



LEGISLATION, REGULATIONS & STANDARDS

FDA Announces Investigation into Real Water

The U.S. Food and Drug Administration (FDA) has announced an investigation into Real Water alkaline water, which is allegedly the link between several cases of acute non-viral hepatitis. The investigation comes amid the filing of several lawsuits alleging harm to consumers of the water, including children. The agency announced that Real Water was not cooperating with the investigation because it failed to provide records or access to facilities.

“The FDA is committed to protecting the health of Americans and is especially concerned when there is a food safety issue impacting our youngest, and some of the most vulnerable in the population – infants and young children,” a press release stated. “Upon learning about reports of acute non-viral hepatitis in Nevada, impacting five young children, the FDA quickly activated a team to further investigate. We are working closely with the CDC, state and local partners to complete our investigation and monitor for any additional illnesses.”

Candy Company Misrepresents Number of Servings, Plaintiffs Allege

Kilwins Quality Confections Inc. sold chocolate and other candy products in containers that “materially overstate the volume of the contents,” according to a plaintiff. *Rand v. Kilwins Quality Confections Inc.*, No. 21-1513 (N.D. Ill., E. Div., filed March 18,

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Shook 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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2021). The consumer argues that the company's shredded-chocolate containers "materially overstate the actual volume of, and the number of servings contained in, the containers and packaging in which they are advertised and sold and similarly materially understate the caloric content of a serving." The jars of chocolate were labeled as containing 20 servings of two tablespoons despite containing only 16 servings of that size, the plaintiff argues, and the caloric content of one serving is 140 calories rather than 110 calories as listed on the package. "While Kilwins has recently *quietly* corrected labeling on the mislabeled products, it has failed to compensate thousands of consumers who, over the three (3) to five (5) year period preceding the correction, have, upon information and belief, been overcharged," the complaint notes.

Consumers Allege Kombucha Contains High Alcohol Levels

Three consumers have filed a putative class action alleging Kombucha 221 B.C. sells kombucha that contains "more than twice the allowed alcohol" for a nonalcohol beverage. *Brothers v. Mad at S.A.D. LLC*, No. 21-60542 (S.D. Fla., filed March 9, 2021). The plaintiffs, who allege they purchased the kombucha for consumption at work, argue that the kombucha beverages "are sold to unsuspecting children, pregnant women, persons suffering with alcohol dependence issues, and a host of other people for whom alcoholic consumption may pose a grave and immediate safety risk." The complaint asserts that the nature of kombucha allows the product to continue fermenting, growing to a higher percentage of alcohol by volume by the time the product is consumed.

"While Plaintiffs do not know whether BC Kombucha is below 0.5 alcohol by volume at the moment it leaves Defendant's distribution center, what is clear is that the beverages are significantly above the 0.5 threshold at the time of sale and consumption," the plaintiffs argue. "Under federal law, Defendant cannot turn a blind eye to what happens to BC Kombucha products after they leave Defendant's facilities, and, considering that continued fermentation and high alcohol content is an industry-wide problem, Plaintiffs allege on information and belief that Defendant knowingly and willfully distribute BC Kombucha in violation of Federal and State laws that require such beverages to contain the government warning." The plaintiffs allege fraud, negligent misrepresentation, unjust enrichment and violations of state consumer-protection statutes.



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ABOUT SHOOK

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.

Shook 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

Senators Introduce Baby Food Safety Act

inspections, subject to FDA, USDA and FTC regulation.

U.S. Sens. Amy Klobuchar (D-Minn.) and Tammy Duckworth (D-Ill.) have introduced the Baby Food Safety Act of 2021, which aims to “require manufacturers of infant and toddler food to implement preventive controls to comply with performance standards under Section 104 of the FDA Food Safety Modernization Act (FSMA).” The act would establish action levels for heavy metals in infant and toddler foods at 10 parts per billion (ppb) of inorganic arsenic, 5 ppb cadmium, 5 ppb lead and 2 ppb mercury, effective one year after enactment. The act would also require the Secretary of Health and Human Services to regularly review the regulatory limits and provide reports to Congress summarizing progress on the issue.



OEHHA to List PFOA on Prop. 65 List

The California Office of Environmental Health Hazard Assessment (OEHHA) has announced that it intends to add perfluorooctanoic acid (PFOA) to the list of substances known to cause cancer or reproductive harm under the state’s Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). PFOA, known as a “forever chemical,” can be found in nonstick surfaces and food packaging, among other items. OEHHA will accept comments on the determination until May 3, 2021.

EFSA Releases Guidance on Allergen Labeling, GMOs, Infant Formula, More

The European Food Safety Authority (EFSA) has released several guidance documents to aid stakeholders in complying with EU regulations on food issues implemented on March 27, 2021. The publications provide guidance on:

- Applying for an exemption from mandatory food allergen labeling;
- Renewing applications for genetically modified organisms (GMOs) in food and feed;
- Preparing applications for genetically modified plants;
- Applying for authorization of a novel food;
- Preparing applications for substances to be used in food-contact plastics;
- Applying to make health claims about foods;
- Preparing an evaluation for infant formula manufactured from protein hydrolysates; and
- Submitting notifications for traditional foods from third countries.

Bill Limiting Meatpacking Line Speeds Reintroduced

U.S. Sen. Cory Booker (D-N.J.) and Reps. Rosa DeLauro (D-Conn.) and Bennie Thompson (D-Miss.) have reintroduced the Safe Line Speeds During COVID-19 Act “to protect worker, consumer, and animal safety by suspending all current and future [U.S. Department of Agriculture] waivers and regulations that allow companies to increase production line speeds at meatpacking plants during the COVID-19 pandemic,” according to a [press release](#). The act would suspend all speed waivers for the duration of the COVID-19 public health emergency declaration as well as suspending implementation of the New Swine Slaughter Inspection System.

“The ongoing COVID-19 outbreaks at meat plants over the last year have raised serious questions about the safety conditions inside these plants,” DeLauro is quoted as saying. “Even before the COVID-19 pandemic, these workers experienced injuries at a higher rate than comparable occupations. And now, faster line speeds make it impossible for workers to practice social distancing and comply with safety guidelines. That is why I am proud to join the leadership shown by Senator Booker and Representative Thompson in introducing this legislation that will reign in these reckless line speed waivers for the duration of the COVID-19 public health emergency.”

USDA Announces Codex Meetings on Food Additives and Contaminants

The U.S. Department of Agriculture (USDA) has announced public meetings to discuss U.S. positions for Codex Alimentarius Commission sessions on [food contaminants](#) and [additives](#). The contaminants meeting will be held April 12, 2021, and will address issues such as maximum levels of cadmium in chocolate, levels of lead in multiple food categories, radioactivity in water, methylmercury in fish and aflatoxins in spices. The meeting on additives, which will be held May 11, 2021, will include a discussion on proposed draft specifications for identity and purity of food additives.

LITIGATION

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