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BOTTLED WATER

FDA Safety and Consumer Protections Are Often Less Stringent Than Comparable EPA Protections for Tap Water



GAO

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Highlights of [GAO-09-610](#), a report to congressional requesters

Why GAO Did This Study

Over the past decade, per capita consumption of bottled water in the United States has more than doubled. With this increase have come several concerns in recent years about the safety, quality, and environmental impacts of bottled water. The Food and Drug Administration (FDA) regulates bottled water under the Federal Food, Drug, and Cosmetic Act as a food and is responsible for ensuring that domestic and imported bottled water is safe and truthfully labeled.

Among other things, GAO

- (1) evaluated the extent to which FDA regulates and ensures the quality and safety of bottled water;
- (2) evaluated the extent to which federal and state authorities regulate the accuracy of labels and claims regarding the purity and source of bottled water; and
- (3) identified the environmental and other impacts of bottled water. GAO reviewed FDA data, reports, and requirements for bottled water; conducted a state survey of all 50 states and the District of Columbia; reviewed bottled water labels; and interviewed FDA officials and key experts.

What GAO Recommends

GAO recommends that FDA

- (1) issue a standard of quality for DEHP, or publish its reasons for not doing so, and
- (2) implement its findings regarding methods that are feasible for conveying information to consumers regarding the quality and safety of bottled water. FDA generally agreed with GAO's recommendations.

View [GAO-09-610](#) or [key components](#). For more information, contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov.

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What GAO Found

FDA's bottled water standard of quality regulations generally mirror the Environmental Protection Agency's (EPA) national primary drinking water regulations, as required by the Federal Food, Drug, and Cosmetic Act, although the case of DEHP (an organic compound used in the manufacture of polyvinyl chloride plastics) is a notable exception. Specifically, FDA deferred action on DEHP in a final rule published in 1996 and has yet to either adopt a standard or publish a reason for not doing so. GAO also found that FDA's regulation of bottled water, particularly when compared with EPA's regulation of tap water, reveal key differences in the agencies' statutory authorities. Of particular note, FDA does not have the specific statutory authority to require bottlers to use certified laboratories for water quality tests or to report test results, even if violations of the standards are found. Among GAO's other findings, the state requirements to safeguard bottled water often exceed FDA's, but still are often less comprehensive than state requirements to safeguard tap water.

FDA and state bottled water labeling requirements are similar to labeling requirements for other foods, but the information provided to consumers is less than what EPA requires of public water systems under the Safe Drinking Water Act. Like other foods, bottled water labels must list ingredients and nutritional information and are subject to the same prohibitions against misbranding. In 2000, FDA concluded that it was feasible for the bottled water industry to provide the same types of information to consumers that public water systems must provide. The agency was not required to conduct rulemaking to require that manufacturers provide such information to consumers, however, and it has not done so. Nevertheless, GAO's work suggests that consumers may benefit from such additional information. For example, when GAO asked cognizant officials in a survey of the 50 states and the District of Columbia, whether their consumers had misconceptions about bottled water, many replied that consumers often believe that bottled water is safer or healthier than tap water. GAO found that information comparable to what public water systems are required to provide to consumers of tap water was available for only a small percentage of the 83 bottled water labels it reviewed, companies it contacted, or company Web sites it reviewed.

Among the environmental impacts of bottled water are the effects on U.S. municipal landfill capacity and U.S. energy demands. Regarding impacts on landfill capacity, GAO found that about three-quarters of the water bottles produced in the United States in 2006 were discarded and not recycled, on the basis of figures compiled by an industry trade association and an environmental nonprofit organization. Discarded water bottles, however, represented less than 1 percent of total municipal waste that EPA reported entered U.S. landfills in 2006. Regarding the impact on U.S. energy demands, a recent peer-reviewed article found that the production and consumption of bottled water comprises a small share of total U.S. energy demand but is much more energy-intensive than the production of public drinking water.

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Abbreviations

DEHP	di(2-ethylhexyl)phthalate
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
IBWA	International Bottled Water Association
PET	polyethylene terephthalate

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United States Government Accountability Office
Washington, DC 20548

June 22, 2009

The Honorable Henry Waxman
Chairman
Committee on Energy and Commerce
House of Representatives

The Honorable Edward Markey
Chairman
Subcommittee on Energy and Environment
Committee on Energy and Commerce
House of Representatives

Over the past decade, the per capita consumption of bottled water in the United States has more than doubled—from 13.4 gallons per person in 1997 to 29.3 gallons per person in 2007. With this increase have come several concerns, raised by public interest groups in recent years, over bottled water's quality and safety. For example, water quality testing conducted by some of these and other groups has shown that bottled water is not necessarily cleaner than tap water. Furthermore, bottled water, like tap water, has been found in some cases to have contamination levels in excess of water quality standards used by the Environmental Protection Agency (EPA) for public water systems and adopted by the Food and Drug Administration (FDA) for bottled water. In addition to the concerns about the quality and safety of bottled water, consumer groups have also questioned whether consumers are adequately informed about the source of bottled water, how it is treated, and its quality. Finally, bottled water's potential environmental impact also has come under scrutiny. Several organizations have raised concerns about a low recycling rate for plastic water bottles, the amount of energy used to manufacture and transport the product, and the impact of groundwater extraction on local resources.

In this context, you asked us to (1) evaluate the extent to which federal and state authorities, as well as their counterparts in other countries, regulate the quality of bottled water to ensure its safety; (2) evaluate the extent to which federal and state authorities regulate the accuracy of labels or claims regarding the purity and source of bottled water; and (3) identify the environmental and other impacts of bottled water.

To address these objectives, we reviewed relevant FDA documents, policies, and guidance as well as related laws and regulations pertinent to

the oversight of bottled water at the federal and state levels; analyzed data from the FDA databases that track inspections, import examinations, and recalls; conducted a telephone survey of all 50 states and the District of Columbia; and conducted interviews with EPA and FDA officials and a variety of experts from nonprofit organizations and industry associations. We also examined bottled water labels¹ and contacted companies to determine the information they provide to consumers. A total of 83 bottled water labels were examined after removing duplicate labels or labels that were not for bottled water that were collected from GAO staff in each of our 11 field offices and at headquarters. In addition, we reviewed how several of the top exporting countries—including Canada, Fiji, and Turkey as well as the European Union and its member states—regulate bottled water. Finally, we interviewed experts and other knowledgeable officials and conducted a literature review regarding the environmental impacts of bottled water. We conducted this performance audit from June 2008 to June 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions on our audit objectives. Appendix I discusses our scope and methodology in more detail.

Background

The rapid growth in the consumption of bottled water has been attributed to a variety of factors. In a 2002 survey, The Gallup Organization (Gallup) found that the leading reason that consumers purchased bottled water was due to health-related issues; taste was the second leading reason, and the convenience of bottled water was also a factor.

Tap water and bottled water are regulated under two different federal laws—the Safe Drinking Water Act and the Federal Food, Drug, and Cosmetic Act (FFDCA), respectively. Under the Safe Drinking Water Act, EPA, or states that have primary enforcement responsibility,² are

¹Bottled water labels collected and reviewed were for different brands of bottled water sold in the United States.

²Under the Safe Drinking Water Act, states can seek primary enforcement responsibility for public water systems if they adopt drinking water regulations that are no less stringent than the national primary drinking water regulations and meet other statutory and regulatory requirements. States with primacy are responsible for inspecting their public water systems, with EPA regional offices providing oversight.

responsible for protecting the public from the risks of contaminated drinking water from public water systems and for ensuring that the public receives information on the quality of the water delivered by these systems.³ Specifically, the law requires EPA to establish national primary and secondary drinking water regulations for public water systems to control the level of contaminants in drinking water. National primary drinking water regulations are legally enforceable standards that protect water quality by limiting the levels of specific contaminants that can adversely affect public health and are known or anticipated to occur in water. Such standards take the form of either maximum contaminant levels or treatment techniques. EPA currently has national primary drinking water regulations for 88 contaminants. The agency may also set monitoring requirements to assist in determining whether public water systems are in compliance with the Safe Drinking Water Act. National secondary drinking water regulations are nonenforceable guidelines to control contaminants in drinking water that primarily affect the aesthetic or cosmetic qualities—such as taste, odor, or color—relating to public acceptance of drinking water. Although not required by EPA, states with primary enforcement responsibility may choose to adopt these secondary regulations as enforceable regulations in the state. Under the law, EPA regulations also require that public water systems provide consumer confidence reports—also known as annual water quality reports or drinking water quality reports—to their customers each year. These reports summarize local drinking water quality information about the water’s sources, any detected contaminants, and compliance with national primary drinking water regulations as well as information on the potential health effects of certain drinking water contaminants.

Because the FFDCA treats bottled water as a food, FDA, within the Department of Health and Human Services, has broad statutory authority to ensure that bottled water that is sold in interstate commerce is safe, wholesome, and truthfully labeled. FDA has established specific regulations for bottled water, including a standard of quality, a standard of identity, and current good manufacturing practices. FDA establishes allowable levels for contaminants under the standard of quality for bottled water sold in interstate commerce on the basis of the national primary drinking water regulations established by EPA. By law, no later than

³These regulations apply to public water systems, which provide the public with water for human consumption through pipes or other constructed conveyances and have at least 15 service connections or regularly serve at least 25 individuals.

180 days before the effective date of a national primary drinking water regulation, FDA is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems, but not in water used for bottled water.⁴ FDA's standard of quality regulation must be no less stringent than EPA's maximum contaminant level for drinking water, or no less protective of public health than the treatment technique required by the national primary drinking water regulation. If FDA fails to promulgate a standard of quality by the statutory deadline, the EPA national primary drinking water regulation will be considered as the standard of quality for bottled water.⁵ When establishing a standard of quality regulation for bottled water, FDA also establishes monitoring requirements that the agency determines to be appropriate.

Under FDA's standard of identity regulation for bottled water, the agency defines bottled water as water that is intended for human consumption and that is sealed in bottles or containers with no added ingredients, except that it may contain safe and suitable antimicrobial agents. The standard of identity regulation also defines various types of bottled water, such as "artesian water," "ground water," and "spring water," among others.

FDA has also established current good manufacturing practice regulations specific to bottled water. These regulations cover protection of the water source from contamination; sanitation at the bottling facility; and sampling and testing requirements for microbiological, chemical, and radiological contaminants. Bottled water is one of the few foods subject to both current good manufacturing practice regulations for foods in general and to current good manufacturing practice regulations specific to the commodity itself. Bottlers must test their source water once a week for microbiological contaminants, unless it comes from a municipal source, which must meet EPA testing requirements. Source water must be tested

⁴Prior to August 6, 1996, FDA was required to promulgate a standard of quality regulation within 180 days of EPA promulgating a national primary drinking water regulation, or publish in the *Federal Register* its reasons for not promulgating a standard of quality regulation.

⁵This "hammer provision" was enacted on August 6, 1996. Prior to its enactment, if FDA failed to promulgate a standard of quality regulation by the statutory deadline, the national primary drinking water regulation was not considered as the standard of quality for bottled water.

at least once a year for chemical contaminants and once every 4 years for radiological contaminants. Finished bottled water must be tested weekly for microbiological contaminants and at least annually for chemical, physical, and radiological contaminants. If bottled water contains contaminants at levels considered injurious to health, it is deemed to be adulterated and is subject to enforcement action.

To ensure that bottled water facilities and bottled water meet federal requirements, FDA uses a multipronged approach. The agency (1) requires bottlers to use water sources (e.g., wells, springs, and public drinking water systems) that have been tested and approved by government agencies having jurisdiction, such as state or local agencies; (2) inspects domestic bottling plants for proper operating practices and cleanliness; (3) inspects labels to confirm that labeling complies with FDA regulations; and (4) requires bottlers to test their source water and bottled water periodically to ensure compliance with the bottled water standard of quality. Furthermore, FDA tests selected samples of domestic source waters and finished bottled water for contaminants. Finally, for imported bottled water, FDA uses the same review process that applies to all imported food products.

