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Dreaming No Longer: California Issues Draft Safer Consumer Products Regulations

A major step forward in the state's Green Chemistry Initiative

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On October 31, 2011, the California Department of Toxic Substances Control (CDTSC) released an "informal draft" of its Safer Consumer Products Regulations. The draft does a good job of outlining how CDTSC intends to implement key mandates contained in the state's Green Chemistry Initiative, which directs regulators to evaluate safer alternatives to chemicals that are believed to be toxic. This "Washington Watch" column summarizes key provisions of this precedent-setting, game-changing regulatory development.

Background: California Green Chemistry Initiative

In 2008, California adopted "green chemistry" legislation, including Assembly Bill 1879. 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 Program, the state's Office of 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.

Initial Versions of the SCPA Regulations

CDTSC issued draft Safer Consumer Product Alternatives (SCPA) regulations on June 23, 2010. These were followed by proposed regulations on September 17, 2010, and revised proposed regulations on November 16, 2010.²

The November 2010 version of the regulations prompted significant concern from environmental groups, as well as from Assembly Member Mike Feuer, the author of the 2008 law. Assemblyman Feuer outlined his concerns in a letter to CDTSC dated December 3, 2010. The specific concerns raised by stakeholders in late 2010 included, among others:

- the proposed exemption of certain chemicals;
- the decision to focus for the first five years on children's products, personal care products, and household cleaning products; and
- the process by which "chemicals of concern" and "priority products" were identified and "alternatives assessments" conducted.

In a reply to Feuer's letter, Linda S. Adams, California's Secretary for Environmental Protection, noted that stakeholders had raised "substantive and valid concerns" about the

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revised proposed regulations. Responding to these issues, she announced that the Department "has agreed to take additional time to be responsive to the concerns raised and revisit the proposed regulations." Despite the January 2011 deadline, Adams effectively suspended the rulemaking process in late 2010.

Adams stated that CDTSC and its regulation development team would "reconvene" the state's Green Ribbon Science Panel in early 2011 to address the "programmatic issues that have been brought to our attention via the public comment process." She continued, "[t]his additional time and expertise will help ensure that the vision behind this component of the Green Chemistry Initiative and implementing statute AB 1879 is fully realized." Adams apparently was persuaded that the revised proposed regulations were inconsistent with the letter and spirit of the Green Chemistry Initiative and that, as a result, the Panel really needed to start over again.

Informal Draft Regulations: Key Changes from Prior Iterations

The October 2011 "informal draft" regulations contain a number of important changes from prior proposed versions of the rules. Among the significant changes are the following:

- removal of the exemption for chemicals that are "unintentionally" added to products,
- removal of the exemption for chemicals for which there is "no exposure pathway,"
- elimination of the initial focus on certain types of products, and
- expansion of the criteria and processes by which chemicals of concern and priority products are identified and prioritized and "alternatives assessments" are conducted.

Prior versions of the regulations had contemplated an exemption for nanomaterials. In the informal draft regulations, however, there is no mention of nanomaterials or any specific exemption for them. To the extent that nanomaterials have not yet been identified on the lists from which CDTSC will derive its chemicals of concern, such nanomaterials will not, at least initially, be subject to the requirements of the regulations.

The discussion that follows outlines key provisions of the informal draft regulations. The core provisions of the "Safer Consumer Products" program will be implemented in several stages, as described below.

Developing a Chemicals-of-Concern List

The first step will be for CDTSC to establish a chemicals-of-concern list. This step must be completed within 30 days after the effective date of the regulations. CDTSC states that the list will include approximately 3,000 chemicals of concern.

Under California Code of Regulations Chapter 55, Section 69502.2(a) as proposed, 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:

 the chemical is identified as exhibiting a hazard trait on one or more of 15 different lists already selected by other agencies and organizations, such as California's Proposition 65; the European Union Directive on Dangerous Substances Category 1 Carcinogens and Category 1 Reproductive Toxins; the International Agency for Research on Cancer Groups' 1, 2A, and 2B Carcinogens; and the United States Environmental Protection Agency (US EPA) Toxics Release Inventory List of Persistent, Bioaccumulative, and Toxic Chemicals;

- the chemical is identified by one or more of four lists based on exposures or environmental or toxicological endpoints: Center for Disease Control's National Report on Human Exposure to Environmental Chemicals; OSPAR List of Chemicals for Priority Action; OSPAR List of Substances of Possible Concern; and US EPA National Waste Minimization Program List of Persistent and/or Bioaccumulative and Toxic Priority Chemicals; or
- the chemical is identified by one or more of the following three sources of "reliable" information: Grandjean & Landrigan Identification of Neurotoxicants; National Toxicology Program, Office of Health Assessment and Translation reports; and US EPA Integrated Risk Information System (IRIS) identification of carcinogens.

