The Safer Consumer Products Regulation – California's Green Chemistry Initiative

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The California Department of Toxic Substances Control ("DTSC" or the "Department") has proposed what should be the final version of the California Safer Consumer Products Regulation (the "Regulation"), also known as California's Green Chemistry regulation. While the current version of the Regulation is subject to a public comment period until February 28, 2013, the consensus expectation is that DTSC's extensive work with business groups, health care advocates, and environmentalists since the last failed revision has yielded a regulation that will become law, with an expected effective date of July 1, 2013. The Regulation promises to significantly impact commerce in California, and has the potential to transform the national landscape as the first regulation codifying a green chemistry approach that requires extensive alternatives analyses and end-of-life product management.

This paper provides an overview of the Regulation as currently proposed, and the compliance obligations that the Regulation places on manufacturers, importers, assemblers, and retailers. When the Regulation is approved by the Department, we will provide updates regarding any changes in the final version.

EXECUTIVE SUMMARY

The Regulation contains four components: (1) DTSC's identification of "Candidate Chemicals"; (2) DTSC's identification of "Priority Products" containing those Candidate Chemicals; (3) "Responsible Entity" (manufacturer, importers, assemblers, or retailers) notification and alternatives analysis; and (4) DTSC's imposition of regulatory responses to address hazards of the product or alternatives.

The Regulation draws its initial Candidate Chemical list from a defined list of existing state, federal, and international laws and regulations that identify substances with hazard traits or environmental or toxicological end points, including carcinogens, reproductive toxins, mutagenic toxins, neurotoxins, endocrine disruptors, toxic air contaminants, and water pollutants. Currently, there are approximately 1,200 Candidate Chemicals. The Regulation authorizes DTSC to add new Candidate Chemicals after the publication of the initial list.

DTSC will identify Priority Products by assessing potential human, animal, or environmental exposure to Candidate Chemicals from a product during the product's lifecycle. DTSC will also assess the potential for that exposure to have widespread adverse impacts on public health or the environment. The initial list will consist of products that contain Candidate Chemicals that have been the focus of regulation by various California agencies. The initial list may contain no more than five Priority Products. Using these criteria, DTSC has narrowed the universe of Candidate Chemicals down to approximately 230 for the first Priority Products list. The Regulation requires DTSC to issue a work plan to develop the initial list of Priority Products within one year of its effective date, and to finalize the list of Priority Products over the next three years. Once a Candidate Chemical is associated with a Priority Product, it is referred to as a Chemical of Concern ("COC"). DTSC must develop a new work plan to designate new products over the following three years within one year of the expiration of the prior plan, resulting in a four-year product listing process.

Once DTSC lists a Priority Product, "Responsible Entities" (starting with manufacturers, but potentially including others who place the product into the stream of commerce in California) must notify DTSC of the product and begin the assessment process. A Responsible Entity may either cease new distribution of the product in California, remove the COC from the product, or begin an alternatives analysis. If choosing either of the first two options, the Responsible Entity must notify DTSC and certify the removal. While the Regulation places the compliance obligation on manufacturers, downstream entities are responsible to comply if the manufacturer does not, either by stepping into the shoes of the manufacturer, or ceasing new orders of the product in California. The Regulation contains no sell-through deadline for existing inventory already in stores.

The alternatives analysis process is divided into two phases: the preliminary alternatives analysis ("Preliminary AA") and the final alternatives analysis ("Final AA"). The Preliminary AA seeks to identify potential alternatives, based on a variety of factors, including product performance requirements, legal requirements, and feasibility. If the Responsible Entity completes the Preliminary AA and determines no alternative is less hazardous than the current product, it may conclude the AA process. However, it must notify consumers of the COC in the product and initiate research to develop alternatives. If the Responsible Entity completes the process and determines some alternatives exist, it must submit the Preliminary AA to DTSC, get DTSC approval, and then complete the Final AA process.

