Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

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CONTENTS

LEGISLATION, REGULATIONS & GUIDANCE

Energy Drink Makers Testify Before Skeptical Senators

The U.S. Senate Committee on Commerce, Science, and Transportation conducted a July 31, 2013, **hearing** to consider issues relating to the purported marketing of energy drinks to children and the alleged adverse health effects attributed to the use of products with elevated levels of caffeine and other stimulants. Among those testifying were Red Bull North America, Inc. Vice President and General Manager Amy Taylor, Monster Beverage Corp. Chair and CEO Rodney Sacks and Yale University Rudd Center for Food Policy & Obesity Senior Research Scientist Jennifer Harris.

Sens. Jay Rockefeller (D-W.Va.), Richard Durbin (D-Ill.) and Richard Blumenthal (D-Conn.) challenged the companies' marketing practices and referred to data showing a surge in emergency room visits from consumption of the products. The executives defended their products, saying they had been proven safe and were targeted to the 18- to 34-year-old market. Sen. John Thune (R-S.D.) thanked the chair for calling the hearing, noting that caffeine has been safely consumed for thousands of years, and indicated his interest in "hearing the steps that the companies represented here today are taking to ensure their products are safe, as well as the efforts they are undertaking to ensure their products are marketed appropriately." *See Republican Press Office News Release*, July 31, 2013.

FDA Issues Final Rule for "Gluten-Free" Labeling

The U.S. Food and Drug Administration (FDA) has issued a final rule defining the term "gluten-free" for voluntary food labeling. Among other things, the rule defines "gluten-free" to mean that a food does not contain (i) an ingredient that is a gluten-containing grain (e.g., spelt wheat); (ii) an ingredient derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour); or (iii) an ingredient derived from a gluten-containing grain that has been processed to remove gluten (e.g., wheat starch). In addition, a food must contain less than 20 parts per million of gluten to use the term "gluten-free" on its label. According to FDA, a food

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that bears the claim "no gluten," "free of gluten" or "without gluten" on its label and fails to meet the requirements for a "gluten-free" claim will be deemed misbranded. The rule will take effect 30 days after its publication in the *Federal Register*. *See FDA News Release*, August 2, 2013.

FDA Proposes Two Rules to Increase Imported Food Safety

The U.S. Food and Drug Administration (FDA) has proposed two rules under the Food Safety Modernization Act (FSMA) for **verifying foreign suppliers** and **accrediting third-party auditors**. Part of the agency's effort "to ensure that imported food meets the same safety standards as food produced in the United States," the proposed rules would (i) require importers to verify "that their foreign suppliers are implementing modern, prevention-oriented food safety practices," and (ii) "strengthen the quality, objectivity, and transparency of foreign food safety audits on which many food companies and importers currently rely to help manage the safety of their global food supply chains."

In particular, the rules establishing foreign supplier verification programs would hold U.S. importers responsible for ensuring that human and animal food produced abroad meets the safety standards set forth in the Federal Food, Drug, and Cosmetic Act and is neither adulterated nor misbranded "with respect to food allergen labeling." In addition, FDA has proposed creating a program to recognize foreign accreditation bodies—such as government agencies—that "would in turn accredit third-party auditors to audit and issue certifications for foreign food facilities and food, under certain circumstances."

"FSMA provides the FDA with a modern tool kit that shifts the paradigm for imports, as well as domestic foods, from a strategy of reaction to one of systematic prevention," said FDA Deputy Commissioner for Foods and Veterinary Medicine Michael Taylor in a July 26, 2013, press release. "Rather than relying primarily on FDA investigators at the ports to detect and respond to food safety problems, importers would, for the first time, be held accountable for verifying, in a manner transparent to the FDA, that the food they import is safe." The agency will accept comments on the proposed rules until November 26, 2013. *See Federal Register,* July 29, 2013.

Upcoming FDA Meeting to Discuss Chemical Hazards in Food

The U.S Food and Drug Administration (FDA) has **announced** a public meeting of the Food Advisory Committee on September 23-24, 2013, in Silver Spring, Maryland. The committee plans to discuss detection signals for chemical hazards in foods, dietary supplements and cosmetics, and review information sources and chemical hazard data. FDA will accept comments until September 16, 2013. *See Federal Register,* July 23, 2013.