Requiring creation of this initial chemicals-of-concern list is a significant development that represents a change from prior versions of the regulations. CDTSC has stated that developing this "immediate robust" list of chemicals of concern will send "immediate signals to the marketplace." The Department also states that creating a larger list is "much less likely to motivate early (sometimes regrettable) chemical substitutions."

Exempt Products

While the regulations themselves do not exempt any chemical, several products are otherwise exempt from the regulations. These include:

- products exempted by law, including 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;
- products manufactured or stored in, or transported through, California solely for use out of state; and
- products that CDTSC determines are regulated by one or more federal and/or other California state regulatory program(s), and/or applicable international trade agreements, that in combination address the same adverse public health and environmental impacts and exposures pathways that would otherwise be the basis for the product being listed as a priority product and provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product was listed as a priority product.

Updating the Chemicals-of-Concern List

The regulations establish a process by which CDTSC can identify and "periodically update" the chemicals-of-concern list with additional chemicals. In deciding whether to add a chemical to the list, the Department will consider potential adverse impacts, potential exposures, availability of reliable information to substantiate the potential adverse impacts and exposures, and the availability of safer alternatives. Any proposed revision to the chemicals-of-concern list will be made available for public comment for 45 days and CDTSC will hold one or more public workshops to provide an opportunity for oral comments.

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. Under this procedure, CDTSC would review the petition and determine whether it is complete within 60 days of receipt. CDTSC must conduct a technical review of the petition and prepare a notice of decision, but the regulations do not specify deadlines for these steps.⁷

Developing a Priority Products List

During the next stage, CDTSC will evaluate and prioritize products that contain chemicals of concern in order to develop a list of "priority products" for which alternatives assessments 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 regulations: ⁸

- the potential adverse impacts from the chemicals 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 "availability of reliable information to substantiate the potential adverse impacts and exposures";
- the extent to which other regulatory programs regulate the products; and
- the existence (if any) of a known "readily available safer alternative, that is functionally acceptable and technologically and economically viable."

This last criterion is, of course, the most difficult to quantify. Whether alternatives are "functionally acceptable" and "technologically and economically viable" are concepts on which consensus is often difficult to achieve.

The regulations also provide criteria by which CDTSC is to prioritize among products. For example, the proposal contemplates prioritizing formulated products that are applied directly to the body, dispersed as an aerosol or vapor, or applied to hard surfaces with the likelihood of runoff or volatilization. 9

Information Required for Each Priority Product

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

- the chemicals of concern that are the basis for the product being listed as a priority product;
- the *de minimis* level for the chemicals of concern:
- for each assembled product, the components that are the basis for the product being listed as a priority product ("[t]his/these component(s) is/are the component(s) to which the de minimis level applies, and which is/are the required minimum focus of the alternatives assessment"); and
- the date when the entity must submit to CDTSC a preliminary alternatives assessment report. 10

Timeframe for Developing the Priority Products List

The first proposed priority products list is to be made available for public comment no later than 180 days after the effective date of the regulations. 11 CDTSC anticipates that its initial list will include only two to five products. The Department must review its priority product list at least once every three years.

Any proposed priority product list must be made available for a 45-day public comment period. CDTSC must hold one or more public workshops to accommodate oral comments.

Responsibility for Priority Product Notification and Alternatives Assessments

Within 60 days after a product is placed on the priority product list, the product's "responsible entities" will be required to provide notification to CDTSC, stating that their products are priority products or that they satisfy an exemption. Responsible entities will include manufacturers, importers, and retailers who sell products in California.

The responsibilities for these 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 notice is posted on a "failure to comply" list on CDTSC's website. ¹³

As discussed in more detail below, responsible entities (generally manufacturers) must perform "alternatives assessments" for the listed chemicals of concern in priority products. The purpose is to determine how best to limit potential exposures or potential adverse public health and environmental impacts from the chemicals of concern.

