# Integrating Safer Alternatives into Chemical Policy: Developing a Regulatory Framework for AB 1879

December 22, 2009

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# Introduction

Over the past generation, while strides have been made in identifying hazardous characteristics of chemicals, there has been little progress in developing and implementing public policies to replace hazardous chemicals with safer substitutes. New legislation in California (AB 1879) has the potential to change this by identifying hazardous substances in consumer products, requiring the analysis of alternatives, and authorizing regulatory action to reduce or eliminate the chemical hazard. Whether AB 1879 is successful in facilitating the innovation of safer substitutes will depend, in great measure, on the precise regulatory framework developed by the agency charged with implementing the law – the Department of Toxics Substances Control (DTSC). While this legislation is novel, case studies focusing on evaluating safer alternatives for specific hazardous substances provide insight into the form of regulation likely to lead to success.<sup>1</sup> Other models that provide insight include work conducted on designing a structure for risk reduction regulation for the European Union,<sup>2</sup> as well as United States' Significant New Alternatives policy (SNAP) program evaluating alternatives for ozone-depleting substances.<sup>3</sup>

This white paper describes a regulatory framework for effective implementation of AB1879. The framework seeks to provide the flexibility needed for the regulation to evolve while keeping to core values of protectiveness, public participation, and seeking safer substitutes.

## **Regulatory Framework**

Figure 1 shows the recommended regulatory structure as well as a recommended timeline for implementation. Each of the boxes shown in Figure 1 describes key steps in the regulatory framework (from defining adverse health impacts, to evaluating alternatives, to taking regulatory action), identifies who is responsible for each step (e.g., government agency, manufacturer, third party, public), and the highlights the essential activities being performed in each step. The arrows connecting the boxes represent the relationship between each step. While this suggests a somewhat linear implementation process, the actual process will be substantially more dynamic.

The timeline which accompanies the framework is designed to show the need to stage implementation in order to create sufficient time to develop methods, material, and the social infrastructure necessary for full-scale implementation. What follows is a description of each of the regulatory steps, how these steps are connected, and how this framework is best implemented over time.

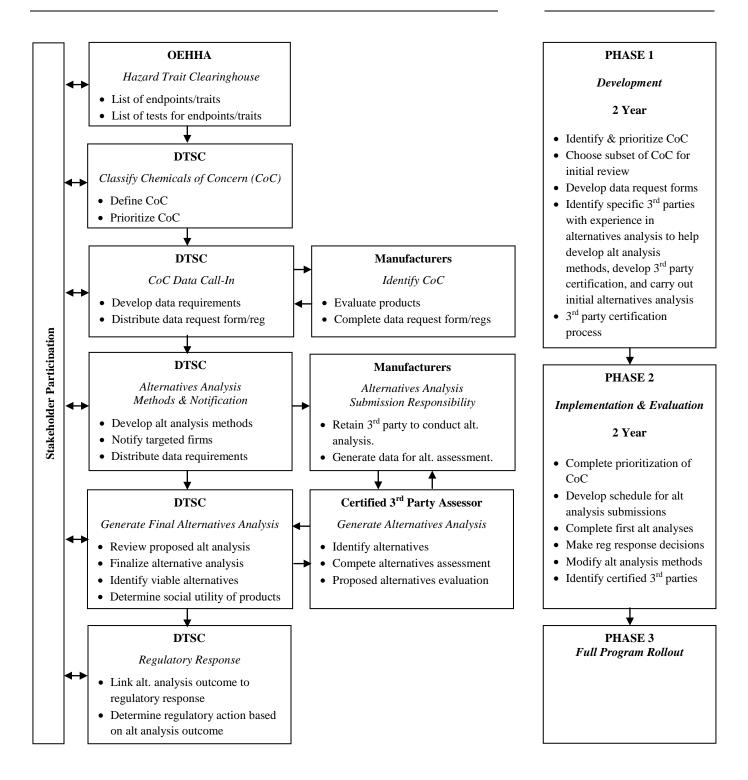
<sup>&</sup>lt;sup>1</sup> Peter J. Sinsheimer, et al., The Viability of Professional Wet Cleaning as a Pollution Prevention Alternative to Perchloroethylene Dry Cleaning 57 Journal of the Air & Waste Management Association 172. Also see Toxics Use Reduction Institutes. Five Chemicals Alternatives Assessment Study, July 2006. Timothy F. Malloy and Peter Sinsheimer, Innovation, Regulation, and the Selection Environment, 57 Rutgers Law Review 183 (2004).