EFSA Concludes BPA Exposure "Lower Than Previously Estimated"

The European Food Safety Authority (EFSA) has **issued** a draft assessment of consumer exposure to bisphenol A (BPA), provisionally concluding that "for all population groups diet is the major source of exposure to [BPA] and exposure is lower than previously estimated." According to a July 25, 2013, news release, EFSA used exposure modeling and new human biomonitoring data to refine its estimate of dietary BPA exposure levels for infants and toddlers (375 nanograms per kilogram of body weight per day) as well as the general population above age 18 (132 ng/kg bw/day). In addition, the agency found that dietary BPA exposure was highest among children ages 3 to 10, "explainable by their higher food consumption on a body weight basis."

"By comparison, these estimates are less than 1% of the current Tolerable Daily Intake (TDI) for BPA (0.05 milligrams/kg bw/day) established by EFSA in 2006," stated EFSA, which identified canned food and non-canned meat and meat products "as major contributors to dietary BPA exposure for all age groups." The assessment also named thermal paper "the second most important source of BPA after the diet (potentially accounting for up to 15% of total exposure in some population groups)." As part of its two-stage consultation on BPA, the agency will accept public comments on the draft until September 15, 2013, before issuing its full risk assessment.

Japan Lifts Ban on U.S. Wheat Imports

Japan has reportedly announced that it will resume purchasing U.S. white wheat, ending a two-month suspension that was implemented after genetically engineered crops were found on an Oregon farm in April 2013. According to a news source, Japan imports nearly five million tons of wheat per year—60 percent of which comes from the United States—but does not allow genetically modified wheat. Purchases of western-white wheat reportedly resumed on August 1, while purchases of soft-white wheat for livestock feed will resume August 7. *See japantoday.com,* August 2, 2013.

EFSA Approves Use of Advantame Sweetener

The European Food Safety Authority (EFSA) has **concluded** that the sweetener advantame is safe for human consumption. Derived from aspartame and vanillin, advantame is reportedly 37,000 times sweeter than sugar and 100 times sweeter than aspartame and can be used to enhance flavors such as fruit, citrus and mint and to extend the sweetness duration in chewing gum. The agency has established an acceptable daily intake of 5 mg per kilogram of bodyweight per day. *See ajinomoto.com.*

LITIGATION

FDA Seeks More Time to Promulgate Two Food Safety Regulations

The U.S. Food and Drug Administration (FDA) has filed a motion for reconsideration or stay of a court order establishing rulemaking deadlines under the Food Safety Modernization Act. *Ctr. for Food Safety v. Hamburg*, No. 12-4529 (U.S. Dist. Ct., N.D. Cal., Oakland Div., motion filed July 19, 2013). More information about the litigation appears in Issues 481, 487 and 489 of this *Update*. Scheduled to be heard on August 28, 2013, the motion contends that two of the seven rulemakings at issue, the sanitary transport rule and the intentional adulteration rule, pose challenges that preclude their issuance by the court's deadline. Requesting that the court reconsider its order largely on the basis of arguments already rejected, the agency also asks the court to stay the order pending the Solicitor General's determination whether to authorize an appeal and, if an appeal is authorized, while the appeal is pending.

Prop. 65 Suit Filed Against Clif Bar & Co. for Lead in Food Products

The Environmental Research Center, which frequently files lawsuits to enforce California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65), has sued Clif Bar & Co., alleging that it fails to warn consumers that its protein, energy, electrolyte, and snack bars contain lead, a substance known to the state to cause cancer, birth defects and other reproductive harm. *Envtl. Research Ctr. v. Clif Bar & Co.*, No. 13-532935 (Cal. Super. Ct., San Francisco Cnty., filed July 18, 2013). The plaintiff seeks injunctive relief and civil penalties of $2,500 per day for each violation of Prop. 65.

