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Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

February 1992

FOOD SAFETY AND QUALITY

Limitations of FDA's Bottled Water Survey and Options for Better Oversight

GAO/RCED-92-87

GAO

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Resources, Community, and
Economic Development Division

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February 10, 1992

The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

In your April 23, 1991, letter and in subsequent discussions with your office, you asked us to review the adequacy of the Food and Drug Administration's (FDA) 1990 Bottled Water Survey.[1] In response to the February 1990 voluntary recall of benzene-contaminated Perrier mineral water and to gather information on proposed bottled water standards, FDA conducted a survey of domestic and imported bottled waters. Primarily on the basis of its preliminary survey results, FDA testified before your Subcommittee on April 10, 1991, that the nation's bottled water was safe.

On the basis of questions raised during the hearings, the Subcommittee was concerned about the adequacy of FDA's survey and the safety of bottled water. As a result, you asked whether (1) FDA's survey results were representative of the nation's bottled water supply, (2) FDA's tests covered all regulated contaminants, and (3) FDA's test for unregulated contaminants was warranted. In addition, you asked us to identify opportunities for improving oversight of the bottled water industry and/or reducing related costs.

Results in Brief

FDA's bottled water survey was not designed to reach any conclusions about the safety of the nation's bottled water. Thus, the survey alone does not provide an adequate basis for FDA's statement that bottled water is safe. The survey did not use probability-based statistical sampling and its results only represent inspections of 49 domestic bottled water plants and tests of 112 domestic and imported bottled water samples. (FDA estimates that there are about 475 domestic plants; it does not know how many foreign bottlers import water into the United States.) Moreover, to control costs

[1]FDA defines bottled water as water that is sealed in bottles or other containers and is intended for human consumption.

FDA tested the bottled water samples for the presence of only 9 of 31 regulated contaminants.[2] FDA officials believed that testing for the 22 other regulated contaminants would have significantly increased the cost of the survey.

FDA also tested for 11 unregulated contaminants. FDA's decision to test for unregulated contaminants appears warranted because (1) the agency had proposed or was considering new standards for these contaminants; (2) one of the contaminants was benzene, which received much media attention when it was found in Perrier; and (3) the cost of performing these tests was small—about $32,000, or 4 percent of the total survey cost of $850,000. Specifically, FDA tested each sample to quantify its bacteria level and conducted a screening test on each sample to detect the presence of 11 unregulated volatile organic chemicals (VOCs), including benzene.

As requested, we identified ways to improve FDA oversight of the bottled water industry and/or reduce related costs. In a report we issued in March 1991, we made several recommendations to help ensure the safety of bottled water and improve FDA's oversight of the bottled water industry.[3] These recommendations were aimed at correcting procedural and administrative weaknesses largely unique to FDA's regulation of the bottled water industry.

In response to your current request, we identified other approaches for improving oversight—establishing a plant registration requirement, using third-party inspection results, and increasing FDA's own inspections. Unlike our March 1991 recommendations, however, these approaches involve broad policy issues, the adequacy of FDA's overall level of resources, and problems that are common to most other types of food products. As a result, we believe that the benefits and costs of these approaches should be assessed within the context of FDA's overall mission and regulation of the entire food industry. As we continue to review the adequacy of the federal government's food safety activities, we plan to evaluate these approaches. In the meantime, the International Bottled Water Association (IBWA)[4] has

[2]For this report, contaminants for which there are bottled water standards are referred to as regulated contaminants. See app. I for a listing of all these contaminants in effect in 1990 and those for which FDA tested.

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

[4]IBWA is a trade association whose members account for more than 80 percent of the bottled water sold in the United States, according to IBWA officials.

indicated a willingness to explore with FDA the feasibility of a third- party inspection program for the bottled water industry.

Background

FDA is primarily responsible for ensuring the safety of bottled water sold in interstate commerce, while the Environmental Protection Agency (EPA) is responsible for regulating most other drinking water sources, including setting allowable levels for contaminants in public water systems. States are responsible for the safety of bottled water sold in intrastate commerce.

