

REGULATION OF BOTTLED WATER

HEARING

BEFORE THE

SUBCOMMITTEE ON COMMERCE, TRADE,
AND CONSUMER PROTECTION

OF THE

COMMITTEE ON ENERGY AND
COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

—————
JULY 8, 2009
—————

Serial No. 111-56



Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

—————
U.S. GOVERNMENT PRINTING OFFICE

74-089

WASHINGTON : 2012

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800
Fax: (202) 512-2104 Mail: Stop IDCC, Washington, DC 20402-0001

COMMITTEE ON ENERGY AND COMMERCE

HENRY A. WAXMAN, California, *Chairman*

JOHN D. DINGELL, Michigan

Chairman Emeritus

EDWARD J. MARKEY, Massachusetts

RICK BOUCHER, Virginia

FRANK PALLONE, JR., New Jersey

BART GORDON, Tennessee

BOBBY L. RUSH, Illinois

ANNA G. ESHOO, California

BART STUPAK, Michigan

ELIOT L. ENGEL, New York

GENE GREEN, Texas

DIANA DEGETTE, Colorado

Vice Chairman

LOIS CAPPS, California

MICHAEL F. DOYLE, Pennsylvania

JANE HARMAN, California

TOM ALLEN, Maine

JANICE D. SCHAKOWSKY, Illinois

CHARLES A. GONZALEZ, Texas

JAY INSLEE, Washington

TAMMY BALDWIN, Wisconsin

MIKE ROSS, Arkansas

ANTHONY D. WEINER, New York

JIM MATHESON, Utah

G.K. BUTTERFIELD, North Carolina

CHARLIE MELANCON, Louisiana

JOHN BARROW, Georgia

BARON P. HILL, Indiana

DORIS O. MATSUI, California

DONNA M. CHRISTENSEN, Virgin Islands

KATHY CASTOR, Florida

JOHN P. SARBANES, Maryland

CHRISTOPHER S. MURPHY, Connecticut

ZACHARY T. SPACE, Ohio

JERRY McNERNEY, California

BETTY SUTTON, Ohio

BRUCE BRALEY, Iowa

PETER WELCH, Vermont

JOE BARTON, Texas

Ranking Member

RALPH M. HALL, Texas

FRED UPTON, Michigan

CLIFF STEARNS, Florida

NATHAN DEAL, Georgia

ED WHITFIELD, Kentucky

JOHN SHIMKUS, Illinois

JOHN B. SHADEGG, Arizona

ROY BLUNT, Missouri

STEVE BUYER, Indiana

GEORGE RADANOVICH, California

JOSEPH R. PITTS, Pennsylvania

MARY BONO MACK, California

GREG WALDEN, Oregon

LEE TERRY, Nebraska

MIKE ROGERS, Michigan

SUE WILKINS MYRICK, North Carolina

JOHN SULLIVAN, Oklahoma

TIM MURPHY, Pennsylvania

MICHAEL C. BURGESS, Texas

MARSHA BLACKBURN, Tennessee

PHIL GINGREY, Georgia

STEVE SCALISE, Louisiana

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION

BOBBY L. RUSH, Illinois
Chairman

JAN SCHAKOWSKY, Illinois
Vice Chair

JOHN SARBANES, Maryland

BETTY SUTTON, Ohio

FRANK PALLONE, New Jersey

BART GORDON, Tennessee

BART STUPAK, Michigan

GENE GREEN, Texas

CHARLES A. GONZALEZ, Texas

ANTHONY D. WEINER, New York

JIM MATHESON, Utah

G.K. BUTTERFIELD, North Carolina

JOHN BARROW, Georgia

DORIS O. MATSUI, California

KATHY CASTOR, Florida

ZACHARY T. SPACE, Ohio

BRUCE BRALEY, Iowa

DIANA DeGETTE, Colorado

JOHN D. DINGELL, Michigan (ex officio)

CLIFF STEARNS, Florida
Ranking Member

RALPH M. HALL, Texas

ED WHITFIELD, Kentucky

GEORGE RADANOVICH, California

JOSEPH R. PITTS, Pennsylvania

MARY BONO MACK, California

LEE TERRY, Nebraska

MIKE ROGERS, Michigan

SUE WILKINS MYRICK, North Carolina

MICHAEL C. BURGESS, Texas

CONTENTS

	Page
Hon. Bart Stupak, a Representative in Congress from the State of Michigan, opening statement	1
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement	3
Hon. Marsha Blackburn, a Representative in Congress from the State of Tennessee, opening statement	5
Hon. Michael C. Burgess, a Representative in Congress from the State of Texas, opening statement	6
Hon. Joe Barton, a Representative in Congress from the State of Texas, opening statement	7
Hon. Donna M. Christensen, a Representative in Congress from the Virgin Islands, prepared statement	138

WITNESSES

John Stephenson, Director, Natural Resources and the Environment, Govern- ment Accountability Office	10
Prepared statement	12
Answers to submitted questions	141
Joshua M. Sharfstein, Deputy Commissioner, U.S. Food and Drug Adminis- tration	20
Prepared statement	23
Jane Houlihan, Senior Vice President for Research, Environmental Working Group	39
Prepared statement	41
Answers to submitted questions	144
Joseph K. Doss, President, International Bottled Water Association	84
Prepared statement	86

REGULATION OF BOTTLED WATER

WEDNESDAY, JULY 8, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMERCE, TRADE,
AND CONSUMER PROTECTION,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:04 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Bart Stupak [Chairman of the Subcommittee] presiding.

Members present: Representatives Stupak, Christensen, Walden, Burgess, Blackburn and Barton (ex officio).

Staff present: David Rapallo, General Counsel; Theodore Chuang, Chief Oversight Counsel; Stacia Cardille, Counsel; Anne Tindall, Counsel; Scott Schloegel, Investigator; Jennifer Owens, Special Assistant; Ken Marty, HHS-OIG Detailee; Lindsay Vidal, Special Assistant; and Jen Berenholz, Deputy Clerk.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This meeting will come to order.

Today we have a hearing titled "Regulation of Bottled Water." The chairman, the ranking member and the chairman emeritus will be recognized for 5-minute opening statements. Other members of the subcommittee will be recognized for 3-minute opening statements. I will begin.

Food safety is an extremely important issue that this committee has held nearly a dozen hearings on over the past 2 years. Time and again we hear from individuals who want more information so they can make wise decisions about what they eat and drink. My constituents are no exception. Today's hearing on bottled water hits close to home. My vastly rural district in northern Michigan contains more shoreline than any other Congressional district except Alaska but we have a keen awareness of water quality issues. Michigan is also home to a large bottled water facility in Mecosta County that has not been without controversy over the years.

In 2008, Americans consumed 8.6 billion gallons of bottled water. Bottled water is a billion-dollar-a-year industry with sales up more than 83 percent this decade. Many Americans believe that the water they drink from a bottle is healthier than the water that comes from their faucets. The Water Research Foundation found that nearly 56 percent of bottled water drinkers cite health and safety as the primary reason they choose bottled water over tap water. As a result, Americans are willing to pay top dollar for bot-

tled water, which costs up to 1,900 times more than tap water and uses up to 2,000 times more energy to produce and deliver.

Over the past several years, however, bottled water has been recalled due to contamination by arsenic, bromate, cleaning compounds, mold and bacteria. In April, a dozen students at a California junior high school reportedly were sickened after drinking bottled water from a vending machine. Consumers may not realize but many of the regulations that apply to municipalities responsible for tap water do not apply to companies that produce bottled water. I would like to put up a chart that outlines some of these differences.

[Chart.]

For example, municipal tap water suppliers are required to tell their consumers within 24 hours if they find dangerous contaminants that exceed federal levels but this requirement does not apply to bottled water companies. Certified laboratories must be used to test tap water but bottled water has no similar requirement. Tap water suppliers provide their customers with annual consumer confidence reports that detail the sources of their water, any contamination found, the likely cause of contamination and any potential health effects. Bottled water distributors are not required to provide this report to consumers. Instead, bottled water consumers rely on limited information found on labels and in some cases on company Web sites.

Some companies exacerbate this problem by exaggerating claims about the health benefits of their products. For example, Poland Springs explains the history of its water by saying, "When Joseph Ricker was revived from his deathbed, reputedly by drinking the spring's water and lived another 52 years, the water's health benefits became legendary." Mountain Valley Water Company provides similar accounts of its water, stating "Clinical tests at hospitals in New York, St. Louis and Philadelphia demonstrated improvements in the health of patients suffering from kidney and liver disorders and rheumatism as a result of drinking Mountain Valley Water." Aquamantra spring water explains that the words written on its labels, mantras such as "I am healthy" and "I am loved" permeate the liquid, influencing the taste and beneficial properties of water. The company also claims that Aquamantra uses the design of its label to affect the molecular structure of the water.

Today the subcommittee will receive two new reports that raise questions about why the regulations governing bottled water are weaker than those governing tap water, as well as widespread public perception that bottled water is healthier than water from the tap. The first is a report by the Government Accountability Office that was originally requested by our former colleagues, Hilda Solis and Al Wynn. In this report, GAO examines whether federal and State authorities are adequately ensuring the safety of bottled water and the accuracy of claims regarding its purity and health benefits. The second report is by the Environmental Working Group, which conducted an 18-month survey of bottled water labels and Web sites and concluded that just two of the 188 bottled water companies surveyed provided consumers with information on the source of their water, the manner in which it is treated and any contaminants present. Given these findings by GAO and Environ-

mental Working Group, the subcommittee is sending today to a dozen bottled water companies letters requesting information on the source of their water, their treatment methods and results of their contaminant testing for the past 2 years.

Even when water is treated at municipal facilities and then bottled, there still may be questions about contaminants such as pharmaceuticals that may be present in the treated water. Environmental Working Group reports an estimated 25 percent of bottled water brands that rely on tap water are drawing from supplies that collectively contain 260 pollutants. According to Associated Press, drugs have been found in municipal water samples across the country. Officials in Philadelphia discovered 56 pharmaceuticals or by-products in treated drinking water. Anti-epileptic and anti-anxiety medications were detected in the treated drinking water for 18.5 million people in southern California. And drinking water here in Washington, D.C., and surrounding areas testified positive for six pharmaceuticals. For these reasons, I have introduced H.R. 1359, the Secure and Responsible Drug Disposal Act of 2009, which will provide for proper disposal through drug take-back programs so individuals are not simply flushing their medications down the toilet into our water systems. I am also proud to be the original cosponsor of the Food Safety Enhancement Act of 2009, which passed out of this committee last month and which is again ready for Floor action, and which provides FDA with much-needed authority to assessing testing records of food and water supplies.

I look forward to today's hearing, and I ask for unanimous consent that reports issued today and the other documents in the binder prepared by staff be entered into the official record. Without objection, they will be entered in the record and will be used throughout the hearing.

Mr. STUPAK. I next would like to turn to my friend, Mr. Walden from Oregon, for his opening statement, please.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you, Mr. Stupak.

My home State of Oregon and the 2nd Congressional district which I represent is home to a number of water bottlers including those located in the small central Oregon community of Culver, EARTH20, and the eastern Oregon town of Cove with Artesian Blue, and in the northern portion of my district in The Dalles, H2 Oregon. These successful businesses are in many cases providing much-needed job opportunities in areas of Oregon that have been hard hit by today's weak economy. In fact, Mr. Chairman, our unemployment rate is second only to yours in Michigan.

Today's hearing raises some valid questions regarding the differences in regulation between the Food and Drug Administration and the EPA regarding bottled water. However, I should note, concern that with all of the life-threatening health priorities facing the FDA including numerous foodborne illness outbreaks, complications with acetaminophen and swine flu pandemic, this issue does to me seem a little secondary in terms of the FDA's overwhelming workload on other issues.

We should also put this hearing in context. The two reports that are the focus of today's hearing point out a few noteworthy findings but do not assess the safety of the bottled water itself. Neither the Government Accountability Office, GAO, nor the Environmental Working Group, EWG, conducted any testing of the bottled water or the bottles themselves while completing their reports. The regulations for bottled water do differ from those promulgated for tap water, mostly because bottled water is considered a food product and is therefore regulated by the Food and Drug Administration, whereas tap water is regulated by the Environmental Protection Agency. However, FDA does require that the standards of quality for bottled water must be no less protective of public health than the EPA standard. Under the FDA regulations, bottlers must follow current Good Manufacturing Practices, also known as GMPs.

FDA actually requires more safeguards from water bottlers than other food processors. The GMPs for bottled water are commodity specific. Under these GMPs, bottlers must, among other things, test their source of water once a week for microbiological contaminants and test finished bottled water weekly for microbiological contaminants. Now, some of the water bottlers in my district follow a practice of testing their water every hour in order to meet the requirements of purchasers of their products, so they are doing hourly water testing.

I do have a few questions for FDA. One discrepancy between EPA and FDA is in the case of a chemical substance called DEHP. This is a phthalate, a substance added to plastics to change their physical characteristics, and I am sure you are familiar with it. FDA has yet to establish a standard for this contaminant in bottled water, even though the EPA did over a decade ago. An FDA taskforce is supposedly examining the information surrounding DEHP and I want to ask the deputy commissioner when we can expect a ruling from your agency. And the question that I will speak to in a minute is about recycled bottles themselves. I have some tell me that the use of recycled bottles perhaps produces more leaching or whatever it is that comes out of the plastic than first-time use, and I would be curious to know if that is the case.

Conducting inspections is one way the FDA ensures the bottlers are following GMPs. Concerns have been raised on how frequently the plans are inspected and what access FDA inspectors have to plant records regarding testing and other important information during the inspection, and I would be curious to know the legislation passed unanimously out of the full committee that expands FDA's inspection process, if that would apply in these cases and therefore you will get new authority if the House and the Senate Act. I would like to hear from the deputy commissioner as well on how the agency can improve the inspection process and if you do need any additional authorities. Congress needs to act. We need to know exactly what the agency needs and why. Currently, bottlers are not required to disclose the source of their water, the treatment process used or the detection of any contaminants. The question is, should they, and I look forward to your response on that.

Mr. Chairman, I would conclude by thanking you for this hearing but I would also like to raise the issue that July 8th has come and gone. A number of us on this side of the aisle have raised questions

of the Environmental Protection Agency regarding bottled-up science, and we expect the EPA to respond to our inquiries regarding Dr. Allen Garland and his report that is not allowed to be considered in the endangerment finding process, and if the EPA is unwilling to respond in a timely manner, which may well be the case, I do hope that our request of this subcommittee to have an oversight hearing on what appears to be the bottling up of science and debate on the whole carbon issue will be granted an opportunity for a hearing and a full investigation. So we will be coming back to you on that issue, and I thank you for your time.

Mr. STUPAK. Thank you, Mr. Walden.

Ms. Blackburn, opening statement, please.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman, and I do want to welcome our witnesses and thank them for being with us today.

As you have heard, we all are concerned about bottled water, the product that is there. We are also concerned about tap water and the work the EPA does there. And I will submit a written statement. Mr. Chairman, I want to take my time to just say I would prefer that we be spending this time to look at other issues that are important to our constituents that the FDA and EPA deal with. There are other committee issues that we could be looking at such as the options for reducing health care costs for our constituents and looking at how you do that through patient-driven, consumer-driven, patient-centered health care. We should be looking at the Medicare trust fund and the pressures that are on that trust fund, the ballooning costs of Medicaid if we move to a public option as we move into health care reform or even from my State, the lessons that should have been learned from TennCare, which was the test case for Hillary Clinton health care back in 1994. My State still has this. It is the greatest public health care in the country. That would be a great opportunity for us to look at what is affecting us with health care. Certainly there are more pressing issues. We are appreciative of your time to be before us today, and while we all are concerned with leaching chemicals that come from plastics into bottled water, we are indeed very concerned with what we see as sequestering evidence from EPA employees. We are concerned with what we see, health care issues that are affecting all of our constituents and a lack of willingness to address those in a patient-centered, consumer-driven manner, and I yield back my time.

Mr. STUPAK. Thank you. Let me just respond that, you know, we had a hearing just before we broke here not even 2 weeks ago on health insurance on rescissions where companies rescind health care to people who have it, and next week is scheduled all week in committee for the health care markup bill, so I am sure we will have plenty of opportunities to speak of health care.

Mr. Burgess for opening statement, please.

**OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BURGESS. Thank you, Mr. Chairman, and maybe I should take a second to respond to your response, and isn't it a shame that we have a Subcommittee on Health within the Committee on Energy and Commerce and we are to have no markup on what is going to be the greatest change in the delivery of health care in America since the institution of Medicare in 1965. Certainly the people who were in Congress in 1965 likely could have never foreseen what Medicare would become, at least as far as the price of that federal program, and wouldn't we all be in better shape today if perhaps a little more care was taken back in 1965 and the object lesson for us today is, we need to take good care and exercise due caution as we structure this major fundamental change to American health care.

