NATIONAL ASSOCIATION OF Manufacturers

June 05, 2026

The Honorable Jessica Kramer
Assistant Administrator
Office of Water
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

**Re: Comments of the National Association of Manufacturers; Drinking Water Contaminant Candidate List 6, 91 Fed. Reg. 17,186 (April 12, 2026); Docket No. EPA–HQ–OW–2022–0946**

Dear Assistant Administrator Kramer:

The National Association of Manufacturers ("NAM") respectfully submits these comments on the draft contaminant candidate list ("CCL") issued by the U.S. Environmental Protection Agency ("EPA"), *Drinking Water Contaminant Candidate List 6—Draft,* 91 Fed. Reg. 17,186 (April 6, 2026) ("CCL 6").

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.9 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

The EPA's draft CCL 6 includes 75 chemicals, four chemical groups, and nine microbes. The NAM appreciates the opportunity to submit comments on the draft CCL 6 and supports the EPA's efforts to identify research needs and prioritize information development for contaminants that may warrant future evaluation under the Safe Drinking Water Act ("SDWA"). The NAM's comments focus on the proposed listings for microplastics and pharmaceuticals, both of which EPA identifies as areas warranting additional research and data collection.

The NAM recognizes that the EPA has previously included chemical groups on prior CCLs, including CCL 5, which included cyanotoxins, disinfection byproducts, and per- and polyfluoroalkyl substances ("PFAS") as chemical groups.[1] However, those prior listings generally had more concrete organizing principles than do the CCL 6 proposed listings for microplastics and pharmaceuticals. For example, disinfection byproducts are organized around formation through drinking water disinfection, cyanotoxins around a biological toxin category, and PFAS around chemical structural criteria. By contrast, "microplastics" is a heterogenous material category, not a conventional chemical class, and "pharmaceuticals" encompasses a broad range of substances meeting the general definition of a "drug" under the Federal Food, Drug, and Cosmetic Act ("FFDCA"). This distinction makes the inclusion of clear limiting principles especially important if the Agency includes either group in a finalized CCL 6.

Group listings may be appropriate tools for organizing research priorities, but they should not be treated as findings that every substance, particle, or material within the group presents the same

[1] Drinking Water Contaminant Candidate List 5—Final, 87 Fed. Reg. 68,060, (Nov. 14, 2022).

drinking water risk, occurs in public water systems at levels of public health concern, or should be regulated on a group-wide basis.

As the EPA recognizes in the draft notice, the CCL is the first step in the SDWA regulatory framework. The inclusion of a contaminant on the CCL, whether individually or as part of a group, does not mean that the contaminant will necessarily be regulated. Rather, the CCL identifies unregulated drinking water contaminants that may warrant further investigation for potential health effects and occurrence in drinking water. Determinations of whether or not to regulate under the SDWA require demonstrating, at least and in the aggregate, that: the contaminant may have an adverse effect on human health; the contaminant is known to occur or is substantially likely to occur in public water systems with a frequency and at levels of public health concern; and that regulation presents a meaningful opportunity for health risk reduction.[2]

The NAM questions whether the EPA needs to finalize overly broad group listings for pharmaceuticals and microplastics on the CCL 6 in order to identify research needs and prioritize further information development. The EPA could continue to use other research planning tools, public nominations, and Science Advisory board consultations to identify the information needed to refine potential future contaminant categories. If the EPA moves forward to finalize any group listing for microplastics or pharmaceuticals, it is imperative that clear and explicit guardrails be applied. Further, the EPA should clearly state that any future regulatory determination, Unregulated Contaminant Monitoring Rule ("UCMR") monitoring decision, or National Primary Drinking Water Regulation ("NPDWR") development will be based on contaminant-specific, subgroup-specific, or otherwise clearly defined categories supported by validated methods and fit-for-purpose health and occurrence data in alignment with the Trump administration's commitment to Gold Standard Science.[3] The EPA should also explain how it will define each group for SDWA purposes, identify priority subgroups or individual substances, and determine when the available science is sufficient to support further action.

## I. Microplastics Listing Should be Treated as a Research Prioritization Step if Retained

The NAM recognizes the growing public and scientific interest in microplastics, including drinking water sources. The EPA's framing of microplastics in draft CCL 6 appears to be intended as a first step toward defining and better understanding the potential public health risks from drinking water exposure. The NAM agrees there is insufficient evidence to support treating "microplastics" as a single contaminant for regulatory purposes.