While EPA sets primary (health-based) and secondary (aesthetics-based) public drinking water standards, FDA sets standards for bottled water. Under section 410 of the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA has 180 days to amend bottled water standards to reflect any new or revised primary drinking water standards adopted by EPA or publish, in the Federal Register, FDA's reasons for not adopting EPA's standards.

FDA's Bottled Water Survey Inconclusive

FDA's 1990 bottled water survey cannot be used to reach any conclusions about the safety of the nation's bottled water. Even if the survey had incorporated probability-based sampling, the results would still have limited value because, to control costs, FDA tested for the presence of only about one-third of the regulated contaminants. As a result, the survey reflects the results of a limited number of plant inspections and bottled water tests.

Survey Design

FDA's 1990 bottled water survey was not based on a probability sample, nor was there any formal design that considered or estimated the cost of such a survey. Instead, FDA officials arbitrarily decided to inspect 50 domestic bottled water plants and test 100 bottled water samples—50 domestic and 50 imported. (Ultimately 49 domestic plants were inspected and 112 bottled water samples were tested—49 domestic and 63 imported.) FDA did not inspect any foreign bottled water plants because it lacks the jurisdiction to do so. The survey cost about $850,000 to conduct.

FDA headquarters directed each of the 21 district offices to inspect a specific number of domestic bottled water plants and to collect one bottled water sample from each plant inspected. FDA gave the district offices discretion in selecting which bottlers to inspect and sample, but it asked them to give preference to those plants that previous inspections had shown to produce bottled water using questionable manufacturing processes.

FDA headquarters also required four districts to collect a number of imported bottled water samples. The four districts were told to collect as many different bottled water brands as possible but to include, at a minimum, a specific number of samples from selected countries. In addition, two of the four districts were told to collect 10 discretionary samples, giving preference to bottled waters originating from countries potentially affected by the nuclear power plant failure at Chernobyl.

FDA instructed its districts to test the domestic and imported water samples for compliance with 9 of the 31 regulated contaminants. According to FDA officials, they selected eight of the nine regulated contaminants because they considered them to be the most significant in terms of toxicology or they had previously found excessive levels of the contaminant in bottled water. The officials said they selected the other regulated contaminant—total trihalomethanes—because it could be included, at no additional cost, as part of the screening test they were conducting for unregulated contaminants. FDA did not test for the other 22 regulated contaminants because the officials believed that the additional tests necessary would have significantly increased the cost of the survey.

Survey Limitations

FDA's 1990 survey was a judgmental survey, that is, FDA officials used their judgment to determine the number of (1) domestic plants to inspect, (2) domestic and imported bottled waters to sample, and (3) tests and types of tests to conduct on the samples. Judgmental samples cannot be used to make generalizations about the characteristics of the larger universe from which the samples were selected. Probability-based statistical sampling is the only method that can serve this purpose.

In statistical sampling, the universe of items being studied—such as all bottled water plants—is carefully defined, the size of the sample to be taken is objectively determined using accepted statistical methods, and the actual samples are drawn in a way that incorporates their probability of selection. Thus, the sample results can be used to estimate the characteristics of the universe in a precise and quantifiable way.

FDA officials said they used a judgmental sample because their experience had shown that statistical sampling costs too much. But as the following examples show, FDA's casualness in defining the universe, selecting the samples, and limiting the number of standards to test against leaves questions as to the value of the survey and the information it provided about the overall compliance of bottled waters with FDA standards:

- In the two districts we visited, FDA officials selected the bottlers they inspected for the survey from the agency's Official Establishment Inventory. The inventory, however, listed only about 410 bottled water plants, although FDA headquarters and district officials acknowledged that about 475 plants were operating at the time the selections were made. As a result, not all of the 475 had a chance of being selected for the survey.
- Having started with an incomplete inventory of bottled water plants, the two districts we visited selected the specific plants to inspect primarily on the basis of the bottlers' locations. For example, the San Francisco district selected two of the three bottlers it inspected because they were close to each other and to the district office. Thus, travel costs would be kept to a minimum. While the districts might have saved travel time and costs, the plants more distant from the FDA offices had little chance of being selected.
- Because the domestic bottled water samples selected for testing were linked directly to the plants selected for inspection, many domestic waters were eliminated from consideration for the same reasons that many plants were eliminated.
- The New York district collected samples of imported bottled waters on a first-in, first-sampled basis. A district official responsible for collecting the samples explained that because he did not know when any given brand of bottled water would arrive, he sampled the first bottled water shipment, regardless of brand, that arrived from a country he needed. As a result, New York selected multiple samples of some brands while other brands had no chance of being selected.

Because of such limitations, projections about the safety of the nation's bottled water supply cannot be made on the basis of FDA's survey results. The survey's usefulness is further limited by the scope of the testing accomplished.

As discussed above, FDA instructed its districts to test the selected samples for only 9 of 31 regulated contaminants. FDA officials testified at the April 1991 hearings that resource limitations prevented them from testing for all 31 regulated contaminants. However, FDA did not estimate the cost of testing the samples for any single contaminant, several contaminants, or all the contaminants covered by the standards.

Furthermore, FDA tested for the contaminants it considered most significant in terms of toxicology. However, 12 of the remaining 22 regulated but untested contaminants are also related to health concerns. FDA officials also stated at the April 1991 hearings that testing for the nine regulated contaminants could show if some of the other contaminants were present

or absent. But according to agency laboratory officials, the tests the agency conducted for the nine contaminants would not provide any indication of the presence or absence of other regulated contaminants.

Survey Results

When FDA testified at the April 1991 hearings that the nation's bottled water was safe, it based its conclusions primarily on preliminary survey results. The survey showed that about 75 percent of the 49 inspected plants were in compliance with FDA regulations and 1 of the 112 bottled water samples tested violated FDA's standards—the sample contained 0.18 milligrams per liter of arsenic, which exceeded the 0.05 milligrams per liter standard. FDA did not consider the instances of noncompliance to be significant health concerns.

FDA Testing for Unregulated Contaminants Warranted

In addition to testing for the presence of some regulated contaminants, FDA decided to test each sample to quantify the level of bacteria present and to detect and quantify the level of 11 unregulated VOCs. This decision appears warranted because FDA was considering a bottled water bacteria standard and was evaluating whether it should adopt the health-based VOC standards established and the ones proposed by EPA for public drinking water. In addition, the cost of performing these tests was only about $32,000, or 4 percent of the total survey cost of $850,000, and one of the VOCs was benzene, which received much media attention when it was found in Perrier.

FDA used a heterotrophic plate count to quantify the bacteria level present in each sample. When plate counts exceeded 100 per milliliter, FDA did follow-up tests to identify and quantify the species of bacteria present. The follow-up tests identified two samples that contained pseudomonas aeruginosa, a pathogenic bacteria. FDA officials said that the levels of pseudomonas aeruginosa found were hazardous and required corrective action.

FDA also used a screening test on each sample to detect and quantify the level of 11 VOCs, such as benzene and vinyl chloride, that are not regulated in bottled water. EPA has set health-based public drinking water standards, and FDA has proposed bottled water quality standards, for 7 of these 11 VOCs. EPA has also proposed health-based standards for the other four VOCs. If these standards are adopted for public drinking water, FDA will be required by law to consider adopting the standards for bottled water as well. The screening test revealed that 12 of the bottled water samples

contained some but not excessive levels of 1 or more of the 11 unregulated VOCs.

Opportunities for Improved FDA Oversight

In our March 1991 report, we made various recommendations to correct procedural and administrative weaknesses in FDA's regulatory program for bottled water. In response to your current request, we have identified other approaches to improve FDA's oversight of bottled water, including (1) requiring bottlers to notify FDA when they begin operations, (2) testing the use of third-party inspection results, and (3) increasing FDA's own inspection and testing activities, if necessary. These approaches, however, involve more complex issues affecting the entire food industry and FDA's overall level of resources.