Importantly, alternatives assessments need not be performed if a product "is no longer placed into the stream of commerce in California by any person on and after the date that the product is listed as a [priority product]" or if the product is a "bulk chemical that is placed into the stream of commerce in California and that meets the definition of 'consumer product' . . . but that is not packaged for sale to, or end use by, a retail consumer." ¹⁴

Opt Out

Manufacturers, importers, and retailers can "opt out" of these requirements by providing CDTSC with a notice containing information "demonstrating to the Department's satisfaction that the product is no longer placed into the stream of commerce in California." 15

De Minimis Exemption

Entities that are able to satisfy a *de minimis* exemption can submit to CDTSC a *de minimis* exemption notification that will exempt them from the requirement to perform an alternatives assessment. The *de minimis* level is defined as:

 0.01% by weight for chemicals exhibiting one of nine specific hazard traits (carcinogenicity, developmental toxicity, reproductive toxicity, endocrine toxicity, genotoxicity, immunotoxicity, neurotoxicity, bioaccumulation, or environmental persistence);

- 0.1% by weight for chemicals that do not exhibit any of the nine specific hazard traits; or
- a lower or higher level if specified by CDTSC. 16

For a formulated product, the *de minimis* determination is based on the cumulative concentration in the product of all chemicals of concern that are the basis for the priority-product listing. In order to qualify for the *de minimis* exemption, the cumulative concentration of such chemicals that exhibit the same hazard trait or environmental or toxicological endpoint and mode of action cannot exceed the *de minimis* level.

For an assembled product, the *de minimis* determination is based on the cumulative concentration of all chemicals of concern that are a basis for the priority- product listing in each component that is a basis for the priority-product listing. In order to qualify for the *de minimis* exemption, the cumulative concentration of such chemicals that exhibit the same hazard trait or environmental or toxicological endpoint and mode of action cannot exceed the *de minimis* level.

A responsible entity that cannot satisfy the *de minimis* exemption criteria must submit a priority product notification and conduct an alternatives assessment.

Conducting Alternatives Assessments

CDTSC's regulations include general provisions for conducting alternatives assessments. The Department will also issue guidance materials to assist persons in conducting alternatives assessments. ¹⁷ Under the regulations, alternatives assessments must be conducted in two stages.

First Stage

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

- identify the following priority product criteria:
 - function, performance, technical feasibility, and legal requirements that must be met for any potential alternative;
 - the function of the chemicals of concern in meeting the priority product's function, performance, technical feasibility, 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 chemicals of concern in the priority product;
- screen and compare alternative chemical(s) from "available" information; and
- develop a work plan and implementation schedule for the second stage of the alternatives assessment.¹⁸

Second Stage

In the second stage of the alternatives assessment process, the responsible entity must identify those factors that are relevant for comparing alternatives. ¹⁹ These include factors that, in conjunction with an associated exposure pathway and life cycle segment:

- make a "demonstrable contribution to the adverse impacts of the priority product and/or one or more alternatives under consideration," or
- make a "demonstrable difference between two or more alternatives being considered, including the [priority product]."

The responsible entity must evaluate and compare the priority product and each alternative with respect to several listed factors (and associated exposure pathways and life cycle segments). These factors include the following:

- multimedia life cycle impacts and chemical hazards (including physical chemical hazards, adverse public health impacts, adverse environmental impacts, physicochemical properties, environmental fate properties, materials and resource consumption impacts, and adverse waste and end-of-life impacts);
- product function and performance, including useful life (expressed in single use or number of applications, days, months, or years of the priority product and the potential alternatives), functional and performance comparisons, and technological and economic feasibility of alternatives (considering the extent to which a functionally acceptable alternative is currently available in the marketplace, the affordability of any currently available functionally acceptable alternative, and the purchase price differential between the priority product and alternatives); and
- economic impacts, taking into account both internalized and externalized costs during the life cycle of the priority product and alternatives, including costs to government agencies, the public, businesses, and consumers.

The responsible entity's identification of exposure pathways must consider both:

- chemical quantity information (quantities of chemicals of concern necessary to manufacture the priority product or alternative and estimated volume and/or mass of the chemicals of concern or substitute chemical that would be placed in the stream of commerce in California), and
- exposure potential (i.e., those exposure potential factors considered when prioritizing priority products).

