State CEC Rule Development and Management Strategies Toolkit

February 2020

Contents

Acronyms

AG: Attorney General

ASDWA: Association of State Drinking Water Associations

ASTSDR: Agency for Toxic Substances and Disease Registry

AWWA: American Water Works Association

BCA: Benefit-Cost Analysis

CAPs: Customer Assistance Programs

CCI: Clear Communication Index

CCR: Continuity of Care

CEC: Contaminant of Emerging Concern

CERC: Crisis and Emergency Risk Communication

CDC's: Centers for Disease Control and Prevention

COI: Cost of Illness

DOD: Department of Defense

EPA: Environmental Protection Agency

ERLN: Environmental Response Laboratory Network

FEMA: Federal Emergency Management Agency

FDA: Food and Drug Administration

FSTRAC: Federal State Toxicology & Risk Analysis Committee

GIS: Geographic Information System

HBVs: Health Based Values

HRLs: Health Risk Limits

HHS: Department of Health and Human Services

ITRC: Interstate Technology & Regulatory Council

IRIS: Integrated Risk Information System

LQI: Lower Quintile Income

MCL: Maximum Contaminant Level

MDH: Minnesota Department of Health

MNELAP: Minnesota Department of Health Environmental Laboratory Accreditation Program

MPART: Michigan PFAS Action Response Team

MSDS: Material Safety Data Sheets

NAISC: North American Industry Classification System

NPDES: National Pollutant Discharge Elimination System

NELAP: National Environmental Laboratory Accreditation Program

NIH: National Institute of Health

NLM: National Library of Medicine

PFAS/PFNA: Perfluorooctanoic Acid

PFOS: Perfluorooctanesulfonic Acid

PFHxS: Perflurohexanesulphonic Acid

QA/QC Quality Assurance and Quality Control

RCAP: Rural Community Assistance Partnership

RCRA: Resource Conservation & Recovery Act

RIA: Regulatory Impact Analysis

SDWA: Safe Drinking Water Act

SONAR: Statement of Need and Reasonableness

SOPs: Standard Operating Procedure

SRF: State Revolving Fund

TMF: Technological, Managerial and Financial

TRI: Toxic Release Inventory

USEPA: United States Environmental Protection Agency

UCMR: Unregulated Contaminant Monitoring Rule

WLA: Washington Library Association

WTP: Willingness to Pay

State CEC Rule Development & Management Strategies Toolkit

Introduction

In recent years, state drinking water agencies have found themselves on the front lines of risk assessment, management, and communications for contaminants that have emerged as public concerns—often with considerable uncertainties about toxicity, occurrence, and treatment. In the absence of federal regulations, states have the difficult job of formulating strategies for managing risks for these Contaminants of Emerging Concern (CECs).

CECs are contaminants that are unregulated or are regulated at a level that may no longer be considered adequately protective of human and ecological health. A CEC may be a contaminant that has been newly discovered in the environment or one that has been known about for a long time but is generating increased public attention or interest in the scientific community due to new scientific information about its impacts on public health or the environment. A defining characteristic of CECs is that there is significant uncertainty about the risks they pose, their occurrence in the environment, the level of public exposure, and/or how to effectively treat water to remove the contaminant—often in the context of public alarm.

The Association of State Drinking Water Administrators (ASDWA) worked with a team of state drinking water administrators to develop this toolkit for state drinking water agencies. The toolkit is intended to help these agencies move from a strong signal of potential risk from a CEC in drinking water to managing risk to an acceptable level, potentially including creating a state-specific CEC rule establishing a Maximum Contaminant Level (MCL) or treatment technique. The toolkit draws heavily on participating states' recent experience managing risks from Per- and Polyfluoroalkyl Substances (PFAS) but generalizes from this experience to be broadly applicable to other CECs.

The toolkit is built around a set of modules that walk users through key steps of risk assessment and risk management:

- Module 1: Conduct a Self-Assessment of Regulatory Context and Capacity and Address Current Public Health Concerns as Needed
- Module 2: Characterize Health Effects
- Module 3: Characterize Occurrence
- Module 4: Identify Analytical Methods
- Module 5: Characterize Treatment and Compliance Options
- Module 6: Characterize Benefits, Costs, and Economic Considerations
- Module 7: Pursue Intermediate Management Strategies
- Module 8: Pursue CEC Rule Development (MCL or Treatment Technique)

Each module contains a series of steps for users to consider, accompanied by information about useful resources and examples from state experience. The modules are designed to be rigorous enough to move

users through the process of developing a state-specific CEC rule, but the modules are also designed to be useful for states that are undertaking management steps through means other than a rule—or have not yet determined their approach. For example, the toolkit can help states establish advisory levels that can be used to require or encourage drinking water systems to undertake intermediate management strategies to reduce public exposure to CECs.

The toolkit is designed to help states organize their thinking and gain insight from relevant resources but does not offer comprehensive guidance. It recognizes that states are often stretched very thin on resources and personnel, especially when confronting new challenges, but the tool is designed with an assumption that states have enough resources and capacity to undertake the steps in each module as appropriate for their situation.

Although many implementation issues need to be addressed in creating a state-specific CEC rule, this module (and toolkit) stops short of covering specific actions and capacities needed to manage rule implementation on an ongoing basis, such as deployment of treatment technologies in specific drinking water systems.

It is difficult to provide consistent guidance on the amount of time and capacity states will need to go through all of the CEC management activities outlined in the toolkit. The demands that managing different CECs put on state agencies may vary widely given the state of the science and where and how CECs are occurring. Your state's particular legal and regulatory context—as well as what capacity currently exists or will need to be built over time—will influence what the state can do and over what time period. Some actions can occur simultaneously while others are in sequence. Your state may not have the luxury of taking the time you need but rather may be responding to legislated timelines and public demands. As outlined in Module 1, we recommend that you map out needed steps and timelines that fit your particular context.

Although this is a public document, it is intended for use by state regulators and assumes a level of subject matter understanding consistent with a state drinking water professional. Information provided in this toolkit should never supersede state policies or requirements.

Risk Communication

Because an important aspect of CEC risk management is addressing public concerns and creating a shared understanding of how to address CEC risks appropriately, the toolkit includes risk communication insights. Risk communication is a leadership tool designed to convey information for an emotionally charged topic (including all public health and CEC topics) in a manner that maintains an appropriate level of concern while returning the emotionally charged topic to one of reasoned discourse where an effective exchange of information is possible. The primary mantra of risk communication is: "Be first, be right, be credible."[1] Typically, risk communication is a discussion of a negative outcome and the probability that the adverse outcomes will occur. One objective of risk communication is to empower both personal and community decision-making when fear or anxiety are present and objective data are limited or highly uncertain.

[1] See: Centers for Disease Control, *Crisis and Emergency Risk Communication Manual*.

The toolkit provides a brief overview of risk communication before the modules. Situation-specific examples and advice for how to bring the risk communication thought process to CEC risk assessment and management are then provided as part of each module.

Using the Toolkit

The toolkit is structured based on a logical progression of considerations for you as you move from initial recognition of potential risk through the process of assessing that risk and then managing it. Depending on your state's objective for using the toolkit, you may focus on a specific module or you may aim for an initial reconnaissance level understanding of each module.

You may use the toolkit in different ways based on where you are in the process of assessing and managing CEC risk and your legal and regulatory authority. For example:

- **If you are seeking to develop a state-specific drinking water rule** you may progress from Module 1 through Module 8 (Pursue CEC rule development) in sequence.
- **If your state does not have authority to develop a state-specific rule but is seeking to manage risk by requiring that drinking water systems undertake intermediate management strategies,** you may progress from Module 1 through Module 7 (Pursue intermediate management strategies).
- **If you are seeking a better understanding of public exposure you** may progress from Module 1 through Module 3 (Characterize occurrence) or Module 4 (Identify analytical methods).

You may be well on the road to assessing and managing risk and may simply be interested in one or two topics covered by the modules, such as benefit-cost analysis (Module 6). Recognizing that you may not follow a linear path through the modules, there are links throughout to other modules for complementary or necessary actions or resources.

Each module provides you with an articulation of topic-specific:

- *End Goals* – the signal that you have successfully completed the module.
- *Introduction* – a brief overview of the module topic and contents.
- *Questions to Consider* – questions that represent the module sub-objectives that likely need to be addressed to reach the End Goal.
- *Key Implementation Steps and Lessons* – a step-by-step overview of how to progress through the module and reach the End Goal.

In addition, each module includes call out boxes to provide you with communication and collaboration ideas, insights from recent state experiences, and links to additional resources.

Communication and Collaboration	These call-out boxes provide risk communication and collaboration advice that you can use throughout the process of managing CEC risk to build understanding for appropriate actions.
State Experience	One of the best ways to learn is from other state experiences. These call-out boxes highlight the experiences of specific states or groups of states that offer lessons or examples. Many of the specific examples draw on states' experience with assessing and managing risks from PFAS.
Resources	These call-out boxes identify resources that will allow you to go deeper into specific topics, including guidance, tools, and examples.

Development of the Toolkit

Content for this toolkit was developed through desk research as well as individual and collective input from drinking water professionals from ten states: California, Colorado, Connecticut, Massachusetts, Michigan, Minnesota, New Hampshire, New Jersey, Pennsylvania, and Vermont. Representatives from these states reflected on and shared their experience and expertise managing CECs through one-on-one interviews, an in-person workshop, and module-specific webinars over the course of six months to share their insights, lessons learned, and resources. In addition, state drinking water professionals from Ohio, Rhode Island, and Wisconsin reviewed and provided feedback on a draft of the toolkit.

Risk Communication

To remove the barriers states may encounter when communicating about CECs, states can utilize strategic research-based risk communication techniques. Because creating the permanent record of CEC materials in a manner that supports understanding and appropriate risk management is an inherent part of each module, the Toolkit provides readers with an introduction into risk communication up-front, and then provides topic specific tips in each module. Using risk communication approaches in the development of memoranda and reports, as well as in public outreach, can significantly support the appropriate use of science, numbers, risk, probability, and uncertainty in both public and personal decision-making.

Risk Communication Messaging Best Practices

Research informs us that when fear or high anxiety are present, the brain can deter the conversation to the amygdala (the primitive portion of the brain) where the decision under consideration is restricted to should I fight, freeze or flee. No other decision is possible when the brain is processing in the amygdala (it is a core feature of human survival).Therefore, if you want to address CECs without a fight or standoff with the legislature, the community, or your staff, it helps to take the time to respectfully acknowledge any fear or anxiety that might be present and to help people move the dialogue back to reasoned discourse. This is done by acknowledging the emotion and providing empathy. For example, *"I know you are concerned we may not have sufficient information to make a decision based on definitive science; that was a real concern for me when working on earlier drinking water regulations, but I have confidence we can still make a good decision."* Throughout the CEC process look for and address the anxiety in all your audiences. Is a utility concerned about media reports? Is state staff worried about inadequate resources, or the community worried about their infants? Remember, every conversation about a CEC is a public health conversation, and therefore a risk communication situation.

Risk communication messaging best practices also help when uncertainty and complexity make it difficult to know how to use information appropriately in decision-making. One communication technique to use when information overload and inadequacy create barriers, is to identify and respond to each specific audience's questions of critical concern. For example, if you are addressing community members who have health concerns, then articulate clearly right up front that you want to talk about health concerns (and skip the technical challenges and talk about them later).

Risk communication best practices also help overcome the silent cognitive heuristics (e.g., mental shortcuts) our brains take to make decision-making easier for us. For example:

- The overconfidence bias allows us to trust our own opinion over data; potentially preventing us from using probabilities appropriately.
- Our choice to simply believe someone we already trust (even if they know nothing about this topic) rather than look at the data ourselves makes it hard to use facts to affect opinion.
- The confirmation bias which means most people do not want new information -- they only want to hear (and remember) information that confirms what they already believe -- makes it hard to share information in a way that creates appropriate risk understandings.

Other risk messaging best practices that can be used to create and maintain reasoned discourse with all audiences, whether written or oral, include:

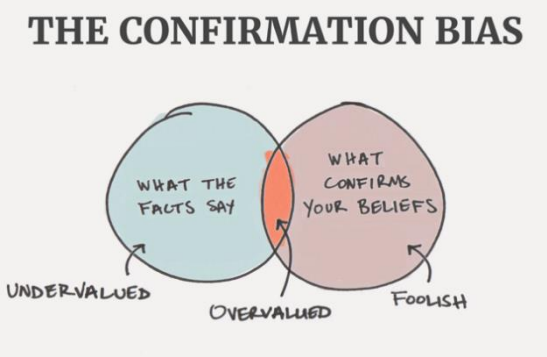

Figure 1: Be aware of "cognitive heuristics" that affect our human ability to process information. See https://jamesclear.com/common-mental-errors for additional insights.

- Create talking points using the 27/9/3 Rule: This communication rule is based on the knowledge that the human brain can only process 27 words or less, that can be spoken in 9 seconds or less, that contain 3 points or less; and that anything more actually detracts from the message. If you cannot remember the 27/9/3 Rule, this is also the KISS rule (Keep It Simple and Short).
- Share information in layers. Limit the information shared in each new layer to three pieces of information. If more information needs to be shared add another layer.
- Frame the messages using questions of concern. Put the most important information at the beginning and use headers and graphics to help people know what is important. Remember that most people will only read the headers so make sure the headers tell the story you are trying to tell.

Science, numbers, and risk can be very difficult to convey to lay people in a manner that supports their ability to use them appropriately in decision-making. The Centers for Disease Control and Prevention (CDC)'s Clear Communication Index (CCI) provides states with a set of research-based criteria for developing and accessing public health communication products. The CCI is designed to support the construction of and evaluation of public health communications to evaluate how effectively they are incorporating risk communication best practices. The CCI evaluates documents for: engagement, readability, accuracy, clarity, presentation of numbers and science, integration of risk communication best practices, and overall ability of the reader to make good public health decisions for themselves and their families based on the information presented.

Resources

For a further introduction to risk communication, see the following resources:

- World Health Organization's an Introduction to Risk Communication
- USEPA's Risk Communication Webpage
- Federal Emergency Management Agency (FEMA)'s Lesson 5: Risk Communication
- Center for Disease Control (CDC) Gateway to Health Communication

To learn more about cognitive heuristics, see the following resources:

- Thinking-Fast-Slow-Daniel-Kahneman
- 24 Cognitive Biases
- Heuristics Revealed
- Crucial Conversations: Tools for Talking When Stakes are High. Edition 2 by Kerry Patterson, Al Switzler, Joseph Grenny, Ron McMillan.

Risk Communication Planning

A primary risk communication technique is to build a strategic communication plan that is proactive, outcome- and objective-focused and audience targeted. For example, one desired outcome might be to build understanding of how to appropriately use limited available scientific technical data in the decision and this objective will probably need to be reached with internal management, community thought leaders, and legislative audiences. When well-articulated and implemented, a strategic communication plan can help states build the specific kinds of knowledge needed by each audience group to create both an appropriate understanding of the risk and support for an appropriate approach to CEC management.

When creating a communication strategy, consider the CDC's definition that the objective of all health communication (and therefore all CEC conversations) is *to inform and influence decisions and actions to improve health.*[2] Here are some essential strategic planning steps identified by the CDC that you may want to consider when creating a communication strategy:

- Review background information to define the problem (What's out there?)
- Set communication objectives (What do we want to accomplish?)
- Analyze and segment target audiences (Who do we want to reach? And what are they interested in?)
- Develop and pretest message concepts (What do we want to say?)
- Select communication channels (Where do we want to say it?)
- Select, create, and pretest messages and products (How do we want to say it?)
- Develop a promotion and production plan (How do we get it used?)
- Implement communication strategies and conduct process evaluation (Getting it out there)
- Conduct outcome and impact evaluation (How well did we do?)

You may want to consult with a risk communication specialist to support development of a communication plan that serves as a strategic tool. Often once developed state staff find they can implement the strategic plan without additional outside support. Articulating the full range of important audiences associated with each objective is a critical component of risk communication. You may want to consider creating a table of contacts with columns that allow you to identify contacts by specific attribute, for example, what each audience can contribute to meeting each objective and how each will participate. Creating groups of contacts that are important for success at each step of the CEC process ensures that those who need to be included early in the process -- so they build understanding along the way -- are identified early and systematically included.

When thinking about contacts and groups of audiences, also begin to identify the questions of critical concern in the forefront of each audience group. Research shows that if a decision creates anxiety, we cannot move forward and learn until any fundamental questions have been answered. For example, many people may have difficulty entering a reasoned conversation about CEC management until they know where the CEC comes from. Using a question as a message header helps to frame the discussion in a manner that makes it easy for a full range of audiences to easily find their question of concern and the answer. Critical questions also serve as important engagement messages as we are all listening for what we want to hear.

[2] See: Centers for Disease Control, Health Communication Basics.

The "Questions to Consider" noted at the beginning of each module can be used as headers when creating reports as they represent questions likely to be on people's minds.

Because a primary risk communication best practice is to respond not react, you should never be defensive. It is useful to ensure your state can answer the important but tough questions you may face at any time during the CEC review. Below is a list of difficult questions faced by other states during their CEC rule making process with suggested responses using risk communication techniques. You may want to consider how you would personalize answers to these questions to meet your situation specific needs and opportunities.

- **Why hasn't anything been done about this CEC yet?**

  Keep the focus on the fact that you are doing something now, while sharing your concern and empathy. For example, everyone here at the state public health agency is concerned with public safety; as our understanding and concern for the CEC has grown, we have tackled the challenge as quickly as possible because our children drink this water also. Never be defensive, stick to your mantra that you are concerned and focused today.

- **Why is this other state doing it differently?**

  Use the 27/9/3 or KISS rule. Identify the 2-3 primary reasons why your state is doing it differently and develop a short answer. (Sharing more than three reasons begins to reduce understanding and support). Consider regulatory requirements, administrative procedures, and whether there is a legislative mandate for this CEC. For example, one state may be required to consider costs while another is not.

