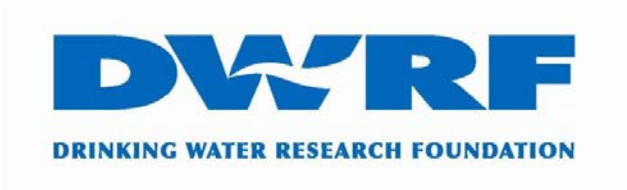
# Bottled Water and Tap Water

## *Just the Facts*

### A Comparison of Regulatory Requirements for Quality and Monitoring of Drinking Water in the United States




Drinking Water Research Foundation
Alexandria, Virginia USA

Authored by Robert R. Hirst, DWRF General Manager
Contributions by Joseph A. Levitt, J.D. and Joseph Cotruvo, Ph.D.

October, 2011 (Revised March, 2014)

*This page intentionally left blank.*

## Contents

## List of Tables

# 1. ACKNOWLEDGEMENTS

The author acknowledges and is very thankful for the contributions of two long-time colleagues and former federal officials to this report.

Joseph A. Levitt, J.D.
(formerly Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration)
Partner, Hogan Lovells US LLP
Washington, DC

Joseph Cotruvo, Ph.D.
(formerly Director, Drinking Water Standards Division, U.S. Environmental Protection Agency)
President, Joseph Cotruvo & Associates LLC
Washington, DC

# 2. EXECUTIVE SUMMARY

The information presented in this report supports the fact that drinking water, whether from the tap or a bottle, is generally safe, and that regulatory requirements for both tap water and bottled water provide Americans with clean, safe drinking water. There are some differences in regulations for each, but those differences highlight the differences between drinking water delivered by a public water system and drinking water delivered to the consumer in a sealed container. In summary, let's look at four significant conclusive comparisons.

## CONTAMINANT LEVELS

Federal regulation of contaminants in municipal drinking water and bottled water are the same for approximately 80% of the contaminants regulated by both the EPA and FDA. When compared side-by-side, although it appears that EPA has established a few maximum contaminant levels (MCLs) for contaminants that FDA has not, as explained earlier in the report, these few contaminants are not regulated by FDA because they are unlikely to be present in bottled water. This is not unlike waivers made available to public water systems for chemical contaminants never used or applied in the area surrounding their water sources.

When compared side-by-side, it becomes clear that FDA's standards of quality (SOQs) for bottled water are indeed at least as stringent as EPA's MCLs for tap water. Upon further examination, there are actually 14 contaminants for which FDA has established SOQs that are either more stringent than corresponding EPA MCLs, or are not regulated as health-based MCLs in tap water. Those contaminants are:

| | | | |
|---|---|---|---|
| Aluminum | *Escherichia coli (E. coli)* | Manganese | Total coliform |
| Chloride | Fluoride | Nickel | Total Dissolved Solids |
| Copper | Iron | Silver | Total Recoverable Phenolics |
| | Lead | Sulfate | Zinc |

## CONSEQUENCES OF NON-COMPLIANCE

Bottled water that contains contaminant(s) that exceed FDA SOQs for contaminants in bottled water may not be distributed for public consumption, or must be recalled from the marketplace. Public drinking water that exceeds EPA MCLs requires a notification of the public alerting them to the presence of the contaminant(s), with directives or instructions for avoiding being exposed to the contaminant(s). However, the non-compliant water continues to flow through the PWS distribution system. A comparison of SOQ and MCL exceedances yields that there have been a total of six (6) Class I recalls of bottled water in the past 22 years. Approximately 11,000 MCL violations for public drinking water occurred at more than 5,200 PWSs in one year (2010), involving almost 23 million U.S. citizens.

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. By contrast, in 2006, the Centers for Disease Control and Prevention (CDC) estimated that 16.4 million people become sick annually from municipal water supplies.

## MONITORING REQUIREMENTS

Without bias toward either tap water or bottled water, both EPA and FDA have substantial monitoring and testing requirements for drinking water. However, FDA current Good Manufacturing Practices (cGMP) regulations include requirements that:

- Are generally more frequent than community water systems (CWSs);
- Do not allow for averaging of test results;
- Are consistent, regardless of number of consumers;
- Are generally not subject to local monitoring waivers or reductions in test frequency; and

- Are more frequent on a per gallon basis.

## DISTRIBUTION OF FINISHED WATER

Perhaps the most notable difference between tap water and bottled water is the method of delivery. Community water systems deliver water to consumers (businesses and private residences) through miles of underground iron (unlined and poly-lined), polyvinyl chloride (PVC), and lead service lines that can be subject to leakage with age of the system and accidental failures, resulting in the risk of post-treatment contamination of the water that is delivered to consumers. Bottled water is delivered to consumers in sanitary, sealed containers that were filled in a bottling facility under controlled conditions in a fill room.

# 3. INTRODUCTION

This report was written with the clear objective of setting aside the rhetoric and focusing on the actual regulatory requirements for monitoring the quality of bottled water and tap water, and comparing the health-based standards and aesthetic criteria established for both. To begin, the regulations for both public drinking water and bottled water are reviewed in this report. The Safe Drinking Water Act's National Primary and Secondary Drinking Water Regulations, regulated by the U.S. Environmental Protection Agency ("EPA"), govern public drinking water quality and monitoring. The Federal Food, Drug and Cosmetic Act and associated regulations for bottled water, regulated by the U.S. Food and Drug Administration ("FDA"), govern quality and monitoring of bottled water.

This report addresses groundwater and surface water-sourced public drinking water and bottled water regulations relating to groundwater sources. This then relates to natural bottled waters (spring water and artesian water) as they are sourced from groundwater. Purified bottled waters that are normally sourced from either surface water or groundwater-sourced community water systems are also compared.

Next, a comparison of the EPA maximum contaminant levels (MCLs) and FDA standards of quality (SOQs) is presented, with detailed discussions on any differences. This report also looks at established EPA and FDA monitoring programs for tap water and bottled water. Finally, comparisons are made between bottled water facilities and public drinking water treatment utilities.

In the end, the two distinct regulatory frameworks for bottled water and public drinking water reflect their respective differences, while each helps ensure the safety and quality of the water provided to consumers.

Public water systems provide quality water – for human consumption and other uses (e.g., washing clothes and bathing, as well as industrial and commercial uses) - through a piped distribution system to specific communities. Public water systems are granted exclusive rights to provide water to consumers in a particular geographic or municipal area. Consumers do not, therefore, have a choice of which public water system will provide water to their homes or businesses.

Bottled water is a packaged food product sold in individual, sanitary, sealed containers. It is intended solely for human consumption. Consumers have a variety of bottled water choices available to satisfy their particular tastes and price preferences. It is sold in many different package sizes, including 3- and 5-gallon containers used in bottled water coolers, 2 ½ gallon refrigerator-size containers, and "on-the go" half-liter, one-liter, and 1.5 liter convenience – size packages. Consumers choose bottled water for several reasons – taste, quality, and convenience. Bottled water is also an alternative to other packaged beverages (such as carbonated beverages and energy drinks) when consumers want to avoid or moderate calories, caffeine, sugar, artificial flavors or colors, alcohol and other ingredients.

Data is presented on the safety of drinking water based on statistics from the EPA, FDA, and the Centers for Disease Control and Prevention (CDC).

# 4. REGULATORY OVERVIEW

Public drinking water and bottled water are both regulated extensively. That regulation originates in an array of international, federal, state, and local agencies, and in some cases, by trade associations. There are health-based standards for both waters, and those standards are, with few exceptions, equally applicable. In fact, in 1996, the U.S. Congress mandated through the Safe Drinking Water Reauthorization Act that bottled water be regulated as stringently as public drinking water ("tap water").

Tap water regulations have originated from the Safe Drinking Water Act (SDWA) and its reauthorized versions since 1974, and the U.S. Environmental Protection Agency develops and administers regulations to ensure that Americans enjoy a safe supply of drinking water. Although bottled water contains water, it is separated from tap water in the way it is delivered to the consumer. Rather than being distributed in underground water mains and smaller distribution system piping, bottled water is packaged in a sealed container, making it a packaged food product. That packaging process occurs under defined and controlled conditions, such as via stainless steel fillers housed in a fill room in a bottling plant, and packaged and sealed in plastic or glass containers.

