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LEGISLATION, REGULATIONS AND STANDARDS

FDA Reopens Comment Period on Draft Evaporated Cane Juice Guidance

The U.S. Food and Drug Administration (FDA) has <u>reopened</u> the comment period on its draft industry guidance titled "Ingredients Declared as Evaporated Cane Juice" on food labels.

First published for comments in October 2009, the draft guidance advises industry of "FDA's view that the common or usual name for the solid or dried form of sugar cane syrup is 'dried cane syrup,' and that sweeteners derived from sugar cane syrup should not be declared on food labels as 'evaporated cane juice' because that term falsely suggests the sweeteners are juice," and they are not "juice" as defined in federal regulations, 21 C.F.R. 120.1(a).

FDA seeks "additional data and information to better understand the basic nature and characterizing properties of the ingredient, the methods of producing it, and the differences between this ingredient and other sweet-eners." Among the specific questions the agency has raised are (i) "How is 'evaporated cane juice' manufactured?"; (ii) "Is there a uniform industry standard for this ingredient as traded in the marketplace?"; (iii) "Does the name 'evaporated cane juice' adequately convey the basic nature of the food and its characterizing properties with the principles in § 102.5(a)?"; and (iv) "Applying the principles for common or usual names in § 102.5, in what way does 'dried cane syrup' fail to identify or describe this ingredient's basic nature or characterizing properties or ingredients?" Comments are requested by May 5, 2014. See Federal Register, March 5, 2014.

WHO Seeks Comments on Sugar Intake Guidance

The World Health Organization (WHO) has <u>launched</u> a public consultation on its draft guidance for sugar intake that aims to help countries limit sugar consumption and address public health issues such as obesity and tooth decay. The action follows increasing concern that consumption of free sugars, particularly in the form of sugar-sweetened beverages, "may result in both reduced intake of foods containing more nutritionally adequate calories and an increase in total caloric intake, leading to an unhealthy diet, weight gain and increased risk of noncommunicable diseases (NCDs)."



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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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The organization also cites concern about the role free sugars play in the development of dental disease, noting that they are the most prevalent NCDs globally despite the treatment and prevention improvements of the last decade. WHO estimates that the cost to treat dental disease—5 to 10 percent of the health budgets in many industrialized countries—would exceed the financial resources available for all health care for children in most lower-income countries.

While WHO's 2002 guidance set a maximum limit of 10 percent of daily calories from sugar, WHO now suggests that a reduction to less than 5 percent of daily calories from sugar would "have additional benefits." The suggested limits would "apply to all monosaccharides (such as glucose, fructose) and disaccharides (such as sucrose or table sugar) that are added to food by the manufacturer, the cook or the consumer, as well as sugars naturally present in honey, syrups, fruit juices and fruit concentrates." Comments will be accepted until March 31, 2014. See WHO News Release, March 5, 2014.

EFSA Lowers Exposure Limits for Inorganic Arsenic

The European Food Safety Authority (EFSA) has <u>updated</u> its analysis of the occurrence of arsenic in food in Europe, setting lower estimates of dietary exposure to inorganic arsenic than the agency reported in 2009.

The analysis includes nearly 3,000 data samples of inorganic arsenic, evidently more toxic than organic compounds, and EFSA reports that the estimates' accuracy has improved due to new consumption and occurrence data and a more detailed classification of foods.

Arsenic, which has been linked to health problems such as skin lesions, cardio-vascular disease and some forms of cancer, is a widely found contaminant that occurs both naturally and as a result of human activity. It appears in various forms, which can be either organic—containing carbon—or inorganic. Food, particularly grain-based processed products, such as wheat bread, rice, milk, dairy products, and drinking water are the main sources of exposure for the general European population. Although the European Union has not established recommended maximum levels of arsenic in food, some member states have set national guidelines.

