

December 3, 2010

Via email: gcregs@dtsc.ca.gov

Regulations Coordinator
Department of Toxic Substances Control
Regulations Section
PO Box 806
Sacramento, CA 95812-0806

Re: Department of Toxics Substances Control
Safer Consumer Products Alternatives – Proposed Regulations, R-2010-05
Text of Proposed Regulations – Post-Hearing Changes (November 2010)

Regulations Coordinator:

We write on behalf of the 33 undersigned environmental and environmental justice groups, consumer advocates, 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.

We provide these comments to the Department of Toxic Substances Control (DTSC) in response to the November 16, 2010 revisions to the proposed Safer Consumer Products Alternatives Regulations (R-2010-05) (“Revised Regulations”) within the established 15-day public comment period. The Revised Regulations incorporate revisions to the regulations proposed on September 14, 2010 (“Proposed Regulations”).

I. Introduction

First, our bottom line:

We oppose promulgation of the Revised Regulations and urge DTSC to withdraw them in their entirety.

CHANGE expressed support for the Proposed Regulations in its November 1, 2010 comments filed with DTSC. But the Proposed Regulations have now been radically restructured, and have strayed far from the discussions of the preceding two years of regulatory development. We have regrettably concluded that the new features of the revised regulations will render them so ineffective and burdensome that they should be jettisoned altogether. In these comments we explain the major reasons for this conclusion.

Should DTSC conclude that it wishes to promulgate the Revised Regulations over our substantive objections, it should nevertheless withdraw them because it has failed to provide the legally required opportunity for public comment. It is simply unconscionable

for DTSC to attempt force through a radically restructured regulation of this importance to the people of California without obtaining meaningful public input. Or, at the very least, DTSC should provide for a 45-day comment period and public workshop to discuss the implications of the Revised Regulations.

In our comments below we address each of these issues, beginning with DTSC's procedural error.

II. The 15-Day Comment Period Is Illegal.

Should DTSC wish to promulgate the Revised Regulations over the substantive objections we set forth in the next section, it should nevertheless withdraw them because the 15-day notice and comment period is illegal.

DTSC may establish a shortened 15-day notice and comment period for changes to proposed regulations that are "(1) nonsubstantial or solely grammatical in nature, or (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action."¹ DTSC asserts that the "sufficiently related" provision applies here.²

But the Revised Regulations differ so greatly from the Proposed Regulations, which were the product of a two-year process in which CHANGE and other signatories to these comments participated at every step of the way, that DTSC's position is not credible. Numerous highly significant changes, including deletion of one-third of the original text, amounting to a complete restructuring and raising numerous new issues have been adopted with virtually no public discussion or input. Many of the revisions contained in the Revised Regulations have never been discussed in public and could not possibly have been anticipated. Unfortunately, with these last-second, surprise revisions DTSC has undermined its two-year process for seeking public input and discussion. This is precisely the sort of abuse of government power and special interest political influence that Government Code § 11346.8(c) was intended to prevent. This illegal process for promulgating the Revised Regulations renders them invalid and they should be withdrawn.

We have attempted to respond to the Revised Regulations in the 15 days provided by DTSC, and these comments summarize some of our major concerns. But we have not been able to include herein all of our concerns. Nor have we even begun to develop and offer specific solutions to the many new problems created by the restructuring. There simply has not been enough time to do so. Thus, if DTSC does not withdraw the Revised Regulations in their entirety, then we request that DTSC provide at the very least a 45-

¹ California Government Code § 11346.8 (c). See also Title 1, California Code of Regulations § 42; Government Code § 11346.8(e) (requests for additional time should be granted where new issues are raised and member of public requests additional time to respond).

² See DTSC's November 16, 2010 "15-Day Public Notice And Comment Period Notice Of Public Availability Of Post-Hearing Changes And Availability Of Documents Added To the Rulemaking File," at page 3 (citing Title 1, CCR § 42).

day comment period including a public workshop to work through the new proposal contained in the Revised Regulations.

