

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FMSA Implementation Strategies Focus of Upcoming FDA Meeting . . .	1
Cal/EPA Extends Comment Period on Proposal to List Styrene Under Prop. 65	1
New Food Safety Agency Takes over FSA's Former Duties in Scotland . . .	2

LITIGATION

Whiskey-Labeling Exemption Is Unconstitutional, Says Tennessee AG	2
Hershey Escapes Chocolate-Labeling Suit	3
Florida Federal Courts Allow "Natural" Pretzel Challenges to Continue	4
Jury Finds for Heinz in "Dip & Squeeze" Packet Dispute	5
Wrongful-Death Suit Alleges Quorn® Mycoprotein Caused Fatal Allergy Reaction.	5
Townsend Farms and Costco Sued over Hepatitis Outbreak	6
Sentences Determined for First Prosecutions in U.K. "Horsemeat Scandal"	6

SCIENTIFIC/TECHNICAL ITEMS

New Study Alleges Relationship Between Moderate SSB Consumption and Diminished Liver Health; Anti- Sugar Crusader Condemns Industry over Added-Sugar Labeling	7
Study Measures Exposure to Free and Conjugated Forms of BPA.	8

LEGISLATION, REGULATIONS AND STANDARDS

FMSA Implementation Strategies Focus of Upcoming FDA Meeting

The U.S. Food and Drug Administration (FDA) has established a docket for comments related to the agency's implementation of food safety standards mandated under the Food Safety Modernization Act (FMSA) and **announced** an April 23-24, 2015, public meeting in Washington, D.C., to solicit input about operational work plans.

Operational work plan discussions will focus on produce safety, preventive controls for animal feed and food manufacturing facilities, measures to address intentional adulteration, the Foreign Supplier Verification Program, and FDA's third-party accreditation program. Meeting participants will also have the opportunity to attend various break-out sessions on particular topics. Registration information is available on [FDA's website](#), and stakeholders may submit written or electronic comments to the docket by May 26. *See Federal Register*, March 24, 2015.

Cal/EPA Extends Comment Period on Proposal to List Styrene Under Prop. 65

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) has extended the comment period about whether styrene meets the criteria for authoritative bodies listings under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65) until April 29, 2015. OEHHA **announced** its intent to list styrene as a chemical known to the state to cause cancer under the authoritative bodies listing mechanism of Prop. 65 on February 27. Styrene is used in the manufacture of various consumer products, including polystyrene packaging, synthetic rubber and food containers.

Two previous attempts to list styrene as known to cause cancer under Prop. 65's Labor Code listing mechanism failed. The agency's latest attempt relies on findings in the National Toxicology Program's (NTP's) 2011 *Report on Carcinogens* which concluded that styrene is "reasonably anticipated to be a human carcinogen" based on studies showing that

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 560 | APRIL 3, 2015

inhalation and oral exposure to the chemical increased the incidence of malignant and combined incidence of benign and malignant lung tumors in male and female mice. The National Research Council confirmed NTP's findings on the carcinogenicity of styrene in a 2014 review assessment. *See OEHHA News Release*, March 26, 2015.

New Food Safety Agency Takes over FSA's Former Duties in Scotland

Food Standards Scotland (FSS) officially launched on April 1, 2015, assuming responsibilities previously overseen by the U.K. Food Standards Agency (FSA). FSS was established under the Food (Scotland) Act 2015 as a non-ministerial office, "part of the Scottish Administration, alongside, but separate from the Scottish Government."

"This is a great day for the Scottish consumer and for Scotland's food and drink sector," Public Health Minister Maureen Watt was quoted as saying. "We now have a new food body that is uniquely placed to focus on our own particular needs and priorities." *See FSS News Release*, April 1, 2015.

LITIGATION

Whiskey-Labeling Exemption Is Unconstitutional, Says Tennessee AG

The Tennessee Office of the Attorney General has released an **opinion** finding that a state law requiring products labeled as "Tennessee Whiskey" or similar designations to be filtered through charcoal unconstitutionally exempts Prichard's Distillery because the statute includes a grandfather clause created to apply only to the distillery.

The 2013 law codified the "Lincoln County Process" of making whiskey, which requires that the product is (i) manufactured in Tennessee; (ii) composed of 51 percent corn; (iii) distilled to no more than 80 percent alcohol by volume; (iv) aged in new, charred oak barrels in-state; (v) filtered through maple charcoal before aging; (vi) placed in the aging barrels at no more than 62.5 percent alcohol by volume; and (vii) bottled at no less than 40 percent alcohol by volume. If a product does not fulfill each requirement, it cannot be advertised, labeled or referred to as "Tennessee Whiskey" or "Tennessee Sour Mash Whiskey" (or the alternative spelling of "whisky").

