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Toxics in Consumer Products: California's Green Chemistry Regulations at a Crossroad

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Sustainable Technology & Policy Program
stpp

Introduction Americans are awash in chemicals—in our workplaces, our homes and our communities. Approximately 27 trillion pounds of chemicals are produced or imported into the United States every year, more than one trillion of them in California alone.[1] More than 6,000 different chemicals are produced in volumes exceeding 25,000 lbs annually, with more than one third of those used in consumer or commercial products such as paints, household cleaners, electronics, toys and clothing.[2] Many of those chemicals have been detected in the environment and in the bodies of men, women and children. The Centers for Disease Control and Prevention's biomonitoring program, which collects and analyzes the blood and urine of a nationally representative sample of the civilian U.S. population every two years, has detected hundreds of man-made chemicals in those samples.[3] Likewise, there is widespread contamination of breast milk, including chemicals such as polychlorinated biphenyls (PCBs), DDT and its metabolites, dioxins, dibenzofurans, polybrominated diphenyl ethers (PBDEs), and heavy metals.[4]

Regulatory action regarding chemical use and exposure at the federal level has been notoriously slow and ineffective. Congress addressed the regulation of chemicals as chemicals with the passage of the federal Toxic Substances Control Act (TSCA) in 1976.[5] Some thirty-five years later, the strong consensus among policymakers, academics, environmental groups, and even industry is that TSCA is a failure. The well-documented flaws of the federal program include the weak authority EPA possesses for testing and review of new and existing chemicals, the onerous administrative and substantive hurdles the agency must clear in order to regulate, and the limited funding provided for implementation of the program.[6] These and other problems have functionally frozen the TSCA program; for example, since 1976 EPA has taken comprehensive regulatory action regarding existing chemicals in only five instances.[7] Yet despite repeated reform efforts in Congress, the statute remains unchanged.[8]

In the face of relative inaction at the federal level, state governments have moved to address hazardous chemical use. Over the last ten years, at least eighteen states have passed laws banning or restricting the use of specific chemicals in consumer products such as bisphenol A (BPA), lead, cadmium, toxic flame retardants, and phthalates.[9] Four states in particular—California, Maine, Minnesota, and Washington—went beyond piecemeal chemical-by-chemical regulation to also adopt new, more comprehensive chemical regulation programs.[10] (Table 1 compares key components of the four state programs.) This brief evaluates the California legislation, identifying four critical flaws that threaten to undermine its success and providing a set of recommended revisions.

The recommendations include:

- Add provisions for the review of new chemicals and new uses of existing chemicals before their introduction into commerce;
- Require consumer product manufacturers and other relevant parties to provide regulators with necessary data regarding the chemicals used in consumer products;
- Clarify the statute's focus on prevention rather than management of toxic chemicals by incorporating an express preference for the adoption of safer alternative products; and
- Authorize a regulatory fee program to provide adequate resources for implementation of the legislation.

I. Overview of the California Program

Of the handful of comprehensive state programs recently enacted, California's 2008 legislation was the boldest, enacting a prevention-based regulation applicable to all consumer products. It is prevention-based in that it focuses on the identification and adoption of safer alternatives to hazardous chemicals in consumer products. The basic concept underlying the statute is straightforward: manufacturers of commercial and consumer products ought to design safety into those products. In doing so, however, they should avoid "regrettable substitution," the replacement of one hazardous chemical with another presenting similar or even worse hazards. *Alternatives analysis*—the identification, assessment and comparative evaluation of alternatives to hazardous chemicals—is the centerpiece this new comprehensive regulatory program. Alter-

Table 1 | Comparing Broad-Based State Programs

	California AB 1879	Maine Toxic Chemicals in Children's Products	Minnesota Toxic Free Kids Act	Washington Children's Safe Products Act
Year Enacted	2008	2008	2009	2008
Applicability	Consumer products	Children's products	Children's products	Children's products
Chemical Identification and Prioritization	✓	✓	✓	✓
Data Submission	✓	✓		✓
Testing				
Alternatives Analysis	✓	✓		
Intervention	✓	✓		
Resources		✓		

Table 2 | Key Components of California's Program

Section 25252(a)	"[E]stablish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern…"
Section 25253(a)	"[E]stablish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern…"
Section 25253(b)	"[S]pecify the range of regulatory responses that the department may take following the completion of the alternatives analysis…"

natives analysis can provide a transparent, rigorous methodology for identifying safer substitutes and avoiding regrettable substitution. While several other states also require businesses to engage in alternatives analysis in limited circumstances,[11] California is unique in that it systematically links the the results of those alternatives analyses to mandatory regulatory responses.

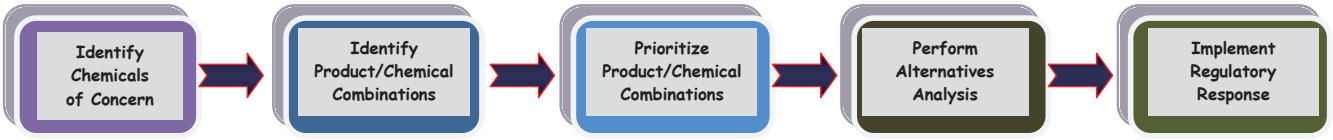
California's program springs from Assembly Bill 1879 and Senate Bill 509 (collectively AB 1879). These bills direct the Department of Toxic Substances Control (DTSC) to craft regulations implementing a comprehensive chemicals program.[12] That program consists of the three steps depicted in Table 2: identifying and prioritizing the chemicals of greatest concern in consumer products; performing alternative analyses which compare health, environmental and economic trade-offs of those product/chemical combinations with potentially safer alternatives; and selecting regulatory responses ranging from outright bans to no action at all and everything in between.

Although the precise contours of the program are still under development as DTSC continues to work on the implementing regulations, DTSC has informally announced a basic framework in an informal set of draft regulations.[13] (The framework is depicted in Figure 1.) At present, DTSC first intends to streamline the identification of chemicals of concern by relying upon existing lists of chemicals developed by authoritative organizations such as domestic and international

What is alternatives analysis?

Alternatives analysis is a scientific method for identifying, comparing and evaluating competing courses of action. In the case of chemical regulation, it is used to determine the relative safety and viability of potential substitutes for existing products or processes that use hazardous chemicals. For example, a business manufacturing nail polish containing formaldehyde as a resin would compare its product to alternative formulations using other resins. Alternatives may include drop-in chemical substitutes, material substitutes, changes to manufacturing operations, and changes to component/product design. The methodology compares the alternatives to the regulated product and to one another across a variety of attributes, typically including public health impacts, environmental effects, technical performance and economic impacts on the manufacturer and the consumer. It can identify trade-offs between the alternatives and, if desired, generate an evaluation of the relative overall performance of the original product and its alternatives.

Figure 1 | Framework for Regulation under AB 1879



government agencies and scientific bodies. Those lists, some of which are described in Table 3, name approximately 3000 unique chemicals or chemical compounds.

Next, the agency will identify consumer products that contain any of those 3000 chemicals. By way of example only, such product/chemical combinations could include such items as nail polish containing formaldehyde, or shampoo with a phthalate ingredient. DTSC will then prioritize the resulting product/chemical combinations for further review based upon a set of prioritization criteria concerning hazard, likelihood of exposure, and availability of alternatives. Over time, and presumably in accordance with the product/chemical combination rankings derived from the prioritization process, DTSC will require product/chemical manufacturers to complete alternative analyses for their respective consumer products. Finally, based upon the alternative analyses, the agency will develop regulatory responses.

The framework described above is only an informal proposal at this point. DTSC plans to issue a formal proposed set of regulations in February 2012. Regardless of the ultimate content of those regulations, however, the program faces substantial challenges stemming from limitations of the underlying statute. Despite the innovative nature of AB 1879 and the high hopes that it has engendered, the deficiencies of AB 1879 are strikingly similar to those of the federal TSCA program. This brief focuses on four central common aspects of TSCA and AB 1879: pre-market review of chemicals; testing and

Table 3 | Examples of Chemical of Concern Source Lists

SOURCE	TYPES OF HAZARDS COVERED
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)	• Carcinogenicity • Reproductive Toxicity • Developmental Toxicity
Canadian Environmental Protection Act Environmental Registry's Persistent, Bioaccumulative, and Inherently Toxic to the Environment	• Bioaccumulation • Persistence
US EPA Toxics Release Inventory Persistent, Bioaccumulative and Toxic Chemicals	• Bioaccumulation • Persistence • Various Toxicological Hazard Traits
Category A and B Carcinogens, Report on Carcinogens, US Department of Health and Human Services National Toxicology Program	• Carcinogenicity
International Agency for Research on Cancer (IARC), Groups 1, 2A, and 2B carcinogens	• Carcinogenicity
Priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act	• Various Toxicological Hazard Traits • Various Environmental Hazard Traits • Various Exposure Potential Hazard Traits

data collection; regulatory intervention; and funding. In each of these areas, AB 1879 is as flawed as, and in some instances even more flawed than, TSCA. This brief offers recommendations concerning each of these deficiencies, some of which can be implemented through regulation, but most of which will require legislative action.

