Flexible Packaging Association
Connecting. Advancing. Leading.

185 Admiral Cochrane Drive
Suite 105
Annapolis, MD 21401

Tel (410) 694-0800
Fax (410) 694-0900

www.flexpack.org

June 3, 2026

U.S. Environmental Protection Agency (EPA)
Office of Ground Water and Drinking Water
1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460
Submitted via: regulations.gov Docket ID: EPA-HQ-OW-2022-0946

RE: RFI on the U.S. Environmental Protection Agency's Draft Sixth Contaminant Candidate List (CCL 6): Microplastics in Drinking Water. Docket ID No. EPA-HQ-OW-2022-0946

Dear Assistant Administrator Kramer,

The Flexible Packaging Association (FPA) appreciates the opportunity to comment on the U.S. Environmental Protection Agency (EPA) Draft Drinking Water Contaminant Candidate List 6 (CCL 6), published April 6, 2026, and specifically on the proposed inclusion of *microplastics* as a candidate contaminant group. These comments are submitted in the spirit of constructive engagement and reflect our genuine commitment to the protection of public health and the integrity of the Safe Drinking Water Act (SDWA) regulatory framework.

FPA is the voice of the U.S. manufacturers of flexible packaging and their suppliers. The association's mission is connecting, advancing, and leading the flexible packaging industry. Flexible packaging is produced from paper, plastic, film, aluminum foil, or any combination of those materials, and includes bags, pouches, labels, liners, wraps, rollstock, and other flexible products. Flexible packaging is the fastest-growing and second largest segment of the U.S. packaging industry, representing $51.5 billion in annual sales and approximately 98,000 flexible packaging manufacture employees in the U.S.

We wish to be direct at the outset: the FPA does not dispute that microplastics in drinking water are a legitimate subject of scientific concern and continued investigation**.** However, based on careful review of the current scientific literature, including the World Health Organization (WHO)

authoritative assessment[1] and the EPA's own statements on microplastics in drinking water[2], we believe the science has not yet advanced to a stage where inclusion of microplastics on the CCL 6 adds meaningful regulatory value, and may in fact consume significant resources that would be better directed toward better-established risks. Although there has been significantly more research on this issue since the WHO published their comprehensive summary of data in 2019, the academic community is still steadfast that the scientific body of work has not yet advanced to the degree that key sources, risks and interventions can confidently be identified.[3] We urge EPA to seriously consider this conclusion and whether microplastics should be included in finalizing the CCL 6.

No Scientifically Agreed-Upon Definition of Microplastics Exists

A foundational prerequisite for inclusion on the CCL is that the subject contaminant be sufficiently defined to allow meaningful occurrence monitoring, exposure assessment, and health evaluation. *Microplastics fail this threshold test.*

While the EPA defines microplastics as plastic particles ranging in size from 5 millimeters (mm) to 1 nanometer (nm), the WHO has explicitly acknowledged:

> *"…this is a rather arbitrary definition and is of limited value in the context of drinking-water since particles at the upper end of the size range are unlikely to be found in treated drinking-water."* [4]

This is not a minor technical quibble. Without a meaningful definition:

---

[1] World Health Organization (WHO). (2019). *Microplastics in Drinking-Water*. Geneva: World Health Organization. License: CC BY-NC-SA 3.0 IGO.

[2] As noted within the FAQ's associated with this Regulatory filing "*As of the publication of the draft CCL 6, there remain significant data gaps for microplastics that will require further research before the Agency can fully understand the risks associated with microplastics in drinking water*."

