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LEGISLATION, REGULATIONS AND STANDARDS

Advocacy Groups Seek to Ban Eight Substances Under Delaney Clause

A June 10, 2015, **petition** filed by consumer and environmental groups asks the Food and Drug Administration (FDA) to ban the following synthetic substances widely used in baked goods, ice cream and beverages: (i) benzophenone (also known as diphenylketone); (ii) ethyl acrylate; (iii) eugenyl methyl ether (also known as 4-allylveratrole or methyl eugenol); (iv) myrcene (also known as 7-methyl-3-methylene-1,6-octadiene); (v) pulegone (also known as p-menth-4(8)-en-3-one); (vi) pyridine; (vii) styrene; and (viii) *trans,trans*-2,4-hexadienal. Signed by the Center for Science in the Public Interest, National Resources Defense Council, Center for Environmental Health, Environmental Working Group, Center for Food Safety, Consumers Union, and Improving Kids' Environment, the petition claims that the flavorings are not safe for use in human food under the Delaney Clause of the Food Additives Amendment Act (21 U.S.C. § 348 (c)(3)(A)) because the National Toxicology Program and other agencies have linked them to animal or human cancers.

The groups argue that the Delaney Clause applies not only to food additives but also GRAS substances, urging FDA to establish "zero tolerance for [] seven flavors as well as one flavor, *trans,trans*-2,4-hexadienal, approved by the Flavor and Extract Manufacturers Association's (FEMA's) expert panel as 'generally recognized as safe' (GRAS)." They also remind the agency to remove acetamide and quinolone from its "Everything Added to Food in the United States" database as these two flavorings are no longer considered GRAS.

"Our view is consistent with FDA's own regulations," concludes the petition. "FDA regulations expressly state that the same safety standard applies to food additives and GRAS substances. Under the current regulations, GRAS status based on scientific procedures 'require[s] the

same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient.'"

NYC Board of Health Considers Salt Warnings for Certain Restaurant Fare

The New York City (NYC) Board of Health has reportedly agreed to consider a proposed amendment to **Article 81** of the NYC Health Code that would require food items containing more than 2,300 milligrams of sodium to be singled out on menus and menu boards with a salt-shaker icon and an accompanying warning statement.

The **proposed initiative** would affect restaurant chains with more than 15 locations nationwide, and the mandated warning would state that the "sodium content of this item is higher than the total daily recommended limit (2,300 mg). High sodium intake can increase blood pressure and risk of heart disease and stroke." Health officials assert that the average NYC adult consumes about 3,200 mg of salt daily (40 percent more than the recommended daily limit) and that restaurant and processed foods are the greatest sources of dietary sodium. If adopted, the warnings would take effect on December 1, 2015, and reportedly apply to about 10 percent of menu selections offered by chain restaurants covered under the proposal. Violators of the regulation would face $200 fines. *See BBC News* and *Associated Press*, June 10, 2015.

California Municipal Lawmakers Continue to Target Soft Drink Consumption

The San Francisco Board of Supervisors has unanimously passed three proposals aimed at reducing the consumption of sugar-sweetened beverages (SSBs) in the San Francisco Bay Area. The first, legislation introduced by Supervisor Scott Wiener, would mandate warnings on most billboards and advertisements for SSBs with 25 or more calories. Text of the warning would read: "Drinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay. This is a message from the City and County of San Francisco."

"We know health warnings work," Wiener was quoted as saying. "They worked with cigarettes and they'll work here."

The other two proposals would (i) prohibit advertisements for SSBs on city-owned property and (ii) prevent city departments and contractors from using city funds to purchase SSBs. All three pieces of legislation

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must pass another vote by the board and be approved by the mayor before they are enacted. *See The Wall Street Journal* and *Press Release of Supervisor Scott Wiener*, June 9, 2015; *Associated Press*, June 10, 2015.

