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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

District Court Refuses to Stay FSMA Rulemaking Deadlines

Three days after the U.S. Food and Drug Administration (FDA) filed a motion for emergency stay pending appeal before the Ninth Circuit, the federal district court that had established November 30, 2013, as the deadline for the agency to publish notices of proposed rulemaking (NPRM) for specific food safety rules under the Food Safety Modernization Act denied the motion for stay pending appeal that FDA filed before it in September. *Ctr. for Food Safety v. Hamburg*, No. 12-4529 (U.S. Dist. Ct., N.D. Cal., order entered October 21, 2013). Details about the emergency stay request based on delays attributable to the federal government shutdown appear in Issue 501 of this *Update*.

According to the district court, FDA failed to show that it would be irreparably injured absent a stay. The court recognized that the agency was unprepared to issue a final rule on the intentional adulteration of food by the November 2013 deadline, "But that is not what the injunction requires," the court stated. "Rather, the FDA must merely promulgate an NPRM by November 30 that meets minimum APA [Administrative Procedure Act] requirements, or that provides notice to interested parties, or that discloses information bearing on the NPRM that the FDA currently possesses." The court further noted, "The FDA alleges it currently lacks sufficient information on which to base its rule. But the FDA can remedy this deficiency after the NPRM is issued by using public comment to collect more information before the agency promulgates a final rule."

FDA Seeks to Regulate Animal Food

The U.S. Food and Drug Administration (FDA) has issued a proposed rule that would establish current good manufacturing practice (CGMP), hazard analysis and risk-based preventative controls for animal food. According to an October 29, 2013, *Federal Register* notice, "FDA is taking this action to provide greater assurance that animal food is safe and will not cause illness or injury to animals or humans and is intended to build an animal food safety system for the future that makes modern, science and risk-based preventive controls the norm across all sectors of the animal food system."

Billed as "part of the Food Safety Modernization Act's larger effort to modernize the food safety system for the 21st century," the proposed rule would require domestic and foreign animal-food manufacturing facilities registered under

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the Federal Food, Drug, and Cosmetic Act to develop a formal plan to prevent foodborne illness as well as respond to "any problems that may arise." In addition to creating new CGMP for the manufacturing, processing, packing, and holding of animal food, the new rules would direct these establishments to (i) "maintain a food safety plan," (ii) "perform a hazard analysis," (iii) "institute preventative controls for the mitigation of those hazards," (iv) monitor these controls and verify their effectiveness, (v) take appropriate corrective action when necessary, and (vi) document these corrective actions.

As FDA Deputy Commissioner for Foods and Veterinary Medicine Michael Taylor further explained in an October 29 press release, "This proposed rule on animal food complements proposed rules published in January 2013 for produce safety and facilities that manufacture food for humans to set modern, prevention-based standards for food safety. They also work in concert with standards proposed in July 2013 to help ensure that imported foods are as safe as those produced domestically."

FDA will accept comments on the proposed rule until February 26, 2014. It has also **announced** three public meetings to discuss the new provisions and gather feedback from stakeholders, scheduled for November 21 in College Park, Maryland, November 25 in Chicago, Illinois, and December 6 in Sacramento, California. *See Federal Register,* October 29, 2013.

FDA Issues Report on Pathogens in Imported Spices

The U.S. Food and Drug Administration (FDA) has **released** a draft of its spice risk report, which calls attention to the most common microbial hazards and filth in imported spices, along with possible sources of contamination. The report, "Pathogens and Filth in Spices," also evaluates current mitigation techniques, recommends options and identifies research needs and data gaps. According to FDA, a **notice** about the report will be published in the November 4, 2013, *Federal Register.*

Calling the findings a "wake-up call" to spice producers, FDA revealed that of the products tested between 2007 and 2010, (i) spices are twice as likely to be contaminated as other types of imported food; (ii) 12 percent of spices imported into the United States were contaminated with insect parts, excrement, rodent hair and other materials; (iii) 7 percent of the shipments contained *Salmonella*; and (iv) spices imported from Mexico and India apparently have the highest rate of contamination.