Shook 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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FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 560 | APRIL 3, 2015

The law was passed to differentiate Tennessee whiskey from bourbon; most of the requirements reflect federal standards of identity for bourbon, but charcoal filtering is unique to the Tennessee statute. Prichard's Distillery owner Phil Prichard says that requirement "was designed to benefit one company"—Jack Daniel's—but Tennessee Attorney General Herbert Slatery argues that Prichard's Distillery is the company receiving special treatment under the statute. The provision exempts from the law distilleries "located in a county that authorized the manufacturing process by referendum" in 1979 and that were "first licensed by the state alcoholic beverage commission" in 2000—specificity that only applies to Prichard's Distillery. "There is no discernable reason to distinguish one distillery from other existing distilleries on this basis," the opinion states, "especially since the exemption at issue is purportedly one that distinguishes Tennessee Whiskey from bourbon." Accordingly, the opinion finds that the exemption violates the federal and Tennessee constitutions. *See The New York Times*, March 19, 2015.

Hershey Escapes Chocolate-Labeling Suit

A California federal court has granted Hershey's motion for summary judgment in a lawsuit originally alleging that the company mislabels its Kisses®, cocoa products and Ice Breakers® mints with respect to healthy diet claims, sugar-free claims, serving sizes, and the content of antioxidants, nutrients, vanillin, and polyglycerol polyricinoleic acid. *Khasin v. The Hershey Co.*, No. 12-1862 (N.D. Cal., San Jose Div., order entered March 31, 2015). The claims were previously cut to a single unfair competition claim over the use of the statement "natural source of flavanol antioxidants" on dark chocolate and cocoa products. Additional information about these rulings appears in Issues [463](#) and [523](#) of this *Update*.

The plaintiff argued that Hershey's claim implied that flavanol antioxidants conferred health benefits, despite evidence showing no such benefit. He failed to prove that the statement in question would be likely to mislead reasonable consumers, the court said. The plaintiff "testified in his deposition that Hershey's products are candy, not health foods," the court noted, and the statement on the packaging had not led him to believe otherwise. The plaintiff could not cite any extrinsic evidence supporting his claim that a reasonable consumer would be misled, and even if the court agreed that the statement violated U.S. Food and

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 560 | APRIL 3, 2015

Drug Administration guidelines on nutrient content claims, “not every regulatory violation amounts to an act of consumer fraud.” The court also refused to find that the plaintiff had suffered an economic injury based on the price premium he argued that he paid based on the “natural source of flavanol antioxidants” statement.

Florida Federal Courts Allow “Natural” Pretzel Challenges to Continue

A Florida federal court has granted in part and denied in part a motion to dismiss a putative class action alleging that Snyder’s-Lance, Inc. misleadingly labels its pretzels and chips as “natural” despite containing “unnatural genetically-modified organisms (‘GMOs’) and, in many cases, other unnatural artificial and synthetic ingredients.” *Barron v. Snyder’s-Lance, Inc.*, No. 13-62496 (S.D. Fla., order entered March 20, 2015). The court first found that the plaintiffs sufficiently pled economic harm because they paid a premium price based on the “natural” representation on the labels; requiring them to compare rival products on the dates and at the locations that the plaintiffs purchased Snyder’s-Lance products would be “both impractical and impracticable. Unsurprisingly, it is also unsupported by law,” the court said.

Summarizing precedent on the issue, the court then determined that the plaintiffs offered enough of a definition of “natural” to survive the pleadings stage. The plaintiffs’ allegation “that a reasonable consumer would be misled by Defendant’s Products’ ‘natural’ label is (1) plausible and (2) a question not ripe for resolution at this stage of the proceedings.” The court then dismissed without prejudice the plaintiffs’ request for an injunction for failing to allege that they intend to repurchase Snyder’s-Lance products and the plaintiffs’ class claims in several states because they lacked standing.