III. Our Bases for Objecting to the Revised Regulations

A. The Revised Regulations Perpetuate Shortcomings of the Proposed Regulations

We very briefly note here that the Revised Regulations perpetuate shortcomings of the Proposed Regulations that CHANGE and other signatories to these comments have noted frequently as they were developed over the past two-years. Chief among these are that they fail to:

- Provide a mechanism for taking prompt action on chemicals known to be hazardous.
- Require industry to develop a basic level of hazard information about their products as a condition for putting them on the market.
- Place the burden of proof on industry to show their products are reasonably safe.
- Require release to the public of substantial information relating to whether products pose a threat to human health and the environment, thus allowing it to be withheld from the public and to remain secret.

We recognize that the extent to which AB 1879 requires DTSC to pursue these central objectives of chemicals policy reform is somewhat ambiguous. But we believe the statute does provide DTSC with authority to take meaningful steps to advance these goals. We again express our regret that it has chosen not to do so.

Despite these shortcomings, CHANGE supported the Proposed Regulations in the hope that they would constitute a modest step forward in the reform of chemicals policy. But now the Revised Regulations contain so many additional shortcomings that we do not believe they should be promulgated, as we explain in the next section.

B. The Revised Regulations Will Be Ineffective and Unduly Burdensome --- They Should Be Withdrawn

The Revised Regulations would impose unreasonable burdens on DTSC, provide only minimal incentives for industry to genuinely reexamine and reduce its use of toxic chemicals in consumer products rather than evade the regulations, and make any oversight by the public and the market virtually impossible. The Revised Regulations would not promote the development and adoption of safer chemicals to any significant

degree, if they would do so at all. Accordingly, their implementation would simply not be worth the effort and costs to DTSC, to the public for the oversight efforts it would have to expend and even to industry if it chooses to respond by generating counterproductive paperwork, as the Revised Regulations unfortunately invite it to do.

Below are some of the significant new features of the Revised Regulations which, in conjunction with the other major problems identified above, lead us to oppose their promulgation:

1. The Revised Regulations Impose a Limited “Duty to Comply” That Renders Them Virtually Unenforceable. The Revised Regulations no longer place the duty to comply with its provisions on the entire product supply chain, but now limit that duty principally to product manufacturers.³ DTSC may create a limited duty to comply for individual retailers only if product manufacturers fail to comply and DTSC notifies retailers of a specific requirement and time frame for response, a duty that can be discharged if retailers cease ordering the product.⁴ No other element of the supply chain, including distributors and importers, is held accountable under any circumstances for responding to the requirements of the Revised Regulations. Meanwhile, for the only potential responsible entities, product manufacturers and retailers, the Revised Regulations eliminate numerous responsibilities, including the obligation reasonably to become aware of the chemical contents of products.⁵

This structural change renders the Revised Regulations utterly unenforceable. Modern supply chains often involve many parties dispersed about the globe, and many of them, including retailers and even final product manufacturers typically have little idea of the chemical content of the products they assemble or sell. DTSC has chosen to place the primary duty to comply on product manufacturers, but many of these are distant from California with no direct contact or direct obligations to the State. Apparently recognizing this, DTSC has chosen retailers as the only other potentially responsible entity, but this is the most dispersed and fragmented element of the supply chain and the least likely to know the chemical content of consumer products.

DTSC seems to be planning to encourage compliance by purchasing products from individual retailers and testing them to detect failures to comply and then posting notices of such failures on its website.⁶ But DTSC does not now and will never have the resources necessary to do this on any meaningful scale, and we believe it fundamentally inappropriate for government to assume responsibility for tracking down the chemical content of products. At best this strategy would address only a handful of products in an ad hoc and utterly ineffective fashion.

³ § 69301.1(a)(72); § 69301.3(a)(1).

⁴ § 69301.3(a)(1), (c).

⁵ Compare Revised Regulations § 69301(b) with Proposed Regulations § 69301(b).

⁶ See § 69301.3(d); personal communications with DTSC staff.

Without making the entire supply chain accountable for the chemical contents of products, as did the Proposed Regulations and as the European Union has done with its REACH regulation, DTSC has virtually no hope of obtaining cooperation by the various elements of supply chains or productive responses from industry rather than evasive finger pointing, assertions of lack of knowledge and responsibility, or even no responses at all. The limited duty to comply provided by the Revised Regulations instead encourages companies to remain ignorant of the chemical contents of products they sell and promotes further balkanization of product supply chains, including departure from California of manufacturers along with California jobs.