According to FDA, given the quantity of spices consumed, the number of illnesses is relatively low compared to other foodborne illnesses. "People's tendency to eat small amounts of spices with meals generally lowers the probability of illness from contaminated spices relative to similarly contaminated foods consumed in larger amounts," noted an agency statement. FDA also said that it is possible that illnesses caused by contaminated spices are underre-

ported, because the spices are often part of multi-ingredient dishes. The agency is reportedly taking steps to strengthen spice safety by (i) developing a training center focused on supply chain management for spices and botanical ingredients and (ii) proposing preventive controls for hazards identified by manufacturers as reasonably likely to occur. Additional details about contaminated spices appear in Issue 496 of this *Update*. *See FDA News Release,* October 30, 2013.

FDA Warns Licorice May Cause Heart Trouble

The U.S. Food and Drug Administration (FDA) has issued a statement cautioning people older than age 40 about eating too much black licorice—2 ounces per day for two weeks. FDA experts explain that black licorice contains glycyrrhizin, a sweetening compound that can cause the body's potassium levels to plummet, leading to an irregular heart rhythm, high blood pressure, edema, lethargy, and possibly heart failure, said FDA. The agency also warned that black licorice can interact negatively with some medications and supplements. According to FDA Director of Cosmetics and Colors Linda Katz, potassium levels are usually restored with no permanent health problems when black licorice consumption stops.

Mexico Senate Passes Tax on Soft Drinks

Mexican lawmakers have reportedly approved a 1 peso-per-liter tax (US 23 cents) on sugar-sweetened beverages (SSBs) and an 8 percent tax on junk food. The controversial legislation, which aims to curb rising obesity levels, was approved in a 73-50 vote and is expected to take effect January 1, 2014.

According to news sources, Mexico, whose obesity and diabetes rates surpass those of the United States, will be the first major market to tax SSBs, following a handful of other Latin American and European countries. Mexicans reportedly consume more than 700 8-ounce servings of SSBs annually. More details about the legislation appear in Issue 501 of this *Update*.

LITIGATION

Court Narrows Labeling Claims Against Frito-Lay

A federal court in California has significantly narrowed the consumer-fraud claims that may be asserted against Frito-Lay involving a number of its snack products labeled as "All Natural," "0 Grams Trans Fat" and "No MSG." *Wilson v. Frito-Lay N. Am., Inc.*, No. 12-1586 (U.S. Dist. Ct., N.D. Cal., order entered October 24, 2013). All claims dismissed were with prejudice.

The court dismissed claims based on products the plaintiffs did not purchase, because they failed to specify how or whether the 85 products added in their second amended complaint were substantially similar to the purchased products. The court also dismissed any claims based on statements the company made

on its Website. According to the court, the Food and Drug Administration (FDA) may have warned other companies about whether their Websites constituted labeling, but it had not done so as to the defendant's products. The court also said, "The website address appears below Defendant's physical address, not near the ingredients list or any nutritional facts. Nowhere on any Product's packaging does Defendant direct consumers to its website for more facts about the labeled Product. The Court therefore does not find that Defendant's website constitutes 'labeling' under the FDCA [Food, Drug, and Cosmetic Act]." The court also observed that the plaintiffs failed to plead "that they ever saw, read, or were even aware of any website before this suit."

The court further took issue with the plaintiffs' Unfair Competition Law (UCL) "misbranding theory," i.e. that the labels are "unlawfully misbranded under the FDCA and the Sherman Law, and are therefore actionable under the UCL's unlawfulness prong even absent allegations of reliance." In the court's view, simply alleging that a product is unlawfully labeled, without more, is not enough to state a claim. The UCL requires an economic injury as a result of the unfair competition alleged. "Otherwise plaintiffs who had no contact with the allegedly unlawful activity would have standing to sue," the court said. And "Plaintiffs' argument that they were harmed because the allegedly misbranded products were 'legally worthless and had no economic value,' is insufficient to save this claim."

