Preempting Bottled Water Microplastics Fraud Claims

By **Tariq Naeem and Brenda Sweet** (March 11, 2024)

Tariq Naeem

Brenda Sweet

Microplastics are of growing interest to scientists and the public, due to concerns about their presence in the food and water supply. While studies do not yet support a link between microplastics and human harm, varied forms of litigation have commenced alleging microplastics contamination.

These include Daly v. The Wonderful Company LLC and Daly v. Danone Waters of America LLC, consumer fraud complaints filed in the Circuit Court of Cook County, Illinois, this year against the manufacturers of Fiji and Evian bottled waters, respectively.[1]

This article explores the science and regulations related to microplastics, their applicability to microplastics and bottled water, and how those regulations may preempt lawsuits alleging consumer fraud claims arising from microplastics contamination.

Microplastics: Background

Microplastics are generally defined as pieces of plastic less than 5 millimeters in size, with nanoplastics being a subset of microplastics less than 1 micrometer in size. Microplastics are divided into two main categories according to their source.

Primary microplastics are released directly into the environment as small particles — e.g., microbeads in cosmetics or industrial pellets. Secondary microplastics result from the degradation of larger plastic objects — e.g., plastic bags, bottles or tires.

News reports describe microplastics as having been detected in every corner of the globe — including inhospitable environments such as the ocean floor, the tops of mountains and polar regions. They have also been found throughout the food supply — for example, in seafood, meat and drinking water.

Despite this reported ubiquity, the regulation of microplastics in our environment is only in its earliest stages. To date, the only U.S. federal law targeting microplastics in consumer products is the Microbead-Free Waters Act, passed in 2015, which bans microbeads from rinse-off cosmetics.[2]

The U.S. Environmental Protection Agency released its draft national strategy to prevent plastic pollution in April 2023, but has not issued any microplastics-specific regulations as to pollution or drinking water standards, nor has it taken any further official action. Among U.S. states, California has been assessing strategies for managing microplastics in drinking water since 2018, but it too has yet to implement any regulations around this effort.

In recent years, scientists have published numerous articles about potential health risks associated with human exposure to microplastics. Research shows that microplastics are distributed widely throughout the human body from inhalation and ingestion, including in the lungs, blood, breast milk and elsewhere.

While in vitro studies have shown that microplastics may cause inflammation, fibrosis, oxidative stress and cytotoxicity to human tissue, there are no reliable studies showing clinically significant health impacts from human exposure to microplastics at ordinary levels found in the environment. Further, researchers acknowledge that many variables might influence the likelihood that microplastics cause harm, including the type, size, shape and concentration of microplastics to which humans are exposed.

Nevertheless, these many uncertainties have not prevented some commentators from speculating that microplastics might cause adverse effects to the digestive, respiratory, endocrine, reproductive and immune systems.

Consumer Fraud Claims Against Bottled Water Manufacturers

Consumer fraud claims asserting microplastics contamination of food products are relatively new. Bottled water has emerged as an early target of such lawsuits.

While plaintiffs will claim that microplastics leach into bottled water from the plastic bottles themselves — and there is some evidence that mechanical stress from opening and closing the cap releases microplastics into the bottled water — research has detected the presence of microplastics at all stages of bottled water production, including at the water source, and during bottle washing, filling and capping.

As a result, the presence of microplastics in bottled water cannot be attributed solely to the manufacturing process.

Bottled water is regulated by the U.S. Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act. Like all other food products regulated by the FDA, bottled water may be sold to consumers unless it is "adulterated" or "misbranded."

Bottled water would be adulterated if, for example, it contained a poisonous or deleterious substance that may render it injurious to health.[3] Bottled water would be misbranded if, among other circumstances, its labeling was false or misleading in any particular.[4]

The FDA has also promulgated regulations establishing specific standards of identity and quality for bottled water — parts of which incorporate EPA contaminant levels for public water systems.[5]

At this time, neither the EPA nor the FDA regulate the presence of microplastics in drinking or bottled water. The FDA does, however, regulate materials like plastic that come into contact with food and beverages, as either food contact substances or food additives.

A "food contact substance" is defined by the FDA as one that is intended for packaging food, but is not intended to have any technical effect on such food.[6] Food contact substances are subject to premarket notification requirements, with the FDA allowed 120 days to object to their use. If the agency does not object, the food contact substance may be used.[7]

The FDA's definition of a "food additive" includes any food containers or packages that may reasonably be expected to become a component, or to directly or indirectly affect the characteristics, of food packed in the container.[8] Food additives undergo a formal premarket approval process, and by regulation, the FDA has identified the plastics already determined safe for use as indirect food additives, and under what conditions they may be used.[9]

While state consumer fraud laws across the country vary in some respects, the basic premise of these laws is to bar unfair or deceptive acts in connection with consumer transactions. Typically, these laws permit recovery of economic damages based on what the consumer would have paid for the product if the alleged deception had not occurred.

With respect to alleged microplastics contamination of bottled water, plaintiffs have asserted consumer fraud claims based on representations that the bottled water was "pure" or "natural" despite the alleged presence of microplastics. Other potential claims could arise based on similar terms used in the product labeling or advertising for bottled water, or for the failure to disclose in product labeling that bottled water contains microplastics.

