



# **Regulatory Review Process for LT2**

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# Outline

- Provide Overview of Statutory Requirements and Considerations for the LT2 Review
- Discuss Previous Six-Year Reviews, Key Elements Typically Considered, and Outcome of the Review
- Provide Overall LT2 Review Plan and Timeframes
- Discuss Requirements Under Review for LT2
- Discuss Type of Information/Data of Interest for the Review



# Statutory Requirements and Considerations for the LT2 Review

## 1996 SDWA Amendments Section 1412(b)(9)

- Requires EPA to review each existing National Primary Drinking Water Regulation (NPDWR) at least once every six years and revise, if appropriate.
- Any revision of an NPDWR shall be promulgated in accordance with section 1412, except that each revision “shall maintain, or provide for greater, protection of the health of persons.”



# Statutory Requirements and Considerations for the LT2 Review (con't)

## Jan 2011 - E.O. 13563 (Improving Regulation & Regulatory Review)

- Required each federal agency to develop a plan (consistent with law, resources and regulatory priorities) to periodically review “existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency’s regulatory program more effective or less burdensome in achieving the regulatory objectives.”

## Aug 2011 – EPA Final Plan

- Listed 35 agency-wide regulations including LT2; Stated “EPA intends to evaluate effective and practical approaches that may maintain, or provide greater protection of, the water treated by public water systems and stored prior to distribution to consumers. EPA plans to conduct this review expeditiously to protect public health while considering innovations and flexibility as called for in EO 13563.”



# Statutory Requirements and Considerations for the LT2 Review (con't)

## SDWA 1412(b)(6)(C):

- Does not allow EPA to use costs and benefits in establishing the treatment technique for *Cryptosporidium*; this authority applies if we were to consider revisions to LT2.
- *Disinfectants and disinfection byproducts.— The Administrator may not use the authority of this paragraph to establish a maximum contaminant level in a Stage I or Stage II national primary drinking water regulation (as described in paragraph (2)(C)) for contaminants that are disinfectants or disinfection byproducts, or to establish a maximum contaminant level or treatment technique requirement for the control of Cryptosporidium.*



# Previous Six-Year Review Efforts

- **July 2003** – EPA developed a review protocol and completed the 1<sup>st</sup> Six Year Review; reviewed 69 NPDWRs and decided to revise 1 NPDWR (Total Coliform Rule).
- **March 2010** – EPA completed 2<sup>nd</sup> Six Year Review using review protocol\* developed during first review; reviewed ~ 85 NPDWRs and decided to revise 4 NPDWRs (acrylamide, epichlorohydrin, tetrachloroethylene and trichloroethylene).
- **No later than 2016** – EPA expects to complete 3<sup>rd</sup> Six Year Review including the review of LT2.

\*Protocol based on recommendations from the National Drinking Water Advisory Council (NDWAC).



# Technical Review Elements

- Review typically includes evaluation of health risk, analytical methods, treatment technologies/techniques, occurrence, and implementation-related items.
- Overall goal – review technical elements to determine if the basis for the current regulation (MCLG, MCL or TT, or other regulatory requirements\*) has changed and if it is appropriate to consider revisions while maintaining or providing greater protection of public health (no backsliding allowed).
- Review elements considered and questions asked differ slightly for “chemical vs. microbial” regulations and “MCL vs. TT” regulations.

See Appendix A for definitions for MCLG, MCL and TT.



