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EPA Listing Signals New Scrutiny Of Drugs In Drinking Water

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On April 2, the U.S. Environmental Protection Agency published its draft Sixth Contaminant Candidate List, or CCL 6, which for the first time identifies pharmaceuticals as a contaminant group to be evaluated for potential future drinking water regulations under the Safe Drinking Water Act, or SDWA.

The EPA's action should be viewed as an initial, procedural step and not a regulatory mandate. The draft CCL 6 does not itself establish new drinking water standards or require immediate action by water systems or industry.

It can, however, lead to real consequences by acting as an initial screening step under the SDWA to identify substances for potential regulation. It is the start of a process that can shape future research priorities, monitoring requirements and potential regulatory action.

For example, the EPA included per- and polyfluoroalkyl substances as a broad class in the fifth CCL in 2022, which contributed to expanded monitoring and data collection that later supported regulatory action. Pharmaceuticals could follow a similar pathway, now that they have been identified as a contaminant group in the draft CCL 6.

At the same time, the EPA separately announced human health benchmarks for 374 pharmaceuticals. These pharmaceuticals are known to occur in groundwater and surface water, and are all active ingredients in products approved by the U.S. Food and Drug Administration.

While these benchmarks are not enforceable, they provide a framework that states, tribes and water systems can use to assess risk and evaluate potential responses — and may accelerate the practical significance of the EPA's action relative to other newly listed contaminants, including microplastics.

What Draft CCL 6 Covers

The CCL is the EPA's preliminary list of unregulated drinking water contaminants that require further study for potential regulation under the SDWA. It identifies priority substances for research, monitoring and future regulatory consideration, and the EPA must make a regulatory determination on at least five

contaminants identified on the CCL.

The draft CCL 6 identifies four priority contaminant groups — pharmaceuticals, microplastics, PFAS and disinfection byproducts — along with 75 individual chemicals and nine microbes that may be found in drinking water. The EPA has described the action as a means to prioritize research, funding and information collection to better understand potential health risks, and to support future regulatory decision-making.

The EPA's inclusion of pharmaceuticals is notable because it marks the first time the agency has elevated pharmaceuticals as a distinct contaminant group within the CCL framework. This inclusion provides support for increased monitoring and scientific investigation.

Although the benchmarks are not independently enforceable, the EPA has historically issued similar benchmarks in other contexts that states and local regulators have used as a basis for monitoring, risk prioritization and, in some cases, the development of more stringent standards.

Significance for Pharmaceutical Companies

The EPA's action signals increased federal attention on pharmaceuticals in drinking water, and starts a process by which these substances could end up more specifically regulated under the agency's regulatory framework.

For pharmaceutical companies, the most immediate implication is the increased likelihood of near-term federal scrutiny, including the development of data and the dissemination of publicly available information that could lead to state or local action.

Even more immediately, the availability of human health benchmarks provides a tool that regulators and other stakeholders can use now, even in the absence of enforceable federal limits.

For example, states, tribes and local water systems may rely on these benchmarks to assess water quality risks, prioritize monitoring or inform local regulatory approaches. This dynamic could lead to a more fragmented regulatory landscape in which expectations vary across jurisdictions.

The EPA's focus also raises questions about how pharmaceutical compounds enter water systems, including through manufacturing discharges, wastewater treatment processes, and downstream use and disposal. Companies may face increased inquiries from regulators, customers and other stakeholders regarding these pathways.

In addition, the development of a federal and state record regarding the presence and potential health effects of pharmaceuticals in drinking water may contribute to future enforcement or litigation risk, particularly if benchmarks or subsequent regulatory actions are cited as evidence of known or foreseeable risk.

Monitoring, Methods and Other Open Questions

A central issue for these developments is how quickly the EPA moves from candidate listing to monitoring and potential regulation.

The agency often uses the CCL to select substances for inclusion in the Unregulated Contaminant

Monitoring Rule, or UCMR, which requires public water systems to monitor for listed contaminants to generate national occurrence data.

Inclusion in a future UCMR cycle would be a consequential step for pharmaceuticals, as it would provide a broader evidentiary basis for regulatory determinations.

Unlike microplastics, which face unresolved challenges related to definitions, analytical methods and laboratory capacity, pharmaceuticals may be less constrained by threshold methodological issues.

However, questions remain regarding prioritization among the large number of pharmaceutical compounds, variability in occurrence across water systems, and the feasibility of large-scale monitoring and treatment.

These scientific and operational considerations will likely shape both the pace and scope of any future regulatory action.

Timeline and Next Steps

The publication of the draft CCL 6 in the Federal Register opened a 60-day public comment period. The EPA has stated that it will consult its Science Advisory Board before finalizing the list, which the agency expects to complete by Nov 17.

Separately, the EPA is expected to update the UCMR later this year. That process may be particularly important for pharmaceuticals, as inclusion in the rule would represent a significant step toward the collection of national occurrence data and potential future regulation.

What Companies Should Do Now

Companies in the pharmaceutical sector should consider taking several near-term steps in response to the EPA's action.

First, it would be timely to assess whether any manufacturing processes, wastewater streams or disposal practices could contribute to pharmaceutical residues entering water systems, and evaluate whether existing environmental compliance programs adequately address those pathways.

Companies should also be tracking the EPA's next steps, including the CCL 6 public comment process, Science Advisory Board review and forthcoming monitoring rule, as well as any parallel developments at the state or local level.

Additionally, some companies may want to consider whether participation in the comment process is warranted — either individually or as part of a group or association — particularly on issues such as definitions, methods, monitoring feasibility and implementation timing.

Finally, companies should be prepared for potential additional inquiries from regulators, customers, investors and other stakeholders as attention to pharmaceuticals in drinking water continues to increase.

Conclusion

The EPA's decision to include pharmaceuticals in the draft CCL 6 does not establish new drinking water limits, but it is an important step in that direction. It signals that the agency is moving these substances further into the SDWA regulatory pipeline while broader questions about monitoring, prioritization and regulatory scope remain unresolved.

While microplastics have drawn significant attention, pharmaceuticals may present a more immediate set of regulatory and risk management considerations given the availability of human health benchmarks and a more developed analytical foundation.

Entities that manufacture or use pharmaceuticals, or that may otherwise contribute to pharmaceutical residues entering water systems, should stay apprised of the EPA's rulemaking and related developments as this area continues to evolve.

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