CALIFORNIA SAFER CONSUMER PRODUCTS (SCP) REGULATIONS: BACKGROUND, IMPLEMENTING REGULATIONS, ADMINISTRATIVE PROCESS, AND IMPLICATIONS FOR ISSA MEMBERS

A Presentation at the ISSA Forum
Hyatt Regency Crystal City, Arlington, Virginia
(June 21, 2017)

Presented by:
Jon Benjamin, Esq., Farella Braun + Martel LLP (California)
Gary Whitmyre, D.A.B.T., toXcel LLC (Virginia)
What Is It?: A green chemical/green products initiative in California

Legislation Enacted 2008: Assembly Bill AB-1879 (Feuer) and Senate Bill SB-509 (Simitian)

Regulatory framework effective October 1, 2013

SCP Goals: Enhance public health, safety, and protection of the environment by promoting the development and introduction of “safer” consumer products that are “benign by design.”

Basic administrative process:
- Identify “chemicals of concern” in designated “priority products”
- Reduce toxic chemicals in consumer products
INTENT OF SCP REGULATIONS:

• To evaluate chemicals that may be of concern in consumer products, to determine how best to limit exposure(s) and/or reduce the level of hazard posed by chemicals of concern in consumer products, and to encourage the development of safer “greener” products.
IMPLEMENTATION:

- Identification of “Priority Products” & “Candidate Chemicals” by the State, based on numerous authoritative lists
- The public process includes Workshops, Proposed and Promulgated Decisions, with Notice and Comment Processes
- The program is managed by the Department of Toxic Substances Control (DTSC), which is part of the California EPA
- Who is subject to this regulatory program? Primarily manufacturers, but also formulators (“assemblers”), distributors, and sellers of identified Priority Products in California.
RESPONSIBILITY FOR COMPLIANCE:

• **Manufacturer**: controls manufacturing process; specifies chemicals

• **U.S. Importer**: distributes a product *into* California

• **“Assemblers”**: formulate product using listed chemicals of concern

• **Retailers**: sell product *within* California
AUTHORITATIVE LISTS:

- Sources of listing include 23 authoritative lists of chemicals with a “hazard trait”, such as an environmental or toxicological endpoint
- Example authoritative lists include those from:
  - California Proposition 65, USEPA’s Integrated Risk Information System (IRIS), International Agency for Research on Cancer (IARC), Agency for Toxic Substances and Disease Registry (ATSDR), the National Toxicology Program (NTP) Report on Carcinogens, National Toxicology Program Study Reports, California Toxic Air Contaminants (TACs), California Maximum Contaminant Levels (MCLs) and Reference Exposure Levels (RELs), EC Lists, Health Canada.
  - Chemicals identified as containing carcinogens or reproductive toxicants pursuant to Proposition 65 may disproportionately influence designation of Priority Products/Chemicals.
AUTHORITATIVE LISTS (continued):

• MORE SPECIFICALLY:
  - ATSDR neurotoxicants
  - California listed chemicals for air and water
  - Canada persistent/bioaccumulative/ecotoxic
  - CDC 4th report on human exposure
  - EC-listed carcinogens/mutagens/reproductive toxicants
  - EC-listed respiratory sensitizers
  - EC-listed endocrine disruptors
  - IARC carcinogens (Groups I, 2a, 2b),
  - IRIS carcinogens and neurotoxic chemicals
  - California Proposition 65-listed chemicals
  - California OEHHA noncarcinogens with RELs
  - NTP-listed carcinogenic/reproductive/developmental toxicants
  - Chemicals on USEPA Toxic Release Inventory (TRI)
  - Canada PBiT (Persistent, Bioaccumulative, and Inherently Toxic to the Environment) Chemicals
THE ADMINISTRATIVE PROCESS:

• California DTSC identifies candidate chemicals

• California DTSC identifies Priority Products (PPs)

• Manufacturer or other responsible entity notifies DTSC regarding match of “priority product” to selected “chemicals of concern”
  - Manufacturer of PPs that will continue to be sold in California, no matter where they are located, must notify DTSC that its product appears on the PP list and agree either to reformulate the product quickly to remove the chemical(s) of concern or replace with safer alternative.
  - In addition, Manufacturer must stop selling PP in California unless they agree to participate in the new and untested Alternatives Assessment (AA) process with DTSC, which may result in significant regulatory action in response to the AA process and reports.

• Manufacturer, or others completes Alternatives Analysis (AA)

• California DTSC issues regulatory response
PRIORITY PRODUCTS:

- A Priority Product (PP) is a consumer product identified by California that contains one or more candidate chemicals associated with a hazard trait (for humans and/or environment).
- DTSC proposes the PP-chemical combinations of concern
- Priority Product list developed based on both hazard traits and exposure potential for chemicals in the product(s).
- DTSC further prioritizes PP-chemical combinations based on additional factors such as waste production, life cycle impacts, and availability of safer alternatives.