OEHHA Agrees to Accelerate Chemical Review and Prop. 65 Listings

To settle litigation filed in 2007 by environmental and union interests, California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has agreed to a number of actions that would remove certain steps from the Proposition 65 (Prop. 65) chemical-listing process that would accelerate the listings. *Sierra Club v. Brown*, No. RG07356881 (Cal. Super. Ct., settlement endorsed July 3, 2013). The agreement will affect OEHHA's authoritative bodies listings as to specific chemicals and its Carcinogen Identification Committee listings. Not affected by the agreement, and yet to be determined by the court, is the plaintiffs' motion for judgment on the pleadings requiring OEHHA to list all International Agency for Research on Cancer (IARC) Group 3 chemicals for which IARC finds sufficient evidence of carcinogenicity in animals. According to a news source, the court will hold a hearing to consider whether to approve the agreement on August 15, 2013. *See InsideEPA.com*, July 25, 2013.

Magistrate Recommends Hold on "100% Natural" Suit Against General Mills

A federal magistrate has recommended that General Mills' motion to dismiss a putative consumer fraud class action be denied without prejudice and that, under the primary jurisdiction doctrine, the suit be stayed "pending action by the FDA [Food and Drug Administration] with respect to the referral made by Judge Rogers in *Cox v. Gruma*. *Van Atta v. General Mills, Inc.*, No. 12-2815 (U.S. Dist. Ct., D. Colo., recommendation entered July 18, 2013). At issue is the company's claim that its granola bars are "100% Natural" when they allegedly contain genetically modified organisms (GMOs).

Finding that the food-labeling issue falls within FDA's regulatory authority and that the agency "has not issued a rule which requires products containing GMOs to be labeled as such, nor has the FDA issued a rule regarding whether products labeled 'natural' may contain GMOs," the magistrate found invocation of the primary jurisdiction doctrine appropriate. In this regard, the magistrate stated, "The issues of fact in this matter are not within the conventional experience of judges, they require the exercise of administrative discretion, and they require uniformity and consistency in the regulation of the business entrusted to the particular agency." The parties had 14 days to file written objections and an additional 14 days to respond to another party's objections.

Former Employees Sue Beverly Hills Restaurant over Wages

According to a news source, upscale Rodeo Drive sushi restaurant Urasawa has been sued by former employees who claim they were forbidden from taking breaks and were not paid the overtime they worked. Apparently, a California Labor Department investigation has confirmed the complaints targeting chef and owner, Hiroyuki Urasawa, whose menu includes dishes served with caviar and 24-karat gold flakes and can cost a couple in excess of $1,000. Among those seeking back wages is Heriberto Zamora, who was reportedly forced to buy his own $700-set of knives when he was earning just $9 per hour. Zamora claims he was fired nine hours into his shift when he asked to go home with a fever and cough. *See The New York Times*, July 20, 2013.

Olive Oil Plaintiffs Show Sufficient Damages Under CAFA

A federal court in New York has determined that while plaintiffs alleging they were sold olive-residue oil, or Pomace, instead of the "100% Pure Olive Oil" appearing on the labels of The Gourmet Factory's Capatriti-brand products could not maintain a cause of action under the Magnuson Moss Warranty Act, their claims did exceed the $5-million threshold for maintenance of the action in federal court under the Class Action Fairness Act (CAFA). *Ebin v. Kangadis Food Inc. d/b/a The Gourmet Factory*, No. 13-2311 (U.S. Dist. Ct., S.D.N.Y., order entered July 26, 2013).

The plaintiffs apparently based their amount-in-controversy allegation on documents that the defendant submitted in parallel litigation brought by an olive oil trade association. Details about that suit appear in Issues 470, 482 and 483 of this *Update*. Thus the court rebuffed the defendant's attempt to fault the plaintiffs for failing to conduct an independent investigation into the amount-in-controversy before filing the complaint, observing "Defendant cites no authority for the remarkable notion that plaintiffs cannot in good faith rely on defendant's own representations to this Court." Based on either the full retail price paid for the products or on the benefit of the bargain, calculated by taking the price the plaintiffs actually paid for what they thought was pure olive oil and subtracting the general price of the Pomace they actually received, the court found that the roughly $10.9-million amount derived from sales in New York and New Jersey adequately met the CAFA jurisdictional requirement.

Appeals Court Rejects NYC Size Limits on Sugary Drinks; Mayor Plans Appeal

Applying separation-of-power principles that defeated a state administrative body's effort to regulate smoking in public places, *Boreali v. Axelrod*, 71 N.Y.2d 1 (N.Y. 1987), a New York appeals court has affirmed a lower court ruling invalidating the "Portion Cap Rule" promulgated by the New York City Department of Health and Mental Hygiene (Department). *In re N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dept. of Health & Mental Hygiene*, No. 2013 NY Slip Op 05505 (N.Y. App. Div., decided July 30, 2013).