GAO's Prior Recommendations to Improve Oversight

We made various recommendations in our March 1991 report to strengthen FDA's oversight of bottled water. First, we recommended that FDA comply with section 410 of FFDCA—which requires timely setting of bottled water quality standards—and develop and issue mineral water quality standards. Second, we recommended that FDA seek legislation giving it authority to require bottlers to use certified laboratories when performing FDA-required tests and to report certain test results to FDA. Third, we recommended that FDA revise regulations to require that bottlers keep self-monitoring records for at least 5 years, or since FDA's last inspection. And fourth, we recommended that FDA work with the states to routinely obtain state inspection and test results.

In commenting on our recommendations, the Department of Health and Human Services (HHS) agreed with the first and fourth recommendations but disagreed with the other two. We continue to believe that these recommendations are valid and needed to improve FDA's oversight.

Establishing a Plant Registration Requirement

FDA does not have a complete inventory of domestic bottled water plants, and it only inspects those plants it does know about, on average, about once every 4 years. While FDA is responsible for overseeing all bottled water plants operating in interstate commerce, it does not have an effective system to identify such plants. At the April 1991 hearings, we testified on the need for an FDA system to register or identify bottled water plants under its jurisdiction. Similarly, HHS' Office of the Inspector General (OIG) recommended in a August 1991 food safety inspection report that, among

other things, FDA design a uniform system that ensures a systematic identification of all food firms under its jurisdiction.[5]

FDA does not have the legal authority to require such registrations and, according to FDA officials, does not have the resources needed to operate a registration program. The FFDCA provides explicit registration authority for infant formula, drugs, and devices. According to an HHS attorney responsible for FDA food activities, the act does not provide explicit registration authority for any other food, although FDA has required low-acid canned food plants to register because of their high risk levels. Furthermore, in responding to the OIG recommendation, the Public Health Service, FDA's parent organization, agreed that a national registration system would be beneficial but argued that such a system would require resources that are devoted to higher priority work.

While a national registration system would require some resources, it is not clear that such resource requirements would be any greater than what is now being used by FDA for identifying bottlers and other food plants under its jurisdiction. Currently, FDA identifies plants under its jurisdiction in a variety of ways, such as reviewing newspapers, magazines, trade periodicals, state inventory records, and consumer complaints. But this approach does not identify all plants under FDA's jurisdiction. For example, in 1990, FDA's bottled water inventory listed about 410 domestic bottled water plants, yet FDA officials estimated that about 475 bottled water plants were involved in interstate commerce.

A national bottled water plant registration system could be as simple as requiring bottlers operating in interstate commerce to notify FDA when they initiate operations. With such information FDA would know who is bottling water, thus providing greater assurance that each and every bottler receives a periodic inspection and produces safe products under sanitary conditions.

Using State and Third-Party Inspection Results

Bottled water plants in some states are subject to periodic state inspections and water quality tests. Our March 1991 report recommended that FDA routinely obtain and use the results of these state inspections and tests. The Secretary, HHS, agreed that such results are a valuable resource and said FDA would use state information whenever practicable for oversight of the entire food industry, including the bottled water industry. FDA officials told us they were developing information on all state food safety inspection

[5]FDA Food Safety Inspection (OEI-05-90-01070, Aug. 1991).

and testing programs in order to make greater use of state inspection and testing information.

With proper controls, FDA could also use third-party inspection results to supplement and/or supplant its own inspections. Third-party inspection results could provide FDA with valuable information it currently does not have—for example, information on foreign bottlers over whom it lacks jurisdiction. By using third-party inspection results, FDA would improve its oversight of bottled water.

To ensure safe bottled water products, IBWA requires each domestic member and, beginning in April 1991, each foreign member to undergo an annual unannounced third-party inspection. Domestic members are inspected by the National Sanitation Foundation (NSF)[6] and foreign members are inspected by an approved third party, such as NSF, or a foreign government organization. According to IBWA, its agreement with NSF calls for NSF to verify that the bottlers are in compliance with all applicable federal, state, and foreign government regulations.

