

ISSUE 491 | JULY 19, 2013



#### **CONTENTS**

Legisia	ition	, ĸeg	gui	ations	and	Sta	ındaı	as
			_			- 1		

FDA Updates Guidance on Salmonella in Animal Food1
FDA Seeks Information on Salmonella Risk from Tree Nuts
EFSA to Complete Draft Opinion on Acrylamide in 2014
Canada Seeks Information on Phthalates for Priority Assessment
UK Government Rejects Minimum Unit Pricing for Alcoholic Beverages3
ASA Upholds Complaint Claiming Beer Ad Condoned Alcohol Consumption at Football Stadium

### Litigation

Court Dismisses Consumer Fraud Claims Against Soy Yogurt Maker4
Court Dismisses Certain Claims Against Yogurt Maker
Putative Class Claims Truvia® Falsely Advertised as "Natural"6
Putative Class Claims Boar's Head Misrepresents Lower Sodium Claims 6
California Class Members Seek to Set Aside Settlement of "Evaporated Cane Juice" Claims
Court Tentatively Rejects Prop. 65 Lead Warnings for Fruit and Vegetable Products

## **Legal Literature**

Law Review Note Finds Model for Fast Food Litigation in Canada 10
Comment Focuses on FSMA's Potential Effects on Litigation

### **Other Developments**

CSPI Criticizes Retired Basketball	
Star's Soft Drink Pitch	1

## Media Coverage

INY I Raises Conc	erns over	Real	LIIE	and	
Online Tracking					12

### Scientific/Technical Items

Researchers Link FTO Gene to Increa	ased
Ghrelin Levels	13

## LEGISLATION, REGULATIONS AND STANDARDS

## FDA Updates Guidance on Salmonella in Animal Food

The Food and Drug Administration (FDA) has published new **guidance** on *Salmonella*-contaminated food for animals. Titled "Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals" (CPG), the guidance finalizes the draft CPG that was announced in August 2010 and includes the following changes: (i) the title has changed from "*Salmonella* in Animal Feed" to "*Salmonella* in Food for Animals" to clarify that it covers all animal food, including pet food and animal feed, and (ii) the term "direct human contact animal feed" has been replaced with the term "pet food" and includes treats and chews. FDA has also announced (i) the removal of 21 CFR 500.35 "Animal feeds contaminated with *Salmonella* microorganisms," and (ii) the withdrawal of "Compliance Policy Guide Sec. 690.700 *Salmonella* Contamination of Dry Dog Food." *See Federal Register*, July 16, 2013.

### FDA Seeks Information on Salmonella Risk from Tree Nuts

The Food and Drug Administration (FDA) has issued a <u>request</u> for comments, scientific data and information to use in risk assessment of human salmonellosis associated with the consumption of tree nuts, including almonds, cashews, pistachios, pine nuts, Brazil nuts, macadamia nuts, and walnuts.

The risk assessment seeks to quantify the public health risk associated with eating tree nuts potentially contaminated with *Salmonella* and evaluate the impact of interventions to prevent contamination with the bacterium or to reduce contamination levels. FDA said an assessment is necessary in light of "outbreaks of human salmonellosis linked to tree nuts during the past decade, by product recalls, and by *Salmonella* isolation from tree nuts during surveys." Comments will be accepted until October 16, 2013. *See Federal Register*, July 18, 2013.

## EFSA to Complete Draft Opinion on Acrylamide in 2014

Responding to a request from the European Commission, the European Food Safety Authority (EFSA) has <u>announced</u> plans to complete a draft scientific opinion on acrylamide by mid-2014 using "hundreds of scientific studies" as



ISSUE 491 | JULY 19, 2013

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.

For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

> Mark Anstoetter 816-474-6550 manstoetter@shb.com



or

Madeleine McDonough 816-474-6550 202-783-8400 mmcdonough@shb.com



If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com);

well as new data from food business operators, consumer organizations and other stakeholders. According to a July 15, 2013, news release, EFSA's Panel on Contaminants in the Food Chain (CONTAM Panel) will use information and research solicited in April 2013 to assess "the toxicity of acrylamide for humans and update its estimate of consumer exposure through the diet." After a public consultation, the CONTAM Panel aims to finalize its assessment during the first half of 2015.