## 4.1. THE FOOD AND DRUG ADMINISTRATION'S BOTTLED WATER REGULATIONS

Bottled water is subject to comprehensive government regulation at both the federal and state level. In addition, the International Bottled Water Association (IBWA) has adopted industry standards (IBWA Bottled Water Code of Practice) that are, in some instances, more stringent than FDA or EPA requirements. As mandated by federal law, FDA's bottled water standards must be no less stringent and no less protective of the public health than EPA's regulations for public drinking water.[1]/

Any comparison of FDA's regulation of bottled water and EPA's regulation of municipal (tap) water begins with Section 410 of the Federal Food, Drug, and Cosmetic Act (FFDCA or "the Act"), 21 U.S.C. § 349. Under that provision, FDA's standards of quality (SOQs) for bottled water must be "no less stringent" than EPA's corresponding maximum contaminant level (MCL) for tap water. Similarly, FDA's establishment of treatment techniques for bottled water must be "no less protective of the public health" than EPA's corresponding treatment techniques for tap water. Thus, by law, FDA's regulations must be equivalent or stronger than EPA regulations in each of these areas.

The statute includes a process to ensure this level of parity. Section 410 provides that whenever EPA issues a new national primary water drinking regulation for a contaminant under section 1412 of the Safe Drinking Water Act, 42 U.S.C. § 300g-1, FDA has 180 days to either issue a corresponding regulation for bottled water or publish a rationale for why the EPA's regulation is not applicable to bottled water. If FDA does not do either within the prescribed timeframe, then the EPA regulation becomes applicable to bottled water by operation of law. This is often referred to as the "hammer provision," because the hammer falls if FDA does not act in time. Thus, the statute assures parity in the regulation of bottled water and tap water, either through required FDA action or, in the absence of such action, by operation of law.

In addition to assuring parity with EPA regulation, FDA applies to bottled water the myriad of statutory and regulatory provisions applicable to all packaged food and beverage products. Thus, bottled water is subject to all the same general rules and penalties as makers of carbonated beverages, energy drinks, and juice products. These include requirements to register facilities with the FDA (21 CFR § 1.225 – 1.243), maintenance of records (21 CFR § 1.326 – 1.368), recall procedures (21 CFR § 7.40 – 7.59); food labeling (21 CFR Part 101), and good manufacturing practices for food and beverage products (21 CFR Part 110). Similarly, bottled water producers are subject to the same penalties as other makers of packaged food products, including seizure (21 U.S.C. § 334(a)), injunction (21 U.S.C. § 332), and criminal prosecution (21 U.S.C. § 333), as well as administrative detention (21 U.S.C. § 334(g)). In addition, FDA has regulations

[1]/ Federal Food, Drug, and Cosmetic Act § 410, 21 U.S.C. § 349.

specific to bottled water with respect to good manufacturing practices (21 CFR Part 129), standards of identity (21 CFR § 165.110(a)), and standards of quality (21 CFR § 165.110(b)). These requirements are described in greater detail below.

### 4.1.1. Regulations for all FDA-regulated packaged food and beverage products, including bottled water

As a packaged food product, bottled water is subject to all the same statutory and regulatory requirements as FDA applies to other packaged food products, including other packaged beverage products such as carbonated beverages, energy drinks and juice products. These include:

#### 4.1.1.1. Registration of Food Facilities

Under Section 415 of the Act, all bottled water facilities in the United States, and all foreign bottled water facilities that process water intended for consumption in the United States, are required to register with the FDA (21 CFR § 1.225 – 1.243). Facilities are also required to update their registration if any significant changes occur. Beginning in 2012, all facilities will be required to renew their registrations every two years. FDA's requirement for registration includes ALL packaged food facilities, including bottled water, even those who believe they operate exclusively within one state (21 CFR § 1.225(b)). This is consistent with Section 709 of the Act, 21 U.S.C. § 379a, which provides for a presumption of interstate commerce for all FDA-regulated products.

#### 4.1.1.2. Maintenance of Records and Access by FDA

Under Section 414 of the Act, all bottled water facilities are required to maintain records of their manufacturing process for 2 years, and to make those records available to FDA for inspection under designated circumstances (21 CFR § 1.326 – 1.368).

#### 4.1.1.3. Recall Procedures

Under Section 206 of the new Food Safety Modernization Act, FDA is empowered to recall high risk adulterated products. In addition, bottled water companies are subject to FDA's regulations for conducting product recalls (21 CFR § 7.40 – 7.59). These regulations describe, for example, the classification of the recall based on risk (Class 1 designates high risk, Class 2 moderate risk, and Class 3 no or negligible risk), the depth of the recall (consumer level, retail level, or wholesale level), and effectiveness checks (to ensure the recall procedures are followed). Every FDA district office across the country has a designated recall coordinator to monitor and oversee the conduct of packaged food and beverage product recalls.

#### 4.1.1.4. Labeling

Bottled water companies are also subject to FDA's extensive regulations governing food labeling, including identification of the manufacturer or distributor, net weight of contents, ingredient labeling, and nutrition labeling (21 CFR Part 101). Bottled water, by virtue of having an insignificant level of nutrients such as calories, fat, and cholesterol, is exempt from full nutrition labeling unless a claim (e.g., "low sodium") is made.

#### 4.1.1.5. Good Manufacturing Practices

Bottled water companies are subject to the general current good manufacturing practice (cGMP) regulations applicable to all foods (21 CFR Part 110), which includes requirements, among others, for personnel, equipment, facilities, and manufacturing production and process controls.

#### 4.1.1.6. PENALTIES

Bottled water facilities are subject to all of FDA's general enforcement powers applicable to packaged food and beverage products. Through the Federal court system, FDA may seek seizure of bottled water that is adulterated or misbranded (21 U.S.C. § 334), seek a court-ordered injunction against a bottled water facility if they are manufacturing or distributing adulterated or misbranded product (21 U.S.C. § 332), or seek criminal prosecution for significant violations (21 U.S.C. § 333). FDA may also detain foods administratively for a limited period of time, pending initiation of court proceedings to seize the product of concern (21 U.S. C. § 334(g)).

#### 4.1.1.7. FDA FOOD SAFETY MODERNIZATION ACT (FSMA)

Under new legislation signed into law on January 4, 2011, bottled water companies (like all food and beverage companies) will soon be subject to a myriad of additional requirements, including: preparation and implementation of both a food safety plan and a food defense plan; verification of the quality of their suppliers, including foreign suppliers; and expanded records maintenance and access by government inspectors. FDA has also been given the broader power to suspend a facility's registration, order a product recall, and detain adulterated or misbranded food. These new requirements and authorities will become effective on a staggered basis over the next two years. Under FSMA, FDA is also directed to increase the frequency of on-site inspections of food and beverage facilities.

### 4.1.2. REGULATIONS SPECIFIC TO BOTTLED WATER

In addition to the regulations applicable to all packaged food and beverage products, FDA also has a series of regulations designed exclusively for bottled water.

#### 4.1.2.1. PARITY TO EPA REGULATIONS

As noted, by law FDA is required to ensure that bottled water regulations are no less stringent and no less protective of the public health than EPA's regulation of tap water. Under the hammer provision in Section 410 of the Act, FDA has promulgated companion regulations for contaminants (70 Fed. Reg. 33694 (June 5, 2009)), determined that the EPA regulations are not applicable to bottled water (66 Fed. Reg. 35439 (July 5, 2001)), and allowed the EPA requirement to become effective by operation of law (63 Fed. Reg. 42199 (August 6, 1998)). Thus, each option under Section 410 has been invoked, and in all cases the standards for bottled water are no less stringent or protective of the public health as those applicable to tap water, or else the FDA has determined that the tap water regulation is not applicable to bottled water.

#### 4.1.2.2. STANDARDS OF IDENTITY FOR BOTTLED WATER

FDA's regulations specific to bottled water start with standards of identify (21 CFR § 110.65(a)), which define with reasonable precision the different kinds of bottled water, including "artesian water," "groundwater," "distilled water," "deionized water," "reverse osmosis," "mineral water," "purified water," "sparkling water," "spring water," "sterile water" and "well water." The regulations also include definitions for the more general terms, "bottled water" and "drinking water." These are the terms that bottled water companies use on their labels to describe their bottled water products. In this way, consumers have easy access to knowing the type of water they are purchasing. Bottled water products are misbranded unless the water in the bottled conforms to the applicable Standard of Identify on the product label.

#### 4.1.2.3. STANDARDS OF QUALITY FOR BOTTLED WATER

FDA's regulations also provide, at great length and detail, standards of quality (SOQs) for bottled water products (21 CFR 165.110(b)). These regulations establish enforceable, quantifiable limits for 91 microbiological, physical, chemical, and radiological substances. These are the standards that are comparable to EPA's MCLs for tap water, and will be discussed in greater detail below.

