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# Regulating Contaminants Under the Safe Drinking Water Act (SDWA)

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**Elena H. Humphreys**  
Analyst in Environmental  
Policy

## Regulating Contaminants Under the Safe Drinking Water Act (SDWA)

Detections of contaminants in public water supplies in numerous states have raised questions about drinking water quality and have increased congressional interest in the Environmental Protection Agency's (EPA's) efforts to regulate contaminants under the Safe Drinking Water Act (SDWA). Congress is particularly interested in the EPA's process for evaluating new contaminants for potential regulation. Detections of already-regulated contaminants, such as lead, have also raised concerns about the effectiveness of certain existing regulations.

SDWA is the key federal law that authorizes EPA to promulgate regulations to control contaminants in public water supplies. Since its enactment in 1974, EPA has issued drinking water regulations for 100 contaminants. Congress has twice revised the act's process for evaluating contaminants and developing drinking water regulations (in 1986 and 1996). In 1986, Congress directed EPA to develop regulations for 83 contaminants within 3 years, and adopt regulations, every 3 years, for at least 25 new contaminants. In 1996, when this regulatory schedule proved unworkable, Congress amended SDWA to establish a risk-based process that prioritizes contaminants for regulation based on health effects and occurrence.

Under SDWA, EPA follows a multistep process to evaluate and prioritize contaminants for regulation. This process includes identifying contaminants of potential concern, assessing health risks, collecting national occurrence data (and developing reliable and field-tested analytical methods necessary to do so), and making determinations as to whether a contaminant warrants regulation. Since 1996, EPA has considered over 7,500 contaminants for potential regulation, revised existing regulations, and established new regulations and standards for several contaminants.

When EPA determines that a contaminant warrants regulation, SDWA directs EPA to propose a "national primary drinking water regulation" and request public comment within 24 months. Within 18 months of the proposal, EPA is required to promulgate a final rule. EPA is required to establish a nonenforceable maximum contaminant level goal (MCLG) at a level at which no known or anticipated adverse health effects occur and allowing for an adequate margin of safety. Drinking water regulations generally specify a maximum contaminant level (MCL)—an enforceable limit for a contaminant in public water supplies. SDWA requires EPA to set the MCL as close to the MCLG as "feasible," taking treatment efficacy and costs into consideration. Concurrent with proposing a regulation, SDWA requires EPA to publish a "health risk reduction and cost analysis" for each contaminant covered by the proposed regulation and make a determination whether or not the benefits of regulation outweigh the compliance costs.

EPA's regulations generally take effect three years after promulgation, though the agency may allow up to two additional years, under certain conditions. For each drinking water regulation, SDWA requires EPA to identify a list of best available technologies, treatment techniques, and other means that EPA finds feasible for meeting the MCL. In addition, EPA is required to identify treatment technologies that achieve the MCL and are affordable for small systems. Each regulation also establishes associated monitoring and reporting requirements. SDWA requires EPA to review—and, if necessary, revise—each existing national primary drinking water regulation every six years. SDWA also requires that any revisions to drinking water regulations maintain or provide greater health protection.

Under the current SDWA statutory framework, evaluating and developing regulations for contaminants requires data, including data from peer-reviewed scientific studies on potential health effects and nationally representative occurrence data. For some contaminants, the availability or development of (1) data, (2) analytical methods to detect contaminants in drinking water, and (3) treatment technologies pose technical and resource challenges.

Congressional attention has centered on EPA's implementation of SDWA regulatory development provisions. Some stakeholders also have raised concerns about regulatory costs for communities. In recent Congresses, some Members have raised concerns that the act's process is lengthy and complicated and does not allow for the timely regulation of contaminants of concern in drinking water. Others have expressed concern that proposals to expedite regulation by removing elements of SDWA regulatory development provisions (e.g., the requirement to use peer-reviewed science or a health-risk-based approach) may result in increased costs to communities without commensurate public health protection. This debate was heightened prior to EPA's determination to regulate per- and polyfluoroalkyl substances (PFAS) in 2021, yet stakeholders raised similar concerns after EPA's 2024 finalization of a regulation for six PFAS.

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## Introduction

Detections of contaminants in public water supplies have raised questions about the quality of drinking water and have increased congressional interest in the Environmental Protection Agency's (EPA's) efforts to regulate contaminants under the Safe Drinking Water Act (SDWA).

Congress enacted SDWA in 1974 to address the quality of public drinking water supplies and protect public health.<sup>1</sup> A key part of the act is the authority for EPA to regulate contaminants in public water supplies. Since enactment, Congress has revised the act's process for contaminant regulation twice, in 1986 and in 1996. The 1996 amendments established specific contaminant identification, assessment, and regulatory determination processes for the purpose of focusing regulatory resources and requirements toward contaminants of greatest public health concern.

Since 1996, EPA has updated several drinking water regulations, promulgated regulations for additional contaminants under other SDWA authorities, and evaluated more than 7,500 contaminants for potential regulation. In April 2024, EPA finalized a national primary drinking water regulation (NPDWR) for six per- and polyfluoroalkyl substances (PFAS).<sup>2</sup>

SDWA requires EPA to use the best available, peer-reviewed science to characterize a contaminant's health effects and occurrence in water supplies to determine whether a contaminant warrants national regulation. EPA has long recognized that limited data on unregulated contaminants of concern has hindered the agency's ability to make regulatory determinations.<sup>3</sup> In a 2011 report, the U.S. Government Accountability Office (GAO) made a similar finding.<sup>4</sup> EPA's efforts to develop peer-reviewed science necessary to support regulatory determinations for unregulated contaminants—or to update existing contaminant regulations—have been affected by data availability and available agency resources, among other factors.

This report discusses the SDWA provisions relevant to how EPA evaluates contaminants to determine whether a contaminant warrants an NPDWR. It also provides an overview of the regulatory development process, and analyzes certain issues that may affect implementation of SDWA regulatory development provisions. Regarding specific SDWA drinking water regulations, some have raised concerns over how the agency calculates costs when developing drinking water standards. For individual contaminants, costs vary and involve specific considerations, as does the ability of water systems to afford such costs. This report does not discuss EPA's calculation of costs for each regulation.

In addition to the agency's work related to contaminant regulation, EPA has issued other SDWA regulations applicable to public water systems. These include regulations to reduce lead content in drinking water pipes and plumbing and to increase consumer information and public notification about drinking water quality and compliance.<sup>5</sup> The report is primarily limited to

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<sup>1</sup> Safe Drinking Water Act of 1974 (P.L. 93-523), enacted December 16, 1974.

<sup>2</sup> U.S. Environmental Protection Agency (EPA), "PFAS National Primary Drinking Water Regulation," 89 *Federal Register* 32532-32757, April 26, 2024.

<sup>3</sup> See, for example, Table 2, "Information Gaps for the CCL 2 Chemical Contaminants," EPA, "Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List," 73 *Federal Register* 44251-44261, July 30, 2008.

<sup>4</sup> U.S. Government Accountability Office (GAO), *EPA Should Improve Implementation of Requirements on Whether to Regulate Additional Contaminants*, 11-254, May 27, 2011, at <https://www.gao.gov/products/GAO-11-254>.

<sup>5</sup> Other regulations include the "Use of Lead Free Pipes, Fittings, Fixtures, Solder, and Flux for Drinking Water" rule (85 *Federal Register* 54235-54259) and "right-to-know" rules (e.g., public notification rule [65 *Federal Register* 25982-26049] and consumer confidence report rule [63 *Federal Register* 44512-44536]).

EPA's implementation of the process outlined in SDWA Section 1412 "National Drinking Water Regulations" for evaluating contaminants for regulation.<sup>6</sup>

## History of SDWA Section 1412 "National Drinking Water Regulations"

The Safe Drinking Water Act of 1974 established the federal role in regulating contaminants in public water supplies. The 1974 act directed EPA to promulgate "national interim primary drinking water regulations," with enforceable standards (i.e., maximum contaminant levels), for a list of contaminants based on the 1962 U.S. Public Health Service interstate carrier drinking water quality standards.<sup>7</sup> It also directed the National Academy of Sciences to conduct a study and recommend maximum contaminant levels to protect human health. EPA was required to set the interim regulations' revised levels as close as "feasible" to the National Academies of Sciences' recommended levels—using the best available technology, treatment techniques, and other means—taking costs into consideration.<sup>8</sup> The act provided EPA with discretionary authority to issue drinking water regulations for additional contaminants.<sup>9</sup> By 1985, EPA had issued interim regulations with standards for the initial list of contaminants, yet EPA had revised existing regulations or established regulations for few other contaminants.

In the 99<sup>th</sup> Congress, concerns about the pace at which EPA issued drinking water regulations prompted legislation intended to expedite regulation of drinking water contaminants.<sup>10</sup> In the Safe Drinking Water Act Amendments of 1986 (P.L. 99-339), Congress directed EPA to promulgate drinking water regulations for 83 contaminants by June 1989 and for 25 additional contaminants every 3 years thereafter.<sup>11</sup> Following the 1986 amendments, EPA promulgated new regulations and revised existing regulations for more than 80 contaminants, attempting to keep pace with the statutory requirements. Water utilities, state drinking water regulators, and EPA expressed concern that the regulatory schedule imposed significant burdens and did not prioritize contaminants based on risk to public health.<sup>12</sup> In its report on the 1996 SDWA amendments, the

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<sup>6</sup> 42 U.S.C. §300g-1.

<sup>7</sup> U.S. Congress, House Committee on Interstate and Foreign Commerce, *Safe Drinking Water Act*, 93<sup>rd</sup> Cong., 2<sup>nd</sup> sess., July 10, 1974, H.Rept. 93-1185, pp. 1-11. (SDWA, as amended, comprises Title XIV of the Public Health Service Act, 42 U.S.C. §§300f-300j-26.) With congressional approval, the Nixon Administration established the U.S. Environmental Protection Agency (EPA) in 1970 under an executive branch reorganization plan, which consolidated numerous federal pollution control responsibilities that had been divided among several federal agencies. In 1970, Congress transferred responsibility for implementation and enforcement of the interstate carrier drinking water standards from the Public Health Service to EPA. See Appendix B for the 1962 standards, EPA, *25 Years of the Safe Drinking Water Act: History and Trends*, EPA 816-R-99-0007, Washington, DC, December 1999, p. 6.

<sup>8</sup> According to the House report accompanying the 1974 act, "the level (i.e., drinking water standard) should be achievable by large metropolitan water systems treating relatively clean source water." U.S. Congress, House Committee on Interstate and Foreign Commerce, *Safe Drinking Water Act*, 93<sup>rd</sup> Cong., 2<sup>nd</sup> sess., July 10, 1974, H.Rept. 93-1185, p. 18.

<sup>9</sup> Safe Drinking Water Act (P.L. 93-523), Section 2(a). As discussed in U.S. Congress, Senate Committee on Environment and Public Works, *Safe Drinking Water Act Amendments of 1985*, 99<sup>th</sup> Cong., 1<sup>st</sup> sess., May 15, 1985, S.Rept. 99-56.