The rule would have limited the sale of certain sugary soft drink to 16 ounces in food service establishments over which the Department has authority under a memorandum of understanding with the state's Department of Agriculture and Marketing. Thus the rule would have applied to restaurants, delis, fast-food franchises, movie theaters, stadiums, and street carts, but not to grocery stores, convenience stores, corner markets, gas stations, and other similar locales. It would not have applied to alcoholic beverages, milk shakes, fruit smoothies, mixed coffee drinks, mochas, lattes, and 100 percent fruit juices.

According to the court, this lack of uniformity in application demonstrated that the Board of Health, which adopted the Department's recommended rule without change, took into account non-health policy considerations and therefore exceeded its authority, which is derived from the legislative body, here, the City Council. As the court noted, "administrative agencies may only effect policy mandated by statute and cannot exercise sweeping power to create whatever rule they deem necessary." Because the rule did not "fill a gap in an existing regulatory scheme" but instead represented writing on a clean slate and because both city and state legislative bodies have been unable to adopt laws targeting sugar sweetened beverages, the court was compelled to

rule that the action violated the separation-of-powers doctrine. The court did not reach the argument that it was arbitrary and capricious.

In response to the court's ruling, Mayor Michael Bloomberg said, "Today's decision is a temporary setback, and we plan to appeal this decision as we continue the fight against the obesity epidemic." *See Office of the Mayor News Release*, July 30, 2013.

Court Grants Narrow Class Certification in "All Natural" Suits

A federal court in California has granted motions to certify California classes of consumers in two separate consumer-fraud lawsuits involving the "all natural" claims on products made by Bear Naked, Inc. and the Kashi Co. *Thurston v. Bear Naked, Inc.*, No. 11-2890, *Astiana v. Kashi Co.*, No. 11-1967 (U.S. Dist. Ct., S.D. Cal., orders entered July 30, 2013). Details about the latter suit, a consolidated matter, appear under the plaintiff's name Bates in Issue 408 of this *Update*.

The court agreed with Bear Naked that the named plaintiffs failed to sufficiently show that "natural" has a uniform definition among class members, that a sufficient number of class members would have relied to their detriment on the representation or that the company's "representation of natural in light of the presence of the challenged ingredients would be considered to be a material falsehood by class members." Still, the court determined that the plaintiff made a sufficient showing of materiality to justify certification of a class as to "hexane-processed soy ingredients." This is apparently listed in federal regulations as a "synthetic organic chemical manufacturing industry chemical," and, unlike the other ingredients, the defendant did not refute the charge that hexane is unnatural. Accordingly, the court found that common issues exist and predominate with respect to the products containing these ingredients.

Refusing to apply California law to a nationwide class of consumers under the rationale of *Mazza v. American Honda Motor Co.*, 666 F.3d 581 (9th Cir. 2012), given the material differences in the consumer protection laws of various states, the court thus certified a class of "All California residents who purchased Bear Naked, Inc's food products on or after September 21, 2007 in the State of California that were labeled '100% Pure & Natural' or '100% Natural' but which contained Hexane-Processed Soy Ingredients."

The class claims against Kashi Co. involve nearly 100 products and two product representations: "Nothing Artificial" and "All Natural." Finding that (i) common issues predominated with respect to most of the ingredients for the same reasons set forth in the *Bear Naked* litigation, and (ii) California consumer protection law could not be applied on a nationwide basis, the court certified a "Nothing Artificial" California class for products containing "Pyridoxine Hydrochloride, Alpha-Tocopherol Acetate and/or Hexane-

Processed Soy ingredients" and an "All Natural" California class for products containing "Pyridoxine Hydrochloride, Calcium Pantothenate and/or Hexane-Processed Soy ingredients."

LEGAL LITERATURE

Increased Government Activity on Food in Post-2012 Election Period?

University of Illinois Associate Professor of Agricultural Law A. Bryan Endres has co-authored a recently published update of the law suggesting that federal government action on a variety of agriculture- and food-related topics, moribund in the months preceding the 2012 presidential election, could increase during the next few years in light of increasing public interest in food production and safety issues. "United States Food Law Update: Shrouded by Election-Year Politics, State Initiatives and Private Lawsuits Fill in the Gaps Created by Congressional and Agency Ossification," *Journal of Food Law & Policy*, Spring 2013.