#### 4.1.2.4. GOOD MANUFACTURING PRACTICES FOR BOTTLED WATER

In addition to the cGMP regulations applicable to all packaged food and beverage products, FDA has additional GMP regulations applicable specifically to bottled water (21 CFR Part 129). These regulations cover a broad range of topics, including buildings and facilities, equipment, and production and process controls. In particular, the bottled water GMP regulations require that source water for bottling be from an approved source that has been inspected and the water sampled, analyzed, and found to be of safe and sanitary quality. The regulations also specify the frequency with which testing for contaminants must occur. In general, FDA relies on the "agency of jurisdiction," which usually refers to the state or local government, for the oversight of source water (21 CFR 129.35).

#### 4.1.2.5. COLIFORM AND *E. COLI* IN SOURCE WATER AND FINISHED PRODUCT

FDA's most recent bottled water regulation, which became effective December 1, 2009, provides for added microbial testing of both source water and finished bottled water products. Issued in response to EPA's Groundwater rule, this FDA regulation mandates weekly testing for coliform in source water and then for *E. coli* if coliform results are positive. FDA's regulation also requires that corrective action must be taken if positive, confirmed *E. coli* is found in source water in order to rectify or eliminate the cause of the contamination. Once corrective action is taken, at least 5 negative tests must be found from the source within a 24-hour period in order for the bottler to resume use of the source. Bottled water companies must also conduct regular testing of finished product to ensure that no *E. coli* is present. Thus, this relatively new FDA regulation establishes a zero tolerance for *E. coli* in both source water and finished product.

#### 4.1.2.6. SURFACE WATER

Finally, FDA has determined that EPA rules governing surface water are not applicable to bottled water because groundwater intended for bottling cannot be under the direct influence of surface water (21 CFR 165.110(a)(2)(ii)). For those bottled water facilities which obtain their water from municipal water sources, those sources themselves are separately subject to EPA regulation and must meet surface water requirements.

### 4.2. THE U.S. EPA'S REGULATION OF GROUNDWATER SOURCES

In the early days of the new Safe Drinking Water Act, the new U.S. Environmental Protection Agency focused its mission of treatment of surface waters, as surface waters are obviously more vulnerable to contamination from surface runoff, wastewater discharges, and airborne contaminants. During the 1980s and 1990s, more emphasis was placed by EPA on PWSs using groundwater sources.

#### 4.2.1. THE SURFACE WATER TREATMENT RULE (SWTR)

In 1989, EPA addressed contamination of surface waters by promulgating the Surface Water Treatment Rule (SWTR). The SWTR sought to prevent waterborne diseases caused by viruses, *Legionella,* and *Giardia lamblia*. Studies indicated that illnesses attributable to contaminated groundwaters were gaining attention. The event that highlighted this new awareness of waterborne disease was the outbreak of

Cryptosporidiosis in Milwaukee, caused by the parasite *Cryptosporidium parvum (C. parvum)*. Studies indicated that illnesses attributable to contaminated groundwaters were also gaining attention.

### 4.2.2. The Interim Enhanced Surface Water Treatment Rule (IESWTR)

In 1998, EPA published the Interim Enhanced Surface Water Treatment Rule (IESWTR), which for the first time addressed control of microbial contaminants, including *C. parvum* in both surface waters and groundwaters under the direct influence of surface water, known as "GUDI." Although the IESWTR built upon the effectiveness of the SWTR, it only applied to systems using surface water or GUDI sources serving 10,000 or more persons, leaving American citizens utilizing smaller public water systems unprotected from these microbial contaminants through regulation.

### 4.2.3. Long Term 1 and 2 Enhanced Surface Water Treatment Rules

In 2001, EPA partially corrected this gap with the publication of the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR). This new rule addressed protection of smaller public water systems serving fewer than 10,000 persons from *C. parvum* and other microbial contaminants. The Long Term 2 ESWTR was intended to further extend public health protection. These new EPA microbial regulations regulated contaminants in drinking water through a maximum contaminant level called a "treatment technique." This means that when a drinking water or source water exceeds an MCL for one of the microbial contaminants mentioned above, the water must be treated to reduce or eliminate the contaminant. Treatment techniques include filtration, ultraviolet light, and other techniques that provide EPA-approved barriers against the contaminants.

### 4.2.4. The Ground Water Rule (GWR)

The most recent advance in groundwater-sourced public drinking water regulation came in 2006 with the publication of EPA's final Ground Water Rule (GWR), which became effective December 1, 2009. The Rule goes further than past rules by specifying appropriate use of disinfection while addressing other components of groundwater treatment systems to ensure public health protection. Detection of total coliform bacteria in groundwater sources continues to trigger additional source water monitoring, sanitary surveys, and other response actions. Virtually ALL groundwater-sourced public water systems are subject to this new rule.

### 4.2.5. The National Primary and Secondary Drinking Water Regulations

The EPA's standards for drinking water quality are incorporated in the National Primary Drinking Water Regulations (NPDWRs). The NPDWRs draw their authority from the Safe Drinking Water Act (SDWA), and establish enforceable maximum contaminant levels (MCLs) and MCL Goals (MCLGs) for finished public drinking water. They also established a standardized monitoring framework (SMF) for determining drinking water monitoring and testing requirements and frequencies. Most compliance testing done under the NPDWRs is performed on samples collected after treatment, but before the water enters the distribution system, also known as "point of entry" monitoring. Therefore, many water quality results do not necessarily represent the quality of the water at the consumer's tap. Exceptions to this are samples collected for total coliform, lead, copper, and trihalomethanes, which are collected at consumer taps.

EPA has also established the National Secondary Drinking Water Regulations. These regulations establish "secondary" MCLs (SMCLs) that cover aesthetic qualities of water, and are used as guidelines for adjusting water treatment techniques. The secondary MCLs are, therefore, not enforceable health-based standards.

# 5. COMPARISON OF QUALITY STANDARDS

EPA and FDA each have detailed regulations related to maximum allowable contaminant levels. In fact, EPA has Maximum Contaminant Level (MCL) regulations for 96 contaminants, and FDA has Standards of Quality (SOQ) regulations for 91 contaminants, for a net difference of 5. But that is not the entire story. In fact:

- The maximum allowable contaminant levels are the same for 83 contaminants;
- FDA has standards for 4 contaminants/water properties that EPA does not;
- FDA has set stricter levels than EPA for 14 contaminants; and
- EPA has standards for 11 contaminants that FDA does not.

Thus, the contaminant levels are exactly the same for the vast majority of contaminants. Let's now examine where these differences do differ, and why.

## 5.1. FDA HAS STANDARDS IN 4 AREAS WHERE EPA DOES NOT.

There are 4 instances where FDA has standards in this area and EPA does not. These relate to two inorganic contaminants (lead and copper) and two water properties (color and odor):

**Lead:** FDA has set a mandatory level of 0.005 ppm, whereas EPA requires that no more than 10% of the stagnant first draw samples collected in a vulnerable system exceed the EPA's action level of 0.015 ppm. Thus, EPA's action level is three times as high as FDA's SOQ.

**Copper**: FDA has set a mandatory level of 1.0 ppm, whereas EPA has no mandatory level. Instead, EPA has set an action level of 1.3 ppm. Again, EPA's action level higher is than FDA's SOQ. An action level differs from an MCL in that it requires that a treatment technique be applied rather than being a defined MCL.

**Color:** FDA has set a mandatory standard of 15 Units. EPA maintains a secondary MCL (not health based) of 15 Units.

**Odor**: FDA has set a mandatory standard of 3 T.O.N. (Threshold Odor Number). In contrast, EPA maintains a guideline of 3 T.O.N.

## 5.2. FDA HAS STRICTER STANDARDS THAN EPA FOR 14 CONTAMINANTS

There are also 14 instances where FDA has set stricter standards for bottled water than EPA has set for tap water. EPA Secondary MCLs (SMCLs) exist for aesthetic purposes only and are not enforceable standards because they are not health-based.