*Included in this consideration is (1) whether the Product creates significant harm to the public or environment; (2) whether the Product creates an important exposure pathway for the chemical of concern; and (3) whether the chemical exposure created by the product adversely impacts sensitive groups, such as children and the elderly.

**Also probably factored into selection is whether Candidate Chemicals and Candidate Products have been the subject of litigation actions or regulatory activity in the recent past, such as those under Proposition 65 enforcement and related settlements.
FIRST GROUP OF PRIORITY PRODUCTS:

• Children’s foam-padded sleeping products containing TDCPP or TCEP (now a proposed regulation)

• Spray Polyurethane Foam systems containing unreacted Methylene Diphenyl Diisocyanates (now a proposed regulation)

• Paint strippers containing methylene chloride (not yet formally proposed by regulation)
CALIFORNIA SAFER CONSUMER PRODUCTS (SCP) REGULATIONS: PRIORITY PRODUCT WORK PLAN

SELECTION OF WORK PLAN CATEGORIES:

• DTSC’s final 2015-2017 Work Plan describes product categories from which DTSC will select Priority Products over a 3-year period. See [http://dtsc.ca.gov/SCP/PriotityProductWorkPlan.cfm](http://dtsc.ca.gov/SCP/PriotityProductWorkPlan.cfm), which has background information and a link to the Work Plan document.

• Update of Work Plan to be published 1 year before the expiration date of the current Work Plan to indicate focus for next 3-yr period.

• The selected product categories:
  - Provide clear pathways of exposure to one or more candidate chemicals
  - Contain chemicals detected in biomonitoring, indoor air/dust studies
  - Contain chemicals that may impact children or workers
  - Contain chemicals observed in water quality monitoring
SEVEN INITIAL PRODUCT CATEGORIES:

- Beauty, personal care, and hygiene products
- Building products, painting products, adhesives, sealants, flooring
- Household and office furniture and furnishings
- Cleaning products
- Clothing
- Fishing and angling equipment
- Office machinery
CLEANING PRODUCTS:

- Examples of products included in this product category are:
  - Air fresheners
  - Detergents
  - Floor Waxes and Wax Removers
  - Oven Cleaners
  - Window Cleaners
  - Bathroom Cleaners
  - Surface Cleaners
  - General Purpose Cleaners
  - Scouring Cleaners
  - Carpet Cleaners
  - Floor Cleaners
  - Deodorizers
  - Spot Removers

Potential Candidate Chemicals in Cleaning Products:*

- Alkyl phenol ethoxylates (nonyl phenol ethoxylates, or NPEs, as example)
- Hydrogen fluoride
- Phthalates
- Triclosan
- Volatile solvents, including n-hexane, methyl ethyl ketone, n-methyl-pyrrolidone, toluene, and xylene.

WORK PLAN IMPLEMENTATION:

- DTSC hosted a Workshop and Webinar on November 15, 2016 to kick off stakeholder engagement for implementing the work plan.

- Workshops and Webinars* subsequently held including:
  - Stakeholder discussion of aquatic monitoring and hazard traits of nonylphenol ethoxylates (NPEs)** and triclosan (January 11, 2017)
  - NPEs and triclosan: potential aquatic impacts (February 8, 2017)
  - Chemicals in nail products: health and safety impacts (March 2, 2017)
  - Perfluoroalkyl and polyfluoroalkyl substances (PFASs) in carpets, rugs, indoor upholstered furniture, and furniture care and treatment products (January 31, 2017).

*See all “Workshops & Events” tab at www.dtsc.ca.gov/SCP/Workshops.cfm.

**NPEs are listed for Priority Action under the Oslo and Paris Conventions for Protection of the Marine Environment of the North-East Atlantic.
ASKS THE QUESTIONS:

• Does a SCP-listed chemical really need to be in a product to obtain adequate product performance?

• What alternative(s) reduce the impacts and hazard for people and the environment?
ALTERNATIVES ANALYSIS (AA) REPORTS:

• Compares a priority product [and its identified chemical(s) of concern] with alternatives such as substitution of the chemical(s) and product redesign/re-formulation.

• Two reports required to be submitted by responsible entity(s).

• The Preliminary Alternatives Assessment (AA) Report, which:

  (1) identifies why a chemical of concern, or a substitute of it, is necessary to meet certain product criteria, such as function, performance, technical and legal requirements;

  (2) identifies and conducts an initial screening of alternatives to the usage of the chemical of concern, and proposes a Work Plan.; and

  (3) is due to DTSC within 180 days after formal listing of the priority products.
The Final Alternatives Assessment (AA) Report:

(1) The Final AA requires a more detailed assessment of alternatives, in which the Product and each alternative must be evaluated with respect to relevant considerations, including associated exposure pathways and life-cycle segments.

(2) The responsible party selects an alternative that will replace or modify the Priority Product, decide not to modify the Priority Product, or discontinue the distribution of the Priority Product in California.