# Outcome of the Review

## **“No Action” appropriate at this time:**

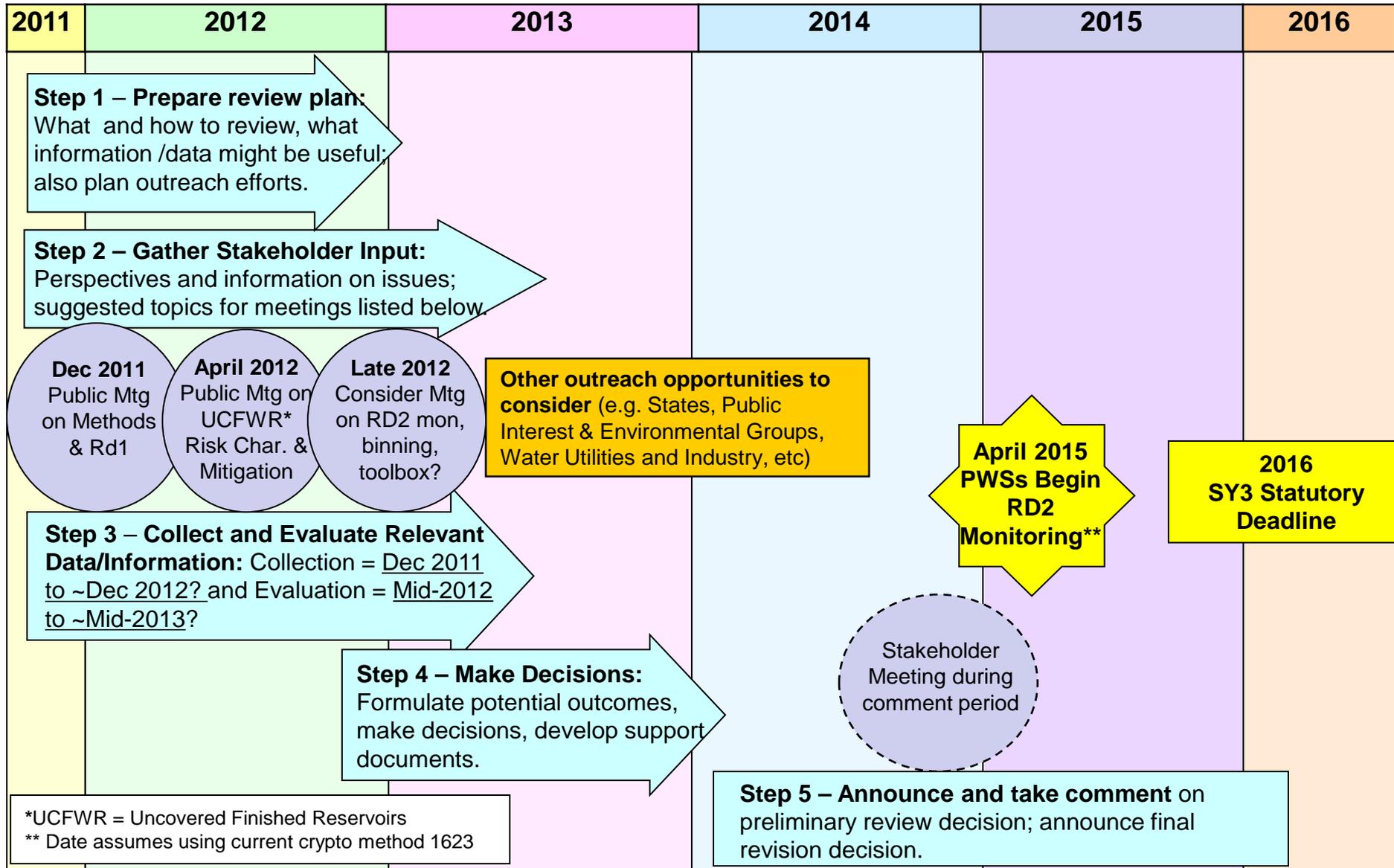
- NPDWR remains appropriate after review of available data/information;
- Even though there may be potential changes in basis of the NPDWR, found little/no meaningful opportunity for health risk reduction and/or cost savings while maintaining/providing greater protection public health;
- Risk assessment in process/planned; or
- Data or information gaps.

**OR**

## **“Revise” Decision**

- EPA plans to initiate rulemaking revision process for particular NPDWR(s).
- Final decision to revise depends on outcome of analyses performed during the rulemaking process.

