



Regulatory Updates for Chemistry and Microbiology

Office of Ground Water and Drinking Water
Standards and Risk Management Division
Technical Support Center

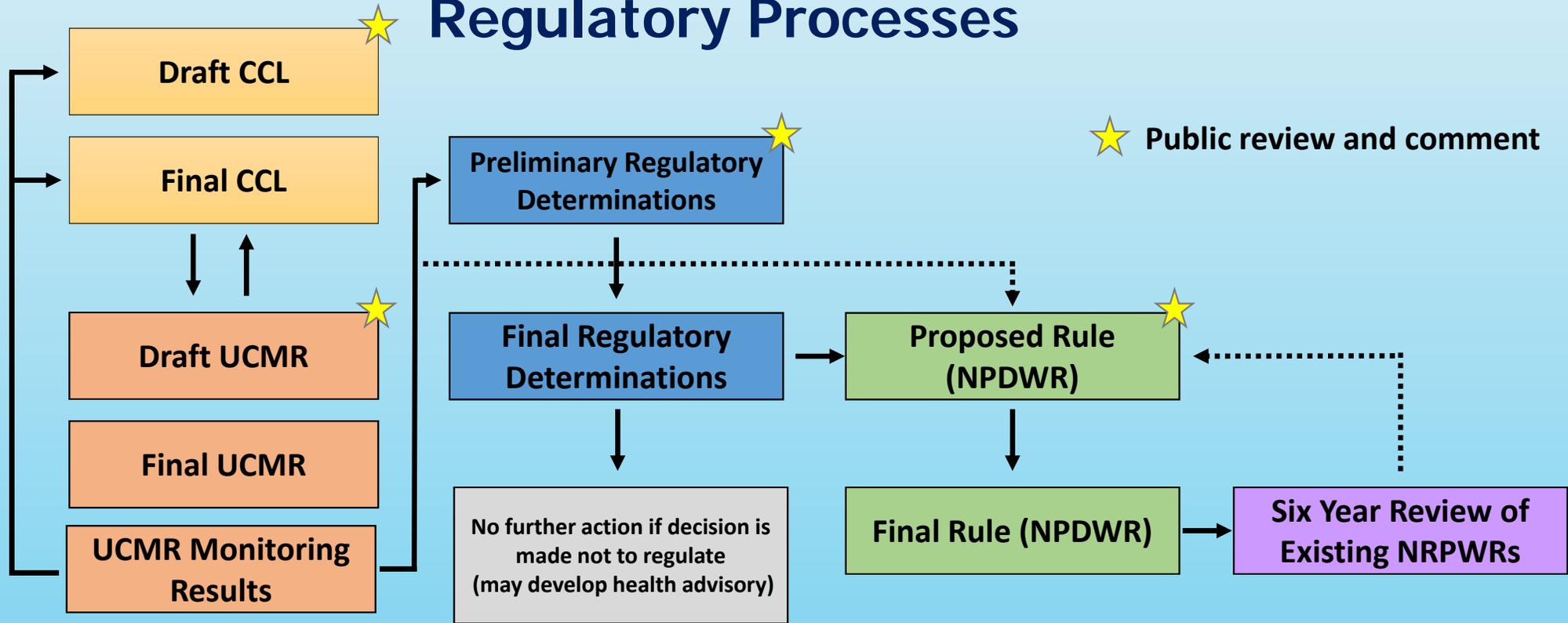


Regulatory Analysis, Rule Development, and Stakeholder Support

- Contaminant Candidate List
- Unregulated Contaminant Monitoring Rule
- Regulatory Determination
- Rule Development/Revision
 - Perchlorate
 - Lead and Copper Rule (LCR)
- Six Year Review of Regulations
- Stakeholder Support: Legionella and TCR
- Drinking Water Method Approval

CCL, UCMR, Regulatory Determination, Rule Development, and Revisions

General Flow of Safe Drinking Water Act (SDWA) Regulatory Processes



Increased specificity and confidence in the supporting data (e.g. health, occurrence, treatment) is needed at each stage.