**Figure 5.1 A Comparison of FDA standards of quality and EPA maximum contaminant levels**

| Contaminant | FDA SOQ | EPA Level |
|---|---|---|
| Fluoride | Variable[2]/ | 4 mg/l / SMCL = 2 mg/l |
| Nickel | 0.1 mg/l | "Remanded" |
| Aluminum | 0.2 mg/l | 0.2 mg/l (SMCL) |
| Chloride | 250 mg/l | 250 mg/l (SMCL) |
| Iron | 0.3 mg/l | 0.3 mg/l (SMCL) |
| Manganese | 0.05 mg/l | 0.05 mg/l (SMCL) |
| Silver | 0.1 mg/l | 0.1 mg/l (SMCL) |
| Sulfate | 250 mg/l | 250 mg/l (SMCL) |
| Total dissolved solids | 500 mg/l | 500 mg/l (SMCL) |
| Zinc | 5 mg/l | 5 mg/l (SMCL) |
| Phenols | 0.001 mg/l | No MCL |
| Total Coliform | 0 | ≤5% of monthly samples |
| Turbidity | 0.5 NTU | 1/5 NTU (30-day Avg.)[3]/ |

## 5.3. EPA HAS STANDARDS FOR 11 CONTAMINANTS WHERE FDA DOES NOT

There are 11 instances where EPA has set an MCL or treatment technique for tap water and FDA has not issued a corresponding requirement for bottled water. The reasons for those differences are as follows:

### 5.3.1. FOUR TREATMENT TECHNIQUE MCLS (*VIRUSES, CRYPTOSPORIDIUM, GIARDIA,* AND *LEGIONELLA*)

FDA has not set a standard of quality for bottled water for these organisms because they are only found in surface water or groundwater sources under the direct influence of surface water, and bottled water groundwater sources are not permitted to be under the direct influence of surface water (21 CFR §165.110(a)(2)(ii)). Any bottled water sourced from a municipal water system would have already been subject to the EPA standards. In addition, *Legionella* is of concern as an inhalation hazard only.

### 5.3.2. TWO TREATMENT TECHNIQUE MCLS (ACRYLAMIDE AND EPICHLOROHYDRIN)

FDA food additive regulations prohibit or restrict use of these chemicals in the production of bottled water. (21 CFR 177)

---

[2]/ Variable, based on added fluoride, natural fluoride, and annual ambient temperature in region of packaging and distribution. At the time of publication, EPA was considering a new standard for added fluoride of 0.7 mg/l.

[3]/ Bottled water is regulated more stringently due to EPA's monthly averaging of turbidity in groundwater.

#### 5.3.3. ONE MCL FOR ASBESTOS

FDA has not set a standard for asbestos because asbestos is not used in the bottling process, piping or equipment. Note that even under EPA regulations, public water systems do not test for asbestos if it is not present in their distribution systems. If a PWS is vulnerable to asbestos, the monitoring is accomplished by the PWS.

#### 5.3.4. THREE MCLS FOR ALDICARB, ALDICARB SULFOXIDE AND ALDICARB SULFONE

FDA stayed final action in 1994 pending EPA adoption of aldicarb levels. The International Bottled Water Association (IBWA) has adopted EPA's final levels in Appendix A of its *Bottled Water Code of Practice*.

#### 5.3.5. ONE MCL FOR DI-2-ETHYLHEXYL PHTHALATE (DEHP)

FDA did not establish a standard of quality for this contaminant as it is also an approved food contact material. However, FDA is currently undertaking a rulemaking to establish an SOQ for DEHP in bottled water (75 Fed. Reg. 16363 (Apr. 1, 2010)). DEHP is not found in any packaging material used in the bottled water industry.

### 5.4. A NOTE ABOUT "AVERAGING" TEST RESULTS.

A significant difference exists between EPA and FDA regulations in terms of how some contaminant levels are measured. EPA requires a few contaminants to be averaged over a 30-day, quarterly, or 12-month period to determine compliance with MCLs or action levels. Examples include:

- **Turbidity:** 30-day monthly average for groundwater;
- **Total Trihalomethanes (TTHMs):** average of four distribution samples each quarter, may be reduced to one sample per quarter; and
- **Bromate:** running 12-month annual average.

For bottled water under FDA regulation, averaging is NOT permitted for determining compliance with SOQs. Rather, FDA follows a "one strike and you're out" policy. That is a significant difference.

### 5.5. CONSEQUENCES OF MCL/SOQ EXCEEDANCES

There are also important differences between the FDA and EPA regulatory schemes in terms of what the consequences of an exceedance of an MCL or SOQ really are.

For FDA-regulated bottled water, the consequence is direct: the product must be removed from the market by conducting a product recall. As noted earlier, FDA classifies recalls based on risk, Class I being a high (or acute) risk to health, Class II being a moderate (or remote) risk to health, and Class III being a no risk or negligible risk to health.

In contrast, when public drinking water is found to exceed the legal limits for MCLs, the water supply continues to consumers, with applicable public notifications (e.g., health alerts, boil water alerts).

#### 5.5.1. BOTTLED WATER SOQ EXCEEDANCES AND RECALLS

According to FDA records, over the past 20 years, there have been only 6 Class I recalls of bottled water: 5 for extreme levels of arsenic in imported product from one foreign company, and 1 for mislabeling of isopropyl alcohol as purified water. In addition, there have been approximately 50-60 Class II and Class III recalls, again over the past 20 years.

### 5.5.2. PWS MCL Exceedances and Public Notifications

The USEPA annually publishes pivot tables that document all reported PWS MCL and other violations of the NPDWRs. For this report, records from 2010, downloaded from EPA's web site, were reviewed.

For one year (2010), EPA reported the following violations for public water systems (PWSs):

- 11,382 MCL violations at 5,278 PWSs, affecting over 23 million consumers;
- 2,948 Total Coliform Rule violations at 2,164 PWSs, many of which involved boil water alerts.

EPA reported this is out of a total of 52,873 PWSs in 2010. [4]/

## 5.6. Comparison of Regulatory Contaminant Limits

Differences between regulated contaminants in public drinking water and bottled water are few, but there are differences. As of the date of this publication, EPA regulates 96 chemical, physical, radiological, and microbiological contaminants in public drinking water. FDA regulates 91 contaminants in bottled water. There are 4 contaminants regulated in bottled water that are not regulated in public drinking water, and 11 contaminants that are regulated in public drinking water that are not regulated in bottled water. The net difference is 7 contaminants "in favor" of tap water, but that is not the entire story. This section will examine the regulated contaminants for each and provide background information that explains why there are differences.

### 5.6.1. Microbiological Contaminants and Water Characteristics

There are notable differences in standards for microbiological contaminants between bottled water and tap water. With the promulgation of FDA's new "Bottled Water Microbial Rule," effective December 1, 2009, bottled water is now regulated against a standard specifically for total coliform (TC) and *Escherichia coli* (*E. coli*) in BOTH non-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 adulterated.
2. If *E. coli* is detected and confirmed in finished product water, that product is deemed adulterated under provisions of the FFDCA.

EPA currently has no enforceable standard for either total coliform or *E. coli* in source waters. Under the 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.

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 either total coliform or *E. coli*, the finished product is considered to be adulterated and subject to recall. FDA clearly stated its policy on adulterated product in the 2009 Bottled Water Microbial Rule.

---

[4]/ Information taken from EPA pivot tables for 2010, released January 10, 2011, available at http://water.epa.gov/scitech/datait/databases/drink/pivottables.cfm.

*"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 required to collect a specified number of samples per month, as is discussed in the monitoring section (Sections 6.1-6.3, page 29). 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.

Table 5.1 is a comparison of microbiological standards for microbiological standards for bottled water and tap water.

TABLE 5.1 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:<br><br>MPN: <2.2 organisms per 100 ml. (8)<br><br>MF: <4 CFU per 100 ml; arithmetic mean shall not exceed 1 coliform organism per 100 ml. (8) | Finished water:<br><br>No more than 5% of monthly samples valid for total coliform when 40 or more samples are collected per month. For <40 samples per month, no more than one sample valid. |
| | *Escherichia coli (E. coli)* | None detected in source water.<br><br>If detected, source water not of a safe, sanitary quality. | No MCL in source water.[5]/ |
| | | None detected in finished product.<br><br>If detected, product is deemed adulterated. | None detected in finished water. |

In addition, EPA has established a guideline for heterotrophic plate count (HPC) bacteria of 500 CFU/ml as a means of maintaining certain levels of 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 faecal 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*.

[5]/ The proposed USEPA Revised Total Coliform Rule, published in the *Federal Register* on July 14, 2010, does propose an MCL for *E. coli* in source water.

EPA includes criteria for three water characteristics parameters in public drinking water, but the criteria are employed as indicators of aesthetic issues. Two of the parameters – color and pH – have no health-based MCLs associated with them. Turbidity is often used to determine the need for a public notification should it exceed its established MCL (see Table 3.1.2).

TABLE 5.2 COMPARISON OF WATER PROPERTIES STANDARDS

| Water Properties | FDA SOQ | EPA MCL |
|---|---|---|
| Color | 15 units | 15 units (Secondary MCL) |
| Turbidity | 0.5 NTU | 0.3 NTU for >95% of analyses, not to exceed 1 NTU for any single result. |
| pH | NA | 6.5-8.5 (Secondary MCL) |

FDA requires that both source water and finished product for bottled water meet the standards of quality in the following standards comparisons for chemical and radiological contaminants. If the source does not meet the FDA SOQs, treatment must be applied to bring the source water into compliance. EPA does not apply its drinking water MCLs to either groundwater or surface water sources.

