Bottled Water Regulation and the FDA

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Bottled water is an increasingly popular beverage in the U.S. Total U.S. bottled water sales have grown from roughly 6% to more than 13% per year over the last five years, according to data from MarketResearch.com and from the Beverage Marketing Corp (BMC).[1,2] Based on these growth rates, BMC has predicted that bottled water may soon become the nation's second most popular beverage after soft drinks.[3]

Another indicator of bottled water's popularity is the steady stream of questions about bottled water flowing into the U.S. Food and Drug Administration's (FDA) regulatory and consumer information staff. Who regulates bottled water? How is it regulated? Is bottled water tested and inspected? This article will summarize FDA's approach to regulating bottled water, covering such topics as pertinent regulations, statutory authority and requirements for regulation of bottled water, and inspections and sampling.

REGULATING BOTTLED WATER

In the U.S., bottled water and tap water are regulated by two different agencies; the FDA regulates bottled water and the U.S. Environmental Protection Agency (EPA) regulates tap water (also referred to as municipal water or public drinking water). EPA's Office of Ground Water and Drinking Water has issued extensive regulations on the production, distribution and quality of drinking water, including regulations on source water protection, operation of drinking water systems, contaminant levels and reporting requirements.

FDA regulates bottled water as a food. The Federal Food, Drug, and Cosmetic Act (FFDCA) provides FDA with broad regulatory authority over food that is introduced or delivered for introduction into interstate commerce. Under the FFDCA, manufacturers are responsible for producing safe, wholesome and truthfully labeled food products, including bottled water products. It is a violation of the law to introduce into interstate commerce adulterated or misbranded products that violate the various provisions of the FFDCA.

FDA has established specific regulations for bottled water in Title 21 of the *Code of Federal Regulations* (21 *CFR*), including standard of identity regulations (21 *CFR* § 165.110[a]) that define different types of bottled water, such as spring water and mineral water, and standard of quality regulations (21 *CFR* §165.110[b]) that establish allowable levels for contaminants (chemical, physical, microbial and radiological) in bottled water. FDA also has established Current Good Manufacturing Practice (CGMP) regulations for the processing and bottling of bottled drinking water (21 *CFR* part 129). Labeling regulations (21 *CFR* part 101) and CGMP regulations (21 *CFR* part 110) for foods in general also apply to bottled water. It is worth noting that bottled water is one of the few foods for which FDA has developed specific CGMP regulations or such a detailed standard of quality.

21 CFR Part 129. These regulations require that bottled water be safe and that it be processed, bottled, held and transported under sanitary conditions. Processing practices addressed in the CGMP regulations include protection of the water source from contamination, sanitation at the bottling facility, quality control to assure the bacteriological and chemical safety of the water, and sampling and testing of source water and the final product for microbiological, chemical, and radiological contaminants. Bottlers are required to maintain source approval and testing records to show to government inspectors. Checking adherence to part 129 regulations is an important part of FDA inspections of bottled water plants.

21 CFR § 165.110. This section establishes a standard of identity and a standard of quality for bottled water. Under the standard of identity (165.110[a]), FDA describes bottled water as water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may contain safe and suitable antimicrobial agents. Fluoride also may be added within the limits set by the FDA. The name of the food is "bottled water" or "drinking water." FDA also has defined various other types of bottled water, such as "artesian water," "artesian well water," "ground water," "mineral water," "purified water," "sparkling bottled water," and "spring water" (Table 1). Bottled water labeled with any of these terms must meet the appropriate definitions under the standard of identity or it will be considered misbranded under the FFDCA. For example, a bottle labeled as containing "mineral water" must meet

the following criteria, among others: the water must contain no less than 250 parts per million (ppm) total dissolved solids; it must come from a geologically and physically protected underground water source; and it must contain no added minerals. "Mineral water" also must have a constant level and relative proportions of minerals and trace elements at the point of emergence from the source, with due account being taken of natural fluctuation cycles. FDA established its definitions for different types of bottled water in 1995 (60 *FR* 57076). These preempted state definitions existing at that time, some of which varied from state to state.

