Title: WHITE PAPER
Essential Information to Consider in the 6-Year Review of The Long Term (2) Enhanced Surface Water Treatment Rule (LT2)

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I. Purpose and Objectives.

This white paper has been prepared to contribute the perspective of this academic researcher to the EPA mandatory 6-year review of the Long Term (2) Enhanced Surface Water Treatment Rule (LT2). This perspective is the product of long-established and continuing specialized and comprehensive experience with *Cryptosporidium* and *Giardia* in water. Active involvement in every aspect of information development relevant to the regulation of *Cryptosporidium* and *Giardia* in water and their significance to public water supply has provided the author with background both unique among experts in this field and directly relevant to major elements of the LT2 regulation that are the subject of this review. Examining the existing regulation and its current status in light of the data collected in LT2 Stage 1 monitoring, and having examined in detail the position of the USA regulated public water supply (PWS) community with respect to the structure and implications of the existing regulation, it is clear that both technical and procedural aspects of the regulation require re-examination. The purpose of this white paper is specifically to illuminate both technical and procedural aspects of the regulation that have compromised its ability to provide appropriate guidance for effective and efficient management of *Cryptosporidium* and *Giardia* in public water supplies.

Specific objectives of this white paper are: 1) to bring specific technical and procedural issues to public attention; 2) to stimulate discussion relevant to both technical and

procedural issues; and 3) to suggest a course of action capable of providing an improved basis for protecting public health in relation to *Cryptosporidium* and *Giardia* in water.

II. USEPA LT2 6-Year Review Framework.

As stated on the USEPA website, http://water.epa.gov/lawsregs/rulesregs/sdwa/lt2/publicmeeting.cfm: "*To initiate LT2 regulatory review, EPA hosted public meetings on December 7, 2011 to discuss* Cryptosporidium *analytical methods and the source water monitoring data from LT2, and on April 24, 2012, to discuss information that may inform the regulatory review of the LT2 Rule uncovered finished water reservoir requirement. On November 15, 2012, EPA hosted a public meeting concerning monitoring, binning and microbial toolbox information.*

As part of the review, EPA will assess and analyze information regarding occurrence, treatment, analytical methods, health effects and risk from all relevant waterborne pathogens to evaluate whether there are new or additional ways to manage risk while assuring equivalent or improved protection. The Agency plans to complete its review of the LT2 Rule no later than 2016."

In a presentation at the April 24, 2012 public meeting (Miller, 2012) the EPA further amplified on the review framework quoting statutory, regulatory, and Executive Order sections:

- E.O. 13563 states that periodic review is to determine if regulation should be modified, streamlined, expanded, or appealed to make (it) more effective or less burdensome in achieving (its) regulatory objectives;
- EPA emphasized that it will seek to evaluate effective and practical approaches to maintain or enhance protection of water provided to consumers by public water systems (PWS);
- EPA observes that costs and benefits cannot be used in relation to treatment techniques required for control of *Cryptosporidium*;

Further, EPA identified "Technical Review Elements" to be included in the LT2 6-year review, stating specifically the overall goal – review of technical elements to determine if the basis for the current regulation including the MCLG and Treatment Technique (TT) has changed and if it would be appropriate to consider revisions that would maintain or enhance public health protection:

- health risk;
- analytical methods;
- treatment technologies/techniques;
- occurrence; and
- implementation-related items

The context for examining these technical review elements described by EPA is comprised of the primary LT2 requirements: 1) Source water monitoring; 2) Treatment requirements (including toolbox options) associated with bin levels resulting from source water monitoring; 3) Requirement pertaining to finished water reservoirs; and 4) Disinfection profiling and benchmarking (for systems planning to make disinfection changes. Information and analysis presented in this white paper is principally directed to source water monitoring provisions of the regulation which form the basis for identifying the relative risk associated with each regulated PWS and any risk management procedures that may be required.

Finally, EPA identified seven primary questions pertaining to the LT2 review:

1. What data/information informs the health risk for LT2?
2. What is the national occurrence of *Cryptosporidium* in source waters?
3. What is the impact of Method 1623 improvements on measured occurrence?
4. To what extent does the binning structure identify high risk systems?
5. How effective are the toolbox options and how much mitigation credit is warranted?

6. What are the best strategies to assess and address risks from uncovered finished water reservoirs? And
7. How effective are the current disinfection profiling and benchmarking requirements?

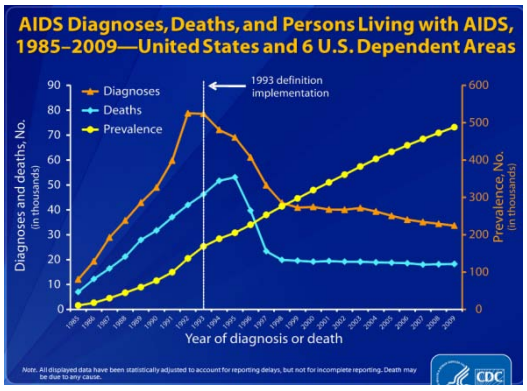
In this white paper information will be identified that is either new or apparently not previously taken into account pertaining only to the first four questions. No attention is devoted to items 5, 6, or 7. The information and analysis is presented below in effort to suggest improved monitoring procedures that will result in data forming the basis to improve both regulatory and PWS ability to quantify and manage risk associated with *Cryptosporidium* and *Giardia* in source water. This will improve public health protection making the regulation more effective and less burdensome.

