Review Paper

Microbial Health Risks of Regulated Drinking Waters in the United States

A Comparative Microbial Safety Assessment of Public Water Supplies and Bottled Water

DRINKING WATER RESEARCH FOUNDATION

www.thefactsaboutwater.org

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September, 2013

Editors' note -- In April 2015 an updated and reformatted version of this review paper was published through the *International Journal of Environmental Research and Public Health*'s Topics in Public Health, Dr. David Claborn (Ed.), ISBN: 978-953-51-2132-9, InTech, DOI: 10.5772/58879. Linkage and citation information for that version of this work is shown below:

http://www.intechopen.com/books/topics-in-public-health/microbial-health-risks-of-regulated-drinking-waters-in-the-united-states-a-comparative-microbial-saf

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1. ACKNOWLEDGEMENTS

The author acknowledges and is very thankful for the contributions of two primary sources for this report:

1. The Environmental Engineering Program of the Yale School of Engineering and the Yale School of Medicine's Department of Laboratory Medicine for hosting (and comprehensively web-archiving*) the symposium entitled "Your Drinking Water: Challenges and Solutions for the 21st Century." Its presentations, delivered just prior to National Drinking Water Week (May 3-9, 2009), included both warnings and solutions from experts for the protection of the quality, safety, and availability of drinking water in America.

2. The Drinking Water Research Foundation for publishing the Federal regulations review: "Bottled Water and Tap Water - Just the Facts: A Comparison of Regulatory Requirements for Quality and Monitoring of Drinking Water in the United States**" – Robert R. Hirst, DWRF General Manager with contributions by Joseph A. Levitt, J.D., (formerly Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration) and Joseph Cotruvo, Ph.D (formerly Director, Drinking Water Standards Division, U.S. Environmental Protection Agency).

In addition, the author wishes to thank:

Martin Allen of the American Water Works Association Research Foundation is thanked for review of this document. Lize-Mari Russo is thanked for her excellent technical assistance. ***

* http://www.yaleseas.com/watersymposium/

** http://www.thefactsaboutwater.org/uploads/BW PWS Just the Facts 2011 Final.pdf

*** http://www.intechopen.com/books/topics-in-public-health/microbial-health-risks-of-regulated-drinking-waters-in-the-united-states-a-comparative-microbial-saf

2. ABSTRACT

Drinking water regulations are designed to protect the public health. In the United States, the Environmental Protection Agency (EPA) is tasked with developing and maintaining drinking water regulations for the 276,607,387 people served by the country's 54,293 community water systems. The Food and Drug Administration (FDA) regulates bottled water as a food product. By federal law, the FDA's regulations for bottled water must be at least as protective of public health as the EPA's regulations for public water system drinking water. Despite many similarities in EPA and FDA regulations, consumer perception regarding the safety of drinking waters varies widely. This paper examines and compares the microbial health risks of tap water and bottled water, specifically examining differences in quality monitoring, regulatory standards violations, advisories, and distribution system conditions. It also includes comparison data on the number of waterborne illness outbreaks caused by both tap and bottled water.

Based on a review of existing research, it is clear that as a consequence of the differences in regulations, distribution systems, operating (manufacturing) practices, and microbial standards of quality, public drinking water supplies present a substantially higher human risk than do bottled waters for illness due to waterborne organisms.

Keywords: Microbial health risks, drinking water, community water system, bottled water, waterborne illness, distribution systems

3. INTRODUCTION

The *quality* of drinking water in the United States is extensively monitored and regulated by federal, state and local agencies, yet there is increasing public concern and confusion about the safety and quality of drinking water – both from public water systems and from bottled water products. In the US, tap water and bottled water are regulated by two different agencies: the Environmental Protection Agency (EPA) regulates public water system water (tap water) and the Food and Drug Administration (FDA) regulates bottled water. Federal law requires that FDA's regulations for bottled water must be at least as protective of public health as EPA standards for tap water.[1]

The *quantity* of publically supplied water which is directly consumed as drinking water is estimated by the American Water Works Association to be less than four tenths of one percent (<0.4%) of the total produced.[2] As a food product, however, 100% of bottled water is intended for human consumption.

With respect to public water supplies, researchers estimate that more than 500 boil alerts occurred in the United States in 2010.[3] In addition, the Centers for Disease Control and Prevention (CDC) reports that waterborne diseases, such as *Cryptosporidiosis* and *Giardiasis,* cost the U.S. healthcare system as much as $539 million a year in hospital expenses.[4] In 2006, EPA researchers reported an estimated 16.4 million cases of acute gastrointestinal illness per year are caused by tap water.[5] Subsequent research has estimated that number of illnesses to be closer to 19.5 million cases per year.[6]

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[1] Federal Food, Drug, and Cosmetic Act, Chapter IV, Section 410, § 349 (2010).

[2] Roberson, A., P.E. (2009). Your Drinking Water: A 21st Century Challenge and Solutions, slide #4. Yale Drinking Water Symposium. Retrieved January 2013 from http://www.yaleseas.com/watersymposium/powerpoints.html

[3] Brigano F. A., Ph.D. and Burke T. A. (August 2010). When is the Next Boil Water Alert? *Water Conditioning & Purification*. Retrieved October 2012 from http://www.wcponline.com/pdf/August%20Flowing%20Issues.pdf

[4] Centers for Disease Control and Prevention. (July 14, 2010). *Waterborne Diseases Could Cost over $500 Million Annually in U.S.* (press release). Retrieved October 2012 from http://www.cdc.gov/media/pressrel/2010/r100714.htm

[5] Messner, M., Shaw, S., Regli, S., Rotert, K., & Soller, J. (2006) An approach for developing a national estimate of waterborne disease due to drinking water and a national estimate model application. *Journal of Water and Health* 4(Supp. 2), 201.

[6] Reynolds, K.A., Mena, K.D., & Gerba, C.P. (2008). Risk of waterborne illness via drinking water in the United States. *Reviews of Environmental Contamination and Toxicology,* 192,117-58. Retrieved October 2012 from http://www.ncbi.nlm.nih.gov/pubmed/18020305

In contrast, a survey of state bottled water regulatory authorities, dated June, 2009 and conducted by the Government Accountability Office (GAO), found there were zero outbreaks of foodborne illness from bottled water over a 5-year period. Moreover, in testimony before a July 9, 2009 Congressional hearing, an FDA official stated that the agency was aware of no major outbreaks of illness or serious safety concerns associated with bottled water in the past decade.[7] In addition, a review of FDA's recall database reveals that only two Class I recalls of bottled water products have occurred since 1990. The first, occurring in Puerto Rico in June, 1990, was a recall of isopropyl alcohol that was labelled as "distilled water." The second recall, in 2007, involved five Armenian mineral water products imported into the U.S. with excessive arsenic levels, as discovered by testing completed by FDA.