2015 Contaminant Candidate List (CCL)

- **Published final CCL 4 – November 17, 2016**
 - Lists 97 chemicals or chemical groups and 12 microbial contaminants
 - Includes chemicals used in commerce, pesticides, biological toxins, disinfection byproducts, pharmaceuticals and waterborne pathogens.
 - CCL 4 info at:
<https://www.epa.gov/ccl/contaminant-candidate-list-4-ccl-4-0>

Third Unregulated Contaminant Monitoring Rule (UCMR 3)

- Completed monitoring in 2015 and data reporting in 2016
- 28 chemicals and 2 viruses
- Contaminants include hormones, perfluorinated compounds (e.g., PFOS/PFOA), VOCs, metals (including Cr⁺⁶ and total Cr), 1,4-dioxane, chlorate and pathogens
- Data are posted to the National Contaminant Occurrence Database (NCOD) (www.epa.gov/dwucmr)

Fourth Unregulated Contaminant Monitoring Rule (UCMR 4)

- Final UCMR 4 published in FR December 20, 2016 (81 FR 92666)
www.epa.gov/dwucmr/fourth-unregulated-contaminant-monitoring-rule
- UCMR 4 stakeholder public meeting/webinar scheduled for April 12, 2017
 - Registration deadline: April 7, 2017
www.eventbrite.com/e/ucmr-4-publicstakeholder-meeting-registration-28264984329
- Monitoring period: Jan 2018 thru Dec 2020

UCMR 4 – 30 Contaminants

- **10 Cyanotoxins/Groups**
 - "total microcystins" by ELISA
 - 6 microcystin congeners (MC-LA, MC-LF, MC-LR, MC-LY, MC-RR, MC-YR) and nodularin by EPA Method 544
 - anatoxin-a and cylindrospermopsin by EPA Method 545
- **2 Metals** (EPA Method 200.8 or equivalent SM, ASTM method)
 - germanium
 - manganese
- **3 Brominated HAA groups** (EPA Method 552.3 or 557)
 - HAA5
 - HAA6-Br
 - HAA9
- **9 pesticides** (EPA Method 525.3)
 - alpha-hexachlorocyclohexane
 - chlorpyrifos
 - dimethipin
 - ethoprop
 - oxyfluorfen
 - profenofos
 - tebuconazole
 - total permethrin (cis- & trans-)
 - tribufos
- **3 Alcohols** (EPA Method 541)
 - - 1-butanol
 - - 2-methoxyethanol
 - - 2-propen-1-ol
- **3 Semivolatile Organic Chemicals** (EPA Method 530)
 - - butylated hydroxyanisole
 - - o-toluidine
 - - quinolone

SDWA Regulatory Determination

- Formal decision on whether EPA should initiate the development of a National Primary Drinking Water Regulation (NPDWR) for a specific contaminant or group of contaminants
- SDWA requires EPA to make regulatory determinations for at least 5 CCL contaminants every 5 years.
 - Both positive and negative determinations count towards the 5
- Third regulatory determination (RD3) published January 4, 2016.
 - RD3 is based on evaluation of 116 chemicals and microbes listed in CCL3

SDWA Regulatory Determination

EPA must regulate if...

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

SDWA Regulatory Determination

if all three criteria are met...

- The Administrator determines that all three statutory criteria are met
- Administrator makes a final determination that a national drinking water regulation is needed
- The Agency has 24 months to propose and publish
 - Maximum Contaminant Level Goal (MCLG)
 - National Primary Drinking Water Regulation (NPDWR)
- After proposal the Agency has 18 months for publish a final MCLG and NPDWR

