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

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FOOD SAFETY AND QUALITY

Stronger FDA Standards and Oversight Needed for Bottled Water

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

Dear Mr. Chairman:

After the voluntary recall of benzene-contaminated Perrier mineral water in February 1990, your Subcommittee launched an investigation of the bottled water industry. In a June 4, 1990, letter you asked us to supplement your ongoing investigation by assessing the adequacy of the Food and Drug Administration's (FDA) bottled water standards and the effectiveness of FDA's oversight program to ensure that these standards are met. As later agreed with your office, we also discuss the regulation of drinking water sold in intrastate commerce (produced and marketed within the boundaries of a single state) and the reliability of terms and graphics used on bottled water labels. (See app. I for further details.)

FDA is primarily responsible for ensuring the safety of bottled water sold in interstate commerce,[1] 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. FDA sets bottled water quality standards and oversees how these standards are met by inspecting records and sanitary conditions at bottling plants, testing bottled water samples, and requiring bottlers also to test their water periodically. States are responsible for the safety of bottled water sold in intrastate commerce.

Results in Brief

FDA can do more to ensure the safety of bottled water. FDA has not adopted, in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), all health-based public drinking water standards established by EPA that set maximum levels for certain harmful contaminants, such as benzene—a known carcinogen. Also, after temporarily exempting "mineral water" from bottled water standards in 1973, FDA has not developed

[1]FDA defines bottled water as water that is sealed in bottles or other containers and is intended for human consumption. Bottled water excludes soda, seltzer, flavored, and vended water products.

alternative standards for it or even defined it.[2] As a result, bottled water, including mineral water, may contain levels of potentially harmful contaminants that are not allowed in public drinking water.

FDA's oversight of bottled water does not ensure that bottled water meets existing federal regulations and standards. Because FDA does not have a complete inventory of bottlers, it may not have inspected some domestic plants, and it does not inspect foreign bottling operations because it lacks jurisdiction over them. Further, of the 31 contaminants for which there are standards, FDA tested for 5 or fewer contaminants in 94 percent of the tests we reviewed. To supplement its oversight efforts, FDA relies on its requirement that bottlers self-test their water periodically. However, FDA does not require bottlers to report test results to FDA or use certified laboratories for the tests. In addition, FDA's requirement that bottlers keep test results for 2 years does not allow enough time for FDA inspection. While FDA inspected about half of the domestic bottlers two or more times in the last 5-3/4 years, it only inspected the other half once. Finally, FDA does not routinely obtain and use state inspection and test results to help eliminate duplicative inspections and tests.

FDA and the International Bottled Water Association (IBWA) believe that bottled water is safe but recognize that some gaps in federal regulation should be closed.[3] FDA officials said they do not have specific authority to require bottlers to use certified laboratories or report test results. IBWA has developed a model regulation that has been adopted by some states and has petitioned FDA to develop more stringent bottled water regulations. IBWA's model regulation and petition, among other things, require that bottled water meet FDA's quality standards and EPA's health-based drinking water standards, define and apply such standards to mineral water, require bottlers to undergo an annual third-party inspection, and require bottlers to use testing laboratories approved by the state or certified by EPA.

Background

Bottled water consumption in the United States has increased almost fourfold in 10 years—from 488 million gallons in 1979 to about 1.7 billion gallons in 1989. Bottled water consumption has been attributed to a variety of factors, including taste, a real or perceived health benefit, and

[2]Although FDA has not officially defined mineral water, it is generally considered a type of bottled water that contains various dissolved minerals, such as copper, iron, sulfate, and zinc.

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

an absence of contaminants. About half the participants in a 1990 survey of California consumers said they drank bottled water because it tasted better than tap water, about a quarter cited safety and health reasons, and a quarter said bottled water was free of contaminants.[4] A 1985 nationwide survey reported similar results.[5]

Two primary federal laws protect the public from contaminants in drinking water—the Safe Drinking Water Act and FFDCA. The Safe Drinking Water Act makes EPA responsible for ensuring that the public is provided with safe drinking water. Under FFDCA, FDA, an agency of the U.S. Department of Health and Human Services, is responsible for protecting the public from unsafe food or drink. A June 1979 memorandum of understanding outlines each agency's specific responsibilities.