<sup>&</sup>lt;sup>2</sup> Nordic Council of Ministers: The Use of Decision-Aid Methods in the Assessment of Risk Reduction Measures in the Control of Chemicals, 1997. Nicholas A. Ashford, *Legislative Approaches for Encouraging Clean Technology*, 7 Toxicology and Industrial Health, 335 (1991).

<sup>&</sup>lt;sup>3</sup> See 59 Fed. Reg. 13044 (March 18, 1994). (final rule establishing SNAP program).

## AB 1879 FRAMEWORK

## TIMELINE



#### Identifying Hazard Traits/Endpoints (OEHHA)

The first step in the AB 1879 regulatory framework is identification of the adverse characteristics of chemicals which lead to their classification as "chemicals of concern." Under companion legislation, SB 509, California's Office of Environmental Health Hazard Assessment (OEHHA) is tasked with developing a clearinghouse of adverse characteristics including toxicological endpoints (e.g., cancer, developmental toxicity, endocrine disruption), environmental endpoints (e.g., aquatic toxicity, ozone depleting potential) and hazard traits (e.g., structural features, bioaccumulation potential, persistence in the environment).<sup>4</sup>

For each trait or endpoint, OEHHA should include in the clearinghouse the range of tests which can be used to determine whether a chemical exhibits the adverse characteristic. In addition, OEHHA should also develop methods for articulating the magnitude of the adverse characteristic such as severity of the outcome (i.e., from mild irritant to fatality), strength of the association (e.g., weak carcinogen vs. strong carcinogen), and ecological fate (e.g. degree of persistence, degree of bioaccumulation).

## Defining and Prioritizing Chemicals of Concern (DTSC)

Under AB 1879, DTSC is responsible for defining "chemicals of concern" (CoC). DTSC should establish two entry points for classification as a CoC: (1) those chemicals exhibiting a hazard trait, characteristic, and/or endpoint identified in the clearinghouse; and (2) those chemicals specifically listed as chemicals of concern by DTSC (e.g., lead, n propyl bromide) which, logically, would have tested positive for at least one of the hazard traits/endpoints defined by DTSC.<sup>5</sup> The federal hazardous waste regulations use a similar two-pronged approach in defining a waste as "hazardous" – any waste exhibiting certain characteristics (i.e., reactivity, toxicity, flammability, or combustibility) or specifically listed by EPA.<sup>6</sup> To implement the two pronged approach, DTSC must develop standards (either tests or narrative criteria) for confirming the existence of the relevant hazard trait, toxicological endpoint, or environmental endpoint.

DTSC must also develop methods for prioritizing CoC in order to stage implementation. While the statute identifies three prioritization factors to consider – the volume of chemical in commerce, potential for exposure in consumer products, and potential effects on sensitive subpopulations – the agency may consider any other factor. DTSC may prioritize chemicals based on different groupings, including: chemicals used in high volume, chemicals directly released from the product during use, reuse, or

<sup>&</sup>lt;sup>4</sup> SB 509 does not define toxicological endpoint, environmental endpoint, and hazard trait. OEHHA developed a preliminary definition of hazard trait as a broad term which incorporates toxicological outcomes, environmental outcomes, structural features, See Hoover, Sara. Update on OEHHA's Hazard Trait Research. Green Chemistry Science Panel Meeting, October 14, 2009.