Regulatory Determination 3 (RD 3) January 4, 2016

- **4 Determined not to regulate**
 - 1,3-Dinitrobenzene
 - Dimethoate
 - Terbufos
 - Terbufos Sulfone
- **1 Preliminary determination to regulate**
 - Strontium

www.epa.gov/ccl/regulatory-determination-3

Rule Development/Revision

- Perchlorate
- Reduction of Lead

Rule Development: Perchlorate

- Developing a proposed perchlorate standard
 - Particular concern to infant and fetal nervous system development.
 - Evaluating occurrence data.
 - Evaluating the feasibility of analytical methods and treatment technologies to remove perchlorate.
 - Examining the costs and benefits of potential standards.
- Following up on SAB recommendations (May 2013) to develop a perchlorate MCLG using Physiologically Based Pharmacokinetic (PBPK) modeling.
 - EPA and FDA scientists have developed a PBPK (also known as a biologically-based dose response (BBDR)) model that can be used to derive an MCLG.
 - EPA intends to conduct an expert peer review of the model, model report and a report of the application of the model to inform the development of an MCLG.

Rule Development: Perchlorate

- Peer Review – undertaking an independent, external, panel peer review.
 - The BBDR model and model report are being peer reviewed.
 - Two FRNs were published September 30, 2016.
 - The agency released the following peer review materials:
 - An interim list of peer review candidates;
 - The peer review charge questions; and
 - The BBDR model and report.

Rule Development: Revisions to the Lead and Copper Rule

- EPA requested the NDWAC form a working group to provide stakeholder input on several key rule revision issues
- In December 2015 the NDWAC provided the following recommendations:
 - Proactive Lead Service Line Replacement programs
 - More robust public education requirements for lead and LSLs
 - Strengthening Corrosion Control Treatment requirements
 - Modify monitoring requirements to provide for consumer requested tap samples for lead
 - Tailor water quality parameters for each system and increase frequency of monitoring
 - Establish a health based household action level
 - Separate copper requirements focused on water corrosive to copper
 - Establish appropriate compliance and enforcement mechanisms

Rule Development: Revisions to the Lead and Copper Rule

- EPA received recommendations from other concerned stakeholders.
- EPA will consider national experience in implementing the current rule, including lessons learned from the events in Flint, to develop proposed improvements to the LCR.
- Our current expectation is that revisions to the rule will be proposed in 2017.
- Published the “LCR Revisions White Paper” in October 2016

www.epa.gov/sites/production/files/2016-10/documents/508_lcr_revisions_white_paper_final_10.26.16.pdf

- highlighting key challenges, opportunities, analytical issues and options that include: lead service line replacement, improving optimal corrosion control treatment requirements, consideration of a health-based benchmark, the potential role of point-of-use filters, clarifications or strengthening of tap sampling requirements, increased transparency, and public education requirements.

Six Year Review of Regulations

Six Year Review

- EPA must review existing National Primary Drinking Water Regulations (NPDWRs) every six years and, if appropriate, revise

Background

- Completed the **1st** Six Year Review of 69 NPDWRs (2003); made decision to revise TCR
- Completed the **2nd** Six Year Review of 71 NPDWRs (2010) and identified PCE, TCE, acrylamide and epichlorohydrin as candidates for revision
- Completed the **3rd** Six Year Review of 76 NPDWRs (Jan 11, 2017) and identified Chlorite, Cryptosporidium (under the SWTR, IESWTR and LT1), Haloacetic acids, Heterotrophic Bacteria, Giardia lamblia, Legionella, Total Trihalomethanes, and Viruses (under the SWTR) as candidates for revision.
 - first time a Six Year Review addresses microbial and disinfection byproduct regulations

<https://www.epa.gov/dwsixyearreview>

Major Elements of Six-Year Review

- Health Effects
- Contaminant Occurrence and Exposure Analysis
- Analytical Method Improvements
- Treatment Methods Feasibility
- Implementation Issues

Any Change Must Maintain or Increase Public Health Protection

- MCLs can be lowered, but not raised because it might adversely affect public health.
- New or additional ways to manage risk are evaluated

Stakeholder Support/Guidance: Legionella and TCR

Stakeholder Support

- *Legionella*
 - A multi-agency taskforce has been participating in the data compilation
 - EPA, CDC, ASDWA, state primacy agencies