Drinking water experts have begun turning their attention to the distribution systems that carry the EPA-regulated public system drinking water from treatment plants to consumers. Emerging research has found that microbial issues in distribution systems are causing significant waterborne illness outbreaks, and that the outbreak incidence has been steadily increasing since the late 1980s.[8]

The purpose of this review paper is to help educate the public about the importance of access to safe drinking water and inform policy makers and the general public about issues such as water distribution systems, infrastructure repair, safe water availability, and EPA's regulation of public water systems for microbial contaminants and how this compares with FDA's regulation of bottled water. All of these topics combined are potentially major contributing factors to impending health concerns and risks related to drinking water in the United States.

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[7] House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. *Regulation of Bottled Water*, Hearing. (July 8, 2009). Statement of Joshua M. Sharfstein, M.D., Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration, Department of Health and Human Services. Retrieved January 2013, http://www.fda.gov/NewsEvents/Testimony/ucm170932.htm

[8] National Research Council Division on Earth and Life Studies, Water Science and Technology Board Committee on Public Water Supply Distribution Systems. (2005). Public Water Supply Distribution Systems: Assessing and Reducing Risks, National Research Council of the National Academies. Retrieved October 2012 from http://www.nap.edu/catalog.php?record_id=11262

4. COMPARISON OF REGULATIONS, STANDARDS, MONITORING AND ADVISORIES

4.1 REGULATIONS

Public drinking water and bottled water are both regulated extensively. These regulations include an array of international, federal, state, and local agencies, and in some cases, trade associations. There are health-based standards for both tap and bottled waters, and these standards are, with few exceptions, the same.[9]

Unlike tap water compliance failures, which generally result in monetary fines and requirements for corrective action, under the *Park Doctrine,* the failure of a bottled water product to meet the FDA Standards of Quality can result in criminal liability for the responsible person(s) in the manufacture and distribution of a food product which causes adverse health consequences to the public.[10]

4.2 STANDARDS

There are notable differences in standards for microbiological contaminants between bottled water and tap water. With the promulgation of FDA's "Bottled Water Microbial Rule," effective December 1, 2009, bottled water now has standards specifically regulating total coliform (TC) and *Escherichia coli* (*E. coli*) in both non-Public Water System (PWS) source water AND all finished product water. There are specific requirements for follow-up monitoring in the event of a positive test result for total coliform, i.e., each positive TC result must be evaluated for presence of *E. coli*. The FDA Rule also makes clear that:

1. If *E. coli* is detected and confirmed in non-PWS source water, that source water is not of a safe and sanitary quality for bottling, and must not be used as a source for bottled water. If that water is used for bottling, the finished product is considered by FDA to be adulterated.
2. If *E. coli* is detected and confirmed in finished product water at any level, that product is also deemed adulterated under provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

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[9] Hirst, R. (2011). *Bottled Water and Tap Water: Just the Facts*. Drinking Water Research Foundation. Retreived October 2012 from http://www.thefactsaboutwater.org.

[10] FDA Regulatory Procedures Manual. (2011). Chapter 6, 49. Retrieved January 2013 from http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074317.pdf

EPA currently has no enforceable standard for either total coliform or *E. coli* in source waters. Under the EPA Groundwater Rule (GWR), groundwater-sourced PWSs must engage in additional source water testing and implement a sanitary survey, specified levels of treatment, and other corrective actions, but the source is not removed from service. However, the U.S. EPA published the revised Total Coliform Rule (rTCR) as a final rule on February 13, 2013. Although not yet promulgated, the Rule will affirm a new standard for *E. coli* in public drinking water, and will also require an investigation and corrective action at groundwater sources that test positive for *E. coli*. The revised TCR removes the standard for total coliform, while FDA continues to regulate bottled water for both total coliform and *E. coli*.

With regard to response when a microbial standard is exceeded, bottled water compliance is determined from each individual test result *in both the source and the finished product*. When one sample exceeds the standard of quality for *E. coli*, and the bottler continues to use the source for bottling, the finished product is considered by FDA to be adulterated and subject to recall. FDA also clearly stated its policy on adulterated finished product in the 2009 Bottled Water Microbial Rule.

> *"If E. coli is present in bottled water, then the bottled water is deemed to be adulterated under section 402(a)(3) of the act (§ 165.110(b)(2)(i)(B); § 165.110(d))." 74 Fed. Reg. 25651 (May 29, 2009)*

Public water systems are currently required to collect a specified number of samples per month, as is discussed in the monitoring section (Section 4.3). The current EPA TCR MCL for total coliform is "no more than 5% of monthly samples are valid for total coliform." For example, if a small groundwater-sourced community water system collects only the required minimum of 25 samples per month, one of those samples may test positive for total coliform, but the system would be in compliance with the TCR. The TCR requires positive test results for total coliform to be confirmed for presence of *E. coli.* If any of the coliform samples are positive for *E. coli*, a public notification, usually with a boil water order, is issued to consumers. The new USEPA revised Total Coliform Rule will require public notification only for *E. coli* when it becomes effective in a few years (date to be determined).

Table 4.2 is a comparison of microbiological standards for microbiological standards for bottled water and tap water.

TABLE 4.2 COMPARISON OF MICROBIOLOGICAL STANDARDS

Microbiological Contaminants		FDA SOQ	EPA MCL
	Total coliform	If positive for total coliform, follow-up testing required to determine presence of *E. coli* in source water.	No MCL in source water.
		Finished product: MPN: <2.2 organisms per 100 ml. (8) MF: <4 CFU per 100 ml; arithmetic mean shall not exceed 1 coliform organism per 100 ml. (8)	No MCL in finished water.
	Escherichia coli (E. coli)	None detected in source water. If detected, source water not of a safe, sanitary quality.	No MCL in source water.[11]
		None detected in finished product. If detected, product is deemed adulterated.	None detected in finished water. None detected in any of the follow-up samples if initial sample is positive.

In addition, EPA has established a guideline for heterotrophic plate count (HPC) bacteria of 500 CFU/ml as a means of demonstrating adequate levels of disinfection in the distribution system. This is not a health-based standard, and it is only used to indicate adequate disinfection in the distribution system. There are no standards or guidelines for HPC in bottled water. However, in 2002, the World Health Organization published a report on HPC bacteria in drinking water, concluding that "The available body of evidence supports the conclusion that, in the absence of fecal contamination, there is no direct relationship between HPC values in ingested water and human health effects in the population at large." Therefore, the HPC bacteria found in natural bottled waters is considered to be part of the natural flora of the water, and does not pose a health risk in the absence of fecal indicators such as *E. coli*.[12] Although HPC is not an FDA-required test for bottled water, most bottled

[11] USEPA Revised Total Coliform Rule – Final Rule, published in the *Federal Register* on February 13, 2013, requires an MCL for *E. coli* in source water.

[12] Allen, M., Edberg, S., & Reasoner, D. (2004). HPC Bacteria in Drinking Water: Public Health Implications Heterotrophic plate count bacteria—what is their significance in drinking water? *International Journal of Food Microbiology,* 92(3).

water companies currently, or will under upcoming rules under the Food Safety Modernization Act (FSMA), monitor for HPC as part of their ongoing internal sanitation control and environmental monitoring programs.

