FOOD & BEVERAGE LITIGATION UPDATE
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SHOOK HARDY & BACON

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Issues Draft Guidance on Inorganic Arsenic in Rice Cereals for Infants

The U.S. Food and Drug Administration (FDA) has issued draft guidance proposing an action level of 100 µg/kg for inorganic arsenic in rice cereals for infants.

The agency has also released supporting documentation for its proposal as well as a risk assessment that includes (i) "a quantitative estimate of lung and bladder cancer risk from long-term exposure to these products and the predicted impact of various scenarios to reduce the risk," and (ii) "a qualitative assessment of certain potential non-cancer risks, in certain susceptible life stages."

"We conclude that the 100 µg/kg action level will help protect the public health and is achievable with the use of current good manufacturing practice, but we especially welcome comments and information bearing on the achievability and public health benefits and risks of 100 µg/kg, as compared with other potential action levels (including no action level)," states FDA, which will consider comments submitted by July 5, 2016. "If the guidance is finalized consistent with the draft, we intend to consider the action level of 100 µg/kg or 100 ppb inorganic arsenic, in addition to other factors, when considering whether to bring enforcement action in a particular case." *See Federal Register,* April 6, 2016.

Meanwhile, in an April 1, 2016, statement, U.S. Rep. Rosa DeLauro (D-Conn.) called on FDA to set action levels for inorganic arsenic in all rice products, not just infant rice cereals.

"The FDA's new draft guidance for limiting the levels of inorganic arsenic found in infant rice cereal is a great first step in protecting the health of infants and I am pleased that the agency is finally taking action on this important public health issue," DeLauro said. "However, the new guidance does not go far enough in ensuring the health of all Americans... The FDA should immediately expand the guidance to include proposed action levels on all rice based products. In the meantime, Congress should pass the Reducing food-based Inorganic Compounds Exposure (RICE) Act, which would do just that."

FDA Issues Sixth Major Rule Under FSMA

The U.S. Food and Drug Administration (FDA) has issued a finalized rule under the Food Safety Modernization Act (FSMA) that is intended to help prevent the contamination of human and animal food during transportation. Among other things, the sanitary transportation rule requires those transporting food by motor or rail vehicle to follow recognized best practices for hygiene, including the provision of appropriate temperature control, cleaning between loads and security measures. The rule was initially proposed in February 2014 and its final iteration took into consideration the comments of some 200 stakeholders. *See Federal Register*, April 6, 2016.

Consumer Organizations Sue to Compel FDA Action on Perchlorate

Several consumer organizations, including the Center for Food Safety, Environmental Working Group and Natural Resources Defense Council, have filed a petition for a writ of mandamus in the U.S. Court of Appeals for the Ninth Circuit seeking a writ compelling the U.S. Food and Drug Administration (FDA) to address the groups' administrative petition filed in December 2014. *Breast Cancer Fund v. FDA*, No. 16-70878 (9th Cir., petition filed March 31, 2016). FDA missed a June 2015 deadline to respond to the groups' petition, which implored FDA to rescind food-contact approval for perchlorate, "an endocrine-disrupting chemical that interferes with the thyroid gland" used in food packaging.

"Perchlorate is primarily used in rocket fuel. There is no reason FDA should allow a chemical like this in or on food products," Andrew Kimbrell, executive director of Center for Food Safety, said in a March 31, 2016, press release. "It is irresponsible, illegal, and indefensible for FDA to continue withholding a response to our petition when human health is at stake."

Environmental Groups Sue FDA over GE Salmon Approval

Food and Water Watch, the Center for Food Safety, Friends of the Earth and other consumer and environmental groups have filed a lawsuit against the U.S. Food and Drug Administration (FDA) arguing the agency approved the use of genetically engineered (GE) salmon AquaBounty for human consumption without properly investigating related environmental risks. *Inst. for Fisheries Res. v. Burwell*, No. 13-1574 (N.D. Cal., filed March 30, 2016).

