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LEGISLATION, REGULATIONS AND STANDARDS

U.S. Codex Delegates Schedule Meeting to Discuss Standards for Fats and Oils

The U.S. Department of Agriculture's Office of the Under Secretary for Food Safety and the Food and Drug Administration's Center for Food Safety and Applied Nutrition have **announced** a January 13, 2015, public meeting in College Park, Maryland, to discuss draft U.S. positions for consideration during the 24th Session of the Codex Committee on Fats and Oils slated for February 9-13 in Melaka, Malaysia.

Agenda items at the January meeting include a proposed draft standard for fish oils and discussion papers focusing on (i) cold pressed oils and (ii) amended standards for sunflower seed oils and high oleic soybean oil. *See Federal Register*, November 19, 2014.

CSPI Seeks Disclosure of Sesame Seeds on Food Labels

The Center for Science in the Public Interest (CSPI) has filed a citizen petition with the U.S. Food and Drug Administration (FDA) seeking a rule that would require sesame seeds and sesame products to be disclosed on food labels in the same way that allergens, such as milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soy, are disclosed. CSPI asks that sesame be added to FDA's list of allergens in its "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" to address both labeling and cross contact issues related to food manufacturing practices." The petition includes letters from parents of purported sesame-allergic children "explaining why better labeling is so important for their families." They claim that reactions to sesame have been severe and life-threatening. See CSPI News Release, November 18, 2014.

Navajo Nation Council Approves "Junk" Food Tax

In a 10-4 vote, the Navajo Nation Council has approved a tax on "junk" foods sold on the largest reservation in the United States. If President Ben Shelly signs the measure into law, the Healthy Dine Nation Act of 2014 would apply to items like cookies, chips and soft drinks, and the revenue generated would be directed to a fund supporting farmers markets, the planting of vegetable gardens, purchase of exercise equipment, and other health-focused projects. Shelly evidently vetoed similar legislation earlier in 2014, reportedly saying



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that he supported the goals of the tax initiative but guestioned its implementation. Proponents of the tax reportedly cite the high rates of diabetes among American Indians and Alaska Natives—the highest among U.S. racial and ethnic groups—as the main reason to pass the legislation. See Associated Press, November 15, 2014.

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LITIGATION

Kentucky Appeals Court Issues "Whiskey Fungus" Ruling

A Kentucky Court of Appeals panel has reversed a trial-court determination that trespass and nuisance claims filed by residents alleging damage from the ethanol emissions of nearby distilleries are preempted under the Clean Air Act (CAA). Merrick v. Brown-Forman Corp., No. 2013-CA-002048-MR (Ky. Ct. App., decided November 14, 2014). A federal court considering similar issues has also found that state law-based claims are not preempted. That ruling is summarized in Issue 519 of this *Update*.

In the Kentucky state-court proceeding, the circuit court dismissed the action, ruling that the "federal Clean Air Act preempts source state air quality tort claims of the type asserted by" the plaintiffs. They allege that the atmospheric ethanol the distilleries emit promotes the growth of "whiskey fungus" that causes a "pervasive black film covering virtually every outdoor surface," which requires cleaning and power washing to remove. Plaintiff Bruce Merrick owns a company that makes stadium seating and claims that the whiskey fungus destroys any inventory stored out of doors and has "doubled the cost of replacing a commercial roof, and has otherwise caused substantial and ongoing pecuniary damages." The complaint alleges negligence, nuisance and trespass claims and includes "an assertion that affordable and effective technology exists to capture or otherwise prevent the release of ethanol vapors."

The defendants claimed that they comply with all federal laws, which preempt "all actions arising under state statutory and common law," and that the fungus is naturally occurring in the environment. They filed a motion to dismiss, arguing that the state-tort claims arising from ethanol emissions, which are governed by the federal CAA, are preempted. Relying on a 2011 U.S. Supreme Court ruling finding that the CAA preempts federal common law claims, the circuit court concluded that the state-law tort claims were preempted because the plaintiffs had "not cited any authority decided since [then] that supports the argument that state tort claims are not preempted."

The court of appeals found persuasive a 2013 Third Circuit Court of Appeals ruling that the CAA "does not preempt state common law claims based on the law of the state where the source of the pollution is located." According to the court, the language in the case is "clear, unambiguous and subject to but one interpretation," in contrast with a 2010 Fourth Circuit Court of Appeals deci-



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sion, "which held with less clarity that conflict preemption principles 'caution at a minimum against' allowing state nuisance law to contradict joint federal-state air quality rules." The court of appeals also noted that the circuit court erroneously placed the burden on the plaintiffs to demonstrate the absence of preemption and cited U.S. Supreme Court precedent placing the burden of persuasion on the party asserting federal preemption of state law. The court remanded the matter for further proceedings.

