



# *Drinking Water Standards and Development of Regulations*

February 7, 2022

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# North Carolina Drinking Water Act

- NCDEQ has primary enforcement authority for Safe Drinking Water Act implementation
  - NC adopts the federal drinking water standards /regulations
  - Implemented by the Public Water Supply Section
- Generally, *NC adopts the federal drinking water standards/regulations by reference* (after the EPA has performed all the necessary steps required for federal development of regulations and finalized the standard).
- A few cases exist where NC has used its authority under the NC Drinking Water Act to diverge from federal regulations
  - NOT developing state-specific regulatory levels



# *Federal Safe Drinking Water Act (SDWA)*

Congress enacted the **Safe Drinking Water Act (SDWA)** in 1974 and amended and reauthorized it in 1986 and 1996.

- Authorizes EPA to set national standards for drinking water to protect against health effects from exposure to naturally-occurring and man-made contaminants
- Applies to Public Water Systems:
  - Water system serving 15 or more connections, or 25 or more people 60 or more days per year
    - Community
    - Non-transient non-community
    - Transient non-community



**Contaminant  
Candidate List  
(CCL)**

**Unregulated  
Contaminant  
Monitoring Rule  
(UCMR)**

**1996 SDWA Amendments provided for:**

**Regulatory  
Determinations  
(RD)**

**6 Year Review of  
NPDWRs**

# *Federal Development of Regulations: Contaminant Candidate List*

## **Contaminant Candidate List (CCL) – Published every 5 years**

- EPA collects data and encourages research on listed contaminants to better understand their health impacts and levels in drinking water:
  - Known or anticipated to occur in drinking water,
  - Not subject to any proposed or promulgated federal drinking water regulation,
  - Include contaminants of the greatest public health concern in drinking water.
- Used for:
  - Identifying priority contaminants for information collection, and
  - Making Regulatory Determinations for contaminants with sufficient health and occurrence data
- The draft CCL5 (published July 19, 2021) includes 66 chemicals, 3 chemical groups (PFAS, cyanotoxins, and DBPs), and 12 microbes.

# *Federal Development of Regulations: Unregulated Contaminant Monitoring Rule*

- SDWA requirements for UCMR Program
  - Occurrence monitoring for up to 30 unregulated contaminants, every 5 years
    - **UCMR 5 – 29 PFAS + lithium, Sampling 2023-2025**
  - Collect data for unregulated contaminants suspected to be present in drinking water
  - Require PWSs serving population >3,300 people as well as a nationally representative sample of PWSs serving < or = 3,300 people to monitor
- EPA manages program in partnership with states

# *Federal Development of Regulations: Regulatory Determination*

- EPA's formal decision of whether it should regulate a contaminant
- Must make a determination for at least 5 contaminants from the most recent CCL every 5 years.

To regulate a contaminant, SDWA requires that EPA determine whether:

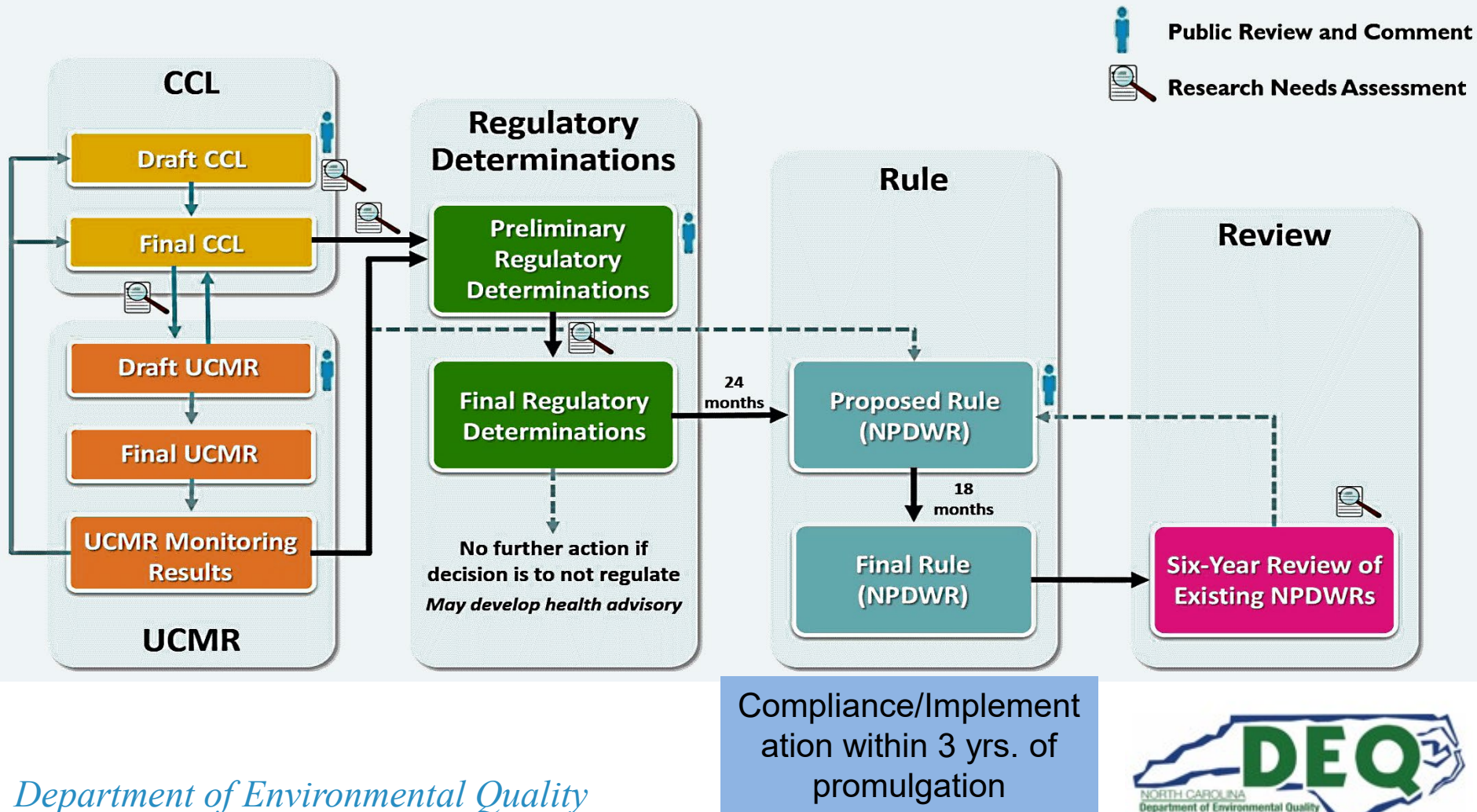
- *The contaminant may have an **adverse effect** on the health of persons;*
- *The contaminant is known to occur or there is a substantial likelihood the contaminant will **occur in public water systems** with a frequency and at levels of public health concern; and*
- *In the sole judgment of the Administrator, regulation of the contaminant presents a **meaningful opportunity for health risk reductions** for persons served by public water systems.*

Note: If EPA decides not to regulate a contaminant, they may still develop a non-enforceable health advisory.

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# Federal Safe Drinking Water Act: Regulatory Analysis Process



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# Federal Development of Regulations:

## MCLGs

EPA reviews health effects data, then sets a maximum contaminant level goal (MCLG)

- **MCLG** - *the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety.*
- Non-enforceable public health goals. Analogous to a Health Advisory Level
- Consider only public health and not the limits of detection and treatment technology effectiveness. Therefore, they **sometimes are set at levels which water systems cannot meet** because of technological limitations.

