

The Facts About Bottle Water Regulation

For decades, several environmental groups have claimed that US tap water presented a serious public safety hazard. Yet during the past several years, they have refocused efforts on attacking bottled water.

Key among their claims is the idea that bottled water does not meet basic regulatory standards that are applied to tap water, suggesting that it could pose a higher risk than tap water. This claim has resonated with the public and is quoted widely by the media and even by public health publications. Yet it is not accurate.

Research shows that bottled water standards are at least as rigorous as tap water standards. In fact, bottled water regulations exceed tap water standards in some respects.

Policy resolutions

Misinformation is producing considerable policy interest in regulating bottled water. In June 2008, the US Conference of Mayors passed a resolution on bottled water stating, "The US Conference of Mayors encourages cities to phase out, where feasible, government use of bottled water and promote the importance of municipal water."¹

The conference issued a similar resolution on the value of tap water in 2007.² As a result, mayors around the nation began to look at the issue more closely and some have taken action.

Some cities such as San Francisco, CA have simply decided not to buy bottled water and some such as New York City, NY are considering employing filtration systems as an alternative to bottled water. Such moves may save cities some money; however, other cities are going further in denying access to bottled water in the absence of a good alternative.

In July 2007, the Ann Arbor, MI, city council passed a resolution barring city vendors from selling commercially bottled water at city events. The city said it would sell reusable water bottles that can be filled with tap water. It is not clear where people would refill the bottles when at a city-sponsored event.

In Canada, school districts announced this year that they are considering removing bottled water from school vending machines.³ This move could lead students to choose less healthy options if they forget to carry bottled water to school or drink from water fountains that are not filtered.

Critics have also raised concerns about the quality of schools' tap water. Earlier this year, the government in Toronto, Canada banned bottled water sales via vending machines and the like in city buildings.

Other cities are using the issue to raise taxes. Chicago, IL applies a tax of five cents per bottle of water, regardless of size. Each bottle in a case is taxed separately, which means for the typical case of 24 bottles costing about \$3.99 (USD), the tax comes to about 30 percent. Florida has considered a statewide tax.

Regulations

According to a study produced by the Natural Resources

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Defense Council (NRDC) in 1999, bottled water is not as strictly regulated as tap water.⁴ This study is widely cited as a

key authority on the issue in the press and in public health publications. Yet a comparison of each set of standards reveals the NRDC claims are not accurate.

The US EPA sets standards for tap water under the *Safe Drinking Water Act*⁵ and the Food and Drug Administration (FDA) sets standards for bottled water under the *Federal Food, Drug, and Cosmetic Act (FFDCA)*.⁶

FDA regulations are based on US EPA standards and are mostly the same, with the exception of a few areas where tap water regulations do not apply or where the FDA includes additional or more stringent requirements. According to the US EPA, both sets of standards produce bottled and tap water that is safe.⁷

Under the *SDWA*, US EPA regulates more than 80 drinking water contaminants that might be found in public water systems. For each regulated contaminant, the US EPA usually specifies a maximum contaminant level goal (MCLG), which represents the level of a contaminant that the agency ideally wants to allow in drinking water.

US EPA uses MCLG as a guide in setting the enforceable standard, the maximum contaminant level (MCL), which represents the amount of that contaminant that systems may legally allow in tap water. For example, the agency allows systems to provide only drinking water that contains no more than 0.005 milligrams of benzene per liter of water.

When US EPA determines that it is technically or economically infeasible to monitor for a contaminant, it is directed by Congress to promulgate mandatory treatment techniques. These techniques could include mandatory installation of filtration devices.

The *FFDCA* requires that FDA apply *SDWA* standards to the extent they make sense for bottled water. Its version of an MCL is known as a Standard of Quality (SOQ). According to the *FFDCA*, SOQs must be "no less stringent" than US EPA MCLs and "no less protective" than US EPA treatment techniques.⁸

In other words, FDA has two choices when setting a regulation. It must either be equivalent to US EPA standards or it must be more stringent. The law does not allow FDA to set standards that produce a lower quality product.

Setting standards

When deciding on a SOQ, FDA must review US EPA regulations for tap water, once the agency finalizes or revises them to assess whether they are applicable to bottled water. If the FDA finds that the tap water regulations are applicable, it must propose those same regulations for bottled water within 180 days after US EPA issues the tap water standards.

The *SDWA* of 1996 demands that if FDA fails to act, US EPA tap water regulations become the standards for bottled water. As a result, FDA has overwhelmingly applied US EPA's tap water standards to bottled water. Like US EPA, FDA requires that the

water be tested regularly to ensure that standards are met. (A comparison of FDA and US EPA standards can be reviewed at the website: <http://www.bottledwater.org/public/pdf/IBWA%20CODE%20OF%20PRACTICE%202008%20FINAL.pdf> and viewing Appendix A.)