<sup>&</sup>lt;sup>5</sup>AB 1879, 25252 (b) (1) reads: "In adopting regulations pursuant to this section, the department shall develop criteria by which chemicals and their alternatives may be evaluated. These criteria shall include, but not be limited to, the traits, characteristics and endpoints that are included in the clearinghouse data pursuant to Section 25256.1." <sup>6</sup> 40 C.F.R. Part 261 (2009).

disposal; chemicals used in specific sectors; chemicals used by specific subpopulations (e.g., pregnant women, infants, workers); or specific sub-grouping of chemicals (e.g., chemicals that are persistent, bioaccumulative, and toxic). DTSC's Straw Proposal for Safer Alternative Regulations dated September 28, 2009 (Straw II), for example, prioritized CoC based on their potential to be directly released to the environment.<sup>7</sup> Given the scope of AB1879, it is essential that the prioritization system be tailored to the capacity of the agency to evaluate the data received of CoC in order to effectively move forward with regulation.

## Data Call-In for Chemicals of Concern (DTSC)

After identifying and prioritizing chemicals of concern, the agency must develop standard data requirements to be used in determining whether products contain CoC. In this regard, while seeking standardized data, DTSC should retain the authority to require submission of additional chemical or process-specific information where appropriate. The standard requirements could be set out in a data submission form or in generally applicable regulation, as appropriate.

Along with the data submission requirements, DTSC must establish a timeframe for submission. Penalties, including prohibiting the distribution of the consumer product, must be developed for late, incomplete, and/or inaccurate submissions. In addition, auditing procedures must be developed to ensure data quality. Finally, DTSC must consider how to stage the call-in requests so as not to overwhelm the agency's capacity to evaluate submitted forms.

## Identifying Chemicals of Concern in Consumer Products (Manufacturers)

Manufacturers of consumer products used in California must determine whether their products contain one or more chemicals of concern. This requires evaluation of every chemical in the product based upon the data required by DTSC. Secondary data can be used in cases where existing tests have already been completed or where the manufacturer has knowledge that the product contains a specific chemical already listed by DTSC. Where there are gaps in the data for a chemical in a product, primary data collection will be required. The manufacturer must provide complete documentation for the data submitted to support the accuracy of the data.

Because many consumer products are composed of different components manufactured by different firms (e.g., automobiles, cell phones, television), DTSC must determine the appropriate level in the chain-of-commerce upon which to focus. Each firm must notify DTSC of the results of the product evaluations, even those cases in which no chemicals of concern are identified in the product. Negative findings not only indicate a measure of the product's safety but the test results are essential for compiling a database of non-hazardous chemicals.

<sup>&</sup>lt;sup>7</sup> Straw Proposal for Safer Alternative Regulations dated September 28, 2009 (Straw II), p. 18, 6.XXXX.8 Prioritization of Chemicals of Concern.

#### Alternatives Analysis (DTSC)

This section focuses upon substantive aspects of alternative analysis followed by a discussion of the relative roles of government, business and third parties. The process of identifying viable alternatives, *alternatives analysis*, consists of two separate yet related components. The first, *alternatives assessment*, includes identification of potentially viable alternatives and systematic assessment of the technical, health, safety, environmental, and economic attributes of the baseline chemical/product and those alternatives. While alternatives assessment is largely a data-driven, objective process, it involves significant application of best professional judgment and discretion. In setting default assumptions (e.g., data from peer review journals more reliable than trade journals), it also involves value choices which are often not apparent. The second component of alternatives analysis is *alternatives evaluation*, conducted after the alternatives assessment is completed. It is a largely subjective balancing of the respective attributes (e.g., lower toxicity vs. higher cost) of the baseline chemical/product and the alternatives with the goal of selecting the option that best fits the decision criteria guiding the evaluator.

#### Alternatives Assessment

The starting point of the alternatives analysis process is the selection of the attributes to be compared. In other words, what aspects of the chemical/product and the competing alternatives are most relevant to the decision-maker in determining whether a safer, viable alternative exists? The nature of the data to be developed and the metrics to be used in comparing alternatives depend upon the attributes selected. The statute provides some indication of the relevant attributes; Section 25253(a) (2) identifies a series of factors for consideration. Those factors can be categorized into five general criteria: human health impacts, environmental impacts, resource impacts, technical performance, and economic impacts. See Table 1.