# Federal Development of Regulations:

## MCLGs

The way EPA determines MCLGs depends on the type of contaminant targeted for regulation:

- **Microbial contaminants** – MCLG is set at *zero* because ingesting one protozoan, virus, or bacterium may cause adverse health effects.
- **Chemical contaminants that are carcinogens** – MCLG is set at *zero* if there is evidence that a chemical may cause cancer AND there is no dose below which the chemical is considered safe. (If a chemical is carcinogenic and a safe dose can be determined, EPA sets the MCLG at a level above zero.)
- **Chemical contaminants that are non-carcinogens but can cause adverse non-cancer health effects** (for example, reproductive effects) - MCLG is based on the *reference dose*. [A **reference dose** (RfD) is an estimate of the amount of a chemical that a person can be exposed to on a daily basis that is not anticipated to cause adverse health effects over a lifetime.]

# Federal Development of Regulations: MCLs and Treatment Techniques

Once the MCLG is determined, EPA sets an enforceable standard. In most cases, the standard is a maximum contaminant level (**MCL**). When there is no reliable method that is economically and technically feasible to measure a contaminant at concentrations to indicate there is not a public health concern, EPA sets a “**treatment technique**” rather than an MCL.

- **MCL** - *the maximum level of a contaminant allowed in water which is delivered to any user of a public water system. The MCL is set as close to the MCLG as feasible. Not a zero-risk value.*
- **Treatment technique** - *an enforceable procedure or level of technological performance which public water systems must follow to ensure control of a contaminant. (Treatment technique rules also list the best available technology for meeting the standard and compliance technologies available and affordable for small systems.)*

Taking cost into consideration, EPA must determine a “feasible” MCL or treatment technique. This is defined by SDWA as the level that may be achieved with:

- use of the best available technology or treatment approaches
- other means which EPA finds are available (after examination for efficiency under field conditions, not solely under laboratory conditions)

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# *Federal Development of Regulations: Health Risk Reduction and Cost Analysis*

SDWA requires a health risk reduction and cost analysis (HRRCA) to:

- Analyze the likely quantifiable and non-quantifiable benefits of compliance with the proposed standard, and
- Analyze certain increased costs resulting from the proposed drinking water standard.

EPA must consider:

- **Incremental costs and benefits** associated with the proposed and alternative MCL values,
- The contaminant's **adverse health effects** on the general population and sensitive subpopulations,
- Any **increased health risk** to the general population that may occur as a result of the new MCL, and
- Other **relevant factors** such as data quality and the nature of the risks.

Where the benefits of a new MCL do not justify the costs, EPA may adjust the MCL for a particular class or group of systems to a level that "**maximizes health risk reduction benefits at a cost that is justified by the benefits.**"

# *Federal Development of Regulations: Turning a Standard into an Implementable Rule*

During the development of drinking water rules, EPA must also determine/develop:

- Monitoring schedules and compliance requirements:
  - Who? Which type of water systems are regulated?
  - Where to sample? entry point, distribution system, etc.
  - When? Frequency of sampling: initial, reduced, increased
  - Exceptions? Waivers, variances or exemptions?
  - Sampling? Sample collection methods, sample sizes, holding times
  - Analytical methods and detection limits
  - Lab capacity

# *Federal Development of Regulations: Turning a Standard into an Implementable Rule*

During the development of drinking water rules, EPA must also determine/develop:

- Database compliance routines for identifying and tracking violations
- Mandatory language and health effects language to be used in Public Notifications and Consumer Confidence Reports
- Best available treatment (BAT) technologies
- Significant documentation to help with rule implementation (quick reference guides, primacy package applications, trainings, implementation guidance manuals)

*\*All decisions must be based on data and sound science, which may not yet exist for contaminants not part of the EPA regulatory development process.*

# State Development of Regulations

Although NC generally adopts the federal standards/regulations by reference, NC's rule-making process can still have a lengthy timeline due to the following required steps:

- Preparation and submittal of a fiscal note
- OSBM certification of the fiscal note
- Filing a rule-making notice in the NC Register
- Public hearing requirement
- Comment period
- Approval by the Commission for Public Health for adoption of a permanent rule
- Preparation of permanent rule submission forms and rule language for the Rules Review Commission (RRC)
- Approval by the RRC at one of their scheduled meetings

Example: NC adopted the federal Revised Total Coliform Rule by reference. NC's rule-making process began with preparation and submittal of a fiscal note in Oct. 2014. The final Rule was approved at the RRC meeting in June 2015, and the Rule became effective July 1, 2015.

