California microplastics case dismissed, MAHA Commission releases its report, federal PFAS priorities change, IARC classifies automotive gasoline, and more.

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California Microplastics Case Dismissed for Lack of Actual Reliance and Threshold Dose

A Northern District of California judge issued a sweeping dismissal of a microplastics class action that would have lowered the bar on the sufficiency of allegations of potential hazards from microplastics. In her order, the court rejected plaintiffs' attempts to hold defendants liable for violating California consumer protection laws by allegedly deceiving consumers about the potential existence of microplastics in infant bottles and sippy cups. Rather, the court insisted that plaintiffs must assert that microplastics present "an unreasonable safety hazard" based on the reasonably anticipated use of the products themselves. *Cortez v. Handi-Craft Co., Inc.*, No. 24-3782 (N.D. Cal., filed April 29, 2025).

The plaintiffs claimed that by portraying infant bottles and sippy cups as safe for use by infants and young children, even referring to them as "#1 Pediatrician Recommended," Handi-Craft Company had participated in a "campaign of reckless deception." When used as intended, the plaintiffs alleged the bottles and cups leached hazardous microplastics into infants' food and drink. The plaintiffs brought claims for violation of California's Unfair Competition Law (UCL); violation of California's False Advertising Law (FAL); violation of the California Consumers Legal Remedies Act (CLRA); breach of warranty; and unjust enrichment. Handi-Craft subsequently filed a motion to dismiss. The court dismissed the claims without prejudice, granting plaintiffs leave to amend their complaint.

The court dismissed the UCL, FAL and CLRA claims as to affirmative statements because the plaintiffs did not allege that they ever saw the products' "BPA Free" and "#1 Pediatrician Recommended" labels. The court also generally dismissed the plaintiffs' CLRA claim for failure to comply with the notice requirement of sending a demand letter to the defendant's principal place of business within California.

The court dismissed the UCL, FAL and CLRA claims as to fraudulent omissions because the plaintiffs failed to plausibly allege an unreasonable safety hazard that the defendant therefore had a duty to disclose. Notably, the plaintiffs failed to identify a threshold at which microplastics exposure to children would become unreasonably unsafe. Additionally, insofar as plaintiffs suggested that *no amount* of microplastic exposure can be safe, the court held that such an expansive theory of harm would "impermissibly broaden the duty to disclose to any *potential*—and not just unreasonable—safety hazard." The plaintiffs also failed to plausibly allege that the defendant had actual knowledge of the alleged risks of its products because the complaint lacked substantiated facts of exclusive knowledge. General industry knowledge of the alleged risks was lacking because the plaintiffs merely provided publicly available studies that did not reference defendant's products and only had general conclusions about the potential health risks associated with microplastics.

The court dismissed the breach of warranty claim because the plaintiffs failed

to allege they actually relied on the "BPA Free" and "#1 Pediatrician Recommended" labels. The court dismissed the unjust enrichment claim, as it was based on the same conduct as the statutory claims, and thus was subject to dismissal for the same reasons as the UCL, FAL and CLRA claims.

Also notably, the court dismissed the plaintiffs' request for injunctive relief, concluding that they failed to plausibly allege actual and imminent injury. The court noted that while the plaintiffs alleged they wanted to repurchase the defendant's products in the future, they also stated in their complaint that there was no safe level of microplastics. Accordingly, the plaintiffs' claims that they would repurchase were contradictory and implausible.

Ultimately, the plaintiffs voluntarily dismissed their case on May 20, 2025, instead of amending their complaint. As the *Cortez* court's opinion illustrates, plaintiffs who bring deceptive labeling microplastics cases should be prepared to allege actual reliance on any alleged unlawful labeling. The plaintiffs must also allege, with specific thresholds necessary to cause harm, how an alleged safety hazard was unreasonable, and be able to allege with substantiated facts that a defendant or the industry knew of the alleged unreasonable hazard. Absent these showings, microplastics cases that allege these types of claims face an uphill battle.

Make America Healthy Again Commission Releases Childhood Health Assessment

President Donald Trump's Make America Healthy Again (MAHA) Commission, created by executive order, reported to the president that "[t]he cumulative load of thousands of synthetic chemicals that our children are exposed to through the food they eat, the water they drink, and the air they breathe may pose risks to their long-term health, including neurodevelopmental and endocrine effects." The Commission's Report, "Make Our Children Healthy Again Assessment," is the first step in the administration's attempt to identify

the root cause of childhood diseases.