II. AB 1879 Lacks Mechanisms for Pre-Market Review

In pre-market review, the manufacturer must obtain some type of government approval or acquiescence prior to introducing a new chemical into commerce, and prior to putting an existing chemical to a new use. Many Americans mistakenly assume that the chemicals in the products they use have been carefully reviewed and affirmatively approved by some government agency. In fact, federal law has minimal pre-market review for most chemicals. By some estimates as few as 500 of the thousands of chemicals in commerce have been closely evaluated for health effects by EPA and other agencies.[14] As written, AB 1879 lacks any pre-market review.

A. Pre-Market Review under Federal Law

TSCA incorporates a very weak pre-market review scheme. A company may not manufacture or import a new chemical unless it has submitted a pre-manufacture notice (PMN) to EPA at least ninety days before manufacturing or importing begins. TSCA also requires a PMN where an existing chemical is put to a significant new use.[15] The PMN must include basic information such as chemical identity, uses, exposure routes, and existing health and safety data. If EPA determines during that ninety day period that the chemical presents an unreasonable risk of injury to health or the environment, the agency must take regulatory action to address the risk. Absent affirmative action by the agency, the manufacturer is free to begin production or import after the ninety day period expires.[16]

TSCA has garnered substantial criticism regarding the effectiveness of the screening, testing and ultimate regulation of new chemicals.[17] The short ninety day review period essentially places EPA staff in a race against time in making often complex assessments. PMNs typically provide little information to support reasoned risk regulation: 67% of PMNs include no test data of any kind and 85% include no health data.[18] For the more than 36,000 PMN reviews it performed between 1979 and 2006, EPA took regulatory action in only approximately 2,000 cases.[19]

B. Pre-Market Review in California

Critics of TSCA's pre-market review mechanism will find little solace in California's AB 1879. On its face, AB 1879 provides ***no*** systematic pre-market review process for new chemicals. Indeed, it lacks even a minimal pre-market notification requirement as is found in TSCA. Before a chemical can be regulated, DTSC must identify it as a "chemical of concern," prioritize it for regulatory evaluation, and complete an extensive alternatives analysis. At least as written, the statute seems to allow unrestricted introduction of new chemicals into commerce, subject to later review and perhaps regulation by DTSC after completion of comprehensive identification, prioritization and evaluation processes.

In the case of California's nascent chemicals program, even minimal pre-market review such as that provided under TSCA could serve two important roles. First, it could minimize the likelihood of "regrettable substitution" resulting from strategic responses to the identification of chemicals of concern. Consider the manufacturer of a household cleaner containing Chemical A, a suspected reproductive toxin. If Chemical A is named as a chemical of concern in the first step of AB 1879 implementation, the manufacturer may attempt to avoid AB 1879 applicability by promptly switching to Chemical X, an alternative chemical not identified as a chemical of concern. Now if Chemical X is benign, the goals of AB 1879 have been achieved—the market will have moved to a safer alternative. But if Chemical X is itself hazardous, or is of unknown toxicity, AB 1879 has been subverted by a regrettable substitution. Pre-market review, even of the limited form built into TSCA, would provide the agency with information and authority to deflect regrettable substitution.

Second and more broadly, pre-market review could prevent new, potentially harmful chemicals from causing harm before regulators can "catch up" to them. New chemicals and consumer products are constantly entering the marketplace, but scientific studies of their toxicity and exposure pathways typically lag years or even decades behind. Moreover, once in commerce, new chemicals and products often gain market, economic and political footholds that complicate public health policy decision-making. One need only consider the rapid proliferation of new technologies such as cellular telephones for an example of this phenomenon. As a practical matter, once embedded in the marketplace, chemicals in consumer products enjoy an advantage simply by already being in use. The performance and economic value of such chemicals are well-established. Simply put, they work. Consequently consumers are used to the product's formulation, and manufacturers and retailers have strong economic incentives to defend their continued usage.

C. Recommendations for Pre-Market Review

Although it fails to establish explicit pre-market review, AB 1879's language does afford DTSC substantial discretion in crafting chemical identification and prioritization procedures. Creative use of that discretion could provide some focus on new chemicals and existing chemicals put to new uses. In particular, the statute sets out skeletal requirements for the identification and prioritization process, mandating only that the process include a multimedia life cycle evaluation[20] and that it consider the chemical's volume, extent of exposure and effect on sensitive subpopulations.[21] One could imagine an identification and prioritization process in which *all new uses* of chemicals in consumer products—or at least new chemicals or chemical uses meeting certain threshold criteria relating to volume of production, exposure potential, or structural features—were subject to some form of review as product/chemical combinations. This would at least expedite the initiation of substantive review of new chemicals.

However, even assuming that DTSC successfully adopts some form of limited default review for new chemicals, the statute is still deficient. "Review" is only half of "pre-market review"; the other half is the prohibition against distribution or use of a chemical prior to completion of that review. Here AB 1879 falls far short of even TSCA. As currently structured, the law withholds the authority to restrict the distribution or use of a chemical of concern until *after* the chemical and its potential alternatives are evaluated in an alternatives analysis. In other words, a manufacturer is free to introduce its new chemical into commerce without restriction under AB 1879, without even the minimal 90 day waiting period called for under TSCA.

This particular deficiency calls for a legislative resolution. AB 1879 should be amended to provide for the development and implementation of a systematic pre-market review mechanism. The mechanism would operate in tandem with the process for review of existing chemicals. Initially, the mechanism will likely have to utilize a screening approach in which some new chemical uses undergo more extensive testing than others, or some other type of phased approach. As a practical matter, the pre-market review will evolve as new toxicological testing approaches, such as high throughput assays, are developed and validated.[22] Such methods are expected to significantly reduce the delay and expense associated with conventional toxicological testing.[23]

III. Information Generation and Submission Authorities under AB 1879 are Inadequate

Without doubt, reliable information regarding a chemical's identity and uses, hazards, and likely exposure routes is central to effective policy formulation and implementation. Production of such information entails two essential, related functions.

First, the relevant information must be created or collected, typically but not exclusively by the chemical or product manufacturer. Take the case of the potential impacts of phthalates or other potentially hazardous chemicals in perfumes or other

personal care products. Regulation of such products requires information regarding the identity and uses to which the chemicals are put in those products, their potential toxic effects, and the nature and amount of human and environmental exposures occurring in the production, use and disposal of the product and chemical. Such information may not be readily available to any single entity in the supply chain. Indeed, data regarding health effects may not be available at all and thus must be generated through toxicity testing of some sort.

Second, the information must be made available to the decision-maker—in this case DTSC. TSCA contains elaborate mechanisms for both at the federal level, although those mechanisms have been roundly criticized as slow and largely ineffective. However, as flawed as TSCA's information generation and submission authorities may be, they are far superior to those available to DTSC under California law.

A. Generation and Collection under TSCA

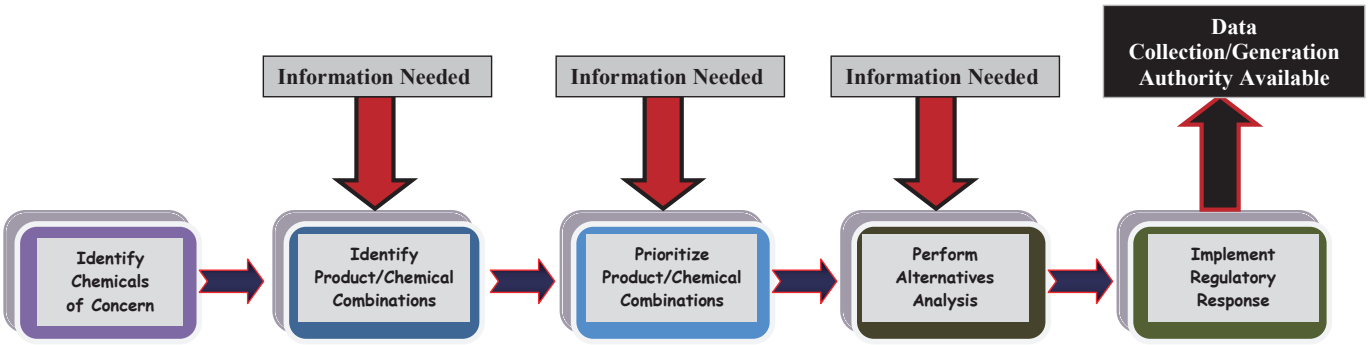
Consider the generation of information. Suppose that a manufacturer intends to market a new chemical, and thus must first submit a PMN to the agency. Under TSCA, the manufacturer need only include information regarding the chemical's identity, and intended uses, hazards and likely exposures that are known to the manufacturer or reasonably ascertainable. Thus, the manufacturer must pull together reasonably available information regarding its expected production volume and uses, and likely worker exposure scenarios, but need not contact customers to determine uses and possible worker exposures, nor perform screening or testing of the chemical for toxicity or other hazards.[24] Now consider the case of an existing chemical; that is, one that is already listed on the TSCA Inventory of Chemical Substances. Here again, the manufacturer is under no obligation to initiate toxicity testing or other hazard evaluation absent a specific agency directive.