In addition, as Messner, et.al. (2006) notes, pathogens have a wide range of resistance to public water system disinfection and *Cryptosporidium* is the most resistant. "Free chlorine, the most commonly used disinfectant, achieves virtually no inactivation of *Cryptosporidium* but appears very effective for inactivating most viruses."[13] FDA permits only the use of ground water not under the direct influence of surface water, as defined in 21 C.F.R. §141.2, as source water for bottling. Exclusion of such source waters also precluded the need to regulate bottled water for surface water parasites like *Cryptosporidium parvum* and *Giardia lamblia*.

4.3 MONITORING

It is in the area of monitoring activities that tap water and bottled water truly diverge. One major reason for this divergence is the method of delivery. Tap water is delivered to consumers through systems of underground piping, while bottled water is packaged in a sealed container and delivered to consumers through retail outlets and home delivery.

4.3.1 EPA Monitoring Requirements - Microbiological Testing Frequencies

Testing frequency for total coliform at groundwater and surface water-sourced Community Water Systems (CWSs) is based primarily on the population served. The number of samples required is prescribed on a monthly schedule. Therefore, a CWS will collect a minimum of anywhere from 1 up to 480 samples per month. The following table, which lists the number of samples to be tested, is taken from 40 CFR 141:

Retrieved January 2013 from http://www.sciencedirect.com/science/article/pii/S0168160503004537

[13] Messner, M., et. al., (2006). 213.

TABLE 4.3 CWS MONITORING SCHEDULE FOR TOTAL COLIFORM (FROM THE USEPA RTCR)[14]

Population served	*Minimum number of samples per month*
2,501 to 3,300	3
3,301 to 4,100	4
4,101 to 4,900	5
4,901 to 5,800	6
5,801 to 6,700	7
6,701 to 7,600	8
7,601 to 8,500	9
8,501 to 12,900	10
12,901 to 17,200	15
17,201 to 21,500	20
21,501 to 25,000	25
25,001 to 33,000	30
33,001 to 41,000	40
41,001 to 50,000	50
50,001 to 59,000	60
59,001 to 70,000	70
70,001 to 83,000	80
83,001 to 96,000	90
96,001 to 130,000	100
130,001 to 220,000	120
220,001 to 320,000	150
320,001 to 450,000	180
450,001 to 600,000	210
600,001 to 780,000	240
780,001 to 970,000	270
970,001 to 1,230,000	300
1,230,001 to 1,520,000	330
1,520,001 to 1,850,000	360
1,850,001 to 2,270,000	390
2,270,001 to 3,020,000	420
3,020,001 to 3,960,000	450
3,960,001 or more	480

A small noncommunity water system that serves $\leq$ 1,000 people would collect one sample per quarter, with an opportunity for reduced monitoring of once per year.

4.3.2 FDA Monitoring Requirements

Bottled water sources (other than municipal water sources) are required to be tested for total coliform weekly at each source used for bottling. If any source water sample is positive for total coliform, FDA requires that it be evaluated for presence of *E. coli*. If a sample is confirmed to be contaminated with *E. coli*, the source is considered not suitable for bottling,

[14] USEPA Revised Total Coliform Rule published on February 13, 2013 as a final rule, but not promulgated as of the publication date.

and any product that contains water from that source is considered by FDA to be adulterated.

Each bottled water finished product type (spring water, purified water, fluoridated water, etc.) is required to be tested for total coliform weekly. If any product sample is positive for total coliform, FDA requires that it be evaluated for presence of *E. coli*. If a sample is confirmed to be contaminated with *E. coli*, the product type is considered by FDA to be adulterated.

To fully understand a comparison of bottled water testing and public water system testing, one must look at the relative size of the operations and the amount of water processed by each. FDA states in the preamble to their March 3, 2003 direct final rule for radionuclides that they base sample frequency on the following:

> *"According to EPA's per capita total water use estimates applied to bottled water, an average bottled water facility processes as much water as a municipal system serving between 42 and 72 households… serving between 100 and 500 people, which is the closest category EPA presents."*

Applying this principle, a community water system serving between 100 and 500 people is required by the USEPA to test a minimum of one (1) total coliform sample per month. FDA requires one (1) total coliform sample per week.

4.3.3 Comparisons of Bottled Water Plant Testing and PWS Testing for Total Coliform

For more direct comparison of bottled water and public water testing, here are examples of each for total coliform.

In table 4.3.3, a large bottled water plant packaging approximately 250,000 gallons per day is compared to New York City, which, according to 2009 data, distributed approximately 1.086 billion gallons of water per day within its distribution system.

Table 4.3.3 total coliform testing comparison – Large City

Bottled Water Plant (large bottler, 1)	**New York City** (large city)
250,000 gallons per day	1.086 billion gallons per day
7.5 million gallons per month	32.58 billion gallons per month
1 sample per week; 4 samples per month	480 samples per month (~16 samples per day)
1 sample per 1,875,000 gallons	***1 sample per 67,875,000 gallons***
Sample Ratio: 36:1	

Disclaimer: Both the bottled water plant and New York City likely test more than the minimum number of samples each month. Numbers above based on minimum regulatory requirements.

As the table above shows, even though New York City is required to collect a minimum of 480 samples per month, when those samples are viewed on a gallons of water produced basis, the bottled water plant tests 36 times more frequently than the New York City system. Of course, this assumes only the minimum number of samples required by FDA and EPA is collected. In all likelihood, both the bottled water plant and New York City are collecting more than the minimum number of samples.

Next, let's compare that large bottled water plant with a smaller public water system – the groundwater-based CWS serving 10,000 that we've reviewed earlier in this paper:

TABLE 4.3.4 TOTAL COLIFORM TESTING COMPARISON – SMALL CITY

Bottled Water Plant (large bottler, 1)	**CWS Serving 10,000** (small city)
250,000 gallons per day	1.2 million gallons per day
7.5 million gallons per month	36 million gallons per month
1 sample per week; 4 samples per month	10 samples per month
1 sample per 1,875,000 gallons	***1 sample per 3,600,000 gallons***
Sample Ratio: 2:1	

The gallons of water produced by either system are much closer, but the bottled water plant still samples twice as frequently by gallons.

Next, the Table 4.3.5 below compares a small home and office delivery (HOD) bottled water plant with the CWS serving 10,000 people.

Table 4.3.5 total coliform testing comparison – Small City, small Bottler

Bottled Water Plant (small bottler, 1)	**CWS Serving 10,000** (small city)
25,000 gallons per day	1.2 million gallons per day
750,000 gallons per month	36 million gallons per month
1 sample per week, 4 samples per month	10 samples per month
1 sample per 187,500 gallons	***1 sample per 3,600,000 gallons***
Sample Ratio: 19:1	

The ratio of bottled water samples tested versus the number of CWS samples tested is up to 19:1. Once again, this assumes both the bottled water plant and the community water system are collecting only the minimum number of samples required by their respective regulations.

