

C H A P T E R 2

The Myth and Reality of Bottled Water

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Sales and consumption of bottled water have skyrocketed in recent years. From 1988 to 2002, the sales of bottled water globally have more than quadrupled to over 131 million cubic meters annually (BMC 2003). Bottled water sales worldwide are increasing at 10 percent per year, while the volume of fruit drinks consumed is growing less than 2 percent annually and beer and soft drink sales are growing at less than 1 percent per year (Bottled Water Web 2003). More than 50 percent of Americans drink bottled water occasionally or as their major source of drinking water—an astounding fact given the high quality and low cost of U.S. tap water.

Why the great growth in bottled water sales? Bottled water typically costs a thousand times more per liter than high-quality municipal tap water. Are consumers willing to pay this price because they believe that bottled water is safer than tap water? Do they have a real taste preference for bottled water? Or is the convenience of the portable plastic bottle the major factor? Are they taken in by the images portrayed in commercials and on the bottles?

The answers are consequential. We estimate that total consumer expenditures for bottled water are approximately \$100 billion per year—a vast sum that both indicates consumers are willing to pay for convenient and reliable drinking water and that society has the resources to make comparable expenditures to provide far greater quantities of water for far less money by investing in reliable domestic supplies.

Ironically, despite its cost, users should not assume that the purity of bottled water is adequately protected, regulated, or monitored. Even where regulations exist, bottled water plants typically receive far less scrutiny from inspectors than other food plants or municipal water systems. In many places, such as the United States, bottlers themselves do most sampling and testing, which opens the door to fraud, misreporting, and inadequate protection. Ultimately, the provision of clean water to all will not come from sales of bottled water but from effective actions of communities, governments, and municipal providers to provide a safe and reliable domestic water supply.

This chapter reviews the recent history of and trends in bottled water, the regulations governing bottled water production and sale, and growing concerns about the costs and implications of bottled water use. We also address growing concerns in both industrialized nations where high-quality tap water is readily available and in poorer developing countries where the high cost of bottled water raises questions about equity and access to basic water services for all.

Bottled Water Use History and Trends

The global consumption of bottled water is growing faster than 10 percent per year with substantial growth in sales volumes on every continent. The slowest growth is occurring in European countries, where bottled water has long had a commercial foothold. Even there, growth rates of five to ten percent per year are common. The highest growth rates are occurring in Asia and South America, with annual sales increases of 15 percent or more in places as diverse as Egypt, Kuwait, the United States, and Vietnam.

In 2002, the Beverage Marketing Corporation (BMC) estimated total consumption of bottled water at more than 131 billion liters, up from 72 billion liters in 1996. Table 2.1 shows annual global consumption from 1996 to 2002 (estimated), along with the annual percent increase. Figure 2.1 shows the trend in global consumption since 1996.

According to the Beverage Marketing Corporation (2003), global per-capita bottled water use has risen from 12.6 liters per-capita per year (lpcy) in 1996 to over 21 lpcy in 2002 (see Figure 2.2). Changes in per-capita consumption of bottled water are even more dramatic, however, when evaluated on a regional or national basis. Figure 2.3 shows trends in continental per-capita consumption over this period. The rate of increase is extremely high in South America, where use has doubled from 14 to 28 lpcy, and in Asia, where use is growing by 20 percent per year and has increased from under 4 to more than 8 lpcy. Total per-capita use, however, is still dominated by consumers in North America and Europe, where annual use is 85 and 64 lpcy, respectively.

The top ten bottled water-consuming countries are shown in Data Table 6 (in the Data Section) and Figure 2.4 for 1997 through 2002. By far, the greatest consumption occurs in the United States, followed by Mexico. In the past few years, however, consumption in China has grown enormously. In 1997, China was the ninth largest consumer

TABLE 2.1 Total Global Consumption of Bottled Water, 1996 to 2002

Year	Thousands of Cubic Meters	Percent Change
1996	72,675.62	–
1997	80,649.10	11.00
1998	87,838.89	8.90
1999	97,848.00	11.40
2000	107,381.48	9.70
2001	117,876.24	9.80
2002(P)	131,412.11	11.50

Note: Data for 2002 are preliminary.

Source: Courtesy of the Beverage Marketing Corporation (2003).

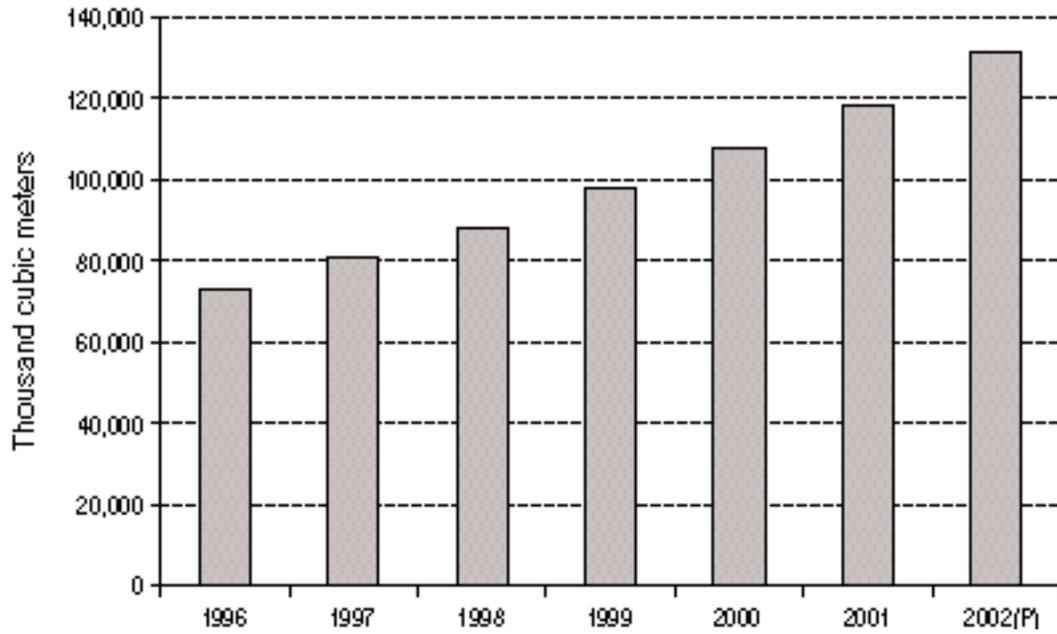


FIGURE 2.1 Total global bottled water consumption, 1996 to 2002.

Note: Data for 2002 are preliminary.

Source: Beverage Marketing Corporation, with permission.

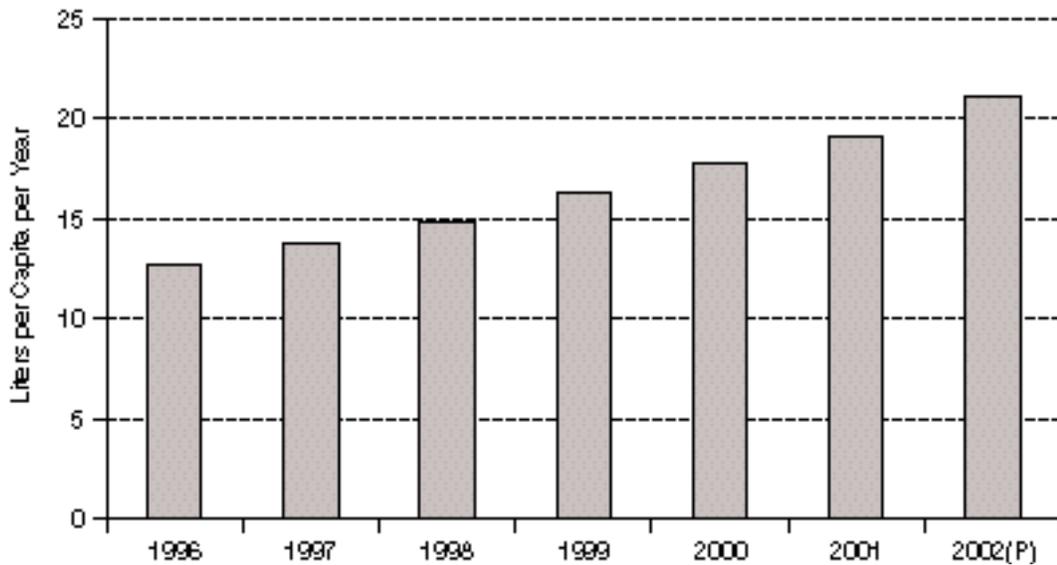


FIGURE 2.2 Per-capita consumption of bottled water, 1996 to 2002.