<sup>10</sup> U.S. Congress, Senate Committee on Environment and Public Works, *Safe Drinking Water Act Amendments of 1985*, 99<sup>th</sup> Cong., 1<sup>st</sup> sess., May 15, 1985, S.Rept. 99-56.

<sup>11</sup> According to the Senate Debate on these amendments, setting regulatory schedules for specific contaminants is not normally a legislative function (Sen. Durenberger, "The Safe Drinking Water Act Amendments Conference Report," Senate debate, *Congressional Record*, May 21, 1986, pp. 6284-6301).

<sup>12</sup> U.S. Congress, House Committee on Commerce, *Safe Drinking Water Act Amendments of 1996*, 104<sup>th</sup> Cong., 2<sup>nd</sup> sess., June 24, 1996, H.Rept. 104-632, p. 6.

House Committee on Commerce stated that, particularly for small water systems, the 1986 regulatory schedule resulted in increased compliance costs without a commensurate increase in public health protection.<sup>13</sup>

Adding to these findings, a 1993 outbreak of *Cryptosporidiosis* in Milwaukee’s public water supply focused congressional attention on whether the regulatory pace established by the 1986 SDWA amendments reduced EPA’s focus on high-risk contaminants, such as microbial pathogens that pose acute health risks. In response to calls for “a more streamlined and flexible approach to controlling drinking water contamination consistent with continued protection of the public health,”<sup>14</sup> the 104<sup>th</sup> Congress amended SDWA to establish the current health risk-based regulatory process.<sup>15</sup> The House Committee on Commerce stated that the purpose of the Safe Drinking Water Act Amendments of 1996 was

to help make more effective and more cost-effective Federal regulation of drinking water and to help small communities pay for improvements to their public water systems, while ensuring that health protections are maintained or improved.<sup>16</sup>

**Table 1** outlines EPA actions and timelines regarding the regulation of contaminants since the 1974 enactment of SDWA.

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<sup>13</sup> H.Rept. 104-632, p. 10.

<sup>14</sup> H.Rept. 104-632, p. 6.

<sup>15</sup> P.L. 104-182.

<sup>16</sup> H.Rept. 104-632, p. 6.

**Table I. SDWA Contaminant Regulation Timeline**

<b>Date</b>	<b>National Primary Drinking Water Regulations (NPDWRs)</b>	<b>Type of Regulatory Action (# of Contaminants)</b>	<b>Cumulative # of Regulated Contaminants</b>
December 1975 and July 1976	National Interim Primary Drinking Water Regulations	New (22)	22
November 1979	Total Trihalomethanes Rule	New (1)	23
April 1986	Fluoride Rule	Revised (1)	23
July 1987	Phase I NPDWRs	New (8)	31
June 1989	Total Coliform Rule	Revised (1)	31
June 1989	Surface Water Treatment Rule	New (4) and Revised (1)	35
January 1991 and July 1991	Phase II NPDWRs	New (27), Revised (11), and Deleted (1)	61
June 1991	Lead and Copper Rule	New (1) and Revised (1)	62
July 1992	Phase V NPDWRs	New (22) and Revised (1)	84
June 1995	Nickel NPDWR	Remanded (1)	83
December 1998	Stage I Disinfectant and Disinfection Byproduct Rule	New (6) and Revised (1)	89
December 1998	Interim Enhanced Surface Water Treatment Rule	New (1) and Revised (2)	90
January 2000	Lead and Copper Rule	Revised (2)	90
December 2000	Radionuclides Rule	New (1) and Revised (4)	91
January 2001	Arsenic Rule	Revised (1)	91
June 2001	Filter Backwash Recycling Rule	Revised (1)	91
January 2002	Long Term I Enhanced Surface Water Treatment Rule	Revised (2)	91
January 2006	Long Term II Enhanced Surface Water Treatment Rule	Revised (1)	91
November 2006	Groundwater Rule	New (3)	94
October 2007	Lead and Copper Rule	Revised (2)	94
October 2009	Aircraft Drinking Water Rule	New <sup>a</sup>	94
February 2013	Revised Total Coliform Rule	Revised (1)	94
December 2021	Lead and Copper Rule	Revised (1)	94
April 2024	Per- and polyfluoroalkyl substances (PFAS) Rule	New (6)	100

**Source:** Compiled by CRS from the U.S. Environmental Protection Agency (EPA) website “Regulation Timeline: Contaminants Regulated Under the Safe Drinking Water Act” at <https://www.epa.gov/sdwa/regulation-timeline-contaminants-regulated-under-safe-drinking-water-act>.

- a. The Aircraft Drinking Water Rule addresses microbial contaminants in water served by aircraft that meet the SDWA definition of a *public water system*. The contaminants addressed in the rule, total coliform and *Escherichia coli* (*E. coli*), are regulated under an existing rule for other public water systems.

## Regulated Public Water Systems

National primary drinking water regulations apply to *public water systems*. SDWA generally defines a *public water system* as a system that provides water through pipes or other conveyances to at least 15 service connections or that regularly serves at least 25 individuals.<sup>17</sup> Primary enforcement responsibility (primacy) of public water system compliance with SDWA requirements, including drinking water regulations, may be assumed by states that meet statutory criteria, under SDWA Section 1413.<sup>18</sup>

Public water systems can be divided into three subset categories: (1) community water systems, (2) non-transient non-community water systems, and (3) transient non-community systems. *Community water systems* are systems that regularly serve at least 25 individuals year-round.<sup>19</sup> Federal drinking water regulations apply to these systems, which collectively provide drinking water to more than 322 million individuals. As presented in **Table 2**, more than 50% (26,577) of community water systems serve 500 or fewer individuals, yet these systems serve roughly 1.4% of the total population served by community water systems. *Non-transient non-community water systems*, such as schools or factories, have their own water supplies and generally serve the same individuals for more than six months but not year-round. Most drinking water regulations apply to these systems. *Transient non-community water systems*, such as campgrounds and gas stations, provide their own water to transitory customers. Only regulations for contaminants that pose immediate health risks apply to these systems.

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<sup>17</sup> 42 U.S.C. §300f(4). The act does not specify ownership of public water systems.

<sup>18</sup> 42 U.S.C. §300g-2. Currently, 49 states, the territories, and the Navajo Nation have applied for and received primacy for the drinking water program. EPA retains implementation and enforcement authority for Wyoming, the District of Columbia, and Indian tribes other than the Navajo Nation.

<sup>19</sup> 42 U.S.C. §300f(15).

**Table 2. Public Water System Statistics**

		Very Small	Small	Medium	Large	Very Large	Total
Population served		500 or fewer	501 to 3,300	3,301 to 10,000	10,001 to 100,000	100,001 or more	
<b>Community water system</b>	# of Systems	26,577	13,282	5,013	4,055	469	49,397
	Pop. Served	4,525,250	19,114,428	29,518,867	117,103,336	152,492,594	322,754,475
	% of Systems	53.80%	26.89%	10.15%	8.21%	0.95%	100%
	% of Pop. Served	1.40%	5.92%	9.15%	36.28%	47.25%	100%
<b>Non-Transient non-community system</b>	# of Systems	14,571	2,431	144	45	3	17,194
	Pop. Served	2,041,430	2,621,545	829,507	1,005,615	453,484	6,951,581
	% of Systems	84.74%	14.14%	0.84%	0.26%	0.02%	100%
	% of Pop. Served	29.37%	37.71%	11.93%	14.47%	6.52%	100%
<b>Transient non-community system</b>	# of Systems	73,780	3,039	85	17	0	76,921
	Pop. Served	6,974,364	2,841,441	425,958	437,314	0	10,679,077
	% of Systems	95.92%	3.95%	0.11%	0.02%	0.00%	100%
	% of Pop. Served	65.31%	26.61%	3.99%	4.10%	0.00%	100%
<b>Total</b>	<b># of Systems</b>	<b>114,928</b>	<b>18,753</b>	<b>5,242</b>	<b>4,117</b>	<b>472</b>	<b>143,512</b>

**Source:** Prepared by CRS from EPA's Safe Drinking Water Information Systems, Water System Summary report generated on May 13, 2024.

## Regulating Contaminants in Public Water Supplies

As revised in 1996, SDWA's regulatory development provisions reflect themes of prioritizing contaminants for regulation based on public health risk, considering compliance costs to communities with health risk reduction benefits, and science-based decisionmaking. The act requires EPA to identify contaminants that may require regulation, assess health risks based on the best available peer-reviewed science, conduct a monitoring program to estimate the frequency and levels of a contaminant's occurrence, and make determinations of whether a drinking water regulation is warranted.

EPA's ability to implement these provisions—and to set scientifically sound standards—depends on the availability of health effects and occurrence data as well as agency resources to collect such data, among other factors. For many unregulated contaminants, health effects and occurrence data may not be available and/or may take time to generate. The availability, as well as the development, of such data poses challenges for EPA in evaluating contaminants for regulation and for establishing regulations with enforceable standards for contaminants. (For further discussion, see “Data Availability and Quality.”)

## Identifying Contaminants for Consideration

SDWA requires EPA, every five years, to publish a list of unregulated contaminants known or anticipated to occur in public water systems that may warrant regulation.<sup>20</sup> EPA has termed this

<sup>20</sup> SDWA §1412(b)(1)(B); 42 U.S.C. §300g-1(b)(1)(B). This provision directs EPA to consider contaminants defined as (continued...)

list the *contaminant candidate list* (CCL). Prior to publishing a final CCL, EPA is required to consider contaminant occurrence, to give notice and provide an opportunity for public comment, and to consult with the scientific community, including the Science Advisory Board.<sup>21</sup> In selecting contaminants for regulatory consideration, SDWA requires EPA to select contaminants that present the greatest public health concern, taking into consideration a contaminant's health effects on specified population subgroups (e.g., infants, children, and pregnant women) who may be at greater risk due to exposure to a contaminant.<sup>22</sup>

Over time, EPA has revised the process to identify and list contaminants on the CCL.<sup>23</sup> In 2009, EPA published CCL 3, which was developed using a revised process based on recommendations and advice from the National Research Council and National Drinking Water Advisory Council (NDWAC).<sup>24</sup> For CCL 3, EPA identified a broad "universe" of 7,500 potential drinking water contaminants, which was narrowed to 61 on the final CCL through a screening process along with public and expert input.<sup>25</sup> This revised process was intended to be more easily reproducible than the process EPA used to develop the first and second CCLs.<sup>26</sup>

Once the CCL is developed, EPA continues to evaluate listed contaminants to inform regulatory decisionmaking.<sup>27</sup> EPA typically divides the listed contaminants into groups: those prioritized for drinking water research (e.g., health effects, analytical methods, treatment technologies), those that require additional occurrence data, and those prioritized for future drinking water regulations.

For previous cycles, the agency carried forward contaminants from one CCL to the next to continue evaluating contaminants. EPA published the final, fifth CCL (or CCL 5) in November 2022, and noted that for this cycle, the agency attempted to improve its process for developing the CCL based on recommendations from the public and the Science Advisory Board.<sup>28</sup> **Appendix A** includes details about the first, second, third, fourth, and fifth contaminant candidate lists.

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hazardous substances under §101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA; 42 U.S.C. §9601(14)) and substances that are registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. §§136 et seq.).