- **Why is this other state using data differently?**

  Consider keeping the answer focused on how your state is using the data to protect health in your state. For example, *in order to be highly proactive in protecting public health we have chosen to use this data in this way. If you would like more technical details, you can find them on our website* (and make sure the additional detail layer is available).

- **Why don 't you do more right now if you know there might be a risk to my family's health?**

  Example script: *We take your family health and safety very seriously. That is why we are sharing our current knowledge in an open and transparent manner in a series of health advisories put out jointly with the state department of health, so the public has the information they need to determine if they need to take additional actions prior to our final rule making. You can access public health advisory information at (link).*

- **Is my water safe?**

  Example script: *It is our agency's primary objective, every day, to ensure our community drinking water meets all Federal and State Drinking Water standards. As you probably know, the United States has one of the highest standards of safety for drinking water in the world. In addition, we follow current work being conducted by scientists at USEPA, the CDC and universities across the globe who are continuously looking for ways to improve drinking water safety.*

Because we are always learning more, safety is an on-going moving target that we must continuously strive for. At this time, we are reviewing emerging guidance on monitoring and testing for a wide range of contaminants of emerging concern. If you have information you would like to share with us, please send us links. If you would like to learn more and stay updated on our contaminants of emerging concern program, please visit (link).

Resources

You can increase your overall understanding of how to apply risk communication best practices by engaging in on-line or in-person trainings offered by:

- CDC: Training in Crisis and Risk Communication
- Agency for Toxic Substances and Disease Registry (ATSDR): Environmental Health Resources Self Learning Module: Risk Communication
- You can also use the checklists and processes shared in the recently released *Trending in an Instance* (AWWA, 2019) to assess your strategic use of risk communication. This guide provides water professionals with an overview of how to use risk communication both proactively and reactively with a focus on social media.
- Use CDC'S Clear Communication Index (CCI) to comply with the Plain Writing Act of 2010 and achieve goals set forth in the National Action Plan to Improve Health Literacy and the CDC's Action Plan to Improve Health Literacy. The 20 items in CCI build on and expand plain language techniques described in the Federal Plain Language Guidelines.
- The ATSDR Communication Toolkit will help you improve communication efforts with local communities. The Toolkit offers customizable tools for simplifying communication, guidance on responding to different levels of concern, and a way to set realistic expectations and measure the usefulness of the public health assessment process.
- The ATSDR Primer on Health Risk Communication provides a framework of principles and approaches for the communications of health risk information to diverse audience.

You can increase your understanding of how to develop strategic communication for health using tools developed by:

- The National Prevention Information Network
- American Water Works Association (AWWA): Public Communications Toolkit
- The Rural Health Information Hub
- The National Institute of Health (NIH)'s Risk Communication, Risk Assessment and Regulations tools can assist you in creating appropriate risk perceptions.

If you want to learn more about how to use communication to create appropriate risk perceptions, consider these resources:

- Risk perception in toxicology--part II: toxicology must be the solution not the problem
- Intuitive toxicology: expert and lay judgments of chemical risks
- Communicating exposure and health effects results to study subjects, the community and the public: strategies and challenges

	• ATSDR's Communication Toolkit Community Concern Assessment Tool
State Experience	The **Minnesota** Department of Health Drinking Water Risk Communication Toolkit provides detailed resources for how to develop a strategic communication plan and develop communications materials for customers and share messages. Minnesota also hosts a webpage with communications and education materials for the CEC PFAS.

Module 1: Conduct a Self-Assessment of Regulatory Context and Capacity, and Address Current Public Health Concerns as Needed

Module 1 End Goal: Understand your legal and regulatory environment related to managing CECs and build awareness of the internal and inter-departmental capacity to undertake this work. Identify emergency, near-term measures to manage CEC risks while longer-term solutions are being developed.

Introduction

States have different authorities for regulating CECs in drinking water relative to the role of the US Environmental Protection Agency (EPA). Some states have the authority to set state-specific Maximum Contaminant Levels (MCLs) or treatment techniques independent of the federal government while others do not. Before embarking on a systematic assessment and management of CEC risks in drinking water, you should understand the legal and regulatory authorities and requirements that govern the steps you can or must take.

Beyond the opportunities and constraints established by your state's regulatory and legal context, the personnel capacity and resources of your state to assess and manage CECs influences the direction you may take. In most situations, a team is needed to successfully guide a CEC process from start to finish. You may find you need to borrow heavily from other states or the federal government in some areas and do your own work in others. You may need to strengthen capacity by hiring or contracting for certain skills, such as toxicology, economic analysis, or risk communication. Inevitably, you will need to collaborate with other departments, agencies, and stakeholders.

While you determine long-term risk management opportunities and what is needed to pursue them, you also need to manage immediate risks to populations exposed to CECs. This may mean working with water systems to take emergency measures to limit exposure by, for example, switching customers to alternative sources of water.

Questions to Consider

- What are your opportunities for managing CECs in drinking water given state-specific laws and regulations that determine possible pathways for regulating CECs?
- What are the key considerations in assessing internal capacity to do the work of CEC management and what specific types of capacities may be needed?
- How should you organize and coordinate the work on CEC risk assessment, management, and communications?
- What types of emergency measures should be considered for managing risk from CECs in drinking water while longer-term solutions are being developed?

Key Implementation Steps and Lessons

1. Assess your state's legal and regulatory context to determine possible paths for managing CECs in drinking water.

While the details of drinking water regulation differ considerably from state to state, some key considerations are relevant for determining the risk management paths you may take based on your state's legal and regulatory context.

What are your state-level authorities for establishing a state-specific CEC rule?

Most U.S. states have delegated authority from the USEPA to regulate drinking water. Of these, some can only adopt (or be no more stringent than) federal drinking water standards. Others have the authority to establish state-specific regulations for MCLs or treatment techniques that can be more stringent than the federal government or issued in the absence of federal regulation. (Some of these states allow entities to petition an agency for an MCL or some other type of regulatory response). It is important for you to understand your state's authorities to know whether you can develop a state-specific drinking water rule, and if so, how it can differ from a federal rule. State drinking water agencies should consult with the state Attorney General's office and/or executive management regarding state authorities.

State Experience	For examples of the various federal and state regulatory authorities governing CECs, see the Interstate Technology & Regulatory Council (ITRC) fact sheet on PFAS, Regulations, Guidance, and Advisories for Per- and Polyfluoroalkyl Substances (PFAS).

Resources	For information about delegation of state regulatory authorities, see USEPA's Primacy Enforcement Responsibility for Public Water Systems.

What aspects of drinking water does your state drinking water agency have authority over?

While all state drinking water programs have authority over public drinking water systems, some also have jurisdictional authority for private wells, bottled water, or other sources of drinking water. If your drinking water program does not have direct authority over drinking water that may be exposing people to CECs, you will likely need to partner with other agencies or entities that have that authority.

State Experience	**Vermont's** drinking water regulators have authority over domestic bottled water and treat it like a public water system. Under the Private Well Testing Act, **New Jersey's** drinking water regulators have authority over private wells subject to sale or lease or new private wells (but not necessarily all private wells) and can require testing these wells for CECs.

To what extent do regulations prescribe specific aspects of drinking water risk assessment and management for CECs (versus agency discretion)?

If your state has authority to establish drinking water rules, state laws and regulations may be prescriptive about some aspects of the rules. For example, there may be rules governing how you can determine a health-based level for CECs in drinking water (see Module 2). Or, your state may require that impacts on special populations and sectors be considered as part of setting rules related to treatment (see Module 5), or that benefits of a rule must be demonstrated to justify the costs, or that the costs are affordable (see Module 6).

If you are pursuing regulation of CECs, what are administrative procedures for rule development?

You should understand what will be required procedurally, especially regarding rule justification, impact analysis, and public notice and participation so that you comply with administrative procedure rules during the process and build toward required elements of the rule. To be clear on administrative procedure requirements (and get help with legal support for the process), you should consult the State Attorney General's office.

Communication and Collaboration	Collaborate from the beginning with the Attorney General's (AG) office. If possible, identify a contact who will work with your agency throughout the rule making process. After meetings with the AG and other legal advisors, state agencies may want to write up, in plain English, what they understand is needed and ask the legal team for review, as sometimes legalize can be misinterpreted.

Resources	For an overview of the federal Administrative Procedure Act, which is a model for many state requirements for administrative procedure, see USEPA Summary of the Administrative Procedure Act.

What justifications will be needed for your state to develop a drinking water rule?

You may need to establish justification before a rulemaking process begins. Most rules will require a justification when considered by the rulemaking body. Examples of justification characteristics or considerations might be occurrence of the CEC, populations impacted, health risks, etc. Work closely with the AG and other legal advisors when articulating justifications to make sure you hit the mark and can translate legalize appropriately into English. See Module 8 for more on rule justification.

Communication and Collaboration	Think about justifications as rule making objectives; referring to the objective is a communication strategy that can be used to keep the discussion outcome oriented and to embrace and regulate high emotions.

State Experience	**Minnesota** requires a Statement of Need and Reasonableness (SONAR) before working on the technical aspects of a rule. The SONAR walks through every aspect of a rule to show that there are no unintended social or economic consequence or impact on other rules and demonstrates statutory authority. Similarly, **California** requires a Statement of Necessity.

In the absence of a drinking water rule, what are your state's abilities to influence CEC management for unregulated CECs?

Whether or not your state has the authority to establish a state-specific drinking water rule, you may have other ways to manage CECs in drinking water through intermediate management strategies. For example, some states can take action based on state specific or USEPA health advisories or their equivalents for drinking water and other media (see Module 7). You may have authority to require water systems to sample for CECs or to require public notice of sample results in which CECs are detected.

2. Describe the context and process your state will take for assessing and managing CECs

Based on the authorities and options available to your state, you can create a *CEC Regulatory Context and Process* briefing document and use it to create a common understanding and starting point for the process your state will take to manage CECs. Consider structuring the document so that it addresses an intended audience's critical questions by using each toolkit module's Questions to Consider as a section heading.

As a component of the briefing document, you can develop a draft "pathway" diagram that lays out the *required* steps as well as any additional steps you will follow as part of your CEC management effort. The modules in this toolkit can provide an outline for organizing the process. You can increase the robustness and usefulness of the pathway diagram by integrating administrative procedures. Create a table that lays out tasks and subtasks, as well as the resources that will be needed to undertake them.

Creating a CEC process diagram that lays out important steps is valuable for:

- Organizing your internal team and partnerships.
- Identifying capacity needs and gaps.
- Articulating resource needs.
- Managing and refining the steps over time.
- Communicating the process internally and externally.

Communication and Collaboration	Recognize, right from the start, that you are creating a permanent record of the CEC process. This permanent record can assist or harm the agency if it needs to legally defend its process at a later date, e.g., if lawsuits are brought fighting the rule establishment. Care needs to be taken as the administrative record is assembled and added to over time. Consider applying risk messaging best practices in your memos and other documentation articulating findings from each assessment component. Graphics are a highly recommended risk communication best practice for sharing complex information and processes.

3. Assess your state's internal and external capacity

Assessing and managing CEC risk, not to mention rule development, can take considerable amounts of time. Like legal and regulatory authority, capacity needs and constraints can influence your state's options and direction and should be anticipated early in the process of managing CECs. While you can draw on the work of others, you need to ensure that your own decisions and regulatory processes are legally defensible, limiting the ability to simply adopt standards or approaches from another state.

You can begin by assessing internal capacity to support the rule development process itself. Who needs to make final and interim decisions, who will gather and share complex scientific summaries, and who will perform all the technical tasks laid out for each step along the pathway?

In most situations, a team is needed to successfully guide a CEC process from start to finish. You can support the assessment process by articulating, at the start, the membership, hierarchy and responsibilities of the small oversight team (i.e., CEC oversight team) that will manage the CEC process.

It can take time to build capacity—including lead times related to budgeting, hiring, and contracting—so you should assess capacity upfront to understand what it will take to assess and manage risks. Key internal capacity needs often include:

- Toxicology and risk assessment (see Module 2)
- Engineering for treatment technologies (see Module 5)
- Economic analysis (see Module 6)
- Risk communications and facilitation for stakeholder meetings
- Legal support for regulatory development and rulemaking (see Module 8)

At this point, you can also proactively assess external capacity, including lab capacity to conduct analysis of drinking water for CECs (see Module 4).

When assessing external capacity, consider other states or associations that may be partners in your work. If a CEC is of concern in your state, it is likely that at some point every state will have to at least consider it, determine if it is a problem, and determine how to manage risks. To connect to broader drinking water communities, bring up potential CECs at ASDWA meetings or through the regional ASDWA Board Liaison. Look for opportunities to collaborate with other states to share resources. Regionally, states may be able to

jointly invest in shared capacity (e.g., for toxicology or economic analysis) rather than doing it independently.

You can assess you risk communication capabilities by examining you current CEC-focused understanding of:

- The full range of important audiences/contacts, including staff, utilities, scientists, experts, state and local elected officials, and community groups.
- What each audience is likely to contribute and how each will participate.
- The questions of critical concern in the minds of each audience group.
- How to acknowledge emotions and provide empathy when fear or high anxiety are present.
- How to apply risk communication messaging best practices.
- How to overcome the common brain shortcuts that prevent people from using incomplete and uncertain information effectively in decision-making.

Communication and Collaboration	• Reach out to additional internal departments, partner agencies, and other entities as part of context and capacity reconnaissance. Consider asking each person contacted who else should be included in the conversation. • For controversial CEC rulemaking, you may want to consider hiring a professional facilitator to integrate the community into the process from the beginning.
State Experience	Some states have established task forces or other types of teams that address the CEC PFAS across state government and coordinate agency activities. For example: • **Michigan:** The Michigan PFAS Action Response Team (MPART) brings together representatives from seven state departments led by an Executive Director linked to the Governor's office. It works on a range of PFAS issues through topical workgroups. • **Connecticut:** The Interagency PFAS Task Force was established by the Governor to develop the state's PFAS Action Plan. Led by the Department of Public Health and Department of Energy and Environmental Protection, the Task Force brought together representatives from a broad variety of state agencies.

4. Prepare and undertake immediate response emergency measures as needed

As you begin the process of identifying long-term risk management solutions, you also may need to consider how to manage any short-term or immediate public health risks to populations exposed to the current levels of the CEC. Emergency responses to current CEC exposure could include:

- Consumer/public notifications as required by law, to all consumer or vulnerable populations.

- Educational and outreach information to increase the public's ability to make informed personal health decisions.
- Boil advisories, if appropriate.
- Do not drink/use orders or advisories, if appropriate.
- Alternate water orders or advisories, such as hauled or bottled water.
- Point of use information strategies (e.g., filtering).
- Enhanced monitoring.

Managing short-term public health risks can be a useful way to begin the collaboration needed to manage long-term risk. Determine how, and with whom you will partner in this "triage" phase to put in place emergency or emergency-like responses. You may want to establish, early in the process, the institutional alignment needed with public health agencies (local, state and federal) as well as with local utilities who may be able to help you coordinate with customers. Public notice needs to occur quickly.

Institutional coordination with state and local health officials, state and local emergency management agencies, local elected officials, utilities, and community groups can provide states with significant support for development and delivery of public health notices that may need to occur right away. Ideally, affected water systems will be used to help the public make informed personal health decisions prior to rule making or other state actions. Having a risk communication or public health communication partner on the team may be useful for developing notices that create the desired behavior change.

Throughout the CEC risk assessment and risk management efforts, revisit the need for continued, revised, and/or additional emergency measures. Some of these measures may also be considered as strategies for longer-term risk management, for example as intermediate measures (see Module 7) or alternatives to treatment (see Module 5).

Communication and Collaboration

As you communicate about emergency measures, you may want to focus strategic communication efforts on populations considered vulnerable based on what is known about CEC occurrence and concentration (i.e., the whole population may not be at risk). Collaborate with public health agencies to develop a list of contacts for reaching specific populations that may be vulnerable to the specific CEC so that the probability that engagement with those who need to know are increased. You may want to use the CDC's Clear Communication Index as an exemplary public health communications evaluation tool to ensure your educational materials, advisories, and notices follow risk communication best practices.

States may want to modify or develop new notifications and emergency response measures for CECs that incorporate crisis communication best practices, including:

- What do residents and/or water systems need to do?
- What will happen to them if they do not comply?
- Where and how do stakeholders get additional information?

You can use the checklist in *Trending in an Instance* (AWWA, 2019) to help guide your thinking and develop an appropriate media response plan.

Resources	
	• USEPA Public Notification Rule for the Safe Drinking Water Act ensures that consumers will know if there is a problem with their drinking water. For more information, see: USEPA Public Notification Rule. • CDC's Planning for an Emergency: Strategies for Identifying and Engaging At-Risk Groups • CDC's Reaching At-Risk Populations • CDC's Crisis and Emergency Risk Communication (CERC) program teaches you how to craft messages that tell the public what the situation means for them and their loved ones, and what they can do to stay safe. The six principles of CERC are: 1) Be First 2) Be Right 3) Be Credible 4) Express Empathy 5) Promote Action 6) Show Respect.

Module 2: Characterize Health Effects

Module 2 End Goal: Develop a health-based level for the CEC in drinking water that is protective of human health

Introduction

Health effects characterization is about understanding and describing the nature of the CEC and the size and scope of its impact on human health. A health-based level is the concentration of the CEC in drinking water that is likely to pose little or no health risk to humans, including vulnerable subpopulations. This concentration is a function of how toxic a chemical is (that is, the minimum quantity that will cause health effects), the duration, timing and level of exposure, and the amount of water individuals drink during the exposure period.

Generally, health-based levels are based solely on health effect considerations. Other factors such as the ability to detect or monitor a chemical, the cost of controlling a chemical, or background concentrations of a chemical are not considered in development of a health-based number.