FDA officials acknowledged that FDA could benefit from third-party inspection results, but they voiced concerns about the quality and practical use of such results. FDA officials said that third-party inspection organizations may not meet FDA inspection standards. Even if they did, FDA could not be sure that individual inspectors complied with FDA procedures and requirements. Therefore, FDA could not base regulatory actions on third-party inspection results. FDA officials also said that because of equity concerns, they would not want to certify or tacitly approve a single third-party organization.

While FDA's concerns are valid, they are not necessarily overriding. FDA could, for example, establish controls to ensure that third-party inspections meet FDA standards, including procedures to validate the quality and reliability of the inspections. Similarly, while FDA may not be able to base regulatory actions on third-party inspection results, FDA could use third-party inspections to target problem food establishments, thereby making more efficient use of its limited inspection resources.

IBWA officials said they would be willing to explore such a program with FDA for the bottled water industry. These officials added that IBWA has long

[6]NSF describes itself as a provider of independent third- party inspection services. As such, it is committed to serving the interests of IBWA rather than the direct interests of individual bottlers, regardless of who is paying for the inspection.

sought stronger federal and state bottled water regulation and oversight to ensure safe bottled water products. IBWA officials said that although they could not force individual members to submit third-party inspection results directly to FDA, they believed many bottlers would recognize the potential benefits of sharing the reports with FDA.

Increasing FDA's Inspection and Testing Activities

Another approach for improving oversight would be to increase FDA inspection and testing activities. Increased FDA inspections would improve oversight of domestic bottlers. Also, since FDA lacks jurisdiction over foreign bottlers, it could increase testing of foreign products to ensure that they meet U.S. standards. However, such actions would increase FDA's costs and may be difficult to accomplish with FDA's current level of resources.

FDA has identified the collection of user fees as a possible solution to its resource problems. FDA believes that regulated industries should contribute to the cost of ensuring the safety of their products because they receive benefits in the form of increased consumer confidence and protection from liability. A July 1990 OIG report concluded that user fees are a legitimate way to recover FDA inspection costs.[7]

FDA currently imposes user fees for, among other things, certifying color additives, supervising the destruction and reconditioning of products, and inspecting imported tea. These user-fee programs result from specific legislation authorizing the collection of such fees.

During the last several years, FDA has requested expanded user-fee authority from the Congress for activities such as premarket product approval. However, the Congress has inserted specific language in FDA's annual appropriations acts prohibiting FDA from collecting new user fees not specifically authorized by law. In effect, FDA must seek legislative authority for charging user fees on a case-by-case basis. Explicit authority for FDA to collect a fee from bottled water plants to cover FDA's oversight costs would be similar to the authorities that the Congress has provided FDA for other user-fee supported activities.

IBWA officials are concerned about the equity of charging bottled water plants a user fee because other beverage producers, such as soda water plants, are not subject to such fees. They also cited the fact that IBWA members already undergo an annual third-party inspection. However,

[7]Implementing User Fees in the Food and Drug Administration (OEI-12-90-02020, July 1990).

inequities already exist in bottled water inspection and testing. FDA inspects domestic plants but not foreign plants and not all domestic or foreign bottlers are IBWA members subject to IBWA's third-party inspection requirement. Furthermore, as mentioned earlier, IBWA is not certain that all of its members would be willing to share third-party inspection results with FDA. A possible solution would be for FDA to charge bottlers who are either unwilling to share third-party inspection results or not subject to third-party and/or FDA inspections for the cost of FDA inspections or tests necessary to ensure that the products are safe.

Conclusions

FDA's 1990 survey results are not necessarily representative of the nation's bottled water because the survey did not use probability-based statistical sampling. Thus, the survey alone does not provide an adequate basis for FDA's statement that bottled water is safe. Even if FDA had designed a representative survey, the results would still be of limited value because FDA tested for only 9 of 31 regulated contaminants.