Similarly, another Florida federal court has denied much of a motion to dismiss filed by Snack Factory LLC in a putative class action alleging that the company mislabels its Pretzel Chips as “all natural” despite containing synthetic ingredients like maltodextrin, soybean oil and dextrose. *Seidman v. Snack Factory, LLC*, No. 14-62547 (S.D. Fla., order entered March 26, 2015). The court first dismissed Snack Factory’s arguments against class certification, noting that they were more appropriate for that later stage of the proceedings.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 560 | APRIL 3, 2015

As in *Snyder's-Lance*, the court found that the allegations of economic harm based on premium pricing were sufficient and that the plaintiff lacked standing for an injunction because he does not intend to purchase the product again. The plaintiff in *Snack Factory* also alleged breach of an express warranty under the Magnuson-Moss Warranty Act, and the court refused to dismiss the claim. "Under Florida law, '[a]ny description of [a good] which is made as part of the basis of the bargain creates an express warranty that the goods shall conform to the description,'" the court said. Accordingly it found that the claim can continue because the "all natural" claim created an express warranty.

Jury Finds for Heinz in "Dip & Squeeze" Packet Dispute

A federal jury in Pennsylvania has found that H.J. Heinz Co. did not appropriate the idea of a dual-opening condiment packaging, the "Dip & Squeeze" packet, from a man who proposed a similar idea during a meeting with the company. *Wawrzynski v. H.J. Heinz Co.*, No. 11-1098 (W.D. Penn., verdict entered April 1, 2015). The plaintiff claimed that after he presented his "Little Dipper" packaging to the company in 2008, Heinz commissioned him to create samples for testing then abruptly ended the relationship in 2009. The "Dip & Squeeze" packet was introduced in 2010. After a three-day trial, the jury found that the man's idea was novel but different from the product that Heinz ultimately pursued. Additional details on the case appear in Issues [531](#) and [552](#) of this *Update*. See *Law360*, April 1, 2015; *Legal Intelligencer*, April 2, 2015.

Wrongful-Death Suit Alleges Quorn® Mycoprotein Caused Fatal Allergy Reaction

The parents of an 11-year-old boy who died in 2013 have filed a wrongful-death lawsuit against Quorn Foods, Inc. and several distributors alleging that the mycoprotein in a Quorn® Turk'y Burger caused their son to go into anaphylactic shock, which resulted in his death. *Bengco v. Quorn Foods, Inc.*, No. BC576522 (Cal. Super. Ct., C.D. Los Angeles Cnty., filed March 24, 2015). The complaint calls Quorn's product "highly processed mold," to which the boy had a severe allergy.

According to the complaint, the product label of Quorn's Turk'y Burger lists "Mycoprotein (47%)" as the first ingredient, and the description explains that "'myco' is Greek for 'fungi.'" The description also explains that "[t]here are believed to be over 600,000 varieties of fungi in the

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 560 | APRIL 3, 2015

world, many of which are among the most sought after foods like varieties of mushrooms, truffles, and morels” but the product is not, the complaint notes, a variety of mushroom, truffle or morel.

The plaintiffs allege that the product is defective by design and seek compensatory, punitive and exemplary damages from each defendant for the strict liability cause of action. They further allege failure to warn and false and misleading advertising under California law.

Townsend Farms and Costco Sued over Hepatitis Outbreak

The estate and survivors of an 89-year-old woman who died after eating imported pomegranate seeds linked to a Hepatitis A outbreak have filed a wrongful-death lawsuit against Townsend Farms Inc., Costco Wholesale Corp. and others alleging strict liability for a product defect, negligence and breach of implied warranties. *Schelitzche v. Townsend Farms Inc.*, No. BC576437 (Cal. Super. Ct., Los Angeles Cnty., filed March 23, 2015). The complaint details the 2013 outbreak of Hepatitis A virus, which the U.S. Food and Drug Administration, Centers for Disease Control and Prevention, and state and local health agencies apparently traced to 3-pound bags of Townsend Farms Organic Antioxidant Blend frozen berries sold at Costco. The plaintiffs seek wrongful-death and survival damages and other general, punitive and exemplary damages. While the plaintiffs’ suit is the first to claim wrongful-death damages, details of other lawsuits stemming from the same Hepatitis A outbreak appear in Issues [486](#) and [489](#) of this *Update*.

Sentences Determined for First Prosecutions in U.K. “Horsemeat Scandal”

According to a Crown Prosecution Service [press release](#), Peter Boddy and David Moss have been sentenced in the first prosecutions stemming from the “horsemeat scandal” of 2013. Moss, the slaughterhouse manager, was convicted of falsifying an invoice during a U.K. Food Standards Agency investigation and received a four-month suspended prison sentence. Slaughterhouse owner Boddy was fined £8,000 for failing to keep adequate records that could trace the origin of the meat, and each defendant must also pay costs of £10,442 within six months. “This deception is serious—the absence of proper records means that it is not possible to identify whether the horsemeat may have entered the human food chain,” the prosecutor said. “It also means that if there was a problem with the horsemeat it would not be possible to recall it.”