There are some cases where the standards vary because of differences between delivery systems. Since tap water travels through pipes, regulations need to address potential contamination from pipes. Sanitary packaging for bottled water means that regulations related to food and food packaging apply to bottled water.

FDA regulations are more stringent for some chemicals, including regulations of lead, copper, fluoride and phenols. Dr. Henry Kim, a supervisory chemist at FDA's Center for Food Safety and Applied Nutrition, Office of Plant and Dairy Foods and Beverages, points out the difference between regulations for lead in both tap and bottled water.

He notes that US EPA standards tolerate a higher level of lead than FDA standards for bottled water, because lead can leach from the pipes into water before it reaches the tap, making it more difficult to control.⁹ US EPA requires that tap water contain no more than 15 parts per billion of lead, while the FDA standard is much more stringent at five parts per billion. FDA opts for a more stringent standard simply because it is more readily attainable for bottled water.

Non-applicability

Some tap water regulations do not apply to bottled water because the issues they address deal with tap water purification issues and pipe delivery, which obviously do not concern bottled water. For example, US EPA regulates two substances—acrylamide and epichlorohydrin—because they are used in tap water treatment plants and can enter the water there.

But these substances are not used to purify or package bottled water; hence, they are not an issue and do not warrant FDA regulation.¹⁰ FDA also does not have a regulation for asbestos because it is not a problem in bottled water sources.

US EPA regulates asbestos because it is used in cement pipes that distribute tap water.¹¹ FDA does not employ US EPA regulation for phthalates¹² because FDA applies standards related to food additives to ensure that such chemicals remain at levels below health concerns.

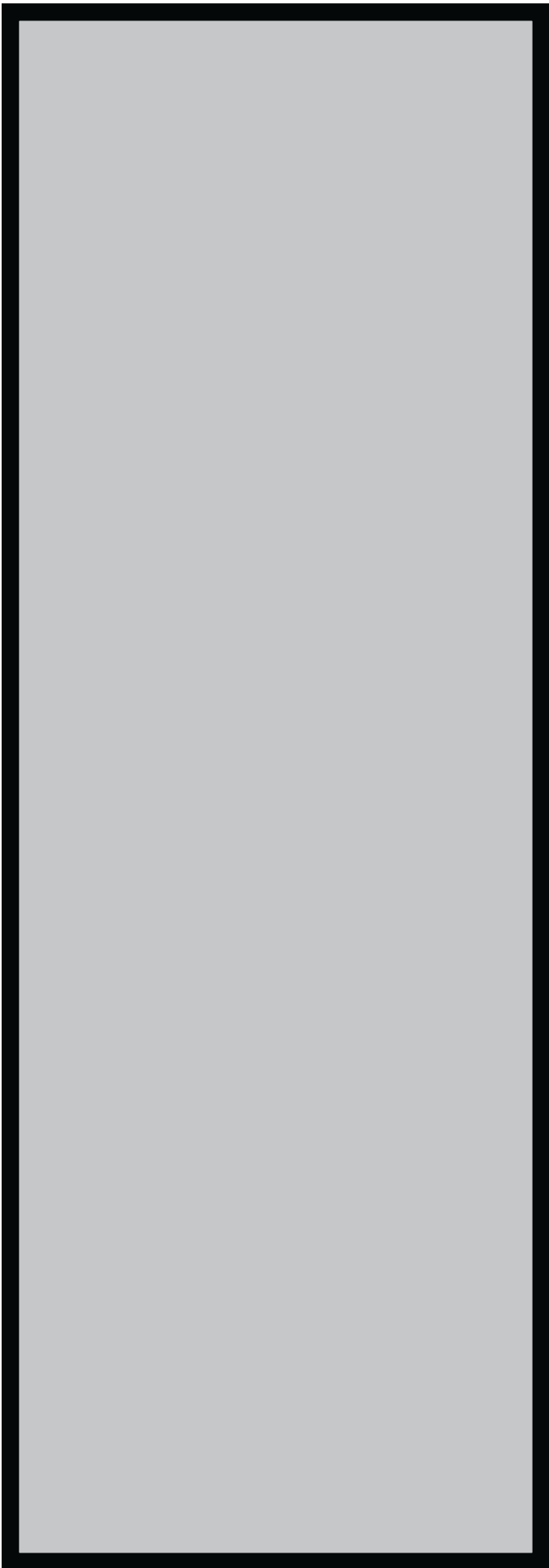
Moreover, most bottled water comes in polyethylene terephthalate (PETE or PET) plastic containers, which do not contain phthalates. FDA does not apply US EPA's *Enhanced Surface Water Treatment Rule* because it applies only to surface water. Bottled water typically comes from underground sources or from tap water that has already complied with US EPA's surface water rule.