States are also responsible for regulating bottled water. Under FDA's current good manufacturing practice regulations for bottled water, only approved sources of water can be used to supply a bottled water facility. The states or localities are responsible for approving sources of water, which may involve inspecting the source and reviewing water quality analyses. Some states also conduct inspections of bottled water facilities under contract with FDA. In addition, the states are solely responsible for regulating bottled water manufactured and sold within a single state, which does not generally fall under FDA jurisdiction.

In addition to federal and state regulations and requirements for bottled water, industry standards have been established, through a code of practice, by the International Bottled Water Association (IBWA), to which its members are required to adhere. According to IBWA, its membership includes about 80 percent of the bottled water manufacturers in the United States.⁶ To be a member, IBWA requires bottled water facilities to undergo an annual plant inspection, conducted by an independent third-party

⁶IBWA's membership does not include two of the largest bottled water manufacturers in the United States—The Coca-Cola Company (Dasani) and PepsiCo, Inc. (Aquafina).

organization, to assess compliance with all applicable regulations. The code of practice also establishes security standards that IBWA-member bottled water facilities must meet to ensure a secure facility. Such security standards are not required by FDA for bottled water facilities, but the agency does have guidance available for the facilities to follow.⁷ In addition, IBWA's code of practice also contains water quality standards for bottled water, some of which are more stringent than those of FDA under the standard of quality. (See app. II for a comparison of these standards.)

FDA's Bottled Water Standard of Quality Regulations Are Similar to EPA's Drinking Water Standards, but the Agency's Authority to Enforce Them Is Weaker

FDA's bottled water standard of quality regulations, for the most part, mirror EPA's drinking water requirements, although the case of DEHP (an organic compound widely used in the manufacture of polyvinyl chloride plastics) is a notable exception. However, FDA's implementation of these regulations, particularly when compared with EPA's implementation of its regulations concerning tap water, reveal key differences that reflect the limited nature of FDA's approach to regulating bottled water. At the heart of these differences is that EPA regulates tap water under the Safe Drinking Water Act, while FDA regulates bottled water as a "food" under the FFDCA, which does not grant FDA statutory authority to implement regulations similar to those of EPA. These differences are amplified by the fact that among the foods it regulates, using a risk-based approach, FDA generally accords bottled water a low priority.

FDA's Standard of Quality Regulations for Bottled Water Generally Mirror EPA's Drinking Water Requirements, Except in the Case of DEHP

We found that, for the most part, FDA's bottled water standard of quality regulations are equivalent to EPA's regulations for drinking water, but FDA has yet to set a standard for DEHP. Under the FFDCA, FDA is required to establish standard of quality regulations for bottled water that are no less stringent than the maximum contaminant levels established in EPA's national primary drinking water regulations, and the agency has done so for most contaminants. In most cases where FDA has not adopted EPA's national primary drinking water regulations, the agency has provided a rationale for not doing so. For example, FDA stated that it did not adopt EPA's maximum contaminant level for asbestos or EPA's treatment technique for the parasite *Cryptosporidium* because if

⁷FDA has issued a Guidance for Industry entitled *Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance* that identifies preventive measures operators of food establishments, including bottled water manufacturers, may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions.

municipal water is used as a source, it already has to meet EPA regulations, and it is unlikely that other sources of water, such as springs and aquifers, would contain these contaminants.

One exception, however, is the case of a phthalate, DEHP.⁸ FDA has yet to establish a standard for this contaminant, even though EPA established a national primary drinking water regulation for it in 1992 and FDA's statutory deadline for adopting the standard was in January 1993.⁹ EPA found that the potential health effects from exposure to DEHP above the maximum contaminant level could include reproductive difficulties, liver problems, and increased risk of cancer. Although FDA proposed a standard in August 1993, the agency subsequently deferred action on DEHP and has yet to either adopt a standard or publish a reason for not doing so.¹⁰ The agency delayed action on DEHP in 1996 because the compound was already approved for use in packaging that comes in contact with food (including bottled water), which FDA believed could have created a potential conflict with FDA's proposed standard of quality for DEHP. According to FDA officials, an agency task force is currently examining information regarding the use of phthalates, including DEHP, in food contact materials. The results of this work by the task force will be used to set a standard for DEHP, but it is unclear when FDA will complete the study. Because FDA has not established a standard of quality for DEHP in bottled water, bottled water facilities are not required to test for it.

⁸Di(2-ethylhexyl)phthalate, commonly referred to as DEHP, is an organic compound widely used as a plasticizer in manufacturing polyvinyl chloride (or PVC) plastics.

⁹Prior to August 6, 1996, FDA was required to promulgate a standard of quality regulation within 180 days of EPA promulgating a national primary drinking water regulation, or to publish in the *Federal Register* its reasons for not promulgating a standard of quality regulation. If FDA failed to promulgate a standard of quality, the national primary drinking water regulation was not automatically considered to be the standard of quality for bottled water, as it is now.

¹⁰As shown in appendix II, IBWA has set a standard for DEHP that is the same as the maximum contaminant level set by EPA.

FDA's Regulation of Bottled Water Has Generally Been Limited and Differs from EPA's Regulation of Drinking Water in Key Ways

While FDA's standard of quality regulations for bottled water are generally consistent with EPA's drinking water requirements, FDA's regulation of bottled water has been limited. Among our key findings are that (1) when compared with EPA's regulation of public water systems, several key differences reflect the limited nature of FDA's regulation of bottled water, particularly regarding how violations are reported and whether the use of certified laboratories is required; (2) because FDA's experience over the years has not shown that bottled water poses a significant public health risk, the agency devotes fewer resources to the enforcement of bottled water regulations than it does for higher risk foods; (3) while state regulatory requirements for bottled water often meet or exceed those of FDA, the requirements vary across the states and, in some states, are still less comprehensive than state requirements for tap water under the Safe Drinking Water Act; and (4) FDA's oversight of imported bottled water is limited.

FDA's Regulation of Bottled Water Is Generally Weaker Than EPA's Regulation of Tap Water

FDA's regulation of bottled water differs from EPA's regulation of drinking water in key ways, largely because FDA does not have the specific statutory authority to regulate bottled water in the same manner EPA regulates drinking water. These differences relate to how violations are reported, whether bottlers are required to use certified laboratories to test their water, and the retention of water quality testing records.

- *How violations are reported:* The FFDCA does not specifically authorize FDA to require bottlers to report test results, even if violations of the standard of quality regulations are found. Instead, inspectors review testing records when they inspect bottling facilities. In contrast, under the Safe Drinking Water Act, public water systems must notify the public as well as the appropriate regulatory agency (e.g., state environmental agency) within 24 hours of detecting certain violations of the national primary drinking water regulations that have significant potential to have serious adverse effects on human health as a result of short-term exposure. For violations that have the potential to have serious adverse effects on human health and all other violations, public water systems must provide notice within 30 days and 1 year, respectively. FDA officials told us that to comply with the Food and Drug Administration Amendments Act of 2007,¹¹ the agency is developing a means for all food facilities it regulates to report instances when there is a reasonable probability that the use of, or exposure to, a food will cause serious adverse health consequences or death to humans or animals. This act

¹¹Pub. L. No. 110-85 (2007), *codified at* 21 U.S.C. § 350f.

required FDA to establish, by September 2008, a Reportable Food Registry—an electronic portal by which responsible parties or public health officials may submit such instances to FDA. FDA officials have told us that the registry is still under development, and that it is taking steps to create an interim Reportable Food Registry by the end of fiscal year 2009.

- *Whether certified laboratories are used:* Another key difference is that FDA does not require bottle water facilities to use certified laboratories for water quality tests. Public water systems are required by the Safe Drinking Water Act to use such laboratories. In this regard, bottled water is treated like other food products, which generally are not required to be tested by certified laboratories. Instead, under the bottled water current good manufacturing practice regulations, sample analysis of source water and finished products may be performed by competent commercial laboratories. EPA and state-certified laboratories are cited as examples of competent commercial laboratories, but use of these certified laboratories is not required. FDA officials have stated that they are not aware of any special grounds or particular need to require the use of certified laboratories for bottled water. In addition, under the Safe Drinking Water Act, operators of public water systems must be certified to ensure that their public water system provides an adequate supply of safe, potable drinking water. There is no such requirement for operators of bottled water facilities.
- *Retention of water quality testing records:* FDA requires that bottled water facilities retain the results of all water quality tests for up to 2 years. On the other hand, EPA requires that public water systems retain the results of microbiological tests for 5 years and the results of chemical tests for 10 years. As we discuss in the following section, because FDA inspections of bottled water facilities are infrequent and because reporting is not required if problems are found, FDA would most likely not be aware that a contamination problem existed if a facility was not inspected within a 2-year time frame.

FDA's Risk-Based Approach Accords Low Priority to Inspections of Bottled Water Facilities

The FFDCa also authorizes FDA to inspect bottled water facilities and sample products. According to FDA, since bottled water has had a relatively good safety record over the years, bottled water facilities are generally assigned a low priority for inspection, unless a facility has had violations in the past. On average, FDA has devoted approximately 2.6 full-time-equivalent positions per fiscal year to inspecting bottled water facilities in fiscal years 2000 through 2008. Specific inspection tasks for bottled water facilities include (1) verifying that the water used by the

plant for its product and for its operations are obtained from an approved source;¹² (2) checking whether bottled water labeling complies with FDA regulations; (3) inspecting washing and sanitizing procedures; (4) inspecting filling, capping, and sealing operations; and (5) determining whether the firms analyze, on schedule, their source water and finished products for the contaminants listed in the standard of quality and whether the firms meet the standard of quality's allowable levels for the contaminants. In general, inspectors take water samples only "for cause" (i.e., if they observe a potential problem or if the facility has a history of contamination).

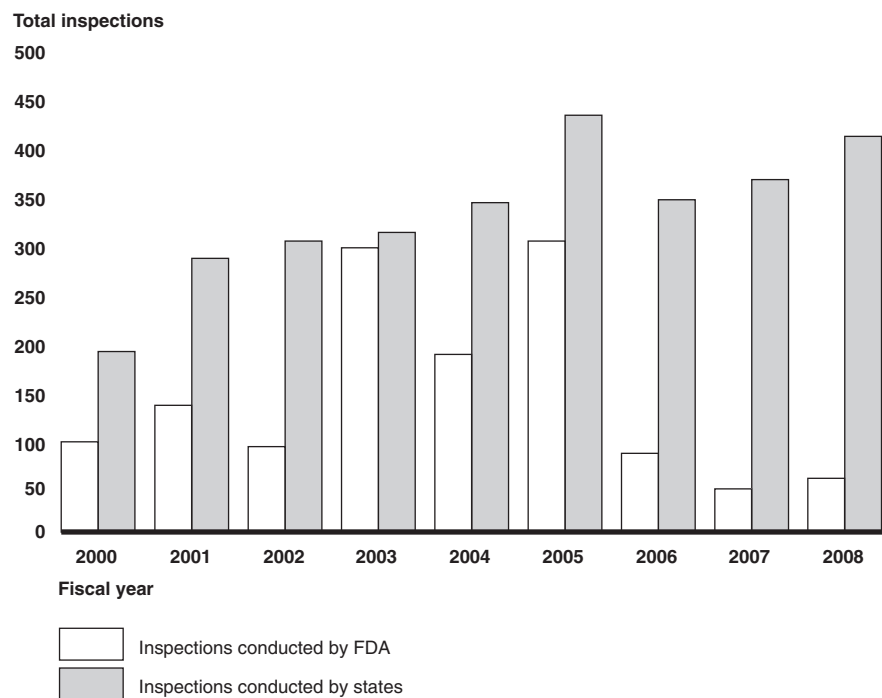
We have found that the frequency of bottled water inspections varied. Domestic bottled water inspections generally averaged about 475 per fiscal year, but increased dramatically in fiscal years 2003 and 2005, to about 600 and 740, respectively. According to FDA officials, the increase in inspections in fiscal years 2003 and 2005 was most likely due to an increased focus on ensuring the security of all food facilities. Because FDA's database of registered food firms does not capture data that would identify all U.S. firms manufacturing bottled water, we could not determine the percentage of bottled water facilities inspected. On the basis of interviews with FDA officials in the eight district offices we contacted, however, inspections of bottled water facilities took place at varying frequencies. For example, three of the district offices with which we spoke stated that bottled water facilities are inspected once every 2 to 3 years by the district office or by the state under contract with FDA. Other district offices reported inspecting bottled water facilities less often.