<sup>21</sup> The 1978 Environmental Research, Development, and Demonstration Authorization Act (P.L. 95-477) directed EPA to establish the Science Advisory Board to provide scientific advice to the Administrator (42 U.S.C. §4365).

<sup>22</sup> SDWA §1412(b)(1)(C); 42 U.S.C. §300g-1(b)(1)(C).

<sup>23</sup> For the first CCL, EPA used screening and evaluation criteria for chemical contaminants from the National Drinking Water Advisory Council (NDWAC) and convened an expert panel of microbiologists to recommend microbiological contaminants. EPA also solicited public input through a hotline.

<sup>24</sup> NDWAC, "National Drinking Water Advisory Council Report on the CCL Classification Process to the U.S. Environmental Protection Agency," May 19, 2004. National Research Council (NRC), "Classifying Drinking Water Contaminants for Regulatory Consideration," National Academy Press, Washington, DC. EPA, "Drinking Water Contaminant Candidate List 3-Draft," 73 *Federal Register* 9628-9654, February 21, 2008, at <https://www.federalregister.gov/documents/2008/02/21/E8-3114/drinking-water-contaminant-candidate-list-3-draft>.

<sup>25</sup> To develop CCL 3, EPA evaluated 284 data sources and selected approximately 7,500 contaminants. EPA then used specified criteria (i.e., potential to occur in public water systems and potential for public health concern) to reduce the number of contaminants that EPA included on the preliminary CCL. For the preliminary CCL 3, EPA included 532 contaminants. The agency then evaluated contaminants listed on the preliminary CCL further for their occurrence and health effects through scoring and "structured classification models" to identify priority contaminants to include on the final CCL. EPA solicited public input and expert review throughout the development of CCL 3. When finalized, CCL 3 included 116 contaminants.

<sup>26</sup> EPA, "Drinking Water Contaminant Candidate List 3-Draft," 73 *Federal Register* 9628-9654, February 21, 2008, at <https://www.federalregister.gov/documents/2008/02/21/E8-3114/drinking-water-contaminant-candidate-list-3-draft>.

<sup>27</sup> For more information, see EPA website "Basic Information on the CCL and Regulatory Determination" at <https://www.epa.gov/ccl/basic-information-ccl-and-regulatory-determination>.

<sup>28</sup> EPA, "Drinking Water Contaminant Candidate List 5-Final," 87 *Federal Register* 68060-68085, November 14, 2022.

## Evaluating Contaminant Occurrence

To gather data on contaminant occurrence at a national level, EPA is required to administer a monitoring program for unregulated contaminants in public water supplies. SDWA directs EPA to publish, every five years, a rule (Unregulated Contaminant Monitoring Rule [UCMR]) listing no more than 30 unregulated contaminants to be monitored by public water systems.<sup>29</sup> Only a nationally representative sample of public water systems serving 10,000 individuals or fewer are required to conduct monitoring.<sup>30</sup> EPA funds the monitoring costs for this representative sample of small public water systems.<sup>31</sup> EPA uses monitoring results from the UCMR to assess the frequency and levels of a contaminant's occurrence nationwide.

EPA generally selects the list of unregulated contaminants for a UCMR based on the CCLs, but may select other unregulated contaminants as well. SDWA directs EPA to include specific contaminants in the UCMR when such contaminants have been nominated by the governors of seven or more states.<sup>32</sup>

For each contaminant included in a UCMR, EPA specifies an analytical method that water system operators and participating laboratories must use to measure the contaminant in drinking water.<sup>33</sup> EPA may be unable to include one or more contaminants of concern in a particular monitoring rule/cycle if no validated analytical method is available to detect and measure the contaminant in drinking water. UCMRs set a minimum reporting level (MRL) for each contaminant. MRLs are based on the capability of the analytical method and are typically set at levels below health-based reference levels, where established. Prior to finalizing the UCMR, EPA seeks public input by publishing a proposed contaminant list in the *Federal Register*.

SDWA requires community water system operators to provide UCMR monitoring results to their customers in the consumer confidence report.<sup>34</sup> Additionally, EPA may require public water systems to notify consumers specifically about the levels of contaminants for which UCMR monitoring was required.<sup>35</sup> EPA publishes the UCMR monitoring results and reports the number of detections at or above the MRL, as well as detections above EPA's health-based reference levels, when available.

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<sup>29</sup> SDWA §1445(a)(2); 42 U.S.C. §300j-4(a)(2). This provision requires all systems serving more than 10,000 people and a sample of smaller systems to monitor for the contaminants. In the America's Water Infrastructure Act, P.L. 115-270, Congress amended §1445 to require public water systems serving between 3,300 and 10,000 individuals to conduct monitoring—subject to the availability of appropriations. This requirement took effect three years after the date of enactment of P.L. 115-270 (i.e., October 23, 2021). The National Defense Authorization Act, Fiscal Year 2020 specified for the fifth UCMR that any PFAS with a validated test method not count toward the 30 contaminant limit (P.L. 116-92, §7311; 15 U.S.C. §8911).

<sup>30</sup> SDWA §1445(a)(2); 42 U.S.C. §300j-4(a)(2). EPA estimates that approximately 83% of the population receives water from public water systems that serve more than 10,000 individuals. This requirement took effect three years after the date of enactment of P.L. 115-270 (i.e., October 23, 2021).

<sup>31</sup> SDWA §1445(a)(2)(C)(ii); 42 U.S.C. §300j-4(a)(2)(C)(ii). This provision directs EPA to cover testing and laboratory analysis costs for small systems, using funds reserved from the annual DWSRF capitalization grant (SDWA §1452(o); 42 U.S.C. §300j-12(o)).

<sup>32</sup> SDWA §1445(a)(2)(B)(ii); 42 U.S.C. §300j-4(a)(2)(B)(ii).

<sup>33</sup> The contaminants for which monitoring is required are divided into those for “assessment monitoring” (using test methods that are widely used) and for “screening survey” (using test methods that are newer and less available).

<sup>34</sup> SDWA §1414(c)(4)(B)(v); 42 U.S.C. §300g-3(c)(4)(B)(v). Community water system operators are required to provide their customers with an annual consumer confidence report on their drinking water quality and SDWA compliance. Community water systems serving more than 10,000 individuals are required to biannually produce and distribute such reports.

<sup>35</sup> SDWA §1414(c)(1)(C); 42 U.S.C. §300g-3(c)(1)(C); and SDWA §1414(c)(2)(F); 42 U.S.C. §300g-3(c)(2)(F).

The agency uses UCMRs to gather national occurrence data. These data support evaluation and prioritization of contaminants on the CCL and inform EPA's review of contaminants that may warrant regulation.<sup>36</sup> **Appendix B** contains information on the first, second, third, fourth, and fifth UCMRs.

## Determining Whether or Not to Regulate

Using occurrence and health effects data, EPA is required, every five years, to make a determination about whether or not to regulate (a regulatory determination [RD]) for at least five contaminants on the CCL.<sup>37</sup> Under SDWA, to make a positive determination to regulate a contaminant, EPA must find that

- a contaminant may have an adverse health effect;
- it is known to occur or there is a substantial likelihood that it will occur in public water systems with a frequency and at levels of public health concern; and
- in the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by water systems.<sup>38</sup>

In selecting unregulated contaminants for regulatory consideration, SDWA requires EPA to give priority to contaminants that “present the greatest public health concern.”<sup>39</sup> EPA is specifically required to take into consideration a contaminant's health effects on specified population subgroups (e.g., infants, children, pregnant women) that may be at greater risk due to exposure to a contaminant.<sup>40</sup>

Before making a final determination, EPA is required to provide notice and opportunity for public comment on the preliminary RD.<sup>41</sup> If EPA makes a determination to regulate a contaminant, the agency then begins to develop a drinking water regulation. Under the statute, a determination not to regulate a contaminant is a final agency action and subject to judicial review.<sup>42</sup> However, EPA reconsiders such contaminants for inclusion on the CCL if new occurrence or health effects information becomes available.<sup>43</sup>

To evaluate contaminants for regulatory determinations for CCL 3 and CCL 4, EPA used a process that included three phases—(1) data availability assessment, (2) data evaluation, and (3) regulatory determination assessment.<sup>44</sup> In the final phase, Regulatory Determination Assessment Phase, EPA evaluates each contaminant using the statutory criteria outlined in SDWA Section

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<sup>36</sup> EPA, “Revisions to the Unregulated Contaminant Monitoring Regulation for Public Water Systems,” 64 *Federal Register* 50556-50620, September 17, 1999.

<sup>37</sup> SDWA §1412(b)(1)(B)(ii); 42 U.S.C. 300g-1(b)(1)(B)(ii). Nothing in the statute prevents EPA from making a regulatory determination outside of the five-year timeline.

<sup>38</sup> SDWA §1412(b)(1)(A); 42 U.S.C. §300g-1(b)(1)(A).

<sup>39</sup> SDWA §1412(b)(1)(C); 42 U.S.C. §300g-1(b)(1)(C).

<sup>40</sup> SDWA §1412(b)(1)(C); 42 U.S.C. §300g-1(b)(1)(C).

<sup>41</sup> SDWA §1412(b)(1)(B)(ii); 42 U.S.C. §300g-1(b)(1)(B)(ii).

<sup>42</sup> SDWA §1412(b)(1)(B)(ii)(IV); 42 U.S.C. §300g-1(b)(1)(B)(ii)(IV).

<sup>43</sup> EPA, “Announcement of Preliminary Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List,” 79 *Federal Register* 62716-62750, October 20, 2014.

<sup>44</sup> EPA, “Announcement of Preliminary Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List,” 79 *Federal Register* 62716-62750, October 20, 2014.

1412(b)(1)(A). Under these criteria, EPA evaluates uncertainties or limitations of the health effects and occurrence data for a contaminant.<sup>45</sup>

EPA uses available peer-reviewed health effects assessments to derive health reference levels (HRLs). HRLs are a preliminary estimate of the concentration below which adverse health effects are unlikely to occur.<sup>46</sup> For contaminants with carcinogenic effects (i.e., potential increased risk of developing certain cancers), EPA develops an HRL using a quantitative estimate of carcinogenic risk to calculate a level in drinking water equivalent to a one-in-a-million increased risk of cancer from a lifetime of exposure.<sup>47</sup> For noncarcinogenic contaminants, EPA estimates the relative source contribution, which is the percentage of the general population's potential exposure from drinking water to a contaminant (relative to other exposure pathways [including food, inhalation, and dermal contact]).

EPA reviews the occurrence data for each contaminant, evaluating the number of public water systems (and the population served) with detections at or above the HRL and above one-half of the HRL.<sup>48</sup> Using these data, EPA evaluates whether the contaminant occurs locally, regionally, or nationally, and uses these findings to assess whether the contaminant warrants regulation under the statutory criteria.

The first, second, third, and fourth regulatory determinations are discussed briefly below. (See **Appendix C** for additional details.)