The MAHA Report claims to have identified four major drivers believed to be behind the rise in childhood chronic disease, including the cumulative load of chemicals in our environment. According to the report, "[n]early 25% of U.S. children live within close proximity to one of 1,341 Superfund sites," and these sites, "depending on their level of contamination and clean up status, could further compound their risk for chemical exposures and associated adverse outcomes." Aside from chemicals in the environment, the report also blames childhood chronic disease on poor dietary habits—including the consumption of ultra-processed foods high in calories and additives and low in nutritional value—the pervasive use of technology, and abuse of prescription medication.

The report's focus on environmental chemicals is not novel. The chemicals specially targeted in the report are those frequently reported in the popular literature, including persistent organic pollutants and pesticides, PFAS, microplastics, metals, phthalates, bisphenols, and fluoride. Critics of the report have noted it to be short on new science.

The report identifies the need to better understand the cumulative load of multiple exposures and how it may impact children's health. The report also identifies new and potential regulatory changes, including the implementation of federal drinking water standards for two PFAS compounds, potential revisions to the federal drinking water standard for fluoride, and an updated U.S. government health assessment on common herbicides that is expected in 2026. The report also notes that the U.S. Environmental Protection Agency will consider regulatory determinations for another four PFAS compounds. The implications of potential regulatory changes on the remediation of Superfund sites, chemical, pesticide, and consumer product manufacturing, and other industries may be significant.

The report concludes by recommending the implementation of several research initiatives, such as AI-Powered Surveillance and Precision Toxicology, and states that the MAHA Commission will immediately begin working on developing an implementation strategy, which is due in August 2025.

IARC Re-classifies Automotive Gasoline as Group 1 "Carcinogenic to Humans"

Thirty-seven years after an International Agency for Research on Cancer (IARC) Working Group classified automotive gasoline as a Group 2B "possibly carcinogenic to human" chemical, another IARC Working Group has reclassified it as well as "some oxygenated gasoline additives." On March 21, 2025, the IARC Working Group determined that automotive gasoline is a Group 1 "carcinogenic to humans" chemical based on what it alleges is sufficient evidence of cancer in human and experimental animal studies along with strong mechanistic evidence in exposed humans and experimental studies. According to the Working Group, automotive gasoline causes urinary bladder cancer and acute myeloid leukemia (AML) in adults. The Working Group reportedly found "limited" evidence that automotive gasoline causes myelodysplastic syndromes (MDS), non-Hodgkin lymphoma, multiple myeloma, and cancers of the stomach and kidney. Moreover, the group found "limited" evidence for automotive gasoline causing acute lymphoblastic leukemia (ALL) in children.

Five gasoline additives—volatile compounds increasing the combustion efficiency of gasoline—were also evaluated:

1. Methyl tert-butyl ether (MTBE)
2. Ethyl tert-butyl ether (ETBE)
3. Tert-butyl alcohol (TBA)
4. Diisopropyl ether (DIPE)
5. Tert-amyl methyl ether (TAME)

Based on the Working Group's assessment, the evidence of carcinogenicity for the additives was not as strong as the evidence of carcinogenicity for

automotive gasoline. MTBE and ETBE were classified as Group 2B “possibly carcinogenic to humans” based on purportedly “sufficient” evidence for cancer in experimental animal studies, with ETBE also having “strong” mechanistic evidence in experimental systems. MTBE and ETBE are no longer used in the United States but are used in other countries. TBA, DIPE and TAME were classified as Group 3 “not classifiable as to its carcinogenicity.” The Working Group further determined that there is “inadequate” evidence to show the five additives cause cancer in humans.

According to IARC, the primary route of exposure to automotive gasoline is through inhalation of vapor in occupational and general populations. Workers may be exposed to gasoline additives during production and by gasoline vapors containing the additives. The Working Group found the general population can be exposed to additives from vapors at gas stations, air pollution and gasoline spills contaminating water and soil.

IARC acknowledged that the risk of cancer associated with substances assigned the same classification can be very different based on a variety factors such as route and duration of exposure. IARC does not make health care recommendations. IARC evaluations have been used in litigation to support personal injury lawsuits. Given widespread use of automotive gasoline, some litigation is likely to occur due to the Working Group’s classification. The Working Group’s assessment should be carefully analyzed rather than simply taken at face value. The IARC Working Group’s detailed assessment will be formally published as Volume 138 of the IARC Monographs.

6PPD-Q: An Emerging Substance on the Move

6PPD [(N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine) (CASRN 793-24-8)], an organic chemical used as a stabilizing additive in rubbers, has gained attention from regulators and litigators in recent months. Since 1970, 6PPD has commonly been used as an antidegradant in vehicle tires. It is an

effective antioxidant, protecting the rubber from reactions with ground-level ozone and other reactive oxygen species, keeping the tire surface smooth. When 6PPD reacts with ozone in the air, it can form 6PPD-quinone (6PPD-Q). As tires contact roads, they can release minute tire-wear particles. When it rains, stormwater can wash these particles off roads and parking lots into water bodies.