The Final AA process involves the quantitative and qualitative assessment of the alternatives as compared to the original product. The assessment includes comparison of health and environmental impacts, product function and performance, economic impacts, and exposure factors. Based on the results of the Final AA, the Responsible Entity must develop a work plan to implement the selected alternatives. DTSC must review and approve the Final AA and work plan.

In conjunction with approval of the Final AA, DTSC may also impose regulatory responses, which may include consumer notification of the COC or alternative, use restrictions, prohibitions, safety measures and administrative controls, end-of-life management requirements, and research and development requirements.

DTSC will enforce the Regulation primarily through publication of non-compliant Responsible Entities and products on its website, but it may also initiate enforcement actions under the hazardous waste provisions of the California Health & Safety Code, which authorize criminal and civil penalties of up to $25,000 per violation.

I. RELEVANT BACKGROUND

The Regulation has been a work in progress for several years, as DTSC issued its first proposed regulation in June 2010, followed by several sets of revisions that drew criticism from both industry and consumer advocates. On July 27, 2012, DTSC issued a substantially revised version of the regulation that addressed much of the criticism. Following public comment to the July 2012 draft, DTSC performed a final round of edits containing additional substantial revisions, issuing the current proposal on January 29, 2013. The public comment period ends on February 28, 2013. Assuming DTSC does not revise the Regulation following review of the public comments, DTSC is

targeting an effective date of July 1, 2013. Although we expect that this will be the final version, we anticipate legal challenges to the Regulation that may result in further delay.

II. THE REGULATION

The Regulation contains four components. It first requires DTSC to identify Candidate Chemicals, and then requires DTSC to identify Priority Products containing those Candidate Chemicals. Once a Candidate Chemical is associated with a Priority Product, it becomes a COC. After DTSC has published the list of Candidate Chemicals and Priority Products, the Responsible Entities – the manufacturer or importer, with resort to assemblers and retailers only if the other two fail to comply – of these products must notify DTSC of the Priority Product and perform an alternatives analysis to identify alternative approaches that can reduce or eliminate the amount of, or exposure from, the COC in the product. An alternative may be a reduction, elimination, or substitution of a COC, adjustment of the manufacturing process, redesign of a product, or any other change that reduces adverse public health and environmental impacts or exposures. Assemblers and retailers may cease ordering the product for sale in California if they wish to opt out of the alternatives analysis process. Finally, DTSC may impose regulatory responses (whether using an alternative or not), including notice to consumers, restriction of COCs, prohibition of the COC, engineered safety measures and administrative controls, end-of-life management, and research and development to develop safer alternatives.

A. Candidate Chemicals

The Regulation draws its initial Candidate Chemical list from a number of existing state, federal, and international laws and regulations that identify substances exhibiting a hazard trait and/or environmental or toxicological end point. 22 Cal. Code Regs., § 69502.2(a). These include carcinogens, reproductive toxins, mutagenic toxins, neurotoxins, endocrine disruptors, toxic air contaminants, and water pollutants. For example, chemicals listed under California's Proposition 65, the EU's Annex VI, and the State of Washington's Persistent, Bioaccumulative, and Toxic Chemicals list, among many others, will be included in the initial listing. *Id.* If finalized, the Regulation will declare more than 1,200 chemicals to be Candidate Chemicals based on their identification by these existing lists.

After publishing the initial list, DTSC may identify additional Candidate Chemicals by analyzing a number of factors, including hazard traits, environmental or toxicological endpoints, and adverse impacts on health and the environment, sensitive populations (i.e., schools, hospitals, elderly care facilities), environmentally sensitive habitats, and endangered and threatened species. *Id.*, § 69502.2(b). The Regulation also contains a petitioning process to add or remove Candidate Chemicals, but a party may not petition to remove a Candidate Chemical as long as it remains on any of DTSC's source lists. *Id.*, § 69504.