Each of these general criteria would be broken into a series of specific subattributes, each having default measures and data requirements for purposes of comparison. These metrics would allow direct comparison of the targeted chemical/product and the alternatives with respect to the respective sub-attributes. For example, within the human health impacts criteria, the targeted chemical/product would be compared to alternatives with respect to series of sub-attributes, including carcinogenicity, reproductive toxicity, developmental toxicity, etc. While most attribute metrics and data requirements may be fairly standard, some—such as technical performance—will vary depending upon the chemical/product in question, requiring development of case-specific metrics and data requirements. Moreover, in some cases the metrics (whether standard or case-specific) will be quantitative while in others qualitative measures may be developed.

Assessment Criteria	AB1879: Section 25253 (a) (2)
Human Health &	• Potential hazards posed by those alternatives (Sec. 2).
Public Safety	• Critical exposure pathways (Sec 2).
	• Public health impacts, including potential impacts to sensitive
	subpopulations, including infants and children (K).
	• Air emissions (F).
Environmental	• Water quality impacts (E).
Impact	• Greenhouse gas emissions (I).
	• Waste and end-of-life disposal (J).
	• Environmental impacts (L).
Resource Impacts	• Materials and resource consumption (C).
	• Water conservation (D).
	• Production, in-use, and transportation energy inputs (G).
	• Energy efficiency (H).
Technical	• Product function or performance (A).
Performance	
Cost	• Economic impacts (M).
	• Useful life (B).

 Table 1: Categorization of Section 25253(a)(2) Factors

## **Alternatives Evaluation**

Based upon the alternatives assessment, the decision-maker next engages in alternatives evaluation to determine whether viable, safer alternatives are available. In some cases, this may be a relatively straightforward exercise. For example, consider the case of a cheaper, commercially available alternative that neither contains a chemical of concern nor has any other negative health, environmental or resource impacts. Likewise, the judgment is fairly clear where the baseline chemical/product and alternative exhibit the same hazards but at substantially different magnitudes. In many other cases, however, the choices will likely be significantly more difficult, requiring trade-offs within general 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.

While the alternatives evaluation is inherently subjective, the decision-making process should be directed by clearly articulated program expectations and still more specific decision rules. Such expectations and decision rules can be derived from the statute, from the evaluation of other similar regulatory programs as well as learned over time from implementing AB1879 regulations. 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.<sup>8</sup> SNAP identifies a series of guiding principles for that program, including reliance upon a qualitative comparative risk approach.<sup>9</sup> The Superfund statute and implement regulations establish a more explicit array of program expectations coupled with set of nine narrative decision criteria.<sup>10</sup> Selection among remedial alternatives in the Superfund programs is driven through a balancing of five criteria: long-term effectiveness, reduction of toxicity through treatment, short-term effectiveness, implementability, and cost-effectiveness.<sup>11</sup> The regulations provide decision rules articulating the relative weight to be accorded the decision criteria *vis-à-vis* each other:

The balancing shall emphasize long-term effectiveness and reduction of toxicity, mobility, or volume through treatment. The balancing shall also consider the preference for treatment as a principal element and the bias against off-site land disposal of untreated waste. <sup>12</sup>

Superfund guidance documents further refine the meaning and relative weight to be accorded to nine decision criteria in various circumstances.<sup>13</sup>

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, multicriteria evaluations. No doubt there are others. The approach adopted in those programs—the balancing of narrative, weighted criteria—can be adopted in the alternatives evaluation 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 assessment 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 CoC product). The more specific the program goals, expectations, and decision rules, the more guided DTSC will be in determining the overall viability of alternatives relative to the baseline.

<sup>&</sup>lt;sup>8</sup> See 40 C.F.R Sections 300.430.

<sup>&</sup>lt;sup>9</sup> See 59 Fed. Reg. 13044, 13046 (March 18, 1994).

 $<sup>^{10}</sup>$  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).