Under the standard of quality (165.110[b]), FDA establishes allowable levels for contaminants in bottled water. There are microbiological standards that set allowable coliform levels; physical standards that set allowable levels for turbidity, color and odor; and radiological standards that set levels for radium-226 and radium-228 activity, alpha-particle activity, and beta particle and photon radioactivity. The standard of quality also includes allowable levels for more than 70 different chemical contaminants. (For complete information on allowable levels for chemical or other contaminants, see 21 *CFR* 165.110[b].)

Section 165.110(b) also lists methods that the FDA will use to determine whether bottled water samples comply with the quality standard. Bottlers are not required to use these methods in their own facilities; alternate methods are acceptable. Whatever method they use, bottlers are responsible for ensuring that their bottled water can pass the tests used by FDA in its own laboratories, should testing be performed by the FDA.

What happens if bottled water contains a substance at a level greater than that allowed under the quality standard? Section 165.110(c) states that when the microbiological, physical, chemical or radiological quality of bottled water is below that prescribed in the quality standard, the label of the bottled water bottle must contain a statement of substandard quality, such as "Contains Excessive Bromate," "Contains Excessive Bacteria," or "Excessively Radioactive." However, including a label of substandard quality may not be sufficient. Regardless of whether bottled water bears a statement of substandard quality, it is considered adulterated if it contains a substance at a level considered injurious to health under section 402(a)(1) of the FFDCA.

TYPE	DEFINITION
Artesian Water	Water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer.
Mineral Water	Water containing not less than 250 ppm total dissolved solids that originates from a geologically and physically protected underground water source. Mineral water is characterized by constant levels and relative proportions of minerals and trace elements at the source. No minerals may be added to mineral water.
Purified Water	Water that is produced by distillation, deionization, reverse osmosis or other suitable processes and that meets the definition of "purified water" in the U.S. Pharmacopeia, 23d Revision, Jan. 1, 1995. As appropriate, also may be called "demineralized water," "deionized water," "distilled water," and "reverse osmosis water."
Sparkling Bottled Water	Water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at emergence from the source.
Spring Water	Water derived from an underground formation from which water flows naturally to the surface of the earth at an identified location. Spring water may be collected at the spring or through a bore hole tapping the underground formation feeding the spring, but there are additional requirements for use of a bore hole.

Table 1. Various types of bottled water.
(For complete regulatory definitions, see 21 CFR 165.110(a)(2).)

Another noteworthy point about section 165.110 is that it allows for the use of safe and suitable antimicrobial agents, such as ozone (see 21 *CFR* §184.1563 for details on ozone usage). The FDA does not specifically require that bottlers use antimicrobial agents in bottled water as long as the water is safe for human consumption.

Inspection of Bottled Water Plants

FDA monitors and inspects bottled water products and processing plants under its general food safety program, not a specific bottled water program. Because FDA's experience over the years has shown that bottled water has a good safety record, bottled water plants generally are assigned low priority for inspection. The agency, however, inspects violative firms more frequently depending on the number, significance and recurrence of violations. In addition, FDA's field offices follow up on consumer and trade complaints and other leads, as appropriate, on potentially violative bottled water products.

General information about what FDA inspectors look for during inspections can be found in the Investigations Operations Manual published by FDA's Office of Regulatory Affairs (ORA). More detailed information about inspections of bottled water facilities can be found in the *Guide to Inspections of Manufacturers of Miscellaneous Food Products, Volume II*. Both of these documents can be accessed at www.fda.gov by following links to ORA and subsequently to inspection references. Specific items mentioned in the inspection guide for bottled water establishments include: (1) verifying that the plant's product water and operational water supply are obtained from an approved source; (2) checking whether any source claims on the label comply with the definitions in 165.110(a); (3) inspecting washing and sanitizing procedures; (4) inspecting the

filling, capping, and sealing operations; and (5) determining whether the firms analyze their source water and product water for the chemical and microbiological contaminants listed in165.110(b) according to the required schedules.