Eighth Circuit Says Likelihood of MSG to Cause Harm Is Factual Matter

In a dispute over commercial liability insurance coverage, the Eighth Circuit Court of Appeals has ruled that a trial court erred in deciding, as a matter of law, that a recall of sausage breakfast sandwiches prompted by contamination with monosodium glutamate (MSG) was a covered incident. *Hot Stuff Foods*, *LLC v. Houston Cas. Co.*, Nos. 14-1192, -1194 (8th Cir., decided November 17, 2014).

When MSG is added to foods, it must be disclosed on the product label. Hot Stuff Foods makes sausage breakfast sandwiches with sausage that does not contain MSG and does not include it on package labels. The company also distributes sausage that contains MSG and learned in January 2011 that some of the MSG sausage was inadvertently used in the breakfast sandwiches. Because the product contained MSG not disclosed on the labels, it was misbranded under federal law. The company promptly reported the situation to Food and Drug Administration and U.S. Department of Agriculture representatives and, following consultation, issued a voluntary recall, which included nearly 200,000 cases of breakfast sandwiches distributed between August 2010 and early January 2011. Approximately 40,000 cases of mislabeled sandwiches remained in commerce during the recall.

Hot Stuff sought indemnification under a malicious product tampering/accidental product contamination policy issued by the defendant, which "denied coverage on the ground that the claim did not involve an 'Accidental Product Contamination' as defined in the policy." Hot Stuff brought this declaratory judgment action to recover its loss. The trial court granted Hot Stuff's motion for partial summary judgment, ruling that the company was entitled to indemnification of its covered losses, but that the damages required a jury trial. The jury awarded Hot Stuff more than \$750,000 for its recall and crisis response expenses and \$200,000 for lost gross profit. The insurance carrier appealed the grant of partial summary judgment and the lost gross profit damages award.

The policy at issue defined "accidental product contamination," in relevant part, as "any accidental . . . contamination . . . or mislabeling . . . provided always that the consumption or use of the Named Insured's CONTAMINATED PRODUCT(S) has, within 120 days of such consumption or use, either resulted, or may likely result, in: (1) physical symptoms of bodily injury, sickness or



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disease or death of any person(s) "The Eighth Circuit disagreed with the district court that the term "may likely result" created an ambiguity and concluded that the lower court improperly read "likely" out of the policy. It also found that "the parties' summary judgment motions urged erroneous interpretations; [the insurance carrier] argued that 'may' should be ignored, while Hot Stuff urged the court to ignore 'likely.""

In the Eighth Circuit's view, the parties by contract "fixed where in the range of product contamination risks coverage should end by choosing a term requiring more than a possibility of physical injury ('may'), but less than a probability ('likely')."The terms are not ambiguous, the court opined, although "the standard may be hard to apply in ambiguous fact situations." At issue here is "whether the presence of 0.06 to 0.13 grams of undisclosed MSG in the Sausage Breakfast Sandwiches that Hot Stuff distributed and then recalled 'resulted, or may likely result in' physical symptoms of injury or illness in any of the persons who consumed those products." Noting that some sensitive individuals may experience adverse reactions to MSG and discussing a conflict between the parties' experts, the court determined that the issue "cannot be answered by a summary judgment record that consists of inconclusive government reports and scientific studies and the dueling opinions of experts far removed from the relevant marketplace."

The court determined that damages need not be retried, but stated that "unless the district court determines on remand that summary judgment is appropriate based on the full trial record, the coverage question must be submitted to a jury." The court further found no error in the lost gross profits award or the district court's denial of Hot Stuff's request for attorney's fees.

Wolfgang's FACTA Suit to Proceed with Amended Complaint

A New York federal court has rejected Wolfgang's Steakhouse and ZMF Restaurants LLC's motion to dismiss a case alleging that the restaurant violated the Fair and Accurate Credit Transactions Act of 2003 (FACTA) by printing credit-card expiration dates on receipts. *Fullwood v. Wolfgang's Steakhouse, Inc.*, No. 13-7174 (U.S. Dist. Ct., S.D.N.Y., order entered November 14, 2014). The court found that the plaintiff's amended complaint insufficiently supported its allegation that Wolfgang's knew of the ramifications of violating FACTA yet wilfully disregarded the law, but granted her leave to amend.