EPA is responsible for public water systems and sets primary and secondary water quality standards for those systems. Primary standards establish legal maximum levels for certain contaminants and are aimed at protecting human health. Secondary water quality standards set recommended maximum levels for contaminants related to taste, odor, and other aesthetic concerns.

FDA sets water quality standards—i.e., legally enforceable maximum contaminant levels for bottled water sold in interstate commerce. Under section 410 of FFDCA, FDA has 180 days to amend its bottled water standards to reflect any new or revised primary drinking water standards adopted by EPA or to publish, in the Federal Register, FDA's reasons for not adopting EPA's standards. (See app. II for a listing of current bottled water standards and public drinking water standards.)

To ensure that bottlers and bottled water meet federal requirements, FDA uses a multipronged approach. FDA (1) requires bottlers to use water sources (wells, springs, public drinking water systems, etc.) that have been inspected, tested, and approved by appropriate regulatory organizations, such as EPA or state agencies; (2) inspects domestic bottling plants for proper operating practices and cleanliness; and (3) requires bottlers to test their source water and bottled water periodically to ensure compliance with bottled water quality standards. As a final check on this system, FDA tests selected samples of domestic source waters and both domestic and imported bottled water for contaminants.

[4]The Field Institute, Californians' Views On Water (May 1990).

[5]Audit and Surveys, Inc., Public Attitudes Toward Drinking Water Issues (Princeton, N.J., Dec. 1985).

States are responsible for regulating intrastate bottlers but are not required to mirror FDA regulations. As a result, state regulations vary. They may, for example, set additional bottled water quality standards, inspect bottling plants, test source and product water for contaminants, approve water sources, and require bottlers to test their source and product water periodically.

Bottled Water Quality Standards Are Incomplete

FDA has not complied with the FFDCA provision requiring timely action on setting bottled water quality standards and has exempted mineral water from those standards. Without quality standards, some bottlers, FDA, and some state regulators are not required to test for contaminants regulated in public drinking water. As a result, bottled water, including mineral water, may contain levels of potentially harmful contaminants not allowed in public drinking water.

FDA Slow to Set Quality Standards

Although FDA has adopted or proposed adopting almost all of EPA's primary public drinking water standards, FDA has not complied with the section 410 timing requirement since 1976, or the last four times that EPA has set new or revised 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 (VOCs), including benzene, already regulated in public drinking water.[6] (See app. III for specific dates of EPA's and FDA's actions.)

FDA officials said other regulatory priorities and limited resources caused the delay. They said that the agency had decided to work on higher priority issues, such as safety-related regulations for methylene chloride in hair spray and lead in ceramic ware, rather than publish a notice in the Federal Register announcing that FDA was developing a regulation, even though such notification is required by law.

Prompt action by FDA to adopt new or revised primary public drinking water standards will remain an issue during the next few years as EPA implements a 1986 amendment to the Safe Drinking Water Act requiring it to consider setting additional drinking water standards. On January 30, 1991, for example, EPA issued new or revised primary public drinking water standards for 32 substances and estimates that it will issue another 29 by March 1992. When FDA adopts such standards, bottlers are required to test their water to ensure that the standards are not

[6]VOCs are mostly industrial chemicals and solvents that readily evaporate into the air.

exceeded. In addition, FDA and states that automatically adopt FDA's bottled water quality standards may also test bottled water samples to ensure that they comply with the standards.

Mineral Water Exempted From Quality Standards

When FDA first developed bottled water quality standards in 1973, it exempted mineral water. FDA announced in 1973 that it would develop separate quality standards for mineral water; however, it has yet to develop such standards or even to define mineral water. As a result, unlike drinking and bottled water, mineral water is not regulated by any federal water quality standard.

FDA exempted mineral water because it could not apply EPA's water quality standards directly to mineral water, as it had done for bottled water. FDA believed the water's mineral content could exceed certain existing secondary water quality standards, such as that for total dissolved solids.