Sampling and Testing

As with other types of food, FDA periodically collects and analyzes samples of bottled water. Samples come from several different sources. Some samples are collected during inspections if the inspector's observations warrant collection to test for contaminants or if the bottled water facility has a previous history of contamination. Other samples are collected in response to trade or consumer complaints. Starting in FY 2003, bottled water samples will be collected as part of FDA's Total Diet Study. Finally, samples of foreign bottled water products offered for entry into the U.S. may be collected and tested to determine if they are in compliance with all applicable U.S. laws and FDA regulations.

FDA laboratories may test the water for microbiological, radiological or chemical contamination. Individual samples are not tested for all possible contaminants cited in the quality standard, but for selected contaminants, depending on the reason for the sampling. For example, suspected microbiological contamination may result in microbiological analysis. (However, as noted, bottlers are required to maintain testing records to show to government inspectors for all the contaminants in the quality standard.) FDA also may review the labeling on bottled water samples.

State and Local Regulations

In addition to the FDA, state and local governments also regulate bottled water. The FDA relies on state and local government agencies to approve water sources for safety and sanitary quality, as specified in part 129.3(a). Also, some states have regulations that differ from FDA's in content or coverage. For example, Texas requires water haulers transporting water in a tank truck or trailer to maintain a minimum chlorine residual of 0.5 mg/L in the water, whereas FDA does not have any specific regulations requiring chlorination of water.[4] The International Bottled Water Association (IBWA), a trade association representing bottled water companies, also has developed a model code of regulations that its members must follow.

Developing New Regulations at FDA

Section 410 of the FFDCA provides FDA with specific instructions on establishing quality standard regulations for bottled water in response to developments at EPA. Under section 410, when EPA establishes new maximum contaminant levels (MCLs) or treatment techniques for contaminants in public drinking water as part of a National Primary Drinking Water Regulation (NPDWR), FDA is required to establish a standard of quality regulation for the same contaminants in bottled water, or to make a finding that such a regulation is not necessary to protect the public health because the contaminant is not present in water used for bottled drinking water. For treatment techniques, section 410 requires that bottled water be subject to requirements no less protective of the public health than those applicable to water from public water systems using the techniques required by EPA's NPDWRs. If FDA adopts an allowable level under the qual-

FAQs About Bottled Water

What must I do to get my bottled water product approved for importation into the U.S.?

FDA's food import procedures can be found on the CFSAN website (www.cfsan.fda.gov/~lrd/imports.html). There are no special import procedures for bottled water.

I'm interested in starting a bottled water business. What must I do to get FDA approval?

FDA does not approve bottled water firms or bottled water products. However, some states may require approval of bottled water products sold within their states. It is the responsibility of the bottled water manufacturers to ensure that their products in interstate commerce comply with all applicable provisions of the FFDCA and FDA's regulations for bottled water.

Do I have to use the testing methods cited in FDA's regulations for bottled water?

No, these are the methods that FDA will use when the agency tests samples of bottled water for compliance purposes. Whatever method they use, bottlers are responsible for ensuring that their bottled water can pass the tests used by FDA in its own laboratories, should testing be performed by the FDA.

What is the shelf life for bottled water?

Bottled water is considered to have an indefinite safety shelf life if it is produced in accordance with CGMP and quality standard regulations and is stored in an unopened, properly sealed container. Therefore, FDA does not require an expiration date for bottled water. However, long-term storage of bottled water may result in aesthetic defects, such as off-odor and taste. Bottlers may voluntarily put expiration dates on their labels.

Are plastic containers for bottled water regulated?

The materials used to produce plastic containers for bottled water are regulated by the FDA as food contact substances. Food contact substances must be approved under FDA's food additive regulations.

Can ingredients be added to bottled water?

Bottled water is defined in 21 *CFR* 165.110 as water that contains no added ingredients, except for optional antimicrobial agents or fluoride. Therefore, firms cannot add any other ingredients to their bottled water products and still call it "bottled water" (or "mineral water" or "purified water"). The name of a product with ingredients added must include the added ingredient, such as "bottled water with minerals added" or "bottled water with raspberry flavor." The resulting product is a multicomponent beverage and must bear an ingredient list on the label or labeling. If the water ingredient is highlighted as a bottled water, such as spring water, the water ingredient must comply with FDA's bottled water regulations.

ity standard regulations, the level in bottled water must be no less stringent than EPA's MCL for drinking water; FDA's regulation must have the same effective date as EPA's regulation and must publish its regulation no later than 180 days before the effective date.