Note: Data for 2002 are preliminary.

Source: Beverage Marketing Corporation, with permission.

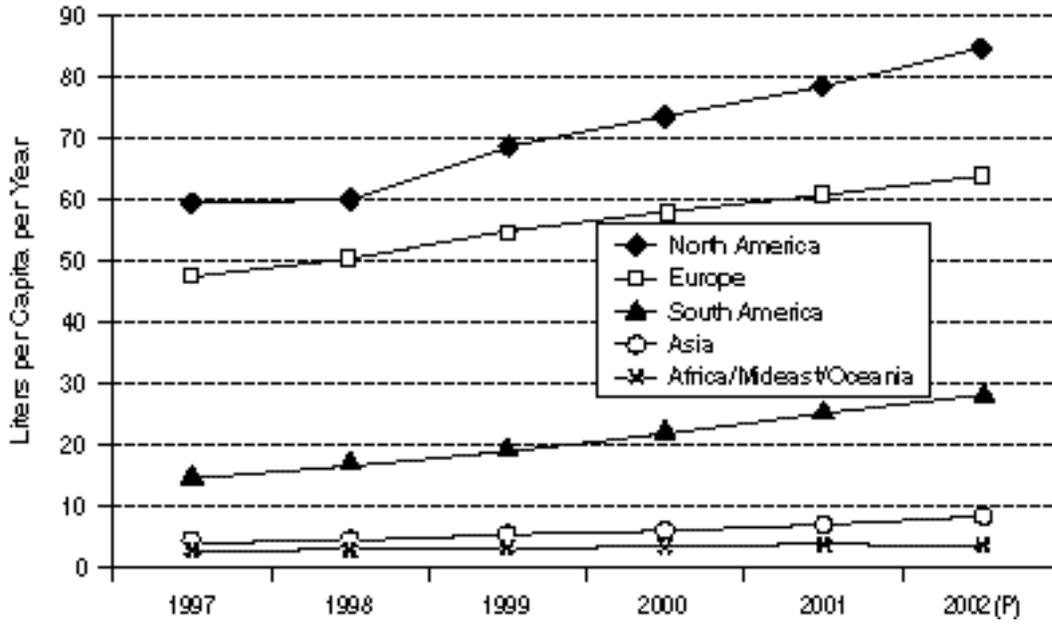


FIGURE 2.3 Per-capita bottled water consumption by continental region, 1997 to 2002. *Source:* Beverage Marketing Corporation, with permission.

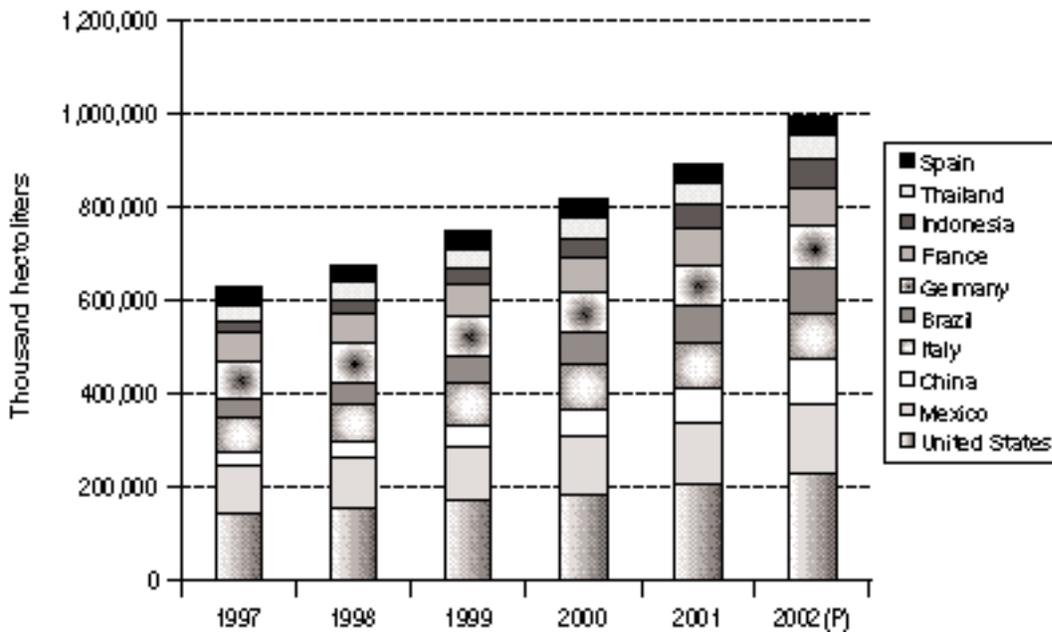


FIGURE 2.4 Top ten bottled water consuming countries, 1997 to 2002. *Source:* Beverage Marketing Corporation, with permission.

TABLE 2.2 Bottled Water Sales in China, 1997 to 2002

	Sales (million liters)
1997	2,750
1998	3,540
1999	4,610
2000	5,993
2001	7,605
2002	9,887

Note: Data for 2002 are preliminary.

Source: Beverage Marketing Corporation, with permission.

of bottled water. By 2002, China had moved up to become the third largest bottled water consuming country, going from 2.7 billion liters in 1997 to 9.9 billion in 2002 (Table 2.2).

While there are thousands of bottling companies, the industry is undergoing a rapid consolidation as major bottlers tighten their holds on key markets. Nestle S.A., for example, owns dozens of brand names including Arrowhead and Poland Springs in the United States (with the third and fourth largest market shares in the United States in 2001), and the well-known brand, Perrier. In 2001, the largest selling brands in the United States were Aquafina (a Pepsi product), with revenues of \$645 million, Dasani (a Coca-Cola product) with revenues of \$560 million, Poland Spring, Arrowhead, and others as shown in Table 2.3. Box 2.1 shows the three leading U.S. purveyors of bottled water.

Box 2.1 Largest U.S. Sellers of Bottled Water in 2001

Nestle S.A.'s water division sells 70 bottled water brands in 160 countries. Its North American subsidiary sells nine domestic brands, including Arrowhead, Poland Spring, and Deer Park, and five imported brands, including San Pellegrino and Perrier. Nestle Waters North America, Inc. had revenues of \$2.1 billion in 2001. Its market share is 32.5 percent and growing.

PepsiCo comes in second place with its Aquafina product, which currently has a 14 percent market share but is the top-selling, single-serve bottled water in the United States. In 2001, Aquafina sales grew nearly 45 percent and comprised 4 percent of all of Pepsi's beverage sales.

Coca-Cola sales are in third place with Dasani a 12 percent market share in 2001. Sales grew 90 percent or so in 2002. Coca-Cola recently entered into a production, marketing, and distribution partnership with France's Groupe Danone, owner of several brands, including Evian.

Sources: Bobala 2003, McKay 2002.

TABLE 2.3 Leading United States Bottled Water Brands, 2001

	2001 U.S. Market Share (%)	2001 Volume Growth (%)
Aquafina	13.80	45
Dasani	12.00	95.50
Poland Spring	11.20	29
Arrowhead	6.60	50
Aberfoyle	5.60	33
Crystal Geyser	5.50	15
Evian	3.80	–5

Note: Nestle S.A. owns both Arrowhead and Poland Spring (and many other brands, see Box 2.1).

Source: McKay 2002.

TABLE 2.4 Summary Results of Bottled Water Price Surveys

	Average Price per Cubic Meter (US\$)
California Tap Water 2003	0.50
Nepal 2003	206
India 2003	267
France 2004	332
Spain 2003	411
Malawi 2004	825
South Africa 2003	857
Italy 1999	879
California 2003	995
Switzerland 1998	1,616

Note: Prices vary. These reflect the average of all the options available in surveyed stores. Currency conversions were done using rates at time of survey, uncorrected for inflation.