States face a range of contexts for engaging in risk assessment. Work in this module is influenced by how prescriptive your regulatory context is regarding the approach to developing a health-based level and availability of staff with the necessary risk assessment skills.

States use a range of approaches to develop a health-based level. Some states have a very prescriptive process for developing a health-based level, others have more flexibility. This module includes information on building risk assessment capacity, conducting a literature review to understand the toxicity of the CEC, and points to existing resources with guidance on how to develop your health-based level.

The nature of the CEC in terms of its health effects (e.g., acute, short-term, or chronic) will inform decisions you make about the types of water systems to sample in Module 3 and which water systems are subject to the MCL Rule in Module 8. For example, will you sample community, non-transient/non-community systems (or a subset of these like schools and daycares), transient non-community systems, etc.?

States face a range of contexts for engaging in risk assessment. Work in this module is influenced by how prescriptive your regulatory context is regarding the approach to developing a health-based level and availability of staff with the necessary risk assessment skills. Keep in mind that after exploratory and evaluation work, you may decide a health-based level is not needed.

Questions to Consider

- Is toxicological data for the CEC available?
- Is the CEC carcinogenic or non-carcinogenic? Is there developmental or reproductive toxicity?
- What is the dose-response relationship?
- What is the level of no observable effect?
- What safety or uncertainty factors should be incorporated into a health-based level?

- Are health effects of concern from the CEC chronic, short-term, and/or more complex (such as involving short-term exposures that can have long-term consequences like lead or impact target organs or bodily functions like the reproductive, immune or endocrine systems)?
- What are likely impacts to vulnerable populations (e.g., infants, pregnant women and fetuses)?
- What populations, exposure routes and pathways, and effects should be used to set protective levels?
- What is the regulatory context for the health characterization?

Key Implementation Steps and Lessons

1. Ensure adequate capacity for toxicology and health risk assessment

Toxicology and risk assessment capacity is critical to successful health effects characterization. If you are establishing a CEC rule, it is important that you ensure adequate capacity for toxicology and health risk assessment throughout the process.

Many agencies responsible for regulating drinking water do not have toxicologists or health risk assessors on staff. You can increase risk assessment capacity through partnerships, hiring, or contracting. For example, you can partner with other agencies (such as health departments) or engage external expertise like through a Science Advisory Board or a university. You may also be able to connect with toxicologists/risk assessors from other states who have or are dealing with the same CEC. The Federal-State Toxicology & Risk Analysis Committee (FSTRAC) is an organization that provides this network. The FSTRAC website provides names and contact information for state members: https://19january2017snapshot.epa.gov/water-research/fstrac-members_.html.

State Experience	Some states engage an existing or convene a new advisory body to review and assess the health effects literature and science. • **New Jersey's** Drinking Water Quality Institute is a key step in New Jersey's process for determining whether a CEC is of concern in the state. The Institute includes academics, water systems, retired health officers, toxicologists, and others. The New Jersey Department of Environmental Protection has a research scientist on staff and funds a research scientist position in the Department of Health. • **Massachusetts** establishes a Health Effects Advisory Committee comprised of academics and health department and environment department staff to provide input and review materials regarding health effects of drinking water contaminants.

Communication and Collaboration	• Consider asking everyone involved in the toxicology assessment: 1) who else they think should be included, 2) what questions need to be addressed as part of the CEC review process, and 3) who they think will have the specific knowledge needed to answer each question. • If using or building a team of expert advisors, ensure that all critical audiences have at least one trusted source on the team. People often believe a source they trust above a process. However, make sure they are experts you trust as well. If you are using already developed teams, make sure that you make teams accessible to all interested parties. • For controversial issues with the potential for significant misunderstandings, a science fair type event (where interested parties can walk around and personally ask questions of a variety of experts) is significantly more powerful than a presentation.

2. Review literature on toxicology to understand health effects, including uncertainty or safety factors

Conduct a literature review to gather information about what is known about the toxicity of the CEC. The literature review should not be limited to a PubMed type search as it will miss 'gray literature' such as guidance values and technical review documents from state, federal, and international agencies. Consider the following about the CEC when conducting your literature review:

- Whether it poses carcinogenic and/or non-carcinogenic risks.
- Whether it poses chronic, short-term, acute, or other types of health risks.
- Whether it poses risks of developmental or reproductive toxicity.
- Whether it affects sensitive populations (e.g., infants).
- What is known about the level of no observable effect and the dose-response relationship.
- What is known about occurrence and exposure.
- Whether there are important uncertainties (data gaps) in the science that may suggest including uncertainty factors when setting health-based levels.

Consider reaching out to other states and sharing literature review findings and strategies so you can avoid reinventing the wheel.

The type of health effect will influence many aspects of risk assessment and management, including stringency of risk limits (such as health-based levels, advisory levels, and MCLs). It will also influence what type of drinking water systems may pose risks to users and therefore what types of systems should be monitored (for example, whether to sample transient non-community systems where chemicals posing short-term risks or exposures may be of most concern). The type of health effects will also influence how benefits of the regulation may be calculated and characterized (see Module 6).

As you pull the science together consider the following decisions you will encounter when you derive your health-based level:

- Whether to pursue a chemical-by-chemical approach or group “like” CECs.
- Whether to use human or animal data.
- If you use animal data, which animal study(s) or studies will you select.
- What endpoint (critical effect(s)) from any given animal study will you use.
- How to adjust for differences in how humans versus laboratory animals handle the chemical in the body (e.g., metabolize, eliminate) or differences in how sensitive humans versus laboratory animals are to the effects.
- How to adjust for differences in how the chemical is handled in the body or sensitivity across different human populations (e.g., vulnerable populations).
- Important data gaps and whether to apply uncertainty factors.
- How much uncertainty factors influence the outcome.

Resources

Consider the following literature sources to understand health effects, including uncertainty or safety factors.

- USEPA Comp Tox Chemicals Dashboard is a one-stop-shop for available chemistry, toxicity, and exposure information for over 875,000 chemicals. The Dashboard contains literature search tools (e.g., PubMed Abstract Sifter). In the future, the tool will help users identify chemicals that have a similar structure to the CEC of interest which may provide insight into the CEC of interest's toxicology. **Minnesota** starts with USEPA CompTox Chemicals Dashboard to confirm CAS Number and chemical name and structure, as well as to gain an initial understanding of the quantity and type (e.g., chronic, sub chronic, reproductive, etc.) of available toxicity information. Using the tool's literature search option, staff build queries to search a variety of data sources. Time is of the essence in the CEC context. Minnesota is exploring predictive and alternative toxicological models that can be used to provide risk context. Minnesota, in partnership with USEPA, is also exploring whether chemical use, monitoring data, and exposure predictions within the Dashboard can be used to better understand potential exposure to the CEC.
- Integrated Risk Information System (IRIS) identifies and characterizes the health hazards of chemicals found in the environment.
- Materials safety data sheets (MSDS) supplied by chemical manufacturers.
- The HHS (Department of Health and Human Services) National Toxicology Program includes three organizations assigned to conduct research and develop data to support environmental, occupational, and food and drug regulations.
- USEPA Toxics Release Inventory (TRI) reports the release, transfer, and disposal of toxic chemicals from certain facilities.
- The European Chemicals Agency has information on the chemicals manufactured and imported in Europe. It covers their hazardous properties, classification and labelling, and information on how to use them safely.
- OECD eChemPortal provides free public access to information on the properties of chemicals, including physical chemical properties, ecotoxicity, environmental fate and behavior, and toxicity.
- ATSDR (Agency for Toxic Substances and Disease Registry) toxicological profiles succinctly characterize the toxicologic and adverse health effects information for a set of toxic substances. Each peer-reviewed profile identifies and reviews the key literature that describes a substance's toxicologic properties. The profile is not intended to be an exhaustive document; however, more comprehensive sources of specialty information are referenced. See for example the Toxicological Profile for Perfluoroalkyls (draft for public comment).

- Health advisories and models from USEPA and other states that have established health advisories, action plans, or standards.
- USEPA/state standards: ITRC tables with federal and state standards and guidance for PFAS
- USEPA Action Plan: USEPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan
- USEPA Health Advisory: USEPA Drinking Water Health Advisories for PFOA and PFOS webpage and Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA) – May 2016
- State health effects models: Transgenerational toxicokinetic model and its use in derivation of Minnesota PFOA water guidance *Journal of Exposure Science & Environmental Epidemiology*. This model calculates serum concentrations in a chronically exposed mother and her infant. It does not predict health effects.

Communication and Collaboration	
	• Engage with important audiences including health and environmental agency staff, concerned and affected community members, academic institutions, community advocacy groups, representatives for the business community, and municipalities. Consider the context within which other groups are thinking about the CEC. What information do you want to include in your search parameters to ensure you gather the information others are looking for, as well as to fill gaps in current understanding? For example, even if you have enough information to believe the CEC is not carcinogenic, if there is a large group that is concerned that it is, make sure your literature review includes the information you may already have that illustrates it is not carcinogenic so that everyone concerned has that knowledge and trusts that you looked. Ask and listen to know what others are looking for and need. • **Minnesota** announces that it is conducting an initial review of a chemical to a list of subscribers. Minnesota also reaches out to federal and state toxicology and risk assessment groups, such as the Federal-State Toxicology & Risk Analysis Committee (FSTRAC), to identify other states who have or are dealing with the CEC. • **New Jersey** does a "call for information" to water systems, certified laboratories, engineers, environmental groups, industry groups, site remediation professionals, and other interested parties to complement the literature review. • **Massachusetts** holds regular stakeholder meetings during the investigative phase to provide updates on its process for understanding and managing the CEC and allow for input from stakeholders. Massachusetts also does a "call for information" to stakeholders. See Stakeholder Engagement Announcement.

3. Share information and coordinate in level-setting with other state programs, agencies, or departments involved in CEC management (e.g., cleanup, surface water, etc.)

Many CECs are not just an issue for drinking water regulators but also those responsible for managing and regulating groundwater, surface water, land contamination, emergency response, and other programs. Consider partnering with relevant programs and agencies to develop your health-based number. Several state agencies and departments may have experience with a CEC, regulatory authority, and/or have valuable capacity to share. The actions that one agency takes may have implications for others and one agency alone is unlikely to manage CEC risk comprehensively.

State Experience	• **Massachusetts** first developed soil and groundwater clean-up standards, which provided a framework for a drinking water MCL. The clean-up and drinking water programs are located within the same agency, which facilitates collaboration. • In **New Hampshire**, once a drinking water standard is set, other programs need to set equivalently protective levels for groundwater, soil, etc. or at least manage these resources so that they don't contribute to drinking water contamination above the level.
Communication and Collaboration	• You can prime the collaborative process by bringing people together and asking them to share what they think are the important objectives and the primary challenges/barriers (e.g., specific knowledge and data gaps, as well as communication needs) for the health effects characterization phase of the work. • Examine current understanding of participating scientists, managers, executive teams and the community to identify misunderstandings, data and knowledge gaps, initial perceptions, and questions of concern. • This information can be used to help target the literature review, identify questions of critical concern, gather important information early in the process and create an opportunity for meaningful engagement for others. Making it clear that the CEC process will include each department and group in a meaningful way and will continue over time is a powerful engagement tool. You may want to develop an engagement process and calendar that makes this commitment obvious to all.

4. Develop a health-based level as appropriate

A state-derived health-based level is the concentration of a chemical in drinking water that, based on the current level of scientific understanding, is likely to pose little or no health risk to humans, including vulnerable subpopulations. This concentration is a function of how toxic a chemical is (that is, the minimum quantity that will cause health effects), the duration, timing and level of exposure, and the amount of water individuals drink during the exposure period. Health-based levels are often designed to protect populations who are most vulnerable to the potentially harmful effects of a contaminant. Certain life-stages may be more susceptible, such as pregnant women, developing fetuses, and infants. Populations may be vulnerable because of increased susceptibility and/or higher exposures.

Because the health-based level is intended to ensure negligible risk to vulnerable subpopulations, it is typically derived using a series of safety factors to account for scientific uncertainties (e.g., susceptibility of humans versus laboratory animals, lack of studies on developmental effects) and potential variabilities (e.g., differences in intake rates, durations of exposure, and sources of exposure). The selection and magnitude of these factors are based on existing scientific knowledge from the body of data available on

other chemicals with larger/full datasets. It is important to understand how the cumulative effect of a series of safety and related uncertainty factors impacts the ultimate risk estimates, and how this may result in a very stringent health-based concentration level for drinking water. It is common practice to limit the magnitude of the total uncertainty value. If there are too many uncertainties this indicates that there is insufficient data to calculate a health-based number. Total uncertainty factors for PFAS developed by most states have ranged from 30 to 300. Uncertainty factors influence how to estimate the public health benefits (See Module 6), where the precautionary assumptions may overstate the risk reduction to be realized from a rule.

Sometimes, health effects are not clear, and states will need to make judgements based on available data (for example, some view PFAS as a chronic concern and others view PFAS as a short-term/acute concern). Water intake rates and relative source contribution factors (used to account for non-water ingestion sources of exposure) can vary by state agencies, sometimes resulting in different drinking water values despite similar reference doses. Some states have found it useful to engage in peer review as they finalize their health-based level.

The health-based number may be different from a health advisory level (See Module 7) or MCL (Module 8) because these other levels may take into account non-health factors such as the ability to detect or monitor a chemical, the cost of control or treatment, or background concentrations.

States use a range of approaches to develop a health-based level. Some states have a very prescriptive process for developing a health-based level, others have more flexibility. In general, approaches consider the following USEPA human health risk assessment steps:[3]

- **Planning - Planning and Scoping process**
  Begin the process of a human health risk assessment with planning and research. Make judgments early about the purpose, scope, and technical approaches that will be used.
- **Step 1 - Hazard Identification**
  Determine whether exposure to the CEC can cause an increase in the incidence of specific adverse health effects (e.g., cancer, birth defects) and whether adverse health effects are likely to occur in humans. Develop a weight of evidence based on available scientific data for a given chemical (or group of chemicals) and characterize the link between the negative effects and the CEC. Specific information on hazard assessment approaches can be found in UEPA's specific risk assessment guidelines relevant for the kind of effect being considered. See USEPA Risk Assessment Guidelines.
- **Step 2 - Dose-Response Assessment**
  Determine health effects at different exposure levels to articulate the relationship between exposure to the CEC and health effects, the dose-response. Document the dose-response relationship(s) over the range of observed doses. Data may be insufficient to identify the dose that is low enough to prevent the effect in the human population. Make inferences about the critical region where the dose level begins to cause the adverse effect in humans.
- **Step 3 - Exposure Assessment**
  Examine what is known about the frequency, timing, and levels of contact with the CEC.

[3] Find more information at USEPA's Conducting a Human Health Risk Assessment webpage.

- **Step 4 - Risk Characterization**
  Integrate information on hazard, exposure, and dose-response and estimate the likelihood that adverse health effects will occur in exposed people.

If your CEC likely has multiple routes of exposure, you will need to understand the contribution of drinking water versus non-drinking water sources to exposure. See USEPA Decision Tree for determining the relative source contribution in USEPA's Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000) Document or the California Environmental Protection Agency's Risk Assessment for Chemicals in Drinking Water: Estimation of Relative Source Contribution. Use information from Module 3 on occurrence of the CEC in drinking water.

The toxicology literature on the CEC of interest may evolve over time and it may be useful to periodically review the science to determine if new science and data changes the way you think about your health-based number and if a revision may be warranted.

Resources	ToxTutor is a self-paced tutorial covering key principles of toxicology for users of the National Library of Medicine (NLM) chemical and toxicology databases. ToxTutor is a useful beginner's resource for understanding toxicology.

State Experience	States have documented their approach to setting health-based values in public reports. Review the following reports for insight into how states derive health-based values. • In **Minnesota,** there are currently three types of health-based water guidance. Minnesota guidance values developed since 2008 utilize methodology designed to account for highly exposed populations and different durations of exposure (e.g., one day, up to 30 days, more than 30 days or 10% of a lifetime, or more than 10% of a lifetime). This is a unique approach. The Minnesota Department of Health's approach is based on recommendations from USEPA's Risk Assessment Forum Technical Panel (2002) following their review of the Reference Dose and Reference Concentration Process. See **Minnesota's** How Health-Based Values and Health Risk Limits are Calculated for insight into Minnesota's process for developing a health-based value. • See **New Hampshire's** Summary report on the NHDES development of the Maximum Contaminant Levels and Ambient Groundwater Quality Standards for Perfluorooctanesulfonic Acid (PFOS), Perfluorooctanoic Acid (PFOA), Perfluorononoic Acid (PFNA) and perfluorohexanesulfonic acid (PFHxS) for insight into New Hampshire's process for developing a health-based value. See Appendix 3. • See **New Jersey's** Technical Analysis of New Jersey's Proposed Health-Based Maximum Contaminant Level (MCL)for Perfluoro octane Sulfonate (PFOS) for insight into New Jersey's process for developing a health-based value. • See **Michigan's** Health-Based Drinking Water Value Recommendations for PFAS in Michigan, 2019 for insight into Michigan's process for developing a health-based value.

Communication and Collaboration	• Identify and respond to communications opportunities. Risk communication is always a proactive activity – be the first in to be the trusted source. You may need to explain why you arrived at a different health-based level than used by USEPA or another state. Pre-develop answers using risk messaging best practices (Risk Communication). The evolution of the science and communications doesn't mean there's been a mistake. It's important to let people know and expect this. • In **Minnesota**, staff communicate with stakeholders prior to defining a health-based number. Initial communications are based on currently available information, and the approach and information evolve as the review progresses. Staff release Health-Based Values (HBVs) to the public by posting the guidance and accompanying information on the Human Health Based Water Guidance Table. Staff also notify subscribers via the Minnesota GovDelivery email subscription service. While the Minnesota Department of Health always welcomes public comments, there is no formal public comment period for HBVs. If the CEC is found in Minnesota's groundwater the HBV are typically taken through a formal rule process, which does include a formal public comment period. • **Massachusetts** has found that ongoing stakeholder engagement helps to surface issues that will likely come up in public meetings. Early identification of issues provides staff with the opportunity to anticipate and try approaches to addressing the issue in advance of a public meeting.

