ISSUE 484 | MAY 17, 2013

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FTC Sends Letters to Businesses in Advance of New COPPA Requirements

The Federal Trade Commission (FTC) has reportedly sent letters to more than 90 businesses in an effort to educate them about updates to the Children's Online Privacy Protection Act (COPPA) that take effect July 1, 2013. According to a May 15, 2013, FTC press release, the agency sent separate letters to both domestic and foreign companies "**that may be collecting images or sounds of children**" as well as those "**that may be collecting persistent identifiers from children**." The letters explain to recipients that under the new rules, personal information now includes (i) "a photograph or video with a child's image, or an audio file that has a child's voice," and (ii) "persistent identifiers, such as cookies, IP addresses and mobile device IDs, that can recognize users over time and across different websites or online services."

"Companies whose apps collect, store or transmit this information, as well as other personal information previously covered by the rule like a child's name or address, must get parents' consent before collecting the information," states the commission. "In addition, companies must also ensure that any third party receiving the information can keep it secure and confidential, as well as abiding by new rules affecting how the information is stored and retained."

TTB Issues Industry Circular on Social Media Advertising of Alcohol Beverages

The U.S. Treasury Department's Alcohol and Tobacco Tax and Trade Bureau (TTB) has issued **guidance** to industry on the "Use of Social Media in the Advertising of Alcohol Beverages."

According to the May 13, 2013, circular, TTB considers that the advertising provisions of the Federal Alcohol Administration Act (FAA Act) apply to all advertisements "including social media." The guidance aims to provide "a basis for voluntary compliance with the FAA Act and the TTB advertising regulations with regard to social media, both in terms of required mandatory statements and prohibited practices or statements."

Shook, Hardy & Bacon L.L.P.

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TTB defines social media outlets as social network services, video sharing sites, blogs, microblogs, forums or comment sections on Websites, apps for mobile devices, and links and quick response codes. Applicable to advertisements for wine, distilled spirits and malt beverages, the requirements include posting a responsible advertiser name and address and avoiding prohibited statements, including false health claims.

TTB Amends Standards for Pisco and Cognac

The U.S. Treasury Department's Alcohol and Tobacco Tax and Trade Bureau (TTB) has **issued** a final rule amending the standards for cognac and pisco, a type of brandy manufactured in Peru and Chile. According to TTB, the final rule honors an international agreement with Peru and Chile recognizing pisco as a distinctive product of those countries in exchange for the recognition of Bourbon Whiskey and Tennessee Whiskey as distinctive products of the United States.

The final rule clarifies that pisco is "a type of brandy that must be manufactured in accordance with the laws and regulations of either Peru or Chile" and removes "Pisco brandy" from the list of examples of geographic designations in the distilled spirits standard of identity. Under the new rules, qualifying products can now bear the name "Pisco" or any of its equivalents—"Pisco Perú," "Pisco Chileno" or "Chilean Pisco"—without needing to add the term "brandy" to the label, "in the same way that a product label with the type designation 'Cognac' is not required to also bear the class designation 'brandy.'" Making a technical correction, the bureau has also removed "Cognac" from "the list of examples of geographical names that are not names for distinctive types of distilled spirits, and that have not become generic," because the term "Cognac" is already defined under §5.22(d)(2) of TTB regulations (27 CFR 5.22) "as grape brandy distilled in the Cognac region of France, which is entitled to be so designated by the laws and regulations of the French Government." *See Federal Register,* May 16, 2013.

FDA Issues Final Rule on Irradiation of Animal Feed and Pet Food

The U.S. Food and Drug Administration (FDA) has issued a final **rule** that amends the regulations for "irradiation of animal feed and pet food to provide for the safe use of electron beam and x-ray sources for irradiation of poultry feed and poultry feed ingredients." The revised rule states that ionizing radiation is limited to (i) "gamma rays from sealed units of cobalt-60 or cesium-137"; (ii) "electrons generated from machine sources at energy levels not to exceed 10 million electron volts"; (iii) "x-rays generated from machine sources at energies not to exceed 5 million electron volts"; and (iv) "x-rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 (MeV)." *See Federal Register,* May 10, 2013.

EFSA and ECDC Issue Report on Antimicrobial Resistant Bacteria

The European Food Safety Authority (EFSA) and European Centre for Disease Control and Prevention (ECDC) have issued their third joint **report** "on antimicrobial resistance in zoonotic bacteria affecting humans, animals and foods." Based on data collected by member states in 2011, the report notes the "continued presence of resistance to a range of antimicrobials in *Salmonella* and *Campylobacter,* the main bacteria causing food-borne infections in the European Union (EU)," although co-resistance to more than one critically important antimicrobial remains low overall.