LITIGATION

4-MEI Consolidated Class Action to Continue in California

A California federal court has refused to dismiss a class action consolidated from nine lawsuits against PepsiCo, Inc. alleging that the company concealed its products' content of 4-methylimidazole (4-MEI), a chemical listed as known to cause cancer or reproductive harm under the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). *Sciortino v. Pepsico*, No. 14-0478 (N.D. Cal., order entered June 5, 2015). The lawsuits were filed after a January 2014 *Consumer Reports* test reportedly found that the caramel coloring in PepsiCo sodas contained 4-MEI at levels higher than the Prop. 65 safety threshold of 29 micrograms. Details of a similar lawsuit dismissed in March 2015 requesting medical monitoring appear in Issue **557** of this *Update*.

The court first discussed the notice requirements under Prop. 65, which require 60 days of notice of the alleged violation to government agencies to provide a "non-adversarial opportunity for public agencies to pursue investigation, settlement, and cure." Two of the plaintiffs initially filed lawsuits alleging misrepresentation then later amended their complaints to assert Prop. 65 claims as well. PepsiCo argued that the strategy was "artful pleading designed to circumvent" the 60-day notice requirement of Prop. 65. The court disagreed on one complaint, denying PepsiCo's motion to dismiss, and agreed on the other, granting the motion to dismiss the initial complaint's Prop. 65 claim but noting that the dismissal "has little practical effect" because the Prop. 65 claim as a whole will continue.

The court then turned to PepsiCo's argument that the plaintiffs misinterpret the chemical level limits of Prop. 65. The company asserted that exceeding the 29-microgram limit in a single 12-ounce can does not violate Prop. 65 because the statute calculates consumption on lifetime exposure patterns. The court disagreed, finding the complaint's claim

plausible because "the average *daily* exposure to a consumer who drinks more than one serving per day exceeds 29 micrograms." It left the challenge to the calculation methodology to the summary judgment or trial stage.

The plaintiffs' claims were also not preempted by federal law, the court found. PepsiCo argued that the caramel coloring that created 4-MEI as a byproduct was approved by the U.S. Food and Drug Administration (FDA), but the court found that this approval did not expressly or impliedly preempt Prop.65 enforcement. The claims of material misrepresentation could also proceed, the court found, because PepsiCo could not point to any provisions in federal law that would preempt them.

Finally, the court discussed PepsiCo's argument that FDA had primary jurisdiction over the case because the agency "is currently considering whether more stringent guidelines are needed regarding exposure to 4-MeI" from the caramel coloring. The court disagreed that FDA's deliberations amounted to primary jurisdiction, noting that the agency "appears to have stated that it is solely considering tightening its restrictions of 4-MeI."

Kashi Settles GMO False Ad Class Action for Nearly $4 Million

Kashi Co., a unit of Kellogg Co., has agreed to pay up to $3.99 million in a class action alleging that the company advertised its products as "All Natural" despite containing genetically modified organisms (GMOs). *Eggnatz v. The Kellogg Co.*, No. 12-21678 (S.D. Fla., motion for preliminary approval filed June 5, 2015). The proposed settlement agreement provides class members who can prove they purchased the products a full refund and those without proof $0.55 per package, totaling a minimum of $2 million and maximum of $3.99 million in claims. Kashi will also remove the "All Natural" label from products containing the contested ingredients and provide class members with compliance information on the Non-GMO Project Verified seals displayed on some of its products. The settlement agreement applies to the national class but excludes California residents due to a settlement in a case involving similar claims.

ECJ Rules in Labeling Case Challenging German Tea Product

The European Court of Justice (ECJ) has found that a correct and complete list of ingredients can be part of an overall misleading food

label in a case challenging a German tea company's "Felix Raspberry and Vanilla Adventure" ("Felix Himbeer-Vanille Abenteuer") product for having no flavorings derived from raspberries or vanilla. *Bundesverband der Verbraucherzentralen und Verbraucherverbände v. Teekanne GmbH & Co. KG*, No. C-195/14 (E.C.J., order entered June 4, 2015).