B. Priority Products

The Regulation applies to any consumer product containing Candidate Chemicals. *Id.*, § 69503.1. DTSC may designate any such product as a Priority Product if the product potentially

exposes any human or aquatic, avian, or terrestrial animal or plant organism to the Candidate Chemical in the product during the product's lifecycle, and the exposure creates the potential for a significant widespread adverse impact on public health or the environment. *Id.*, § 69503.2. DTSC will evaluate not only the adverse impacts of products during their use, but also during their manufacture and after being discarded by consumers. *Id.*

In assessing exposures and adverse impacts, the Regulation requires that the Department consider the product and chemical combination under a number of factors, including hazard traits, environmental or toxicological end points, aggregate effects, cumulative effects with other chemicals, physiochemical properties, environmental fate, impacts on the populations at risk (human or otherwise), and the Candidate Chemical's potential to degrade, react, or metabolize into another Candidate Chemical, as well as end of life impacts and any current regulation by other California or federal laws that provides adequate protection. *Id.*, § 69503.3(a). The Department must also consider the potential for exposure based on market presence, statewide sales, and the target audience, as well as use of the product (household and/or workplace presence). *Id.*, § 69503.3(b).

The Regulation requires that the initial list of Priority Products contain Candidate Chemicals that appear on the chemical lists referenced in Section 69502.2(1) and meet the requirements listed in Section 69502.2(2). *Id.*, § 69503.6. In sum, these are chemicals that appear on the major regulatory lists of carcinogens, reproductive toxins, neurotoxins, and persistent, bioaccumulative toxins, including Proposition 65, REACH, and EPA chemical lists, and have been focused on by California public health agencies, including the California Department of Public Health, the State Water Resources Control Board, and the Office of Environmental Health Hazard Assessment. They also include chemicals identified on the Centers for Disease Control and Prevention's national report on human exposure, and chemicals identified for priority action under the Oslo and Paris Conventions for the protection of marine environment. Based on these criteria, DTSC has narrowed the universe of Candidate Chemicals down to approximately 230 for the initial Priority Products list.

The initial Priority Products list must contain no more than five products, although it may identify more than one COC for each product. *Id.*, § 69503.6. DTSC must publish its initial list of proposed Priority Products for public review and comment within 180 days of the effective date of the Regulation. *Id.* Within one year of the effective date, the Department must issue a work plan outlining the Priority Products it intends to list over the subsequent three-year period.[1] *Id.*, § 69503.4. To add new Priority Products after the initial list, DTSC must issue new work plans within one year of the expiration date of the prior work plan product listing. *Id.* Thus, the product prioritization process will function on a four-year cycle. The Regulation requires the Department to review and revise the Priority Product list at least every three years. *Id.*, § 69503.5.

[1] The Regulation requires the listing of "complex durable products" on a component basis, with no more than 10 components listed in any three-year period. *Id.*, § 69503.4(c). A complex durable product must have at least 100 manufactured components, be commonly understood to last more than five years, and not be a single-use product. *Id.* The Regulation excludes children's products and products worn or applied to the human body from this exception. *Id.*

C. Responsible Entity Notification and Alternatives Analyses

1. Responsible Entity Notification

For Priority Products, the Department must provide a detailed list of the product and chemical combination at issue. *Id.*, § 69503.5. After the Department publishes the list, Responsible Entities must provide a Priority Product notification to DTSC within 60 days of the listing (unless DTSC provides a later compliance date). *Id.*, § 69503.7. The notification must identify the Responsible Entity, including whether it is the manufacturer, importer, assembler, or retailer. *Id.* The notification must also identify the product and provide a description, including brands and product names. *Id.* For Priority Products coming onto the market after the initial listing, the Responsible Entity must provide the notification within 60 days of the product entering the stream of commerce in California. *Id.*

As noted above, the Regulation places the primary responsibility for compliance on product manufacturers, but it will proceed down the supply chain until it finds a Responsible Entity. *Id.*, § 69501.2. If the product manufacturer does not comply, the Department will provide notice of non-compliance to the importer, followed by the assembler or retailer. *Id.* While only the manufacturer must comply with the Regulation, in the event of manufacturer non-compliance, the importer, assembler, and retailer must cease new distribution of the product in the stream of commerce in California or step into the shoes of the manufacturer. *Id.* Existing inventory already on store shelves will not be impacted, and the Regulation sets no sell-through deadline. If the downstream entities cease new distribution and ordering of the product for the California market, they must provide certifications attesting to the removal of the product from sale in the state. *Id.* DTSC will use its website as the primary means of notice of failure to comply.

