

**Attachment K –
Review of Regulations and Guidelines
for Bottled Waters**

Attachment K

Seattle Public Schools Drinking Water Quality Program

Review of Bottled Water Regulatory and Water Quality Requirements

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Part A – Key Questions and Answers

Q: How is bottled water regulated?

A: Bottled water is considered a food product, and as such, it is regulated at the federal level under the jurisdiction of the Food and Drug Administration (FDA). The FDA regulates bottled water products under the Federal Food, Drug, and Cosmetic Act (FFDCA) and has established specific regulations in Title 21 of the Code of Federal Regulations (CFR). The scope of the FFDCA is limited to interstate commerce; therefore, federal regulations do not apply to bottled water that is packaged and sold within the same state, which applies to about 60 to 70% of bottled water sales. In these instances, bottled water is only subject to any state regulations that may exist. Washington State has adopted the federal regulations verbatim.

Q: How is tap water from a public water supply regulated?

A: Tap water obtained from a public water system (such as the one owned by Seattle Public Utilities) is regulated at the federal level by the Environmental Protection Agency (EPA). The federal regulatory framework governing tap water quality is the Safe Drinking Water Act (SDWA) and its amendments. These regulations cover source water protection, treatment, distribution, operations, water quality, and reporting. Individual states have the authority to adopt additional regulations; however, they must be at least as stringent as federal requirements. In Washington State, Chapter 246-290 of the Washington Administrative Code incorporates the requirements of the SDWA and its amendments.

Q: How is compliance with bottled water regulations enforced?

A: The FDA monitors and inspects bottled water products and processing plants under its general food safety program, not a specific bottled water program. Bottled water plants generally are assigned low priority for inspection due to limited resources. The FDA generally relies on individual states to enforce state and federal bottled water regulations, but most states also have very limited resources to oversee and implement bottled water programs. According to a 1999 survey, Washington State has only one-third of full-time-equivalent (FTE) staff dedicated to bottled water market regulation.

Q: What water quality monitoring requirements exist for bottled water?

A: Federal water quality monitoring requirements for bottled water include weekly testing for coliform and annual testing for various chemical compounds. However, the regulations do not require the use of state- or EPA-certified laboratories for the analyses, as is required for public water systems. Bottled water quality monitoring is typically performed at the source. There is no federal requirement that bottlers monitor water quality after storage, shipment to end-users, or at the point-of-use. There is also no requirement to place a bottling date on the label.

Q: What source protection requirements exist for bottled water supplies?

A: Federal source water protection requirements for bottled water state that the supply for each plant “shall be from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction”. Therefore, the FDA relies on state and local government agencies to approve water sources for safety and sanitary quality. According to a recent study by the National Resources Defense Council (NRDC), there are no federal regulations governing the protection of bottled water sources from pollution sources, nor are there any rules for disapproval of sources once they become contaminated. In 1990, government investigators reviewing bottler records found that 25% of the bottlers audited had no documentation of source approval.

In Washington State, bottlers must go through a source approval process with DOH in order to become licensed. The process includes site inspection and water quality analysis. While ongoing source monitoring is required per federal requirements, they are not used for license renewal.

Q: What source protection requirements exist for public water systems?

A: In Washington State, public water systems are required to prepare and implement source water protection programs in accordance with WAC 246-290-135 and SDWA requirements. The programs must be reviewed, approved by DOH, and updated at regular intervals.

Q: What water quality standards exist for bottled water, and how do they compare to the standards for tap water?

A: The FDA has established standard of quality regulations for bottled water which set forth allowable levels for various contaminants, including coliform, turbidity, color, disinfection byproducts, and inorganic, volatile organic, and synthetic organic compounds. However, the regulations contain a clause that permits bottled water containing contaminant levels above these minimum levels to still be packaged and sold providing that the label contains the language “contains excessive chemicals or bacteria” or “substandard quality”. The minimum standards for the quality of bottled water are generally comparable to those for tap water with regard to chemical compounds, but less stringent with regard to bacteriological quality. For example, the standard of quality regulations do not prohibit or limit the occurrence of fecal coliform bacteria, *E. coli*, *Giardia*, *Cryptosporidium*, viruses, or *Legionella* in bottled water. These microbes are strictly regulated in public water systems.

Q: What reporting and notification requirements exist to inform the public about the quality of bottled water, and how do they compare to the standards for tap water?