<sup>&</sup>lt;sup>11</sup> Each of these criteria is further broken down into underlying factors or sub-criteria. 40 CFR Section 300.430

<sup>&</sup>lt;sup>12</sup> 40 CFR Section 300.430(f)(1)(ii)(E) (2009).

<sup>&</sup>lt;sup>13</sup> See EPA, Guidance on Remedial Actions for Contaminated Water at Superfund Sites, EPA/540/G-88/003 (December 1988).

In developing decision rules, care must be taken to ensure that the rules do not undermine the underlying policies of the statute. To some degree, the Straw Proposal for Safer Alternative Regulations dated September 28, 2009 (Straw II) incorporates default decision rules for identification of safer alternatives. One is embedded in the definition of "safer alternative" itself, excluding any alternative that exhibits "significant life cycle impacts" regardless of whether the alternative has reduced hazard, exposure and ecological impacts. Section 6.xxxx.11. Another rests within the alternative assessment provisions, eliminating any alternative containing a chemical of concern assigned to both (1) the same hazard category as a chemical in the baseline product and (2) an additional hazard category. Section 6.xxxx.13(b). These decision rules are deeply flawed. Neither reflects the notion of comparative evaluation inherent in alternatives assessment, nor the importance of establishing metrics of sufficient refinement to allow meaningful comparison of alternatives. The question is not simply whether the potential alternative has more hazard characteristics or life cycle impacts; rather, it is the extent to which the number, nature and magnitude of the hazards posed by the alternative are more or less acceptable than those posed by the baseline product. Thus, in the case of the definition of "safer alternative," one could easily imagine a case in which the "significant" life cycle impact (such as increased energy requirements) may be preferable to the hazard presented by the baseline product.

No doubt, in many instances the alternatives evaluation will be complex, requiring the balancing of numerous incommensurables among several alternatives. Formal decision theory in the form of multi-criteria decision analysis (MCDA) can assist in the systematic performance of that balancing. Such methods allow decision makers to analyze "multiple streams of dissimilar information" in a standardized manner.<sup>14</sup> There are a variety of methods available, reflecting a range of theoretical foundations. For example, some approaches seek the optimal alternative, while others simply rank alternatives. Some are compensatory—allowing a high "score" in one attribute to offset a low score in another, while others are partially compensatory.<sup>15</sup>

To a limited degree, MCDA has been applied in environmental decision-making; in one case the Superfund remedial selection process was woven into a MCDA approach.<sup>16</sup> However, MCDA is simply a tool for systematizing the decision-process; it is driven by the preferences and values of the decision maker which are incorporated into the algorithms of the particular MCDA approach chosen. Likewise, the selection of the particular approach itself can affect the ultimate outcome. Therefore, the decision maker must develop a deep understanding of its own goals, preferences and values before adopting MCDA. In the early stages of AB 1879 implementation, DTSC should thus

<sup>&</sup>lt;sup>14</sup> I. Linkov, et al. Multi-Criteria Decision Analysis: A Framework for Structuring Remedial Decisions at Contaminated Sites, in COMPARATIVE RISK ASSESSMENT AND ENVIRONMENTAL DECISION MAKING 15, 17 (2004)

<sup>&</sup>lt;sup>15</sup> I. Linkov, F.K. Sattersstrom, et al., From Comparative Risk Assessment to Multi-Criteria Decision Analysis and Adaptive Management: Recent Developments and Applications, 32 Envt. International 1072, 1075-76 (2006).

<sup>&</sup>lt;sup>16</sup> *Id*; Brian J. Grelk, *et al.*, *Making the CERCLA Criteria Analysis of Remedial Alternatives More Objective*, Remediation 87 (Spring 1998).

engage in evaluation and decision making without use of MCDA so as to develop such an understanding. Ultimately, with enough direct experience with alternatives evaluation, the agency should select one or more appropriate MCDA models.