Additionally, FDA has increasingly relied on states to inspect bottled water facilities. FDA establishes contracts with state agencies to inspect particular facilities, including bottled water facilities. State officials performing inspections as part of an FDA contract perform inspections the same way that an FDA inspector would perform an inspection. Like FDA inspectors, state-contracted inspectors do not generally take samples, unless there is a reason to do so. States that conduct contract inspections are audited by FDA district offices to ensure that their inspections are equivalent to FDA inspections. Twenty-two of the 26 states under the

¹²FDA relies on state and local government agencies to approve water sources. Source water must be of a safe and sanitary quality, according to the applicable laws and regulations of state and local government agencies having jurisdiction over the water. FDA does not review these laws and regulations, however, and the states or localities must consult with EPA if they need assistance.

jurisdiction of seven of the eight district offices we contacted conduct bottled water inspections under contract with FDA.¹³ Our review indicates that from fiscal years 2000 through 2008, the state share of bottled water inspections has increased in recent years (see fig. 1). From fiscal years 2000 through 2005, the states, under contract with FDA, conducted about 65 percent of the bottled water inspections, while from fiscal years 2006 through 2008, the states conducted about 86 percent of the bottled water inspections. Overall, the states conducted approximately 70 percent of the bottled water inspections from fiscal years 2000 through 2008.

Figure 1: Bottled Water Facility Inspections Conducted by FDA and States, Fiscal Years 2000 through 2008



Source: GAO analysis of FDA data.

Furthermore, FDA coordinates with states to better leverage inspection resources. We found that all eight FDA district offices we contacted obtained the results of inspections conducted by the states under contract

¹³In the eighth district office we contacted, contracts have recently been established with 2 of the 3 states under the district's jurisdiction. However, to date, no bottled water facilities have been assigned for inspection.

with FDA. Most states shared this information with FDA through an electronic database, which also gave the states access to a food firm's inspectional history. If any collected samples violated the standard of quality, the states generally shared this information as well, according to officials from the FDA district offices. Such information-sharing, according to FDA officials, allows the agency to leverage resources so that it can focus on more high-priority food inspections and ensures that they have complete information on facility inspections.

In contrast, we found that most of the FDA district offices we contacted did not have agreements to obtain the results of bottled water facility inspections that states conduct under their own authority, not under contract with FDA. Still, all of the district offices with which we spoke said that state officials would most likely contact them if a serious problem at a bottled water facility surfaced during a state inspection.

On the basis of inspections conducted by FDA and the states under contract with FDA, potential problems were identified in approximately 35 percent of the bottled water inspections conducted between fiscal years 2000 and 2008, but FDA took little enforcement action. A majority of the bottled water facilities that were inspected and found to have potential problems were designated as "voluntary action indicated," meaning the inspector found objectionable conditions, but the district office determined that such objectionable conditions were not sufficient enough to warrant any administrative or regulatory action by FDA. Accordingly, the firms in those cases were left to take corrective actions voluntarily. FDA also indicated that there were a small number of cases in which FDA referred issues related to bottled water quality to local public health authorities that have their own enforcement authorities. On the basis of a review of FDA's food recalls database, from fiscal years 2002 through 2008, bottled water has been recalled 23 times, primarily for excessive levels of contaminants, such as arsenic and bromate. Also during this period, FDA issued three warning letters to bottled water facilities for various violations, including failure to maintain documentation and inadequate sanitary practices.

State Requirements for Bottled Water Often Exceed FDA's, but Are Still Often Less Comprehensive Than State Requirements to Safeguard Tap Water

States have enacted their own laws and regulations in an effort to better ensure the quality and safety of bottled water. Nonetheless, (1) the laws and regulations are less consistent than state laws in protecting tap water, pursuant to the Safe Drinking Water Act, and (2) FDA does not have the statutory authority to oversee state regulation of bottled water, while the Safe Drinking Water Act requires EPA to oversee primacy states' regulation of tap water.

Our survey of 50 states and the District of Columbia identified variability in their requirements in governing certain key practices that protect and ensure bottled water quality and safety. For example, respondents in 31 states indicated that their states require that microbiological tests be done by a certified laboratory.¹⁴ Respondents in 12 states, however, do not require the use of a certified laboratory for such tests. States also exhibit variability in terms of what they require of bottled water facilities in reporting the results of quality tests to the state. For example, 21 respondents said their states require bottlers to notify the states if they detect violations in their samples, and 20 require bottlers to submit water quality test results to the states on a periodic basis, whether or not they are in violation.¹⁵ On the other hand, 20 states do not require that water quality tests or violations be reported to the state. Furthermore, states exhibited variability in the frequency at which bottled water facilities are inspected. Officials from 38 states reported that they inspected bottled water facilities annually or more often, whereas officials from 10 states indicated that their states inspected bottled water facilities less frequently than once a year.

In contrast to the diverse practices among state authorities in regulating bottled water, the framework under the Safe Drinking Water Act for regulating tap water requires a high degree of consistency among the states. For example, one condition of being given primary enforcement responsibilities (or primacy) for their public water systems, is that states must have adopted and be implementing adequate procedures for the enforcement of state drinking water regulations that are no less stringent than EPA's national primary drinking water regulations. Among other requirements, the adequate procedures must include the following: (1) statutory or regulatory enforcement authority adequate to compel compliance, (2) maintenance of an inventory of public water systems operating in the state, (3) a systematic program for conducting sanitary surveys of public water systems, and (4) a program for the certification of laboratories conducting analytical measurements of drinking water contaminants.

The FFDCA and the Safe Drinking Water Act also require different levels of federal oversight. Specifically, under the Safe Drinking Water Act, states

¹⁴Five other states allow bottled water facilities to perform microbiological tests in-house, but are required to have tests verified periodically by a certified laboratory.

¹⁵These states are not mutually exclusive, some states require bottlers to do both practices.

may be given primary responsibility for regulating drinking water with EPA conducting systematic oversight, whereas FDA retains responsibility for regulating bottled water under the FFDCA. At least annually, for example, EPA must review a state's compliance with requirements for having primary enforcement responsibility. If the states do not meet these requirements, EPA must initiate proceedings to withdraw primacy approval. In addition, primacy states must submit quarterly reports to EPA that include both new violations of national primary drinking water regulations and new enforcement actions that states took against public water systems for those violations. In contrast, FDA does not have the statutory authority to grant states responsibility for bottled water regulation, nor does it have statutory authority to review state bottled water regulations or the enforcement actions taken by the states.

FDA's Oversight of Imported Bottled Water Is Limited

FDA has provided limited oversight of imported bottled water, since relatively few bottled water imports are physically examined or sampled. The agency follows a two-tier strategy to oversee the importation of bottled water and the importation of food in general. First, FDA's Prior Notice Center reviews information about scheduled food imports to determine whether there are any terrorism-related concerns or serious health risks associated with the products. Second, after the information pertaining to the articles offered for import is transmitted to U.S. Customs and Border Protection in the form of an entry, data pertaining to FDA are sent to an automated database, where they are screened. At this point in the process, the entry data are evaluated electronically and either are allowed to proceed or are flagged for review. To determine whether an article offered for import warrants further examination, reviewers are to take into account the perceived risk and whether an import alert has been issued for the particular commodity, importer, or country of origin. Since 2004, only one import alert has been associated with bottled water.¹⁶ The entry reviewer can request entry documentation pertaining to the product, review the product label, and request that the product be examined or sampled. If the agency finds a problem with an import—for example, contamination—the shipment is detained while the importer or agent is given a period of time to present exonerating evidence. If the importer or agent cannot provide evidence to overcome the apparent violation within the 10-day detention and hearing period, barring any extensions, the

¹⁶This import alert was established in March 2007 in response to FDA testing of three samples of bottled water that were imported from three different manufacturers in Armenia and were found to contain high levels of arsenic.

shipment is refused. After a refusal is issued, the importer must either destroy or export the article out of the United States within 90 days. FDA also examines other articles offered for import as part of general surveillance to meet its work plan. For example, FDA increased its review of bottled water imports as a result of the events of September 11, 2001.

Our review of data from FDA's imports database indicates that FDA's oversight of imported bottled water has been limited. From fiscal years 2004 through 2008, there were 263,314 import entry lines¹⁷ associated with either bottled water or bottled spring or mineral water. Of these, approximately 50 percent of the bottled spring or mineral water and 33 percent of the bottled water were permitted to proceed without further review, while the remainder was subject to an on-screen review. Of the imports reviewed on screen, about 1 percent of the bottled spring or mineral water and about 4 percent of the bottled water were examined further. A smaller percentage of the bottled water imports was sampled for quality testing.

In addition to reviewing FDA's responsibilities for ensuring the quality and safety of bottled water imports, we also reviewed how several top exporting countries—including Canada, Fiji, and Turkey as well as the European Union and its member states—regulate bottled water. We found that, like the United States, these countries have established definitions for different types of bottled water and water quality standards to ensure safety. We identified a couple of examples in which foreign regulations are more stringent than FDA regulations. For example, Canadian regulations specify that bottled water cannot contain any coliform bacteria. In addition, Turkey requires that inspections of bottled water facilities be conducted more frequently than FDA requires. Specifically, licensed drinking water facilities are subject to inspections annually by the Ministry of Health and every 3 months by the local health authority. Licensed natural mineral waters are subject to inspections every 3 months by the ministry and every month by the local health authority. Manufacturers are responsible for the costs of the ministry's and local health authority's analyses of bottled water.

¹⁷According to FDA, an entry line is each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately.

FDA's Oversight of Bottled Water Is Limited by its Authority under the FFDCA and Its Resource Constraints

A number of concerns emerge regarding FDA's regulation of bottled water under the FFDCA and its enforcement practices, particularly in comparison with EPA's regulation of drinking water under the Safe Drinking Water Act. These observations, however, should be viewed in the context of the legal limitations placed by the FFDCA on FDA, and the constrained resources that have affected FDA's overall capabilities in recent years. The legal constraints arise because while the Safe Drinking Water Act authorizes EPA to require water samples to be tested by certified laboratories and violations of national primary drinking water regulations to be reported within certain time frames to EPA or the state agency with primary enforcement responsibility, the FFDCA does not grant FDA similar authority. Rather, the FFDCA requires FDA to regulate bottled water as a food—as opposed to drinking water subject to the Safe Drinking Water Act—and does not specifically authorize FDA to require that foods, including bottled water, be tested by certified laboratories or that violations of the standard of quality be reported to FDA.

In addition to these legal constraints, bottled water's status as a food has subjected it to many of the same problems more generally affecting FDA oversight of food safety. As we noted in January 2007,¹⁸ for example, when we designated federal oversight of food safety as a “high-risk” area affecting public health and the economy, federal oversight of food safety is fragmented, with about 15 agencies having food safety roles. We specifically cited FDA's resource constraints, noting in 2008¹⁹ that while the number of domestic firms under FDA's jurisdiction increased from fiscal years 2001 through 2007 from about 51,000 firms to more than 65,500, the number of firms inspected declined from 14,721 to 14,566 during the same period. We cited resource constraints as a contributing factor, noting that the number of full-time-equivalent positions at FDA devoted to food safety oversight had decreased by about 19 percent from fiscal years 2003 through 2007. Along those same lines, we noted in 2005²⁰ that while FDA was responsible for regulating about 80 percent of the nation's food supply, it accounted for only 24 percent of expenditures in fiscal year 2003 among the federal agencies with food-safety-related

¹⁸GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007).

¹⁹GAO, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods*, [GAO-08-597](#) (Washington, D.C.: Sept. 9, 2008).

²⁰GAO, *Overseeing the U.S. Food Supply: Steps Should Be Taken to Reduce Overlapping Inspections and Related Activities*, [GAO-05-549T](#) (Washington, D.C.: May 17, 2005).

responsibilities (these other agencies included the U.S. Department of Agriculture, EPA, and the National Marine Fisheries Service).

In light of its resource constraints, *FDA's Food Protection Plan*, issued in 2007,²¹ cites the need to focus general food safety inspections based on risk. In addition, although not yet fully defined, FDA has indeed begun to take a more risk-based approach in identifying firms for safety inspections and has identified bottled water to be a low-risk food product. The result of this approach, therefore, has led FDA to devote fewer resources to bottled water oversight for general food safety because of a need to focus on higher-risk food products, such as seafood and fresh produce.