Teekanne advertises its tea product as fruit tea with natural flavorings and a raspberry-vanilla taste, and the label features depictions of raspberries and vanilla flowers and a seal indicating the product contains only natural ingredients. The ingredient list includes "natural flavouring with a taste of vanilla" and "natural flavouring with a taste of raspberry," according to the court. "That list thus expresses, in a manner free from doubt, the fact that the flavourings used are not obtained from vanilla and raspberries but only taste like them," the court said. "The fruit tea is therefore presented in such a way as to be capable, even in the case of a reasonably well-informed and reasonably observant and circumspect consumer, of creating a false impression as to its composition." The court further notes that the ingredient list is displayed in small script intended to dissuade consumers from noticing it. "[T]he list of ingredients, even though correct and comprehensive, may in some situations not be capable of correcting sufficiently the consumer's erroneous or misleading impression concerning the characteristics of a foodstuff that stems from the other items comprising its labeling," the court said, and remanded the case to a German court for determination of costs.

Putative Class Action Challenges Source of Bulleit® Bourbon

A consumer has filed a putative class action against Diageo Americas Supply alleging that its Bulleit® bourbon is not produced in Lawrenceburg, Kentucky, as its label states. *M'Baye v. Diageo Ams. Supply, Inc.*, No. 15-1216 (S.D. Cal., filed June 1, 2015). The complaint asserts that Diageo does not operate a distillery in Lawrenceburg and further alleges that Kirin Brewing Co., "a separate and distinct entity," makes and distributes the bourbon. The plaintiff points to phrases in the bourbon's marketing—"small batch," "ingredients of the very highest quality" and "distinctively clean and smooth"—as evidence that the company intended to position it as a high-end product to justify its sale price of about $53. For allegations of false advertising, unfair competition and misrepresentation, the plaintiff seeks class certification, an injunction, restitution, damages and attorney's fees.

Inko's® Tea Contains Unnatural Ascorbic Acid, Proposed Class Action Alleges

A group of plaintiffs has filed a putative class action against Inko's Tea alleging that the company's tea products contain ascorbic acid, "a non-natural, highly chemically processed ingredient regularly used as a preservative," despite advertising the products as "100% Natural." *Collazo v. Inko's Tea, LLC*, No. 15-3070 (E.D.N.Y., filed June 8, 2015). Inko's has consistently presented its products as "100% All-Natural," the complaint asserts, and contains "nothing but pure, freshly brewed tea from tea leaves with no added ingredients or preservatives." The plaintiffs admit that "natural" has not specifically been defined, but assert "there is no reasonable definition of 'All Natural' that includes ingredients that even if sourced from 'nature,' are subjected to extensive transformative chemical processing before their inclusion in a product." The complaint cites 51 statutes—one in each state and the District of Columbia—that the allegedly misleading "All Natural" marketing violates in addition to the federal Food, Drug, and Cosmetic Act. The plaintiffs seek certification of nationwide, California and New York classes, a declaratory judgment, damages, restitution and attorney's fees.

Watkins Sues McCormick over Slack-Filled Packaging

Watkins Inc., a Minnesota-based company known for its black pepper, has filed a lawsuit against McCormick and Co., Inc., a global purveyor of spices, alleging that McCormick recently began underfilling its pepper containers but continued using the same size of packaging. *Watkins Inc. v. McCormick and Co.*, No. 15-2688 (D. Minn., filed June 9, 2015). The complaint provides photographic comparisons of Watkins and McCormick tins, a photo of McCormick's 2-ounce tin alongside the 1.5-ounce tin in a store selling each for the same price, and several photos of stores with shelf tags incorrectly listing the previous size but offering the reduced-size product. "McCormick intentionally kept the tin the same size, with the same price, notwithstanding the 25% decrease in ground black pepper fill, in a manner that misleads retailers and consumers," the complaint asserts. Watkins alleges that McCormick has violated the Lanham Act and several state business practices acts as well as engaged in unfair competition. The company seeks an injunction, damages and attorney's fees.