A: There are currently no mandatory federal reporting or customer “right-to-know” requirements for bottled water. Bottlers are not required to routinely notify the FDA of monitoring results, contamination problems, or violations. Rather, they are only required to maintain plant records for a period of two years and have them available should the FDA (or state) wish to inspect the facility. According to an NRDC study, “FDA inspections are quite rare (every four to five years or less frequently).” In contrast, public water systems in Washington State are required to report source, treatment, and system monitoring results to DOH according to specific schedules/timelines for compliance determination. Public water systems are also required to notify their customers of monitoring results, both on a routine basis in the form of an annual “state-of-the-water” report known as a Consumer Confidence Report (CCR), and on an emergency basis for violations that have potential to impact health.

Part B – Narrative

1.0 Regulatory Framework

Bottled Water

Bottled water is considered a food product, and as such, it is regulated at the federal level under the jurisdiction of the Food and Drug Administration (FDA). The FDA regulates bottled water products under the Federal Food, Drug, and Cosmetic Act (FFDCA) and has established specific applicable regulations in Title 21 of the Code of Federal Regulations (CFR). These regulations include the following:

- Standard of identity regulations (21 CFR 165.110[a]), which define different types of bottled water, such as spring water and mineral water.
- Standard of quality regulations (21 CFR 165.100[b]), which establish allowable levels for contaminants in bottled water.
- Current good manufacturing practices (CGMP) for the processing and packaging of bottled drinking water (21 CFR 129), which are intended to provide assurance that bottled water products are processed, bottled, held, and transported under sanitary conditions and are safe for human consumption.

In addition, regulations on labeling (21 CFR 101) and CGMP for foods in general (21 CFR 110) also apply to bottled water.

The scope of the FFDCA is limited to interstate commerce; therefore, federal regulations do not apply to bottled water that is packaged and sold within the same state, which applies to about 60 to 70% of bottled water sales [2]. In these instances, bottled water is only subject to any state regulations that may exist. States are under no legal obligation to adopt the FDA bottled water standards, although many have. Washington State has adopted the federal regulations verbatim [2].

The FDA regulations only apply to specific forms of bottled water, as described in the standard of identity provisions. Products labeled as water, carbonated water, disinfected water, filtered water, seltzer water, soda water, sparkling water, or tonic water are not considered bottled water and are exempt from federal regulation.

The International Bottled Water Association (IBWA), a trade association comprised of voluntary membership from bottled water companies, provides a limited degree of industry regulation. The IBWA sets manufacturing requirements and has developed a model code of regulations that its members must follow [8]. Bottled water producers who are members of IBWA are inspected annually by NSF International for conformance with IBWA and FDA requirements. Roughly 85 to 90% of the domestic bottled water market and 35 major imported brands are produced by member companies [2]. Since membership is optional however, this is not equivalent to an enforceable federal regulatory program.

Tap Water

Tap water obtained from a public water supply (like Seattle Public Utilities) is regulated at the federal level by the Environmental Protection Agency (EPA). The federal regulatory framework governing tap water quality is the Safe Drinking Water Act (SDWA) and its amendments. These regulations cover source protection, treatment, distribution, operations, water quality, and reporting. Individual states have the authority to adopt additional regulations; however, they must be at least as stringent as federal requirements. In Washington State, Chapter 246-290 of the Washington Administrative Code incorporates the requirements of the SDWA and its amendments.

2.0 Compliance Enforcement

Bottled Water

The FDA monitors and inspects bottled water products and processing plants under its general food safety program, not a specific bottled water program. Bottled water plants generally are assigned low priority for inspection due to limited resources and FDA has commented that “bottled water products are a relatively low public health problem” [2]. In 1995, FDA refused an IBWA petition asking for annual FDA inspections of bottlers, citing low priority and lack of resources [6]. As a result, the FDA generally relies on individual states to enforce state and federal bottled water regulations [7]. According to a study by the National Resources Defense Council (NRDC), the FDA has no formal system to track the adequacy of state regulations, inspection results, enforcement, source water approvals, or other aspects of state bottled water programs [2].

Most states have very limited resources to oversee and implement bottled water programs. According to the NRDC study, Washington State has only one-third of full-time-equivalent (FTE) staff dedicated to bottled water market regulation. The state requires that bottled water producers be licensed, with annual renewals. The NRDC survey indicated that the state has recently issued civil penalties against two bottlers for violations of federal requirements [2].

Tap Water

In Washington State, the Department of Health (DOH) Division of Drinking Water is responsible for implementation and enforcement of state and federal drinking water laws.