Ultimately, as we recommended in 2007,²² a fundamental reexamination of the federal food safety system will be needed to look across the activities of individual programs within specific agencies with food-safety-related responsibilities. Toward that end, in 2001 we recommended, among other things, that Congress enact comprehensive, uniform, and risk-based food safety legislation and commission the National Academy of Sciences or a blue-ribbon panel to analyze alternative organizational food safety structures in detail.²³ We believe that FDA's lack of authority and resources to effectively regulate bottled water, as compared with how EPA regulates tap water, should be part of that reexamination.

²¹Department of Health and Human Services, FDA, *Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply* (Washington, D.C.: November 2007).

²²[GAO-07-310](#).

²³GAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, [GAO-02-47T](#) (Washington, D.C.: Oct. 10, 2001).

FDA and State Bottled Water Labeling Requirements Resemble Those for Other Food Types, but Demand Less Information Than Is Required for Tap Water

FDA Regulations Require Bottled Water Labels to Contain Specific Information, in Addition to Information Required for All Food Products

Because it is considered a food, bottled water must comply with FDA's general requirements for food labeling,²⁴ which include ingredient and nutrition information. These requirements include the name of the product; the name and address of the manufacturer, packer, or distributor; and the net contents. Although not required, bottled water labels may also include the type of water (i.e., standard of identity). In addition, like other food products, bottled water is subject to the same general prohibitions against misbranding.

Responding to a petition from IBWA for FDA to more closely regulate bottled water in the face of inconsistent state regulation of bottled water, FDA in 1995, modified and expanded the standard of identity regulation, including definitions for different types of bottled water, such as mineral water and spring water (see table 1). According to FDA regulations, if a bottled water label includes a standard of identity, the water must satisfy that standard's requirements or the product will be considered misbranded. For example, bottled water labeled as mineral water must, among other things, contain not less than 250 parts per million of total dissolved solids and originate from a geologically and physically protected underground water source, with no minerals artificially added. For bottled water that comes from a public water system, the standard of identity regulations require its label to clearly state that the product comes from a municipal source or community water system, unless the water has been treated and meets the standard of identity for purified, distilled, deionized,

²⁴21 C.F.R. Part 101.

sterile, or sterilized water. Carbonated water, soda water, seltzer water, sparkling water, and tonic water are considered soft drinks and are not regulated as bottled water. In addition, other terms used on the label about the source, such as “glacier water” or “mountain water,” are not definitions included in the standard of identity regulation and may not be used to convey that the water comes from a pristine area.

Table 1: Types of Bottled Water Under the Standard of Identity Regulation

Type	Definition
Artesian water or artesian well water	Water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer.
Groundwater	Water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure but not under the influence of surface water (water open to the atmosphere).
Mineral water	Water containing not less than 250 parts per million of total dissolved solids, coming from a source tapped at one or more boreholes or springs, originating from a geologically and physically protected underground water source. Mineral water has a constant level and relative proportions of minerals and trace elements when it emerges from the source. No minerals may be added.
Purified or demineralized water	Water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes that meets the definition of “purified water” in <i>U.S. Pharmacopeia</i> , 23rd revision. Purified water is essentially free of all chemicals (it must not contain more than 10 parts per million of total dissolved solids) and may also be free of microbes if treated by distillation or reverse osmosis. Purified water may alternatively be labeled according to how it is treated, for example, deionized water, distilled water, or reverse osmosis water. In addition, these processes can modify the term drinking water (i.e., purified drinking water).
Sparkling bottled water	Water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide from the source 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. Spring water can be collected only at the spring or through a borehole tapping the underground formation feeding the spring. There must be a natural force causing the water to flow to the surface through a natural orifice. If a borehole and external force are used to collect the spring water, additional requirements are imposed. The location of the spring must be identified.
Sterile or sterilized water	Water that meets the requirements under “Sterility Tests,” <i>U.S. Pharmacopeia</i> , 23rd revision. Sterilized water is free from all microbes.
Well water	Water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer.

Source: 21 C.F.R. § 165.110(a).

As with other foods, FDA guidance provides that when inspecting bottled water facilities, investigators should review labels to ensure that they are accurate and meet regulations. As we have previously mentioned,²⁵

²⁵GAO-08-597.

however, FDA often has limited assurance that companies are complying with food-labeling requirements, partly because FDA investigators are not required to keep track of labels reviewed. Therefore, in the absence of reliable FDA data, we were not able to determine the extent to which FDA reviews bottled water labels, or to substantiate the claims of FDA officials that they have not come across any widespread problems with bottled water labeling. Our own review of bottled water labels revealed that the information they contain—although limited—is generally accurate. Specifically, of the 83 labels we reviewed from across the country, only 1 included an unclear statement on the label regarding the standard of identity. In this case, the label listed the water as “mountain spring water” but after contacting the company, we determined that the water was actually artesian and not spring water as defined by FDA. The real question, however, is whether the label information is sufficient to adequately inform consumers about a water bottle’s contents. As we discuss in the following section, the actions of a number of states, and our own review, suggest that consumers could benefit from additional information.

Many States Have Adopted FDA’s Labeling Regulations, but Some States Require That Labels Contain Additional Information

Many states have adopted FDA’s labeling regulations, but some states require additional information. For example, bottled water sold in New Mexico must be labeled with the treatment methods used in its production. Also, bottled water sold in Massachusetts is required to include information on the label identifying the type and the location of the source water (by municipality, state, or country). Massachusetts state officials said this requirement was put in place because of strong consumer demand for such information. Some states have also established further restrictions regarding source listings. For example, Alaska defines “glacier water” as either (1) runoff directly from the natural melting of a glacier, (2) water obtained from the melting of glacial ice at a food-processing establishment, or (3) water from a stream flowing directly from a glacier and not diluted or influenced by a nonglacial stream.

As a related matter, California recently passed legislation requiring that, as a condition of being licensed in the state, a bottled water facility must annually prepare a bottled water report and make the report available to each customer upon request. The report must include, among other things, information on the source, treatment method, and health disclosures for certain contaminants that may be found in the water. According to California state officials, this legislation was passed to require that this information be made available so that the state’s consumers are afforded the same water quality “right-to-know” protections and regulatory

oversight of bottled water as those established for tap water. Labels on bottled water from facilities licensed in California are now required to include a statement about how consumers can access the annual report.

Such consumer right-to-know reports have been required by EPA for public water systems since 1998. These “consumer confidence reports” summarize information on sources, on any detected contaminants, and on compliance with primary drinking water regulations, among other information. Consumer confidence reports are one of several right-to-know provisions that were included in the Safe Drinking Water Act Amendments of 1996. These amendments contain several other provisions to improve public information about drinking water, including requiring public notification when a public water system fails to meet a maximum contaminant level.

FDA Identified Methods to Better Inform Customers about the Contents of Bottled Water, but Was Not Required to Implement Them

The Safe Drinking Water Act Amendments also required FDA to study the feasibility of the appropriate methods to inform customers about the contents of bottled water. In its 2000 report,²⁶ FDA concluded that certain methods were feasible for the bottled water industry to provide the same type of information to consumers that the Safe Drinking Water Act requires public water systems to provide in an annual consumer confidence report—including the source and levels of contaminants tested for and found in the water.²⁷ FDA further concluded that it would be feasible and appropriate for the industry to update the information annually and provide it by enabling the consumer to contact the producer directly through a telephone number or address listed on the label, or through a combined approach where some information about the water would be included on the label and the rest would be obtainable on request. Nonetheless, the agency was not required to take action on its findings and has yet to do so. FDA officials explained that since bottled water is not considered a significant health risk, and, in light of the agency’s limited available resources, FDA does not anticipate initiating a rule making in response to the study’s findings.

²⁶65 Fed. Reg. 51,833 (Aug. 25, 2000).

²⁷FDA was not required to determine whether such information requirements are necessary. Furthermore, FDA was not required to review whether it was feasible and appropriate to inform consumers right away, as is required of public water systems, if contaminant levels exceed standards.

Additional Information about Bottled Water Would Be Beneficial to Consumers

Our work suggests that consumers may benefit from additional information. For example, when asked whether consumers in their state had misconceptions about bottled water, 24 of the 51 state and District of Columbia officials responding to our survey replied that consumers believe that bottled water is safer, is healthier, or is of higher quality than tap water. Their responses were consistent with a 2002 EPA-sponsored Gallup survey, which found that the main reason consumers either filtered tap water or purchased bottled water was due to health-related concerns. In a separate poll, the Water Research Foundation, in 2003, found that about 56 percent of the bottled water drinkers cited safety and health as the primary reason they sought an alternative to tap water.

IBWA has also endorsed the concept that a consumer has a right to comprehensive information about bottled water, believing that the most feasible way for consumers to obtain this information is through a request to the bottler. In fact, IBWA requires that its members include a telephone number on their labels so consumers can contact the company and request information that should be readily available to the company.

Nonetheless, our review of bottled water labels revealed that, when compared with what public water systems are required to provide to consumers of tap water, very few bottled water facilities provide such information to consumers, either through labels, company Web sites, telephone calls to company representatives, or any combination of these avenues. Of the 83 bottled water labels that we reviewed, 9 did not have contact information, such as a telephone number, Web address, or e-mail; 5 labels had only a postal address as a means of contacting the company. Bottled water labels for 12 brands did not contain source information, nor was this information available by telephone or a Web site review. In addition, 16 brands did not contain water quality treatment information on the label, nor was this information available by telephone or a Web site review. Furthermore, only 1 of the bottled water labels that we reviewed contained limited water quality or health-related information, and this information was available from just 34 of the bottled water companies that we had telephoned or from reviewing their Web site. Thirteen of the water quality reports that we did obtain were incomplete or unclear. For example, several of the water quality reports had test results for only some of the contaminants tested or did not reflect the most recent tests conducted; other reports only described which contaminants were tested or how often the tests were conducted.

Production and Consumption of Bottled Water Has Varied Impacts on the Environment

In addition to the safety and consumer issues associated with bottled water, some parties have raised concerns about the environmental impacts associated with its manufacture and transportation and with the extraction of water associated with its production. Among these issues are the impacts on (1) municipal landfill capacity of discarded water bottles, (2) the effects on U.S. energy demands from the manufacture and transport of plastic bottles for drinking water, and (3) communities and the environment of groundwater extraction for the purposes of bottling water.

Most Plastic Water Bottle Containers Are Discarded Rather Than Recycled, Although They Appear to Have a Minimal Impact on the Nation's Municipal Landfill Capacity

Most plastic water bottles produced in the United States are discarded rather than recycled. The most common water bottles are made of a plastic called polyethylene terephthalate, or PET.²⁸ Precise information on the amount of PET in the bottled water containers produced, recycled, and discarded each year is not available. Representatives of the beverage industry and an environmental nonprofit organization reported that about 827,000 to 1.3 million tons of PET plastic water bottle containers were produced in the United States in 2006. Our analysis of data provided by these groups indicated that about 76.5 percent of these PET plastic water bottles were discarded in 2006, which is equivalent to about 632,655 to 999,001 tons of PET, or less than about 1 percent of the 170 million tons of the total discarded U.S. municipal solid waste and about 26 to 41 percent of the 2.4 million tons of total discarded PET plastic. Most discarded water bottles end up in U.S. landfills, although some bottles become litter or are incinerated, according to the officials with whom we spoke. Precise information was not available regarding the amount of discarded PET water bottles that ended up in U.S. landfills versus discarded PET water bottles that were incinerated or became litter.

The near-term impact of the PET plastic water bottles in municipal landfills appears to be minimal. For example, an official from EPA's Office of Resource Conservation and Recovery and an expert in solid waste management from the Solid Waste Association of North American told us that PET plastic is an inert material and, therefore, does not react when in contact with other materials in the waste stream. They also noted that PET plastic is not known to leach contaminants, nor is it associated with any

²⁸Polyethylene terephthalate (PET, or PETE) is a plastic resin that is commonly used to package beverages and other food products, cosmetics, and household cleaners. PET is the type of plastic labeled with the #1 code on or near the bottom of a container.

known risks to public health or the environment while in a landfill. However, they emphasized that in a landfill, PET plastic water bottle containers are typically compacted and shielded from the sunlight and the atmosphere. According to the solid waste management expert, under these conditions it is not known precisely how long it takes for the PET plastic to decompose, although decomposition will occur over a very long time horizon, possibly thousands of years. Thus, this expert told us that for landfill management purposes, solid waste experts assume that PET plastic will never decompose.