Module 3: Characterize Occurrence

Module 3 End Goal: Understand where and to what extent CECs are occurring in the drinking water supply. Establish sufficient understanding of occurrence to support MCL rule development (or other interventions) and design of ongoing monitoring and impact surveillance.

Introduction

Characterizing where CECs occur in your state's drinking water systems is critical for understanding who is at risk and the extent of the risk. For drinking water contaminants, characterizing occurrence often means understanding which water systems in the state may have the CEC of interest in finished waters and the concentrations of the CEC found in these systems. Occurrence information is important for defining your health-based level (Module 2) and implementing appropriate risk management actions.

This module describes a range of approaches for understanding occurrence, from using existing USEPA Unregulated Contaminant Monitoring Rule (UCMR) or utility data and engaging in targeting sampling to collect new data to implementing a statewide sampling plan. A key challenge for you may be getting water systems to sample prior to having a regulation in place. It is important to understand and use your authority to require or encourage systems to sample.

Occurrence information informs assessment of the population being exposed and the levels of exposure. By indicating the number and size of systems impacted by a potential rulemaking or policy, occurrence information also supports treatment cost estimation (Modules 5 and 6), and associated benefit-cost and affordability estimation (Module 6). See Module 4 for complementary content on analytical methods and lab capacity.

Plan early for the possibility you'll find the CEC when you look for it. You will need to communicate with water systems, the general public, agency stakeholders, and others about the results, so make sure you have a response prepared. Even if results come in below health-based levels or health advisories, determine how you will communicate these results.

Communication and Collaboration	Consider identifying important audiences for occurrence data (e.g., communities with CEC occurrences, vulnerable populations, etc.) and developing audience-specific messages. A lack of communication about occurrence findings is likely to come back and bite you by making you appear not open—and therefore not to be trusted. You can remove this concern by communicating proactively. Build in time to develop relevant standard operating procedures, scripts, and field orders (how to order systems to take action) so that you are ready when sampling detects the CEC.

Questions to Consider

- Do we have existing evidence that CECs are present in state drinking water systems?
- What are likely sources of the CEC and where should we focus initial sampling to characterize occurrence?
- Should we do comprehensive statewide sampling, and how should we design a sampling program?
- Which types of water systems should sample (e.g., community, transient-non community, all non-transient non-community or entities that are not water systems but provide water vulnerable communities such as schools or hospitals)?
- Should only finished water be sampled, or should sources also be evaluated for sampling?
- How should we address systems with many sources and entry points when it may be very expensive to sample all entry points?
- Should a prioritization approach be utilized?
- How should we collaborate across state agencies and programs to collect, share, and analyze occurrence data and tap a range of authorities and information sources?

Key Implementation Steps and Lessons

1. Identify and assess currently available data to begin to understand occurrence

To begin understanding occurrence of a CEC in the drinking water system, start with data that is currently available. Data may be available to you through national sampling efforts for unregulated chemicals or you may request data directly from utilities. When assembling data at this early stage, recognize that it may not be comparable across data sources, and it may have limited utility beyond an initial screening-level analysis. You should assess the utility of available data considering its age, analytical methods used, detection limits, source water versus finished water testing, the type of systems sampled, and sampling locations.

USEPA UCMR program collects data nationally from large water systems serving more than 10,000 people and some small systems on a selected set of contaminants that are suspected of being present in drinking water but for which USEPA has not set national health-based standards under the Safe Drinking Water Act. UCMR has been a valuable source of information for states on PFAS, six of which were added to the list of monitored chemicals in 2012. However, UCMR may not cover CEC's of interest to a state. Also, the data only cover large water systems and some small systems, which may miss occurrence of CEC's in other types of systems and private wells. Find occurrence data here: Occurrence Data for the Unregulated Contaminant Monitoring Rule.

Beyond national monitoring programs, states can ask or require utilities to share data they may have on CEC's. Utilities may be reluctant to share data if not required to do so, and the authority and ability to require data sharing varies by state. States have found that publicly owned systems are more likely to share data than privately owned systems. Publicly owned systems may also be subject to open records laws or requests under the Freedom of Information Act.

As you begin assembling data on CEC occurrence, determine how you will receive, store, and organize the data you gather, recognizing it may be in different forms. Determine if the data you gather will be available to the public via your agency's web site.

2. Establish cross-departmental/agency collaboration for collecting and sharing occurrence data

CECs of concern for state drinking water programs are also likely to be of concern for state programs responsible for other environmental media, such as surface water and groundwater programs, cleanup programs, and others. These agencies may also be interested in gathering and analyzing data on CEC occurrence. Early in the process of understanding occurrence, identify and engage other state regulatory programs to share data and work together to understand occurrence across media and programs. Module 7 includes a list of non-drinking water risk management actions that may suggest state programs with whom it would be useful to collaborate.

State Experience

- In **New Hampshire**, the hazardous waste program required facilities to sample regulated sites for PFAS and found that the majority had PFAS contamination.
- In **New Jersey**, some water systems were motivated to be the most protective and voluntarily sampled for PFAS. This was a useful source of information.
- In **New Hampshire**, a Drinking Water and Groundwater Trust Fund allowed the state to sample hundreds of homes, which the state used as an opportunity to sample for PFAS and many other anthropogenic and naturally occurring contaminants.

Collaboration with other programs may give drinking water agencies the opportunity to benefit from these agencies' CEC sampling efforts. For example, if a state cleanup agency is sampling potentially contaminated sites for a CEC, that information can inform drinking water agencies about where CECs may be contaminating sources of drinking water. Similar opportunities may exist for state sampling programs for ambient water quality, air quality, fish or shellfish, private wells, and others.

Communication and Collaboration

Consider creating interactive opportunities for group brainstorming and sharing to overcome cognitive heuristics. Workshops either in-person or online can be great motivators to provide information as it provides individuals an opportunity to learn and show off what they have already learned. Many of those who provide information are probably very interested in what others are finding. Committing to future opportunities to see what others are doing is another good motivator for sharing.

For PFAS, several states have established internal teams or task forces among drinking water, surface water and groundwater programs, cleanup, and other programs to share information about potential sources of contamination, existing occurrence data, and coordination of sampling efforts.

State Experience	**Cross-departmental/agency collaboration** • **Pennsylvania's** cross-program collaboration on PFAS includes Safe Drinking Water, Clean Water, and Hazardous Sites Cleanup programs. The environmental cleanup program keeps the drinking water program apprised as it detects CECs in samples. The surface water program is adding PFAS to its ambient water quality monitoring and will keep DEP apprised of detections. • **Massachusetts** sees a strong link between data needs for drinking water risk management and cleanup programs—e.g., identifying sites, sampling, reducing exposure and risk, etc. Massachusetts's efforts to establish an MCL for drinking water are coordinated with the cleanup program's work to develop guidelines. • In 2017 the **Michigan** PFAS Action Response Team (MPART) was created as a temporary body by executive directive to investigate sources and locations of PFAS and protect drinking water and public health. MPART includes: Department of Environment, Great Lakes, and Energy (previously the Department of Environmental Quality); Department of Health and Human Services; Department of Natural Resources; Department of Agriculture and Rural Development; Department of Transportation; Department of Military and Veteran Affairs; and Department of Licensing and Regulatory Affairs.

3. Collect and assemble information on where CECs are likely to occur and conduct exploratory targeted sampling of potential occurrence

Building from information collected in Steps 1 and 2, collect and assemble information on where CECs are likely to occur and use that information to target early sampling efforts. For PFAS, several states gathered information on facilities that used PFAS-containing fire-fighting foam and other products that were likely sources of PFAS contamination. States then used this information to predict where contamination was most likely to occur and conducted exploratory targeted sampling of water systems in these areas.

A key challenge you will face when trying to identify sources of CECs that may have contaminated drinking water is that there often is not good information about where CECs are used or produced.

To overcome this challenge when looking for sources of PFAS contamination try surveying possible users of PFAS containing materials. In Pennsylvania, the state fire marshal surveyed fire departments about use of fire-fighting foam containing PFAS and the Department of Transportation surveyed transportation agencies about possible use of PFAS-containing chemicals in transportation activities. These surveys helped

assemble a map of possible sources. States can use other information about use of CEC-containing products like Material Safety Data Sheets (MSDS). USEPA CompTox Chemicals Dashboard is a resource for product functional uses (e.g., emulsion stabilizer, flame retardant).

State Experience

States are using a variety of methods to identify targets for sampling.

- **Minnesota** is pursuing a targeted approach to sampling for PFAS by first identifying 1) the most likely sources (industrial facilities, fire-fighting foam use, metal plating industry, wastewater locations likely to be contaminated) and 2) which groundwater and surface water supplies are most vulnerable. The State Pollution Control Agency has launched an effort to develop a probabilistic model using industry codes and records review to determine likely sources.
- **Michigan** developed and is using a PFAS heat map to understand the location of PFAS results.
- **Vermont** staff engaged its Air Division because the division had North American Industry Classification System (NAISC) codes that identify where PFAS material was likely in use.
- **Connecticut** is completing a land use risk assessment for 80 of the state's largest water systems where systems are required to submit information about land uses that may indicate PFAS contamination. See Circular 2018-20 describing the request and Source Water PFAS Assessment Form.

Remember that any communication about occurrence data will set expectations for future communication. Keep in mind that detection limits can decrease over time. Think strategically (and in advance) about expectations and how they will be addressed. For the public, any detectable (i.e., above zero) level may be unacceptable without translation. Even in cases where there is no detection, there is a need to explain what this means and if there are plans to confirm results with future sampling. Multiple exposure routes, for example in PFAS, can make communication even more complex.

Communication and Collaboration

- In **Pennsylvania**, drinking water administrators need to understand the results first. Anything over standards get communicated immediately. Staff have Standard Operating Procedures (SOPs), scripts, and field orders ready to go before sampling occurs.
- In **Michigan**, systems wanted 2–3 weeks to review results, but instead they got 48 hours. It took two months for MPART (Michigan PFAS Action Response Team) to develop a letter for systems with the results.

4. Design and implement statewide sampling plan

To fully characterize CEC occurrence in drinking water, you should consider a statewide sampling program and plan. Statewide sampling plans typically include:

- Sample location and frequency.
- Quality assurance & quality control (QA/QC).
- Sampling procedures.
- Sample designation.
- Sample handling.
- Analysis and results.

Developing a statewide sampling plan can be time and resource intensive. Start by defining the scope and purpose of your statewide sampling plan, addressing the series of questions outlined below.

What is the purpose of statewide sampling? Sampling plans can have different purposes whether you are in investigated mode or MCL rule mode. If you're directed by the legislature to set an MCL, you may need to develop statistically representative occurrence data to support the MCL process. In other circumstances, your strategy may be to focus on drinking water systems with the greatest potential for contamination (e.g., near sites that generate, use, or dispose of CEC) and the greatest potential for exposure (e.g., community water systems and non-transient, non-community systems, schools, daycares).

State Experience	**Pennsylvania** based its PFAS sampling plan on an analysis of Geographic Information System (GIS) layers that identified public water systems within a half mile of potential sources of PFAS.

How much funding is available for statewide sampling? Statewide sampling can be very expensive. States found sampling costs for PFAS to be a few hundred dollars for each sample, running to $2,000,000 in Colorado for quarterly sampling of all entry points at community and non-transient non-community systems using $300 per sample. Determine how much funding is available for your sampling effort. States may choose a strategy based on costs.

Where in the drinking water life cycle will you look for the CEC? Given the type of contaminant you're looking for determine where in the drinking water life cycle you need to be looking for it from source to tap. This information will help you determine how (if needed) to collect data from a statistically representative sample. Consider whether to sample groundwater, surface water, or industrial sources based on what you know about the nature of the CEC in your state.

State Experience	**Vermont** is going to regulate manganese in terms of the contaminant being a distribution contaminant. This choice impacts Vermont's manganese sampling plan in that the plan will be designed to not miss the CEC where it exists.

What types of water systems should be sampled? Use data and information from this module and Module 2 on health effects to determine who to include in your statewide sampling plan. Using this module, determine where CECs occur in your state's drinking water systems to identify who is likely at risk for exposure. The type of health effect influences what type of drinking water systems may pose risks to users and therefore what types of systems should be monitored (for example, whether to sample transient non-community systems where only chemicals posing short-term risks may be of concern). Consider sampling all community water systems and at least subsets of non-community water systems like schools. Additionally, your statewide sampling plan could prioritize locations mostly likely to find contamination (e.g., proximity to likely source) to understand the scope of the problem. Consider whether it is appropriate and within scope to sample transient and non-transient non-community water systems and private wells.

How will you get systems to sample in the absence of regulation? It can be difficult to collect occurrence data when it is not required by regulation. Understand and use the authority you have to require or encourage water systems to sample. If you have no authority, ask systems to sample. Determine who has an incentive to engage in sampling, like private water systems. Consider methods to incentive sampling, like press releases to facilitate public engagement. Could the data gathered be "grand-parented" into future regulations to "count" as initial monitoring, which would save the system money? Could you publish on your website the entire inventory of systems and identify the systems that choose to sample?

State Experience	
	• **Pennsylvania** has general authority for unregulated contaminants. If the state has reason to believe a CEC is present in drinking water and a public health risk exists, staff can require water systems to sample. • **California** has a rule that if a water system samples, they must report the data to the state.

Will you consider data from other media and private wells? Determine whether and how you will interpret data from other media. States will have to have to deal with the information they and the public become aware of from private wells and non-drinking water sources. For example, Department of Defense sampling or clean up results will need to be interpreted in the context of co-located or neighboring drinking systems.

How will you ensure quality control? In the case of PFAS, states have pursued state-funded statewide sampling to ensure consistency and integrity of results (e.g., reducing false positives) compared with water systems doing their own sampling. It takes time to go through every sample and complete a full QA/QC evaluation. Explore whether QA/QC staff working in other media can be engaged in QA/QC for the CEC of interest.

State Experience	
	• **Pennsylvania** has had success using volunteers with strict protocols (no makeup, etc.) for quality control. See Massachusetts Department of Environmental Protection Field Sampling Guide for PFAS. • **Michigan** resampled every detection to confirm findings. It was costly to validate the findings, but a worthwhile exercise to ensure integrity of the results.

Resources	Statewide sampling plans and guidance (PFAS) include the following: • Pennsylvania Department of Environmental Protection Bureau of Safe Drinking Water PFAS Sampling Plan, April 2019 • Vermont Agency of Natural Resources Perfluoroalkyl Substances (PFAS) Statewide Sampling Plan, June 2019 • Michigan PFAS Sampling Guidance

Module 4: Identify Analytical Methods

Module 4 End Goal: Assess and ensure ability to detect the CEC at adequate levels and get reliable lab data in the timeframes and volumes necessary.

Introduction

An analytical method is the approach used to measure the amount of a contaminant in a water sample. Some CECs may have approved methods across media (e.g., drinking water, wastewater, etc.), and some may lack established methods for any media. A key activity in the assessment of an analytical method is determining whether and to what degree the method can detect the CEC at levels below risk limits. See information and steps in Module 2 regarding your health-based level (a type of risk limit) to understand what detection limit you desire. Other risk limits include state health advisories (Module 7) and MCLs (Module 8).

Analytical methods generally describe how to:

- Collect, preserve, and store the sample.
- Gather, separate, identify, and measure contaminants in the sample.
- Meet quality control criteria.
- Report the results of the analysis.

Water sample analysis provides data that are required to demonstrate compliance or meet monitoring objectives. Analytical methods are challenging in the CEC context because the demand for and availability of methods can be limited, and access to accredited lab capacity is often still growing. Accreditation means a lab has been certified to successful use the analytical method of choice.

Information and insight gained in this module informs sampling plan design (Module 3) and is important for the development of CEC rules (Module 8).

Questions to Consider

- Do analytical methods already exist that can detect the CEC at concentrations below health-based levels in drinking water? Or, is any detect considered a problem?
- Do new or more accurate analytical methods need to be developed?
- What is the current capacity of state labs (number and quality) to analyze the CECs and to what level of detection?
- How robust are approved analytical methods?

Key Implementation Steps and Lessons

1. Determine if analytical methods for detecting the CEC in drinking water already exist

To understand whether analytical methods for a CEC exist, start by exploring research lab methods and commercially available methods within your state and elsewhere. Analytical methods are developed by a variety of entities, including:

- USEPA
- National Water Quality Laboratory at the U.S. Geological Survey
- Consensus method organizations such as Standard Methods and American Society for Testing and Materials
- Universities
- Water laboratories
- Commercial vendors

If the CECs are analyzed under the federal Unregulated Contaminant Monitoring Rule (UCMR), you can learn about the methods that were used—and their limitations. For example, states used USEPA Method 537.1 to analyze for six PFAS chemicals under the UCMR program. However, this method is not sufficient for analyzing all 4,000+ PFAS compounds.

A primary way to determine the adequacy of currently available methods is to determine whether and to what degree the method can detect the CEC at levels below risk limits. See information and steps in Module 2 regarding your health-based level (a risk limit) to understand desired detection limits. Other risk limits include state health advisories (Module 7) and MCL rules (Module 8).

Determine what methods your state deems adequate. You may have to put existing methods through validation to confirm acceptability and defensibility. Adequacy of a method may be determined by answering the following questions:

- Can you achieve sensitivity requirements needed to achieve desired risk limits (i.e., your health-based level or health advisory)?
- Do you have proper instrumentation for the method?
- How defensible (reliable) is the method?
- Are the data reproducible?
- Will stakeholders have confidence in the results?
- Do the methods meet anticipated regulatory monitoring requirements?

