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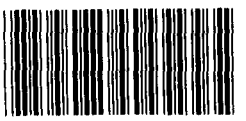
# GAO Testimony





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## FDA Could Do More to Ensure the Safety of Bottled Water

Statement of
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Before the Subcommittee on Oversight and
Investigations,
Committee on Energy and Commerce
House of Representatives

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the Food and Drug Administration's (FDA) regulation of bottled water. Our testimony today is based on our March 12, 1991, report responding to the Subcommittee's request that we assess FDA's bottled water standards and the effectiveness of FDA's oversight in ensuring that these standards are met.[1]

In summary, FDA could do more to ensure the safety of bottled water. In setting bottled water standards, FDA has not met the Federal Food, Drug, and Cosmetic Act's (FFDCA) requirements for adopting the health-based public drinking water standards set by the Environmental Protection Agency (EPA). Further, FDA has exempted "mineral water" from bottled water standards. As a result, bottled water, including mineral water, may contain potentially harmful contaminants at levels that are not allowed in public drinking water.

To oversee the safety of bottled water, FDA relies heavily on its requirement that bottlers periodically self-test their water. FDA has little assurance, however, that such tests are done or that the results are reliable because it does not require bottlers to (1)

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[1]Food Safety and Quality: Stronger FDA Standards and Oversight Needed for Bottled Water (GAO/RCED-91-67, Mar. 12, 1991).

keep test results long enough for FDA inspection, (2) report test results to FDA, or (3) use certified laboratories for testing.

During our review two other questions about the regulation of drinking water products surfaced--whether intrastate water products are adequately regulated and whether bottled water labels are accurate.

Before providing more detail on our findings, let me briefly give you some background on how bottled water is defined and regulated.

## BACKGROUND

FDA defines bottled water as water that is sealed in bottles or other containers and is intended for human consumption. Mineral water, although not officially defined, is generally considered a type of bottled water that contains various dissolved minerals, such as copper, iron, sulfate, and zinc. Bottled water excludes soda, seltzer, flavored, and vended water products.

Bottled water consumption in the United States has increased from about 488 million gallons in 1979 to about 1.7 billion gallons in 1989. According to recent published surveys, about half of the consumers surveyed said they drank bottled water because it tasted better than tap water, about a quarter cited safety and health

reasons, and about a quarter believed that bottled water is free of contaminants.

FDA, under FFDCA, is primarily responsible for setting quality standards and ensuring the safety of bottled water sold in interstate commerce, while EPA, under the Safe Drinking Water Act, is similarly responsible for setting standards and ensuring the safety of public water supplies. States are responsible for the safety of bottled water sold in intrastate commerce.

## BOTTLED WATER QUALITY STANDARDS ARE INCOMPLETE

Section 410 of FFDCA gives FDA 180 days to amend its standards to reflect any new or revised health-based drinking water standards adopted by EPA, or to publish, in the Federal Register, FDA's reasons for not adopting EPA's standards. FDA has not complied with the section 410 timing requirement since 1976, or the last four times EPA adopted new or revised health-based drinking water standards.

For example, FDA took almost 3 years--2-1/2 years longer than the law allows--to propose bottled water standards for seven volatile organic chemicals including benzene--a known carcinogen--that were already regulated in public drinking water. In the interim, FDA chose to work on what it felt were higher priority issues, such as safety-related regulations for methylene chloride in hair spray.

FDA's timeliness in adopting new or revised health-based drinking water standards will remain an issue during the next few years as EPA considers setting new or revised drinking water standards as required by a 1986 amendment to the Safe Drinking Water Act. On January 30, 1991, for example, EPA issued new or revised health-based drinking water standards for 32 substances and estimates that it will issue another 29 standards by March 1992.