Source: Local price data was provided to the author by Moench, M., Water Nepal, M., Turton, A., Smets, H., and Lane, J. Prices for Switzerland 1998, Italy 1999 provided by <http://www.bottledwaterweb.com/pricescan.html>. Prices for California 2003 from three surveys by author.

The Price and Cost of Bottled Water

By any standard, bottled water is hugely expensive to consumers compared to reliable high-quality municipal water supply. In regions where no such municipal supply is available, bottled water may provide a temporary and vital source of safe drinking water. The key word, however, is “temporary”—bottled water should not be considered a permanent alternative to reliable municipal supply for many reasons, including cost, control, and equity. Failure to provide municipal supply often affects the poorest populations of peri-urban areas, leaving them to pay the inflated prices for water provided by private vendors or bottled water purveyors.

Surveys on the prices of bottled water are limited. Data from a series of surveys conducted between 1998 and 2003 in the United States, Europe, Nepal, South Africa, Malawi, and India are presented in Table 2.4 and Figure 2.5, compared to the price of high-quality municipal tap water in California. As this table shows, bottled water in most industrialized nations costs between \$500 and \$1000 per m³. Even in Nepal, where per-capita annual income in 2002 was only about \$230 (The World Bank 2002),

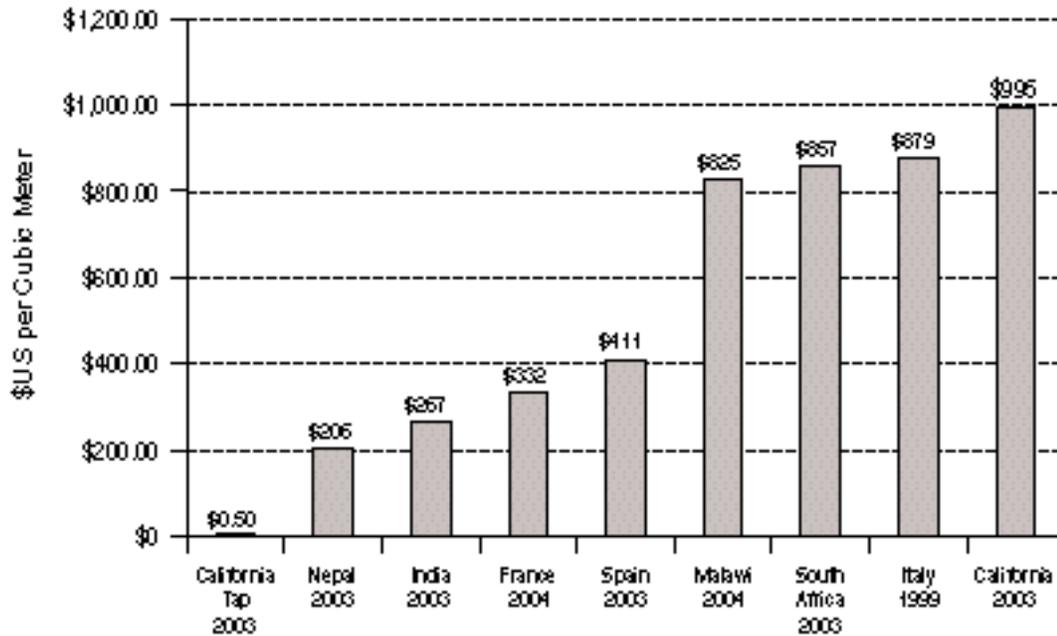


FIGURE 2.5 Price of bottled water.

Note: Prices found in a survey for Switzerland exceeded \$1,500 per m³, but may not reflect average prices there.

bottled water costs over \$200 per m³. This is in stark contrast to the cost of high-quality municipal water, which is usually well below \$1 per m³.¹ Even water from desalination facilities, considered the most expensive source of municipal supply, is rarely more than \$2 per cubic meter and the price of desalination has been dropping.

What justifies such a high price? Quite simply, consumers are willing to pay it. The cost of production for bottled water is quite low—spring owners may sell water to bottlers for only a few pennies per liter. The cost of labor, bottling, plastic bottles, transportation, and marketing greatly increases the overall costs, but bottled water remains a product with high profits—profit margins of 25 percent or more have been reported (Berberoglu, no date; Olson 1999), providing a major incentive for beverage companies to push bottled water production and sales.

Overall, we estimate that total consumer expenditures for bottled water approach \$100 billion annually, assuming an average of \$750 per cubic meter for the 131 billion liters sold annually. This sum greatly exceeds the money that would be required to produce a comparable amount of water from high-quality, reliable municipal systems.

The Flavor and Taste of Water

Highly subjective preferences for taste and flavor in water help drive the market for bottled water. Water has different flavors and tastes depending on its origin, type and duration of storage, treatment, and method of delivery. Other than concerns (valid or not) about water quality, the most common reason offered to explain the growing use of bottled water is dissatisfaction with the taste of locally available tap water.

1. The author pays around \$600 per acre-foot, or around 50 cents per cubic meter³ for high-quality drinking water in California.

The taste of water reflects different concentrations of minerals and trace elements. Highly mineralized water can sometimes taste metallic. High levels of bicarbonates can taste salty. Water with hydrogen sulfide smells and tastes like rotten eggs. Certain types of plastic bottles can impart a plastic taste. For carbonated waters, customers are willing to accept higher levels of minerals (Bottled Water Web, *Water Taste*, 2003).

Professor William Bruvold of the University of California at Berkeley conducted and published findings on the taste of minerals in water in the 1960s. His study showed that certain combinations and concentrations of minerals in water were more acceptable than others (Pomento 2001). In 1998, the Metropolitan Water District of Southern California surveyed customers' perceptions of tap water quality and flavor. At that time 56 percent of the customers rated their tap water as fair and poor. Consumers believed that taste problems were increasing over time and 77 percent of consumers agreed that local water utilities "should be expected to provide tap water that looks and tastes as good as bottled water." Only 22 percent were very satisfied with how their tap water "looks and tastes" (Suffet 2000). Taste and odor concerns appear more important to consumer confidence in Southern California than meeting quality standards, a finding similar to that found in an evaluation of seven consumer surveys across the U.S. (Torobin et al. 1999). Consumers who reported fair or poor aesthetic water quality were the same ones who had less favorable perception of the safety of their local tap water.

The subjective nature of water tastes has been revealed regularly during taste testing. Several taste testings have been held to judge both tap and bottled water, with revealing results. At a blind water tasting held by the *San Francisco Chronicle* in 1980, samples of municipal waters from around the San Francisco Bay area were collected and rated by a panel of food and wine experts. Included among the tap waters was an example of a French non-carbonated bottled water. All of the judges gave it poor marks except for a French wine maker, who remarked, "This water reminds me of home." Indeed, this particular water was actually what he drank at home, demonstrating that we all develop a preference for what we are used to drinking, and that our brains have strong taste recall (Pomento 2001).

At a water tasting in Atlanta that became famous for its tongue-in-cheek rating system, ten Southern U.S. municipal waters were rated on a scale from zero (sludge), to 13 (nirvana). Memphis won with comments such as, "...On the nose, at first it was cottony...a refreshing texture." Judges rated New Orleans, "...for its neutrality, this is Swiss of the waters." Dallas was said to be, "...crude, with an edge." About Houston, judges noted, "...bring on the chlorine...It was like a chemistry lab...", and for one of the judges, "...that brought back unpleasant memories." Atlanta's water, was described "...like having a gulp of a swimming pool." Water from Charlotte, North Carolina was described as tasting "like when you have a Band-Aid on your finger and you get in the shower and you get out and suck the water out of the Band-Aid...It's like a wet Band Aid." And of Orlando, Florida's water, judges said, "...It's the reason most people don't drink water" (Bottled Water Web, *Water Taste*, 2003).

In another, unscientific but blind tasting conducted by the Pacific Institute at its December 2003 holiday party, 40 individuals expressed no clear preference among tap water, two spring waters, and highly processed bottled municipal water sold at supermarkets. While a majority of people preferred what turned out to be the local tap water (and the fewest number disliked this water), there was little agreement about taste and almost random success at trying to identify which water was which.

