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FOOD & BEVERAGE LITIGATION UPDATE

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FIRM NEWS

Shook Attorneys Discuss False Labeling Claims Based on Alleged Product Testing in *Law360*

In a recent **article** for *Law360*, Shook, Hardy & Bacon Class Actions & Complex Litigation Co-Chair **Jim Muehlberger** and Agribusiness & Food Safety Associate **Jeff Lingwall** discuss the new wave of putative class action litigation against food and nutraceutical companies brought by plaintiffs bearing product test results that allegedly indicate deviations from labeled amounts.

They explain U.S. Food and Drug Administration (FDA) standards for evaluating nutrition labeling and attendant provisions of the Federal Food, Drug, and Cosmetic Act/Nutrition Labeling and Education Act, advocating anticipatory measures by companies, given the advent of product testing websites, crowdfunded research and the increased scrutiny of the dietary supplement industry. Such measures, they say, include ensuring that (i) production processes (and those of any contract manufacturers) produce FDA-compliant test results and (ii) performing regular product testing to assure compliance with nutrition labeling per FDA-testing procedures.

LEGISLATION, REGULATIONS AND STANDARDS

USDA Seeks Public Comment on Biological Agents and Toxins Posing Serious Danger to Animal and Plant Health

The U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service is soliciting public comment on its current **list** of select agents and toxins with the potential to pose a severe threat to animal or plant health or to animal or plant products. The agency's biennial review and republication of the list is required under provisions of the Agricultural Bioterrorism Protection Act of 2002.

Criteria for determining whether an agent or toxin is placed on the list include the (i) effect of exposure to the agent/toxin on animal or plant health and on the production and marketability of animal or plant products; (ii) pathogenicity of the agent/toxin and the methods of transference to animals or plants; and (iii) availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by exposure to the agent/toxin. Comments should be **submitted** by April 28, 2015. *See Federal Register*, February 27, 2015.

Shook, Hardy & Bacon L.L.P.

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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If you have questions about this issue of the *Update* or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com).

Cal/EPA Launches New Effort to List Styrene Under Prop. 65

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) has **announced** its intent to list styrene as a chemical known to the state to cause cancer under the authoritative bodies listing mechanism of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Styrene is used in the manufacture of various consumer products, including polystyrene packaging, synthetic rubber and food containers.

Two previous attempts to list styrene as known to cause cancer under Prop. 65's Labor Code listing mechanism failed. The agency's latest attempt relies on findings in the National Toxicology Program's (NTP's) 2011 *Report on Carcinogens*, which concluded that styrene is "reasonably anticipated to be a human carcinogen" based on studies showing that inhalation and oral exposure to the chemical increased the incidence of malignant and combined incidence of benign and malignant lung tumors in male and female mice. The National Research Council confirmed NTP's findings on the carcinogenicity of styrene in a 2014 review.

OEHHA is accepting public comments about whether styrene meets the criteria for authoritative bodies listings until March 30, 2015. *See OEHHA News Release*, February 27, 2015.

DTU's National Food Institute Rejects EFSA's Assessment of Bisphenol A

The Technical University of Denmark's (DTU's) National Food Institute has **rejected** the European Food Safety Authority's (EFSA's) recent bisphenol A (BPA) assessment, claiming that the agency's decision to set the tolerable daily intake (TDI) at 4 micrograms per kilogram body weight per day does not adequately protect consumers. After examining EFSA's toxicological evaluation, National Food Institute's researchers criticized the scientific opinion for not applying an appropriate uncertainty factor and failing to take into account animal studies allegedly showing the effects of BPA on reproductive health and neurological development.

The National Food Institute has instead proposed a TDI of less than 0.7 µg/kg bw/day to protect against "endocrine disrupting effects." In particular, the scientists note that, according to EFSA, men and women at the highest exposure levels are currently exposed to more than 1 microgram of BPA per kilogram per day, "while children and teenagers are exposed to between 1.26 and 1.45 micrograms per kilogram [per] day."

"[C]omparison of the exposure to the TDI recommended by the National Food Institute shows that humans with a high exposure may exceed the safe limit. Their intake can come from food, cash receipts and cosmetics," said Ulla

Hass, head of the National Food Institute's Research Group. "The health risks of bisphenol A are of concern particularly for highly exposed persons. The concern applies particularly to pregnant or breastfeeding women as well as children as they will be sensitive to potential effects that occur even at low doses of the compound." *See National Food Institute News Release*, February 23, 2015.

LITIGATION

California Federal Court Dismisses 4-MEI Suit Against PepsiCo Inc.

