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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

New York Lawmaker Reintroduces *Trans* Fat Labeling Bill

Rep. Steve Israel (D-N.Y.) has reintroduced a bill (H.R. 3612) that would require clearer labeling of *trans* fat on food packaging. The move follows the U.S. Food and Drug Administration's recent preliminary determination that partially hydrogenated oils, a major source of artificial *trans* fat in processed foods, are not deemed generally recognized as safe (GRAS) for use in food.

Current regulations, which permit food companies to label products that contain partially hydrogenated oils as having 0 grams of *trans* fat if the value per serving is 0.4 grams or less, have been criticized by Israel and others, who point out that consumers can unknowingly exceed the recommended consumption of *trans* fat by eating multiple servings of a product containing 0.4 grams in a day.

Israel's legislation would amend this regulation to require manufacturers to indicate that a product contains less than 0.5 grams *trans* fat by using an asterisk in the "amount per serving" column and a note at the bottom of the label explaining that the product "contains less than 0.5 grams trans fat." Foods not containing *trans* fat could still list "0g" on the label. *See News Release of Rep. Steve Israel,* November 7, 2013.

FSIS Issues *Salmonella* Action Plan

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has released its *Salmonella* Action Plan outlining steps the agency will take to address its "most pressing problem"—*Salmonella* in meat and poultry products. Key elements of the plan include modernizing an "outdated" poultry slaughter inspection system and shifting FSIS inspectors to more offline, food-safety duties, which the agency said will prevent at least an estimated 5,000 illnesses annually.

The plan also calls for FSIS to (i) establish new performance standards; (ii) develop new strategies for "inspection and throughout the full farm- to table-continuum"; (iii) address all potential sources of *Salmonella*; and (iv) focus the agency's "education and outreach tools on *Salmonella*."

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Although lauded by many food-safety advocates, critics claim that it "completely ignores" one of the most crucial issues the meat industry faces—antibiotic-resistant *Salmonella*. "It is shocking for the agency to have stayed on the sidelines of this public health crisis, particularly in the two and a half years since [we] petitioned the agency to declare certain strains of antibiotic-resistant *Salmonella* to be adulterants," said a statement from the Center for Science in the Public Interest (CSPI). "FSIS's failure to address antibiotic resistance in its Action Plan for *Salmonella* is a weakness that continues to leave the public at risk." While noting that the action plan does make "some important improvements," CSPI asserts that FSIS "should go further, however, and test every poultry and beef slaughter plant every week for *Salmonella*." *See FSIS News Release* and *CSPI News Release,* December 4, 2013.

FSIS Reopens Comment Period on Labeling for Mechanically Tenderized Beef

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **reopened** the comment period on a proposed rule concerning the description designation for needle- or blade-tenderized beef. First published in the June 10, 2013, *Federal Register,* the proposed rule would require "the descriptive designation 'mechanically-tenderized' on the labels of raw or partially-cooked needle- or blade-tenderized beef products, including beef products injected with marinade or solution, unless these products are to be fully cooked at an official establishment." Because the first comment period expired during the recent partial government shutdown, the agency will now accept feedback until December 24, 2013. Additional details about the proposed rule appear in Issue **486** of this *Update*. *See Federal Register,* December 3, 2013.

FDA Changes References in Food Additive Regulations

In response to a petition filed by the U.S. Pharmacopeial Convention, the U.S. Food and Drug Administration (FDA) has **issued** a final rule that amends select food-additive regulations referring to "food-grade specifications from prior editions of the Food Chemicals Codes (FCC) to incorporate by reference food-grade specifications from the FCC 7th Edition." The rule took effect November 29, 2013, but objections and requests for hearing may be filed until December 30. *See Federal Register*, November 29, 2013.