Bottled Water Quality

The public perception, and probably the reality, is that bottled water is regularly of high quality. This belief is encouraged by publicly reported problems with tap water and by aggressive advertising by bottled water companies and water filter sales pitches. In 2004, a company that produces filters for tap water was advertising that their product can produce tap water “the quality of bottled water,” as though that guarantees an improvement (Procter and Gamble 2004). In many developing countries with unreliable and inconsistent municipal water supplies, bottled water quality may be a better source of safe water than tap water. But this cannot be universally assumed, nor should it be the goal of water providers. Standards vary from place to place, testing is irregular and inconsistent, and contaminated source water may lead to contaminated products. Over the past few years, there have been an increasing number of reports of water-quality problems with bottled water.

In a highly publicized case, a newspaper in Mumbai, India contracted with an independent water-quality laboratory to conduct tests for pesticides in bottled water samples and raw-water samples from bottled water plants (Mid-Day Mumbai 2003). The results were compared to European Economic Community standards (Directive 80/778/EEC), which provide water-quality guidelines for 62 parameters on the “quality of water intended for human consumption” and is used as a norm at the European level.

Altogether, 26 samples of 13 bottled water brands and raw water samples collected from different bottled water plants in Mumbai were tested for 12 organochlorine pesticides and 8 organophosphorus pesticides most commonly used in India. The results of the study showed pesticides in every sample, whether raw or bottled. The organochlorine Lindane was detected in all the raw water samples with a minimum concentration of 0.0007 mg/l and a maximum of 0.0042 mg/l. The organophosphorus pesticide Chlorpyrifos, a moderately persistent insecticide used against mosquito and fly larvae, aphids, and other insects was also detected in all the raw water samples analyzed (Center for Science and Environment 2003).

Similar problems were found with the bottled water samples. Lindane was present in all 26 samples. A minimum concentration of 0.0005 mg/l and maximum concentration of 0.0041 mg/l was detected. This maximum concentration is 40 times higher than the prescribed EEC limit of 0.0001mg/l. Chlorpyrifos was also detected in all 26 samples analyzed. The minimum concentration found was 0.0001mg/l, just at the limit permitted by the EEC Drinking Water Directive. The maximum concentration detected was 0.0075 mg/l, 75 times above the EEC limit. The average concentration of total pesticides analyzed in 26 bottled water samples was 0.0036 mg/l, 7.2 times higher than the total recommended pesticide limit of 0.0005 mg/l (Center for Science and Environment 2003). In a follow-up study, similar problems were then found in bottled water samples in India’s capital (Mathur et al. 2003).

Pip (2000) describes water-quality testing of 40 domestic and imported brands of bottled water purchased in Manitoba, Canada. These waters were examined for total dissolved solids (TDS), chloride, sulfate, nitrate-nitrogen, cadmium, lead, copper, and radioactivity. The samples showed great variation in quality, with some violations of the Canadian Water Quality Guidelines for drinking water for TDS, chloride, and lead. A number of deficiencies were found with respect to product labeling. In the United

States, periodic problems with bottled water lead to recalls of product from stores (see Box 2.3). These examples hint at the kind of problems that already exist and that would be found with more regular and consistent monitoring.

Regulating Bottled Water

Perhaps the most charitable thing that can be said about the myriad and complex regulations around bottled water is that they are byzantine. Four levels of contradictory and complex regulation apply to the bottled water industry: international, national, local, and trade associations standards. These different levels are not consistent with each other. As a result, the practical effect of regulation varies widely from place to place. In some regions, consumers of bottled water can be assured of reliable and consistently high water quality. In others, no such assurances are possible. While many countries have national standards for bottled waters and some have national certification schemes, no universally accepted international standard certification scheme yet exists.

In the United States, the Food and Drug Administration (FDA) regulates bottled water as a food. Some state and industry standards also apply. And most U.S. bottled water is as safe and reliable as regulated tap water, albeit vastly more expensive.

In Canada, bottled water is also regulated as a food product, under the Canadian Food and Drugs Act and Regulations. These regulations set standards for microbiological quality, composition, and labeling, which are then enforced by the Canadian Food Inspection Agency (CFIA). Bottled water is also subject to the requirements of the Consumer Packaging and Labeling Act and Regulations. The CFIA also sets and enforces requirements under these acts to protect consumers against fraud in bottled water content, packaging, labeling, and advertising. As part of its enforcement role, the CFIA can inspect products, labels, and establishments involved in the sale, manufacture, and distribution of bottled water. In addition, some Canadian provincial and municipal ministries and agencies may regulate and inspect bottled water (Health Canada 2003).

For Australia and New Zealand, minimum standards for bottled water are set by the Food Standards Code of *The Food Standards Australia New Zealand* (FSANZ). The primary Standard is 2.6.2 “Non-Alcoholic Beverages & Brewed Soft Drinks.” Bottlers must also comply with codes on labeling, contaminants, microbiological and processing requirements, and food safety regulations. Bottlers in Australia and New Zealand may choose to be subject to standards developed by the Australasian equivalent to the International Bottled Water Association (IBWA)—the Australasian Bottled Water Institute (ABWI). ABWI members must meet standards that are, in some cases, stricter than the FSANZ standards. The ABWI has a model code for processing, third-party audits, and labeling, but their mission also includes promoting bottled water use. ABWI is a member of the International Council of Bottled Water Associations (ICBWA). A fundamental requirement of membership is that each member association must have in place an approved, third-party audit program and certified model code and be in compliance with that code (ABWI 2003).

The intergovernmental body for the development of internationally recognized standards for food is the Codex Alimentarius Commission (CAC). The World Health Organization, one of the co-sponsors of the CAC, has advocated the use of the *Guide-*

lines for Drinking-Water Quality as the basis for all bottled water standards (WHO 2000, Fact Sheet 256). This chapter is not the place for a comprehensive survey or review of all bottled water standards, though such a survey would be valuable. The focus below is on United States standards and their application with some reference to similar standards in other countries and regions.

United States Federal Regulations

In the United States, bottled water and tap water are regulated by different federal agencies. The United States Environmental Protection Agency (EPA) regulates municipal water or public drinking water under the federal Safe Drinking Water Act.² EPA's Office of Ground Water and Drinking Water is responsible for issuing regulations that cover the production, distribution, and quality of drinking water, including regulations on source water protection, operation of drinking-water systems, contaminant levels, and reporting requirements. Bottled water is regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA).³

FDA regulations cover packaged water sold in individual containers at retail outlets and larger containers sold to residential and office markets. Under the FFDCA, manufacturers are responsible for producing safe, wholesome, and properly labeled food products, including bottled water products. It is a violation of the law to introduce into interstate commerce adulterated or misbranded products that violate the various provisions of the FFDCA (Posnick and Kim 2002).

The FDA has established specific regulations for bottled water in the Code of Federal Regulations (C.F.R.)—21 Code of Federal Regulations—including (i) standard of identity regulations that define different types of bottled water, (ii) standard of quality regulations that establish allowable levels for contaminants (chemical, physical, microbial, and radiological) in bottled water, and (iii) Current Good Manufacturing Practice (CGMP) regulations for processing, bottling, and labeling. Bottled water is one of the few “foods” for which the FDA has developed specific CGMP regulations or such a detailed standard of quality (Posnick and Kim 2002).

Standards of Identity

Because of the great variety of “types” of water, certain FDA “standards of identity” have been set for labeling and identifying bottled water. Standard of identity requirements are designed to ensure that bottled water manufacturers meet the requirements of specific definitions for labeling. The FDA's labeling rules establish standardized definitions for specific terms found on bottled water labels such as “artesian,” “distilled,” “deionized,” “drinking,” “mineral,” “purified,” “sparkling,” “spring,” and “sterile.” (See Box 2.2). For example, under the standard of identity regulations, bottled water may only be labeled “mineral water” if it: (1) contains not less than 250 parts per million (ppm) total dissolved solids; (2) comes from a source tapped at one or more boreholes or springs; (3) originates from a hydrogeologically protected source; and (4) contains no added minerals.⁴ If these terms appear on a label, the consumer should be able to assume that specific meanings apply.

