Revised Total Coliform Rule and Making Pennsylvania Food Safe

Phyllis Butler Posy
Vice President for Strategic & Regulatory Affairs, Atlantium Technologies

PA-AWWA SE District and WWOAP Eastern Section Spring Meeting
March 11, 2015

Only Medium Pressure does more for less!
How Does RTCR Impact Food Safety?

- **The Goods News:** The quality of drinking water in the US has provided a broad sense of security to the public because the risk of contaminated drinking water getting an individual sick is very low.

- **The Bad News:** Fine if you drink it but just because it is safe to drink does not mean it is safe for other purposes, like food manufacturing.

- **Bottom Line/Take Home Message:**
  - The RTCR will determine what quality water customers will get
    - **Level of Protection:** Coliform-positive water - without fecal positive - could include food safety related pathogens, eg: salmonella, listeria, norovirus, etc.
    - **Timing and Relevance of Information:** The “Find and Fix” process will allow water that has been tested positive for coliform to be used by customers and they won’t necessarily know until they get the CCR.
  - Overall better for individuals, who get a 95% protection umbrella on 4 log virus disinfection standards in Pa, no increase in risk.
  - **But what about for food manufacturers?**
The TCR Gave Generalized Protection to All

such as those at schools, campgrounds, factories, and restaurants. Private water supplies, such as household wells that serve one or a few homes, are not regulated by EPA. For information on household wells, see “How Safe Is The Drinking Water In My Household Well?” on page 18 of this booklet.

Cost of Making Water Safe Continues to Rise

Much of the existing water infrastructure (underground pipes, treatment plants, and other facilities) was built many years ago. In 1999, EPA conducted the second Drinking Water Infrastructure Needs Survey, and found that drinking water systems will need to invest $150 billion over a 20-year period to ensure clean and safe drinking water.

Water suppliers must promptly inform you if your water has become contaminated by something that can cause immediate illness. Water suppliers have 24 hours to inform their customers of violations of EPA standards “that have the potential to have serious adverse effects on human health as a result of short-term exposure.” If such a violation occurs, the water system will announce it through the media, and must provide information about the potential adverse effects on human health, steps the system is taking to correct the violation, and the need to use alternative water supplies (such as boiled or bottled water) until the problem is corrected.

Systems will inform customers about violations of less immediate concern in the first water bill sent after the violation, in a Consumer Confidence Report, or by mail within a year. In 1998, states began compiling information on individual systems, so you can evaluate the overall quality of drinking water in your state. Additionally, EPA must compile and summarize the state reports into an annual report on the condition of the nation’s drinking water. To view the most recent annual report, see www.epa.gov/safewater/annual.
The quality/microbial integrity of the water you get today from a regulated Public Water System is based on the Total Coliform Rule and EPA Standards:

- Routine coliform testing (frequency system size dependent, at least monthly)
- Translates into an operating standard requirement that 95% of the water distributed by a Public Water System must be on-spec (5% flex)
- Strong Public Notification rules: Various triggers
- No violation/notice until 5% or more of the coliform tests are positive
- Monitoring Violations do not trigger public notice

Advantages and disadvantages for food processors
...but assumed by most to be good enough for everyday use and often considered GRAS
EPA Risk Assessment Based on Family of Four

EPA Protects Drinking Water per the Safe Drinking Water Act

- Original rules based on rule of thumb assessment: an acceptable risk is less than 1:10,000 water-related illness in a year
- For a family of four using about 300 gallons per day that translates into one illness in about 3.5 years.

This level of acceptable risk requires that only 95% of water sent to the distribution system meet on-spec values.
Public Water systems campaigned against public notice rules as not useful

Testing for indicators instead of targets
- Coliform is not necessarily a pathogen
- Does not always indicate fecal contamination
- To the extent that it demonstrates a pathway, focus should be “find and fix”
- **Most waterborne disease comes from viruses which we do not test for anyway**

Viruses in groundwater: research showed that they survived, were infective, especially embedded in biofilms in chlorinated systems, where the strongest pseudomonas biofilms are resistant to chemical disinfectants

... And the Revised Total Coliform Rule was enacted...effective April 2016.
Does EPA/SDWA Protect Large Farm & Plant Water?

Does a 95% acceptable risk ensure food safety?

- EPA rules focus on **direct** consumption, drinking and household use patterns.
- A food manufacturing facility can pass contamination on
- Higher consumption of 10,000 – 500,000 gpd means more opportunity for contamination
- A food manufacturing facility has various temperature and moisture zones
- EPA rules don’t consider nutrients and micro-friendly conditions at farms and manufacturing facilities or conditions in transport and on the shelf.
- **In food safety terms**: this is the equivalent of 5 of every 100 gallons produced at a milk plant to be at risk
When the EPA “Reformed “ the Total Coliform Rule

...they forgot to ask the food manufacturers!