[3] Cai, T.; Tang, Z.; Gu, T.; Tong, K.; Wang, X.; Chen, H.; Zhou, X.; Long, Z.; Hao, C.; Chen, C.; et al. (2025) "Microplastics in Drinking Water: A Review of Sources, Removal, Detection, Occurrence, and Potential Risks." Toxics: 13, 782. https://doi.org/10.3390/toxics13090782
Chandra, Shaneel; Walsh, Kerry B. (2024) "Microplastics in Water: Occurrence, fate and removal" Journal of Contaminant Hydrology 264, 104360 https://doi.org/10.1016/j.jconhyd.2024.104360

[4] World Health Organization (WHO). (2019). *Microplastics in Drinking-Water*. Geneva: World Health Organization. License: CC BY-NC-SA 3.0 IGO.

- Monitoring data collected by different utilities cannot be meaningfully compared;
- The "universe" of what EPA is proposing to study is undefined;
- No enforceable or even informational standard can be rationally derived;
- Regulated entities have no guidance on what to measure or how.

The CCL 6's group listing approach for microplastics compounds this problem. We note that the EPA has not yet described the scope and boundaries of microplastics; the scientific basis for grouping; nor the intended path from a group listing to any future determinations. Without answers to these questions, the microplastics listing cannot be made actionable.

Heterogeneity Renders Group Risk Assessment Unreliable

Microplastics as a class include:

- *Multiple polymer chemistries* (polyethylene, polypropylene, polyethylene terephthalate, polystyrene, polyvinyl chloride, nylon, and many others);
- *Particle sizes* ranging over six orders of magnitude (from sub-micron nanoplastics to 5 mm particles);
- *Diverse shapes* (fragments, fibers, films, beads, pellets);
- *Variable chemical additive loads* (plasticizers, flame retardants, UV stabilizers, colorants);
- *Variable sorbed environmental contaminants* (hydrophobic organic chemicals, heavy metals); and
- *Variable biological surface colonization* (biofilm composition differs by particle type, age, and environmental origin).

The WHO has confirmed that in drinking water studies, fragments and fibers predominated, with polyethylene terephthalate and polypropylene being the most frequently detected polymers. But even this partial characterization cannot be generalized across treatment

systems, geographic regions, or source water types. A single CCL group listing cannot capture this variability in any scientifically meaningful way.

Existing Microplastics Studies Lack Reliability

The quality of the scientific literature on microplastics in drinking water is insufficient to support the rigor that a CCL listing implies. The WHO reviewed 52 studies and concluded: *"…that most of these studies are not fully reliable because their methods lacked sufficient quality control. Results should therefore be interpreted with caution."* More recent scientific reviews came to similar conclusions.[5]

Specific quality control deficiencies identified include:

- Inadequate sample treatment protocols;
- Insufficient laboratory preparation and clean air conditions;
- Absence of positive controls; and
- Inconsistent polymer identification methods.

The range of reported microplastic concentrations in drinking water — from 0 to 10,000 particles/L in individual samples, and mean values from 10^{-3} to 1,000 particles/L[6] reflects this methodological chaos far more than it reflects actual variation in contamination. This is a five-to-seven order of magnitude range in reported values. Such data cannot support a rational future regulatory determination.

[5] Cai, T.; Tang, Z.; Gu, T.; Tong, K. ;Wang, X.; Chen, H.; Zhou, X.; Long, Z.; Hao, C.; Chen, C.; et al. (2025) "Microplastics in Drinking Water: A Review of Sources, Removal, Detection, Occurrence, and Potential Risks." Toxics: 13, 782. https://doi.org/10.3390/toxics13090782
Chandra, Shaneel; Walsh, Kerry B. (2024) "Microplastics in Water: Occurrence, fate and removal" Journal of Contaminant Hydrology: 264, 104360 https://doi.org/10.1016/j.jconhyd.2024.104360

[6] World Health Organization (WHO). (2019). *Microplastics in Drinking-Water*. Geneva: World Health Organization. License: CC BY-NC-SA 3.0 IGO.