"In 2005, EFSA stated that acrylamide may be a human health concern and that efforts should be made to reduce exposure to this substance through the diet," said the agency. "EFSA's comprehensive assessment of this scientific issue will allow EU decision-makers to take account of the latest scientific findings in managing possible risks associated with the presence of acrylamide in the food chain."

## Canada Seeks Information on Phthalates for Priority Assessment

Environment Canada has <u>issued</u> a notice directing manufacturers and importers to provide information about their use of phthalates in food and beverage contact materials, among other consumer products. According to the July 13, 2013, announcement in the *Canada Gazette*, the government has identified more than 30 phthalate substances for priority assessment under its Chemicals Management Plan. To this end, Environment Canada has asked industry for details about the manufacture, importation and use of these substances "for the purposes of assessing whether [they] are toxic or capable of becoming toxic, or for the purpose of assessing whether to control [them]."

The notice applies to those stakeholders who (i) imported or manufactured more than 100 kilograms of any of the listed substances at a concentration equal to or above 0.001 percent by weight; (ii) used more than 1,000 kilograms of a substance at that concentration; or (iii) imported phthalate-containing products intended for children younger than age 6; for direct contact with food, beverages, cosmetics, or personal care products; for inhalation, skin exposure or contact with mucous membranes; or for use in clothing and footwear, furniture, flooring, or electronics. In particular, the agency has asked for data on the use of phthalates in "food and beverage products, mixtures or manufactured items," as well as "single or multi-layered packaging consisting of paper, plastic, metal, foil or other materials which have or may have direct contact with food." These data include any unpublished studies on the human health or ecological impact of phthalates, in addition to descriptions of the facilities where phthalates are manufactured or used.

Respondents who fail to submit the required information are subject to fines and/or jail terms under the Canadian Environmental Protection Act. Environment Canada will accept responses to its notice until November 13, 2013.



ISSUE 491 | JULY 19, 2013

## **UK Government Rejects Minimum Unit Pricing for Alcoholic Beverages**

The U.K. Home Office has <u>issued</u> its response to a public consultation on its alcohol strategy, laying out a number of new measures but stopping short of instituting a scheme that would have priced alcoholic beverages per unit of alcohol. Under the new strategy, the government has vowed, among other things, to (i) take action "on irresponsible promotions in pubs and clubs," (ii) facilitate "targeted action by pubs and clubs themselves to curb irresponsible drinking," (iii) put an end to deep discounts on alcohol that made it possible for consumers to purchase beverages for less than the cost to retailers, and (iv) free "responsible business and community groups from unnecessary red tape, while maintaining the integrity of the licensing system." At the same time, however, the Home Office ultimately declined to implement minimum unit pricing (MUP) because it found little evidence that the plan would "reduce problem drinking without penalizing all those who drink responsibly."

The decision reportedly drew criticism from health and consumer groups that advocated MUP as a way to reduce the consumption of alcoholic beverages. "Today's announcement confirms that the government has caved in to lobbying from big business and reneged on its commitment to tackle alcohol sold at pocket money prices," Alcohol Health Alliance Chair Ian Gilmore was quoted as saying. "We know that minimum pricing will work and there is a huge level of support from frontline workers, including doctors and the police. Alternative measures outlined in today's announcement will have little or no impact—they are just a smokescreen to hide how the government has turned its back on public health." See U.K. Home Office Press Release and The Guardian, July 17, 2013.

## ASA Upholds Complaint Claiming Beer Ad Condoned Alcohol Consumption at Football Stadium

The U.K. Advertising Standards Authority (ASA) has <u>upheld</u> two complaints alleging that a recent advertisement for Heineken beer "condoned or encouraged the consumption of alcohol in a football stadium within sight of the pitch, which was an illegal activity," and "condoned or encouraged people to take glass bottles into a football stadium, which was not permitted." The TV commercial in question apparently featured a man traveling to the UEFA Champions League final game, where he and a woman were shown taking a seat in view of the field and "clinking the two bottles of Heineken together in a celebratory fashion." Although Heineken UK Ltd. described the ad as a "light-hearted" and "tongue-in-cheek" fantasy, ASA ultimately agreed with complainants that the final scene implied that the main characters "were going to consume beer during the football match."