Analytical methods may evolve over time as labs improve scientific methods for detecting contaminants with greater accuracy at lower concentrations. As more states investigate a CEC and the science evolves (which can happen rapidly), reporting and detection limits will go down. You may experience developing a risk management strategy based on currently available analytical methods only to find these methods change significantly. This can lead to an iterative process between evolving analytical capacity and defining risk limits for risk management action. In some cases, a method will need to be completely redeveloped to achieve new targets. The evolution of analytical methods has consequences for your work developing health-based numbers, health advisories, and MCL rules.

To keep up with the evolving science, explore and implement analytical method flexibility which allows laboratories to modify approved methods as new understanding emerges.

Communication and Collaboration	Review the CDC's Communicating During the Data Analysis Phase, for information and ideas about messaging regarding analytical methods.

Resources

There are several resources available for more information about analytical methods:

- Learn more from USEPA Learn about Drinking Water Analytical Methods webpage.
- UCMR3 Fact Sheet: Searching for Emerging Contaminants in Drinking Water
- The National Contaminant Occurrence Database (NCOD) site describes water sample analytical data that USEPA is currently using and has used in the past for analysis, rulemaking, and rule evaluation. NCOD data include Unregulated contaminant occurrence data.
- ASDWA's Per- and Polyfluoroalkyl Substances (PFAS) Laboratory Testing Primer for State Drinking Water Programs and Public Water System
- See Analytical Methods for Drinking Water for information on how USEPA evaluates methods developed by others.
- The National Environmental Laboratory Accreditation Management System (TNI LAMS) provides a database to identify method codes and analytes.
- See list of Laboratories Approved by USEPA for the Third Unregulated Contaminant Monitoring Rule UCMR 3 and UCMR 4.
- Each EPA Region maintains an EPA regional laboratory, which may be able to analyze samples or help identify potential analytical support, see the list of EPA regional laboratory contacts.

2. Determine approach if existing analytical methods are inadequate

If adequate analytical methods don't already exist for a CEC of interest, you may need to contribute to developing new methods or refining existing ones. Developing a totally new method is difficult, but there is a range of opportunities for method modification and refinement.

Sometimes an analytical method exists but needs to be validated and approved to make sure the method meets your state's standards for quality assurance and quality control (QA/QC). Use your state lab or lab accreditation program to identify and use a quality control manual check list— which likely includes criteria such as reproducibility, accuracy standards, levels of precisions, accepted recovery, etc.—to determine whether a method can be validated and approved or what further modifications are needed to meet your state's adequacy and acceptability requirements.

Existing analytical methods for detecting CECs in wastewater or other media may be adapted for drinking water. If the CEC can be detected in more complex media, like wastewater or surface water, it can likely be detected in drinking water where there is less material that can lead to signal interference.

In the absence of other alternatives, engage the entities listed in Step 1 to explore opportunities to develop or refine analytical methods. Reach out and work with people who have done this analysis in the past rather than reinventing the wheel. Literature searches are an avenue to identify organizations and people with relevant experience. Try to identify which labs (in state or out-of-state) are on the cutting edge of innovation and contact them for insight and help.

Manufacturers often have the most information on the CECs they produce and may be a resource for methods development. Engaging industry in methods development or refinement can be challenging. In some cases, industry may be a responsible party and the public may feel there is a conflict of interest in engaging industry in methods development.

State Experience	• **Pennsylvania:** Department of Defense (DOD) was active in Pennsylvania in developing analytical methods for PFAS, but the public did not trust methods coming from DOD. • **Minnesota**: In 2003, Minnesota's Public Health Laboratory (MN PHL) developed a method to test for PFOS and PFOA. In 2006, they developed a LC/MS/MS method to look for the seven PFAAs identified at the 3M waste disposal sites (PFBA, PFBS, PFPeA, PFHxA, PFHxS, PFOA, PFOS). MN PHL is currently working toward validating an updated method utilizing isotope dilution and solid phase extraction based on the recently released USEPA Method 533. This method will target more than 20 PFAAs including short chain isomers (e.g., PFBA, GenX) at lower detection limits (< 5 ppt).
Communication and Collaboration	Public perception of methods may vary based on the source of the method. Public water systems may refute methods. Consider reaching out to water systems about your methods prior to reaching out to the public. If the public is concerned about your approach, consider holding a science fair type event where individuals can ask experts one-on-one about your analytical methods.

3. Determine guidelines for sampling and analysis to ensure accuracy and credibility

Particularly in the context of CECs, it is important that you take steps to ensure the accuracy, credibility, and comparability of CEC sample collection and lab analysis. This is especially important when systems are doing their own sampling and contracting for their own analysis. Without quality control, you risk ending up with data that can't be used or trusted.

There are two options for organizing and implementing sampling. Water systems can sample for the CEC themselves, or your state health or environmental agency can lead sampling. Evaluate your state's sampling capacity to ensure that adequately trained personnel and sufficient sampling equipment are available.

Especially when systems are doing voluntary sampling, systems need to have a process for sampling and quality control to avoid false positives (e.g., from sample contamination). It is important to conduct education and training on sampling methods for systems that are doing their own sampling.

Resources	See these resources on sampling and analysis: • USEPA's Sampling Guidance for Unknown Contaminants in Drinking Water • Minnesota's Perfluorinated Chemicals (PFCs) Analytical Checklist – Environmental Laboratory Accreditation Program (MNELAP) • Standard Methods for the Examination of Water and Wastewater

4. Assess and build access to state-accredited lab capacity

Assessing and building your access to state-accredited lab capacity includes three components: 1) You have access to labs that are accredited (i.e., certified) to use the desired CEC analytical method; 2) Accredited labs have sufficient staff to analyze samples for anticipated volumes; and 3) Accredited labs have sufficient equipment to analyze samples for anticipated volumes. If you are pursuing an MCL rule, your state will need to have access to accredited lab capacity. If you are not pursuing an MCL rule right now (in investigative mode), you just need to understand lab capacity. Access to accredited lab capacity has implications for activity in Module 3 and how quickly results can be produced.

Once a state announces it is headed toward an MCL rule, labs usually see this as a signal and will start to build capacity (build a market). When a state is in exploratory mode and not definitively headed toward an MCL rule (in investigative mode) labs may not have the incentive to build up capacity.

If the CEC was included in UCMR, anticipate that once UCMR ends the USEPA's accreditation program for that CEC's analytical method will end. This impacts your access to accredited lab capacity. There are two options for accessing accredited labs. You can stand up an accreditation program in your state to self-certify your labs for the method of interest, or other states can offer the accreditation certification (e.g., Pennsylvania uses New Jersey to accredit labs). Explore reciprocity agreements with other state labs. To explore which path you might pursue, start by identifying what rules and regulations guide state lab accreditation activities and procedures.

Building access to accredited lab capacity is important because large sampling efforts (e.g., statewide sampling) can overwhelm in-state lab capacity, especially when labs aren't already analyzing CECs through national programs like UCMR. If you are initiating large new sampling efforts, assess whether there are enough accredited labs available to do the volume of analysis needed using approved methods. If labs are over-burdened, there may be delays in receiving results. Assess both the ability of labs to analyze the anticipated volume of samples and ability of labs to implement approved analytical methods. Labs need sufficient equipment and well-trained staff to be efficient and effective.

Because it can take time to build capacity where needed—including securing funding if required—it is important to assess state lab capacity early. Use a survey or convening of stakeholders to assess lab capacity. Determine the availability of state and USEPA certified labs that have the capability to use the

chosen analytical. Look at all certified labs and their USEPA-certified versus proprietary methods and reporting capabilities to reach target numbers. A place to start is state labs used in UCMR for analysis. Seek assistance from regional lab organizations to understand lab capability and capacity. Build lab capacity funding into requests to the state legislature for resources to address CECs.

Consider staged implementation of monitoring to allow more time for labs to build capacity. Engage labs that are already certified and have capacity first. Consider establishing a support network of labs with analytical capability and capacity to handle the CEC to help ensure that samples can be processed properly and expeditiously.

State Experience

- **Minnesota** is currently able to keep up with demand for PFAS analytics between its Public Health Laboratory and a lab in Canada. However, in the future it will likely need greater capacity. Minnesota is pursuing legislative funding to increase capacity. Learn more about Minnesota's accreditation program: Minnesota Department of Health Environmental Laboratory Accreditation Program (MNELAP).
- **New Jersey** broke water systems up into groups, with each sampling at different times. This spread out demand for lab capacity.

Resources

- See these resources for information on accredited lab capacity:
- The National Environmental Laboratory Accreditation Program (NELAP) offers certification based upon nationwide criteria that use quality systems to ensure the integrity of analytical data. Reciprocal certification is available to the thirteen accrediting authorities that participate in the NELAP. NELAP can be a forum for sharing information about lab accreditation. NELAP attempts to have state consistency through NELAP accreditation. NELAP makes it easier for reciprocity between states.
- To assist in locating laboratories capable of providing the necessary support, USEPA's Compendium of Environmental Testing Laboratories (Laboratory compendium) provides users with real-time data related to laboratory contact, capability and capacity information, and ERLN (Environmental Response Laboratory Network)/WLA (Washington Library Association) Membership status, through a secure, web-based tool. The Laboratory Compendium is available to federal, state, and local emergency response, laboratory and water utility personnel. Access is secured through an application process.
- See USEPA Manual for the Certification of Laboratories Analyzing Drinking Water Criteria and Procedures Quality Assurance.

Module 5: Characterize Treatment and Compliance Options

Module 5 End Goal: Demonstrate treatability, including identifying and assessing treatment and compliance options (including effectiveness and cost) for reducing CECs in drinking water to acceptable levels of risk.

Introduction

Often, managing risk from CECs in drinking water means treating water to reduce the concentration of CECs to an acceptable level. If you are developing rules for state specific MCLs or treatment techniques, demonstrating the ability to treat (and in some cases demonstrating related factors like technological and economic feasibility) is an important element of moving forward with rulemaking. Even if you are not pursuing rules, you may need to develop information about treatment options.

For new CECs, states and the federal government often don't have specifications on the best available treatment technologies. In the absence of federal recommendations on treatment, the design, construction, and study of efficacy for new treatment technologies—and/or application of existing technologies to new CECs—falls to states.

Questions to Consider

- What are the treatment goals, and are they short-term or long-term?
- What treatment options are available to reduce the CEC in drinking water?
- What is the effectiveness, cost, and other advantages and disadvantages of treatment options?
- How do cost and effectiveness of treatment options vary according to water system size, source water type, the presence of other contaminants, or other relevant factors?
- What are consequences of treatment regarding residuals and waste that can lead to further contamination—or other unintended consequences?
- Are treatment technologies likely to change corrosion chemistry, which would necessitate an evaluation of potential issues under the lead and copper rule?
- Will water systems have the technical and managerial capacity to successfully install and properly operate and maintain the associated treatment processes (and/or other compliance requirements)?
- How should states ensure that installed treatment meets appropriate specifications?

Key Implementation Steps and Lessons

1. Understand treatment options through literature reviews, calls for ideas, and/or piloting experience in other states

When considering potential treatment options for a CEC, you should cast a broad net. There are often not many (if any) full-scale implementation examples of treatment options for CECs, so it can be difficult to find

existing information about their effectiveness and cost. Resource constraints may limit your capacity to identify and assess treatment options.

Conduct a call for information from other states, universities, water systems, consulting engineers, and other stakeholders about potential treatment technologies and information from testing or piloting. Conduct a literature search to identify and understand treatment and compliance options. Industry may approach you with possible new treatment technologies.

Communication and Collaboration	Consider holding brainstorm sessions with experts and operators to gain insight and information on treatment technologies. Prime the session with off the wall ideas—planning under large uncertainty requires thinking outside the box, which often requires priming. When an idea is shot down, dig deep to find the individual elements that don't work. Not throwing out the whole idea helps people think deeper and create new approaches under large uncertainty.
Resources	Although there is no single source that states can go to for information about CEC treatment options, centers of relevant expertise include USEPA Office of Research & Development, the Interstate Technology and Regulatory Council (ITRC), and the Water Research Foundation's Leaders Innovation Forum for Technology (LIFT) initiative.

2. Pilot treatment options and conduct feasibility analysis for in-state systems

Promising treatment technologies should be piloted with drinking water systems in your state to understand their effectiveness given the specific characteristics of in-state water systems, drinking water chemistry, and other factors. It is important to look at the chemistry of the water, not just the CEC, to determine which treatment options may be most feasible and effective in your state. States may want to consider a process for vetting which potential treatment options to pilot in order to prevent the expenditure of resources on riskier technologies.

Pilots should focus on collecting data to inform whether treatment options are likely going to be effective and economically feasible. Identify what challenges related to residuals, simultaneous compliance, or other issues may need to be considered. To understand costs, you should gather information on capital and operating costs and then calculate net-present value over the life of the treatment technology. Explore affordability (Module 6), and technical, managerial, and financial (TMF) capacity issues for small systems to implement piloted treatment options. Understand the capacity of state administrators to offer guidance on treatment to small systems. Universities may be good partners for bench-scale or larger pilot studies.

Resources	Several states' approaches for piloting treatment are modeled after the Great Lakes - Upper Mississippi River Board (GLUMRB) 10 State Standards.

State Experience	Examples of state guidance and approval processes for pilot treatment activities, including examples for PFAS treatability, include: • **California** specifications for treatment pilots: Water Treatment Technology Approval Process. • **Minnesota:** Pilot Testing for Wastewater Treatment Facilities

3. Assess alternatives to treatment

In addition to identifying and testing treatment options, you should assess other measures or mechanisms for reducing risk that may be effective alternatives to treatment. Examples of alternatives include:

- Operational changes, including blending with other sources and discontinuing or reducing use of contaminated sources.
- Using alternative sources.
- Water conservation.
- Infrastructure improvements to wells (e.g., drilling deeper).
- Connections to another system for all or a portion of the water supply.
- Treatment at point of use or point of entry (i.e., in-home treatment).
- Source water protection.

While you may pursue some of these alternatives as short-term emergency measures to quickly reduce exposure (see Module 1) or as intermediate measures (see Module 7), some may also serve as longer-term management solutions in lieu of treatment.

Alternative measures may be required in construction approval (where needed to meet technical standards) or operating conditions (where operating techniques like blending are required). State drinking water rules will typically not specify these alternatives, but rather leave it up to systems' engineers to determine what is most appropriate to meet established treatment goals or regulatory requirements.

Communication and Collaboration	Think through and consider your communications strategy for helping residents understand your choice to use an alternative to treatment. Clearly explain what these alternatives will achieve and how they will help improve public health. This will help audiences believe the state is not simply taking an easier or less effective approach.

State Experience	For PFAS, **Minnesota** pilot tested and evaluated removal by small, in-home filters to provide residents of affected communities with information regarding options available to them for PFAS removal from their water.

4. Characterize possible unintended consequences of treatment options

When evaluating treatment options, you should consider unintended consequences, including how treatment options may alter water chemistry and/or generate residuals in treatment-related waste streams. These issues can affect how systems are simultaneously complying with existing drinking water regulations (i.e., "simultaneous compliance challenges"). For example, some coal-based Granulated Active Carbon used in the treatment of PFAS can have high arsenic levels, and treatment through ionic exchange can impact water chemistry (e.g., increasing corrosion rates). Changes in corrosion chemistry may necessitate an evaluation of potential issues under the federal Lead and Copper Rule.

Understand the impact of contaminated material from treatment going to landfills and whether disposal will lead to additional contamination. The cost of simultaneous compliance and availability of appropriate disposal for managing residuals should be factored into the assessment of treatment options. Special or additional monitoring may be needed post-treatment to understand unintended consequences.

Communication and Collaboration	When communicating unintended consequences to the public, consider framing the consequences in relation to the overall objective of protecting public health and safety so that no one thinks this is an excuse not to do something.
State Experience	**Colorado** found that the cost of properly disposing of radium and uranium that was removed from drinking water could be just as expensive as the cost of removing it.
Resources	For more guidance on simultaneous compliance, see USEPA Simultaneous Compliance Guidance Manual.

5. Develop state treatment protocols for chosen treatment options

You often can't pilot treatment technologies in each water system, so you should instead establish protocols for drinking water systems to test treatment options themselves. Protocols should include performance and/or compliance monitoring. The goal is to have systems demonstrate the efficacy of the treatment process (i.e., ability to treat) rather than guiding what treatment looks like for each system. If you are pursuing a CEC rule, ability to treat is an important component of rule development (see Module 8).

New treatment options may require different types of certifications for system operators. If there is a shortage of certified operators, you may need to factor in the time and resources needed to obtain certifications for new treatment options.

Communication and Collaboration	Examples of states working together on treatment protocol development (and sharing what has already been developed), include the Great Lakes Upper Mississippi River Board, and the 10 States Standards process.

State Experience	**Ohio** has had success working with the State American Water Works Association (AWWA) to develop white papers on treatment approaches for contaminants. See, for example, the white paper Aeration to Reduce Trihalomethanes.
Resources	For more information about certification of drinking water system operators, see USEPA Information for States about Certifying Operators of Drinking Water Systems.

6. Develop design review standards for treatment

You should establish specifications for treatment and processes for reviewing and approving treatment plans from drinking water systems. These assure that treatment technologies or other steps taken will achieve protective levels and, if your state's drinking water CEC rule is established, get systems into compliance. States use different approaches for the review and approval process, including using design review standards or criteria, permitting requirements, or construction standards in a CEC rule.