2. The Alternatives Analysis Process

Once the Department lists a Priority Product, a Responsible Entity has three options: (1) cease new distribution of the Priority Product in California; (2) remove the COC from the Priority Product; or (3) enter the alternatives analysis process.[2]

If the Responsible Entity opts to cease new distribution of the Priority Product in California or remove the COC from the Priority Product, it must provide notification to DTSC that identifies the action it will take and the rationale for so doing. *Id.*, § 69505.2. In all cases, the Responsible Entity must cancel any existing orders, notify upstream or downstream customers as applicable, and certify that it has taken all actions within 90 days of notice to the Department. *Id.* As noted above, existing inventory already on store shelves will not be impacted, and the Regulation sets no sell-through deadline.

[2] The Regulation permits the use of an "Alternate Process AA" if the alternative provides all the information the Regulation requires. *Id.*, § 69505.4. However, the Department must approve of the use of the alternative approach. *Id.* A Responsible Entity may also use a previously completed alternatives assessment, as long as it provides all necessary information on the Priority Product at issue. *Id.* The Responsible Entity may supplement a previously completed alternatives assessment with information on the current Priority Product to fill in any gaps. *Id.*

If the Responsible Entity removes the COC from the Priority Product, it must also include in its notice to DTSC testing protocols to ensure it has removed the COC. *Id.* If the Responsible Entity is removing the COC and replacing it with another chemical, it must provide detailed information on the replacement chemical, its use in the product, and all public health and environmental hazard information. *Id.* A replacement chemical must not be a Candidate Chemical, or it must already be used to manufacture the same product in the same way, either by the Responsible Entity or a similar manufacturer. *Id.*

If the Responsible Entity opts to pursue the alternatives analysis process, it must undertake two phases of analysis: (1) initial product evaluation that leads to the development of a Preliminary AA; and (2) development of a Final AA.

The Regulation exempts COCs in a Priority Product that are contaminants below the Alternatives Analysis Threshold ("AAT") or Practical Quantification Limit ("PQL") for that chemical. *Id.*, § 69505.3. The Regulation defines a contaminant as a chemical that is not intentionally added, and is either a naturally occurring contaminant in the raw material from which the product is made, found in air or water frequently used as a processing agent or ingredient to manufacture the product, commonly found in recycled material used to manufacture the product, or a processing agent, reactant, by-product, or intermediate used during manufacture that is not intended to remain in the finished product. *Id.*, § 69501.1(a)(26). The Responsible Entity bears the burden of proof to demonstrate that a COC is a contaminant. *Id.*, § 69505.3. The PQL is the lowest concentration of a chemical that can be reliably measured within specified limits. *Id.*, § 69501.1(a)(12), (52). The PQL may vary as between Responsible Entities, products, and chemicals, and the Responsible Entity must determine the PQL and provide evidence supporting its determination to DTSC. DTSC must assess and approve the determination for the exemption to apply. The AAT is equal to the PQL unless DTSC issues a specific AAT with the Priority Product listing.

3. The Preliminary AA

Within 180 days of the Department's listing (or entry into the California stream of commerce), the Responsible Entity must submit a Preliminary AA. The Preliminary AA consists of the first four stages of the Alternatives Analysis process, including:

(1) Identification of Priority Product requirements and COC functions;
(2) Identification of alternatives;
(3) Comparison of the existing COCs to alternatives;
(4) Consideration of other factors.