Saudi Arabia Adopts Energy Drink Regulations

Saudi Arabia authorities have reportedly prohibited the sale of energy drinks at all government, education, sports, and health facilities and outlawed all forms of advertising, including the sponsorship of any sporting, social or cultural events by energy drink companies. Expected to significantly affect what industry experts cite as one of the world's top-10 markets for energy drinks, the action follows a recent Interior Ministry study highlighting the



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purported "adverse effects of energy drinks." The ban on advertisements and promotions includes all print, audio and visual media, and the new regulations will require companies to put health warning labels on energy drink products. *See Alarabiya.net*, March 5, 2014.

OEHHA Extends Comment Period on Beta-Myrcene as Carcinogen

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has <u>extended</u> the comment period on its notice of intent to list beta-myrcene as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). OEHHA took the action at the request of several trade organizations, including the Flavor and Extract Manufacturers Association, North America Juice Products Association, and Renewable Citrus Products Association. The new comment deadline is March 24, 2014.

OEHHA has proposed adding beta-myrcene—a natural food-plant constituent used as a flavoring agent in food and beverages—to the Prop. 65 list under the authoritative bodies listing mechanism. According to the agency, the National Toxicology Program and several other institutions have concluded that the chemical causes kidney cancer in male rats and liver cancer in male mice. See OEHHA News Release, March 4, 2014.

In other OEHHA action, the Developmental and Reproductive Toxicant Identification Committee will \underline{meet} on March 19 to discuss, among other matters, its reconsideration of the listing under the Labor Code of six chemicals as known to the state to cause reproductive toxicity. Among them are diglycidyl ether, a derivative of bisphenol A used in epoxy resins, and α -methylstyrene, used in the manufacture of plasticizers, resins and polymers. The committee is also scheduled to consider "how to tabulate data from epidemiological and animal studies in hazard identification documents." Those wishing to speak during the meeting for longer than five minutes may request additional time at least three business days before the meeting. See OEHHA News Release, March 7, 2014.

LITIGATION

Black Farmers Not Included in Settlement Denied Reconsideration

A federal court in Washington, D.C., has reportedly refused to reconsider its denial of hundreds of claims by African-American farmers who alleged that they were owed a share of the \$1.25-billion settlement fund established to compensate a class of farmers allegedly discriminated against by the U.S. Department of Agriculture's (USDA's) loan application process. *In re Black Farmers Discrimination Litig.*, No. 08-0511 (U.S. Dist. Ct., D.D.C., order entered March 5, 2014). Information about the lawsuit and a dispute over attorney's fees appears in Issue 490 of this *Update*.



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According to a news source, the court determined that it lacked authority to alter the terms of the settlement agreement, which provided that claims determinations would be considered final and not subject to court review. "This may be cold comfort to claimants who feel that their claims were denied in error; but without the Settlement Agreement, the amount of relief attainable by members of the plaintiff class would have been less than ten percent of what has actually been made available to the class under the settlement," the court said. Many non-prevailing claimants reportedly alleged that their claims were wrongfully denied on the grounds that they failed to timely complain about discrimination or failed to apply for USDA assistance within the relevant time period. See The National Law Journal, March 6, 2014.

POM Wonderful Seeks Class Decertification in False Advertising MDL

According to a news source, counsel for POM Wonderful LLC has urged federal district court Judge Dean Pregerson to decertify the nationwide class action he certified in consolidated false-advertising multidistrict litigation, arguing that the U.S. Supreme Court's decision in *Comcast v. Behrend* and the plaintiffs' failure to establish a valid damages model supported the company's request. *In re POM Wonderful LLC Mktg. & Sales Practices Litig.*, MDL No. 2199 (U.S. Dist. Ct., C.D. Cal., motion argued March 3, 2014). Additional information about the court's decision to certify the class appears in Issue 457 of this *Update*.

While the judge did not rule on the motion, he apparently expressed skepticism about whether the plaintiffs would be able to establish that class members purchased the juice for its various advertised health benefits only, rather than buying it for other reasons, such as taste, color or shelf location. He also reportedly asked whether the class certification stage was the appropriate time to consider how a potential claims process would work. *See The National Law Journal*, March 4, 2014.