In our prior report, we made recommendations directed at solving regulatory problems unique to the bottled water industry. Since then, we have taken a broader look at ways for FDA to improve its oversight. While these additional approaches have potential to strengthen oversight of bottled water, they also involve policy issues that affect the entire food industry and FDA's overall level of resources. In addition, the approaches, especially registration and user fees, are not without controversy. Consequently, we believe that an assessment of their advantages and disadvantages should not be limited to the bottled water industry. As we continue to review the adequacy of the federal government's food safety activities, we plan to consider the need for a national registration system for food establishments, third-party inspections to supplement and/or supplant FDA's inspections, and user fees to support additional FDA inspection and testing.

Furthermore, we continue to believe that the recommendations in our prior report rejected by HHS are valid and needed to improve oversight of the bottled water industry. In addition, IBWA has indicated a willingness to explore with FDA the feasibility of a third-party inspection program for the bottled water industry. Not only could such a program supplement and/or supplant FDA's own inspections, but it could provide useful information on the feasibility of using third-party inspections for other food industries.

Recommendations

We recommend that the Secretary, HHS, improve FDA's oversight of bottled water by reconsidering his decision regarding our prior recommendations that relate to the use of certified laboratories and the retention of test records for a longer period of time. In addition, we recommend that the Commissioner, FDA, develop a program, in cooperation with the International Bottled Water Association and the National Sanitation Foundation, to test the feasibility of using third-party inspection results.

We conducted our review between June and November 1991, primarily at FDA headquarters and at FDA field offices in San Francisco and New York, in accordance with generally accepted government auditing standards. (Further details on our objectives, scope, and methodology are provided in app. II.)

We briefed FDA officials on the facts presented and general conclusions drawn in our draft report and made technical changes where appropriate. However, as requested, we did not obtain written comments on this report.

As arranged with your office, unless you publicly announce its contents earlier, we will make no further distribution of this report until 30 days from the date of this letter. At that time we will send copies to the Secretary, Department of Health and Human Services, and the Commissioner, Food and Drug Administration. Copies will also be made available to interested parties on request.

This work was done under the direction of John W. Harman, Director, Food and Agriculture Issues, (202) 275-5138. Other major contributors are listed in appendix III.

Sincerely yours,

J. Dexter Peach
Assistant Comptroller General

Contents

Abbreviations

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
GAO	General Accounting Office
HHS	Department of Health and Human Services
IBWA	International Bottled Water Association
NSF	National Sanitation Foundation
OIG	Office of the Inspector General, Department of Health and Human Services
VOC	volatile organic chemical

FDA's Bottled Water Standards and EPA's Public Drinking Water Standards

As of December 1990, the Environmental Protection Agency (EPA) had established 42 public drinking water standards—29 primary standards and 13 secondary standards—and the Food and Drug Administration (FDA) had established 31 bottled water quality standards. Most of FDA's bottled water standards mirror EPA's public drinking water standards.

Table I.1: Maximum Contaminant Levels or Guidelines

Substance or property	FDA quality standards	EPA primary standards	EPA secondary standards
Inorganic chemicals (mg/L)			
Arsenic[a]	0.05	0.05	
Barium	1.0	1	
Cadmium[a]	0.01	0.01	
Chloride	250.0		250
Chromium	0.05	0.05	
Copper	1.0		1
Fluoride[a]	1.4-2.4[b]	4.0	2.0
Iron	0.3		0.3
Lead[a]	0.05	0.05	
Manganese	0.05		0.05
Mercury	0.002	0.002	
Nitrates[a]	10.0	10	
Phenols	0.001		
Selenium	0.01	0.01	
Silver	0.05	0.05	
Sulfate	250.0		250
Total dissolved solids	500.0		500
Zinc	5.0		5
Organic chemicals (mg/L)			
Total trihalomethanes[a]	0.10	0.10	
Vinyl chloride[c]	[d]	0.002	
1,1-dichloroethylene[c]	[d]	0.007	
1,2-dichloroethane[c]	[d]	0.005	
1,1,1-trichloroethane[c]	[d]	0.20	
Carbon tetrachloride[c]	[d]	0.005	
Trichloroethylene[c]	[d]	0.005	
para-dichlorobenzene	[e]	0.075	
Benzene[c]	[d]	0.005	
Endrin	0.0002	0.0002	
Lindane	0.004	0.004	