The first step in the Preliminary AA process is identification of the Priority Product requirements that any alternative must also meet, including functional, performance, and legal issues regarding the Priority Product. *Id.*, § 69505.5(a). The analysis must then determine whether the COC at issue is necessary to achieving any of those requirements. *Id.* If the COC is not necessary

to the Priority Product's requirements, the Regulation suggests that the Responsible Entity should consider removing the COC without replacing it. *Id.*

In the second step, the Responsible Entity must identify alternatives to the COC. *Id.*, § 69505.5(b). To do so, the Responsible Entity must research and evaluate alternatives, including COC replacement, product redesign, or manufacturing changes, depending upon the type of exposure posed by the Priority Product life cycle. *Id.* For example, if the exposure risk only occurs during the manufacturing process, adjustments to the manufacture of the product may alleviate the adverse effects.

The third step in the process only applies to alternative replacement chemicals. *Id.*, § 69505.5(c). It consists of comparing the existing COC hazard profile against the replacement chemical. *Id.* If the alternative chemicals pose the same or greater adverse effects as the COC, the alternative need not be considered further. *Id.*

In the fourth step, the Responsible Entity considers other factors and information that impact the alternatives analysis, such as product function, economic impacts of adoption of alternatives, and other factors unrelated to health and safety. *Id.*, § 69505.5(d). If these factors render an alternative impractical, the Responsible Entity may eliminate it as an option. *Id.*

If the Responsible Entity completes the first four steps of the Preliminary AA process and determines that no functionally acceptable and technically feasible alternative is available, it may submit an Abridged AA containing the findings of the first four steps and continue to produce and sell the Priority Product in its present form. *Id.*, § 69505.4. However, the Regulation requires Responsible Entities to implement mandatory regulatory responses, including notification to consumers of COCs in the Priority Product, which must be both on the Responsible Entity's website and at the point-of sale. *Id.* The Responsible Entity must also initiate research and development projects or challenge grants to design safer alternatives, improve the performance of safer alternatives, decrease the cost of safer alternatives, or increase the market penetration of safer alternatives. *Id.* The Responsible Entity must include an implementation timeline for these regulatory responses in the Abridged AA. *Id.*

If the Responsible Entity completes the first four steps and has identified possible alternatives, it must then assemble the information from the first four steps into the Preliminary AA report for submission to DTSC. *Id.*, § 69505.5(e). The Preliminary AA report should also outline remaining steps for completion and submission of the Final AA. *Id.* DTSC will publish Preliminary AA reports on its website for public review and comment. *Id.*, § 69501.5. Following public review and comment, DTSC will either approve the Preliminary AA or notify the Responsible Entity of deficiencies and request additional information. *Id.*, § 69505.8. The Responsible Entity must submit this additional information to obtain approval to move on to the next phase. *Id.*

4. The Final AA

After receiving approval of the Preliminary AA report from the Department, the Responsible Entity must undertake the comparison of the Priority Product and COC to the alternatives. *Id.*, §

69505.6. The first step in this process is identifying the factors relevant to comparison. *Id.*, § 69505.6(a). The Regulation specifies consideration of four factors: (1) adverse health and environmental impact factors; (2) product function and performance factors; (3) economic impacts; and (4) exposure factors. *Id.* The Regulation requires that DTSC issue guidance on the AA process once the Regulation is adopted. *Id.*, § 69505. Responsible entities must only assess factors that will make a material difference between the original and alternatives.

For adverse health and environmental impact factors, the Responsible Entity must evaluate the COC and its alternatives for adverse environmental impacts, adverse public health impacts, adverse waste and end-of-life effects, environmental fate, materials and resource consumption impacts, physical chemical hazards, and physicochemical properties. *Id.*, § 69505.6(a).