"We considered that the ad could give the impression to viewers that such behavior, which was either illegal (in the case of consuming alcohol) or not



ISSUE 491 | JULY 19, 2013

permitted (in the case of bringing glass bottles into the stadium), was acceptable when that was not the case, and there was a risk that viewers could attempt to copy that behavior," said the agency, which concluded that the ad breached BCAP Code rules 1.2 (social responsibility), 1.3 (legality) and 4.9 (harm and offense). "We therefore concluded that the ad was socially irresponsible, because it condoned or encouraged behavior that was either illegal or not permitted."

### LITIGATION

## **Court Dismisses Consumer Fraud Claims Against Soy Yogurt Maker**

A federal court in California has dismissed without prejudice a putative class action alleging that Wholesoy & Co. misleads consumers by (i) listing "organic evaporated cane juice" instead of "sugar" or "dried cane syrup" as an ingredient on its soy yogurt products in violation of Food and Drug Administration (FDA) labeling rules, and (ii) marketing its soy product as yogurt because it fails to comply with FDA's standard of identity for "yogurt." *Hood v. Wholesoy & Co.*, No. 12-5550 (U.S. Dist. Ct., N.D. Cal., decided July 12, 2013). The court agreed with the company that the complaint must be dismissed under the primary jurisdiction doctrine because its resolution would require the court to decide an issue committed to the agency's expertise "without a clear indication of how FDA would view the issue."

Specifically, the court found that the evaporated cane juice guidance document on which the plaintiff relied is expressly "not a 'legally enforceable' standard, but only a suggestion. Given that statement, it is unclear why FDA subsequently has issued two warning letters citing that guidance. At a minimum, this indicates to the Court that the FDA's position is not settled. So far as it appears, FDA has not yet set a uniform enforcement standard." The court also opined that "FDA does not appear to have spoken at all as to whether 'soy yogurt' should be subject to the same standards as dairy yogurt. It is not apparent to the Court whether the FDA would consider the addition of the word 'soy' in front of yogurt to mean that the product was subject to that same Standard of Identity or, like 'butter' versus 'peanut butter,' subject to a completely different standard. . . . Many products contain soy and the need for the FDA to administer a comprehensive approach is compelling."

The court found it appropriate to defer to FDA's authority and expertise "to say what the appropriate rules should be with respect to 'soy yogurt' and 'evaporated cane juice.' Rendering a decision based on what this Court believes the FDA might eventually decide on either of these issues 'would usurp the FDA's interpretive authority."



ISSUE 491 | JULY 19, 2013

## **Court Dismisses Certain Claims Against Yogurt Maker**

A federal court in California has dismissed some of the consumer fraud claims filed against Chobani, Inc. in putative class litigation alleging that the company mislabels its yogurts as containing "evaporated cane juice," misleads consumers by stating that its products do not contain added sugar and falsely states that its products are "all natural" because they contain artificial ingredients, flavorings, coloring, and chemical preservatives. *Kane v. Chobani, Inc.*, No. 12-2425 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered July 12, 2013).

The court granted with leave to amend (i) the motion to dismiss as to the evaporated cane juice claims to the extent they are based on products not purchased by the plaintiffs; and (ii) the motion to dismiss the plaintiffs' Unfair Competition Law (UCL), False Advertising Law (FAL) and Consumers Legal Remedies Act (CLRA) claims based on the "no sugar added" and "all natural" representations, finding that the plaintiffs did not sufficiently allege reliance. The plaintiffs have 30 days to file an amended complaint.

The court granted the motion to dismiss the plaintiffs' UCL, FAL and CLRA claims based on the defendant's alleged violation of the standard of identity for yogurt on the ground of primary jurisdiction, but allowed the plaintiffs to seek leave to amend if "FDA retracts its previous notice that it intends to amend the Standard of Identity for Yogurt." The court dismissed with prejudice the unjust enrichment, Song-Beverly Act and Magnuson-Moss Warranty Act claims, but denied the defendant's motion to dismiss "in all other respects."