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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The complaint alleges that AquaBounty received approval for two facilities only but has told its investors that it will expand in 2016; the organizations assert that FDA should have investigated the environmental effects of AquaBounty's "necessary outgrowth" rather than limiting its analysis to the effects of two facilities. The complaint further alleges that FDA "failed to consult with the federal fish and wildlife agencies to insure that its approval for AquaBounty's application was not likely to jeopardize endangered and threatened species or adversely modify critical habitat" and challenges whether FDA had the statutory authority to regulate GE animals as a "new animal drug" under the federal Food, Drug, and Cosmetic Act.

"It's clear that the market has rejected GE salmon despite FDA's reckless approval," a spokesperson for Friends of the Earth said in a March 31, 2016, press release. "Major retailers including Costco, Safeway and Kroger won't sell it and polls show the vast majority of people don't want to eat it. Yet under this approval it won't be labeled, violating our fundamental right to know what we are feeding our families."

LITIGATION

Sixth Circuit Affirms Dismissal of Anheuser-Busch Alcohol Content MDL

The U.S. Court of Appeals for the Sixth Circuit has affirmed an Ohio court's dismissal of multidistrict litigation alleging Anheuser-Busch intentionally overstates the alcohol content on its malt beverages. *In re Anheuser-Busch Beer Labeling Mktg. & Sales Prac. Litig.*, No. 14-3653 (6th Cir., order entered March 22, 2016). The lower court had dismissed the case based on a Federal Alcohol Administration Act (FAAA) rule allowing content variations of up to 0.3 percent under state and federal law, and the appeals court reached the same conclusion in its de novo review. On appeal, the plaintiffs argued the FAAA rule was intended to apply only to unintentional variance, but the court disagreed, finding no evidence that the law sought to prohibit intentional variations within the 0.3 percent tolerance.

No Restitution from Peanut Corp. Executives for *Salmonella* Outbreak

A Georgia federal court has reportedly ruled that four former executives of Peanut Corp. will not be forced to pay restitution to the victims of a *Salmonella* outbreak linked to nine deaths and 714 illnesses. The execu-

tives—Stewart Parnell, Michael Parnell, Samuel Lightsey and Daniel Kilgore—are each serving federal prison terms for knowingly shipping *Salmonella*-tainted peanut butter and faking related lab-test results. The court reportedly found that the loss estimates provided by the prosecutors were invalid because they included unrecoverable costs, including attorney's fees. Further, the victims received more than $12 million from Peanut Corp.'s insurer, and the punitive factor of restitution would be reduced because requiring payment "would ultimately be for naught or close-to-naught," as the executives received long prison sentences. *See Associated Press*, April 7, 2016.

Class Certification Denied in Bigelow Tea Antioxidants Suit

A California federal court has refused to certify a class of consumers alleging that R.C. Bigelow Inc. misled them by over-representing the amount of antioxidants contained in its green tea. *Khasin v. R.C. Bigelow, Inc.*, No. 12-2204 (N.D. Cal., order entered March 29, 2016). The court previously refused to allow the plaintiff to seek financial records to calculate damages. Additional details appear in Issue 575 of this *Update*.

In its certification analysis, the court found fault with the plaintiff's three suggested damages models: (i) a restitution calculation, (ii) statutory damages or (iii) a nominal alternative. The plaintiff argued that the restitution calculation model should amount to payments of the full purchase price of the product because the tea is allegedly "legally worthless" for failing to meet U.S. Food and Drug Administration requirements on antioxidant nutrient claims. The court refused to find that consumers received no benefit from drinking the tea, "in the form of enjoyment, nutrition, caffeine intake, or hydration." The court further noted that it had previously "expressly stated that the proper measure of restitution in a product mislabeling case is 'not the full purchase price of all profits.'" In addition, the court rejected the proposed statutory or nominal damages, finding that the plaintiff had not proved the actual damages or breach of duty required to earn such damages.

The court also rejected the plaintiff's request for an injunction preventing Bigelow from mislabeling its products, noting that it was unconvinced by a declaration that the plaintiff would consider buying Bigelow tea again if its labels complied with California law. Further, the plaintiff could not demonstrate that he could be misled in the future by the same claims because he now knew of Bigelow's alleged deception. Accordingly, the court denied the plaintiff's motion for class certification.

