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Chemicals

Practitioner Insights: Challenges of Regulating Chemicals of Emerging Concern

The processes for identifying chemicals of emerging concern (CECs) have evolved and can have broad and significant implications. Once those chemicals are identified, there are challenges that have become particularly acute as data are gathered at extremely low laboratory method detection limits that demonstrate the presence of man-made substances in water, often including the water we drink. This article describes the evolution from data gathering, to public concern and demand for answers, to potential regulatory action. Especially for substances for which there is limited information on health effects and the frequency of their occurrence in water resources, it identifies the need for coordinated national leadership to insure that the regulatory response is appropriate and to the degree possible, consistent across jurisdictions.

How Do Chemicals of Emerging Concern Come to Be Identified and Regulated? **Safe Drinking Water Act** The Safe Drinking Water Act (SDWA) is probably the most important source of federal authority for identifying and regulating emerging chemicals. It requires the EPA to establish national primary drinking water regulations applicable to public water supply systems. To regulate a contaminant under the act, the EPA must consider if: 1) it may have adverse human health effects, 2) it is known or likely to frequently occur in public water systems at levels of public health concern, and 3) regulating the contaminant would present a meaningful opportunity for health risk reductions (SDWA § 1412(b)(1)(A)). Regulations typically take the form of quantitative maximum contaminant levels. Maximum contaminant levels presently exist for 94 contaminants. While the contaminant levels are only enforceable as standards for public drinking water supplies, they also are relied on as de facto environmental clean-up criteria under other federal and many state regulatory programs.

New drinking water regulations, and new contaminant levels, are developed by the EPA through a process that is designed to occur in waves. Each wave starts with the development of a ''contaminant candidate list'' (CCL)—a list of unregulated contaminants identified by the EPA as priorities for data gathering and regulatory decision making. By law, EPA must compile and publish a new candidate list every five years (§ 1412(B)(1)(b)(i)). In doing so, the agency must consult with the scientific community, including its own Science Advisory Board, and also must solicit and consider public comments.

The EPA's approach to developing contaminant candidate lists has evolved since the first one was issued in 1998. CCL1 was developed based on a review of readily available information by technical experts, including the National Drinking Water Advisory Council, and contained 50 chemicals and 10 microbial contaminants. CCL2 (2005) included the same contaminants minus a handful that were determined not to warrant regulatory action. After being criticized for the narrow sweep of CCL1 and CCL2, the EPA devised a new process for CCL3 (2009) with input from the National Academy of Sciences. That process started with the identification of a broad initial ''universe'' of 7,500 potential drinking water contaminants. The EPA systematically narrowed this initial universe into a final list of 116 candidates by considering a variety of selection criteria. Among those criteria were: health effects, environmental releases, production quantities, and occurrence in public water supplies. The most recent candidate list (CCL4) was published in November 2016. It includes 97 chemical and 12 microbial contaminants. Some of these contaminants were carried over from CCL3, while others were selected based on public nominations. Among the contaminants on CCL4 are chemicals used in commerce, pesticides, biological toxins, disinfection byproducts, pharmaceuticals, and waterborne pathogens.

When compiling a new CCL, the EPA must consider data on the occurrence of contaminants in public water systems (§ 1412(b)(1)(B)). To ensure that ''occurrence data'' are available, the EPA is required to publish a list, every five years, of up to 30 unregulated contaminants to be monitored in water supply systems (§ 1445(a)(1)(D)(2)). These lists are published under the Unregulated Contaminant Monitoring Rule (UCMR). Results of testing performed under the rule are stored in a national contaminant occurrence database (NCOD) that is available to the public.

Notwithstanding the Safe Drinking Water Act's demanding regulatory development process, and maybe because of it, the EPA has proceeded slowly in establishing new maximum contamination levels. Over the last 20 years, the contamination levels have been established for only nine contaminants and contaminant groups. These include mostly disinfection byproducts (from treatment of raw water) plus uranium and two microbial contaminants (E. coli. and cryptosporidium). To-date the EPA has made only one positive regulatory determination for a contaminant on the CCL—perchlorate. Although the determination for perchlor-

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ate was made in 2011, the EPA has not yet promulgated a drinking water regulation.