EU Committee Proposes Tougher Penalties for Food Fraud

The European Parliament's Environment, Public Health and Food Safety Committee has approved a **draft report** of legislation that calls for stronger policing of the food industry and tougher penalties for fraud. With an aim to strengthen procedures for detection and prevention of fraudulent practices in the European food chain, the legislation calls for, among other things, (i) a clear, European Union (EU)-wide definition of the term "food fraud"; (ii) enhancements to the Food and Veterinary Office's role and resources in food-fraud

cases; (iii) legal obligations for food business operators to report fraudulent behavior; (iv) a "more policing approach" by enforcement bodies; (v) fines of "at least double the amount of the economic advances sought"; and (vi) the forfeiture of registrations for repeat offenders. The report noted that olive oil, fish, organic foods, milk, and grains are the top five products most at risk of food fraud in the EU.

FSA-Commissioned Study Examines Aspartame's Alleged Health Effects

The U.K. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) has **released** a December 2013 position paper on the purported health effects of aspartame, which is currently being reviewed by the European Food Safety Authority as part of its re-evaluation of all food additives. Commissioned by the U.K. Food Standards Agency (FSA), the paper apparently analyzes a double-blind randomized crossover study conducted by University of Hull York Medical School researchers, who asked 50 participants with self-diagnosed adverse reactions to aspartame to consume a snack bar without knowing whether it contained the substance in question.

Based on the study's findings, which compared the responses of these participants to a control group, COT has concluded that "the results presented did not indicate any need for action to protect the health of public." The committee will release the full minutes of its discussion once the study has been accepted for publication into a peer-reviewed scientific journal. *See FSA News Release,* December 4, 2013.

Canada Takes Steps to Approve GM Salmon

Environment Canada has **published** a significant new activity notice that will allow AquaBounty Technologies, Inc. to produce genetically modified (GM) salmon eggs. According to the company, the agency determined that GM salmon "is not harmful to the environment or human health when produced in contained facilities." AquaBounty CEO Ron Stotish said, "This is a significant milestone in our efforts to make AquAdvantage® Salmon available for commercial production. However, our eggs and fish will not be available for sale until they are approved by the relevant national regulatory bodies." The company notes that Environment Canada reached its conclusion "following a risk assessment conducted by Fisheries and Oceans Canada involving a panel of independent scientific experts knowledgeable in the fields of transgenics and fish containment technology." *See Canada Gazette*, November 23, 2013; *AquaBounty Technologies New Release*, November 25, 2013.

OEHHA Seeks Comments on Draft Templates for Tabulating Studies and Data

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has issued a request for public comments on draft templates for tabulating epidemiology studies and data from animal studies for use by members of the agency's Science Advisory Board Development and Reproductive Toxicant Identification Committee. Comments are requested by December 23, 2013. *See OEHHA News Release*, December 4, 2013.

Meanwhile, during the December 5 meeting of OEHHA's Carcinogen Identification Committee, diisononyl phthalate, a plasticizer used in food-contact materials, and butyl benzyl phthalate, a chemical used in food conveyor belts, were discussed as candidates for addition to the Proposition 65 list of chemicals known to the state to cause cancer. *See Proposition 65 News*, December 5, 2013.

LITIGATION

Class Cert. Denied in Suit Against Chipotle

Finding that individual issues predominate over common ones in a putative class action alleging that Chipotle Mexican Grill sold conventionally raised meats despite advertising its use of "naturally raised" meats, a federal court in California has denied the plaintiff's motion for class certification. *Hernandez v. Chipotle Mexican Grill, Inc.*, No. 12-5543 (U.S. Dist. Ct., C.D. Cal., order entered December 2, 2013). Additional details about the case appear in Issue 451 of this *Update*.

According to the court, when and where a class member ate at Chipotle and which meat she ate can only be handled individually. The court deemed these issues significant because the allegations are based on the company's in-store menu signboards and paper menus and because the dates on which "naturally raised" meats were unavailable to specific stores varied over the course of five years. The court also noted that when Chipotle experienced "naturally raised" meat shortages, it would instruct individual stores to post signs to so inform customers, typically at the tortilla station. This further raised individual issues as to whether a sign was posted or a class member saw it.

With few records available to pinpoint specific purchases involving a "very low price transaction," the court found the class action mechanism not fair and efficient. The court concluded, "The claims would require claimants to list every time they ate at Chipotle, the date—at least month and year, the specific location—'San Francisco' is not going to be good enough, and the specific item purchased. The Court is confident that very few people will be able to provide that information. People will either (1) lie, (2) attempt to fill out the claim form as best they can but be unable to do so accurately, or, most

likely, (3) not bother. Money would be given out basically at random to people who may or may not actually be entitled to restitution. This is unfair both to legitimate class members and to Chipotle."

