

# California's Green Chemistry Initiative

Presented by

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## Overview of Topic

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- California's Green Chemistry Initiative
- Overview of basic laws
  - Assembly Bill ("AB") 1879: Safer alternatives regulation for "consumer products"
    - "Consumer products" defined as "a product or part of the product that is used, bought or leased for use by a person for any purposes"
  - Senate Bill ("SB") 509: Toxic Information Clearinghouse
  - AB 289: Authority to issue chemical data call-ins
- Jan. 29, 2013 proposed Safer Consumer Products Regulations (under AB 1879) ←

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## California's Green Chemistry Initiative

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- A new, comprehensive chemical management and consumer product policy directed toward “design of a new consumer products economy – inventing, manufacturing and using toxic-free, sustainable products”
- Developed over two years, with numerous technical and stakeholder workshops led by the California Department of Toxic Substances Control (“DTSC”)
- Culminated in DTSC's Dec. 2008 *California Green Chemistry Initiative – Final Report* (the “Report”)

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## California Green Chemistry Initiative

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- The Report identified six policy recommendations to implement a comprehensive program
  - Accelerate the quest for safer products ←
  - Create an online toxics clearinghouse ←
  - Create an online product ingredient network
  - Expand pollution prevention and product stewardship programs
  - Develop green chemistry workforce education and training, research and development, and technology transfer
  - Move toward cradle-to-cradle economy

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## California Green Chemistry Initiative

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- AB 1879 and SB 509, passed in September 2008, are the foundation of the Initiative
  - AB 1879 captures the policy recommendation of “accelerate the quest for safer products”
  - SB 509 captures the policy recommendation of “create an online Toxics Information Clearinghouse”
- AB 289, passed in 2006, authorizes state environmental agencies like DTSC to issue mandatory data call-ins on chemicals

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## AB 1879 – Overview

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- Safer alternatives regulation
- Requires DTSC to develop regulations to
  - Identify chemicals of concern
  - Prioritize chemicals of concern
  - Create a process for safer alternatives assessments of products containing prioritized chemicals of concern
    - Requires a lifecycle analysis
  - Impose regulatory actions based on outcome of safer alternatives assessments
- Most definitions are borrowed from SB 509

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## AB 1879 – Overview

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- Created the Green Ribbon Science Panel to advise DTSC on scientific and policy issues
  - 25 members from industry, academia, and non-governmental organizations
- Requires proposed regulations to be reviewed by the Environmental Policy Council
  - Made up of heads of California's EPA and its constituent boards and departments
  - Purpose of review is to ensure that regulations will pose no adverse impact on human health or the environment

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## AB 1879 – Overview

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- Current status of implementation
  - After releasing initial draft regulations in 2010, DTSC abruptly withdrew them amid controversy regarding their scope
  - In 2011, DTSC started over with a new Director, consulted with the Green Ribbon Science Panel, held public meetings, and responded to inquiries from the Legislature
  - On Oct. 31, 2011, DTSC released informal draft regulations for public comment
  - On July 27, 2012, DTSC released proposed regulations for public comment
  - On Jan. 29, 2013, DTSC released *revised* proposed regulations with a comment period ending Feb. 28, 2013 ←

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## SB 509 – Overview

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- Online Toxics Information Clearinghouse
- Provide science-based information on the hazards and environmental and toxicological endpoints of chemicals
- California's Office of Environmental Health Hazard Assessment ("OEHHA") has identified hazard traits, toxicological and environmental endpoints, and other information about chemicals
- DTSC will develop data quality and other information requirements

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## SB 509 – Overview

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- Current status of implementation
  - On January 19, 2012, OEHHA formally adopted regulations identifying hazard traits, toxicological and environmental endpoints, and other information about chemicals to be included in the Clearinghouse
  - DTSC has partnered with the University of California, Davis to identify infrastructure needs

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## AB 289 – Overview

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- Authorizes State environmental agencies to require “manufacturers” to submit chemical information, e.g., fate and transport, human bioconcentration factors, analytical test methods, and “other relevant” information about fate and transport
- “Manufacturer” is a person who produces a chemical in California or who imports a chemical into the State for sale in California
- Purpose is to identify chemical information gaps and develop information about chemicals in California commerce

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## AB 289 – Overview

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- Current status of implementation
  - DTSC first issued a data call-in (“DCI”) for carbon nanotubes (“CNTs”) to 26 entities
    - Responses were due in Jan. 2010
  - DTSC next issued a DCI for nano cerium oxide, nano silver, nano titanium dioxide, nano zero valent iron, nano zinc oxide, and quantum dots
    - Much narrower in scope than the DCI for CNTs
    - Responses were due in Dec. 2011 or Jan. 2012

