Status Report on EPA Regulations

Phil Oshida
Acting Director
Standards and Risk Management Division
Office of Ground Water and Drinking Water

National Drinking Water Advisory Council Meeting
October 4, 2012

Overview

Rule Development and Other Actions
- Contaminant Candidate List (CCL)
- Unregulated Contaminant Monitoring Rule (UCMR)
- Regulatory Determination process
- Regulation Development
- Six-Year Review & Other Regulatory Reviews/Revisions
Rule Development and Other Actions

General Flow of SDWA Regulatory Processes

At each stage, need increased specificity and confidence in the type of supporting data used (e.g. health, occurrence, treatment).
CCL
Contaminant Candidate List

Contaminant Candidate List 4 (CCL 4)

• Spring 2012- Invite public to nominate contaminants to be considered for inclusion in CCL 4
  – May-June 2012
  – Nominations submitted via the web and mail

• Summer 2013- Expect to publish Draft CCL 4 for public review and comment

• October 2014- Expect to publish Final CCL 4
UCMR
Unregulated Contaminant Monitoring Regulation

UCMR 2: Final Results

- 25 contaminants monitored, including brominated flame retardants; nitrosamines; explosives; insecticides, pesticides, degradates
- Results are posted on the Web (NCOD) at: http://water.epa.gov/lawsregs/rulesregs/sdwa/ucmr/data.cfm
- 13 of 25 contaminants were not detected
- Detections above method reporting limits:
  - 5 of 6 nitrosamines (predominantly NDMA)
  - 6 of 11 insecticides/pesticides/degradates
  - 1 of 3 explosives
UCMR 3

- Proposal published March 3, 2011
- Final rule published May 2, 2012
- [water.epa.gov/lawsregs/rulesregs/sdwa/ucmr/ucmr3/index.cfm](http://water.epa.gov/lawsregs/rulesregs/sdwa/ucmr/ucmr3/index.cfm)
- Monitoring will occur from 2013-15
- 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

UCMR 3 – Contaminants

- Pharmaceuticals (EPA Method 539)
  - 17-α-ethynylestradiol
  - 17-β-estradiol
  - equilin
  - estriol
  - estrone
  - testosterone
  - 4-androstene-3,17-dione
- Metals (EPA Method 200.8)
  - cobalt
  - molybdenum
  - strontium
  - vanadium
  - (total) chromium
- EPA Method 218.7
  - hexavalent chromium
- Volatile Organic Compounds (EPA Method 524.3)
  - 1,1-dichloroethane
  - 1,2,3-trichloropropane
  - 1,3-butadiene
  - bromochloromethane
  - chlorodifluoromethane
  - chloromethane
  - methyl bromide
- EPA Method 522
  - 1,4-dioxane
- EPA Method 300.1
  - chlorate
UCMR 3 – Contaminants (cont.)

- Microbials
  - 2 viruses
    - enterovirus (qPCR & cell culture)
    - norovirus (qPCR)
  - "Indicator organisms"
    - Total coliform
    - E. coli
    - enterococci
    - coliphage
    - aerobic spores

- Perfluorinated Chemicals (EPA Method 537)
  - Perfluorococane sulfonate (PFOS)
  - Perfluorooctanoic acid (PFOA)
  - Perfluoroheptanoic acid (PFHpA)
  - Perfluorononanoic acid (PFNA)
  - Perfluorobutane sulfonic acid (PFBS)
  - Perfluorohexane sulfonic acid (PFHxS)

Hexavalent Chromium

- Drinking Water Standard
  - Total Chromium (Cr\(^{+3}\) & Cr\(^{+6}\)) MCL is 0.1 mg/L (100 ppb) established in 1991.
  - When toxicological review is completed, EPA will consider all relevant information to determine whether the drinking water standard for total chromium needs to be revised.

- Toxicological Review
  - Sept 2010, peer review draft IRIS Toxicological Review of Cr\(^{+6}\) proposed to classify Cr\(^{+6}\) as likely to be carcinogenic to humans when ingested.
  - Based on the recommendations of an external peer review panel, EPA will consider the results of recent research on Cr\(^{+6}\) before finalizing the IRIS assessment.
  - EPA anticipates that a revised draft assessment for Cr\(^{+6}\) will be released for public comment and external peer review in 2013, and that a final assessment will be completed by 2015.