The EPA aptly identifies "significant data gaps" that must be addressed before the Agency can fully understand the risks, if any, associated with microplastics in drinking water.[4] The identified data gaps include the need for a health-based definition, validated detection technology, better understanding of microplastics combined with other substances, and improved source attribution.

The NAM supports continued Agency research and strategic filling of data gaps on microplastics without finalizing a listing of microplastics as an overly broad group in CCL 6. If microplastics are included in the final CCL 6, the NAM recommends the Agency preserve a clear distinction indicating that listing microplastics may help prioritize research. Additionally, the Agency should clarify that such a decision does not imply microplastics as a broad group occur in public water systems at levels of

[2] Safe Drinking Water Act § 1412(b)(1)(A).
[3] Exec. Order No. 14,303, *Restoring Gold Standard Science*, 90 Fed. Reg. 22,601 (May 29, 2025). In particular, the NAM emphasizes that the Executive Order requires agencies transparently acknowledge and document scientific uncertainties, use science that comports with the legal standards applicable to the relevant determinations, and apply a "weight of scientific evidence" approach. These requirements are especially relevant for CCL 6 and subsequent determinations because the proposed CCL include broad contaminant categories and the proposed listing of microplastics is a departure from the standard CCL selection process.
[4] 91 Fed. Reg. 17,193.

public health concern nor that regulation of the group would lead to a presumption of a meaningful opportunity for health risk reduction.

## II. A Health-Based, Drinking-Water-Relevant Definition of Microplastics Must Be Developed Before Proceeding to Monitoring or Regulatory Determination

The EPA correctly identifies the need for a "health-based definition" of microplastics, including the characteristics most associated with potential adverse health effects in humans from drinking water exposure, such as color, polymer, shape, and size.[5] The EPA should not proceed as though microplastics are a single, uniform group because the science has yet to establish clear hazard and risk profile for such a categorization in regards to its occurrence in drinking water.

The NAM agrees that the term "microplastics" may encompass particles that vary by size range, polymer type, particle morphology, surface chemistry, additives, aging or weathering, sorbed chemicals, or associated biological and environmental matrices. These are important differences that require consideration when contemplating a definition of microplastics in an SDWA context, as they may affect detection, exposure, bioavailability, hazard identification, and risk characterization.

The EPA should therefore initiate a transparent process, with the Science Advisory Board, to develop a fit-for-purpose definition for microplastics in drinking water. That definition should identify the particle characteristics relevant to potential human health effects from ingestion through drinking water and should acknowledge diversity of particle size, polymers, additives. The EPA should also recognize that microplastics may be co-located with other biological, inorganic, organic, and other environmental materials and molecules.

## III. Validated Analytical Methods are Necessary Before Any National Monitoring Requirement for Microplastics

The EPA appropriately recognizes that reliable microplastics monitoring depends on validated analytical methods with appropriate quality control, accuracy, and precision.[6] This should be a prerequisite to any national monitoring requirement.

Method validation is necessary to ensure that monitoring results reflect true differences in occurrence, not artifacts of sampling, extraction, preparation, contamination, particle identification, calibration, recovery, detection capability, or reporting conventions. Without robust, validated, and reproducible methods, monitoring data would lack the demonstrated accuracy, precision, sensitivity, selectivity, quality controls, and measurement traceability needed to support meaningful comparison across laboratories, public water systems, regions, and time periods.

Microplastics analysis presents unique methodological challenges. Sampling, extraction, preparation, identification, and quantification methods are not yet standardized across the field. Samples can be contaminated by air, labware, filters, clothing, reagents, and handling.[7] Matrix effects can also affect extraction efficiency, particle recovery, and quantitation.[8] Methods may differ in whether they report particle counts, mass, polymer type, size distribution, morphology, or other distinct parameters.

[5] *Id.*
[6] *Id.*
[7] D. Materić, Nanoplastics measurements must have appropriate blanks, *Proc. Natl. Acad. Sci. U.S.A*. 121 (48) e2411099121, https://doi.org/10.1073/pnas.2411099121 (2024).
[8] Hankett, J.M., Holtz, J.L., Walker-Franklin, I. et al. Matrix Matters: novel insights for the extraction, preparation, and quantitation of microplastics in a freshwater mesocosm study. *Micropl.&Nanopl.* 3, 13 (2023). https://doi.org/10.1186/s43591-023-00062-6.