New Study Alleges Relationship Between Moderate SSB Consumption and Diminished Liver Health; Anti-Sugar Crusader Condemns Industry over Added-Sugar Labeling

A study examining the relationship between sugar-sweetened beverage (SSB) consumption and liver health among premenopausal women has reportedly found that habitual, moderate intake “may elicit hepatic lipogenesis.” Maya Shimony, et al., “The relationship between sugar-sweetened beverages and liver enzymes among healthy premenopausal women: a prospective cohort study,” *European Journal of Nutrition*, March 2015. Relying on data from a prospective cohort of 259 healthy women, researchers with the National Institutes of Health and George Washington University’s Milken Institute School of Public Health measured serum levels of alanine and aspartate aminotransferases (ALT and AST), biomarkers used to assess overall liver health.

The study claims that for every additional cup of SSB consumed and every 10-gram increase in added sugar and total fructose per day, “log ALT increased by 0.079 U/L (95 % CI 0.022, 0.137), 0.012 U/L (95 % CI 0.002, 0.022), and 0.031 (0.012, 0.050), respectively, and log AST increased by 0.029 U/L (-0.011, 0.069), 0.007 U/L (0.000, 0.014), and 0.017 U/L (0.004, 0.030), respectively.” Compared to women who drank less than 1.5 cups of SSB per day, those who consumed more than 1.5 cups apparently also had 13.5 percent higher ALT and 10.8 percent higher AST levels.

Meanwhile, University of California, San Francisco Pediatrics Professor Robert Lustig has penned a *Los Angeles Times* **opinion piece** lamenting the lack of labeling for added sugars. According to Lustig, “Sugar starts to fry your liver at about 35 pounds per year, just like alcohol would at the same dosage. This is because fructose—the sweet molecule of sugar—is metabolized in the liver just like alcohol... And we’re at 100 pounds per year, triple our limit. That is why children now get the diseases of alcohol consumption—type 2 diabetes and fatty liver disease—without ever drinking alcohol.”

Lustig advocates that the U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) work together “to implement the USDA Dietary Guidelines Advisory Committee’s (DGAC) recommenda-

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 560 | APRIL 3, 2015

ABOUT SHOOK

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.

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.



tion to limit added sugar consumption to 10% of total calories.” Urging FDA to adopt nutrition labeling changes that would specify the amount of added sugar in each product, Lustig criticizes food and beverage companies for viewing this information as proprietary. “If the DGAC’s recommendation becomes government policy, then the Nutrition Facts label will show that that a typical bowl of breakfast cereal provides 33% of the daily value for added sugar for adults, and a 12-ounce can of soda provides 90%,” claims Lustig. “If added sugars should only be 10% of total calories, the industry’s claim would wash away. It would be forced to reformulate.”

Study Measures Exposure to Free and Conjugated Forms of BPA

Canadian researchers have published a study measuring free and conjugated forms of bisphenol A (BPA) and triclosan (TCS) in urinary samples obtained from 2,000 pregnant women enrolled in the Maternal-Infant Research on Environmental Chemicals (MIREC). Tye Arbuckle, et al., “Exposure to Free and Conjugated Forms of Bisphenol A and Triclosan among Pregnant Women in the MIREC Cohort,” *Environmental Health Perspectives*, April 2015. Billed as “the largest national-level data” to address both the free and conjugated forms of these phenols, the results evidently suggest that exposure varies by material age, household income, education, and smoking factors, depending on the type of consumer products used by individuals.

In particular, researchers detected conjugated BPA and TCS in 95 and 99 percent of samples, and free-form BPA and TCS in 43 and 80 percent of samples, respectively. “Significant predictors of BPA included material age < 25 vs. ≥ 35 years, current smoking, low vs. high household income, and low vs. high education,” note the authors. “For TCS, urinary concentrations were significantly higher in women ≥ 25 years of age, never vs. current smokers, and women with high household income and high education.”

The authors also argue that more biomonitoring studies are needed to measure exposure to free BPA and TCS, as these “may be more toxicologically active than the conjugated forms.” As they explain, “These data will be important in assessing potential risks of these chemicals and in developing profiles of exposure, particularly in identifying women with elevated exposures.”