In the absence of a federal definition of mineral water and a set of related federal quality standards, at least 5 of the 10 states we visited and IBWA have developed their own definitions and standards for mineral water. For example, California defines mineral water as water exceeding 500 milligrams of total dissolved solids per liter and requires that mineral water meet all state health-related bottled water quality standards.

In 1988, IBWA 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 primary drinking water standards. FDA planned to respond to IBWA's 1988 petition by the end of 1990 but postponed its response because of higher priority requirements. FDA officials said they are considering withdrawing the mineral water exemption from bottled water quality standards but are still assessing the advantages and disadvantages of a mineral water definition based on an arbitrary level of total dissolved solids. Such a definition could unfairly restrict some bottlers from labeling their product as mineral water. However, without mineral water standards or a definition of mineral water, any product labeled mineral water is exempt from quality standards.

Impact of Slow Standard Setting and Mineral Water Exemption

Because FDA (1) delayed amending its bottled water quality standards to reflect all EPA standards for public drinking water and (2) did not apply bottled water quality standards to mineral water, bottlers were not required to, and FDA did not, test for benzene. Also, states that rely on federal bottled water quality standards for state regulatory purposes were probably not testing for benzene.

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 the bottled water quality standards and applied them to mineral water, then bottlers, some state regulators, and/or FDA would have been testing for benzene. With such additional testing, the chances for earlier identification of the contaminated Perrier mineral water would have increased.

FDA Oversight Does Not Ensure That Bottlers Meet Federal Standards

FDA's oversight does not ensure that bottlers and bottled water products meet existing federal regulations and standards. FDA relies heavily on self-testing by domestic and foreign bottlers to ensure quality but does not require these bottlers to report test results to FDA, keep test records long enough to allow for FDA inspection, or use certified laboratories for the tests. Also, FDA is not making full use of state inspection and test results.

FDA Oversight of Bottled Water

FDA does not have a specific inspection timetable, but agency officials said that, given available resources and the low safety risk of bottled water, they try to inspect each domestic bottled water plant at least once every 4 years. FDA lacks jurisdiction over foreign bottled water operations and, unless invited, does not inspect them.

From the beginning of fiscal year 1985 through third-quarter fiscal year 1990, FDA conducted or contracted with states for 869 inspections at 410 domestic bottled water plants and identified 64 violations requiring immediate correction and reinspection. About half of the 410 plants were inspected two or more times, while the other half were inspected once. Some domestic plants may not have been inspected at all by FDA

during this time because FDA does not have a complete inventory of bottled water firms operating in interstate commerce. For example, FDA estimated that 475 firms were operating in 1990, yet FDA has inspection/inventory records for only 410 firms. FDA noted that it has difficulty identifying all interstate bottled water firms because it does not have legal authority to require them to register.

FDA also tests bottled water samples for contaminants. FDA officials said that they generally do such tests in response to consumer complaints, at the discretion of an FDA inspector, or as part of a special national or district survey. For example, in response to the Perrier incident, FDA initiated a 1990 nationwide survey in which it planned to test 48 domestic and 63 imported bottled water samples. Preliminary survey results show that one domestic and two imported mineral water samples exceeded federal bottled water quality standards. The domestic sample and one imported sample contained about twice the allowed 2.4 milligrams per liter of fluoride, and the other imported sample contained more than three times the allowed .05 milligrams per liter of arsenic. FDA officials told us these quantities did not pose a risk to public health.

To determine the extent of FDA's routine testing of domestic and imported bottled water, we reviewed test records from October 1, 1987, to June 30, 1990, for 5 of the 21 FDA districts—Boston, Chicago, Detroit, Minneapolis, and San Francisco. Available records showed that none of the 21 domestic samples or 47 imported samples was tested for all 31 contaminants for which quality standards exist; 18 of the domestic samples and 46 of the imported samples were tested for 5 or fewer contaminants.