Commonly used techniques such as microscopic analysis, thermal analysis, mass spectrometry, spectroscopic analysis, energy spectrometry, and combinations of analytical techniques all have strengths and limitations.[9] These limitations complicate efforts to compare results across studies or translate environmental detection into drinking water exposure and risk.

The EPA should develop, validate, and peer review standardized drinking water methods before considering microplastics monitoring under the UCMR or any other national monitoring program. At minimum, the EPA should specify target particle size ranges, polymer identification criteria, sample collection procedures, field and laboratory blank requirements, contamination-control protocols, reporting units, method detection limits, interlaboratory validation expectations, and data comparability criteria, and a federal laboratory quality or accreditation program requiring ongoing proficiency for laboratories conducting national monitoring. The need for this type of rigor is consistent with the Agency's own recognition that reliable microplastics detection requires validated analytical methods with appropriate quality control, accuracy, and precision. The EPA should also consider methodological work already underway in state and international contexts, including California's drinking water methods using Raman[10] and infrared spectroscopy,[11] while ensuring that any federal approach is appropriate for national SDWA implementation.

## IV. Distinguish Between Environmental Presence, Human Exposure, and Drinking Water Risk of Microplastics

The EPA should clearly distinguish between the detection of microplastics in environmental or biological media, potential human exposure, and the statutory questions relevant to SDWA regulation. The mere existence of microplastics in the environment does not establish that microplastics occur in finished drinking water at levels of public health concern, nor that regulation would present a meaningful opportunity for health risk reduction.

For purposes of the SDWA, the EPA should separately evaluate source water occurrence, finished water occurrence, potential distribution system contributions, and aggregate exposure from non-drinking-water sources. Drinking water may be one potential exposure pathway, but the EPA should assess its relative contribution before using SDWA tools. Studies evaluating human exposure pathways for microplastics reinforce that drinking water should be considered in the context of total exposure, rather than assumed to be the dominant or most risk-relevant pathway.[12]

The EPA should also distinguish empirical detection from physiological relevance. In evaluating potential health concerns, the EPA should focus on whether detected particles are likely to be bioavailable, persistent in biological systems, capable of crossing or interacting with relevant biological barriers, and particles are present at concentrations with characteristics associated with plausible

[9] Miao Li, Zhongxing Zhao, Zhenxia Zhao, and Min Li, Review of Techniques for the Detection, Removal, and Transformation of Environmental Microplastics and Nanoplastics, ACS Applied Materials & Interfaces 2025 17 (14), 20560-20589, DOI: 10.1021/acsami.5c02306.

[10] State Water Resources Control Board, Standard Operating Procedures for Extraction and Measurement by Raman Spectroscopy of Microplastic Particles in Drinking Water (Sept. 24, 2021).

[11] State Water Resources Control Board, Standard Operating Procedures for Extraction and Measurement by Infrared Spectroscopy of Microplastic Particles in Drinking Water (Sept. 24, 2021).

[12] Muneera Al-Mansoori, Stuart Harrad, Mohamed Abou-Elwafa Abdallah, Synthetic microplastics in hot and cold beverages from the UK market: Comprehensive assessment of human exposure via total beverage intake, Science of The Total Environment, Volume 996, 2025, 180188, ISSN 0048-9697, https://doi.org/10.1016/j.scitotenv.2025.180188.

adverse effects.[13] This approach would help ensure the Agency does not treat environmental presence, analytical detection, or reported biological detection as equivalent to demonstrated risk.

Accordingly, the NAM recommends that EPA develop an exposure and risk-evaluation framework for microplastics that distinguishes exposure, dose, bioavailability, hazard, and risk, which informs monitoring criteria. Such a framework should prioritize monitoring data directly relevant to the statutory criteria for a SDWA regulatory determination, including occurrence in public water systems at levels of public health concern and whether any SDWA regulation would meaningfully reduce risk for persons served by public water systems. EPA should also assess drinking water exposure in relation to other exposure pathways before determining whether SDWA tools are the appropriate mechanism for risk reduction.

## V. Clear Study-Quality and Compatibility Criteria Should be Applied

The literature on microplastics is rapidly developing, but study quality still varies significantly. The EPA should not rely on studies that lack appropriate contamination controls, use poorly characterized materials, do not distinguish plastic particles from other particles, extrapolate from high-dose or non-oral exposure scenarios, or present detection as equivalent to harm.