Recognizing that adequate toxicity and hazard information would be lacking for many chemicals, TSCA does empower EPA to require testing by manufacturers. Under Section 4, if there is insufficient data and experience to evaluate a chemical's effects, EPA can mandate testing for a chemical in two circumstances. The first is if the chemical may present an unreasonable risk of injury to health or the environment. The second is if there may be substantial human exposure or environmental releases of the chemical. EPA, however, has compelled testing of relatively few chemicals under TSCA. The process is resource-intensive—it requires EPA to generate substantial evidence to meet

Table 4 | TSCA Information Submission Mechanisms

		Regulatory Mechanism				
		PMN	PAIR	HaSDR	CDR	Sec. 8(e)
Information Type	Chemical Identity	✓			✓	
	Chemical Uses	✓			✓	
	Hazard Information	✓		✓		✓
	Exposure Information	✓	✓		✓	

Figure 2 | Information Needs for AB 1879 Process



and withstand judicial scrutiny. Accordingly, the process is both slow and expensive, taking somewhere between two and ten years to complete.[25] EPA has instead relied largely on informal testing agreements to gather toxicity information from chemical manufacturers.[26]

Even absent any significant automatic obligation to *collect or generate* fresh information, manufacturers of new chemicals and many existing chemicals alike do face a significant tangle of requirements concerning *submission* of existing information in TSCA, as set out in Table 4. For chemicals just entering commerce, the PMN is the initial trigger.[27] For certain chemicals already in commerce (and those that complete the PMN process),[28] the information reporting provisions of the Preliminary Assessment Information Rule (PAIR), the Health and Safety Data Reporting rule (HaSDR), and the Chemical Data Reporting (CDR) rule set the standard.[29] Section 8(e) of the statute layers on yet another reporting obligation, requiring manufactures to notify the agency of information that reasonably supports the conclusion that their product presents a substantial risk of injury to health or the environment.

B. Data Generation/Submission Authorities under California Law

DTSC will need substantial amounts of information at each step of AB 1879 implementation. Figure 2 illustrates each of those points along the process. After DTSC identifies the 3000 or so chemicals of concern, it will have to identify consumer products in California in which those chemicals are found. Such an undertaking will require the collection of a tremendous amount of data from a large number of manufacturers, importers, retailers and other parties.

The administrative challenges here are substantial. For example, for many consumer products, the manufacturer of the consumer product may not know the identity of the chemicals within its products, and may have limited ability to obtain that information from out-of-state or foreign distributors or suppliers—entities that may be located one or more levels up the supply chain. Yet the statute provides no explicit authority for DTSC for this potentially massive undertaking.

Next, having identified product/chemical combinations containing chemicals of concern, DTSC will engage in a prioritization process that requires additional data regarding the products, including the hazards, the nature, quantity and duration of exposures during each product's entire life cycle, and the availability of alternatives. Here again, the information—to the extent it exists at all—could be dispersed across a wide range of companies, individuals and agencies within and beyond California. Once again, DTSC has no explicit authority to require regulated parties to generate, collect or submit such information. Lastly, to meaningfully review the alternatives analyses submitted to it, DTSC will likewise need additional information concerning the health and environmental effects, economic impacts and technical performance of potential alternatives.

To be fair, DTSC does have some limited data generation and submission authority within AB 1879 and under other legislation, most notably AB 289. Under AB 1879, one of the specifically identified regulatory responses is the imposition of "requirements to provide additional information needed to assess a chemical of concern and its potential alternatives."[30] However, as Figure 2 demonstrates, this authority is only available *after* the alternatives analysis for that product/chemical combination is complete. Thus, it is of little use to DTSC as it seeks to identify, prioritize and evaluate product/chemical combinations.

The second source of information authority lies outside of AB 1879, in Section 57018 of the Health and Safety Code (generally referred to as AB 289). That section establishes an elaborate administrative process by which regulators can obtain information regarding a chemical from its manufacturer. The reach of AB 289 is somewhat limited. It only applies to entities that manufacture or import chemicals in California, and thus does not appear to reach most consumer product manufacturers or distributors.

The scope of data covered by AB 289 is likewise limited; the law focuses upon analytical detection methods and "other information" on the fate and transport of the chemical in the environment.[31] These categories are narrow. An analytical detection method is a testing procedure used to identify the presence and concentration of a chemical in a medium such as air or groundwater.[32] Fate refers to where a chemical ends up when released into the environment, and transport refers how it gets there.[33] Neither analytical testing methods nor fate and transport appear to cover the generation and submission of toxicity testing data or other health and safety information. This conclusion is supported by the scant legislative history of AB 289; staff analysis repeatedly emphasized the need to secure reliable methods for detecting chemicals in environmental media and humans rather than health and safety testing.[34] Indeed, proponents of the law specifically noted the difference between the federal high production volume program (which included toxicity testing) and AB 289 (which did not).[35]

In its informal draft regulations for AB 1879, DTSC incorporates a creative, elegant approach to encourage *voluntary* submission of information by consumer product and chemical manufacturers, importers and retailers. Section 69501.5 of the draft regulations provides that DTSC shall seek necessary information by requesting it from those entities. Should a company refuse DTSC's request, the agency is required to identify the recalcitrant party in a "Failure to Respond List" on the agency's website. This "shaming" approach is clearly designed to pressure companies to provide information voluntarily, or face the potential negative reputational impact of being branded uncooperative. However, while protection of reputation clearly plays some role in business behavior, the strength of the influence is uncertain and very contextual.[36]

C. Recommendations regarding Data Generation and Submission

With respect to information submission requirements, DTSC should adopt a broad interpretation of the language in AB 289. In particular, because the statute explicitly covers information regarding "fate and transport," it appears that data regarding the commercial distribution, uses and management practices is ostensibly within AB 289's reach. Such information is essential to understanding the manner in which the relevant chemicals may enter the environment. DTSC has exercised such authority to some extent already in its call-in regarding carbon nanotubes.[37] Assertion of that authority over health and safety testing is substantially more problematic, for the reasons discussed above. Thus, the limited reach of AB 289 to chemical manufacturers and importers requires expansion through legislative action.

At the legislative level, revisions to AB 1879, AB 289, or both will be needed to provide DTSC with clear, adequate authority to require that manufacturers, importers and retailers of consumer products containing chemicals of concern (1) register with DTSC and (2) submit information required for AB 1879 implementation, including data regarding composition, distribution and use of the consumer products and existing health and safety data regarding the products and chemicals they contain. The

revision should address the issue of data that is not in the possession or control of the chemical manufacturer by extending to all entities and individuals having relevant information (i.e., use and exposure information held by distributors or commercial end users). Legislation should also provide DTSC with express authority to require health and safety testing. Alternatively, or as a supplement, the statute could provide for a government testing program, perhaps akin to the activities of the National Toxicology Program at the federal level.[38] Such a program would require significant funding, whether implemented in-house or through a grant program.

IV. Incorporating a Preventative Approach into Regulatory Intervention

TSCA was designed to balance two primary concerns: public health and national economic health.[39] In a variety of places and through sundry mechanisms, the statute tempers the pursuit of health and safety with an eye towards protecting the economic status quo. The protection of entrenched economic interests played at least some role or, in some views, *the* major role in hindering effective chemical regulation in the United States. As we shall see, TSCA adopts a very conventional approach to regulating hazardous chemicals; it essentially allows their continued use subject to use restrictions, work practice standards and other exposure controls.

Through its emphasis on alternatives analysis, AB 1879 signals the adoption instead of a preventative approach focused on forcing the creation and adoption of safer alternatives. On closer examination, however, AB 1879 incorporates some of the same limitations on regulation found in TSCA, particularly when one considers the impact of generally applicable administrative requirements found in California law.

A. Regulatory Intervention under TSCA

Section 6 of TSCA grants EPA a fairly wide spectrum of policy tools for dealing with a chemical found to present an unreasonable risk[41] of injury to health or the environment. These tools include banning the chemical for a particular use, limiting the manner in which it is used, and imposing labeling or notice requirements. EPA must jump several hurdles before deploying this impressive range of tools under Section 6, hurdles that a succession of reports have cited as substantial barriers to effective regulation. One hurdle in particular—the obligation to use the least burdensome requirement—stands out.

