

## The Facts About Water

### REGULATIONS

#### Filtered Water

##### **Water Filter Regulations**

A water filter can be defined as any device which reduces impurities from a water supply. Within the broad category of water filters there are many different types of units.

Filters can be categorized and compared based upon the following criteria:

- Filter type
- What you are filtering for, such as by-products, taste or lead, for example
- Where the unit is installed or used, such as the countertop or under the sink
- The rated service life of the filter, usually expressed in months or gallons

##### **Regulations**

**Federal:** There are no federal regulations regarding the design or effectiveness of water filters.

**State:** Four of the 50 U.S. states (California, Iowa, Massachusetts, and Wisconsin) have regulations and requirements for some types of water filters installed, sold or distributed in their state.

##### **Standards**

**Federal:** There are no federal standards regarding the design or effectiveness of water filters.

**State:** The four states with water filter requirements mandate that manufacturers making claims covered by their state statutes and regulations, submit data.

##### **Testing Frequencies**

**Federal:** None

**State:** The frequency of testing varies.

##### **Compliance & Enforcement**

**Federal:** None

**State:** Compliance with state regulations is generally enforced through annual requirements to renew certifications/licenses, submission of testing data, and regulator follow-up on complaints or other information regarding changes in the manufacturer's products or claims.

##### **Protection Guarantees**

**Federal:** In contrast to bottled water, there are no federal regulations regarding the design or effectiveness of water treatment filters.

**State:** Because the source of the water may contain contaminants which the filter is not designed to reduce or contaminants in excess of the levels for which the unit was tested, state regulations are not intended to provide a guarantee that the final filtered water will meet all EPA safe drinking water act requirements.

*References:*

- California Department of Human Services, Health and Safety Code: Division 104, Part 12, Chpt 5, Article 3. 2003.
- Iowa Department of Public Health, Iowa Administrative Code 641-Chapter 14: Residential Water Treatment.
- Massachusetts Office of Consumer Affairs and Business Regulation. 248 CMR 10.00: Uniform State Plumbing Code.
- NSF International, NSF/ANSI 42-2007a: Drinking Water Treatment Units-Aesthetic Effects. Ann Arbor: NSF International, 2007.
- NSF International, NSF/ANSI 53-2007a: Drinking Water Treatment Units-Health Effects. Ann Arbor: NSF International, 2007.
- Wisconsin Department of Commerce, Wisconsin Administrative Code: Chapter Comm 81: Definitions and Standards.
- Wisconsin Department of Commerce, Wisconsin Administrative Code: Chapter Comm 84: Plumbing Products.

## **Bottled Water**

### **Bottled Water Regulations**

Bottled water is defined by the United States Food and Drug Administration (FDA) as “water intended for human consumption that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents.” All products meeting the definition for bottled water can be labeled as such.

However, the FDA has created additional identities which can be used instead of the term “bottled water” to identify bottled water products. These terms distinguish types of bottled water based upon the source (spring water, artesian water, well water), treatment processes used (distilled water, demineralized water, reverse osmosis water, deionized water), or the presence or absence of specific constituents of the water (mineral water, purified water, sterile water, and sparkling water). These additional standards of identity can be used in lieu of the term “bottled water.”

### **Regulations**

**Federal:** The FDA regulates bottled water as a packaged food product. FDA regulations that must be met for food products include requirements regarding naming, good manufacturing practices (GMPs), labeling and quality.

**State:** All states regulate bottled water. The FDA relies on the states to approve bottled water sources. In addition to this source approval jurisdiction, states have established and enforce their own rules and regulations regarding bottled water.

All 50 U.S. states regulate bottled water produced within their state. Twenty-three states also regulate out-of-state bottlers, requiring manufacturers to provide documentation demonstrating compliance with state requirements and obtain a license, registration, or other approval prior to distributing product.

### **Standards**

**Federal:** The FDA has established allowable levels for contaminants in bottled water (chemical, physical, microbial and radiological) referred to as the Standards of Quality (SOQ's). By law FDA standards for bottled water must be as stringent and protective of public health as U.S. Environmental Protection Agency standards for public water supplies. As a result of this stringency, the list of contaminants FDA regulates for bottled water finished products in 21 CFR 165 is very similar to the list of contaminants EPA regulates for public water supplies in 40 CFR. In a few instances FDA has determined that an EPA regulated substance is not applicable to bottled water because the substance is not likely to be found. And, in a few instances, FDA bottled water standards are more stringent than EPA's public drinking water standards (e.g. copper, fluoride, lead, nickel and phenols).