Court Allows EJC Claim Amendment

In a putative class action against Amy's Kitchen, a federal court in California has dismissed with leave to amend claims that the company has mislabeled its products by listing "evaporated cane juice" (ECJ) or "organic evaporated cane juice" as an ingredient. *Figy v. Amy's Kitchen, Inc.*, No. 13-3816 (U.S. Dist. Ct., N.D. Cal., order entered November 25, 2013).

The company argued that the plaintiff "failed to allege that he relied on the products' ingredient labeling" and thus lacked standing under the state's Unfair Competition Law (UCL). According to the plaintiff, "reliance on a label misrepresentation is not a necessary element of a claim under the unlawful prong of the UCL." Interpreting and applying *In re Tobacco II Cases*, 46 Cal. 4th 298 (2009), and *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310 (2011), the court held, "because the statutes plaintiff relies on prohibit specific types of misrepresentation on food labels—the listing of an ingredient by a name other than its common or usual name—the actual reliance requirement applies to plaintiff's claim even though it is brought under the unlawful prong of the UCL."

The court also rejected the plaintiff's argument that an inference "of reliance arises wherever there is a showing that a misrepresentation was material." In the court's view, "a plaintiff must still at minimum allege that he saw the representation at issue." The court ordered the plaintiff to file an amended complaint, if he chooses to do so, by December 13, 2013.

Putative Class Alleges Whole Foods Products Contain GM Ingredients

Texas and California residents have filed a putative class action against Whole Foods Market Services, Inc. in a Texas federal court, alleging that the company's private label lines include falsely labeled additive-laden and genetically modified (GM) foods, despite promises that its products contain "nothing artificial" and that it enforces "strict quality standards." *Gedalia v. Whole Foods Mkt. Servs., Inc.*, No. 13-3517 (U.S. Dist. Ct., S.D. Tex., Houston Div., filed November 28, 2013). Among purported transgressions are (i) organic infant formula containing 25 ingredients "prohibited from being in organic foods" as well as 30 artificial ingredients, and (ii) organic soy and almond milk containing "ingredients not permitted in organic foods."

The complaint also alleges that the company reneges on its promise to avoid ingredients grown from genetically engineered seed and relies on a Cornucopia Institute study purportedly showing that Whole Foods' 365 Everyday Value® products "were contaminated with high levels of genetically engineered ingredients," citing, in particular, the company's Corn Flakes that allegedly contain

"more than 50% genetically engineered corn." The plaintiffs further challenge the company's claim that its products do not contain any of the ingredients on a publicly available "unacceptable ingredients for foods" list. According to the complaint, many of the listed ingredients are in the company's private label products. They further take issue with the company's "natural" product representations.

Seeking to certify a nationwide class of consumers and state subclasses, the plaintiffs allege violation of the California Organic Products Act, Consumers Legal Remedies Act, False Advertising Law, and Unfair Competition Law; breach of express warranty, breach of implied warranty of merchantability and warranty of fitness for particular purpose; deceit and/or misrepresentation, fraudulent concealment and constructive fraud in violation of common law and California statutory law; unjust enrichment; and negligence and negligent misrepresentation. They seek declaratory relief, restitution, disgorgement, attorney's fees, costs, injunctive relief, and statutory and punitive damages.

Meat Packer to Pay $3 Million in FCA Litigation

In False Claims Act (FCA) litigation arising from the sale to the U.S. Department of Agriculture of beef processed from the alleged abuse of downer cattle, Westland Meat Co. has reportedly agreed to pay more than $3 million, or most of its owners and investors' remaining assets. *United States ex rel. The Humane Soc'y of the U.S. v. Westland/Hallmark Meat Co.*, No. 08-0221 (U.S. Dist. Ct., C.D. Cal., judgment filed November 27, 2013).