4-MEI Action Filed Against PepsiCo

A California resident has filed a putative statewide class action against PepsiCo, Inc., alleging that the company "touts Pepsi One as follows—'Full Flavor and One Calorie are now living in complete harmony inside Pepsi One—the drink that unites the taste of regular cola with all the things you like about diet cola'—without disclosing that it contains the caramel-coloring chemical 4-methylimidazole (4-MEI), identified by the state as a carcinogen under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Ree v. PepsiCo, Inc., No. 14-0328 (U.S. Dist. Ct., C.D. Cal., filed March 4, 2014). According to the complaint, the absence of the disclosure "was a material and substantial factor which influenced [the plaintiff's] decision to purchase Pepsi One. In fact, Plaintiff would not have purchased the Product had she known that it contained 4-MEI well in excess of Proposition 65 guidelines."



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The plaintiff includes information from a *Consumer Reports* article about the chemical to support her claim that the failure to disclose was false and misleading. Alleging violations of the California Unfair Competition Law and Consumers Legal Remedies Act, untrue and misleading advertising, breach of contract, intentional and negligent misrepresentation, unjust enrichment, and breach of express warranty, the plaintiff seeks injunctive relief, restitution and disgorgement, an accounting, attorney's fees, and costs.

Chipotle Employees File Wage-and-Hour Class Action

A former Chiptole Mexican Grill employee has brought a wage-and-hour complaint against the company, including claims of harassment, gender discrimination, retaliation, battery, and wrongful termination. *Roberts v. Chipotle Mex. Grill, Inc.*, No. BC537487 (Cal. Super. Ct., Los Angeles Cnty., filed February 26, 2014).

Filing on behalf of herself and in a representative capacity on behalf of others, plaintiff Tedi Roberts claims that Chipotle (i) failed to pay legally required overtime or compensation for hours worked; (ii) failed to provide legally required meal periods and rest periods or accurate wage statements; (iii) failed to take action when she complained about sexual harassment and battery; (iv) refused to change her schedule or provide a transfer to help her avoid further harassment, battery, embarrassment, and humiliation; and (v) retaliated against her—terminated her employment—for complaining about the conditions of her employment including through the "protected activity" of social networking. Roberts avers that she has complied with administrative exhaustion requirements and received a right-to-sue letter from the California Department of Fair Housing and Employment.

She brings 14 causes of action against Chipotle, including intentional infliction of emotional distress, and seeks payment of earned wages, overtime and waiting time compensation; payment of statutory obligations, penalties and damages; an accounting; penalties and special, general and punitive damages; loss of income; interest; attorney's fees; and costs.

Organic Winemaker Faces Prison and Fine for Refusing to Spray Grapes

A French organic winemaker has reportedly appeared in court to answer to charges that he defied an official order to spray his vineyard with a pesticide to prevent the spread of a leafhopper insect believed to be responsible for a devastating bacterial disease that has affected vines in Burgundy's Côte-d'Or region, where Emmanuel Giboulot produces Côte de Beaune and Hautes-Côtes de Nuits organic wines. He claims that the pesticide does not work and is harmful to pollinating insects such as bees. He also apparently insists that more natural means can be used to fight the disease.



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According to a news source, Giboulot faces a six-month prison sentence and €30,000 (US\$41,000) fine for failing to apply the insecticide treatment to his vineyard in July 2013. An online petition about his case has reportedly been signed by more than 40,000 supporters, and a large crowd gathered outside the Dijon court on March 3, 2014, before his appearance. Prosecutors have requested that Giboulot pay a €1,000 fine, and the court will reportedly render its verdict on April 7.

Claiming that 30 acres of vines in the region have been uprooted and the "flavescence dorée" disease threatens more than one-half of the Burgundy region's vineyards, officials contend that preventative treatment is necessary. Giboulot, however, disagrees. He was quoted as saying, "I am not irresponsible and I am not trying to be radical. I simply do not believe that systematic treatment, even without any symptoms of the disease, is the solution. I want to show people that there are options, and that we need to think about our own health and that of our customers. My father began converting to organic farming in the 1970s, and we are now fully organic and biodynamic. I don't want to undo decades of work applying a treatment where the effects on the health of the vines and the public are as yet unproven." Biodynamic farming methods, said to be used by 450 wine producers globally, apparently incorporate ecological and spiritual approaches to farming. See The Guardian and Agence France-Presse, February 23, 2014; Natural Products Online, February 25, 2014.