2. 42 U.S.C. § 300f (United States Code, Title 42, Chapter 6A, Subchapter XII, Part A)

3. 21 U.S.C. § 301 (United States Code, Title 21, Chapter 9, Subchapter 1)

4. 21 C.F.R. § 165.110(a)(2)(iii)

Box 2.2 United States FDA Product Definitions for Bottled Water

The Food and Drug Administration (FDA) Standards of Identity guide what can be put on bottled water labels in the United States. If a bottler calls water “glacial” it has to come from a glacier. “Artesian” water has to flow above the water table and “naturally sparkling” has to come from a natural carbonated spring. Sodium declarations such as “sodium free,” “very low sodium,” and “low sodium” have explicit meanings: “sodium-free” must be less than 5 milligrams of sodium per serving (usually 360 ml); “very low sodium” may contain 35 milligrams or less of sodium per serving; and “low sodium” may contain 140 milligrams or less per serving. These kinds of claims trigger the inclusion of the Nutrition Facts panel as required by the Nutrition Labeling and Education Act of 1990. The FDA product definitions for bottled water are:

Artesian Water/Artesian Well Water

Bottled water from a well that taps a confined aquifer (a water-bearing underground layer of rock or sand) in which the water level stands at some height above the top of the aquifer is identified as Artesian water.

Drinking Water

Drinking water is water sold for human consumption in sanitary containers. It must have no calories or sugar. Drinking water may be sodium-free or contain very low amounts of sodium. Flavors, extracts, or essences may be added to drinking water, but they must comprise less than one percent by weight of the final product or the product will be considered a soft drink. “Carbonated water,” “seltzer water,” “soda water,” and “tonic water,” are considered soft drinks.

Infant Brands

Special labeling is required for products marketed for infants. If a product is labeled “sterile,” it must be processed to meet the FDA requirement for commercial sterility. Otherwise, the labeling must indicate it is not sterile and should be used in preparation of infant formula only as directed by a physician or according to infant formula preparation instructions (Bottled Water Web Regulations 2003, at <http://www.bottledwaterweb.com/regulations.html>).

continues

Mineral Water

Mineral water is distinguished from other types of bottled water by “its constant level and relative proportions of mineral and trace elements” at the source. According to Title 21 (21CFR165.110) of the *Federal Register*, “mineral water” must contain at least 250 parts per million (ppm) of total dissolved solids (TDS). No minerals can be added to this product. Sources must be “tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source.” If the TDS content of mineral water is below 500 ppm or greater than 1,500 ppm, the statement “low mineral content” or “high mineral content,” respectively, must appear on the label.

Municipal Water

Municipal water is used as a source for approximately 25 percent of the bottled water sold in the United States. Water bottled from municipal water supplies must be clearly labeled as such. Municipal water that has received further processing and treated to the appropriate level can be labeled as “distilled” or “purified” water.

Natural

The word “natural” is allowed for bottled water derived from springs or wells where the natural chemical (mineral and trace elements) composition of the water has not been altered.

Purified Water

Water that has been produced by distillation, deionization, or reverse osmosis and that meets the definition of purified water in the United States Pharmacopoeia may be labeled as purified bottled water.¹ Bottled water treated by one of these processes may also be called “distilled water” if it is produced by distillation, “deionized water” if the water is produced by deionization, or “reverse osmosis water” if the process used is reverse osmosis.

1. The United States Pharmacopoeia is a nongovernmental, standards-setting organization that advances public health by ensuring the quality and consistency of medicines, promoting the safe and proper use of medications, and verifying ingredients in dietary supplements (www.usp.org).

Box 2.2 *continued*

Sparkling Water

Sparkling water is water that contains the same amount of carbon dioxide that it had at the source, though it can be removed and then replaced. Soda water, seltzer water, and tonic water are not considered bottled waters. They may contain sugar and calories and are regulated separately as soft drinks. In 1990, the FDA made Perrier drop the words “Naturally Sparkling” from its label when it was revealed that Perrier artificially carbonated its water after taking it out of the ground (Mowen and Minor 2001).

Spring Water

The term spring water is restricted to water collected from a spring that originates from an underground formation from which water flows naturally to the surface of the earth, or from a borehole that connects to the formation. Spring water collected from a borehole must have all the physical properties, before treatment, and be of the same composition and quality as the water that flows naturally to the surface of the earth. Controversy has arisen when bottlers drill wells near springs in order to extract water more quickly than natural flow rates. In the United States, the spring must continue to flow even when water is pumped from the same aquifer. European bottlers using boreholes do not have to maintain a flow from the spring. This issue became the focus of debate at a meeting of Codex Alimentarius in Bern, Switzerland.² On one side was the National Spring Water Association, which is lobbying in both the United States and Europe for the term “spring” to only be used in bottled water products using water that flows from a natural opening. In contrast, the International Bottled Water Association (IBWA) endorses the use of boreholes as an acceptable method of spring water extraction. In either case, bottled water products cannot use the term “spring” if the water is substantially processed or from a municipal source (von Wiesenberger 2003).

Well Water

Well water is simply bottled water from a bored, drilled, or otherwise constructed hole in the ground, which taps the water of an aquifer.

2. The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines, and codes of practice. The main purposes of this Codex are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations (see <http://www.codexalimentarius.net/>).

Sources: United States Code of Federal Regulations 21, Bottled Water Web (2003), Posnick and Kim 2001, United States Pharmacopoeia (2003).

Other terms, however, have no clear definitions and can be misleading to the consumer. For example, terms like pure, purest, pristine, premium, mountain water, and clean are advertising descriptors with no official meaning. These terms do not accurately describe the source or purity of the water, nor do they certify that the water is safe (Suffet 2000). Images on bottled water can also contribute to confusion and misunderstanding about contents. Aquafina (a Pepsi product), like many other bottled waters, puts images of mountains and snow on the label, despite the fact that Aquafina is bottled using processed municipal water. Such images are not adequately regulated. Seltzer, soda water, and tonic water are considered soft drinks and are excluded from these regulations.

Food misbranding provisions require that food labeling contain certain information, such as the name of the manufacturer, and not contain certain other types of prohibited information, such as false or misleading statements. For bottled water, labels must contain a statement of identity, the name and location of the manufacturer, the net weight of the contents, and ingredients if the product contains more than one ingredient. Depending on what nutrients and minerals are present or added, some bottled waters have to bear nutrition labeling. The FDA requires that all nutrient content claims, such as sodium free, and health claims comply with specific definitions. In 1924 the Supreme Court ruled that the Food and Drugs Act must address statements that may mislead or deceive. In part, this decision was the result of unsubstantiated health claims for bottled waters. Today in the United States, health claims are allowed only when there is a proven link between the nutrient and certain health conditions, such as significant amounts of calcium and protection against osteoporosis.

Bottled water is also misbranded if its labeling contains false or misleading statements. For instance, a label that falsely states that the product is free from a certain contaminant would be misbranded under this provision. A bottle of water with more than 0.3 mg/l of iron would be misbranded unless its label stated “Contains Excessive Chemical Substances” or “Contains Excessive Iron.”⁵

Despite these protections, the information provided by labels in the United States is still limited. For example, the “Nutrition Facts” panel (common to all United States food products) for water tends to show that water has no fat, carbohydrates, and proteins, but the label carries no other mineral analysis. European labels carry a more informative mineral analysis that provides consumers with information on the levels of calcium, magnesium, potassium, and other nutrients. Although certain mineral waters may be useful in providing essential micronutrients, such as calcium, the World Health Organization *Guidelines for Drinking-Water Quality* do not make recommendations regarding minimum concentrations of essential compounds because of the lack of convincing evidence on the beneficial effects of consuming such mineral waters (WHO 2000).

Quality Standards

Bottled water products must comply with the FDA’s Quality Standards in Section 165.110(b) of Title 21 of the *Code of Federal Regulations* (CFR). Bottled water manufacturers must ensure that their products meet some, though not all, of the federal

5. 21 C.F.R. § 165.110(c)

standards of quality for tap water, which establish allowable levels of substances related to microbiological quality (e.g., limits on coliform organisms), physical quality (e.g., turbidity, color, and odor), organic and inorganic chemical quality, and radiological quality. The FDA has established allowable levels in the standard of quality for approximately 75 substances.