Consumer fraud claims arising from the nondisclosure of microplastics are likely preempted by the FDCA, which prevents states from imposing labeling requirements — including lawsuits based on state consumer fraud laws — that are not identical to FDA regulations.[10]

For example, in In re: Bisphenol-A (BPA) Polycarbonate Plastic Products Liability Litigation, the U.S. District Court for the Western District of Missouri in 2009 dismissed claims alleging failure to disclose the presence of BPA in baby formula, because the FDA has exempted disclosure of "incidental additives" from food labeling under Title 21 of the Code of Federal Regulations, Section 101.100(a).

The court found BPA to be an incidental additive under these regulations, because it was used in conformity with the FDA's conditions for the use of polymers or plastics in contact with food. Thus, the plaintiffs' claims in this case were preempted.[11]

While BPA is a chemical, not a plastic, the same regulations described above could preempt claims alleging failure to disclose the presence of microplastics in bottled water, assuming bottled water manufacturers followed the FDA's conditions for their use in Title 21, Section 177.1010 and the following sections.

With respect to claims that consumers were misled into believing that products were free of microplastics, FDCA preemption will depend upon the nature of the representations contained in the labeling or advertising.

For example, in 2018, a plaintiff filed Baker v. Nestle SA, a consumer class action, in the U.S. District Court for the Central District of California, claiming Nestle's description of its bottled water as "pure" was false and misleading under state consumer fraud laws based on the alleged presence of microplastics. As noted above, however, the FDA has established a standard of identity for bottled water.

As part of that regulation, the FDA expressly defined the conditions under which bottled water can be described as "purified water," and this definition makes no reference to microplastics.[12] Because Nestle's bottled water complied with the FDA's definition of "purified water," regardless of the presence of microplastics, the court found the plaintiff's claims preempted.[13]

In other words, the plaintiff sought to impose a definition of purified water that was different from what the FDA defined as permissible labeling. Thus, the court dismissed the plaintiff's case.

FDCA preemption will be more uncertain for microplastics consumer fraud claims that are not based on FDA standards of identity or other related provisions for bottled water. As an

example, in January, plaintiffs filed Daly v. The Wonderful Company LLC in Illinois, accusing The Wonderful Company of "intentionally labeling its products as Natural Artisan [sic] Water when they contain microplastics."

The plaintiffs also alleged that "bottled water that is contaminated with microplastics is not natural," and thus "natural" labeling is false and misleading.[14] Unlike the term "pure," however, the term "natural" has not been defined by FDA regulations, despite the agency having soliciting comments from interested persons about whether and how it should do so.[15]

So, while other fact-specific defenses may apply to bar plaintiffs' claims or prevent class certification, FDCA preemption as described above is unlikely to apply.

Conclusion

Food products like bottled water are increasingly likely to be targets of consumer fraud complaints due to alleged microplastics contamination, despite the lack of scientific evidence that human exposure to microplastics causes harm. Depending on the labeling or advertising at issue, the FDCA can provide a powerful preemption defense to such claims.

Tariq Naeem is a partner and Brenda Sweet is counsel at Tucker Ellis LLP.

[1] Daly v. The Wonderful Company LLC, Cook County Case No. 2024CH00349 (Jan. 18, 2024); Daly v. Danone Waters of America LLC, Cook County Case No. 2024CH01053 (Feb. 20, 2024).

[2] California passed a similar measure in 2015. In 2023, the European Union also banned microplastics in consumer products, but only those added intentionally to products that release the microplastics during use.

[3] If the poisonous or deleterious substance is not an added substance, however, the product is not adulterated if the quantity of the substance does not ordinarily render it injurious to health. 21 U.S.C. § 342(a).

[4] 21 U.S.C § 343(a).

[5] 21 U.S.C. § 349; 21 C.F.R. § 165.110.

[6] 21 C.F.R. § 170.3(e)(3).

[7] 21 U.S.C. § 348(h).

[8] See 21 C.F.R. § 170.3(e)(1).

[9] See 21 U.S.C. § 348; 21 C.F.R. § 177. FDA approvals for the plastics used to bottle water date back several decades, and while courts have not directly determined whether

private plaintiffs can recover damages from a manufacturer's use of those plastics to bottle water, such claims may be preempted.

[10] 21 U.S.C. § 343-1.

[11] See In re: Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig., No. 08-1967-MD, 2009 WL 3762965, at *5 (W.D. Mo. Nov. 9, 2009).

[12] 21 C.F.R. § 165.110(1)(2)(iv).

[13] See Baker v. Nestle SA, No. 2:18-cv-3097, 2019 WL 960204 (C.D. Cal. Jan. 3, 2019).

[14] Daly v. The Wonderful Company LLC, Cook County Case No. 2024CH00349 (Jan. 18, 2024).

[15] In light of the FDA's recognition of the need to evaluate the use of "natural" in food labeling, however, an argument exists that plaintiffs' claims should be stayed or dismissed pursuant to the primary jurisdiction doctrine pending the FDA's resolution of this issue. See, e.g., Kane v. Chobani LLC, 645 Fed. Appx. 593 (9th Cir. 2016) (staying litigation pursuant to primary jurisdiction doctrine based on the FDA's actions to assess definition of "natural" under the FDCA, because the issue "implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch") (internal citation omitted).