### 5.6.2. INORGANIC CHEMICALS (IOCS)

TABLE 5.3 COMPARISON OF INORGANIC CHEMICAL STANDARDS

| Primary Inorganic Chemicals (IOCs) | FDA SOQ | EPA MCL |
|---|---|---|
| Antimony | 0.006 | 0.006 |
| Arsenic | 0.01 | 0.01 |
| Barium | 2 | 2 |
| Beryllium | 0.004 | 0.004 |
| Bromate | 0.010 | 0.010 |
| Cadmium | 0.005 | 0.005 |
| Chlorine | 4.0 | 4.0 |
| Chloramine | 4.0 | 4.0 |
| Chlorine dioxide | 0.8 | 0.8 |
| Chlorite | 1.0 | 1.0 |
| Chromium | 0.1 | 0.1 |
| Cyanide | 0.2 | 0.2 |
| Fluoride | Variable[6]/ | 4 / SMCL = 2 |
| Lead[7]/ | 0.005 | 0.015 AL |
| Mercury | 0.002 | 0.002 |
| Nickel | 0.1 | "Remanded" |
| Nitrate-N | 10 | 10 |

[6]/ Concentration of fluoride depends upon added or natural fluoride and annual ambient temperature at location of manufacturing and distribution.

[7]/ FDA SOQ is an enforceable health standard. EPA action level is established to permit no more than 10% of stagnant first draw samples from vulnerable consumer taps to exceed 0.015 mg/l.

| Primary Inorganic Chemicals (IOCs) (Continued) | FDA SOQ | EPA MCL |
|---|---|---|
| Total Nitrate + Nitrite as N | 10 | 10 |
| Selenium | 0.05 | 0.05 |
| Thallium | 0.002 | 0.002 |

| Secondary Inorganic Chemicals | FDA SOQ | EPA SMCL[8]/ |
|---|---|---|
| Aluminum | 0.2 | 0.2 |
| Chloride | 250 | 250 |
| Copper | 1 | 1.3 AL |
| Iron | 0.3 | 0.3 |
| Manganese | 0.05 | 0.05 |
| Silver | 0.1 | 0.1 |
| Sulfate | 250 | 250 |
| Total Dissolved Solids (TDS) | 500 | 500 |
| Zinc | 5 | 5 |

[8]/ EPA SMCLs are established for aesthetic qualities of water and are not enforceable MCLs.

## 5.6.3. VOLATILE ORGANIC CHEMICALS (VOCS)

TABLE 5.4 COMPARISON OF VOLATILE ORGANIC CHEMICAL STANDARDS

| Volatile Organic Chemicals (VOCs) | FDA SOQ | EPA MCL |
|---|---|---|
| 1,1,1-Trichloroethane | 0.2 | 0.2 |
| 1,1,2-Trichloroethane | 0.005 | 0.005 |
| 1,1-Dichloroethylene | 0.007 | 0.007 |
| 1,2,4-Trichlorobenzene | 0.07 | 0.07 |
| 1,2-Dichloroethane | 0.005 | 0.005 |
| 1,2-Dichloropropane | 0.005 | 0.005 |
| Benzene | 0.005 | 0.005 |
| Carbon tetrachloride | 0.005 | 0.005 |
| cis-1,2-Dichloroethylene | 0.07 | 0.07 |
| trans-1,2-Dichloroethylene | 0.1 | 0.1 |
| Ethylbenzene | 0.7 | 0.7 |
| Methylene chloride (Dichloromethane) | 0.005 | 0.005 |
| Monochlorobenzene | 0.1 | 0.1 |
| o-Dichlorobenzene | 0.6 | 0.6 |
| p-Dichlorobenzene | 0.075 | 0.075 |
| Haloacetic Acids (HAA5) (2) | 0.06 | 0.06 |
| Styrene | 0.1 | 0.1 |
| Tetrachloroethylene | 0.005 | 0.005 |
| Toluene | 1 | 1 |
| Trichloroethylene | 0.005 | 0.005 |
| Vinyl chloride | 0.002 | 0.002 |
| Xylenes (total) | 10 | 10 |
| Total Trihalomethanes | 0.08 | 0.08 |

## 5.6.4. SEMIVOLATILE/SYNTHETIC ORGANIC CHEMICALS (SVOCS/SOCS)

TABLE 5.5 COMPARISON OF SEMIVOLATILE/SYNTHETIC ORGANIC CHEMICAL STANDARDS

| Semivolatile Organic Chemicals (SVOCs) | FDA SOQ | EPA MCL |
|---|---|---|
| Benzo(a)pyrene | 0.0002 | 0.0002 |
| Di(2-ethyhexyl)adipate | 0.4 | 0.4 |
| Di(2-ethyhexyl)phthalate (DEHP) | 0.006 | 0.006 |
| Hexachlorobenzene | 0.001 | 0.001 |
| Hexachlorocyclopentadiene | 0.05 | 0.05 |
| Total Recoverable Phenolics | 0.001 | NA |

| Synthetic Organic Chemicals (SOCs) | FDA SOQ | EPA MCL |
|---|---|---|
| 2,4,5-TP (Silvex) | 0.05 | 0.05 |
| 2,4-D (Dichlorophenoxy acetic acid) | 0.07 | 0.07 |
| Alachlor | 0.002 | 0.002 |
| Aldicarb | NA | 0.003 |
| Aldicarb sulfone | NA | 0.003 |
| Aldicarb sulfoxide | NA | 0.004 |
| Atrazine | 0.003 | 0.003 |
| Carbofuran | 0.04 | 0.04 |
| Chlordane | 0.002 | 0.002 |
| Dalapon | 0.2 | 0.2 |
| Dibromochloropropane (DBCP) | 0.0002 | 0.0002 |
| Dinoseb | 0.007 | 0.007 |

| Synthetic Organic Chemicals (SOCs) (Continued) | FDA SOQ | EPA MCL |
|---|---|---|
| Dioxin (2,3,7,8 Tetrachlorodibenzo-p-dioxin) | $3x10^{-8}$ | $3x10^{-8}$ |
| Diquat | 0.02 | 0.02 |
| Endothall | 0.1 | 0.1 |
| Endrin | 0.002 | 0.002 |
| Ethylene dibromide | 0.00005 | 0.00005 |
| Glyphosate | 0.7 | 0.7 |
| Heptachlor | 0.0004 | 0.0004 |
| Heptachlor epoxide | 0.0002 | 0.0002 |
| Lindane | 0.0002 | 0.0002 |
| Methoxychlor | 0.04 | 0.04 |
| Oxamyl (vydate) | 0.2 | 0.2 |
| Pentachlorophenol | 0.001 | 0.001 |
| Picloram | 0.5 | 0.5 |
| Polychlorinated biphenyls (PCBs) | 0.0005 | 0.0005 |
| Simazine | 0.004 | 0.004 |
| Toxaphene | 0.003 | 0.003 |

## 5.6.5. RADIOLOGICAL CONTAMINANTS

TABLE 5.6 COMPARISON OF RADIOLOGICAL CONTAMINANT STANDARDS

| Radiological Contaminants | FDA SOQ | EPA MCL |
|---|---|---|
| Gross Alpha Particle Radioactivity | 15 pCi/L | 15 pCi/L |
| Gross Beta Particle and Photon Radioactivity | 4 millirems/yr | 4 millirems/yr |
| Radium 226/228 (combined) | 5 pCi/L | 5 pCi/L |
| Uranium | 0.030 | 0.030 |

# 6. COMPARISON OF MONITORING REQUIREMENTS

Monitoring activities is where 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.

## 6.1. EPA MONITORING REQUIREMENTS

The National Primary Drinking Water Regulations (NPDWRs) established a Standardized Monitoring Framework (SMF) for determining compliance monitoring for public water systems. The framework is based partly on population served and partly on system type (i.e., groundwater or surface water-sourced). It includes a system of reduced monitoring and monitoring waivers for many regulated contaminants, based on chemical use and length of time of MCL compliance (system history and vulnerability). The framework is complex, and waivers and reduced monitoring often result in different monitoring schemes between systems of similar size.

A USEPA quick reference guide to the SMF is available at
http://www.epa.gov/safewater/pws/pdfs/qrg_smonitoringframework.pdf

The SMF allows States to grant waivers or reduction in monitoring frequencies to water systems to reduce the sampling frequencies up to once every 3, 6 or 9 years for inorganic compounds, synthetic organic compounds, and volatile organic compounds. Waivers or reductions in monitoring frequency are also available for nitrate-nitrogen, nitrite-nitrogen, radionuclides, and asbestos. Waivers of sampling requirements are granted for specified contaminants based on both a vulnerability assessment and the analytical results of previous sampling. The vulnerability assessment may be based on a determination that either the contaminant has not been used in the area or that the system is not susceptible to contamination.