Many of the chemicals now in the regulatory limelight are on the contaminant candidate list or were tested under the Unregulated Contaminant Monitoring Rule. For example, the third monitoring rule (UCMR3, 2013–2015) and CCL4 both included perfluoroalkyl substances and 1,4-dioxane. In May 2016, the EPA has published a lifetime health advisory (LHA) of 0.070 parts per billion (ppb) for two perfluoroalkyl substances, PFOA and PFOS. The lifetime health advisory is to be applied to PFOA and PFOS individually, or in combination, if both chemicals are present above the reporting limit. At least 14 states have proposed or established their own threshold values for PFOA and/or PFOS in groundwater and/or drinking water. The lowest of these is in New Jersey, where a draft maximum contamination level of 0.013 ppb has been published for PFNA. Similarly, the EPA has published an lifetime health advisory of 200 ppb for 1,4-dioxane. At least 18 states have developed or recommended threshold values for 1,4-dioxane, some below 1 ppb.

Toxic Substances Control Act

The Toxic Substances Control Act requires that those who manufacture, import, process, or distribute chemical substances comply with its ''substantial risk'' information reporting provisions, for example Section 8(e). The detection of chemicals of emerging concern in drinking water, under certain circumstances, may generate these reporting obligations. For example, in 2004 the EPA took enforcement action against DuPont for perfluorooctanoic acid (PFOA) in the environment around its Washington Works plant in Parkersburg, W. Va., alleging, among other things, that ''by 1991 DuPont had information that the chemical was in water supplies at a greater level than the company's exposure guidelines indicated would be without any effect to members of the community.'' That enforcement action was settled for more than $10 million.

In 2016, with bipartisan support, Congress passed a significant TSCA reform measure known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Among the key reforms is a new affirmative requirement for the EPA to systematically assess and manage the safety of existing chemicals. The Lautenberg Act also gives the EPA expanded authority to obtain testing information from manufacturers, for both existing and new chemicals (or new uses). While the impact of these reforms remains to be seen, it is certainly possible that the EPA's expanded powers will yield data that could raise new concerns about some of the more than 86,000 chemical substances currently registered for commercial use under TSCA.

Comprehensive Environmental Response Compensation and Liability Act

The EPA has recently asserted the power to consider risks associated with ''pollutants'' or ''contaminants'' that are not listed as Superfund hazardous substances in its decision to add a site in Hoosick Falls, N.Y., to the Superfund National Priorities List. Additionally, the EPA has added a variety of chemicals of emerging concern to its regional screening level (RSL) tables, which it uses to screen chemicals at Superfund sites.

Uncertainty and Implications Around Emerging Contaminants After a chemical of emerging concern is detected in drinking water, stakeholders—especially affected communities—understandably want to know what this presence means. This generates pressure for answers, and for a number of reasons, specific numeric criteria can be seen as the most effective form of answer. Detections above the criterion require action; below the criterion there is no cause for concern. The challenge for setting specific criteria for chemicals of emerging concern is that both health effects data and occurrence data may be materially limited. The lack of scientific support can make any criterion chosen inherently uncertain. In addition, any number that is chosen will matter a great deal because it will define those who are perceived to be at risk, which water resources are deemed unsuitable for human consumption, and determine where inherently limited resources will be dedicated.

Setting a number as close to zero as possible, for example on the rationale that no amount of a man-made substance should be present in drinking water, may be politically expedient. But it could lead to unintended and unwarranted consequences, such as generating concern among residents about exposures that may not involve any significant risk. It could also divert resources and attention away from drinking water quality issues with known adverse effects, such as lead. It may also push small water suppliers and municipalities into the arms of large private water utilities that may be better able to consistently monitor for trace contaminants and finance and manage treatment systems capable of removing them. Where the scientific underpinning is limited or uncertain, the potential exists for these disruptions to be unwarranted, but difficult to reverse.

Therefore, a significant challenge faced by regulatory agencies and interested groups is how to respond where insufficient science exists to set a health based standard.

The Drive for Specific Numeric Values

There are multiple reasons why stakeholders may seek specific numeric values for chemicals of emerging concern in drinking water. Decisions need to be made regarding which water resources are okay for continued use and which need either to receive treatment or to be taken off-line. In the absence of standards, water suppliers are in the difficult situation of making determinations on continued use, for example, of resource wells, when concerns about emerging contaminants are raised. Blending the water with other sources to achieve non-detect for the contaminants may help, but only where that is possible. In addition, funding for treatment from state or similar resources may be unavailable where the chemical is not regulated, depending on the terms of individual loan or grant programs.

Specific numeric values also can be valuable to potentially responsible parties to delineate the extent of their responsibilities. Specific numeric values can be used to define contaminant plumes and the degree of treatment necessary to meet cleanup objectives. And there may be perception and potential cost recovery issues that potentially responsible parties must consider in taking action in the absence of regulatory standards.

In addition, specific numeric values give governmental agencies and others a framework in which to communicate with the public and respond to the sometimes difficult questions that arise.