The court has also denied the plaintiffs' motion for a preliminary injunction to stop the defendant from selling its yogurt products and order the company to remove and recall the products from its distributors and retailers. Applying federal standards to the request, the court was not persuaded that the plaintiffs would experience "any significant, much less irreparable harm, if Defendant is not required to re-label its yogurts at this time." Rather, according to the court, the harm to the defendant and retailers "would be substantial."

Meanwhile, an organization opposed to genetically modified foods—GMO Inside—has reportedly called on Chobani to cease marketing its Greek yogurt products as "real" and "natural" until the company stops using milk from cows fed with genetically modified feed. The group is urging consumers to sign a petition and post comments on Chobani's Facebook page. Chobani reportedly issued a statement in response: "GMO is complex and weighs on the balance of our commitments, particularly affordability, as non-GMO ingredients are fewer and more costly. We are in the infancy of exploring how we as a company, together with our suppliers, will navigate this important issue. We have never made claims that our products are GMO-free." See Advertising Age, July 17, 2013.



ISSUE 491 | JULY 19, 2013

## Putative Class Claims Truvia® Falsely Advertised as "Natural"

A Hawaii resident has filed a putative nationwide class action against Cargill, Inc., alleging that the company falsely advertises its Truvia® sweetener product as "natural" when it is actually made from ingredients that are "either synthetic or harshly chemically processed." *Howerton v. Cargill, Inc.*, No. 13-0336 (U.S. Dist. Ct., D. Haw., filed July 8, 2013).

According to the complaint, the company markets the product with "natural imagery such as the leaves of the stevia plant," yet "the stevia-derived ingredient, Reb A, is not the natural crude preparation of stevia, but rather is a highly chemically processed and purified form of the stevia leaf extract," and Reb A "comprises only 1% of Truvia." The plaintiff alleges that "the main ingredient, erythritol, which Cargill also purports to be a natural ingredient derived through natural processes, is not made like it is in nature, but rather is synthetically made. Cargill describes the process of obtaining stevia leaf extract as 'similar to making tea,' but does not tell the consumer that Cargill then adds ethanol, methanol, or rubbing alcohol to this so-called 'tea' in a patented multi-step process to purify it." The plaintiff claims that the product is priced some 300 percent more than Sweet 'N Low® and 67 percent more than Splenda® and that she "suffered an injury by purchasing the Product at inflated prices."

Seeking to certify a nationwide class and statewide subclass of consumers, the plaintiff alleges unjust enrichment, violation of a Hawaii law proscribing unfair methods of competition and unfair or deceptive acts or practices, violation of Hawaii's Uniform Deceptive Trade Practice Act, breach of express and implied warranty under multiple state laws, and violation of the states' consumer fraud laws. She also seeks injunctive relief, a corrective advertising campaign, an order requiring the defendant to "notify each and every individual and/or business who purchased the Product of the pendency of the claims" to give them an opportunity to obtain restitution, restitution, disgorgement, and damages.

### Putative Class Claims Boar's Head Misrepresents Lower Sodium Claims

A New York resident has filed a putative class action against Boar's Head Provisions Co., alleging that the company's advertising and labeling representations—"47% lower sodium," "42% lower sodium," and "40% lower sodium"—for some of its deli meats, including turkey breast and ham, contain as much sodium as its regular deli meat products and a higher percentage of sodium than stated when compared to U.S. Department of Agriculture (USDA) reference products. *Mackles v. Boar's Head Provisions, Co., Inc.*, No. 13-4855 (U.S. Dist. Ct., S.D.N.Y., filed July 12, 2013).



ISSUE 491 | JULY 19, 2013

According to the complaint, the defendant's representations are inaccurate by a factor of more than 10 percent. The plaintiff also alleges that when he asked the company about the lower-sodium claims on its product labels, he received a letter stating that they "were submitted to and approved by the USDA." On further investigation, the plaintiff allegedly learned from USDA that companies must ensure labeling accuracy, and "[r]egardless of what reference food they are using (their own regular product, market leader, USDA data, etc) the company has to ensure that the claims remain accurate." USDA's alleged response to a Freedom of Information Act request about Boar's Head applications to approve lower-sodium product labels was "that a search by knowledgeable staff in FSIS [Food Safety and Inspection Service] failed to locate any documents that would be responsive to your request."