The plaintiffs will be allowed to proceed with their "All Natural" and "O Grams Trans Fat" claims, with the court finding their pleadings sufficient to survive a motion to dismiss. As to the "No MSG" labels, the court found that FDA statements about use of this labeling claim ambiguous before a November 2012 announcement interpreting the agency's MSG rules. Thus, the court ruled that the defendant could not be held liable for failing to comply "with a regulation that was not explicitly clarified until November 19, 2012." Finally, the court agreed with the defendant that the plaintiffs cannot pursue claims under California law on behalf of consumers who purchased the defendant's products in other states.

Wage-and-Hour Class Action Against Starbuck's Settled, Attorney's Fees Slashed

A federal court in California has given final approval to the settlement of a wage-and-hour class action against Starbucks Corp., including less than half of what plaintiffs' counsel originally requested as attorney's fees. *York v. Starbucks Corp.*, No. 08-7919 (U.S. Dist. Ct., C.D. Cal., decided October 29, 2013). Starbucks apparently objected to the request for nearly $4.5 million, excluding nearly $250,000 in unreimbursed costs, characterizing it as "astonishing." Thereafter, the parties agreed to attorney's fees and costs of $1.9 million, and the court found the request reasonable. Under the agreement, 14,800 employees will receive payments of up to $900, for a total of $3 million, for alleged denial of statutorily mandated meal breaks and wage statements that failed to list the applicable overtime rate in violation of the California Labor Code. *See Law360*, October 28, 2013.

State Court Denies Request to Close Hot Sauce Factory

Telling counsel for Irwindale, California, that it was "asking for a very radical order on 24-hour notice," a superior court has reportedly denied the city's request that the maker of an Asian hot sauce cease production until purportedly aggressive odors can be reduced. *Irwindale v. Huy Fong Foods,* No. n/a (Cal. Super. Ct., Los Angeles Cnty., filed October 28, 2013). A hearing on the city's motion for preliminary injunction has been scheduled for November 22, 2013. According to news sources, Huy Fong Foods, which makes a popular Sriracha chili sauce, opened its Irwindale plant in 2012 when its Rosemead facility could not keep up with demand. Irwindale residents began complaining of pungent pepper and garlic fumes, burning eyes, irritated throats and headaches, especially when the company crushes the peppers.

The city cited the company in October 2013 for violation of an ordinance forbidding noxious manufacturing emissions and filed suit after the company's owners balked at installing a $600,000 filtration system. The company reportedly contends that it has been cooperating with the city and that its employees manage the fumes without complaint. *See The Los Angeles Times*, October 28, 2013; *NewsTimes.com*, October 31, 2013.

Beer Consumers Allege AB Misleads About Kirin Beer Origins

For the second time in a month, attorneys with three Florida law firms have filed litigation on behalf of state consumers alleging that Anheuser-Busch Cos. (AB) sells a formerly imported beer "in a way that misleads consumers into believing that Kirin beer is still made in and imported from Japan, and accordingly sell[s] Kirin beer at prices substantially higher than those of domestic beer." *Suarez v. Anheuser-Busch Cos., LLC*, No. n/a (Fla. Cir. Ct., Miami-Dade Cnty., filed October 25, 2013). Information about the Beck's beer litigation, asserting virtually identical claims on behalf of a putative nationwide class against AB in federal court, appears in Issue **500** of this *Update.*

Brought in the names of just two consumers, the Kirin beer litigation notes that external, six-pack, bottled beer packaging fails to state that the product "is brewed in the U.S.A. with domestic ingredients. In fact, the packaging for Kirin Beer has an image of the mythical *Kirin*, next to Japanese characters." According to the complaint, individual bottle labels, which can be viewed only by removing a bottle from the pack, state "Brewed under Kirin's strict supervision by Anheuser-Busch, Los Angeles, CA and Williamsburg, VA." The complaint also asserts that the company's Website claims that "Kirin Ichiban and Kirin light are imported Japanese style pilsners."

The plaintiffs contend that consumers are deceived into paying more for what they believe is an imported product made with quality ingredients and that retailers, restaurants and bars are also confused; many allegedly charge more for the product than for domestic beer. Alleging violation of the Florida Deceptive

and Unfair Trade Practices Act, the plaintiffs seek declaratory and injunctive relief, attorney's fees, costs, and other unspecified relief.