III. LT2 Review--Technical Issues

A. Health Risk Information. The perspective on health risk relative to *Cryptosporidium* has evolved over the period of development and implementation of LT2. When first promulgated in 1989, the Surface Water Treatment Rule (SWTR) referred to *Giardia*, virus, and *Legionella* as pathogens requiring control, USEPA, 2005a. *Cryptosporidium* was found for the first time in surface water, Ongerth and Stibbs, 1987, and was becoming recognized as a waterborne pathogen of particular significance following outbreaks in Carrolton GA (1987) and at Swindon in Oxfordshire, England (1988). Particular concern for *Cryptosporidium* was developing as a product of three special characteristics: 1) recognition that no chemotherapeutic agents effective against cryptosporidiosis have been found; 2) the role of cryptosporidiosis in the early stages of the AID's epidemic that came to light in the mid 1980's; and 3) recognition that it was not inactivated by practical levels of oxidizing disinfectants. These factors along with additional waterborne outbreaks, notably in Milwaukee, WI, contributed to taking a highly conservative view of *Cryptosporidium* as a waterborne pathogen in the development of succeeding generations of the SWTR leading ultimately to LT2.

At present, 2013, it is reasonable to reconsider the relative importance particularly of *Cryptosporidium* and *Giardia* in light of developments since the decade of the 1990's including three main factors: 1) Chemotherapeutic regimens have been developed for HIV and opportunistic infection management resulting in the virtual elimination of mortality once associated with cryptosporidiosis; 2) The roughly comparable record of waterborne outbreaks due to both *Giardia* and to *Cryptosporidium*; 3) USA epidemiologic data compiled by the CDC; and 4) development of effective disinfection for *Cryptosporidium* by UV irradiation.

1. In the first 10 years of the AIDs epidemic, 1983 to 1993, effective chemotherapy for control of HIV infections was not available resulting in high mortality due to opportunistic infections. In that period, infections with *Cryptosporidium* accounted for ca. 5% of AIDs mortality. As chemotherapeutic regimens for control of HIV improved beginning in the mid 1990s AIDs mortality due to all causes began to fall (Figure 2a and 2b). By 2000 opportunistic infections



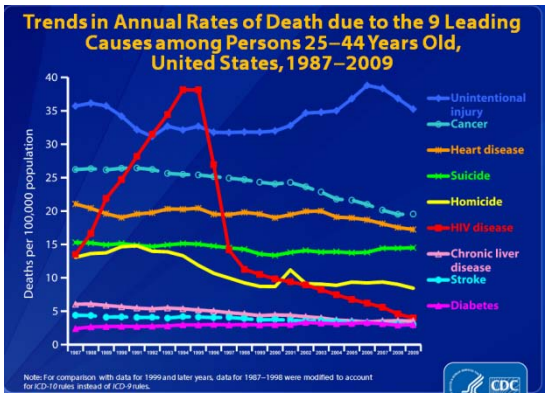


Figure 1a and 1b. CDC summaries of USA AIDS deaths, 1985-2009 (1a, from: http://www.cdc.gov/hiv/pdf/library_slideSet_Greenberg_Plenary.pdf), and death rates due to leading causes among persons 25-44, 1987-2009 (1b, From: http://www.cdc.gov/hiv/ppt/statisticssurveillance_HIV_mortality.ppt).

had become controllable so that AIDs deaths due to opportunistic infection were virtually eliminated. In other immune impaired groups subject to opportunistic infection such as transplant patients and persons undergoing cancer chemotherapy manipulation of suppressive treatments can be altered to allow recovery of immune function that is effective for clearance of *Cryptosporidium* infections. Accordingly, cryptosporidiosis is no

longer of such special concern, little different from waterborne enteric viral infections that cause similar pathology, higher incidence, and likely the most common cause waterborne outbreaks in the US, USEPA, 2005b, Hall et.al., 2013.

2. According to CDC records from 1997 to 2005 (USEPA, 2005) 16 waterborne outbreaks occurred attributed to *Giardia* and 9 water related outbreaks were attributed to *Cryptosporidium*. Without any effort to estimate the relative importance of the two pathogens as waterborne agents it is clear that both are amply capable of causing wide-spread infection in the water consuming public if presented the opportunity. Earlier literature can be cited to document community-wide waterborne outbreaks due to both agents.

3. Accumulation of epidemiologic data by CDC over the period of reporting records, 1993 to 2012, *Giardia* infections in the USA population have occurred at rates ranging from 8 to 14/100,000 per year, averaging about 8/100,000 per year over the last 10 years, Figure 1a, Yoder et al, 2012. With comparable data beginning in 1995 *Cryptosporidium* infections in the USA population have occurred at rates ranging from 1 to 4.5/100,000

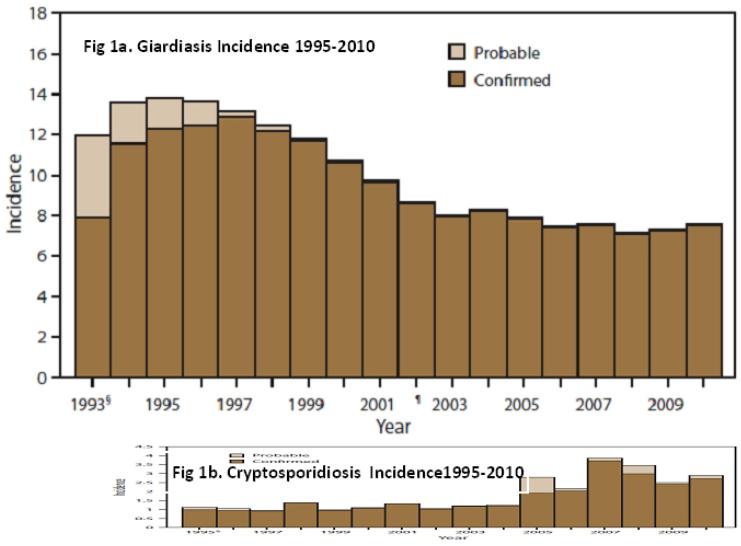


Figure 1a and 1b. CDC summaries of USA giardiasis (Fig 1a) and cryptosporidiosis (Fig 1b) incidence rates/100,000 per year, 1993-2010, from Yoder et al 2012a & Yoder et al 2012b. Note: Vertical scale of Fig 1b reduced to the same as Fig 1a.