These requirements will apply to EPA's recent regulatory activity on arsenic. In January 2001, EPA published a final rule lowering its standard for arsenic in public drinking water from 50 ppb to 10 ppb, effective January 2006. After further review of its revised standard for arsenic in drinking water, the EPA confirmed the 10 ppb standard on Oct. 31, 2001. As a result, FDA must establish a quality standard for arsenic in bottled water of 10 ppb or less, or make a finding that such regulation is not necessary, no later than 180 days before January 2006. An example of other recent regulatory activity by EPA is the final rule that established an MCL for uranium in drinking water, which is effective December 2003.

FDA has generally adopted EPA's MCLs for contaminants in public drinking water as allowable levels for the same contaminants in the quality standard regulations for bottled water. However, in some cases, FDA standards for bottled water are different than EPA standards for public drinking water. Lead is an example. In 1991, EPA adopted a requirement that public water systems treat their water to reduce lead when lead levels consistently exceed 15 parts per billion (ppb). The 15 ppb level took into account the fact that lead appears in public drinking water from corrosion of public water distribution systems and residential plumbing. However, leaching of lead from distribution systems is not a factor for bottled water and, based on its survey data, FDA concluded that bottlers can readily produce bottled water products with lead levels below 5 ppb. In 1994, FDA adopted an allowable level for lead at 5 ppb as a bottled water quality standard regulation (59 *FR* 26933). This action was consistent with FDA's goal of reducing consumers' exposure to lead in drinking water to the extent practicable.

Recent regulatory activities

Disinfectants and disinfection byproducts. In 2001, FDA adopted EPA's MCLs and maximum residual disinfectant levels (MRDLs) for four disinfection byproducts (bromate, chlorite, haloacetic acids and total trihalomethanes) and for three disinfectants (chloramine, chlorine and chlorine dioxide), respectively, as allowable levels in its standard of quality regulations for bottled water (66 *FR* 16858, March 28, 2001). FDA also revised the source water monitoring requirements in the CGMP regulations for bottled water to allow flexibility in testing for these seven contaminants in cases where they would not be expected to be found in source water. The Jan. 1, 2002 effective date for this regulation is the same as the effective date of EPA's regulations for the same contaminants in public drinking water.

Interim Enhanced Surface Water Treatment Rule. In a *Federal Register* notice of July 5, 2001 (66 *FR* 35439), FDA announced that it would not issue a standard of quality regulation in response to an EPA rule (63 *FR* 69477) establishing treatment technique requirements for improved control of *Cryptosporidium* in public drinking water obtained from surface water or ground water under the influence of surface water. FDA concluded that such a regulation is not necessary to protect the public health because bottled water is produced either from ground water that is not under the influence of surface water (see the definition in 165.110(a)(2)[ii]) or from water from public water systems, which is already treated according to EPA standards. Therefore, source waters used for bottling are not expected to contain *Cryptosporidium*.

Bottled Water Feasibility Study. Under the Safe Drinking Water Act Amend-ments of 1996 (Section 114[b]), FDA was required to publish for notice and comment a draft study and a final study on the feasibility of appropriate methods of informing consumers about the contents of bottled water. FDA published a notice requesting comments on this issue on Nov. 12, 1997 (62 *FR* 60721) and a draft feasibility study on Feb. 22, 2000 (65 *FR* 8718). Based on comments, FDA published a final study report on Aug. 25, 2000 (65 *FR* 51833). The final study report evaluates information received from the comments and identifies appropriate and feasible methods for conveying information about the contents of bottled water to consumers.

Conclusion

Bottled water is regulated as a food under the FFDCA by the FDA. Specific FDA regulations in the bottled water area cover CGMPs for bottled water production and a standard of identity and quality for bottled water. Recent regulatory activity on bottled water includes adoption of allowable levels of certain disinfectants and disinfection byproducts in the quality standard for bottled water and publication of a feasibility study on the appropriate methods for providing consumers with information on the contents of bottled water. The frequency of questions on bottled water reflects public interest in this increasingly popular drink.

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