In addition to not promptly setting bottled water quality standards, FDA has not set any quality standards for mineral water. When FDA first developed its bottled water quality standards in 1973, it exempted mineral water because it could not directly apply EPA's water quality standards to mineral water. FDA said at that time that it would develop separate quality standards for mineral water. However, 18 years later it has yet to develop such standards or even to define mineral water. As a result, unlike public drinking water supplies and bottled water, mineral water is not regulated by any federal water quality standards.

The importance of setting bottled and mineral water quality standards in a timely manner is illustrated by last year's Perrier incident. In January 1990, a North Carolina county laboratory found benzene levels exceeding EPA's public drinking water standard in Perrier mineral water. The laboratory was using Perrier as a quality control sample to ensure the accuracy of its testing

equipment. After learning of the benzene problem, the Perrier company analyzed historical production samples and found that benzene first appeared in May 1989--8 months before it was identified by the North Carolina laboratory. If FDA had promptly amended its bottled water quality standards and applied them to mineral water, then bottlers would have been required to test for benzene, and FDA and those states that have adopted FDA's standards would also have been testing for benzene, thus increasing the chances for earlier detection of the contaminated Perrier mineral water.

In 1988 the International Bottled Water Association (IBWA)--an industry trade association--petitioned FDA to enact stronger federal regulations that would, among other things, require FDA to define and develop mineral water quality standards and adopt all EPA health-based drinking water standards. In addition, in the absence of comprehensive and up-to-date FDA standards, some states have defined and set their own mineral water quality standards.

## FDA OVERSIGHT DOES NOT ENSURE THAT BOTTLERS MEET FEDERAL STANDARDS

FDA relies heavily on its requirement that bottlers test their water periodically to ensure that they meet federal bottled water quality standards. However, FDA has little assurance that these tests are done or that the results are reliable because it does

not require bottlers to keep test results long enough to allow for FDA inspection, report the test results to FDA, or use certified laboratories for the tests.

Although FDA requires bottlers to keep test results for 2 years, it (1) inspected about half of the 410 domestic bottlers only once in 5-3/4-years,[2] (2) may not have inspected some domestic plants because it does not have a complete inventory of domestic bottlers, and (3) does not inspect foreign bottling operations because it lacks jurisdiction over them. As a result, FDA may not know if bottlers are doing the required tests.

Public water systems and bottlers in some states are subject to stricter record-keeping and reporting requirements than FDA's. For public water systems, EPA requires that self-testing records be kept for at least 5 years for microbial contaminants and 10 years for chemical contaminants. EPA also requires that all test results be reported to the responsible state regulatory agencies, with violative results reported within 48 hours. For bottled water, all 10 states we visited required bottlers to keep test records for longer than the state's inspection cycle, and 4 states also required bottlers to report test results.

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[2]FDA inspected the other half of the domestic bottlers two or more times in the 5-3/4-year period reviewed.

FDA also lacks assurance that self-testing results are reliable. FDA regulations specify that either "qualified bottling plant personnel" or "competent commercial laboratories" use approved water quality test methods. FDA, however, has not defined qualified personnel or competent laboratories, and it does not require that such personnel or laboratories seek certification or otherwise establish their qualifications. In contrast, EPA requires that certified laboratories be used to test public drinking water samples, and 7 of the 10 states we visited require that certified laboratories meeting certain qualifications be used to test bottled water samples.

According to FDA, EPA has authority under the Safe Drinking Water Act to require that public water systems use certified laboratories and report test results. FDA said that under FFDCA it has no such authority for most food manufacturers, including bottlers.

Finally, FDA does not routinely obtain and use state inspection and test results to help eliminate duplicative inspections and tests. FDA could improve its oversight of bottled water firms and products by routinely using state inspection and testing results. Such information could help eliminate duplicate inspections and tests, thereby freeing FDA resources for other activities, such as testing more imported bottled water samples and inspecting firms or testing products posing a greater health risk.

## OTHER CONCERNS

During our review two other concerns were raised about drinking water products--whether intrastate water products are adequately regulated and whether bottled water labels are accurate.