- Monitoring
  - January 2011 - EPA provided guidance to water systems on enhanced monitoring and analysis for Cr\(^{+6}\).
  - May 2012 - EPA included Cr\(^{+6}\) monitoring requirement in final UCMR 3.
Regulatory Determinations

Three Regulatory Determination Criteria

SDWA requires EPA to consider the following criteria in evaluating whether to regulate a contaminant:

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; **and**

3) In the sole judgment of the Administrator, regulation of such contaminant presents a **meaningful opportunity for health risk reduction** for persons served by public water systems.

*SDWA Section 1412(b)(1)*
Potential Outcome of Determinations

- No Regulatory Determination
  - Insufficient data to assess contaminant against the three statutory criteria

- Positive Determination
  - Answer “yes” decision for “all three” criteria
  - Begin process to develop a drinking water regulation

- Negative Determination
  - Answer “no” for “any one” of the three criteria
  - Do not develop a drinking water regulation
  - Can develop a health Advisory as a non-regulatory option

Status of Regulatory Determinations 3 (RD3)

- Since CCL3 publication (Oct 2009), gathered & evaluated available health and occurrence information for 116 contaminants

- June 2011 – Held Stakeholder meeting in DC to discuss health and occurrence information for a short list of contaminants; meeting materials can be found at: [http://water.epa.gov/scitech/drinkingwater/dws/ccl/index.cfm](http://water.epa.gov/scitech/drinkingwater/dws/ccl/index.cfm)

- Oct 2011 – Held Expert Review meeting
RD3 Approach – Three Main Phases

Phase 1: Data Availability: Evaluated 116 CCL contaminants and identified 35 that "appear" to have sufficient health and occurrence data to warrant further evaluation.

Phase 2: Data Evaluation: Further evaluating health and occurrence data for 35 contaminants to identify "X" contaminants that have complete information in time for regulatory determinations; focusing on contaminants with known or likely occurrence at levels of health concern in water systems.

Phase 3: Regulatory Determination Assessment: Evaluate information for "X" contaminants against the three SDWA criteria – (1) adverse health, (2) known/likely occurrence in PWSs and (3) meaningful opportunity (sole judgment of Administrator).

Short List of 35 Contaminants Being Further Evaluated for Regulatory Determinations 3

- 1,1,1,2-Tetrachloroethane
- 1,2,3-Trichloropropane (TCP)
- 1,3-Dinitrobenzene
- 1,4-Dioxane
- Methyl Tertiary Butyl Ether (MTBE)
- Methyl Bromide
- Nitrobenzene
- PFOS and PFOA
- RDX
- Cobalt
- Molybdenum
- Strontium
- Vanadium
- Acephate
- Dimethocarb
- Disulfoton
- Diuron
- Molinate
- Terbufos and Terbufos Sulfone
- Acetochlor & ESA and OA Degradates
- Alachlor ESA & OA Degradates
- Metolachlor & ESA and OA Degradates
- Chlorate
- Nitrosamines (5)
  - N-nitrosodimethylamine (NDMA)
  - N-nitrosodiethylamine (NDEA)
  - N-nitrosodi-n-propylamine (NDPA)
  - N-nitrosopyrrolidine (NPYR)
  - N-nitrosodiisopropylamine (NDiPA)
Nitrosamines Being Evaluated as a Group for RD3

<table>
<thead>
<tr>
<th>Factors</th>
<th>Details</th>
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<tbody>
<tr>
<td>Public Health</td>
<td>~100M people served by systems with at least single detection of at least one of the nitrosamines</td>
</tr>
<tr>
<td>Health Benefit</td>
<td>~10M people served by systems that have co-occurring nitrosamines; potential for greater public health risk due to additivity of cancer risk</td>
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<tr>
<td>Issues</td>
<td>Exposure from food may be &gt; drinking water for some age groups but drinking water is the primary exposure source for bottle-fed infants</td>
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<td>Constraining chloramine use to reduce nitrosamines could make it more difficult to comply with prior DBP rules</td>
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<td>Also, some questions about other ways that nitrosamines may be formed</td>
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Next Steps for Regulatory Determinations (RD3)

- Finish compiling/evaluating occurrence & health information.
- Expect to publish preliminary determinations in 2012/2013.
- Expect to publish final determinations in 2013/2014.
Perchlorate