As part of the second stage of an alternatives assessment, 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." CDTSC will have an opportunity effectively to override a responsible entity's decision to retain an existing priority product (or a decision 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 both functionally acceptable and technologically and economically feasible.

Alternatives Assessment Reports

A preliminary alternatives assessment report will be due 180 days from the date that a product is listed on the final priority product list, unless CDTSC specifies a different deadline. This report must include:

- an executive summary,
- information about the preparer,
- supply chain information,
- a description of the facility or facilities (including location) where the priority product is produced,
- product information (including any brand name or product name under which the
 product is placed into the stream of commerce in California, any component that is
 the focus of the alternatives assessment, and identification of any chemical of
 concern in the product or component),
- methodology used to conduct the alternatives assessment,
- supporting information (this does not need to be included in the report itself, but must be cited in the report and made available to CDTSC upon request),
- scope of alternatives (identification and description of the alternatives chosen to be
 evaluated and compared, with an explanation of the rationale for selecting and
 screening out specific alternatives at each stage of the alternatives comparison
 process),
- scope of comparison factors (identification and explanation of which factors and associated exposure pathways and life cycle segments were determined to be relevant for evaluation and comparison of the priority product and its alternatives),
- comparison of alternatives,
- the selected alternative (if any),
- a work plan and proposed schedule for implementing the selected alternative (if applicable), and
- "any regulatory response(s) that the responsible entity wishes to propose that would best limit the exposure to, or reduce the level of adverse public health and environmental impacts posed by, any [chemical of concern] that will be in the selected alternative or that is in the Priority Product if the decision resulting from the [alternatives assessment] is to retain the Priority Product." ²¹

A final alternatives assessment report will be due no later than 12 months after the date CDTSC issues a notice of compliance for the preliminary alternatives assessment report unless CDTSC approves an extension request. The extension generally cannot exceed 24 months. ²²

Certified Assessor Requirements

Beginning January 1, 2015, alternatives assessments must be performed, and reports must be completed, by or under the responsible charge of an assessor certified by an accreditation body designated by CDTSC.²³ This is a significant difference from the initial versions of the regulations, which required third-party verifications of alternatives assessments.

Trade Secret Protection

A person may assert a claim of trade secret protection with respect to any documents or information submitted to CDTSC.²⁴ Such claims must be substantiated by providing certain information to CDTSC as specified in the regulations. The claimant must also provide a redacted copy of the documentation being submitted, with the trade secret information removed. CDTSC states that trade secret protection "may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient."

Regulatory Responses for Priority Products/Selected Alternatives

Once a final alternatives assessment report is submitted, the CDTSC must determine that the report is compliant (i.e., not deficient). The Department then will specify a proposed due date for implementation of a regulatory response, if one is required. The regulatory response will apply to certain selected alternatives that are placed into the stream of commerce in California, or to any priority product if an alternative is not selected. In assigning a due date, CDTSC must consider the complexity of implementing the regulatory response. ²⁵

No regulatory response is required for a selected alternative if CDTSC determines, after review of the final alternatives assessment report, that the selected alternative does not contain a chemical of concern in a concentration exceeding the *de minimis* level and does not pose significant potential adverse public health or environmental impacts.²⁶

Product Information for Consumers

For priority products that continue to be offered for sale in California (and selected alternatives that contain chemicals of concern above the *de minimis* level), the responsible entity must make the following information available to consumers prior to any exposure to the chemical of concern (and no later than 12 months after the Department issues a notice of compliance for the final alternatives assessment report for the product):

- 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,
- information about product end-of-life management programs or requirements,
- safe handling procedures for the product, 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. ²⁷

End-of-Life Management Requirements for Certain Finished Products

Specific requirements apply to priority products or selected alternatives 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 two years after the CDTSC issues a notice of compliance with the final alternatives assessment 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.²⁸

Supplemental Information Requirements

CDTSC can require a responsible entity to provide information supplementary to the final alternatives assessment report if the Department determines that this information is necessary for developing and ensuring implementation of a regulatory response. CDTSC can also require responsible entities to obtain or develop, and provide to the Department, any information needed to fill information gaps identified in the final alternatives assessment report, if CDTSC determines that such information is needed to evaluate the initial regulatory responses imposed for the product.²⁹

Product Sales Prohibition (Override Notification)

If a responsible entity decides in a final alternatives assessment report to retain an existing priority product, or select an alternative that still contains a chemical of concern, CDTSC can override the responsible entity's decision 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. 30

If CDTSC issues an override notification, the responsible entity will have no more than one year to cease placing the product into the stream of commerce.

