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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

U.S. Government Appeals WTO Ruling on COOL Rules

The United States has appealed the World Trade Organization's (WTO's) ruling in favor of Canada and Mexico in a dispute over U.S. country-of-origin labeling (COOL) regulations requiring pork and beef products originating outside the United States to carry labels specifying their sources.

The appeal notification circulated to WTO members indicated that the United States has challenged several of the panel's findings, including that the detrimental impact does not stem exclusively from legitimate regulatory distinctions because "the amended COOL measure entails an increased recordkeeping burden and increased segregation," "the current labels provided by the amended COOL measure have a potential for label inaccuracy," and "the amended COOL measure continues to exempt a large proportion of muscle cuts." Appeals are heard by three members of a permanent seven-member appellate body unaffiliated with any government, and the appellate body generally has three months to conclude its report. Additional information on the WTO panel's ruling appears in Issue 542 of this *Update*.

FDA Finalizes Calorie-Disclosure Rules for Restaurants and Vending Machines

The U.S. Food and Drug Administration (FDA) has finalized two rules under the 2010 Patient Protection and Affordable Care Act that require chain restaurants and vending machine operators to disclose calorie information on menus or at the point of purchase. Generating more than 1,100 public comments, the federal rules aim to standardize labeling requirements "to provide consumers with more nutritional information about the foods they eat outside of the home."

Effective December 1, 2015, the menu-labeling final rule applies to restaurants and similar retail food establishments with more than 20 locations, as well as food facilities in movie theaters, amusement parks and other entertainment venues. According to FDA, which narrowed the scope of the rule to focus on restaurant-style food, the new labeling provisions cover standard menu items, certain alcohol beverages and multi-serving dishes labeled on a per-serving basis, but exempt "condiments, daily specials, temporary menu items, and food that is part of a customary market test." Chain restau-

rants must also display on menu and menu boards (i) a succinct statement concerning suggested daily caloric intake, and (ii) a statement regarding the availability of written nutrition information.

Under the second **final rule**, which takes effect December 1, 2016, vending machine operators who own or operate more than 20 machines must provide "clear and conspicuous" calorie disclosures for each item on sale unless this information is already visible to prospective purchasers. Calorie disclosures must meet FDA requirements for type size, color and contrast and can appear "in, on or adjacent to the vending machine, so long as the sign is in close proximity to the article of food or selection button."

"Americans eat and drink about one-third of their calories away from home and people today expect clear information about the products they consume," said FDA Commissioner Margaret Hamburg. "Making calorie information available on chain restaurant menus and vending machines is an important step for public health that will help consumers make informed choices for themselves and their families." *See FDA News Release*, November 25, 2014; *Federal Register*, December 1, 2014.

HHS and USDA Schedule Meeting of 2015 Dietary Guidelines Advisory Committee

The U.S. Department of Health and Human Services (HHS) and Department of Agriculture (USDA) have scheduled a meeting of the 14-member **committee** charged with developing the federal government's "2015 Dietary Guidelines for Americans" for December 15, 2014, from 8 a.m. to 5:30 p.m. EST. The meeting is accessible to the public by Webcast only and registration is required to view the proceedings.

Aimed at promoting consumption of foods and beverages that assist in maintaining a healthy weight and preventing disease, the guidelines were first issued in 1980, are revised every five years, and provide the basis for federal food and nutrition policy and education efforts. The next iteration of the guidelines will be published during fall 2015. Information about the December 15 meeting agenda, Webcast registration and the committee's requests for written comments may be found **here**. See *Federal Register*, November 26, 2014.

EFSA Responds to "Urgent Request" for Avian Flu Advice

The European Food Safety Authority (EFSA) has **launched** a risk assessment in response to the European Commission's urgent request for scientific advice on the H5N8 avian influenza A virus detected in Germany, the Netherlands and the United Kingdom. Focusing on the role of wild birds as vectors, EFSA plans to release a December 2014 report that will provide risk managers "with

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independent scientific advice and assistance on animal health and welfare related to avian influenza and any possible food safety issues." *See EFSA News Release*, November 26, 2014.

In a related development, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service has **amended** an interim rule restricting the importation of live birds and poultry, hatching eggs and poultry products "from regions where any subtype of highly pathogenic avian influenza (HPAI) is considered to exist." Effective December 1, 2014, the final rule now permits the importation of HPAI-resistant species, including pigeons and doves, as well as live birds vaccinated against avian influenza as part of approved official programs. Additional details about the interim final rule appear in Issue **379** of this *Update*. *See Federal Register*, December 1, 2014.