According to the findings, "a high proportion of *Campylobacter* bacteria… was resistant to the critically important antimicrobial ciprofloxacin" in addition to other commonly used antimicrobials. The data also suggested that *Salmonella* resistance "to at least three different antimicrobial classes[] was high overall in the EU," with a large proportion of the bacteria in humans and animals already resistant to commonly used antimicrobials and, in the case of poultry, to ciprofloxacin. "If we do not want to lose a number of antimicrobials which today provide an effective treatment against bacterial infections in humans, then joint efforts in the EU, including the Member States, healthcare professionals, industry, farmers and many others are needed," said EFSA Director of Risk Assessment and Scientific Assistance Bernhard Url in a May 16, 2013, press release.

EFSA Reduces TDI for Phenol

The European Food Safety Authority (EFSA) has lowered the tolerable daily intake (TDI) of phenol—a chemical used to make coatings, adhesives and inks in food contact materials—from 1.5 to 0.5 mg/kg bw/day. The action follows a request from the German Federal Institute for Risk Assessment asking EFSA's Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) to reassess the TDI because the original value was "within the same dose range which was reported to be associated with some haematotoxic and immunotoxic effects in an oral study on phenol." In its scientific **opinion** on the toxicological evaluation of phenol, EFSA stated that the chemical was last evaluated in 1984.

The derived TDI does not consider the hazard of possible oxidation products such as quinones and hydroquinones, which CEF suggested should be evaluated separately. The panel also concluded that the "European Commission should consider other routes of exposure, including flavorings, smoked food products, floor waxes, cosmetics and disinfectants when setting a restriction for phenols in food contact materials."

More States Consider GM Labeling Bills, Sunstein Deems Them Unnecessary

The Vermont House of Representatives has passed a bill (**H. 112**) that would require labeling of foods with genetically modified (GM) ingredients. According to the legislative findings recited in the proposal, "There is a lack of

consensus regarding the validity of the research and science surrounding the safety of genetically engineered foods, as indicated by the fact that there are peer-reviewed studies published in international scientific literature showing negative, neutral, and positive health results." The findings also suggest that GM crops pose environmental hazards.

The measure, which requires Senate approval, would define what constitutes genetic engineering, prohibit any GM food from bearing a "natural" label and require placement of the term "'genetically engineered' immediately preceding any common name or primary product descriptor of a food." If enacted, the proposal would take effect on the first of two dates: "18 months after two other states enact legislation with requirements substantially comparable to the requirements of this act for the labeling of food produced from genetic engineering," or July 1, 2015. The House approved the bill 99-42.

Meanwhile, the Maine Legislature's Agriculture, Conservation and Forestry Committee approved a GM labeling proposal (**L.D. 718**) on May 14, 2013, by an 8-3 vote. This bill would require a "conspicuous disclosure that states 'Produced with Genetic Engineering'" on foods and seed stocks. It would also prohibit the use of "natural" to describe any food or seed stock subject to the disclosure requirement.

According to former administrator of the White House Office of Information and Regulatory Affairs Cass Sunstein, such labels should not be required because they would unnecessarily alarm consumers, and "inevitably lead many consumers to suspect that public officials, including scientists, believe that something is wrong with GM foods—and perhaps that they pose a health risk." Sunstein lists the organizations that have apparently endorsed the position that GM foods pose no risks to human health or the environment, including the American Association for the Advancement of Science, American Medical Association and World Health Organization. And while Sunstein agrees that consumers "have a right to know," unless these purported risks can be scientifically validated, "the argument for compulsory GM labels rests on weak foundations." *See Bloomberg*, May 12, 2013.

LITIGATION

SCOTUS Declines Review of Contaminated Pet Food Claims

The U.S. Supreme Court has denied the request to review a Washington appeals court dismissal of claims filed by a man who alleged that contaminated pet food caused his cat's death. *Earl v. Menu Foods Income Fund, Inc.*, No. 12-1083 (U.S., cert. denied May 13, 2013). According to a news source, the defendant had recalled some of its pet foods due to melamine contamination, but the plaintiff apparently failed to produce admissible evidence that those foods were implicated in his pet's death. In its opposition to the plaintiff's petition to the Court, Menu Foods reportedly stated that no federal question

was presented. Rather, at issue was whether state law on the preservation and destruction of evidence had been properly applied. *See Bloomberg BNA Product Safety & Liability Reporter*, May 13, 2013.