State Experience	States use a variety of ways to ensure that treatment meets state standards. • **Colorado** uses design review criteria for drinking water and wastewater projects. • **Pennsylvania** issues design and permitting standards through the rule making process that establishes the MCL (see: Safe Drinking Water Program Public Water System Permitting). • **Minnesota** has a Plan Review for Treatment Plants • **New Jersey** has general construction standards in the State Safe Drinking Water Act Rules that are reviewed and updated as needed as part of any CEC rule proposal.

7. Consider capacity and impacts on small systems (and larger systems, too)

Small systems may face unique financial or operating challenges for implementing new treatment approaches for CECs. See Module 6 for detailed information on assessing costs, benefits, and affordability for small systems. Small systems may struggle with auxiliary issues like building construction plus instrumentation and controls compared to their current system. Treating for CECs can be a drastic change in complexity. Fiscal and other challenges are experienced by some mid-sized and large systems as well.

USEPA has grant programs to help overcome financial challenges for small systems. States also have assistance programs; for example, Vermont can forgive 50% of the principal on State Revolving Fund (SRF)

construction loans for certain disadvantaged systems.[4] However, special consideration needs to be given to operating costs as grant programs typically only cover capital cost for the actual infrastructure. In addition, there may be opportunities for utilities and state agencies to work together to help target SRF monies and Principal Forgiveness opportunities.

Recognizing the challenges small systems face for treating some contaminants, the federal Safe Drinking Water Act allows states to use variances for small public water systems (fewer than 10,000 customers) to allow them to utilize treatment technologies that are considered more affordable and protective but don't remove contaminants to the levels specified in federal regulation (i.e., the variance technology provisions in the federal SDWA). However, USEPA has determined that there are affordable compliance technologies for all existing standards, and so variances have not yet been made available for any federal MCLs.[5] State drinking water programs generally don't pursue variances, instead seeking to ensure that all residents have equal access to safe water.

Communication and Collaboration	States may want to use specific examples (e.g., "in City X which has only 200 customers") rather than "small systems" when framing impacts.
State Experience	In **California**, ongoing work is exploring the impact of MCLs on small rural systems. A good example is provided by work funded by the state and led by the University of California-Davis and Corona Environmental Consulting, which explores affordability impacts for meeting the nitrate MCL, with options of having capital outlays, and potentially O&M expenses, covered by the state.
Resources	• USEPA provides additional information about Drinking Water Grants and Small Drinking Water System Variances. • The Rural Health Hub has resources to support working with small systems. • The online Rural Community Assistance Partnership (RCAP) Resources Library has a variety of resources that are useful to small, rural drinking water and wastewater systems. • The Water Research Foundation has examined opportunities for regionalization and other forms of utility partnerships to facilitate compliance and reduce costs. See for example: Feasibility of Small System Restructuring to Facilitate SDWA Compliance.

[4] See: Vermont DEC, Drinking Water State Revolving Fund.
[5] See: Congressional Research Service, Safe Drinking Water Act (SDWA): A Summary of the Act and Its Major Requirements. (2017)

Module 6: Characterize Benefits, Costs, and Economic Considerations

End Goal for Module 6: A clear understanding of the economic considerations of potential MCL levels or other rulemakings, including benefits, costs, economic impacts, and affordability.

Introduction

It can be important for states to understand the benefits of reducing exposure to CECs, as well as understanding the costs and associated economic impacts of potential regulatory actions. Depending in part on your governing statutory language and administrative requirements, and your goals (e.g., promulgating an MCL or developing an advisory level), you may be required or desire to conduct a formal benefit-cost analysis (BCA) to help with selecting the regulatory level. You may also undertake economic analysis to report on the economic impacts of the MCL or other potential regulatory choices. Additional economic considerations may also be relevant, such as assessing the economic impacts on communities and businesses, and associated impacts on affordability and economic feasibility.

This module outlines the steps that are important in assessing the public health benefits and costs of a potential state regulatory action, and for conducting a benefit-cost analysis of various regulatory options a state may be considering. The full range of benefits, costs, and other economic considerations can be considered, regardless of whether they can be quantified, expressed as dollar values, or instead need to be evaluated more qualitatively.

Questions to Consider

- What state-level statutes and guidelines affect how benefit, cost, and other economic analyses are approached?
    - To assess economic impacts of potential regulation on target groups (e.g., small businesses, small communities).
    - To provide information on costs to water systems and customers, as well as the public health and other benefits received.
    - To guide selection from among regulatory options (e.g., select MCL level).
- What methods and data can you use to assess costs and benefits?
- What can you quantify given available data and methods versus describe qualitatively?
- What technical capacity and financial resources will you need to do the analysis?
- How can you deal with uncertainty about costs and benefits?
- What are affordability considerations for smaller systems, and low-income households in larger systems? What are the economic impacts on small businesses?
- How do costs and benefits change as one looks incrementally at different potential MCL levels?

- How do benefit-cost tradeoffs vary across communities of different size (large versus small systems)?
- How can the resource needs for states to develop and implement an MCL be considered?
- What benefits, costs, and other economic considerations are important to each audience group?
- Are you presenting economic and financial concepts and findings in a manner that supports using the information appropriately in decision-making?

Communication and Collaboration	Be audience-aware when sharing economic and financial information. This means examining how each audience commonly thinks about and uses economic and financial information in order to help them become aware of how to use the information at hand differently, if needed. For example, many economic and financial terms are similar, but have very different meanings. This means that people may think they understand but may be using the information incorrectly in this situation.
Resources	• **Colorado** provides an example describing the process and statutory framework under which it may issues new drinking water standards, starting at page 3, Annual Report to the Water Quality Control Commission and Colorado Legislature. • **Minnesota** operates under statutory mandates regarding the economic assessments state regulators must develop: MN Stat. § 14.131 subparts (1), (2), (5) and (6) deal with economic considerations; MN Stat. § 14.127, subd. (1) talks about cost thresholds for small city or small business: subd. 6 and MN. Stat. § 115.43, subd. 1 talk about specific economic factors to consider.

In order to discuss the use of economic tools with others, you need to first have a significant understanding of how each tool will be used. You may want to collaborate with a partner who is more versed in these tools to provide a content-rich training for the team managing CECs in your state.

Key Implementation Steps and Lessons

1. Determine state-specific requirements and procedures for assessing costs and benefits, for conducting Benefit-Cost Analysis (BCA), and for conducting other economic analyses

There are several steps to consider when determining state-specific requirements and procedures for BCAs, and/or for related economic analyses as may be required or desired under state law or policies. Those steps include:

Review state law

You can review state laws and administrative procedures to determine BCA and related economic analysis requirements. For example, under state-specific versions of the Safe Drinking Water Act, some states do not have to consider cost in setting an MCL, and instead can focus solely on health impacts. Other states (e.g., Pennsylvania, California, and New Hampshire) must consider cost and/or economic impacts on businesses or households in developing an MCL.

Communication and Collaboration	Work closely with legal departments as the law is not always clear and you may need help interpreting requirements. Iterate your understanding back to legal collaborators to make sure your understandings are accurate. Consider periodically sharing your economic work with legal colleagues to ensure they both understand and are confident you are meeting the applicable rules. In addition, colleagues in regulatory programs for wastewater or other related sectors may have direct experience in developing economic analyses that meet state-specific requirements. Check with your counterparts in these departments for potential insights and examples.

Consider when BCA and/or other economic analyses fit in the process

Where in your state's rulemaking process does BCA and/or related economic analyses occur? For example, the BCA and/or economic impact analysis may be required ahead of any formal MCL-setting rulemaking process, or as part of the MCL-setting process itself, or to report on impacts once the regulatory level has been set. As part of regulatory procedures, BCA and/or related economic considerations may or may not need be taken into account in establishing an MCL or other regulatory action.

2. Ensure understanding of the use of economic analysis in CEC reviews

You should ensure you have confidence in your knowledge of economic analysis and the differences between a benefit-cost analysis, an economic impact analysis, and an affordability analysis. A simple definition for each is:

- **Benefit-cost analysis (BCA)**: A tool to provide relevant information about what benefits are anticipated, what costs may be incurred, and how the benefits compare to the costs. A BCA typically includes both quantitative and qualitative information (e.g., because it often is challenging to confidently quantify all public health benefits). A BCA can be used to examine how costs and benefits may vary between large and small communities. A BCA also is useful to explore how much additional (incremental) costs are incurred at increasingly stringent potential regulatory levels, compared to how much additional benefit may be gained (this is called an "incremental" analysis of alternative regulatory options). Most important, recognize that a BCA is a "tool" to help organize and communicate relevant information to decision-makers and the public; it is not a "rule" that governs whether or how stringently to set a standard.
- **Economic impact analysis**: A tool to assess how the costs and/or other requirements imposed by a potential regulatory action may adversely impact the fiscal viability of various businesses and/or

communities of concern. For drinking water standards, the economic impact analysis would typically focus on the potential adverse effects on small communities and the water utilities serving them. These fiscal impacts arise from the compliance costs and administrative burdens associated with monitoring and reporting requirements and, where needed, the installation and operation and maintenance of any necessary new treatment processes. Economic impacts to be considered may include whether the affected entities face challenges gaining access to financing for required treatment upgrades, whether sufficient State Revolving Fund (SRF) monies would be available to assist utilities/communities in need, and whether the increase in compliance costs would cause water rate increases that might force local businesses to close and/or residential customers to face economic hardships due to escalating water bills. An economic impact analysis provides information that may be used to assess whether a potential regulatory action might be fiscally burdensome to some entities, and/or how SRF monies or other fiscal assistance may be targeted to minimize adverse impacts.

- **Affordability analysis**: A tool to examine whether households (or communities) may face economic hardships (i.e., forgo other essential expenditures that support public health) if/when water bills increase to pay for additional treatment and related regulatory requirements. An affordability analysis for a potential drinking water regulation typically would focus on households served by small water utility systems (where the cost per household often is relatively high) and low-income households in larger systems (e.g., examining how the water bill compares to the income of a household at the 20th percentile of the income distribution, known as the Lowest Quintile Income (LQI) household). An affordability analysis may be useful for assessing what type and level of economic support (e.g., SRF funding), potential regulatory relief (e.g., variances), and/or targeted customer assistance programs (CAPs) may be considered to provide economic relief to households and communities facing affordability challenges.

It is also helpful to understand how the three different types of economic analysis may be used to inform regulatory considerations and decision-making. For example, a BCA is primarily aimed at helping to consider if the benefits of a potential rulemaking justify the expense – that is, is a potential state action a worthwhile investment of its citizen's resources, and/or at what stringency does a standard make the most sense. However, a BCA can also reveal which communities (e.g., rural areas served by small systems) may bear a disproportionate share of the costs compared to the share of public health protection provided. This information may then be used to assess fiscal needs and guide how SRF monies or other economic support may be directed.

Economic impact and affordability assessments focus primarily on who bears the expense, and whether the cost may impose significant adverse consequences on those households, businesses, and/or other affected entities. These analyses may help guide thinking about how stringently to set a standard, but more often are focused on ascertaining what might be done to alleviate the economic hardships that may be imposed (e.g., what types and levels of assistance may be needed).

Other types of economic analyses and terminology also may be used. For example*, cost-effectiveness analysis* may be applied to indicate the cost per cancer case avoided (or cost per other relevant health endpoint) to help identify where the greatest health benefit per dollar spent may be attained. The term "Regulatory Impact Analysis" (RIA) may also be used in some settings, and often entails a combination of benefit-cost and economic impact assessments. "Economic Feasibility" is another economic concept that

may apply in a state context and may entail an assessment of fiscal capability (e.g., access to financing), and a notion of imposing a reasonably affordable cost, and it may also include benefit-cost considerations.

Communication and Collaboration	In order to discuss the use of economic tools with others, you need to first have a significant understanding of how they will use each tool. You may want to collaborate with a partner who is more versed in these tools to provide a content-rich training for the drinking water staff working on CECs. Recognize that very few lay people understand the differences or methods used across these various types of economic analyses, or how they may be used to inform decision-making. Consider providing an interactive training (e.g., dashboard) that allows users to play with using the information in various scenarios so that people can really understand how the information can be applied to evaluate different potential regulatory and related funding decisions. Interacting with information is a strong tool for overcoming our brain shortcuts when perceived risk is high.

Consider other states' experience

Look at USEPA methods and guidance, and what other states are doing to estimate and portray costs and benefits (e.g., for PFAS, several states are using New Hampshire's approach to considering costs and benefits as an approach), and then assess what you can do as a state. Likewise, other states may offer useful examples and guidance on how to conduct and interpret economic impact and affordability analyses

Review other BCA, economic impact, and affordability analyses

Review independent BCA analyses, and critiques of USEPA and other benefit-cost analyses (e.g., as filed in formal comment submissions by American Water Works Association (AWWA) on USEPA proposed rules) to recognize possible limitations and alternative approaches/best practices. Likewise, examine other examples of economic impact analyses and affordability assessments that may have been developed by other departments or divisions within your state, or from other states.

Communication and Collaboration	Use both graphics and words when sharing information with numbers. CDC's Health Communications Tools can help you effectively share percentages and risks.

Resources

The resources listed below can help you understand the issues related to quantifying health benefits and estimating costs of compliance. Some resources also explain the standard framework for characterizing benefits and costs.

- Quantifying Public Health Risk Reduction Benefits, WRF Report 90884, 2002. (Raucher et al., 2002)
- An Economic Framework for Evaluating the Benefits and Costs of Water Reuse. 2006. Final Project Report and User Guidance. 03-006-02. Water Reuse Foundation, Alexandria, VA.
- Estimating the Cost of Compliance with Drinking Water Standards: A User's Guide. 1995. ISBN 0-89867-828-5. AWWA Research Foundation, Denver, CO.
- USEPA Economic Analysis and Statutory Requirements
- USEPA Federal Guidelines for Cost Benefit Analysis: *Guidelines for Preparing Economic Analyses*
- Office of Management Budget, Circular A-4 on Regulatory Analysis.
- "New Perspectives on the Costs and Benefits of Mitigating Radon in Drinking Water." Raucher, R., D. Crawford-Brown and M. Harrod. 2005. *Public Works Management & Policy* 10(1):10–22.
- There are numerous other examples/applications/critiques available, such as AWWA-sponsored reports and public comment filings on past federal regulations. While these past analyses and critiques may apply to contaminants already regulated, the economic analysis issues raised, and illustrations offered in these past evaluations remain directly applicable to CECs. Examples of past methods applications and critiques pertain to compounds such as radon, arsenic, and microbial/disinfection byproducts.

3. Ensure adequate capacity to conduct a health-based benefit and cost analyses

Many state drinking water regulatory agencies do not have internal toxicology/risk assessment and related public health economics (see Module 2), or other BCA capacity. The lack of in-house expertise may be especially applicable to drinking water programs housed in an environmental or natural resource management agency (as opposed to those located within public health agencies). Consider retaining a toxicologist/public health expert, and/or hiring an economist or contracting for appropriate types of economic analysis services. Consider whether the external support needed is periodic or permanent.

Reach out to other states to ascertain how they marshalled the necessary technical expertise and developed associated economic analyses. Other states also may have relevant examples of BCA, economic impact, and/or affordability assessments.

Note also that economic analyses need to rely heavily considerations raised in prior modules. Specifically:

- A cost analysis (as well as the related affordability and economic impact analyses) for a potential MCL or other policy draws upon: 1) the estimated occurrence for the CEC in question (Module 3), which indicates the number and size distribution of water systems likely to require compliance efforts; 2) the type of treatment and non-treatment alternatives that may be implemented (Module 5); and the monitoring requirements and analytic approaches (Module 4).
- An assessment of the public health benefits of a potential MCL or other policy action draws upon: 1) public health risk assessment and related dose-response information (described in Module 2); coupled with 2) the estimated levels of exposure (dose), which draws upon the occurrence analysis (Module 3).

Often, the occurrence and cost information need to be developed in a manner that conveys the following key pieces of information that will help inform and guide decision-making and the public:

- How much capital cost and other "up-front" expenditure will be required, for water systems of different sizes, to integrate additional treatment processes and related compliance efforts into their existing systems.
- How much will it cost water systems of different sizes to properly operate and maintain new treatment or other compliance processes?
- What are the total annualized costs of compliance (i.e., combining annualized capital and annual O&M costs) for water systems, by water system size category? How much will this increase household water bills each year, in systems of different sizes?
- How much do the annualized cost per system and household change when MCLs of greater or lesser stringency are considered?

Other cost-related information may also be useful, such as a cost per volume of water treated (e.g., $ per thousand gallons) and a net present value calculation of costs over an extended time period (e.g., 20 or 30 years of compliance).

If there is information available to quantify any of the anticipated health benefits (e.g., number of excess cancer cases avoided over a 70-year "lifetime" period, or number of children with reduced exposures to a CEC with key developmental risks), then this information may be compiled to inform decision-making and the public. This may take the form of a cost-effectiveness analysis revealing, for example, the cost per estimated excess cancer case avoided, or the cost per child gaining reduced exposure to a CEC. These forms of cost-effectiveness analysis can provide useful insights in the absence of more definitive benefits calculations.

Communication and Collaboration	Your state public health agency, and/or a state-affiliated university, may be able to provide relevant economics and related public health policy expertise. Specialty consultancies may also be retained. Consider collaborating with other regulatory programs within your state (e.g., a wastewater or groundwater management program) to ascertain whether and how they have addressed similar economic analysis requirements and whether they possess or are tapped into the expertise necessary for developing the applicable economic analyses.

4. Characterize costs

There are several steps to consider when characterizing costs to systems resulting from regulatory actions. Those steps include:

1. Assess the scale and type of response needed

Use available occurrence data (Module 3) to estimate the scale and type of response that may be necessary (i.e., how many systems, of what size, and of what source water types are expected to be impacted). The number and mix of water systems impacted by a potential MCL will vary depending on the stringency of the MCL being considered.