Bottled water regulations set testing methodologies and time frames to determine compliance with FDA Quality Standards for both source water and product water. Source water—that is the water taken for processing and packaging—must be obtained from an approved source and conform to applicable state and local laws and regulations. Bacteriological analysis of source water must be done at least weekly. Chemical analysis of source water must be done at least annually. Radiological analysis must be performed at least once every four years.

Product water—that is the bottled water itself—is also subject to regulation. Representative bacteriological analysis of product samples must be done at least once per week for each type of water produced. Chemical, physical, and radiological analysis must be done at least annually on an appropriate sample from a batch or segment of a continuous production run for each type of water produced. All records as well as government approvals of source water must be available for official review.⁶

Good Manufacturing Practices

The Food and Drug Administration promulgates Good Manufacturing Practice (GMP) requirements. Bottled water is subject to GMPs for both food and specific bottled water processing and bottling practices. General food GMPs govern such areas as plant construction and ground maintenance, sanitary maintenance of buildings and fixtures, and sanitary facilities, water supply, plumbing, and sewage disposal. These also apply to bottled water for quality control of receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing product.⁷

In addition to general food GMPs, there are specific bottled water GMPs that apply to facilities, sanitation, product quality and testing, and record keeping. A fundamental requirement of the bottled water GMPs is that all product water be obtained from a source that has been “...inspected and the water sampled, analyzed and found to be of a safe and sanitary quality according to applicable laws and regulations of state and local government agencies having jurisdiction...”⁸ GMPs specific to bottled water processing and bottling also contain rules on use of approved test and sample methods; adequate sanitization of all product water contact surfaces; protection of single service containers, caps, and seals; and sanitary filling, capping, closing, sealing, and packaging of containers. Bottlers must also maintain and retain records of product sample analysis, source approvals, and all records that may be required for official review.⁹ If bottlers do not comply with these regulations, their product can be considered adulterated and they may be subject to regulatory action.

Food Adulteration

The FDA deems a food to be adulterated if it contains an added “poisonous or deleterious substance which may render it injurious to health” [FFDCA Section 402(a)(1)].

6. 21 C.F.R. § 120.80(h).

7. 21 C.F.R. Part 110

8. 21 C.F.R. § 129.3(a)

9. 21 C.F.R. Part 129

Bottled water may be deemed adulterated if it contains industrial contaminants, unapproved pesticides, or other substances harmful to health. The FDA deems a food to be adulterated “if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food” [Section 402(a)(3)]. Bottled water could be deemed adulterated under this provision if it becomes contaminated during processing by dirt or other debris.

The FDA also deems bottled water to be adulterated if it has been “prepared, packaged, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health” [Section 402(a)(4)]. Bottled water may be deemed adulterated if it was not manufactured in substantial compliance with the Good Manufacturing Practices. A food is adulterated if a bottled water container “is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health” [Section 402(a)(6)].

Bottled water is also considered adulterated if any valuable constituent has been removed from the product, any substance has been wholly or partially substituted, damage or inferiority has been concealed in any manner, or if any substance has been added to the product or its packaging to increase the product’s weight or value or reduce its quality or strength.¹⁰ The FDA has tools available to it, in theory, to enforce these provisions, but the provisions for sampling and testing have some important and worrisome loopholes.

Sampling and Testing, and FDA Inspections of Bottled Water Plants

Bottled water plants are subject to FDA monitoring and inspection. Specific items inspected in bottled water establishments include: (1) verifying that the plant’s product water and operational water supply are obtained from an approved source; (2) checking whether source claims on the label comply with FDA definitions; (3) inspecting washing and sanitizing procedures; (4) inspecting the filling, capping, and sealing operations; and (5) determining whether the firms analyze source water and product water according to the required schedules. Despite these inspection requirements, bottled water plants generally are given low priority for inspection because of their relatively good safety record compared to other food plants, and because of financial constraints on the ability of the FDA to monitor at all (Posnick and Kim 2002).

Even more problematic, most sampling and testing of bottled water are done by the bottlers themselves. Samples may be collected by the FDA during inspections if the inspector’s observations indicate it is necessary or if the facility has a previous history of contamination. Samples are also collected in response to trade or consumer complaints. Samples of foreign bottled water products offered for entry into the United States may also be collected and tested to determine if they are in compliance with applicable United States laws and regulations.

FDA laboratories may test the water for microbiological, radiological, or chemical contamination. Individual samples are not tested for all possible contaminants cited in the quality standard, but for selected contaminants, depending on why a sample may have been taken. The FDA also may review the labeling on bottled water samples.

While bottled water companies are required to comply with specific quality standards, as described above, there is a major loophole to the testing requirements: bottlers are not required to use FDA-listed methods in their own facilities, nor are they

10. FFDCA §§ 402(a),(b)

required to have independent water laboratories run the tests. In theory, bottlers are responsible for ensuring that their bottled water could pass the tests used by the FDA in its own laboratories, but such independent testing rarely occurs.

FDA Enforcement/Regulatory Action

The FDA has a selection of enforcement tools available to it for violation of food standards. These have occasionally, though rarely, been applied to the bottled water industry. If a product is adulterated or misbranded and a company declines to comply with applicable requirements or declines to take action to correct the violation, the FDA may take civil and criminal action. Typically, however, the FDA first sends “warning letters” and requests for voluntary recalls. If these mechanisms do not work, the FDA may ask the Department of Justice to bring either a civil seizure or an injunction against the products and/or company involved. If the conduct warrants criminal prosecution, the FDA may seek such action from the Department of Justice as well. These criminal cases may be either misdemeanors or felonies, depending on the circumstances involved, and may result in monetary penalties and jail sentences. In all cases, the FDA may issue warnings to the public as a means to protect public health.

State Regulations

In addition to FDA regulatory requirements, the bottled water industry is subject to state regulatory requirements. A significant responsibility of the states is inspecting, sampling, analyzing, and approving sources of water. States also have the responsibility to certify testing laboratories and the authority to perform unannounced spot inspections. Some states perform annual inspections as well and some states (e.g., California, Pennsylvania, and Florida) have adopted regulations that are stricter than federal requirements (Fine Waters 2003; Bottled Water Web 2003).

Bottled Water Industry Associations: Standards and Rules

There are a number of international bottled water industry groups that also maintain their own memberships, standards, and rules. The International Bottled Water Association (IBWA), for example, is active in monitoring and reviewing bottled water standards and in supporting commercial bottled water activities. IBWA has established a quality assurance program comprising a set of standards called the model code. In some cases, the model code establishes tougher requirements than United States federal and state authorities and may also provide a model for countries where regulatory authority over bottled water is weak or non-existent.

For example, as a condition of membership in the IBWA, bottlers are subject to an annual, unannounced plant inspection administered by an independent, internationally recognized, third-party inspection organization. This inspection audits quality and testing records, reviews all areas of plant operation from source through finished product, and checks compliance with FDA Quality Standards, Good Manufacturing Practices, and any state regulations (IBWA 2003).

The International Council of Bottled Water Associations (ICBWA) is a group of groups, including the IBWA, the Canadian Bottled Water Association, the Latin American

Bottled Water Association, and several others (see www.icbwa.com). The ICBWA requires its members to meet “Codex Alimentarius Commission, national, regional, and industry standards for bottled water.” Each member association is required to have a Model Code outlining good manufacturing practices and quality control standards. Each bottling production plant is required to undergo an annual, unannounced plant inspection to determine compliance with standards set forth in the Model Code. These inspections are conducted by International Council-approved, third-party organizations that audit quality and testing records, and review plant operation from source to finished product. Two other conditions of bottler membership within each member association are regular microbial testing using qualified personnel and an annual water analysis administered by an independent laboratory covering more than 150 possible compounds (<http://www.icbwa.org/standards.htm>).