4.4 Advisories

4.4.1 When Public Drinking Water Does Not Meet EPA Standards – Advisories

Public water systems must notify their customers when they violate EPA or state drinking water regulations (including monitoring requirements) in cases when the drinking water may pose a risk to consumer's health.[15] Under the EPA notification rule, there are three tiers of notification, depending on the seriousness of the violation. Table 4.4 shows how public system drinking water violations are assessed.

TABLE 4.4.1 EPA'S 3 TIERS OF PUBLIC NOTIFICATION:

	Required Distribution Time	**Notification Delivery Method**
Immediate Notice (Tier 1)	Any time a situation occurs where there is the potential for human health to be immediately impacted, water suppliers have 24 hours to notify people who may drink the water of the situation.	Water suppliers must use media outlets such as television, radio, and newspapers, post their notice in public places, or personally deliver a notice to their customers in these situations.
Notice as soon as possible (Tier 2)	Any time a water system provides water with levels of a contaminant that exceed EPA or state standards or that hasn't been treated properly, but that doesn't pose an immediate risk to human health, the water system must notify its customers as soon as possible, but within 30 days of the violation.	Notice may be provided via the media, posting, or through the mail.
Annual Notice (Tier 3)	When water systems violate a drinking water standard that does not have a direct impact on human health (For Example, failing to take a required sample on time) the water supplier has up to a year to provide a notice of this situation to its customers.	The extra time gives water suppliers the opportunity to consolidate these notices and send them with Annual Water Quality Reports (Consumer Confidence Reports).

Source: EPA, "Water: Public Notification Rule"

[15] EPA website (n.d.). *Water: Public Notification Rule*. Retrieved November 2012 from http://water.epa.gov/lawsregs/rulesregs/sdwa/publicnotification/basicinformation.cfm

The EPA reports that in 2011, 93.2 percent of US public water systems met health-based standards for drinking water. Also in that year, the EPA reports US public water systems had 8,431 total coliform rule violations affecting 9,837,344 people.[16]

4.4.2 When Bottled Water Does Not Meet FDA Standards – Advisories

Under FDA rule (21 C.F.R.§165.110), bottled water that "contains a substance at a level considered injurious to health under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act), or that consists in whole or in part of any filthy, putrid or decomposed substance, or that is otherwise unfit for food under section 402(a)(3) of the act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) of this section. If *E. coli* is present in bottled water, then the bottled water will be deemed adulterated under section 402(a)(3) of the act."[17] Adulterated food and beverages should not enter the food supply, and if they do, *the manufacturer could face criminal or civil penalties and mandatory recalls. Criminal penalties could be assessed under the Park Doctrine, which places responsibility for adulterated product on company owners and/or senior management.*

The FDA's website recall database indicates that in 2011 and 2012 there was one incidence of a bottled water Class II recall.[18] Mountain Pure, LLC voluntarily recalled 23,000 16.9 oz. bottles of its Mountain Pure bottled water in Clinton, AR on May 4, 2011 because of a biological contamination. In a FDA press release, the Arkansas Department of Health said it was unlikely that a healthy person would get sick from drinking the water, but people with a weakened immune system might be at higher risk.[19]

4.4.3 People Who Have Immune-Compromised Illnesses

Waterborne diseases can lead to serious acute, chronic and sometimes fatal health consequences, especially for people who have compromised immune systems. Both the CDC and the EPA advise people who have immune-compromised illnesses (such as people

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[16] EPA. (2011). *Fiscal Year 2010 Drinking Water and Ground Water Statistics*. Retrieved December 2012 from http://water.epa.gov/scitech/datait/databases/drink/sdwisfed/upload/new_Fiscal-Year-2010-Drinking-Water-and-Ground-Water-Statistics-Report-Feb-2012.pdf

[17] FDA. (2010), *CFR-2010-title21-vol2, PART 165—BEVERAGES*. Retrieved December 2012 from http://www.gpo.gov/fdsys/pkg/CFR-2010-title21-vol2/pdf/CFR-2010-title21-vol2-sec165-110.pdf

[18] FDA. (n.d.). *Safety – Recalls*. Retrieved December 2012 from http://www.fda.gov/Safety/Recalls/default.htm

[19] FDA. (2011). *Safety – Recalls* (press release). Retrieved December 2012 from http://www.fda.gov/Safety/Recalls/ucm254580.htm

undergoing chemotherapy, living with HIV/AIDS, transplant patients, children and infants, elderly and pregnant women) to consider taking extra precautions with their drinking water.[20] An EPA video and accompanying booklet aimed at educating health care providers about drinking water tells providers to advise these patients to "to consider alternatives to tap water."[21]

[20] EPA. (2009) *Water on Tap: what you need to know*. Retrieved December 2012 from http://water.epa.gov/drink/guide/upload/book_waterontap_full.pdf

[21] EPA. (2004) *Tap into Prevention*. Retrieved December 2012 from http://www.epa.gov/ogwdw/healthcare/pdfs/booklet_healthcarevideo_suppliement.pdf

5. COMPARISON OF ESTIMATED INCIDENCES OF PUBLIC WATER SYSTEM-BORNE AND BOTTLED WATERBORNE DISEASES

5.1 EPA APPROACH TO A NATIONAL ESTIMATE

Research into drinking water-related incidences of acute gastrointestinal illness (AGI) is sparse largely due to gaps in data caused by reporting uncertainties. However, the EPA has developed an analytical approach and model for generating a national estimate of AGI illness due to drinking water and using this model, it is estimated that public water systems cause 16.4 million cases of AGI per year in the United States.[22]

A Messner, et al. (2006) study uses AGI to measure public water system health risk because AGI is the broadest indicator of health effects associated with most water-borne pathogens and allows for comparison to national data on AGI incidence due to all causes. His study focuses on public water systems because 94% of the US population lives in a community that is served by public water systems. He acknowledges that water-borne diseases caused by non-public water systems could be significant, but a lack of data makes it difficult to include non-public water systems in calculating a national estimate.

In his research, Messner, et al. (2006) cites a Laval household intervention study that shows significant differences in Highly Credible Gastrointestinal Illness (HCGI) incidences between tap water drinkers and bottled water drinkers. "The difference in incidence between the two groups of 0.26 cases of HCGI per person-year represents the estimated attributable risk to drinking tap water."[23]

Meanwhile, a much broader study by Reynolds, et al. (2008) calculated all possible water-borne infections and illnesses associated with exposure to pathogens in drinking water, not just AGI, and concluded the estimated number of water-borne illnesses per year in the US is 19.5 million cases.[24]

5.2 OUTBREAKS ASSOCIATED WITH BOTTLED WATER

The FDA testified before a United States House of Representatives Subcommittee on Oversight and Investigations in July 2009 that the agency was aware of no major outbreaks

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[22] Messner, M., et. al., (2006). 201.

[23] Ibid., 207.