The plaintiff brought her putative class action after receiving a receipt from Wolfgang's that displayed her credit card's expiration date. She did not, however, allege any actual damages from the disclosure. Under FACTA, actual damages can be awarded for both negligent and willful violations; only willful violations, however, can result in the statutory and punitive damages that the plaintiff seeks. Accordingly, the court devoted much of its decision to determining whether the restaurant's conduct was willful.



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Under the amended complaint's allegations, the court found that it was not. The plaintiff argued that Wolfgang's had notice of FACTA's requirements because its agreements with credit-card companies incorporated the requirements into their binding guidelines. According to the court, however, those agreements did not attribute the policies to FACTA, and thus the restaurant may have not known that the guidelines were actually required by federal law. The plaintiff proposed amending the complaint to allege that, "in addition to the general publicity around FACTA's requirements, Defendants were notified by multiple sources at least monthly of requirements created by FACTA itself, and that Defendants negotiated an insurance contract that specifically highlighted the importance of compliance with FACTA." These allegations, if properly pleaded, may sufficiently support the plaintiff's assertion that the restaurant's FACTA violations were willful, the court said, so it allowed the plaintiff to amend the complaint.

Bud Light Lime-A-Ritas® Too High-Calorie to Be "Light," Putative Class Action Says

A consumer has filed a putative class action in California state court alleging that Anheuser-Busch's "Lime-A-Rita" malt beverages have too many calories and carbohydrates to be sold under the Bud Light Lime® label. Cruz v. Anheuser-Busch, LLC, No. BC563150 (Cal. Super. Ct., Los Angeles Cnty., filed November 12, 2014). The plaintiff alleges that she purchased Bud Light Lime Lime-A-Rita® believing it to be low in calories and carbohydrates, but later learned that a serving of 8 fluid ounces contains between 192 and 220 calories and 22.8 to 23.6 g of carbohydrates compared to Bud Light's 110 calories and 6.6 g of carbohydrates. "In general, 'light' may generally describe a zero calorie or a reduced calorie food, and consumers such as Plaintiff and the Class understand the 'light' label on a product that has a reduced or low number of calories," the complaint asserts. The plaintiff attributes the level of calories to high-fructose corn syrup, and because of its alleged association with "obesity, cardiovascular disease, diabetes and non-alcoholic fatty liver disease," she "never suspected high fructose corn syrup would be present in a product labeled as 'light' such as the Bud Light Lime 'Rita Products." She alleges violations of California consumer protection, false advertising and unfair competition laws as well as breach of express warranty. She seeks class certification, an injunction, attorney's fees, and costs.

EU Court of Justice Allows Retailer Liability for Poultry with Salmonella

The European Union's (EU's) Court of Justice has determined that the law requires fresh poultry meat to satisfy the microbiological criteria for foodstuffs and that national law may impose a penalty on "a food business operator which is active only at the distribution stage" for placing a contaminated food product on the market. *Reindl v. Bezirkshauptmannschaft Innsbruck*, No. C-443/13 (E.C.J., decided November 13, 2014).



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The issue arose from an Austrian proceeding involving a fine imposed on a food retail manager after a sample from her store of vacuum-packed fresh turkey breast produced and packed by another company was found to be contaminated with *Salmonella Typhimurium*. The Unabhāngiger Verwaltungssenat in Tirol stayed the proceeding and referred to the EU court the questions whether (i) food business operators "active at the food distribution stage" are subject to the full regime under Regulation (EC) No 2073/2005, and (ii) the microbiological criterion in the regulation's annex must "also be observed at all stages of distribution by food business operators not involved in production (being involved exclusively at the distribution stage)."

Noting that the microbiological criterion expressly applies to "[p]roducts placed on the market during their shelf-life," defined as "either the period corresponding to the period preceding the 'use by' or the minimum durability date," the court determined that fresh poultry meat must satisfy the criterion "at all stages of distribution, including the retail sale stage." While EU regulations do not contain provisions relating to the liability of food retailers, the court interpreted this omission as meaning that "in principle, they do not preclude national legislation," which, in this case, allowed for such liability. The court cautioned, however, that any penalties must be "effective, proportionate and dissuasive" and left it to the national court to determine whether the penalty imposed complied with the principle of proportionality.