While the plaintiff seeks to certify a class of "all purchasers" of the specified Boar's Head products, he appears to limit the class to New York purchasers, noting his belief that "there are thousands of New York consumers who are members of the Class." Alleging damages in excess of \$5 million, violation of New York's deceptive acts and practices law and breach of express warranty, the plaintiff seeks injunctive relief, attorney's fees and costs.

## California Class Members Seek to Set Aside Settlement of "Evaporated Cane Juice" Claims

Two California residents who filed a putative class action in a California federal court against, among others, a company that makes "Horizon," "Silk," "International Delight," and "Land O'Lakes" brand products with labels including as an ingredient "evaporated cane juice" in alleged violation of Food and Drug Administration (FDA) requirements, have filed a complaint in intervention and motions to set aside a nationwide class settlement approved by a federal court in Florida. Singer v. WWF Operating Co., No. 13-21232 (U.S. Dist. Ct., S.D. Fla., filed July 12, 2013).

According to the California plaintiffs, the Florida action was filed on April 8, 2013, as a statewide putative class action and then amended nine days later for purposes of securing preliminary approval of a nationwide class settlement. The California plaintiffs filed their putative statewide class action on April 29 and allege that they had extensive communications with defendant's counsel who requested from them a 30-day extension to answer the California complaint just four days before the fairness hearing before the Florida court pertaining to the nationwide class settlement. The Florida court apparently gave final approval to the settlement on June 28.

The California plaintiffs also allege that defendant's counsel never advised them about the proposed nationwide class settlement, which included their claims, yet counsel made certain representations to the Florida court that



ISSUE 491 | JULY 19, 2013

the defendant had complied with Rule 23 notice requirements. They further allege that the defendant misrepresented to the Florida court that a settlement of \$800,000—of which \$272,500 would be distributed to the class—was fair and reasonable and that "issues of FDA compliance, preemption and primary jurisdiction minimized the likelihood of Plaintiff's success," despite California decisions allowing misbranding cases to proceed under California consumer law.

The complaint in intervention states, "This action resolved over the course of nine days, and only to Defendant's benefit. The result was far from a settlement that protected the class and absent class members' rights. Rather, it is merely an agreement Defendant used to rid itself of exorbitant liability for all of its misbranded products." The California plaintiffs urge the court to set aside the settlement order under Rule 60(b)(4), arguing that it is "void for Defendant's failure to provide the required Rule 23(c)(2) individual notice and due process rights to Intervenors, as well as for Defendant's failure to provide timely and proper CAFA [Class Action Fairness Act] notice."

As to the latter, CAFA requires that "final approval of a proposed settlement not be issued earlier than 90 days after the later of the dates on which the appropriate Federal official and the appropriate State official are served with the notice required under subsection (b)." Arkansas was allegedly served on May 16, and 90 days thereafter is August 14, according to the complaint.

## Court Tentatively Rejects Prop. 65 Lead Warnings for Fruit and Vegetable Products

A California court has tentatively determined, following a 10-day bench trial, that the levels of lead in canned or packaged fruit, vegetable and grape drink products, or baby foods, are below the regulatory "safe harbor" exposure level under Proposition 65 (Prop. 65) and therefore that the companies which make them are not required to provide Prop. 65 warnings to consumers. <u>Envtl. Law Found. v. Beech-Nut Corp.</u>, No. RG11 597384 (Cal. Super. Ct., Alameda Cnty., tentative decision entered July 15, 2013). Because few Prop. 65 cases go to trial, the court was faced with a number of questions of first impression, primary among them application of the "naturally occurring" defense.

The parties did not dispute the presence of lead in the products or that it has been identified as a known carcinogen and reproductive toxin under Prop. 65. Beech-Nut Corp., the original defendant, was joined at trial by a number of other food and beverage manufacturers, including Del Monte Foods; Dole Packaged Foods, LLC; Gerber Products Co.; Seneca Foods Corp.; Tree Top, Inc.; and Welch's Foods, Inc. They claimed that no warnings were required because they were preempted by federal law, the lead in their products is naturally occurring and does not constitute an "exposure" under Prop. 65, or that they have established that the exposures are below the regulatory "safe harbor" level of 0.5 micrograms per day.