## Regulatory Determination Cycles

In the first CCL, EPA initially categorized 20 contaminants as having sufficient health effects data and occurrence information to support RDs, and noted that the agency would use this list to select five or more contaminants to make regulatory determinations in 2001.<sup>49</sup> Subsequently, EPA found that the available health effects and occurrence data were insufficient to support RDs for 12 of the 20 contaminants.<sup>50</sup> EPA selected nine contaminants for the first cycle of regulatory determinations, and determined that none presented a meaningful opportunity of health-risk reduction, citing few detections or low risk of adverse health effects, among other reasons.<sup>51</sup>

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<sup>45</sup> EPA, *Chapter 2: Evaluation of Health and Occurrence Data*, EPA Report 815-R-08-012, Washington, DC, June 2008.

<sup>46</sup> EPA, "Regulatory Determination 3 Supporting Document," EPA 815-R-15-014, December 2015. For a nonthreshold toxicant, such as a carcinogen, EPA derives an estimated concentration below which adverse health effects have a defined low probability of occurring. EPA states that "an HRL is not a final determination on establishing a protective level of a contaminant in drinking water for a particular population; it is derived prior to development of a complete health and exposure assessment and can be considered a screening value." EPA, "Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List," 85 *Federal Register* 14098-14142, March 10, 2020.

<sup>47</sup> EPA, *Chapter 2: Evaluation of Health and Occurrence Data*, EPA Report 815-R-08-012, Washington, DC, June 2008.

<sup>48</sup> EPA, "Announcement of Preliminary Regulatory Determinations for Priority Contaminants on the Contaminant Candidate List," 67 *Federal Register* 38222-38244, June 3, 2002. EPA added sodium to the initial list of eight contaminants evaluated for possible regulation.

<sup>49</sup> EPA, "Announcement of the Drinking Water Contaminant Candidate List," 63 *Federal Register* 10285-10286, March 2, 1998.

<sup>50</sup> EPA, "Announcement of Preliminary Regulatory Determinations for Priority Contaminants on the Contaminant Candidate List," 67 *Federal Register* 38222-38244, June 3, 2002.

<sup>51</sup> EPA, "Announcement of Preliminary Regulatory Determinations for Priority Contaminants on the Contaminant Candidate List," 67 *Federal Register* 38222-38244, June 3, 2002.

For the second cycle in 2007, EPA made final determinations not to regulate 11 contaminants, due to highly regionalized contaminant occurrence or few detections at levels of public health concern.<sup>52</sup> EPA solicited comments and provided an update on assessments of other CCL 2 contaminants, including perchlorate and methyl tertiary-butyl ether (MTBE).<sup>53</sup>

### Regulatory Determination: Perchlorate

In 2008, EPA made a preliminary negative determination for perchlorate, but did not finalize the determination.<sup>54</sup> In 2011, EPA reversed the proposed negative determination and published a final regulatory determination that perchlorate warranted regulation, noting that the agency would begin the process of proposing a drinking water regulation.<sup>55</sup> After proposing a perchlorate regulation in 2019,<sup>56</sup> EPA published in 2020 a “Notice of Final Action” in the *Federal Register* withdrawing the 2011 positive regulatory determination for perchlorate.<sup>57</sup> In 2023, the U.S. Court of Appeals for the D.C. Circuit vacated EPA’s 2020 withdrawal of its regulatory determination.<sup>58</sup> SDWA requires EPA to propose and finalize a drinking water regulation for perchlorate. Following the 2023 decision, the spring 2024 *Unified Regulatory Agenda* did not provide a timeline for a proposed drinking water regulation for perchlorate and final rule.

For the third cycle in 2014, EPA made a preliminary determination to regulate strontium, and proposed not to regulate four other contaminants.<sup>59</sup> In the final RD 3, EPA determined not to regulate four contaminants due to low detections and/or low risk to public health.<sup>60</sup> For strontium, EPA delayed a final determination to consider additional newly identified scientific data about the contribution of other sources of strontium exposure.<sup>61</sup>

In March 2021, EPA finalized regulatory determinations for contaminants on CCL 4. EPA determined to regulate two PFAS (i.e., perfluorooctanoic acid [PFOA] and perfluorooctane sulfonate [PFOS]) and not to regulate six other chemicals.<sup>62</sup> In the *Federal Register* notice for the preliminary RDs, EPA provided an update on the agency’s efforts to evaluate strontium for regulation.<sup>63</sup>

<sup>52</sup> EPA, “Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations,” 72 *Federal Register* 24016-24058, May 1, 2007. EPA stated its intent to finalize a determination by December 2008.

<sup>53</sup> EPA, “Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations,” 72 *Federal Register* 24016-24058, May 1, 2007. For perchlorate, EPA solicited additional information on exposure and associated health effects, and EPA delayed the RD for MTBE while the agency revised the health risk assessment.

<sup>54</sup> EPA, “Drinking Water: Preliminary Regulatory Determination on Perchlorate,” 73 *Federal Register* 60262-60282, October 10, 2008.

<sup>55</sup> EPA, “Drinking Water: Regulatory Determination on Perchlorate,” 76 *Federal Register* 7762-7767, February 11, 2011.

<sup>56</sup> EPA, “National Primary Drinking Water Regulations: Perchlorate,” 84 *Federal Register* 30524-30569, June 26, 2019.

<sup>57</sup> EPA, “Drinking Water: Final Action on Perchlorate,” 85 *Federal Register* 43990-44002, July 21, 2020.

<sup>58</sup> *Natural Resources Defense Council v. U.S. EPA*, 20-1335 (U.S. Court of Appeals for the D.C. Circuit 2023).

<sup>59</sup> EPA, “Announcement of Preliminary Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List,” 79 *Federal Register* 62716-62750, October 20, 2014.

<sup>60</sup> EPA, “Announcement of Preliminary Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List,” 79 *Federal Register* 62716-62750, October 20, 2014.

<sup>61</sup> EPA, “Announcement of Final Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List,” 81 *Federal Register* 13-19, January 4, 2016.

<sup>62</sup> EPA, “Announcement of Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List,” 86 *Federal Register* 12272-12291, March 3, 2021.

<sup>63</sup> EPA, “Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List,” 85 *Federal Register* 14098-14142, March 10, 2020.

Following EPA’s positive regulatory determination in 2021, the agency made an out-of-cycle regulatory determination in March 2023. As a part of a proposed rule, EPA proposed that several other PFAS (i.e., perfluorohexane sulfonic acid [PFHxS], perfluorobutane sulfonic acid [PFBS], hexafluoropropylene oxide dimer acid [HFPO-DA] and its ammonium salt [also known as GenX chemical], and perfluorononanoic acid [PFNA]) warranted regulation under SDWA.<sup>64</sup> In April 2024, EPA finalized a positive regulatory determination for PFHxS, PFNA, and HFPO-DA, individually, and for these substances and PFBS, as a mixture.<sup>65</sup>

## Promulgating a Drinking Water Regulation

Once the Administrator determines to regulate a contaminant, SDWA requires EPA to propose a “national primary drinking water regulation” within 24 months and request public comment on the proposal. EPA is required to promulgate a final rule within 18 months after the proposal.<sup>66</sup> EPA can extend the deadline to publish a final rule for up to nine months by notice in the *Federal Register*.<sup>67</sup>

For each contaminant that EPA determines to regulate, EPA is required to establish a maximum contaminant level goal (MCLG) at a level at which no known or anticipated adverse health effects occur and which allows an adequate margin of safety.<sup>68</sup> Regulations also include a maximum contaminant level (MCL)—an enforceable limit for a contaminant in public water supplies—or a treatment technique if an MCL is not feasible.<sup>69</sup> These regulations can cover multiple contaminants and generally establish an MCL for each contaminant covered by the regulation.<sup>70</sup>

For each drinking water regulation, SDWA requires EPA to identify a list of best available technologies, treatment techniques, and other means that EPA finds to be feasible for the purposes of meeting the MCL. In addition, EPA is required to identify treatment technologies that achieve the MCL and are affordable for small systems.<sup>71</sup> Each regulation also establishes associated monitoring and reporting requirements.

When developing regulations, EPA is required to (1) use the best available, peer-reviewed science and supporting studies and data; and (2) make publicly available a risk assessment document that discusses estimated risks, uncertainties, and studies used in the assessment.<sup>72</sup>

Once finalized, regulations generally take effect three years after promulgation.<sup>73</sup> EPA may allow up to two additional years if the Administrator determines that more time is needed for public

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<sup>64</sup> EPA, “PFAS National Primary Drinking Water Regulation Rulemaking,” 88 *Federal Register* 18638-18754, March 29, 2023.

<sup>65</sup> EPA, “PFAS National Primary Drinking Water Regulation,” 89 *Federal Register* 32532-32757, April 26, 2024.

<sup>66</sup> SDWA §1412(b)(1)(E); 42 U.S.C. §300g-1(b)(1)(E).

<sup>67</sup> SDWA §1412(b)(1)(E); 42 U.S.C. §300g-1(b)(1)(E).

<sup>68</sup> SDWA §1412(b)(4)(A); 42 U.S.C. §300g-1(b)(4)(A).

<sup>69</sup> SDWA §1412(b)(4)(B); 42 U.S.C. §300g-1(b)(4)(B).

<sup>70</sup> By definition, a “primary drinking water regulation” includes an MCL and an MCLG for each contaminant, if technically and economically feasible. SDWA §1401(1); 42 U.S.C. §300f(1).

<sup>71</sup> SDWA §1412(b)(4)(E)(ii); 42 U.S.C. §300g-1(b)(4)(E)(ii).

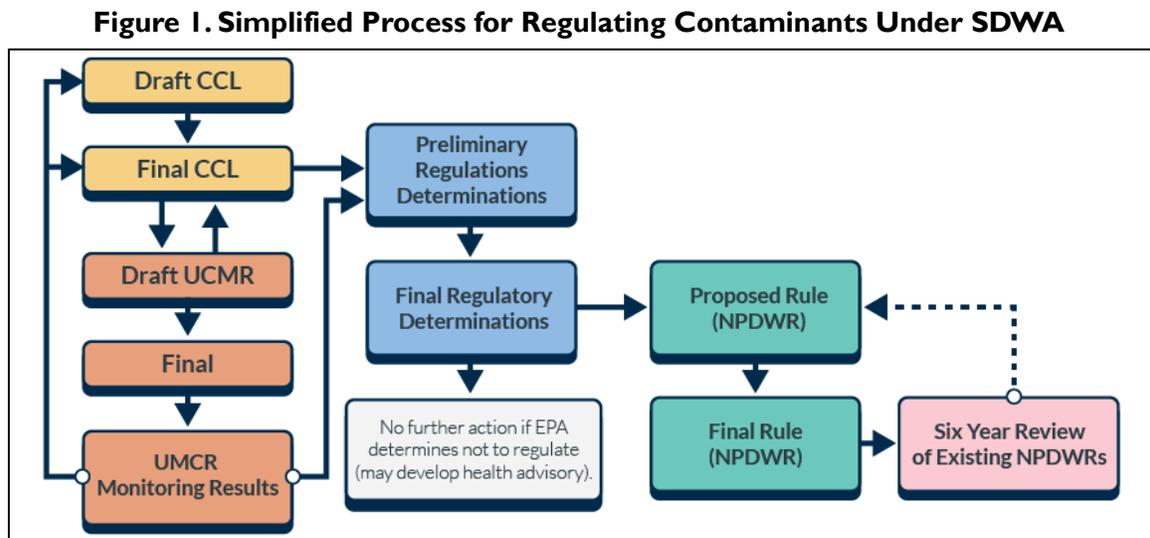
<sup>72</sup> SDWA §1412(b)(3); 42 U.S.C. §300g-1(b)(3).

