

Washington Watch

One Step Closer: California Proposes Safer Consumer Products Regulations

The state's Green Chemistry Initiative spurs game-changing new rules

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The California Department of Toxic Substances Control (CDTSC) is one step closer to implementing the state's Green Chemistry Initiative (GCI), which directs regulators to evaluate safer alternatives to chemicals that are believed to be toxic. CDTSC's latest plan for implementing the GCI is set out in its proposed Safer Consumer Products Regulations, published on July 27, 2012.

These are not "garden variety" chemical regulations that impose a restriction here or there to prevent a perceived risk. Far from it. These regulations are game-changers. They ultimately will transform the way manufacturers select raw materials and make consumer products. As a result, these regulations are likely to influence significantly — and permanently — the way consumer products are conceived, formulated, and distributed.

This "Washington Watch" column summarizes the core elements of the proposed Safer Consumer Products Regulations, highlighting significant changes from prior proposals.

Background: A Preemptive Strategy

In 2008, California adopted "green chemistry" legislation, including Assembly Bill 1879.¹ This statute directed CDTSC to adopt regulations establishing "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." The regulations, which originally were to be issued by January 1, 2011, must prioritize chemicals of concern in consumer products and establish procedures for evaluating safer alternatives to toxic chemicals through a science-based approach.

Under California's Green Chemistry Initiative, the state's Office of

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Environmental Health Hazard Assessment (OEHHA) was tasked with specifying hazard traits, environmental and toxicological endpoints, and other relevant data for inclusion in a state Toxics Information Clearinghouse. CDTSC will use information from the clearinghouse to help identify chemicals of concern in consumer products.

CDTSC's implementing regulations have gone through several iterations, including an initial draft released on June 23, 2010, a revised draft released on November 16, 2010, and an "informal draft" released on October 31, 2011. CDTSC describes the newest proposed regulations as reflecting a "preemptive strategy that reduces the use of toxic substances in the design of products and industrial processes with the aim of creating safer and sustainable products that do not threaten human health or persist in the environment."² CDTSC is correct to use the term "preemptive": The goal of these regulations is not to manage risk, but to prevent it.

Developing a "Chemicals of Concern" List

Within 30 days after the Safer Consumer Products Regulations become effective, CDTSC is required to establish a "chemicals of concern" list. Under the proposed regulations, a chemical of concern is defined as a substance that exhibits a hazard trait or an environmental or toxicological endpoint as identified by OEHHA pursuant to Health and Safety Code Section 25256.1 and that meets one or more of the following criteria:³

- the chemical is identified as exhibiting a hazard trait or an environmental or toxicological endpoint on one or more of 14 different lists already selected by other agencies and organizations — such as California's Proposition 65; the European Commission's 1272/2008, Annex VI, Category 1A and 1B chemicals, identified due to carcinogenicity, reproductive toxicity, and/or mutagenicity; the International Agency for Research on Cancer Groups 1, 2A, and 2B Carcinogens; the United States Environmental Protection Agency (US EPA) Toxics Release Inventory List of Persistent, Bioaccumulative, and Toxic Chemicals; chemicals for which a reference dose or reference concentration has been developed based on neurotoxicity in US EPA's Integrated Risk Information System; and chemicals that are identified as High Production Volume Persistent Bioaccumulating Toxins by the European Union;
- the chemical is identified as belonging to one or more specified types of chemicals (e.g., chemicals for which notification levels have been established by the California Department of Public Health; chemicals for which primary maximum contaminant levels have been established

in California; priority chemicals that are identified under the California Environmental Contaminant Biomonitoring Program).

The latest proposed regulations remove some of the more controversial entries on the “list of lists” from which CDTSC will derive its chemicals of concern. Nonetheless, the proposal still includes a large number of such sources. These include lists identifying chemicals that have been determined to exhibit certain hazard traits (such as carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, endocrine disruption, neurotoxicity, and/or persistent bioaccumulative toxicity), along with exposure indicator lists for water quality, air quality, and biomonitoring.