ISSUE 491 | JULY 19, 2013

As to preemption, the defendants argued "that requiring their labels to carry a warning to the effect that the products contain lead . . . would be an obstacle to federal objectives and amount to misbranding under the FDCA [Food, Drug, and Cosmetic Act]." Essentially, they contended that the federal government has a policy of promoting the consumption of these foods, and a Prop. 65 warning on product labels would deter consumers from buying the products. The court determined that the defendants failed to identify a federal policy "with which a Prop. 65 warning would be in direct conflict" or to produce evidence that a "warning would result in California consumers eating fewer fruits and vegetables."

Noting that the "naturally occurring" defense is not a part of the statute, but rather has been adopted through formal rulemaking by the Office of Environmental Health Hazard Assessment (OEHHA), the court also determined that the defendants (i) failed to offer evidence "that the small amounts of lead in their products are present 'solely as a result of absorption or accumulation of the chemical which is naturally present in the environment"; and (ii) did not show what portion of the lead in their products was naturally occurring. According to the court, OEHHA's rule "required Defendants either to establish that the lead in their products was solely geogenic or to establish the proportions that were geogenic. They did neither."

In ruling that the defendants also failed to demonstrate efforts to achieve the "lowest level currently feasible" as part of the "naturally occurring" defense, the court rejected the plaintiff's argument that food manufacturers must comply with all of the guidelines of the Codex Alimentarius Commission's *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods*. The court noted that the Codex recommendations have not been adopted by the Food and Drug Administration and were, in fact, adopted in 2004, more than 15 years after the implementing regulations were enacted. Thus, in the court's view, OEHHA could not have had the recommendations in mind when drafting the regulations. The court also stated, "[M]any of the recommendations in the Codex are not realistically achievable and would accomplish very little. For example, the recommendations to test each grower's soils for lead would require tremendous expenditures and would have little effect on the amount of lead in the products."

As to its conclusion that the defendants had established the safe harbor defense, the court was persuaded by their primary nutrition expert, Barbara Peterson, who based her finding that the average user who consumed the products was exposed to less than 0.5 micrograms per day of lead, averaged over a scientifically appropriate period of 14 days, on average lead test results for the products rather than evaluating each individual test score separately. She obtained consumption data from the NHANES database and averaged the survey data, analyzing it with a geometric mean rather than an arithmetic mean.



ISSUE 491 | JULY 19, 2013

She also did not, as the plaintiff's expert did, rely on the 85<sup>th</sup> percentile of the NHANES data as representative of what the average consumer eats on one or more eating occasions on the same day. According to the court, the plaintiff's expert only did so because counsel asked her to focus on the 85<sup>th</sup> percentile without explaining why. The court rejected the plaintiff's reliance on a case involving touch-up paint containing toluene, stating "DiPirro does not stand for the proposition that consumer data at the 85<sup>th</sup> percentile of consumption data which overstates the amounts of a listed chemical average users are exposed to is an appropriate substitute for actual consumption data to determine intake or exposure for average users."

The court further rejected the plaintiff's effort to elevate the views of their OEHHA witness regarding Peterson's averaging approach to the level of agency policy. According to the court, "on the present record, The Court cannot find that what was said in Dr. Donald's 1991 declaration constituted a policy of OEHHA, or that the policy he testified to at trial is one which was well known and of longstanding.... There is no evidence that Dr. Donald's declaration performed the function of advising those responsible for compliance with Prop. 65 of any policy of OEHHA regarding averaging or frequency of exposure." The court also found his "expression of policy" unclear.

The parties have 15 days to file and serve any objections.