per year, averaging about 2.5/100,000 per year over the most recent 5 years, Figure 1b. According to these data *Giardia* infections occur in the USA population at more than 3 times the rate of *Cryptosporidium* infections. Additional comparison by qualified medical professionals should be solicited regarding the relative significance of typical cases of cryptosporidiosis and of giardiasis. Although *Giardia* infections are characteristically treatable whereas those of *Cryptosporidium* are not, description of typical case characteristics for *Giardia* infections appear to be more significant than those of *Cryptosporidium* (CDC, 2013a and 2013b)

4. The effectiveness and application of UV irradiation for control of *Cryptosporidium* is well documented elsewhere.

B. National Occurrence of *Cryptosporidium* (and *Giardia*) in Source Water. Several factors and sources of information must be considered in effort to understand the "occurrence" of *Cryptosporidium* and of *Giardia* in any geographic area such as the USA.

B1. <u>The factors include</u>: a) the sources, distribution, and fate of *Cryptosporidium* and *Giardia*; b) selective vs comprehensive monitoring; c) the difference between "occurrence" and an objective measure of concentration; d) independent means of understanding & corroborating environmental measurements.

B2. Sources of information include: a) Data published in peer-reviewed literature; b) Data produced in response to the Information Collection Rule (ICR) and the Supplemental Survey (ICR SS); and c) most recently the LT2 stage 1 data.

B 1. Factors Pertaining to Cryptosporidium and *Giardia* Occurrence-What and how to monitor.

a. Sources of both *Cryptosporidium* and *Giardia* that ultimately find their way into water are similar and over-lapping...the feces of infected animals including humans. A description of factors affecting the sources, fate, and distribution are provided in an (as yet) unpublished

manuscript, Ongerth, 2012. Essential features include: a) virtually all animals including humans (in sewage discharges), both herbivores and carnivores, from small rodents to large wild (e.g. bear, deer, elk) and domestic animals (e.g. beef & dairy cattle, pigs, sheep) are continuous sources; b) these sources are present in appreciable numbers in every watershed throughout not only the USA but world-wide. Accordingly, *Cryptosporidium* and *Giardia* presence must be considered not only ubiquitous but continuous. Any monitoring data must be examined with knowledge of sources in the specific watershed in mind.

b. Factors pertaining to comprehensive vs. selective monitoring for *Cryptosporidium* and *Giardia* require further discussion:

i) The classical public health principle applied to monitoring the microbial quality of water is to favor monitoring of broad and consistently present organism groups that indicate the presence of fecal contamination. The development of this "indicator organism" principle was based historically on experience with epidemic pathogens causing typhoid and cholera;

ii) Ability to monitor for specific pathogens is complex and demanding while monitoring for indicator organisms is more efficient due to their relatively high numbers and consistency of appearance in addition to the relative simplicity and low cost of the tests;

iii) Requirements for consistent effectiveness of water treatment dictate that treatment and operation capable of meeting indicator organism standards also provide effective control of all waterborne pathogens that may be present. This has been shown to apply specifically to *Cryptosporidium* and *Giardia*;

iv) Both *Cryptosporidium* and *Giardia* have been found to include numerous species and subtypes capable of human infection (Fayer, 2011) ...and additions to the list continue to be found (Chalmers, 2011). Yet, no one knows how to identify the specific genetic determinants of the species or subtypes that confer ability to cause disease, let alone a waterborne outbreak, Bouzid et al, 2013.

v) The main *Cryptosporidium* species for example, that are associated with human infection, *C. parvum* and *C. hominis*, are the most widely distributed and appear to account for the largest majority of organisms found in surface water.

vi) Conditions that affect the apparent viability of *Cryptosporidium* and *Giardia* at the point of monitoring are not well-defined and undoubtedly will vary with transit time and conditions.

The logical conclusion of items bi) through bvi) above, citing Murphy's Law and the precautionary principle, is that monitoring will be of greatest value to guide watershed management and water treatment operation if it is conducted to identify the maximum potential that could be present under adverse circumstances. Accordingly, monitoring should target all *Cryptosporidium* oocysts and *Giardia* cysts using the immunofluorescent agents available for detection of the broadest range of species, and should not discriminate on the basis of apparent viability.

c. Of critical and over-riding importance to all quantitative understanding and interpretation of *Cryptosporidium* and *Giardia* in water, is the fact that raw numbers of organisms resulting from superficial analysis of water samples provide only the lowest level qualitative indication of organism occurrence. Any quantitative interpretation absolutely and irrevocably requires measurement of recovery efficiency, specifically relevant to the sample(s) providing the data, and use of the measured recovery efficiency to calculate concentration in each and every sample.

