Q3 | Food and CPG Legal Trends

PERKINSCOIE

PERKINS COIE IS PLEASED TO PUBLISH ITS Q3 FOOD AND CPG LEGAL TRENDS REPORT.

This report is a bite-sized version of our annual Year in Review, providing timely insights on quarterly trends. In Q3 2023, the Consumer Packaged Goods (CPG) industry continued to face a meaningful threat of class-action activity, with continued filings against companies in the food, beverage, and personal care space. Recent months have also seen significant regulatory developments relevant to food, beverage, and CPG companies on both the federal and state level.

Beyond our Food & Consumer Packaged Goods Litigation Blog and annual Year in Review, we also monitor filings on a daily basis and provide real-time information to clients and key contacts via our Food and Consumer Packaged Goods Litigation Update. To inquire about receiving this daily email report about cases filed, Proposition 65 notices, and industry decisions, please email Kellie Hale at KHale@perkinscoie.com.

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REGULATORY

Federal and state agencies have made significant developments in Q3 2023 regarding food and CPG products. We review several of these regulatory developments below:

FEDERAL DEVELOPMENTS

- **FDA releases public inventory of unapproved food additives.** In July 2023, FDA released a public inventory of certain food ingredients that the agency has determined are unsafe because they are unapproved additives that are not generally recognized as safe (GRAS) when used as intended. FDA developed this inventory as part of its post-market surveillance of food ingredients. Notable ingredients included in the inventory are cannabidiol (CBD), melatonin, Delta-8-tetrahydrocannabinol (Delta-8-THC), and caffeinated alcoholic beverages.
- **FDA releases updated Draft Guidance to facilitate CGMP and HARPC compliance for human food.** On September 26, 2023, the FDA added two new chapters to the agency's draft guidance *Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food*. These two new chapters, focusing on food allergen programs and acidified foods, aim to facilitate compliance with FDA's current good manufacturing practices (CGMPs) and preventive controls for human food.
- **FDA publishes draft guidance for cosmetic facility registrations and product listings.** The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) represents the most significant change to how the federal government regulates cosmetic products in decades. Pursuant to MoCRA, the FDA has worked toward establishing a new system, including a submission portal for the cosmetic product facility registrations and product listings mandated by the new law. The agency anticipates this submission portal will be available to industry stakeholders in the coming days.

In August 2023, Illinois expanded potential use of consumer-owned containers at retail and restaurants

STATE DEVELOPMENTS

- **California passes ban on certain food additives.** In September 2023, California legislature passed AB 418, which prohibits the use of certain food additives in that state. As passed, the bill prohibits the use of brominated vegetable oil, potassium bromate, propylparaben, and Red Dye No. 3, effective January 1, 2027. Governor Gavin Newsom signed the bill on October 7, 2023.
- **Illinois expands potential use of consumer-owned containers at retail and restaurants.** In August 2023, Illinois legislators passed HB 2086, which provides retailers and restaurants the option to allow consumer-owned containers to fill or refill bulk or ready-to-eat foods. Further guidance is expected from the Illinois Department of Public Health about food safety standards for consumer-owned containers used in this way, including but not limited to sanitation practices, procedures to prevent cross-contamination, and handwashing requirements.

FOOD AND SUPPLEMENTS

Food, beverages, and supplements continue to be prime targets of consumer class action lawsuits. For both the food and beverage category and the supplement category, California remains the state with the most numerous filings. In the food and beverage category, Florida is seeing a rise in cases, tying in Q3 with New York as the second most active jurisdiction for plaintiffs to file.

FOOD AND BEVERAGE TRENDS

In the third quarter of 2023, many plaintiffs advanced litigation theories in the food and beverage space. Five of these theories are highlighted below.