Perchlorate Status

- The status of the development of a Perchlorate Regulation will be covered in the next presentation, “Consultation on the Regulation of Perchlorate in Drinking Water,” by Mr. Eric Burneson.
Six-Year Review and Other Regulation Reviews/Revisions

Revised Total Coliform Rule

- Identified in Six-Year Review 1 as needing revision
- EPA published the proposed revisions to the TCR in the *Federal Register* on July 14, 2010
  - The proposal was based on the Agreement in Principle signed by the Federal Advisory Committee in September 2008
  - The proposal takes a more proactive approach to public health protection
  - Monitoring results shift from informing public notification to informing investigation and corrective action
- Hope to promulgate final rule in 2012
Carcinogenic VOCs Group

- TCE and PCE were identified in Six-Year Review 2 as needing revision.
- EPA has initiated the process to develop a group cVOC standard and will:
  - Develop a group NPDWR for regulated and unregulated carcinogenic VOCs (cVOCs) that improves or maintains public health protection.
  - Assess potential cVOCs for the group based upon similar health effect endpoints; common analytical method(s); common treatment or control processes; and occurrence/co-occurrence in drinking water.
  - Evaluate options for setting a cVOC MCL(s) and examine the feasibility of analytical methods & treatment technologies, and costs/benefits for the group.
  - Hold consultations from 2012 - 2013:
    - Public Stakeholder meeting
    - Science Advisory Board
    - National Drinking Water Advisory Council
    - Small Business Regulatory Enforcement Fairness Act (SBREFA)
    - National Tribal Water Council
- EPA expects to propose a regulation in Fall 2013.

Lead and Copper Rule Revisions

- Lead and Copper Rule promulgated in 1991
- Revised in 2000 and 2007

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<tbody>
<tr>
<td>Lead service line replacement (LSLR)</td>
<td>Evaluating revisions to the LSLR requirements.</td>
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<tr>
<td>Sample Site Selection</td>
<td>Evaluating revisions to the criteria better address the latest information about lead sources</td>
</tr>
<tr>
<td>Tap sampling</td>
<td>Evaluating different protocols to for collecting tap samples for lead and copper</td>
</tr>
<tr>
<td>Measures to ensure optimal corrosion control treatment (OCCT)</td>
<td>Evaluating OCCT requirements to better ensure optimal corrosion control and effective water quality parameters monitoring</td>
</tr>
<tr>
<td>Copper</td>
<td>Evaluating approaches to better address copper</td>
</tr>
<tr>
<td>Lead Reduction in Drinking Water Act of 2011</td>
<td>Incorporate changes new definition of &quot;Lead Free&quot; from Lead Reduction in Drinking Water Act</td>
</tr>
</tbody>
</table>
Lead and Copper Rule Revisions
Outreach and Consultations

- Stakeholder meetings October 2008 and November 2010
- Science Advisory Board 2011 review of partial lead service line replacement
- NDWAC consulted in 2011 on range of lead and copper rule issues.
- Stakeholder Meeting on the Lead Reduction in Drinking Water Act August, 2012
- EPA intends to publish the proposed LCR long-term revisions in early 2013.

Six Year Review 3
Background

- 1996 SDWA Amendments require EPA to review and, if appropriate, revise existing National Primary Drinking Water Regulations (NPDWRs) every 6 years.
  - 2003: completed first Six Year Review of 69 NPDWRs; made decision to revise TCR
  - 2010: completed second Six Year Review of 71 NPDWRs; made decisions to revise tetrachloroethylene (PCE), trichloroethylene (TCE), acrylamide and epichlorohydrin
- Occurrence analysis is a key component in the 6-year review process.
  - Limited occurrence data set (representing 15 States) used for first Six Year Review.
  - Early 2005: EPA Information Collection Request (ICR) to gather a more robust dataset; allows EPA to ask States to voluntarily submit their occurrence data.
  - Overwhelming State response - 46 States plus several tribes, territories and DC. These data are the largest, most comprehensive set of drinking water compliance monitoring data ever compiled and analyzed by EPA and were instrumental in decision making.
Six Year Review 3
Occurrence Data Collection

- OGWDW to send a formal request for data to the States in fall 2012.
  - We encourage States to participate in this data collection effort.
- We will be asking for data for the period of January 2006 to December 2011.
- Our goal for the data collection is to make the procedure(s) as easy as possible for the States.
  - States can submit data in virtually any electronic format including: upload to a File Transfer Protocol site; sending a CD, using extraction script for SDIWS/State users
- Once data are QA/QC’d and analyzed for Six Year Review purposes, they will be stored in the National Contaminant Occurrence Database (NCOD).