[24] Reynolds, K.A., et. Al., (2008)

of illness or serious safety concerns associated with bottled water in the past decade.[25] And said: "Because FDA's experience over the years has shown that bottled water has a good safety record, bottled water plants generally are assigned a relatively low priority for inspection."

At that same hearing, the Government Accountability Office (GAO) made public its report on bottled water, which found that based on a survey of water quality or food and health protection officials in all 50 states and the District of Columbia there was no evidence that bottled water caused any illnesses during the previous five years.[26]

Meanwhile, the CDC attributes just five cases of AGI to bottled water in the past 10 years.[27] (One case of AGI in 2007 caused by an unidentified agent, one case of AGI in 2004 caused by gasoline byproducts, and three cases of AGI in 2003 caused by the chemical bromate, unidentified chemical cleaning product, and unidentified agent.)

5.3 Outbreak Comparison

The following table summarizes the estimated incidences of Public Water System-borne and Bottled Waterborne diseases.

[25] House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. *Regulation of Bottled Water*, Hearing. (July 8, 2009). Statement of Joshua M. Sharfstein, M.D., Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration, Department of Health and Human Services. Retrieved January 2013, http://www.fda.gov/NewsEvents/Testimony/ucm170932.htm

[26] United States Government Accountability Office (2009) *Report on Bottled Water,* "Appenix III, Telephone survey administered to Officials from 50 States and the District of Columbia, and Summary of Responses". GAO-09-610. Retrieved December 2012 from http://www.gao.gov/new.items/d09861t.pdf

[27] CDC. (n.d.). *Reported Outbreaks Associated with Bottled Water, Commercially Bottled Water*. Retrieved November 2012 from http://www.cdc.gov/healthywater/drinking/bottled/

TABLE 5.3 DRINKING WATER SOURCES & ESTIMATED CASES OF AGI 2003 - 2012

Drinking Water Sources & Estimated Cases of AGI 2003 - 2012											
Tap Water:	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
EPA	16.4m	16.4m	16.4m	16.4m	16.4m	16.4m	16.4m	16.4m	16.4m	16.4m	164m
Reynolds	19.5m	19.5m	19.5m	19.5m	19.5m	19.5m	19.5m	19.5m	19.5m	19.5m	195m
Bottled Water:	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
FDA	0	0	0	0	0	0	0	0	0	0	0
GAO	n/a	n/a	n/a	n/a	n/a	0	0	0	0	0	0
CDC	3	1	0	0	1	0	0	0	0	0	5

6. . DISTRIBUTION SYSTEM AND CONTACT SURFACE COMPARISONS

6.1 CAUSES OF WATERBORNE DISEASE

EPA-mandated protocols are designed to effectively eliminate pathogens from public water system drinking water, but treatment inadequacies and interruptions, as well as public drinking water distribution system failures, have been associated with waterborne disease outbreaks.[28] In fact, recent research indicates distribution system failures are increasingly the cause of waterborne outbreaks.[29]

The pipes that connect treatment plants to consumers' taps span 1 billion miles in the United States.[30] Researchers studying public health risks associated with contamination occurring in public water supply distribution systems have found a list of probable causes including: cross connections and backflow, intrusion caused by pressure transients, nitrification, permeation and leaching, water main repair and replacement, aging infrastructure and microbial growth inside distribution pipes.[31]

6.2 Number of OUTBREAKS CAUSED BY PUBLIC WATER SUPPLY DISTRIBUTION SYSTEMS

Data from the CDC's passive drinking water surveillance system indicates the incidence of public water supply waterborne disease outbreaks has actually decreased since the 1980s, presumably due to EPA's Surface Water Treatment Rule and the Total Coliform Rule. However, the number of outbreaks due to public water supply distribution system issues and failures has remained relatively consistent despite an apparent increase in the percentage of those outbreaks (see chart 6.2 below). It is also the case that if contamination occurs but only affects a small number of people, it may not be reported and investigated as an outbreak. "Indeed, it has been acknowledged that a fairly sizable number of cases of cryptosporidiosis could be occurring in a large city such as New York City without detection of a possible outbreak."[32]

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[28] Reynolds, K.A., et. al., (2008).

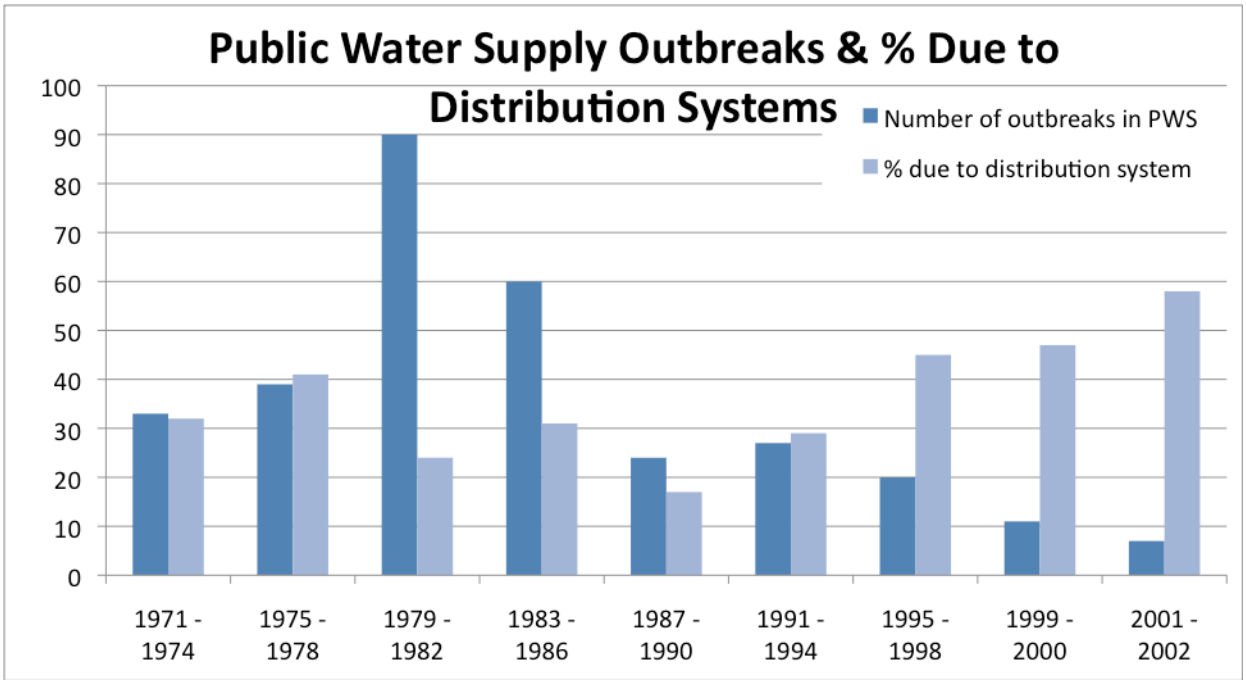
[29] Allen, M. (2009). Integrity of Distribution Systems: Role of Microbial Monitoring, supplemental paper, 16-19. Yale Symposium. Retrieved January 2013 from http://www.yaleseas.com/watersymposium/pdfs/allen1.pdf

[30] Kirmeyer, C.J., Richards, W., & Smith, C.D. (1994). An Assessment of Water Distribution Systems and Associated Research Needs, *AWWA Research Foundation: Distribution Systems*.