Knowledgeable officials from the beverage and PET plastic-manufacturing industries told us that bottled water companies have made significant investments in recent years to “light-weight,” or reduce the amount of PET plastic in each bottle. For example, Nestlé Waters North America reported in its 2008 *Corporate Citizenship Report* that it introduced a 12.4 gram half-liter PET water bottle on the market in 2008 that reduced the amount of PET plastic in its half-liter bottles by 30 percent, compared with the average half-liter plastic beverage container on the market in the previous year. These officials believed that these efforts will lead to substantial reductions over the next few years in the amount of PET plastic associated with discarded water bottles. It is unclear what impact efforts to produce bottles with less plastic will have on the total amount of PET plastic associated with discarded water bottles until more municipal solid waste statistics become available.

Manufacture and Transportation of Bottled Water Is Considerably More Energy-Intensive Than for Tap Water, and the Energy Costs Vary Substantially

We identified two organizations that have attempted to document the effects on U.S. energy demands of the manufacture and transportation of bottled water. Among the analyses we reviewed, the most comprehensive was a peer-reviewed study published in February 2009 by the Pacific Institute that computed the energy required for various phases of bottled water production, transport, and use.²⁹

Specifically, the institute computed the energy required to make PET plastic material, to fabricate the bottles using the PET material, process the water before bottling, fill and seal the bottle, transport the bottled water for sale to end-users, and chill it for use. Because transportation energy costs can vary, depending on the distance from a bottling plant to

²⁹P. H. Gleick and H. S. Cooley, Pacific Institute, “Energy Implications of Bottled Water,” *Environmental Research Letters*, vol. 4, no. 014009 (2009).

market and the mode of transportation, the institute evaluated the energy costs for the following three transportation scenarios for transporting filled water bottles from a bottling plant to a point of sale in Los Angeles, California: (1) locally produced purified bottled water, delivered within 200 kilometers (about 125 miles) of a bottling plant by truck; (2) spring water transported from the island nation of Fiji in the South Pacific by cargo ship to Los Angeles and then delivered locally within 100 kilometers (about 60 miles); and (3) spring water transported from France by cargo ship to the eastern United States, transported by freight rail to Los Angeles, and distributed locally by truck. The results of these three scenarios apply to water shipped from the three locations and consumed in Los Angeles and, therefore, are not representative of all U.S. transportation of bottled water from the bottling plant to the point of sale. According to Pacific Institute officials, these scenarios were chosen to try to provide a low, medium, and high range for energy costs associated with the manufacture and transportation of bottled water.

Although the Pacific Institute's study was the most comprehensive analysis of the energy impacts of bottled water that we identified, certain aspects of its scope and methodology limit the generalizability and certainty of its results. For example, the scope of the institute's study did not include energy estimates for all phases of bottled water production and use, such as the energy required to transport or convey the water to the bottling plant from either a municipal source or a self-supplied surface or groundwater source, nor did the study include the energy required for bottled water waste collection, disposal, and recycling. In addition, the institute's analysis and results focused on the energy required for the production, transport, and use of a typical 1-liter PET bottle of water, which the institute estimated weighs about 38 grams. Lighter and heavier PET bottles could have significantly different energy impacts.

The Pacific Institute's study presented two major findings. First, the energy required to produce and use a typical 1-liter PET bottle of water weighing 38 grams varies substantially, depending on the mode of transportation and the distances traveled from the bottling plant to the point of sale. For example, the institute estimated that transportation energy costs varied from about 25 percent (1.4 megajoules per liter)³⁰ of the total energy footprint for "purified" bottled water produced in Los Angeles and delivered locally within 200 kilometers (about 125 miles) of

³⁰A megajoule is equal to 1 million joules; a joule is a unit of work or energy.

the bottling plant by truck, to about 57 percent (5.8 megajoules per liter) for “spring” water bottled in France, transported overseas by cargo ship, and transported by rail from the eastern United States to Los Angeles. Second, although the overall production and consumption of bottled water makes up a small share of the total U.S. energy demand, bottled water is much more energy-intensive than public drinking water. For example, on the basis of all the energy inputs for bottled water manufacture and use and the three transportation scenarios calculated, the institute estimated that the total energy required to bring a typical 1-liter PET bottle of water weighing about 38 grams to the consumer in Los Angeles would typically range from about 5.8 to about 10.2 megajoules per liter, or about 1,100 to 2,000 times the energy cost of producing tap water (about 0.005 megajoules per liter).³¹

Groundwater Extraction for Bottled Water Is Small Relative to Groundwater Withdrawals for Other Uses, but Can Have Noticeable Localized Impacts

According to state officials in Maine, Michigan, New Hampshire, and Vermont, existing groundwater extraction for the purposes of bottled water has not had an adverse impact on state waters or the environment and is small relative to other groundwater uses. However, these officials said that large-scale groundwater extraction can adversely impact local groundwater availability, surface water flows, and dependent resources. We chose to speak with officials in these four states about the impacts of groundwater extraction because in each of these states, local communities have expressed concerns about bottled water production, and recent state legislation was enacted to address these concerns. Among the cases we reviewed, we found that such concern centered on water extracted from a groundwater source by the bottled water producer, rather than water purchased from a municipal source.

State officials told us that existing groundwater extraction for bottled water does not have a significant impact on state groundwater supplies. For example, state officials in Maine told us that in 2007, bottled water production constituted about 3 percent (or 650 million gallons) of the 19 billion gallons of total groundwater extracted in the state. Similarly,

³¹The energy required for the manufacture, transport, and use of bottled water also results in carbon dioxide emissions. We did not review any comprehensive peer-reviewed studies of carbon dioxide emissions associated with the manufacture, transport, and use of bottled water in the United States. The Pacific Institute, Container Recycling Institute, and IBWA provided us with information about the greenhouse gas emissions associated with various aspects of bottled water production and use. We did not independently verify the accuracy or completeness of the data they provided.

officials from the four states told us that existing groundwater withdrawals for bottled water are small relative to other groundwater uses. For example, a geologist from the New Hampshire Department of Environmental Services reported that most groundwater extraction in the state goes to municipal water systems, residential subdivisions, golf courses, power plants, and manufacturers of beverages other than bottled water. In addition, Michigan state officials told us that in areas of Michigan where groundwater can be limited, most groundwater extraction goes to agricultural and mining activities.

While groundwater extraction may have minimal impacts on state groundwater supplies, it can, in some cases, alter local groundwater levels and flows to nearby surface waters, according to the U.S. Geological Survey.³² For example, pumping groundwater from a single well diverts the groundwater toward the extraction well in the area around the well. As a result, pumping can lower the local water table shared by nearby well users. When the aquifer is shallow and connected to a nearby stream, the pumping can diminish the available surface water supply by diverting some of the groundwater that otherwise would have flowed into the stream or by drawing flow from the stream into the surrounding aquifer. Reductions of surface water flows as a result of groundwater extraction are likely to be of greatest concern during periods of low flow. Groundwater extraction can also affect natural resources dependent on groundwater flowing to surface waters. For example, changes in the water that flows to and from a stream may affect temperature, oxygen levels, and nutrient concentrations in the stream. These changes may in turn affect aquatic life, such as certain fish populations whose spawning success may be greater where surface water temperature is modulated by incoming groundwater. The impacts from a single groundwater extraction site on local ground and surface waters depend on factors that include, among other things, the rate of water withdrawals, type and physical characteristics of an aquifer, degree of connection between the aquifer and surface waters, and rates of precipitation.

The state officials we interviewed told us that while they have not seen adverse large-scale impacts on water supplies and the environment from existing bottled-water-related groundwater extraction, concerns among

³²T. C. Winter, et al, U.S. Geological Survey, *Ground Water and Surface Water: A Single Resource*, U.S. Geological Survey Circular 1139 (Denver: 1998). W. M. Alley, et al., U.S. Geological Survey, *Sustainability of Ground-Water Resources*, U.S. Geological Survey Circular 1186 (Denver: 1999).

some local communities in these states about their effect have led to some conflict and litigation.³³ For example, in 2001 residents in Mecosta County, Michigan, sued a water bottler, alleging that its withdrawals reduced water levels of a nearby stream and wetlands and unlawfully interfered with their water rights.³⁴

State officials in Michigan, Maine, and Vermont told us that to address these concerns and ensure that effective groundwater resource protections were in place, their state legislatures enacted new or amended requirements for extracting groundwater for bottled water. For example, in 2006 and 2008, Michigan's safe drinking water act was amended to require, among other things, a permit for a water-bottling operation that uses a new or increased groundwater withdrawal of more than 200,000 gallons per day. The law also requires that permitted groundwater withdrawals of more than 2 million gallons per day do not result in an individual or cumulative adverse impact, which refers to decreasing a stream's or river's flow or reducing the abundance or density of fish populations.

Conclusions

While FDA's standard of quality regulations for bottled water are generally consistent with EPA's drinking water quality requirements, the agency could do more to ensure the safety of bottled water, either by (1) promptly adopting EPA's health-based public drinking water standard for the phthalate, DEHP, and setting monitoring requirements for this contaminant or (2) publishing in the *Federal Register* a rationale for not doing so. We further believe FDA should act expeditiously after its DEHP task force study ends, since FDA's statutory deadline for acting on DEHP was more than 15 years ago. Without a standard or monitoring requirement in place, bottled water facilities are not required to test for and potentially identify harmful levels of a contaminant that is currently regulated in public drinking water. In addition, to prevent public misconceptions about the health and safety of bottled water and to match

³³ A geologist from the New Hampshire Department of Environmental Services told us that data for bottled water extraction approved prior to August 1998 are not available to reliably assess the local impacts that may have occurred.

³⁴ See *Mich. Citizens for Water Conservation v. Nestle Waters N. Am. Inc.*, 709 N.W. 2d 174 (Mich. App. 2005) (the court ruled that while the bottling company could have "fair participation" in the common water resources of the area, the company's pumping of approximately 24 percent of the base flow of a stream exceeded fair participation), *affirmed in part and reversed in part on other grounds* 737 N.W. 2d 447 (Mich. 2007).

consumer right-to-know standards pertaining to tap water, FDA could help to ensure that consumers have more complete product information by implementing its findings regarding the appropriate and feasible methods for informing consumers about the contents of bottled water.

Although we have also raised a number of broader concerns about FDA's oversight of bottled water facilities—particularly in comparison with EPA's regulation of public water supply systems under the Safe Drinking Water Act—we acknowledge that many of these concerns reflect the legal limitations the FFDCA imposes on the agency and the decline in resources that has hampered overall food safety responsibilities in recent years. Regarding FDA's effectiveness, we have recommended in the past that a fundamental reexamination of the federal food safety system be undertaken, including enactment of comprehensive, uniform, risk-based food safety legislation. We believe that FDA's lack of authority and resources to effectively regulate bottled water should be part of this reexamination.

Recommendations for Executive Action

We recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to take the following two steps:

- Issue a standard of quality regulation for DEHP, or publish in the *Federal Register* the agency's reasons for not doing so 1 year after the conclusion of its task force study on this matter.
- Implement FDA's findings on methods that are feasible for conveying information about bottled water to customers, such as, at a minimum, requiring that companies provide on the label contact information directing customers on how to obtain comprehensive information. Should FDA determine that it lacks the necessary authority to implement its findings, it should seek legislation to obtain such authority.