OTHER DEVELOPMENTS

EWG Ramps Up Pressure on Companies Using Azodicarbonamide in Foods

The Environmental Working Group (EWG) has followed up FoodBabe.com's Vani Hari's petition to Subway about using azodicarbonamide (ADA)—a "chemical used to make yoga mats, shoe soles and other rubbery objects"—in its U.S. food products, by launching its own petition directed to major brands purportedly using the chemical in some 500 food products. Details about Hari's petition appear in Issue 512 of this *Update*.

The EWG <u>list</u> of food products containing ADA, ranging from bread, croutons and pre-made sandwiches and snacks to pastries, rolls, perogies, and bagels, was derived from the organization's database of 80,000 food products.

The synthetic ingredient is apparently listed on product labels, but, according to EWG "has been largely overlooked because it is not known to be toxic to people in the concentration approved by the federal Food and Drug Administration—45 parts per million." EWG claims that commercial bakers switched to ADA in the early 1990s to condition their dough after California regulators added potassium bromate, then a common dough conditioner, to its Proposition 65 list as known to the state to cause cancer. The World Health



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Organization has reportedly found that workers exposed to large volumes of ADA have reported respiratory symptoms and skin sensitization. *See EWG News Release*, February 17, 2014.

Largest U.S. Grocery Stores Join Pledge Against GE Salmon

The nation's two largest grocery stores, Kroger and Safeway, have pledged not to sell genetically engineered (GE) salmon, joining a growing group of stores, including Target, Whole Foods, Trader Joe's, Aldi, H-E-B, Meijer, Hy-Vee, Marsh, and Giant Eagle, that have already rejected the GE salmon currently under final review by the U.S. Food and Drug Administration (FDA).

Nearly 2 million people, including scientists, fishermen, business owners, and consumers, have written to FDA opposing its approval of GE salmon, reportedly the first of some 30 other species of GE fish under development. If approved, the salmon would be the first GE animal in the U.S. food supply, and FDA has indicated that it will likely not be labeled as a product of genetic engineering. *See Friends of the Earth News Release*, March 3, 2014.

MEDIA COVERAGE

New Book About Caffeine Generates Buzz

Mother Jones has **published** a March 5, 2014, interview with journalist Murray Carpenter about his forthcoming book, *Caffeinated: How Our Daily Habit Helps Us, Hurts, and Hooks Us,* which aims to "bring[] us the inside perspective at the additive that *Salt Sugar Fat* overlooked." Speaking with Maddie Oatman about "how much caffeine is healthy, where the industry stands on labeling, and the most pretentious coffee preparation he's observed," Carpenter notes that current regulations do not require foods or supplements to disclose caffeine content on labeling.

"There's some voluntary labeling initiatives underway: The American Beverage Association has recommended bottlers do that, but you can still find energy drinks that don't tell you how much caffeine is in them," Carpenter is quoted as saying. "It's not impossible for coffee and tea to start doing this. And for the products where caffeine is blended in very specific amounts, I don't see any reason consumers should be left in the dark."

In particular, Carpenter reports that "a healthy daily dose of caffeine" varies from person to person, depending on age, size, and other genetic factors that can influence caffeine metabolism. But he stops short of issuing a straightforward answer on the overall health impact of caffeine consumption. "This is the question I got all the time: What's the verdict? Is it good or is it bad?," concludes Carpenter. "If I had a simple answer, it would have been a five-page book. It can be more effective than I had any idea, in terms of improving your



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alertness, your cognition, your athletic ability. It can have stronger more acute effects on sleep and anxiety than I'd imagined. It can be terrific. I think it's important that everybody recognize how much is good for them, what it does for them when they take it, what they feel like when they don't take it, and experiment."

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FOOD & BEVERAGE LITIGATION UPDATE

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB 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.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.