Wrongful Death Suit Filed Against Red Bull

The grandmother of a 33-year-old who allegedly died from cardiac arrest after ingesting a Red Bull "energy drink" while playing basketball has filed a survival and wrongful death action against the company. *Terry v. Red Bull N. Am., Inc.*, No. 506504/2013 (N.Y. Sup. Ct., Kings Cnty., filed October 24, 2013). The complaint recites a number of adverse incidents around the world since 2000 allegedly linked to consumption of the product and cites studies indicating that its use can produce symptoms associated with cardiovascular disease.

Claiming that the product proximately caused the decedent's death, the plaintiff alleges strict liability (design defect and failure to warn); negligence (design, manufacture and sale, and failure to warn); fraud; breach of implied warranties; punitive damages for the willful, wanton and malicious production of a beverage with "dangerous levels of caffeine and other stimulants"; and wrongful death. She seeks $5 million for each cause of action and $50 million in punitive damages for a total of $85 million, as well as costs.

According to news sources, the plaintiff claims that her grandson, a construction worker with a 13-year-old son, was healthy and a regular drinker of Red Bull. She has also filed a lawsuit against the city, claiming that the school gymnasium in Brooklyn where her son collapsed was not equipped with a defibrillator or other life-saving gear, and that it took 40 minutes for an ambulance to arrive. The medic's report apparently referenced the decedent's consumption of an energy drink before he died. *See New York Daily News* and *The Huffington Post*, October 28, 2013.

OTHER DEVELOPMENTS

American Academy of Pediatrics Calls for "Media Diet"

The American Academy of Pediatrics (AAP) recently **issued** a policy statement calling on doctors to review patient media use and work with parents to scale back their children's "entertainment screen time." The latest in an ongoing series of policy statements addressing media violence, infant media use, and obesity and the media, AAP's recommendations include encouraging parents to (i) "limit the amount of total entertainment screen time to <1 to 2 hours per day," (ii) "discourage screen media exposure for children <2 years of age," (iii) "keep the TV set and Internet-connected electronic devices out of the child's bedroom," and (iv) "monitor what media their children are using and accessing, including any Web sites they are visiting and social media sites they may be using." In addition, AAP has requested that physicians "ask two media questions and provide

age-appropriate counseling for families at every well-child visit: How much recreational screen time does your child or teenager consume daily? Is there a TV set or an Internet-connected electronic device (computer, iPad, cell phone) in the child's or teenager's bedroom?"

The policy also urges AAP and its local chapters "to challenge manufacturers of products with public health implications (tobacco, alcohol, food) to… make socially responsible decisions on marketing products to youth." To this end, AAP has advised its members to back "strong regulations—self-regulation is not likely to work—that would restrict the advertising of junk food and fast food to children and adolescents," as well as legislation that would ban alcohol advertising from television.

"A healthy approach to children's media use should both minimize potential health risks and foster appropriate and positive media use—in other words, it should promote a healthy 'media diet,'" one of the policy's authors, Majorie Hogan, said in an October 28, 2013, press release. "Parents, educators and pediatricians should participate in media education, which means teaching children and adolescents how to make good choices in their media consumption." *See Pediatrics,* October 27, 2013.

In a related development, *NPR* has **published** a special series titled "Raising Digital Natives: Technology and Our Kids" that focuses on issues surrounding the increasing use of electronic media by infants, children and teenagers. "It's especially good timing — the American Academy of Pediatrics this morning released new guidelines on whether parents should allow screen time, updating previous rules for the touch screen generation," writes *NPR's* Elise Hu in an October 28, 2013, article announcing the new series, which includes segments on digital citizenship, teen social media use, and the effect of screen time on young children. "And the nonprofit Common Sense Media is showing that among children under age 2, 38 percent had used mobile devices like iPhones and tablets. For children 8 and under, the average amount of time they spend using mobile devices has tripled since a similar survey two years ago."