Agency Comments and Our Evaluation

We provided the Environmental Protection Agency and the Department of Health and Human Services' Food and Drug Administration with a draft of this report for their review and comment. EPA provided oral comments, stating that the agency agreed with the report's findings. In its written response, FDA first noted that the agency "strives continually to advance its public health mission, and this includes efforts to improve the safety, sanitation, suitability, and proper labeling of bottled water." It then expressed general agreement with our two recommendations. Regarding the first recommendation on issuing a standard of quality regulation for

DEHP in bottled water, FDA agreed that it should reassess whether to issue the regulation as soon as possible after the conclusion of the task force study on phthalates. However, FDA noted that our recommended 180-day time frame to issue a DEHP standard for bottled water did not provide enough time for a notice and comment rule making. Accordingly, we changed the time frame in the recommendation from 180 days to 1 year. In the event that FDA decides to promulgate a standard of quality regulation for DEHP, we think that 1 year provides FDA with sufficient time to conduct rule making since it will be based on the study's results. Moreover, we think FDA should move expeditiously on DEHP since the statutory deadline for taking action was more than 15 years ago. Regarding our recommendation to improve the way in which information about bottled water is conveyed to consumers, FDA agreed that bottled water should be labeled with contact information that allows consumers to more easily contact the manufacturer to obtain comprehensive information about the product. The agency said it intends to pursue this issue with bottled water manufacturers. FDA also provided comments to improve the draft report's technical accuracy, which we have incorporated as appropriate. Appendix IV contains a reprint of FDA's letter.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, and other interested parties. The report also will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix V.

A handwritten signature in black ink, reading "John B. Stephenson". The signature is written in a cursive style with a long horizontal flourish at the end.

John B. Stephenson
Director, Natural Resources and Environment

Appendix I: Scope and Methodology

To evaluate the extent to which federal and state authorities regulate the quality of bottled water to ensure it is safe and the extent to which they regulate the accuracy of labels or claims about the purity and source of bottled water, we reviewed federal and state bottled water regulations. We compared the standard of quality regulations that apply to bottled water with the Environmental Protection Agency's (EPA) standards under the Safe Drinking Water Act. We interviewed officials in the Food and Drug Administration's (FDA) Center for Food Safety and Nutrition, Office of Regulatory Affairs, and eight FDA District Offices, among other FDA offices; EPA; nonprofit organizations, such as the Natural Resources Defense Council, the Environmental Working Group, and the Food and Water Watch; and the International Bottled Water Association (IBWA). Our definition of "bottled water" in this report includes any food product that meets FDA's standard of identity for bottled water. We did not conduct water quality analyses of bottled water to determine if the product met the standard of quality. We also did not conduct a systematic review of source water approval or testing records at bottled water facilities.

We also researched bottled water laws and regulations in the 50 states and the District of Columbia. We selected 10 states¹ for in-depth reviews because their standard of quality, testing requirements, or both, differed from FDA standards and from 1 state that adopted FDA's requirements.² To learn more about state regulations and enforcement policies, we held interviews by telephone with regulatory officials in 8 of the 10 states, in person with Ohio and Massachusetts officials, and in writing with Wisconsin officials. On the basis of these discussions, we developed a briefer set of questions on implementing and enforcing bottled water regulations. After we drafted this questionnaire, we asked for comments from state officials in 4 of the 10 states selected for in-depth review. We conducted these pretests to check that (1) questions were clear and unambiguous, (2) terminology was used correctly, (3) the information could be feasibly obtained, and (4) the survey was comprehensive and unbiased. Three of the four pretests were administered over the telephone.

¹These 10 states are California, Georgia, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Missouri, Wisconsin, and Vermont. Ohio is the state that has the same requirements as FDA.

²After speaking with officials in some of these states, we learned that their state bottled water requirements mirror FDA requirements. For example, 1 state recently enacted new legislation that mirrors FDA requirements but was not yet reflected in the state code.

Next, we administered our survey by telephone to state officials responsible for bottled water oversight in all of the remaining states and the District of Columbia. (App. III shows the questions that we asked and a summary of the responses that we received.) We made the telephone calls in December 2008 and January 2009. All states responded to our questions. Some state officials were unable to answer all of the questions during our first call; they subsequently provided the information later via telephone or e-mail.

We also examined bottled water labels and contacted companies to determine the information they provide consumers about the source, treatment, and quality of their products. We did not evaluate whether label information was false or misleading. To obtain bottled water labels, we asked GAO staff in each of our 11 field offices and at headquarters to collect about 10 labels per office from bottled water that is specific or unique to their region.³ After removing duplicate bottled water labels and labels that were not for bottled water but for some other beverage, such as “electrolyte-enhanced” waters, we were left with 83 labels for bottled water sold in containers ranging in size from 8 ounces to 1 gallon. This sample does not represent the universe of bottled water available to consumers in the United States. We systematically reviewed the labels and recorded whether contact information was provided—such as a telephone number, Web address, e-mail, or complete postal address—that would allow a consumer to contact the bottled water company and readily obtain more information about the product than what is listed on the label. We also recorded whether the source of the water, treatment method, and any quality test results were included on the label, or whether this information was available by accessing the company’s Web site or by telephoning the company. We used the Web addresses and telephone numbers listed on the label, if available. We contacted 61 companies by telephone and conducted Web site reviews for 47 companies.

To determine how authorities in other countries ensure the safety of bottled water, we reviewed how several top exporting countries—including Canada, Fiji, and Turkey as well as the European Union and its member states—regulate bottled water. We were not able to review the laws in all of the top 10 exporting countries because information in

³GAO field offices are located in Atlanta, Georgia; Boston, Massachusetts; Chicago, Illinois; Dallas, Texas; Dayton, Ohio; Denver, Colorado; Huntsville, Alabama; Los Angeles, California; Norfolk, Virginia; San Francisco, California; and Seattle, Washington.

English was limited. In addition, we reviewed only the legal requirements in these countries; we were not able to assess how the laws are implemented or enforced.

We also analyzed data from FDA databases that track domestic and foreign inspections, import examinations, and recalls. Regarding FDA inspections of domestic and foreign bottled water facilities, as well domestic inspections conducted by states under contract with FDA, we analyzed data from the Field Accomplishments and Compliance Tracking System for fiscal years 2000 through 2008. Regarding FDA reviews of bottled water imports, we analyzed data from the Operational and Administrative System for Import Support for fiscal years 2004 through 2008. In addition, we worked with FDA to obtain all warning letters that had been issued to bottled water facilities for fiscal years 2002 through 2008. Finally, we analyzed data from FDA's Recall Enterprise System for recalls that were issued for bottled water from November 2002 (when the system began) through fiscal year 2008. We assessed the reliability of these data and found them to be sufficiently reliable for our purposes. To assess the reliability of these data, we reviewed related documentation and worked closely with agency officials to identify any data problems. Because of the variance in how bottled water and other beverages are coded as a product in the Field Accomplishments and Compliance Tracking System, some of our analysis regarding inspections may include other beverage or product types, such as ice or flavored waters. However, our conversations with FDA officials indicated very few entries included these other beverage or product types.

To identify the environmental and other impacts of bottled water, we reviewed the following three subtopics: (1) the impact of discarded water bottles on municipal landfill capacity; (2) the effects on U.S. energy demands from the manufacture and transport of plastic bottles for drinking water; and (3) the impacts, if any, on communities and the environment of groundwater extraction for the purposes of bottling water.

To address the impact of discarded water bottles on municipal landfill capacity, we interviewed knowledgeable officials from the American Beverage Association and its consultant, Northbridge Environmental Management; the Container Recycling Institute; IBWA; and the National Association of PET Container Resources to obtain information on the

quantities of PET plastic water bottles⁴ that are produced and recycled. We did not independently verify the accuracy and completeness of the data provided by these organizations. Using figures provided to us by the American Beverage Association and the Container Recycling Institute for the amount of PET plastic water bottle containers produced in 2006—the most recent year for which data were available—and for the national recycling rate in 2006 for all PET containers, provided to us by the National Association of PET Container Resources, we calculated a range of estimates for the quantity of PET plastic water bottles that were discarded in that year. We used these data and figures from EPA’s 2006 national municipal solid waste characterization to calculate how much discarded PET water bottles comprised as a share of the total discarded PET plastic and total discarded municipal solid waste in the United States. To assess the accuracy and completeness of EPA’s municipal solid waste characterization data, we reviewed EPA documentation and interviewed knowledgeable officials from the EPA contractor Franklin Associates (a division of the Eastern Research Group), which prepared the agency’s 2006 national municipal solid waste characterization, Northbridge Environmental Management, and the Solid Waste Association of North America. Finally, we interviewed EPA officials from the Office of Resource Conservation and Recovery and the Director of the Applied Research Foundation of the Solid Waste Association of North America to collect information regarding the impacts of discarded PET plastic water bottle containers in landfills.

To identify the effects on U.S. energy demands of the manufacture and transport of bottled water, we interviewed officials from EPA’s Office of Solid Waste and knowledgeable officials from three nonprofit environmental organizations—the Earth Policy Institute, Food and Water Watch, and the Pacific Institute. We identified two studies that focused specifically on bottled drinking water, one by the Earth Policy Institute and a second by the Pacific Institute. We reviewed the scope and methodology of these studies and selected the Pacific Institute’s study for more in-depth evaluation because it was more comprehensive and documented in a peer-reviewed article.⁵ Specifically, we assessed the

⁴Polyethylene terephthalate (PET, or PETE) is a plastic resin that is commonly used to package beverages and other food products, cosmetics, and household cleaners. PET is the type of plastic labeled with the #1 code on or near the bottom of a container.

⁵P. H. Gleick and H. S. Cooley, Pacific Institute, “Energy Implications of Bottled Water,” *Environmental Research Letters*, vol. 4, no. 014009 (2009).

Pacific Institute's methodology to determine its validity and summarized the studies' key findings relevant to our objective.

To identify the impacts, if any, on communities and the environment of groundwater extraction for bottling water, we reviewed and synthesized information published by the U.S. Geological Survey about the impact of groundwater extraction on aquifers, surface waters, and dependent natural resources. We reviewed newspaper articles, books, journal articles, and public policy reports to identify states where conflicts or litigation over groundwater extraction have taken place. Among the states identified, we selected Maine, Michigan, New Hampshire, and Vermont for more in-depth review. Specifically, we chose Michigan and Vermont because legislation was recently enacted in these states regarding groundwater extraction that included specific provisions related to bottled water production. We chose Maine and New Hampshire because these states recently enacted or amended laws governing groundwater wells or withdrawals that apply to certain bottled water production facilities. In these states, we interviewed officials who oversee groundwater extraction for bottled water to obtain information on groundwater use, on known impacts of groundwater extraction from bottled water production, and on existing regulations of groundwater extraction for bottled water production.

We conducted this performance audit from June 2008 to June 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions on our audit objectives.