Microbiological management

When it comes to managing microbiological agents, FDA regulations vary from US EPA's; but again, they must be "no less protective." Instead of mandating specific filtration or disinfection methods, FDA mandates that water meet the same standards as all food products.

These include sanitary production and packaging regulations as well as rules to ensure products are not adulterated with any harmful substance. In other words, FDA regulates the final product and gives bottled water companies some leeway in how they reach that level of quality.¹³

This means that when companies bottle water, the product must not present any human health threat and the company must be able to demonstrate that fact to FDA inspectors or face enforcement penalties. Specifically, regulations demand



that bottled water not be adulterated with the addition of any “deleterious substance that may be injurious to health,” which includes additives from the containers that might enter the water in trace amounts, such as phthalates.¹⁴

There are many good reasons why FDA takes this approach. In particular, one of the qualities that many consumers like about bottled water is that many kinds come from natural sources and are not subject to the types of treatment techniques—such as chlorination—that affect the flavor of the product. Chlorination is not necessary for bottled water as it is for tap water, because bottled water is not delivered to the consumer via pipes, where it can become contaminated. Sanitary packaging essentially performs the same role that chlorine performs during pipe transport.

Moreover, much bottled water comes from groundwater sources, which according to US EPA, are less likely to become contaminated and hence, do not require the same kind of disinfection.¹⁵ According to the agency, “Ozone is preferred by bottlers, though it is more expensive than chlorine, because it does not leave a taste and because bottlers do not need to worry about maintaining disinfectant in water sealed in a container. Untreated water, whether from a bottle or from a tap, will have the characteristic taste of its source.”¹⁶

The International Bottled Water Association (IBWA) reports that its members provide 85 percent of the bottled water in the US. Membership demands that companies employ a multi-barrier approach, which may include steps such as source protection, source monitoring, reverse osmosis, micron filtration, distillation, ozonation and final disinfection.¹⁷

Consumers who may choose to contact companies to learn about disinfection techniques before selecting a brand, if the information does not already appear on the label.

Information found on the label is also FDA-regulated. Labeling regulations demand that bottled water labels contain only accurate information.

Products that do not meet FDA standards are considered misbranded. Regulatory definitions for specific terms—‘ground water,’ ‘mineral water,’ ‘purified water’ and ‘sparkling water’ are all defined in FDA regulations.¹⁸

Good manufacturing practices

Bottled water providers must also meet good manufacturing practices.¹⁹ Under these regulations, source water must come from an approved source that meets all the laws and regulations of the government that has jurisdiction of the water source.

Good manufacturing practices include regulations on processing, packaging, transport and storage to ensure sanitary conditions. They also mandate that bottled water companies regularly monitor the water source and final products to ensure they comply with safety regulations. Other regulations involve specific identity and quality requirements for bottled water.²⁰

Nonetheless, some environmental activists have suggested that bottled water is of a lower quality because FDA only regulates water in interstate commerce. They suggest that because a large share of bottled water is produced solely intrastate, then such water must be of a lower quality as it does not fall under FDA jurisdiction.

For example, an NRDC spokesperson suggested in congressional testimony that as much as 40 percent of bottled water is not covered by FDA regulations.²¹ Even if this claim were correct, it should not be alarming. In addition to state regulation of bottled water to ensure safety, bottled water has a tremendous safety record, with very few problems reported.²²

In any case, the contention that bottled water providers



produce water that is of lower quality than demanded by FDA is highly unlikely. In fact, the data in NRDC's own report shows that an overwhelming majority of bottled water meets or exceeds federal water standards.²³

According to NRDC, it "commissioned independent lab testing of more than 1,000 bottles of 103 types of bottled water from many parts of the country."²⁴ NRDC reports that only four waters failed (two exceeded standards for fluoride and two for coliform bacteria) to meet federal standards.²⁵ That is an impressive compliance rate.

Jurisdiction

Moreover, given the broad definition of interstate commerce, it is unlikely that anyone could make a legal case that any bottled water does not fall under FDA's jurisdiction. Today 'interstate commerce' covers most/all commercial activity in the US.