For the product function and performance factors, the Responsible Entity must evaluate the useful life of the product with the existing and alternative chemicals, the function and performance of the Priority Product with each alternative, and the functional, technical, and economic feasibility of each alternative. *Id.*

For economic impacts, the Responsible Entity must evaluate the COC and its alternatives for public health and environmental costs, including costs to governmental agencies and nonprofit organizations that manage waste, environmental cleanup, remediation, and/or protection of natural resources, water quality, and wildlife. *Id.*

For exposure factors, the Responsible Entity must evaluate the COC and its alternatives to compare the quantities of chemical needed to manufacture the Priority Product with an alternative, as well as the quantities of chemical that would be placed into the stream of commerce in California as a result of the manufacture of the Priority Product. This assessment must include aggregate effects, cumulative impacts of the alternative with other chemicals, and impacts on human and wildlife populations. *Id.*

In the second step, the Responsible Entity actually performs the comparison of the COC and its alternatives using the factors chosen above. *Id.*, § 69505.6(b). The Responsible Entity must use available quantitative information and analytical tools, supplemented by qualitative information as necessary. *Id.*

After completing the comparison, the third step requires the Responsible Entity to incorporate any other information necessary to compare the products, such as product function, economic impacts of adoption of alternatives, and other factors unrelated to health and safety, to the extent these issues are not captured by the previous steps. *Id.*, § 69505.6(c).

In the fourth step, the Responsible Entity determines whether to retain the Priority Product in its existing form, or to choose an alternative. In either case, the analysis performed in the previous steps must be consistent with the ultimate decision. *Id.*, § 69505.6(d).

Finally, the Responsible Entity must prepare the Final AA report for submission to DTSC. *Id.*, § 69505.6(e). The Final AA must explain the selection of alternatives for comparison, the

rationale for selecting those alternatives, and the rationale for screening out other alternatives. *Id.* It must also explain what factors the Responsible Entity used for comparison, the basis for using them, and provide information to support these conclusions. *Id.* The Final AA must also include a detailed plan for implementing the selected alternatives, including key milestones and dates for implementation. *Id.*

D. DTSC Assessment and Adoption of Regulatory Responses

In evaluating a Final AA, the Department must consider specific criteria, including the timeliness of the report, whether the Responsible Entity addressed all requirements, the consistency of the analysis and conclusions, and the reliability of the information used. *Id.*, § 69505.8. Within 60 days of receiving the Final AA report, DTSC will notify the Responsible Entity of the report's completeness. *Id.* If issuing a notice of deficiency, the Department will identify what is needed, and the Responsible Entity must provide supplemental information. *Id.* Once the Department approves the Final AA, the Responsible Entity must implement the plan it has outlined.

In addition to requiring the use of the alternatives outlined in the Final AA, DTSC may also require that the Responsible Entity implement certain regulatory responses, including: (1) notice to consumers; (2) use restrictions; (3) prohibitions; (4) safety measures or administrative controls; (5) end-of-life management requirements; and (6) green chemistry research and development. The Department may require regulatory responses when it determines they are necessary to protect public health and/or the environment. *Id.*, § 69506.

In selecting regulatory responses, the Department must consider whether alternatives and responses are functionally acceptable, technically feasible, and economically feasible. *Id.* DTSC must also consider public health and environmental protection, and the effectiveness of the regulatory response on adverse impacts, including waste and end-of-life effects. *Id.* The Department must also consider the ability of consumers to understand and act upon any regulatory response involving consumer action. *Id.* Finally, DTSC must consider any adverse impacts on sensitive resources or subpopulations, existing federal or state legal requirements, the costs of the regulatory response, the ability of Responsible Entities to comply, the costs to the government and public agencies, the administrative burden in overseeing the response, and the ability to enforce. *Id.*

The Department will issue regulatory response requirements no later than 90 days after issuing a notice of compliance or notice of disapproval of a Final AA. *Id.*, § 69506.1. DTSC will publish the proposed regulatory response for public review and comment. *Id.* Within 30 days of the Department's final determination of regulatory responses, Responsible Entities must provide notice of required regulatory responses to the other entities in the supply chain for the Priority Product, except for the ultimate purchaser. *Id.*, § 69506.10. The Responsible Entity must provide the Department with a copy. *Id.* Responsible entities must also provide notice to DTSC upon implementing a regulatory response. *Id.*