<sup>73</sup> SDWA §1412(b)(10); 42 U.S.C. §300g-1(b)(10).

water systems to make capital improvements (states have the same authority for individual water systems).<sup>74</sup>

SDWA requires EPA to review each existing national primary drinking water regulation every six years. The review is intended to identify current health effects assessments, changes in technology, and/or other factors that would support the revision of a regulation to be more protective of public health.

**Figure 1** outlines the SDWA processes for contaminant evaluation, regulation, and regulatory review.



**Source:** Modified by CRS from EPA.gov.

**Notes:** CCL = contaminant candidate list, UCMR = unregulated contaminant monitoring rule, NPDWR = national primary drinking water regulation.

## Maximum Contaminant Level Goals

Drinking water regulations specify a nonenforceable MCLG, which is based solely on health effects data. Unlike an MCL, the MCLG does not reflect cost or technical feasibility considerations. For contaminants with carcinogenic effects and for microbial contaminants, EPA typically sets the MCLG at zero.<sup>75</sup>

For contaminants with noncarcinogenic effects, EPA derives an MCLG based on a reference dose, which is an estimate of the amount of a contaminant that a person can be exposed to on a daily basis that is not anticipated to cause adverse health effects for sensitive life stages and meaningful populations (e.g., infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other sensitive subpopulations) over a lifetime.<sup>76</sup> This amount incorporates

<sup>74</sup> SDWA §1412(b)(10); 42 U.S.C. §300g-1(b)(10). EPA used this authority to provide two additional years for community water systems serving 10,000 or fewer people to comply with the revised arsenic rule. EPA, "Proposed Rule: Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring," 65 *Federal Register* 38888-38983, June 22, 2000.

<sup>75</sup> For more information, see EPA website "How EPA Regulates Drinking Water Contaminants" at <https://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants#standards>.

<sup>76</sup> EPA, "Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List," 85 *Federal Register* 14098-14142, March 10, 2020.

uncertainty factors to provide a margin of protection for sensitive subpopulations and to account for uncertainties in the data.<sup>77</sup>

In developing an MCLG for noncarcinogens, EPA also estimates the general population's exposure to a contaminant from drinking water and other sources (e.g., food, dust, soil, and air). After considering other exposure routes, EPA estimates the proportion of exposure attributable to drinking water (i.e., the relative source contribution [RSC]).<sup>78</sup> When exposure information is not available, EPA uses a default assumption that 20% of exposure to a contaminant is attributable to drinking water. EPA applies the RSC to ensure that an individual's total exposure from all sources remains within the estimated protective level.<sup>79</sup> The MCLG provides the basis for calculating an MCL.<sup>80</sup>

## Feasibility and Maximum Contaminant Levels

SDWA generally requires EPA to set the MCL as close to the MCLG as “feasible.”<sup>81</sup> The act defines “feasible” to mean feasible with the use of the best available (and field demonstrated) treatment technologies, taking cost into consideration.<sup>82</sup> The level at which EPA is able to set the MCL is determined by the ability of a treatment technology to reduce a contaminant to a certain level. EPA's ability to set the MCL at the MCLG also depends on the availability of a test method that is sensitive enough to detect the contaminant at the MCLG. For contaminants regulated for noncarcinogenic effects, EPA generally has set the enforceable standard at the same level as the MCLG. If it is not technologically or economically feasible to ascertain the level of a contaminant in drinking water, EPA may establish a treatment technique in lieu of an MCL.<sup>83</sup> For example, EPA's Lead and Copper Rule includes a treatment technique—primarily relying on corrosion control, among other actions—because lead and/or copper generally enters the water after it leaves the plant.<sup>84</sup>

When developing an MCL that is feasible, EPA identifies and considers the costs to “large” water systems, as guided by legislative history.<sup>85</sup> Large water systems, serving more than 10,000 individuals, comprise roughly 9% of the number of community water systems and serve a majority (83%) of individuals regularly served by such systems.<sup>86</sup> By considering the costs to these systems, Congress intended that MCLs would be established at protective levels that are

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<sup>77</sup> EPA, “Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List,” 85 *Federal Register* 14098-14142, March 10, 2020.

<sup>78</sup> Other exposure routes include food ingestion, inhalation, and dermal contact.

<sup>79</sup> See, for example, EPA, *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)*, EPA 822-R-16-005, May 2016, p. 32, [https://www.epa.gov/sites/default/files/2016-05/documents/pfoa\\_health\\_advisory\\_final-plain.pdf](https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_health_advisory_final-plain.pdf).

<sup>80</sup> The Safe Drinking Water Act does not prohibit states from setting stricter standards.

<sup>81</sup> SDWA §1412(b)(4)(B); 42 U.S.C. §300g-1(b)(4)(B). EPA may set a standard at other than the feasible level if the feasible level would lead to an increase in health risks by increasing the concentration of other contaminants or by interfering with the treatment processes used to comply with other SDWA regulations. In such cases, the standard or treatment techniques must minimize the overall health risk (SDWA §1412(b)(5); 42 U.S.C. §300g-1(b)(5)).

<sup>82</sup> SDWA §1412(b)(4)(D); 42 U.S.C. §300g-1(b)(4)(D).

<sup>83</sup> SDWA §1412(b)(7)(A); 42 U.S.C. §300g-1(b)(7)(A).

<sup>84</sup> 40 C.F.R. §§141.80-141.91.

<sup>85</sup> The meaning of “large” water system has changed over time. Prior to the 1996 SDWA amendments, EPA's 1991 Lead and Copper Rule identified large systems as those serving 50,000 or more individuals, as guided by legislative history. The 1996 SDWA Amendments added SDWA §1412(b)(4)(ii), which required EPA to identify compliance technologies for small water systems defined as those serving 10,000 or fewer individuals.

<sup>86</sup> From EPA's “Safe Drinking Water Information Systems: Water System Summary” report at <https://ofmpub.epa.gov/apex/sfdw/f?p=108:1:::NO:1::>. Report generated on May 13, 2024. The search parameters were “public water systems.”

achievable for large systems, and thus provide affordable drinking water to a majority of individuals served by public water systems. This approach may make compliance with certain regulations less affordable for small water systems. To address affordability, SDWA includes numerous provisions intended to support small system compliance. For discussion of some of these provisions, see “Variances and Exemptions.”

## Additional Health Risk Reduction and Cost Considerations

SDWA provides EPA with limited authority to establish an MCL at a level other than the “feasible” level in certain circumstances. EPA may use this authority if, based on a “Health Risk Reduction Cost Analysis,” the Administrator determines that the benefits of the feasible level “would not justify the costs of complying with the level.”<sup>87</sup> In such a case, EPA may—after providing opportunity for public comment—set the standard at a level that “maximizes health risk reduction benefits at a cost that is justified by the benefits.” However, this authority is not available if the benefits that would be experienced by (1) large water systems, and (2) those other systems unlikely to receive small system variances (e.g., systems serving up to 10,000 persons), would justify the costs.<sup>88</sup> EPA has used this authority to establish MCLs at a level that was higher (i.e., less protective) than what would be “feasible” for two contaminants—uranium and arsenic.<sup>89</sup> For both contaminants, EPA established the MCL at a level higher than what was determined “feasible” because the agency estimated that the costs to treat these contaminants would be incurred primarily by small water systems.<sup>90</sup>

## Health Risk Reduction Cost Analysis

Concurrent with proposing a regulation, SDWA requires that EPA publish and seek public comment on a “health risk reduction and cost analysis” (HRRCA) for each contaminant covered by the proposed regulation.<sup>91</sup> While several congressional and presidential initiatives require certain federal agencies to evaluate costs and benefits of rulemakings,<sup>92</sup> SDWA outlines the specific costs and benefits that EPA is required to estimate when preparing an HRRCA and

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<sup>87</sup> SDWA §1412(b)(6)(A); 42 U.S.C. §300g-1(b)(6)(A).

<sup>88</sup> SDWA §1412(b)(6)(B); 42 U.S.C. §300g-1(b)(6)(B).

<sup>89</sup> For uranium, EPA revised the MCL from 20 µg/L—which EPA considered the “feasible” level—to 30 µg/L due to (1) the generation of additional health effects studies that indicate that “there is not a predictable difference in health effects due to exposure” between the two levels, and (2) the cost differences between treating to the two different levels (65 *Federal Register* 76708-76753). In EPA’s proposed arsenic rule, EPA determined that 3 µg/L was “feasible.” EPA used this authority to set the revised MCL at a level where the benefits from health risk reduction outweigh the costs, at 10 µg/L (66 *Federal Register* 6976-7066). As with the previous standard (set at 50 µg/L), the MCL applies only to community water systems.

<sup>90</sup> EPA, “National Primary Drinking Water Regulations; Radionuclides; Final Rule,” 65 *Federal Register* 76715, December 7, 2000. EPA, “National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring,” 66 *Federal Register* 7033-7034, January 22, 2001. Small water systems primarily rely on groundwater for their drinking water source. Some groundwater sources have naturally occurring contaminants such as arsenic and radionuclides (including uranium). Under these rules, such system that rely on groundwater, which are primarily small water systems, would face costs to treat for such naturally occurring contaminants.

<sup>91</sup> EPA may promulgate an interim standard without first preparing a health risk reduction and cost analysis or making a determination as to whether the benefits of a regulation would justify the costs if the Administrator determines that a contaminant presents an urgent threat to public health. SDWA §1412(b)(1)(D); 42 U.S.C. 300g-1(b)(1)(D). *Cryptosporidium* is exempt from the health risk reduction and cost analysis requirement (SDWA §1412(b)(6)(C); 42 U.S.C. 300g-1(b)(6)(C)).

<sup>92</sup> For more information, see CRS Report R41974, *Cost-Benefit and Other Analysis Requirements in the Rulemaking Process*, coordinated by Maeve P. Carey.

requires EPA to present the uncertainties of such an analysis.<sup>93</sup> The HRRCA is intended to provide a transparent analysis of the costs and benefits, calculated using the available science, as well as EPA's assumptions when developing a drinking water regulation. To prepare an HRRCA, EPA estimates the baseline conditions prior to drinking water regulation (based on contaminant occurrence and effectiveness of existing treatment technologies already in use); estimates national-level costs and benefits associated with the regulation of a specific contaminant; and assesses distributional impacts and equity concerns.<sup>94</sup>

At the public water system level, EPA estimates costs associated with treatment (e.g., installation and operation of contaminant removal technologies), training for staff, monitoring and analyzing water samples, and management and oversight.<sup>95</sup> In addition, the analysis may include costs to primacy agencies to enforce regulations. SDWA directs EPA to evaluate costs for compliance with the proposed MCL (and alternative MCLs), but specifically excludes compliance costs for other proposed or promulgated drinking water regulations.<sup>96</sup>

When developing an HRRCA, EPA calculates primarily the benefits of avoided mortality or morbidity (illness) from reduced exposure to a contaminant through drinking water for specified sensitive subpopulations and for the general population. As provided in SDWA, sensitive subpopulations include

infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.<sup>97</sup>

EPA quantifies health benefits through a variety of methods, primarily estimating the cost of illness or the cost of reduced physical and mental well-being. Other methods include estimating willingness-to-pay to avoid negative health impacts. EPA may include other quantifiable and nonquantifiable benefits such as “enhanced aesthetic benefits” (e.g., improved taste), avoided materials damage (e.g., reduced corrosivity of drinking water), avoided costs of household or water system actions to prevent contamination, as well as non-use benefits, among others.<sup>98</sup>

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<sup>93</sup> SDWA §1412(b)(3)(C); 42 U.S.C. 300g-1(b)(3)(C).