"Natural" Prego® Sauces Alleged to Contain Unnatural Canola Oil

In an amended complaint, a plaintiff has alleged that Campbell Soup Co.'s Prego® sauces contain canola oil with genetically modified organisms (GMOs) despite the products' "100% Natural" label claims. *Nelson v. Campbell Soup Co.*, No. 14-2647 (S.D. Cal., amended complaint filed June 8, 2015). The complaint asserts that 90 percent of canola crops in the United States are genetically modified, and because Campbell does not "undertake additional expensive steps to purchase and verify a supply from non-GMO growers," the canola oil used in Prego® products includes GMOs. The plaintiff argues that a "reasonable California consumer, like Plaintiff, would not expect a Product labeled '100% Natural' to contain ingredients made from genetically modified crops, which are, by definition, artificial and synthetic." She seeks damages and attorney's fees for her allegations of unfair competition and false advertising.

OTHER DEVELOPMENTS

SSB Taxes and Food Marketing Among Topics at Upcoming Childhood Obesity Conference

Public health advocates from around the United States will convene in San Diego, California, on June 29-July 2, 2015, for the **8th Biennial Childhood Obesity Conference**. The "Marketing to Kids" track of the two-day event will include a mini-plenary session titled "Taxing Sugar-Sweetened Beverages for Public Health: What Have We Learned from the Mexico, Berkeley and San Francisco Initiatives"; "Effective Marketing to Build Public Support to Curb Unhealthy Food Marketing to Children"; and "Would You Eat 91 Cubes of Sugar: A Look at Several Strategies for Decreasing Consumption of Sugary Drinks."

Other sessions will include **"Toward Healthier Diets: Where Non-Governmental Organizations and Industry Clash and Cooperate"** and "Warning Labels on Sugary Drinks: Promoting Informed Choices." Supporters of the event include the California Department of Public Health, California Endowment and Robert Wood Johnson Foundation.

MEDIA COVERAGE

New Yorker Sounds Alarm on Avian Influenza

A June 9, 2015, *New Yorker* article warns that the latest strain of highly pathogenic avian influenza (HPAI) cut a swathe through the domestic poultry industry despite the best efforts of health officials and scientists working to contain it. Arguing that bird flu poses a greater threat than Ebola to human health, the article notes that the viruses responsible for recent global pandemics—including the H1N1 virus in 2009—started in animals before jumping to humans.

"If H1N1 had been more virulent, it would have killed millions of people," biologist Nathan Wolfe told *The New Yorker's* Michael Specter. "Maybe tens of millions. Once it got out there, that thing burned right through the forest. We caught an amazingly lucky break, but let's not kid ourselves. Luck like that doesn't last."

In addition to describing the costs to producers, the federal government and consumers, the article also points out that the poultry farms affected by the 2015 HPAI outbreak are located next to "many of the largest hog-production facilities in the United States." As Specter explains, "That makes for a particularly ominous convergence: epidemiologists consider pigs an ideal mixing vessel for human and animal flu viruses, because the receptors on their respiratory cells are similar to ours."

SCIENTIFIC/TECHNICAL ITEMS

Tufts Study Allegedly Links SSBs to Non-Alcoholic Fatty Liver Disease

Analyzing data from more than 2,500 participants enrolled in a National Heart, Lung and Blood Institute study, Tufts University researchers have reportedly concluded that "a daily sugar-sweetened beverage [SSB] habit may increase the risk for non-alcoholic fatty liver disease (NAFLD)." Jiantao Ma, et al., "Sugar-sweetened beverage, diet soda and fatty liver disease in the Framingham Heart Study cohorts," *Journal of Hepatology,* June 2015.

The study relied on self-reported dietary questionnaires to assess consumption of SSBs—including soda and other sweetened carbonated

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Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

beverages, fruit punches, lemonade and non-carbonated fruit drinks—then used computer tomography (CT) scans "to measure the amount of fat in the liver." Although the study found no association between diet soda intake and NAFLD, it evidently reported "a higher prevalence of NAFLD among people who reported drinking more than one [SSB] per day compared to people who said they drank no [SSBs]."

"Our study adds to a growing body of research suggesting that sugar-sweetened beverages may be linked to NAFLD and other chronic diseases including diabetes and cardiovascular disease," said one of the authors in a June 5, 2015, press release. "Few observational studies, to date, have examined the relationship between sugar-sweetened beverages and NAFLD. Long-term prospective studies are needed to help ascertain the potential role of sugar-sweetened beverages in the development of NAFLD."