No Validated Standard Method Exists

The EPA cannot meaningfully list microplastics as a CCL candidate for potential regulation without a validated standard analytical method. The Agency cannot later issue a National Primary Drinking Water Regulation — or even meaningful monitoring requirements under an Unregulated Contaminant Monitoring Rule (UCMR) — for a contaminant it cannot consistently measure. While we understand the addition of a contaminant to the CCL permits for further study and does not assume regulation will follow, we strongly assert that method development should precede CCL listing, not follow it. Otherwise, the monitoring data that the CCL listing is intended to generate will be of limited interpretive value.

No Established Tolerable Daily Intake or Health-Based Benchmark for Microplastics

To date, neither EPA, WHO, nor any other major regulatory body has established for microplastics:

- A health-based guideline value for drinking water;
- A tolerable daily intake (TDI);
- A reference dose (RfD); or
- Any equivalent health-protective benchmark.

EPA's CCL 6 listing cannot logically be premised on protecting against risks that cannot yet be quantified. The SDWA's risk-based framework requires more than scientific unease — it requires a path to risk characterization. That path does not currently exist for microplastics. We note that in April of this year, the federal government, through Health and Human Services, Advanced Research Projects Agency for Health (ARPA-H) is beginning the process of developing this necessary toolbox through the launch of its initiative Systematic Targeting Of MicroPlastics (STOMP). In their press release ARPA-H noted:

> *"---to date, we are still remarkably in the dark. We don't have a precise way to measure microplastics in our organs, nor do we understand which ones are affecting us in what ways—because each plastic works differently. This is*

important: We can't clear what we can't measure, and we can't develop interventions that are precise, safe, and effective for impacts we don't understand."[7]

The FPA argues that this research should be completed prior to the EPA acting on microplastics within the CCL 6. According to STOMP timelines, the earliest initial data could be ready in two and one half years, and it will be at least five years before the conclusion of these findings. We therefore argue that microplastics should not be on the CCL until this research is concluded.

Treatment Is Already Effective — Undermining the Case for Regulation

A critical consideration in evaluating whether a CCL listing is appropriate is whether regulation would meaningfully reduce risk. Several studies on treatment effectiveness indicate that most microplastics can be removed from drinking water with proper treatment.[8]

Conventional drinking water treatment processes — coagulation, flocculation, sedimentation, filtration — are designed to remove particulate matter across a range of sizes and densities. These processes incidentally capture microplastic particles without any microplastic-specific modifications. This means that:

1. Utilities operating optimized treatment systems are already achieving meaningful microplastic reduction as a co-benefit of compliance with existing turbidity and particle removal requirements; and
2. Regulatory requirements specifically targeting microplastics would likely impose monitoring and reporting costs without producing commensurate additional treatment improvements in well-operated systems.

[7] Health and Human Services (HHS) (April 2026) "ARPA-H launches groundbreaking, $144 million program to combat toxic microplastics in the human body" https://www.hhs.gov/press-room/arpa-h-launches-groundbreaking-144-million-program-combat-toxic-microplastics-human-body.html
[8] Please review previous papers referenced

The WHO recommends that water suppliers "…*ensure that control measures are effective, including optimizing water treatment processes for particle removal and microbial safety, which will incidentally improve the removal of microplastic particles*."[9] This co-benefits approach, improving treatment for established risks while incidentally reducing microplastics, is more cost-effective and scientifically grounded than a microplastics-specific regulatory track.

Opportunity Cost of Regulatory Attention

The SDWA framework requires EPA to prioritize contaminant candidates most likely to "*present public health risk*." Every monitoring program designed around microplastics, every UCMR cycle devoted to poorly defined microplastic measurements, and every EPA staff-hour spent on microplastics occurrence analysis represents an opportunity cost. Unlike monitoring costs for contaminants with established health-based guidelines, these costs cannot be justified by a clear protective benefit — because no health-based threshold has been established for microplastics.

FPA argues that EPA resources would be better directed toward contaminants for which:

- Validated analytical methods exist;
- Dose-response data support risk characterization;
- Treatment options are distinct and specific; and
- The evidence of harm at realistic exposure levels is credible.

