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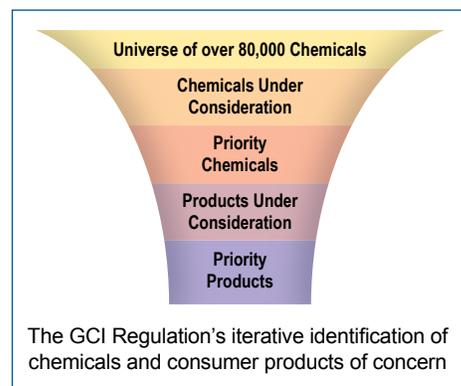
California's New Green Chemistry Requirements Can Force Product Reformulation and Mandate End of Life Management

California's Green Chemistry Initiative ("GCI") is groundbreaking and aggressive. The GCI will have a profound impact on all companies selling or distributing consumer products for use in California. In short, manufacturers, producers, chemical/materials suppliers, importers, distributors, licensors, and retailers ("Responsible Entities") will be required to show that their products do not contain designated harmful substances, or face additional burdens, up to and including a ban on the sale of products statewide. GCI will also allow the California Department of Toxic Substances Control ("DTSC") to require specified products to be appropriately managed at the end of their useful life.

The GCI marks a fundamental shift away from managing products as waste at the end of their life, to a focus on pollution prevention, product stewardship, disclosure of product and chemical information, and identifying alternatives to mitigate environmental impacts and better protect public health.

DTSC's Proposed Requirements

In September 2008, the California State Legislature approved and Governor Schwarzenegger signed [Assembly Bill 1879](#) and [Senate Bill 509](#), which, taken together, form the GCI. The proposed GCI regulations create a systematic, science-based process to evaluate chemicals of concern that will allow DTSC to advance alternatives to promote safer products.



In September 2010, DTSC issued its Green Chemistry Proposed Regulation for Safer Consumer Products (the "Proposed Regulations") for public comment. The public comment period ends on **November 1, 2010**.

Under the law, DTSC is required to adopt final regulations on or before January 1, 2011. The adopted regulations will be implemented over four years. The regulatory process will begin with identifying chemicals under consideration for regulation and will ultimately yield a final list of products ("Priority Products") that must comply with the core GCI mandates; namely, information disclosure, alternatives assessment, potential product reformulation and/or potential sales bans.

GCI Affects Chemical Use and May Force Products To Be Re-Designed

With limited exceptions, products that are used, sold or distributed in California will be subject to GCI's requirements, *regardless of where they are manufactured or*

produced. The Proposed Regulations apply to all consumer products (broadly defined as “a product or part of the product that is used, brought or leased for use by a person for any purposes”) placed into the stream of commerce in California, as well as chemicals exhibiting a “hazard trait.” California’s Office of Environmental Health Hazard Assessment (“OEHHA”) is required to adopt a list of “[hazard traits](#),” but until that list is promulgated, the interim definition includes carcinogens, reproductive toxins, mutagens and persistent bioaccumulative toxic chemicals.

With limited exceptions, products that are used, sold or distributed in California will be subject to GCI’s requirements, regardless of where they are manufactured.

There are a few limited exceptions to the Proposed Regulations. For example, they would not apply to products manufactured, stored or transported through California *solely for use out-of-state*. Exemptions also exist for *de minimis* chemical quantities (*not* applicable for nanomaterials), prescription drugs, pesticides, and for mercury-containing lights. Additionally, the Proposed Regulations do not apply to unintentionally added chemicals not known to be present after exercising due diligence.

Three-Step Implementation Process

The Proposed Regulations establish a three-step iterative process to identify safer product alternatives that will lead DTSC to determine

whether, and if so how, the product will be regulated going forward:

- **Step One.** DTSC will evaluate and prioritize chemicals and products to develop a list of “Priority Products” that contain “Priority Chemicals”;
- **Step Two.** Responsible Entities will be required to assess alternatives, based on the use of Priority Chemicals in Priority Products, with the objective of identifying and selecting a viable safer alternative, if one exists;
- **Step Three.** DTSC will impose regulatory requirements to limit the public health and/or environmental threats, if any, posed by the Priority Product or by the alternative chemical/product selected. DTSC’s regulatory response can range from no action taken to requiring labeling to restricting or banning the sale of the product in California.