EWG Guide Targets "Dirty Dozen" Endocrine Disruptors

The Environmental Working Group (EWG) and Keep A Breast Foundation have released an October 2013 **report** detailing how to avoid exposure to certain endocrine disruptors allegedly found in food, food packaging and other consumer products. Titled "The Dirty Dozen: 12 Hormone-Altering Chemicals and How to Avoid Them," the report singles out bisphenol A, dioxins, atrazine, phthalates, perchlorate, fire retardants, lead, arsenic, mercury, perfluorinated chemicals, organophosphate pesticides, and glycol ethers as among "the worst hormone disrupters."

In particular, EWG argues that the interference of these substances with hormone production and signaling has been linked to cancer, reproductive problems, obesity, early puberty, heart disease, and other health conditions. To this end, the report urges consumers to avoid canned foods, thermal receipts, plastic food containers, plastic wrap, and non-stick pans, among other products. It also recommends that readers increase their consumption of organic products as well as sustainable seafood, such as wild salmon or farmed trout. "There is no end to the tricks that endocrine disruptors can play on our bodies," opines the report: "increasing production of certain hormones; decreasing production of others; imitating hormones; turning one hormone into another; interfering with hormone signaling; telling cells to die prematurely; competing with essential nutrients; binding to essential hormones; accumulating in organs that produce hormones." *See EWG Press Release,* October 28, 2013.

SCIENTIFIC/TECHNICAL ITEMS

Red Meat Consumption Purportedly Associated with Increased Mortality Risk

A recent meta-analysis has allegedly found that "high consumption of red meat, especially processed meat, may increase all-cause mortality." Susanna Larsson and Nicola Orsini, "Red Meat and Processed Meat Consumption and All-Cause Mortality: A Meta-Analysis," *American Journal of Epidemiology,* October 2013. Based on data from nine prospective studies, the meta-analysis focused on reported relative risks associated with the consumption of unprocessed red meat ("beef, pork, lamb, or game") and processed meat ("any meat preserved by smoking, salting, curing, or by the addition of chemical preservatives").

"Overall," states the study, "those in the highest category of processed meat and total red meat consumption had increased all-cause mortality of 23% and 29%, respectively, compared with those in the lowest category." The authors also noted that unprocessed red meat "was not significantly associated with all-cause mortality," hypothesizing that the added salt in processed meat "may increase all-cause mortality by increasing the risk of major chronic diseases, including cardiovascular disease."

"Results from the dose-response meta-analysis suggested that processed meat and total red meat consumption is associated with all-cause mortality in a nonlinear fashion with a steeper increase in all-cause mortality at intakes below approximately 1 serving per day," concludes the study. "This finding suggests that all-cause mortality is elevated even at low intakes of processed meat and total red meat."

"Inflammatory Dietary Pattern" Allegedly Linked to Risk of Depression

A recent study has reportedly concluded that an "inflammatory dietary pattern" (IDP) is linked to higher depression risk, raising questions about whether chronic

inflammation "may underlie the association between diet and depression." Michael Lucas, et al., "Inflammatory dietary pattern and risk of depression among women," *Brain, Behavior and Immunity,* October 2013.

Defined as a dietary pattern that is positively associated with all inflammatory biomarkers, IDP for the purposes of the study represented a diet "relatively high in sugar-sweetened soft drinks, refined grains, red meat, diet soft drinks, margarine, other vegetables, and fish but low in wine, coffee, olive oil, green leafy and yellow vegetables." Using food questionnaire data from 43,685 women enrolled in the Nurses' Health Study over a 12-year follow-up period, Harvard School of Public Health researchers reported a dose-response relationship between IDP score and depression risk for both stricter and broader definitions of depression.

"In this large prospective cohort of middle-age and older women free from depression or severe depressive symptoms at baseline, we used an empirical statistical method to derive a diet pattern score that was associated with markers of inflammation, and observed that depression risk increases with increasing score of this IDP," explain the study's co-authors. "These observations suggest that the association between dietary factors and depression may be mediated in part by inflammation."

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