In *Wickard v. Filburn* (1942), the Supreme Court ruled that wheat grown and consumed on a farm is considered to be part of interstate commerce because interstate commerce is affected, as the farmer does not have to buy wheat in the marketplace. In *Gonzales v. Raich* (2005), the Court ruled that marijuana grown in a home for medicinal use under California law was considered interstate commerce and subject to federal law as well. In addition, if any part of a food product or packaging involves accessing materials that are produced or affect interstate commerce, it legislates the produce covered.

The *Food, Drug, and Cosmetics Act* directs that courts shall presume for enforcement purposes all food products, including bottled water, are part of interstate commerce. Specifically, the law reads, "In any action to enforce the requirements of this Act respecting a device, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist."²⁶

In US Senate testimony, an NRDC representative acknowledged that the most likely case is that bottled water falls under FDA jurisdiction. In a footnote to the claim that the water is not regulated by FDA, the NRDC staffer notes: "However, the bottled water industry, by and large, has a significant effect on interstate commerce and many of the products used in the bottling plants—such as the bottles, labels, the caps—move through interstate commerce even if the source of the water may be intrastate. Given the prevalence of moving plastic bottles through interstate commerce, most, if not all, bottled water should fall under FDA's watch."²⁷

Public/private compliance

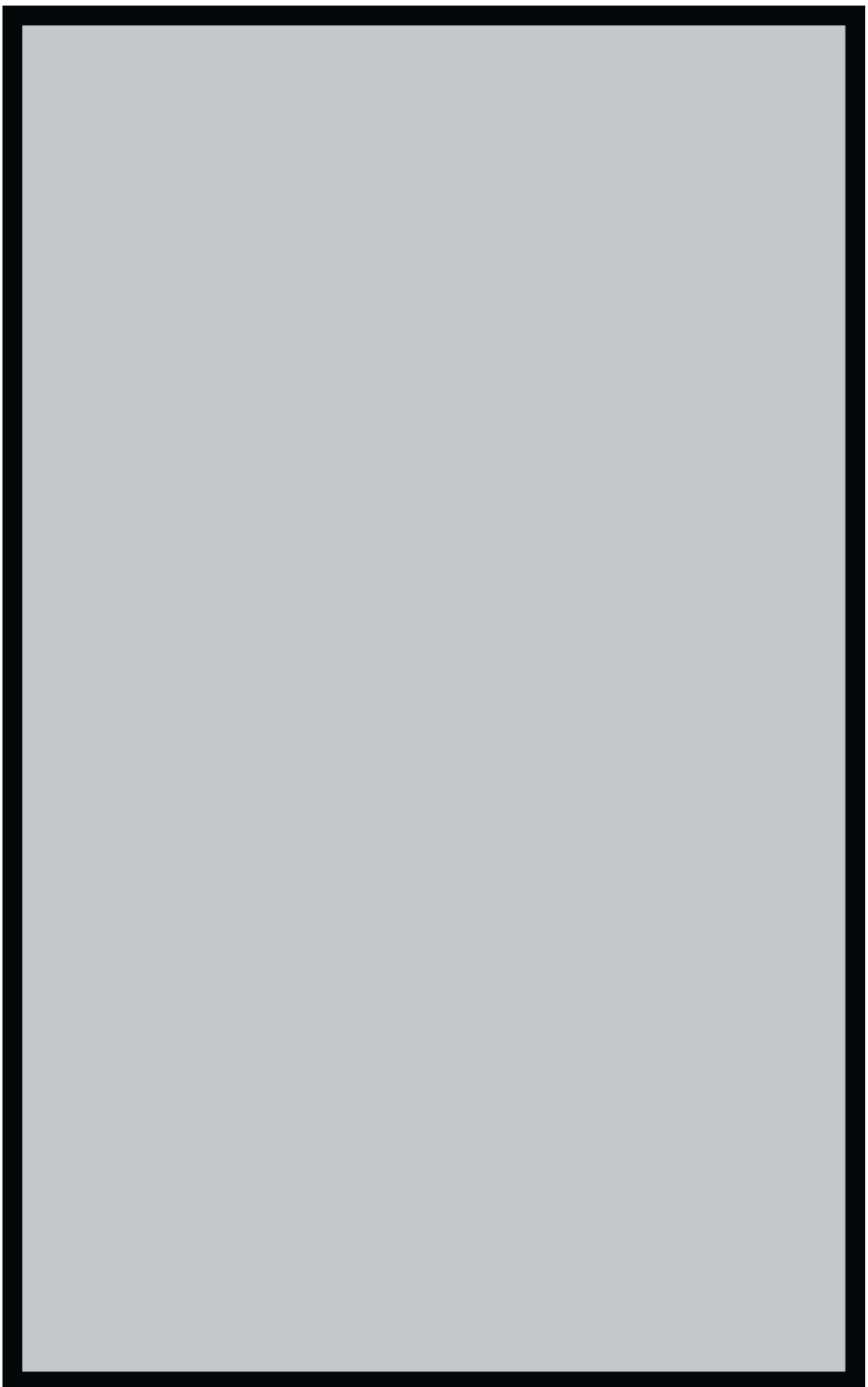
Bottled water providers must also comply with other standards—both public and private. There are state-level regulations, some of which (such as those

from California, Pennsylvania and Florida) are more stringent than federal regulations.