The following illustrates the basic structure of the SMF:

TABLE 6.1 USEPA STANDARDIZED MONITORING FRAMEWORK

| Standardized Monitoring Framework – Compliance Cycles and Period | | | | | |
|---|---|---|---|---|---|
| 2nd Compliance Cycle | | | 3rd Compliance Cycle | | |
| 1st Period | 2nd Period | 3rd Period | 1st Period | 2nd Period | 3rd Period |
| 2002 | 2005 | 2008 | 2011 | 2014 | 2017 |
| 2003 | 2006 | 2009 | 2012 | 2015 | 2018 |
| 2004 | 2007 | 2010 | 2013 | 2016 | 2019 |

The first 9-year compliance cycle was completed in December, 2001.

The following illustration is taken from the USEPA's quick reference guide and outlines the SMF in more detail for various types of public water systems (i.e., surface water, groundwater, combination surface/groundwater, population served, etc.).

**Table 6.2 EPA Standardized Monitoring Framework, Part 1**

**STANDARDIZED MONITORING FRAMEWORK**

| IOCs, SOCs, VOCs | | Second Cycle | | | | | | | | | Third Cycle | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1st Period | | | 2nd Period | | | 3rd Period | | | 1st Period | | | 2nd Period | | | 3rd Period | | |
| | | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 |
| Inorganic Contaminants (IOCs)[1] | Groundwater (Below MCL) | | | | | | | | | | | | | | | | | | |
| | Waiver[2] | | | | | * | | | | | | | | | * | | | | |
| | No Waiver | | * | | | * | | | * | | | * | | | * | | | * | |
| | Surface Water (Below MCL) | | | | | | | | | | | | | | | | | | |
| | Waiver[2] | | | | | * | | | | | | | | | * | | | | |
| | No Waiver | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | Groundwater and Surface Water (Above MCL)[3] | | | | | | | | | | | | | | | | | | |
| | Reliably and Consistently ≤ MCL for Groundwater Systems | | * | | | * | | | * | | | * | | | * | | | * | |
| | Reliably and Consistently ≤ MCL for Surface Water Systems | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | > MCL or Not Reliably and Consistently ≤ MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |
| | | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| Synthetic Organic Contaminants (SOCs) | Population >3,300 (Below Detection Limit) | | | | | | | | | | | | | | | | | | |
| | Waiver | | X | | | X | | | X | | | X | | | X | | | X | |
| | < Detect and No Waiver | | ** | | | ** | | | ** | | | ** | | | ** | | | ** | |
| | Population ≤ 3,300 (Below Detection Limit) | | | | | | | | | | | | | | | | | | |
| | Waiver | | X | | | X | | | X | | | X | | | X | | | X | |
| | < Detect and No Waiver | | * | | | * | | | * | | | * | | | * | | | * | |
| | Above Detection Limit | | | | | | | | | | | | | | | | | | |
| | Reliably and Consistently ≤ MCL[4] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | ≥ Detect or Not Reliably and Consistently ≤ MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |
| | | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| Volatile Organic Contaminants (VOCs) | Groundwater (Below Detection Limit) | | | | | | | | | | | | | | | | | | |
| | < Detect, Vulnerability Assessment, and Waiver[5] | | | | * | | | | | * | | | | | | * | | | |
| | No Waiver[6] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | Surface Water (Below Detection Limit) | | | | | | | | | | | | | | | | | | |
| | < Detect, Vulnerability Assessment, and Waiver[7] | | X | | | X | | | X | | | X | | | X | | | X | |
| | No Waiver[8] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | Above Detection Limit | | | | | | | | | | | | | | | | | | |
| | Reliably and Consistently < MCL[4] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | ≥ Detect or Not Reliably and Consistently ≤ MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |

TABLE 6.3 EPA STANDARDIZED MONITORING FRAMEWORK, PART 2

## STANDARDIZED MONITORING FRAMEWORK

| | EXCEPTIONS | Second Cycle | | | | | | | | | Third Cycle | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1st Period | | | 2nd Period | | | 3rd Period | | | 1st Period | | | 2nd Period | | | 3rd Period | | |
| | | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 |
| Nitrate | CWSs & NTNCWSs | | | | | | | | | | | | | | | | | | |
| | Surface Water with 4 Quarters of Results < 1/2 MCL[1] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | Groundwater Reliably and Consistently < MCL[1] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | ≥ 1/2 MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |
| | TNCWSs | | | | | | | | | | | | | | | | | | |
| | Standard Monitoring | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| Nitrite | < 1/2 MCL | | | | | # | | | | | | | | | # | | | | |
| | Reliably and Consistently < MCL[3] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | ≥ 1/2 MCL or not Reliably and Consistently < MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |
| | | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| Radio-nuclides | < Detection Limit | ! | | **** | | | | | | | | * | | | | | | * | |
| | ≥ Detection Limit but ≤ 1/2 MCL | | | **** | | | | | * | | | | | * | | | | | |
| | > 1/2 MCL but ≤ MCL | | | **** | | | | | * | | | * | | | * | | | * | |
| | > MCL | | | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |
| | | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| Asbestos | Waiver | | X | | | X | | | X | | | X | | | X | | | X | |
| | No Waiver, Reliably and Consistently ≤ MCL, or vulnerable to asbestos contamination[10] | * | | | | | | | | | * | | | | | | | | |
| | > MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |

**Legend**

* = 1 sample at each entry point to distribution system (EPTDS).

** = 2 quarterly samples at each EPTDS. Samples must be taken during 1 calendar year during each 3-year compliance period.

**** = 4 quarterly samples at each EPTDS within time frame designated by the primacy agency.

X = No sampling required unless required by the primacy agency.

# = Systems must monitor at a frequency specified by the primacy agency.

! = When allowed by the primacy agency, data collected between June 2000 and December 8, 2003 may be grandfathered to satisfy the initial monitoring requirements due in 2004 for gross alpha, radium 226/228, and uranium.

[1]Until January 22, 2006 the maximum contaminant level (MCL) for arsenic is 50 µg/L; on January 23, 2006 the MCL for arsenic becomes 10 µg/L.

[2]Based on 3 rounds of monitoring at each EPTDS with all analytical results below the MCL. Waivers are not permitted under the current arsenic requirements, however systems are eligible for arsenic waivers after January 23, 2006.

[3]A system with a sampling point result above the MCL must collect quarterly samples, at that sampling point, until the system is determined by the primacy agency to be reliably and consistently below the MCL.

[4]Samples must be taken during the quarter which previously resulted in the highest analytical result. Systems can apply for a waiver after 3 consecutive annual sampling results are below the detection limit.

[5]Groundwater systems must update their vulnerability assessments during the time the waiver is effective. Primacy agencies must re-confirm that the system is non-vulnerable within 3 years of the initial determination or the system must return to annual sampling.

[6]If all monitoring results during initial quarterly monitoring are less than the detection limit, the system can take annual samples. If after a minimum of 3 years of annual sampling with all analytical results less than the detection limit, the primacy agency can allow a system to take 1 sample during each compliance period. Systems are also eligible for a waiver.

[7]Primacy agencies must determine that a surface water system is non-vulnerable based on a vulnerability assessment during each compliance period or the system must return to annual sampling.

[8]If all monitoring results during initial quarterly monitoring are less than the detection limit, the system can take annual samples. Systems are also eligible for a waiver.

[9]Samples must be taken during the quarter which previously resulted in the highest analytical result.

[10]Systems are required to monitor for asbestos during the first 3-year compliance period of each 9-year compliance cycle. A system vulnerable to asbestos contamination due solely to corrosion of asbestos-cement pipe must take 1 sample at a tap served by that pipe. A system vulnerable to asbestos contamination at the source must sample at each EPTDS.

### 6.1.1. CHEMICAL AND RADIOLOGICAL TESTING FREQUENCIES

A groundwater-based community water system (CWS) serving a population of 10,000 that is in full compliance with the NPDWR MCLs and has no waiver from monitoring for IOCs would monitor for inorganic chemicals once every 3 years in accordance with the following schedule (outlined in red). A CWS serving 10,000 from a surface water source would monitor for inorganic chemicals annually.