In October 2011, CDTSC estimated that the chemicals of concern list would include approximately 3,000 chemicals. CDTSC now plans to release a list containing approximately 1,200 chemicals of concern, noting that the difference will reflect the removal of chemicals covered by other regulations (e.g., pesticides), as well as removal of other chemicals determined not to be relevant to consumer products. The current proposal would exclude approximately 500 chemicals now used only in pesticides and drugs. CDTSC notes that these chemicals could be added to the chemicals of concern list in the future if manufacturers begin to use them in products that are not excluded under California Health and Safety Code Section 25251.

Exempt Products

While the proposed regulations do not exempt any chemical *per se*, certain products would be exempt. These include:⁴

- products exempt from the definition of “consumer product” as specified in California Health and Safety Code Section 25251 (e.g., dangerous prescription drugs and devices; dental restorative materials; medical devices; pesticides; food; and packaging associated with dangerous prescription drugs and devices, dental restorative materials, and medical devices); and
- consumer products manufactured or stored in, or transported through, California solely for use out-of-state.

Importantly, the proposed Safer Consumer Products Regulations would apply to businesses placing consumer products into the stream of commerce in California, regardless of the place of manufacture of those products.⁵

An older version of the proposed regulations contained an exemption for products regulated by other laws, as long as those laws provide

protections with respect to the same public health and environmental adverse impacts and exposure pathways addressed by the Safer Consumer Products Regulations. The latest proposal eliminates that exemption. Instead, it provides that CDTSC will “consider” this factor during the product prioritization process.⁶

Older versions of these regulations also contemplated an exemption for nanomaterials. That exemption is not mentioned in the latest proposed regulations. To the extent that regulatory agencies have not yet identified nanomaterials on the lists from which CDTSC will derive its chemicals of concern, however, those nanomaterials will not be subject to the Safer Consumer Products Regulations, at least initially.

Adding or Removing Chemicals of Concern

The proposed regulations establish a process by which CDTSC can identify additional substances as chemicals of concern after considering potential adverse impacts, potential exposures, availability of reliable information, and availability of safer alternatives.⁷

Under the regulations as proposed, any person can petition CDTSC to evaluate a claim that a chemical or product should be listed as a chemical of concern or a priority product. Interestingly, the latest proposal would also add a provision stating that any person may petition to remove a chemical from the chemicals of concern list; “add the entirety of an existing chemicals list;” add or remove a product from the priority products list; or establish or revise an alternatives analysis threshold for a chemical of concern in a priority product.⁸

The proposed regulations continue to provide that CDTSC must “periodically update” the chemicals of concern list to reflect changes to the sources from which the list is drawn.⁹ Specific timing requirements under which CDTSC would have to review and update the chemicals of concern list (e.g., every three years) have been eliminated, however.

Developing a “Priority Products” List

CDTSC will evaluate and prioritize products that contain chemicals of concern in order to develop a list of “priority products” for which alternatives analyses must be conducted. To identify products of high priority, CDTSC will evaluate the potential adverse health and environmental impacts posed by the chemicals of concern in each product based on several factors listed in the proposed regulations (these factors are somewhat similar to those proposed in previous iterations of the regulations):¹⁰

- the potential adverse impacts from the chemical of concern (e.g., hazard traits, environmental fate properties) and potential exposures (e.g., market presence, types of uses, frequency and duration of exposure);
- the “extent of information that is available to substantiate adverse impacts and exposures,” recognizing that “[a]ll other factors being equal, a product for which there is a greater amount of information to substantiate adverse impacts and exposures, relative to other products being evaluated, shall be given a higher priority”; and
- the extent to which other regulatory programs regulate the product.

Previous versions of the regulations required CDTSC to consider the existence, if any, of a known “readily available safer alternative, that is functionally acceptable and technologically and economically viable.” The new proposed regulations have removed this factor.

In choosing priority products, the proposed regulations provide that CDTSC must give priority to the following:¹¹

- products that contain a chemical of concern with a significant ability to contribute to or cause adverse public health and environmental impacts; and
- cases where there is “a significant ability for the public and/or aquatic, avian, or terrestrial animal or plant organisms to be exposed to the Chemical(s) of Concern in the product in quantities that would contribute to or cause adverse public health or environmental impacts.” CDTSC’s review “may include consideration of how widely the product is distributed in commerce and how widely the product is used by consumers.”