IBWA members (who supply 85 percent of the bottled water sold in the US) comply with even stricter industry standards. In addition, the association's membership is subject to unannounced sanitary inspections by two independent groups: the National Sanitation Foundation and Underwriters Laboratories.²⁸

In the rare case that a bottle of water does not meet a standard, or does not meet California standards, there is still little public health consequence. In fact, a high success rate of meeting US EPA/FDA standards indicates that bottled water meets exceedingly high safety standards.

US EPA regulators design the regulations with safety factors to ensure that even if consumers are exposed to contamination



many times higher than levels allowed by regulation, they would not suffer any public health impact. This despite environmentalist claims suggesting that trace level chemicals in our water may cause cancer.

In their landmark study on cancer in 1981, when standards were not nearly as stringent, scientists Richard Doll and Richard Peto noted, "With the possible exception of asbestos in a few water supplies, we know of no established human carcinogen that is ever present in sufficient quantities in large US water supplies to account for any material percentage of the total risk of cancer."²⁹

A periodic exceedance for chemical contaminants should be of little concern. In fact, US EPA regulators do not expect every sample of tap water to meet the agency's standards for chemical contaminants. Instead, the levels are averaged over a period of time because the risks of such trace-level chemicals are associated with long-term exposures to contaminants at vastly higher levels over a long period of time.

Periodic exceedances of the exceptionally cautious standards are of no consequence, particularly since exceedances were on the order of one to a few parts per billion. Importantly, bottled water still meets an even more stringent standard on this point. Unlike US EPA regulations for tap water, bottled water companies are not expected to meet the standard on average. They must meet it with every single sample, which makes FDA standards more stringent in this respect.

Insufficient testing

Finally, environmental activists suggest that bottled water testing is insufficient compared to tap water regulations. NRDC notes that tap water regulations require local governments to test for bacteria and chemical contaminants far more often than

bottled water companies.

But there are good reasons for these differences. Tap water must be tested frequently because its source and delivery system make it much more susceptible to contamination, since tap water often comes from surface water sources and then travels through pipes. When the volume of water tested is taken into account, bottled water receives more testing per gallon of water.³⁰

In the end, both US tap and bottled water meet very high standards and Americans face relatively low risks. Each has its own challenges and benefits and each serve different needs.

Fortunately, Americans rarely suffer from serious water quality problems. Activist campaigns that suggest otherwise are not productive as they divert attention away from more significant issues, misleading consumers, the media and even some public health professionals about the facts.

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8. §410 of the *Federal Food, Drug, and Cosmetic Act*, codified at 21 USC §349.

9. Anne Christiansen Bullers, "Bottled Water: Better Than the Tap?" *FDA Consumer*, July-August 2002, http://www.fda.gov/FDAC/features/2002/402_h2o.html.

10. *Federal Register*, Vol. 58, 382.

11. *Federal Register*, Vol. 59, 61533.

12. Phthalates are chemicals that can be released from the plastic container in trace amounts. However, phthalates are generally not used in containers for water.

13. These regulations refer to: 21 CFR Part 129; by Lauren M. Posnick, Sc.D. and Henry Kim, Ph.D., Catherine Bailey, M.Ed., "Bottled Water Regulation and the FDA," *Food Safety Magazine*, August/September 2002, <http://www.cfsan.fda.gov/~dms/botwatr.html>. The FDA explains: "These regulations require that bottled water be safe and that it be processed, bottled, held and transported under sanitary conditions. Processing practices addressed in the CGMP regulations include protection of the water source from contamination, sanitation at the bottling facility, quality control to assure the bacteriological and chemical safety of the water, and sampling and testing of source water and the final product for microbiological, chemical, and radiological contaminants. Bottlers are required to maintain source approval and testing records to show to government inspectors. Checking adherence to part 129 regulations is an important part of FDA inspections of bottled water plants."

14. See *Federal Food Drug and Cosmetics Act* §402(a) (1) and 21 CFR §165.110(c).

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