## Roles of Relevant Parties in Alternatives Analysis

Beyond establishing the substantive standards for alternatives analysis, the regulation must also determine the administrative process to be followed in evaluating chemicals in consumer products and their alternatives. The process should be driven by accepted principles of risk governance, including transparency and the opportunity for meaningful public participation. Of particular importance in this context, however, are the relative roles of the manufacturer and DTSC in the alternatives analysis process. Given the relative resources, knowledge-bases and capacities of manufacturers and the agency, the process should be akin to that used in typical permitting programs, as described below.

DTSC would establish the protocols and standards to be followed in performing alternatives analysis, including the data generation and quality requirements, the attributes to be considered and the relevant metrics, the weights to be applied, and the controlling decision rules. The manufacturers would be legally responsible in the first instance for identifying potential alternatives and for collecting, generating and evaluating the data concerning the baseline chemical/product and the alternatives. DTSC would retain oversight authority over the manufacturer's analysis throughout the process, and ultimately the manufacturer would submit a proposed alternatives analysis to DTSC for review and approval. Based upon its review of the alternative analysis, DTSC would make the final determination of whether a safer viable alternative is available. If the alternative analysis is incomplete or inadequate, DTSC could require correction or complete the analysis itself.

While the manufacturer would be legally responsible for preparing and submitting a proposed alternatives analysis, the regulation should mandate that the manufacturer retain an independent third party consultant certified by DTSC as qualified to perform the work.<sup>17</sup> The certification requirement will 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

<sup>&</sup>lt;sup>17</sup> 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).

often come from outside the existing manufacturer.<sup>18</sup> To protect both the substantive evaluation and the legitimacy of the process, the alternatives analysis work must be conducted by a neutral party without a financial interest in its outcome.<sup>19</sup> Moreover, by requiring use of independent third party alternatives analysis, the program will encourage innovation. Outside firms are more likely to invest in the development safer alternatives knowing their innovation will be evaluated in a fair and object matter. This, in term will motivate the regulated manufacturer to develop safer substitutes in-house or risk losing market share.

Stakeholder input is also essential throughout regulatory implementation to assure the agency appropriately considered stakeholder values. There will undoubtedly be many decision-points along the way in the regulatory process, from development of methods and protocols of general application through review of alternative analyses to crafting of product-specific regulatory responses. DTSC must systematically integrate meaningful public participation into each of these decision points.

## Regulatory Response (DTSC)

After an alternatives evaluation is complete, DTSC must determine the regulatory response, if any, that best limits exposure or to reduce the level of hazard posed by the relevant chemicals of concern.<sup>20</sup> In some cases, that response may be to phase-out or ban the chemical of concern in the particular consumer product. In other cases use restrictions, notifications or other responses may be more appropriate, while in still other cases a combination of responses may be needed. For example, suppose that a commercially viable alternative, while safer than the baseline product, still presents significant hazards. The regulatory response might be a phase out of the baseline product, coupled with use restrictions and product labeling for the alternative.

The statute provides no express direction for selecting regulatory responses beyond the explicit goals of limiting exposure or reducing the level of hazard. However, the statute's strong focus on alternatives analysis indicates that adoption of viable safer alternatives is the preferred mechanism for achieving those goals. The statute identifies eight specific types of response actions. Taking into account the implicit preference for adoption of safer, viable alternatives, the types of response actions set out in Section 25253(b) (1)-(8) can be linked to several generic alternatives analysis outcomes as expressed in Table 2.

<sup>19</sup> 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.

<sup>&</sup>lt;sup>18</sup> 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).

<sup>&</sup>lt;sup>20</sup> A.B. 1879, Section 25253(a)(1).