3.0 Monitoring Requirements

Bottled Water

At the federal level, water quality monitoring requirements for bottled water are incorporated in the CGMP regulations (21 CFR 129.35). The requirements include the following:

- Bacteriological analysis of source water must be done at least once per week.
- Chemical analysis of source water must be done at least annually.
- Analytical methods must be approved by the government agency having jurisdiction.
- Plants must maintain sampling records including date, product, production code, and results, and the records must be available to government or other inspectors for two years.

Monitoring is typically performed at the bottling plant. However, water quality can deteriorate with time, particularly in the absence of a disinfectant residual (which is typical for bottled water supplies). There is no federal requirement that bottlers test water after storage, shipment to end-users, or at the point-of-use. Also, there is no requirement to place a bottling date on the label.

Regarding quality control, the bottled water industry does *not* require the use of state- or EPA-certified laboratories for water quality analyses, as is required for public water systems. Also, there are no training or certification requirements for bottling plant personnel. In contrast, the SDWA amendments of 1996 required operators of public water systems to receive state-approved training and certification depending on the level of competence needed.

According to the NRDC survey, although federal monitoring regulations are required in Washington state, they are not reported are used for license renewals [2].

Tap Water

Monitoring requirements for public water systems are described in various SDWA regulations. The requirements depend on several factors, including the parameter, waivers, system size, and other factors.

4.0 Source Protection Requirements

Bottled Water

Federal source water requirements for bottled water are incorporated in the CGMP regulations (21 CFR 129). The regulation simply states that the water supply for each plant “shall be from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction” [3]. Therefore, the FDA relies on state and local government agencies to approve water sources for safety and sanitary quality.

According to the NRDC report, there are no guidelines for what is required of state and local rules, nor is there any explanation of what should be done if there are no state or local rules or jurisdiction. The report also cites that there are no specific federal regulations for the protection of bottled water sources from pollution sources (e.g., setbacks from hazardous waste facilities, industrial facilities, septic tanks, or underground fuel storage tanks), nor are there any rules for disapproval of sources once they become contaminated. In 1990, government investigators reviewing bottler records found that 25% of the bottlers audited had no documentation of source approval [5].

In Washington State, bottlers must go through a source approval process with DOH in order to become licensed. The process includes site inspection and chemical, physical, and bacteriological analysis. While ongoing monitoring is required per the federal CGMP requirements, they are not used for license renewal [2].

Tap Water

In Washington State, public water systems are required to prepare and implement source water protection programs in accordance with WAC 246-290-135 and SDWA requirements. The programs must be reviewed, approved by DOH, and updated at regular intervals. The requirements include comprehensive planning measures intended to preserve source water quality, including delineation of sanitary control, wellhead protection, and watershed control areas, land use inventory, hydrology, property ownership, restrictive covenants, susceptibility assessments, monitoring and control of activities, and contingency plans.

5.0 Water Quality Standards

Bottled Water

The FDA has established standard of quality regulations for bottled water in 21 CFR 165.110[b]. These regulations set forth allowable levels for various contaminants, including coliform, turbidity, color, disinfection byproducts, and inorganic, volatile organic, and synthetic organic compounds also regulated under the Phase II/V Rules for tap water. However, the regulations contain a clause that permits bottled water containing contaminant levels above these minimum levels to still be packaged and sold providing that the label contains the language “contains excessive chemicals or bacteria” or “substandard quality”.

Since the 1996 SDWA amendments, the FDA has been required (per section 410 of the FFDCA) to either adopt for bottled water any new drinking water standard or treatment technique developed by the EPA for tap water, or alternately justify waiving the requirement and publish the reasons in the Federal Register. However, this requirement has not yet been legally applied to contaminants for which EPA had issued tap water standards *before* the enactment of the 1996 SDWA amendments, which includes the Surface Water Treatment Rule and Total Coliform Rule.

Based on review of standard of quality regulations, the minimum standards for the quality of bottled water are generally comparable to those for tap water with regard to chemical compounds but less stringent with regard to bacteriological quality. A comparison of the regulations is provided below.