FDA Relies on Bottlers to Self-Test Their Products

FDA requires bottlers to test source and product waters weekly for microbiological contaminants and annually for most other contaminants to ensure that they meet federal bottled water quality standards. However, FDA does not have assurance that these tests are done or that the results are reliable because it does not require bottlers to keep test results long enough for FDA to review, use certified laboratories, or report the test results to FDA.

Although FDA requires bottlers to keep test results for 2 years, it inspected about half of 410 domestic bottlers only once in 5-3/4-years. Moreover, because FDA lacks jurisdiction, it does not inspect foreign bottling operations. As a result, FDA may be unaware of bottlers that are not doing the required tests. For example, during an inspection we observed,

the National Sanitation Foundation, a third-party inspection and testing organization serving IBWA members, found that the bottler under review was not doing the FDA-required tests, except for an occasional source water test for microbial contaminants.

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 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.

EPA and state regulatory officials said these record-keeping requirements allow regulatory officials to (1) review historical test data to verify that the tests were done, (2) gain insight into a particular or recurring problem, and (3) learn of and respond to contaminated water problems.

Besides lacking assurance that bottlers do required tests, FDA lacks assurance that such tests are done correctly or that the 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 be certified or otherwise establish their qualifications to do the required tests.

In contrast, for public drinking water, EPA requires certified laboratories to analyze the test samples and has a program to ensure that the laboratories can correctly do the required tests. Similarly, for bottled water, 7 of the 10 states we visited also required the use of certified laboratories. State officials said that results from uncertified laboratories are not always reliable.

To help ensure the safety of bottled water, IBWA has developed a model regulation, which some states have adopted, and it has petitioned FDA to develop more stringent bottled water regulations. IBWA's model regulation and petition, among other things, require bottlers to undergo an annual third-party inspection and to use certified testing laboratories.

FDA said that it does not have specific authority to require bottlers to report test results or to use certified laboratories. FDA said that although the Safe Drinking Water Act gives EPA the authority to require public water systems to use certified laboratories and report test results, FFDCA has no such provisions for most food manufacturers, including bottlers. FDA officials told us that they are considering seeking stronger legislative authority related to these matters.

Better FDA Coordination With States Would Improve Oversight

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.

Regulatory officials responsible for bottled water in 9 of the 10 states we visited said that they aim to inspect each bottling plant operating within their state at least annually. Additionally, such states as Florida, New York, and California select and analyze many bottled water samples. In 1990 Florida randomly selected 100 different bottled water samples and analyzed them for compliance with EPA's primary drinking water standards. New York and California are also developing programs that include annual testing of bottled water samples.

In our September 1989 report on FDA's inspection program,[7] we said that FDA could free more of its inspection resources for higher priority work if it were to make better use of state inspections of low-risk food producers, such as bottlers, bakeries, and warehouses with no history of serious problems.

Currently, FDA is not taking advantage of all available state inspection and testing information. Although all five FDA districts obtained state inspection and test results reporting serious problems or violations, only one routinely obtained such reports when only minor problems or no violations were noted. For example, Michigan inspects bottled water plants at least annually but gives FDA's Detroit district office only violative inspection results.

[7]Domestic Food Safety: FDA Could Improve Inspection Program to Make Better Use of Resources (GAO/HRD-89-125, Sept. 27, 1989).

Obtaining state inspection and test results would help FDA identify and eliminate some duplicative inspections and tests, thus freeing resources for other program activities.

Conclusions

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.

Recommendations

To protect consumers from potentially contaminated bottled water, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to (1) comply with section 410 of FFDCA, which requires timely setting of bottled water quality standards, and (2) develop and issue mineral water quality standards.

To ensure the performance and reliability of required bottled water tests, we recommend that the Commissioner of FDA seek legislation giving FDA specific authority to require domestic bottlers involved in interstate commerce and foreign bottlers to

- use laboratories that have been certified by federal or state agencies to analyze public drinking water or bottled water, or demonstrate that they can accurately test bottled water quality and
- report to FDA the results of required chemical and radiological tests within 30 days, and violative results from all required tests within 48 hours.

Also, we recommend that the Commissioner of FDA revise FDA's regulations to require that bottlers keep all self-monitoring records for at least 5 years, or since FDA's last inspection.