The entities potentially affected by the RTCR are PWSs that are classified as community water systems (CWSs) (e.g., systems that provide water to year-round residents in places like homes or apartment buildings) or non-community water systems (NCWSs) (e.g., systems that provide water to people in locations such as schools, office buildings, restaurants, etc.); State primacy agencies; and local and tribal governments. The RTCR applies to approximately 155,000 PWSs that serve approximately 310 million (M) individuals.
When the EPA “Reformed “ the Total Coliform Rule

...they forgot to ask the food manufacturers!

Food Processors and Manufacturers are not even on the radar!

And it was not much different in Pennsylvania!

The following Board members were present:
Penny McCoy, Pennsylvania Rural Water Association
E. Lee Koch, Pennsylvania Municipal Authorities Association
Daniel E. Standish, American Water Works Association
Mike Sienkiewicz, Pennsylvania Manufactured Housing Association
Felicia S. Dell, County Commissioners Association of Pennsylvania
Serena DiMagno, Water Works Operators Association of Pennsylvania
Dave Phillips, Pennsylvania Association of Realtors
Sean Sanderson, Pennsylvania Department of Community and Economic Affairs
Brion Johnson, Pennsylvania Infrastructure Investment Authority
Stanley Brown, Pennsylvania Public Utilities Commission
Thomas W. Essig, Jr., RCAP Solutions, Inc.
Susanne Gantz, Rural Utilities Service/Rural Development
Mary Roland, State Board for Certification of Sewage Treatment Plant and Waterworks Operators
Julie Kollar, The League of Women Voters of Pennsylvania

The following Alternate members were present:
James Steele, Pennsylvania Home Builders Association
Chip Bilger, Water Works Operators Association of Pennsylvania
Mary Gaiski, Pennsylvania Manufactured Housing Association
Sean Donnally, Pennsylvania Public Utilities Commission
Alexis Kricher, Pennsylvania Department of Community and Economic Affairs
Christine Caldara Piatos, The Center for Rural Pennsylvania
Robert H. Boos, Pennsylvania Infrastructure Investment Authority
Raquel Greene, USDA Rural Development
Erin Gannon, Pennsylvania office of Consumer Advocate
James Wheeler, Pennsylvania Association of Township Supervisors
Lisa Daniels, Pennsylvania Department of Environmental Protection

The following organizations were not represented:
Pennsylvania Association of Conservation Districts, Inc.
They forgot to ask the food manufacturers!

- Moving to total fecal coliform means that all the “general” microbial contaminants won’t trigger concern
- Moved away from Boiled water orders except in the most onerous cases of clear and present danger in the immediate future
- Corrective Action means “Find and fix” ; Level one assessment
- But the timing could mean that the food plant would be operating – unknowingly – with coliform in their water, in their packaging and in their product!
They forgot to ask the food manufacturers!

Pennsylvania Agriculture: PA's Leading Economic Enterprise

- 2,300 Food Processing Companies
- “Snack Food Capitol of the World”: $5.1 Billion/yr
- Meat, Poultry, Fish: $4.3 Billion/yr
- #1 State in canned fruit, veggie specialty products, potato chips
- Growing in Dairy and Eggs
• The FDA defers to the EPA on water related issues.
• You would think that food safety planning would have to consider the risk!
• But, here is what the Food Safety Modernization Act (FSMA) says:

For example, one of the six areas of sanitation is the safety of water used in food operations. In many facilities, the water is supplied by a municipal water authority that monitors the water and alerts its customers of any safety problems. ...a requirement for written procedures does not appear to be necessary.

The FDA assumes that a food facility will always know the status of its municipal water supply and does not need to consider it within its food safety plan.
Can rules designed to make water safe for individuals be applied to food manufacturing facilities?

- A PWS serving 10 households and a large manufacturing facility has the same testing requirements as a supplier that serves 10 households and no manufacturing facility.

- A system that has a positive total coliform sample can take more samples and stay under the threshold for public notice or violation, masking a potential food safety risk.

- Where public notification is required, samples reflect water already used: food manufacturers who used contaminated water would most likely have already shipped the product before they could take action.

*Using municipal water, a food manufacturer could conceivably inoculate their pipes with difficult to trace or treat microbes and go about business as usual.*
Once RTCR is fully implemented in 2016, there will be less information and less protection for food manufacturers & processors who use municipal water.