OTHER DEVELOPMENTS

Rome Framework for Action and Declaration on Nutrition Adopted

According to a joint World Health Organization (WHO)/Food and Agriculture Organization (FAO) news release, the ministers and senior officials of 170 countries convening in Rome have adopted a Framework for Action and a Declaration on Nutrition. Opening the Second International Conference on Nutrition, WHO Secretary General Margaret Chan reportedly criticized the production of what she characterized as less healthy industrialized food and called attention to the consequences of its contribution to obesity and overweight along with the emergence of diabetes, cancers and heart disease.

The commitments and recommendations set forth in the framework and declaration are intended to ensure "that all people have access to healthier and more sustainable diets." They also commit the governments to prevent malnutrition "in all its forms, including hunger, micronutrient deficiencies and obesity." Among other matters, governments are urged to "educate and inform their citizens about healthier eating practices" and reinforce obesity initiatives "by the creation of healthy environments that also promote physical activity from a young age." Governments are asked to "encourage a reduction in trans fats, saturated fats, sugars and salts in foods and drinks, and improve the nutrient content of foods through regulatory and voluntary instruments."



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The countries have recommended that the U.N. General Assembly endorse the Declaration and Framework and "consider declaring a Decade of Action on Nutrition for 2016-2025." See Joint WHO/FAO News Release and Prensa Latin News Agency, November 19, 2014.

Meanwhile, the McKinsey Global Institute has issued a report titled "Overcoming obesity: An initial economic analysis" that calls obesity "a critical global issue, requiring a comprehensive intervention strategy rolled out at scale." According to the report, more than 2.1 billion people, or nearly 30 percent of the global population, are overweight or obese, and obesity is responsible "for about 5 percent of all deaths worldwide." It calls for a systemic, sustained portfolio of initiatives to address the problem, including education, personal responsibility, reductions in default portion sizes, changed marketing practices, and restructured urban and educational environments to foster physical activity. It also recommends engagement from multiple sectors, such as governments, retailers, food and beverage companies, restaurants, employers, the media, educators, and health-care providers. Among the 74 specific recommendations are a number that would require regulation, including food labeling, advertising restrictions, and changes in taxes and agricultural subsidies.

Rudd Center Report Targets Advertising Sugar-Sweetened Beverages to Children

The Rudd Center for Food Policy and Obesity has published **Sugary Drink** FACTS 2014, a report funded by the Robert Wood Johnson Foundation that targets trends in beverage advertising to children. Claiming that companies spent \$866 million on advertising for sugar-sweetened beverages (SSBs) in 2013, the report argues that even though youth-oriented TV programs and websites showed fewer SSB ads in 2013 than in 2010, the advertising available "is still overwhelmingly for unhealthy drinks."

The authors point out that as SSB advertising on children's websites declined by 72 percent, "the popularity of energy drinks and regular soda brands on social media increased exponentially from 2011 to 2014." According to the report, energy drink and regular soda brands now represent 84 percent of the 300 million Facebook likes for the brands included in the analysis, 89 percent of 11 million Twitter followers, and 95 percent of 1.8 billion YouTube views. In addition, these brands purportedly engaged both celebrities and regular users "to virally increase their social media reach, with retweets, regrams, and revines, as well as teen-targeted contests inviting users to post videos and photos on various platforms."

Alleging that companies spend four times as much to advertise SSBs as they spend on 100-percent juice and plain water, the report authors have urged the beverage industry to "stop marketing sugary drinks and energy drinks to children and teens." Among other things, they recommend that companies



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not only refrain from social-media marketing practices that disproportionately appeal to teens, but that they "strengthen the CFBAI [Children's Food and Beverage Advertising Initiative] self-regulatory pledges to cover children up to age 14; ensure that companies' self-regulatory policies cover all media; expand definitions of child-directed marketing; and increase the number of companies participating in the program." The report also calls on regulators to require "straightforward and easy-to-understand labeling, including disclosing calories, added sugars, and artificial sweetener content on the front of all packaging."

"Despite promises by major beverage companies to be part of the solution in addressing childhood obesity, our report shows that companies continue to market their unhealthy products directly to children and teens," said Rudd Center Director of Marketing Initiatives Jennifer Harris. "They have also rapidly expanded marketing in social and mobile media that are popular with young people, but much more difficult for parents to monitor." See Rudd Center Press Release, November 19, 2014.