2. High Burdens to Show Threats to Human Health or Environment. The Revised Regulations place enormous burdens on DTSC to establish threats to human health and the environment for each individual chemical and each individual product. These new requirements apply throughout, including to identification of Chemicals of Concern,⁷ identification of Priority Products,⁸ development of regulatory responses for selected safer alternatives⁹ and presumably to regulatory responses as well.¹⁰

DTSC must now show that individual chemicals can cause “adverse impacts” to air, water, soil, public health, and ecological systems, the definition of which is framed in terms of actual adverse impacts of individual chemicals, sometimes limiting “impacts” to definitions contained in current laws.¹¹ DTSC must also develop “reliable” exposure information, which is defined in terms of either monitoring information that exists for relatively few chemicals or modeling that can establish point exposures associated with adverse impacts.¹² This type of evidentiary requirement to show that a chemical is a Chemical of Concern ignores the modern reality that the cumulative impact of numerous chemicals and other factors often lays at the root of modern health and environmental problems. It subverts the intent of AB 1879 to promote reduction of exposures to hazardous chemicals, and reasserts the chemical-by-chemical risk approach that has proved so ineffective.

Thus, at every turn, DTSC has assumed significant burdens of data gathering and technical analysis as well as high legal burdens of proof. Every judgment that DTSC would make can be challenged and appealed in court. This would drive DTSC into resource-intensive analysis of a limited number of chemicals, often, one would expect, the very same chemicals which have been well studied and are already the subject of existing laws, which will in turn function to remove those chemicals from consideration under these Regulations (see discussion herein below of impact of other laws).

The high burdens now placed on DTSC throughout the Revised Regulations will assuredly lead to the paralysis-by-analysis that is a feature of current chemicals regulation

⁷ § 69302.3.

⁸ § 69303.3

⁹ § 69306.2(b).

¹⁰ § 69306.6(a).

¹¹ § 69301.1(a)(4)-(8).

¹² § 69301.1(a)(71).

under the federal Toxics Substances Control Act and that has made that law so ineffective.

3. Fewer Controls on Claims of Confidentiality of Information. The Revised Regulations further encourage industry claims of confidentiality of information relating to the health and environmental impacts of chemicals in products. Provisions of the Proposed Regulations that have been eliminated include those that: (1) required specific public identification of claims of confidentiality and their bases,¹³ (2) set forth procedures for DTSC review of such claims,¹⁴ and (3) identified specific information that could not be claimed as a trade secret under the “hazard trait submission” section of AB 1879.¹⁵

These changes weaken DTSC’s controls and public scrutiny of confidentiality designations and so further encourage those designations. In particular, without general guidelines describing what is and is not permissible under the “hazard trait submission” provision of AB 1879, industry designations can only be challenged on a case-by-case basis by either DTSC or through litigation by third parties. Experience under TSCA has proved how aggressive industry is likely to be on confidentiality designations and how difficult those designations will be to confront on a case-by-case basis.

The confidential information provisions of the Revised Regulations ensure that neither the public nor the market will have any real access to many of the decisions, analyses and Reports made under the Regulations, including Chemicals of Concern prioritization and listings, Priority Product prioritization and listings, alternatives assessments and AA Reports, and regulatory responses.

This lack of transparency saps the Revised Regulations of any ability to assure the public of the quality of the decisions that will be made under them, and also deprives the public and the market of any ability to respond to information generated by the program.

4. Elimination of Exposures Addressed by Other Laws. The Revised Regulations expand the impact of any federal or state law or regulation, or ratified international treaty, that “addresses” (not eliminates) an exposure pathway for a chemical. Now, any exposure that is “addressed” by such a law must be eliminated from consideration by DTSC throughout the regulation, including when DTSC considers whether (1) a chemical is a Chemical of Concern,¹⁶ (2) a product is a Priority Product,¹⁷ and (3) an alternative is a safer alternative.¹⁸ A Priority Product can be exempted from the Revised Regulations entirely if all exposure routes that would cause its listing are addressed by an existing law.¹⁹ One can expect aggressive industry assertions that particular exposure routes for a chemical of concern is “addressed” by another law or regulation.