Information Required for Each Priority Product

In any proposed or final priority products list, CDTSC must include the following information for each product:¹²

- the chemical(s) of concern and the hazard trait(s) that are the basis for the product being listed as a priority product;
- “[i]f applicable, the component(s) and/or homogeneous material(s) within a component, to which the alternatives analysis threshold

applies, and which is/are the required minimum focus of the [alternatives analysis]" (with additional requirements for each priority product that is a "highly durable product"); and

- the due date for submission of a preliminary alternatives analysis report, which will be 180 days after the date the product is listed on the final priority products list, unless otherwise specified.

Components and Homogeneous Materials

The proposed regulations no longer distinguish between "assembled" and "formulated" products. CDTSC defines "consumer product" to include components and "homogeneous materials within a component"¹³ in order to provide the department with flexibility to name as a priority product any identifiable constituent, part, or homogeneous layer of material that is in a finished product or that makes up the finished product.

As an example, CDTSC notes that a motor vehicle may be made of thousands of parts, but that a chemical of concern may be used in only one component of the vehicle. Under the proposed regulations, "CDTSC may name a uniquely identifiable component as being subject to the requirement for an alternatives analysis, such as a tire or CDTSC could name only the outer homogeneous layer of a tire as the Priority Product." If CDTSC names only the homogeneous material, the concentration of the chemical of concern "will not be diluted with the weight of the entire assembly or subassembly."

Alternatives Analysis Threshold

Prior versions of the proposed regulations included a *de minimis* exemption for chemicals of concern present in priority products at very low levels (e.g., 0.01 percent by weight). In the new proposed regulations, CDTSC has changed the term "*de minimis* level" to "alternatives analysis threshold," which is defined as a concentration by weight as specified by CDTSC.¹⁴ CDTSC has thus removed the specific default thresholds provided for in earlier drafts of the regulations.

The proposed regulations specify the criteria that CDTSC will use in setting the alternatives analysis threshold for each chemical of concern in a priority product. They also outline the procedure by which a responsible entity can submit an alternatives analysis threshold exemption notification in order to seek an exemption from the requirement to conduct an alternatives analysis.¹⁵

Limits on the Initial Priority Products List

CDTSC has previously suggested that its initial list of priority products would probably include only two to five products. The proposed regulations now explicitly state that the initial list shall contain no more than five products.¹⁶

Prior to January 1, 2016, CDTSC may list a product as a priority product only if the product is being included on the basis of one or more chemicals of concern in the product that meet both of the criteria noted above (even though the proposed regulations state that a product can be listed if either criterion can be met).¹⁷ CDTSC also must review the priority products list at least once every three years.¹⁸

A new element of the proposed regulations is the requirement that CDTSC develop, no later than January 1, 2014, a Priority Product Work Plan that “identifies and describes the product categories that the Department will evaluate to identify products to be added to the Priority Products list during the next three (3) years.” The work plan “must include a general explanation of the decision to select the identified product categories for evaluation during the life of the work plan.” Subsequent work plans will be issued no later than one year before the three-year expiration date of the current work plan.¹⁹

Priority Product Notifications

Within 60 days after a product is placed on the priority products list, “responsible entities” will be required to provide notification to CDTSC stating that their products are priority products, unless they submit “alternative notifications.” Responsible entities will include manufacturers, importers, and retailers who sell products in California.²⁰ Alternative notifications include:

- alternatives analysis threshold exemption notification;
- priority product removal notification and, if applicable, priority product replacement notification (if the priority product has been removed from the market); and
- chemical of concern removal notification (where the only change is the removal of the chemical of concern from the priority product without adding a substitute chemical).²¹

As was the case under prior versions of the proposed regulations, the

requirements for responsible entities are tiered, such that primary responsibility will lie with the manufacturer (the person that makes the product or the person who controls the specifications and design of, or use of materials in, the product). The importer will have responsibility if the manufacturer fails to comply. Retailers will be required to comply only if the manufacturer and importer (if any) fail to comply and this information is posted on a “failure to comply” list on CDTSC’s website.²²

