

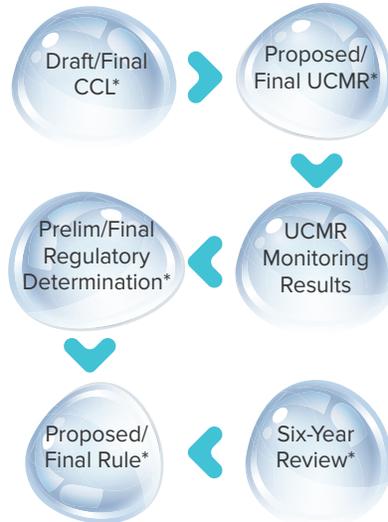
Safe Drinking Water Act (SDWA) Regulatory Development Process



MAY 2019

The 1996 Amendments to the Safe Drinking Water Act (SDWA) provided a step-by-step framework for both the development of new drinking water regulations and the review of all existing regulations. The development of a new regulation follows a multi-step process, with each step on five-year cycles:

1. [Contaminant Candidate List \(CCL\)](#)
2. [Regulatory Determination \(RegDet\)](#)
3. Regulation/National Primary Drinking Water Regulation (NPDWR)



The figure shows how these steps fit together, along with the [Unregulated Contaminant Monitoring Rule \(UCMR\)](#). Opportunities in the process for public input and comment are marked with an asterisk.

A separate but related regulatory effort is the review of all existing regulations every six years (Six-Year Review) that evaluates new data to assess whether a regulation needs to be revised.

CONTAMINANT CANDIDATE LIST (CCL) AND UNREGULATED CONTAMINANT MONITORING RULE (UCMR)

The CCL is the starting point of EPA's regulatory development process. It is, therefore, a list of drinking water contaminants that are known to — or anticipated to — occur in public water systems, and may require regulation by EPA. Contaminants become candidates for this list from analyses of toxicity and occurrence data, and from nominations by the public.

EPA is required by the SDWA to publish a new CCL every five years. The Fourth CCL (CCL4) was published in late 2016 and includes 97 chemicals and chemical groups and 12 microbial contaminants. The table illustrates the last four rounds of CCLs, UCMRs as well as the Regulatory Determinations (RegDets).

Once the CCL is determined, the next step is to review data; therefore, robust national occurrence data is required. If there is no national occurrence data for a particular contaminant, EPA can require monitoring of the contaminant through the Unregulated Contaminant Monitoring Rule (UCMR). UCMRs are limited to no more than 30 contaminants (every five years), and the monitoring is required for all water systems that serve more than 10,000 people.



	First	Second	Third	Fourth
CCL	1998	2005	2009	2016
	60 Contaminants	51 Contaminants	116 Contaminants	109 Contaminants
UCMR	1999	2007	2012	2016
	26 Contaminants	25 Contaminants	30 Contaminants	30 Contaminants
RegDet	2003	2008	2016	Coming in 2021
	9 Not Regulated	11 Not Regulated	4 Not Regulated 1 Needs more research	

Typically, the contaminant is monitored for four consecutive quarters within a three-year window.

In the past, EPA selected a statistical sample of systems of less than 10,000 people in order to estimate the national occurrence for those systems. The latest set of SDWA Amendments in the America's Water Infrastructure Act of 2018 could potentially extend the required monitoring to all systems serving between 3,300 and 10,000 people, depending on future appropriations. The Fourth Unregulated Contaminant Monitoring Rule (UCMR4) for 30 contaminants was finalized in late 2016. Monitoring is ongoing, and will last through 2020.

REGULATORY DETERMINATION (RegDet)

After a contaminant has been monitored, EPA determines whether to develop a National Primary Drinking Water Regulation (NPWDR) for a contaminant. The SDWA requires EPA make regulatory determinations for at least five contaminants on the CCL, on five-year cycles. The SDWA specifies three criteria that must be met in order for a national regulation to be developed for a contaminant:

Contaminant has adverse health effects on people. + Contaminant known to occur/substantial likelihood to occur in a public water system at frequency and level of concern. + Regulation of contaminant presents meaningful opportunity to reduce health risks for populations served by public water.



Regulatory determinations aren't necessarily a binary yes or no decision to regulate. EPA can decide that more research is needed or that some type of guidance or a health advisory is more appropriate than a regulation. It's important to note that the third criterion is at the sole discretion of the Administrator, and that all criteria must be satisfied for a positive regulatory determination. Additionally, the interpretation of the words in the criteria can influence what action is taken.

EPA made its third round of regulatory determinations (RegDet 3) in early 2016. In this round of decisions, EPA decided not to regulate four of the 116 CCL3 contaminants: dimethoate; 1,3-dinitrobenzene; terbufos; and terbufos sulfone. The Agency also decided to delay the final regulatory determination on strontium to consider additional data and decide whether there is a meaningful opportunity for health risk reduction by regulating strontium in drinking water.

REGULATION

Once EPA has made the determination to issue a National Primary Drinking Water Regulation (NPWDR), the Agency has 24 months to develop a proposed regulation. After the proposal date, EPA has 18 months to finalize the regulation, but the Agency can request an extension to that deadline if needed.

EPA follows a multi-step process for the development of the regulation:

Selecting the appropriate MCL is complicated as the decision involves evaluating several science and policy options. The SDWA mandates the use of the best-available, peer-reviewed science to evaluate analytical methods and treatment, and to consider small systems impacts and affordability. The SDWA also mandates a significant benefit-cost analysis and requires EPA to determine if benefits of the proposed MCL "justify" the costs.



The MCLG is a health-based goal and doesn't take costs or feasibility into consideration. EPA utilizes peer-reviewed risk assessments to set the MCLG at a level where there are no adverse effects to the human health that allows for an adequate margin of safety. Feasibility, in the determination of an MCL, is defined as using the best technology and treatment techniques "under field conditions and not solely under laboratory conditions."

EPA must consult with its Science Advisory Board (SAB) and the National Drinking Water Advisory Council (NDWAC). EPA may also conduct a "negotiated rulemaking" with stakeholders under the provisions of the Federal Advisory Committee Act (FACA). As part of the regulatory development process, EPA requests public comment on

drafts or proposals for each step, which is vital for soliciting a broad range of perspectives for decision-making. Many organizations submit public comments such as water systems and their respective associations, state regulators (including ASDWA), environmental advocacy groups, public interest groups, local elected officials and individual members of the public.