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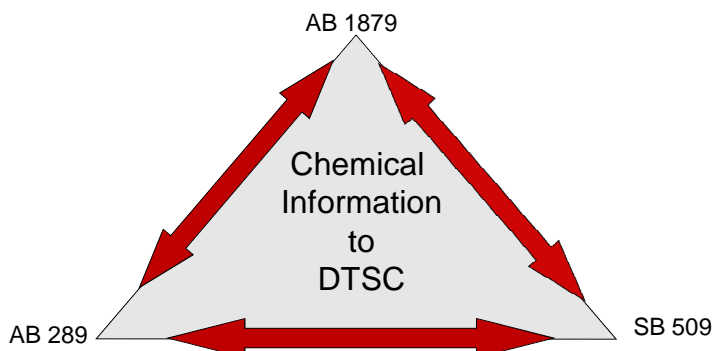
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## AB 1879, SB 509, and AB 289

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- The three laws aim to provide a coordinated, interrelated flow of chemical information to DTSC



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## Jan. 29, 2013 Proposed Safer Consumer Products Regulations

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- Components
  - Definitions
  - Identification of “Candidate Chemicals,” which become “Chemicals of Concern” (“COCs”) when matched with a product in the Priority Product list
  - Identification and prioritization of consumer products containing COCs
  - Safer alternatives assessments of prioritized consumer products
  - Regulatory action

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## 2013 Proposed SCP Regulations – Definitions

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- “Responsible entity” means a manufacturer, importer, assembler, or retailer
- “Consumer product” means “a product or part of the product that is used, brought, or leased for use by a person for any purposes” or “when applicable, a component of an assembled ‘consumer product’”
  - Broad definition
  - But there are numerous specific exclusions

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## 2013 Proposed SCP Regulations – Definitions

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- “Consumer product” specifically excludes
  - A “dangerous drug” or “dangerous device,” as defined in section 4022 of the Business of Professions Code (i.e., prescription drugs and prescription medical devices)
  - “Dental restorative materials,” as defined in subdivision (b) of section 1648.20 of the Business and Professions Code
  - A “device,” as defined in Section 4023 of the Business of Professions Code (certain non-prescription medical devices)
  - The packaging associated with any of the above

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## 2013 Proposed SCP Regulations – Definitions

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- “Consumer product” specifically excludes
  - “Food,” as defined in subdivision (a) of section 109935 of the Health and Safety Code (which tracks the definition of “food” under the Federal Food, Drug, and Cosmetic Act)
  - A “pesticide,” as defined in section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. § 136(u))

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## 2013 Proposed SCP Regulations – Definitions

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- “Chemical” means either of the following
  - “An organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical [*TSCA ends here*], and any degradate, metabolite, or reaction product of a substance with a particular molecular identity”
  - “A chemical ingredient, which means a substance comprising one or more of any substance, element, ion, uncombined radical, degradate, metabolite, or reaction product substances described above”

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## 2013 Proposed SCP Regulations – Identification of COCs

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- Criteria in AB 1879
  - The volume of the chemical in commerce in California
  - The potential for exposure to the chemical in a consumer product, and
  - The potential effects on sensitive subpopulations, including infants and children

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## 2013 Proposed SCP Regulations – Identification of COCs

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- Broad criteria capture many (~ 3,000) chemicals for a Candidate Chemicals List (initial list of COCs)
  - Many different types of chemicals
    - Carcinogens and mutagens
    - Reproductive and developmental toxins
    - Persistent, bioaccumulative, and toxic (“PBT”) chemicals
    - Neurotoxins
    - Respiratory sensitizers
    - Air, water, and marine pollutants and contaminants
    - Chemicals with exposure limits
    - Chemicals identified by biomonitoring

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## 2013 Proposed SCP Regulations – Identification of COCs

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- Broad criteria capture many (~ 3,000) chemicals for a Candidate Chemicals List (initial list of COCs)
  - Chemicals listed or otherwise identified by many different agencies, organizations, and jurisdictions
    - State of California
    - Washington State
    - U.S. – EPA, National Toxicology Program, and Agency for Toxic Substances and Disease Registry
    - European Commission
    - Environment Canada
    - International Agency for Research on Cancer

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## 2013 Proposed SCP Regulations – Identification of COCs

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- Additions to the COC list to be based on hazard traits or endpoints, as identified by OEHHA
- Additions to the COC list also may be accomplished by petitions submitted to DTSC
- DTSC creates its own authority to require the submission of already existing chemical information and to require the generation of new chemical information

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## 2013 Proposed SCP Regulations – Consumer Products

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- Identification and prioritization of consumer products to be based on the following
  - Potential for adverse impacts posed by the COCs in the product due to potential exposures during the lifecycle of the product
  - The extent and quality of available information
  - Extent to which COC or product is regulated under other California or U.S. laws
  - Whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible

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## 2013 Proposed SCP Regulations – Consumer Products

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- Priority Product List will be made available for public comment
- Within 60 days after the Priority Product List is finalized or a Priority Product enters California commerce, whichever is later, a responsible entity must notify DTSC that its product is a Priority Product
- Other products may be added to the Priority Product List by means of a petition to DTSC

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## 2013 Proposed SCP Regulations – Safer Alternatives Assessment

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- Goal: “identifying and analyzing alternatives to determine how best to eliminate or reduce potential exposures to, or the level of potential adverse impacts posed by, the Chemical(s) of Concern in the Priority Products”
- Requires an evaluation of the availability of potential alternatives and potential hazards posed by such alternatives, as well as an evaluation of critical exposure pathways
- Must meet both statutory and regulatory criteria

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## 2013 Proposed SCP Regulations – Safer Alternatives Assessment

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- AB 1879 requires analysis of the following
  - Emissions of air pollutants
  - Contamination of surface water, groundwater, and soil
  - Disposal or use of the byproducts and waste materials
  - Worker safety and impacts to public health
  - Other anticipated impacts to the environment

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## 2013 Proposed SCP Regulations – Safer Alternatives Assessment

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- AB 1879's requirements
  - Lifecycle assessment that includes the following
    - Product function or performance
    - Useful life
    - Materials and resource consumption
    - Water quality impacts
    - Air emissions
    - Energy efficiency
    - Greenhouse gas emissions
    - Waste and end-of-life disposal
    - Public health, environmental, and economic impacts

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## 2013 Proposed SCP Regulations – Safer Alternatives Assessment

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- A responsible entity or someone acting on its behalf must conduct an alternatives assessment (“AA”) on a Priority Product
  - Use of certified assessors is no longer required ←
- A Preliminary AA must be submitted *quickly*: within 180 days after the Priority Product List is finalized
  - Identification of product requirements and possible alternatives, including reducing or eliminating the COC(s)
  - Initial screening of alternative chemicals, and
  - A proposed work plan and schedule for the Final AA

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## 2013 Proposed SCP Regulations – Safer Alternatives Assessment

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- Final AA must be submitted within 12 months after DTSC approves the Preliminary AA
- Final AA must include the following
  - Identification of factors relevant to a comparison of alternatives
  - Comparison of Priority Product and alternatives, and
  - An alternatives selection decision, which can be to retain original Priority Product, with proper justification
  - Summary of, and response, to any public comments ←
- DTSC must issue guidelines for conducting AAs before it finalizes an initial Priority Products List

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## 2013 Proposed SCP Regulations – Safer Alternatives Assessment

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- A responsible entity can avoid the AA process by filing any of the following notifications
  - Chemical Removal Intent Notification, with or followed by Chemical Removal Confirmation Notification
  - Product Removal Intent Notification, with or followed by Product Removal Confirmation Notification
  - Product-Chemical Replacement Intent Notification, with or followed by Product-Chemical Replacement Confirmation Notification
  - Alternatives Analysis Threshold Notification (see next slide)

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## 2013 Proposed SCP Regulations – Safer Alternatives Assessment

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- Alternatives Analysis Thresholds (“AATs”) ←
  - Replaces “de minimis” chemical thresholds below which no AA is required for a Priority Product
  - AATs will apply to COCs present in Priority Products solely as contaminants
  - DTSC can no longer establish an AAT specific to a COC in a Priority Product
  - Instead, the AAT is now the Practical Quantitation Limit for the COC in question

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## 2013 Proposed SCP Regulations – Regulatory Action

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- The outcome of DTSC's evaluation of the Final AA may be any of several possible regulatory actions
  - Consumer information in the form of a material safety data sheet used for hazardous chemicals in the workplace
  - Further research and development
  - Restrictions (e.g., on concentrations of COCs in the product)
  - Bans
  - End-of-life management (including requirement for providing financial guarantees)
  - “Any other outcome”

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## Areas of Concern for Industry

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- Broad definition of “consumer products”
- Identification and prioritization of COCs in consumer products
  - DTSC’s promise to reduce 3,000 COCs to 1,200 is uncertain
- Safer alternatives assessments
  - Numerous evaluation criteria make effort data-intensive
  - Deadlines are potentially short
  - May conflict with existing business practices for alternatives analyses
- Trade secret issues arise early and continue throughout
  - And justification of trade secret claims remains burdensome

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## Recommendations for Industry

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- Communicate any concerns with the proposed SCP Regulations to DTSC before the public comment period closes on February 28, 2013
- Monitor implementation of AB 1879 and SB 509, especially as regards Priority Product lists, safer alternatives assessments, and the protection of trade secrets
- Manage supply chain relationships to avoid possible disruptions

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