We also could have had a hearing on medical devices in this subcommittee, which I have asked for for some and has yet been forthcoming, so there are ways we could have made use of this time today, Mr. Chairman, but here we are and we are going to talk about bottled water this morning, and that is important. Normally I have a bottle of water here so that if I get parched in the hour that I have to address the committee, but now we are stuck with D.C. water which there used to be a little sign in my office in the Longworth Building that said do not drink the tap water. I don't know if that has changed but I am a little reluctant to drink what is before us today.

A pretty broad definition of food would be one that included bottled water, and the tremendous breadth and depth of the responsibility entrusted to our good friends at the Food and Drug Administration is this \$11 billion industry known as bottled water. The average American consumer is unlikely to think that the FDA would be the primary regulator of bottled water but it is. The regulatory responsibility of bottled water is split between the Environmental Protection Agency and the federal Food, Drug and Cosmetic Act with the Food and Drug Administration overseeing the process of taking public water in its natural form in the environment into a convenient plastic container for sale to the American consumer.

Now, as much I appreciate the collegiality, the intelligence and the willingness of Dr. Sharfstein to appear here today as a representative of the Food and Drug Administration, it does seem odd to only have the Food and Drug Administration here to answer tough questions and to not have the Environmental Protection Agency to answer questions that would fall into their jurisdiction about the standards for municipal water versus bottled water. Currently, bottled water requires a higher threshold of testing than municipal water. Municipal water is required to be tested every 4 years, bottled water every year. In fact, bottled water is currently one of the few stand-alone industries with its own Code of Federal Regulations regarding Good Manufacturing Processes. From the definition of water to the testing and sampling of products, from the length of time the records must be kept, currently 2 years, and how they should be available to the Food and Drug Administration as well as the role of the Environmental Protection Agency, the State and local government agencies in helping to ensure the safety

and sanitation and quality of water, this burgeoning industry has seemingly existed in a compliance-oriented manufacturing system rarely, if ever, producing bad actors. It would seem that this industry is an example of the ingenuity and innovation of the marketplace to create a product which had, if you will pardon the pun, an unquenchable need for a convenient, transportable water and this good idea has been met with significant market success.

We must ensure that the trust and faith of consumers and that the government places in the bottled water industry are not misguided. More Americans drink bottled water than milk or beer combined, so if there is any step in this multilayer process to deliver this food product where the trust and faith is misallocated, then certainly I look forward to having the science point to a solution. Furthermore, any deficiencies in the regulation of bottled water, any potential fraud in the process of producing bottled water and any alleged environmental issues of draining of our natural resources and the burdensome transportation costs of moving the end product, we will certainly look forward to seeing what is sure to be voluminous evidentiary proof.

Thank you, Mr. Chairman, for your indulgence. I will yield back the balance of my time.

Mr. STUPAK. No problem. I didn't want you to get parched. As you know, in the Health Subcommittee, you guys did hold a hearing on medical devices last month and the 510K approval process, so those hearings are being taken. This hearing—

Mr. BURGESS. But I would submit the investigatory part of that has not been completed, at least to my satisfaction, and I think this subcommittee would be the appropriate place to have that. In addition, we have got the whole question of biosimilars out there that would probably just roll into this health care bill and we have not had the FDA in to talk to us about the science of biosimilars. So there is stuff we could be doing, is the point I am trying to make.

Mr. STUPAK. Absolutely, and this committee has been very active, as you know, for the last 2 years and we hold many, many hearings, and this one with the two reports being released today, it really dovetails into everything we have been doing for the last couple of years in food safety, and whether it is BPA or the PET that we talked about here, or as Mr. Walden brought up, the DEHP, why has it taken 15 years to put out regulations for that, certify labs' test results, all that is contained in this hearing so it is not just strictly bottled water, false advertising. That is what this whole thing is about, sort of wraps up everything we have been doing for the last few years, and we do have these two reports coming out today so we thought it was appropriate to have the hearing today. Very good.

Mr. Barton, opening statement, please.

**OPENING STATEMENT OF HON. JOE BARTON, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BARTON. Thank you, Mr. Chairman. Let me say before I give my prepared statement how much I personally appreciate you, so don't take some of what I am about to say too personally.

But I think it does say something, given the serious issues which you have traditionally tackled as your subcommittee chairmanship along with Ranking Member Walden that today's hearing does not rank at the top of that list, and it shows when you look on your side how much support there is. They may all be here but they are disguised as empty chairs, if they are.

Mr. STUPAK. Well, you know, most of the committee is down in the Consumer Protection because we are putting a new administrator in there and that is where most of them are. In fact, that is why we started a little late because I am also on that subcommittee and I had to stop by there.

Mr. BARTON. Well, Greg and I will take over if you want to go down there.

Mr. WALDEN. Could we have a vote on that right now?

Mr. BARTON. Anyway, Mr. Chairman, today's hearing does examine several interesting questions surrounding the differences between bottled water and tap water. These differences arise in regulatory approaches as well as in processing, treatment and public perception. Several of the witnesses today including the Government Accountability Office and the Food and Drug Administration will discuss and possibly debate ways in which bottled water regulations should be changed and possibly improved. Other witnesses including the Environmental Working Group and the International Bottled Water Association will discuss ways industry can be more transparent and responsive to consumer inquiries. I don't have a problem with transparency, in fact, I am pushing transparency in the upcoming health care debate, and as you well know, I am certainly pushing transparency at the Environmental Protection Agency where Mr. Walden and I have asked the EPA to release their documents concerning their suppression of the EPA report within its own agency debating whether there really is an endangerment finding with regard to CO₂.

So those of us on the minority are concerned whether this particular hearing is the best use of our limited oversight hearing times. We have confronted the issue of swine flu pandemic. We have confronted safety of products like Tylenol. As I said a minute ago, Mr. Chairman, this one just doesn't seem to be up to that standard of excellence which you have established for your oversight. I hope that after this hearing you will consider supporting Mr. Walden and myself on getting information about the EPA's suppression of the document which we call Carbon Gate regarding the CO₂ and the endangerment finding. We also hope that you will work with us, as I talked with you yesterday informally about doing more hearings and doing some action times on the automobile dealer closure issue. I know that is something that is very important to you personally. We await your response and Mr. Waxman's response.

So Mr. Chairman, we always appreciate when you hold a hearing. We always participate and we are looking forward to going on to a little bit more intense issues in the future. Again, thank you for holding this hearing.

Mr. STUPAK. Well, thanks, Mr. Barton. And, you know, one of the reasons why we are having this hearing because I think as we have seen on your side a little bit, maybe we assume because it is in a

bottle like this it is healthy, it is clean, it is pure, and that is an assumption I think we erroneously are making, so we are doing a hearing to try to get to the issues here because I don't think we have to wait for a deadly outbreak of disease in bottled water like we have seen in salmonella in peanut butter last year, and we can't say there is zero risk here. Between 2002 and 2008, there were 23 recalls of bottled water. Now, that is about one every quarter. Most of them stemmed from an elevated level of contaminants such as arsenic and bromate, both of which cause cancer. Over the past 6 years the FDA has issued three warning letters to bottled water companies for violating safety regulations, and that is in addition to dozens of other problems found in the EPA inspections at water bottling facilities.

In 2007, the FDA issued a press release against drinking mineral water imported from Armenia because the arsenic level was 50 times greater than the federal standard. And then, like I said, last month in southern California, we have girls sick at a high school who were buying bottled water out of a vending machine. So these are problems the FDA has uncovered and they only have about two or three employees devoted to it, and like I said earlier, I think just because it comes in a bottle, we assume it is healthier for us. That is what most Americans assume. We find that is not the case and that is the reason for the hearing, and all the other things we have done this year on salmonella, institutional review boards, dual use, so we have got a lot going on here.

Mr. Walden, go ahead.

Mr. WALDEN. Well, Mr. Chairman, just two points, one I didn't mention in my testimony but I know that water is also an ingredient in many other drinks, and I guess the question I would have for our panel is, well, just because it is clear and in those bottles, how is that treated or monitored versus if it is colored and sugared and perhaps carbonated. Does somebody check the water that goes into that as well? Are there different standards there? The second point I would make on, I think it is Santa Clara, the junior high students, my understanding is that the FBI may be involved in investigation there so it might be more of a tampering issue. Is that correct?

Mr. STUPAK. They are involved but no one has reached a conclusion whether it is tampering.

Mr. WALDEN. Right. I understand. I wasn't trying to jump to a conclusion. Thank you, Mr. Chairman.

Mr. STUPAK. OK. You bet. That is a good segue into our first panel. Let me introduce our first panel of witnesses with Mr. Joseph Stephenson, who is director of National Resources and the Environment at the Government Accountability Office. We have Dr. Joshua Sharfstein, who is the principal deputy commissioner at the U.S. Food and Drug Administration, Ms. Jane Houlihan, who is the senior vice president for research at the Environmental Working Group, and Mr. Joseph K. Doss, who is the president of the International Bottled Water Association.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that you have the right under the rules of the House to be advised by counsel during your testimony. Do you wish to be represented by counsel? Mr. Stephenson.

Mr. STEPHENSON. No.

Mr. STUPAK. Dr. Sharfstein, Ms. Houlihan? No. OK. Then I am going to ask you to please rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses have replied in the affirmative. You are now under oath. We will now hear 5-minute opening statement from our witnesses. You may submit a longer statement for the record and would be included in today's hearing. Mr. Stephenson, we will start with you.

TESTIMONY OF JOHN STEPHENSON, DIRECTOR, NATURAL RESOURCES AND THE ENVIRONMENT, GOVERNMENT ACCOUNTABILITY OFFICE; JOSHUA M. SHARFSTEIN, DEPUTY COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION; JANE HOULIHAN, SENIOR VICE PRESIDENT FOR RESEARCH, ENVIRONMENTAL WORKING GROUP; AND JOSEPH K. DOSS, PRESIDENT, INTERNATIONAL BOTTLED WATER ASSOCIATION

TESTIMONY OF JOHN STEPHENSON

Mr. STEPHENSON. Thank you, Mr. Chairman and Mr. Walden. I am pleased to be here today to discuss the quality and safety of bottled water and its environmental impacts.

Over the past decade, the per capita consumption of bottled water in the United States has more than doubled from 13.4 gallons per person in 1997 to 29.3 gallons per person in 2007. That is over 200 bottles a year for every man, woman and child and an \$11 billion plus market. With this increase come several questions and concerns over bottled water's quality and safety. My testimony is based upon the report that we are issuing to the committee today which is going to be publicly released.

In summary, we found that FDA's safety and consumer protections are less stringent for bottled water than comparable EPA protections for tap water. While FDA's standards for bottled water generally mirror the standards for nearly all of the 88 contaminants covered by EPA's national primary drinking water regulations, there is one notable exception, DEHP, which is a plasticizer used to soften plastic, which has been linked to reproductive and liver problems and increased cancer risk. It has been regulated by the EPA in tap water since 1992 but FDA deferred action on DEHP in a rule published in 1996 and has yet to either adopt a standard or publish a reason for not doing so, even though the statutory deadline for acting was more than 15 years ago. Since DEHP is used in food packaging as well as bottled water, this is a broader issue that FDA is still studying. Nevertheless, our report recommends that FDA expeditiously promulgate a DEHP standard for bottled water.

More broadly, we found that FDA, unlike EPA, does not have the statutory authority to require bottlers to use certified laboratories for water quality tests or to report test results, even if violations of the standards are found. Most tests are done by the bottlers themselves. Several states have requirements to safeguard bottled water that exceed those of FDA but are still less comprehensive

than for tap water. In addition, while FDA bottled water labeling requirements are similar to labeling requirements for other foods, they provide consumers with far less information about the source and quality of water than what EPA requires of public water systems under the Safe Drinking Water Act. For example, public water systems must annually provide consumer confidence reports that summarize water quality information about the water sources, detected contaminants and compliance with national primary drinking water regulations as well as information on the potential health effects of certain contaminants. FDA does not require bottled water companies to provide similar information. In a study mandated by the 1996 amendments to the Safe Drinking Water Act, FDA concluded that it was feasible for the bottled water industry to provide the same type of information to consumers that public water systems must provide. However, the agency was not required to act on its findings and has yet to do so.

A survey of 50 States and the District of Columbia showed that consumers have misconceptions about bottled water, believing that it is safer and healthier than tap water. We also found that information comparable to what public water systems are required to provide to consumers of tap water was available for only a small percentage of the 83 bottled water labeled we examined, companies we contacted or company Web sites we reviewed. We believe that consumers would benefit from better information on the quality and safety of bottled water, and our report also recommends that FDA implement the results of this study to accomplish this.

In examining the environmental effects of bottled water, we found that only about 25 percent of water bottles are recycled and that the remaining 75 percent are discarded in municipal landfills where they never decompose and essentially remain forever. While this is over 900,000 tons of plastic annually, it represents less than 1 percent of municipal waste.

Another issue is the amount of energy used to manufacture and transport bottled water. Another study estimates the energy use at 5.8 megajoules per liter. At the current rate of consumption, this is the equivalent of the energy used by 4.7 million households for a year and is 1,000 to 2,000 times the energy used for tap water. We also found that groundwater extraction for bottled water facilities in selected areas and that Michigan and other States have passed laws to minimize the impact of stream levels and wetlands.

Finally, I would note that some of our bottled water findings are indicative of FDA's overall food safety oversight problems that led to GAO's designating it a high-risk area in January 2007 and again in 2009 when we called for a fundamental reexamination of the federal food safety system. We believe that FDA's lack of authority and resources to effectively regulate bottled water should be part of that reexamination.

Mr. Chairman, that concludes the summary of my statement and I will be happy to answer questions at the appropriate time.

[The prepared statement of Mr. Stephenson follows:]

United States Government Accountability Office

GAO

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

For Release on Delivery
Expected at 10:00 a.m. EDT
Wednesday, July 8, 2009

BOTTLED WATER

FDA Safety and Consumer Protections Are Often Less Stringent Than Comparable EPA Protections for Tap Water

Statement of John Stephenson, Director
Natural Resources and Environment



July 8, 2009

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the quality and safety of bottled water and its environmental impacts. Over the past decade, the per capita consumption of bottled water in the United States has more than doubled—from 13.4 gallons per person in 1997 to 29.3 gallons per person in 2007. With this increase have come several concerns, raised by public interest groups in recent years, over bottled water's quality and safety. For example, water quality testing conducted by some of these groups, and others, has shown that bottled water does not necessarily have lower levels of contamination than tap water. Furthermore, bottled water's potential environmental impact has also come under scrutiny. Several organizations have raised concerns about a low recycling rate for plastic water bottles, the amount of energy used to manufacture and transport the product, and the impact of groundwater extraction on local resources. My testimony is based on our June 2009 report,¹ which is being publicly released today and addresses three issues: (1) the extent to which federal and state authorities regulate the quality of bottled water to ensure its safety, (2) the extent to which federal and state authorities regulate the accuracy of labels or claims regarding the purity and source of bottled water, and (3) the environmental impacts of bottled water.

To address these questions, we reviewed relevant Food and Drug Administration (FDA) documents, policies, and guidance, as well as related laws and regulations pertinent to the oversight of bottled water at the federal and state levels; analyzed data from the FDA databases that track inspections, import examinations, and recalls; conducted a survey of all 50 states and the District of Columbia; and conducted interviews with Environmental Protection Agency (EPA) and FDA officials and a variety of experts from nonprofit organizations and industry associations. We also examined bottled water labels and contacted companies to determine what information they provide to consumers.² Finally, we interviewed

¹GAO, *Bottled Water: FDA Safety and Consumer Protections Are Often Less Stringent Than Comparable EPA Protections for Tap Water*, GAO-09-610 (Washington, D.C.: June 22, 2009).

²A total of 83 unique bottled water labels were examined after removing duplicate labels, or labels that were not for bottled water. Labels were collected from GAO staff in each of our 11 field offices and at headquarters.

experts and other knowledgeable officials and reviewed the literature regarding the environmental impacts of bottled water. A full description of our scope and methodology is included in appendix I of our report.

We conducted this performance audit from June 2008 to June 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Mr. Chairman, the following summarizes our findings on each of the three issues discussed in our report:

- *Federal and state regulation of the quality of bottled water.* FDA's bottled water standard of quality regulations generally mirror EPA's national primary drinking water regulations under the Safe Drinking Water Act, as required by the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended, although the case of DEHP (an organic compound widely used in the manufacture of polyvinyl chloride plastics) is a notable exception. Specifically, FDA deferred action on DEHP in a final rule published in 1996, and has yet to either adopt a standard or publish a reason for not doing so, even though FDA's statutory deadline for acting on DEHP was more than 15 years ago. More broadly, we found that FDA's regulation of bottled water (including its implementation and enforcement), particularly when compared with EPA's regulation of tap water, reveals key differences in the agencies' statutory authorities. Of particular note, FDA does not have the specific statutory authority to require bottlers to use certified laboratories for water quality tests or to report test results, even if violations of the standards are found. Among our other findings, the states' requirements to safeguard bottled water often exceed those of FDA, but are still often less comprehensive than state requirements to safeguard tap water.
- *Federal and state regulation of the accuracy of labels or claims of purity.* FDA and state bottled water labeling requirements are similar to labeling requirements for other foods, but the information provided to consumers is less than what EPA requires of public water systems under the Safe Drinking Water Act. Public water systems must annually provide consumer confidence reports that summarize local drinking water quality information about the water's sources, detected contaminants, and compliance with national primary drinking water regulations as well as information on the potential health effects of certain drinking water contaminants. FDA does not require bottled water companies to provide

this information. Rather, as in the case of other foods, bottled water labels are required to list ingredients and nutritional information and are subject to the same prohibitions against misbranding. In 2000, FDA concluded that it was feasible for the bottled water industry to provide the same types of information to consumers that public water systems must provide.