In addition, to improve FDA's oversight of bottled water, we recommend that the Commissioner of FDA work with the states to routinely obtain state inspection and test results.

Matters for Congressional Consideration

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, the Congress may wish to revise 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.

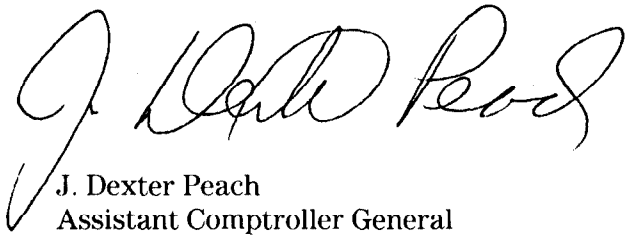
We conducted our review between June and October 1990 primarily at FDA and EPA headquarters and at FDA field offices in Boston, Chicago, Detroit, Minneapolis, and San Francisco in accordance with generally accepted government auditing standards. (Further details on our objectives, scope, and methodology are provided in app. IV.)

FDA, EPA, and IBWA officials reviewed a draft of this report for technical accuracy, and changes were made where appropriate. However, as requested, we did not obtain formal written comments on this report.

As arranged with your office, unless you publicly announce it 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; the Commissioner, Food and Drug Administration; the Administrator, Environmental Protection Agency; and other interested parties.

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 V.

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
IBWA	International Bottled Water Association
VOC	volatile organic chemical

Regulation of Intrastate Drinking Water and Reliability of Bottled Water Labels

During our review, we identified concerns related to the regulation of drinking water sold in intrastate commerce and the reliability of terms and graphics used on bottled water labels.

Are Intrastate Water Products Adequately Regulated?

Each state is responsible for regulating drinking water sold in intrastate commerce, but some states do not have regulations and programs for all types of drinking water. As a result, some intrastate drinking water may not be adequately regulated.

During 1989, about 862 million gallons of the bottled water sold in the United States were delivered to homes and offices, and another 130 million gallons of drinking water were sold through vending machines. Typically, delivered water is sold locally in 1.5-gallon, 2.5-gallon, or larger-size bottles, and vended water is obtained from a local source and sold through machines to customers who provide their own containers. Industry and state regulatory officials said that some delivered water and perhaps all vended waters are sold within their state of origin.

As previously mentioned, federal regulation of drinking water is divided between FDA and EPA. FDA presently regulates bottled water sold in interstate commerce and generally leaves regulation of bottled water sold in intrastate commerce to the states.

EPA regulates both public drinking water systems, such as systems that regularly serve at least 15 connections or 25 individuals, and transient drinking water systems, such as vended water systems. EPA considers vended water to be a transient water system because it (1) is not sold in sealed containers, (2) generally comes from a continuous source like public drinking water, and (3) does not continually serve the same customers. EPA requires transient systems to test periodically only for selected primary-standard contaminants, such as bacteria and nitrates, that can cause acute health problems. However, EPA drinking water program officials said that EPA has no active national program for overseeing the safety and quality of vended water.

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, as the following examples show.

- 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.
- Arizona regulates, inspects, and tests bottled water but has no state regulations or programs for vended water.
- Other states, such as Minnesota and New York, currently do not have vended water regulations.

Are Bottled Water Labels Accurate?

Consumers may be paying as much as 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. While much of this water may receive additional treatment to remove chemicals, such as fluoride and chlorine, or to improve its taste, odor, or color, it does not have to be purer or meet higher health-based standards than tap water. Although some consumers may willingly pay for this additional treatment, others may be misled by terms and labels used on bottled water products.

Under section 401 of FFDCA, FDA may define and set food standards to protect the consumer. Specifically, section 401 allows FDA to promulgate regulations fixing and establishing for any food a reasonable definition and standard of identity when such action will promote honesty and fair dealing in the interest of consumers.

