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OUT OF THE BOX

Legal guidance for the consumer product + retail industry

CALIFORNIA ANNOUNCES FIRST CONSUMER PRODUCTS SUBJECTED TO NEW GREEN CHEMISTRY RULES

By Peter Hsiao, William Tarantino, and Robert Falk[1]

After nearly four years of regulatory wrangling with industry groups and environmentalists, the California Department of Toxic Substances Control (the "Department") released its long-awaited list of priority chemical-product combinations (collectively referred to as "Priority Products") that will serve as the trial balloon for the state's Safer Consumer Products Regulation, known to many as the Green Chemistry Initiative.

The Priority Product list was the subject of intense speculation with stakeholders wondering if the Department would take on an entire industry, such as toys or personal care products. Of greater general concern was how an agency that is traditionally associated with hazardous waste site cleanups and landfill permitting and staffed accordingly was going to transform itself into a thoughtful consumer product regulator. The state's announcement of initial Priority Products for actual regulation under its Green Chemistry Initiative may end some of that speculation, but not all.

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The proposed Priority Products (and associated chemicals of concern) are:

1. children's foam-padded sleeping products containing the flame retardant TDCPP, also known as chlorinated tris;
2. spray polyurethane foam systems, commonly used in home insulation, containing unreacted diisocyanates; and
3. paint strippers, varnish removers, and industrial-strength surface cleaners containing methylene chloride.

Finalizing these as Priority Products and triggering actual regulation of them under California's Green Chemistry Initiatives requirements will take the Department at least a year.

The Department's announcement highlighted the three criteria that were the basis for its selection, and presumably the criteria for selection of future products: the potential for the chemical to create significant harm to the public or the environment; the potential for the product to create a pathway for exposure to the chemical of concern; and whether the chemical exposure impacts sensitive subpopulations, such as children or the elderly.

But a desire to get its Green Chemistry program off the ground with limited controversy in an election year for the governor and legislature likely also played a significant role as each of these Priority Products has also been the target of litigation or regulatory activity in the recent past. Additionally, the Department may be looking to "pilot test" its full regulatory program by addressing less than a handful of products that have already been subject to scrutiny at the federal level or that have previously been "regulated" through standards set in Proposition 65 settlements or other consumer litigation.

For example, tris-containing upholstered furniture, including children's foam-padded sleeping pads, were the subject of extensive Proposition 65 private enforcement litigation in 2013 and early 2014. Settlements of these Proposition 65 cases have already resulted in manufacturers' commitments to eliminating the use of chlorinated tris and two related flame retardant chemicals that were listed under Proposition 65, TCEP and TDBPP.

Methylene chloride-containing cleaners and paint strippers have been the recent subject of U.S. Occupational Health & Safety advisories and Centers for Disease Control reports. Spray polyurethane foam systems have also recently been the subject of several nationwide false advertising class actions related to their health effects.

In addition, each of the chemicals implicated in the Department's Priority Products announcement has previously been listed under California's Proposition 65. The overlap with Proposition 65 is not unexpected the Department's "super list" of 1,100 chemicals of concern that may be the target of future chemical-product regulation. It borrows heavily from the lists maintained by its sister agency, the Office of Environmental Health Hazard Assessment, which maintains the list for Proposition 65 and the state's other toxics programs.

"To prepare for the regulation, a company's thorough understanding of chemicals in its consumer products--especially those chemicals on California's Green Chemistry list-is of critical importance."

The lack of a more ambitious startup of California's Green Chemistry Initiative may not be indicative of its future. To be sure, the Department plans to expand the Priority Product list over time to cover a significantly greater number of products and chemicals, and announced its intention to name additional product/chemical combinations for regulation in October 2014. Also, once the initial Priority Product list is finalized by the Department, regardless of where they may be located, a manufacturer of one of these products will have real legal obligations arise under the Safer Consumer Products Regulation if the product continues to be sold in California. For example, a manufacturer must notify the agency that its product appears on the Priority Product list and agree to either (1) reformulate the products quickly to remove the chemical or replace the chemical with a safer alternative, or (2) stop selling the product in California absent engaging in an untested alternatives assessment process with the Department, which may then take further regulatory action.