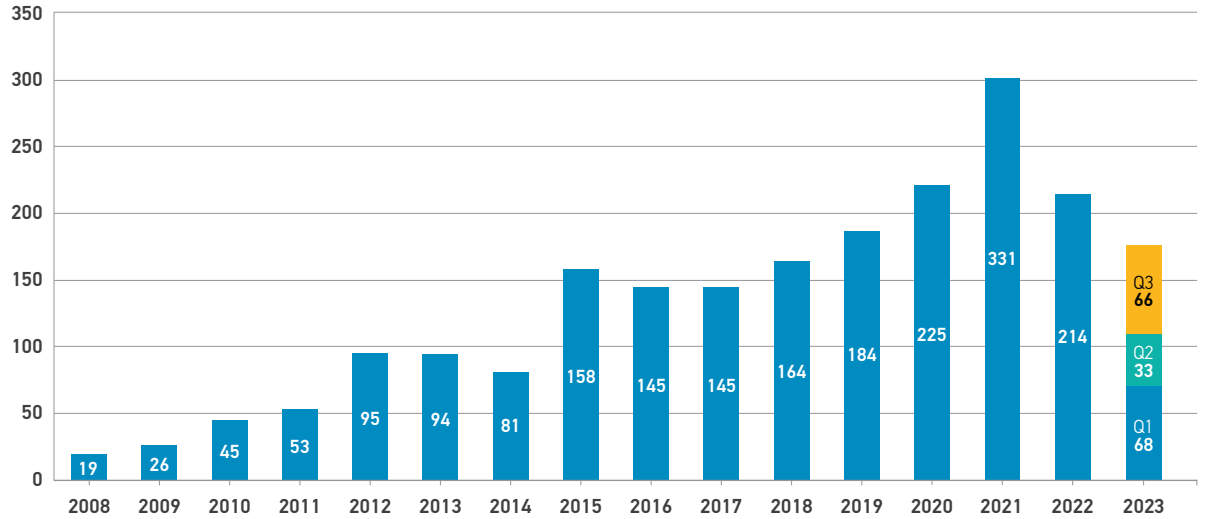
First, as in Q2, plaintiffs' most popular litigation theory related to food and beverages pertaining to representations about preservatives. Throughout Q3, plaintiffs targeted products that contained phrases such as "no artificial preservatives" or "no preservatives." In these cases, the plaintiffs alleged that these statements are false and misleading because of the presence of certain purported preservatives. Namely, the plaintiffs have focused on the presence of dipotassium phosphate, which they allege is a synthetic preservative, and the presence of additional purported preservatives, such as citric acid, sodium benzoate, and/or ascorbic acid.

Flavor representations provided another popular theory advanced in Q3s. These cases focused on explicit and nonexplicit flavor representations that led consumers to believe that the product contained different flavorings than its actual ingredients. A few of these cases focused specifically on the product name and images representing flavors such as fruit, arguing that a consumer would believe the product was flavored with the actual ingredient, not artificial flavors. Others focused on direct statements such as "naturally flavored" as supposedly deceptive because of the presence of alleged artificial flavor ingredients.

Lawsuits alleging deceptive advertising based on the comparison between the image used in the advertisement and the actual product gained in popularity in Q3. These lawsuits made headlines, with complaints including images of what the plaintiffs claimed

FOOD AND BEVERAGE CLASS ACTIONS

FIGURE 1



they thought they were receiving compared to what they actually received. The plaintiffs alleged the advertisements were deceptive not only in quality of the product but also in quantity—they thought they were purchasing a bigger portion. These lawsuits largely targeted fast-food companies.

The industry also saw several claims related to the phrase "made with." Whether that statement was "made with real butter" or "made with whole grain," the plaintiffs in these cases challenged the labeling of the product with regard to the alleged predominance of the highlighted ingredient. Namely, the plaintiffs felt the label was deceptive if the highlighted ingredient was not the most abundant ingredient.

We also saw a rise in Q3 cases related to per- and polyfluoroalkyl substances (PFAS), heavy metals, and other trace contaminants in food products. In these cases, some plaintiffs alleged that the product should not be marketed as a healthy product, despite containing healthy ingredients, because testing revealed the presence of PFAS or other contaminants. In addition, the plaintiffs alleged the failure to disclose the presence of these contaminants was deceptive. In these cases, the plaintiffs asserted price premium theories, alleging that they overpaid for the product or would not have purchased the product at all had the presence of the contaminant been disclosed.