**State:** The standard of quality regulations for bottled water are issued under the authority of the Standards of Identity and, therefore, pre-empt state laws that conflict with the FDA Standards of Quality. Several states have regulations which require bottled water be analyzed for and demonstrate compliance with the additional contaminants not regulated by FDA as listed in the states' safe drinking water act.

### Testing Frequencies

**Federal:** The FDA outlines the minimum sampling and testing required of source water and final product for the microbiological, chemical and radiological contaminants standards of quality.

The FDA requires that product samples are to be taken and analyzed by the plant "as often as necessary, but at a minimum frequency of" once each week for microbiological contaminants and once each year for chemical and radiological contaminants. This testing must be performed at the frequency specified by FDA. FDA does not allow for waivers or exemptions from this testing.

The FDA also requires bottlers to collect and analyze source water samples "as often as necessary, but at a minimum frequency" of once each year for chemical contaminants, once every four years for radiological contaminants, and once each week for microbiological contaminants. FDA does allow for some exceptions to the source testing frequency if the source originates from a public water system in compliance with the EPA Safe Drinking Water Act or can demonstrate that such a reduction is consistent with state issued waivers under EPA regulations.

In addition to product and source analysis, requires bottlers to analyze product water (water which has been processed through the plant water treatment equipment but has not yet been bottled) "as often as is necessary to ensure uniformity and effectiveness of the processes performed by the plant." As well as perform quarterly microbiological sterility tests for Total Coliform and Plate Count on the containers (bottles) and closures (caps) being used.

**State:** Some states' bottled water regulations require analysis for some or all of the state regulated contaminants to be performed at a frequency other than that specified by the FDA for source, product or both. This is particularly common in states where bottled water regulations are based in part on the state's safe drinking water act. Therefore the state requires bottlers to test for contaminants at the same frequency as a public water supplier, such as Kentucky, Pennsylvania and Alaska.

### Compliance

**Federal:** FDA is responsible for verification of compliance:

- To ensure compliance, the FDA monitors and inspects bottled water products and bottling facilities under its general food safety program.
- FDA also periodically collects and analyzes samples of bottled water products to verify compliance as part routine plant inspections, follows up on consumer or trade complaints, and customs inspections of foreign bottled water products being imported to the U.S.

**State:** State's are responsible for enforcing state bottled water regulations:

- To ensure compliance with state regulations, states inspect bottled water sources and production facilities located in their state.
- Some states also collect samples of bottled water from retail shelves for routine compliance checks or in response to consumer or trade complaints. These samples are checked to ensure the manufacturer holds proper licenses and the product is properly labeled.
- In some cases, states also perform analysis of the bottled water samples for independent verification of compliance with quality standards.

### Protection Guarantees

In contrast to water filters, there is protection guarantees for bottled water. Each unit of bottled water product manufactured, sold, or distributed within the United States is required to be in compliance with the labeling and the bottled water standards of quality.

Non-compliant products containing contaminants that exceed the Standard of Quality may be considered adulterated under the FFDCA and subject to FDA enforcement actions including inspection of the facility, use of warning letters, request for voluntary recalls, civil actions (including seizures or injunctions), and criminal prosecution.

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The Food and Drug Administration. *Federal Food, Drug, and Cosmetic Act: Section 417-Reportable Food Registry*. 12 Sept 2008 <<http://www.fda.gov/opacom/laws/fdcact/fdact4a/html>>.

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## **Tap Water**

### **Tap Water Regulations**

A public water system is defined by the Environmental Protection Agency (EPA) as "a system for the provision to the public of water for human consumption through pipes or other constructed conveyances, if such system has at least fifteen service connections or regularly serves at least twenty-five individuals." A public water system can be either publicly or privately owned.

### **Regulations**

**Federal:** The United States Environmental Protection Agency (EPA) regulates public water systems with the Safe Water Drinking Act (SWDA)

The SDWA gives the EPA the authority to set national health-based standards for drinking water to protect against contaminants that may be found in drinking water. EPA regulations implementing SWDA are found in Title 40 of the Code of Federal Register.