Florida Creamery Loses First Amendment Challenge to "Skim Milk" Standard of Identity and Labeling Requirements

A Florida federal court has rejected a Florida dairy farmer's challenge to the state's standard of identity for skim milk, which dictates that its nutrient content must be the same as that of unfortified whole milk, requiring the addition of vitamin A after processing. *Ocheesee Creamery v. Putnam*, No. 14-0621 (N.D. Fla., Tallahassee Div., order entered March 30, 2016). The farmer's company, Ocheesee Creamery, skimmed the cream from milk and sold the leftover product as "skim milk" without fortifying it with vitamin A. Florida inspectors told the dairy farmer she must adjust the nutrient level or label the milk "imitation," and she filed a lawsuit challenging the rule. Additional details on the case appear in Issue 555 of this *Update*.

The court found that the state standard of identity and its federal counterpart in the federal Food, Drug, and Cosmetic Act "easily pass muster" under the First Amendment test for commercial speech. "Ocheesee cites dictionary definitions that describe skim milk as precisely what Ocheesee sells: milk from which the cream has been skimmed," the court notes. "And it is undoubtedly true that a typical consumer would think 'skim milk' is simply milk from which the cream has been skimmed. Far from a condemnation of the standard of identity and nutritional standards for skim milk, these sources show how well the standard of identity and nutritional standard have worked: consumers take for granted the nutritional value of skim milk without even knowing that the vitamins have been restored."

Bread Crumbs Suit Against Kroger Dismissed

A California federal court has granted The Kroger Co.'s motion to dismiss a lawsuit alleging the company's bread-crumbs product includes partially hydrogenated oil, which contains *trans* fat, despite labeling the product as "0g Trans Fat." *Hawkins v. Kroger Co.*, No. 15-2320 (S.D. Cal., order entered March 17, 2016).

The court found that the mislabeling claims failed for two reasons. First, a challenge to a "0g Trans Fat" labeling claim is preempted, the court said, because U.S. Food and Drug Administration regulations require that foods with less than one-half of a gram of *trans* fat be labeled as "0g." Second, the plaintiff failed to prove actual reliance on the allegedly deceptive statements, the court found, rejecting her argument that she "is a busy person and cannot reasonably inspect every ingredient of every food that she purchases" despite having bought the bread crumbs six

times per year for 15 years but only noticing the *trans* fat claim in August 2015. "Plaintiff cannot possibly have relied on the allegedly false statement because she purchased [the product] for 15 years before learning of the statement," the court said. Accordingly, the court concluded the plaintiff did not have standing to sue and dismissed the case.

Chocolate Makers Under Fire for Alleged Lead and Cadmium Content

Consumer group As You Sow has notified the state of California that a number of chocolate manufacturers are allegedly selling chocolate with levels of lead and cadmium that exceed limits set by the state's Safe Drinking Water and Toxic Enforcement Act (Prop. 65). Testing by the organization allegedly indicated that 35 of the 50 chocolate products sampled—including those from Trader Joe's, Whole Foods, Godiva and Lindt, among others—contained enough lead or cadmium to trigger Prop. 65 warning requirements. As You Sow has filed 60-day notices with 18 manufacturers based on its testing; following the 60-day period, the organization may initiate litigation against the companies if public officials have not sought enforcement of the statute.

"Lead and cadmium accumulate in the body, so avoiding exposure is important, especially for children," As You Sow President Danielle Fugere said in a March 23, 2016, press release. "Our goal is to work with chocolate manufacturers to find ways to avoid these metals in their products."

OTHER DEVELOPMENTS

CSPI Charts Decline in Sodium Content of Packaged Foods

The fourth edition of a Center for Science in the Public Interest (CSPI) survey has reported a 4-percent reduction in sodium across 451 packaged and restaurant foods over a 10-year period. Titled "Salt Assault: Brand-name Comparisons of Processed Foods," the report claims that, on average, surveyed items reduced their sodium content by 41 milligrams per 100 grams of product.

