Q4 | Food and CPG Legal Trends

PERKINSCOIE

PERKINS COIE IS PLEASED TO PUBLISH ITS Q4 FOOD AND CPG LEGAL TRENDS REPORT.

This report is a bite-sized version of our annual year in review, providing timely insights on trends so far this year. In Q4 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 receive this daily email report about cases filed, Proposition 65 notices, and industry decisions, please email Kellie Hale at KHale@perkinscoie.com to inquire about this.

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REGULATORY

Federal agencies made significant developments in Q4 2023 regarding food and consumer packaged goods. We provide below an overview of several of these regulatory developments:

- **FDA Opens Cosmetics Direct, an Electronic Submission Portal.** The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) represents the most significant change in decades to the way that the federal government regulates cosmetic products. Pursuant to MoCRA, the U.S. Food and Drug Administration (FDA) has established a new electronic submission portal, Cosmetics Direct, for the cosmetic product facility registrations and product listings mandated by the new law. The agency announced the availability of the new submission portal on December 18, 2023.
- **FDA Releases Final Guidance Regarding Cosmetic Product Facility Registrations and Product Listings.** On December 18, 2023, the FDA issued final industry guidance designed to assist stakeholders with cosmetic product facility registration and product listing submissions to the FDA. The guidance describes who is responsible for making the registration and listing submissions, what information should be included, how and when it should be submitted, and certain exemptions to the registration and listing requirements.
- **FDA Issues Draft Supplemental Guidance Regarding Menu Labeling.** On December 13, 2023, the FDA published an update to its Menu Labeling Supplemental Guidance to facilitate compliance with the FDA's menu labeling rule. This rule applies to standard menu items offered by "covered establishments" defined as restaurants and similar retail food establishments with 20 or more locations doing business under the same name and offering for sale substantially the same menu items, as well as restaurants and similar retail establishments that register to voluntarily subject themselves to the menu labeling requirements. The draft supplemental guidance states that covered establishments may voluntarily declare added sugars for standard menu items and clarifies that nutrition information may be provided via third party platforms (TPPs).

The FDA proposed a rule to revoke authorization of brominated vegetable oil in food.

- **FDA Announces New Food Traceability Resources.** On November 30, 2023, the FDA announced the availability of new resources to facilitate compliance with the agency's Food Traceability Rule. The Food Traceability Rule imposes new record-keeping requirements for stakeholders that manufacture, process, pack, or hold certain foods. The new resources are designed to assist stakeholders with the Food Traceability Rule's compliance requirements well ahead of the January 2026 deadline.
- **FDA Proposes Rule To Revoke Authorization of Brominated Vegetable Oil in Food.** On November 2, 2023, the FDA proposed a rule that would revoke the regulation authorizing the use of brominated vegetable oil (BVO) in food. In announcing the proposed rule, FDA noted that the action was part of the agency's regulatory authority over ingredients added to food, which includes reassessing previously evaluated food ingredients and addressing safety concerns.

FOOD AND SUPPLEMENTS

In the fourth quarter of 2023, food, beverages, and supplements continued to be prime targets of consumer class action lawsuits. For both the food and beverage and the supplement categories, California remained the state with the most plaintiff filings. However, in the food and beverage category, Florida was the third most popular jurisdiction for Q4 filings, nearly surpassing New York.