However, the agency was not required to conduct a rulemaking requiring that manufacturers provide such information to consumers, and has yet to do so. Nevertheless, our work suggests that consumers may benefit from such additional information. For example, when we asked cognizant officials in a survey of the 50 states and the District of Columbia whether their consumers had misconceptions about bottled water, many replied that consumers often believe that bottled water is safer or healthier than tap water. Their responses were consistent with a 2002 EPA-sponsored Gallup survey, which found that the main reason consumers either filtered tap water or purchased bottled water was due to health-related concerns. We also found that information comparable to what public water systems are required to provide to consumers of tap water was available for only a small percentage of the 83 bottled water labels we reviewed, companies we contacted, or company Web sites we reviewed.

- *The environmental impacts of bottled water.* Among the environmental impacts of bottled water are its effects on U.S. municipal landfill capacity and U.S. energy demands. Regarding its impacts on landfill capacity, we found that about three-quarters of the water bottles produced in the United States in 2006 were discarded and not recycled, on the basis of figures compiled by an industry trade association and an environmental nonprofit organization.³ Regarding the impact on U.S. energy demands, a recent peer-reviewed article noted that while the production and consumption of bottled water comprises a small share of total U.S. energy demand, it is much more energy-intensive than the production of public drinking water.⁴

Our report released today recommends that the Secretary of Health and Human Services direct the Commissioner of FDA to issue a standard of quality regulation for DEHP, or publish in the *Federal Register* the agency's reasons for not doing so 1 year after the conclusion of its task force study on the issue. FDA generally concurred with the recommendation, agreeing that it should reassess whether to issue the

³The two organizations are the American Beverage Association and the Container Recycling Institute.

⁴P. H. Gleick and H. S. Cooley, Pacific Institute, "Energy Implications of Bottled Water," *Environmental Research Letters*, vol. 4, no. 014009 (2009).

regulation for DEHP as soon as possible after the conclusion of the task force study on phthalates.⁵ The report also recommends that FDA implement its findings on methods that are feasible for conveying information about bottled water to customers. FDA agreed that bottled water should be labeled with contact information allowing consumers to more easily contact the manufacturer to obtain comprehensive information about the product, and said it intends to pursue this issue with bottled water manufacturers.

Despite the concerns our report raised regarding FDA's regulation of bottled water under the FFDCFA (particularly in comparison with EPA's regulation of drinking water under the Safe Drinking Water Act), we concluded that its observations must be viewed in the context of the legal limitations placed by the act on FDA, and the constrained resources that have affected FDA's overall capabilities in recent years. The legal limitations arise because while the Safe Drinking Water Act authorizes EPA to require water samples to be tested by certified laboratories, and violations of national primary drinking water regulations to be reported within certain time frames to EPA or the state agency with primary enforcement responsibility, the FFDCFA does not grant FDA similar authority. Rather, the FFDCFA requires FDA to regulate bottled water as a "food." As such, it does not specifically authorize FDA to require that bottled water be tested by certified laboratories or that violations of the standard of quality be reported to FDA.

In addition to these legal constraints, bottled water's status as a food has subjected it to many of the same problems more generally affecting FDA oversight of food safety. As we noted in January 2007,⁶ for example, when we designated federal oversight of food safety as a "high-risk" area affecting public health and the economy, federal oversight of food safety is fragmented, with about 15 agencies having food safety roles. We specifically cited FDA's resource constraints, noting in 2008⁷ that while the number of domestic firms under FDA's jurisdiction increased from fiscal

⁵Phthalates are a class of chemical compounds primarily used as a plasticizer, added to plastics to increase flexibility, transparency, durability, and longevity and found in a variety of food containers and packaging.

⁶GAO, *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: January 2007).

⁷GAO, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods*, GAO-08-597 (Washington, D.C.: Sept. 9, 2008).

years 2001 through 2007 from about 51,000 firms to more than 65,500, the number of firms inspected declined from 14,721 to 14,566 during the same period. We cited resource constraints as a contributing factor, noting that the number of full-time-equivalent positions at FDA devoted to food safety oversight had decreased by about 19 percent from fiscal years 2003 through 2007.

Ultimately, as our January 2007 report recommended, a fundamental reexamination of the federal food safety system will be needed to look across the activities of individual programs within specific agencies with responsibilities related to food safety. Toward that end, we had previously recommended in 2001 that the Congress, among other things, enact comprehensive, uniform, and risk-based food safety legislation and commission the National Academy of Sciences or a blue-ribbon panel to analyze alternative organizational food safety structures in detail.⁵ We continue to believe that such a fundamental reexamination is needed, and believe that FDA's lack of authority and resources to effectively regulate bottled water should be part of it.

Mr. Chairman, this concludes my statement. I would be pleased to respond to any questions you or other Members of the Subcommittee may have.

Contacts and Acknowledgments

For questions about this statement, please contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov. Individuals who made key contributions to this testimony include Steve Elstein, Assistant Director; Brian M. Friedman; Nathan A. Morris; Kelly A. Richburg; and Jeanette Soares.

⁵GAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, GAO-02-47T (Washington, D.C.: Oct. 10, 2001).

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

GAO's Mission	The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.
Obtaining Copies of GAO Reports and Testimony	The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday afternoon, GAO posts on its Web site newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to www.gao.gov and select "E-mail Updates."
Order by Phone	<p>The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's Web site, http://www.gao.gov/ordering.htm.</p> <p>Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.</p> <p>Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.</p>
To Report Fraud, Waste, and Abuse in Federal Programs	<p>Contact:</p> <p>Web site: www.gao.gov/fraudnet/fraudnet.htm E-mail: fraudnet@gao.gov Automated answering system: (800) 424-5454 or (202) 512-7470</p>
Congressional Relations	Ralph Dawn, Managing Director, dawnr@gao.gov , (202) 512-4400 U.S. Government Accountability Office, 441 G Street NW, Room 7125 Washington, DC 20548
Public Affairs	Chuck Young, Managing Director, youngc1@gao.gov , (202) 512-4800 U.S. Government Accountability Office, 441 G Street NW, Room 7149 Washington, DC 20548



Mr. STUPAK. Thank you, Mr. Stephenson.
Dr. Sharfstein, would you like to make your opening statement?

TESTIMONY OF JOSHUA M. SHARFSTEIN

Dr. SHARFSTEIN. Thank you very much. We appreciated the GAO report, and I especially appreciate that he finished with exactly 2 seconds left. I was watching. I have never seen that before.

Good morning, Mr. Chairman and members of the subcommittee. I am Dr. Joshua Sharfstein, the principal deputy commissioner of the Food and Drug Administration of the Department of Health and Human Services. I want to thank the committee for your work on a wide range of health issues and for the opportunity to discuss FDA's regulation of bottled water today.

As has been mentioned, bottled water and tap water are regulated by two separate agencies. FDA regulates bottled water while the EPA regulates tap water, also referred to as municipal water or public drinking water. EPA has regulations on the production, distribution and quality of public drinking water including source water protection, operation of drinking water systems, contaminant levels and reporting requirements.

The Food, Drug, and Cosmetic Act provides FDA with regulatory authority over food and as part of that, bottled water that is introduced into interstate commerce. Under the Food, Drug, and Cosmetic Act, manufacturers are responsible for producing safe, wholesome and truthfully labeled food products. It is a violation of the law to introduce into interstate commerce adulterated or misbranded products.

FDA has established specific regulations for bottled water in the Code of Federal Regulations. These regulations include standard identity regulations that define different types of bottled water such as spring water versus mineral water and standard quality regulations that establish allowable levels for chemical, physical, microbial and radiological contaminants. FDA has established Good Manufacturing Practice regulations for the processing and bottling of bottled drinking water. Labeling and GMP regulations for foods in general also apply to bottled water. Federal law requires FDA to set similar standards for bottled water as exist for municipal water or explain why they should not apply. FDA has established such standards for more than 90 contaminants and in some cases such as for lead or copper, the FDA limits are stricter for bottled water than for municipal water. And another point to make in this regard is that the way that the testing is done is different. For example, take the lead standard. Any test that is high is violative when that is done on FDA-regulated bottled water; for the municipal water only a percentage of the samples is above a certain level. The municipal water supply failed that. So they are allowed to have certain failures and not have it as a failure for the municipal water supply. So it just illustrates that there is a different approach that is taken in a few contexts.

FDA monitors and inspects bottled water products and processing plants as part of the general food safety program. Inspections occur approximately once every 1 to 3 years. The agency inspects violative firms more frequently, depending on the number, significance and recurrence of violations. FDA's field offices follow

up on consumer and trade complaints and other leads on potentially violative bottled water products. As for other types of food, FDA periodically collects and analyzes samples of bottled water. Samples of foreign bottled water offered for entry may be collected and tested to determine if they are in compliance with the laws and regulations, and labs may test the water for microbial, radiological or chemical contamination.

In recent years, FDA has promulgated a number of quality standards for bottled water in conjunction with EPA. Most recently, on May 29, 2009, FDA published a final rule to require that bottled water manufacturers test source water and finished bottled water products for total coliform organisms and to prohibit distribution of products containing any *E. coli*, an indicator of fecal contamination. FDA is also requiring that before a bottler can use source water from a source that has tested positive for *E. coli*, the bottler must take appropriate measures to rectify or eliminate the cause of the problem, and the bottler must keep records of such actions.

In general, FDA's oversight of bottled water, I think can be described as successful. The agency is aware of no major outbreaks of illness or serious safety concerns associated with bottled water over the past decade. FDA is aware the GAO report released today highlights a number of issues that the agency faces in regulating bottled water. FDA has worked with GAO to provide information and assist with their investigation.

Let me address some of the issues that GAO has raised, and let me say that while I do believe that FDA's oversight has been generally successful, I also believe that there is room for improvement. First, GAO found that FDA has not yet set a standard for the phthalate known as DEHP. This was contemplated in 1996 but the Administration at the time did not pursue this because of a legal issue we could discuss further if you want known as prior sanction. We are now revisiting this decision and intend to pursue a DEHP standard as anticipated under the law.

Second, GAO found that FDA labeling regulations for bottled water provided for less information about the sources and quality of water than required by FDA for municipal systems. FDA has found that it would be feasible for manufacturers of bottled water to provide such information to consumers. However, the Food, Drug and Cosmetic Act does not provide a mechanism to require bottlers to make that information available so Congress would have to take additional action.

Third, GAO expressed concern that FDA cannot require the submission of results to the agency on tests conducted by bottled water manufacturers. This is a fair point and a part of the oversight of water and food in general that should be strengthened. In fact, it would be strengthened by the food safety legislation that the committee is showing so much leadership on.

Fourth, GAO has pointed out that FDA does not have specific authority to mandate the use of certified laboratories. This is also a reasonable point, and FDA does require the use of methods that are at least as sensitive as FDA's methods but the food safety legislation passed by the committee would also be extremely helpful here.

I would also mention that the food safety legislation provides for food safety plans, hazard analyzes and preventive controls that will complement FDA's Good Manufacturing Practices for bottled water facilities and generally strengthen the system of oversight for bottled water, and for foreign-produced bottled water, the Act would require importers to register with FDA, comply with Good Importer Practices and give FDA the authority to require certification as a condition of importation.

So we will continue to work with this committee on the legislation, which we think is very important, and I am pleased to be here and look forward to your questions.

[The prepared statement of Dr. Sharfstein follows:]



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Testimony of
Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner of Food and Drugs
Food and Drug Administration

Hearing on
Regulation of Bottled Water

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives

July 8, 2009

Release Only Upon Delivery

Good morning Mr. Chairman and Members of the Subcommittee. I am Joshua Sharfstein, Principal Deputy Commissioner of Food and Drugs at the Food and Drug Administration, which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to discuss with you today the regulation of bottled water.

Bottled water is an increasingly popular beverage. According to the Beverage Marketing Corporation, the amount of bottled water consumed in the United States has doubled over the past 10 years. Specifically, between 1998 and 2008, the average per capita consumption of bottled water has increased from 14.7 to 28.5 gallons.

A possible indicator of bottled water's popularity is the volume of questions about bottled water coming into the Food and Drug Administration's (FDA or the Agency) regulatory and consumer information staff. People frequently contact us to ask questions such as: Who regulates bottled water? How is it regulated? Is bottled water tested and inspected? My testimony will summarize FDA's approach to regulating bottled water. I will cover such topics as our legal authority to regulate bottled water, what regulations and guidance are in place, and inspections.

FDA REGULATION OF BOTTLED WATER

In the United States, bottled water and tap water are regulated by two different agencies: FDA regulates bottled water and the Environmental Protection Agency (EPA) regulates tap water, also referred to as municipal water or public drinking water. EPA's Office of Ground Water and Drinking Water has issued extensive regulations on the production, distribution and quality of

public drinking water, including regulations on source water protection, operation of drinking water systems, contaminant levels, and reporting requirements.

Under our statutory authority, FDA regulates bottled water as a food. The Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) provides FDA with broad regulatory authority over food that is introduced or delivered into interstate commerce. Under the FD&C Act, manufacturers are responsible for producing safe, wholesome and truthfully 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 Act.

FDA has established specific regulations for bottled water in Title 21 of the *Code of Federal Regulations* (21 CFR). These regulations include standard of identity regulations in 21 CFR § 165.110(a), that define different types of bottled water, such as spring water and mineral water, and standard of quality regulations in 21 CFR § 165.110(b), that establish allowable levels for chemical, physical, microbial and radiological contaminants in bottled water. FDA also has established current Good Manufacturing Practice (cGMP) regulations for the processing and bottling of bottled drinking water in 21 CFR part 129. Labeling regulations (21 CFR part 101) and cGMP regulations (21 CFR part 110) for foods in general also apply to bottled water.

Current Good Manufacturing Practice Regulations -- 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 ensure 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.

Standard of Identity Regulations -- Under the standards of identity regulation at 21 CFR 165.110(a), FDA defines bottled water as water that is intended for human consumption and that is sealed in bottles or other containers, with no added ingredients except that it may contain safe and suitable antimicrobial agents. Fluoride also may be added within the limits set by FDA. The name of the food is "bottled water" or "drinking water." FDA also has defined various other types of bottled water, such as "artesian water," "artesian well water," "ground water," "mineral water," "purified water," "sparkling bottled water," and "spring water."

Bottled water labeled with any of these terms must meet the appropriate definitions under the standard of identity or it will be considered misbranded under the FD&C Act. For example, a bottle labeled as containing "mineral water" must meet the following criteria, among others: the water must contain no less than 250 parts per million (ppm) total dissolved solids; it must come from a geologically and physically protected underground water source; and it must contain no added minerals. "Mineral water" also must have a constant level and relative proportions of minerals and trace elements at the point of emergence from the source, with due account being taken of natural fluctuation cycles. FDA established its definitions for different types of bottled water in 1995. These preempted state definitions existing at that time, some of which varied

from state to state. We have provided, in an appendix to our testimony, a table which provides several of these definitions.

Standard of Quality Regulations -- Under the standard of quality regulation at 21 CFR 165.110(b), FDA establishes allowable levels for contaminants in bottled water. There are microbiological standards that set allowable coliform levels; physical standards that set allowable levels for turbidity, color and odor; and radiological standards that set levels for radium-226 and radium-228 activity, alpha-particle activity, beta particle and photon radioactivity, and uranium. The standard of quality also includes allowable levels for more than 70 different chemical contaminants.

Section 165.110(b) also lists methods that FDA will use to determine whether bottled water samples comply with the quality standard. Bottlers are not required to use these methods in their own facilities; alternate methods are acceptable. Whatever method they use, bottlers are responsible for ensuring that their bottled water can pass the tests used by FDA in its own laboratories, should testing be performed by FDA.

What happens if bottled water contains a substance at a level greater than that allowed under the quality standard? Section 165.110(c) states that when the microbiological, physical, chemical or radiological quality of bottled water is below that prescribed in the quality standard, the label of the bottled water bottle must contain a statement of substandard quality such as "Contains Excessive Bromate," "Contains Excessive Bacteria," or "Excessively Radioactive." Such labels solely indicate to the consumer that a quality standard has not been met. We are not aware of

firms that currently are availing themselves of their option to use such a disclaimer on the label. Even if such a labeling statement is used, labels cannot be used to ameliorate food safety deficiencies. Regardless of whether bottled water bears a statement of substandard quality, it is considered adulterated if it contains a substance at a level considered injurious to health under section 402(a)(1) of the FD&C Act.