# Overall LT2 Review – “Tentative” Sequence of Events and Timeframes



\*UCFWR = Uncovered Finished Reservoirs  
 \*\* Date assumes using current crypto method 1623



# Primary LT2 Requirements Under Review

- Source water monitoring and treatment requirements (including toolbox options).
- Requirement to either treat discharge or cover uncovered finished water reservoirs (4-log for viruses, 3-log for *Giardia*, and 2-log for *Cryptosporidium*).
- Disinfection profiling and benchmarking for *Giardia* and viruses (for those systems planning to make significant changes in disinfection).



# Questions pertaining to LT2 Review

- Primary Questions
  - What data/information informs the health risk for LT2?
  - What is the national occurrence of *Cryptosporidium* in source waters?
  - What is the impact of Method 1623 improvements on measured occurrence?
  - To what extent does the binning structure identify high risk systems?
  - How effective are the tool box options and how much mitigation credit is warranted?
  - What are the best strategies to assess and address risks from uncovered finished water reservoirs?
  - How effective are the current disinfection profiling and benchmarking requirements?
- What data or information exists to inform this review?



# Health Risk Information

- Data Available and/or Sought
  - *Cryptosporidium* infectivity at the species level; which *Cryptosporidium* species are infectious to humans?
  - Information on other microbial contaminants of potential concern
  - Outbreaks involving *Cryptosporidium* or other contaminants of concern
  - Public health surveillance and epidemiology information
  - Dose-response information on other contaminants of potential concern



# National Source Water Occurrence of *Cryptosporidium*

- Data Available and/or Sought
  - Monitoring data by system size, type and source water
  - Round 1 monitoring data (2006-2012)
  - Information Collection Rule (ICR) data (ICR method; 1997-1998)
  - ICR Supplemental Survey (ICR SS) data (method 1623;1999-2000)
  - Matrix spike recoveries for each data set
  - Grandfathered monitoring data
  - Other data that might inform national perspective on the occurrence or the interpretation of the occurrence of *Cryptosporidium*?



# Method 1623 Performance (with and without enhancements)

- Data Available and/or Sought
  - Matrix spike data for existing method from Round 1 and ICR SS
  - Matrix spike studies for enhanced 1623 method
  - Matrix spike information associated with grandfathered monitoring data



# Extent that Rule Structure Identifies High Risk Systems (with/without enhanced 1623)

- Data Available and/or Sought
  - *E. coli* with *Cryptosporidium* data from round 1 and ICR SS
  - *Cryptosporidium*, *Giardia*, and virus data from ICR (1997-1998)
  - Other utility-specific monitoring data?
  - Monitoring data for other pathogens of potential concern?



# Toolbox Options and Mitigation Credits

- Data Available and/or Sought
  - What data are available to inform removal or inactivation credits for existing or new tools?
  - Utility experience with toolbox options
  - Levels of removal or inactivation achieved by utilities using the toolbox options



# Occurrence of Contaminants in Open Finished Water Reservoirs and Strategies to Address Risks

- Data Available and/or Sought
  - Monitoring data and techniques that inform relative risk of *Cryptosporidium* and other pathogens entering and leaving reservoir?
  - Data informing the potential zoonotic transmission of microorganisms that might occur in open reservoirs?
  - Data informing effectiveness of open reservoir contaminant control programs (including crypto levels)?
- Thoughts on How to Analyze
  - Statistical analysis demonstrating numbers of samples needed to conclude that the water leaving the reservoir is of no greater risk than water entering
  - Evaluation of effectiveness of control programs
  - Characterization of informative value of indicator systems



**If you have any data and other information that would inform the review of the LT2 rule please send it to:**

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## Appendix A

**MCLG or Maximum Contaminant Level Goal** is the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.

**MCL or Maximum Contaminant Level** is the maximum permissible level of a contaminant in water delivered to any user of a public water system and is set as close to the MCLG as is feasible.

**TT or Treatment Technique** is a process used in lieu of an MCL when it is not economically or technologically feasible to ascertain the level of the contaminant.