LITIGATION

Court Dismisses Lawsuit Challenging FDA's Inaction on Mercury Labeling

A federal court has granted summary judgment for the U.S. Food and Drug Administration (FDA) in a lawsuit brought by the Center for Science in the Public Interest (CSPI) and Mercury Policy Project (MPP) alleging that the agency has egregiously delayed a response to the organizations' 2011 petition urging FDA to require the labeling of mercury levels in seafood. *CSPI v. FDA*, No. 14-0375 (U.S. Dist. Ct., D.D.C., order entered November 21, 2014). Additional information about the complaint appears in Issue **517** of this *Update*.

Assessing precedent, the court noted six considerations relevant in evaluating agency delay and found that three were in question here. CSPI and MPP argued that FDA's delay was unreasonable because statutorily, the agency has six months to approve, deny or tentatively respond to citizen petitions; while FDA technically complied with this regulation, they argued, the deadline "provides a framework within which to gauge FDA's delay in issuing a final response." The court disagreed, finding that the regulations do not dictate when an ultimate response is issued, but rather the time frame is guided by the Administrative Procedures Act's requirement of action "within a reasonable time." Further, the court noted, FDA has been actively working on the subject of mercury levels in seafood, resulting in the agency issuing draft guidance in June 2014 on recommended seafood intake for children and pregnant women. Additional information on the draft guidance appears in Issue **525** of this *Update*.

The court also examined the effects of the delay on human health and welfare. CSPI and MPP successfully argued that the delay affected the health and welfare of U.S. citizens, but the court held that this consideration alone was insufficient to support a finding of egregious delay. FDA's mission is to

preserve human health and welfare, the court noted, so the argument would be more persuasive against an agency that does not prioritize health so highly.

Finally, the court considered how a court-ordered expedited action would affect FDA's other priorities. MPP and CSPI argued that mercury in seafood is a high priority for FDA, so expediting a response would not detract from the agency's other concerns. FDA acknowledged the high priority of the issue but argued that "rushing a decision on Plaintiff's detailed labeling recommendations at this juncture would force it to take action without due deliberation and would thereby draw resources from actually resolving issues related to mercury consumption." The court agreed, and concluding that the delay did not yet warrant judicial intervention, granted summary judgment for FDA.

Court Details Dismissal of Olive Oil Owners from False-Labeling Class Action

After granting a motion for summary judgment in favor of Kangadis Food Inc.'s (KFI's) owners, a New York federal court has issued an order further explaining its decision to dismiss the owners from a false-labeling class action. *Ebin v. Kangadis Family Mgmt. LLC*, No. 14-1324 (U.S. Dist. Ct., S.D.N.Y., order entered December 1, 2014). Additional information about the initial dismissal appears in Issue **543** of this *Update*.

The court held that the plaintiffs "totally failed" to properly argue that the court should pierce the corporate veil and hold the owners liable for KFI's actions. To satisfy the second prong of the piercing-the-veil test, the plaintiffs had to show that the owners, "through their domination, abused the privilege of doing business in the corporate form to perpetrate a wrong or injustice" against the plaintiffs. The court found that rather than providing an argument satisfying the second prong, the plaintiffs merely provided a "wholly conclusory statement" that a "reasonable jury could certainly find that the class members who purchased a tin labeled '100% Pure Olive Oil,' but instead received pomace oil, suffered an injury that was caused by Kangadis's [sic] domination of KFI." They failed to argue, the court said, that the owners "used their domination as a means to accomplish a fraud that justifies holding defendants derivatively liable for the claims for relief, as opposed to the corporation itself. Logically, the fraud or wrong that a party must show when trying to pierce the veil must be independent from the wrongs that it seeks to remedy in the underlying causes of action. Otherwise, upon a showing of domination, the mere existence of valid causes of action would usurp the entire second prong of the analysis."

Settlement Reached in Jamba Juice "All Natural" Smoothie Kits Class Action

After a California federal court certified the class for liability but not for damages, the parties to a class action alleging that Jamba Juice mislabeled its smoothie kits as "all natural" despite containing synthetic ingredients like gelatin and xanthan gum have reached a settlement. *Lilly v. Jamba Juice Co.*, No. 13-2998 (U.S. Dist. Ct., N.D. Cal., plaintiffs' motion for settlement approval filed December 1, 2014).

Under the proposed settlement agreement, Jamba Juice will remove "all natural" from its smoothie kit labeling and advertising by March 2015. The agreement will remain in force until the smoothie kits no longer contain the allegedly unnatural ingredients or the U.S. Food and Drug Administration classifies the ingredients as natural. The plaintiffs' attorneys will also receive $425,000 in costs and fees. Additional information about the class certification appears in Issue **539** of this *Update*.