[31] National Research Council Division on Earth and Life Studies, Water Science and Technology Board Committee on Public Water Supply Distribution Systems. (2005).

[32] National Research Council. (1999). Watershed Management for Potable Water Supply: the New York City Strategy. The National Academies Press. 249.

TABLE 6.2 PUBLIC WATER SUPPLY OUTBREAKS & % DUE TO DISTRIBUTION SYSTEMS



Source: "Public Water Supply Distribution Systems: Assessing and reducing risks," *National Academy of Sciences,* 2005.

In a more recent update of the above data, CDC reports that in 2009-2010, there were 33 drinking water outbreaks. Of the 33 outbreaks, 25 (75.8%) occurred in community water systems.

6.3 Types of Distribution Deficiencies

Cross-connections and backflow issues pose serious public health threats. A backflow occurs when non-potable water flows directly into the drinking water supply through a cross connection, which occurs when the system has low water pressure or the non-potable system has backpressure.[33] A study that monitored public drinking supply distribution system failures from 1981 to 2002 found that 50% of waterborne outbreaks were the result of backflow.[34] A study by the University of Southern California examined the plumbing systems

[33] National Research Council Division on Earth and Life Studies, Water Science and Technology Board Committee on Public Water Supply Distribution Systems. (2005).

in 188 homes and found 9.6 percent had a direct cross connection that presented a health risk.[35]

Water main breaks are another serious problem in the United States. Each day more than 700 water mains break,[36] exposing distribution system water and pipe interiors to external microbial and chemical contaminants, both during the break and the repair process. The EPA estimated in 2002 that 5 percent of all waterborne outbreaks due to distribution system deficiencies were caused by water main repairs or the installation of new pipes.[37]

Issues with finished water storage (uncovered and reservoirs) is another cause of waterborne outbreaks as drinking water quality degrades over time and is susceptible to external contamination from wildlife, rain and algae.[38] Other public water supply distribution system risks include: biofilm build-up (the growth of bacteria on distribution system pipes and household plumbing), low-pressure intrusions[39] caused by leaks, permeation and leaching (in fact, 7 billion gallons leak from public water supply distribution pipes each day in the US[40] and the cost of water losses in 1994 was estimated $2.8 billion annually[41]).

Biofilm build-up, by itself, has been the subject of study by the EPA, which has concluded that: "Biofilms likely exist in all distribution systems, and are recognized as a normal part of the distribution system". Moreover, "…a wide range of primary and opportunistic pathogens

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[34] Prevost, M. (2009). Evaluating the Potential Causes of Excess GI Illnesses Observed in the Payment's Distribution System, *Yale University Drinking Water Symposium*. Retrieved November 2012 from http://www.yaleseas.com/watersymposium/

[35] National Research Council Division on Earth and Life Studies, Water Science and Technology Board Committee on Public Water Supply Distribution Systems. (2005).

[36] Cromwell, J., Speranza, E., & Reynolds, H. (2001). Reinvesting in Drinking Water Infrastructure: Dawn of the Replacement Era. Denver, CO. American Water Works Association.

[37] EPA. (2002). New or Repaired Water Mains. Retrieved November 2012 http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/upload/neworrepairedwatermains.pdf

[38] National Research Council Division on Earth and Life Studies, Water Science and Technology Board Committee on Public Water Supply Distribution Systems. (2005).

[39] Le Chevallier, M. (2009). Water Quality Risk Modeling, slides 27-29. *Yale Drinking Water Symposium*. Retrieved January 2013 from http://www.yaleseas.com/watersymposium/powerpoints.html

[40] Ibid., slides 27 - 29

[41] EPA. (2002). New or Repaired Water Mains. Retrieved November 2012 from http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/upload/neworrepairedwatermains.pdf

have demonstrated the ability to survive, if not grow, in biofilms. These pathogens are of both fecal and non-fecal origin, and have a multitude of pathways through which they can enter the distribution system. Some of the pathogens identified as growing or potentially surviving in biofilms include *Legionella*, *Mycobacterium avium* complex, *Pseudomonas aeruginosa*, poliovirus 1, coxsackievirus B and several species of fungi. …Once becoming established as part of the biofilm, pathogens can be protected from disinfection."[42]

6.4 Costs to Address Deficiencies in US Public Water Supply Distribution Systems

According to the EPA's *Drinking Water Infrastructure Needs Survey and Assessment, 2009,* the national assessment of public water system infrastructure needs shows a total twenty-year capital improvement need of $334.8 billion, to repair or replace thousands of miles of pipe, thousands of treatment plants, storage tanks and other assets to protect the public health.[43] Table 6.4 shows the majority of need is to address deficiencies with the public water supply distribution systems which include co-residency of leaking water pipes in the same trenches with leaking sewage lines.[44]

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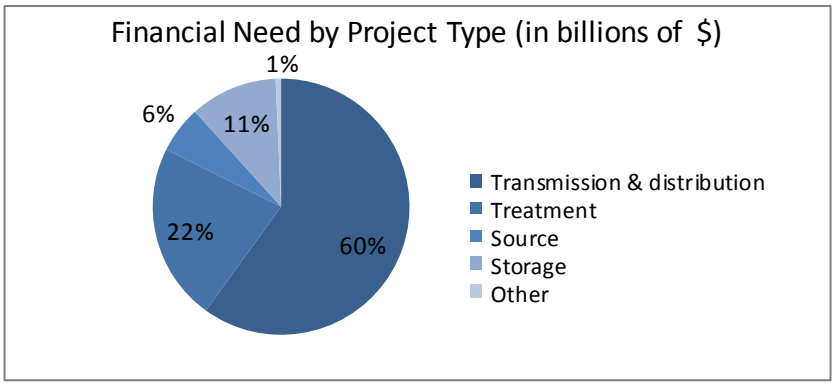
[42] EPA. (2002). Health Risks from Microbial Growth and Biofilms in Drinking Water Distribution Systems, *Office of Ground Water and Drinking Water Distribution System White Paper*. 2 & 36. Retrieved January 2013 from http://www.epa.gov/ogwdw/disinfection/tcr/pdfs/whitepaper_tcr_biofilms.pdf

[43] EPA. (2009). Drinking Water Infrastructure Needs Survey and Assessment. Retrieved November 2012 from http://water.epa.gov/infrastructure/drinkingwater/dwns/upload/2009_03_26_needssurvey_2007_report_needssurvey_2007.pdf

[44] Le Chevallier, M. (2009). Separation from Sewer Lines, slide 16. *Yale Drinking Water Symposium*. Retrieved January 2013 from http://www.yaleseas.com/watersymposium/powerpoints.html

