



A MESSAGE FROM THE CHAIR

This month marks the 20th anniversary of Shook, Hardy & Bacon’s *Food and Beverage Litigation and Regulatory Update* (FBLU). Since publishing its first edition in October 2002, Shook has continuously covered the legal, legislative, regulatory and scientific developments affecting the food, beverage and agriculture industry.

The [first issue](#) highlighted many trends that are still relevant today, including the first wave of enforcement actions brought against food manufacturers and restaurants under California’s Safe Drinking Water and Toxic Enforcement Act (Prop 65). We also noted an emerging focus on addressing obesity-related health issues through both legislation and class action litigation targeting the purported “addictive” quality of certain food and beverage products. That year also saw the Food and Drug Administration (FDA) signal its intention to address products that may contain acrylamide, a chemical byproduct of high-temperature cooking processes. Nearly 20 years later, the courts continue to hear debate over acrylamide warnings, with the Ninth Circuit recently upholding a preliminary injunction blocking a requirement to warn California consumers about the presence of acrylamide in food and beverages under Prop 65 ([FBLU 775](#)).

In addition to the regulatory milestones illustrated below, Shook has followed the evolving legal landscape around “[natural](#)” and “[organic](#)” marketing claims; [country-of-origin labeling](#); [food colorings](#) and [additives](#); [the use of antibiotics in animal feed](#); and hundreds of other topics of interest. Over the years, we provided more than 200 updates tracking regulatory and legislative efforts to remove bisphenol A (BPA) from food packaging, starting in 2007 with an independent panel study conducted by the Center

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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.

For additional information about Shook’s capabilities, please contact



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for the Evaluation of Risks to Human Reproduction of the National Toxicology Program ([FBLU 226](#)).

We also looked ahead to the future of food, keeping tabs on litigation and regulations related to new technologies such as plant-based [milk](#) and [meat alternatives](#), [bioengineered salmon](#), [genome-edited beef](#), [the use of QR codes on food labels](#) and beyond. In fact, nanotechnology made its first appearance in the FBLU in [August 2006](#), when FDA launched its Nanotechnology Task Force and solicited public comment on the use of nanotechnology in FDA-regulated products. And in 2021, we reported on the USDA's final rule on hemp cultivation ([FBLU 758](#)).

We look forward to continuing our reports on the latest trends and issues affecting your industry. In addition to the current authors on the byline, the newsletter has been the product of many Shook contributors over the years, including Senior Counsel [Leo Dreyer](#), current editor Laura Markey, and former editors Mary Boyd, Dale Walker and Alison Talbott. Thank you for reading the *Food and Beverage Litigation and Regulatory Update*, and we hope you enjoy our 785th edition.

- [Madeleine McDonough](#), Chair of Shook, Hardy & Bacon



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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

inspections, subject to FDA, USDA and FTC regulation.

20 YEARS

Food and Beverage Regulatory Developments

- 2002** Farm Bill requires "country of origin labeling" for several food products.
- 2003** FDA adds *Trans* fat as mandatory on the nutrition facts panel.
- 2004** FALCPA passes, mandating label disclosures for 8 major food allergens.
- 2007** Reportable Food Registry created to help FDA track adulterated foods.
- 2010** Affordable Care Act passes with measure requiring calorie counts on menus.
- 2011** FDA Food Safety Modernization Act signed into law.
- 2014** Congress mandates that FSIS regulate "catfish" as "meat."
- 2015** FDA publishes final regulation for 5 of the 7 pillars of FSMA.
- 2016** Nutrition Facts labels updated, including adding "Added Sugars." National bioengineered food labeling law passes.
- 2018** FDA extends compliance dates for Nutrition Facts panel updates. Farm Bill authorizes production of hemp. First, and only, FDA mandatory food recall issued.
- 2021** FASTER Act adds sesame as ninth major food allergen.
- 2022** FDA proposes updated definition for "healthy" nutrient content claim.



2002

In the 2002 Farm Bill, Congress amended the Agricultural Marketing Act of 1946 to require retailers to notify their customers of the country of origin of covered commodities.

2003

FDA amended its regulations on nutrition labeling to require the inclusion of *trans* fats on the Nutrition Facts panel for conventional foods and dietary supplements. The change was intended to help consumers in maintaining healthy dietary practices.

2004

The Food Allergen Labeling and Consumer Protection Act of 2004 sought to help consumers with food allergies and their caregivers to more easily identify and avoid foods containing major food allergens. The Act identified eight major food allergens: milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat and soybeans.

2007

In its Food and Drug Administration Amendments Act of 2007, Congress required the Secretary of Health and Human Services to establish within FDA a Reportable Food Registry. The purpose of the registry is to provide a reliable means to track patterns of adulterated food and aid FDA in targeting its limited inspection resources.