Alternatives Analysis Outcome	Regulatory Response
<ul> <li>I. Safer alternative stablished as viable</li> <li>II. Where: <ul> <li>No safer viable alternative for certain use, or</li> <li>Safer viable alternative viable but with residual hazard, or</li> <li>III., below</li> </ul> </li> </ul>	<ul> <li>For baseline CoC: Prohibiting the use of the chemical of concern in the consumer product. (5)</li> <li>For Alternative with residual hazard: See below</li> <li>As appropriate for CoC and/or alternative: <ul> <li>Prohibiting the use of the chemical of concern in the consumer product where the hazards associated with the product outweigh the social utility of the product. (5)</li> <li>Imposing requirements on the labeling or other type of consumer product information. (3)</li> <li>Imposing a restriction on the use of the chemical of concern in the consumer product. (4)</li> </ul> </li> <li>Imposing requirements that control access to or limit exposure to the chemical of concern in the consumer product. (6)</li> <li>Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists. (8)</li> </ul>
III. Data missing for complete alternatives assessment	Imposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives,(2) and, as appropriate, response from II., above
IV. For all CoC and alternatives	As appropriate, imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product. (7)

Table 2: Relationship Between Alternatives Analysis Outcomes and RegulatoryResponse

This is not to suggest that identification of a safer viable alternative will invariably trigger immediate prohibition of the baseline chemical/product. First, in many cases a variety of factors may support a gradual phase-out rather than an abrupt ban. For example, while the alternative may be available, time may be required to develop the production or distribution capacity to fill the expanded market demand. Likewise, in other cases, a phase out over time would provide small businesses the ability to recover their investment in the prior technology.<sup>21</sup> In setting the phase-out period, DTSC will balance the need for a gradual elimination against the health and environmental impacts of delay, taking into account expected effect of potential interim risk management options.

Second, while there is a strong preference for prohibition or phase-out of a baseline chemical/product where a safer viable alternative exists, in some cases, that preference may give way to other compelling factors not otherwise considered in the

<sup>&</sup>lt;sup>21</sup> Timothy F. Malloy and Peter Sinsheimer, *Innovation, Regulation and the Selection Environment*,57 Rut. L. Rev. 183 (2004).

alternatives analysis. For example, compelling factors may exist where DTSC finds on the basis of substantial evidence that state or federal law restricts the use of the alternative in some way or that severe economic dislocation would occur.<sup>22</sup> In such cases, the prohibition or phase-out may be postponed. Here again, in making such a determination, DTSC would consider the health/environmental impacts and the effectiveness of other response actions available under the statute.

## <u>Timeline</u>

Given the broad scope of AB 1879 and the innovative regulatory features it involves, implementation of the statute requires development of significant new capacities within government and the private sector. To support the development of those capacities, implementation should move forward in three phases.

Phase one—lasting two years—would focus on data collection and development of alternatives analysis capacity. Regarding data collection, during phase one DTSC would identify chemicals of concern (by name or by characteristic as described above) and collect relevant data using standardized data submission requirements and forms.<sup>23</sup> During that process, and using available information, DTSC would also identify a small subset of chemicals of concern to undergo the first round of alternatives analysis. DTSC would collaborate with qualified third parties having experience in alternatives analysis to develop alternatives analysis methods and standards, to develop a program for certification of independent third party alternatives analysts, and begin alternatives analysis on the first set of targeted chemicals of concern.

Phase two—also two years in length—would build upon the groundwork laid in phase one. Based upon the data collection begun in Phase one, DTSC would complete its prioritization of chemicals of concern, and develop a schedule for submission of future rounds of alternatives analyses reflecting those priorities. The first round of alternatives analyses would be completed, and used by DTSC to support appropriate regulatory responses. Based upon the lessons learned from the first round of analyses, DTSC would modify the its alternatives analysis methods as necessary and perhaps identify one or more multi-criteria decision analysis models for future analyses. By the end of phase two, DTSC will implement the third party certification process and begin to certify analysts.

Phase three would begin full scale implementation of the program, in accordance with the prioritization schedule developed by DTSC. By developing appropriate methods and program procedures through a phased approach, DTSC will create the necessary infrastructure resulting in an effective regulatory process for phasing out hazardous chemicals in consumer products and phasing in the safest alternatives.

<sup>&</sup>lt;sup>22</sup> The term severe economic dislocation has the meaning set out in 209(a) of the Public Works and Economic Development Act of 1965.

<sup>&</sup>lt;sup>23</sup> As appropriate, DTSC could supplement the standard data requirements with chemical-specific or usespecific testing and information submission requirements.