Details on litigation related to the *Cyclospora* outbreak, a complaint alleging a soda contains three times the amount of sugar indicated on the label, a California law on sell-by dates, and more.

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SPOTLIGHT

FDA Denies Citizen Petition for PFAS Food Tolerances

By Jennifer E. Hackman

A citizen petition submitted on November 1, 2023, (and supplemented on May 15, 2025) requested that the U.S. Food and Drug Administration (FDA) establish regulatory limits for per- and polyfluoroalkyl substances (PFAS) in foods. The petition asked FDA to establish "tolerances" (legally binding maximum levels) for residues of either 26 or 30 PFAS at the method detection limit (MDL)—the lowest level that can be reliably measured—and to apply those limits to foods including produce, dairy, seafood and animal feed commodities. Alternatively, the petition requested FDA establish a combination of tolerances and "action levels" (nonbinding enforcement thresholds used as guidance) for certain PFAS and foods.

The petition relied on authorities under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §§ 342, 346), which governs adulterated food and allows FDA to set contaminant limits, as well as FDA's regulations at 21 C.F.R. Part 109 addressing unavoidable contaminants.

In a letter dated June 17, 2026, FDA denied the petition in full. FDA concluded that the petition did not provide sufficient scientific evidence to support establishing tolerances or action levels for the specific PFAS, foods and levels requested. FDA noted that the petition did not provide the type of data FDA typically relies on, including toxicological reference values for some of the PFAS cited, exposure data and feasibility (achievability) analyses needed to set limits. FDA also emphasized that it retains discretion under the FD&C Act to determine whether and when to establish tolerances or action levels, and that it is not required to do so in response to a citizen petition.

FDA also rejected arguments that it must set limits at zero or at detection limits in accordance with food additive provisions such as the "Delaney Clause" (a provision often understood to impose a zero-tolerance standard for carcinogens). Rather, FDA explained that contaminants like PFAS are regulated under adulteration provisions, not food additive rules, and thus are not subject to a zero-tolerance mandate.

Importantly, FDA reiterated that it can take enforcement action even without established limits if a contaminant renders food "injurious to health" under section 402(a)(1) of the FD&C Act. Although it denied the petition, FDA emphasized that addressing PFAS in food remains a priority and outlined several ongoing and planned agency actions:

- **Data development and monitoring**
    - Testing thousands of food samples and expanding analytical methods to detect more PFAS at lower levels.
    - Increasing laboratory capacity and continuing nationwide surveillance programs such as the Total Diet Study, FDA's long-standing program that measures chemical contaminants in commonly consumed foods.
- **Targeted risk management and enforcement**

    - Conducting safety assessments and taking action where PFAS poses a health concern (e.g., recalls, import refusals).
    - Using tools such as import alerts to block contaminated products.
- **Regulatory development**
    - Actively considering whether to establish action levels for PFAS in certain foods as more data becomes available.
    - Reviewing EPA's drinking water standards to determine whether to regulate PFAS in bottled water.
- **Research and policy evolution**
    - Developing approaches to assess cumulative exposure to multiple PFAS.
    - Continuing to gather data through requests for information and scientific studies.

FDA emphasized that the science on PFAS is rapidly evolving and that regulatory limits generally require a stable and mature evidentiary record before being set.

As to potential implications for stakeholders, FDA's denial means there are currently no binding federal tolerances or action levels for most PFAS in food, though FDA retains authority to take action against products deemed unsafe, even without formal thresholds. As a result, companies face ongoing compliance uncertainty.

At the same time, FDA's expanded monitoring efforts suggest greater oversight of supply chains, particularly for higher risk categories such as seafood and products sourced from regions with known contamination. FDA's statements suggest that action levels or other guidance may be forthcoming, particularly as more toxicological and exposure data are developed. The focus on PFAS—alongside EPA and state actions—signals a continued trajectory toward tighter controls, even if formal limits are not yet established.

This article originally appeared in Material Concerns: Legal Updates on Substances of Emerging Concern. Shook's Environmental team's proactive approach to protecting clients' business interests and avoiding expensive litigation includes monitoring industry trends, legislative and regulatory developments, key judicial cases, plaintiffs' bar activities and the latest scientific literature. To learn more about Shook's environmental capabilities,

please contact Practice Co-Chairs Thomas J. Grever or James F. Thompson, or for more information about Material Concerns please contact Partner Jennifer E. Hackman.

FIRM NEWS

Shook Partner Presents on FDA Recalls and Detentions

Shook Partner Katie Gates Calderon presented "Recalls and Detentions: Understanding the Scope of FDA and Related Agencies' Authority" at the American Conference Institute's Food Law and Regulation Boot Camp virtual conference on July 17. Her presentation discussed effectively recalling products once an issue is discovered, correcting regulatory mishaps, working with state and federal government to streamline the recall process, and properly addressing publicity issues.

LEGISLATION, REGULATIONS & STANDARDS

California "Sell-By Date" Prohibition Takes Effect

On July 1, a California law took effect that prohibits the use of consumer-facing "sell by" dates. AB 660 requires food manufacturers to use uniform terminology when labeling products with "quality" or "safety" dates, in addition to banning the use of "sell-by" dates. According to the California Department of Food Agriculture, the law seeks to address consumer confusion that results in food waste.

FDA Issues Final Rule Updating Orange Juice Standard of Identity

The U.S. Food and Drug Administration (FDA) has issued a final rule amending the Standard of Identity (SOI) for pasteurized orange juice. The rule lowers the minimum orange juice soluble solids content from 10.5° to 10° Brix and permits up to 15% *Citrus reticulata* juice or *Citrus reticulata* hybrid juice, by volume. The rule takes effect August 19.