SUPPLEMENTS TRENDS

False facts were the main supplement litigation theory advanced in Q3. Specifically, these cases focus on the efficacy of certain supplement products that purportedly cannot provide the promised benefit. An example is a pain reliever that reportedly does not relieve pain, or dietary memory supplements that do not actually improve memory. These cases rely on scientific studies to support the theory that the products cannot work as advertised.

Plaintiffs also introduced supplement cases alleging failure to disclose the presence of heavy metals and other allegedly harmful contaminants, similar to those in the food and beverage category.

BEAUTY, COSMETICS, AND PERSONAL CARE

U.S. companies selling cosmetics are gearing up to comply with the upcoming December 29, 2023 deadlines under the new Modernization of Cosmetics Regulation Act (MoCRA). MoCRA will not only change the regulation of cosmetic companies in the United States, but it will also affect litigation facing the industry. Cosmetic companies can expect increasing scrutiny from plaintiffs' lawyers and should be prepared to substantiate the safety of their products and claims made in connection with their products—particularly given that their MoCRA-required records, reporting, and product testing may be fair game in discovery.

UPCOMING DEADLINES FOR COMPLIANCE WITH MoCRA

By December 29th, beauty and personal care companies must register their facilities and list their cosmetic products with the U.S. Food and Drug Administration (FDA), substantiate the safety of their products, meet new adverse reporting requirements, implement new cosmetic labeling requirements for professional use products, and be prepared to comply with the FDA's new mandatory recall authority.

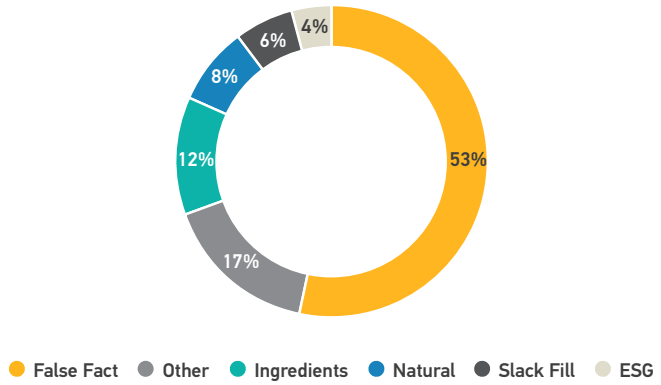
MANDATORY FACILITY REGISTRATION AND PRODUCT LISTING

Cosmetic facilities must be registered and cosmetic products must be listed with the FDA no later than December 29, 2023:

- **Facility registrations.** Each person who owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States must register each facility no later than December 29, 2023. This includes facilities that are located outside of the United States. Registrations must be renewed every two years. Note that facilities solely engaged in the labeling, relabeling, packaging, repackaging, holding, or distribution of cosmetics products need not be registered.
- **Product listings.** Cosmetic companies must submit a cosmetic product listing no later than December 29, 2023. Products already on the market as of the date of enactment must be listed no later than one year after that date. New products need to be listed within 120 days of entering the U.S. market. Thereafter, product listings must be updated annually. This includes an update that the product was discontinued.

PERSONAL CARE CLASS ACTIONS: 2023 FILINGS BY TYPE

FIGURE 2



SAFETY SUBSTANTIATION

By this same December 29 deadline, cosmetic companies must also ensure adequate substantiation of the safety of each cosmetic product and maintain records supporting their safety. The term "adequate substantiation of safety" means tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe. The term "safe" means that the cosmetic product, including any ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

The FDA can review safety substantiation documentation if it has a "reasonable belief that the cosmetic product is likely to be a threat of serious adverse health consequences or death." Companies should establish a safety substantiation policy to address these new requirements and should consider retaining a certified toxicologist to conduct a risk assessment on their products.

ADVERSE EVENT REPORTING REQUIREMENTS

Cosmetic companies, by the above December 29 deadline, will be required to submit any report received of a serious adverse event associated with the use in the United States of a cosmetic product manufactured, packed, or distributed by the company. A "serious adverse event" means an adverse event that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, an infection or significant disfigurement, or one that requires a medical or surgical intervention to prevent such an outcome.