Court Decides What Makes Yogurt Yogurt

A federal court in New York has dismissed putative class claims filed against Dannon Co., alleging that its Activia® yogurt products are not actually yogurt because they contain filler products including milk protein concentrate (MPC), an ingredient that the Food and Drug Administration (FDA) purportedly prohibits from use in yogurt. *Conroy v. The Dannon Co., Inc.*, 12-6901 (U.S. Dist. Ct., S.D.N.Y., decided May 9, 2013). The defendant challenged the claims on the ground that the "plaintiff's allegations are premised on a misunderstanding of the FDA's standard of identity for yogurt."

The court agreed with Dannon that while MPC is not included in the list of permissible ingredients for yogurt, it is a permitted "other optional ingredient" despite FDA's failure to include MPC in its 1981 definition of the phrase. According to the court, the issue in the case was the proper interpretation of a stay FDA imposed in 1982 on certain provisions of its yogurt standards of identity rule in response to objections. The plaintiff contended that the stay struck the entire "other milk-derived ingredients" list "such that no milk-derived ingredients may be added to yogurt."

The court disagreed, finding that FDA explained that it issued the stay in "response to objections concerning the replacement of the phrase 'other milk-derived ingredients … with a limited list of names of milk-derived ingredients.' The objectors had argued [that] the replacement of the broad term with a limited list did not promote honesty and fair dealing because it barred the use of other safe, nutritional, and functional milk-derived ingredients, and did not appear to have any rational factual basis. The FDA concluded that 'the objectors raise[d] a genuine and substantial issue of fact that must be resolved at a public hearing' and issued a stay."

Thus, the court concluded that, in context, FDA's action "means that paragraph (d)(1) is only stayed insofar as it limits the kinds of safe and suitable milk-derived ingredients that may be used" and not that MPC is prohibited. The court further noted that in 2004, "FDA expressly stated that MPC may be added to yogurt … in an FDA-issued memorandum from the Milk Safety Branch to all Regional Food and Drug Directors."

The court also rejected the plaintiff's claims that Activia® was adulterated due to its MPC content, because FDA has never determined that it is generally recognized as safe. In the court's view, "FDA would not have made the clear and unambiguous statement that MPC may be used in yogurt 'if that same permissible addition would render the yogurt illegally adulterated.'" Finding that the plaintiff failed to demonstrate that amending her complaint would not be futile, the court denied her informal request to amend her complaint.

Court Allows Third Amended Complaint in Suit Claiming HFCS Is Not "Natural"

A federal court in California has granted in part and denied in part the motion to dismiss filed by General Mills in litigation alleging that certain of its Nature Valley® products are deceptively labeled and advertised as "natural" because they contain sweeteners, such as high-fructose corn syrup (HFCS), high-maltose corn syrup or maltodextrin and rice maltodextrin, which are purportedly "highly processed" and therefore not "natural." *Janney v. General Mills*, No. 12-3919 (U.S. Dist. Ct., N.D. Cal., filed May 10, 2013). The plaintiffs are represented by Center for Science in the Public Interest attorney Stephen Gardner.

The court disagreed with General Mills that the primary jurisdiction doctrine barred the claims, finding that the Food and Drug Administration "has signaled a relative lack of interest in devoting its limited resources to what it evidently considers a minor issue, or in establishing some 'uniformity in administration' with regard to the use of 'natural' in food labels." The court also determined that as to the labeling and advertising of five specifically named products, the plaintiffs had sufficiently pleaded fraud under California law.

The court agreed with the defendant, however, that the complaint "does not plead fraud with particularity with regard to two areas—the online marketing sources (the Nature Valley® website, Facebook, Flickr, YouTube, plus presumably Twitter, which is pled in the [first amended complaint] but which General Mills does not mention); and the 'unidentified products.'" According to the court, "Plaintiffs' vague description of the products they contend are at issue (apart from the Named Products) leaves General Mills (and the court) to guess which of its products (and which statements about those products) General Mills will be required to defend in this case." The court ordered the plaintiffs to file an amended complaint no later than June 7, 2013.

Wage and Rest Break Claimants Settle California Suit Against Starbucks

The plaintiffs in putative class litigation alleging inaccurate wage statements and denial of required meal breaks have filed a motion for preliminary approval of a class action settlement brought against Starbucks in 2008. *York v. Starbucks Corp.*, No. 08-7919 (U.S. Dist. Ct., C.D. Cal., W. Div., motion filed May 10, 2013).

Without admitting liability, the company has apparently agreed to pay $3 million to resolve the claims of California Starbucks employees who fall into one or two subclasses: (i) the "Meal Break Settlement Subclass," including "all persons employed by Starbucks within the state of California in the job categories of café attendant, barista, or shift supervisor during the period from December 2, 2004, to January 31, 2013"; and (ii) the "Wage Statement Settlement Subclass," including "all persons employed by Starbucks in the state of California in the job categories of café attendant, barista, shift supervisor, assistant store manager, or store manager during the period from December 2, 2007, to January 31, 2013."