In a report presented to ASDWA in October 2013, an industry & regulatory task force on boil water advisories showed that less than 10-15% of over 508 notices reviewed for the first six months of 2010 would have been required under the new rules.

The study looked at the impact and costs and benefits of public notices and boil water advisories, using data about the impact on local immediate water illness.

The study did not consider outbreaks contributed by food manufactured in the communities subject to the boil water advisories.

When questioned on this point, the study’s primary author said that food manufacturers were not specified constituents by the 42 states or the 12 water utilities that participated.
How can Pennsylvania’s reputation for safe food be protected?

- Engineers and public water suppliers have no legal obligation to alert Pennsylvania’s food manufacturers and processors to the impact of these changes

- But should they?
• Food manufacturers think the water they are getting is good, and usually it is.
• Do food manufacturers understand the product you are giving them?
• A coliform hit may not change the status of drinking water, but it may change the status of food manufacturing water.
• What advice can you give them to protect themselves?
• **Should you be encouraging food manufacturers to add protection for their own use?**
The FDA’s Pasteurized Milk Ordinance currently required coliform-free water or continuous disinfection

- Industry hesitant to add chemicals because of flavor profile and pipe corrosion
- UV recognized as a substitute, based on 8 criteria

UV can provide 4 log virus with no chemical, no DBPs

- Effective instantaneous disinfection – on demand, no chemical by products, no off flavors, safe; Biofilm control with some types of UV; “Best Available Technology” for compliance with EPA Crypto rule
- Continuous recordkeeping means good documentation for preventive controls
PMO Compliant UV : 8 criteria

1. Dose equivalent to EPA 4 log virus RED (bioassay)
2. Time delay to assure Minimum dose (not average)
3. Frequent cleaning without disassembly
4. One Accurately calibrated sensor per lamp
5. In-line UVT meter
6. Flow diversion if dose is not achieved (no off-spec)
7. Flow control to assure minimum dose
8. Made from UV, water safe and food safe materials
Grade “A” Pasteurized Milk Ordinance

(Includes provisions from the Grade “A” Condensed and Dry Milk Products and Condensed and Dry Whey—Supplement I to the Grade “A” PMO)

2009 Revision

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration

ULTRAVIOLET LIGHT DISINFECTION OF WATER

The use of ultraviolet light (UV) to disinfect drinking water has been demonstrated to be an effective process that can inactivate microbes generally targeted by standard chemical disinfectants as well as pathogens that are resistant to other treatments such as Cryptosporidium. However, in the design of a water treatment system with UV light, the dairy farm, milk plant, receiving station or transfer station permit holder must exercise care to insure that all other requirements of this Ordinance relating to source, protection from contamination and, chemical and physical characteristics are met. UV disinfection does not change the chemical or physical characteristics of the water such as reducing or removing turbidity, mineral levels, or arsenic, etc., so additional treatment, if otherwise dictated, may still be required. Nor does UV treatment provide residual disinfection. Some supplies may require routine chemical disinfection, including the maintenance of a residual disinfectant throughout the distribution system, and there may continue to be a need for the periodic flushing and disinfection of the water distribution system. In addition, materials present in water can give rise to significant transmission difficulties so that it may be necessary to pretreat some supplies to remove excessive turbidity and color. Color, turbidity, and organic impurities can interfere with the transmission of UV energy and may decrease the disinfection efficiency below levels required to insure the destruction of pathogenic organisms. In general, color and turbidity measurements do not provide an accurate measure of their impact on UV disinfection efficacy. UV transmissivity (% UVT) multiplied by time measures disinfection efficiency. As a result, an in-line ultraviolet transmissivity (UVT) analyzer is needed to assure that the proper dose is provided on a continuing basis; and it may be necessary to pretreat the water supply to assure consistent water quality.

The use of UV to meet the bacteriological requirements of the PMO is acceptable provided the equipment used meets the criteria described herein. Water systems that are within the scope of the U.S. Safe Drinking Water Act as amended and 40 CFR Part 141, or State programs that have adopted these regulations shall be regulated under this Act and these regulations. Individual water systems that are not regulated under this act and regulations may be continuously disinfected using UV light based technologies provided the following criteria are met.