# State Implementation of Federal Regulations

With every adoption of a new federal drinking water standard/regulation, NC's Public Water Supply Section staff must perform outreach efforts to inform water system owners, operators, engineering consultants, and laboratory personnel of the new requirements. They must also perform other tasks to effectively implement the new requirements and to determine and track compliance.

- Outreach efforts include:
  - Mass-mailings
  - Training workshops
  - Webinars
- Other implementation tasks:
  - Prepare and submit a primacy package to EPA for approval to implement the new federal rule in the State of North Carolina
  - Develop applicable forms
  - Update laboratory analyses forms and analytical results submittal procedures
  - Become skilled with any new database compliance routines
  - Develop guidance documents, as necessary.



# *State Implementation of Federal MCLs and Health Advisories*

## MCLs

- Our actions are prescribed in the Federal Regulations
  - MCL compliance calculations
  - Increased monitoring triggers
  - Public notification language and methods

## Health Advisories (HAs)

- Manganese and Cyanotoxins
  - EPA provided more guidance including specific health related language to use when notifying the public
  - We communicate the information to the water system and encourage public notification
  - We provide technical assistance to reduce contamination levels
  - We do not make a value judgement pertaining to consumption of the water

# *North Carolina Drinking Water Act*

- NCDEQ primary enforcement authority for Safe Drinking Water Act implementation
  - NC adopts the federal drinking water standards/ regulations
- The North Carolina Drinking Water Act - G.S 130A-315
  - Provides broad authority for State primacy; to implement the National Primary Drinking Water Regulations.
- Examples of divergence from federal drinking water regulations

# North Carolina Drinking Water Act

- NC has used its authority under the NC Drinking Water Act to develop regulations to take Primacy for the federal regulations, with few changes. For example:
  - Iron and manganese (enforceable state standard based on federal secondary MCL)
  - Arsenic (adopted earlier)
  - Trihalomethanes (adopted earlier for small systems)
  - Chlorine residual (at coliform sites)
  - Has **not** included developing state-specific regulatory levels, but expanding the applicability of EPA-established levels

## State Staff Resources, Expertise and Funding

- Unlike anything NCDEQ has ever done
- Resource needs, new staff capabilities, and funding would be very significant

## Extra monitoring and treatment costs for water systems

- Many water systems already struggle with maintaining compliance with existing drinking water requirements

Lack of current data to make informed decisions

- Much research and analysis is needed relating to:
  - Contaminant occurrence
  - Health effects
  - Analytical methods
  - Treatment technologies
  - Costs, benefits, and economic analysis (i.e., fiscal note)

## *Considerations/Constraints for State Development of Regulations: Following MCL Development*

- Monitoring schedules and compliance requirements:
  - Who? Which type of water systems are regulated?
  - Where to sample? entry point, distribution system, etc.
  - When? Frequency of sampling: initial, reduced, increased
  - Exceptions? Waivers, variances or exemptions?
  - Sampling? Sample collection methods, sample sizes, holding times
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# *Considerations/Constraints for State Development of Regulations: Following MCL Development*

- Database compliance routines for identifying and tracking violations
- Mandatory language and health effects language to be used in Public Notifications and Consumer Confidence Reports
- Best available treatment (BAT) technologies
- Training and Guidance documents and materials for the state and for utilities

# Conclusions

- US EPA has an established, comprehensive, deliberative process to set MCLs. It is slow but, it has worked to minimize risk while considering multiple factors.
  - NC does not currently have the expertise or resources in place to create an equivalent process.
- Safe drinking water has never meant zero-risk
  - MCLs for many contaminants including DBPs, VOCs, SOCs, and metals at levels > MCLGs or Health Advisory levels.
- Creating a NC MCL could potentially conflict with a federally developed MCL necessitating reconciliation between the two.



# Questions?

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