The agreement does not include attorney's fees, although a procedure for their determination is established in the proposal, and the agreement provides Starbucks with a limited right to cancel if five percent or more of the class members "validly and timely opt out of the Settlement or submit timely written objections." The motion has been scheduled for a June 10 hearing.

OTHER DEVELOPMENTS

IOM Report on Salt Recommendations Draws Criticism

The Institute of Medicine (IOM) recently issued a **report** assessing the scientific evidence behind government recommendations that adults in the general population reduce dietary sodium intake to less than 2,300 milligrams per day and that certain groups of people at a greater risk of developing cardiovascular disease (CVD) reduce their salt consumption to 1,500 mg per day. At the request of the Centers for Disease Control and Prevention, the IOM committee responsible for the report focused on new studies examining sodium's direct effect on health outcomes as opposed to previous research that used high blood pressure as "a widely accepted biological predictor of risk for CVD and stroke."

Based on this new research, the IOM report concludes that while the latest science still supports salt reduction recommendations for the general population, there is little or no new evidence to back the 1,500 mg/day recommendation for specific population subgroups, which include African Americans, people ages 51 and older, and those with certain medical conditions. In particular, the IOM committee reportedly found "no evidence for benefit and some evidence suggesting risk of adverse health outcomes associated with sodium intake levels in ranges approximately 1,500 to 2,300 mg/day among those with diabetes, kidney disease, or CVD." Noting a lack of strong evidence either confirming or refuting that "these subgroups should be treated differently than the general U.S. population," the report also lays out a research agenda meant to close "a number of data and methodological gaps" that currently "make comparisons across studies difficult."

"These new studies support previous findings that reducing sodium from very high intake levels to moderate levels improves health," said IOM Committee Chair Brian Strom in a May 14, 2013, press release. "But they also suggest that lowering sodium intake too much may actually increase a person's risk of some health problems."

Meanwhile, health and consumer groups have criticized the report for allegedly failing to take the larger picture into account. "While the American Heart Association [AHA] commends the IOM for taking on the challenging topic of sodium consumption, we disagree with key conclusions," AHA CEO Nancy Brown was quoted as saying. "The report is missing a critical component – a comprehensive

review of well-established evidence which links too much sodium to high blood pressure and heart disease." *See AHA Press Release,* May 14, 2013.

The Center for Science in the Public Interest (CSPI) has since described the IOM report as fatally limited "by a narrow charge to examine only studies that looked at hard endpoints like heart attacks and strokes." To this end, CSPI echoed IOM's call for additional large-scale studies and urged health authorities to continue relying on the "mountain of evidence that higher sodium intakes raise blood pressure, and that high blood pressure raises the risk of cardiovascular disease." *See CSPI Press Release,* May 14, 2013.

Center for Food Safety Publishes "Guide to Food Industry Front Groups"

Public interest advocacy organization the Center for Food Safety has issued a report titled "Best Public Relations Money Can Buy: A Guide to Food Industry Front Groups," authored by food activist and attorney Michele Simon. The report describes what front groups are and how they purportedly function, drawing parallels with a cigarette industry trade group, which, according to Simon, by distorting science "effectively delayed public policy on tobacco for decades. The food industry's current effort to distort science is similar, but somewhat more subtle, operating through less obvious front groups."

Among the groups mentioned are (i) the U.S. Farmers and Ranchers Alliance—"[t]he group calls itself 'farmers and ranchers' because that sounds better than Monsanto and the Pork Board"; (ii) No on 37—a group fighting a ballot initiative in California that would have required labels on foods with genetically modified ingredients; it allegedly "claimed to be a 'coalition of family farmers, grocers, food companies, small businesses and others,' [but] they were in fact funded by leading biotech, pesticide, and junk food companies"; (iii) American Council on Science and Health—funders purportedly include General Mills, PepsiCo and the American Beverage Association; and (iv) Center for Consumer Freedom—with funding at one time from major food industry companies, this is "the attack dog of the food industry," claims Simon.