Funded in part by the U.S. Department of Agriculture National Institute of Food and Agriculture, the article covers a range of topics including (i) consumer fraud suits challenging the "all natural" promotions for processed food products, (ii) efforts by animal rights organizations to require the humane handling of food animals, (iii) country-of-origin and genetic modification labeling initiatives, (iv) state and local government efforts to address rising obesity rates, (v) state "ag gag" laws proscribing filming in food processing facilities, and (vi) the use of antibiotics in livestock and the litigation that will force the Food and Drug Administration to hold hearings some 30 years after initiating a process to withdraw approval from the use of penicillin and tetracycline for other than health-related reasons.

The authors conclude, "In sum, these tensions among the various market forces are likely to continue, along with greater government involvement in the next years as the nation moves beyond the 2012 election season."

MEDIA COVERAGE

National Geographic Highlights History of Sugar Consumption

"It seems like every time I study an illness and trace a path to the first cause, I find my way back to sugar," opines University of Colorado-Denver nephrologist Richard Johnson in an August 2013 *National Geographic* special feature examining the history of sugar consumption. Titled "Sugar Love: A Not So Sweet Story," the article authored by Rich Cohen traces the spread of sugar from its New Guinea origins throughout the world, in the process raising questions about the sweetener's impact on heart disease, diabetes

and obesity in modern populations. As Johnson asks, "Why is it that one-third of adults [worldwide] have high blood pressure, when in 1900 only 5 percent had high blood pressure? Why did 153 million people have diabetes in 1980, and now we're up to 347 million? Why are more and more Americans obese? Sugar, we believe, is one of the culprits, if not the major culprit."

In particular, the article claims that even as Americans have reduced their consumption of saturated fats, obesity rates have continued to rise, partly because food producers have replaced the fatty ingredients in their products with sugar. According to Cohen, however, health and nutrition experts are now warning that sugar is not only a source of empty calories, but the cause of fatty liver, high blood pressure and other metabolic disease. "It has nothing to do with its calories," Robert Lustig, an endocrinologist at the University of California, San Francisco, was quoted as saying. "Sugar is a poison by itself when consumed at high doses."

OTHER DEVELOPMENTS

CSPI Urges Dannon to Remove Carmine from Yogurt

The Center for Science in the Public Interest (CSPI) has asked Dannon to stop using carmine—a dye reportedly derived from the dried, crushed bodies of cochineal insects—to fruit-flavored yogurt to give it a pink color. According to the advocacy watchdog, Dannon's practice not only cheats consumers, "who might expect that the named fruits—and not the unnamed creepy crawlies—are providing the color," but also puts consumers at risk because it has been linked to allergic reactions ranging from hives to anaphylactic shock. *See CSPI News Release*, July 24, 2013.

Rudd Center Names New Director

Yale University's Rudd Center for Food Policy & Obesity has announced researcher Marlene Schwartz as its next director following the departure of Kelly Brownell for Duke University's Sanford School. According to a July 19, 2013, press release, Schwartz previously served as co-director of the Yale Center for Eating and Weight Disorders, where she studied "how children's diets and health are influenced by home, school, and community environments," as well as the impact of local, state and federal policies on nutrition.

"Right now, we live in a world where it is difficult for parents to feed their children well, and people are discriminated against based on body size and weight. This must change," said Schwartz, whose work received support from the Robert Wood Johnson Foundation, U.S. Department of Agriculture, National Institutes of Health, American Heart Association, and Horizon Foun-

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dation. "At the Rudd Center, we are working to create a world that supports parents' efforts to raise nourished, healthy children, and eliminates weight stigma and discrimination."

SHB NEWS

SHB Partners Launch Class Action Blog

Shook, Hardy & Bacon Class Actions & Complex Litigation Partners Andrew Carpenter, Scott Kaiser and Gregory Wu have launched the Missouri & Kansas Class Action Blog to provide up-to-date information about federal and state rulings in class action decisions arising in these states. New posts can be accessed by subscribing to the blog or through the authors' LinkedIn pages.

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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.