TABLE 6.4 CWS MONITORING SCHEDULE FOR INORGANIC CHEMICALS

**STANDARDIZED MONITORING FRAMEWORK**

| IOCs, SOCs, VOCs | | Second Cycle | | | | | | | | | Third Cycle | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1st Period | | | 2nd Period | | | 3rd Period | | | 1st Period | | | 2nd Period | | | 3rd Period | | |
| | | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 |
| Inorganic Contaminants (IOCs)[1] | Groundwater (Below MCL) | | | | | | | | | | | | | | | | | | |
| | Waiver[2] | | | | | * | | | | | | | | | * | | | | |
| | No Waiver | | * | | | * | | | * | | | * | | | * | | | * | |
| | Surface Water (Below MCL) | | | | | | | | | | | | | | | | | | |
| | Waiver[2] | | | | | * | | | | | | | | | * | | | | |
| | No Waiver | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | Groundwater and Surface Water (Above MCL)[3] | | | | | | | | | | | | | | | | | | |
| | Reliably and Consistently ≤ MCL for Groundwater Systems | | * | | | * | | | * | | | * | | | * | | | * | |
| | Reliably and Consistently ≤ MCL for Surface Water Systems | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | > MCL or Not Reliably and Consistently ≤ MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |

A CWS serving 10,000 people would subscribe to the following schedule for synthetic organic chemicals, with no waivers:

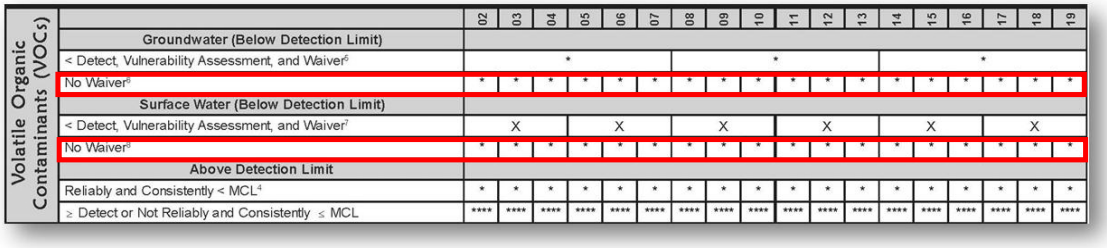
TABLE 6.5 CWS MONITORING SCHEDULE FOR SYNTHETIC ORGANIC CHEMICALS

| | | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Synthetic Organic Contaminants (SOCs) | Population >3,300 (Below Detection Limit) | | | | | | | | | | | | | | | | | | |
| | Waiver | | X | | | X | | | X | | | X | | | X | | | X | |
| | < Detect and No Waiver | | ** | | | ** | | | ** | | | ** | | | ** | | | ** | |
| | Population ≤3,300 (Below Detection Limit) | | | | | | | | | | | | | | | | | | |
| | Waiver | | X | | | X | | | X | | | X | | | X | | | X | |
| | < Detect and No Waiver | | * | | | * | | | * | | | * | | | * | | | * | |
| | Above Detection Limit | | | | | | | | | | | | | | | | | | |
| | Reliably and Consistently ≤ MCL[4] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | ≥ Detect or Not Reliably and Consistently ≤ MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |

As you can see, both groundwater and surface water-sourced CWSs are required to collect samples for SOC testing for two consecutive quarters once every 3 years. Had they acquired a waiver for one or more of the SOCs, they would do no testing for one or more of those SOCs.

Groundwater and surface water-sourced CWSs would follow the monitoring schedule for volatile organic chemicals (VOCs) illustrated in the following diagram:

**TABLE 6.6 CWS MONITIORING SCHEDULE FOR VOLATILE ORGANIC CHEMICALS**

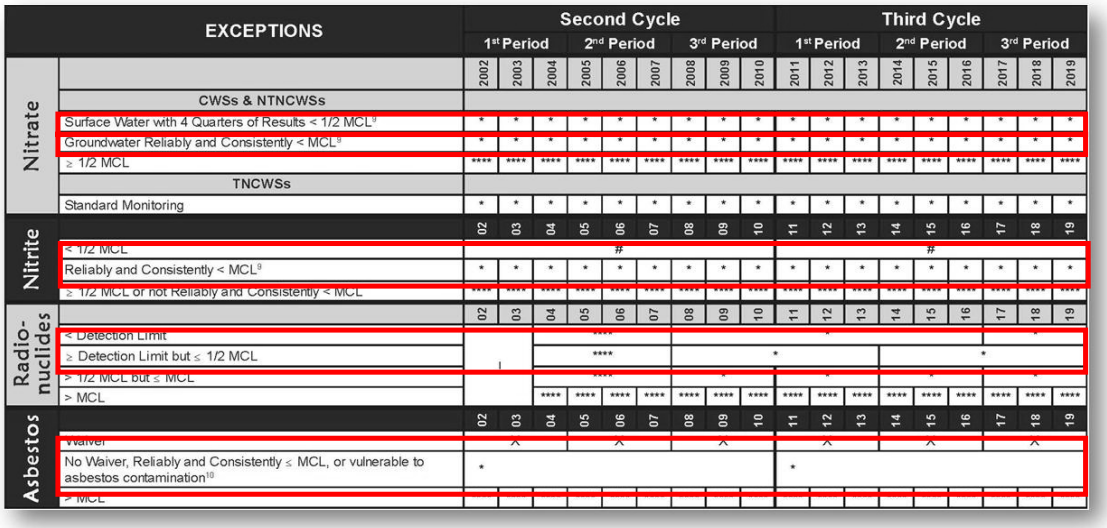


| | | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Volatile Organic Contaminants (VOCs) | **Groundwater (Below Detection Limit)** | | | | | | | | | | | | | | | | | | |
| | < Detect, Vulnerability Assessment, and Waiver[6] | | | * | | | | | * | | | | | | * | | | | |
| | No Waiver[5] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | **Surface Water (Below Detection Limit)** | | | | | | | | | | | | | | | | | | |
| | < Detect, Vulnerability Assessment, and Waiver[7] | | X | | | X | | | X | | | X | | | X | | | X | |
| | No Waiver[8] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | **Above Detection Limit** | | | | | | | | | | | | | | | | | | |
| | Reliably and Consistently < MCL[4] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | ≥ Detect or Not Reliably and Consistently ≤ MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |

The monitoring frequency for VOCs is annual, just as it is for bottled water.

Groundwater and surface water-sourced CWSs serving 10,000 customers, in full compliance with the NPDWRs, would monitor for nitrate-nitrogen, nitrite-nitrogen, radionuclides, and asbestos as follows in the next illustration.

**TABLE 6.7 CWS MONITORING SCHEDULE FOR NITRATE, NITRITE, RADIONUCLIDES, AND ASBESTOS**



| EXCEPTIONS | | Second Cycle | | | | | | | | | Third Cycle | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1st Period | | | 2nd Period | | | 3rd Period | | | 1st Period | | | 2nd Period | | | 3rd Period | | |
| | | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 |
| Nitrate | **CWSs & NTNCWSs** | | | | | | | | | | | | | | | | | | |
| | Surface Water with 4 Quarters of Results < 1/2 MCL[9] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | Groundwater Reliably and Consistently < MCL[9] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | ≥ 1/2 MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |
| | **TNCWSs** | | | | | | | | | | | | | | | | | | |
| | Standard Monitoring | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| Nitrite | < 1/2 MCL | | | | | # | | | | | | | | | # | | | | |
| | Reliably and Consistently < MCL[9] | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| | ≥ 1/2 MCL or not Reliably and Consistently < MCL | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |
| | | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| Radio-nuclides | < Detection Limit | | | | **** | | | | | | | * | | | | | | * | |
| | ≥ Detection Limit but ≤ 1/2 MCL | | | | **** | | | | * | | | | | | * | | | | |
| | > 1/2 MCL but ≤ MCL | | | | **** | | | | * | | | * | | | * | | | * | |
| | > MCL | | | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** | **** |
| | | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| Asbestos | Waiver | | X | | | X | | | X | | | X | | | X | | | X | |
| | No Waiver, Reliably and Consistently ≤ MCL, or vulnerable to asbestos contamination[10] | * | | | | | | | | | * | | | | | | | | |
| | > MCL | | | | | | | | | | | | | | | | | | |

In this example, the groundwater and surface water-sourced CWSs would test annually for nitrate-nitrogen if they are "reliably and consistently" below the MCL for nitrate-N. Regarding nitrite-N, the primacy agency having jurisdiction determines the frequency of testing, but it will likely be no more often than annually.

Radionuclides for groundwater and surface water CWSs are tested either every 9 years or every 6 years, depending on the results of the initial quarterly rounds of testing between 2004 and 2007. If radionuclides were below detectable levels, then the testing frequency is reduced to once every 9 years.