2010

The Affordable Care Act required that many chain restaurants and other similar retail food establishments list the calorie counts of the food they sell. The final rule took effect in 2018.

2011

Congress passed the FDA Food Safety Modernization Act, allowing FDA to shift its focus to preventing food safety problems rather than just responding to them. The law was the largest overhaul of the country's food safety system since the passage of the Federal Food, Drug and Cosmetics Act in 1938.

2014

Through the 2014 Farm Bill, Congress amended the Federal Meat Inspection Act, removing the term "catfish" and replacing it with "all fish of the order Siluriformes" as being subject to Food Safety

and Inspection Service jurisdiction and inspection. FDA was previously responsible for regulating catfish as “seafood.”

2015

FDA published final rules for five of the seven pillars of the Food Safety Modernization Act, including Preventive Controls for Human Food, Preventive Controls for Animal Food, Foreign Supplier Verification Program, Produce Safety and Accredited Third-Party Certification. The following year, the FDA published final rules for the final two: Sanitary Transportation and Intentional Adulteration.

2016

FDA revised the Nutrition Facts label to highlight calories, servings per container and serving-size declarations through a combination of increased type size and boldface. The update also included requirements for labeling added sugars and Vitamin D and potassium values.

Congress passed the National Bioengineered Food Disclosure Law requiring food and beverage manufacturers to disclose the use of ingredients made with genetically modified organisms (GMOs). The law defined bioengineered foods, required a mandatory standard for disclosure and also allowed certified organic products to bear “non-GMO” labels.

2018

The FDA extended the compliance dates for changes to food nutrition labels to 2020 and 2021. Rules included in the extension included those defining a single-serving container and requiring dual-column labeling for certain containers.

The passage of the 2018 Farm Bill authorized the production of hemp (defined as cannabis and derivatives of cannabis with extremely low concentrations of THC) and removed it from the definition of marijuana in the Controlled Substances Act.

After several products containing powdered kratom that were manufactured, processed, packed or held by Triangle Pharmaceuticals LLC were found to contain *Salmonella*, the FDA issued its first—and only—mandatory recall order of a food product in order to protect public health.

2021

The Food Allergy Safety, Treatment, Education and Research Act (FASTER) required that, starting on January 1, 2023, any food “introduced or delivered for introduction into interstate

commerce” must appropriately declare the presence of sesame as a major food allergen.

2022

The FDA announced a proposed update to guidance on how the term “healthy” can be used in marketing and labeling food products. The proposed framework uses a food-group based approach and would require a food product to be limited in certain nutrients, such as saturated fat, sodium and added sugars.

LITIGATION

Contaminated Trader Joe’s Chicken Burgers Dispute Survives Motion to Dismiss

A federal court has denied a bid by Pilgrim’s Pride to throw out claims it misrepresented chicken it packaged and sold as “boneless” that wound up in recalled Trader Joe’s Chili Lime Chicken Burgers for having excessive amounts of bone. *Innovative Solutions Int’l Inc. v. Houlihan Trading Co., Inc.*, No. 22-296 (W.D. Wash., entered October 18, 2022).

The suit stems from the plaintiff’s 2021 purchase of approximately 240,000 pounds of chicken product from the Houlihan Trading Company. Pilgrim’s Pride, also a defendant, was the original producer, processor and packager of the chicken, according to the order. The chicken was labeled and included supporting documentation that it was “boneless” by industry standards. The plaintiff used the chicken to make and sell Trader Joe’s Chili Lime Chicken Burgers and sold the burgers to Trader’s Joe’s.

After the grocery chain began to receive reports of bones in the burgers in September 2021, it stopped selling them to investigate. The plaintiff found excessive and large bones in the raw chicken product during an inspection, and hired a third party to x-ray the product. The third party concluded the entire shipment of chicken was contaminated with excessive bone fragments, leading Trader Joe’s to issue a recall of approximately 100,000 pounds of raw chicken patty products. Trader Joe’s also discontinued the product.

The plaintiff filed suit against multiple defendants in the supply chain for breach of contract, breach of express and implied warranty, negligent misrepresentation, negligence and violation of Washington’s Consumer Protection Act. Pilgrim’s Pride moved to dismiss the claims against it, arguing in part that there was no privity of contract between the plaintiff and Pilgrim’s Pride.

The court disagreed, holding that the plaintiff pleaded sufficient facts to support its claims. Discussing the plaintiff's breach of implied warranty claim, the court noted that the plaintiff alleges it regularly engaged in business with Pilgrim's Pride and that representatives from Pilgrim's Pride were present when the x-ray inspection occurred.

"Additionally, Plaintiff asserts Defendants (including Pilgrim's Pride) had reason to know the purpose for which the chicken product was needed based on communications between the parties," the court said. "Drawing reasonable inferences in favor of Plaintiff and accepting Plaintiff's version of facts as true, it is plausible that Pilgrim's Pride was aware of Plaintiff's intention to use the chicken for burgers and that it was involved with the process such that Plaintiff was a third-party beneficiary."