The EPA should establish clear criteria for weighting studies in the CCL, UCMR, and regulatory determination context. Greater weight should be given to studies that include validated or well-described analytical methods, appropriate field and laboratory blanks, contamination-control procedures, transparent size thresholds, polymer identification, matrix-specific recovery data, replicates, uncertainty analysis, realistic exposure conditions, and physiologically relevant endpoints. EPA should also consider whether a study's design is relevant to drinking water ingestion and whether its findings can support conclusions about public water system exposure at levels of health concern.

This type of evidentiary framework would improve transparency and help ensure that any potential future decisions are based on high-quality, reproducible, and fit-for-purpose science. It would also help EPA to identify which research gaps are most important to address before any future SDWA monitoring or regulatory decision.

## VI. The Inclusion of "Pharmaceuticals" as a Contaminant Group Is Overly Broad

The NAM appreciates the EPA's longstanding interest in understanding the presence and potential significance of pharmaceuticals in drinking water, and we recognize the Agency's important work through the Federal Workgroup on Pharmaceuticals in Water alongside the U.S. Food and Drug Administration ("FDA"), the U.S. Geological Survey ("USGS"), and the U.S. Department of Agriculture ("USDA").

However, the NAM believes that defining the "pharmaceuticals" contaminant group by reference to the statutory definition of "drugs" under the FFDCA is overly broad for the purposes of CCL prioritization. That statutory definition encompasses thousands of heterogeneous compounds, spanning biologics, topical formulations, inhaled therapies, vaccines, and highly targeted oncology agents, many of which could never plausibly occur in drinking water at levels approaching public health concern due to their route of administration, metabolic profile, rate of environmental degradation, removal during conventional water treatment, and limited to no use of wastewater as drinking water. Listing an entire statutory class, rather than specific active pharmaceutical ingredients ("APIs") or scientifically defined

[13] Pan, Y., Janjua, T.I., Thomas, K.V. et al. A critical review of micro- and nanoplastic permeation in the human body. Micropl.&Nanopl. 6, 21 (2026). https://doi.org/10.1186/s43591-026-00177-6.

sub-classes, risks diluting the Agency's research and prioritization resources and may create public confusion about the nature and magnitude of any potential risk.

In addition, public trust in medicines and the government process to approve them is critical. By including all "drugs" as defined by the FFDCA, the EPA risks causing public concern over medicines that are not at all likely to impact human health through drinking water.

We respectfully recommend that EPA remove the broad FFDCA-based definition and use the next five-year review cycle to study whether the agency should include specific APIs or narrower sub-classes of APIs selected on the basis of transparent, clear, science-based prioritization criteria, including likelihood of occurrence in drinking water, pharmacological potency, environmental persistence, and margin of exposure.

## VII. The HHB-Rx Must Be Clearly Framed as a Screening Tool and Should Be Renamed Accordingly

The EPA's 2026 Human Health Benchmarks for Pharmaceuticals ("HHB-Rx") provide screening-level values for 374 pharmaceuticals to help identify APIs warranting further evaluation. The NAM appreciates the Agency's clear statement that these values are "not regulations or enforceable levels."[14] However, the name HHB-Rx itself undermines that message. The term "benchmark" carries a strong connotation of a standard, threshold, or action level. This connotation is plainly inconsistent with EPA's own stated intent that the values are intended for screening purposes, and creates a very real risk that HHB-Rx values will be misinterpreted by state and local regulators, public water systems, the public, and litigants as health-based standards or de facto action thresholds. That risk will be amplified if these values are disseminated through secondary sources, such as media coverage or state and local guidance documents, that may omit the qualifying context EPA provides.

The designation "Human Health Benchmarks" is not prescribed by the SDWA or any implementing regulation. It is an administrative label coined by the Agency, first applied to pesticides (the "HHBPs" began development in 2012), that has been extended to pharmaceuticals. EPA therefore has full discretion to adopt a more descriptive name, such as *"Informational Screening Values for Pharmaceuticals (ISV-Rx)"* or *"Preliminary Screening Levels for Pharmaceuticals (PSL-Rx),"* that accurately communicates the limited, non-regulatory, non-enforceable nature of these values. Other EPA programs have adopted similar nomenclature to reinforce clarity of intended application of the values. For example, the Agency's Regional Screening Levels ("RSLs") for hazardous waste site assessments under CERCLA are clearly labeled as "screening" tools, which has helped maintain appropriate expectations regarding their use and limitations.