The alternative assessment (AA) requirement is highly structured and unprecedented in consumer product regulation. The manufacturer of the consumer product or other responsible entities must submit an analysis to the Department that describes alternatives to mitigate exposure to the chemical of concern at all points during the product's lifecycle. The AA is conducted in two stages, with a report sent to the Department at the end of each stage. First, the AA must identify why the chemical of concern or a substitute is necessary to meet certain product criteria, such function, performance, technical, and legal requirements. Next, the AA must identify and conduct an initial screening of alternatives to the

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usage of the chemical of concern, and propose a work plan proposed for the second stage. This first stage, the Preliminary AA Report, must be submitted 180 days after the formal listing of the Priority Products.

The second stage requires a more detailed assessment of alternatives. The product and each alternative must be evaluated with respect to relevant factors and associated exposure pathways and life-cycle segments. At this stage, the responsible entity selects an alternative that will replace or modify the Priority Product or decides not to modify the Priority Product (or discontinue the distribution of the product in California). A Final AA Report is due to the Department within a year after the date Department issues a notice of compliance for the Preliminary AA Report, unless an extension of up to one additional year is approved.

The Department will then issue a regulatory response, which can include content or use limitations, mandatory recycling programs, or a ban on the use of the chemical, among other options. As with most environmental laws, the Department may seek civil penalties and injunctive relief against companies that fail to comply with these requirements. The details of the regulation and additional useful guides can be found at the Green Chemistry portal web page at http://www.mofo.com/green-chemistry.

California's action comes as bipartisan, efforts to update the federal Toxic Substances Control Act (TSCA) have stalled. The proposed legislation, named the Chemical Safety Improvement Act, would change the standard used by the U.S. EPA to assess the safety of chemicals in consumer products and revitalize its authority to regulate under TSCA.

Significantly, the proposed federal legislation also contains provisions that would potentially preempt both California's Green Chemistry Initiative and Proposition 65. California's legislative delegations and agencies have expressed their strong opposition to those preemption provisions.

Although the scope of the current Priority Product list is relatively narrow, implementation of this regulation is "must see" watching for consumer product companies and retailers. To prepare for the regulation, a company's thorough understanding of chemicals in its consumer products—especially those chemicals on California's Green Chemistry list—is of critical importance. This is especially true as large retailers and institutional purchasers begin to institute their own independent requirements for chemical content, which in some cases has resulted in an effective ban the sale of certain products; even absent any regulatory requirement.

As it has done before, California is poised to set national and cross-border precedents for chemical and consumer product regulation that will have impacts even far beyond the state's sizeable market of 37 million consumers.

FDA ISSUES FINAL GUIDANCE DISTINGUISHING LIQUID DIETARY SUPPLEMENTS FROM BEVERAGES

By Claudia Vetesi

What is the difference between a conventional beverage and a liquid dietary supplement? While many consumers might not know (or care) about the distinction, the difference is crucial for manufacturers because conventional beverages and dietary supplements are subject to different federal regulations on labeling, advertising, manufacturing, and composition, among others. The Food and Drug Administration (FDA) recently finalized its draft guidance on liquid dietary supplements representing its current thinking on the topic.

FDA's 2009 Draft Guidance—A Vague Start

The Federal Food, Drug, and Cosmetic Act (FDCA) provides that a dietary supplement cannot "be represented for use" as a conventional food, but provides little guidance on how to distinguish between the two categories. Does it depend on the product name or claims about the product? The size or shape of the container?

In 2009, FDA issued draft guidance to assist beverage and supplement manufacturers with some of these questions: "Guidance for Industry: Factors That Distinguish Liquid Dietary Supplements from Beverages and Other Conventional Foods." In the draft guidance, FDA explained that it considers factors such as labeling and advertising, product name, product packaging, serving size, recommended daily intake, directions for use, marketing practices, and composition in determining whether a product is a beverage or supplement.

While a welcome step, FDA's draft guidance did not discuss the factors with specificity. For example, the FDA did not elaborate on when a product's name, labeling, or packaging would suggest the product is being represented for use as a conventional food or dietary supplement. As a result, companies were left to navigate between the two regulatory landscapes without any real direction.

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FDA's Final Guidance—More Detail, More Flexibility

After numerous requests from Congress and the industry to clarify the line between a conventional beverage and liquid supplement, FDA published final guidance representing its current thinking on the subject in January 2014. FDA issued two documents: "Distinguishing Liquid Dietary Supplements from Beverages" and "Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements."