In choosing the appropriate regulatory inter-

Prevention versus Management

Most public health regulation adopts the conventional risk management approach to the use of chemicals. With limited exceptions, risk management accepts the use of the hazardous chemical in a production process or in the resulting product as a given, and attempts to protect workers, consumers and the environment by reducing the resulting exposure to the chemical to acceptable levels. Sometimes those levels are based upon health concerns, but more often they are driven by considerations of the technical or practical feasibility of exposure controls and by how expensive the exposure controls will be. Take the example of a new pesticide intended for spraying on a farm field. Exposure controls might include requiring certain types of spraying equipment, mandating the use of respirators for workers, or creating buffer zones around the fields to protect adjacent homes or schools.

A prevention-based approach instead starts with the question of whether the toxic chemical ought to be used at all. Rather than setting safe exposure levels and requiring exposure controls, a prevention-based approach seeks safer alternatives to the chemical first, and relies upon exposure controls as a secondary level of protection. In the pesticide example, therefore, a prevention-based approach would only allow the use of the toxic pesticide if no safer, viable alternative was available. [40]

vention under TSCA Section 6, EPA must act "to the extent necessary to protect adequately against [the unreasonable risk] using the *least burdensome requirements*."[42] The first and last major rule-making under Section 6—the ban of asbestos in a range of applications—fell victim to this provision. In *Corrosion Proof Fittings v. EPA*, the 5th Circuit Court of Appeals invalidated the rule due in large part to EPA's failure to consider whether restrictions less draconian than a ban would provide adequate protection against the risks of asbestos. Along the way, the court concluded that the least burdensome requirement standard places a heavier burden on the agency "when it seeks a partial or total ban of a substance than when it merely seeks to regulate that product."[43] The opinion provided little guidance on how the burden can be met beyond a vague reference to consideration of the costs and benefits of regulation under each alternative.[44]

The least burdensome alternative standard raises dual concerns. By placing a heavier burden on the agency for rules adopting a ban, the *Corrosion Proof Fittings* court's interpretation creates a hierarchy among the regulatory options available to EPA, essentially encouraging restrictions on use rather than mandatory substitution with safer substitutes. Beyond that, the least burdensome alternative creates the means for regulated parties to delay regulatory actions and subsequent judicial challenges. For example, in the asbestos case, after having spent ten years developing a rule banning asbestos, EPA was instructed by the court to study the problem even further.

B. Regulatory Intervention under California Law

AB 1879 was intended to integrate principles of prevention into mainstream regulation, and create a preference for the adoption of safer alternatives.[45] Despite the references to alternatives analysis elsewhere in the statute, the operative language of AB 1879 is surprisingly conventional. The agency is directed to take action "to best limit exposure or to reduce the level of hazard posed by a chemical of concern."[46] This trigger for regulatory action does not incorporate the concept of replacing hazardous products with safer alternatives, instead focusing upon risk management strategies of reducing exposure and minimizing hazard. The statute is devoid of any suggestion that substitution of hazardous chemicals with safer alternatives is the preferred approach. Indeed, it is unclear what factors are relevant to identifying the "best" approach to limit exposure and reduce hazard. [47]

Additionally, other provisions of California administrative law expressly inject "least burdensome alternative" requirements into rulemaking under AB 1879. Under Section 57005 of the California Health and Safety Code, in setting a standard for a chemical of concern, DTSC must consider whether there is any *less costly alternative (or combination of alternatives) that would be equally as effective in achieving the statutory mandates*.[48] On its face, such a requirement appears reasonable, but the rub lies in implementation. For example, according to agency guidelines, "equally as effective" means that an alternative or combination of alternatives would "achieve at least the equivalent level of environmental protection consistent with the purpose of the proposed regulation and applicable statutory mandates. . . ." How that definition will be applied in comparing a ban of a toxic chemical with mandatory use restrictions or product labeling is unclear. In theory, both approaches may reduce exposure to equivalent levels, assuming that the use restrictions are conscientiously implemented, or the label warnings and directions understood and followed. In practice, implementation of use restrictions is highly variable, whether because of intentional noncompliance, negligence or confusion on the part of the responsible party.[49] Substitution of a hazardous chemical with a safer alternative can, to a large degree, avoid such concerns. As one pioneer of prevention in industrial hygiene observed, "What you don't have, can't leak."[50]

Section 57005's "less costly alternative" standard applies to major regulations, meaning those rules that will have an economic impact of greater than ten million dollars on the state's businesses. The California Administrative Procedure Act (CAPA) imposes its own alternatives requirements on all rulemaking. The notice of proposed

adoption of any regulation must include a statement that no reasonable alternative would be as effective as the proposed measure in carrying out the purpose of the statute and less burdensome to affected private persons.[51] Under other sections of that statute, the agency must describe its reasons for rejecting all reasonable alternatives, specifically including those alternatives that would lessen any adverse impact on small businesses.[52]

There is little agency guidance on the application of these various alternatives provisions, and even less case law. Consequently it is difficult to say whether Section 57005's "less costly alternative" mandate or CAPA's "less burdensome alternative" standard will be interpreted similarly to TSCA's "least burdensome requirement" standard. And there is some meaningful basis for treating these state law standards differently.[53] For example, the state law standards both incorporate the proviso that the alternative must be as effective as the proposed regulation. TSCA requires only that the alternative adequately protect against the risk; presumably under TSCA an adequate, less burdensome measure could trump an environmentally superior but more burdensome measure. Yet caution is warranted here—the term "equally as effective" and its administrative definition are rife with ambiguity.

C. Recommendations regarding Regulatory Intervention

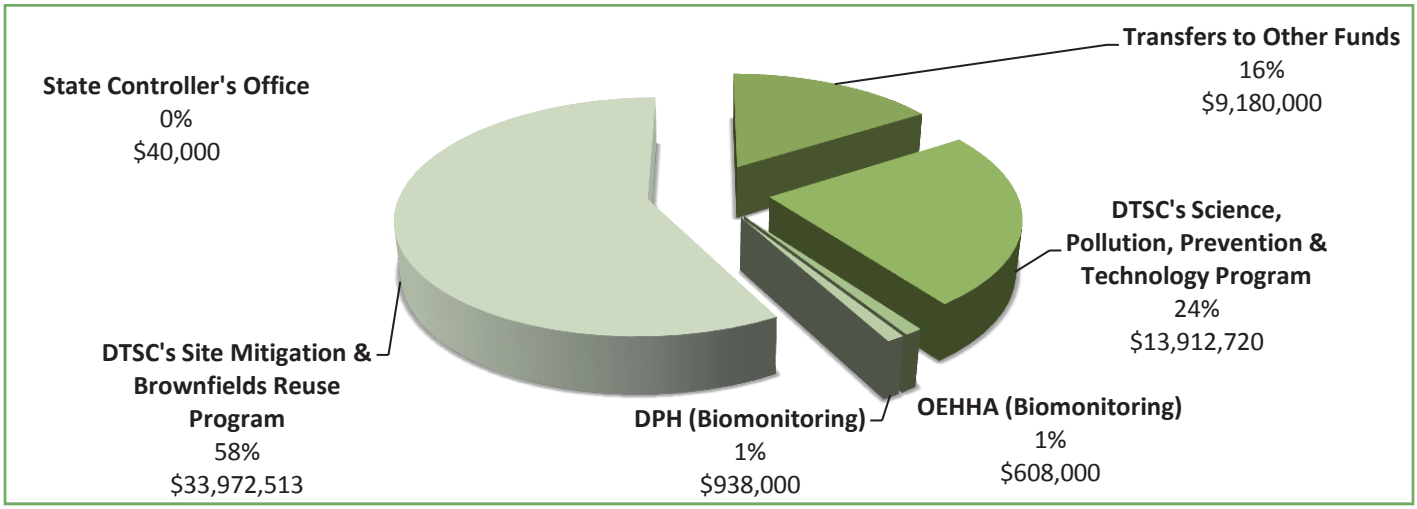
Section 25251.1(b) of AB 1879,[54] the existing trigger for regulatory action, does not incorporate an explicit prevention-based approach to chemicals in consumer products. Rather it provides for action needed "to best limit exposure or to reduce the level of hazard posed by a chemical of concern." The standard should be revised by the legislature to create an explicit preference for safer alternatives. For example, Section 25251.1(b) could be modified to provide that: "Such regulations shall ensure that in evaluating particular chemicals and potential alternatives, the department will implement regulatory responses designed to protect human health and the environment and to maximize the use of alternatives of least concern where such alternatives are commercially available and economically feasible."