Another noteworthy point about section 165.110 is that it allows for the use of safe and suitable antimicrobial agents such as ozone. FDA does not specifically require that bottlers use antimicrobial agents in bottled water as long as the water is safe for human consumption.

Inspection of Bottled Water Plants

FDA monitors and inspects bottled water products and processing plants as part of its general food safety program. Because FDA's experience over the years has shown that bottled water has a good safety record, bottled water plants generally are assigned a relatively low priority for inspection. The Agency, however, inspects violative firms more frequently, depending on the number, significance and recurrence of violations. In addition, FDA's field offices follow up on consumer and trade complaints and other leads, as appropriate, on potentially violative bottled water products.

In Fiscal Years (FY) 2007 and 2008, FDA and state agencies under contract to FDA conducted 412 and 468 inspections of bottled water facilities, respectively. In the first nine months of FY 2009, FDA and state contract agencies have conducted 253 inspections.

Information about what FDA inspectors look for during inspections generally is found in the Investigations Operations Manual published by FDA's Office of Regulatory Affairs (ORA), and more detailed information about inspections of bottled water facilities is found in the Guide to Inspections of Manufacturers of Miscellaneous Food Products, Volume II. Specific items mentioned in the inspection guide for 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 any source claims on the label comply with the definitions in 21 CFR 165.110(a); 3) inspecting washing and sanitizing procedures; 4) inspecting the filling, capping, and sealing operations; and 5) determining whether the firms analyze their source water and product water for the chemical and microbiological contaminants listed in 21 CFR 165.110(b), according to the required schedules.

Sampling and Testing

As with other types of food, FDA periodically collects and analyzes samples of bottled water. Samples come from several different sources. Some samples are collected during inspections if the inspector's observations warrant collection to test for contaminants or if the bottled water facility has a previous history of contamination. Other samples are collected in response to trade or consumer complaints. Finally, samples of foreign bottled water products offered for entry into the United States may be collected and tested to determine if they are in compliance with all applicable U.S. laws and FDA 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 the reason for the sampling. For example, suspected microbiological contamination may result in microbiological analysis. (However, as noted, bottlers are required to maintain testing records to show to government inspectors for all the contaminants in the quality standard.) FDA also may review the labeling on bottled water samples.

State and Local Regulations

In addition to FDA, state and local governments also regulate bottled water. FDA relies on state and local government agencies to approve water sources for safety and sanitary quality, as specified in part 129.3(a). The International Bottled Water Association (IBWA) also has developed a model code of regulations that its members must follow.

Developing New FDA Regulations

It is important to note that under section 410 of the FD&C Act, FDA must follow specific instructions on establishing quality standard regulations for bottled water in response to regulatory developments at EPA concerning public drinking water.

Under section 410, when EPA establishes new maximum contaminant levels (MCL) or treatment techniques for contaminants in public drinking water as part of a National Primary Drinking Water Regulation (NPDWR), FDA is required to establish a standard of quality regulation for the same contaminants in bottled water, or to make a finding that such a regulation is not necessary to protect the public health because the contaminant is not present in water used for bottled drinking water. For treatment techniques, section 410 requires that bottled water be

subject to requirements no less protective of the public health than those applicable to water from public water systems using the techniques required by EPA's NPDWRs. If FDA adopts an allowable level under the quality standard regulations, the level in bottled water must be no less stringent than EPA's MCL for drinking water; FDA's regulation must have the same effective date as EPA's regulation and be published no later than 180 days before the effective date.

FDA has generally adopted EPA's MCLs for contaminants in public drinking water as allowable levels for the same contaminants in the quality standard regulations for bottled water. However, in some cases, FDA standards for bottled water differ from EPA standards for public drinking water. Lead is an example. In 1991, EPA adopted a requirement that public water systems treat their water to reduce lead when lead levels consistently exceed 15 parts per billion (ppb). The 15 ppb level took into account the fact that lead appears in public drinking water from corrosion of public water distribution systems and residential plumbing. However, leaching of lead from distribution systems is not a factor for bottled water and, based on its survey data, FDA concluded that bottlers can readily produce bottled water products with lead levels below 5 ppb. In 1994, FDA adopted an allowable level for lead at 5 ppb as a bottled water quality standard regulation. This action was consistent with FDA's goal of reducing consumers' exposure to lead in drinking water to the extent practicable.

Recent Regulatory Activities

In recent years, FDA has promulgated a number of quality standard regulations for bottled water in response to EPA regulatory activity. In March 2001, FDA adopted EPA's MCLs and maximum residual disinfectant levels (MRDL) for four disinfection byproducts (bromate,

chlorite, haloacetic acids and total trihalomethanes) and for three disinfectants (chloramine, chlorine and chlorine dioxide), respectively, as allowable levels in its standard of quality regulations for bottled water, with the same effective date as that for EPA's regulations for the same contaminants in public drinking water.

In March 2003, FDA issued a final rule that amended its quality standard for bottled water by adopting EPA's MCL for uranium public drinking water as the allowable level for the same contaminant in bottled water.

In June 2005, FDA issued a final rule that amended its bottled water quality standard regulations by revising the existing allowable level for the contaminant arsenic. The revised allowable level for arsenic in bottled water is the same as EPA's MCL for arsenic in public drinking water.

This year, on May 29, 2009, FDA published a final rule in the *Federal Register* (74 FR 25664), to require that bottled water manufacturers test source water for total coliform, and to require, if any coliform organisms are detected, that bottled water manufacturers determine whether any of the coliform organisms are *Escherichia coli* (*E. coli*), an indicator of fecal contamination. FDA's final rule also amends its bottled water regulations to require, if any coliform organisms are detected in finished bottled water products, that bottled water manufacturers determine whether any of the coliform organisms are *E. coli*.

Bottled water containing *E. coli* will be considered adulterated, and source water containing *E. coli* will not be considered to be of a safe, sanitary quality and will be prohibited from use in the

production of bottled water. FDA is also requiring that, before a bottler can use source water from a source that has tested positive for *E. coli*, the bottler must take appropriate measures to rectify or eliminate the cause of *E. coli* contamination of that source, and that the bottler must keep records of such actions. Existing regulatory provisions require bottled water manufacturers to keep records of new testing required by this rule. The rule is effective on December 1 of this year.

ISSUES REGARDING FDA'S REGULATION OF BOTTLED WATER

General Accountability Office (GAO) Report

FDA has worked with GAO to provide information and assist with their investigation into bottled water regulation, and we have provided responses to their draft report. FDA is aware that the forthcoming GAO report highlights a number of challenges that the Agency faces in regulating bottled water.

While FDA has not seen the final version of the report, we understand that key concerns include that FDA currently does not have the ability to require the submission to the Agency of results from the testing conducted by and on behalf of bottled water manufacturers, and that FDA does not have specific authority to mandate the use of certified laboratories. These concerns are at least partially addressed by recent and pending legislation, as we discuss later below.

While GAO found FDA's standard of quality regulations generally equivalent to EPA regulations, it noted that FDA has not yet set a standard for di(2-ethylhexyl)phthalate (DEHP).

GAO also found that FDA labeling regulations for bottled water provided for less information about the sources and quality of water than that required by EPA for municipal systems. On these two issues, we understand that GAO will recommend that the Secretary of HHS direct the Commissioner of FDA to:

- Issue a standard of quality regulation for DEHP or publish in the *Federal Register* the Agency's reasons for not doing so within 180 days of the conclusion of its task force study on the issue.
- Implement FDA's findings on methods that are feasible for conveying information about bottled water to customers, such as, at a minimum, requiring that companies provide on the label contact information directing customers how to obtain comprehensive information. Should FDA determine it lacks the necessary authority to implement its findings, it should seek legislation to obtain such authority.

DEHP

In the case of DEHP, FDA proposed in a 1993 *Federal Register* notice to adopt EPA's maximum contaminant level for this chemical in tap water as the allowable level in the bottled water quality standard regulations. A comment to this proposal pointed out that this chemical is permitted under the FD&C Act for use in certain types of food containers and closures. The comment raised the concern that lawful uses might result in levels of DEHP that would exceed the allowable level. Therefore, FDA's final rule published on March 26, 1996, stated that the Agency was deferring final action on the proposed allowable level for DEHP in bottled water.

FDA agrees with GAO that it should make a decision regarding establishing a level for DEHP in bottled water. At this time, therefore, FDA has decided to move forward on making such a decision and has begun the decision making process.

Bottled Water Feasibility Study on Additional Disclosures to Consumers

Under the Safe Drinking Water Act Amendments of 1996, section 114(b), FDA was required to publish for notice and comment a study on the feasibility of appropriate methods of informing consumers about the contents of bottled water. FDA published a notice requesting comments on this issue in November 1997 and a draft feasibility study in February 2000. Based on these comments, FDA published a final study report on August 25, 2000 (65 FR 51833). The final study report evaluates information received from the comments and identifies appropriate and feasible methods for conveying information about the contents of bottled water to consumers. FDA believes it is feasible for bottled water manufacturers to provide consumers with additional information on bottled water comparable to the data provided by municipal water systems. However, the FD&C Act does not provide FDA with the authority to require bottled water manufactures to disclose such information.

Food Safety Enhancement Act (FSEA)

FDA believes that the legislation currently being developed by the Energy and Commerce Committee takes some positive steps in providing additional authority that will help to fill some of the gaps identified by GAO. Specifically, section 102 provides for food safety plans, hazard analyses and preventative controls that will complement FDA's cGMPs for bottled water facilities. For foreign-produced bottled water, FSEA requires importers to register with FDA

and to comply with good importer practices, and gives FDA the authority to require certification as a condition of importation, in certain instances.

FSEA also provides FDA with the authority to establish science-based performance standards in section 103, routine access to records (section 106), and stronger criminal and civil penalties for violations of the FD&C Act (sections 134 and 135).

Finally, we note that upon implementation of the Reportable Food Registry provisions of the Food and Drug Administration Amendments Act of 2007 (PL 110-85), which FDA anticipates in early fall, bottlers will be required to report the results of tests showing that products in commerce pose a threat of serious adverse health consequences or death.

CONCLUSION

FDA regulates bottled water as a food under the FD&C Act and is responsible for ensuring that bottled water is safe and truthfully labeled. Specific FDA regulations for bottled water cover cGMPs for bottled water production and standards of identity and quality. Recent regulatory activity includes adoption of maximum allowable levels for critical contaminants, including certain disinfectants and disinfection byproducts, uranium, arsenic, and the adoption of testing and remediation requirements for the prevention of *E.coli* contamination.

FDA will carefully consider the conclusions of the GAO report and factor their findings into our future regulatory decisions. We will also continue to work with the Committee in your efforts to craft a bill that enhances food safety.

Thank you for the opportunity to testify.

APPENDIX

Table 1. Various types of bottled water.	
TYPE	DEFINITION
Artesian Water	Water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer.
Mineral Water	Water containing not less than 250 ppm total dissolved solids that originates from a geologically and physically protected underground water source. Mineral water is characterized by constant levels and relative proportions of minerals and trace elements at the source. No minerals may be added to mineral water.
Purified Water	Water that is produced by distillation, deionization, reverse osmosis or other suitable processes and that meets the definition of "purified water" in the U.S. Pharmacopeia, 23d Revision, Jan. 1, 1995. As appropriate, also may be called "demineralized water," "deionized water," "distilled water," and "reverse osmosis water."
Sparkling Bottled Water	Water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at emergence from the source.
Spring Water	Water derived from an underground formation from which water flows naturally to the surface of the earth at an identified location. Spring water may be collected at the spring or through a bore hole tapping the underground formation feeding the spring, but there are additional requirements for use of a bore hole.
(FOR COMPLETE REGULATORY DEFINITIONS, SEE 21 CFR 165.110(A)(2).)	

Mr. STUPAK. Thank you, Doctor.
Ms. Houlihan, would you pull that mic over.

TESTIMONY OF JANE HOULIHAN

Ms. HOULIHAN. Mr. Chairman and members of the subcommittee, I am Jane Houlihan, senior vice president for research at Environmental Working Group. We are a nonprofit research and advocacy organization in Washington, D.C. Thank you for holding this hearing.

Today we are releasing an 18-month survey of labels and Web sites for 188 bottled waters. Here is what we found. Consumers spent about 1,900 times more for bottled water than for tap water yet they often have no way to learn essential facts about what is actually in the bottle. Only two of 188 bottled waters make public three basic facts routinely disclosed by local tap water utilities. These are the specific name and location of the water source, purification methods and chemical pollutants that remain in the water after treatment. These two brands are Ozarka Drinking Water and Penta Ultra-Purified Water, the only two of 188 doing so.

Bottled water companies are not required to make these basic facts public, and here is the reason: they enjoy a regulatory holiday under the federal Food, Drug and Cosmetic Act with near-complete latitude on what, if any, information to share with consumers. In contrast, every one of the Nation's 52,000 municipal water suppliers produces an annual water quality report giving its water source and pollutant testing results as required under the Safe Drinking Water Act. EPA calls these reports the centerpiece of consumers' right to know about water quality.

This double standard is unfair to consumers who have a right to know what is in the water they buy. Surveys show that over half of bottled water drinkers choose it because they are worried about the safety of their tap water. They believe it is free of contaminants. They do it for their health. But in too many cases, consumers have no way to check if the purity they are looking for is what they are actually getting.

So where does the water come from? Our survey found that 30 percent of bottled waters provide no information whatsoever about their water source on the label but 37 percent fully divulge both the name and location of their water source, and the remaining 33 percent give generic information like spring or deep aquifer. If you could look at figure 1 in your packet, please, this is a brand that is doing the right thing. It is Great Value. It is called in your figure a smaller brand. It is not in the top 10 but it is actually distributed by Walmart. You will see on the label the source clearly indicated as municipal supply, Fort Worth, Texas, so you know exactly where this water comes from. You will also see the treatment method on this label, reverse osmosis. Let us look at the next figure by way of contrast. On the other end of the spectrum is Dasani. On this label, you will see that the product is pure and it is crisp and it has a fresh taste but nowhere on this label will you find the source of that water. Dasani is one of 30 percent of the brands not giving any information on source along with Whole Foods, Food Lion, CVS, Kroger store brands and many other brands.

How is bottled water purified? Bottled water companies are not required to disclose what, if any, methods they use to purify their water. Municipal water suppliers aren't required to disclose this information either but most of them do. We found that 44 percent of bottled waters provide no treatment information on labels. One-third provide no information on labels or Web sites.

If you look at figure 2 in your packet, you will see a label for Ozarka. This is a Nestle brand that is actually doing the right thing. You will see on this label the water comes from the Houston municipal water supply, but it doesn't stop there. It is further treated by reverse osmosis, carbon filtration, microfiltration and ozonation. Now, for contrast, let me read to you what you will see on a Fiji label. "The purest water comes from the purest clouds. Our rainfall is purified by trade winds as it travels across the Pacific Ocean to the islands of Fiji," and that is all the information you will see on treatment on that label, and Fiji is one of the 60 percent of bottled waters that print marketing claims of purity from among those waters that don't label their treatment methods. Consumers have no way to know if the claims are true.

What pollutants are in bottled water? Every tap water utility publishes an annual water quality report listing all their results for the year but only 18 percent of bottled waters do the same. Those that do include all eight domestic Nestle brands. Those that don't include Aquafina, which is a Pepsi brand, and figure 3 of your packet. Without data, consumers are left with marketing claims, and these are extensive. You have heard Poland Springs, a man who lived 52 additional years after drinking the water. Mountain Valley Springs became known as a remedy for the treatment of gout, rheumatism and other diseases. Evian claims its water is a symbol of health, general well-being. Valdix water is extremely pure but they don't publish a test report. And finally, Aquamantra's water resonates with the energy and frequency of well-being. When you pay a premium price for bottled water, you deserve more than just claims. We recommend that bottled water labels and Web sites disclose the same information that the law requires of municipal water utilities and that this disclosure be mandatory. Consumers have a right to know where their bottled water comes from, how or if it is treated and the pollutants it contains.

Thank you for your time.

[The prepared statement of Ms. Houlihan follows:]

Testimony of Jane Houlihan, MSCE
Senior Vice President for Research
Environmental Working Group

Before the

SUBCOMMITTEE ON OVERSIGHT & INVESTIGATIONS
COMMITTEE ON ENERGY & COMMERCE
U.S. HOUSE OF REPRESENTATIVES

On

“The Regulation of Bottled Water”

Wednesday, July 8, 2009
Rayburn 2322, 10 a.m

Mr. Chairman and distinguished Members of the Subcommittee: My name is Jane Houlihan, and I am the Senior Vice President for Research at Environmental Working Group (EWG), a nonprofit research and advocacy organization based in Washington, DC, Ames, Iowa, and Oakland, California. I thank the members of the subcommittee for holding this important hearing and for the opportunity to testify.