Although bottled water falls within its jurisdiction, FDA has not established standards of identity or otherwise defined some of the terms commonly used on bottled water labels. As previously mentioned, for example, FDA has not defined mineral water, which does not have to meet federal bottled water quality standards. As a result, bottlers may call their product mineral water, and consumers can purchase it under the mistaken belief that it must meet certain standards of quality.

Bottlers use many terms to describe their products' purity, source, process, health attributes, and/or targeted market. For example, we observed labels indicating

- the purity of the product, such as "pure," "crystal pure," and "premium,"

- the filtering or bottling process used, such as "purified," "distilled," and "steamed distilled,"
- the source of the product, such as "artesian," "pure artesian," "well," "glacial," "spring," and "natural spring,"
- the product's health characteristics, such as "salt-free," "sodium-free," and "caffeine-free," and
- the targeted market for the product, such as "nursery" and "infant."

With few exceptions, FDA has not defined the terms commonly found on water products. Although it has published criteria for indicating sodium content, these criteria may mislead consumers. FDA regulations state that products having less than 5 milligrams of sodium per serving may be labeled sodium-free. Thus, Perrier's 23-ounce bottle of mineral water, which contains 11.5 milligrams of sodium, may be labelled "sodium free" because each 8-fluid ounce serving contains only 4 milligrams of sodium. The president of the Perrier Group, among others, has acknowledged that Perrier's claims, though legal, nevertheless provoke media reports and consumer complaints questioning the accuracy of such sodium-free statements. Such actions erode consumer trust in the bottled water industry and in the government's ability to regulate it.

Few restrictions limit bottlers in their choice of label terms or graphics. Terms such as "nursery" water may imply a certain standard of quality that does not exist. Label graphics may represent 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 defined some of these terms, and IBWA has developed guidelines for its members to follow. Of the 10 states we visited, 5 have defined some of the terms listed above and 3 require that the water source be identified on the label. For example, Texas regulations help protect consumers from misleading marketing by prohibiting references on bottled water labels to contents or ingredients, such as caffeine, that are not normally found in drinking water. Connecticut requires the water source, such as a spring or municipal system, to be identified on the product label.

IBWA's "Code of Advertising Standards" states that bottled water labels and advertising should not mislead consumers. The IBWA model code defines at least 10 water types and 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.

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

As of November 1990, EPA has established 42 public drinking water standards—29 primary standards and 13 secondary standards—and FDA has established 31 bottled water quality standards. Most of FDA's bottled water standards mirror EPA's public drinking water standards.

Table II.1: Maximum Contaminant Levels or Guidelines

Substance or property	FDA quality standards	EPA primary standards	EPA secondary standards
Inorganic chemicals			
Milligrams per liter			
Arsenic	0.05	0.05	
Barium	1.0	1	
Cadmium	0.01	0.01	
Chloride	250.0		250
Chromium	0.05	0.05	
Copper	1.0		1
Fluoride	1.4 - 2.4[a]	4.0	2.0
Iron	0.3		0.3
Lead	0.05	0.05	
Manganese	0.05		0.05
Mercury	0.002	0.002	
Nitrates	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			
Milligrams per liter			
Total Trihalomethanes	0.10	0.10	
Vinyl Chloride	[b]	0.002	
1,1-Dichloroethylene	[b]	0.007	
1,2-Dichloroethane	[b]	0.005	
1,1,1-Trichloroethane	[b]	0.20	
Carbon Tetrachloride	[b]	0.005	
Trichloroethylene	[b]	0.005	
para-Dichlorobenzene	[c]	0.075	
Benzene	[b]	0.005	
Endrin	0.0002	0.0002	
Lindane	0.004	0.004	
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	

(continued)

Substance or property	FDA quality standards	EPA primary standards	EPA secondary standards
Physical characteristics			
Corrosivity			Noncorrosive
Foaming agents			0.5[d]
pH			6.5 - 8.5[e]
Turbidity	5[f]	5[f]	
Color	15[g]		15[g]
Odor	3[h]		3[h]
Microbiological standards			
Coliforms	2.2/100[i]	1[j]	
Radiological standards			
Gross Alpha	15[k]	15[k]	
Combined Radium 226 & 228	5[k]	5[k]	

[a]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.