The court granted Pilgrim's Pride's motion to dismiss the plaintiff's negligence claim after finding that the plaintiff failed to allege that any party other than Houlihan owes a duty to the plaintiff, but allowed the plaintiff leave to amend its complaint.

Heavy Metals Baby Food Suit Dismissed for Lack of Standing

A Virginia federal court has held that plaintiffs alleging Gerber Products Co. sold baby foods adulterated with heavy metals do not have standing to sue. *In re Gerber Prods. Co. Heavy Metals Baby Food Litig.*, No. 21-0269 (E.D. Va., Alexandria Div., entered October 17, 2022). The plaintiffs did not assert standing on the basis of personal injury but rather argued that the injury they allegedly suffered was economic harm for having purchased "a product that was 'worthless or worth less' than the purchase price due to Defendant's material omissions."

"Plaintiffs have not alleged the Baby Food Products failed to provide Plaintiffs' children with nourishment or to otherwise perform as intended," the court noted. "Although Plaintiffs never explicitly address whether they or their children consumed the Baby Food Products, the Court can infer the Baby Food Products performed as intended based on Plaintiffs' acknowledgement that they purchased said products repeatedly and 'frequently.' ... Plaintiffs paid for safe and healthy food for their children and apparently received just that—the benefit of their bargain. Accepting the pleadings as alleged, Plaintiffs' only complaint is that the Baby Food Products' levels of Heavy Metals are 'unsatisfactory to [them].' [] Without more, such an assertion does not amount to a concrete and particularized injury."

The court found that the price-premium theory also failed for lack of evidence. “Plaintiffs fall short of establishing a price premium theory of economic harm for the same reasons they do not successfully articulate a benefit of the bargain theory: they fail to allege any facts showing the value of Baby Food Products was less than what Defendant falsely represented or what Plaintiffs believed it to be at the time of purchase.”

The court also determined that the question of setting levels of allowable amounts of heavy metals in baby foods is within the primary jurisdiction of the U.S. Food and Drug Administration (FDA). “It is important to note that the ‘FDA’s testing has shown there [is] no immediate health risk to children from exposure to toxic elements at the levels currently found in food.’ [] Plaintiffs ask the Court to substitute its judgment on what levels of Heavy Metals in baby food are safe for the FDA’s judgment. This type of scientific determination is particularly within the FDA’s discretion and expertise.” The court granted Gerber’s motion to dismiss without prejudice.

Court Dismisses Labeling Claims Against Baby Food Maker

A federal court has dismissed a putative class action against baby and toddler-food manufacturer Sprout Foods Inc. after finding the plaintiffs failed to bring plausible claims that the company’s product labeling is misleading. *Davidson v. Sprout Foods Inc.*, No. 22-1050 (N.D. Cal., entered October 21, 2022).

The plaintiffs, a California couple, alleged the company’s product packaging contained statements about nutrition content, such as “3g of Protein, 4g of Fiber and 300mg Omega-3 from Chia ALA,” that constitute “nutrient content claims” in violation of U.S. Food and Drug Administration regulations. They alleged that Sprout violated the California False Advertising Act, the California Consumer Legal Remedies Act and the California Unfair Competition Law (UCL). They also brought claims of common-law fraud and unjust enrichment.

In reviewing the plaintiffs’ fraud claims, the court found that the plaintiffs claim to make two showings: that the labels communicate a message that the products provide physical health benefits for children, and that they are harmful nutritionally and developmentally. While they plausibly argue the first, the court said the second “is harder to swallow.”

“Plaintiffs suggest that the Products are harmful for children because they contain ‘high amounts of free sugars,’ but they do

not place this averment in context by describing at what point ‘high’ sugar content crosses into harmful levels (or even why, in particular, these sugar levels are harmful),” the court noted. “Plaintiffs also argue that pouch-based foods may be unhealthy for developing children, but they rely for support on speculative research conclusions and hypothetical scenarios to argue these products are harmful—for instance, that pouches ‘*may* lead to long term health risks,’ (emphasis added), or may be harmful if overly relied on by parents, or ‘can be a gateway to bad long-term snacking habits and routine overeating.’”

The court said it is unclear why the products are *per se* harmful, “rather than harmful only after a series of contingencies outside the scope of this case.”

“Finally, Plaintiffs do little to explain why, even if these averred harms exist, they outweigh any potential benefits of the Products—such as protein or fiber intake—such that the Products no longer provide any physical health benefits,” he said.

The court concluded that the plaintiffs have not provided enough to state plausibly that the product labels are misleading and dismissed the California law claims with leave to amend. The court separately found the plaintiffs’ claim under the “unlawful” prong under the UCL was preempted by federal law and must be dismissed, and dismissed the unjust enrichment claim.