Reasons for this requirement are described in detail in a recent publication, Ongerth, 2013a. Lack of recovery efficiency measurements and corresponding concentration data have undoubtedly severely compromised ability to describe and elucidate potentially useful correlations between *Cryptosporidium* and *Giardia* concentrations and other more easily monitored water quality parameters. Although many references in the literature

have explored such potential relationships the most common result has been the lack of apparent relationships. This should be no surprise in light of the significant systematic variation in recovery efficiency at any individual sampling site and its independence from occurrence, Ongerth, 2013a. Exploring the potential relationships between measured concentrations of *Cryptosporidium* and of *Giardia* and other water quality parameters (e.g. turbidity, coliforms, *E. coli*) should be a high priority of future large-scale monitoring.

d. Independent means of corroborating environmental measurements are a widely used tool for establishing the most likely interpretation of data resulting from application of complex analytical technology such as Method 1622/23. One such independent means consists of using information available in the watershed surveys required under the ESWTR to compute likely watershed production rates for oocysts and cysts using typical flowrates at a given sampling point with information on land use and potential contamination sources. Such estimates can be compared to previously published data on *Cryptosporidium* (Hansen & Ongerth, 1991), and *Giardia* (Ongerth, 1989) production rates per mi^2/day, (see also, Ongerth, 2013b).

B 2. Sources of data on *Cryptosporidium* and *Giardia* in water.

a. <u>Published Literature Data</u>. Only three previously published papers in peer-reviewed journals include data on *Cryptosporidium* and *Giardia* expressed as true concentration: a) Ongerth and Stibbs, 1987; Ongerth, 1989; and Hansen and Ongerth, 1991. These sources describe *Giardia* and *Cryptosporidium* concentrations in high-quality protected watersheds used as unfiltered water supplies for Seattle and Tacoma as well as other lower quality sources, e.g. Figure 3. In water from the highest quality protected watersheds, *Giardia* concentration averaged < 0.1/L while *Cryptosporidium* concentration

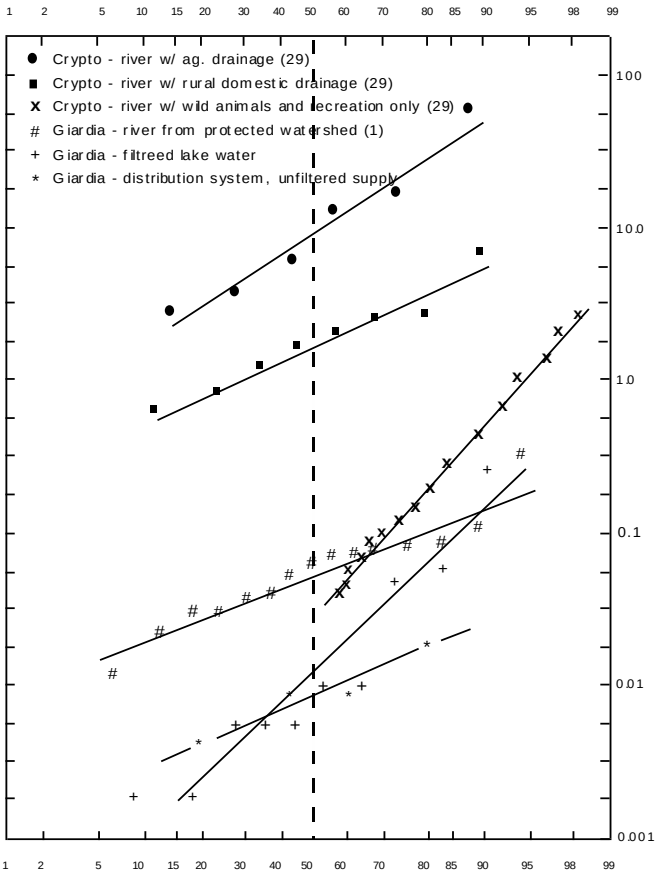


Figure 3. Cumulative frequency distributions of *Giardia* cyst and *Cryptosporidium* oocyst concentrations defined in studies of river water, filtered lake water, and distribution system samples. (Ongerth 1994, unpublished)

averaged < 0.05/L but were significantly more variable. *Cryptosporidium* concentrations in water from areas having dairy farming had average concentrations averaging up to 10/L. These data provide a baseline for estimating minimum concentrations of *Cryptosporidium* and *Giardia* likely to be found in highest quality surface waters along with information on the range of variability in concentrations from these example watersheds.

Other published reports are valuable to indicate the scope and breadth of *Cryptosporidium* and *Giardia* occurrence in sources of water supply across the US, but not for quantitative comparison. An example of *Cryptosporidium* and *Giardia* occurrence data resulted from a survey sponsored by the AWWA-RF (LeChevallier et al, 1991a, 1991b). Samples of ca. 100 L collected from 66 surface water locations in 14 US states and 1 Canadian province were analysed by the ASTM/ICR method. *Giardia* cysts were found in 69 of 85 samples ranging

from 0.04 to 66 cysts/L (raw numbers not adjusted for recovery). *Cryptosporidium* oocysts were found in 74 of 85 samples, ranging from 0.07 to 484 oocysts/L (raw numbers not adjusted for recovery). These data are important in describing the virtually universal distribution of *Cryptosporidium* and *Giardia* in surface water supplies across the United States. Other similar data are of minor importance compared to the ICR SS and LT2 data sets described below.

b. ICR SS Data. Data on *Cryptosporidium* and *Giardia* in surface water were collected under the ICR and ICR SS. The ICR will not be discussed here due largely to the less reliable method of analysis used prior to introduction of the current Method 1622 and 1623 used in the ICR SS. Analysis of the ICR SS data by EPA and contractors, represented in detail in the Occurrence and Exposure Assessment, USEPA 2005a and appendices, focussed principally on forecasting results of LT2 monitoring under consideration at the time. Although superficial analysis of data from individual sites was made, little attention was paid to the results. A detailed examination of individual site data has been made and submitted for potential publication, Ongerth, 2013c.