Today, EWG is releasing our 18-month survey of bottled water labels and websites, including top domestic and imported brands. This is what we've found: consumers spend 1,900 times more for bottled water than for tap water, yet they rarely know basic information about exactly what's in their water bottle.

Our survey shows that far too often consumers have no simple way to learn three essential facts: 1) where their bottled water comes from, 2) how or if it's treated, and 3) what chemical pollutants it contains.

We analyzed labels and websites from 188 bottled water brands to learn which bottlers voluntarily disclose the same information required of community water suppliers. We found that many choose to disclose no information at all to their customers on water source and purity. Instead, they simply make claims of purity and health benefits not backed by public data.

We also found:

- Just 2 of 188 bottled waters – Ozarka Drinking Water and Penta Ultra-Purified Water – list specific water sources and treatment methods on their labels, and offer a recent water quality test report on their websites.
- Many large bottled water brands obscure basic data about their products. None of the top 10 U.S. domestic bottled water brands (BMC 2007) label both their specific water source and treatment method for all their products. Yet some of these brands claim their products are

*Testimony – Jane Houlihan
 “The Regulation of Bottled Water”
 July 8, 2009
 page 2 of 5*

"pure," "crisp," and "perfect." These claims are potentially misleading and imply an absence of contamination not possible for the drinking water industry to achieve.

- 100% of community tap water systems publish water quality test results annually. Only 18% of bottled waters do the same, publishing on their websites current bottled water quality reports, including contaminant testing results, for each of their products.¹

1. Consumers have a right to know where their bottled water comes from.

Unlike community tap water suppliers, bottled water companies enjoy a regulatory holiday from FDA. This double standard is unfair to consumers, who have a right to know what's in the water bottle they buy. Bottled water brands are not required to disclose the source of their water or the results of water quality testing. In contrast, all 52,000 community tap water suppliers nationwide produce an annual water quality report detailing for all their customers both their water source and their pollutant testing results, as required under the federal Safe Drinking Water Act. An estimated 58% of these reports also describe water treatment methods.

The Environmental Protection Agency (EPA) considers mandatory annual tap water quality reports to be "the centerpiece of the right-to-know provisions in the 1996 Amendments to the Safe Drinking Water Act." Both EPA and the states have authority to take enforcement action against water systems that fail to comply with the reporting requirements "to ensure that consumers' right-to-know is respected by all water suppliers" (EPA 2006).

Federal law requires community tap water suppliers to publish the name and location of their water sources. Bottled water companies are not required to do the same. Companies that package water from a municipal treatment plant without further purifying it must label the water as "from a community water system" or, alternatively, "from a municipal source." Because most water bottlers conduct some additional treatment, they escape this regulation. In those cases they can use terms such as "purified," "deionized" or "distilled" on the label — which often mean little to consumers. The bottom line is that the FDA does not require clear source identification on bottled water labels. Consumers need much more.

We investigated whether or not bottled waters are choosing to label where their water comes from. We found that 37% of bottled waters fully divulge the name and location of their water source, while 30% provide no information whatsoever. The remaining 33% give generic information like "spring" or "deep pristine crystalline rock aquifer."

Community water systems must report to their customers any potential sources of pollution the water sources. Bottled water companies don't. Instead of referencing a rigorous assessment, Fiji claims its Natural Artesian Water is "untouched by man" and "far from pollution."

Without basic data on bottled waters, consumers are forced to rely on marketing claims to inform their purchases. Labels from some brands with undisclosed, mysterious sources claim the water is "essential," "pure" or "crystal-fresh." Possibly, but consumers may just be paying for tap water.

¹ Bottled waters that publish test results include Poland Spring, Nestlé Pure Life, Arrowhead Mountain Spring Water and Perrier. Products that don't include Culligan Purified Drinking Water, Refreshe Purified Drinking Water and Giant Acadia Filtered Drinking Water.

Testimony – Jane Houlihan
"The Regulation of Bottled Water"
 July 8, 2009
 page 3 of 5

2. Consumers have a right to know how their bottled water is treated.

The government does not require bottled water companies to disclose the methods used to purify their water, or even to state if their water has been treated in any way. While community water suppliers are not required to disclose treatment methods to their customers, they often do. Our survey of 2008 annual water quality reports found that 58% of 55 water utilities from 48 states and Washington D.C. told their customers how they treat the water. FDA regulations allow water bottlers to label their products with ambiguous descriptions such as "purified water" or "demineralized water," as long as they treat the water with a "suitable process" (FDA 2008a).

Unfortunately for consumers, the regulations fall short of requiring companies to disclose exactly what (if any) treatment processes they employ. This matters, because not all treatment methods are equal. Consumers need to know which ones are used to make informed decisions about their drinking water. Disclosing treatment methods is critical for bottled water companies, because people who buy their products may believe that the water is purer than tap water. But 33% of bottled waters we surveyed provide no information on labels or websites about how or if the water is treated; 44% provide no treatment information on labels.

The popular bottled water brand Fiji takes a creative approach to disclosure, claiming that the rainfall replenishing its aquifer is "purified by equatorial winds." But in 2005, lab tests commissioned by The Boston Globe in 2005 found "unusually high levels" of bacteria in Fiji water (Boston Globe, 2005). Furthermore, EWG's label research show that among bottled waters that fail to print water treatment information on labels, 60% instead print marketing claims of purity, using words like "pristine source." Consumers have no way to know if the claims are true.

3. Consumers have a right to know what pollutants are in their bottled water.

Four of every 5 bottled waters do not publish results of water quality testing. For these waters, consumers have no way to know the range and levels of pollutants found in the water. According to FDA requirements, bottled water companies are required to test their source water once a year for chemical contaminants, at a minimum, and once every 4 years for radiological contaminants. Waters taken from non-public water sources must be tested at least once a week for microbiological contamination (FDA 2008b).

While tap water suppliers are required to disclose water quality testing results to their consumers, the FDA only requires that bottlers maintain testing *records* to show government inspectors (FDA 2002). While some companies choose to make water quality test results available to the public, this disclosure is voluntary. Many choose to withhold this information. Nor are bottled water companies required to disclose the potential health effects or likely sources of any contaminants detected above health-based limits, as community water systems are required to do.

Few water sources are completely free of detectable contaminants. An estimated 25% of bottled water brands that rely on tap water (NRDC 1999) are drawing from supplies that collectively contain at least 260 pollutants, according to EWG's 2002-2005 survey of tap water testing conducted by community water supplies (EWG 2005).

4. Many bottled water labels' health claims and claims of purity are potentially misleading.

Test results for bottled water may be lacking, but claims of purity abound. Some companies indulge in superlatives. Volvic, for example, claims that its products are "extremely pure and distinctly

*Testimony – Jane Houlihan
"The Regulation of Bottled Water"
July 8, 2009
page 4 of 5*

different" (Volvic 2009). Ice Mountain Natural Spring Waters goes even further, claiming that its waters are "pure as the driven snow" (Nestlé 2009). The website of Aquamantra Natural Spring Water wins the prize for original claims, however, stating that its water "resonates with the energy and frequency of well-being." According to Aquamantra, the quality of the drinker's thoughts determines the quality of the water; therefore, the company writes affirmative mantras on the bottles. Aquamantra asserts that these mantras "actually change the molecular structure of the water, and most definitely changes the flavor of the water" (Aquamantra 2009). Perhaps the assertions are true, but without federal standards to regulate claims and require disclosure, buyers should beware.

RECOMMENDATIONS

To eliminate the imbalance between tap water and bottled water and to give consumers more information about what they're drinking, EWG recommends that bottled water companies disclose to consumers on labels and websites the same information that tap water companies are required by law to provide. And we recommend that government officials make this disclosure mandatory.

Bottled water companies should:

- Provide easy-to-access water quality reports disclosing all test results.
- List on the label treatment methods used to purify the water; and clear, specific information on the water source and location.
- Test for unregulated chemicals that may leach from plastic bottles.

In conclusion, EWG strongly believes that the public has the right to know where its bottled water comes from, how or if it's treated, and what chemical contaminants the water contains.

Thank you for your time. I welcome the opportunity to answer any questions you may have.

Attachments

Figures
Report: Bottled Water Scorecard

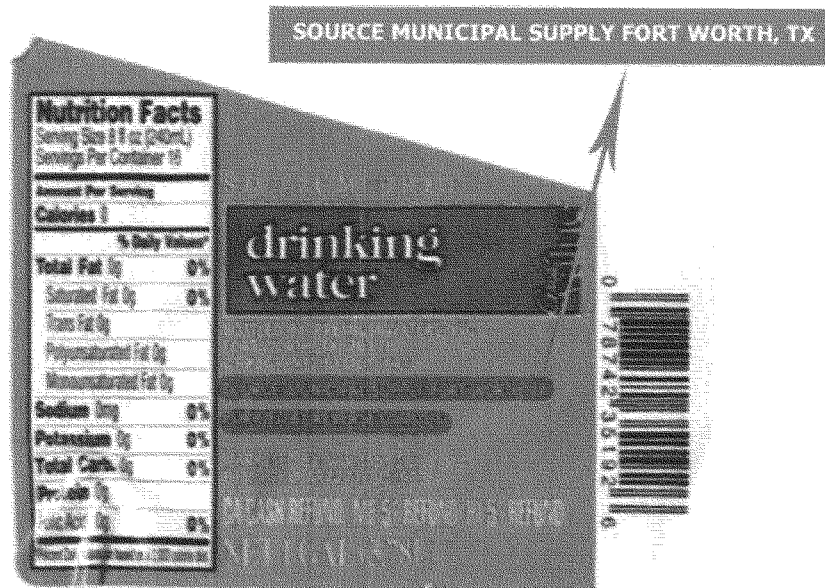
*Testimony – Jane Houlihan
 “The Regulation of Bottled Water”
 July 8, 2009
 page 5 of 5*

References

- Aquamantra. 2009. Aquamantra. Stimulate Your Soul. Available: http://aquamantra.com/site.php/spgs/read/taste_the_difference [accessed July 5 2009].
- BMC (Beverage Marketing Corporation). 2007. Bottled Water in the U.S. 2007 Edition. Available: <http://www.beveragemarketing.com>.
- Boston Globe. 2005. Water wars: In the final analysis, the price is all that separates them. Available: http://www.boston.com/business/articles/2005/09/18/water_wars/ [accessed June 23 2009].
- EPA (U.S. Environmental Protection Agency). 2006. Consumer Confidence Reports (CCRs): Basic Information. Available: <http://www.epa.gov/OGWDW/ccr/basicinformation.html> [accessed June 23 2009].
- EWG (Environmental Working Group). 2005. National Tap Water Quality Database. Available: <http://www.ewg.org/sites/tapwater/> [accessed July 5 2009].
- FDA (U.S. Food and Drug Administration). 2002. February/March 2002 Ask the Regulators - Bottled Water Regulation and the FDA. Available: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/BottledWaterCarbonatedSoftDrinks/ucm077079.htm> [accessed June 24 2009].
- FDA (U.S. Food and Drug Administration). 2008a. CFR - Code of Federal Regulations Title 21: PART 165- Beverages. Subpart B--Requirements for Specific Standardized Beverages . Available: <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=165.110&SearchTerm=bottled%20water> [accessed June 24 2009].
- FDA (U.S. Food and Drug Administration). 2008b. CFR - Code of Federal Regulations Title 21: Part 129- Processing and Bottling of Bottled Drinking Water. Available: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=129&showFR=1> [accessed June 24 2009].
- Nestlé (Nestlé Waters North America). 2009. Ice Mountain. Available: <http://www.nestle-watersna.com/Menu/OurBrands/Ice+Mountain.htm> [accessed July 5 2009].
- NRDC (National Resources Defense Council). 1999. Bottled water. Pure drink or pure hype? Available: <http://www.nrdc.org/water/drinking/bw/exesum.asp> [accessed July 5 2009].
- Volvic. 2009. Clean taste crisp finish. Available: <http://www.volvic-na.com/> [accessed July 5 2009].
- Nestlé (Nestlé Waters North America). 2009. Ice Mountain. Available: <http://www.nestle-watersna.com/Menu/OurBrands/Ice+Mountain.htm> [accessed July 5 2009].
- Volvic. 2009. Clean taste crisp finish. Available: <http://www.volvic-na.com/> [accessed July 5 2009].

ATTACHMENT - FIGURES

Figure 1. Some smaller brands identify the exact water source on the label.



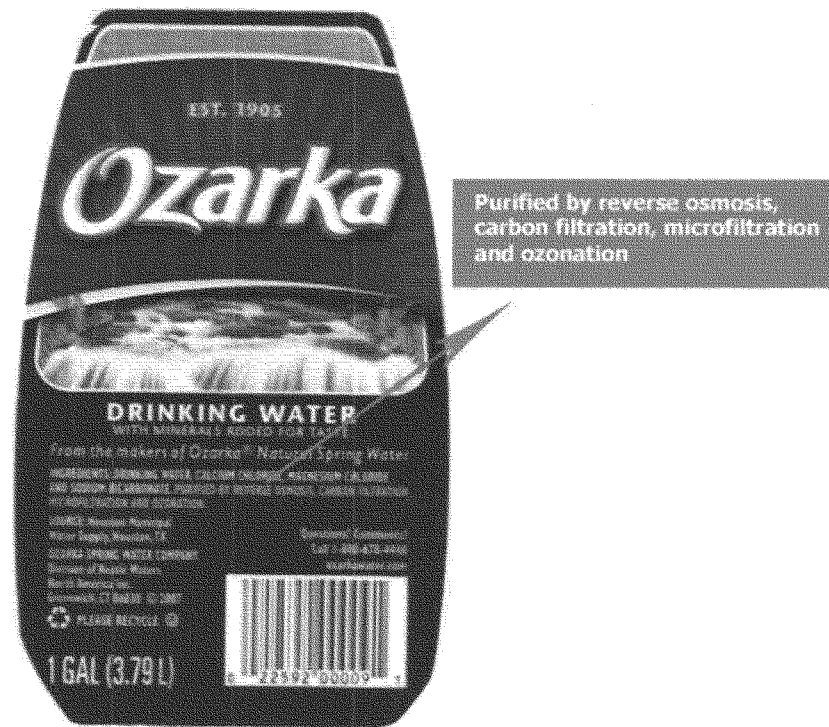
Great Value Drinking Water labels its specific source: "Municipal supply, Fort Worth, TX."

Figure 1 cont. Some large national brands do not identify the water source on the label.



Dasani label provides no information on its water source.

Figure 2. Detailed information on purification methods fits easily on the label.



Ozarka Drinking Water labels its treatment methods - "Purified by reverse osmosis, carbon filtration, microfiltration and ozonation."

Figure 3. Posting detailed test results is easy and boosts consumer confidence.



Water Analysis Report

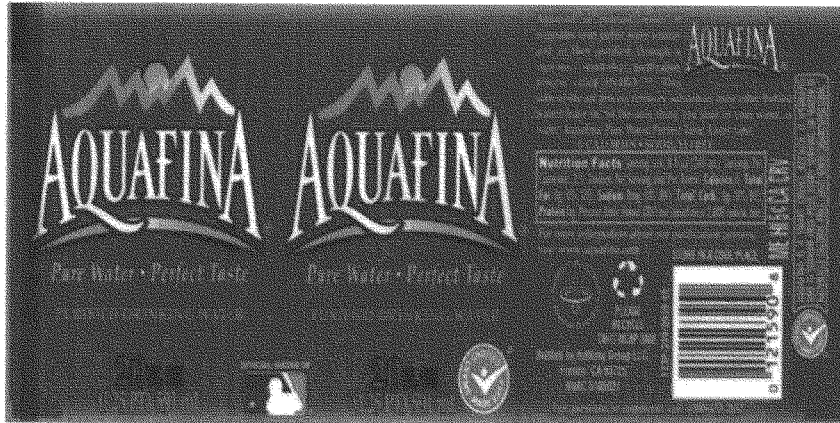
Report Date: December 2008
 Testing Period: 1st – 3rd Quarter 2008

WATER TYPE
 NESTLÉ PURE LIFE®
 PURIFIED WATER
 ENHANCED WITH MINERALS
 FOR TASTE

SUBSTANCE	MCL*	MCL**	LEVEL FOUND
Volatile Organic Compounds			
Benzene	0.0005	0.005	ND
Carbon tetrachloride	0.0005	0.005	ND
Chlorobenzene (Monochlorobenzene)	0.0005	0.100	ND
1,2-Dichlorobenzene (o-DCB)	0.0005	0.000	ND
1,4-Dichlorobenzene (p-DCB)	0.0005	0.075	ND
1,1-Dichloroethane (1,1-DCA)	0.0005	0.005	ND
1,2-Dichloroethane (1,2-DCA)	0.0005	0.005	ND
1,1-Dichloroethylene	0.0005	0.007	ND
cis-1,2-Dichloroethylene	0.0005	0.070	ND
trans-1,2-Dichloroethylene	0.0005	0.100	ND
1,2-Dichloropropane	0.0005	0.035	ND
1,3-Dichloropropane (Telomer II)	0.0005	0.0005	ND
Ethylbenzene	0.0005	0.200	ND
Methylene chloride (Dichloromethane)	0.0005	0.005	ND
Methyl-tert-Butyl-ether (MTBE)	0.002	0.015	ND
Gasoline	0.0005	0.100	ND
1,1,2,2-Tetrachloroethane	0.0005	0.001	ND
Tetrachloroethylene	0.0005	0.005	ND
Toluene	0.0005	1.000	ND
1,2,4-Trichlorobenzene	0.0005	0.070	ND
1,1,1-Trichloroethane (1,1,1-TCA)	0.0005	0.200	ND
1,1,2-Trichloroethane (1,1,2-TCA)	0.0005	0.005	ND
Trichloroethylene (TCE)	0.0005	0.005	ND
Trichlorofluoromethane (Freon 11)	0.005	0.150	ND
1,1,2-Trifluoro-1,2,2-Tetrafluoroethane (Freon 113)	0.070	1.200	ND
Trihalomethanes (THM - Total)	0.0005	0.080	ND - 0.004
Vinyl Chloride (VC)	0.0005	0.002	ND
Xylenes (Total)	0.0005	0.000	ND

Nestlé Pure Life Purified Water’s online water quality report gives test results for dozens of chemicals.