The Humane Society had whistleblower videos showing slaughterhouse employees kicking, beating and dragging disabled cattle to slaughter, prompting the largest recall of beef in U.S. history over bovine spongiform encephalopathy concerns. Details about the video appear in Issue **247** of this *Update*. The agreement apparently reduces the bankrupt company's liability to some $155 million, from a previous treble-damages judgment of nearly $500 million. According to a news source, the case involved disputed topics under FCA case law: implied certification and damages calculations. *See Law360*, November 27, 2013.

U.S. Seeks Psychiatric Exam of Stewart Parnell

According to court records, prosecutors have filed a motion for psychiatric examination as to Stewart Parnell, who is under criminal indictment for actions relating to the 2009 nationwide *Salmonella* outbreak linked to the peanut products made by the Blakely, Georgia, Peanut Corp. of America plant that Parnell owned. *United States v. Parnell*, No. 12cr12 (U.S. Dist. Ct., M.D. Ga., motion filed December 4, 2013). Information about the criminal charges appears in Issue **472** of this *Update*. Parnell has filed a motion to sever defendant and counts. The criminal proceedings against him are currently joined to charges against other company employees.

ERC Claims Diet Shakes and Bars Contain Lead

The Environmental Research Center (ERC) has reportedly filed a lawsuit under Proposition 65 (Prop. 65) against a company that allegedly sells "meal replacement" shakes and "hunger blocker" bars containing lead, a chemical known to California as a reproductive toxicant and cause of cancer. *ERC v. Ideal Shape LLC*, No. n/a (Cal. Super. Ct., Alameda Cnty., filing date n/a).

Under Prop. 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, private litigants such as ERC may bring enforcement actions after notifying an alleged violator that it has failed to provide warnings with products containing listed chemicals. ERC sent such a letter to Ideal Shape on May 17, 2013, alleging Prop. 65 violations every day since at least May 17, 2010. *See Courthouse News Service*, November 25, 2013.

OTHER DEVELOPMENTS

NY State PTA Takes Stand Against Antibiotic Overuse in Livestock

The New York State Parent Teacher Association (PTA) has reportedly become the first PTA in the country to pass a **resolution** that calls on Congress and the U.S. Food and Drug Administration "to protect human health by prohibiting the overuse and misuse of antibiotics in food animal production." Representing hundreds of thousands of parents, teachers and students who note that "antibiotic resistance has become a global public health crisis," the group's resolution supports legislation that would improve labeling on meat and poultry products and make antibiotic use on the farm more transparent. The resolution also (i) advocates public disclosure on the amount, type and purpose of antibiotic use during food animal production; (ii) encourages schools to serve meat and poultry from farms that use antibiotics only to treat disease; and (iii) supports education for parents and schools on how antibiotic use in livestock production contributes to antibiotic resistance. *See Pew Charitable Trusts News Release,* November 25, 2013.

SCIENTIFIC/TECHNICAL ITEMS

Lead Content of Brewed Teas Target of New Study

Canadian researchers have **warned** that many off-the-shelf brewed teas purportedly contain lead in excess of levels considered safe for pregnant and lactating women. Gerry Schwarlfenberg, et al., "The Benefits and Risks of Consuming Brewed Tea: Beware of Toxic Element Contamination," *Journal of Toxicology,* December 2013. Using 30 samples of black, green, white, and oolong teas obtained from supermarkets and health food stores, the study's authors steeped the teas using one tea bag and 250 mL of distilled water for 3-4 minutes and 15-17 minutes.

The results evidently showed that "all brewed teas contained lead," with 73 percent of teas brewed for three minutes and 83 percent of teas brewed for 15 minutes having lead levels ranging from 0.1 µgm/L to 4.39 µgm/L. According to the study, California's Proposition 65 currently sets an acceptable limit for lead in reproductive health at 0.5 µgm/L per day. In addition, the study notes that aluminum levels exceeded recommended guidelines in 20 percent of brewed teas.

"Toxic contamination by heavy metals was found in most of the teas sampled. Some tea samples are considered unsafe," conclude the study's authors. "There are no existing guidelines for routine testing or reporting of toxicant levels in 'naturally' occurring products. Public health warnings or industry regulation might be indicated to protect consumer safety." *See National Post,* December 1, 2013.