In contrast to the 2009 draft guidance, the final guidance on liquid dietary supplements provides concrete examples to assist in determining whether a given product is a conventional beverage or a liquid dietary supplement. For example:

- **Labeling and advertising.** FDA will consider statements and graphics on product labels, labeling, and advertising, including websites and social media. In this regard, a product with a Supplement Facts panel (as opposed to the Nutrition Facts panel found on conventional foods) may still be a conventional food if the product includes statements that it is intended to "refresh" because such a statement represents that it is intended for use as a beverage (or, in other words, a conventional food).
- **Product name.** Product or brand names that use conventional food terms such as "beverage," "drink," "water," or "soda" indicate that the product is a conventional food.
- **Product packaging.** Packaging a liquid product in a red twelve-ounce pop-top aluminum can bearing a silver stripe with the name "cola supplement" printed in script on the can could be considered an implied representation that the product is a cola-flavored soft drink that is intended to be consumed in a single serving like other canned soft drinks, and therefore is a conventional beverage.
- **Serving size and recommended daily intake.** Liquid products that suggest through their labeled serving size or recommended daily intake (e.g., "Drink up to three 16-ounce bottles per day") that they are intended to be consumed in amounts that provide all (or a significant part) of the entire daily drinking fluid intake of an average person are effectively being represented as a conventional food.
- **Recommendations and directions for use.** Recommendations or directions to use a product as a "thirst quencher" suggest the product is a beverage. In comparison, recommendations or directions to use a liquid product to supplement the diet in a manner consistent with other dietary supplements (e.g., by taking one tablespoon three times a day) suggest the product is a dietary supplement.
- **Marketing practices.** A product is likely to be considered a conventional food if the marketing compares the product to beverages or markets the product based on typical beverage criteria (e.g., taste, refreshment, and thirst-quenching ability), markets the product as an accompaniment to a meal, uses html tags that cause the product to appear in the results of an electronic search for sodas, juices, or other beverages, or pays for the product to be

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displayed in the beverage section of retail stores. That said, promoting a liquid vitamin C supplement as an alternative to drinking orange juice would not represent the product as a conventional food because this would be promoting the product as a more convenient source for vitamin C, not as a beverage to quench thirst, provide fluids, or accompany a meal.

"While FDA's final guidance is not a regulation, a company's noncompliance with the guidance can have legal ramifications. Companies in the food and dietary supplement industries should review the FDA's final guidance carefully, and assess existing labeling and marketing practices."

- **Composition.** FDA recognizes that there is an overlap between the ingredients in some dietary supplements and conventional foods (e.g., amino acids, proteins, vitamins, water). Simply adding an ingredient listed as a dietary ingredient in the FDCA to a product universally recognized as a beverage does not by itself transform the beverage into a dietary supplement. For example, adding a botanical such as ginkgo to Kool-Aid would not automatically create a product that could be marketed as a "ginkgo supplement."
- **Other representations about a product.** Other representations about a product could suggest that it is being represented as a conventional food, such as a patent filing describing the product as a type of "bottled water."

FDA notes that while a single factor may be determinative of whether the product is represented as a conventional food, in most circumstances a combination of factors would be considered. Accordingly, FDA has signaled it will conduct a case-by-case analysis to determine whether a product should be properly labeled as a conventional food or beverage as opposed to a dietary supplement.

The second document issued by FDA in connection with its final guidance—"Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements"—serves to remind manufacturers and distributors about the FDCA's existing requirements regarding substances added to conventional foods and dietary supplements, such as GRAS status of those substances, and whether they are a dietary ingredient.

Why Does the Guidance Matter?

While FDA's final guidance is not a regulation (and therefore not binding on the agency or industry), a company's noncompliance with the guidance can have legal ramifications. For example, if FDA believes a product is misbranded as a dietary supplement, the agency may issue a warning letter referring to this guidance, or take other enforcement actions. In addition, private plaintiffs may bring a class action lawsuit based on alleged noncompliance with the guidance under various states' unfair competition or health and safety laws. As readers may be aware, there has been a surge of class action lawsuits filed against food companies based on alleged misbranding under the FDCA, including lawsuits alleging products misbranded or mislabeled as dietary supplements when they are conventional foods, and vice versa.