Observations of major importance included in the site-by-site analysis of the ICR SS data include: 1) Both *Cryptosporidium* and *Giardia* are present at detectable levels in surface waters from watersheds having representative characteristics from relatively undeveloped to highly developed and having a corresponding range of organism sources; 2) Occurrence of both organisms characterised by annual sets of measurements conforms to approximately log-normal distributions that describe both the apparent level (neglecting recovery measurement) and the degree of variability, Figure 4; 3) Both organisms appear to be present continuously at levels spanning approximately 2-3 orders of magnitude; 4) The distributions of both organisms were truncated by the limit of detection due to the limited 10 L sample volumes and Matrix Spike (MS)-measured recoveries;

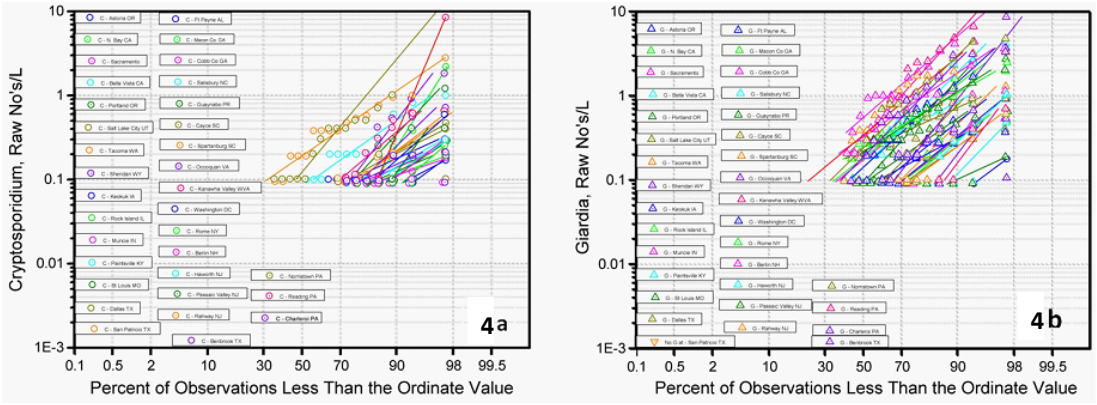


Figure 4a & 4b. Cumulative frequency distributions of ICR SS *Cryptosporidium* occurrence (4a) and *Giardia* occurrence (4b), both raw no's/L.

c. <u>LT2 Stage 1 data</u>. Measurement of the occurrence of only *Cryptosporidium* was required of nearly 1700 surface water-using PWS across the US under LT2 during the period from 2006-2010. Each PWS serving >10,000 collected at least 24 consecutive monthly samples for analysis by Method 1622. The resulting data, with some significant exclusions (e.g. grandfathered data) were made available in mid 2011. The EPA provided a simple summary of results in a public meeting presentation, Messner, 2011, indicating: a) 93% of nearly 45,000 sample analyses were zeros (i.e. no organisms were found); b) no organisms were found in any of the minimum of 24 consecutive monthly samples taken at more than half of the >3000 sampling sites included; d) The average *Cryptosporidium* occurrence level described by the LT2 data was about 1/5 of that described by *Cryptosporidium* data collected in the ICR SS. No more detailed analysis of the LT2 data by EPA has been published as of mid 2013.

In effort to understand the LT2 data and implications for individual PWS the LT2 data were examined on an individual site basis, Ongerth, 2013a and 2013b. Observations of major importance included in the site-by-site analysis of the LT2 data include: 1) *Cryptosporidium* are present at detectable levels in surface waters from watersheds having representative characteristics ranging from relatively undeveloped to highly developed and having a

corresponding range of organism sources; 2) The raw occurrence data describe a spectrum spanning approximately 2-3 orders of magnitude, Figure 5; 3) *Cryptosporidium* occurrence

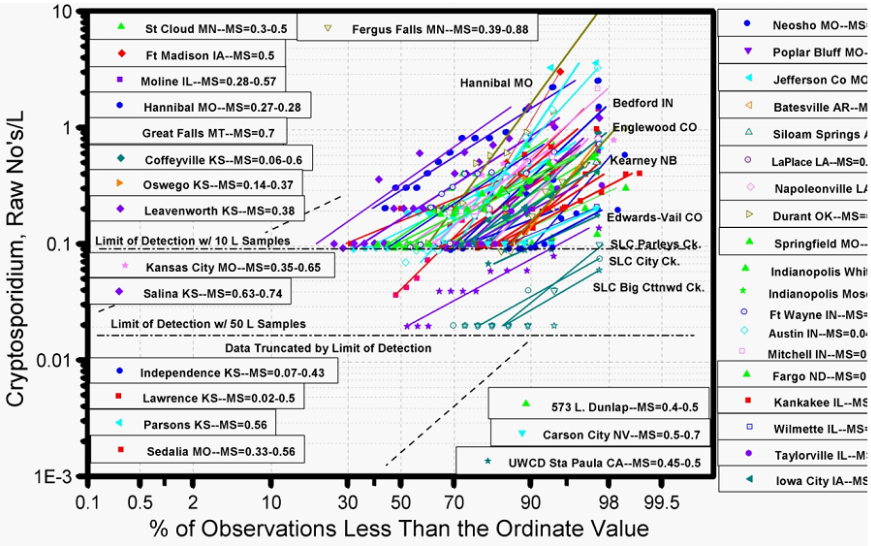


Figure 5. Cumulative frequency of LT2 *Cryptosporidium* occurrence at 50 representative sampling locations in regions across the USA, Ongerth (2012b).

characterised by annual sets of measurements conforms to approximately log-normal distributions that describe both the apparent level (neglecting recovery measurement) and the degree of variability; 3) Data collected by a limited number of PSWs having analysed samples of 20, 30, and 50 L volumes confirm that *Cryptosporidium* are present continuously although the distributions are truncated by the limit of detection due to limited sample volumes and Matrix Spike (MS)-measured recoveries.