TABLE 6.4 FINANCIAL NEED BY REPAIR TYPE



Source: EPA, "Drinking Water Infrastructure Needs Survey and Assessment," 2009

In 2002, the EPA released a *Clean Water and Drinking Water Infrastructure Gap Analysis Report,* which calculated a "funding gap" of more than $500 billion dollars over the next 20 years. (Includes $122 billion for clean water capital costs, $102 billion for drinking water capital costs, $148 billion for clean water operation and maintenance and $161 billion for drinking water operation and maintenance.[45])

6.5 Water Distribution

Under FDA rule (21 CFR Part 129), bottled water is: "required to be safe and that it be processed, bottled, held and transported under sanitary conditions. Processing practices addressed in the Current Good Manufacturing Practice (CGMP) regulations include protection of the water source from contamination, sanitation at the bottling facility, quality control to assure the bacteriological and chemical safety of the water, and sampling and testing of source water and the final product for microbiological, chemical, and radiological contaminants. Bottlers are required to maintain source approval and testing records to show to government inspectors."[46]

In addition, bottled water companies are required to conduct daily in-house total coliform monitoring on finished product of each product type and quarterly microbial rinse/swab tests

[45] EPA. (2002). Clean Water and Drinking Water Infrastructure Gap Analysis Report. Retrieved November 2012 from http://water.epa.gov/infrastructure/sustain/infrastructureneeds.cfm

[46] FDA. (n.d.). For Consumers – Bottled water and carbonated soft drinks guidance documents and regulatory information. Retrieved November 2012 from http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm077065.htm

which may be performed in-house by qualified plant personnel or by an approved laboratory on containers (incoming as well as those immediately from the washer) and closures as stipulated in 21 CFR Section 129.80 (f).[47] This specific standard of sanitation for the interior of bottles and caps is: "*No more than one of the four samples may exceed more than one bacterium per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms*." For example, not more than one of four 500 ml containers shall exceed 500 CFUs of bacteria. None of the containers are permitted to be positive for coliform bacteria. In comparison, there is an EPA guideline of 500 CFU/ml of heterotrophic plate count bacteria for public drinking water in the distribution system, beyond which the public water system must adjust disinfection levels to reduce the bacteria count. However, distribution pipes may still be lined with biofilms that may contribute to the bacteria load in the water.

Throughout the bottled water distribution system, each bottle is sealed and must remain sealed until it is opened by the consumer, eliminating risk of contamination during the distribution process. In addition, in the unlikely event that a problem with bottled water occurs, the product can be easily identified and recalled using a lot number printed on the bottled water container.

[47] International Bottled Water Association. (2012). Bottled Water Model Code of Practice. Retrieved November 2012 from http://www.bottledwater.org/files/IBWA_MODEL_CODE_2012_1212_FINAL_0.pdf

7. CONCLUSIONS

The quality of drinking water in the United States is extensively monitored and regulated by federal, state and local agencies, yet a close examination of both public system drinking water and bottled water processing and distribution procedures reveals striking differences that could explain why consumers have safety concerns regarding tap water. This paper has shown that on a gallon for gallon basis bottled water is tested more often than tap water. It is also the case that water quality breach notification differences means tap water drinkers would consume potentially hazardous drinking water before they are notified. Bottled water is tested before the water leaves the plant, and is withheld or withdrawn if the water does not meet FDA water quality standards.

A comparison of waterborne illness outbreaks reveals overwhelming evidence that the microbial health risks associated with drinking tap water are far greater than that of bottled water, with 195 million illnesses in the past 10 years for tap water compared to fewer than a dozen for bottled water.

In examining public water supply distribution systems, this paper highlights how deficiencies in these systems are key factors and causes of compromised tap water quality.

Overall, water is a precious resource. It has many uses for which there is no substitute and is therefore needed in many different ways for our survival and endurance. Thus, safe drinking water holds great value and to maintain its safety the public needs to stay educated and aware. Our government regulations are working to protect and produce our safe drinking water supply, but more needs to be done. And an informed consumer can help drive policies that will meet the needs of the American people—and ensure a safe drinking water supply.

8. BIBLIOGRAPHY

J. Bartram, J. Cotruvo, M. Exner, C. Fricker, A. Glashmacher, eds., World Health Organization (2003). "Heterotrophic Plate Counts and Drinking-water Safety: The Significance of HPCs for Water Quality and Human Health".

F.A. Brigano, Ph.D. and Thomas A. Burke, "When is the Next *Boil Water Alert?," Water Conditioning & Purification,* August 2010, accessed October 2012, http://www.wcponline.com/pdf/August%20Flowing%20Issues.pdf

Centers for Disease Control and Prevention, "Reported Outbreaks Associated with Bottled Water", Commercially Bottled Water, accessed November 2012. http://www.cdc.gov/healthywater/drinking/bottled/

Centers for Disease Control and Prevention, "Waterborne Diseases Could Cost over $500 Million Annually in U.S.," press release, July 14, 2010, accessed October 2012, http://www.cdc.gov/media/pressrel/2010/r100714.htm

J. Cromwell, E. Speranza, and H. Reynolds. 2001a "Reinvesting in Drinking Water Infrastructure: Dawn of the Replacement Era." Denver, CO: AWWA.

Environmental Protection Agency, "Clean Water and Drinking Water Infrastructure Gap Analysis Report," 2002, accessed November 2012, http://water.epa.gov/infrastructure/sustain/infrastructureneeds.cfm

Environmental Protection Agency, "Drinking Water Infrastructure Needs Survey and Assessment," 2009, accessed November 2012, http://water.epa.gov/infrastructure/drinkingwater/dwns/upload/2009_03_26_needssurvey_2007_report_needssurvey_2007.pdf

Environmental Protection Agency, "Fiscal Year 2010 Drinking Water and Ground Water Statistics", June 2011, access December 2012, http://water.epa.gov/scitech/datait/databases/drink/sdwisfed/upload/new_Fiscal-Year-2010-Drinking-Water-and-Ground-Water-Statistics-Report-Feb-2012.pdf

Environmental Protection Agency, "New or Repaired Water Mains," August 2002, accessed November 2012 http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/upload/neworrepairedwatermains.pdf

Environmental Protection Agency, Tap into Prevention, accessed December 2012, http://www.epa.gov/ogwdw/healthcare/pdfs/booklet_healthcarevideo_suppliement.pdf

Environmental Protection Agency, "Water: Public Notification Rule", accessed November 2012, http://water.epa.gov/lawsregs/rulesregs/sdwa/publicnotification/basicinformation.cfm

Environmental Protection Agency, Water on Tap: what you need to know, 2009, accessed December 2012, http://water.epa.gov/drink/guide/upload/book_waterontap_full.pdf

Food and Drug Administration, Safety – Recalls, accessed December 2012, http://www.fda.gov/Safety/Recalls/default.htm

Food and Drug Administration, Safety – Recalls, press release, May 4, 2011, accessed December 2012, http://www.fda.gov/Safety/Recalls/ucm254580.htm