Legionella Treatment Document

- “Technologies for Legionella Control: Scientific Literature Review”
 - EPA 810-R-16-001, Sept 2016, https://www.epa.gov/sites/production/files/2016-09/documents/legionella_document_master_september_2016_final.pdf
- Purpose:
 - To characterize the effectiveness of treatment technologies to control for *Legionella* based on findings from peer reviewed literature
- Audience:
 - States, primacy agencies, system operators, and affected facilities

Method Changes in the Revised Total Coliform Rule

- Rule Effective date: April 2016
- Holding time definition
- Requires de-chlorination agent
- Requires autoclaving of MF equipment
- Revised and clarified the methods table
 - 40 CFR 141.852

Drinking Water Method Approval

Drinking Water Methods

Methods are approved through a Regulatory Approach or Expedited Method Approval Process.

- Many developed at EPA – TSC and/or ORD.
- Some developed by vendors
- Voluntary consensus method standards organizations (National Technology Transfer Act) - ASTM, Standard Methods.
- Alternate Test Procedure (ATP) Program – Evaluates new or modified test methods to determine if “equally effective” in performance relative to a method already approved in regulations.

Drinking Water ATP Program

www.epa.gov/dwanalyticalmethods/drinking-water-alternate-test-procedure-program

- ATP program evaluates modified or new testing methods (alternative testing procedures).
- Methods must undergo sufficient validation to support their use at the national level (multi-lab validation/multi-DW matrices).
 - Single laboratory or Regional approvals are not allowed.
- ATP program does not have authority to approve alternate testing procedures.

The Alternate Test Procedure (ATP) Program is Divided Between Drinking Water and Wastewater

	Drinking Water ¹	Wastewater ²
Application Scope	National	National/Regional/ Laboratory
ATP Review	Any Change Not Allowed In The Method	Only Changes Not Covered by 136.6
Changes Generally Not Allowed	Preservation/ Extraction	Determinative Step

¹ Wendelken.Steve@epa.gov

² Walker.Lemuel@epa.gov

Expedited Method Approval Process

www.epa.gov/dwanalyticalmethods/expedited-drinking-water-analytical-method-approval-requirements

- Frequency of approvals.
 - Publishing FR notices on approximately an annual basis

- Listed in Appendix A to Subpart C of Part 141.
 - State adoption of alternative test methods is optional; however, if these methods are used, laboratory certification requirements extend to the use of methods approved through the expedited process.

- Expedited Method Approvals include:
 - Methods evaluated through the drinking water ATP program;
 - Voluntary Consensus Standard Body methods (Standard Methods and ASTM); and
 - New or revised EPA methods.

Expedited Method Approvals

- Expedited method approval *Federal Register* notices published since June 2008 (73 FR 31616, June 3, 2008):
 - 74 FR 38348 (August 3, 2009)
 - 74 FR 57908 (November 10, 2009)
 - 75 FR 32295 (June 8, 2010)
 - 76 FR 37014 (June 24, 2011)
 - 77 FR 38523 (June 28, 2012)
 - 78 FR 32558 (May 31, 2013)
 - 79 FR 35081 (June 19, 2014)
 - 81 FR 46839 (July 19, 2016)
- Over 150 optional, alternative methods have been approved.

Where can I find Approved Methods?

- Approved methods are listed on OGWDW's web site.
 - <http://www.epa.gov/dwanalyticalmethods/approved-drinking-water-analytical-methods>.
- PDF tables of approved methods now available.
 - Grouped by regulation/monitoring requirement, sorted by contaminant.
- National Environmental Methods Index (NEMI).
 - <https://www.nemi.gov/home/>

Websites

- Drinking Water Regulations <http://www.epa.gov/dwstandardsregulations>
- Laboratory Certification <http://www.epa.gov/dwlabcert>
- Drinking Water Methods <http://www.epa.gov/dwanalyticalmethods>
- Federal Register Notices <https://www.federalregister.gov/>
- EPA OIG hotline <http://www.epa.gov/office-inspector-general/epa-oig-hotline>



Drinking Water Laboratory Certification Team Contacts:

Miller.Carrie@epa.gov

Karapondo.Michella@epa.gov