Appendix II: FDA and IBWA Standards of Quality and Selected EPA Drinking Water Standards

Contaminant	FDA standard of quality	EPA drinking water standard (maximum contaminant level)	IBWA standard of quality
<i>In this table, units are in milligrams per liter, unless otherwise noted.</i>			
Inorganic chemicals			
Antimony	0.006	0.006	0.006
Arsenic	0.01	0.01	0.01
Asbestos	No standard ^a	7 million fibers per liter	No standard
Barium	2	2	1
Beryllium	0.004	0.004	0.004
Cadmium	0.005	0.005	0.005
Chromium	0.1	0.1	0.05
Copper	1 ^b	Treatment technique; ^c action level ^d = in more than 90% of samples in a monitoring period the copper concentration is greater than 1.3 ^e	1
Cyanide	0.2	0.2	0.1
Fluoride	Depends on temperature and other factors	4.0 ^f	Depends on temperature and other factors
Lead	0.005 ^g	Treatment technique; action level = in more than 90% of samples in a monitoring period the lead concentration is greater than 0.015	0.005
Mercury	0.002	0.002	0.001
Nickel	0.1	No standard	0.1
Nitrate (as nitrogen)	10	10	10
Nitrite (as nitrogen)	1	1	1
Total nitrate and nitrite (as nitrogen)	10	10	10
Selenium	0.05	0.05	0.01
Thallium	0.002	0.002	0.002
Organic chemicals			
Acrylamide	No standard ^h	Treatment technique ⁱ	No standard
Alachlor	0.002	0.002	0.002
Atrazine	0.003	0.003	0.003
Benzene	0.005	0.005	0.001
Benzo(a)pyrene	0.0002	0.0002	0.0002
Carbofuran	0.04	0.04	0.04
Carbon tetrachloride	0.005	0.005	0.005

Appendix II: FDA and IBWA Standards of Quality and Selected EPA Drinking Water Standards

Contaminant	FDA standard of quality	EPA drinking water standard (maximum contaminant level)	IBWA standard of quality
<i>In this table, units are in milligrams per liter, unless otherwise noted.</i>			
Chlordane	0.002	0.002	0.002
2,4-D	0.07	0.07	0.07
Dalapon	0.2	0.2	0.2
1,2-Dibromo-3-chloropropane	0.0002	0.0002	0.0002
<i>o</i> -Dichlorobenzene	0.6	0.6	0.6
<i>p</i> -Dichlorobenzene	0.075	0.075	0.075
1,2-Dichloroethane	0.005	0.005	0.002
1,1-Dichloroethylene	0.007	0.007	0.002
<i>cis</i> -1,2-Dichloroethylene	0.07	0.07	0.07
<i>trans</i> -1,2-Dichloroethylene	0.1	0.1	0.1
Dichloromethane	0.005	0.005	0.003
1,2-Dichloropropane	0.005	0.005	0.005
Di(2-ethylhexyl)adipate	0.4	0.4	0.4
Di(2-ethylhexyl)phthalate (DEHP)	No standard	0.006	0.006
Dinoseb	0.007	0.007	0.007
Diquat	0.02	0.02	0.02
Endothall	0.1	0.1	0.1
Endrin	0.002	0.002	0.002
Epichlorohydrin	No standard ^h	Treatment technique ⁱ	No standard
Ethylbenzene	0.7	0.7	0.7
Ethylene dibromide	0.00005	0.00005	0.00005
Glyphosate	0.7	0.7	0.7
Heptachlor	0.0004	0.0004	0.0004
Heptachlor epoxide	0.0002	0.0002	0.0002
Hexachlorobenzene	0.001	0.001	0.001
Hexachlorocyclopentadiene	0.05	0.05	0.05
Lindane	0.0002	0.0002	0.0002
Methoxychlor	0.04	0.04	0.04
Monochlorobenzene	0.1	0.1	0.05
Oxamyl	0.2	0.2	0.2
Pentachlorophenol	0.001	0.001	0.001
Total phenols	0.001	No standard	0.001
Picloram	0.5	0.5	0.5
Polychlorinated biphenyls (PCBs, as decachlorobiphenyl)	0.0005	0.0005	0.0005
Simazine	0.004	0.004	0.004

Appendix II: FDA and IBWA Standards of Quality and Selected EPA Drinking Water Standards

Contaminant	FDA standard of quality	EPA drinking water standard (maximum contaminant level)	IBWA standard of quality
<i>In this table, units are in milligrams per liter, unless otherwise noted.</i>			
Styrene	0.1	0.1	0.1
2,3,7,8-TCDD (Dioxin)	3 × 10 ⁻⁸	3 × 10 ⁻⁸	3 × 10 ⁻⁸
Tetrachloroethylene	0.005	0.005	0.001
Toluene	1	1	1
Toxaphene	0.003	0.003	0.003
2,4,5-TP (Silvex)	0.05	0.05	0.01
1,2,4-Trichlorobenzene	0.07	0.07	0.009
1,1,1-Trichloroethane	0.2	0.2	0.03
1,1,2-Trichloroethane	0.005	0.005	0.003
Trichloroethylene	0.005	0.005	0.001
Vinyl chloride	0.002	0.002	0.002
Xylenes	10	10	1
Residual disinfectants^k and disinfection by-products			
Bromate	0.01	0.01	0.01
Chloramine (as Cl ₂)	4	4	4
Chlorine (as Cl ₂)	4	4	0.1
Chlorine dioxide (as ClO ₂)	0.8	0.8	0.8
Chlorite	1	1	1
Haloacetic acids (five) (HAA5)	0.06	0.06	0.06
Total trihalomethanes (TTHM)	0.08	0.08	0.1
Radiological contaminants			
Gross alpha particle activity (excluding radon and uranium)	15 picocuries per liter (pCi/L) ^l	15 pCi/L	15 pCi/L
Gross beta particle and photon radioactivity	4 millirems per year ^m	4 millirems per year	50 pCi/L
Radium 226/228 (combined)	5 pCi/L	5 pCi/L	5 pCi/L
Uranium	30 micrograms/L	30 micrograms/L	30 micrograms/L
Microbiological contaminants			
Total coliform bacteria, including <i>E. coli</i>	Depends on the analytical method used; ⁿ no positive <i>E. coli</i> ^o	No more than 5% samples total coliform-positive in a month for systems that collect at least 40 samples per month; no positive <i>E. coli</i> ^p	None in a 100 mL sample
<i>Cryptosporidium</i>	No standard ^q	Treatment technique; ^r 99% removal	Treatment technique whenever unprotected surface waters are used

Appendix II: FDA and IBWA Standards of Quality and Selected EPA Drinking Water Standards

Contaminant	FDA standard of quality	EPA drinking water standard (maximum contaminant level)	IBWA standard of quality
<i>In this table, units are in milligrams per liter, unless otherwise noted.</i>			
<i>Giardia lamblia</i>	No standard ^s	Treatment technique; 99.9% removal or inactivation	Treatment technique whenever unprotected surface waters are used
<i>Legionella</i>	No standard ^s	Treatment technique	Treatment technique whenever unprotected surface waters are used
Viruses	No standard ^t	Treatment technique; 99.99% removal or inactivation	Treatment technique whenever unprotected surface waters are used
Heterotrophic plate count (HPC)	No standard ^u	Treatment technique; heterotrophic bacteria concentration less than or equal to 500/mL ^v	No standard
Turbidity	5 turbidity units	1 turbidity unit, except in certain circumstances based on the monthly average and 5 turbidity units based on average for 2 consecutive days	0.5 turbidity units
Additional substances, including physical properties^w			
Aldicarb ^x			0.003
Aldicarb sulfone ^x			0.003
Aldicarb sulfoxide ^x			0.004
Aluminum	0.2	0.05 to 0.2	0.2
Chloride	250 ^y	250	250
Color	15 units ^y	15 units	5 units
Corrosivity	No standard	Noncorrosive	No standard
Foaming agents	No standard	0.5	No standard
Iron	0.3 ^y	0.3	0.3
Manganese	0.05 ^y	0.05	0.05
Methyl tertiary butyl ether (MTBE)	No standard	No standard	0.07
Naphthalene	No standard	No standard	0.3
Odor	3 threshold odor number ^y	3 threshold odor number	3 threshold odor number
pH	No standard	6.5-8.5	5-7 (for purified water), 6.5-8.5 (for other types of bottled water)
Silver	0.1	0.1	0.025
Sulfate	250 ^y	250	250
1,1,2,2-Tetrachloroethane	No standard	No standard	0.001

Appendix II: FDA and IBWA Standards of Quality and Selected EPA Drinking Water Standards

Contaminant	FDA standard of quality	EPA drinking water standard (maximum contaminant level)	IBWA standard of quality
<i>In this table, units are in milligrams per liter, unless otherwise noted.</i>			
Total dissolved solids	500 ^y	500	500
Zinc	5 ^y	5	5

Source: GAO analysis of FDA's Standard of Quality Regulation, EPA's National Primary Drinking Water Regulations, and IBWA's Code of Practice.

^aAs stated in a December 1, 1994, *Federal Register* notice, FDA did not set a standard for asbestos because the agency concluded that the presence of any significant level of asbestos in bottled water was highly unlikely, in part because the major source of asbestos in public drinking water is asbestos-cement pipes used in public water systems distributions. Because those systems must comply with EPA requirements, FDA concluded that most, if not all, bottlers using public water systems as a water source would be unlikely to encounter any significant levels of asbestos in their water source.

^bFDA has a stricter standard than EPA because leaching of copper from distribution systems and residential plumbing is not a factor for bottled water. FDA's standard of quality for copper is equivalent to EPA's national secondary drinking water regulation.

^cTreatment technique refers to a required process intended to reduce the level of a contaminant in drinking water.

^dAction level refers to the level of lead or copper that, if exceeded, triggers treatment or other requirements that a water system must follow.

^eThe national secondary drinking water regulation for copper is 1 milligram per liter.

^fThe national secondary drinking water regulation for fluoride is 2 milligrams per liter.

^gAs stated in a May 25, 1994, *Federal Register* notice, FDA adopted a stricter standard than EPA because leaching of lead from distribution systems is not a factor for bottled water. From its survey data, FDA concluded that most bottlers are using source waters that are free from significant lead contamination and can readily produce bottled water products with lower lead levels.

^hAcrylamide and epichlorohydrin occur as coagulating polymers (flocculents) in the treatment of tap water. As stated in a December 1, 1994, *Federal Register* notice, FDA did not set a standard of quality for these contaminants because EPA determined that establishing MCLs for them was not feasible, and because FDA regulations issued under the Food Additives Amendment of 1958 (Pub. L. No. 85-929) prohibit unsafe use of acrylamide and epichlorohydrin (as flocculents) in the production of bottled water.

ⁱWater systems must certify that when acrylamide is used, the combination of dose and monomer level does not exceed 0.05 percent dosed at 1 parts per million (or equivalent).

^jWater systems must certify that when epichlorohydrin is used, the combination of dose and monomer level does not exceed 0.01 percent dosed at 20 parts per million.

^kFor EPA, the highest level of a disinfectant allowed in drinking water is known as the maximum residual disinfectant level (MRDL). The values listed for chloramine, chlorine, and chlorine dioxide represent the MRDL for these chemicals.

^lPicocuries per liter is a measure of radon concentration.

^mExposure to radiation is generally measured in rems. Most human exposure is so small that it can be measured in millirems (1,000 millirems = 1 rem).

Appendix II: FDA and IBWA Standards of Quality and Selected EPA Drinking Water Standards

^uUsing the multiple-tube fermentation method, not more than 1 of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 mL, and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 mL. Using the membrane filter method, not more than 1 of the analytical units in the sample shall have 4 or more coliform organisms per 100 mL, and the mean of the coliform density of the sample shall not exceed 1 coliform organism per 100 mL.

^vOn May 29, 2009, FDA issued a final rule that (1) requires that source water be tested weekly for total coliform; (2) requires bottled water manufacturers to test for *Escherichia coli* (*E. coli*) if testing detects coliform organisms in the source water or finished bottled water products; (3) prohibits source water containing *E. coli* from being used for bottled water because it would not be considered to be of a safe, sanitary quality; (4) requires bottlers to rectify or otherwise eliminate the source of *E. coli* contamination in source water and keep records of such actions before using source water from a source that has tested positive for *E. coli*; and (5) treats bottled water containing *E. coli* as adulterated. 74 Fed. Reg. 25651 (May 29, 2009).

^wAny fecal coliform-positive repeat sample or *E. coli*-positive repeat sample, or any total coliform-positive repeat sample following a fecal coliform-positive or *E. coli*-positive routine sample constitutes a violation of the maximum contaminant level for total coliforms. For public notification purposes, this violation may pose an acute risk to health.

^xEPA published a final rule on December 16, 1998, establishing treatment technique requirements for improved control of *Cryptosporidium* in certain public drinking water obtained from surface water or groundwater under the direct influence of surface water. As required by the Safe Drinking Water Act, FDA published a notice in the *Federal Register* announcing that it would not issue a standard of quality regulation because bottled water is produced either from groundwater that is not under the influence of surface water or from water from public water systems, which must meet EPA treatment technique requirements. Therefore, source waters used for bottling are not expected to contain *Cryptosporidium*. 66 Fed. Reg. 35439, 35440-41 (July 5, 2001).

^yThe treatment technique requirement generally consists of installing and properly operating water treatment processes, which reliably achieve at least 99 percent (2-log) removal of *Cryptosporidium* between a point where the raw water is not subject to recontamination by surface water runoff and a point downstream before or at the first customer for filtered systems, or *Cryptosporidium* control under the watershed control plan for unfiltered systems.