Food and Drug Administration, Section 410, Federal Food, Drug & Cosmetic Act

Food and Drug Administration HHS, CFR-2010-title21-vol2, PART 165—BEVERAGES, accessed December 2012, http://www.gpo.gov/fdsys/pkg/CFR-2010-title21-vol2/pdf/CFR-2010-title21-vol2-sec165-110.pdf

Government Accountability Office, "Appendix III, Telephone survey administered to Officials from 50 States and the District of Columbia, and Summary of Responses," *United States Government Accountability Office Report on Bottled Water*, GAO-09-610, June 2009, accessed December 2012, http://www.gao.gov/new.items/d09861t.pdf

R. Hirst, "Bottled Water and Tap Water: Just the facts", Drinking Water Research Foundation, accessed October 2012). http://www.thefactsaboutwater.org/uploads/BW%20PWS%20Just%20the%20Facts%202011%20Final.pdf

International Bottled Water Association, *Model Code of Practice,* 2009, accessed November 2012, http://www.bottledwater.org/public/pdf/IBWA05ModelCode_Mar2.pdf

C.J. Kirmeyer, W. Richards, and C.D. Smith, "An Assessment of Water Distribution Systems and Associated Research Needs", *AWWA Research Foundation: Distribution Systems*, 1994.

M. LeChevallier, "Drinking Water: Challenges and Solutions for the Next Century," *Yale University Drinking Water Symposium,* 2009, accessed November 2012, http://www.yaleseas.com/watersymposium/

M. Messner, S. Shaw, S. Regli, K. Rotert, V. Blank and J. Soller, "An approach for developing a national estimate of waterborne disease due to drinking water and a national estimate model application," *Journal of Water and Health* 4(Suppl. 2).

National Academy of Sciences, "Public Water Supply Distribution Systems: Assessing and reducing risks," 2005, accessed October 2012, http://www.nap.edu/catalog.php?record_id=11262

National Research Council, "Watershed Management for Potable Water Supply: the New York City Strategy," The National Academies Press, page 249.

Natural Resources Defense Council, "Climate Change, Water and Risk: current water demands are not sustainable," accessed October 2012, http://www.nrdc.org/globalwarming/watersustainability/index.asp

M. Provost, "Evaluating the Potential Causes of Excess GI Illnesses Observed in the Payment's Distribution System," *Yale University Drinking Water Symposium,* 2009, accessed November 2012, http://www.yaleseas.com/watersymposium/

K.A. Reynolds, K.D. Mena, C.P. Gerba, "Risk of waterborne illness via drinking water in the United States," *Reviews of Environmental Contamination and Toxicology* 2008;192:117-58, accessed October 2012, http://www.ncbi.nlm.nih.gov/pubmed/18020305

Testimony of Joshua M. Sharfstein, M.D., Principal Deputy Commissioner of Food and Drugs, *FDA,* before an United States House of Representatives Oversight and Investigations Subcommittee hearing on bottled water, accessed November 2012. http://www.hhs.gov/asl/testify/2009/07/t20090708a.html

United States Code Statutes:
- Federal Food, Drug, and Cosmetic Act:
  - § 410, Bottled Drinking Water Standards, 21 U.S.C. § 349.
  - § 414, Maintenance and Inspection of Records, 21 U.S.C. § 350c.
  - § 709, Presumption of Interstate Commerce, 21 U.S.C. § 379a.
- FDA Injunction against Distribution: 21 U.S.C. § 332.
- FDA Criminal Penalties: 21 U.S.C. § 333.
- FDA Product Seizure: 21 U.S.C. § 334(a).
- FDA Administrative Detention: 21 U.S.C. § 334(g).

Food Safety Modernization Act: § 206, Mandatory Recall Authority, 42 U.S.C. § 247b-20.
Safe Drinking Water Act", §1412, 21 U.S.C. § 300g-1.

U.S. Food and Drug Administration Regulations:
Facility Registration: 21 CFR §§ 1.225-1.243.
Records Maintenance: 21 CFR §§ 1.326-1.368.
Recall Procedures: 21 CFR § 7.40-7.59.
Food Labeling: 21 CFR § 101.
Current Good Manufacturing Practices: 21 CFR § 110.
Bottled Water CGMPs: 21 CFR § 129.
Bottled Water Standards of Identity and Quality: 21 CFR § 165.110 (a) and (b).
Food Additive Regulations: 21 CFR § 177.
"Bottled Water Microbial Rule", 74 Fed. Reg. 25651 (May 29, 2009)
Rule on Radionuclides, 68 Fed. Reg. 9873 (March 3, 2003)

U.S. Food and Drug Administration Administrative Decisions:
70 Fed. Reg. 33694 (June 9, 2005)
66 Fed. Reg. 35439 (July 5, 2001)
63 Fed. Reg. 42199 (August 6, 1998)

U.S. Environmental Protection Agency Regulations:
Public Water System Quality Standards: 40 CFR 141, Subparts G and L.
Monitoring Requirements: 40 CFR 141, Subparts C, E, I, and L.
"Surface Water Treatment Rule", 54 Fed. Reg. 27486 (June 29, 1989)
"Interim Enhanced Surface Water Treatment Rule", 63 Fed. Reg. 69478 (December 16, 1998)
"Long Term 1 Enhanced Surface Water Treatment Rule", 67 Fed. Reg. 1812 (January 14, 2002)
"Long Term 2 Enhanced Surface Water Treatment Rule", 71 Fed. Reg. 654 (January 5, 2006)
"Ground Water Rule", 71 Fed. Reg. 65574 (November 8, 2006)

U.S. Environmental Protection Agency Resources:
"The Standardized Monitoring Framework: A Quick Reference Guide," EPA 816-F-04-010 www.epa.gov/safewater, March, 2004.
USEPA Public Water System Pivot Tables for FY 2010 (Data from July 1, 2009 through June 30, 2010). Downloaded from http://water.epa.gov/scitech/datait/databases/drink/pivottables.cfm.

Yale University: The "Your Drinking Water: Challenges and Solutions for the 21st Century" Symposium was held at Yale University on April 20th & 21st, 2009. The purpose of the symposium was to bring together individuals who are leaders in their fields and discuss, given his/her area, the following:

- Introduction to his/her area
- Data regarding his/her area
- Analysis of the data
- Challenges faced
- Proposed solutions

The conference was conducted by Stephen Edberg, Professor in the Department of Laboratory Medicine at Yale's School of Medicine, Menachem Elimelech, Professor and Chair of the Chemical Engineering Department and Environmental Engineering Program at Yale's School of Engineering & Applied Science, and Dr. John Sinnott, Associate Dean and Professor at the Infectious Disease and International Medicine Department of the University of South Florida. It is the goal that policy makers and others will use the conference and its publications as the basis for decision making. The conference's publications are in the public domain and include: Full video presentations, supplementary papers, full transcripts, PowerPoint presentations, and speakers' biographies. Accessed January 2013, http://www.yaleseas.com/watersymposium.