When a product becomes subject to an override notification, the responsible entity can avoid the requirement to remove the product from commerce if the entity revises its final alternatives assessment report to select an alternative that does not contain a chemical of concern.³¹

Other Regulatory Responses

Other regulatory responses that CDTSC may impose on priority products or selected alternatives include:

· requiring engineered safety measures to control access, or limit exposure, to the

chemical(s) of concern in the product;

- restricting the use of chemicals of concern in the product;
- 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 principles; and
- requiring the development of a new alternatives assessment. 32

Impact of the Safer Consumer Products Regulations

The informal draft Safer Consumer Products Regulations provide a useful snapshot of where the Green Ribbon Science Panel's thinking stands after months of deliberations. Comments on the informal draft regulations were due December 30, 2011. The informal draft will eventually be followed by revised draft regulations.

The potential impacts of the Safer Consumer Products Regulations are expansive. As the discussion above indicates, the informal draft regulations are cumbersome, containing many definitions, criteria, and procedures.

Under the 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 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 a *de minimis* exemption). Affected companies also will be required to perform alternatives assessments and prepare preliminary and final alternatives assessment 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.

Once the Safer Consumer Products Regulations become effective, CDTSC will issue an initial list of chemicals of concern within 30 days, and an initial list of priority products within 180 days. CDTSC anticipates that the initial list of priority products will include only two to five products.

Because only a small number of products will likely be subject to the regulations initially, interested parties may have an opportunity to learn how the regulations will be implemented — and what changes or refinements may be needed — before the regulations are expanded to a wider range of products. Companies that manufacture or market consumer products in California would be well advised to follow the progress of these potentially groundbreaking new regulations.

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Notes

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

¹ Available at

² The draft, proposed, and revised proposed regulations are available on CDTSC's website at http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/index.cfm #Green_Chemistry_Initiative_Documents_and_Information.

³ Adams, L. S. (2010, December 23). Letter to Assembly Member Mike Feuer. Available at http://www.dtsc.ca.gov/upload/GRSP-12-23-2010.pdf.

⁴ Available at http://www.CDTSC.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Regulations-Informal-Draft-10312011.pdf

⁵ California Code of Regulations (informal draft) chapter 55, section 69502.2(b).

⁶ *Ibid.*, section 69502.3(c)-(d).

⁷ *Ibid.*, sections 69504, 69504.1.

⁸ *Ibid.*, sections 69503.2, 69503.2(c)(4).

⁹ *Ibid.*, section 69503.2(b)(5).

¹⁰ *Ibid.*, section 69503.3.

¹¹ *Ibid.*, section 69503.3(d).

¹² *Ibid.*, section 69503.3(f).

¹³ *Ibid.*, section 69501.3(a)(1).

¹⁴ *Ibid.*, section 69505.1(b).

¹⁵ *Ibid.*, section 69501.3(b) and (c).

¹⁶ *Ibid.*, section 69501.2(a)(25), 69503.4.

¹⁷ *Ibid.*, section 69505.

¹⁸ *Ibid.*, section 69505.3.

¹⁹ *Ibid.*, section 69505.4.

²⁰ *Ibid.*, section 69505.4(c).

²¹ *Ibid.*, section 69505.5.

²² *Ibid.*, section 69505.6(a)(3).

²³ *Ibid.*, sections 69505.1(d), 69508-69508.4.

²⁴ *Ibid.*, section 69510.

²⁵ *Ibid.*, section 69505.6(c)(2).

²⁶ *Ibid.*, section 69506.2.

²⁷ *Ibid.*, section 69506.3.

²⁸ *Ibid.*, section 69506.4.

²⁹ *Ibid.*, section 69506.1.

³⁰ *Ibid.*, section 69506.5.

³¹ *Ibid.*, sections 69506.5, 69506.8.

³² *Ibid.*, section 69506.6.