A California federal court has dismissed a lawsuit arguing that PepsiCo Inc. should provide medical monitoring for a class of Diet Pepsi or Pepsi One purchasers because the company does not warn consumers that 4-methyl-imidazole (4-MEI), a compound in caramel coloring, has allegedly been linked to potential health risks in rodent studies. *Riva v. PepsiCo, Inc.*, No. 14-2020 (U.S. Dist. Ct., N.D. Cal., order entered March 4, 2015). The case was severed from a consolidated class action after the plaintiffs decided to pursue medical monitoring and personal injury claims not included in the consolidated action. Information about the case's transfer of venue appears in Issue 523 of this *Update*.

The court determined that the plaintiffs lacked standing to pursue the claim because "they have not established that the alleged risk of bronchioloalveolar cancer (for which they seek lung scans and testing) is both credible and substantial." The studies cited as support for the plaintiffs' claims did not "show that *humans* experience the same increased risk [as mice], particularly at the exposures alleged. [] The Riva Plaintiffs have effectively invited the Court to engage in an 'ingenious academic exercise in the conceivable to explain how defendants' actions cause their injury.'" Finding that the plaintiffs had ample notice of the issues in contention, the allegations were dismissed with prejudice.

Labeling Dispute over "Milk Protein Concentrate" in Yogurt Dismissed

A California appeals court has affirmed a lower court's ruling dismissing a putative class action alleging that Safeway misbranded its Lucerne brand of Greek yogurt because U.S. Food and Drug Administration (FDA) regulations prohibit the use of "milk protein concentrate" (MPC) in foods labeled as yogurt. *Tamas v. Safeway, Inc.*, No. RIC1206341 (Cal. Ct. App., 4th Dist., Div. 3, order entered February 23, 2015).

The plaintiff argued that a 1981 FDA regulation determining yogurt's "Standard of Identity" (SOI) dictated what ingredients are allowable in products sold as yogurt despite the agency's stay of the regulation soon after it was

issued. FDA promised to schedule a public hearing on the regulation but, as of January 2009, "due to competing priorities and limited resources, FDA has not held a public hearing to resolve these issues and the effective date for these provisions remains stayed. Therefore, these provisions were never in effect. Consequently, cultured milk and yogurts may deviate from the relevant standards in the previously mentioned respects." The agency proposed a new rule that same month but never formally enacted any SOI for yogurt. The court disagreed with the plaintiff's challenge to FDA's actions, finding that FDA had the power to stay its own regulations partially or in their entirety.

The court also declined to consider the plaintiff's policy argument that MPC should be excluded from yogurt because her arguments "sound like just the sort of concerns that are intended to be hashed out before the FDA, as part of its seemingly complicated analysis of which ingredients should be included (or excluded) in a newly enacted yogurt SOI," it noted. "If there is one thing that is absolutely clear in this case, it is that assessing the relative benefits and detriments of allowing MPC to be used as an additive in yogurt is an issue that will have to be decided by the FDA."

"No Sugar Added" Lawsuit Against Ocean Spray Dismissed in California

Refusing to certify the class, a California federal court has granted a partial motion to dismiss in a putative class action alleging that Ocean Spray Cranberries Inc. mislabels its "100% Juice" products as "No Sugar Added" despite adding fruit juice from concentrate. *Major v. Ocean Spray Cranberries, Inc*, No. 12-3067 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered February 26, 2015). The plaintiff argued that adding the concentrate and labeling the products "No Sugar Added" violates California law, which prohibits use of that phrase on food "containing added sugars such as jam, jelly, or concentrated fruit juice." Instead, she asserted, Ocean Spray must include the disclaimer that their products are not low-calorie foods.

Ocean Spray argued that the plaintiff did not rely on the "No Sugar Added" label when purchasing the products, and the court agreed, pointing to a deposition in which the plaintiff admitted that calorie content was not a motivating factor in her purchasing decision. The court also agreed with Ocean Spray's argument that the "No Sugar Added" label was factually accurate, noting that "when asked by Defendant what the 'No Sugar Added' message meant to her, [the plaintiff] stated, '[t]hat there's literally nothing containing sugar that's added to this other than the natural sugar from the fruit.' Defendant argues that Plaintiff's understanding is entirely accurate and directly contradicts her own legal theory."

The court found that because the plaintiff's argument failed to account for the difference between "concentrated fruit juice," as in the California law, and "fruit juice from concentrate," which Ocean Spray uses in its products, her theory relied on an overbroad application of the statute. As the juice products "contain the same amount of sugar that would have existed naturally, the products cannot be said to contain 'added sugars.'" Granting the motion to dismiss, the court deemed moot the plaintiff's motion for class certification.