Companies in the food and dietary supplement industries should review the FDA's final guidance carefully, and assess existing labeling and marketing practices. Changes to labeling and marketing may serve to minimize legal risk.

BROAD REACH OF SEC'S CONFLICT MINERAL RULES AFFECTS MANY PUBLIC COMPANIES IN THE CONSUMER PRODUCT INDUSTRY

By John Rafferty

The Securities and Exchange Commission's conflict mineral rules adopted in August 2012 have been a topic of hot debate among not only manufacturing industry groups, but also retail industry groups, given the extensive conflict mineral diligence obligations imposed on public companies in the manufacturing and retail sectors.

The rules affect a wide range of consumer industries, including electronics, automotive, and jewelry. In addition, although many retailers are not covered by the rules, those retailers that exert some influence over the manufacturing process of the products they sell, such as by identifying the materials, parts or components to be included in the product, may be covered by the rules.

The SEC's conflict mineral rules were upheld by the U.S. District Court for the District of Columbia in July 2013 following a challenge to the rules by the National

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Association of Manufacturers, The Business Roundtable and the U.S. Chamber of Commerce. The plaintiffs appealed this decision and oral arguments for this case were held in January 2014, but it is not clear whether the court will reach its decision before the upcoming filing deadline for disclosures relating to the conflict mineral rules.

We have provided below an overview of the rules as well as general guidance regarding compliance with the new rules. However, the rules are fairly unusual and complex and a number of aspects of the rules remain unclear, as discussed further below.

Background on the Conflict Mineral Rules

The rules require public companies to annually disclose information about their use of specific "conflict minerals" originating in the "Covered Countries." The "conflict minerals" are gold, columbite-tantalite (coltan), cassiterite, and wolframite (including their derivatives, tantalum, tin and tungsten). The "Covered Countries" are the Democratic Republic of the Congo, Republic of the Congo, Central African Republic, South Sudan, Uganda, Rwanda, Burundi, Tanzania, Zambia and Angola.

Three-Step Compliance Process

The SEC's conflict mineral rules envision a three-step compliance process:

1. First, a company must determine whether it is covered by the rules with respect to its use of conflict minerals.

2. Second, a company that is covered by the conflict mineral rules must conduct a "reasonable country of origin inquiry" designed to determine if the conflict minerals originated in the Covered Countries or are from recycled or scrap sources.

3. Third, a company that determines that its conflict minerals originated in the Covered Countries and are not from recycled or scrap sources (or has reason to believe that its conflict minerals may have originated in the Covered Countries and may not be from recycled or scrap sources) must exercise due diligence on the source and chain of custody of its conflict minerals. The company also may need to file a Conflict Minerals Report, as discussed further below.

Public disclosures by companies that are covered by the rules will be made using the new SEC Form SD. The first Form SD disclosure is required to be made with the SEC on May 31, 2014. The disclosure in the form will cover the calendar year beginning January 1, 2013. For each subsequent year, the Form SD will need to be filed by May 31 with respect to the prior calendar year.

Step 1 – Determining Whether a Company is Covered by the Rules.

A public company will be covered by the rules if conflict minerals are (1) "necessary to the functionality" or production of (2) a "product" (3) that is manufactured by the company or "contracted to be manufactured" by the company.

A. "Necessary to the functionality" of the product or production.

The SEC has provided certain factors that companies should consider in determining whether a conflict mineral is necessary to the functionality of a product, such as:

- whether a conflict mineral is contained in *and intentionally added* to the product or any component of the product and is not a naturally occurring by-product;

- whether a conflict mineral is necessary to the product's *generally expected function, use, or purpose*; and

- if a conflict mineral is incorporated for purposes of ornamentation, decoration or embellishment, whether the *primary purpose* of the product is ornamentation or decoration.

The SEC has also provided the following factors that companies should consider in determining whether a conflict mineral is necessary to the production of a product:

- whether the conflict mineral is *intentionally included* in the product's production process, other than if it is included in a tool, machine or equipment used to product the product;

- whether the conflict mineral is *included* in the product; and

- whether the conflict mineral is *necessary to* product the product.

B. Meaning of "product."

The rules do not directly address the question of what constitutes a product. However, the SEC has stated that in order to be a product, it must be an item that enters the stream of commerce by being offered to third parties for consideration.