^zOn June 29, 1989, EPA published a final rule in the *Federal Register* establishing treatment technique requirements for improved control of *Giardia* and *Legionella* in public drinking water obtained from surface water or groundwater under the direct influence of surface water. FDA concluded that a corresponding bottled water regulation was not necessary to protect the public health because bottled water is produced either from water from public water systems, which is already treated according to EPA standards, or from groundwater that is not under the direct influence of surface water. Therefore, source waters used for bottling are not expected to contain *Giardia* or *Legionella*. Because EPA published this final rule before enactment of the Safe Drinking Water Act Amendments of 1996, FDA was not required to publish a notice in the *Federal Register* announcing these findings.

^{aa}FDA officials stated that the agency has not adopted a treatment technique requirement for viruses for the same reason it has not adopted a treatment technique requirement for other microbiological contaminants (i.e., bottled water is produced from groundwater not under the direct influence of surface water or from public water systems, where it is already treated for such contaminants).

^{ab}FDA reviewed the need to regulate HPC and stated that “when bottled waters are free of microorganisms that are of public health significance (i.e., indicated by the absence of coliforms) and are bottled under sanitary conditions in compliance with the current good manufacturing practice regulations, the presence of heterotrophic bacteria that are part of the natural flora in those bottled water normally will not pose a health risk because these organisms do not colonize the digestive tract of humans.” 58 Fed. Reg. 52042, 52047 (Oct. 6, 1993).

Appendix II: FDA and IBWA Standards of Quality and Selected EPA Drinking Water Standards

^uMonitoring for HPC is not required; public water systems may measure HPC concentration in order to meet EPA's residual disinfectant concentration requirement. According to EPA, there is no penalty for having a high HPC level and HPC has no health effects.

^wFor EPA, these substances are as addressed in national secondary drinking water regulations, or secondary standards. National secondary drinking water regulations are nonenforceable guidelines to control contaminants in drinking water that primarily affect the aesthetic (such as taste, odor, or color) or cosmetic qualities (such as skin or tooth discoloration) relating to public acceptance of drinking water. Although not required by EPA, states with primary enforcement responsibility may choose to adopt these secondary regulations as enforceable regulations in the state.

^xEPA promulgated a national primary drinking water regulation for these contaminants on July 1, 1991, but postponed its effective date pending reconsideration of the regulation. 57 Fed. Reg. 22178 (May 27, 1992). To date, EPA has not established a new effective date.

^yMineral water is exempt from FDA's allowable level. The exemptions are aesthetically based, allowable levels and do not relate to a health concern.

Appendix III: Telephone Survey Administered to Officials from the 50 States and the District of Columbia, and Summary of Responses

Below are the questions that we asked during our telephone survey with state water quality or food protection officials from the 50 states and the District of Columbia, and a summary of the responses that the officials provided.¹

1. *Does your state license, permit, or otherwise approve bottled water facilities operating in the state?*

- **Yes – 48 states**
- **No – 0 states**

(states without bottled water facilities excluded)

2. *Does your state approve source water used for bottled water?*

- **Yes – 48 states**
- **No – 0 states**

(states without bottled water facilities excluded)

3. *Does your state require bottled water quality testing to be done by a certified lab?*

Microbiological tests:

- **Yes – 31 states**
- **Yes, tests can be done in-house, but they must be verified periodically by a certified lab – 5 states**
- **No – 12 states**

Other tests:

- **Yes – 40 states**
- **Yes, tests can be done in-house, but they must be verified periodically by a certified lab – 1 state**
- **No – 7 states**

(states without bottled water facilities excluded)

4. *Does your state require bottlers to report the results of water quality tests to the state on a scheduled basis?*

- **Yes – 19 states**
- **Yes, but only for some contaminants – 1 state**
- **No – 28 states**

(states without bottled water facilities excluded)

¹Wisconsin provided its responses in writing.

**Appendix III: Telephone Survey Administered
to Officials from the 50 States and the
District of Columbia, and Summary of
Responses**

5. *Does your state require bottlers to notify the state if water quality tests do not meet the standard?*

- **Yes – 19 states**
- **Yes, but only for some contaminants – 2 states**
- **No – 27 states**

(states without bottled water facilities excluded)

6. *Approximately how often does your state inspect bottled water facilities?*

- **More frequently than once a year – 13 states**
- **About once a year – 25 states**
- **Once every 1-2 years – 8 states**
- **Less frequently than every 2 years – 2 states**

(states without bottled water facilities excluded)

7. *In the past five years, have there been any cases of excessive contaminant levels in the state's bottled water?*

- **Yes – 22 states**
- **No – 29 states**

8. *In the past five years, has the state taken any enforcement actions, such as issuing a warning letter or recall, against water bottlers?*

- **Yes – 24 states**
- **No – 27 states**

9. *In the past five years, has there been any conclusive evidence that bottled water caused illnesses?*

- **Yes – 0 states**
- **No – 51 states**

10. *Has your state come across any instances of mislabeled bottled water?*

- **Yes – 30 states**
- **No – 21 states**

**Appendix III: Telephone Survey Administered
to Officials from the 50 States and the
District of Columbia, and Summary of
Responses**

11. *Has your state conducted studies, surveys, or other analyses related to bottled water?*

- **Yes – 15 states**
- **No – 36 states**

12. *What, if any, misconceptions have you heard from consumers about bottled water?*

- **None – 10 states**
- **Identified a misconception – 41 states**

What additional information do you think could be provided to consumers to clear up these misconceptions?

- **Identified a variety of ways of providing additional information – 20 states**

13. *How many bottled water facilities operate in your state?*

- **Provided specific numbers or ranges – 51 states**

14. *What changes, if any, does the state recommend making to federal bottled water regulations?*

- **Made a variety of recommendations – 23 states**
- **Did not make a recommendation – 28 states**

Appendix IV: Comments from the Department of Health and Human Services' Food and Drug Administration



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUN 5 2009

John B. Stephenson
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

Dear Mr. Stephenson:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "BOTTLED WATER: FDA Safety and Consumer Protections Are Often Less Stringent Than Comparable EPA Protections for Tap Water" (GAO-09-610).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Barbara Pisaro Clark".

Barbara Pisaro Clark.
Acting Assistant Secretary for Legislation

Attachment

**Appendix IV: Comments from the Department
of Health and Human Services' Food and Drug
Administration**



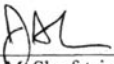
DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DATE: June 3, 2009
TO: Acting Assistant Secretary for Legislation
FROM: Principal Deputy Commissioner of Food and Drugs
SUBJECT: FDA's General Comments to GAO's Draft Report entitled, *Bottled Water-
FDA Safety and Consumer Protection Are Often Less Stringent Than
Comparable EPA Protections for Tap Water (GAO-09-610)*

FDA is providing the attached general comments to the U.S. Government Accountability Office's draft report entitled: *Bottled Water- FDA Safety and Consumer Protection Are Often Less Stringent Than Comparable EPA Protections for Tap Water (GAO-09-610)*.

FDA appreciates the opportunity to review and comment on this draft report before it is published.



Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner of
Food and Drugs

Attachment

**Appendix IV: Comments from the Department
of Health and Human Services' Food and Drug
Administration**

FDA's General Comments to the U.S. Government Accountability Office's (GAO) Draft Report Entitled, *Bottled Water – FDA Safety and Consumer Protections Are Often Less Stringent Than Comparable EPA Protections for Tap Water (GAO-09-610)*

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. GAO has raised some important issues regarding FDA's bottled water program. FDA strives continually to advance its public health mission, and this includes efforts to improve the safety, sanitation, suitability, and proper labeling of bottled water. As an example, on May 29, 2009, FDA published a final rule that increases protection against fecal pathogens in bottled water by requiring more stringent microbiological testing in source water and finished bottled water products. Under the new rule, bottled water containing *E. coli* is deemed adulterated. This final rule ensures that FDA's standards for the minimum quality of bottled water, as affected by fecal contamination, are no less protective of the public health than those set by the Environmental Protection Agency (EPA) for public drinking water.

FDA's Specific Comments on GAO Recommendations

GAO Recommendation 1:

Issue a standard of quality regulation for DEHP or publish in the Federal Register the agency's reasons for not doing so within 180 days of the conclusion of its task force study on the issue.

FDA Response:

FDA agrees with GAO that, upon conclusion of the FDA task force study on phthalates, including di(2-ethylhexyl)phthalate (DEHP), it is appropriate to reassess whether to issue a standard of quality regulation for DEHP in bottled water. In a July 17, 1992, final rule (57 FR 31776), EPA established MCLs for certain contaminants, including DEHP, in drinking water. On August 4, 1993, FDA published a proposed rule (58 FR 41612), and on March 26, 1996, a final rule (61 FR 13258), in the *Federal Register* establishing standard of quality regulations for certain contaminants in bottled water contained in EPA's 1992 final rule. In response to FDA's 1993 proposed rule, FDA received a comment addressing the proposed allowable level for the chemical DEHP. The comment pointed out that this chemical is prior sanctioned in 21 CFR 181.27 for use as a plasticizer when migrating from food-packaging material into foods with high water content and, as such, is approved for use in contact with food in 21 CFR 177.1210. This raised a potential conflict between the proposed allowable level for DEHP and the existing prior sanction for this substance found in § 181.27. Therefore, in FDA's 1996 final rule, FDA stated that additional time was required to evaluate this issue and deferred final action on the proposed allowable level for DEHP.

Currently, an FDA phthalate task force is examining information regarding the use of phthalates, including DEHP, in food contact materials, as well as in other FDA-regulated products. Upon

**Appendix IV: Comments from the Department
of Health and Human Services' Food and Drug
Administration**

conclusion of the task force study, FDA will determine if a standard of quality regulation for DEHP in bottled water is necessary to protect the public health. However, FDA notes that the GAO's recommended 180 day deadline would not provide adequate time for a notice and comment rulemaking (i.e., a proposed rule and a final rule) to establish a standard of quality regulation and may not provide adequate time to publish in the *Federal Register* the agency's reasons for not doing so. Nonetheless, FDA agrees with GAO that it is appropriate to reassess whether to issue a standard of quality regulation for DEHP in bottled water as soon as possible upon conclusion of FDA task force study on phthalates.

GAO Recommendation 2:

Implement FDA's findings on methods that are feasible for conveying information about bottled water to customers, such as, at a minimum, requiring that companies provide on the label contact information directing customers how to obtain comprehensive information. Should FDA determine it lacks the necessary authority to implement its findings, it should seek legislation to obtain such authority.

FDA Response:

FDA agrees with GAO that bottled water should be labeled with contact information that allows consumers to contact the manufacturer to obtain comprehensive information about the product. Although FDA already requires that the name and place of business of the manufacturer, packer, or distributor to be on all food products [21 CFR 101.5], including bottled water, FDA agrees that more complete contact information would make it easier for consumers to contact a bottled water manufacturer and obtain such information. FDA intends to pursue this issue with bottled water manufacturers.

FDA has the statutory authority to require information on food labels, including bottled water, if FDA determines that the information is material and its nondisclosure would render the labeling misleading under sections 201(n) and 403(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(n) and 343(a)] or if such information is required to comply with the standard of identity or standard of quality under section 403(g) and (h) of the Act [21 U.S.C. 343(g) and (h)]. For example, FDA requires bottlers to inform consumers when the quality of bottled water does not meet FDA's standard of quality regulations, by putting a statement of substandard quality on the label [21 CFR 165.100(c)]. Also, FDA requires that, when bottled water comes from a community water system, it be labeled as such (with the exception of purified or sterilized water because consumers buy this water because of its treatments rather than because of its source) [21 CFR 165.110(a)(ii)]. FDA also notes that bottled water containing a substance at a level considered injurious to health is adulterated and therefore cannot be sold to consumers [21 CFR 165.100(d)].

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

John Stephenson, (202) 512-3841 or stephensonj@gao.gov

Staff Acknowledgments

In addition to the contact named above, Steve Elstein, Assistant Director; Brian M. Friedman; Nathan A. Morris; Kelly A. Richburg; and Jeanette Soares made key contributions to this report. Also contributing to this report were Mark Braza, Ellen Chu, Erin Lansburgh, and Minette Richardson. In addition, Matthew Drerup, Paige Gilbreath, Susannah Hawthorne, Stephen J. Jue, Foster Kerrison, Patricia Lentini, Robert Marek, Angela Pun, Carrie W. Rogers, Pam Tumler, and Cheryl A. Williams provided assistance in collecting bottled water labels for our review.

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