FOOD AND BEVERAGE TRENDS

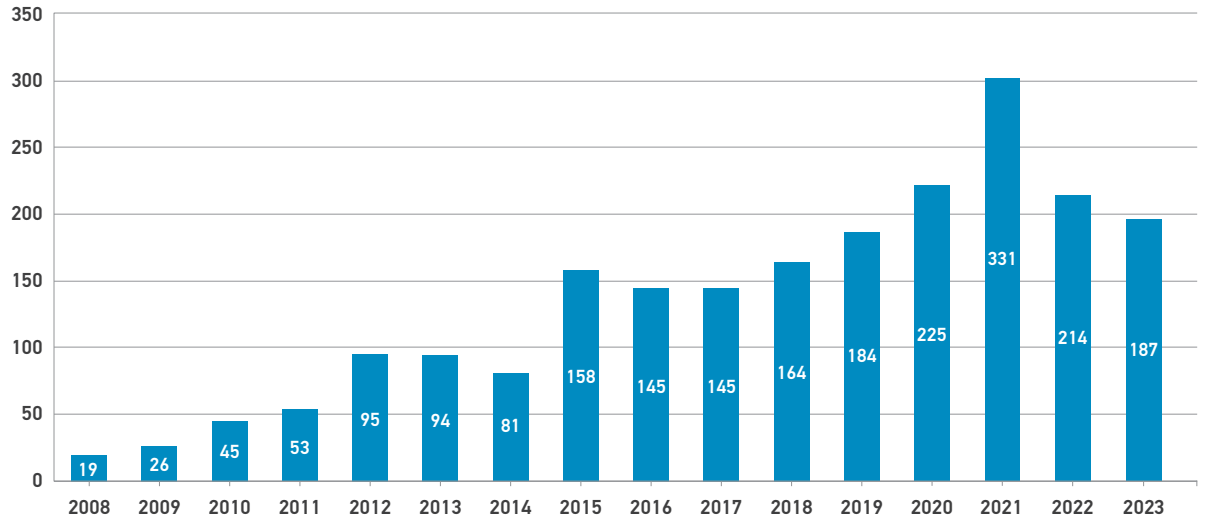
In the fourth quarter of 2023, we saw many repeat litigation theories from Q2 and Q3 advanced by plaintiffs in the food and beverage space.

First, the most popular litigation theory advanced by plaintiffs related to food and beverages in Q4 pertains to representations about preservatives, just as in Q2 and Q3. Throughout Q4, plaintiffs continued to target products that contained phrases such as "No Artificial Preservatives" or "No Preservatives." In these cases, plaintiffs alleged that these statements regarding the absence of preservatives were false and misleading because of the presence of certain purported preservatives. Namely, plaintiffs have focused on the presence of purported preservatives, such as dipotassium phosphate, citric acid, sodium benzoate and/or ascorbic acid. These cases will likely turn on whether the alleged preservative is actually functioning as a preservative or whether the purported preservative is artificial.

The second most popular litigation theory advanced by plaintiffs in this space in Q4 is related to per- and polyfluoroalkyl substances (PFAS), heavy metals, and other trace contaminants in food products. In these microcontaminants cases, plaintiffs alleged that the product should not be marketed as a healthy, safe, or nutritious product, despite containing healthy ingredients, because testing reveals the presence of PFAS or other contaminants. In addition, plaintiffs alleged the failure to disclose the presence of these contaminants was deceptive. Plaintiffs in these cases asserted price premium theories, alleging that they overpaid for the product or would not have paid for the product at all had the presence of the microcontaminant been disclosed.

FOOD AND BEVERAGE CLASS ACTIONS

FIGURE 1



Third, in Q4, there was continued focus on labels with 100% claims such as "100% Juice." In these cases, plaintiffs alleged that the 100% claims were false and misleading because of the presence of additives such as flavor, ascorbic acid, and citric acid. This trend makes clear that if there is anything else in the product, even flavoring or preservatives, aside from the "100%" ingredient, the product is a potential target for these types of claims. Relatedly, in Q4, there was also at least one case focused on zero claims, a label claiming to be "zero calorie" which allegedly was false and misleading. In tandem, these cases demonstrate the litigation risk of making any sort of absolute claim, zero at one extreme and 100 at the other.

Finally, we also saw several claims related to the phrase "made with" just as in Q3. Whether that statement was "made with real butter" or "made with whole grain," plaintiffs were not satisfied with the quantity of the highlighted ingredient. Namely, plaintiffs felt the highlighted ingredient must be the most predominant ingredient, otherwise the label is deceptive. This was especially true if the "made with" claim was also coupled with an image of that ingredient.

Aside from these main litigation theories, plaintiffs also advanced several more niche theories such as deception stemming from describing the product as "raw" or containing "simple" ingredients. Throughout Q4, plaintiffs also continued to bring more traditional consumer deception claims such as slack-fill cases related to packaging and country of origin cases stemming from claims that a product was "made in" a particular country.