C. Method 1623 Performance

1. In comparison to previous methods (e.g. ASTM, ICR) the USEPA Method 1623 provides significantly improved results.

2. Application of Method on an intensive nation-wide scale during a limited monitoring period presents major challenges for analytical laboratories.

a. Method 1622/1623 is a sophisticated and challenging laboratory procedure requiring not only skill on the part of the analyst but independent means of checking the validity of analytical results.

b. analytical volumes (numbers of samples contracted per unit of time (e.g. month) are not on-going but restricted to the regulation-specified time period (3-4 years)

c. sources of the samples are not always familiar to the analysts impairing feedback with the client

3. The matrix spike (MS) provision of Method 1622 and 1623 is not sufficient and is not applied to satisfy its intended purpose:

a. As written, the matrix spike provisions of the method are designed to permit taking matrix (source water) effects into account in measuring the recovery efficiency for *Cryptosporidium* and for *Giardia* in samples having specific matrix characteristics. This was not conceived as a quality control provision. The stipulation that only one MS need be analysed for every 20 samples or once per week does not adequately recognize the systematic variability in recovery efficiency and the major differences in recovery efficiency between sampling sites and between different time periods at the same site, Figure 6, Ongerth, 2013a.

b. The limited MS application prescribed in the existing Method 1622/1623 description was an accommodation included based on the judgement of authors that variability in recovery was more generically related to the Method (i.e. Method 1622/1623 vs. ICR method), without extensive data on which to base informed judgement; and believing that more frequent MS measurement would be prohibitively expensive.

c. Recently published analysis demonstrates that recovery efficiency must be measured with every sample to permit analytical results to be expressed quantitatively, Ongerth, 2013a. Further, current experience with preparation of pre labelled and reproducibly

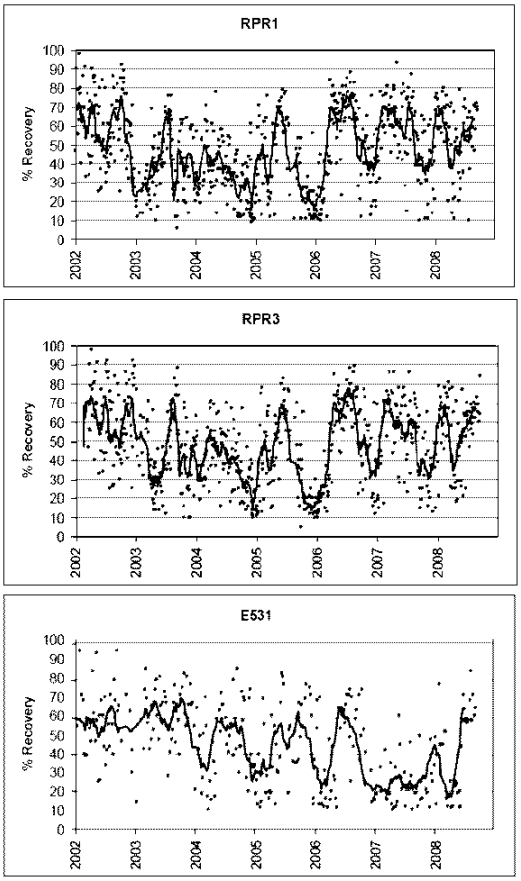


Figure 6. Cryptosporidium recovery efficiency by Method 1623 and moving averages at three sampling stations on a single water source in east-central New South Wales, (from Ongerth, 2013a).

counted seed applied to Method 1622 and 1623 analyses enables internal measurement of recovery efficiency with every sample at additional cost of 10-15% more than single sample unit cost.

4. In the vast majority of cases sample volumes of 10 L are too limited to be of any value. In most respects, analytical results of zero are of no practical value, particularly when essentially no samples at a given site are non zero. Such results can be avoided by preliminary analysis of larger volumes, e.g. 3-5 10 L samples collected from the candidate site at the same time and analysed as 10 L units along with measurement of recovery efficiency. The number of organisms found can be added and divided by the total volume analysed, all divided by the recovery fraction to give a preliminary estimate of concentration. The volume that must be analysed to provide at least a majority of non zero

analytical results can be refined depending on experience. For example, if large numbers of organisms are found consistently the sample volume can be adjusted accordingly (see Ongerth, 2013a).

D. Extent to which High Risk Systems have been identified.

1. Quantitative risk analysis and intuitive reasoning follow the basic principle that risk is directly proportional to the exposure and hence concentration...specifically at low concentration. Accordingly, as stipulated in the Agreement in Principle, PWS using water at increasingly higher *Cryptosporidium* concentration would be required to implement increasingly higher levels of control for *Cryptosporidium* specified in the ascending bin levels above bin 1.