Breyers "All Natural" Putative Class Action Dropped

A putative class action alleging that Conopco Inc., a subsidiary of Unilever United States, mislabeled Breyers ice cream as "all natural" has been voluntarily dismissed with prejudice. *Jefferson v. Conopco*, No. L-7025-14 (Super. Ct. N.J., Bergen Cnty., stipulation of voluntary dismissal filed December 1, 2014). The plaintiff alleged that Breyers' use of cocoa processed with alkali (Dutch-process cocoa) contains the artificial ingredient potassium carbonate, which he argued should preclude the company from labeling its products as natural. The brief stipulation indicates that each party will pay its own attorney's fees and costs. Additional information about the lawsuit appears in Issue **531** of this *Update*.

OTHER DEVELOPMENTS

Pew Report Reviews Animal Antibiotic Labeling Under New FDA Policy

The Pew Charitable Trusts Campaign on Human Health and Industrial Farming has published an **issue brief** concluding that gaps in the U.S. Food and Drug Administration's (FDA's) guidance for antibiotic use in livestock have allowed "some injudicious practices to persist." Released in December 2013, FDA Guidance for Industry #213 aims to combat antibiotic-resistant bacteria by restricting the use of antibiotics in food animals for growth promotion. To this end, the agency asked drug companies to remove "feed efficiency" and "weight gain" indications from product labels and required veterinary oversight when these drugs are added to feed or water.

After reviewing all 287 antibiotics affected by Guidance #213, Pew researchers reported that approximately one-quarter of these drugs "can be used in at least one species of livestock (chickens, turkeys, pigs or cattle) for disease prevention at levels that are fully within the range of growth promotion dosages and with no limit on the duration of treatment." In addition, the guidance does not restrict weight maintenance indications on labels if presented in the context of treating disease.

In the absence of a clear distinction between the appropriate and inappropriate use of antibiotics for disease prevention, the Pew analysis thus recommends that FDA (i) provide a detailed plan "for monitoring and publicly reporting total antibiotic use in food animals," (ii) "establish a clear target for reduction of total antibiotic use in food animals," and (iii) "outline a process and a timeline for reviewing the adequacy of disease prevention label claims to ensure that they effectively prevent bacterial infection and are not used longer than necessary."

New CSPI Report Targets Sodium Levels in U.S. Chain-Restaurant Foods

Citing the role of excess dietary sodium in the development of cardiovascular disease and industry resistance to federal action mandating reductions, the Center for Science in the Public Interest (CSPI) this week issued a **report** claiming that the top 25 U.S. restaurant chains have failed to lower the amount of sodium in nearly 3,000 menu items between 2012 and 2014.

"As a whole, the nation's leading restaurants are failing miserably when it comes to their patrons' heart health," CSPI Executive Director Michael Jacobson said. "And, unfortunately, the U.S. Food and Drug Administration has failed for decades to tell the food industry to lower sodium and by how much."

The public health watchdog reportedly analyzed restaurant sodium data from **Menustat.org**, a New York City health department database providing nutritional information about fare served at the nation's largest restaurant chains. *See CSPI News Release*, December 2, 2014.

SCIENTIFIC/TECHNICAL ITEMS

Study Examines Estrogenic Chemicals Purportedly Released by BPA-Free Thermoplastic Resins

A study led by University of California, Davis, toxicologist Michael Denison and CertiChem, Inc. founder George Bittner has allegedly found that some hard, clear thermoplastic resins made without bisphenol A (BPA) still release chemicals with estrogenic activity (EA). George Bittner, et al., "Chemicals having estrogenic activity can be released from some bisphenol a-free, hard and clear, thermoplastic resins," *Environmental Health*, December 2014. According

to the study, which used in vitro assays "to quantify the EA of chemicals leached into ethanol or water/saline extracts of fourteen unstressed or stressed (autoclaving, microwaving, UV radiation) thermoplastic resins," four types of resin "leached chemicals having significant levels of EA."

In particular, the authors noted that UV radiation increased the probability that certain thermoplastic resins would leach chemicals with detectable EA levels. However, the study stopped short of assigning any human health effects to the consumption of these chemicals, as no scientists or other entities "have identified and characterized the EA and anti-EA of all chemicals and their metabolites in these extracts." Additional details about Bittner's previous work appear in Issue 519 of this *Update*. *See Mother Jones*, December 1, 2014.

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