SUPPLEMENTS TRENDS

In contrast to Q2 and Q3, the most common litigation theory related to supplements advanced in Q4 involved cases alleging failure to disclose the presence of heavy metals and other allegedly harmful contaminants such as PFAS. In addition, in Q4, plaintiffs brought several cases alleging the word "Natural" was misleading because of the presence of synthetic ingredients.

BEAUTY, COSMETICS AND PERSONAL CARE

As the year concluded, several provisions of the Modernization of Cosmetics Regulation Act (MoCRA) went into effect as of December 29, 2023. With these new provisions in effect, we have continued to see an increase in litigation claims being brought against cosmetic companies.

LEGAL AND REGULATORY UPDATES

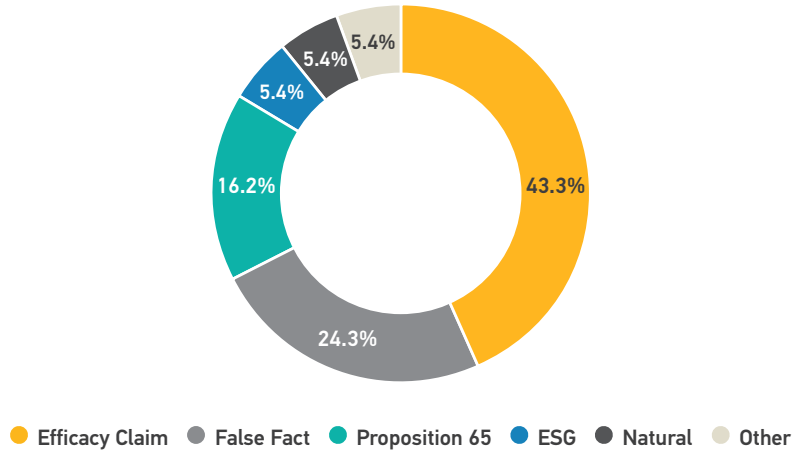
- **MoCRA Updates**

It has been over a year since President Joe Biden signed MoCRA into law, with several provisions in effect as of December 29, 2023. Cosmetic and personal care product companies now must ensure adequate substantiation of the safety of each of their cosmetic products and maintain records supporting adequate substantiation of the safety of their products. There are also specific labeling requirements for professional-use products. Finally, cosmetic and personal care companies are now required to submit within 15 days 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. FDA issued a Cosmetics Constituent Update on December 14, 2023, providing instructions for submitting serious adverse event reports for cosmetics.

In November 2023, the FDA pushed back the deadline for companies to register their cosmetic facilities and cosmetic products until July 1, 2024. The enforcement delay was partly due to the FDA's delay in launching its Cosmetics Direct electronic submissions portal. The FDA finally announced on December 18, 2023, that Cosmetics Direct is now live. While enforcement is delayed, the FDA is encouraging companies to register their cosmetic facilities and products earlier than July 1, 2024. The FDA also issued its Final Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products in December 2023. The Final Guidance includes a new draft "Frequently Asked Questions and Answers," which answers commonly asked questions regarding cosmetic registration and product listing. FDA is accepting comments on the FAQs to be submitted by January 18, 2024.

PERSONAL CARE CLASS ACTIONS: Q4 FILINGS BY TYPE

FIGURE 2



LITIGATION UPDATE

- **FDA Action Leads to Phenylephrine Oral Decongestants Class Action Lawsuits**

  On September 12, 2023, an FDA advisory committee unanimously recommended that oral phenylephrine, the active ingredient in many over-the-counter (OTC) nasal decongestant products, was not effective in reducing nasal congestion. The FDA noted that there are more than 240 products that contain the ingredient phenylephrine, which generated $1.76 billion in sales in 2022 alone. Not surprisingly, a wave of class-action lawsuits followed the FDA's action. Since September, more than 30 putative class-action lawsuits have been filed in which consumers allege that they were misled about the efficacy of the oral cold medicines. We await court rulings on the pending motions to dismiss.

- **The Importance of Clear and Conspicuous Disclaimers on Cosmetic Product Labels and Packaging**

  In the final quarter of 2023, the U.S. District Court for the Northern District of California issued a handful of rulings highlighting the importance of clear and conspicuous labeling of cosmetic products.