Conducting Alternatives Analyses

Responsible entities (generally, but not always, manufacturers) must perform alternatives analyses for priority products, evaluating and comparing each priority product to one or more product alternatives. Under the new proposed regulations (as well as prior versions) alternatives analyses must be conducted in two stages.²³

First Stage

In the first stage of the alternatives analysis process, the responsible entity must:

- identify the product requirements and function — i.e., the function, performance, and legal requirements associated with the priority product that must be met by any potential alternative; the function of the chemical(s) of concern in meeting the priority product’s function, performance, and legal requirements; and whether the chemical of concern or any substitute chemical is “necessary” to meet these functions;
- identify alternative(s) that eliminate or reduce the concentration of the chemical(s) of concern in the priority product and/or reduce or restrict public health and/or environmental exposures to the chemical(s) of concern in the priority product;
- screen the alternative chemical(s) that might be substituted for the chemical(s) of concern, using “available information on hazard traits and toxicological and environmental endpoints,” and “any other relevant data”;
- consider other relevant information and data not specifically identified above; and
- develop a work plan and implementation schedule for stage two of the alternatives analysis process; and prepare and submit a preliminary

alternatives analysis report.²⁴

The new proposed regulations remove a requirement that responsible entities consider the “technical feasibility” of alternatives to the chemical(s) of concern. The new proposed regulations also allow a responsible entity that meets specified requirements to prepare an “abridged alternatives analysis report” if it determines, after completing the first stage, that a functionally acceptable alternative is not available or feasible.²⁵

A preliminary alternatives analysis report must be submitted no later than 180 days after the date the product is listed on the final priority products list unless CDTSC specifies a different date.²⁶

Second Stage

In the second stage of the alternatives analysis process, the responsible entity must take five steps, as set out in the proposed regulations.²⁷

In step one, the responsible entity must identify the factors that are relevant for comparing alternatives. A factor (in conjunction, where applicable, with an associated exposure pathway and life cycle segment) is considered relevant if it “makes a demonstrable contribution to one or more adverse public health, environmental, waste and end-of-life, and/or materials and resource consumption impacts of the Priority Product and/or one or more of the alternatives under consideration” and there is “a demonstrable difference in the factor’s contribution to such impact(s) between two or more of the alternatives being considered.”

The responsible entity must also “collect and use available quantitative information and analysis tools, supplemented by available qualitative information and analysis tools, to identify” a range of listed factors and, “where applicable, the associated exposure pathways and life cycle segments that are relevant for the comparison of the Priority Product and the alternatives still under consideration after completion of” the first stage of the alternatives analysis. The factors to be considered (which are similar to those listed in prior proposed versions of the regulations) include:

- multimedia life cycle impacts and chemical hazards;
- product function and performance;
- economic impacts; and

- exposure pathways (chemical quantity information and exposure factors).

In step two of the second stage, the responsible entity must “use available quantitative information and analyses, supplemented by available qualitative information and analyses, to evaluate and compare the Priority Product and each of the alternatives under consideration with respect to each relevant factor and, where applicable, associated exposure pathways and life cycle segments.”

In step three of the second stage, the responsible entity must “select the alternative that will replace or modify the Priority Product, unless the decision is to retain the existing Priority Product.”

In step four of the second stage, the responsible entity may consider other relevant information and data not specifically identified in the regulations.

In step five of the second stage, the responsible entity must prepare a final alternatives analysis report that contains a schedule for implementing the selected alternative, if any, and/or proposed regulatory responses, if any.

Alternatives Analysis Reports

Preliminary and final alternatives analysis reports must both include the following specific elements:²⁸

- an executive summary,
- information about the preparer of the report,
- information about the responsible entity and supply chain,
- product information (including product brand names and the chemicals of concern that are the basis for the product being listed as a priority product),
- evaluation and comparison of the priority product and its alternatives,
- identification of the factors determined to be relevant for comparison of the priority product and its alternatives,
- methodology used to conduct the alternatives analysis,

- supporting information (this must be cited in the report and made available to CDTSC upon request) and a description of any information gaps,
- the selected alternative(s),
- a work plan and proposed implementation schedule for the selected alternative, and
- in the case of a preliminary report, sufficient information for CDTSC to determine the appropriate due date for submission of the final alternatives analysis report.