¹³ See elimination of § 69310.5 of Proposed Regulations.

¹⁴ See elimination of § 69310.5 of Proposed Regulations.

¹⁵ § 69309.2; AB 1879, HSC § 25257(f).

¹⁶ § 69302.3(a)(4).

¹⁷ § 69303.3(a)(3).

¹⁸ § 69305.3(a)(3).

¹⁹ § 69301(b)(5).

We think it is reasonable to interpret SB 509, the supposed legal source of this requirement, so as to bar DTSC from issuing regulatory responses that conflict with other existing laws.²⁰ But it is simply preposterous to eliminate the health and environmental threats that are permitted, even if partially controlled, by existing laws from all consideration under the Revised Regulations. The fact that the law permits a certain level of exposure to a chemical through the air or water or the workplace simply does not render that exposure harmless, particularly because of the cumulative impact that frequently results from multiple exposures.

Thus, the Revised Regulations undercut the fundamental goal of AB 1879 to examine the full life-cycle of toxic chemicals, to consider cumulative impacts, and to remedy the extreme media-by-media approach taken by our current laws. They will not promote the development of safer alternatives that avoid current legal exposures, and in fact will perpetuate and even encourage those exposures.

5. Limited Lists of Chemicals of Concern and Priority Products. The Revised Regulations ensure that far fewer chemicals and products will be brought under regulatory scrutiny.

With respect to chemicals, the Revised Regulations have eliminated the lists of Chemicals Under Consideration and Priority Chemicals, and now require DTSC to prepare only a list of Chemicals of Concern. This process now requires DTSC to conduct a data intensive, burdensome prioritization process to identify a chemical as a Chemical of Concern.²¹ DTSC must now formally assess and compare the relative threats of chemicals across a wide variety of considerations including numerous physical properties and threats to human health and the environment, exposure potential from consumer products and coverage by other laws and regulations. Once chemicals are prioritized according to each of these three criteria in turn, DTSC then must limit the number of Chemicals in Concern in accord with resources it has available to evaluate products containing them. DTSC has one year to complete its initial list of Chemicals of Concern, including public workshops and opportunities for comment, with no obligation ever to supplement that list.²²

With respect to products, the Revised Regulations have eliminated the list of Products Under Consideration, and now require DTSC to prepare only a list of Priority Products. Once Chemicals of Concern are prioritized according to the process described above, this additional process now requires DTSC to conduct a data intensive, burdensome prioritization process before identifying a class of products as a Priority Product.²³ DTSC must now formally assess and compare the relative threats of different products taking into account the attributes of the relevant chemical of concern within each potential Priority Product, evaluate extensive commercial and use information and then consider

²⁰ SB 509, HSC § 25257.1.

²¹ § 69302.3.

²² § 69302.2.

²³ § 69303.3.

any effect of other laws and regulations. Once products are prioritized according to these criteria, DTSC then must limit the number of Priority Products in accord with the resources it has available to evaluate AA Work Plans and AA Reports and to develop regulatory responses for the products. DTSC has one year to complete its initial list of Priority Products, including public workshops and opportunities for comment, with no obligation ever to supplement that list.²⁴

The data and analytical requirements and burdens of proof placed on DTSC by these two prioritization processes are extensive. They transform the Proposed Regulation's list of properties that could justify designation of a chemical of concern or product of concern into a list of properties that must now all be formally compared chemical-by-chemical and product-by-product in two separate, successive complex prioritization processes. It requires information about the extent of use of individual chemicals and products in the State that often does not exist and that DTSC must try to obtain and compile from diverse manufacturers. It requires DTSC to eliminate from consideration any exposure pathway of a chemical already "addressed" by another law. The use of confidential information will be necessary in both prioritization processes, which will undermine oversight by the public and market. The results of the prioritization processes, which involve many difficult judgments, can be and very likely will be legally challenged. Moreover, the allocation of such large burdens to DTSC provides incentives for industry to work to reduce rather than increase DTSC resources so as to limit the impact of the regulation.