Alternatives to CCL 6 Inclusion

We offer the following constructive alternatives that would advance microplastics science without the premature regulatory signal of CCL inclusion:

1. **Commission a Formal Research Agenda Prior to Listing**

[9] World Health Organization (WHO). (2019). *Microplastics in Drinking-Water*. Geneva: World Health Organization. License: CC BY-NC-SA 3.0 IGO.

EPA could formally commission a targeted microplastics research agenda in coordination with other federal agencies such as ARPA-H. The agenda should address the data gaps including, but not limited to:

- Standardized, validated analytical methods for microplastics in finished drinking water;
- Epidemiological and mechanistic toxicology studies at environmentally relevant exposure levels via ingestion;
- National occurrence characterization using standardized methods across diverse water system types; and
- Dose-response assessment for priority polymer types, sizes, and shapes.

This approach aligns directly with the broader academic community calls for targeted, well-designed and quality-controlled investigative studies and would produce the scientific foundation needed for a future CCL listing to be meaningful.

2. Prioritize Method Development Through Collaborative Research and Voluntary Pilot Programs

Rather than utilizing a formal CCL listing to drive data collection, EPA should leverage its research authorities under SDWA Section 1442 to sponsor voluntary pilot monitoring programs. This could be achieved through a collaborative framework with organizations like the Water Research Foundation (WRF) and a voluntary cohort of public water systems. Such a pilot program would be dedicated strictly to analytical method validation and baseline occurrence characterization under controlled conditions. This approach would avoid the administrative and legal triggers of a formal regulatory listing while generating the high-quality, standardized data necessary to inform future CCL cycles.

3. Conditional Listing Framework

If EPA believes CCL listing for microplastics serves a useful purpose in signaling research priorities, it could consider establishing a "pre-candidate" or "watch list" tier for contaminants where scientific interest is high, but the evidence base is insufficient for standard CCL listing. This would allow EPA to acknowledge the importance of microplastics research without implying the same degree of regulatory proximity as a full CCL listing implies. This is the approach the European regulatory bodies have taken as they have designated microplastics as a “watch list” substances for monitoring.

4. Engagement With International Efforts and WHO

We encourage the EPA to engage with international regulatory bodies currently working on microplastics standards and monitoring frameworks. Alignment with international efforts would reduce duplicative investment, promote comparable data collection, and leverage the substantial resources already being invested globally in the study of microplastics.

5. Transparent Articulation of CCL-to-Regulation Pathway

At minimum, if EPA ultimately proceeds with listing microplastics on the CCL, it should publicly articulate with specificity what regulatory development pathway it envisions for microplastics. What data gaps must be filled before NPDWR development can begin? What would trigger advancement from CCL to regulatory determination? What analytical method would EPA use? How would a health-based standard be derived? Without answers to these questions, the CCL listing creates the illusion of a regulatory trajectory without an actual roadmap.

Conclusion

The FPA wishes to reiterate our acknowledgment that microplastics in drinking water are a legitimate and serious subject for scientific attention. We do not oppose research, method

development, voluntary pilot monitoring, or international coordination. We urge that regulatory tools be reserved for the stage in the scientific process at which they can add genuine value.

That stage has not yet arrived for microplastics. The scientific literature is characterized by methodological inconsistency, definition ambiguity, and a near-complete absence of human dose-response data at realistic exposure levels. Existing drinking water treatment systems already provide co-benefits in microplastic removal. No health-based standard can be rationally derived with the existing evidence base.

Proceeding with a CCL 6 listing for microplastics under these circumstances will not protect public health. It will divert regulatory attention, impose unjustified costs, and risk undermining public confidence in the SDWA's risk-based integrity.

We appreciate the Agency's consideration of these comments and stand ready to engage constructively as this matter develops.

Respectfully,

Kyla Fisher
Director of Regulatory Affairs and Sustainability
Flexible Packaging Association (FPA)