USP Releases Draft Guidance on Food Fraud Mitigation

The U.S. Pharmacopeial Convention (USP) has **proposed** "Guidance on Food Fraud Mitigation," a new appendix to the *Food Chemicals Codex* (FCC), to "offer a framework for the food industry and regulators to develop and implement preventative management systems to deal specifically with economically-motivated fraudulent adulteration of food ingredients." The **guidance** will be published for public comment in the FCC Forum from December 31, 2014, to March 31, 2015, but USP has released it early to provide additional time for review and comment. The document was designed for broad application and to provide a structured approach to characterizing and mitigating food fraud, including guidelines to (i) assess contributory factors, (ii) assess potential impacts and (iii) develop a mitigation strategy. The briefing also promises that "similar guidance sections that tailor this general approach to specific ingredient categories such as milk-based food ingredients" will appear in the future.

SCIENTIFIC/TECHNICAL ITEMS

Researchers Call for Better Energy Drink Labeling

A study of national poison control center data has reported that public and health care providers filed 5,156 incidents of energy drink exposure between October 2010 and September 2013, with 40 percent of cases involving children younger than age 6. Presented at the American Heart Association's Scientific Sessions 2014, the new research warned that among cases with major outcomes, "cardiovascular effects (including an abnormal heart rhythm



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and conduction abnormalities) were reported in 57 percent of cases, and neurologic effects (seizures, including status epilepticus) in 55 percent."

The study also identified moderate or major health outcomes in 42 percent of cases involving energy drinks mixed with alcohol and 19 percent of cases involving alcohol-free energy drinks. Based on these findings, the researchers have evidently called for additional labeling to educate consumers about "energy drinks' high caffeine content and subsequent health consequences."

"The reported data probably represent the tip of the iceberg," said senior author Steven Lipshultz, chair of pediatrics at Wayne State University and pediatrician-in-chief at Children's Hospital of Michigan in Detroit. "Energy drinks have no place in pediatric diets... And anyone with underlying cardiac, neurologic or other significant medical conditions should check with their healthcare provider to make sure it's safe to consume energy drinks." See American Heart Association Press Release, November 16, 2014.

Trans Fat Consumption Allegedly Linked to Diminished Memory

University of California, San Diego, researchers have presented a study at the American Heart Association's Scientific Sessions 2014, claiming that working-age men who consumed higher amounts of *trans* fat "had significantly reduced ability to recall words." According to a November 18, 2014, press release, the study analyzed dietary data from 1,000 healthy men younger than age 45 and asked them to complete a word memory test.

The results evidently showed that "each additional gram a day of *trans* fats consumed was associated with an estimated 0.76 fewer words correctly recalled." Participants who consumed the most *trans* fat remembered 11 fewer words than adults who ate the least *trans* fat, a 10 percent reduction in words remembered.

"Trans fats were most strongly linked to worse memory, in young and middle-aged men, during their working and career-building years," the lead author was quoted as saying. "From a health standpoint, trans fat consumption has been linked to higher body weight, more aggression and heart disease. As I tell patients, while trans fats increase the shelf life of foods, they reduce the shelf life of people."

Phthalates Allegedly Associated with Increased Stress Markers During Pregnancy

A new study has purportedly <u>found</u> that "urinary phthalate metabolites were associated with increased oxidative stress biomarkers" in a population of 482 pregnant women. Kelly Ferguson, et al., "Urinary Phthalate Metabolites and Biomarkers of Oxidative Stress in Pregnant Women: A Repeated



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Measures Analysis," Environmental Health Perspectives, November 2014. In addition to measuring nine phthalate metabolites at 10, 18, 26, and 35 weeks gestation as well as delivery, researchers with the University of Michigan and Harvard Medical School analyzed urinary levels of 8-hydroxydeoxyguanosine (8-OHdG) and 8-isoprostane as biomarkers of oxidative stress.

According to the results, "all phthalate metabolites were associated with higher concentrations of both biomarkers," with mono-benzyl phthalate (MBzP), mono-n-butyl phthalate (MBP), and mono-iso-butyl phthalate (MiBP) showing the strongest association with both outcome measures. "Increases in oxidative stress biomarkers in pregnant women have been associated with pregnancy loss, preeclampsia, preterm birth, and fetal growth restriction," note the study's authors. "These associations with phthalate exposure may be important for pregnancy outcomes that are mediated by oxidative stress mechanisms."

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FOOD & BEVERAGE LITIGATION UPDATE

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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.