Chemical

The standard of quality regulations for bottled water do not contain requirements for acrylamide, epichlorohydrin, di(2-ethylhexyl)phthalate (a plasticizer often found in bottled water packaging), or asbestos. For all other chemical compounds regulated under the SDWA Phase II/V Rules, Radionuclides Rule, and Disinfectants/Disinfection Byproduct Rules, the allowable levels for bottled water are at least as stringent as the federal Maximum Contaminant Levels (MCLs) for tap water. The standard for lead in bottled water (5 ppb) is actually more restrictive than the action level for tap water (15 ppb) since most lead in public water systems is the result of distribution system components.

Few bottled waters contain the fluoride levels found in municipal water supplies. The mineral (which serves to help prevent dental caries) is added to nearly 60 percent of the nation's public water supply [5], but is not typically applied to bottled water.

Bacteriological

Fecal coliform and *E. coli* bacteria are useful indicators of potential contamination from disease-causing microorganisms transmitted in feces. The standard of quality regulations for bottled water do not prohibit or limit the occurrence of *E. coli* or fecal coliform in bottled water. For tap water supplies, these indicator organisms are strictly regulated under the Total Coliform Rule (TCR). The presence of these bacteria in finished tap water is considered an acute violation that requires immediate public notification, reporting, and corrective action.

Total coliform bacteria are naturally present in the environment and are used as indicators that other, potentially harmful bacteria, may be present. The standard of quality regulations for bottled water permit the presence of coliform bacteria up to certain levels, depending on the analytical method used. For tap water supplies, these indicator organisms are regulated under the TCR, which establishes an MCLG of zero. For public water systems, routine and follow-up monitoring is required to ensure that these bacteria are strictly controlled.

The standard of quality regulations for bottled water do not contain requirements on the identification or removal of *Giardia*, *Cryptosporidium*, viruses, or Legionella. These are known pathogens that are often found in surface water and vulnerable groundwater supplies. For public water systems, these microorganisms are regulated under the various surface water treatment rules, which specify source control, filtration, and disinfection treatment technique requirements to continuously ensure specific levels of removal and inactivation.

The standard of quality requirements permit up to 5 NTU of turbidity in bottled water. To ensure effective removal of pathogens, the IESWTR requires that filtered systems produce water containing no more than 0.3 NTU in 95% of monthly samples, and no more than 1 NTU at all times.

The National Resources Defense Council (NRDC), in a recent four-year study on bottled water, commissioned independent lab testing of more than 1,000 bottles of 103 types of bottled water. The results showed that 22% of the waters tested violated strict applicable state (California) limits for bottled water in at least one sample, most commonly for arsenic and SOCs, and another 17% of the waters contained, in at least one sample, more bacteria than allowed under microbiological-purity guidelines (based on HPC) adopted by some states, the industry, and the EU [2].

6.0 Reporting and Notification

Bottled Water

At a federal level, there are currently no mandatory reporting or “right-to-know” requirements for bottled water companies. Bottlers are not required to notify the FDA of monitoring results, contamination problems, or violations. They are only required (per 21 CFR 129.80[h]) to maintain plant records for a period of two years and have them available should the FDA wish to inspect the facility. However, according to an NRDC study, “FDA inspections are quite rare (every four to five years or less frequently).” This suggests that many contamination problems or violations may never come to the department’s attention because the record of the event no longer exists at the time of inspection.

As required section 114b of the 1996 SDWA amendments, the FDA published (65 FR 51833) a final study report on the feasibility of appropriate methods of informing consumers about the contents of bottled water. While the FDA agreed that the conveyance of CCR-type information was important, and could be feasibly accomplished through the inclusion of limited information on the label and information packages with bulk water deliveries, they were not mandated to pass a regulation to enforce these findings.

Tap Water

Public water systems are required to report monitoring results to the EPA or state primacy agency according to specific schedules/timelines for the purpose of monitoring and water quality compliance determination. Water systems are also required to notify its customers of its monitoring results, both on a routine basis in the form of an annual “state-of-the-water” report known as a Consumer Confidence Report (CCR), and on an emergency basis for violations that have potential to impact health. The federal Public Notification Rule (PNR) requires that water systems notify customers of acute violations when they occur. The PNR outlines public notification requirements for violations of MCLs, treatment techniques, testing procedures, monitoring requirements, and violations of a variance or exemption. If violations have the potential for “serious adverse effect,” consumers and the State must be notified within 24 hours of the violation. The notice must explain the violation, potential health effects, corrective actions, and whether consumers need to use an alternate water source. Notice must be made by appropriate media or posted door-to-door. Less serious violations must be reported to consumers within 30 days, in an annual report, or by mail or direct delivery service within one year depending on the severity of the violation.

7.0 References

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