Step 1: Prioritizing Chemicals and Products

Through March of 2012, DTSC will compile the list of “Chemicals Under Consideration,” *i.e.*, chemicals which warrant further study and/or potential control. Initially, DTSC will likely collect chemical information from marketing materials, web-based resources and other information such as the existing Proposition 65 list of over 800 chemicals known to cause cancer, birth defects or other reproductive harm. DTSC can also require information directly from Responsible Entities, including the contents of proprietary formulations, identification of intentionally added chemicals, and chemical and product market data. Responsible Entities, in responding

to DTSC, may use information developed under the U.S. [Toxic Substances Control Act](#) (“TSCA”), [European Registration, Evaluation, Authorisation and Restriction of Chemicals](#) (“REACH”) and/or [Canadian Environmental Protection Act](#) (“CEPA”) programs. From the chemicals on the Chemicals Under Consideration list, DTSC will develop an initial list of “Priority Chemicals,” based on certain factors identified in the Proposed Regulations.

Thereafter, products containing these Priority Chemicals will be evaluated by DTSC using a screening process. Based on certain factors contained in the Proposed Regulations, DTSC will develop an initial list of “Products Under Consideration” by March 1 2013. Based on this Products Under Consideration list, DTSC will then develop and issue its final initial list of “Priority Products” by December 1, 2013.

Prior to finalizing the Priority Chemicals and Priority Products lists, DTSC is required to make the proposed lists available on its website for public review and comment, together with certain supporting documentation. Regarding documentation received from manufacturers, while DTSC is required to protect proprietary confidential business information, it has the discretion to accept or deny a claim of trade secret status, which may allow DTSC to disclose such information.

The initial Priority Chemicals and Priority Products lists referenced above are merely the first chemical and product lists. DTSC intends to update these lists over time, as needed.

DTSC Timeline					
Initiates adoption of Proposed Regulations	Adopt final Regulations	Release of initial list of <i>Chemicals Under Consideration</i>	Release of final initial list of <i>Priority Chemicals</i>	Release of initial list of <i>Products Under Consideration</i>	Release of Final initial <i>Priority Products</i>
September 2010	January 2011	June 2011	July 2012	March 2013	December 2013
Proposed four-year rollout					

Any person may petition DTSC to add to the lists other chemicals and products not initially considered.

Early Chemical Substitution

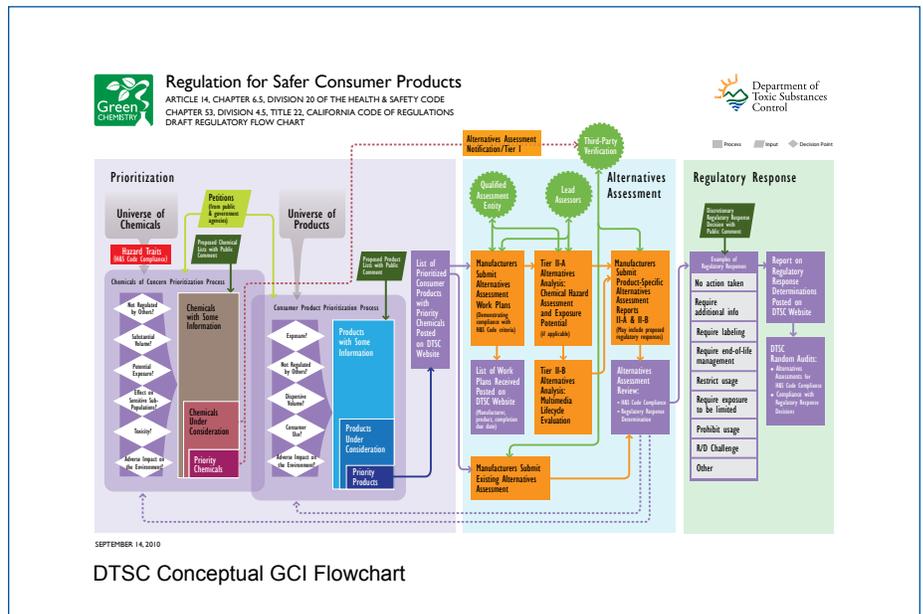
The Proposed Regulations are designed, in part, to encourage manufacturers (and other Responsible Entities) to proactively seek to reformulate products that contain chemicals of concern **before** those products appear on the Priority Products list. However, if a manufacturer voluntarily reformulates, redesigns, replaces, removes or reduces the concentration of a chemical in any product containing a chemical on the Chemicals Under Consideration or the Priority Chemicals lists, the manufacturer must submit an “*Alternatives Assessment Notification*” to DTSC *before* the product is placed into the stream of commerce. One advantage of implementing an early chemical substitution is to avoid the product from being listed on the Priority Products list in the first place.