The final alternatives analysis report must also include additional information regarding the evaluation and comparison of the priority product and its alternatives, an explanation of any differences in information and analyses as compared to the preliminary alternatives analysis report, and sufficient information for CDTSC to determine the appropriate regulatory response(s), if any.

The final alternatives analysis report generally must be submitted no later than 12 months after the CDTSC issues a notice of compliance for the preliminary alternatives analysis report. The responsible entity can request, subject to CDTSC approval, a longer period of time not to exceed 24 months, or up to 36 months if regulatory safety and/or performance testing is required for the alternatives being considered.

Other Key Issues Relating to Alternatives Analysis

CDTSC Review of Alternatives Analysis Reports

Within 60 days after receiving a preliminary or final alternatives analysis report, CDTSC must review the report for compliance with the regulations and issue a notice of compliance, a notice of deficiency, or a notice of ongoing review. The proposed regulations set forth procedures for responsible entities to correct any deficiencies that are identified in the report.²⁹

If the deficiencies are not addressed adequately or in a timely manner, CDTSC can list the product on its “failure to comply” list. CDTSC must post this information on the failure-to-comply list not less than 45 days and not later than 90 days after issuing the notice of non-compliance. This is an extension from prior versions of the proposed regulations, which provided

companies with only 60 days to remedy non-compliance.³⁰

Accreditation Bodies and Certified Assessors

Any person responsible for conducting an alternatives analysis must meet specified educational and experience requirements. Beginning two years after the regulations become effective, any such individual must also be certified as an assessor by a CDTSC-designated accreditation body. The proposed regulations spell out the requirements for assessors and accreditation bodies. CDTSC has dropped a provision (contained in the initial draft regulations) that would have required third-party verifications of alternatives analyses.³¹

Trade Secrets

Persons may assert claims for trade secret protection with respect to documents or information submitted to CDTSC. Claimants must substantiate their assertions and provide a redacted copy of the documentation that they are submitting to CDTSC (with the trade secret information removed). Prior versions of the proposed regulations stated that trade secret protection “may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient.” The new proposed regulations provide:

Trade secret protection may be claimed for the chemical identity of a chemical that is the subject of a hazard trait submission only if the subject of claim is a proposed alternative to a Chemical of Concern in a Priority Product, and the claimant does all of the following: (1) Demonstrates to the Department’s satisfaction that the chemical that is the subject of the claim is a new chemical or a new use of an existing chemical; (2) Provides the Department with sufficient health, safety, and environmental data on the chemical subject to the claim to demonstrate, to the Department’s satisfaction, that it is substantially safer than the existing Chemical of Concern in the Priority Product; and (3) Complies with the [specified] substantiation requirements.³²

Identifying and Imposing Regulatory Responses

Once a final alternatives analysis report is submitted, CDTSC must determine that the report is compliant (i.e., not deficient). CDTSC will then specify a proposed due date for implementation of a regulatory response, if one is required. CDTSC will require implementation of regulatory responses “designed to protect public health and the environment, and maximize the

use of alternatives of least concern, where such alternatives are technically and economically feasible.”³³

The definition of “technically and economically feasible alternative” has been revised in the proposed regulations to mean “an alternative product or chemical for which: (A) The technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period; and (B) The manufacturer’s operating margin is not significantly reduced.”³⁴

In effect, CDTSC will have an opportunity to override a responsible entity’s decision to retain an existing priority product, or to select an alternative that still contains a chemical of concern, based on a determination that a safer alternative exists that does not contain a chemical of concern and that is technologically and economically feasible.

CDTSC states that the changes it has made in the new proposed regulations with regard to regulatory responses are intended to “provide more guideposts for the circumstances under which specified regulatory responses (e.g., use restrictions, sales prohibitions, engineering or administrative controls, and research and development projects) will be required, as well as principles and factors for CDTSC to consider in selecting regulatory responses.”