## LEGAL LITERATURE

### Law Review Note Finds Model for Fast Food Litigation in Canada

According to a recently published law review note, health care reimbursement suits modeled on Canada's Cost Recovery Act and provincial litigation against cigarette manufacturers could be successfully maintained against the food industry for the treatment of obesity-related illnesses. Timothy Poodiack, "The Cost Recovery Act and Tobacco Litigation in Canada: A Model for Fast Food Litigation," *Brooklyn Journal of International Law* (2013). The note includes background on the country's universal health care system, a comparison of issues faced by plaintiffs in U.S. suits against "fast food" companies to issues arising in tobacco litigation, "including assumption of the risk and causation arguments," and an examination of how the Cost Recovery Act can rebut those arguments, "making the Act an attractive model for potential future food litigants in Canada."

## Comment Focuses on FSMA's Potential Effects on Litigation

A recently published law review comment contends that food makers should not be concerned that the Food Safety Modernization Act (FSMA) will increase food borne illness-related litigation or make it easier for plaintiffs to succeed.



ISSUE 491 | JULY 19, 2013

David Benton, "The Impact of Mandatory Recalls on Negligence and Product Liability Litigation Under the Food Safety Modernization Act," San Joaquin Agricultural Law Review (2012-2013). The author opines that the FSMA "will likely have little or no impact on negligence and product liability litigation," but recommends that manufacturers be given limited immunity from civil actions when they comply with a Food and Drug Administration voluntary recall request. He also recommends that the law be amended to expressly preempt state regulation, which would bring the FSMA closer in line with the Food, Drug, and Cosmetic Act as to medical devices.

### OTHER DEVELOPMENTS

### CSPI Criticizes Retired Basketball Star's Soft Drink Pitch

Former basketball star Shaquille O'Neal reportedly plans to endorse a new line of "low calorie sodas" that critics say promote obesity and other health problems. The Soda Shaq line is manufactured by AriZona beverages and will be distributed by convenience retailer 7-Eleven at stores nationwide. A press release **announcing** the product states that Soda Shaq contains no artificial flavors, colors or preservatives, is made with pure cane sugar and contains only 90 calories per serving, allowing fans to "satisfy their sweet tooth without the guilt from the very first clean and refreshing sip."

Consumer advocacy group the Center for Science in the Public Interest (CSPI), however, claims that each 24-ounce can of Soda Shaq contains three servings, or 270 calories, and 17 teaspoons of sugar per can. "Despite the implausible assertion on the label that the non-resealable vessel contains three servings, a single can of Soda Shaq cream soda contains about two to three times as much sugar as the [American] heart association recommends for a whole day," said CSPI.

Noting that as recently as last year, O'Neal professed concern about diabetes and his family members' struggle with the disease, and even stated on a news program that he tries to "stay away from the sodas," CSPI Executive Director Michael Jacobson has called on the retired athlete to reconsider whether he wants to promote a product that allegedly contributes to various health problems. "Clearly, Shaq knows better," said Jacobson. "He has said he avoids soda himself, and worries about obesity and diabetes. But now he's using his name, face and reputation to make those health problems even bigger. It's shameful hypocrisy, presumably motivated by money." See CSPI News Release, July 17, 2013.



ISSUE 491 | JULY 19, 2013

## MEDIA COVERAGE

## NYT Raises Concerns over Real Life and Online Tracking

A pair of recent articles in *The New York Times* has raised questions about the tracking and surveillance practices used by marketers to gather information about consumers shopping in stores and online. The first article, "Attention, Shoppers: Store is Tracking Your Cell," discusses new technology that allows retailers "to track customers' movements by following the Wi-Fi signals from their smartphones." According to *Times* writers Stephanie Clifford and Quentin Hardy, these stores are experimenting with a combination of smartphone tracking, video surveillance and apps to glean data about shoppers "as varied as their sex, how many minutes they spend in the candy aisle and how long they look at merchandise before buying it."

"But while consumers seem to have no problem with cookies, profiles and other online tools that let e-commerce sites know who they are and how they shop, some bristle at the physical version, at a time when government surveillance—of telephone calls, Internet activity and Postal Service deliveries—is front and center," note the authors, who cite several technology experts concerned about how much information is being inferred and shared with others. Retailers, however, have defended the new practices as necessary to remaining competitive in an increasingly online retail environment. "Brick-and-mortar stores have been disadvantaged compared with online retailers, which get people's digital crumbs," said one spokesperson for Cisco's emerging technology group. "[Why... should physical stores] not be able to tell if someone who didn't buy was put off by prices, or was just coming in from the cold?" See The New York Times, July 15, 2013.

