides no standards to guide this decision. Rather, the only substantive guidance in the provision *prohibits* the selection of any alternative that results in greater significant adverse impact on public health or the environment than the original product The provision should be revised to require use of the same standards as those to be used by DTSC in its selection of final regulatory responses (see Selection of Regulatory Responses: 69306.6(a), below).
        i. Note that the standard of "no greater significant adverse impact on public health or the environment" in the regulations creates some confusion, as it is unclear as to how it relates to the factors used for the chemical hazard assessment and the exposure potential assessment For example, the definition of environment, drawn from the Public Resources Code, includes consideration of historic and aesthetic concerns.
    b. This section requires identification of supporting information for the selected alternative, but not for those alternatives that were evaluated but not selected. In order to evaluate the AA Report adequately, DTSC should have access to the relevant information regarding those alternatives that were not selected.

5. Department Review of Work Plan and AA Report: 69305.2(b) & 69305.5.5
    a. These sections do not expressly provide DTSC with the authority to require substantive changes to the Work Plan or final AA Report. In both cases, DTSC has the authority to review the documents for completeness and compliance with the regulations, but it is unclear what the scope of that review would be. The reference to "compliance" with the regulations suggests that it would be a substantive review; however the regulations also suggest in two places that the review may be limited to an administrative review. First, DTSC is given the power to issue either a notice of completeness or a notice of deficiency, terms used in the context of an administrative review of a permit application rather than a substantive review. Second, where a notice of deficiency is issued, the responsible party cures it by submitting additional information. If a substantive review were contemplated, one would expect that DTSC would be authorized to require specific changes or re-evaluation. The regulations should be revised to expressly provide DTSC with substantive review authority.

6. Product Sales Prohibition: 69306.5
    a. This provision requires that DTSC prohibit product sales when a safer alternative containing no chemical of concern exists. The alternative must also be technically and economically feasible, meaning in part that it has a comparable rate of return as the Priority Product. Presumably this provision will have limited application, as it is fairly unlikely that most alternatives will have *no* chemicals of concern particularly as the universe of chemicals of concern grows over time. Nonetheless, it does provide clear direction in the straightforward cases; that is, in those limited cases in which there is a viable, clearly safer alternative with no chemicals of concern and with a comparable rate of return for the manufacturer. In such circumstances, the case for substitution is compelling. Nonetheless, we have several concerns with this provision.
        i. First, we assume that the additional requirement that the alternative be "safer" reflects the fact that the potential impacts of *all* relevant chemicals contained in the product would be evaluated as part of the AA, not simply the chemicals of concern. See Section 69305.3(b)(Chemical Hazard Assessment). This should be made clear in the provision itself.
        ii. Second, the section should emphasize that it is not intended to limit the regulatory response of a ban/phase-out to just these circumstances. While Section 69306.6(a)(1) suggests that this is the case, the point should be more clear made in Section 69306.5 itself. In this regard, two particular examples of cases falling outside the scenario covered by Section 69306.5 are relevant. A ban/phase may e appropriate in situations in which a safer, feasible alternative *does* contain either the same or different chemical of concern(s), but at levels that are of significantly less concern than those of the Priority Product. Likewise, a ban/phase out may also be appropriate where a substantially safer alternative with a less favorable rate of return exists. The point is the existence of a bright line case in Section 69306.5 should not undermine the application of the comparative approach required under the statute for all other cases.

7. Selection of Regulatory Responses: 69306.6(a)
    a. Apart from the three default situations set out in 69306.3-.5, the regulations contain no standards for selecting regulatory responses beyond the statutory language regarding reduction of exposure or hazard. This regulatory standard does not incorporate the green chemistry principles underlying the statute. It should be revised to create a mandatory preference for safer feasible alternatives, and to ensure that in evaluating particular chemicals and potential alternatives, the regulatory responses maximize the use of alternatives of least concern where such alternatives are technologically and economically feasible. In addition, the provision should emphasize that selection is to be based upon a comparative evaluation of the Priority Product and the alternatives with respect to each of the factors set out in Section 69305.3 (AA Evaluation and

Comparison Process and Factors), and should articulate the relative weight to be accorded each of those factors. In addition, the regulations should establish an explicit, mandatory hierarchy of regulatory responses emphasizing prevention over engineering controls over use restrictions. Moreover, the section should expressly provide that these standards are to be applied by the responsible party in identifying regulatory responses in the AA Report, and by DTSC in selecting final regulatory responses.