Supplemental Information Requirements

If CDTSC determines that it needs additional information to select and ensure implementation of a regulatory response, it can require the responsible entity to provide such supplementary information. CDTSC can also require a responsible entity to “obtain or develop” information needed to fill one or more “information gaps” if the Department determines that such information is needed to reevaluate the initial regulatory responses imposed for a selected alternative or a priority product that remains in commerce.³⁵

Selecting Regulatory Responses

In selecting regulatory responses, CDTSC would have to give preference to those that provide “the greatest level of inherent protection.” For purposes of this provision, inherent protection refers to “avoidance or reduction of adverse impact or exposure that is achieved through the redesign of a product or process, rather than through administrative or engineering controls designed to limit exposure to, or the release of, a

Chemical of Concern in a product.”³⁶

CDTSC may consider any or all of the following factors when selecting regulatory responses:

- the likely actual effectiveness of the regulatory response, including the capacity of responsible entities to comply, and the ability of end-users to understand and act upon any information and directions provided with respect to the product;
- the relative cost-effectiveness of the regulatory response as compared to other possible responses;
- the administrative and other burdens that would be placed upon CDTSC, the responsible entities, the product end-users, and the public;
- any unique or additional burdens that would be imposed by the regulatory response upon sensitive subpopulations; and/or
- the ease and efficacy of enforcement of the regulatory response.³⁷

No regulatory response would be required for a selected alternative if CDTSC determines “that no regulatory response is necessary to prevent or limit adverse public health or environmental impacts.”³⁸

The regulatory responses discussed in the new proposed regulations are similar to those previously outlined in prior proposals. Entities generally will be required to adopt two self-implementing responses, when applicable: providing product information to consumers and establishing end-of-life product management programs.

Product Information for Consumers

In the case of “selected alternative products, Priority Products for which an alternative is not selected, and Priority Products which remain in commerce in California pending development and distribution of an alternative product” for an extended period of time, the responsible entity must make certain information available to consumers. The following information must be made available no later than 12 months after the Department issues a notice of compliance on the final alternatives analysis report for the product and prior to exposure to any chemical of concern:

- name of the manufacturer (and importer, if applicable),

- brand name(s), product name(s), and a description of the product,
- information about any chemicals of concern in the product,
- safe handling procedures for the product,
- information about product end-of-life management programs or requirements, and
- address of a website for the manufacturer (and the importer, if applicable) where consumers can obtain additional information about the product, the potential adverse public health and/or environmental impacts posed by the product, and proper end-of-life disposal or management practices.³⁹

The responsible entity must make this information available to consumers in “easily seen, legible, and understandable formats.” The responsible entity must post the information “in a prominent place” on its website and use one or both of the following means of informing consumers at the point of sale about the information: (1) providing the required information on the product packaging or in accompanying written material that is accessible without breaking the product seal; and/or (2) posting the information in a prominent place at the point of retail display.⁴⁰

End-of-Life Product Management Programs

Specific requirements apply to selected alternatives (or priority products if an alternative is not selected) that are sold as finished products and that are required to be managed as hazardous waste in California at the end of their useful life:

- in addition to providing the consumer information noted above, the responsible entity must include a statement indicating that the product is required to be disposed or otherwise managed as hazardous waste at the end of its useful life, and
- within one year after the CDTSC issues a notice of compliance for the final alternatives analysis report, the responsible entity must fund, establish, and maintain an end-of-life management program for the product that meets certain criteria specified in the regulations.⁴¹

Use Restrictions on Chemicals of Concern and Consumer Products

CDTSC may impose restrictions on the use of one or more chemicals of concern in a selected alternative (or in a priority product for which an alternative is not selected), or restrictions on the use of the product itself, “to reduce the ability of the product to contribute to or cause adverse public health and/or environmental impacts.” Use restrictions may include one or more of the following:

- restrictions on the amount or concentration of the chemical(s) of concern permitted in a product;
- restrictions on the settings in which a product may be sold or used;
- restrictions regarding the form in which a product is sold;
- restrictions on who may purchase and/or use a product;
- requirements for training of product purchasers and/or users; and/or
- any other use restriction that reduces the amount of any chemical(s) of concern in the product, or reduces the ability of the product to contribute to or cause an exposure to the chemical(s) of concern in the product.⁴²

Product Sales Prohibitions

If a responsible entity decides in a final alternatives analysis report to retain an existing priority product, or select an alternative that still contains a chemical of concern, CDTSC can prohibit the sale of the product if it determines that:

- a safer alternative exists that does not contain a chemical of concern, and
- the alternative is both functionally acceptable and technologically and economically feasible.