<sup>94</sup> EPA, *Preliminary Health Risk Reduction and Cost Analysis: Revised National Primary Drinking Water Standards for Radionuclides*, Cambridge, MA, January 2000.

<sup>95</sup> For more information, see EPA website, “SDWA Economic Analysis” at <https://www.epa.gov/dwregdev/economic-analysis-and-statutory-requirements>.

<sup>96</sup> SDWA §1412(b)(3)(C)(i)(III); 42 U.S.C. 300g-1(b)(3)(C)(i)(III).

<sup>97</sup> SDWA §1412(b)(3)(C)(i)(V); 42 U.S.C. §300g-1(b)(3)(C)(i)(V).

<sup>98</sup> For more information, see EPA website “National Benefits Analysis for Drinking Water Regulations” at <https://www.epa.gov/sdwa/national-benefits-analysis-drinking-water-regulations>.

### Health Advisories

For unregulated contaminants, health effects and/or occurrence data often are limited. SDWA authorizes EPA to issue health advisories for contaminants in drinking water that are not regulated under the act.<sup>99</sup> Health advisories provide information for states, water suppliers, and public health officials on health effects, test methods, and treatment technologies for specific contaminants. Health advisories are nonenforceable and intended to help states, water suppliers, and others address contaminants for which federal drinking water standards have not been established. Health advisories include levels for contaminants in drinking water that can be used to address different circumstances and exposure durations (e.g., 1 day, 10 days, a lifetime) and technical guidance on identifying, measuring, and treating contaminants. EPA has issued health advisories to address various circumstances: when contaminants do not meet the statutory criteria to warrant a national primary drinking water regulation, as an interim measure while EPA evaluates a contaminant for regulation, or to address a short-term incident or spill.

EPA sets the health advisory levels at concentrations that are expected to be protective of the most sensitive subpopulations (e.g., nursing infants) from any deleterious health effects, with a margin of protection, over the specified duration of exposure. Similar to the calculation of an MCLG, health advisory levels account for exposure from other contaminant sources (e.g., dermal contact, inhalation, and food ingestion).

Some states have used health advisories to inform their own state-specific drinking water regulations. EPA has issued health advisories for more than 200 contaminants to address different circumstances and subsequently established regulations for many of these contaminants.<sup>100</sup>

## Variations and Exemptions

As discussed above, national primary drinking water regulations consider the costs to large water systems, which provide water to 83% of the total population regularly served by public water systems, yet comprise roughly 9% of the total number of community water systems.<sup>101</sup> The remaining 91% of water systems that serve 10,000 or fewer individuals may lack technical, managerial, and financial capacity, leading to regulatory compliance challenges. Congress has long recognized the compliance challenges of “small” systems and has added a suite of provisions to SDWA to address such challenges. Among these, SDWA includes provisions that provide for “variances” from a drinking water standard and “exemptions” (i.e., additional time for compliance with a standard) from drinking water regulations, under specified circumstances.

Specifically for small systems, states may provide variances if EPA cannot identify an affordable technology that reduces the contaminant to the MCL.<sup>102</sup> If EPA identifies no such technology, then the agency is required to identify affordable variance technologies that may not meet the MCL.<sup>103</sup> After identifying variance technologies, states may grant small system variances to systems serving 3,300 or fewer persons if through treatment, an alternative water source, or restructuring, a system cannot afford to comply with the MCL and the variance ensures adequate protection of public health.<sup>104</sup> Under this type of variance, a state would allow the system to use a

<sup>99</sup> SDWA §1412(b)(1)(F); 42 U.S.C. §300g-1(b)(1)(F).

<sup>100</sup> EPA, *2018 Edition of the Drinking Water Standards and Health Advisories Tables*, March 2018, <https://www.epa.gov/system/files/documents/2022-01/dwtable2018.pdf>.

<sup>101</sup> From EPA’s “Safe Drinking Water Information Systems: Water System Summary” report at <https://ofmpub.epa.gov/apex/sfdw/f?p=108:1:::NO:1::>. Report generated on May 13, 2024. The search parameters were “public water systems.” For more information about SDWA and small water systems, see CRS Report R47315, *Small Water Systems: Selected Safe Drinking Water Act (SDWA) Provisions*, by Elena H. Humphreys.

<sup>102</sup> SDWA §1415(e); 42 U.S.C. §300g-4(e). In addition, SDWA §1415 authorizes states to grant a public water system a variance from an MCL if the untreated source water quality prevents meeting MCL even after application of the best technology, and the variance does not result in an unreasonable risk to health.

<sup>103</sup> SDWA §1412(b)(15); 42 U.S.C. §300g-1(b)(15).

<sup>104</sup> SDWA §1415(e); 42 U.S.C. §300g-4(e).

variance technology to comply with a regulation. With EPA approval, states may also grant variances to systems serving between 3,301 and 10,000 persons. Variances are not available for microbial contaminants. For every drinking water regulation, EPA has determined that compliance technologies for all MCLs are affordable for small systems; therefore, small system variances are not available.

SDWA Section 1416 authorizes states to grant public water systems temporary exemptions from drinking water regulations if a system cannot comply for other compelling reasons (including costs). An exemption is intended to give a water system additional time to come into compliance with a regulation and is limited to situations where an exemption would not result in an unreasonable health risk. Exemptions can be issued to a qualified system for up to three additional years beyond the regulation's effective date. Systems serving 3,300 or fewer persons may receive a maximum of three additional two-year extensions for total exemption duration of nine years.

## Six-Year Reviews

SDWA directs EPA, every six years, to review and revise, if necessary, each regulation and requires that any revision maintain or provide greater health protection.<sup>105</sup> EPA considers possible revisions if the revisions could improve the level of public health protection or achieve cost savings while maintaining or improving public health protection.

Since 1996, EPA has completed three cycles of the "Six-Year Review." For the first cycle, EPA determined to revise the Total Coliform Rule.<sup>106</sup> For the second cycle in 2010, EPA determined to revise the regulations for four contaminants (i.e., acrylamide, epichlorohydrin, tetrachloroethylene, and trichloroethylene).<sup>107</sup> For the third cycle in 2017, EPA determined to revise eight regulations, which are part of the following rules: (1) the Stage 1 and the Stage 2 Disinfectants and Disinfection Byproducts Rules, (2) the Surface Water Treatment Rule, (3) the Interim Enhanced Surface Water Treatment Rule, and (4) the Long Term Enhanced Surface Water Treatment Rule.<sup>108</sup> For the fourth cycle in 2024, EPA determined that no additional drinking water regulations warranted revision.<sup>109</sup>

**Table 3** includes a summary of EPA's actions to evaluate or revise contaminants for regulation under the Safe Drinking Water Act since the 1996 SDWA amendments that established the act's current process.

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<sup>105</sup> SDWA §1412(b)(9); 42 U.S.C. §300g-1(b)(9).

<sup>106</sup> EPA, "National Primary Drinking Water Regulations; Announcement of Completion of EPA's Review of Existing Drinking Water Standards," 68 *Federal Register* 42908-42929, July 18, 2003.

<sup>107</sup> EPA, "National Primary Drinking Water Regulations; Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment and/or Information on Related Issues," 75 *Federal Register* 15500-15572, March 29, 2010.

<sup>108</sup> EPA, "National Primary Drinking Water Regulations; Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment and/or Information on Related Issues," 82 *Federal Register* 3518-3552, January 11, 2017.

<sup>109</sup> EPA, *Six-Year Review 4 of Drinking Water Standards*, July 2024, <https://www.epa.gov/dwsixyearreview/six-year-review-4-drinking-water-standards>.

**Table 3. EPA’s Drinking Water Contaminant Regulatory Development Actions**

	First	Second	Third	Fourth	Fifth
<b>Contaminant Candidate List (CCL)</b>	<b>1998</b>	<b>2005</b>	<b>2009<sup>a</sup></b>	<b>2016</b>	<b>2022</b>
	60 contaminants	51 contaminants	116 contaminants	109 contaminants	81 contaminants or groups
<b>Unregulated Contaminant Monitoring Rule (UCMR)</b>	<b>1999</b>	<b>2007</b>	<b>2012</b>	<b>2016</b>	<b>2021</b>
	36 contaminants	25 contaminants	30 contaminants	30 contaminants	30 contaminants
<b>Regulatory Determination (RD)</b>	<b>2003</b>	<b>2008</b>	<b>2016</b>	<b>2021</b>	
<i>Evaluated</i>	9 contaminants	11 contaminants (including perchlorate)	5 contaminants	8 contaminants	
<i>Determination to Regulate</i>	None	None <sup>b</sup>	None <sup>c</sup>	EPA determined to regulate PFOA and PFOS <sup>d</sup>	
				<i>In 2023, EPA made an out-of-cycle determination to regulate six other per- and polyfluoroalkyl substances (PFAS)</i>	
<b>Six-Year Reviews</b>	<b>2003</b>	<b>2010</b>	<b>2017</b>	<b>2023</b>	
<i>Evaluated</i>	69 national primary drinking water regulations (NPDWRs)	71 NPDWRs	76 NPDWRs	All NPDWRs except PFAS	
<i>Chosen for Revision</i>	1 NPDWR	4 NPDWRs	8 NPDWRs	No Additional NPDWRs	

**Source:** Compiled by CRS from epa.gov. For additional detail on CCLs, UCMRs and RDs, and specific references, see **Appendix A**, **Appendix B**, and **Appendix C** respectively.

- Over time, EPA has revised its approach to finalizing the CCL. For CCL 3, EPA identified a broad “universe” of 7,500 potential drinking water contaminants, which the agency narrowed to 116 for the final list through a screening process.
- In 2011, the Administrator determined that regulation was needed for perchlorate, reversing the 2008 negative determination (76 *Federal Register* 7762-7767). In July 2020, the Administrator withdrew the 2011 determination to regulate perchlorate, and made a final determination not to regulate perchlorate (85 *Federal Register* 43990-44002). In 2023, the U.S. Court of Appeals for the D.C. Circuit vacated EPA’s 2020

- withdrawal of its regulatory determination. Therefore, SDWA requires EPA to propose and finalize a drinking water regulation for perchlorate. Following the 2023 decision, the spring 2024 *Unified Regulatory Agenda* did not provide a timeline for a perchlorate proposed drinking water regulation and final rule.
- c. In 2016, EPA delayed the determination for strontium to consider additional data (81 *Federal Register* 13-19).
  - d. In March 2021, EPA finalized determinations to regulate perfluorooctanoic acid [PFOA] and perfluorooctane sulfonate [PFOS] in 86 *Federal Register* 12272-12291.