Section-by-Section Comments

Section	Subsection	Topic	Comment
69301		Deletion of Guiding Principles	Guiding principles were included in the September 2010 draft regulations to provide context and direction for implementation and interpretation of the regulations by agency personnel, businesses, stakeholders and courts. They are essential in listing and prioritization, analysis of alternatives assessment to identify safer substitutes, and linking the alternatives assessment to the appropriate regulatory response. Each of the guiding principles were clearly supported by the language and goals of AB1879. Further, guiding principles have been used in a variety of other federal and state regulatory programs to assist with implementation. The final regulations should include the guiding principles as stated in the September 2010 draft.
69301(b)(4)		General: Applicability—exclusion of chemicals unintentionally added	The term "unintentionally" is too vague, and could include situations in which parties have negligently and routinely allowed inclusion of the CoC. Also, there is no obligation to report presence of unintentional chemical when discovered.
69301(b)(5)		General: Applicability—exclusion of	There is express authority for

		chemicals where other federal/state program "addresses" same public health/environmental threat and pathway	this provision the statute for this exclusion, and it undermines the notion of advancing green chemistry. "Addressing" a chemical may fall far short of the level of protection required under AB 18979 ("best limiting exposure or reducing hazard") and does not necessarily take into account slippage from under-enforcement of the federal/state program. The provisions in SB 509 regarding harmonization of this program with other state and federal authorities is more effectively and legitimately implemented by Section 69306.7 (Exemption from Regulatory Response Requirements).
69301.1(a)		Definitions	
	4	Adverse air quality impacts	This limits impacts to emissions of pollutants specified in other programs, and thus ignores emissions of chemicals that may not necessarily fall within those other programs. For example "toxic air contaminant" is undefined, but likely refers to chemicals specifically designated as toxic air contaminants in CA.
	5	Adverse ecological impacts	This definition seems to require a showing of "causation", that is a direct or indirect causal link between the chemical and the ecological impact. This could be difficult to establish, and lead to substantial litigation. Cause should be replaced with threat or potential threat
	12, 26	Removal of nanomaterials from definition of chemical, and from definition of de minimis level	The definition of nanomaterials is necessary in order to carve such materials out of the de minimis definition. Given the possibility that levels of

			nanomaterials below the de minimis level may be harmful, the application of the de minimis exception is inappropriate with respect to nanomaterials. Moreover, there is no explanation for the removal of nanomaterials as being within the definition of chemical. This could give rise to an inference that DTSC views nanomaterials as outside the definition. At a minimum, this should be clarified in the ISOR.
	26	de minimis	The de minimis exemption should be eliminated. • There is no express authority for this provision in the statute. Indeed, the de minimis concept is inconsistent with the statute's express requirement for a comparative approach. By requiring the use of alternatives analysis as the evaluation tool, the logic of the statute is not to set an *absolute a*cceptable level of a Chemicals of Concern (CoC) in a product but to compare the hazard profile of products containing CoC with alternatives. • There is no principled scientific basis for setting this de minimis level. It fails to recognize the wide range of potency of chemicals and the reality that numerous chemicals exhibit toxicity at levels which are orders of magnitude below the 1,000 parts per million level of the