6PPD and 6PPD-Q have recently piqued the interest of environmental groups. In June 2023, the Center for Biological Diversity filed a notice of intent to California, Oregon and federal transportation departments alleging violations of the Endangered Species Act. Similarly, in November 2023, two commercial fishing groups sued 13 tire manufacturers in California alleging violations of the federal Endangered Species Act and seeking a permanent injunction of the use of 6PPD in tires.

But that's not all—two states have since taken regulatory action to address 6PPD. In March 2024, Washington state enacted a bill to reduce sources and uses of 6PPD in the state. In January 2025, the Washington State Department of Ecology set forth new 6PPD-Q monitoring requirements in its Industrial Stormwater General Permit. In October 2023, the California Department of Toxic Substances Control (DTSC) identified tires containing 6PPD as a "priority product."

Federally, agencies have made efforts to fully understand the effects of this emerging substance. The National Toxicology Program has formed a working group on 6PPD-Q to understand the effects on human health. In November 2024, the U.S. Environmental Protection Agency (EPA) released a 6PPD/6PPD-quinone Action Plan that will run from 2025 to 2028. In December 2024, in response to the tribal petition, EPA finalized a rule under Section 8(d) of the Toxic Substances Control Act (TSCA) that requires manufacturers (including importers) of 6PPD to report lists and copies of unpublished health and safety studies on 6PPD and 6PPD-Q to EPA.

EPA’s PFAS Saga Continues as Changes and Commitments Conflict

On May 12, 2025, the U.S. Environmental Protection Agency (EPA) announced it will delay the commencement of the Reporting Rule under the Toxic Substances Control Act's (TSCA) Section 8(a)(7). In that same announcement, EPA reported that it is also considering reopening the entire Rule to make substantive revisions. The Rule requires manufacturers and importers of PFAS between 2011-2022 to report data on issues of exposure and environmental and human health effects. The agency changed the start date for submissions under the Rule to April 13, 2026, with an alternate end date of April 13, 2027, for small manufacturers reporting exclusively as article importers. EPA explained that the change is necessary because the agency requires more time to prepare the reporting application.

On May 14, 2025, EPA also announced that it plans to withdraw its drinking water standards under the Safe Drinking Water Act (SDWA) for four of the six PFAS subject to earlier EPA regulations (PFHxS, PFNA, HFPO-DA [GenX], and the Hazard Index mixture of these three plus PFBS). These announcements are consistent with EPA’s strategic plan released on April 28, 2025, to address PFAS across all program offices. These actions signal that EPA is taking steps to provide regulated entities more flexibility and potential relief from some federal requirements pertaining to PFAS.

Although EPA has committed to retaining the 4 parts per trillion PFOS and PFOA limits, the agency announced that, by separate regulation, it would propose to extend the compliance date from 2029 to 2031 to provide drinking water systems with additional flexibility. EPA also stated it will be developing a new framework for federal exemption. Challenges to the Biden Administration’s final enforceable drinking water standards for these PFAS are still being litigated in the U.S. Court of Appeals for the District of Columbia Circuit, although those cases are currently stayed at the request of the Trump Administration.

In contrast to the changes aimed at affording industry flexibility with respect to PFAS regulations, EPA Administrator Lee Zeldin has recently emphasized that the current administration will be guided by the mindset that PFAS polluters should pay for contamination and that passive receivers of PFAS contamination should be "protected" for bearing the cost and liability of that contamination. The announcement does not specify many dates or other timeframes for accomplishing various PFAS commitments, but it does make clear that "[t]his list is the first, not the last, of all decisions and actions EPA will be taking to address PFAS over the course of the Trump Administration."

Extended Producer Responsibility Regulations on the Rise

State Extended Producer Responsibility (EPR) regulations are on the rise for packaging, paper products, beverage containers and other similar products. These regulations assign responsibility to producers for the entire life of various products, including after the use of the products has expired. EPR regulations impose reporting requirements and penalties for non-compliant producers. To date, five states have enacted EPR regulations—California, Colorado, Maine, Minnesota and Oregon—while 12 other states have introduced EPR legislation. Unfortunately, but not surprisingly, these states have not coordinated the rulemaking of EPR regulations, meaning that definitions, deadlines, reporting requirements and penalties are different in the enacted and proposed EPR regulations. The regulations also contain various exclusions and limitations to these defined terms depending on the state, even though these critical terms directly affect whether a company is defined as a producer and thus responsible under EPR regulations. Shook attorneys are working to compare and contrast pending and enacted EPR regulations to better organize and coordinate compliance efforts across the United States. Check back for updates on EPR regulations in future issues of *Material Concerns*.

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