## Considerations for Regulatory Determinations

SDWA broadly outlines the regulatory assessment and development process, yet several technical and policy considerations arise when implementing the process. Technical considerations include the availability and quality of health effects and occurrence data, and the availability of validated analytical test methods, as well as sufficient laboratory capacity and availability of a feasible treatment technology. Overarching considerations include prioritizing among thousands of potential contaminants, addressing contaminants that may not meet the act's criteria to warrant regulation but still generate public health concern, and competing priorities for agency resources to support drinking water contaminant evaluation and regulation development.

## Data Availability and Quality

Implementation of the act's process for evaluating contaminants for regulation and developing drinking water regulations depends on data availability and quality. For unregulated contaminants, EPA may lack the necessary health effects and/or occurrence data to consider such contaminants for regulation. To add a contaminant to the CCL, EPA requires initial data to characterize the contaminant's occurrence and adverse health effects.<sup>110</sup> Similarly, when selecting contaminants for monitoring as a part of a UCMR, EPA evaluates a contaminant's health effects, prioritizing contaminants associated with carcinogenic health effects.<sup>111</sup> To make a regulatory determination for a contaminant, EPA requires a peer-reviewed risk assessment and nationally representative occurrence data.<sup>112</sup> Without these data, EPA is unable to evaluate whether a contaminant meets the statutory criteria for regulation. For example, as a part of RD 4, EPA identified that 84 contaminants under consideration lacked either of these data.<sup>113</sup>

To establish an MCLG and drinking water standard, EPA requires a peer-reviewed risk assessment to evaluate a contaminant's health effects, as well as to identify and account for effects on the most sensitive subpopulations.<sup>114</sup> When developing an HRRCA, EPA requires health effects data to estimate benefits associated with reducing the risk of exposure as well as occurrence data and field-tested treatment technologies to estimate the cost of treatment needed to comply. Without data to estimate the costs and benefits of regulating a contaminant, EPA is unable to calculate the benefits from reduced health risks or the regulatory costs to communities and others.

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<sup>110</sup> EPA, "Drinking Water Contaminant Candidate List 3-Draft," 73 *Federal Register* 9628-9654, February 21, 2008.

<sup>111</sup> EPA, "Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems," 76 *Federal Register* 11713-11737, March 3, 2011.

<sup>112</sup> EPA, "Drinking Water Contaminant Candidate List 4-Draft," 80 *Federal Register* 6076-6084, February 4, 2015.

<sup>113</sup> EPA, "Preliminary Regulatory Determinations for Contaminants on the Fourth Contaminant Candidate List," 85 *Federal Register* 14098-14142, March 10, 2020.

<sup>114</sup> EPA, "Preliminary Regulatory Determinations for Contaminants on the Third Contaminant Candidate List," 79 *Federal Register* 62716-62750, October 20, 2014.

The absence of sufficient data for unregulated contaminants has limited EPA's implementation of SDWA regulatory development provisions.<sup>115</sup> EPA has often been unable to include unregulated contaminants for regulatory determinations due to an absence of a peer-reviewed risk assessment or nationally representative occurrence data. For several contaminants evaluated for RDs (e.g., perchlorate, strontium), EPA delayed finalizing determinations to collect additional data.<sup>116</sup> In a 2011 report, GAO concluded that insufficient data to characterize contaminant occurrence or health effects had impeded EPA progress in regulating contaminants in drinking water.<sup>117</sup>

## Availability of Analytical Methods and Laboratory Capacity

EPA's ability to develop contaminant occurrence data for the SDWA regulatory determinations depends on the availability of analytical test methods and laboratory capacity. For each contaminant in an UCMR, EPA requires a widely available analytical test method and sufficient laboratory capacity to support nationwide monitoring.<sup>118</sup> As a part of the UCMR, EPA may assist with the development of new analytical methods and/or identify consensus organization-developed methods.<sup>119</sup>

In preparation of a UCMR, laboratories across the country must receive EPA approval certifying that they have demonstrated that they can perform the method with replicable results.<sup>120</sup> EPA requires laboratories that seek to participate in UCMRs to apply and receive approval through EPA's Laboratory Approval Program, which requires demonstrated method proficiency with analytical standards.<sup>121</sup> EPA cannot select a contaminant for a UCMR without a validated analytical method and sufficient laboratory capacity to support a national monitoring program.

The availability of an analytical test method also informs EPA's ability to establish an MCL as close to the MCLG as "feasible." To assess feasibility, EPA first evaluates the sensitivity of the test method to detect a contaminant at levels close to the MCLG. Without a method that could detect a noncarcinogenic contaminant at the "goal" level, EPA would not be able to set an MCL at the MCLG.<sup>122</sup>

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<sup>115</sup> See, for example, Table 2, "Information Gaps for the CCL 2 Chemical Contaminants," EPA, "Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List," 73 *Federal Register* 44251-44261, July 30, 2008.

<sup>116</sup> EPA, "Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List-Preliminary Determinations," 72 *Federal Register* 24016-24058, May 1, 2007. EPA, "Announcement of Final Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List," 81 *Federal Register* 13-19, January 4, 2016.

<sup>117</sup> GAO, *EPA Should Improve Implementation of Requirements on Whether to Regulate Additional Contaminants*, 11-254, May 27, 2011, at <https://www.gao.gov/products/GAO-11-254>.

<sup>118</sup> EPA, "Drinking Water Contaminant Candidate List 4-Draft," 80 *Federal Register* 6076-6084, February 4, 2015.

<sup>119</sup> EPA, "Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems," 76 *Federal Register* 11713-11737, March 3, 2011. For UCMR 3, EPA developed six analytical methods and identified four equivalent methods from consensus organizations (e.g., Standard Methods and ASTM International).

<sup>120</sup> EPA, "Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems," 76 *Federal Register* 11713-11737, March 3, 2011.

<sup>121</sup> EPA, "Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems," 76 *Federal Register* 11713-11737, March 3, 2011.

<sup>122</sup> For contaminants with carcinogenic effects, EPA sets the MCLG at zero. Without an available treatment technology to reduce a carcinogen to zero, EPA would be unable to set the MCL at the MCLG.

### Consideration of Contaminant Group Regulations

The SDWA definition of a “primary drinking water regulation” specifies that each contaminant has an MCL or a treatment technique. EPA has regulated some contaminants as groups (e.g., different types of disinfection byproduct groups [total trihalomethanes and total haloacetic acids], and gross alpha radionuclides, etc.). EPA has made regulatory determinations for individual contaminants, including as a mixture.

In 2010, EPA released its Drinking Water Strategy, which included a principle to address drinking water contaminants as groups so that drinking water protection can be achieved cost effectively.<sup>123</sup> To issue a single drinking water regulation for a group of contaminants, EPA stated that, at a minimum, all the contaminants must have the same specific adverse health effect (e.g., cancer, endocrine effects, or developmental effects), be measured by the same analytical methods, be treated with the same treatment technology or treatment technique, and/or been shown to occur individually (and possibly co-occur).<sup>124</sup> For RD 3, EPA considered regulating several contaminants as a group, but ultimately decided to address one group of drinking water compounds, carcinogenic volatile organic compounds, through a separate regulatory process.<sup>125</sup>

For certain contaminants, group regulation may pose challenges. Certain contaminants may have some broad chemical similarities; however, such contaminants may have different health effects or require different sampling methods and treatment technologies or do not yet have analytical methods developed to detect their occurrence in drinking water. Establishing an enforceable standard for a group of contaminants also poses a technical challenge as the health risk reduction and cost analysis requires assessment of the risk reduction benefits and compliance costs for each contaminant. Individual contaminants may have varying MCLs depending on the treatment costs and health effects for each contaminant, which would affect the treatment technologies available to public water systems to comply with such a regulation.

## Congressional Interest

Congressional interest in SDWA regulatory development provisions has centered on EPA’s implementation of these provisions, as well as the functionality of the current process.<sup>126</sup> Since the 1996 SDWA amendments, EPA has finalized positive regulatory determinations for seven contaminants. Since 1996, EPA has considered thousands of chemicals for potential regulation, and developed health effects and occurrence data for numerous unregulated contaminants. The agency has also revised several drinking water regulations to tighten standards and has revised and expanded other existing regulations to establish MCLs for additional contaminants. In April 2024, EPA promulgated a national primary drinking water regulation for six PFAS based on a finalized positive regulatory determination.

In the 117<sup>th</sup> and 118<sup>th</sup> Congresses, Members introduced legislation regarding SDWA’s regulatory development provisions primarily intended to expedite the regulation of PFAS.<sup>127</sup> Since EPA’s finalization of the drinking water regulation for six PFAS, some Members have raised concerns that EPA’s regulation “lacks robust scientific support and did not fully consider the financial

<sup>123</sup> EPA, *A New Approach to Protecting Drinking Water and Public Health*, EPA 815F10001, March 2010, <https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1006RG2.txt>.

<sup>124</sup> EPA, “Preliminary Regulatory Determinations for Contaminants on the Third Contaminant Candidate List,” 79 *Federal Register* 62715-62750, October 20, 2014, at <https://www.regulations.gov/document?D=EPA-HQ-OW-2012-0155-0001>.

<sup>125</sup> EPA also considered regulating other contaminants as a group. For further discussion, see EPA, “Preliminary Regulatory Determinations for Contaminants on the Third Contaminant Candidate List,” 79 *Federal Register* 62716-62750.

<sup>126</sup> Recent appropriations acts directed EPA to use specified funds to support MCL development and to brief the conferees on the agency’s plans to develop MCLs for specific drinking water contaminants.

<sup>127</sup> See, for example, Senate Committee on Environment and Public Works, “Stakeholder Comment on Draft PFAS Legislation,” press release, June 22, 2023.

strains for compliance, particularly for rural and historically disadvantaged communities.”<sup>128</sup> These were concerns, among others, about EPA’s implementation of the SDWA regulatory development provisions that were the subject of congressional debate in the 116<sup>th</sup> Congress.

Members were heavily focused on SDWA’s regulatory development provisions during the 116<sup>th</sup> Congress due to widespread concerns about PFAS contamination. Some Members raised concerns that the act’s process was lengthy and complicated and did not allow for the timely regulation of contaminants of concern in drinking water.<sup>129</sup> Other Members expressed concern that proposals to expedite regulation by removing elements of SDWA regulatory development provisions (e.g., the requirement to use peer-reviewed science or a health risk-based approach) could result in compliance costs and affordability challenges for communities to address contaminants that may not pose a significant threat to public health or regulations that are not based on the best available, peer-reviewed science.<sup>130</sup> This debate was heightened prior to EPA’s positive regulatory determination for PFAS in 2021.<sup>131</sup>

When federal drinking water standards are absent, states are authorized to (and have) issued regulations for contaminants, which may vary from state to state. Some Members have argued that this patchwork of regulation undermines public confidence in drinking water quality.<sup>132</sup> Other Members caution that proposals to amend SDWA to increase regulatory pace would add to states’ financial burdens without meaningful health protection, as drinking water regulation enforcement is generally a state responsibility.<sup>133</sup> Other issues include how costs are considered in the standard-setting process, whether the development of a “feasible” standard is sufficiently protective of sensitive subpopulations, and the affordability of regulations for small and disadvantaged communities.