			de minimis definition in the draft regulation. • While the de minimis exclusion is not intended to be absolute, DTSC requires evidence of potential harm at concentrations below the de minimis level (see 69305.3(d)(2)(A)(B)) but provides no standard for disallowance. • As a practical matter, even if these provisions were modified to clarify DTSC's authority to disallow *de minimis* exclusions, the reality of DTSC's limited resources would likely result in *de facto* absolute exemptions as DTSC will be unable to identify and act upon those chemicals that should be removed from the default *de minimis* coverage.
	41	Functionally equivalent: provides alternative must "meet or exceed" rather than "substantially satisfy" the *intended* performance and functionality of the original.	Performance should not trump all other considerations. Therefore, if an alternative is "good enough" it should meet the standard. Moreover, it is inappropriate to look at the nominal "intended" performance of the original product; rather, it should be compared to the ***actual*** performance of the original.
	51, 72	Manufacturer and Responsible party: Limits relevant definition to actual producer and retailer.	These definitions exclude the real party in interest in situations in which the party controlling the product specifications, process and distribution contracts out actual production. Inclusion of such party may be important in a variety of contexts; for example, in the case of analyzing

			economic impacts on manufacturer, and in the event of non-compliance.
	62	Priority Product	This term is extremely misleading. The word "priority" could be interpreted as having positive attributes. Change to "Priority Product of Concern."
	80	Technologically and economically feasible alternative	There are a number of problems with this term. • With respect to the specific definition, the subsection discussing technological feasibility states that "current technological knowledge, equipment, materials and other resources available to the manufacturer are sufficient to develop and implement the alternative." It is important to make it clear that the "manufacturer" in this case could either be the regulated entity or the manufacturer of an alternative. There may be cases in which the manufacturer of a priority product of concern does not have access to an alternative; for example, when an alternative is manufactured by another firm with a patent right on the alternative. • With respect to economic feasibility, the definition introduces the specific economic concept of *rate of return* which is not further defined. In addition, the definition should not include an evaluative component as written it requires that the

			rate of return be "comparable." The relative technical and economic feasibility of the priority Product and alternatives will be evaluated as part of the Product Function and Performance Analysis, and will be taken into account as part of the broader evaluation of all relevant factors set out in Section 69305.3 (AA Evaluation and Comparison Process and Factors). It should not be embedded in the definition as well as a threshold level.[1] • Another threshold criterion is that the alternative has "no significant externalized cost imposed on consumers, public health, or the environment." This criterion should be removed as it will be dealt with under other factors in the evaluation. See Section 69305.3 (AA Evaluation and Comparison Process and Factors).
	83	Definition of trade secret	This section adopts the broader definition in the Civil Code. The statute contemplates the narrower definition (which for example would exclude products under a patent) found in Section 6254.7 of the Government Code.
69301.5(b),(c)		Chemical and Product Information—DTSC to follow sequential steps	This appears to be based upon H&S Code Section 58012, but goes beyond the requirements

[1] We recognize that the requirement of a "comparable" rate of return may be appropriate for the limited purpose of the mandatory product ban of Section 69306.5, however that requirement should be expressly set out in that section only, as it is inappropriate to allow the rate of return to trump other relevant factors when engaging in the AA evaluation and in selecting regulatory responses in cases not covered by Section 69306.5.

			of that section in terms of imposing constraints upon DTSC. For example, nothing in the law requires DTSC to attempt to obtain data from sources requiring payments such as subscriptions. Also, subsection (c) inappropriately limits the scope of information that DTSC can seek. It should be modified to clarify that this list is non-exclusive.
69306.4	(a)(2)(A) 6.	End-of-Life Management Requirements	The regulations should include substantially more specific provisions regarding the level and nature of the guarantee, and the process for demonstrating its sufficiency. Experience in other regulatory programs with financial guarantee mechanisms demonstrates the need for very specific direction and oversight if the mechanism is to be useful.
69307.2		Request for Further Review by the Director	If the Director of DTSC is to be provided the authority to overrule a Department decision then specific guidelines need to be developed to justify such action. The guideline must be consistent with the other substantive requirements of the statute and regulations governing the performance of an AA and selection of a regulatory response. In addition, the right to petition the Director should be granted to all stakeholders not just a responsible entity or manufacturer.