Regulatory Processes

Contaminant Candidate List 3 (CCL 3)

- List of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations
- Contaminants known or anticipated to occur in public water systems and may require regulation under the Safe Drinking Water Act (SDWA)
- EPA considers available data and information on health effects and occurrence to evaluate 7,500 unregulated contaminants
- EPA incorporated information from the public, expert input, and expert review in the CCL process
- CCL3 published in October 2009
CCL3 Final list of 116 contaminants

• 104 chemicals or chemical groups
  • One antibiotic (erythromycin),
  • Nine hormones (17 alpha-estradiol, 17 beta-estradiol, equilenin, equilin, estriol, estrone, ethinylestradiol, mestranol, and norethindrone),
  • Two potential DBPs (Halon 1011, bromochloeromethane, and chlorate) and
  • One CCL perfluorinated compound (PFOS)

• 12 microbiological contaminants

EPA will make a regulatory determination for at least five chemicals on CCL 3 by 2012.
Regulatory Processes

Six year Review

• SDWA requirement to review each National Primary Drinking Water Regulation (NPDWR) at least once every six years
• Second Six-Year Review expected January or February of 2010
• Potential candidates for revision:
  • Trichloroethylene (TCE)
    • EPA released IRIS draft Toxicological Review in November 3, 2009
  • Chromium
    • Total chromium MCL 100 μg /L.
      California draft public health goal for chromium-6 at 0.06 μg/L.
  • Fluoride
    • 2006 NRC report identifies severe dental fluorosis as an adverse health effect and recommended risk assessment update in order to consider revisions
Regulatory Processes

Integrated Risk Information System (IRIS)

- EPA database that contains information on human health effects that may result from exposure to chemical substances in the environment.
- Maintained by Office of Research and Development (ORD)
- IRIS process
  - Draft Toxicological Review for chemical, internal and external scientific reviews
  - EPA responses to review comments and
  - IRIS Summary and final Toxicological Review
- May 2009 revisions to the IRIS process
  - A streamlined review schedule will take no more than 23 months
  - A “rigorous and open” external peer review as well as opportunity for public comment.
- Input will be from health scientists and will focus on scientific and technical comments.
- All written comments from other federal agencies and White House offices will be made public to improve transparency
Arsenic Rule: Round Two?

Round One: Rule-Making History

• 1974 Safe Drinking Water Act (SDWA): 50 micrograms per liter (μg/L) Public Health Service standard grandfathered as Maximum Contaminant Level (MCL)
• 1986 SDWA Amendments direct EPA to review and revise MCL
• 1996 SDWA Amendments feature arsenic and cost-benefit decision-making
• June 2000 EPA proposed MCL at 5 μg/L
• January 2001 EPA promulgated MCL at 10 μg/L with March 23, 2001 effective date
• March 20, 2001 EPA Administrator announced additional steps to reassess associated scientific and cost issues
• October 31, 2001 10 μg/L MCL effective

"...the 10 ppb protects public health based on the best available science and ensures that the cost of the standard is achievable."
Arsenic Rule: Round Two?

ORD is redefining IRIS inorganic arsenic toxicity

• FY03 - FY05 draft assessment and agency/interagency review
• FY05 - FY09 external peer review, including comments from the Science Advisory Board (SAB)
• September 2009 assessment for the cancer health effects of inorganic arsenic was expected
• Assessment reportedly sets out a significant increase in the cancer health risk from the reference dose used by EPA’s Office of Water for the current inorganic arsenic MCL

ORD position
• SAB provided a complete peer review of the assessment in 2007 and
• Time of the SAB review was also the public comment opportunity
Arsenic Rule: Round Two?

Implications

• Toxicity level -- referred to as the “toxicity slope” -- essentially increasing by 17 times, according to an October 2008 agency paper
• Toxicity level from a level of 1.5 per unit dose of inorganic arsenic in milligrams per kilogram of bodyweight per day (mg/kg/day) to about 26 per unit dose mg/kg/day
• Revising the cancer slope could effectively move the current drinking water standard for inorganic arsenic -- the maximum containment level (MCL) -- from 10 ppb to just tenths of a µg/L
• Could result in the reclassification of much of the nation’s natural water supply and soils as carcinogenic
Round Two: A New Rule?