Step 2: Alternatives Assessments: The Core of the GCI

DTSC’s listing an item as a Priority Product triggers the requirement for Responsible Entities to conduct an Alternatives Assessment (“*Tier II AA*”), which is the core of the GCI’s requirements.

Tier II AAs must be performed by a qualified, DTSC-designated assessment entity. A Tier II AA requires a Responsible Entity to pay for and conduct various assessments comparing the public health and environmental impacts of the Priority Product with potential (presumably safer) alternatives. The Tier II AA evaluation must include:

- a *Chemical Hazard Assessment* evaluating chemical information and traits;
- an *Exposure Potential Assessment* analyzing exposure limitations, consumer use and environmental release information; and



DTSC Conceptual GCI Flowchart

- a *Multimedia Life Cycle Evaluation* reviewing product function and performance, materials and resource consumption and economic impacts.

The Tier II AA evaluation will help DTSC define the regulatory response it deems appropriate to impose upon Priority Products.

Step 3: DTSC’s Regulatory Enforcement Authority

Many requirements will apply across the board to identified products. DTSC is also reserving very broad discretion for itself under the GCI regulations to reduce public health or environmental hazards posed by consumer products.

Informed by Tier II AA evaluations, DTSC may, among other things, require product disclaimers, product stewardship funds, audits, fines, penalties; restrict the use of Priority Chemicals; ban the sale of certain consumer products in California; and/or *require any other regulatory responses deemed necessary*.

Steps You Should Consider Taking

Based on the breadth of the Proposed Regulations and potential for product bans or required reformulation, Responsible Entities should consider

taking the following actions for products sold or used in California:

- Participate in the regulatory process by attending workshops and hearings and commenting on the Proposed Regulations. Comments are due by November 1, 2010.
- Evaluate their products’ components and chemicals *now*. Responsible Entities with consumer products that contain chemicals likely to be included on the Priority Chemicals list should participate in the rulemaking processes to ensure your concerns are considered. If needed, such participation will be vital to filing a suit against DTSC to protect your ability to sell your products in California.
- Carefully review the initial chemical and product lists once available. Because only generalized dispute procedures have been defined, and procedures to petition for the removal of a chemical or product from the lists are not yet clear, it is important for companies with chemicals or products on the initial proposed lists to take prompt action to petition for their removal if warranted, or plan for the reformulation of those products.
- Carefully review the Priority Chemicals list before significant

reformulation efforts are made. Manufacturers submitting Alternatives Assessments Notifications should be especially careful not to replace one Priority Chemical with another.

- Work with counsel to ensure maximum confidentiality protections for any business information submitted to DTSC.
- Consider what your competitors are doing. In its *Outline of Regulations for Safer Consumer Products Alternatives*, DTSC stated that “[i]t is anticipated that competition in the marketplace and consumer demand for safer ‘greener’ products will stimulate innovative technologies and processes....”
- Consider re-writing existing agreements with suppliers, vendors, manufacturers, distributors or retailers to clearly detail responsibility for compliance with GCI requirements and to allocate risks from non-compliance. This is one way you can potentially avoid future litigation over the sale or use of your products.

- Require product and/or chemical certifications or warranties from vendors as appropriate.
- Consider implementing vendor audits to ensure the integrity of materials supplied.

Remember, reformulation is not *automatically* required. The Tier II AA evaluation may recommend retaining the Priority Product with the same formulation, potentially accompanied by additional regulatory responses such as warnings or disclaimers.

Given the breadth and vagueness of the Proposed Regulations as well as their potentially Draconian impacts, we anticipate there will be numerous challenges filed against them.

How We Can Help You

[Hunton & Williams'](#) dedicated team of professionals are prepared to help you navigate the complexities of the GCI's requirements. Our broad experience working on similar matters, particularly California's other unique toxic chemicals

in products law, Proposition 65, gives us a unique ability to help you on GCI issues. We stand ready to assist you to monitor and help influence the development of the lists and the ongoing regulatory process. We can help you evaluate how California GCI requirements will impact your business. We can also help you with participating in the public comment process and/or coordinating public testimony. Our California environmental attorneys have considerable experience counseling manufacturers and other industrial clients on regulatory matters, as well as responding to notices of violation, pursuing environmental litigation and negotiating settlements of regulatory infractions.

For more information about Hunton & Williams, or to discuss how the Proposed Regulations may impact your business, please contact one of our attorneys listed in this Alert or visit our website at www.hunton.com.

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