This new process virtually ensures that a very limited number of chemicals will ever be designated as Chemicals of Concern or products as Priority Products. It is a far cry from the intent of AB 1879 and the Proposed Regulations to bring a substantial number of chemicals and products containing them under scrutiny so as to prompt the comprehensive development of a safer chemicals industry.

6. Unreviewable Chemical Substitutions, Including Regrettable Substitutions, Will Result. Manufacturers may avoid the Revised Regulations by removing from their Priority Products any Chemical of Concern, including by replacing it with a known toxic chemical or an unstudied chemical. No notice to DTSC or the public, or any analysis or demonstration of safety of the substitute, is required. The Proposed Regulations contained some efforts to control this problem of potential regrettable substitutions, but those are for the most part now completely eliminated.

Once a Priority Product is put on the final list, the Revised Regulations do require manufacturers to perform an alternatives analysis if they remove a Chemical of Concern from a Priority Product and this results in the addition of a chemical or increase in amount of a chemical.²⁵ But even this requirement, which only attaches once a Priority Product is finally listed, can be entirely evaded if the manufacturer simply removes the original Priority Product from the market and then introduces a new ("Improved!")

²⁴ § 69303.2.

²⁵ § 69303.2(d).

product that does not contain a Chemical of Concern and that is therefore not a Priority Product subject to regulatory requirements.²⁶

Unfortunately, the Revised Regulations are very unlikely to accomplish more than uncontrolled elimination from Priority Products of the few Chemicals of Concern that DTSC will be able to list, which will inevitably sometimes involve regrettable substitutions that society will have no immediate knowledge of.

7. Elimination of Tiers of Alternatives Assessments. The Revised Regulations eliminate the all but one tier of alternatives assessments, and are now limited to a single alternatives assessment process. While this simplifies the regulations, it also eliminates the capacity of the program to result in relatively quick action to substitute or regulate known hazardous chemicals. The need to do this has been highlighted by CHANGE and numerous members of the Green Ribbon Science Panel. The elimination of the additional tiers of alternatives assessments adds to the inability of the Revised Regulations ever to address more than a short list of Chemicals of Concern and Priority Products.

8. “Third-Party Verifier” Renders Oversight Ineffective. The Revised Regulations essentially eliminate the oversight provisions of the Proposed Regulations, which were essential given the limited capacity of DTSC and the lack of transparency created by confidentiality of information. The program for qualifying, accrediting, and monitoring the performance of those who would perform alternatives assessments has been completely eliminated.²⁷ The Revised Regulations do retain a “third-party verifier” and provisions to prevent financial conflicts, but this unaccredited entity is intended simply to verify compliance with the formal requirements for alternatives assessments and does not perform a detailed substantive review.²⁸ The loss of the accreditation program, along with the training that that would entail, will slow the development of quality reliable alternatives assessors, a capacity that implementation of the California Green Chemistry Initiative desperately needs.

Under the Revised Regulations, DTSC is now the only possible substantive reviewer of industry-produced AA Work Plans and AA Reports, and it must issue a notice of deficiency or completeness within 60 days.²⁹ One hopes that DTSC would be able to provide a substantive review of these documents and reject them where appropriate, but this may not be so. DTSC’s authority under the Revised Regulations is framed in terms of reviewing for “compliance” and providing notices of “deficiency” or “completeness,”³⁰ terms that often denote an administrative rather than substantive review.

DTSC’s lack of resources now and in the foreseeable future to perform this oversight task on any kind of significant scale by itself ensures the limited scope of this program.

²⁶ § 69301.3(b).

²⁷ § 69305.1; see elimination in its entirety of former Article 8 of Proposed Regulations.

²⁸ § 69305.1(c).

²⁹ § 69305.5.

³⁰ § 69305.2(b); § 69305.5.

Moreover, the combination of DTSC's lack of resources with the lack of transparency resulting from the confidentiality of information ensure that there is little prospect of any real oversight of, or any reasonable public confidence in, any conclusions to be drawn from the alternatives analyses performed under the Revised Regulations.