Consumer Alleges Ovaltine Packaging Claims Are Misleading

A New York woman has brought a putative class action against Nestlé USA Inc. alleging the company makes misleading claims about the nutrition content of its Ovaltine flavored drink mix products. *McMenamy v. Nestlé USA Inc.*, No. 22-1053 (N.D.N.Y., filed October 11, 2022).

The plaintiff took issue with labeling including “A Good Source of 12 Vitamins & Minerals” and “No Artificial.” She said that under state and federal regulations, the former phrase is a nutrient content claim, meaning that the product should provide between 10 to 19 percent of the recommended daily intake or recommended daily value of no less than 12 vitamins or minerals. She said the product is not a good source of 12 vitamins and minerals because the consumer is required to mix the product with a cup of low-fat Vitamin A & D milk.

“That the Product is not a good source of 12 vitamins and minerals without adding other ingredients is discreetly indicated by the dagger accompanying the front label statement of ‘A Good Source

of 12 Vitamins & Minerals,[†] which corresponds to a smaller statement several lines below, “†When Prepared As Directed,” she said in the complaint.

The plaintiff also alleged the “No Artificial” labeling was misleading because the product’s ingredient list notes it contains a bioengineered food ingredient. She said consumers seeing the prominent representation would not expect the product to contain bioengineered ingredients or ingredients produced with chemical compounds.

The plaintiff alleges Nestlé violated Sections 349 and 350 of New York General Business Law, as well as other state consumer-fraud acts. She also alleges breaches of express and implied warranty, negligent misrepresentation, fraud and unjust enrichment. She is seeking class certification, damages and attorney’s fees.

Evian ‘Carbon Neutral’ Claims Misleading, California Consumer Alleges

A California woman has filed a proposed class action against Danone Waters of America, alleging its Evian Natural Spring Water product packaging made misleading representations about being carbon neutral. *Dorris v. Danone Waters of America*, No. 22-8717 (S.D.N.Y., filed October 13, 2022).

The plaintiff noted in her suit that the defendant represents on all versions of its Evian packaging that the product is “carbon neutral.” As a result, she asserted that reasonable consumers would believe the manufacturing of the product is sustainable and does not leave a carbon footprint, but that impression is false.

“Defendant’s manufacturing of the Product still causes carbon dioxide (‘CO₂’) to be released into the atmosphere,” she said in the complaint. “Accordingly, the carbon neutral claim is false and misleading because the Product’s manufacturing process is not carbon neutral, and consumers would not have purchased the Product, or paid substantially less for it, had they known the carbon neutral claim was not true.”

The plaintiff added that the defendant may contend that the carbon credits it purchases offset the carbon emissions created in the production of its product, but such an explanation appears nowhere on the product’s packaging and reasonable consumers would not consider that the meaning of “carbon neutral.”

The plaintiff is alleging violations of the California Consumers Legal Remedies Act and New York General Business Law Sections 349 and 350, breaches of express and implied warranty, unjust

enrichment and fraud. She is seeking class certification, declarative judgment, damages, prejudgment interest, restitution and attorneys' fees.

Barilla "Italy's #1 Brand of Pasta" Lawsuit to Continue

A California federal court has denied a motion to dismiss a lawsuit alleging Barilla America Inc. misled consumers as to the source of its pasta products by marketing them as "Italy's #1 Brand of Pasta." *Sinatro v. Barilla Am. Inc.*, No. 22-3460 (N.D. Cal., entered October 17, 2022). The court first held that the plaintiffs had standing to sue because the "allegations are sufficient to establish an economic injury for purposes of constitutional standing," but it found that the plaintiff lacked standing for injunctive relief.

Turning to whether a reasonable consumer could be misled by Barilla's claims, the court was unpersuaded by Barilla's argument that "it is not misleading to invoke the company's Italian roots 'through generalized representations of the brand as a whole.'"

"Barilla asks the court to assume that consumers would solely perceive the Challenged Representation to mean that the products at issue are part of the Barilla brand, and not that they are made in Italy from Italian ingredients. In other words, Barilla asks the court to decide as a matter of law that the Challenged Representation can mean only one thing. However, Plaintiffs have alleged that the Challenged Representation appears with the colors of the Italian flag, and that this imagery further reinforces the notion that the products 'are authentic pastas from Italy,'" the court held. "The Challenged Representation is also part of the products' packaging in the context of an alleged marketing campaign that emphasizes the company's Italian identity, including a website 'that markets the Barilla® brand and company as undeniably Italian, dedicated to the manufacturing, marketing, and selling of Italian-made pastas.'"

Finding that the plaintiffs plausibly alleged that reasonable consumers could be confused by the labeling, the court denied Barilla's motion to dismiss.

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