With respect to the less costly/least burdensome alternative requirements embedded in the CAPA and the Health and Safety Code, two legislative modifications are needed. First, the CAPA and the Health and Safety Code should be amended to expressly confirm that availability of alternative regulatory requirements is only one factor to be considered by DTSC rather than a threshold to be cleared in issuing regulations. Second, the "equally as effective" language in Health and Safety Code Section 57005 (or its implementing regulations) should be revised to incorporate a rebuttable presumption that preventative measures will be more effective than risk management approaches such as use restrictions or product labeling.

V. Lack of Resources Endangers the Effectiveness of AB 1879

A regulatory program is only as robust as its funding source. Thus, even carefully crafted, protective statutes can be undercut by under-funding. In programs facing expensive procedural hurdles, the effect of under-funding is exacerbated. The story of the federal TSCA program is illustrative. Even as dollars and personnel flooded the federal Superfund program and Clean Air Act program in the 1990's, TSCA faced a resource drought. The program was underfunded and under-staffed, unable to keep pace with the challenges that faced it, particularly after the *Corrosion Proof Fittings* court further expanded the efforts required for EPA to regulate chemicals.[55] The lesson from TSCA is that you get what you pay for. Congress handed EPA the massive job of prioritizing, testing, evaluating and regulating thousands and thousands of chemicals. Yet neither the TSCA legislation nor the administrations that implemented it ever established adequate, stable funding. Not surprisingly, the federal program has languished.

Figure 3 | CA-TSCA 2009 - 2010 Expenditures [59]



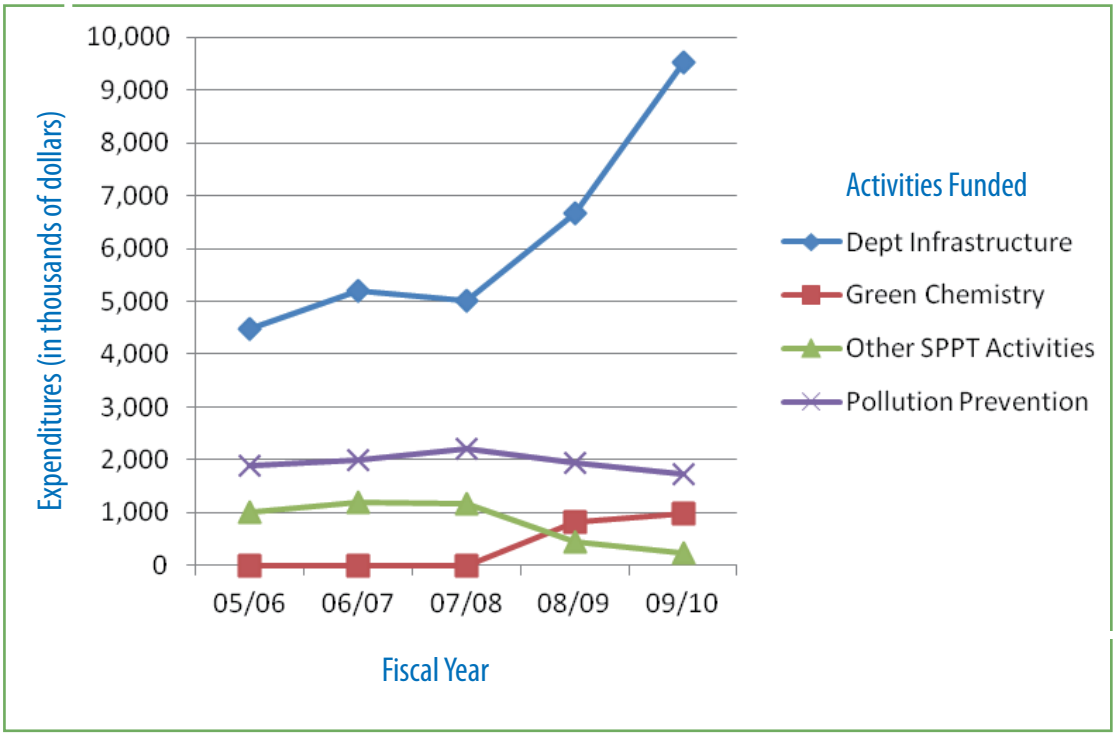
A. Lack of Adequate Resources Will Negatively Affect the Content and Implementation of the AB 1879 Regulations

AB 1879 faces a fate similar to TSCA. Like TSCA, AB 1879 presents the implementing agency with a challenge of heroic proportions but no additional resources. Each step of the AB 1879 process calls for substantial agency effort, from identifying and prioritizing product/chemical combinations, to reviewing alternatives analyses, to selecting regulatory responses. And each of these efforts involves developing and refining new methodologies and regulatory approaches. Take just the task of identifying those product/chemical combinations sold in California that contain chemicals of concern. There is no central registry of such information, no comprehensive scientific literature or databases available. The agency will have to comb a multitude of on-line sources, and collect, review and synthesize information submitted by companies (assuming regulated entities voluntarily submit such data).[56] By way of example, based upon the experience of a research team involved in the identification and prioritization of chemical uses under Canada's chemicals program, simply identifying product/chemical combinations for 3000 chemicals through on-line sources would take between 500 to 750 person/days.[57]

The Senate Environment Committee analysis of the AB 1879 recognized the resource issue in 2008, observing, "While the resources necessary for initiating AB 1879 until January 1, 2011 appear modest, if the state is to provide the necessary wherewithal to provide a genuinely comprehensive program, it is probably inescapable that future legislation needs to more fully consider a fee-based program."[58] The Committee's analysis has proven accurate. Prior to and now during the rulemaking proceedings, DTSC has been able to support its AB 1879 activities by drawing upon monies available in the Toxic Substances Control Account (CA-TSCA). The CA-TSCA, which is funded through a variety of existing fees, supports many of DTSC's programs—most notably the Site Mitigation and Brownfields Reuse program and the Science, Pollution Prevention, and Technology (SPPT) program. (See Figure 3.) In particular, DTSC has situated AB 1879 implementation within the "Green Chemistry" activities of the SPPT program. As Figure 4 illustrates, DTSC's expenditures for green chemistry activities (consisting primarily of AB 1879 implementation efforts) have increased significantly over the last few years, to the apparent detriment of other unidentified SPPT activities.[59]

The situation for AB 1879 funding, and DTSC funding more generally, seems to be growing even more dire. As the Assembly Committee noted, implementing AB 1879 after the regulations are completed will require significantly greater resources. The

Figure 4 | CA Toxic Substance Control Account Expenditures



statute does not provide such resources, and it appears that the existing funding available under CA-TSCA is dwindling. For the past few years, the costs of the largely mandatory activities funded under the CA-TSCA have significantly exceeded the revenues flowing into that fund. The agency covered those excess costs by drawing upon the reserve in the fund built up over prior years.[60] The reserve in the fund shrank from almost 50 million dollars at the start of fiscal year 2009-2010 to a projected 2 million dollars at the end of fiscal year 2012-2013.[61] (See Table V.) Thereafter spending on CA-TSCA funding activities at existing levels, which includes AB 1879 implementation, will outstrip the combined likely revenues and reserve.

The existing and future resource constraints are already affecting AB 1879 implementation. At meetings of the Green Ribbon Science Panel (an advisory panel created under AB 1879), DTSC managers consistently emphasized the role that DTSC's likely limited resources are playing in shaping the informal draft regulations. The agency has made an admirable attempt to craft the best program it can, given those constraints, but the result is a program that relies heavily upon cooperation of ostensibly regulated businesses, and leaves excessive discretion to those businesses.

For example, the informal draft regulations set out a detailed process for alternatives analysis, in which a regulated business submits an alternatives analysis work plan and subsequently a final alternatives analysis report for DTSC review, after which DTSC issues a regulatory response, if needed. Yet, despite the thoughtful attention to process, the regulations leave the decision of whether a safer alternative exists to the *regulated business* without establishing any substantive standards for that decision.[62]

This abrogation of authority is all the more troubling in light of the minimal oversight authority DTSC retains for itself, which is largely limited to the agency's review of the alternatives analysis work plan and later report. That review only looks to whether the work plan and report are "in compliance" with the regulations.[63] Because the regulations are primarily process-based and lack significant substantive standards, the DTSC compliance review does not appear to reach the underlying substance. In this

Table V | CA Toxic Substance Control Account
Historical and Projected Fund Conditions
(all amounts in thousands of dollars)

	Fiscal Year			
	2009-2010	2010-2011	2011-2012	2012-2013
Opening Balance (Prior Reserve & Adjustments)	$50,779	$46,491	$35,011	$19,509
New Revenues	$41,651	$40,768	$42,813	$40,741
Total Available Fund	$92,430	$87,259	$77,824	$60,250
Expenditures	$49,472	$52,248	$58,315	$58,202
Ending Reserve	$42,958	$35,011	$19, 509	$ 2,048

case, therefore, the agency's understandable response to its limited resources functionally transforms AB 1879 into a quasi-voluntary program.