Class of Energy Drink Consumers Not Identifiable, Florida Court Says

A Florida federal court has refused to certify a nationwide class in a case alleging that Vital Pharmaceuticals Inc. conceals the unsafe nature of its Redline® Xtreme energy drink. *Mirabella v. Vital Pharm., Inc.,* No. 12-62086 (U.S. Dist. Ct., S.D. Fla., order entered February 27, 2015). Vital Pharmaceuticals argued that the class was unascertainable because it does not keep a master list of consumers, and customers rarely keep finished bottles that would help prove they belong in the class. The court agreed, finding that the energy drink "generally sold for less than $3.00" and customers were unlikely to retain receipts or other records of purchase; in addition, the company sells a variety of similarly branded products that may render consumers unable to determine whether they belong to the class because they might not remember which product they purchased. "Even Plaintiffs are unable to reliably recall or objectively prove how many bottles of the Product they consumed," the court noted.

Blue Diamond Almond Milk Target of New "All Natural" Action

A consumer has filed a putative class action in New York federal court against Blue Diamond Growers alleging that the company deceptively labels its Almond Breeze Almond Milk as "All Natural" despite containing potassium citrate, Vitamin A Palmitate, Vitamin D2, and D-Alpha-Tocopherol. *Harlam v. Blue Diamond Growers*, No. 15-877 (U.S. Dist. Ct., E.D.N.Y., filed February 19, 2015).

The plaintiff alleges that 18 varieties of Blue Diamond almond milk contain the ingredients at issue, which she asserts are artificial or synthetic and, as a result, reasonable consumers would not expect to find them in products labeled as natural. "The [U.S. Food and Drug Administration] considers use of the term 'natural' on a food label to be truthful and non-misleading when 'nothing artificial or synthetic . . . has been included in, or has been added to, a food that would not normally be expected to be in the food,'" she argues. Alleging unjust enrichment, breach of warranties and negligent misrepresentation, the plaintiff seeks class certification, an injunction, damages, and attorney's fees.

OTHER DEVELOPMENTS

Nanomaterial Concerns Prompt Dunkin' to Remove Titanium Dioxide from Powdered Donuts

Responding to a shareholder resolution filed by As You Sow, Dunkin' Brands Group Inc. has reportedly agreed to reformulate its white powdered donuts to avoid the use of titanium dioxide nanoparticles. In return, the shareholder advocacy group has withdrawn its most recent **resolution**, which claimed that "recent research on the ingestion of inorganic nanoparticles has raised concerns regarding toxicity to humans and the environment."

According to As You Sow, 18.7 percent of shareholders supported a previous resolution asking Dunkin' to identify any products containing nanomaterials. That resolution followed a 2013 report alleging that food-grade titanium dioxide can contain particles less than 100 nanometers "in at least one dimension."

"Insufficient safety information exists regarding these manufactured particles, especially for use in foods; preliminary studies show that nanomaterials can cause DNA and chromosomal damage, organ damage, inflammation, brain damage, and genital malformations, among other harms," claims a March 5, 2015, As You Sow press release.

SCIENTIFIC/TECHNICAL ITEMS

New Studies Estimate Health Costs Associated with Endocrine-Disrupting Chemicals

Three studies **published** in *The Journal of Clinical Endocrinology & Metabolism* have sought to quantify "the burden of disease and associated costs attributable to EDC [endocrine-disrupting chemical] exposures in the European Union." Supported by the Endocrine Society, the research responds, in part, to the EU Commission's request for an impact assessment that addresses the economic implications of restricting, phasing out or authorizing certain EDCs.

To this end, the studies discuss the costs associated with EDCs and their alleged link to **obesity and diabetes**, **male reproductive disorders**, and **neurobehavioral deficits and diseases**. Using "the midpoint of each range for probability of causation" by EDCs, a **fourth paper** estimates the overall median cost of these diseases and disorders at $209 billion annually in Europe. "The primary finding of this manuscript is that there is a substantial probability of very high disease costs across the life span associated with EDC

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exposure in the EU," note the authors. "Thus, regulatory action to limit exposure to the most widely prevalent and potentially hazardous EDCs is likely to produce substantial economic benefits."

In addition, the researchers argue that their approach "will potentially transform decision-making in environmental health by providing a new model for evaluating environmental health risks." This methodology apparently seeks to account for "the substantial uncertainty in EDC-disease relationships" while still providing "a complete assessment of potential costs of failing to prevent chronic disease through the use of safer alternatives to EDCs."

"It produces substantial insights regarding the strength of the epidemiological and toxicological data, placing them alongside the cost of the disease as never done before," states the summary paper. "This approach also documents data gaps in both the epidemiology and toxicology of EDCs, which has only been documented through systematic reviews."

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