Figure 3 continued. Some national brands like Aquafina provide no information at all on contaminant testing.



Aquafina provides no water quality report on its website.

Figure 4. Some smaller brands like Sparkletts provide consumers with 1-800 numbers, most bottlers do not.

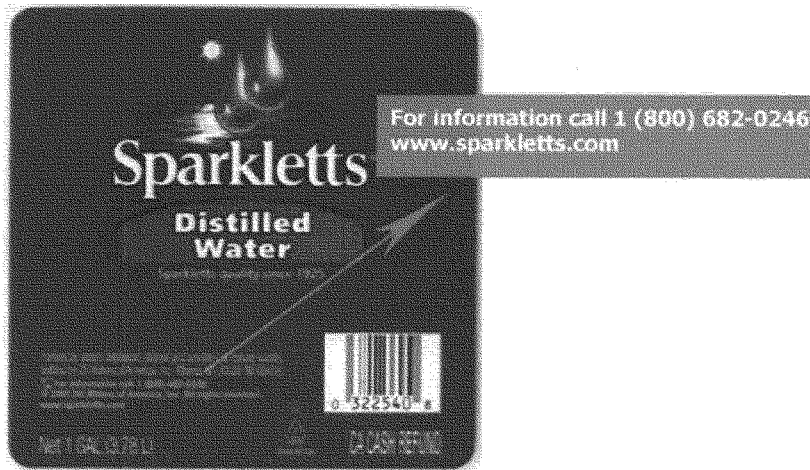
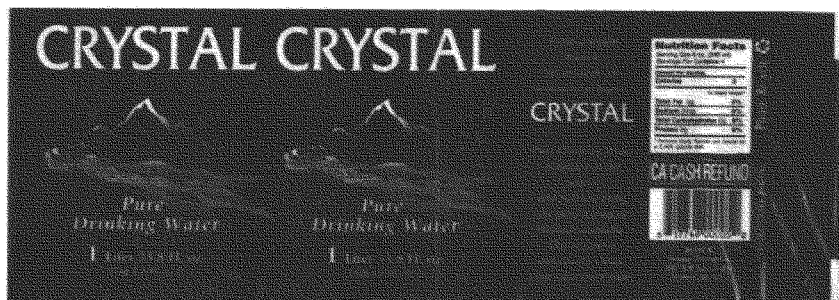
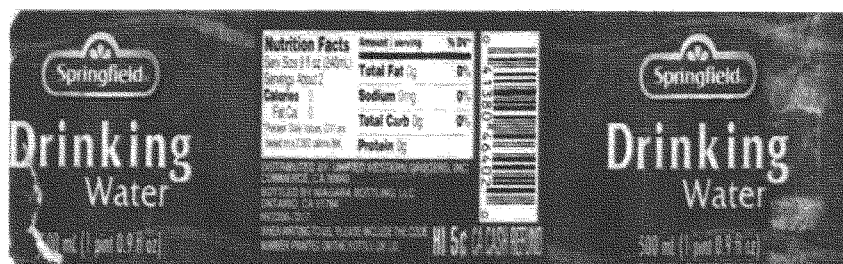


Figure 5. Some bottled water brands provide consumers with no information on water source, treatment, or testing (label or website).



Crystal Cascade Pure Drinking Water - no information on label, no website.



Springfield Drinking Water – no information on label, no website.

**ATTACHMENT
REPORT: BOTTLED WATER SCORECARD**

Bottled Water Scorecard

Bottled water brands
that treat, test and tell



By

Nneka Leiba, MPH, Environmental
Health Researcher

Renee Sharp, MS, Director, EWG
California Office

Sean Gray, MS, Senior Analyst

Jane Houlihan, MS, Senior Vice
President for Research

ENVIRONMENTAL WORKING GROUP
www.ewg.org

Washington, DC
JULY 2009

SUMMARY: Bottled water brands that treat, test, and tell

Only 2 of 188 bottled waters surveyed make public 3 basic facts about their products routinely disclosed by municipal water utilities:

- The water's source;
- Purification methods;
- Chemical pollutants remaining after treatment.

The reason: bottled water companies enjoy a regulatory holiday under the federal Food, Drug and Cosmetic Act, which grants them complete latitude to decide what, if any, information about their water is divulged to customers.

In contrast, every one of the nation's 52,000 municipal water suppliers produces an annual water quality report detailing both its water source and pollutant testing results, as required under the federal Safe Drinking Water Act. An estimated 58% of these reports also describe water treatment methods.

Environmental Working Group's 18-month survey of bottled water labels and websites, including top domestic and imported brands, has found that:

- Just 2 bottled waters – Ozarka Drinking Water and Penta Ultra-Purified Water – list specific water sources and treatment methods on their labels, and offer a recent water quality test report on their websites.
- Major bottled water brands obscure basic data about their products. None of the top 10 U.S. domestic bottled water brands label both their specific water source and treatment method for all their products.
 - Aquafina Purified Drinking Water “originates from public water sources” but fails to name them on the label. The water is treated through a process called “HydRO-7™” that is not explained on the label.
 - Arrowhead Mountain Spring Water lists springs in 6 California cities or counties as possible sources for the water we obtained, and gives no information on how or if the water is treated.
 - Crystal Geyser Natural Alpine Spring Water is bottled at “the CG Roxane Source near California’s Mount Shasta” but offers no information on treatment methods.
 - Dasani Purified Water does not name its water source on the label, but notes the water is treated through reverse osmosis.

- Deer Park Natural Spring Water lists 7 towns in Pennsylvania and Maryland as possible locations for the spring water in the bottled we obtained. No treatment method is listed.
 - Ice Mountain Natural Spring Water lists 2 springs in Michigan as possible sources on the label we assessed, and fails to describe its treatment methods.
 - Nestlé Pure Life Purified Water's label indicates that the water is drawn from either a "deep protected" Pennsylvania well or the public water supply of Allentown, PA, and is treated by either reverse osmosis or distillation.
 - Ozarka Drinking Water is drawn from the "Houston Municipal Water Supply" and treated using "reverse osmosis, carbon filtration, microfiltration and ozonation." Ozarka does not label this information on other products. Labels on Ozarka's Natural Spring Water and Aquapod Natural Spring Water list springs in 2 Texas counties as possible sources, and fail to reveal how the water is treated.
 - Poland Spring Natural Spring Water's label lists 6 towns in Maine as possible locations for its spring water and does not give treatment methods.
 - Zephyrhills Natural Spring Water lists springs in 3 Florida counties as possible sources for its water and provides no information on how or if the water is treated.
- Some of these 10 brands market their products with vague terms like "pure," "crisp," and "perfect." These claims are potentially misleading and imply an absence of contamination not possible for the drinking water industry to achieve.

Methodology

EWG launched an investigation to learn which brands of bottled water tell their customers basic information about the water—where their water comes from, how it is treated, and what contaminants it contains.

Between February and August 2008, volunteers responded to our published email and website requests, and sent to EWG's Washington DC office 163 unique bottled water labels representing 137 brands from 30 states. We created a database detailing the information listed on each brand's label and website.

On January 1, 2009 bottled water brands marketed in California began posting more label and website information required by a new state labeling law. EWG wanted to know how or if the law and the sustained pressure from consumer and public health advocates had affected labeling in other states. In May and June 2009, volunteers sent 85 unique product labels representing 76 brands from 38 states, responding to our renewed requests distributed via email and published on our website. We supplemented our database with this new information.

We graded bottled water brands on how much they tell consumers about what's in the bottle. We failed brands neglecting to provide consumers with significant information on water source, treatment and testing. We compared 2008 and 2009 labels and websites to learn how many brands are telling customers more this year than last. The answer was a heartening 52%, though in nearly every case brands provided less information than tap water suppliers give their customers.

All municipal water systems are required by law to publish water quality test results annually. Only 18% of bottled waters disclose quality reports that include contaminant testing results. Brands that provide this important information to consumers include all 8 Nestlé domestic brands surveyed (Poland Spring, Nestlé Pure Life, Arrowhead, Calistoga, Deer Park, Ice Mountain, Ozarka, and Zephyrhills).

By contrast, Culligan Purified Drinking Water, Refreshe Purified Drinking Water, Giant Acadia Filtered Drinking Water, and 151 other bottled waters offer their customers no water quality test data.

Americans account for less than 5% of the world's population but drink 16% of the bottled water. U.S. bottled water sales rose 85% between 2000 and 2007 (Rodwan 2009), driven by finely-tuned marketing that has exploited consumer anxieties about tap water pollution.

But in 2008, bottled water sales declined for the first time in the decade. This modest 1% drop, retrenching from the previous year's 6% increase in sales (Rodwan 2009), may signal consumers realizing that bottled water is not worth premium prices. Or sagging demand may reflect the struggling economy — or both.

An increasing number of studies raise concerns about plastic bottles' environmental impacts and the purity of their contents. In 2006 Americans threw 36 billion water bottles into trash cans, onto the land as litter or into recycling bins (Doss 2008). The substantial waste management challenge presented by discarded plastic water bottles is frequently in the news.

Last year EWG commissioned tests that found bottled water not necessarily any safer than tap water. Ten brands sampled by EWG contained 38 pollutants ranging from fertilizer residue to industrial solvents. Pollutants in 2 brands exceeded state and industry health standards (EWG 2008).

A number of prominent restaurants, including Del Posto in New York City and Restaurant Nora in Washington DC, now serve filtered tap water instead of bottled water. The city of San Francisco no longer allows employees to purchase bottled water for city business.

Legislation to close loopholes in bottled water standards is under consideration. A California law effective January 1, 2009, requires bottled water companies to post information on the water source, treatment and testing on labels and websites. A bill introduced in the U.S. Senate last year (S 3475) would impose similar requirements nationwide.

Daily decisions on what to drink aren't easy when bottled water companies fail to divulge what's in the bottle. EWG recommends filtered tap water as a first choice. It saves money, it's purer than tap water, and it helps solve the global plastic bottle problem.

We also advocate for the consumer's right to know about bottled water — where it comes from, how and if it's treated, and what contaminants it contains. Bottled water companies should provide this information voluntarily.

Bottle vs Tap — The Double Standard

The Environmental Protection Agency (EPA) calls mandatory annual tap water quality reports the "centerpiece of the right-to-know provisions in the 1996 Amendments to the Safe

Drinking Water Act." Both EPA and state regulatory agencies have authority to take enforcement action against water systems that fail to comply with reporting requirements, "to ensure that consumers' right-to-know is respected by all water suppliers" (EPA 2006a).

When it comes to bottled water, on the other hand, consumers are often left in the dark.

Where Does the Water Come From?



Federal law requires community tap water suppliers to identify their water sources. In Philadelphia's 2008 water quality report, residents learned that "the water... comes from the Schuylkill and Delaware rivers... Each river contributes approximately one-half of the City's overall supply." Davis, California residents learned that they drank "water from 20 municipal wells and one private well. These wells tap into aquifers beneath the city at depths from 210 to 1,730 feet below ground surface."

Source water disclosure - What's required?

FDA does not require that bottled water companies name the specific source of the water on the label. Instead, companies can provide generic terms that imply a general source by describing hydrogeology, water collection methods, or treatment methods (21 CFR 165.110). None of these terms give the specific location and name of the water source:

- ❖ "Artesian" and "spring" waters are groundwater under pressure that flows toward the ground surface.
- ❖ "Well water" is pumped from a hole bored, drilled, or otherwise constructed in the ground that taps the water of an aquifer.
- ❖ "Purified water," "deionized water" or other waters named by treatment method are often municipal waters that have undergone additional treatment.

Companies that package water from a municipal treatment plant without further purifying it must label the water as "from a community water system" or, alternatively, "from a municipal source." Because most water bottlers conduct some additional treatment, they escape this regulation.

Consumers have a right to know much more.

We found that:

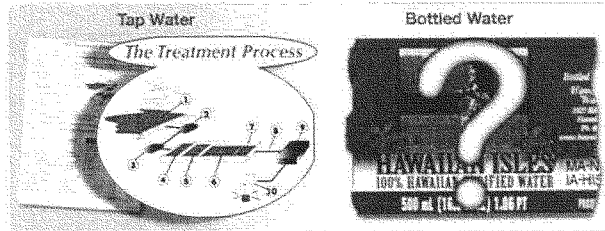
- 30% of bottled waters provide no information on water source whatsoever.
- 33% give generic information like "spring" or "deep pristine crystalline rock aquifer."
- 37% divulge on their label the specific name and location of their water sources. One-sixth of those give a list of possible sources, not the exact source for each bottle.

Many drinking water sources are vulnerable to pollution. Community water systems must report to their customers potential sources of pollution to their water sources, from detailed surveys called Source Water Assessments.

Bottled water companies face no such regulation and are free to make all sorts of hazy marketing claims. Fiji, for instance, claims its Natural Artesian Water is "untouched by man" and "far from pollution." Labels from some brands with undisclosed, mysterious sources claim the water is "essential," "pure," or "crystal-fresh."

Possibly, but it may just be tap water.

How is The Water Treated?



The federal government does not require bottled water companies to disclose exactly how they have treated their water. Community water suppliers are not required to disclose treatment methods either, but they often do. Our survey of 2008 annual water quality reports found that 58% of 55 water utilities in 48 states and Washington D.C. told their customers how they treated the water.

Water treatment disclosure - What's required?

FDA regulations allow bottled waters to label their products with ambiguous terms such as "purified water" or "demineralized water" (FDA 2008a). Unfortunately for consumers, the regulations do not require bottlers to disclose exactly what (if any) treatment processes they employ. Not all treatment methods are equal: consumers have a right to know which methods are used so they can make informed decisions about their drinking water.

Some consumers may believe that bottled water is purer than tap water, but 33% of bottled waters we surveyed provide no information whatsoever on labels or websites about how or if the water is treated. 44% provide no treatment information on labels.

The popular bottled water brand Fiji takes a creative approach to disclosure, claiming that the rainfall replenishing its aquifer is "purified by equatorial winds." But lab tests commissioned by The Boston Globe in 2005 found "unusually high levels" of bacteria in Fiji water (Boston Globe, 2005).

EWG's label research show that among bottled waters that fail to print water treatment information on labels, 60% make unsubstantiated marketing claims of purity, using words like "pristine source." Consumers have no way to know if the claims are true.

What Pollutants Are in the Water?

Tap Water			Bottled Water		
CONTAMINANT	UNITS	MRDL			
Total Organic Carbon (TOC)	ppm	n/a			
Distribution System Results					
Disinfectant Residual (Chloramine)	ppm	4			
Halocetic acids (HAA5)	ppb	80*			
Total Trihalomethanes (THM5)	ppb	80*			

Four of every 5 bottled waters do not publish results of water quality testing, according to EWG's analysis of 188 products. For these waters, consumers have no way to know the range and levels of pollutants found in the water.

Few water sources are completely free of detectable contaminants. For example, the estimated 25% of bottled waters that rely on tap water (NRDC 1999) are drawing from supplies that collectively contain at least 260 pollutants, according to EWG's 2002-2005 survey of tap water testing conducted by community water supplies (EWG 2005).

Water testing disclosure - What's required?

According to FDA regulations, bottled water companies are required to test their source water for chemical contaminants at least once a year, and for radiological contaminants once every 4 years. Waters taken from non-public water sources must be tested at least once a week for microbiological contamination (FDA 2008b).