If CDTSC issues a prohibition-of-sale notification, the responsible entity will have no more than one year to cease placing the product into the stream of commerce (the Department can specify a shorter timeframe).

Even where there are no currently identified safer alternatives that are both functionally acceptable and technically and economically feasible, CDTSC can still issue a notification prohibiting placement of the product into the stream of commerce in California under certain circumstances. Prior to

issuing such a notification, the Department must ask the responsible entity to provide documentation demonstrating to CDTSC's satisfaction that:

- the overall beneficial public health and environmental impacts of the product significantly outweigh the overall adverse public health and environmental impacts of the product; and
- administrative and/or engineering restrictions on the nature and use of the product will adequately protect public health and the environment.

If the responsible entity does not provide the requested documentation within 60 days, or if the submitted documentation does not make the required demonstrations to CDTSC's satisfaction, then the Department can go forward with the notification prohibiting placement of the product in the stream of commerce.

When a product becomes subject to a prohibition-of-sale notification, the responsible entity can avoid the requirement to remove the product from commerce if the entity revises its final alternatives analysis report to select an alternative that does not contain a chemical of concern.⁴³ Importantly, the new proposed regulations would no longer permit CDTSC to implement an inventory recall for a product that is subject to a sales ban.

Other Regulatory Responses

Other regulatory responses that CDTSC may impose include:

- requiring engineered safety measures to control access, or limit exposure, to the chemical(s) of concern;⁴⁴ and
- requiring the responsible entity to initiate a research and development project, or fund a challenge grant, pertinent to the priority product that uses green chemistry and/or green engineering principles.⁴⁵

Summary of Key Changes from Prior Proposals

CDTSC has made some important revisions to its proposed regulations in response to concerns about earlier versions. The new proposal:

- eliminates certain controversial lists from which the chemicals of concern list could be derived;
- revises the former *de minimis* exemption so that there are no longer specific default thresholds;

- extends the time for responsible entities to remedy non-compliance notices regarding an alternatives analysis or regulatory response from 60 to 90 days; and
- eliminates inventory recalls as a regulatory response.

The regulatory procedures involved — from developing a chemicals of concern list to determining appropriate regulatory responses — remain complicated, however, with a large variety of factors to be applied and evaluated at every turn.

Understanding the Impact of the Proposed Regulations

Under the proposed Safer Consumer Products Regulations, companies that place consumer products in the stream of commerce in California may be required to meet a number of responsibilities. CDTSC indicates that these responsibilities can be fulfilled by consortia, trade associations, or other entities, rather than by individual companies. But the regulations do not provide any conditions or criteria for resolving the types of issues likely to be associated with such entities, such as their formation and compensation.

Under the proposed regulations, an affected company will need to notify CDTSC if one of its products is deemed to be a “priority product,” unless the company removes the product from the stream of commerce in California or satisfies the requirements for an exemption (such as the alternatives analysis threshold exemption). Affected companies also will be required to perform alternatives analyses and prepare preliminary and final alternatives analysis reports.

In addition, companies will have to comply with any regulatory response that CDTSC imposes on priority products or selected alternatives that contain chemicals of concern. Companies also may need to respond to information requests from CDTSC, substantiate claims when seeking trade secret protection for the information they submit, and potentially utilize dispute-resolution procedures in response to actions taken by the Department.

Economic Effects

Although CDTSC recognizes that the proposed regulations will have an economic impact on businesses, the Department states that it generally does not expect the regulations “to result in cost increases given the wide variety

of comparable safer products readily available at competitive prices.”⁴⁶ It is unclear how CDTSC arrived at its claim of no increased cost, however.