  First, the court shot down a putative class action addressing efficacy claims related to the defendant's over-the-counter cold sore treatment. In *Tawneya Houser v. GlaxoSmithKline Consumer Healthcare Holdings (US), LLC*, N.D. Cal. Case No. 4:21-cv-09390-JST, the plaintiff alleged that the labeling of the defendant's over-the-counter cold sore treatment was false or misleading because of representations that would lead reasonable consumers to believe that the treatment would typically heal cold sores in 2 ½ days. The court concluded that the representation "You Can Get Rid Of Your Cold Sore In 2 ½ Days*" was not likely to mislead a reasonable consumer because the term "can" denotes possibility, not probability, and even if the representation were misleading, the corresponding disclaimer eliminates any doubt as to its meaning. This case highlights the importance of clear and conspicuous disclaimers if a claim requires qualification or explanation.

  The court similarly dismissed certain claims challenging the labeling and marketing of cosmetic sunscreen products, which represent that they are "24H," which plaintiffs allege mislead consumers to believe that the products provide 24 hours of sunscreen protection. For example, in *Alexis Slaten v. Christian Dior Perfumes, LLC*, N.D. Cal. Case No. 3:23-cv-00409-JSC (October 19, 2023), the court dismissed a putative class action challenging the labeling and marketing of Christian Dior's Forever Foundation, which includes sunscreen. Specifically, plaintiff alleged that the representation of "24H" applied to the products' sunscreen benefits. The court held that the plaintiff failed to plausibly plead that the defendant's product labels were

These rulings demonstrate the importance of providing easily readable, qualifying language on the outside product packaging.

false or misleading to reasonable consumers. After referencing the back labels of the products, the court asserted that no reasonable consumer could interpret the "24H" representation on the front labels as applying to the products' sunscreen because the product packaging provided directions to "reapply at least every 2 hours."

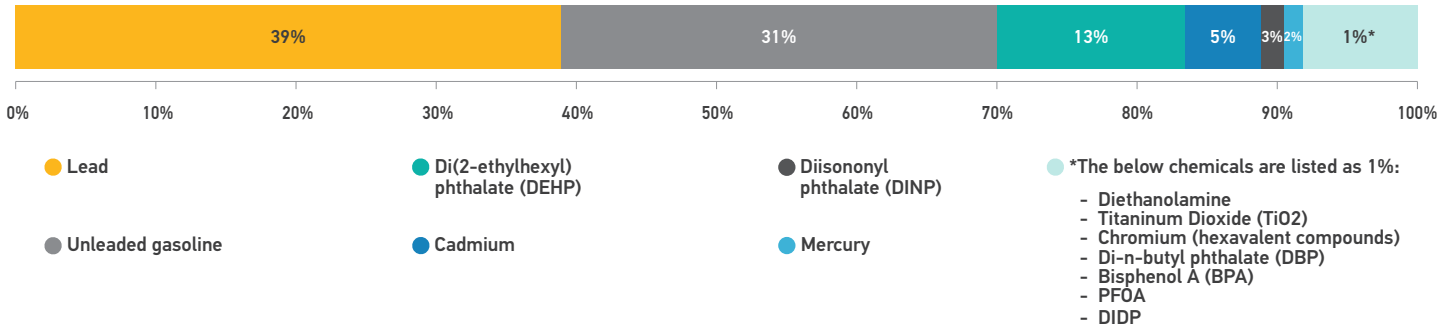
However, in *Lynn Zimmerman, et al. v. L'Oreal USA Inc.*, N.D. Cal. Case No. 22-cv-07609-HSG (December 8, 2023), the Northern District of California only trimmed a putative class action challenging purported sunscreen benefit representations on some of the defendant's cosmetic sunscreen products. Here, plaintiffs alleged that representations such as "Up to 24HR Breathable Texture," "Up to 24H Fresh Wear," and "Sunscreen Broad Spectrum SPF 25" would lead a reasonable consumer to believe that the product provided 24 hours of sunscreen protection when the product's sun protection factor (SPF) lasts only two hours. The court noted that the back label instructions directed consumers to "reapply at least every 2 hours for sunscreen use," but the instructions on at least one of the challenged products are printed underneath a peel-back sticker. The court could not conclude as a matter of law that a reasonable consumer would peel back the sticker on the label in the store prior to purchase, and the court allowed the claim to proceed as to those products. By contrast, where the back label instructions to "reapply at least every 2 hours for sunscreen use" were located directly on the back of the product visible to the consumer prior to purchase, the court concluded the challenged representations were not likely to mislead a reasonable consumer. These rulings demonstrate the importance of providing easily readable, qualifying language on the outside product packaging.