Occurrence

• According to U.S. Geographical Survey maps, most U.S. groundwater contains 1 to 3 µg/L
• Considerably higher concentrations in the Western regions range from 10 to 50 µg/L

Compliance Status in New Mexico

• 90 water systems affected by the Inorganic arsenic Rule
• 20 Notices of Violation issued
ABCWUA Compliance

- Drinking water is currently six µg/L inorganic arsenic

- Strategy to treat surface water, blend it with ground water and couple that with the use of an advanced microfiltration system

- Without access to relatively arsenic-free Colorado River water, meeting EPA’s current MCL would have cost the Water Authority over $200 million
Round Two: A New Rule?

Regulatory Options

• 2010 Six-year review and revision

• No deadline under the six-year review to propose a different standard

• OGWDW must review new risk assessment and factor it into a drinking water regulation

Or

• NO revision due to cost-benefit considerations
Radon Rule Revisited

Rule-Making History

• July 1991 EPA proposed MCLG, MCL and monitoring, reporting, and public notification requirements for radon and a number of other radionuclides
• August 1996 SDWA Amendments directs EPA to withdraw the proposed national primary drinking water regulation for radon-222
• 1996 SDWA Amendments required EPA to propose and finalize MCL and make available an alternative approach:
  Two options
  1. Proposed MCL is 300 picoCuries per liter (pCi/L) and
  2. Proposed alternative maximum contaminant level (AMCL) is 4,000 pCi/L for water systems with Multi Media Mitigation (MMM) programs
• August 1999 Congressional directive for EPA to propose an MCLG and MCL for promulgation by August 2000

December 2009 EPA Regulatory Agenda final action for this rule “to be determined.”
Revised Total Coliform Rule (RTCRI)

Rule-Making History

• 2000-2003 series of TCR and distribution system white papers
• 2003 EPA determined that the TCR needed revising as part of first six-year review
• 2004-2006 another series of TCR white papers
• Draft Revised Total Coliform Rule (RTCR) has been completed and is in EPA internal review
  • No MCL for Total Coliform
  • E.coli MCLG of zero and presence is acute violation
  • Revision of public notification language
  • Tier 2 violation under a RTCR would be the failure to perform an assessment correct sanitary defects identified in an assessment and not simply the presence of TC
• 2010 Final Rule will be proposed
• 2011 or 2012 Final Rule promulgation.

Spring of 2010 Research and Information Collection Partnership (RICP) is expected to announce research and information collection agenda for distribution system
Pharmaceuticals and Personal Care Products (PPCPs)

History

• 2008 Congress and EPA became more interested in the issue of pharmaceuticals and personal care products
• April 2006 ORD, in collaboration with the U.S. Geological Survey, announces an information collection submission to OMB to conduct a sampling program for PPCPs at up to 50 drinking water treatment plants known to be downstream of wastewater treatment plants or point source wastewater discharges.
• September 2009 EPA revised and resubmitted its request to OMB
Pharmaceuticals and Personal Care Products (PPCPs)
Pharmaceuticals and Personal Care Products (PPCPs)

ABCWUA
• September 2009 ABCWUA undertakes program to address disposal of pharmaceuticals and monitor for PPCPs at representative locations
• Analyses:
  • EPA 1694 (pharmaceuticals)
  • EPA 1698 (steroids and hormones)
  • Results in nanograms per liter
  • Blank corrections in progress
• Key findings:
  • Very low level detections of few PPCPs at surface water diversion
  • Most analytes detected at water reclamation plant influent
  • Water reclamation plant effectively reduces PPCPs
• In addition, USGS monitoring 3X per year since 2004 for reduced list of analytes
  • Estimated values for caffeine and an antibiotic
Ground Water Rule

• December 2009 Effective Date
• Four major components:
  • Periodic sanitary surveys of systems that require the evaluation of eight critical elements of a public water system and the identification of significant deficiencies (e.g., a well located near a leaking septic system);
  • Triggered source water monitoring when a system (that does not already treat drinking water to remove 99.99 percent (4-log) of viruses) identifies a positive sample during its Total Coliform Rule monitoring and assessment monitoring (at the option of the state) targeted at high-risk systems;
  • Corrective action is required for any system with a significant deficiency or source water fecal contamination; and
  • Compliance monitoring to ensure that treatment technology installed to treat drinking water reliably achieves 99.99 percent (4-log) inactivation or removal of viruses.