(Continued)

Substance or property	FDA quality standards	EPA primary standards	EPA secondary standards
Methoxychlor	0.1	0.1	
Toxaphene	0.005	0.005	
2,4-D	0.1	0.1	
2,4,5-TP silvex	0.01	0.01	
Physical characteristics			
Corrosivity			Noncorrosive
Foaming agents			0.5[f]
pH			6.5 - 8.5[g]
Turbidity	5[h]	5[h]	
Color	15[i]		15[i]
Odor	3[j]		3[j]
Microbiological standards			
Coliforms[a]	2.2/100[k]	1[l]	
Radiological standards			
Gross alpha[a]	15[m]	15[m]	
Combined radium 226 & 228[a]	5[m]	5[m]	

[a]Regulated contaminants which FDA tested for in its 1990 Bottled Water Survey.

[b]FDA has two fluoride quality standards: 1.4-2.4 when fluoride has not been added to the water, and 0.8-1.7 when fluoride has been added to the water.

[c]Unregulated contaminants that FDA had proposed standards for and tested for in its 1990 Bottled Water Survey. FDA also tested for the following additional unregulated contaminants: tetrachloroethylene (0.005 mg/L), cis-1,2-dichloroethylene (0.07 mg/L), trans-1,2-dichloroethylene (0.1 mg/L), and toluene (1 mg/L).

[d]FDA proposed these standards on July 6, 1990, but as of December 31, 1990, had not adopted them.

[e]FDA deferred adopting this primary standard because EPA was considering developing a stricter secondary standard. FDA wants bottled water standards to address aesthetic concerns, such as unpleasant odors, and thus believes bottled water quality standards should encompass EPA's stricter secondary standards.

[f]Milligrams per liter.

[g]As measured on the pH scale, whose values run from zero to 14, with 7 representing neutrality.

[h]Turbidity units.

[i]Color units.

[j]Odor threshold number.

[k]Most probable number of coliform organisms per 100 milliliters when using the multiple-tube fermentation test method.

[l]Total coliform-positive results per monthly samples for systems that test fewer than 40 samples per month.

[m]Picocuries per liter.

Objectives, Scope, and Methodology

To determine whether FDA's 1990 bottled water survey was representative of the nation's bottled water supply, we reviewed pertinent FDA records including the survey plan, implementing directions, preliminary results, and Official Establishment Inventory listing of bottled water firms. We also interviewed FDA headquarters officials responsible for planning the survey and FDA field office officials who implemented the survey in the San Francisco and New York districts.

To determine whether FDA tested for all bottled water quality standards and whether FDA's test for unregulated contaminants was warranted, we reviewed FDA's survey plans and results, established and proposed public drinking water standards, and bottled water quality standards. We interviewed FDA headquarters officials responsible for determining the contaminants tested and FDA laboratory officials who performed the survey tests in the San Francisco and New York districts.

To identify opportunities for improving FDA's oversight of the bottled water industry and/or reducing related costs, we reviewed pertinent food safety inspection studies and congressional hearings. We reviewed International Bottled Water Association (IBWA) membership requirements and National Sanitation Foundation bottled water plant inspection procedures. We also interviewed officials at IBWA, FDA headquarters, and FDA San Francisco and New York districts.

We conducted our review between June and November 1991 in accordance with generally accepted government auditing standards. However, in accordance with the Subcommittee's request we did not obtain written comments on this report. In lieu of such comments, we briefed FDA officials on the facts presented and general conclusions drawn in our draft report and made technical changes where appropriate.

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