International Standards—The Codex Alimentarius

The closest thing to a universally accepted international certification scheme is the intergovernmental body for the development of internationally recognized standards: the Codex Alimentarius Commission (CAC). The WHO, one of the co-sponsors of the CAC, has advocated use of the Guidelines for Drinking-Water Quality as the basis for standards for all bottled waters. Neither the CAC nor the WHO offer certification of any bottled or mineral water products.

The Codex Alimentarius, or the food code, was initiated by the WHO and the Food and Agriculture Organization (FAO) in 1961 as the principal tool for drawing attention to food safety and quality at the international level. It serves as a reference point for consumers, food producers and processors, and national food regulatory agencies. The Codex Alimentarius system presents an opportunity for countries without their own ability to generate detailed regulations to formulate and harmonize food standards and the codes and regulations governing food safety.

The significance of the Codex for consumer protection was highlighted in 1985 by United Nations Resolution 39/248, which advised that “Governments should take into account the need of all consumers for food security and should support and, as far as possible, adopt standards from the...Codex Alimentarius.”

The Codex Alimentarius is relevant to the international production and trade in bottled water. The advantage of having uniform standards for the protection of consumers is evident, as long as those standards are strict enough to provide real and consistent protection. It is not surprising, therefore, that various international agreements (such as the Agreement on the Application of Sanitary and Phytosanitary Measures [SPS] and the Agreement on Technical Barriers to Trade [TBT]) encourage the international harmonization of food standards. The SPS Agreement, a product of the Uruguay Round of multinational trade negotiations, describes Codex standards, guidelines, and recommendations as the preferred international approaches for aiding international trade in food.

While the growing world interest in Codex activities indicates growing acceptance of the idea of harmonization, consumer protection, and facilitation of international trade, it is difficult in practice for many countries to accept Codex standards as law. Differing legal formats and administrative systems, varying political conditions and national attitudes, and concepts of sovereign rights slow harmonization and hinder the

acceptance of Codex standards. Despite these difficulties, a number of countries are modifying national food standards, or parts of them, based on the Codex Alimentarius (FAO 1999, Codex Alimentarius 2001).

The CAC has developed the Codex Standard for Natural Mineral Waters and an associated code of practice. The Codex Standard describes the product and its labeling, composition and quality, hygiene, and packaging. The CAC health and safety recommendations are recognized by the World Trade Organization as representing the international consensus for consumer protection, but they are not mandatory.

The CAC also has a Codex Standard for Bottled/Packaged Waters to cover drinking water other than natural mineral waters. Under the existing Codex Standard and Code of Practice, natural mineral waters must conform to strict requirements concerning, for example, their collection and bottling without further treatment from a natural source, such as a spring or well. In comparison, the Codex Standard for Bottled/Packaged Waters includes waters from sources other than springs and wells, and covers treatment to improve their safety and quality. The distinctions between these standards are especially relevant given the growing tendency to sell bottled water that is little different in quality from municipal supplies. Ultimately, however, these standards give enormous leeway to national standards and are not in themselves likely to form the basis for specific legislation and wording (Codex Alimentarius 2001).¹¹

Comparison of United States Standards for Bottled Water and Tap Water

Many people purchase bottled water because of concern over the quality of their tap water. Is this concern valid? Unfortunately, it is not possible to draw broad or definitive conclusions because of the wide range of products available and the great differences in tap waters. It is, however, possible to offer some comments on the relative standards themselves. While bottled water and tap water standards are roughly comparable, there are differences in scope, enforcement, and monitoring of those standards that make it impossible to say that bottled water offers any guaranteed improvement over tap water.

As noted above, U.S. bottled water manufacturers must ensure that their products meet FDA standards of quality. These standards establish allowable levels for substances including microorganisms such as coliform, physical parameters such as turbidity, color and odor, and radiological quality for such substances as radium 226. There are also limits specified for individual chemicals, including metals, inorganics, volatile organics, pesticides, trihalomethanes, and fluoride. The FDA standards of quality also establish testing time frames for the various categories of contaminants and specify both the methodologies required for conducting the analysis and the records bottlers must maintain.

Historically, the FFDCA required that, whenever the EPA prescribed a drinking water regulation, the FDA was to consult with the EPA to determine whether that standard should be applied to bottled water. Within 180 days, the FDA was to either adopt a comparable regulation or publish a reason for not doing so. In 1996, the FFDCA

11. See the Codex for detailed information on European standards and practices: ftp://ftp.fao.org/codex/standard/en/cxs_227e.pdf

requirement was strengthened such that if the FDA fails to act within the time provided, the drinking water regulation will automatically apply to bottled water (FDCA § 410, 21 U.S.C. 349).

A report from the Natural Resources Defense Council in 1999 compared FDA and EPA allowable limits for chemical, radiological, and microbiological compounds in drinking water (Olson 1999). At the time of this study, there were 13 substances where FDA bottled water standards were considered weaker than EPA standards for tap water; three bottled water standards that were stricter; and a range of other discrepancies. For example, many unregulated substances must still be monitored in tap water, but not in bottled water.

There are important differences related to water testing as well. Drinking water providers are required to use laboratories certified by a state in accordance with EPA criteria.¹² This system has flaws, since many states permit water systems to collect and submit samples for testing—a potential way to circumvent water quality problems. But the system for bottled water is even less strict. The FDA permits water bottlers to conduct their own tests and to select their own, uncertified laboratories. In 1991, the General Accounting Office criticized this practice, saying “FDA lacks assurance that such [bottled water] 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...[but] 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....” (GAO 1991).

Other Concerns Associated with Bottled Water

Recalls

Even with the limited independent testing done for bottled water, problems are periodically discovered. These include the inappropriate use of poor-quality source water, accidents with bottling equipment or water-handling machinery, or even intentional acts. If contamination is detected, actions can be taken to prevent the consumption of the unsafe water, including recalls and impoundments of shipments. Rules and regulations for dealing with these situations vary around the world with little consistency or reliability.

The United States EPA regulations on tap water require providers to report violations of water-quality standards. In contrast, the FDA relies almost exclusively on voluntary action by bottlers to initiate recalls. Some consumer groups argue that the lack of a stronger requirement for reporting is a major flaw in bottled water protection and regulation. The Natural Resources Defense Council, for example, states, “FDA rules include no provision obligating a bottler to notify FDA or a state of test results, contamination problems, or violations, even in the case of contamination that could pose a serious health threat” (Olson 1999).

12. 40 C.F.R. § 141.28

Box 2.3 Examples of Bottled Water Recalls or Contamination

1990 One of the most famous cases of a food recall in history occurred in 1990 when a few bottles of Perrier in North Carolina were discovered to contain traces of benzene, a carcinogen. The initial response of Perrier was that the source of the benzene was cleaning fluids used inappropriately on bottling equipment in the United States. After a delay, the company recalled 70 million bottles of water. Shortly thereafter, officials in Denmark and the Netherlands announced the discovery of benzene contamination in Perrier sold in their countries as well, leading to a worldwide recall of 160 million bottles of Perrier. The source turned out to be the failure to replace filters that eliminate “naturally occurring” benzene from carbon dioxide in the water. This incident has become a classic case study in the field of food protection, recalls, and public relations (Browning et al. 1990, Mowen and Minor 2001, University of York, 2003).

1990 Recall of Newton Valley Distilled Drinking Water and Newton Valley Artesian Water in one-gallon plastic bottles because of contamination with an unidentified chemical odor and taste. The recall was initiated by the firm in Manitowoc, Wisconsin, and affected about 2,500 cases, or around 15,000 gallons, of product.

<http://www.fda.gov/bbs/topics/ENFORCE/ENF00024.html>

1990 Recall of bottled water of the Island Waters Division, Aqua Vie Beverage Corporation. The water was contaminated with algae and *Pseudomonas aeruginosa*. *Pseudomonas aeruginosa* infection may lead to gastrointestinal illness or other more serious consequences. More than 13,600 cases were recalled.

<http://www.fda.gov/bbs/topics/ENFORCE/ENF00008.html>

1996 Natural Springs bottled water, distributed in Arkansas, Illinois, Kentucky, and Tennessee by Marion Pepsi-Cola Bottling Co., was recalled due to bacterial contamination at levels exceeding federal and state water-quality standards. The presence of coliform bacteria was considered an indicator of problems with the Marion Pepsi-Cola bottled water production lines.