Renaming the HHB-Rx would be a simple and effective measure to reinforce the Agency's own framing, support accurate risk communication, and reduce the potential for unintended regulatory, legal, or public-concern consequences.

Whether or not EPA elects to rename these values, it is essential that the Agency reinforce and prominently label them as:

- Non-enforceable screening values only;
- Not health-based drinking water standards, maximum contaminant levels, or health advisories;
- Not suitable as a basis for regulatory or enforcement action by any federal, state, local, or tribal authority; and

[14] 91 FR 17,193.

- Not evidence that the presence of a pharmaceutical at or above a screening value constitutes a health risk.

The NAM respectfully urges EPA to rename the HHB-Rx and to include explicit disclaimer language to this effect in all future HHB-Rx (or any renamed successor) publications, fact sheets, databases, and communications, and to issue guidance to state, local, and tribal authorities clarifying the intended and appropriate uses of these values. Any revised nomenclature should be applied consistently across all such materials.

## VIII. Validated Analytical Methods and Compound-Specific Hazard Identification are Necessary Before National Monitoring Requirement for Pharmaceuticals

While CCL listing does not impose monitoring obligations itself and the Agency's stated rational for the proposed inclusion of a pharmaceuticals group is intended further understanding of "which specific pharmaceuticals are occurring in drinking water and may be of greatest public health concern,"[15] the CCL is an important input into future UCMR monitoring decision and regulatory determination under the SDWA. The FFDCA definition of "drugs" encompasses thousands of chemically diverse compounds, and there is not currently evidence to establish that this broad universe of substances occur in water at levels of public health concern;[16] further many of these compounds lack validated, nationally deployable analytical methods capable of producing reliable, comparable results across public water systems. The EPA should therefore maintain a clear distinction that any pharmaceuticals group listing on CCL 6 is a research prioritization step, not a predicate for broad, group-wide national monitoring.[17]

The EPA and partners, through the federal workgroup on pharmaceuticals in water, have meaningfully contributed to the scientific record since 2012. This valuable work underscores the need for continued research that is compound- or subgroup-specific and scientifically justified. Given the critical importance of medicines to the American public, it is important to practice thoughtful risk communication that clearly distinguishes between detection of certain pharmaceuticals in environmental media, potential exposure through drinking water, and the statutory questions relevant to SDWA regulation. The NAM recommends that any future UCMR monitoring for pharmaceuticals should be predicated on compound-specific prioritization, validated and fit-for-purpose analytical methods, and a scientifically supported basis for believing that the pharmaceutical in question may plausibly occur in public water systems at levels relevant to human health through drinking water exposure.

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The NAM appreciates the EPA's work to identify research needs and improve the scientific foundation for future drinking water regulatory decisions. The EPA should finalize CCL 6 in a manner that preserves the CCL's role as a research and prioritization tool while avoiding premature conclusions about broad chemical groups. The NAM urges the EPA to continue to not include overly broad group listings in CCL 6 for microplastics and pharmaceuticals. If the Agency moves forward with listing microplastics or pharmaceuticals in CCL 6, it should be clear that future decisions will be based on validated methods, fit-for-purpose health and occurrence data, and contaminant- or subgroup-specific evaluation under SDWA's statutory criteria.

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[15] *Id.*

[16] *Human Health Benchmarks for Pharmaceuticals in Drinking Water*, EPA 822-R26-002, at 1 (Mar. 2026), Doc. No. EPA-HQ-OW-2022-0946-0034. The EPA's HHB-Rx Technical Support Document states that nationwide surveys conducted by the EPA, USGS, and others have reported pharmaceuticals at very low, parts-per-trillion concentrations in finished drinking water and at low concentrations in surface and groundwater source waters.

[17] 91 FR 17,193.

A scientifically disciplined approach will allow the EPA to prioritize legitimate drinking water research needs while avoiding regulatory uncertainty for public water systems, manufacturers, consumers, and other stakeholders.

Sincerely,

Reagan Giesenschlag
Director, Chemicals, Materials, and Sustainability Policy

Christopher Phalen
Vice President, Domestic Policy