The consumer watchdog notes, however, that many products still have room to make additional reductions. Citing "dramatic variations in sodium content across different brands of a given food," the report singles out products in the canned diced tomato, whole wheat bread and ketchup categories—among others—for further improvement. In

particular, CSPI urges the U.S. Food and Drug Administration (FDA) and Department of Agriculture to not only set mandatory sodium limits for processed and restaurant foods, but require warning labels on those that are high in sodium.

"For 40 years, the food industry has offered voluntary action to reduce sodium in packaged foods, and for 40 years, the FDA has obediently observed from the sidelines," said CSPI President Michael Jacobson in an April 5, 2016, press release. "This has resulted in an uneven playing field for industry with some companies stepping up and others doing little. Excess sodium in our foods is prematurely disabling or killing tens of thousands of Americans each year."

MEDIA COVERAGE

Guardian Author Takes on Nutritional Establishment in "The Sugar Conspiracy"

In this April 7, 2016, article about changing dietary recommendations and rising obesity rates, Ian Leslie resurrects the forgotten work of John Yudkin, a U.K. nutritionist who in 1972 authored a book titled *Pure, White, and Deadly* about the purported dangers of excess sugar consumption. Drawing parallels between this earlier research and that of contemporary anti-sugar crusader Robert Lustig, Leslie suggests that the scientific community effectively silenced Yudkin when his data came into conflict with the prevailing "fat hypothesis" backed by "brilliant, charismatic, and combative" Ancel Keys, who posited that dietary fat caused heart disease and other metabolic diseases.

As Leslie explains, "[The] sharp fluctuations in Yudkin's stock have had little to do with the scientific method, and a lot to do with the unscientific way in which the field of nutrition has conducted itself over the years. This story, which has begun to emerge in the past decade, has been brought to public attention largely by skeptical outsiders rather than eminent nutritionists. In her painstakingly researched book, *The Big Fat Surprise*, the journalist Nina Teicholz traces the history of the proposition that saturated fats cause heart disease, and reveals the remarkable extent to which its progress from controversial theory to accepted truth was driven, not by new evidence, but by the influence of a few powerful personalities, one in particular."

In particular, Leslie claims that Keys' so-called Seven Countries Study—which examined health and dietary data from 12,770 men in Italy, Greece, Yugoslavia, Finland, Netherlands, Japan and the United States—set the tone for federal nutritional recommendations even though it only implies a correlation between high-fat diets and heart disease. Meanwhile, new research reportedly continues to cast doubt on this correlation, with recent studies showing that some countries with the highest intakes of saturated fats have the lowest rates of heart disease, while populations with lower cholesterol intakes have higher mortality rates from cardiovascular problems.

"In the last 10 years, a theory that had somehow held up unsupported for nearly half a century has been rejected by several comprehensive evidence reviews, even as it staggers on, zombie-like, in our dietary guidelines and medical advice," writes Leslie in examining how nutritionists have reacted to research challenging the status quo. He specifically takes aim at health authorities who have criticized Teicholz, Lustig and others even as they "slowly" back away from previous advice, "presumably in the hope that if no sudden movements are made, nobody will notice."

"By opening the gates of publishing to all, the internet has flattened hierarchies everywhere they exist. We no longer live in a world in which elites of accredited experts are able to dominate conversations about complex or contested matters. Politicians cannot rely on the aura of office to persuade, newspapers struggle to assert the superior integrity of their stories. It is not clear that this change is, overall, a boon for the public realm. But in areas where experts have a track record of getting it wrong, it is hard to see how it could be worse," concludes Leslie. "If ever there was a case that an information democracy, even a very messy one, is preferable to an information oligarchy, then the history of nutrition advice is it. In the past, we only had two sources of nutritional authority: our doctor and government officials. It was a system that worked well as long as the doctors and officials were informed by good science. But what happens if that cannot be relied on?"

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 inspections, subject to FDA, USDA and FTC regulation.