Some stakeholders have concerns about the third regulatory determination criterion, which gives some discretion to the Administrator to assess what constitutes a “meaningful opportunity for health risk reduction.”<sup>134</sup> Others have argued that proposals that focus on the quantity of drinking

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<sup>128</sup> Senate Committee on Environment and Public Works, “Capito Statement on EPA’s New Drinking Water Standard for PFAS,” press release, April 10, 2024.

<sup>129</sup> See, for example, U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and Climate Change, *There’s Something in the Water: Reforming Our Nation’s Drinking Water Standards*, Testimony of Subcommittee Chairman Tonko, 116<sup>th</sup> Cong., 2<sup>nd</sup> sess., July 28, 2020.

<sup>130</sup> U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and Climate Change, *There’s Something in the Water: Reforming Our Nation’s Drinking Water Standards*, Testimony of Ranking Member Walden, 116<sup>th</sup> Cong., 2<sup>nd</sup> sess., July 28, 2020.

<sup>131</sup> In the 116<sup>th</sup> Congress, legislation was introduced to direct EPA to regulate specific contaminants (e.g., PFOA and PFOS).<sup>131</sup> Other bills would have established a different regulatory process and deadlines for specific contaminants or groups of contaminants (i.e., PFAS). On occasion, Congress has directed EPA to promulgate a regulation for a particular contaminant within a specified time frame. For example, in the Safe Drinking Water Amendments of 1996 (P.L. 104-182), the 104<sup>th</sup> Congress directed EPA to regulate radon, propose a new arsenic standard, and evaluate sulfate for regulation (SDWA §1412(b)(12); 42 U.S.C. §300g(b)(12); SDWA §1412(b)(13); 42 U.S.C. §300g(b)(13)).

<sup>132</sup> U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and Climate Change, *There’s Something in the Water: Reforming Our Nation’s Drinking Water Standards*, Testimony of Subcommittee Chairman Tonko, 116<sup>th</sup> Cong., 2<sup>nd</sup> sess., July 28, 2020.

<sup>133</sup> U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and Climate Change, *There’s Something in the Water: Reforming Our Nation’s Drinking Water Standards*, Testimony of Ranking Member Walden, 116<sup>th</sup> Cong., 2<sup>nd</sup> sess., July 28, 2020. SDWA §1413 (42 U.S.C. §300g-2) requires EPA to delegate primary enforcement authority for SDWA regulations to states that meet certain criteria. Currently, 49 states, the territories, and the Navajo Nation have applied for and received primacy for the drinking water program. EPA retains implementation and enforcement authority for Wyoming, the District of Columbia, and Indian tribes other than the Navajo Nation.

<sup>134</sup> See, for example, U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and Climate Change, *There’s Something in the Water: Reforming Our Nation’s Drinking Water Standards*, 116<sup>th</sup> Cong., 2<sup>nd</sup> sess., July 28, 2020, testimony from Natural Resources Defense Council.

water regulations, or the presence of a contaminant rather than risk, may lead EPA to focus agency resources on promulgating regulations without a scientific basis or on regulating “lower priority” contaminants with fewer health impacts to meet statutory quotas, as happened in the 1986 amendments, which directed EPA to regulate 25 contaminants every 3 years.<sup>135</sup>

Other concerns have involved how, under SDWA, regulatory costs to water systems and customer affordability are considered when EPA sets a drinking water standard. Particularly for small water systems, and communities with declining populations or economies, efforts to accelerate regulatory pace by removing consideration of a contaminant’s health risk reduction benefits or occurrence may increase the cost of providing water and result in more water affordability challenges for people served by such systems. Similarly, representatives of state drinking water administrators have raised concerns over their current resources to enforce drinking water regulations.<sup>136</sup> Others have argued that the act’s current consideration of regulatory costs must be maintained to ensure that the benefits of public health protection are maximized.<sup>137</sup> As EPA, states, and water systems implement drinking water regulations, congressional interest in these issues is likely to continue.

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<sup>135</sup> U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and Climate Change, *There’s Something in the Water: Reforming Our Nation’s Drinking Water Standards*, Testimony of Subcommittee Ranking Member Shimkus, 116<sup>th</sup> Cong., 2<sup>nd</sup> sess., July 28, 2020.

<sup>136</sup> Association of State Drinking Water Administrators, “ASDWA Statement on Final PFAS Drinking Water Standards,” press release, April 2024.

<sup>137</sup> See, for example, U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and Climate Change, *There’s Something in the Water: Reforming Our Nation’s Drinking Water Standards*, 116<sup>th</sup> Cong., 2<sup>nd</sup> sess., July 28, 2020, testimony from Association for State Drinking Water Administrators, and Association of Metropolitan Water Agencies.

## Appendix A. Contaminant Candidate Lists

**Table A-1. Contaminant Candidate Lists (CCLs)**

<b>CCL</b>	<b>Date Issued</b>	<b>Contaminants and Notes</b>
<b>CCL 1</b> 63 FR 10274-10287	1998	60 contaminants (50 chemical contaminants and 10 microbiological contaminants)
<b>CCL 2</b> 70 FR 9071-9077	2005	51 contaminants (42 chemical contaminants or contaminant groups and 9 microbiological contaminants)
<b>CCL 3</b> 74 FR 51850-51862	2009	116 contaminants (104 chemicals or chemical groups and 12 microbiological contaminants)
<b>CCL 4</b> 81 FR 81099-81114	2016	109 contaminants (97 chemicals or chemical groups and 12 microbial contaminants)
<b>CCL 5</b> 87 FR 68060-68085	2022	81 contaminants or groups (66 chemicals, 3 chemical groups [PFAS, cyanotoxins, and disinfection byproducts] and 12 microbial contaminants)

**Source:** Prepared by CRS from *Federal Register* notices.

## Appendix B. Unregulated Contaminant Monitoring Rules

**Table B-1. Unregulated Contaminant Monitoring Rules (UCMRs)**

UCMR	Date Issued	Monitoring Period	Contaminants
<b>UCMR 1</b> (64 FR 50556-50620)	1999	2001-2005	36 contaminants (28 chemical contaminants and 8 microbiological contaminants or contaminant groups) <sup>a</sup>
<b>UCMR 2</b> (72 FR 367-398)	2007	2008-2010	25 unregulated chemical contaminants (3 explosives, 3 acetanilide compounds and 4 associated degradation products, 6 nitrosamines, 5 flame retardants)
<b>UCMR 3</b> (77 FR 26071-26101)	2012	2013-2015	30 contaminants: 29 unregulated contaminants (27 chemical contaminants and 2 viruses) and 1 regulated contaminant (total chromium)
<b>UCMR 4</b> (81 FR 92666-92692)	2016	2018-2020	30 chemical contaminants (9 cyanotoxins and 1 cyanotoxin group; 2 metals; 9 pesticides; 3 brominated haloacetic acid disinfection byproducts groups, 3 alcohols, and 3 semivolatile organic chemicals)  29 of these contaminants are unregulated and 1 (Haloacetic Acids 5) is regulated under the Disinfectant Byproduct Rule
<b>UCMR 5</b> (86 FR 73131-73157)	2021	2023-2025	29 PFAS and lithium <sup>b</sup>

**Source:** Prepared by CRS from epa.gov and *Federal Register* notices.

- a. For UCMR 1, EPA interpreted SDWA Section 1445(a)(2)(B)(i) to mean “that the UCMR list may contain more than 30 contaminants, as long as monitoring is not required for more than 30 contaminants during a five-year listing cycle” (64 FR 50566).
- b. For the fifth rule, the National Defense Authorization Act for Fiscal Year 2020 (P.L. 116-92), Section 7311 directs EPA to include any PFAS (or class of PFAS) with a validated test method and excludes such substances from counting toward the 30 contaminant limit.

## Appendix C. Regulatory Determinations

**Table C-1. Regulatory Determinations (RDs)**

RD Cycle	Date Issued	Contaminants Evaluated			Other Actions Taken
		Positive	Negative	Notes	
<b>RD 1</b> (67 FR 38222-38244)	June 3, 2002	None	<i>Acanthamoeba</i> , aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium, and sulfate	EPA issued guidance on <i>Acanthamoeba</i> and health advisories for magnesium, sodium, and sulfate	
<b>RD 2</b> (73 FR 44251-44261)	July 30, 2008	None	Boron, Dacthal mono-acid (MTP) degradate, Dacthal di-acid (TPA) degradate, 1,1-Dichloro-2,2-bis(p-chlorophenyl)ethylene (DDE), 1,3-Dichloropropene (Telone), 2,4-Dinitrotoluene, 2,6-Dinitrotoluene, s-Ethyl propylthiocarbamate (EPTC), Fonofos, Terbacil, 1,1,2,2-Tetrachloroethane	EPA intended to finalize an RD for perchlorate by December 2008 <sup>a</sup>	EPA issued or revised health advisories for boron, dacthal degradates, 2,4-dinitrotoluene, 2,6-dinitrotoluene, and 1,1,2,2-tetrachloroethane
<b>RD 3</b> (81 FR 13-19)	January 4, 2016	None	Dimethoate, 1,3-dinitrobenzene, terbufos, and terbufos sulfone	EPA delayed a final regulatory determination on strontium	
<b>RD 4</b> (86 FR 12272-12291)	March 3, 2021	PFOS and PFOA <sup>b</sup>	1,1-dichloroethane, acetochlor, methyl bromide, metolachlor, nitrobenzene, and RDX	EPA presented an update on strontium and 1,4-dioxane and 1,2,3-trichloropropane in the proposed RD <i>Federal Register</i> notice (85 FR 14098-14142)	

**Source:** Prepared by CRS from epa.gov and *Federal Register* notices.

- a. In 2011, the Administrator determined that regulation was needed for perchlorate, reversing the 2008 negative determination (76 *Federal Register* 7762-7767). In July 2020, the Administrator withdrew the 2011 determination to regulate perchlorate, and made a final determination not to regulate perchlorate (85 *Federal Register* 43990-44002). In 2023, the U.S. Court of Appeals for the D.C. Circuit vacated EPA's 2020 withdrawal of its regulatory determination. Therefore, SDWA requires EPA to propose and finalize a drinking water regulation for perchlorate. Following the 2023 decision, the spring 2024 *Unified Regulatory Agenda* did not provide a timeline for a perchlorate proposed drinking water regulation and final rule.
- b. In March 2023, EPA made an out-of-cycle determination to regulate perfluorohexane sulfonic acid (PFHxS), perfluorobutane sulfonic acid (PFBS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), and perfluorononanoic acid (PFNA), as a part of its proposed drinking water regulation for perfluorooctanoic acid [PFOA] and perfluorooctane sulfonate [PFOS] (88 *Federal Register* 18638-18754).

## **Author Information**

Elena H. Humphreys  
Analyst in Environmental Policy

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