B. New Revenue Sources and More Rigorous Standards are Needed to Respond to Existing Resource Constraints

There are two primary options available to address the issue of resource constraints. The first directly increases the revenue available to DTSC through new taxes or fees. The second relies upon the market to provide third party oversight of the regulated companies, oversight that DTSC would have provided had adequate resources been available. Under either option, the agency should develop a set of substantive decision rules to guide the review of alternatives analyses and the selection of regulatory responses.

1. Use of Regulatory Fees. The legislature could establish stable funding for the AB 1879 program by creating a broad-based tax or a more focused regulatory fee. The tax might be imposed on chemicals manufactured in or imported into California, or on consumer products more specifically. The regulatory fee would be imposed upon businesses in an amount sufficient to cover the reasonable costs of administering the program.[64] The revenues would be used to fund all aspects of AB 1879 implementation, including prioritization of product/chemical combinations; administration and substantive review of alternatives analyses work plans and reports; development of regulatory responses; inspection; auditing; and enforcement.

The difficulty of enacting such funding mechanisms depends upon their characterization under Article XIII.A of the California Constitution (incorporating Propositions 13 and 26). Section 3 of that Article requires that taxes be approved by a supermajority in the legislature. The term "tax" is broadly defined to include "any levy, charge, or exaction of any kind imposed by the State", with limited exceptions.[65] One pertinent exception is a permitting fee; "tax" does not include "[a] charge imposed for the reasonable regulatory costs to the State incident to issuing licenses and permits, performing investigations, inspections, and audits,… and the administrative enforcement and

adjudication thereof."[66] Fees designed to recover the costs of permitting programs may be approved by a simple majority of the legislature. Given the difficulty involved in securing the supermajority to enacting a broad-based tax, this brief focuses upon the regulatory fee option.

Prior to the passage of Proposition 26, the respective definitions of tax and fee were left to the courts. Under that case law, fees imposed to fund regulatory programs were not considered taxes so long as the fees did not exceed the reasonable cost of the program and were not levied for any revenue purposes unrelated to the program. In *Sinclair Paint Co. v. State Bd. of Equalization*, the California Supreme Court defined regulatory purposes of fees broadly, including support of permitting, oversight, cleanup and mitigation activities, and even "deterring further manufacture, distribution, or sale of dangerous products" and "stimulating research and development efforts to produce safer or alternative products."[67] In that case, a fee was imposed on paint manufacturers based upon market share to fund evaluation, screening, and medically necessary follow-up services for child victims of lead poisoning. However, Proposition 26 appears to narrow the scope of the regulatory fee exemption from the supermajority requirement, expressly limiting it to fees supporting, among other things, a licensing or permitting program.[68] (The exception also includes fees associated with "investigations, inspections, and audits." Depending upon how the courts interpret these three terms, "investigations, inspections and audits" might include some discrete activities by DTSC under AB 1879, such as auditing alternatives analyses or "investigating" the uses and hazards of consumer products.)

Many examples of permitting fees are already on the books, including air quality permitting programs and water rights permitting.[69] Permitting is one form of regulation in which an individual business receives governmental approval to engage in a specific activity subject to particular legally binding terms in the approval.[70] Examples include the issuance of permits to construct new air emission sources, or the registration of new pesticides. Permitting can be contrasted to generally applicable rules that are imposed *en masse* upon an entire population of businesses engaged in similar activities.

Although AB 1879 is not explicitly characterized in its text as a permitting program, the statute and the informal draft regulations essentially describe a permitting process. Individual manufacturers, importers or retailers of specific consumer products must submit an alternatives analysis and recommended regulatory response. DTSC will review those materials, and issue an individualized regulatory response either banning the sale of the product or establishing conditions for its continued sale. This permitting program, which includes identification and prioritization of chemicals of concern and products, review of alternatives analyses, oversight, auditing and enforcement, will impose substantial regulatory costs on DTSC.

The agency should clarify the AB 1879 program's status as a permitting program by more explicitly adopting a permitting structure. For example, the regulations should expressly prohibit the sale of a consumer product containing a chemical of concern unless the regulated entity has complied with the AB 1879 regulations. Compliance obligations would include requirements to register the product/chemical combination, to submit use, distribution, exposure and health and safety data, to perform alternative analyses (if required), and to comply with any relevant regulatory responses.

Under Proposition 26, any permitting fee must meet two critical standards. First, the amount of the fee must be no more than necessary to cover the reasonable costs of the governmental activity—in this case, implementation of the AB 1879 program. Second, the manner in which those costs are allocated to a payor must bear a fair or reasonable relationship to the payor's burdens on the governmental activity.[71] The legislation authorizing an AB 1879 permitting fee need not set out the specific details of the fee program with respect to these two standards. Rather, DTSC must address those standards in crafting the fee program through the rulemaking process. To withstand a court challenge under Proposition 26, however, the legislation should expressly provide as follows:[72]

- The imposition of fees is only for the costs of implementation of the AB 1879 program and not for general revenue purposes.
- The fees collected are to be deposited in the Toxic Substances Control Account and not in the General Fund.
- DTSC is to set the fee schedules so that the total amount of fees collected equals that amount necessary to recover costs incurred in connection with AB 1879 implementation.
- DTSC is to set the amount of total revenue collected each year through the fees at an amount equal to the revenue levels set forth in the annual Budget Act for AB 1879 implementation.
- DTSC is to further adjust the annual fees if it determines that the revenue collected during the preceding year was greater than, or less than, the revenue levels set forth in the annual Budget Act and any revisions to that Act.

2. Market-Based Oversight. In the event that stable funding of DTSC is not achievable, significant portions of the resource-intensive oversight of alternatives analyses could be shifted to the market; that is, to private oversight providers. As in the informal draft regulations, the manufacturer would be legally responsible for submitting a proposed alternatives analysis prepared by a qualified assessor. However, the regulation should also mandate that prior to submission, the manufacturer must obtain certification from an independent third party consultant that the alternatives analysis meets the substantive and procedure requirements of the regulations.[73] (Of course, this assumes that DTSC's regulations ultimately include substantive standards for alternatives analysis, discussed below.)

The independent third party would be licensed for such work by DTSC. The certification requirement would enhance the quality of the submission, and reduce the time and resources required for DTSC review. The requirement that the consultant be independent acknowledges the fact that the manufacturer will have a material stake in the outcome of the analysis, particularly where the potential alternatives could supplant the manufacturer's product. Indeed, studies of innovation of safer alternatives demonstrate that significant innovation in chemicals/products/processes most often come from outside the existing manufacturer.[74] To protect both the substantive evaluation and the legitimacy of the process, the alternatives analysis review would be required to be conducted by a neutral party without a financial interest in its outcome.[75] Moreover, by requiring use of independent third party alternatives analysis, the program would encourage innovation. Outside firms are more likely to invest in the development safer alternatives knowing their innovation will be evaluated in a fair and objective matter. This, in turn, would motivate the regulated manufacturer to develop safer substitutes in-house or risk losing market share.

Clearly the third party oversight model raises serious concerns regarding the independence of the third party, as well as implementation issues regarding certification and development of sufficiently clear and objective standards, methods and protocols. While it is therefore not the optimal solution to the resource issue, and raises political acceptability issues of its own, it does provide significantly more transparency and accountability than a self-executing model in which individual businesses perform analysis and evaluation without any substantial agency oversight.

3. Incorporate Substantive Standards. AB 1879 identifies numerous criteria against which the regulated consumer product and its alternatives are to be evaluated in the alternatives analysis. Generally speaking, the criteria relate to human health impacts, environmental impacts, product performance and economic impacts.[76] The choices made among existing consumer products and their alternatives will likely require trade-offs within criteria (for example, within the human health criteria comparing carcinogenicity with endocrine disruption) or between them (such as balancing an adverse health impact against an environmental impact). The balancing of such incommensurables is by nature a subjective process driven by the values under which a decision maker is operating. Essentially, it requires the decision-maker

to weigh the relative importance of various attributes or combinations of attributes, forcing the decision-maker to confront difficult issues such as the extent to which concerns about risks of cancer or reproductive toxicity trump global warming concerns. Substantive decision rules are essential to guide the inevitable choices presented by these trade-offs.