Groundwater and surface water-sourced CWSs with no waiver for asbestos monitoring are required to sample and test for asbestos during the first 3 year period within each 9 year cycle. However, if the

system is deemed not vulnerable (i.e., no asbestos present in the distribution system), the system receives a waiver.

### 6.1.2. MICROBIOLOGICAL TESTING FREQUENCIES

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

TABLE 6.8 CWS MONITORING SCHEDULE FOR TOTAL COLIFORM

TOTAL COLIFORM MONITORING FREQUENCY FOR COMMUNITY WATER SYSTEMS

| Population served | Minimum number of samples per month |
|---|---|
| 25 to 1,000 1 | 1 |
| 1,001 to 2,500 | 2 |
| 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 |

TOTAL COLIFORM MONITORING FREQUENCY FOR COMMUNITY WATER SYSTEMS—Continued

| Population served | Minimum number of samples per month |
|---|---|
| 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 bottled water plant that collects the minimum of one sample per week (i.e., 4 samples per month) for total coliform testing collects the same number of samples that a CWS serving 3301 to 4100 people would collect. However, our example CWS serving 10,000 people collects a minimum of 10 samples per month.

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!*

## 6.2. FDA MONITORING REQUIREMENTS

FDA requires an extensive list of testing for *each product type* produced at a bottling facility at frequencies that depend upon the contaminants being monitored.

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, 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.

Most chemical testing is required by FDA to be completed for each product type at least annually. If, for example, a company produces a spring water product, a purified water product, and a fluoridated water

product, they must monitor FDA-regulated contaminants in EACH PRODUCT TYPE. These chemical contaminants include inorganic contaminants (21), secondary inorganic contaminants (9), volatile organic chemicals (23), semivolatile organic chemicals (5), synthetic organic chemicals (21), radiological contaminants (4), and water properties (4). Four (4) other synthetic organic chemicals (dioxin, diquat, endothall, and glyphosate) are required to be tested every 3 years.

Source water testing must be completed at each source annually for the same chemicals and contaminants listed above for product water. The sole exception is radiological contaminants, which must be tested every four years. If, for example, a company draws water from four sources, they must monitor FDA-regulated contaminants in EACH SOURCE.

Monitoring frequency reductions and waivers are not provided for in FDA's regulations. However, FDA states in 21 CFR 129.35(A)(4)(ii), "Firms that do not use a public water system as the source of their water may reduce the frequency of their testing of that source, as well as the number of chemical contaminants for which they test the source water, if they can document that such reduction is consistent with a State-issued waiver under EPA regulations (40 CFR Parts 141 and 143)." In all but five states, bottled water is regulated by an agency other than the state agency regulating public water systems; therefore, waivers are not available to most bottled water companies.

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.

## 6.3. Comparisons of Bottled Water Plant Testing and PWS Testing for Total Coliform

For more direct comparison of bottled water and public water testing, let's look at examples of each.

First, we'll compare a large bottled water plant packaging approximately 250,000 gallons per day with New York City, which, according to 2009 data, distributed approximately 1.086 billion gallons of water per day within its distribution system.

TABLE 6.9 TOTAL COLIFORM TESTING COMPARISON

| **Bottled Water Plant** (large bottler, 1 product type) | **New York 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 you can see, 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 are 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 6.10 TOTAL COLIFORM TESTING COMPARISON

| **Bottled Water Plant** (large bottler, 1 product type) | **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, we will compare a small home and office delivery (HOD) bottled water plant with the CWS serving 10,000 people.

TABLE 6.11 TOTAL COLIFORM TESTING COMPARISON

| **Bottled Water Plant** (small bottler, 1 product type) | **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. Finally, when the chemical and radiological testing schemes are compared, the result is illustrated in the following table:

TABLE 6.12 CHEMICAL AND RADIOLOGICAL TESTING COMPARISON

| **Bottled Water Plant Sampling and Analysis (each product type) in Full SOQ Compliance** | **CWS Sampling and Analysis (groundwater / 1 entry point) Serving 10,000 in Full MCL Compliance, With No Waivers** |
|---|---|
| IOCs: ANNUAL | IOCs: Once every 3 years |
| VOCs: ANNUAL | VOCs: ANNUAL |
| SVOCs/SOCs: ANNUAL | SVOCs/SOCs: 2 consecutive quarterly samples every 3 years |
| Radionuclides: ANNUAL | Radionuclides: Once every 6-9 years |

Since FDA does not issue monitoring waivers, and most bottled water companies do not have access to waivers at the state level, bottled water is tested at the minimum frequencies established by FDA for chemical and radiological testing. That is ANNUAL for each bottled water type produced at a bottled water plant. If a plant manufactures a spring water, purified water, and purified water with added fluoride, then it must test annually for the natural source (spring) water and annually for each of the three finished product types.

In comparison, the CWS is testing for inorganic chemicals every 3 years. The community water system examined in this comparison samples more frequently for chemical and radiological parameters ONLY when it is not in compliance with NPDWR MCLs (because EPA requires more frequent monitoring of CWSs found to be out of compliance). In addition, if in compliance with MCLs for some parameters, such as synthetic organic chemicals (SOCs), it has an opportunity to apply for and receive a waiver of testing for those chemicals.

# 7. CONCLUSIONS

The information presented in this report supports the fact that drinking water, whether from the tap or a bottle, is generally safe, and that regulatory requirements for both tap water and bottled water provide Americans with clean, safe drinking water. There are some differences in regulations for each, but those differences highlight the differences between drinking water delivered by a public water system and drinking water delivered to the consumer in a sealed container. In summary, let's look at four significant conclusive comparisons.

## 7.1. CONTAMINANT LEVELS

Federal regulation of contaminants in municipal drinking water and bottled water are the same for approximately 80% of the contaminants regulated by both the EPA and FDA. When compared side-by-side, although it appears that EPA has established a few MCLs for contaminants that FDA has not, as explained earlier in the report, these few contaminants are not regulated by FDA because they are unlikely to be present in bottled water. This is not unlike waivers made available to public water systems for chemical contaminants never used or applied in the area surrounding their water sources.

When compared side-by-side, it becomes clear that FDA's SOQs for bottled water are indeed at least as stringent as EPA's MCLs for tap water. Upon further examination, there are actually 15 contaminants for which FDA has established SOQs that are either more stringent than corresponding EPA MCLs, or are not regulated as health-based MCLs in tap water. Those contaminants are:

| | | | |
|---|---|---|---|
| Aluminum | *Escherichia coli (E. coli)* | Manganese | Total Coliform |
| Chloride | Fluoride | Nickel | Total Dissolved Solids |
| Copper | Iron | Silver | Total Recoverable Phenolics |
| | Lead | Sulfate | Zinc |

## 7.2. CONSEQUENCES OF NON-COMPLIANCE

Water quality that exceeds FDA standard(s) of quality for contaminants in bottled water may not be distributed for public consumption, or must be recalled from the marketplace. Public drinking water that exceeds EPA MCLs requires a notification of the public alerting them to the presence of the contaminant(s), with directives or instructions for avoiding being exposed to the contaminant(s). However, the non-compliant water continues to flow through the PWS distribution system. A comparison of SOQ and MCL exceedances yields that there have been a total of six (6) Class I recalls of bottled water in the past 22 years. Approximately 11,000 MCL violations for public drinking water occurred at more than 5,200 PWSs in one year (2010), involving almost 23 million U.S. citizens.

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. By contrast, in 2006, the Centers for Disease Control and Prevention (CDC) estimated that 16.4 million people become sick annually from municipal water supplies.

## 7.3. MONITORING REQUIREMENTS

Without bias toward either tap water or bottled water, both EPA and FDA have substantial monitoring and testing requirements for drinking water. However, FDA cGMP regulations include requirements that:

- Are generally more frequent than community water systems;
- Do not allow for averaging of test results;
- Are consistent, regardless of number of consumers;
- Are generally not subject to local monitoring waivers or reductions in test frequency; and
- Are more frequent on a per gallon basis.

## 7.4. DISTRIBUTION OF FINISHED WATER

Perhaps the most notable difference between tap water and bottled water is the method of delivery. Community water systems deliver water to consumers (businesses and private residences) through miles of underground iron (unlined and poly-lined), PVC, and lead service lines that can be subject to leakage with age of the system and accidental failures, resulting in the risk of post-treatment contamination of the water that is delivered to consumers. Bottled water is delivered to consumers in sanitary, sealed containers that were filled in a bottling facility under controlled conditions in a fill room.

## 8. BIBLIOGRAPHY

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.

Other Secondary Resources:

"Bottled Water Code of Practice" International Bottled Water Association (2009).

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