SSB Consumption Allegedly Associated with Type I Endometrial Cancer

A recent study funded by the National Cancer Institute has allegedly linked higher intakes of sugar-sweetened beverages (SSBs) to an increased risk of type I endometrial cancer. Maki Inoue-Choi, et al., "Sugar-Sweetened Beverage Intake and the Risk of Type I and Type II Endometrial Cancer among Postmenopausal Women," *Cancer, Epidemiology, Biomarkers & Prevention,* December 2013. After evaluating the dietary intake of 23,039 postmenopausal women enrolled in the Iowa Women's Health Study, University of Minnesota researchers apparently found that compared with women who did not consume SSBs, those in the highest quintile of SSB intake had a 78 percent increased risk of developing type I endometrial cancer while those who reported at least some SSB consumption had "a statistically significant 47 [percent] higher risk."

The study's authors also noted in a December 4, 2013, press release that "previous studies have shown increasing consumption of sugar-sweetened beverages has paralleled the increase in obesity," a purported risk factor for endometrial cancer. The data also apparently suggested that SSB consumption "may increase the risk of type I endometrial cancer independent of its role in weight status, consistent with other studies examining insulin-raising potential of the diet and endometrial cancer."

"The list of potential unhealthy effects from sugar sweetened soft drink consumption is growing," said one of the study's authors. "Since they have no health benefit, it would be prudent to avoid these beverages."

Researchers Claim Energy Drinks Increase Heart Contraction Rates

An ongoing study presented at the Radiological Society of North America's (RSNA's) 99th Annual Scientific Assembly and Annual Meeting has reportedly claimed that energy drinks "significantly increased" heart contraction rates in

healthy adults one hour after consumption. According to a December 2, 2013, RSNA press release, researchers with the University of Bonn, Germany, used cardiac magnetic resonance imaging (MRI) "to measure the effect of energy drink consumption in 18 healthy volunteers," who apparently underwent cardiac MRI before and after consuming an energy drink containing 400 mg of taurine and 32 mg of caffeine. The results evidently showed that, compared to the baseline images, the MRI taken one hour after energy drink consumption "revealed significantly increased peak strain and peak systolic strain rates (measurements for contractility) in the left ventricle of the heart."

"Until now, we haven't known exactly what effect these energy drinks have on the function of the heart," said one of the researchers. "There are concerns about the products' potential adverse side effects on heart function, especially in adolescents and young adults, but there is little or no regulation of energy drink sales… We need additional studies to understand this mechanism and to determine how long the effect of the energy drink lasts."

Meanwhile, Monster Beverage Corp. has issued a December 2 statement describing the study in question as "alarmist and misleading." In particular, the company notes, scientists have long known that taurine "*helps the heart function more efficiently* by improving the pumping force of the heart *without any changes in blood pressure or heart rate*."

"This effect of taurine, called contractility, is widely considered to be beneficial," concludes the statement. "The author's study does not document a negative effect on heart function. Although he concludes that the consumption of energy drinks should be restricted based on his study, this conclusion is unsupported by his data and highly misleading. No evidence exists that increased contractility causes arrhythmia."

Scientific Journal Retracts Animal Study Linking GMOs to Mammary Tumors

The journal *Food and Chemical Toxicology* has announced the retraction of a controversial study purportedly linking genetically modified organisms (GMOs) to mammary tumors in rats. Led by University of Caen Molecular Biology Professor Gilles-Éric Séralin, the November 2012 study garnered public attention for reporting that female rats fed GM maize developed more mammary tumors than a control group raised on conventional feed. After further review, however, the journal's editor-in-chief concluded that "both the low number of animals in each study group and the particular strain selected" were cause for concern.

"A more in-depth look at the raw data revealed that no definitive conclusions can be reached with this small sample size regarding the role of either NK603 or glyphosate in regards to overall mortality or tumor incidence," notes the

journal's retraction statement. "Given the known high incidence of tumors in the Sprague-Dawley rat, normal variability cannot be excluded as the cause of the higher mortality and incidence observed in the treated groups." *See Elsevier.com,* November 28, 2013.

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FOOD & BEVERAGE LITIGATION UPDATE

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.