Many companies already conduct analyses as part of their product stewardship efforts, but it remains to be seen whether compliance with these particular regulations will increase their costs. Even companies that conduct thorough and useful analyses may find it difficult to fit their models into the requirements of CDTSC. The cost to the State of California to administer the regulations also remains unclear.

Fortunately, CDTSC will initially subject only a small number of priority products to the new regulations. This means that interested parties will have an invaluable opportunity to see how these regulations will be implemented in practice, what alternatives analyses reports will look like, and what changes or refinements may be needed.

The New Normal

Stakeholders need to recognize that California's Safer Consumer Products Regulations may well define the regulatory template for the “new normal.” The state's Green Chemistry Initiative is far-reaching at just about every level. As noted at the beginning of this column, these are not your standard chemical regulations. These proposed rules sweep away the existing paradigm, forcing product ingredient substitution based on a rigorous alternatives analysis.

The implementation of the Green Chemistry Initiative will have impacts far beyond the borders of California. Because the state represents such a big market, manufacturers will likely conform their overall consumer-product specifications to California's regulatory criteria. The alternative — maintaining one set of product specs for California, and another set for other markets — is commercially infeasible and legally risky.

When issued in final form, California's Safer Consumer Products Regulations may well become the default standard for consumer-product manufacturers. Stakeholders need to see these regulations for what they are: the new yardstick against which safe consumer products will be measured.

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Notes

¹ Available at http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/ab_1879_GCI.pdf

² Memoranda providing background information are available at <http://www.lawbc.com/regulatory-developments/green-chemistry>. The current proposed regulations are available at <http://www.dtsc.ca.gov/upload/SCPPProposedRegulationsNoUnderlineJuly2012.pdf>.

³ California Code of Regulations chapter 55, section 69502.2(a).

⁴ *Ibid.*, section 69501(b)(2).

⁵ *Ibid.*, section 69501(b)(1).

⁶ *Ibid.*, section 69503.2(a)(3).

⁷ *Ibid.*, section 69502.2(b).

⁸ *Ibid.*, section 69504.

⁹ *Ibid.*, section 69502.3.

¹⁰ *Ibid.*, section 69503.2.

¹¹ *Ibid.*, section 69503.2(b).

¹² *Ibid.*, section 69503.4.

¹³ *Ibid.*, section 69501.1(a)(22).

¹⁴ *Ibid.*, section 69501.1(a)(13).

¹⁵ *Ibid.*, section 69503 et seq.

¹⁶ *Ibid.*, section 69503.4(e).

¹⁷ *Ibid.*, section 69503.3(g).

¹⁸ *Ibid.*, section 69503.4(f).

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- ¹⁹ Ibid., section 69503.3(f).
- ²⁰ Ibid., section 69503.7.
- ²¹ Ibid., section 69503.4 (g)(2) through (g)(4).
- ²² Ibid., section 69501.2.
- ²³ Ibid., section 69505 et seq.
- ²⁴ Ibid., section 69505.3.
- ²⁵ Ibid., section 69505.2(b).
- ²⁶ Ibid., section 69503.4(a)(2)(C).
- ²⁷ Ibid., section 69505.4.
- ²⁸ Ibid., section 69505.5.
- ²⁹ Ibid., section 69505.6.
- ³⁰ Ibid., section 69501.2.
- ³¹ Ibid., section 69508.
- ³² Ibid., section 69510.
- ³³ Ibid., section 69506(a).
- ³⁴ Ibid., section 69501.1(a)(59)
- ³⁵ Ibid., section 69506.2.
- ³⁶ Ibid., section 69506(b).
- ³⁷ Ibid., section 69506(c).
- ³⁸ Ibid., section 69506.3.
- ³⁹ Ibid., section 69506.4(a)(1).
- ⁴⁰ Ibid., section 69506.4(b).

⁴¹ Ibid., section 69506.8.

⁴² Ibid., section 69506.5.

⁴³ Ibid., section 69506.6.

⁴⁴ Ibid., section 69506.7.

⁴⁵ Ibid., section 69506.9.

⁴⁶ California Department of Toxic Substances Control (2012, July). Attachment to the economic and fiscal impact statement (Std. Form 399), Safer Consumer Products Regulations.