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

[c]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.

[d]Milligrams per liter.

[e]As measured on the pH scale, whose values run from 0 to 14, with 7 representing neutrality.

[f]Turbidity units.

[g]Color units.

[h]Odor threshold number.

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

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

[k]Picocuries per liter.

Timeliness of FDA Actions on Setting/Revising Bottled Water Quality Standards

Contaminant category	Date EPA finalized	Date FDA proposed	Days elapsed
Initial standards for 6 organic chemicals, 10 inorganic chemicals, turbidity, and microbiological contaminants	12/24/75	06/21/76[a]	180
Initial standard for radioactivity	07/09/76	01/04/77	179
Initial standard for total trihalomethanes	11/29/79	06/13/80	197
Revised standard for fluoride[b]	02/27/87	09/16/88	567
Initial standards for 8 volatile organic chemicals	07/08/87	07/06/90[c]	1,094
Revised standard for total coliforms	06/29/89	[d]	550[d]

[a]FDA adopted EPA's organic and inorganic chemical standards and already had turbidity and microbiological contaminant standards.

[b]On September 16, 1988, FDA proposed adopting EPA's revised fluoride standard. FDA's proposed fluoride standard was not final as of December 31, 1990.

[c]FDA proposed adopting all 8 volatile organic chemical standards except the para-dichlorobenzene standard for which EPA is considering further action. FDA's proposed standards were not final as of December 31, 1990.

[d]FDA has not announced any action on this standard as of December 31, 1990.

Objectives, Scope, and Methodology

To assess bottled water quality standards, we reviewed pertinent federal and state bottled water laws and regulations. We interviewed senior FDA, EPA, and state health officials, representatives of consumer and environmental organizations, and bottled water industry executives.

To assess bottled water testing requirements, we interviewed FDA headquarters officials and district officials at 5 of FDA's 21 district offices. We reviewed FDA inspection policies and procedures and examined bottled water inspection and testing records for fiscal years 1985 through third-quarter 1990. We observed two FDA, and six state/county bottled water plant inspections.[1] We also observed an inspection conducted by the National Sanitation Foundation, a third-party inspection and testing organization. We reviewed FDA's fiscal year 1990 Domestic and Imported Bottled Water Survey, which was undertaken to assess the adequacy of bottled water manufacturing practices, water quality standards, and food labeling requirements.

In addition, we selected 12 states to determine how individual state regulations supplemented federal bottled water standards and testing requirements. As table IV.1 shows, the 12 states represented a variety of conditions, such as high bottled water consumption levels or rates, reputed strong bottled water regulations, and general geographic location. We visited regulatory officials in 10 states and conducted telephone interviews with regulatory officials in 2 states—Florida and Missouri—to learn about their bottled water regulations.

We conducted our review between June and October 1990 in accordance with generally accepted government auditing standards.

[1]We observed state/county inspections in Arizona, California, Connecticut, New York, Pennsylvania, and Wisconsin.

Table IV.1: Bottled Water Consumption and Quality Standards in 12 Selected States

State	1989 ranking and gallons consumed[a]		Comparison with FDA standards[b]	Geographic location
Arizona	6	67.1	equal	West
California	1	654.3	more stringent	West
Connecticut	13	27.6	more stringent	East
Florida	4	113.9	more stringent	Southeast
Illinois	5	74.1	equal	Midwest
Michigan	14	22.7	equal	Midwest
Minnesota	[c]	[c]	equal	Midwest
Missouri	[c]	[c]	less stringent	Midwest
New York	3	120.1	more stringent	East
Pennsylvania	9	49.3	more stringent	East
Texas	2	120.5	equal	Southwest
Wisconsin	[c]	[c]	more stringent	Midwest

[a]Millions of gallons

[b]"Less stringent" means the state had fewer and/or less strict quality standards than FDA, "equal" means the state mirrored FDA quality standards, and "more stringent" means the state had more and/or stricter quality standards than FDA.

[c]Ranked lower than 15th and consumed less than 15.7 million gallons.

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