(3) The final AA report is due to DTSC within 1 year after the date DTSC issues a Notice of Compliance for the Preliminary AA Report, unless an extension of up to one year is granted by DTSC.

• Consortium, trade association, public-private partnership, non-profit, or other entity may act on behalf of responsible entity(s).

Statutory Framework = “A to M” Criteria:

A. Product function/performance
B. Useful life
C. Materials/resource consumption
D. Water conservation
E. Water quality impacts
F. Air quality impacts
G. Product use, transportation, energy inputs
Statutory Framework = “A to M” Criteria (continued):

H. Energy efficiency
I. Greenhouse gas emissions (global warming)
J. Waste and end-of-life disposal impacts
K. Public health impacts: sensitive subpopulations
L. Environmental impacts
M. Economic impacts
RECAP OF TIMELINE:

• Draft preliminary Alternatives Analysis due 6 months after Priority Product listing by California

• Dept. Toxic Substances Control (DTSC) has 2 months to review the draft alternatives analysis

• Final alternatives analysis report due 12 months later (unless granted an additional one-year extension by DTSC)

• DTSC has 2 months to review.
POSSIBLE REGULATORY RESPONSES:

- California requests additional information and revisions;
- California requests product information for consumers;
- California requests use restrictions/additional safety measures;
- California prohibits sales of the product(s) in California;
- California requires engineering or administrative controls;
- California requires better end-of-life product management;
- California requires industry to contribute to research on green chemistry and green engineering; or
- No regulatory response.
The SCP Regulations are unprecedented in requiring justification of trade secret claims before any request for disclosure is filed with DTSC.

Many of specific requirements to substantiate trade secret claims will be subject to DTSC interpretation.

How Companies manufacturing the first three Priority Products handle trade secret and proprietary information, as well as DTSC’s responses, may set important precedents for other responsible entities coming through SCP process later.
POTENTIAL IMPACTS OF SCP FOR ISSA MEMBERS:

• Now that the first three Priority Products have been selected, what PP’s will be in the second or third tranches (groupings) soon to come?

• It is highly likely that cleaning products with NPEs will be listed as PP’s, perhaps as early as the 2nd tranche (late 2017 to early 2018).

• Cleaning products are listed as potential Product Categories in the Three-Year Priority Product Work Plan 2015-2017

• DTSC has already held several Workshop Webinars regarding NPEs, which is a strong signal.

• Even though NPEs are not viewed as public health concerns, e.g., not listed pursuant to Proposition 65, DTSC’s broad statutory authority under the SCP program includes the ability to choose Priority Products that are viewed as environmental issues, e.g., downstream aquatic impacts.
POTENTIAL IMPACTS OF SCP FOR ISSA MEMBERS (continued):

- California POTWs appear to be lobbying hard to influence DTSC to list products with NPEs as Priority Products.
- For POTW’s, NPEs cause significant potential cost and technical problems.
- Clean Water Act regulations may require POTWs to remove NPEs from their incoming influent waste streams to meet effluent discharge requirements.
- POTWs would prefer to see NPEs replaced/banned so that their forthcoming effluent requirements can be met by source control – i.e., “pollution prevention” - rather than additional tertiary treatment or other effluent controls.
POTENTIAL IMPACTS OF SCP FOR ISSA MEMBERS (continued):


• Statements in the DTSC Summary Document provide Staff’s preliminary views on potential concerns with NPEs. Statements in the document reinforce that DTSC’s concern about NPEs is at more than a cursory level, noting for example, that NPEs are found in multiple work plan product categories, they are persistent and bio-accumulative in the environment, and that toxicity increases with environmental degradation. (See http://www.dtsc.ca.gov/SCP/upload/Background-Document-Aquatic-Impacts.pdf).
**WHAT ISSA MEMBERS SHOULD BE THINKING ABOUT AND DOING NOW:**

- Determine if an exemption applies to a product
- Undertake company-wide product chemical audit & analysis
- Match current chemical analyses to candidate chemicals
- Prepare a Product Removal Notification Application, if appropriate
- Define the roles of “responsible entities” and undertake consortium development
- Monitor the DTSC SCP web portal for developments
- Monitor possible TSCA Reauthorization preemption efforts.
WHAT ISSA MEMBERS SHOULD BE THINKING ABOUT AND DOING NOW:

- Review and comment on next Priority Products Work Plan
- Conduct and develop the preliminary and final Alternative Analyses Reports on Priority Products
- Consider ISSA-based or company-based strategy for the above, with the assistance of internal resources, as well as specialized scientific, legal, and environmental administrative lobbying expertise with SCP program, DTSC contacts and credibility with Agency, as well as toxicological, exposure assessment and health risk assessment and other relevant disciplines.
CALIFORNIA SAFER CONSUMER PRODUCTS REGULATIONS: DTSC CONTACT INFORMATION

Safer Consumer Products Web Portal:
http://www.dtsc.ca.gov/SCP/index.cfm

Email:
SaferConsumerProducts@dtsc.ca.gov
Questions and Discussion