2. EPA analysis of the ICR SS data suggested that only ca 15% of the 80 PWSs, surveyed had appreciable *Cryptosporidium* occurrence. Subsequently, analysis of the LT2 data suggested that only ca 4% or about 75 of 1600 surface water-using PWSs had *Cryptosporidium* levels exceeding bin 1. EPA interpretation of the ICR, ICR SS, and LT2 data, the above principle notwithstanding, suggested that a relatively small proportion of surface water source locations used by LT2-regulated PWSs would have *Cryptosporidium* "concentrations"... represented by raw numbers unadjusted for recovery...above the bin 1 level, i.e. > 0.075/L.

However, it should now be clear that the EPA ICR SS and LT2 data analysis did not recognize that the data actually describe a full spectrum of *Cryptosporidium* occurrence although highly compromised by the lack of recovery efficiency measurements, e.g. Figures 4a, 4b, and 5, Ongerth, 2013b and 2013c. If this later interpretation of the ICR SS and LT2 data is correct then the relation between occurrence/concentration and risk indicating treatment requirements needs to be reconsidered. If, according to the EPA interpretation of the data, only a small proportion of surface water sites exhibit higher

occurrence/concentration, it suggests that the occurrence of *Cryptosporidium* at higher concentration is due to some as yet unidentified threshold phenomenon or combination of circumstances. Furthermore, it suggests that the phenomenon or circumstances produce only a limited range of higher occurrence. These suggestions do not appear to have a logical basis. Knowledge of where and how *Cryptosporidium* (and *Giardia*) originate, what factors contribute to the quantity of their production, and how they are distributed in the environment all suggest that concentrations of these organisms in surface water should reflect the nature and extent of land use, principally related to the extent of animal populations and the nature and intensity of human activities in the watershed. The hydrologic characteristics of watersheds in the USA form a fixed spectrum from relatively dry to relatively wet following geographic and climate driven factors. The hydrologic characteristics drive the transport processes from organism fecal sources, including urban runoff and sewage discharge, into receiving waters resulting in measurable concentrations, Ongerth 2012. This logical framework supports the concept that *Cryptosporidium* and *Giardia* should "occur" in surface waters anywhere (not only the USA) over a spectrum that is measurable and not unlimited, i.e., between some upper and lower limits. The spectrum would correspond to a risk spectrum with a corresponding risk management scale represented by the four bins.

3. As described above, the ICR SS and LT2 data as interpreted by EPA do not describe a logical spectrum of occurrence/concentration and thus cannot have identified the PWSs at higher risk. As interpreted by considering individual site data suggesting occurrence of *Cryptosporidium* covering a spectrum, the occurrence spectrum is not well-aligned with the bin levels representing the risk management structure. The lack of recovery efficiency measurements that specifically correspond to *Cryptosporidium* measurements has contributed to anomalous positions of individual site occurrence data relative to their true positions in the spectrum, e.g., Figures 4a, 4b, and 5, Ongerth, 2013b and 2013c.

4. Presentation of individual site data in the form of cumulative frequency plots illustrates that risk to a PWS related to *Cryptosporidium* (and *Giardia*) is not due to the "level" alone, Ongerth 2013a. This method of presentation illustrates graphically that organism occurrence at any sampling location is not static but occurs over a measurable range and that a broader range represented by a steeper slope (equivalent to a greater standard deviation) presents a greater risk to the PWS than does a more narrow range. It is important to the PWS to know not only how broad the range of organism occurrence is (how steep the slope) but in what period of the annual cycle the highest concentrations are likely to occur. The current approach expressed in LT2 using a running annual average "concentration" needs to be reconsidered to provide the most useful information to PWS.

Related Technical Issues

1. As mentioned above (Item 2) zeros seem to have gained some "respectability"
   a. Some "experts" persist in asserting that a zero means absence
   b. EPA at least tacitly accepts zeros as a valid result

2. The intuitive risk spectrum does not appear to match data from sampling and analysis in the LT2 (or ICR SS) data
   c. 10 L samples are too small
   d. numbers are not accompanied by recovery measurements
   e. comparing numbers w/o recovery correction is apples & oranges

3. The risk picture seems distorted:
   a. Based on numbers not concentration
   b. Tries to estimate chronic risk that can't be measured
   c. See active surveillance reports (e.g. NYC, SF)

4. While the bin relation to "concentration"/occurrence is good in principle, outbreaks have not occurred where (although perhaps when) water quality was worst.
5. Some aspects of the statistical foundation of the occurrence levels need some rethinking. Specifically, multiple volumes taken at a single site at the same time can be considered to be homogeneous, i.e. of the same population, Ongerth. Accordingly, analytical results of the multiple sample components can be aggregated. However, samples taken from the same site weeks or months apart are not of the same population. Ample water quality evidence supports this and analytical results of such independent samples can therefore not be aggregated. For example, 24 10 L samples taken at biweekly intervals from a single sample site are just that…24 independent samples taken from 24 individual populations of water present at those sampling times. They are not equivalent to a 240 L sample. This is a limit-of-detection issue.

IV. LT2 Review--Procedural Issues

1) Under LT2 the consequences of bins higher than 1 are of major financial significance to PWS (ref. LT2 Economic Assessment, 2005).

2) The MCLGs = 0 for *Cryptosporidium* and *Giardia* suggest that that either organism or both may be absent. This is not only unrealistic but completely impossible.

3) Items 1 and 2 above combine to create a strong disincentive for any PWS to monitor with the objective of understanding the true picture of *Cryptosporidium* and *Giardia* in their source(s).

4) The overriding problem now (at July 2013) is that PWSs are virtually unanimously willing to accept LT2 data as showing essentially that there is no problem. Furthermore, they are willing to argue that a second round of monitoring conducted as was the first would produce a very similar if not the same result. Evidence of this assertion should be reflected in the extent of PWS input (or lack of it) to the LT2 6-year Review process.