Serious adverse events must be reported within 15 business days of the receipt of the report; regular updates must be submitted to the FDA as new information is reported. Additionally, cosmetic companies are required to maintain records of any health-related adverse event for at least six years after the reporting of the event. MoCRA provides for inspection of any registered facility, during which the FDA may request copies of all adverse event reports. Failure to provide such records renders a product or facility noncompliant. Companies should work to establish an adverse event reporting program and ensure that they meet the recordkeeping requirements of the MoCRA.

These cases serve as a reminder about the potential for litigation when making broad-based claims

LITIGATION UPDATE

The use of animals in testing the safety of cosmetic products is not banned under MoCRA, but Congress notes that it discourages such activities and recommends that they be phased out. While animal testing is still permitted in the United States, cosmetic and personal care products companies continue to be challenged in courts when touting cruelty-free claims. For example, John Paul Mitchell Systems is currently facing a putative class action in which plaintiffs challenge the company's "cruelty-free" claims, including "never animal tested," "a pioneer in cruelty-free hair care," and "no animal testing," when the company allegedly allows animal testing on numerous products in order to sell products in China where testing on animals is mandatory for companies.

In *Heagney et al. v. John Paul Mitchell Systems*, N.D. Cal. Case No. 3:23-cv-00687, the court denied (in part) John Paul Mitchell's motion to dismiss on August 2, 2023, finding that the company must face the plaintiffs' false advertising claim because it has long marketed its business and its products as "cruelty-free," even though it once imported its products into China and registered them with the Chinese government—at a time when Chinese law required that companies test cosmetic imports on animals as a condition of registration. This court concluded that "[b]y definition, a product that has been animal-tested once—and a company that has animal-tested once—can never be 'cruelty-free' again."

Several other cosmetic companies have faced similar claims. These cases serve as a reminder about the potential for litigation when making unqualified, broad-based claims that can be difficult to substantiate.

PROPOSITION 65

California Proposition 65, formally known as the Safe Drinking Water and Toxic Enforcement Act of 1986, prohibits manufacturers and retailers from knowingly and intentionally exposing California consumers to a chemical known to the state of California to cause cancer, birth defects, or reproductive harm without first providing a "clear and reasonable warning." The regulations and litigation surrounding Proposition 65 have a substantial impact on the consumer products industry—especially those in the food, beverages, and dietary supplements sectors.

PROPOSITION 65 – Q3 BY THE NUMBERS

Plaintiffs filed a whopping 1,070 Proposition 65 presuit notices of violation in Q3 of 2023. Of those, approximately 30% of the notices related to alleged exposures to lead. The trend continued from Q2, reflecting a significant number of notices—15%—targeting gas stations for allegedly exposing consumers to vaporized unleaded gasoline without a warning. There was also a significant uptick in the number of notices relating to Bisphenol A (BPA), which can partially be attributed to the Center for Environmental Health's (CEH) recent focus on polyester-based sports apparel containing spandex or elastane, both of which allegedly include BPA. See the chart on the next page for a detailed breakdown of the top chemicals at issue this quarter.