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. Every company that does business in California should monitor Proposition 65 developments closely.

PROPOSITION 65 – Q4 BY THE NUMBERS

Plaintiffs filed a whopping 1,078 Proposition 65 pre-suit notices of violation in the fourth quarter of 2023. Of those related to food and CPG products, approximately 40% of the notices related to alleged exposures to lead, a 10% increase over the last quarter. A significant number of these lead notices target dried and powdered food/dietary supplements. In particular, the fourth quarter saw an increased focus on dried mushrooms, moringa powder, ashwagandha powder, and hibiscus.



CEH has issued several notices relating to PFAS discharges into sources of drinking water.

The trend continued from earlier in 2023, reflecting a significant number of notices—31%—targeting gas stations for allegedly exposing consumers to vaporized unleaded gasoline without a warning.

There was also an increased number of notices relating to per- and polyfluoroalkyl substances (PFAS) chemicals—specifically, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). Over the past year, the Center for Environmental Health (CEH) has issued several notices relating to PFAS discharges into sources of drinking water, while other plaintiffs have focused on PFAS in a variety of consumer goods such as bibs, cookware, and waterproof hats. See the chart on page 10 for a detailed breakdown of the top chemicals at issue this quarter.

LITIGATION UPDATES

- **Defense Victory in *Consumer Advocacy Group v. Gulf Pacific Rice***

  On December 5, 2023, Judge Berle of Los Angeles Superior Court issued a statement of decision finding for rice sellers in a long-running case involving lead in rice. The lawsuit was commenced by Consumer Advocacy Group (CAG) in 2014 and alleged that certain manufacturers and distributors of rice were in violation of Proposition 65 based on the levels of lead in their rice products.

  After a trial, the court held that the defendants had demonstrated that their rice products did not cause any exposure to lead above the 0.5 ug/day safe harbor. In making this determination, the court followed the exposure analysis as set forth in *Environmental Law Foundation v. Beech-Nut Corporation et al.*, No. A139821, 2015 WL 1212155 (Cal. Ct. App. Mar. 17, 2015), which found that the level of exposure to a Proposition 65 chemical could properly be calculated by averaging exposures over time and over multiple products, rather than by using a maximum exposure from a single product on a single day. Judge Berle also noted that the "average user" of a food is determined by the population as a whole, not by "subpopulations" as the plaintiff had argued. It remains to be seen whether CAG will appeal the decision.

REGULATORY UPDATES

In January 2021, California's Office of Environmental Health Hazard Assessment (OEHHA) announced proposed regulations that would significantly affect how businesses may use short-form Proposition 65 warnings.

When short-form warnings were first introduced in 2016, many businesses chose to use these truncated warnings on their product labels and websites. Currently, OEHHA provides two versions of model Proposition 65 warning labels: a *long-form* warning and a *short-form* warning. The key difference between these two categories is that the long-form warning requires that the business specifically name at least one Proposition 65 chemical that could result in exposure from the product's use; by contrast, the short-

California regulators are considering whether to change short-form warning labels.

form warning requires only a statement of the potential health hazard. The proposed regulations also provide that warnings (both long-form and short-form) may use additional "signal words" such as "CA WARNING" or "CALIFORNIA WARNING."

Previously, a short-form warning could simply read:

- **WARNING: Cancer—www.P65Warnings.ca.gov.**

The proposed regulations would require short-form warnings, to read as follows:

- **CA WARNING: Can expose you to [name of chemical], a carcinogen.**
  See www.P65Warnings.ca.gov.

OEHHA was previously stalled in its efforts to update the short-form warning requirements, but now, nearly three years later, OEHHA is back at it. Most recently, on December 20, 2023, OEHHA issued a notice of extension of the public comment period for their proposed amendments to the short-form warning regulations—providing the public until January 3, 2024, to submit comments.

Contact Us

To learn more about issues facing the food and consumer packaged goods industry, please contact:

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