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C. Whether a company "manufactures" or "contracts to manufacture" a product or component.

There is no definition in the rules of the term "manufacture," because the SEC believes that the meaning of this term is generally understood. The SEC has stated that a company is not considered to have manufactured a product if it only services, maintains or repairs a product. Whether a product is "contracted to be manufactured" by a company depends on the degree of influence the company exercises over the manufacturing of the product. This would include the company's influence over the materials or components to be included in the product. Whether a company exercises influence over the manufacturing of a product for purposes of the conflict mineral rules will be a fact-intensive analysis. Accordingly, this portion of the rule may apply to many retailers who exert some influence over aspects of the manufacturing process of the products they sell.

The SEC has made clear that in order to be covered by the rules, a company must have some actual influence over the manufacturing of the product. The SEC has further stated that a company should not be viewed as "contracting to manufacture" a product if it does no more than:

- specify or negotiate contractual terms that do not directly relate to the manufacturing of the product;
- affix its brand, marks, logo or label to a generic product manufactured by a third party; or
- service, maintain or repair a product manufactured by a third party.

Step 2 – Reasonable Country of Origin Inquiry.

If a company determines that it is covered by the rules, it must conduct a "reasonable country of origin inquiry." This inquiry must be designed to determine if conflict minerals originated in the Covered Countries or come from recycled or scrap sources.

The rules do not provide the steps a company should follow to meet the reasonable country of origin inquiry requirement. However, the SEC has stated that one method of meeting the reasonable country of origin inquiry requirements would be to follow the "supplier engagement" approach in the OECD Due Diligence Guidance, which contemplates that a company would engage with the suppliers in their supply chain to make inquiries about the source of the conflict minerals as well as the smelters or refineries used to process the minerals.

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If a company's reasonable country of origin inquiry results in a conclusion that the conflict minerals in the company's products came from recycled or scrap sources, then the company does not need to file a Conflict Minerals Report with the SEC. The rules provide that if the company's products containing conflict minerals from recycled or scrap sources, then the company can describe those products as "DRC conflict free."

Conflict minerals are deemed to be from recycled or scrap sources if the minerals are from recycled metals (which are reclaimed end-user or post-consumer products), or scrap processed metals (created during product manufacturing).

A company will not be required to proceed to Step 3 below (and therefore will not be required to file a Conflict Minerals Report as an exhibit to the Form SD) if the company knows or reasonably believes, following its reasonable country of origin inquiry, that the conflict minerals in its products did not originate in the Covered Countries, or that such conflict minerals came from recycled or scrap sources. For a company

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whose products contain conflict minerals but where the company is not required to file a Conflict Minerals Report, the Form SD filed by the company must describe the company's reasonable country of origin inquiry and the company's resulting determination that its products did not originate in the Covered Countries (or came from recycled or scrap sources).

Step 3 – Supply Chain Due Diligence and Conflict Minerals Report.

If a company knows (or has reason to believe) based on its country of origin inquiry that (1) the conflict minerals necessary to the functionality or production of its products did originate in the Covered Countries and (2) the conflict minerals are not (or may not be) from recycled or scrap sources, then the company is required by the rules to (A) exercise due diligence with respect to the source and chain of custody of the conflict minerals and (B) file a Conflict Minerals Report as an exhibit to its Form SD with the SEC. The due diligence exercise is aimed at determining the origin and chain of custody of the conflict minerals and whether the minerals financed or benefited armed groups in the Covered Countries.

The Conflict Minerals Report must include certain information, including a description of the measures taken to exercise due diligence on the source and custody chain of the conflict minerals as well as an independent private sector audit of the report. For calendar years 2013 and 2014 only, if the company conducts a due diligence inquiry but is unable to reach a conclusion as to whether its products containing conflict minerals are "DRC conflict free," it must still file the Conflict Minerals Report but no independent private sector auditor is necessary and the company would provide alternative disclosures, including describing the applicable products as "DRC conflict undeterminable."

Conclusion

The SEC's conflict minerals rules impose substantial due diligence and disclosure requirements on a broad range of public companies in the consumer products industry, and many interpretative issues with respect to the rules remain. With the first disclosures under the rules required on May 31, 2014, with respect to calendar year 2013, public companies should now have in place a system of controls and procedures designed to comply with the rules.

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