About 862 million gallons of the bottled water sold in the United States during 1989 were delivered to homes and offices, and another 130 million gallons of drinking water were sold through vending machines. Industry and state regulatory officials said that some of the delivered water and perhaps all of the vended water were sold in intrastate commerce.

Because FDA does not regulate intrastate bottled water and EPA has no active program for vended water, consumers must rely on the states to ensure that these water products are safe to drink. However, some states have only limited bottled and/or vended water regulations or enforcement programs. For example, Missouri regulates microbiological contaminants in bottled water and inspects bottled water plants but does not regulate chemical and radiological contaminants in bottled water and does not regulate vended water.

Concerns were also raised regarding the accuracy of bottled water labels. Consumers may pay from 300 to 1,200 times more per gallon

for bottled water than for tap water because they believe it tastes better, is safe and healthy, or is free of contaminants. Yet according to IBWA officials, as much as 25 percent of the bottled water being sold may in fact be treated tap water drawn from public drinking water systems. Although some consumers may willingly pay for this additional treatment, others may be misled by terms and labels used on bottled water products.

FDA has the authority, but has taken few steps to regulate the terms and graphics commonly found on water products apart from publishing criteria for indicating sodium content. However, these criteria may mislead consumers. For example, water products containing less than 5 milligrams of sodium per serving may be labeled sodium-free. The president of the Perrier Group, among others, has acknowledged that Perrier's sodium-free labels, though legal, nevertheless provoke media reports and consumer complaints questioning the accuracy of such sodium-free statements.

Further, FDA has not prohibited bottlers from using terms such as "nursery" water, which may imply a certain standard of quality that does not exist, or from using label graphics which may portray the water source as a glacier, mountain lake, or waterfall, when, in fact, the water comes from a public system.

To protect consumers, some states have regulated the use of these terms, and IBWA has developed labeling guidelines in its model

code. For example, Texas regulations prohibit label references, such as "caffeine-free," when the contents or ingredients referred to are not normally found in drinking water. IBWA's model code states that supplemental printed information and graphics may appear on the label but may not suggest properties of the product or preparation methods that are not based on fact.

CONCLUSIONS

In closing, Mr. Chairman, FDA could do more to ensure the safety of bottled water by promptly adopting all health-based public drinking water standards and setting standards for mineral water. Without such standards, bottlers are not required to test for and identify all potentially harmful contaminants currently regulated in public drinking water.

FDA could also improve its oversight of bottled water by strengthening its controls over industry self-testing and reporting. However, FDA does not have specific authority to establish such controls. Further, we continue to believe that FDA could achieve greater oversight with the same level of resources and reduce the potential for duplicating state efforts if it were routinely to obtain state inspection and test results.

Our report that you are releasing today recommends that FDA take a number of actions to address these issues. These changes will

strengthen FDA's regulatory oversight of bottled water and more closely align the regulation of bottled water with the regulation of public drinking water. Among other things, we recommend that FDA take the following actions:

-- comply with section 410 of FFDCA, which requires timely setting of bottled water quality standards;

-- develop and issue mineral water quality standards;

-- seek legislation giving FDA specific authority to require domestic bottlers involved in interstate commerce and foreign bottlers to, among other things, use laboratories that have been certified by federal or state agencies to analyze public drinking water or bottled water, or demonstrate that the bottlers can accurately test bottled water quality.

Finally, given FDA's history of delays in setting bottled water standards within legislatively required time frames and in view of the additional standards EPA plans to promulgate in the next few years, our report asks the Congress to consider revising section 410 of FFDCA to provide that primary public drinking water standards apply automatically to bottled water after 180 days unless FDA publishes in the Federal Register its reasons for a delay or an exemption from such standards. Alternatively, the

Congress might authorize EPA to set quality standards for all drinking water.

Mr. Chairman, that concludes my prepared statement. I will be happy to respond to questions that you or members of the Subcommittee might have.

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