While tap water suppliers are required to disclose water quality testing results to their consumers, the FDA only requires that bottlers maintain testing records to show government inspectors (FDA 2002). Some companies voluntarily provide water quality test results to the public, but others withhold this information. Unlike community water systems, bottled water companies are also not required to disclose potential health effects of contaminants that violate standards.

Test results for bottled water may be lacking, but meaningless claims of purity abound. Volvic, for example, advertises that its products are "extremely pure and distinctly different" (Volvic 2009). Ice Mountain Natural Spring Waters boasts that its waters are "pure as the driven snow" (Nestlé 2009a).

The Poland Spring website speaks of "pure quality" and asserts that "our 100% natural spring water is filtered naturally by the earth, captured at the source and continually tested to ensure the

highest-quality" (Poland Spring 2009).

What Poland Spring doesn't tell you is that in 1996, after consumers complained about taste, it recalled some of its bottled water products in Massachusetts because of high chlorine levels. Notably, neither the company nor the local department of health announced the recall (Commonwealth of Massachusetts 2000).

The Poland Spring website recounts its source's legendary curative powers, saying that in 1793, the spring cured a man on his death bed; reinvigorated, he lived 52 more years (Nestlé 2009b).

Mountain Valley Spring Water boasts on their website that by the early 1900's the brand's source water had become well known as a remedy for gout, rheumatism, diabetes and kidney disease (Health Waters 2009).

Aquamantia Natural Spring Water takes the prize for imaginative marketing. The company asserts that its water "resonates with the energy and frequency of well-being." According to Aquamantia, the quality of the drinker's thoughts determines the quality of the water. The labels contain affirmative mantras that, according to the company, "actually change the molecular structure of the water, and most definitely change the flavor of the water" (Aquamantia 2009).

Recommendations

Consumers spend up to 1,900 times more for a bottle of water than the same amount of tap water, yet rarely have basic information about the product (EWG 2008).

EWG recommends that bottled water labels and websites disclose the same information that the law requires of municipal water utilities. We recommend that government officials make this disclosure mandatory:

Bottled water companies should:

- Provide easy-to-access water quality reports disclosing all test results and containing the information required in Consumer Confidence Reports for tap water suppliers.
- List on the label water treatment methods; and clear, specific information on the water source and location.
- Test for unregulated chemicals that may leach from plastic bottles.

We urge consumers to make their first choice filtered tap water. They should consider bottled water a distant second, and then they should pick brands that provide full water source, treatment and quality disclosure and that use advanced treatment methods to remove a broad range of pollutants.

SECTION 1: Bottle vs. Tap - Double Standard

Ask bottled water consumers whether they think a bottled water is being held to significantly tighter standards than tap water, and chances are they will say, "Of course."

That's what the FDA is for, right?

Wrong. The truth is, the government does not mandate that bottled water be any safer than tap water. In fact, the chemical pollution standards are nearly identical. The sole exception is lead: FDA's lead limit for bottled water is three times stricter than the EPA lead standard for tap water. EPA's more lenient standard takes into account the fact that many older houses have lead pipes and lead solder (FDA 2008a; FDA 2002).

It's rare that FDA inspectors visit bottled water plants. The agency's website acknowledges that "bottled water plants generally are assigned low priority for inspection" (FDA 2002).

This lack of oversight has come at a price. Two brands have been recalled by FDA in the past 8 years: Safeway Select in 2001 because of contamination with particulate matter (FDA 2001); and Sam's Choice in 2005 due to mold and bacterial contamination (FDA 2005). Increasing FDA's pace of inspections would provide a much higher chance for these types of problems to be uncovered.

Extensive right-to-know provisions for tap water, absent for bottled water

Since 1999, the vast majority of community water systems around the country have been required to distribute to their customers an annual drinking water quality report, called a "consumer confidence report" (CCR). At a minimum, these CCRs disclose (EPA 2006a):

- The location and name of the lake, river, aquifer, or other source of the drinking water;
- A brief summary of the susceptibility to contamination of the local drinking water source, based on the source water assessments by states;
- Instructions on how to get a copy of the water system's complete source water assessment;
- The level (or range of levels) of any contaminant found in local drinking water, as well as EPA's health-based standard (maximum contaminant level) for comparison;
- The likely source of that contaminant in the local drinking water supply;
- The potential health effects of any contaminant detected in violation of an EPA health standard, and an accounting of the system's actions to restore safe drinking water;
- The water system's compliance with other drinking water rules;
- An educational statement for vulnerable populations about avoiding *Cryptosporidium*;
- Educational information on nitrate, arsenic, or lead in areas where these contaminants may be a concern; and

- Phone numbers of additional sources of information, including the water system and EPA's Safe Drinking Water Hotline.

Because finding accurate, complete information about many bottled water products on the market is nearly impossible, it's clear that many bottled water consumers are choosing products blindly.

FDA's history of foot dragging in bottled water regulations

The FDA has dragged its feet for years in setting strict water quality standards for bottled water and in requiring basic right-to-know disclosure for consumers. The FDA has regulated bottled water in some manner since the federal Food, Drug and Cosmetic Act (FD&CA) was passed in 1938. These regulations addressed little more than ensuring basic sanitary operation and record keeping. In 1974, the agency developed its first bottled water quality standards (GAO 1991).

Under section 410 of FD&CA, the FDA has been required either to apply EPA standards for drinking water contaminants to bottled water or explain why not. Yet a 1991 investigation by the Government Accountability Office found that between 1976 and 1991 the FDA had not complied with this requirement once (GAO 1991). After EPA regulated 7 volatile chemicals regulated in drinking water, FDA delayed for almost 3 years before proposing standards for the same chemicals in bottled water.

This problem was finally addressed in 1996 when Congress modified the law, through amendments to the Safe Drinking Water Act, to say that if the FDA did not issue bottled water regulations for newly regulated contaminants in drinking water, the EPA's tap water standards would automatically apply (FDA 2009). In 1995, the FDA issued "identity standards" for bottled water. For the first time, bottled water labeled as "spring," "artesian," or "purified" water, for example, had to meet certain requirements or be deemed "misbranded" and subject to recall (FDA 2008a).

Despite Congressional efforts, bottled water standards remain behind rules for tap water. In 1996 Congress amended the Safe Drinking Water Act to require, among other things, that community water systems provide customers with annual water quality reports containing extensive information on water source, contaminant levels, potential sources of contaminants, potential health effects of contaminants and educational advice for vulnerable populations.

The 1996 Safe Drinking Water Act Amendments required the FDA to conduct a feasibility study for providing similar information about bottled water. The agency collected comments beginning in 1997 and in 2000 published its findings in a report titled "Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water" (EPA 1997):

In its report, the FDA concluded that it would be appropriate and feasible to require one of the following: (a) information on bottled water labels that would tell consumers how to obtain water quality information from the manufacturer, (b) some water quality information on

bottled water labels and the remainder available through contact with the company, or (c) an information package with bulk distributed with water deliveries.

More than 12 years after it began, the FDA has still not filled this gap in public information:

New California law requires some additional disclosure for bottled water

In 2007, California passed a law (SB 220, Corbett) requiring bottled water companies to disclose some basic right-to-know information to consumers. In order to be sold in California, all bottled water manufactured after January 1, 2009 must have a label that gives consumers at least two ways to contact the manufacturer and request a water quality report. This report must include, among other things:

- The source of the bottled water, "consistent with applicable state and federal regulations";
- A brief description of the treatment process;
- A reference to the FDA web site that provides product recall information;
- The bottled water company's address and telephone number "that enables customers to obtain further information concerning contaminants and potential health effects";
- Information on "the levels of unregulated substances, if any, for which water bottlers are required to monitor pursuant to state or federal law or regulation";
- The number for the FDA's Food and Cosmetic Hotline for customers to call if they have questions about contaminants or potential health effects;
- A statement explaining how some people may be more vulnerable to contaminants in drinking water and directions to these consumers about how they can lessen the risk of infection by microbial contaminants;
- A statement explaining the various types of contaminants that may be present in the bottled water and what their sources may be;
- Statements about the health effects of nitrate and arsenic if the levels in the bottled water exceed certain thresholds.

EWG's review of bottled waters purchased in 2008 and 2009 show that many companies have updated their labels in the last 12 months to comply with California law.

But while California's effort represents an important step in the right direction, much remains to be done. The label is not required to give treatment information. And a loophole in the California law allows bottlers of treated tap water to give less information in their water quality reports. Rather than disclosing test results from the finished product, these companies are allowed to use the results from the applicable utility's consumer confidence reports. This means that even if consumers went to the trouble of obtaining water quality reports, they still might not be able to find out whether the bottled water in question is superior to tap water.

Finally, California law obviously only applies to waters sold in the state, meaning that a vast array of brands sold elsewhere are not covered.

SECTION 2: Where Bottled Water Comes From

EPA requires community water systems to disclose the name and location of the lake, river, aquifer, or other source of their drinking water in their annual Consumer Confidence Reports (CCRs).

Tap water source disclosure: short, simple, informative

The following quotes, taken from 2007 and 2008 Consumer Confidence Reports from around the country, demonstrate how water utilities can provide remarkably specific and informative source data in just one to three sentences:

- Davis, CA — "During 2007, the City pumped water from 20 municipal wells and one private well. These wells tap into aquifers beneath the city at depths from 210 to 1,730 feet below ground surface." (City of Davis Public Works 2008)
- Austin, TX — "Customers of the City of Austin Water Utility... receive their drinking water from two water treatment plants that pump surface water from the Colorado River as it flows into Lake Austin." (Austin Water Utility 2009)
- Philadelphia, PA — "The water that we treat comes from the Schuylkill and Delaware rivers. Rivers are surface water supplies. Philadelphia does not use groundwater. Each river contributes approximately one-half of the City's overall supply." (Philadelphia Water Department 2009)
- Sacramento, CA — "The City of Sacramento has two independent water sources. Our primary water source is river water from the American and Sacramento Rivers, which provide 85 percent of our water supply. Groundwater provides the remaining 15 percent." (City of Sacramento 2009)
- Tampa, FL — "The Hillsborough River is the surface water source that supplies most of Tampa's water demand, an average of 82 million gallons a day. During our dry season, usually April through June, Tampa's river supply is supplemented by the Aquifer Storage and Recovery (ASR) system and regional groundwater, surface water and desalinated seawater purchased from Tampa Bay Water." (Tampa Water Department 2009)

Community water systems are also required to notify consumers of any existing source water assessments and how to obtain them. These assessments pinpoint current and potential sources of pollution in the water source. In certain cases, systems are also required to provide a brief summary of the assessment in the CCR.

Overall, EWG found that 23% of products surveyed contained no source information on either the labels or available websites.

Nearly a third of the bottled water labels we examined, including leading bottled water brands such as Dasani Purified Water and Perrier Sparkling Natural Mineral Water, offered no information about the water's source, generic or specific. Until recently, the major brand Aquafina also fell into this category. However, after extensive pressure from Corporate Accountability International and other consumer groups, Aquafina agreed to modify its labels to say that the water is sourced from unnamed public water supplies.

A third of the labels we inspected included partial or vague source locations, providing the consumer with little or no useful information. Aquamantra Natural Spring Water, as the name implies, sourced from a spring identified on the label as in zip code 92707. The labels of Voss Artesian Water and Meijer Natural Spring Water identify their water sources as "Vatnestrom, Norway" and "deep within Michigan's countryside," respectively.

FDA requires that if the water comes from an underground aquifer, companies may advertise their product as artesian water, ground water, spring water or well water, depending on how the water is tapped or how it flows to the surface. Companies may advertise their product as mineral water if it is ground water that naturally contains 250 or more parts per million of total dissolved solids.

A few brands stand out for source disclosure.

National brands Ozarka and Poland Spring were among the minority of brands that disclosed precise source locations on their labels. Only 69 of the 188 products (37%) analyzed revealed precise sources, such as the name of the spring or aquifer tapped. Poland Spring Natural Spring Water named six springs in Maine from which the water may have been extracted. Ozarka's Natural Spring Water and drinking water products named the springs and community water system from which the water was taken.

Websites of bottled water brands were no more informative.

More than half of the products EWG investigated had no websites. This resource void was especially pronounced among private label brands, including CVS Gold Emblem, American Fare, Kirkland Signature and Holiday Pantry.

For 9% of the products analyzed, including Nursery Purified Water for infants, websites had no any information on water sources.

Websites of another 28% of the products we analyzed listed ambiguous source locations.

Only 9% of the 188 products analyzed had a website disclosing clear, precise water sources. Among these were New Zealand Eternal Artesian Water and Iceland Spring Natural Icelandic Spring Water, both imported. Of that 9%, 1 in 3 provided a list of possible sources, leaving consumers to guess exactly which sources were used to fill a particular bottle.

Manufacturers of just 6% of the products in this investigation provided precise source information on both their product labels and websites. These included Deer Park Natural Spring Water and Evian Natural Spring Water.

SECTION 3: How Bottled Water Is Treated

Federal law does not require information about treatment methods to be distributed to consumers for either bottled water or tap water, but EWG's analysis shows that some community water systems voluntarily give such information in their annual Consumer Confidence Reports (CCRs) more often than bottled water companies do on their product labels.

EWG reviewed the most recent Consumer Confidence Reports available for 55 medium to large cities in 48 states. While the level of detail of information varied tremendously, we found that 58% of the CCRs contained at least some substantive information on municipal utility treatment methods.

In fact, many water quality reports devote half a page or more to explaining the treatment process to consumers. A few community water systems don't treat their water. Their CCRs explain why.

We found no obvious relationship between the size of the community water system and the adequacy of disclosure of treatment information. Treatment information disclosure isn't a matter of resources, but a matter of choice. Some very large systems, such as those in San Diego and Cleveland had no substantive treatment information in their CCRs, but smaller systems such as those in Davis, CA and Anniston, AL did.

The story is little different when it comes to bottled water. EWG found that the labels of 44% of the bottled waters we analyzed lacked any information about treatment methods. These products not only included small, private label brands such as Henry's Farmers Market and Macy's, but also national brands such as Deer Park Natural Spring Water, Ice Mountain Natural Spring Water, Zephyrhills Natural Spring Water and Crystal Geyser Natural Alpine Spring Water.

Websites of bottled waters are only slightly more informative. Those of about a quarter of the products EWG investigated had information on water purification. Another 21% sites contained vague or no information on this subject.

The remaining 54% had no websites at all.

Overall, two-thirds of bottled water products provided some degree of information on how their water was purified either on the product label or on a website.

FDA's weak treatment disclosure rules

While FDA's rules don't universally require treatment information, the agency does have a few minimal requirements. Water labeled "distilled" must actually be distilled. To be labeled "purified," a bottled water must meet certain standards – though the actual treatment method

need not be disclosed. To label a product "sterile water," the bottler must meet certain purity standards, although the actual treatment method need not be disclosed.

Weak FDA standards for bottled water impede consumers' ability to follow the Centers for Disease Control's (CDC) advice that people with compromised immune systems to drink bottled water treated using reverse osmosis, distillation, and/or filtration with an absolute 1-micron filter (absolute indicates the largest hole in the filter). These three methods are known to protect against *Cryptosporidium*, a parasite that can lead to severe illness or even death in people with a weakened immune systems (CDC 2008). But, other than for distilled water, nothing in FDA's rules compels companies to disclose their treatment methods.

EWG recommends that if consumers need to buy bottled water, they choose a brand that provides them with information on treatment methods and uses some kind of advanced treatment.

SECTION 4: Pollutants in Bottled Water

Under the Federal Safe Drinking Water Act, all annual water quality reports (Consumer Confidence Reports) issued by community water suppliers must (EPA 2006b) report:

- Levels of all regulated contaminants, any unregulated contaminants for which monitoring is required, and any disinfection by-products or microbial contaminants for which monitoring is required.
- Likely source(s) of all detected contaminants, to the best of their knowledge.
- Federal Maximum Contaminant Levels (federal drinking water standards) and Maximum Contaminant Level Goals (theoretical federal standards if only health concerns were taken into consideration and economic concerns and technical feasibility were not considered) for each contaminant detected.
- Extensive statements on contaminants and their likely sources, including microbial contaminants, inorganic contaminants, pesticides and herbicides, organic chemical contaminants, and radioactive contaminants.
- Potential health effects associated with arsenic, nitrate, lead, and the disinfection byproducts known as trihalomethanes if detectable levels are below the MCL but above certain health-based thresholds of concern.

These rules cover all public water systems with at least 15 service connections or that regularly serve 25 year-round residents (EPA 2006c).

In contrast, bottled water companies, which sell their products to thousands or millions of people, are not required to make public any of this.

Because of the California law that recently went into effect, a few more bottled water companies seem to be making available more water quality information. However, EWG's analysis shows that these companies remain in the minority. EWG found that none of the 163 labels dating from 2008 indicated the availability of water quality reports were available, but 14% of the 2009 labels contained such information.

Only 20% of bottled water company websites indicated that water quality testing had been conducted. Just 18% – including Poland Spring, Nestlé Pure Life and Perrier – showed current bottled water quality reports, including contaminant testing results, on websites.