The Drive for Low Numeric Values

Laboratory techniques have progressed to the point that detection limits are now lower by orders of magnitude than could previously be reported. This has resulted in trace levels of chemicals of emerging concern that can be detected at parts per trillion levels, apparently with sufficient reliability to substantially lower the floor for potential regulation.

For example, New Jersey has determined that the practical quantification level for the perfluoroalkyl compound perfluorononanoic acid (PFNA) is 5 ppt. This is an extremely small amount, the equivalent of 1 mL of the substance in the volume of water it takes to fill 80 Olympic-size swimming pools (200 million liters or 52,834,400 gallons). Historically, very few substances have been regulated in water below 1 part per billion, even known carcinogens, like benzene and vinyl chloride. The current action level for lead—known to impair cognitive development in children—is 15 ppb for drinking water, more than a thousand times higher than the New Jersey specific groundwater criterion for PFNA of 10 ppt. In fact, there are only two chemicals with regulatory standards stricter at the federal level and in New Jersey, dioxin and polybrominated biphenyls.

In risk assessment, lack of available science on health risk can be addressed through the application of ''uncertainty factors'' in calculating toxicity limits called ''reference doses'' and consequently, regulatory standards. In other words, a standard may end up being stricter because of a lack of robust data on its health effects than it would be if data existed. The difficult question for regulatory leadership is what threshold of scientific uncertainty is too great to justify the proposal of a specific criterion?

Unfortunately, the apparent certainty offered by specific numeric standards for chemicals of emerging concern can be illusory because:

- Standards calculated with limited scientific support and significant levels of uncertainty may prove to be too high or too low as the science evolves.
- Lack of consensus and lack of consistent numeric standards may arise among relevant regulatory authorities, making all standards suspect and confusing to concerned groups.
- The strictness of standards, scientific uncertainty, and lack of consensus can make communications and decision making difficult.

For example, the EPA is using 70 ppt as its non-enforceable health advisory level for PFOA and perfluorooctanesulfonic acid (PFOS) in drinking water—individually or combined. State agencies are often using different levels. For example, Vermont's Department of Environmental Conservation has set a primary groundwater enforcement standard (which applies also to drinking water) for these chemicals at 20 ppt (individually or combined). And, there is no enforceable federal drinking water standard—health advisory levels are not the legal equivalent of maximum contamination levels. Thus, water suppliers can be faced with gathering data on unregulated contaminants but without a clear legal framework in which to evaluate any risk to water supply customers and to take action.

In light of the challenges that emerging PFAS contaminants and inconsistent treatment of them present to those who lead state drinking water programs, in January the Association of State Drinking Water Administrators wrote a letter to the EPA and the Centers for Disease Control and Prevention urging prompt coordinated action by the EPA and CDC, and the Department of Defense in conjunction with the state drinking water directors. It included a table of recommendations in ten areas, from interaction with the states, health risks, to research and development, and laboratories and sampling. This is a call for national coordination and leadership that is badly needed to insure that sound science, policy and a consistent approach are the bases for the response to the concerns that have arisen.

Another challenge with chemicals of emerging concern is that occurrence data can be so limited. For example, not all water supplies are required to sample pursuant to UCMR3. Method detection limits used in that sampling may exceed regulatory proposals, as occurred with PFNA in New Jersey. This means that social and economic impact of a regulatory standard can be very difficult to assess, or may not really be assessed at all.

The effects caused by the uncertainty of new and patchwork regulation of emerging contaminants can be felt by a range of stakeholders from water suppliers, communities, industry and real estate buyers and sellers.

Recent Regulatory Actions in New Jersey and New York Under Gov. Chris Christie's (R) administration, New Jersey set out to lead the country in the regulation of PFAS in drinking water and groundwater. Efforts by Department of Environmental Protection staff and its Drinking Water Quality Institute to establish drinking water standards for PFOA had stalled for years, but in late summer of 2013 things changed. At that time, the department released sampling results from 2009 that showed the presence of PFNA and other PFAS—the name for this class of compounds—in a public water system.

On Jan. 17, 2014, the state Department of Environmental Protection issued a letter to Paulsboro along with a fact sheet, which highlight the challenges of communicating about emerging contaminants in drinking water and states, inter alia:

''At this time, the DEP is not aware of any studies that have directly linked consumption of water with PFNAs with human health effects. However, out of an abundance of caution, the New Jersey Department of Health advises that residents use bottled water for powdered or concentrated infant formula and all other drinking uses for children up to the age of one year until the situation is resolved. Pregnant women and nursing mothers can continue to drink the water because there is no increased risk.''