2. Review existing cost data

Review treatment cost data (informed by the treatment approaches from Module 5) to understand treatment system capital costs and other upfront costs (e.g., land acquisition, financing), and annual operation and maintenance (O&M) costs. Data gathered can include treatment cost data from a literature review and cost data from pilot testing. Data can also include the cost of alternatives to treatment, such as blending of supplies, consolidating with other regional water utilities, or well-deepening.

It often is prudent to develop a *range* of cost estimates (rather than point estimates), given the uncertainties about unit treatment costs and the variability across impacted utilities regarding retrofit and other practical considerations. As noted under Step 3, it is useful to characterize costs in terms of total annualized costs per affected water system, and annual costs per household within those systems, according to different size categories.

3. Consider cleanup and residuals management costs

To consider the full range of associated costs, consider cleanup and residuals management costs. These may include costs to landfills, hazardous waste sites, wastewater discharge to groundwater, and other areas. Consider reaching out to other states to determine what cost information they may have developed and applied for treating the CEC of interest.

Communication and Collaboration	Collaborate closely with utilities when gathering and sharing information about the cost of potential treatment approaches. Utility professionals can often provide a considerable amount of practical insights, such as challenges in accommodating an additional treatment process within an existing treatment facility footprint or in concert with in-place processes (e.g., for simultaneous compliance).

Resources	There are several resources that can help you estimate treatment costs and interpret occurrence data, including: • USEPA has developed treatment technology unit costs. • Estimating the Cost of Compliance with Drinking Water Standards: A User's Guide. 1995. ISBN 0-89867-828-5. AWWA Research Foundation, Denver, CO. • **California** has developed compliance cost estimates for its MCL-setting process. See this example for the state's 2017 rulemaking for 1,2,3 TCP. See especially item #20 for cost curve documentation. Items under #15, #16, and #22 may also include useful cost-estimation materials. • "Cost to Utilities of a Lower MCL for Arsenic," with M.M. Frey, D.M. Owen, Z.K. Chowdhury, R. Raucher and M.A. Edwards. 1998. *Journal AWWA* March:89–102. While this article contains outdated information on arsenic treatment costs, it does lay out the steps and analysis components necessary to develop a cost of compliance estimate for any contaminant.

5. Characterize public health and other benefits

There are several steps to characterize public health and other benefits from regulatory actions. Those steps include:

1. Determine the need to consider benefits

Consider determining if state-specific Safe Drinking Water Act (SDWA) provisions influence the necessity and/or ability to consider benefits as well as costs.

It can be helpful to determine whether your state will consider benefits as well as costs at the outset of a regulatory process, or instead set the MCL according to a health-based standard or prescribed target risk levels, and then complete an economic impact analysis.

2. Identify and describe benefits

The first step is to identify the possible benefits to public health or other considerations from a possible regulatory action. It can be helpful to consider how to effectively describe qualitatively the health risks posed and managed by the potential regulatory action (information gathered during work in Module 2 will be highly relevant for this). In addition to public health risk reduction, a regulatory action may also provide important benefits such as peace of mind, avoided work loss, and other costs of illness, as well as impacts on caregivers (e.g., time lost from work to care for a sick family member), and other quality of life factors. Because health risk reduction benefits often are difficult (and/or controversial) to quantify, it is important to develop a well-articulated description of the potential health benefits and to whom they may accrue.

3. Quantify and monetize benefits

Quantification of the health benefits associated with CECs can be very uncertain and controversial. If quantification is possible and judged to be reliable (e.g., an estimated reduction in the number of adverse health cases based on information collected during work in Module 2 and Module 3), then the next step is to determine a dollar value to assign to the benefit. To the extent that quantification of the benefit is possible/advisable, then consider options for monetizing benefits, which can include approaches such as valuing the avoided Cost of Illness (COI) related to adverse health impacts, or the Willingness to Pay (WTP) to avoid health risks.

Because of the inherent uncertainty regarding quantified (and monetized) health risk reduction benefits, it often is good practice to develop estimated *ranges* for benefits information (rather than stating benefits as point values).

4. Consider timing of health impacts

Consider how the timing of health impacts and benefits may be relevant to the analysis. This may include latencies between exposure and expression of adverse health outcomes such as cancer, and potential effects from "discounting" of future costs and benefits into "present values." For example, reducing exposures to some carcinogens may not be evident in terms of expected reductions in manifested cancer cases for 20 years or longer, due to latencies and risk assessments based on an accumulated lifetime of exposure.

Communication and Collaboration	Utilities are the first line of communication for most of the public about CECs in drinking water. Therefore, utilities can be an important test audience for messages to the public about the benefits of taking action. Work with utilities to make sure your communications materials about health risks and benefits cover their needs and place the utilities in the light of health protector and trusted source.
Resources	There are several references that can help with characterizing pubic health-related benefits and costs, especially related to regulatory actions, including: • Quantifying Public Health Risk Reduction Benefits, Water Research Foundation Report 90884, 2002. (Raucher et al., 2002) • "Balancing Benefits and Costs." Raucher, R. 2001. White Paper developed for Rural Water Partnership Fund, National Rural Water Association. • An Economic Framework for Evaluating the Benefits and Costs of Water Reuse

State Experience	States often have experience with conducting benefit-cost analysis or benefits assessments for a variety of contaminants. Reach out to other states, as well as other regulatory programs within your own state (e.g., wastewater, air quality regulators) to gain insights and examples. See the following examples: • **New Hampshire's** Arsenic rule benefit assessment. • **New Hampshire's** PFAS Update on Cost and Benefit Consideration, see Attachment 2 on pg. 86. • **California** has developed benefit estimates and benefit-cost comparisons for its MCL-setting process. See this example for the state's 2017 rulemaking for 1,2,3 TCP. See especially item #15 for its "Standardized RIA" and related benefit and cost documentation. Items under #22 may also include useful benefits and cost information.

6. Identify, understand, and address uncertainties in benefits and costs

There are several potential sources of uncertainty in benefit and cost estimates for BCAs or other economic analyses. Sources of uncertainty often include:

Lack of full-scale treatment and implementation options

Costs and benefits may be highly uncertain because full-scale treatment implementation examples may be lacking for CECs.

Lack of uniform cost items

When gathering cost estimates from various sources, you will find a lack of uniformity for the cost of items that are reported, making it hard to directly compare estimates on an apples-to-apples basis. Operation and maintenance costs may not include uniform cost categories in estimates across states, which adds to the complexity of estimating costs. Capital cost estimates for the same treatment process may also include different cost categories and/or omit practical considerations related to installation realities within utilities' existing processes and footprints.

Uncertainty factors and health risk estimates

Drinking water health risk assessments often include a series of "safety factors" designed to account for uncertainties that typically arise in risk assessment (e.g., extrapolating from high dose experiments with mice to low dose exposures in humans). These safety factors are part of standard toxicology risk assessment practice in developing dose-response estimates. Uncertainty factors are intentionally included to protect public health when important data gaps exist. In some cases, these safety factors can make the estimated public health benefits larger than might realistically be anticipated for a given potential regulatory standard. Combining a series of uncertainty factors may potentially compound this effect. On the other hand, as scientific knowledge advances, we sometimes discover that the risks are greater than anticipated based on earlier risk assessments. Uncertainty regarding the levels (and types) of risk associated with exposures to CECs in drinking water should be viewed as an inevitable part of the risk management

challenge. Such uncertainties are important to recognize and articulate as part of an objective analysis of regulatory options. One approach to acknowledging these uncertainties is to provide benefits information using ranges rather than point estimates.

It may be useful to explore the manner in which other state drinking water programs (and other regulatory programs within your own state) have addressed uncertainties that inevitably arise in examining public health risks and the associated costs of potential risk-managing regulatory options.

Communication and Collaboration	When characterizing health benefits, consider creating a list of *safety factors* embedded in the underlying risk assessment information and be transparent regarding why they were applied. This can be a difficult concept for lay people to understand. A summary table in which you identify and describe each key uncertainty in the benefit and cost assessments, as well as how that uncertainty (and the manner in which it has been addressed) may impact the applicable health risk, benefit, and/or cost estimates, can be an extremely useful as both a CEC management and communications tool.
Resources	There are several resources that can help with identifying and addressing uncertainties in benefits and costs, including: • Quantifying Public Health Risk Reduction Benefits, WRF Report 90884, 2002. (Raucher et al., 2002) • "The Radon MCL for Drinking Water: Variability, Uncertainty, Precautionary Assumptions, and Related Benefit-Cost Issues for Small Systems," R.S. Raucher and D.J. Crawford-Brown. 2003. National Rural Water Association (NRWA): Regulatory Policy Development Project White Paper and other white papers on uncertainty factors and precautionary assumptions, found at NRDWA a compilation of white papers examining key issues for rural water.

7. Explore affordability and barriers for small systems, and related potential adverse economic considerations.

There are several steps to consider for assessing affordability, economic feasibility, and/or economic impacts from potential regulatory actions. Those steps include:

1. Measure and assess affordability

Explore and measure affordability according to suitable affordability metrics, reflecting economic hardships imposed on lower income households (e.g., households at or near official poverty levels, or at the lowest quintile of income (LQI)).

Assess affordability thresholds for different sized water systems and break out incremental costs of achieving different regulatory levels (i.e., MCLs or other health-based standards) by system size.

Consider the trade-offs of affordability vs. protecting health in disadvantaged communities. How much more will it cost households in small systems to comply with a potential MCL than for a household in a large water system (when both households obtain the same MCL-derived health risk reduction)? Will economically challenged households potentially curtail other essential expenditures (e.g., forgo meals, medical care, or prescription medication) in order to pay elevated water bills? What might be done to reduce the economic hardship that an expensive water bill might impose on some households?

If an assessment of economic impacts on businesses is required, consider if this is for disclosure purposes only, or whether this needs to be included in regulatory determination and standard setting. Also, consider what types of entities may be adversely impacted (e.g., small municipal water systems and their customers), and which may benefit.

Communication and Collaboration	Affordability can mean different things to different people. Consider beginning any conversation or document with a definition of what you mean by affordability. Recognize that there are many different affordability objectives (e.g., to help seniors on fixed incomes, or assist the poorest of the urban poor, and/or consider residents of small economically disadvantaged rural communities). Create opportunities for groups to define their affordability objectives. Creating this space is a meaningful way to encourage stakeholder participation in your analysis and will surface useful information for you to use. It allows you to create affordability measures that specifically connect potential regulatory actions with audience-specific objectives (which can significantly reduce audience concerns of regulatory inadequacy).
Resources	There are several resources that can help with assessing affordability, customer assistance program options, and challenges for small systems, including: • "Developing a New Framework for Household Affordability and Financial Capability Assessment in the Water Sector." Developed for AWWA, WEF and NACWA. 2019. • "Benefit-Cost Analysis for Drinking Water Standards: Efficiency, Equity, and Affordability Considerations in Small Communities," R.S. Raucher with S.J. Rubin, D. Crawford-Brown, and M.M. Lawson. 2011. Journal of Benefit-Cost Analysis 2(1): Article 4. DOI: 10.2202/2152-2812.1004. • Cromwell et al 2010 Best Practices Customer Assistance report for WRF project 4004. As well as related WRF reports and programs. • California state-funded research by the University of California-Davis and Corona Environmental Consulting explores affordability impacts with capital outlays, and potentially O&M expenses, covered by the state.

2. Examine the economic feasibility of recommended treatments

Consider system capacity, especially for small systems. Can small utilities provide the needed technical, managerial, and financial (TMF) expertise to properly perform the necessary operation and maintenance for treatment options? Can the households that they serve afford to bear the necessary costs? Are there opportunities for consolidated management and/or technical or financial support (e.g., via RCAP, SRF) to facilitate small system compliance and affordability?

State Experience	As in other aspects of economic and public health analyses, it may be useful to explore the manner in which other state drinking water programs (and other regulatory programs within your own state) have addressed affordability challenges that often arise in conjunction with the costs of potential risk management regulatory options. See: • Corona-UC Davis small rural system Nitrate compliance cost and affordability study

Module 7: Pursue Intermediate Management Strategies

Module 7 End Goal: Manage CECs in drinking water to an acceptable level of risk in the absence of a state-specific CEC drinking water rule or while in the process of developing a rule.

Introduction

Even if your state doesn't have a state-specific CEC drinking water rule in place, you can often require or encourage drinking water systems to undertake intermediate management strategies to reduce risk when CEC concentrations in drinking water exceed advisory levels set by the state. If your state cannot (or decides not to) establish a state-specific rule, intermediate management strategies may be the extent of your state's risk management efforts. If your state is establishing a state-specific CEC drinking water rule (see Module 8), intermediate management strategies can be undertaken to reduce risk while the rule is being developed. It can be years between the establishment of an advisory level and an MCL rule or treatment technique.

If intermediate management strategies are not sufficient as a long-term solution to CEC contamination in your state, you may need to consider site investigation and remediation and explore long-term strategies like requiring treatment (see Module 5).

This module outlines intermediate management strategies that your state may use to reduce risk. It also describes a menu of approaches states have used to adopt or develop an advisory level that triggers intermediate management strategies. The module also describes CEC management strategies for media other than drinking water that, if undertaken, can reduce CEC concentrations in drinking water.

Questions to Consider

- What are intermediate management strategies drinking water systems can use to reduce CEC risks?
- What are approaches states can use to set advisory levels that can trigger intermediate management strategies?
- What are options for managing risk from CECs in media other than drinking water that may reduce CEC levels in drinking water as well?
- What strategies can be used to prevent or reduce the CEC from entering source water?

Key Implementation Steps and Lessons

1. Understand what intermediate management strategies are available for reducing CEC risk from drinking water.

You can undertake several types of intermediate actions to reduce risk from CECs in drinking water. While these actions reduce exposure to CECs, they stop short of requiring drinking water systems to physically

remove CECs from drinking water through treatment, which requires a drinking water rule (see Module 8). Some of these intermediate management strategies can be undertaken as short-term emergency actions to temporarily limit exposure to CECs (see Module 1) while others are more appropriate as long-term risk management actions.

Key intermediate management strategies include:

- Monitoring. (see Module 3)
- Putting on treatment. (see Module 5)
- Blending higher-quality water sources with lower quality water sources.
- Sharing water resources using interconnections with neighboring water utilities.
- Using alternative sources, either permanently or temporarily.
- Conserving water.
- Shutting wells down.
- Managing well fields to keep contaminants out of well fields where they can seep into the underground drinking water supply.
- Drilling wells in deeper or shallower formations.
- Flushing the system.
- Decontaminating the distribution system.
- Pumping tanks.
- For contaminated private wells, connect households to uncontaminated public water.
- Providing point of entry or point of use treatment devices, and/or bottled water.
- Protecting and managing source water.

Communication and Collaboration

Implementing intermediate management strategies can set public and stakeholder expectations for how CECs will be addressed for other communities, systems, and CECs. States can consider using a communication strategy to manage expectations. States may want to work with collaborative partners (e.g., drinking water systems, local governments, health agencies, state agencies, USEPA, and potentially responsible parties) when developing an approach for using intermediate management strategies to protect public health. You may want to consider the following risk communication approaches to communicate what you're doing and to manage expectations:

- Establish routine communications with partner agencies and local elected officials.
- Host a series of public meeting(s) to communicate with stakeholders about risk and what actions drinking water systems are taking.
- Host forums that offer one-on-one communication opportunities with a range of trusted sources, for example using a science fair type setup where people can speak with experts in an informal situation.

2. Understand and use the state's authority to establish advisory levels that can be used to require or encourage drinking water systems to undertake intermediate management strategies

There are a variety of approaches for adopting or developing an advisory level (or equivalent) that, when exceeded, can be used to require or encourage drinking water systems to undertake intermediate management strategies to reduce risk. Advisory levels are benchmark values that trigger action to protect public health. Advisory levels are often not as fully analyzed as Maximum Contaminant Levels (MCLs) in a CEC drinking water rule (see Module 8). They may be based on a health-based level (see Module 2) but are sometimes adjusted if achieving the health-based level is infeasible or overly burdensome for drinking water systems.

Your state's regulatory context drives how advisory levels are defined and used. Approaches states use include:

- Adopting USEPA's health advisory as a state advisory level
- Using a state-derived health-based level (from Module 2) as an advisory level
- Using a number that emerges from putting a health-based level through a feasibility screen

You should engage USEPA and other states that have established advisory levels (or equivalents) to learn about their approach and methods.

Emerging health effects analysis may necessitate revisiting and refining earlier decisions about advisory levels. However, some states caution that it can be politically difficult to revise an advisory level to be less stringent. Uncertainty may be addressed by building quantitative uncertainty factors into advisory levels and standards.

State Experience

States' approaches to managing risk from PFAS illustrate the range of ways that advisory levels may be set. Most typical is states adopting USEPA's health advisory level for PFAS as a state advisory level.

- **Pennsylvania:** Pennsylvania has authority to respond to unregulated contaminants and enforce USEPA's health advisory levels. Similarly, **Michigan** is using USEPA's health advisory for PFAS.
- **Colorado's** policy is to adopt USEPA's health advisory level if it exists. Colorado does not usually derive its own health advisory level. However, in the absence of an USEPA health advisory level, the state would follow USEPA methods to derive an advisory level, resources permitting.
- **New Jersey's** Drinking Water Quality Institute develops a recommended MCL (that may or may not be the health-based value) that is a health advisory for the public. Each subcommittee of the Institute develops a recommendation, so the health subcommittee does have a health-based level. Prior to establishing a state specific MCL, New Jersey uses USEPA's health advisories. These levels are used to ask water systems to start taking steps such as monitoring.
- **Minnesota:** In Minnesota**,** toxicologists at the Minnesota Department of Health develop Health-Based Values (HBVs) and Health Risk Limits (HRLs) using peer-reviewed science and available public health policies. HBVs and HRLs are developed to protect sensitive or highly exposed populations. They are based only on potential health impacts and do not consider the cost and technology of prevention and/or treatment and may be set at levels that are costly, challenging, or impossible for a water system to meet.
- **California:** California's Notification Levels are health-based advisory levels that are established for chemicals for which there are no formal regulatory standards (e.g., MCLs). When notification levels are exceeded, the drinking water system is required to notify the local governing body of the local agency in which the users of the drinking water reside. The State Water Resources Control Board (SWRCB) also recommends that the utility inform its customers and consumers about the presence of the contaminant and about the health concerns associated with its exposure. Response levels are levels of the contaminant at which SWRCB recommends the drinking water system take the affected water source out of service. These levels range from 10 to 100 times the notification level depending on the chemical. See Drinking Water Notification Levels and Response Levels: An Overview for information on CA's process for moving from a purely health-based number (notification level) to an advisory level (response level).