9. De Minimis Loophole Is Widened. The Revised Regulations widen and make it much easier for manufacturers to obtain the *de minimis* exemption, which permits Chemicals of Concern to remain as components of Priority Products without an alternatives analysis or any regulatory response.

The *de minimis* exemption level is now set at the lower of 0.1% by weight or a California hazardous waste regulatory threshold if there happens to be such a standard for a particular Chemical of Concern.³¹ The Revised Regulations have eliminated numerous controls on the availability of the *de minimis* exemption,³² including provisions permitting DTSC to find that even *de minimis* concentrations of a Chemical of Concern present a threat to human health and the environment.³³ Moreover, the *de minimis* exemption is now triggered automatically when manufacturers file a De Minimis Exemption Notification – it no longer must be approved by DTSC.³⁴

CHANGE, numerous members of the Green Ribbon Science Panel and concerned scientists have all formally stressed the need to eliminate or at least constrain this exemption. One reason for their concern is the public health and environmental reality that some chemicals exhibit adverse effects at very small exposures, particularly in view of the reality of cumulative impacts. Another is that such a provision invites industry to respond to the quest for safer alternatives by instead reformulating their products so as to contain less than the regulatory *de minimis* levels of Chemicals of Concern, and so escape the regulation.

The broad loophole that the Revised Regulations opt for would virtually guarantee that some Priority Products would continue to contain Chemicals of Concern even once the Revised Regulation was fully implemented. While we agree with the need to prioritize efforts to find safer alternatives, we believe that once Priority Products are identified, industry should attempt to develop safer alternatives to the relevant Chemicals of Concern. But such development is only impeded by the existence of a broad, unscrutinized *de minimis* regulatory safe harbor.

10. Nanomaterials Are Exempted. Nanomaterials are completely exempted from the Revised Regulations.³⁵ This exemption cannot reasonably be grounded in any conclusion that nanomaterials are either comprehensively regulated by other laws or that they are unlikely to present a threat to public health or the environment. This exemption is

³¹ § 69301.1(a)(26).

³² Compare Revised Regulations § 69301.1(a)(26) with Proposed Regulations § 69301.2(a)(24).

³³ Provisions eliminated from § 69303.2; Proposed Regulations § 69305.3 eliminated.

³⁴ § 69303.2(d)(3)(A)-(D); Proposed Regulations § 69305.3 eliminated.

³⁵ § 69301.1(a)(12), (13), (16), (19); see also elimination of § 69301.2(a)(50) of Proposed Regulations.

particularly unwarranted since nanomaterials are known to be components of at least some products within the three product categories DTSC must limit its consideration to until 2016: (A) children's products (B) personal care products and (C) household cleaning products.

It is hard to see this exemption as grounded in any factor other than extreme special interest politics.

11. Guiding principles removed. One further, perhaps symbolic, revision is worthy of note here. The Proposed Regulations contained a section articulating the principles intended to guide interpretation of the regulations as they were implemented.³⁶ These guiding principles were rooted in the importance of promoting green chemistry and of reducing or eliminating adverse impacts on human health and the environment through redesign of consumer products and manufacturing.

Removal of these guiding principles from the Revised Regulations weakens how they will be interpreted and implemented by DTSC, by manufacturers and eventually by the courts.

But, sadly, it also reflects the unfortunate turn that the regulatory development process has taken.

Conclusion

Very substantial restructuring has transformed the Proposed Regulations into a form that we can no longer support. Unfortunately, we have concluded that the state of California, the public health, the environment and the business community would all be better served if the Revised Regulations were not implemented at all by DTSC.

Moreover, the process by which the Revised Regulations were promulgated violates Government Code § 11346.8 and renders them invalid.

Accordingly, we oppose promulgation of the Revised Regulations and urge DTSC to withdraw them in their entirety on both substantive and procedural grounds. At the very least, because it has deprived the public, including us, of a full opportunity to comment, DTSC should establish a 45-day comment period including a workshop.

If you have any questions, please contact Ansje Miller at 510-655-3900, x315.

Thank you for your consideration of our concerns,

³⁶ Proposed Regulations § 69301.1 has been eliminated.

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