**State:** Under the SDWA, states that set regulations which are at least as stringent as US EPA's, may apply for, and receive primary enforcement authority.

## Standards

**Federal:** There are two categories of drinking water regulations containing contaminant standards: the National Primary Drinking Water Regulations and the National Secondary Drinking Water Regulations.

### **The National Primary Drinking Water Regulations**

These are limits for contaminants that can adversely affect human health and are known or anticipated to occur in water. Examples include lead and arsenic. The limits, established as Maximum Contaminant Levels (MCLs) or Treatment Techniques (TT), are legally enforceable standards for public water supplies.

### **National Secondary Drinking Water Regulations**

These are limits for contaminants which can adversely affect the aesthetic quality of water (taste, odor, color) or other non-health related undesirable effect. The limits, established as Secondary Maximum Contaminant Levels (SMCLs), are recommended. While the standards are not enforceable at the federal level, some states have chosen to enforce the SMCL standards for public water supplies in their state.

**State:** States' regulations do not have to be identical to that of the EPA, however, the state does have to demonstrate differences are at least as protective of public health. States' drinking water regulations can, therefore, differ from that the EPA. Some differences of state drinking water regulations from that of the EPA may include:

- More stringent maximum contaminant levels
- Standards for contaminants not yet regulated by EPA

## Testing Frequencies

**Federal:** The EPA regulations in 40 CFR 141 and 143 include monitoring schedules for public water systems. The frequency with which a particular public water system is required to test under EPA regulations is based upon the following factors: type of system, system size, source type, detections or known risks, and any monitoring waivers or variances which have been granted. The EPA's Standardized Monitoring Framework, provides guidance to states on creating a monitoring framework which meets EPA criteria.

The Standardized Monitoring Framework shows how the variables of system size, system type, source type, detections and waivers provide a range of monitoring requirement frequencies and schedules. For example, a public water system obtaining water from a groundwater source may qualify for a waiver for some or all of the contaminants classified as VOC's. This ability to qualify for a waiver is another difference between the rigorous testing standards for bottled water as contrasted with tap water. If a public water system did not receive a waiver, and have completed the initial round of monitoring for four quarters with no detects, the system qualifies to reduce testing to annually. A system can qualify for further reduced testing requiring just one sample for each three year compliance period, if they continue to receive no detections for these contaminants.

EPA regulations provide guidance regarding where samples are to be collected. Most contaminants (radiologicals, inorganic chemicals, organic chemicals, volatile organic chemicals, are required to be sampled at the point where the water enters the distribution system. However, total coliform, and sometimes disinfectants, disinfection by-products, and asbestos are required to be collected from points in the distribution system. Lead and copper samples and a handful of other water quality parameters are required to be collected from cold water taps in homes/buildings that are at high risk of lead or copper contamination. However, there is no set testing requirement for microbiological contaminants at the cold water tap.

**State:** Monitoring schedules for individual systems are based upon the EPA regulations or the State Drinking Water Regulations as approved by the EPA if the state has been granted primacy.

### **Contaminant Disclosure**

**Federal:** The EPA Safe Drinking Water Act requires systems who have received a Notice of Violation of the Safe Drinking Water Act that may have “serious adverse effects” to issue public notice within 24 hours of the violation occurring. The notice must include a description of the violation, what actions are being taken to correct the violation, and what actions should be taken by consumers such as not consuming or a boil order. Along with consumers, the State must be notified of the serious effect violation.

The Safe Drinking Water Act also requires every community water system that serves at least 25 residents year round or that has at least 15 service connections to prepare and distribute a consumer confidence report to all municipal customers by the July 1 of each year.

**State:** States granted primacy by the EPA are required to establish and enforce state regulations to include EPA SDWA requirements for monitoring, reporting, performing treatment techniques, record keeping, and public notice requirements. States keep data for systems they regulate in the state data system and are required to submit reports of violations of Maximum Contaminant Levels and treatment techniques, as well as monitoring violations, to the U.S. EPA.

### **Protection Guarantees**

Both EPA and states can take enforcement actions against any water system that is not meeting safety standards. Enforcement actions may include administrative orders, legal actions or fines.

#### *References:*

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