5) If the risk of waterborne outbreaks due to *Cryptosporidium* (and it should be argued due equally to *Giardia*) is truly proportional to the measurable concentration in surface sources then a second round of zeros will provide little if any protection against the inevitable occurrence of further waterborne outbreaks.

V. Summary, Recommendations--A course of action to improve LT2

In summarizing the information provided above the following suggestions are presented as modifications to LT2 that will provide more effective risk management and will assure improved protection of PWSs that is the aim and objective of LT2. Essential elements in a revised LT2 as the basis for protecting public health in relation to *Cryptosporidium* and *Giardia* in water should include the following:

A. Monitoring

1. A second round of monitoring is needed. However, if conducted without alterations described above and listed below, resulting data will not satisfy the intent of the regulation and will only continue to propagate misconceptions regarding risk due to *Cryptosporidium* and *Giardia* in surface water used for public water supply.

2. Analysis of surface water samples to identify risk due to protozoan pathogens must include both *Cryptosporidium* and *Giardia*. Analyzing for both provides a measure of internal corroboration since both are typically found with *Giardia* concentrations typically higher than those of *Cryptosporidium*. The incremental cost of analyzing for both rather than *Cryptosporidium* alone is ca. 10% or less.

3. Monitoring *Cryptosporidium* and *Giardia* in water to provide information most useful to the individual PWS for purposes of watershed and treatment management should

specifically analyse using detection tools designed to detect all species and types regardless of condition with respect to viability.

4. Analysis of *Cryptosporidium* and *Giardia* to identify risk must specifically measure concentration by including measurement of recovery efficiency with each sample. This is possible and practical by use of internal positive control using pre labelled organisms counterstained with a red fluorophore (e.g. Texas Red, Cy3). This procedure can provide required information with an incremental cost of ca. 10-15% compared to analysis w/o internal positive control.

5. Specifying only a minimum sample volume not only permits but tacitly encourages analyses that will result in negative (zero) findings. To effectively (and efficiently) identify the concentrations and variability of *Cryptosporidium* and *Giardia* occurrence the regulation should require non-zero measurement of the ambient concentrations.

B. Unintended consequences of current LT2 monitoring

1. Restricting analytical requirements to *Cryptosporidium* alone rather than including *Giardia* conveys the erroneous impression that *Giardia* is relatively unimportant. Not only are both of relatively equivalent importance, monitoring for both contributes information that is useful and valuable to interpretation of information on the other.

2. As currently written LT2 actively discourages PWS from describing *Cryptosporidium* occurrence in a useful and meaningful way. Both the MCLG = 0 and the bin structure create significant disincentive to obtain non zero analytical results.

   a. The MCLG = 0 suggests that actual absence of *Cryptosporidium* is possible when in fact it is not, Ongerth and Saaed 2012. This is factually incorrect and leads to the dangerous misconception that no risk due to either *Cryptosporidium* or *Giardia* or both may be present for the given source and sampling location.

b. The ascending bin levels are unavoidably associated with major and ascending capital cost with corresponding continuing cost for operation and maintenance. This provides a very strong disincentive to define ambient *Cryptosporidium* levels.

c. The infrequent occurrence of waterborne outbreaks due to both organisms combined with monitoring requirements (limited volume and no meaningful recovery measurement) that facilitate finding predominantly no organisms have combined to create the unreal appearance that in the vast majority of USA surface water locations 93% of the time no one has any cause for concern.

3. The combination of disincentives described above and apparent acceptability of negative findings have combined to not only discourage but to in fact to have prevented constructive dialog between the PWS community and regulatory agencies. At this time, mid 2013, the point at which the EPA is in the process of deciding on reimplementation of LT2 without alteration, the regulated community has at least tacitly accepted the burden of more than $100 million sunk in a second stage of monitoring that would as described above result in not only another 93% zeros but propagation of the dangerous misconception that in fact no one has any cause for concern. If previous waterborne outbreaks attributed to *Cryptosporidium* and to *Giardia* actually have occurred, and if the presence of these organisms in surface waters across the country do in fact represent a risk in some way proportional to their concentration then both technical and procedural changes to LT2 must be considered.

C. A Course of Action for Improving LT2

1. Dialog with the regulated PWS community concerning the issues raised herein is essential for progress toward effective and realistic management of *Cryptosporidium* and *Giardia* in water. Willingness of EPA to re-craft the risk management component (bin structure) of

LT2 and to reformulate the MCLG based on revised monitoring results will likely be a prerequisite to meaningful dialog.

2. A revised monitoring strategy that would permit PWSs to define the concentration characteristics of their source(s) can be articulated:

    a) Each PWS would be required to identify sample volumes through preliminary sampling that would provide positive results in a majority of samples;

    b) All monitoring must include relevant recovery efficiency measurement and calculation of concentration;

    c) Revised monitoring should include analysis for both *Cryptosporidium* and *Giardia;*

    d) Incorporation of the above approach into a revised LT2 would likely require a pilot phase to confirm assertions in a limited (maybe 10-15 PWS) but at least 12 month project.

3. Assessment of risk at an individual surface water source location should take into account both the level (e.g. annual median) and the degree of variability in concentration (e.g. standard deviation)

4. An eventual second phase of LT2 monitoring, including essential elements of recovery efficiency measurement and calculation of concentrations, and based on sample volumes sufficient to provide real (non zero) concentrations in a majority of at least 1 year of monthly samples, should form the basis for a revised risk management framework. This framework should be developed in a negotiated process with the regulated PWS community.

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