Communication and Collaboration	Review and use communications tactics from Risk Communication to communicate with appropriate stakeholders about your advisory level. USEPA guidance on communicating about cyanotoxin risks in drinking water provides insights you can use to communicate effectively about public health advisories.
Resources	For examples of state health advisories see the Interstate Technology & Regulatory Council (ITRC) fact sheet on PFAS, Regulations, Guidance, and Advisories for Per- and Polyfluoroalkyl Substances (PFAS).

3. Explore mechanisms and media beyond drinking water for reducing exposure to CECs in drinking water

Many CECs are not just an issue for drinking water regulators but also groundwater, surface water, land contamination, emergency response, and other programs. Surface water (streams, rivers, and lakes) or ground water (aquifers) can serve as sources of drinking water while contaminated soil or contaminated run-off can transport CECs into drinking water systems.

Your state drinking water program should collaborate with other programs to pursue complementary actions to reduce non-drinking water sources of CEC contamination. These may include efforts to:

- Develop a ground water or surface water CEC standard.
- Deem the CEC a hazardous substance. Getting this definition in place may allow you to require sampling at Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and/or Resource Conservation and Recovery Act (RCRA) sites that already exist.
- Integrate the CEC into source water protection programs.
- Use a narrative standard for part of the National Pollutant Discharge Elimination System (NPDES) water quality permits. Using a narrative water quality standard may allow you to sample NPDES discharges for the CEC and potentially limit permits.
- Regulate cleanup of the CEC at waste site locations.
- Set wastewater limitations or cleanup standards for the discharge or cleanup of chemicals
- Implement a take back program for materials containing the CEC (e.g., fire-fighting foams that contain PFAS).

State Experience	States active in regulating PFAS in drinking water have also undertaken complementary management efforts in other media. For example: • **New Hampshire** adopted an ambient ground water standard (i.e., clean-up standard) for PFAS, which was based on USEPA's health advisory level. • **Colorado** developed a site-specific groundwater standard for PFOA/PFOS which helped facilitate clean-up. • Prior to moving to establish an MCL for PFNA, **New Jersey** developed a groundwater standard for PFNA in tandem with listing PFNA as a hazardous substance. New Jersey's approach to PFAS and PFOA built from this work on PFNA by pursuing a groundwater standard, hazardous substance listing, and MCL concurrently as a combined rule package. • **Massachusetts** undertook a take-back program for fire-fighting foam and free disposal to reduce the risk of future land and water contamination.

4. Following implementation of intermediate management strategies, monitor drinking water to assess effectiveness

Your state should consider monitoring water systems that have undertaken intermediate management strategies to ensure that these strategies have effectively managed CEC contamination. See Module 3 for steps related to monitoring.

Communication and Collaboration	Review and use communications tactics from Risk Communication and consider engaging in ongoing public communication to help rebuild trust among consumers and other stakeholders that the tap water is safe to consume.

Module 8: Pursue CEC Rule (MCL or Treatment Technique)

Module 8 End Goal: Establish and roll out a state-specific drinking water rule to manage CECs in drinking water to an acceptable level of risk.

Introduction

For states developing a state-specific drinking water rule (either MCL or treatment technique), this module brings together the considerations from previous modules to establish core elements of the rule related to contaminant or treatment levels, sampling, analysis, treatment, and economic analysis.

Questions to Consider

- What is the Maximum Contaminant Level or treatment technique level for the CEC?
- How will the rule be designed for monitoring and impact surveillance, analytical methods, and lab certification, treatment, and compliance determination?
- What will the public notice and health effects language be, especially considering whether "do not drink" advice will be included and at what levels for what population?
- What will be included as justification for the rule and analysis of its impacts?
- How should states roll out and communicate new CEC rules?

Communication and Collaboration	Ensure thought leaders for each of your important audience groups knows the rule is coming and create opportunities for these thought leaders and the general public to provide meaningful input. This means they participated, and their concerns have been integrated. It does not mean they got everything they wanted – just that they feel what they wanted was respectfully considered. Engage a sub-group of utilities throughout the rule making process to ensure utility concerns and communications needs are integrated into the communications strategy. You can use this group to develop communication and education materials for other utilities and the public.

Key Implementation Steps and Lessons

1. Outline the general approach to the rule

Early in the rule development process, outline broad considerations of what will be regulated and how. A starting point is revisiting and refining understanding from Module 1 about your states' legal and regulatory authority, specific requirements for any aspects of a CEC drinking water rule, and administrative procedures that must be followed. In addition, you should address questions like the following.

Should the rule specify an MCL or a treatment technique?

A treatment technique may be appropriate in cases where there is no technically or economically feasible method for measuring a CEC at a level that is not a health concern. In this case, you may set a treatment technique as an enforceable procedure or level of technological performance that must be followed by water systems to ensure control of a contaminant. For example, you may opt for a treatment technique because a rule covers a large class of CECs for which there aren't sufficient analytical methods. Or, you may determine that a treatment technique (accompanied by monitoring for a surrogate CEC) is more efficient than an MCL that involves complex monitoring for multiple CECs in a class.

Resources	USEPA describes treatment techniques in its online resource How USEPA Regulates Drinking Water Contaminants (see section on "Once USEPA decides to regulate a contaminant, how does the Agency develop a regulation?"). Additional useful information from USEPA on drinking water rules can be found in USEPA's Drinking Water Rule Quick Reference Guides.

To the extent the CEC is one of a number of chemicals in a class, should the state regulate the CEC individually, as a group within a class, or as an entire class?

States will generally develop rules for CECs as individual chemicals. In some cases, however, CECs might be part of a larger class of chemicals with similar characteristics (e.g., PFAS). In this case, regulating CECs as a group within a class or as an entire class rather than individually can be more efficient. The choice depends largely on the characteristics of the CEC.

State Experience	**New Hampshire** determined not to regulate PFAS as a class because existing toxicological data suggests that each compound has relatively unique toxic-dynamic and kinetic properties.

What are state-specific requirements for rule development?

Understand what you must do or consider in establishing a new rule or policy. Are there specific procedures that need to be followed or items that need to be addressed as part of the rulemaking documents? For example, you may need to look at economic feasibility or impacts on small businesses. You should also understand what you cannot do in establishing a new rule.

State Experience	As an example of state-specific requirements for rule development, see Colorado Revised Statutes 25-1.5-202, which describes state requirements for setting minimum general sanitary standards.

Are there existing monitoring frameworks or methodologies that the state can use?

For chemical CECs (vs. biological), you may be able to use standardized monitoring frameworks for organic, inorganic, and synthetic organic pathways. These standardized frameworks have an established monitoring schedule, which is often familiar to water systems and helps them integrate CEC monitoring into their existing monitoring cycles. Using one of the frameworks can cut down on monitoring violations because drinking water systems are familiar with it. However, using standardized frameworks may impinge on your flexibility to design specific aspects of a rule, such as offering waivers, "grandparenting" data, or dealing with contaminants where lab capacity and testing costs may be critical considerations.

Resources	For more information on standardized monitoring frameworks for different types of chemicals, see USEPA's online resource, Standardized Monitoring Framework: A Quick Reference Guide.
State Experience	After considering the pros and cons of adopting standardized frameworks you may choose instead to make modest modifications to the frameworks to align them more closely with other state rules or needs. For example, **New Hampshire** adopted a slightly modified version of a standardized monitoring framework for PFAS that incorporated the state's preferred approach to waivers.

Should requirements be phased in?

Phasing in requirements can help systems prepare for regulation. It can also help you build capacity for regulation. For example, states concerned about lab capacity can phase in requirements to allow more time for more labs to be certified.

Phase-in scheduling can consider system sources, types, and/or sizes. For example, the federal Long Term 2 Enhanced Surface Water Treatment Rule and Stage 2 Disinfection Byproduct Rule, which require monitoring for pathogens in public water systems, stagger monitoring dates by system size, with smaller systems beginning monitoring after larger systems.

2. Determine a maximum contaminant level(s) for CEC rule based on a health-based level and other considerations

The starting point for developing a numeric MCL or treatment technique is the health-based level described in Module 2. In many states, setting the regulatory level can or must include other considerations than those for a purely health-based value. These may include:

- Ambient or background levels of a CEC
- Detection limits
- Feasibility to treat
- Residuals or simultaneous compliance
- Economic considerations (see Module 6)

Health and other considerations that go into determining MCLs or treatment techniques should be described and justified in establishing the rule.

In draft rules, you may want to present a range of numbers and use the rulemaking process to gather information about which are most appropriate. If new methods or toxicity information become available between draft rule development and final adoption, you may need to incorporate this new information into the rule. However, some states are limited in making major changes between proposed and final rules, so it is important to understand your states' flexibility or constraints.

Communication and Collaboration	Once the MCL or treatment technique level is established, states will need to describe the level and why it was selected. Risk messaging best practices include describing how the level was derived and in what ways it is protective. You may need to explain differences between your state's level compared with other states' levels and, if relevant, why it deviates from the health-based value described in Module 2. Work with a range of audiences to identify and address concerns with the rule. Don't ignore concerns – address them head on.
State Experience	• **New Hampshire** describes the derivation of its PFAS MCL in a summary report supporting the state's rulemaking. The report outlines how the MCL was developed to ensure protection of "human health at all life stages" and provides information that the New Hampshire Department of Environmental Services was required to consider when establishing the MCL, including occurrence, ability to detect, ability to treat, and the costs and benefits to parties affected by the standards. • **New Hampshire** commissioned a technical peer review of its MCL proposal for increased credibility and defensibility (see letter beginning on page 51 of the technical report on MCL development).

3. Develop legal and regulatory language for the CEC rule

Beyond setting a level for acceptable concentrations of CECs in drinking water, developing a rule involves considerations related to monitoring and impact surveillance, analytical methods, treatment options, and compliance determination. The activities described in Module 3, Module 4, and Module 5 inform these aspects of rule design. Key considerations for each in developing an MCL-based rule are described below.

Rule applicability

- Based on the type of health effects (e.g., short-term vs. chronic) and occurrence information, to what water systems does the rule apply? For example, will the rule apply to community systems, non-transient/non-community systems (or a subset of these like schools and daycares), transient non-community systems, etc.?

- Will there be variances or exemptions for different types of systems—for whom and under what conditions?
- Will requirements be phased in for different types of systems—for whom, and how?

Ongoing monitoring and impact surveillance (drawing on Module 3)

- Can/will you use standardized monitoring frameworks?
- What is the monitoring frequency and location?
- Are there conditions where reduced monitoring frequency is allowed?
- Where should samples be collected? For example, point of entry or throughout the distribution system depending on where the contamination is entering the system (source-related, artifact of treatment or distribution system).
- What is the sampling methodology?
- When can you require resampling? What can be done with the results?
- Will there be a waiver process or reduced sampling requirements under some conditions?
- Will you accept grandfathered data that meet certain criteria (e.g., with adequate quality and detection levels) and provide reduced monitoring in return?
- What are record-keeping requirements?
- How will data be accepted and managed within the agency?

Analytical methods and certification (drawing on Module 4)

- What CECs are drinking water systems analyzing for?
- What are required detection limits?
- What are standards for data quality, and procedures for quality assurance and quality control?
- What are analytical methods to be used?
- What are certification requirements for labs?
- How will labs be certified?

State Experience	When determining what CECs to analyze for, you may want to anticipate future sampling needs. If an MCL is in place for one CEC, states can have water systems report other CECs covered by the same analytical method. For example, in its regulations for PFNA, **New Jersey** is asking water systems to also report PFOA and PFAS (same analytical method as PFNA) when they are only required to report PFNA. These data can then be used for reduced monitoring as appropriate in the future in the event of additional MCLs for PFAS chemicals.

Treatment options (drawing on Module 5)

- What is the best available technology for treatment?
- Are there other available technologies that may be effective in some circumstances?
- How and by whom will acceptable treatment technologies be identified and approved, if applicable?
- How will design criteria for various treatment technologies be developed?
- What are the implications of installing treatment for operator certification?

- What is the capital, operations, and maintenance costs of treatment technologies?
- Are there simultaneous compliance issues and how will they be addressed?
- How should treatment residuals be disposed and what regulations apply (e.g., waste rules)?

Compliance determination

- What is the time frame and schedule for compliance?
- How will compliance be determined (e.g., running annual average, one sample with a repeat, or other method)?
- Will there be an initial monitoring period and then a final compliance date?

Public notice

- What public notice requirements will apply to what types of violations, Tier 1, 2 or 3?
- What health effects language will be required to be included in the public notice?
- What recommendations will be included in the public notice, especially considering whether recommending alternate water supplies will be recommended for the entire population or vulnerable subsets of the populations?
- What are Consumer Confidence Report (CCR) and recordkeeping requirements?

Communication and Collaboration	As you develop rules, it is important to communicate with regulated systems about the rules with which they must comply, explaining topics like who is (and is not) regulated and why, etc. Consider communicating interactively with regulated systems through a variety of forums (e.g., in-person or on-line workshops, etc.).
State Experience	It may be useful to understand how other states have developed MCL rules. • **New Hampshire** Department of Environmental Services describes the development of MCLs for PFAS and related CECs in a summary report and summary of a technical background report. • **Massachusetts** Department of Environmental Protection described the development of its PFAS rule in the online resource, Development of a PFAS Drinking Water Standard (MCL).

4. Conduct an impact analysis of the rule

Impact analysis assesses how the costs and/or other requirements imposed by a potential regulatory action may adversely impact the fiscal viability of various businesses and/or communities of concern. See Module 6 for a detailed description of impact analysis.

It may be beneficial to evaluate impacts for a range of possible MCL values prior to determining the appropriate value for your state. Additionally, it may be beneficial to evaluate this with respect to applicability to different types of drinking water systems. An impact analysis may be very different depending on whether or not the rule applies to transient non-community systems, for example.

State Experience	When **New Jersey** issued its proposed MCL rule for Perfluoro nonanoic Acid (PFNA), the proposal included an assessment of the rule's social, economic, environmental, impacts as well as its impacts on jobs, agricultural, housing affordability, and smart growth (impact analysis begins on page 31).

5. Develop a justification for the rule based on information available

New drinking water rules typically need a justification to show the rule is reasonable, addressing legal, scientific, and economic issues. The justification often comes in a rule's preamble, before a description of the technical aspects of a rule. It often includes a summary of:

- Overall health impacts and why it is a health issue that the state needs to address (drawing on Module 2).
- The problem being solved, for example using occurrence data (Module 3) to describe what populations are impacted by the CEC.
- Summary of evidence about the benefits of regulation, including avoided health impacts (drawing on economic analysis described in Module 6).
- What systems, including small systems, are likely going to have to do and the associated costs. This may include an analysis of alternatives (Module 5 and Module 6).

Communication and Collaboration	Stay focused on objectives and why the economic and technically feasible approach you selected provides health and safety value to the public. As appropriate, explain why your state is proceeding differently than other states.

6. Undertake steps required by administrative procedure, including public notice

When developing drinking water rules, you need to follow the administrative procedures specific to your state. Among other things, these procedures generally include public notice and comment requirements.

Communication and Collaboration	Follow administrative procedures for public notice and comment. Apply and test risk communication best messaging practices (See Risk Communication).

7. Roll out and communicate about the CEC rule

When it is time to roll out and communicate about the CEC rule, consider the following strategies:

- Engage thought leaders for each of your important audiences to communicate about the rule. Thought leaders can help you design and facilitate educational opportunities.

- Work closely with utilities to share information with their customers so that risk messaging can be site-specific as needed (i.e., different messages may need to be developed for utilities with higher concentrations).
- Develop training materials for certified operators including specifics about the rule, sampling and laboratory requirements and treatment technologies.
- Create special communications opportunities for vulnerable populations and in locations with high concentrations, to ensure that those who need information to make informed decisions about their personal health have the information they need.
- Hold science fair type educational events where individuals can speak to experts on a one-to-one basis.
- For the general public include how the state is working to protect public health. If you couldn't do everything everyone wanted, talk about why the rule couldn't meet everyone's needs (e.g., reduce risk to zero in every instance) and how what you have done is protective.

Communication and Collaboration	To be most effective, you should build a communications strategy from the beginning of the CEC review process. It may be difficult for states to build support when they roll out a new rule if they have not been communicating effectively about the process with critical audiences all along – bringing important audiences along for the whole ride, not just the last stop.

State Experience

When **New Hampshire** announced its final MCL rule on PFAS, it issued a press release describing the rulemaking process and new standards. Along with the press release, the New Hampshire Department of Environmental Services (DES) held a public discussion of the rule and underlying technical analysis and identified a point of contact for additional information. New Hampshire DES also provided a series of documents explaining the rule and providing guidance for well testing and home/business treatment. Resources included:

- A summary technical report explaining the development of the MCL, with information about health risks, costs, benefits, occurrence, ability to detect, and ability to treat.
- A response to public comments on the initial proposal (draft rule).
- A list of frequently asked questions and answers about PFAS, drinking water, and health effects.
- A well testing fact sheet for private well owners that might be encouraged to test their wells.
- A fact sheet on home or business-based treatment for PFAS.