<http://www.idph.state.il.us/public/press96/water.htm>

JULY 1999 Coca-Cola recalled mineral water in Poland due to bacterial contamination after mold was discovered in bottled water. Sampling at a plant in Sroda Slaska discovered *E. coli*. An estimated 180,000 plastic half-liter containers of Bonaqa Plus mineral water were pulled off store shelves for failing to meet quality standards.

http://www.morningsun.net/stories/070399/usw_0703990018.shtml

continues

2000 Canadian Food Inspection Agency issued a warning about Mount Pelion brand bottled water contaminated with *Pseudomonas aeruginosa*.
<http://www.inspection.gc.ca/english/corpaffr/recarapp/2000/20001020e.shtml>

2000 The Pennsylvania Department of Environmental Protection (DEP) expanded its recall on water bottled by Roaring Springs/Global Beverage Systems Inc. of Latrobe, Westmoreland County, after it was discovered the company distributed bottles of coliform-contaminated water to several retailers.
<http://www.waterindustry.org/New%20Projects/bottled-water.htm>

2000 More than 30,500 cases (with 6-gallon bottles per case) of Safeway brand drinking water, manufactured by the Safeway Bottled Water Division, Tempe, Arizona, were recalled due to particulate matter contamination.
<http://www.fda.gov/bbs/topics/ENFORCE/2001/ENF00679.html>

2000 20,000 gallons of Bareman Dairy Crystal Clear Drinking Water sold in Michigan and northwestern Indiana were recalled after customer complaint led to testing that discovered contamination from an equipment sanitizer. The sanitizer was made of a mix of peroxiacetic acid and hydrogen peroxide.
http://www.wndu.com/news/contact16/contact16_1498.php,
http://www.fda.gov/ora/about/enf_story/archive/2001/ch4/default.htm

2002 The New Hampshire Department of Health & Human Services' Bureau of Food Protection ordered a recall of Granite State Artesian bottled water due to the presence of coliforms. The bottled water, produced by Turner's Dairy in Salem, New Hampshire, was distributed in Massachusetts and in New Hampshire stores located in Nashua, Manchester, Pelham, Salem, and East Derry.
http://www.fda.gov/oc/po/firmrecalls/granite07_02.html

2002 Recall of bottled drinking water, packaged in 12 packs of 20-ounce plastic PET bottles due to contamination with excessive chlorine. The manufacturer was the Southern Bottled Water Company, Anniston, Alabama, with distribution in Florida, Texas, South Carolina, Georgia, Arkansas, and Louisiana. Around 14,000 cases were recalled.
<http://www.fda.gov/bbs/topics/enforce/2002/ENF00755.html>

2002 Recall of bottled Spring Water labeled American Fare Premium Water Quality contaminated with particulate matter. The water was produced by the Glacier Clear LP Company of Orange Springs, Florida, and covered around 4,000 cases, with 12 bottles per case.
<http://www.fda.gov/bbs/topics/enforce/2002/ENF00755.html>

Under the FDA recall program, a recall can be initiated when a firm believes a product may be in violation of FDA standards. In such a case, the firm should (but is not required to) notify the FDA and provide information on: (1) the identity of the product; (2) the reason for the recall and when the problem was discovered; (3) evaluation of the risk involved; (4) time and amount of production; (5) total amount in and nature of distribution; (6) a copy of any recall communication already done or proposed; (7) proposed strategy for the recall; and, (8) the name and coordinates of a company contact.¹³ Upon review of this information, the FDA assigns a recall classification for the ensuing action.

The regulations identify three classes of recall, with different requirements for the extent of the recall, the degree of public warning, and verification and monitoring of the recall. The most serious level is Class I, which is applied when there is a reasonable probability that the product may cause death or illness. A Class I recall leads to individual consumer notification through the media and aims at 100 percent effectiveness. A Class II recall would be used when the health consequences expected are less serious and the supporting activities would be dictated by the situation. Class III is the least serious recall, and may only extend to the wholesale level.

If the FDA determines that a product poses a serious health risk and a company declines to recall that product, the FDA can take further legal action to have that product removed from the market. FDA guidelines recommend, though they do not require, that all food producers, including bottled water companies, have a written recall plan in the event products must be withdrawn from the market because they are adulterated or misbranded.

Some examples of recalls in several countries show the types of water-quality problems that may be found in bottled water and the actions that were taken in response (see Box 2.3).

Selling Bottled Water to the Poor

One of the most controversial aspects of the growing trend toward bottled water is the fact that the populations most in need of improvements in municipal water systems, and hence most likely to need to use bottled water for legitimate health purposes, are those least able to afford the high costs of bottled water. Some worry that increased bottled water sales will reduce pressures on governments to provide necessary improvements in basic water infrastructure (Beck 1999). This controversy has grown in recent years as marketing efforts to sell bottled water have expanded in developing countries.

Perrier, for example, one of the world's leading name brands for water, is now owned by the world's largest food company, Nestle. In 1998, Nestle launched a new initiative named Pure Life to expand bottled water sales to the poorest consumers. Pure Life was launched in Pakistan and soon appeared in Brazil, Argentina, Thailand, the Philippines, China, and Mexico in 2000. In 2001, India, Jordan, and Lebanon followed, and in 2002, Egypt, Uzbekistan, and the United States (Nestle 2003). Nestle's effort to expand in India failed, and sales there ceased in 2003 (Datta 2003).

Nevertheless, sales of bottled water in developing countries are skyrocketing. As noted earlier, sales in China are growing faster than anywhere else, and companies see huge markets developing in Latin America, India, and elsewhere. As Figure 2.3 shows,

13. 21 C.F.R. § 7.46

more bottled water is consumed in Asia today than was consumed in North America in the late 1990s, and while North America and Europe still dominate overall sales, rates of growth are faster in Asia and South America.

Environmental Issues

More than 1.5 million tons of plastic are used to bottle water. Plastics are made from oil and natural gas, both of which are non-renewable resources. The processes used to make plastics can cause serious pollution affecting both the environment and human health if left unregulated. PET (polyethylene terephthalate, a plastic resin and the substance that most water bottles are made of) requires less energy to recycle than glass or aluminum, and releases fewer emissions into the atmosphere, but most plastic bottles are not being recycled, leading to serious landfill and garbage disposal problems. In 2002, only 20 percent of the total PET production available for recycling was actually recycled (NAPCOR 2002). Since plastic degrades at a very slow rate, plastic bottles will remain a waste problem for a long period.

Another growing concern is the local impact of water-bottling plants on the sustainability of groundwater aquifers and their effect on local streams (Glennon 2002). Some localities have mobilized against bottling plants in recent years when the pumping of groundwater for export from a basin was thought to threaten other local waters. In Wisconsin, local opposition to a Nestle's Perrier bottled water plant near Mecan Springs led to the relocation of the plant to Michigan, thought to be more complacent about the risks of this industrial activity. Yet a judge there ordered the Perrier pumping operation shut down when it threatened to affect local surface waters (WMEAC 2003). Michigan water law prohibits the reduction in flow of a stream by water users that export the water from the local watershed. (See also chapter 4 in this book.)

Conclusions

The recent dramatic upward trend in the consumption of high-priced bottled water is likely to continue, barring any dramatic improvement in global access to safe, reliable, and inexpensive domestic water, or any highly publicized, widespread incident of contamination that diminishes the reputation of bottled water. Moreover, the high profit margin for bottled water, the extensive advertising campaigns bottlers can afford to produce, and legitimate advantages of convenience all suggest that bottled water use is here to stay. This is fine. But is bottled water an acceptable alternative to reliable municipal supply? The quality of bottled water is inadequately monitored and regulated in many regions. Its cost is far higher than good quality tap water—often a thousand times more expensive. There are real environmental impacts of extracting large volumes of water from local aquifers and of producing and disposing of plastic containers. We estimate that \$100 billion annually are, conservatively, spent to purchase bottled water worldwide. Our failure to meet basic human needs for water should not open the door to replacing a public good with a private commodity, but rather should motivate us to spend the same resources to produce a more widely available, and far less costly, public product.

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