By March 2014, with no change in the science, the Department of Environmental Protection proposed a groundwater standard of 20 ppt. By November 2015, the department lowered that standard to 10 ppt and issued on its website what it considered an immediately enforceable ''interim'' standard. This standard was later vacated by the Superior Court, Appellate Division in *Chem. Council of New Jersey v. NJDEP*.

By Jan.16, the Department of Environmental Protection had issued a final rule that established a final groundwater cleanup standard of 10 ppt and classified PFNA as a ''hazardous substance.'' The final rule also included a provision that amended the state's existing regulations to allow the department greater flexibility in the methods it could use to calculate groundwater criteria NJAC 7:9C-1.7(c)4iv-v. That regulatory change was essential to the Department of Environmental Protection's goal of issuing the 10 ppt standard for PFNA. For example, contrary to its prior regulation, as well as standard risk assessment practice, the department calculated a reference dose after determining the groundwater criterion. In fact, the department used the groundwater criterion to back-calculate a reference dose.

On the drinking water side, by April 29, 2014, after the Drinking Water Quality Institute had not met for four years, the Department of Environmental Protection commissioner directed the institute to issue maximum contamination level recommendations for PFNA, PFOA, and PFOS. By June 2015, the institute recommended a maximum contaminant level for PFNA of 13 ppt, which the department proposed in August 2017. By February 2017, the Drinking Water Quality Institute recommended a contaminant level of 14 ppt for PFOA. The commissioner of the Department of Environmental Protection announced in November 2017—at a press conference at the headquarters of private water utility New Jersey American Water Co.—plans to adopt that recommendation, which would set the most stringent contamination level for PFOA in the country. The drinking water institute subsequently issued a draft maximum contamination level of 13 ppt for PFOS on November 28, 2017.

By focusing first on PFNA, and promulgating a 10 ppt groundwater remediation standard for this substance as to which very limited information exists as to any health effects or about the frequency of the occurrence of this substances in the state's water resources, the Department of Environmental Protection set the stage for its proposed regulation of the more common constituents, PFOA and PFOA, about which much more is known. The consequences of the department's actions are still unknown due to the general lack of sampling for PFNA to 10 ppt across the state. Having set such a low floor for the regulation of PFAS, New Jersey has left itself little room as to how it will regulate PFOA and PFOS. The consequences of low parts per trillion standards for those more common chemicals in drinking water and groundwater, for example on the viability of municipal water suppliers, could be significant and should be thoroughly evaluated before regulatory action is taken.

In response to occurrences of chemicals of emerging concern in drinking water supplies—including PFOS in the city of Newburgh, PFOA in Hoosick Falls, and 1,4-dioxane on Long Island—New York passed the Clean Water Infrastructure Act of 2017. The law includes requirements for the New York State Department of Health to oversee an expanded testing program for emerging contaminants to all local drinking water systems servicing 25 homes or more. Initially, PFOS, PFOA, and 1,4-dioxane will be monitored as emerging contaminants. It is anticipated that the Drinking Water Quality Council, consisting of 12 members appointed by Gov. Andrew Cuomo, will establish maximum contamination levels for these contaminants by the this fall. In the interim, Cuomo created the statewide Water Quality Rapid Response Team to evaluate drinking water systems near facilities suspected to be frequent users of PFOA, PFOS, and 1,4-dioxane and all sites that are being investigated or remediated under the oversight of the state Department of Environmental Conservation in a Part 375 Environmental Remediation Program.

Confronted with impacts from 1,4-dioxane being found in 71 percent of the tested water supply wells on Long Island; the Clean Water Infrastructure Act invests as much as $900,000 per supply well for treatment systems to meet treatment levels prior to the adoption of maximum contamination levels. It also creates a $75 million rebate program to encourage homeowners and small businesses to replace septic systems.

The action of the New York Legislature, while welcomed by public advocacy groups, also has significant potential for overestimating the toxicity of these newly regulated compounds. In addition, appropriate actions and implications when these compounds are found are further complicated by the fact that regulatory standards have not yet been adopted in New York State.

Conclusions The identification of chemicals of emerging concern and the collection of data at low detection limits from drinking water resources, while intended to address public health concerns, has had significant consequences for water purveyors and potentially responsible parties and created concern among water users. The significance of these impacts, as well as the concerns that can arise while questions regarding actual risk are being assessed, can result in unfounded actions and fears until clear, specific standards are developed based on appropriate levels of science. As the evolving experiences with recent chemicals of emerging concern including PFAS compounds demonstrates, a rush to issue standards with insufficient scientific support can lead to unwarranted consequences. Consistent with the call from the association of state water quality directors to the EPA, the CDC, and Defense Department, coordinated leadership at a national level is needed.

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