1. Notice to Consumers

For any Priority Product that has no alternative selected or will continue to be sold while the Responsible Entity develops an alternative, and for selected Priority Products that will use a Candidate Chemical as an alternative, the Regulation mandates a notice to consumers as a regulatory response. The notice must provide specified information to consumers *prior* to purchase. *Id.*, § 69506.3. This includes a list of any COCs or replacement Candidate Chemicals in the Priority Product and the hazard traits and environmental or toxicological end points for these chemicals. *Id.* The Regulation also requires that the Responsible Entity inform consumers of hazardous waste disposal requirements, if applicable; safe handling and storage information; and end-of-life management information, if applicable. *Id.* Responsible entities must make the information available to consumers on the company's website. *Id.* Responsible entities must also make the information available to consumers on the product packaging without requiring consumers to break the seal, or on a prominent point-of-sale display. *Id.*

2. Use Restrictions

The Regulation authorizes the Department to restrict the use of COCs or replacement Candidate Chemicals in Priority Products, including restrictions on the concentration of the chemical, the use of the chemical, the form in which the product is sold, who may purchase or use the product, or any other restriction that reduces the potential for exposure, as well as requirements for training of product purchasers or users. *Id.*, § 69506.4. The Department may mandate these restrictions even if the Responsible Entity is implementing an alternative.

3. Prohibitions

The Regulation also authorizes DTSC to prohibit the distribution or sale of a Priority Product in California, based on the Department's determination that a more appropriate alternative is available that is functionally acceptable, technically feasible, and economically feasible. *Id.*, § 69506.5(a). The Department may require this regulatory response even if the Responsible Entity seeks to implement an alternative. *Id.*

The Department may also prohibit the sale of a Priority Product in California even if there is no alternative. *Id.*, § 69506.5(b). Prior to doing so, the Department must provide the Responsible Entity with an opportunity to submit information demonstrating that the overall benefit to public health, environmental impacts, and/or social utility of the product outweighs the overall adverse impacts. *Id.* The Responsible entity may also submit technical information demonstrating that restrictions on the use of the product will adequately protect public health and the environment. *Id.*

4. Safety Measures or Administrative Controls

The Regulation authorizes the Department to require a Responsible Entity to develop safety measures that contain or control access to the COC or alternative Candidate Chemical, and/or limit exposure to the COC or alternative Candidate Chemical. *Id.*, § 69506.6. The Department may require this regulatory response if data demonstrates that exposure occurs in a particular

subpopulation or in indoor buildings or other enclosed environments. *Id.* The Department may also require this measure if proper handling would decrease the likelihood for release or exposure. *Id.*

5. End-of-Life Management Requirements

For Priority Products that are sold to consumers as finished products, but must be managed as a hazardous waste at the end of their useful lives, the Regulation mandates end-of-life management. *Id.*, § 69506.7(a). A Responsible Entity may satisfy this requirement individually, or in concert with other manufacturers through the formation of a stewardship organization. *Id.*, § 69506.7(b). The Department must approve any stewardship plan. *Id.*, § 69506.7(c)(1).

Stewardship plans must include identification and description of the collection system employed, such as the steps that the entity/organization will take to ensure compliance with all applicable federal, state, and local laws. *Id.*, § 69506.7(c)(2). If individually managed, the Responsible Entity must provide a financial guarantee to cover future costs. *Id.*, § 69506.7(c)(2)(G). If managed by a stewardship organization, the stewardship plan must identify how each participating member will contribute to fund the organization. *Id.*