Meanwhile, a second article has reported that the World Wide Web Consortium's (W<sub>3</sub>C's) Tracking Protection Working Group, which has attempted for years to set "do not track" standards for advertising networks and data brokers, has decreed that "web users should be able to tell advertising networks not to show them targeted advertisements based on their browsing activities—and those companies should comply." As explained in a July 15, 2013, New York Times article, the working group has not yet determined "what it means when a Web user turns on a Do Not Track signal," but "the decision on ad targeting moves the group... a step closer to reaching consensus."

In issuing its ruling, W<sub>3</sub>C apparently rejected the advertising industry's request to continue using behavioral tracking data as long as it removed certain information. It must now consider other aspects of the online tracking debate, including whether browser manufacturers should set the Do Not Track signal by default. "We are always going to participate in an effort to get something that is meaningful, makes sense and continues to preserve the benefits to consumers in products and services that our members offer,"



ISSUE 491 | JULY 19, 2013

a lawyer representing the Digital Advertising Alliance told the Times. "But participating in a process and agreeing to a failed standard are two different things."

### SCIENTIFIC/TECHNICAL ITEMS

### Researchers Link FTO Gene to Increased Ghrelin Levels

A new study has reportedly detailed how a common gene variant linked to obesity affects the production and reception of ghrelin, the hormone responsible for stimulating hunger. Efthimia Karra, et al., "A link between FTO, ghrelin, and impaired brain food-cue responsivity," Journal of Clinical Investigation, July 2013. According to a July 15, 2013, press release, in the first part of the study, researchers with University College London, the Medical Research Council and King's College London Institute of Psychiatry analyzed ghrelin levels and other indicators of hunger from two groups of participants—those with the high obesity-risk FTO gene (AA group) and those with the low obesity-risk version (TT group)—who were perfectly matched for body weight, fat distribution and social factors such as education level. The results evidently showed that AA group participants not only reported feeling hungrier after a meal than their TT group counterparts, but had "much higher circulating ghrelin levels," suggesting "that the obesity-risk variant (AA) group do not suppress ghrelin in a normal way after a meal."

The second part of the study apparently relied on functional magnetic resonance imaging (fMRI) "to measure how the brain responds to pictures of high-calorie and low-calorie food images, and non-food items, before and after a meal." In this scenario, those with the FTO gene variant "rated pictures of high-calorie foods as more appealing after a meal than the low-risk group," and the fMRI "revealed that the brains of the two groups responded differently to food images (before and after a meal) and to circulating levels of ghrelin." To explain these differences, researchers over-expressed the FTO gene in mouse and human cells "and found that this altered the chemical make-up of ghrelin mRNA (the template for the ghrelin protein) leading to higher levels of ghrelin itself."

"What this study shows us is that individuals with two copies of the obesityrisk FTO variant are biologically programmed to eat more. Not only do these people have higher ghrelin levels and therefore feel hungrier, their brains respond differently to ghrelin and to pictures of food—it's a double hit," the lead author was quoted as saying. "At a therapeutic level this arms us with some important new insights to help in the fight against the obesity pandemic. For example, we know that ghrelin (and therefore hunger) can be



ISSUE 491 | JULY 19, 2013

reduced by exercise like running and cycling, or by eating a high-protein diet. There are also some drugs in the pipeline that suppress ghrelin, which might be particularly effective if they are targeted to patients with the obesity-risk variant of the FTO gene."

## OFFICE LOCATIONS

Geneva, Switzerland +41-22-787-2000 Houston, Texas +1-713-227-8008 Irvine, California +1-949-475-1500

**Kansas City, Missouri** +1-816-474-6550

London, England +44-207-332-4500 Miami, Florida

+1-305-358-5171 Philadelphia, Pennsylvania

+1-215-278-2555
San Francisco, California

+1-415-544-1900 Tampa, Florida

+1-813-202-7100 **Washington, D.C.** +1-202-783-8400

### **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.