Review of Long Term 2 Enhanced Surface Water Treatment (LT2) Rule

- Aug 2011, EPA announced plans to initiate LT2 review in response to E.O. 13563
- Review will be part of the next cycle of the SDWA-mandated Six Year Review scheduled for completion no later than 2016
- Review involves assessment and analysis of data/information on occurrence, treatment, analytical methods, health effects, and public health risks
Review of Long Term 2 Enhanced Surface Water Treatment (LT2) Rule

- Dec 2011, EPA held a public meeting to discuss LT2 Round 1 Crypto monitoring data and improvements to the Crypto analytical method
- Apr 2012, EPA held a public meeting to solicit input and discuss available scientific data that may inform regulatory review of the uncovered finished water reservoir requirement
- Nov 2012, EPA plans to hold a public meeting to discuss data and information related to monitoring, binning, and microbial toolbox options

Thank You!
Appendices

Appendix A. Contaminants on the Second Unregulated Contaminant Monitoring Regulation (UCMR 2)

10 Assessment Monitoring
- 3 Explosive
  - hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)
  - 2,4,6-trinitrotoluene (TNT)
  - 1,3-dinitrobenzene
- 7 Insecticides and Flame Retardants
  - Dimethoate
  - Terbufos sulfone
  - 5 Brominated Flame Retardants

15 Screening Survey
- 9 Acetanilide pesticides/degradation products
  - Acetochlor
  - Acetochlor ESA
  - Acetochlor OA
  - Alachlor
  - Alachlor ESA
  - Alachlor OA
  - Metolachlor
  - Metolachlor ESA
  - Metolachlor OA

- 6 Nitrosamines
  - N-nitroso-diethylamine (NDEA)
  - N-nitroso-dimethylamine (NDMA)
  - N-nitroso-di-n-butylamine (NDBA)
  - N-nitroso-di-n-propylamine (NDEA)
  - N-nitroso-methylisocyanate (NMIA)
  - N-nitroso-pyrrolidine (NPyR)
Appendix B. How We Evaluate the Three SDWA Criteria

<table>
<thead>
<tr>
<th>#</th>
<th>Statutory Criteria</th>
<th>Information To Consider During Evaluation</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Adverse effect on the health of humans?</td>
<td>• Potential adverse health effect(s) (e.g., cancer, thyroid, liver damage) and level at which effect occurs (i.e., level of concern)</td>
</tr>
</tbody>
</table>
| 2  | Known or likely to occur in PWSs at a frequency and level of concern? | • National monitoring data from PWSs and whether it occurs in drinking water at the health level of concern  
  • Other sources of information (e.g., state PWS data, levels in source waters, how much is used/produced, etc.) |
| 3  | In the sole judgment of the Administrator – is there a meaningful opportunity for health risk reduction for persons served by PWSs? | Consider variety of factors which include:  
  • Number of people who may be exposed to the contaminant from drinking water (served by PWSs)  
  • Health effect and potential impact on sensitive populations (e.g., children, elderly, compromised immune systems)  
  • National versus local occurrence in drinking water  
  • Exposure from water versus other sources (e.g., food, air); primarily for non-cancer |

Appendix C - What Factors Do We Consider and How Do We Develop Standards?

Human Health Effects  
Set Public Health Goal or Maximum Contaminant Level Goal (MCLG)  
Set legally enforceable Maximum Contaminant Level (MCL)* or Treatment Technique (TT)*  
Also list treatment technologies; specify methods to measure, how often monitor, when/what to report to state and the public, etc  
Analytical Test Methods  
Treatment Technologies  
Occurrence  
Public and Expert Input  
Economics and Costs/Benefits

* Maximum Contaminant Level (MCL) - the highest level or amount of a contaminant that EPA allows in drinking water.  
*Treatment Technique (TT) – a prescribed process intended to reduce the level of a contaminant in drinking water.