SCIENTIFIC/TECHNICAL ITEMS

New Studies Focus on Sodium and Calorie Content of Restaurant and Processed Foods

Three recent studies published in *JAMA Internal Medicine* have analyzed the nutritional content of restaurant and processed foods, raising questions about consumer, industry and government efforts to curb calorie, sodium and fat consumption. Authored by Center for Science in the Public Interest (CSPI) Executive Director Michael Jacobson and colleagues at George Washington University and Northwestern University, the first study examined changes in the sodium levels of identical processed and restaurant foods from 2005 to 2011. Michael Jacobson, et al., "Changes in Sodium Levels in Processed and Restaurant

Foods, 2005 to 2011," *JAMA Internal Medicine,* May 2013. Using data collected by CSPI, researchers reportedly found that "sodium content in 402 processed foods declined by approximately 3.5%, while the sodium content in 78 fast-food restaurant products increased by 2.6%." Although the study also noted that salt content decreased by 30 percent in some products and increased by 30 percent in others, "the predominant finding is the absence of any appreciable or statistically significant changes in sodium content during six years."

"The strategy of relying on the food industry to voluntarily reduce sodium has proven to be a public health disaster," said Jacobson in a May 13, 2013, CSPI press release. "Inaction on the part of industry and the federal government is condemning too many Americans to entirely preventable heart attacks, strokes, and deaths each year."

Meanwhile, two additional studies focusing solely on restaurant foods have further assessed the calorie and nutrition content of both chain and non-chain venues. Lorien Urban, et al., "The Energy Content of Restaurant Foods Without Stated Calorie Information," *JAMA Internal Medicine,* May 2013. Highlighting the calorie contents of foods served at small- or non-chain restaurants in the United States, one research article concluded that these types of establishments, "which provide no nutrition information, also provide excessive dietary energy in amounts apparently greater than popular meals from chain restaurants or information in national food databases."

The other study examined menu items from 26 chain sit-down restaurants (SDRs) in Canada, compiling nutrition profiles for "3507 different variations of 685 meals, as well as 156 desserts from 19 SDRs." Mary Scourboutakos, et al., Research Letter, "Restaurant Meals: Almost a Full Day's Worth of Calories, Fats, and Sodium," *JAMA Internal Medicine,* May 2013. The results evidently showed that breakfast, lunch and dinner meals from 19 chain SDRs contained, on average, (i) "1128 calories (56% of the average daily 2000 calorie recommendation)"; (ii) "151% of the amount of sodium an adult should consume in a single day (2269 mg)"; (iii) "89% of the daily value for fat (58 g)"; (iv) "83% of the daily value for saturated and *trans* fat (16 g of saturated fat and 0.6 g of *trans* fat); and (v) "60% of the daily value for cholesterol (179 mg)."

Reflecting on this new research, however, a concurrent editorial authored by Los Angeles County Department of Health Services Director Mitchell Katz questioned how far government should go in regulating food consumption beyond its efforts at making nutritional information more readily available and transparent. "Ultimately, the true limitation in regulating food consumption is that unlike tobacco, food is safe and necessary in reasonable doses," writes Katz. "Regulating the maximum of a necessary nutrient, such as salt, will always raise questions of whether the government is going too far in regulating our lives. As we debate the controversial role of government in stemming the interrelated endemics of obesity, diabetes mellitus, and heart disease, we must insist on the right of our patients (as well as ourselves) to know what we are eating, whether fast food or slow, whether large chain, small chain, or individual restaurant."

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FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 484 | MAY 17, 2013

Sugar-Sweetened Beverages Allegedly Linked to Increased Kidney Stone Risk

A recent **study** purportedly concluded that consumption of sugar-sweetened beverages is associated with a higher risk of kidney stone formation while consumption of other beverages such as coffee, tea, beer, and wine, is associated with a lower risk. Pietro Manuel Ferraro, et al., "Soda and Other Beverages and the Risk of Kidney Stones," *Clinical Journal of the American Society of Nephrology,* May 2013. Conducted by a team of researchers from Brigham and Women's Hospital, the study analyzed the data of 194,095 participants from the Health Professionals Follow-Up Study (HPFS) and the Nurses' Health Studies I and II. Those who consumed one or more sugar-sweetened cola servings per day reportedly had a 23 percent higher risk of developing kidney stones compared to those who consumed less than one serving per week. The researchers observed that this was also true for consumption of sugar-sweetened non-cola beverages, such as punch. A lower risk of stone formation was associated with consumption of other beverages, including caffeinated coffee (26 percent); decaffeinated coffee (16 percent); tea (11 percent); wine (31–33 percent); beer (41 percent); and orange juice (12 percent).

"Our prospective study confirms that some beverages are associated with a lower risk of kidney stone formation, whereas others are associated with a higher risk," said co-author Pietro Manuel Ferraro. "Although higher total fluid intake reduces the risk of stone formation, this information about individual beverages may be useful for general practitioners seeking to implement strategies to reduce stone formation in their patients." *See Brigham and Women's Hospital News Release,* May 15, 2013. ■

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