LITIGATION UPDATES

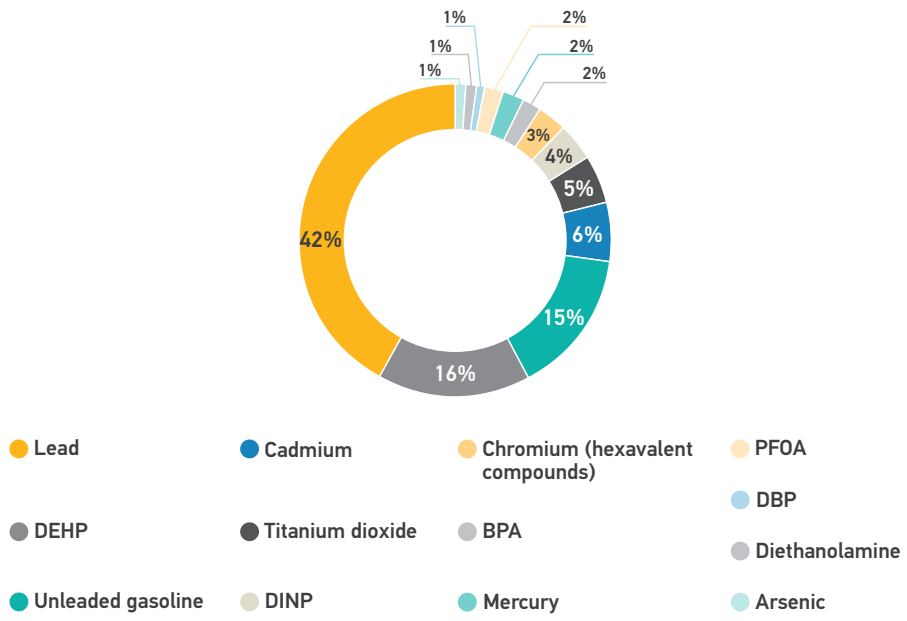
- **California AG Files Proposition 65 Enforcement Suit Targeting Inhalable Hemp Products**

  In May and June of 2023, a Proposition 65 private enforcer, Biosphere Watch Group, SPC, issued a number of 60-day notices to several companies alleging that their sale of inhalable hemp products exposed California consumers to delta-9-THC, marijuana smoke, and beta-myrcene, and did not include a Proposition 65 warning.

  In August 2023, the California attorney general filed a Proposition 65 enforcement lawsuit against those companies. The lawsuit alleges that the companies failed to include warnings required by Proposition 65, but also that the sale of inhalable hemp

Q3: TOP CHEMICALS AT ISSUE

FIGURE 3



products violated Assembly Bill 45 (AB 45). AB 45 prohibits the manufacture and sale of inhalable hemp products in California until the legislature establishes a tax on such products. The complaint, filed in Alameda County Superior Court[1], requests the court block further sales of the inhalable hemp products by the companies, as well as to block the sale of all other industrial hemp products that do not contain appropriate legally sufficient Proposition 65 warnings.

- **CERT Loses Motions to Dismiss and Vacate in *CalChambers* Litigation**

  On August 15, Judge Daniel Calabretta denied the Council for Education and Research on Toxics' (CERT) motion to dismiss and motion to vacate in *California Chamber of Commerce v. Rob Bonta*, the ongoing federal litigation concerning Proposition 65 warnings relating to dietary acrylamide.

Defendant-intervenor CERT filed a motion in late 2021 to dismiss the *CalChamber* case for lack of subject matter jurisdiction. CERT's primary argument was that the plaintiff, California Chamber of Commerce (CalChamber), could not satisfy the case or controversy requirements of Article III because the state attorney general's interests are aligned with CalChamber's interests—essentially claiming that the attorney general had been colluding with CalChamber to undermine Proposition 65. The court definitively rejected this argument, noting that the attorney general has filed several "important, health-protective Prop. 65 lawsuits" and has taken clear steps to defend Prop. 65 in this litigation.

CERT also filed a motion to vacate orders issued previously by Judge Kimberly Mueller: (1) denying CERT's motion for summary judgment, and (2) granting CalChamber's motion for preliminary injunction. CERT alleged that Judge Mueller's orders must be vacated because of alleged financial conflicts of interest at the time she issued the orders and her subsequent recusal from the matter.

Judge Calabretta denied CERT's motion to vacate, noting that Judge Mueller's decision to recuse herself was based on CERT's "uncommonly aggressive, scorched earth efforts" and invasion "of [her] personal life and that of [her] husband" that had occurred *after* Judge Mueller issued the decisions that CERT sought to vacate. Judge Calabretta also noted that the U.S. Court of Appeals for the Ninth Circuit has affirmed the propriety of the preliminary injunction, which has now been in place for almost 2 1/2 years.

[1] *People of the State of California vs. G.E.T. Agriculture LTD, et al.*, Case No. 23CV042554.

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