A stewardship plan must also include program performance goals that quantify approaches to improving capture rate, recyclability, and public education, outreach, and communication. *Id.*, § 69506.7(c)(2)(H). Finally, a Responsible Entity/organization must develop a stewardship plan in consultation with retailers and owners and operators of prospective collection sites. *Id.*, § 69506.7(c)(3). The plan must provide for collection mechanisms, including compensation to participants in the collection process. *Id.*

The Department will publish product stewardship plans for public review and comment. *Id.*, § 69506.7(c)(4). A Responsible Entity with Priority Products subject to stewardship plans must submit an annual report to the Department, which the Department will publish. *Id.*, § 69506.7(c)(5). The report must include the quantity of products sold into California over the prior year, as well as the quantity of products recovered over the same one-year period. *Id.* A manufacturer may seek an exemption, if it can prove that the product stewardship plan is not feasible. *Id.*

6. Green Chemistry Research and Development

For Priority Products in which the Responsible Entity selects no alternative, or when the alternative includes other Candidate Chemicals, the Department may require the Responsible Entity to initiate a research and development project or challenge grant program to develop safer alternatives, improve the performance of safer alternatives, decrease the cost of safer alternatives, and/or increase the market penetration of safer alternatives. *Id.*, § 69506.8.

E. Enforcement

The Regulation authorizes the Department to publish a "Failure to Comply" list on its website. *Id.*, § 69501.2. The Failure to Comply list will include the Responsible Entities and the product. In addition, DTSC may initiate enforcement actions, including penalties and fines, pursuant to the hazardous waste control provisions of the Health & Safety Code (Sections 25180-196). These provisions provide for criminal and civil penalties of up to $25,000 per violation.

F. Miscellaneous

1. Audits

The Regulation permits the Department to audit any information submitted by a Responsible Entity. *Id.*, § 69508. The Regulation requires that Responsible Entities maintain records supporting the AA process for three years from the listing of the Priority Product (or the entry of the product into the California market, if subsequent to the listing). *Id.*, § 69501.3.

2. Trade Secret

To the extent a Responsible Entity makes a trade secret claim in connection with information submitted to the Department, the Department will request detailed information to support the claim. *Id.*, § 69509. This includes information on whether the information is known by employees or others involved in the business who are not bound by nondisclosure agreements, the extent to which information is known outside the business, measures taken to restrict access to and safeguard the information, the value of the information, the amount of effort or cost involved in developing the information, and a description of the potential harm caused by disclosure, as well as others. *Id.* The Responsible Entity must submit documentation to DTSC to support the claim. *Id.* However, the Regulation expressly exempts hazard trait information from trade secret protection, although a chemical being considered as an alternative that is in the patent process may be masked until the patent is granted or denied. *Id.* The Regulation allows for a Responsible Entity to seek judicial review of the Department's determination of a trade secret claim, during which time the Department will not disclose such information. *Id.*, § 69509.1.

3. Exemptions from Regulatory Responses

A Responsible Entity can seek an exemption from a regulatory response if it can show that the regulatory response required by DTSC conflicts with other state or federal law, or duplicates another state law without additional benefits to the public. *Id.*, § 69506.9.

4. Challenges to DTSC Decisions

The Regulation provides for administrative dispute resolution, including informal dispute resolution, administrative appeal, and appeals to the Director of DTSC. *Id.*, § 69507. Responsible entities must request review within 30 days of final notification from the Department. *Id.*, § 69507.4. If no resolution is obtained, a challenger could then resort to the standard judicial challenges to agency action.

III. CONCLUSION

More than five years after then-California Governor Arnold Schwarzenegger first signed an executive order launching the green chemistry program in California, it appears that we finally have the detailed framework of the program and are moments away from its approval. The Regulation will be the first-of-its-kind, representing significant challenges to manufacturers, importers, assemblers, retailers, and even consumers. It is unlikely that we will understand the extent of those challenges for years to come.

This White Paper was prepared by Jeffrey B. Margulies (jmargulies@fulbright.com) and William L. Troutman (wtroutman@fulbright.com) from Fulbright's Environmental Practice Group.