U.S. Department of Health and Human Services Secretary Robert F. Kennedy Jr. lauded the change. “We are cutting red tape, saving the industry more than $50 million each year, strengthening American supply chains, and creating a level playing field for U.S. citrus growers — all while maintaining the safety, quality, and taste Americans expect,” he said in a statement.

Additionally, the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is revising the U.S. Standards for Grades of Orange Juice by revising the limits for Grade B Brix allowances in pasteurized orange juice to reference FDA's SOI for pasteurized orange juice.

INDUSTRY READS

- "Priority Open Recommendations: U.S. Department of Agriculture," Government Accountability Office, July 13, 2026
- Timothy D. Lytton (Guest Essay), "This Is Why Our Fresh Produce Keeps Making Us Sick," *The New York Times*, July 20, 2026
- "Science & Tech Spotlight: Geographic Origin of Food and Other Imports," Government Accountability Office, July 15, 2026

Cyclospora Outbreak Linked To Iceberg Lettuce Prompts Suits

Health officials in several states are investigating a multistate outbreak of *Cyclospora* infections linked to iceberg lettuce from Mexico. The U.S. Food and Drug Administration's traceback investigation identified convergence on Taylor Farms de Mexico as a supplier of shredded iceberg lettuce used by Taco Bell locations where sick people ate before becoming ill. On July 17, Taylor Farms de Mexico recalled all iceberg lettuce sourced from central Mexico.

According to the U.S. Centers for Disease Control and Prevention, at least 1,947 cases have been reported, with 98 hospitalizations; however, more cases have been reported by individual states. As of July 23, the Michigan Department of Health & Human Services listed 8,176 reported cases and 160 hospitalizations. On July 18, FDA announced that a lettuce sample supplied by Taylor Farms tested positive for *Cyclospora*, but the agency called the result a false positive on July 19, *Reuters* reported.

A wave of proposed class actions has been filed by plaintiffs who alleged they contracted cyclosporiasis. The lawsuits have been filed in California, Michigan and Ohio federal courts against Taylor Farms and Taco Bell. *Ayyad v. Pacific Bells, LLC*, No. 26-1648 (N.D. Ohio, filed July 16, 2026); *Gelbspan v. Taylor Fresh Foods, Inc.*, No. 26-07346 (N.D. Cal., filed July 16, 2026); *Parrish v. Taco Bell Corp.*, No. 26-12448 (E.D. Mich., filed July 17, 2026); *Caruso v. Taco Bell of Am. LLC*, No. 26-01661 (N.D. Ohio, filed July 17, 2026).

Halfday Prebiotic Iced Tea Contains 3x Labeled Sugar, Lawsuit Alleges

Halfday Tonics Inc. faces a putative class action alleging that it misled consumers about the sugar content of its prebiotic iced tea beverages. *Kluge v. Halfday Tonics Inc.*, No. 26-6098 (S.D.N.Y., filed July 17, 2026). According to the complaint, the company promises "3g sugar" on the front of the Halfday's Raspberry Iced Tea can and the Nutrition Facts panel. "That promise was false," the plaintiffs allege. "Independent laboratory testing showed that Halfday Raspberry Iced Tea contained approximately 9.69 grams of sugar per can, more than three times the amount Defendant represented."

Rebel Creamery Ordered To Pay Van Leeuwen Ice Cream $23M for Trade Dress Infringement

A federal court in New York has ordered Rebel Creamery to pay Van Leeuwen Ice Cream $23 million in disgorged profits after finding Rebel liable for trade dress infringement under the Lanham Act and New York state law. *Van Leeuwen Ice Cream LLC v. Rebel Creamery LLC*, No. 21-2356 (E.D.N.Y., filed July 16, 2026). According to the ruling, Van Leeuwen sells pints of dairy ice cream in monochrome, pastel cardboard packaging with minimalist designs and black cursive script. The court said Rebel uses a near-identical color scheme and script, with slight design differences to convey dietary information. Van Leeuwen sued Rebel for trade dress infringement, and the court held a bench trial. “The evidence at that trial left no doubt that Rebel infringed and diluted Van Leeuwen’s trade dress and did so intentionally,” the court said. “As a result, Rebel will be enjoined from selling the infringing products and required to redesign its packaging to avoid any further infringement.”

More to Explore

- Shook's latest ***Privacy and Cybersecurity Client Alert*** covers a Colorado telemarketing fraud law that could give rise to litigation exposure for routine

practices even where no telemarketing call, text or other direct solicitation has occurred.

- New York has enacted legislation expanding protection for employees offered severance agreements; the ***National Employment Perspective*** details the No Severance Ultimatums Act.

- The previous issue of the ***Food and Beverage Litigation and Regulatory Update*** focused on a lawsuit alleging the use of erythritol renders a product not "natural," proposed laws on organic imports and lab-created butter, a "health-washing" complaint challenging the calorie content of baked goods, and more.

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As the food and beverage industries become more complex, they require effective legal representation that can quickly evaluate potential liability and craft the most appropriate responses to suspected product adulteration, alleged foodborne outbreaks or environmental contamination claims. For decades, manufacturers, distributors and retailers at every link in the food chain have come to Shook, Hardy & Bacon to partner with a legal team that understands the issues they face in today's evolving food production industry. Shook attorneys work with some of the world's largest food and beverage companies to establish preventative measures, conduct internal audits, develop public relations strategies, and advance tort reform initiatives. Learn more about Shook at www.shb.com