Criteria for the Acceptability of a UV Disinfection Unit:
1. When used to disinfect water to potable drinking water standards, UV light shall be applied so that the entire volume of water receives at least the following dose: UV at 2,537 Angstrom (254 nanometers) at 186,000 microwatt-seconds per square centimeter or equivalent to achieve an EPA log virus reduction equivalent dose.
2. A flow or time delay mechanism shall be provided so that all water moving past the flow stop or divert valve receives the minimum dose required above.
3. The unit shall be designed to permit the frequent cleaning of the system without disassembly of the unit and shall be cleaned often enough to ensure that the system will provide the required dose at all times.
4. An accurately calibrated UV intensity sensor, properly filtered to restrict its sensitivity to the 2,500-2,800 Angstrom (250-280 nanometers) germicidal spectrum, shall measure the UV energy from the lamps. There shall be one (1) sensor for each UV lamp.
Pennsylvania Recognizes Hydro-Optic™ UV

- In the State of Pennsylvania Hydro-Optic UV is recognized for providing 4 log virus credit
- It can achieve 4 log disinfection before the first customer without the need to add more chemicals
- Provides instant virus disinfection with no threat of DBPs
- Complies with the Safe Drinking Water Act and provides 100% safe water, inactivating also the resistant microorganisms that chemicals can’t kill
- Doesn’t change the water taste and odor
- More that 20 units operating in Pennsylvania under PADEP and PDA
What does compliance look like? An Example

- This achieves the minimum dose with dose uniformity with Total Internal Reflection (TIR) principle used in fiber-optics.
What does compliance look like? An Example

- Effective way of “recycling” the UV photons
- No low dose tracks – pathogens cannot escape
- Maintains minimum dose in real time
- Medium Pressure polychromatic technology reduces biofilms through quorum sensing, prevents microbial repair by disabling repair enzymes, efficient in any water temperature
a. Integrated sensor continuously monitors UV lamp intensity

b. UVT sensor continuously monitors water quality for UV transmittance

- Lamp responds automatically to real time sensor readings
- External flow meter transmits water flow rate data
  - The required UV dose is maintained at all times
  - Only the dose you need
  - Most efficient use of UV energy: lower energy consumption, longer lasting lamps

- Calibration utilities and reporting document the control system
- Ultrasonic Cleaning without disassembly maintains system operational reliability
Push-of-the-button generated regulatory reports
Water receives at least the minimum validated RED (Reduction Equivalent Dose); the system displays current readings and records them.
Galliker’s Dairy – Pasteurized Equivalent Water

- Galliker’s produces: milk, chocolate milk, ice-cream, juices and teas.
- Atlantium’s unit is a cost-effective and reliable solution for pasteurized equivalent water
- >95% saving in energy consumption
- Flow through, on-demand operation – constant availability of pasteurized equivalent water
- Water source: treated municipal water (17% of the time, HPC)
- Atlantium water is used for flushing lines between different product production runs (at 90 GPM)
- Water circulates constantly at 12 gpm
- Atlantium Appendix H software is PMO compliant requirement. The software sends alarms and signals to valves, sensor calibration utilities, monitoring and tracking and exception reporting
- Pasteurized equivalent water in compliance with PMO 2009 criteria
- Replaces costly heat process
- HTST pasteurization uses approximately 150 kW per hour
- Atlantium unit uses only 3kW per hour for pasteurized equivalent water
- Fully automated pasteurization: minimal manpower support
- Pasteurized water on-demand: re-task storage tanks
Lots of UV Applications: Reclaim & Save Water

- Reduce/eliminate chemicals; Automated system does “automatic proportioning”
- Reduce CIP costs, need for aggressive treatment
- Control Algae, pseudomonas and other microbes that resist chlorine, chemicals
- Fight biofilms and its causes, excreted Extracellular Polymeric Substances (EPS) that maintains the biofilm structure.
- When measured by a Robbins Device in a plant distribution system, after 4 months, clear impact
- Quorum sensing mechanisms may be interrupted.
- Saves on membrane replacements, 15% more performance from the same membrane

![EPS Thickness Graph](image)

- EPS Thickness
- UV treated vs No UV treatment
- EPS with UV
The Goods News: The quality of drinking water in the US has provided a broad sense of security to the public because the risk of contaminated drinking water getting an individual sick is very low.

The Bad News: Fine if you drink it but just because it is safe to drink does not mean it is safe for other purposes, like food manufacturing.

Bottom line/Take Home Message:

- Food manufacturers in Pennsylvania need to assess what the RTCR means for their incoming water and their food safety plans
- Encourage them not to wait until after the first food illness outbreak... will they want to blame it on you?
- Prevention is worth much more than a “cure”
- UV can provide a food-safe solution
Thank You

Atlantium Technologies Ltd.
Har Tuv Industrial Park
POB 11071, Israel 99100
Tel: +972-2-992 5001
Fax: +972-2-992 5005
info@atlantium.com
www.atlantium.com