Because the alternatives evaluation is so value-laden, the decision-making process should be directed by clearly articulated program expectations and still more specific decision rules. Examples of such decision frameworks can be found in federal environmental law including the Significant New Alternatives Program (SNAP) – designed to verify the safety of substitutes for ozone-depleting compounds, and the Superfund program—regarding the selection of remedial alternatives for contaminated hazardous waste sites.[77] SNAP identifies a series of guiding principles for that program, including reliance upon a qualitative comparative risk approach. [78] The Superfund statute and implementing regulations establish a more explicit array of program expectations coupled with a set of nine narrative decision criteria.[79]

Clearly, both the SNAP and the Superfund programs have deficiencies; reference to those programs is not a general endorsement of their outcomes. However, they do represent well-developed examples of decision frameworks involving complex, multi-criteria evaluations. The approaches adopted in those programs—the balancing of narrative, weighted criteria—can be adopted in the alternatives analysis process as well. The nature and scope of specific decision rules should be a direct extension of the social values underlying the guiding principles and program expectations. The regulation could specifically identify, as a general matter, which alternatives analysis variables carry more weight (e.g., reduction of toxics is generally more weighty than energy impacts); identify relative rankings of specific concerns within variables (e.g., skin irritation less weighty than reproductive toxicity); or express a specific trade-off (e.g., a cost-effective alternative is defined as an alternative where the material cost is no more than 25% greater than the baseline consumer product). Specific program goals, expectations, and decision rules will provide assurance that decisions made under AB 1879 are consistent, transparent, and driven by concerns for social welfare rather than by private interests.

Conclusion AB 1879 has the potential to drive meaningful change in the design of consumer products, and in the shape of chemical policy at the state, national and international level. Achieving that potential, however, requires additional legislation—a mid-course correction of sorts designed to alleviate structural limitations of the statute. Those limitations mirror the well-documented flaws in the federal TSCA legislation, flaws that have caused the federal program to flounder for decades. By taking action now, the California legislature can ensure that AB 1879 flourishes as an effective, meaningful and innovative regulatory program.

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Endnotes

1 EPA, *2006 Inventory Update Reporting: Data Summary* 15 (December 2008). That figure is drawn from chemical industry self-reporting required under EPA's Inventory Update Rule (IUR) for the 2005 reporting year. EPA subsequently replaced the IUR with the Chemical Data Reporting (CDR) rule. 76 Fed. Reg. 50815 (August 16, 2011).

2 EPA, *2006 Update* at 2.

3 *See* Tracey J. Woodruff, *et al*., *Environmental Chemicals in Pregnant Women in the United States: NHANES 2003–2004*, 119 Envt. Health Persp. 878 (2011); Department of Health and Human Services Centers for Disease Control and Prevention, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS (2009).

4 Philip J. Landrigan, *et al, Chemical Contaminants in Breast Milk and Their Impacts on Children's Health*: *An Overview*, 110 Envt. Health Persp. A313 (2002).

5 Toxic Substances Control Act, as amended, 15 U.S.C. 2625, *et seq* (TSCA). President Nixon's Environmental Quality Council raised the alarm about toxic chemicals as early as 1971 with its *Toxic Substances* report. Over the ensuing five years, the Nixon and Ford administrations, the House and the Senate wrangled over successive versions of a comprehensive chemical policy law until finally before ultimately enacting TSCA.

6 *See e.g.,* Richard Denison, *Ten Essential Elements in TSCA Reform*, 39 Envtl. L. Rep. 10020 (2009); United States Government Accountability Office, *Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals*, 8-9 (GAO-07-825, August 17, 2007)(hereinafter GAO, *Comparison*); United States Government Accountability Office, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, 21-22 (GAO-05-458, June 13, 2005); Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, 6 Envtl. Law. 99, 120-123 (1999); John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 Colum. L. Rev. 261 (1991).

7 Lars Koch and Nicholas A. Ashford, *Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and Reach*, 14 J. Cleaner Prod. 31, 41 (2006). Those were polychlorinated biphenyls, fully halogenated chlorofluoroalkanes, dioxin, hexavalent chromium and asbestos.

8 *See* Safe Chemicals Act of 2011, S. 487, 112th Cong., (2011); Kid-Safe Chemicals Act of 2008, S. 3040, 110th Cong. (2008); Child, Worker, and Consumer-Safe Chemicals Act of 2005, S. 1391, 109th Cong. (2005); Child, Worker, and Consumer-Safe Chemicals Act of 2005, H.R. 4308, 109th Cong. (2005).

9 Mike Belliveau*, Healthy States: Protecting Families from Toxic Chemicals While Congress Lags Behind* 14 (2010).

10 CA Assembly Bill No. 1879 (Sep. 29, 2008); 38 MRSA C. 16-D (2008)(Maine Toxic Chemicals in Children's Products Act); Minn. Stat. 116.9401 – 116.9407 (2009)(Minnesota Toxic Free Kids Act); Revised Code of Washington Chapter 70.240 (2008)(Children's Safe Products Act).

11 M.G.L. Chapter 21I (2006)(Massachusetts Toxics Use Reduction Act); 38 MRSA C. 16-D, Section 1695.2 (2008).

12 AB 1879 called for promulgation of the regulations by January 1, 2011. After extensive outreach and rulemaking activity, DTSC withdrew its first set of proposed regulations shortly before the 2011 deadline, restarting the rule development process after a change in leadership. As of the date of this report, DTSC is preparing to issue a revised proposal.

13 DTSC, Safer Consumer Products Informal Draft Regulations, R-2011-02 (October 31, 2011) ("Informal Draft Regs"). These are informal in the sense that DTSC has not issued them through the formal administrative process that would trigger public review and comment.

14 GAO, *Comparison*, *supra* n. 6, at 8-9.

15 For significant new uses of chemicals, however, TSCA places the onus on the agency to identify the new use before a PMN is required. TSCA Section 5(a), 15 U.S.C. 2604(a).

16 TSCA Section 5(a),(f), 15 U.S.C. 2604(a),(f).

17 Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, 6 Envtl. Law. 99, 120-123 (1999); GAO, Comparison, *supra* n. 6, at 8-9.

18 EPA, *Overview: Office of Pollution Prevention and Toxics Laws and Programs* 8 (March 2008).

19 *Id.* at 10-11. EPA reports that another 1705 PMNs were withdrawn during that period in the face of imminent EPA action. *Id.*

20 *See* CA Health and Safety Code Section 25252.5.

21 *See* CA Health and Safety Code Section 25252(a)(1)-(3).

22 The National Research Council defines high throughput assays as "[e]fficiently designed experiments that can be automated and rapidly performed to measure the effect of substances on a biologic process of interest. These assays can evaluate hundreds to many thousands of chemicals over a wide concentration range to identify chemical actions on gene, pathway, and cell function." Toxicity Testing in the 21st Century: A Vision and a Strategy 38 (2007).

23 *Id*. at 37.

24 40 C.F.R. Section 720.3(p). The question of whether something is reasonably ascertainable will depend upon such factors as the nature of the substance, magnitude of sales and profit, and size of the company. 48 Fed. Reg. 21722, 21730 (May 13, 1983).

25 GAO, Comparison, *supra* n. 6, at 9; John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 Colum. L. Rev. 261, 267 (1991).

26 United States Government Accountability Office, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, 21-22 (GAO-05-458, June 13, 2005).

27 40 C.F.R. 720.45(a)(3)

28 This includes substances included in the original TSCA Inventory in 1979, as well as chemicals added to the Inventory through the new chemical provisions of TSCA.

29 The Preliminary Assessment Information Rule (PAIR) is found at 40 C.F.R. Part 712. The Health and Safety Data Reporting rule (HaSDR) is at 40 C.F.R. Part 716. The Chemical Data Reporting (CDR) rule replaced EPA's Inventory Update Rule (IUR) in 2011. *See* 76 Fed. Reg. 50815 (August 16, 2011).

30 CA Health and Safety Code Section 25253(b)(2).

31 AB 289 identifies the following as the type of information targeted: The information that the state agency requests may include, but is not limited to, any of the following: (A) An analytical test method for that chemical, or for metabolites and degradation products for that chemical that are biologically relevant in the matrix specified by the state agency. (B) The octanol-water partition coefficient and bioconcentration factor for humans for that chemical. (C) Other relevant information on the fate and transport of that chemical in the environment. *See* CA Health and Safety Code Section 57019(d)(3).

32 *See* CA Health & Safety Code Section 57018(a)(1).

33 Harold F. Hemond and Elizabeth J. Fechner-Levy, Chemical Fate and Transport in the Environment 2 (2000).

34 Assembly Committee on Environmental Safety and Toxic Materials, Bill Analysis of AB 289 (April 14, 2006).

35 Assembly Third Reading, Bill Analysis of AB 289 (May 31, 2006).

36 *See* David Vogel, *The Market for Virtue: The Potential and Limits of Corporate Social Responsibility* (2005); Andrew A. King and Michael J. Lenox, *Industry Self-Regulation without Sanctions: The Chemical Industry's Responsible Care Program*, 43 Academy of Management Journal 698 (2000).

37 Letter from Jeffrey Wong, DTSC regarding Chemical Information Call-In Carbon Nanotubes (January 22, 2008). (http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/upload/Formal_AB289_Call_In_Letter_CNTs.pdf (accessed September 24, 2009)).

38 *See* Victoria McGovern, *National Toxicology Program: Landmarks and the Road Ahead*, 112 Environmental Health Perspectives A874 (November 2004).

