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RE: Portland Water Bureau LT2 Rule Six-Year Review Comment Submittal

Portland Water Bureau (PWB) appreciates the opportunity to provide comments to the United States Environmental Protection Agency (EPA) on topics related to the six-year review of the LT2 Rule. PWB has attended the three public meetings held by EPA between December 2011 and November 2012 to gather stakeholder input for the six-year review. Our comments are listed below by topic.

1. Method 1623.1

PWB advocates that the Tier 1 validation option for single-laboratory modifications be retained in Method 1623.1 if this method is adopted as part of the LT2 Rule review. PWB believes that the deletion of the Tier 1 validation may impact data quality and hinder the ability of some public water systems to monitor effectively to protect public health.

On June 28th, 2012, EPA announced the approval of Method 1623.1 as an alternative to Method 1623 (USEPA 2005) for the detection of the waterborne parasite *Cryptosporidium* (77FR38523-38530). EPA Method 1623.1 (USEPA 2012) is a modification of Method 1623 which includes filter elution with the addition of sodium hexametaphosphate (NaHMP) and a bead pellet wash step during the IMS procedure. The expedited approval of Method 1623.1 allows public water systems required to monitor for *Cryptosporidium* to use either the established Method 1623 or the revised Method 1623.1.

Method 1623 is a performance-based method which allows the use of alternative components not already listed in the method if equivalent or better performance can be demonstrated. To confirm the acceptable performance of a modified version of Method 1623 for use in a single laboratory, the laboratory must validate the modification according to Tier 1 of EPA's performance-based measurement system. The Tier 1 validation has allowed single laboratories a great amount of flexibility to adopt modifications to Method 1623 to overcome matrix interferences that are unique to a particular source water (or not yet recognized in other source waters) or to address a special need of a client utility (e.g., sample volume >50 L).

Unfortunately, Method 1623.1 eliminates the option of the single-laboratory Tier 1 validation, raising the concerns outlined below about the impact of this decision on the ability of laboratories to make modifications that support data quality.

- While Method 1623.1 appears to provide some improvement in recoveries for some matrices, this method does not improve recoveries for all matrices at all times.¹ A variety of phenomena, some of which are seasonal, have been reported to inhibit *Cryptosporidium* recovery using filtration/immunomagnetic separation/fluorescence assay techniques. Method 1623.1 will not address all of these issues. Therefore, the need for single-laboratories to develop modifications to address unique matrix interferences will remain even if Method 1623.1 is adopted as the required method.
- Under Method 1623.1, the only option available to adopt such modifications would be the Alternative Test Procedure (ATP). Not only is the ATP more burdensome in terms of effort, time, and cost, but it also unnecessarily requires a single-laboratory to validate a method intended for use on a single matrix using several labs and various source waters. The ATP process in these cases will be an impediment to validate modifications that are intended to improve recovery and generate higher quality data. There is not even a guarantee that a modification developed to overcome poor recoveries in one matrix will work for different matrices, since the underlying causes could be different.

The most prudent approach to ensure that laboratories and utilities have the flexibility to adopt modifications that address unique matrix issues is to retain the Tier 1 validation procedure for single-laboratory modifications. If EPA's goal is to guard against the use of sample processing shortcuts or cost-cutting that could compromise data quality, there are more practical approaches than by deleting the option of a Tier 1 validation for single-laboratory modifications.

2. Genotyping

PWB advocates that EPA revise the source water monitoring requirements of the LT2 rule to incorporate recently developed genotyping methods for any detected *Cryptosporidium* oocysts to provide more relevant public health information to public water systems, health agencies, and water customers.

With the exception of the rabbit genotype outbreak in England², only *C. parvum* and *C. hominis* have been identified as causes of waterborne outbreaks of cryptosporidiosis.³ Genotyping of human clinical specimens found that 99.9% of samples contained three species (*C. parvum*, *C. hominis*, and *C. meleagridis*).⁴ To place this in perspective, there are over 16 different *Cryptosporidium* species and 40

¹ See the memorandum submitted to U.S. EPA by PWB titled "Preliminary Results of Side-by-Side Comparison of *Cryptosporidium* Recovery from Bull Run Raw Water Using EPA Method 1623, Method 1623.1, and the ASI/PWB Precoat Method" (December 28, 2012).

² In 2008, an outbreak of cryptosporidiosis in Northamptonshire, England was traced to a rabbit carcass removed by the water company from a tank at the water treatment plant. Chalmers et al. 2009. *Cryptosporidium* sp. Rabbit Genotype, a Newly Identified Human Pathogen. *Emerg. Infect. Dis.* 15(5):829-830.

³ Xiao and Ryan. 2008. Molecular Epidemiology. In *Cryptosporidium and Cryptosporidiosis*. Boca Raton, Fla.: CRC Press.

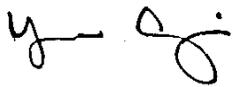
⁴ Leoni et al. 2006. Genetic analysis of *Cryptosporidium* from 2414 humans with diarrhoea in England between 1985 and 2000. *J. Med. Microbiol.* 55(6):703-707.

genotypes that are currently recognized.⁵ These data strongly suggest that all *Cryptosporidium* oocysts detected by Method 1623 do not represent the same level of public health risk, particularly in protected watersheds with no significant sources of *C. parvum* or *C. hominis*. Recent molecular work indicates a strong host adaptation for *Cryptosporidium* and has provided evidence that most wildlife do not carry species of *Cryptosporidium* that infect humans.^{6,7}

Given significant advances in molecular science since the initial development of the LT2 Rule, PWB encourages EPA to integrate these advances in the revision of the LT2 Rule. Genotyping is now a fairly routine technique, with well established protocols (WaterRF Project #4099: *Development and Standardization of a Cryptosporidium Genotyping Tool for Water Samples*). Many well respected scientist studying waterborne *Cryptosporidium* advocate the importance of applying genotyping techniques along with Method 1623. This approach will provide valuable information for evaluating the health risk of waterborne *Cryptosporidium* and for watershed management.

Thank you for the opportunity to comment on the LT2 Rule six-year review.

Sincerely,

A handwritten signature in black ink, appearing to read 'Yone Akagi', with a stylized flourish at the end.

Yone Akagi
Water Quality Compliance Manager
Portland Water Bureau

⁵ Xiao and Ryan. 2008. Molecular Epidemiology. In *Cryptosporidium and Cryptosporidiosis*. Boca Raton, Fla.: CRC Press.

⁶ Xiao et al. 2002. Host adaptation and host-parasite co-evolution in *Cryptosporidium*: implications for taxonomy and public health. *Int. J. Parasitol.* 32(14):1773-1785.

⁷ Zhou et al. 2004. Genotypes of *Cryptosporidium* species infecting fur-bearing mammals differ from those of species infecting humans. *Appl. Environ. Microbiol.* 70(12):7574-7577.