39 42 U.S.C. Section 2601(c) ("It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic and social impact of any action the Administrator takes or proposes to take under this chapter.")

40 *See* Timothy F. Malloy, *Of Natmats, Terrorists, and Toxics: Regulatory Adaptation in a Changing World*, 26 UCLA Journal of Environmental Law & Policy 93, 109-110 (2008).

41 Although the statute does not define "unreasonable risk," the legislative history provides some guidance: "In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society." H.R. REP. NO. 94-1341, at 13-14 (1976).

42 15 U.S.C. 2605(a).

43 *Corrosion Proof Fittings*, 947 F. 2d 1201,1214 (5th Cir. 1991).

44 *Id.* at 1217.

45 *See* Letter dated April 21, 2009 from Assemblyperson Michael Feuer (author of AB 1879) to Maziar Movassaghi, Acting Director, DTSC (observing that '[i]f an alternatives assessment finds that there are viable, safer alternatives, the Department should be obligated to phase out the use of the chemical of concern for that particular use.") (available at http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/GC_Feuer_Input.pdf (last visited January 3, 2012)).

46 *See* CA Health and Safety Code Section 25251.1(b).

47 That said, the use of the words "reduce the level of hazard" appears to move away from an approach tied to quantitative risk assessment.

48 Cal. Health & Safety Code Section 57005. The agency must consider all relevant factors, including the enforceability and technological feasibility of the regulation and associated alternative. California EPA, *Economic Analysis Requirements for the Adoption of Administrative Regulations* (December 9, 1996).

49 Timothy F. Malloy and Peter S. Sinsheimer, Innovation, Regulation and the Selection Environment. 57 *Rut. L. Rev*. 183, 210-211 (2004); Joel Hirschhorn, *et al*., *Towards Prevention:The Emerging Environmental Management Paradigm* in Clean Production Strategies: Developing Preventive Environmental Management in the Industrial Economy 125, 127 (Tim Jackson ed. 1993).

50 Trevor A. Kletz, *What You Don't Have, Can't Leak*, Chemistry & Industry 287 (1987) (discussing the principles of inherently safer design in industrial processes).

51 Cal. Gov't Code Section.11346.5 (a)(13).

52 Cal. Gov't Code Section.11346.2(b)(3)(A),(B).

53 For example, agency interpretation of Section 57005's "less costly" language calls only for a cost-effectiveness analysis; that is, a ranking of alternatives in terms of their respective costs in achieving an equivalent level of protection. California EPA, *Economic Analysis Requirements for the Adoption of Administrative Regulations* (December 9, 1996). Under *Corrosion Proof Fittings*, TSCA's least burdensome requirement standard entails a cost-benefit analysis. *Corrosion Proof Fittings*, 947 F. 2d at 1217.

54 *See* CA Health and Safety Code Section 25251.1(b).

55 Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective, 19-21 (GAO/RCED-94-103, September 26, 1994).

56 *See* Michael A. Jayjock, *et al., Using Publicly Available Information to Create Exposure and Risk-Based Ranking of Chemicals Used in the Workplace and Consumer Products*, 19 J. of Exposure Science and Envt'l Epidemiology 515, 516 (2009).

57 *Id*. at 520 (noting "that 4–6 chemicals can be completed per 8 h workday by junior staff.")

58 Senate Committee on Environmental Quality, A.B. 1879 Analysis at 11.

59 DTSC, Toxic Substances Control Account Expenditure Report for the 2009/10 Fiscal Year 5 (February 2011); E-mail communication with Odette Madriago, DTSC (January 3, 2011). Prior to enactment of AB 1879 DTSC engaged in other voluntary activities focused on encouraging green chemistry. Those activities, which to some degree still continue, were embedded in the Pollution Prevention program in SPPT in fiscal years 2006/07 and 2007/08. *See* DTSC, Toxic Substances Control Account Expenditure Report for the 2007/08 Fiscal Year 6 (February 2009); DTSC, Toxic Substances Control Account Expenditure Report for the 2006/07 Fiscal Year 6 (February 2008). Figure 4 shows a modest increase in Pollution Prevention for those two years, apparently reflecting those activities. *See also* DTSC, Toxic Substances Control Account Expenditure Report for the 2005/06 Fiscal Year 5 (February 2007); DTSC, Toxic Substances Control Account Expenditure Report for the 2008/09 Fiscal Year 5 (February 2010).

60 Historically the state has maintained a reserve for economic uncertainties in CA-TSCA (and most other accounts); for fiscal year 2011-2012 that reserve was over 11 million dollars. *See* Governor's Budget 2011-2012 Proposed Budget Detail, Environmental Protection, EP 49, available at http://2011-12.archives.ebudget.ca.gov/pdf/GovernorsBudget/3890.pdf. (The purpose of a reserve is to address revenue shortfalls and unanticipated expenses that may occur during the year. Absent a reserve, DTSC would have to reduce programs and/or increase revenues to respond to those unanticipated events.)

61 *See* Governor's Budget 2011-2012 Proposed Budget Detail, Environmental Protection, EP 48, available at http://2011-12.archives.ebudget.ca.gov/pdf/GovernorsBudget/3890.pdf; Governor's Budget 2012-2013, Proposed Budget Detail, Environmental Protection, EP 45, available at http://www.ebudget.ca.gov/pdf/GovernorsBudget/3890.pdf.

62 Informal Draft Regs, *supra* n. 13, Section 69505.4(c).

63 *See* Informal Draft Regs, *supra* n. 13, Section 69505.6(b)(1).

64 It will not be enough to simply *authorize* the Department to establish a fee system in support of the program, as AB 32 did; the legislation should *mandate* it. In reviewing AB 32 implementation, the Legislative Analyst's Office has twice admonished the administration's failure to actually implement the authorized fee program. California Legislative Analyst's Office, *Resources 2008-09 Analysis* B-91 through B-95.

65 CA Const. art. VIII.A, § 3(b).

66 CA Const. art. VIII.A, § 3(b)(3).

67 *Sinclair Paint Co. v. State Bd. of Equalization* 937 P.2d 1350, 1356 (1997). The *Sinclair* case was cited extensively with approval in the California Supreme Court's most recent foray into regulatory fees in *CA Farm Bureau Federation v. State Water Resources Control Board*, 51 Cal. 4th 412, 437-438 (2011). While *CA Farm Bureau Federation* was decided after the passage of Proposition 26, the court did not consider the impact of Proposition 26 on the case. *Id*. at 428, n. 2.

68 *See* CA Const. art. VIII.A, § 3; California Legislative Analyst, Analysis of Proposition 26, in Secretary of State, California General Election Official Voter Information Guide 56-59 (2010).

69 CA Health & Safety Code Section 40510(b).

70 Terry Davies, Reforming Permitting 11(2001).

71 CA Const. art. VIII.A, § 3(d).

72 These provisions are drawn from the California Supreme Court's evaluation of the permitting fee legislation at issue in *CA Farm Bureau Federation*, in which the Court upheld the legislation against a facial challenge. *See* 51 Cal. 4th at 438-440 (2011). The court was interpreting case law standards for regulatory fees that were essentially identical to the two standards set out in Proposition 26.

73 Manufacturers may raise concerns regarding the sharing of trade secrets with third parties. As a practical matter, businesses often use outside consultants on matters relating to or involving trade secrets. There are well developed, widely used mechanisms for protecting trade secrets from disclosure in such circumstances, including legally enforceable non-disclosure agreements. Moreover, rules of conduct for professional engineers prohibit the disclosure of trade secrets. *See* Steven D. Maurer and Michael T. Zugelder, *Trade Secret Management in High Technology: A Legal Review and Research Agenda*, 11 Journal of High Technology Management Research 155, 161-165 (2000).

74 Richard Stewart, *Regulation, Innovation, and Administrative Law: A Conceptual Framework*, 69 California Law Review 1256 (1981); Kurt Strasser, *Cleaner Technology, Pollution Prevention and Environmental Regulation*, 9 Fordham Environmental Law Journal (1997).

75 Of course experience in the accounting sector has shown that third parties are not consistently able to maintain their independence and may be "captured" by their clients. John C. Coffee, Jr., *Gatekeeper Failure And Reform: The Challenge Of Fashioning Relevant Reforms*, 84 B.U.L. Rev. 301 (2004). Nonetheless, the likelihood of such capture is substantially increased where the persons performing the analysis are employees of the firm.

76 *See* AB 1879 Section 25253(a)(2).

77 *See* 40 C.F.R Sections 300.430.

78 *See* 59 Fed. Reg. 13044, 13046 (March 18, 1994).

79 For example, Superfund program expectations include use of treatment rather than containment where practical; return groundwater to beneficial uses; use innovative technology where comparable to conventional technology. 40 CFR Section 300.430(a)(1)((iii) (2009).

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