SECTION 5: California beefs up bottled water labeling

California's SB 220 requires bottled water companies to label the name and location of their water source, and to provide consumers with water quality testing reports upon request, effective January 1 2008. EWG assessed the extent to which this law affected labeling practices nationwide.

We compared 2008 and 2009 labels from 54 bottled water products, and found that more than half of these products are providing more information, with many of them complying with the new California requirements:

- 28 bottled water brands gave customers more information in 2008 than in 2009 (Table 1).
- 7 bottled water brands gave customers less information in 2008 than in 2009 (Table 2).
- 19 bottled water companies gave customers the same information in 2008 as in 2009 (Table 3).

Table 1: 28 bottled water brands gave customers more information in 2008 than in 2009

Product	2008	2009	Labels sent from?
Sparkletts Crystal-Fresh Purified Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	CA
Poland Spring Natural Spring	Water Vague source information on website: Ancient aquifers in Maine	Detailed source information on website: "Spring water sources: Poland Spring, Poland Spring, ME; Clear Spring, Hollis, ME; Evergreen Spring, Fryeburg, ME; Spruce Spring, Pierce Pond Township, ME; Garden Spring, Poland, ME; Bradbury Spring, Kingfield, ME and/or White Cedar Spring, Dallas Pk, ME"	NY; MA; NJ; VA; ME
365 Everyday Value Spring Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and email address to get information on water quality	AZ (2009 label from NC showed no change from 2008)
Ozarka Natural Spring	Vague source information on website: Various east-Texas	Detailed source information on website: "Various east-Texas springs located in Henderson, Walker and Wood counties;	TX; MS; KS; OK

Table 1 continued: 28 bottled water brands gave customers more information

Product	2008	2009	Labels sent from?
Water	springs located in Henderson, Walker and Wood counties.	Roher Spring, Henderson County, TX; Moffit Spring, Walker County, TX; Piney Woods Springs, Wood County, TX; Clear Springs, Wood County, TX	
Nestlé Pure Life Purified Water	No source information provided on label.	Source information provided on label: "Deep protected well, [Brenigsville, PA and/or Public Water Supply, Allentown, PA] [Ontario, CA] [Hollis, Maine]"	CT; MD; CA (2009 label from TX showed no change from 2008)
Nestlé Pure Life Purified Water	Label did not guide consumers to water quality information.	Label provides consumers with a phone number and website to get information on water quality.	CT; MD; CA (2009 label from TX showed no change from 2008)
Spring! Natural Spring Water	No information on water purification process available on website.	Water purification process detailed on website: "Microfiltration, Ozonation, Ultra Violet Light (UV) disinfection" OH; UT	
Arrowhead Mountain Spring Water	No source information given on label and only vague source information available on website: "The sources range from the natural springs in US to Canada including sources in a watershed outside of San Francisco"	Both label and website name the water sources. Label: "Arcadia Spring, Calistoga, CA; Lukens Spring, Baxter, CA; Sopiago Spring, El Dorado County, CA; Sugar Pine Spring, Long Barn, CA; White Meadows Spring, Pacific House, CA; Rainbow Lodge/Royal Gorge, Soda Springs, CA; Hope Springs, BC, Canada; SP Spring, Riverside County, CA; Arrowhead Springs, San Bernardino County, CA; Long Point Ranch, Running Spring, CA; Palomar Mountain Granite Springs (PMGS), Palomar, CA; Deer Canyon Springs, San Bernardino County, CA; Coyote Springs, Inyo County, CA". Website: "Arcadia Spring, Calistoga, CA; Lukens Spring, Baxter, CA; Sopiago Spring, El Dorado County, CA; Sugar Pine Spring, Long Barn, CA; White Meadows Spring, Pacific House, CA; Rainbow Lodge/Royal Gorge, Soda Springs, CA; Hope Springs, BC, Canada; SP Spring, Riverside County, CA; Arrowhead Springs, San Bernardino County, CA; Long Point Ranch, Running Spring, CA; Palomar Mountain Granite Springs (PMGS), Palomar, CA; Deer Canyon Springs, San Bernardino County, CA; Coyote Springs, Inyo County, CA"	AZ, CA

Table 1 continued: 28 bottled water brands gave customers more information

Product	2008	2009	Labels sent from?
		County, CA"	
Arrowhead Mountain Spring Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	AZ, CA
Kirkland Signature Premium Drinking Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	CA, CO
Deer Park Natural Spring Water	Vague source information available on website: Original source in Appalachian Mountains outside of Deer Park, Maryland plus additional undisclosed locations	Detailed source information provided on website: "Frontier located in New Tripoli, PA, Bangor, PA, Stroudsburg, PA, Hegins, PA, South Coventry, PA, Pine Grove, PA Newmantown, PA and/or Oakland, MD; Spring of Life, Lake County, FL and/or Crystal Springs, Pasco County, FL; White Springs, Liberty County, FL and/or Blue Springs, Madison County, FL; Glenwood Spring, St Albans, ME; Sweetwater Falls, Hohenwald, TN"	DC, VA; OH; GA
Dasani Purified Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	CA, MI; OR (2009 labels from DC, CA, VA, OH and GA showed no change from 2008)
Fiji Natural Artesian Water	Website did not provide details on purification	Website provided details on purification techniques used to treat the water: "the water is filtered, microfiltered and ultra-violet light is applied" WI; VA; TX	
Fiji Natural Artesian Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	WI; VA; TX
Glaceau Smart Water	No information on water source available on website	Vague information on water source available on website: "Most facilities that purify and bottle smartwater procure water from municipal water systems. At a few plants, however, water is obtained from protected groundwater sources managed by the bottling plant, with approvals from local authorities."	CA
Kirkland Signature	No purification information available on	Purification information provided on product website: "Advanced filtration,	NM

Table 1 continued: 28 bottled water brands gave customers more information

Product	2008	2009	Labels sent from?
Mountain Spring Water	product website	Ozonation and Reverse Osmosis Technologies ⁹	
Zephyrhills Natural Spring Water	Vague source information available on website: Springs in Florida plus additional spring sources	Detailed source information available on website: 400Crystal Springs , Pasco County, FL; Cypress Springs, Washington County, FL and/or Blue Springs, Madison County, FL&E	FL
Market Pantry Purified Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	AR
Ice Mountain Natural Spring Water	Vague source information on website: Several "unique springs" in the Northern United States	Detailed water sources given on website: "Sanctuary and Evert Springs, Stanwood, MI; Frontier Springs located in New Tripoli, PA, Bangor, PA, Hugins, PA, South Coventry, PA, Pine Grove, PA, Stroudsburg, PA and /or Oakland, MD; Glenwood Spring, St Albans, ME; Sweetwater Falls, Hohenwald, TN; Bennett Hill Spring, Red Boiling Springs, TN"	MO; IL
Crystal Geyser Natural Alpine Spring Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and email address to get information on water quality	WA
Crystal Springs Natural Mountain Spring Water	Vague source information available on product label: Springs, Blue Ridge, GA	Detailed water source given on the product label: "Table Rock Spring, Morganton, NC 28655"	NC
Sam's Choice Purified Drinking Water with Flavor Enhancing Minerals	No water quality report available on website	Water quality report available on website with information on source, treatment and water testing results	NC, OK
Sam's Choice Purified Drinking Water with	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	NC; OK (2009 label from VA showed no change since 2008)

Table 1 - continued: 28 bottled water brands gave customers more information

Product	2008	2009	Labels sent from?
Flavor Enhancing Minerals			
Stater Bros. Pure Water Purified Drinking Water	No information available on product label about water source	Vague water source information available on product label: "deep protected wells in southern California"	CA
Stater Bros. Pure Water Purified Drinking Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number to get information on water quality	CA
Evian Natural Spring Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	CA (2009 labels from IL and OR did not change since 2008)
Refreshe Purified Drinking Water	No website available to inform consumers about product	Website available with information on the purification process and water testing	CA
Refreshe Purified Drinking Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	CA (2009 labels from DC, OR and VA unchanged since 2008)
Volvic Natural Spring Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	FL
Camelot Purified Water	No source information given on product label	Source information given on product label: "Lafayette Spring, Lafayette TWP, WI"	WI
Camelot Purified Water	No purification information given on product label	Purification information given on product label: "purified by reverse osmosis" WI	
Trader Joe's Pure New Zealand Artesian Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and email address to get information on water quality	CA
Hinckley Springs Spring Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	KS
Nursery Purified	No source information included on label	Label details water sources: Arrowhead Springs; Millcreek Township.	DC; CA

Table 1 continued: 28 bottled water brands gave customers more information

Product	2008	2009	Labels sent from?
Water		PA/Diamond Spring; Clat Township, PA/ Ephrata Well; Ephrata Township, PA/West Earl Township Municipal Water Supply; Ephrata, PA.	
Nursery Purified Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number and website to get information on water quality	DC; CA
Earth2O 100% Natural Spring Water	Label did not provide information on water purification	Label provides information on water purification: "100% naturally filtered" CA	
Essentia Purified Drinking Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number to get information on water quality	CA
Refreshe Spring Water	Label did not guide consumers to water quality information	Label provides consumers with a phone number to get information on water quality	CA
Refreshe Spring Water	No website available to inform consumers about product	Website available with information on the purification process and water testing	CA

Table 2: 7 bottled water brands gave customers less information in 2008 than in 2009

Product	2008	2009	Labels sent from?
Kroger Purified Drinking Water	Label provided information on purification type: Reverse Osmosis	Label did not provide information on purification type	AR (2009 labels from OH and MI were unchanged from 2008)
Kirkland Signature Mountain Spring Water	Vague source information available on product label: Polk County, Tennessee	No source information available on product label	NM
Acqua Panna Natural Spring Water	Website provides precise source information: Acqua Panna Spring, Tuscany Website provides vague source information: "sources are located 3,700 feet high in the serene Apennines Mountains of Tuscany"	FL	
Mountain Valley Spring Water	Website listed purification techniques used to treat the water	Website did not list purification techniques used to treat the water	FL
Wegmans Spring Water	Label includes vague information about water source: "the CG Roxane Spring source, Moultonborough, CG Roxane, NH 03254"	Label does not disclose water source	NY
New Zealand Eternal Artesian Water- Silica Rich	Label includes vague source information: "New Zealand Aquifer"	No source information disclosed on label	KS
Hinckley Springs Spring Water	Vague source information given on product label: Spring, Rock Springs, WI	No source information given on product label	KS

Table 3: 19 bottled water companies gave customers the same information in 2008 as in 2009

Product	States labels sent from
Aquafina Purified Drinking Water	CA; KS; NE; CT; PA; CO
Simply H2O by Berkley & Jensen Purified Water	FL
Ethos Water Natural Spring Water	FL
Voss Artesian Water	VA
Icelandic Glacial Natural Spring Water	VA
American Fare Purified Water	PA
Naturally Preferred Pure Mountain Spring Water	OH
Springtime Artesian Water	MS
Absopure Natural Spring Water	KS
Evamor Alkaline Artesian Water Beverage	MO
CVS Gold Emblem Natural Spring Water	DC
Iceland Spring Natural Icelandic Spring Water	DC; VA
Trader Joe's Mountain Spring Water	IL
Perrier Sparkling Natural Mineral Water	CA
Contrex Natural Mineral Water	CA
Hawaii Water Ultra-Pure Bottled Water	CA
Gerolsteiner Natural Mineral Water	DC; CA
365 Everyday Value Electrolyte Enhanced Water	DC; CA
Whole Foods Market Italian Still Mineral Water	DC; CA

SECTION 6: Methodology

Interested in finding out how much information bottled water companies make available to their consumers, in February 2008 EWG invited the public to send labels from bottled waters that they had purchased. Between February and August 2008 we received 163 unique product labels representing 137 brands from 30 states.

EWG's researchers logged into a database the details of information on the label regarding water source, treatment and testing. We recorded similar data from company websites.

In January 2009, California's SB 220 went into effect, requiring all bottled waters sold in that state to include on their label the source of the water and contact information for consumers to obtain a report on water quality. Aware that this new rule would prompt changes in the bottled water industry, in May 2009 EWG again invited the public to send us labels of bottled water purchased after the law went into effect. In May and June 2009 we received 85 unique product labels representing 76 brands from 32 states.

We logged the details from this set of labels and corresponding websites into the EWG database and dated the entries appropriately. The final database, a combination of information from products purchased before and after SB220's effective date, consisted of 188 products from 155 brands and 38 states.

EWG researchers analyzed the information in the database and scored each product based on: 1) the transparency of bottled water company with regards to disclosing source, purification and testing information on both their product label as well as on their website, and 2) the efficacy of purification methods used to treat the water. Final scores for each of the 188 products EWG assessed will be available July 2009 at <http://www.ewg.org/health/report/bottledwater-scorecard>.

References

- Aquamantra. 2009. Aquamantra. Stimulate Your Soul. Available: http://aquamantra.com/site.php/spgs/read/taste_the_difference [accessed July 5 2009].
- Austin Water Utility. 2009. City of Austin Water Sources. Available: <http://www.ci.austin.tx.us/water/watersource.htm> [accessed June 24 2009].
- Boston Globe. 2005. Water wars: In the final analysis, the price is all that separates them. Available: http://www.boston.com/business/articles/2005/09/18/water_wars/ [accessed June 23 2009].
- CDC (Centers for Disease Control and Prevention). 2008. Cryptosporidiosis- Treatment. Available: <http://www.cdc.gov/crypto/treatment.html> [accessed June 10 2009].
- City of Sacramento. 2009. 2008 City of Sacramento Water Quality Report. Available: <http://www.cityofsacramento.org/utilities/media-room/publications.cfm> [accessed June 24 2009].
- City of Davis Public Works. 2008. Annual Water Quality Report. Available: <http://cityofdavis.org/pw/water/WaterQuality.cfm> [accessed June 24 2009].
- Commonwealth of Massachusetts. 2000. Money Down the Drain? A Review of Bottled Water in Massachusetts. Available: <http://www.mass.gov/legis/bottledwater.htm> [accessed June 23 2009].
- Doss, J. K. 2008. Written testimony of Joseph K. Doss, President and CEO, International Bottled Water Association before the Subcommittee on Transportation Safety, Infrastructure Security, and Water Quality of the Environment and Public Works Committee, United States Senate; Hearing on Quality and Environmental Impacts of Bottled Water, September 10, 2008.
- EPA (U.S. Environmental Protection Agency). 1997. Bottled Water Study: Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water; Request for Comments. Available: <http://www.epa.gov/EPA-WATER/1997/November/Day-12/w29655.htm> [accessed June 12 2009].
- EPA (U.S. Environmental Protection Agency). 1998. National Primary Drinking Water Regulations: Consumer Confidence Reports. Available: <http://www.epa.gov/fedrgstr/EPA-WATER/1998/August/Day-19/w22056.htm> [accessed January 21 2009].
- EPA (U.S. Environmental Protection Agency). 2006a. Consumer Confidence Reports (CCRs): Basic Information. Available: <http://www.epa.gov/DGWDW/ccr/basicinformation.html> [accessed June 23 2009].

EPA (U.S. Environmental Protection Agency). 2006b. Consumer Confidence Reports (CCR)- CCR Rule. Available: <http://www.epa.gov/OGWDW/ccr/regulations.html> [accessed June 9 2009].

EPA (U.S. Environmental Protection Agency). 2006c. Consumer Confidence Reports (CCR). Available: <http://www.epa.gov/OGWDW/ccr/> [accessed June 9 2009].

EWG (Environmental Working Group). 2005. National Tap Water Quality Database. Available: <http://www.ewg.org/sites/tapwater/> [accessed July 5 2009].

EWG (Environmental Working Group). 2008. Bottled Water Quality Investigation: 10 Major Brands, 38 Pollutants. Available: <http://www.ewg.org/reports/bottledwater> [accessed July 5 2009].

FDA (U.S. Food and Drug Administration). 2001. Recall Notice. Available: <http://www.fda.gov/bbs/topics/Enforce/2001/ENF00679.html> [accessed February 3 2009].

FDA (U.S. Food and Drug Administration). 2002. February/March 2002 Ask the Regulators- Bottled Water Regulation and the FDA. Available: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/BottledWaterCarbonatedSoftDrinks/ucm077079.htm> [accessed June 24 2009].

FDA (U.S. Food and Drug Administration). 2005. Enforcement Report for January 12, 2005. Available: <http://www.fda.gov/Safety/Recalls/EnforcementReports/2005/ucm120332.htm> [accessed June 23 2009].

FDA (U.S. Food and Drug Administration). 2008a. CFR - Code of Federal Regulations Title 21: PART 165- Beverages. Subpart B--Requirements for Specific Standardized Beverages . Available: <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=165.110&SearchTerm=bottled%20water> [accessed June 24 2009].

FDA (U.S. Food and Drug Administration). 2008b. CFR - Code of Federal Regulations Title 21: Part 129- Processing and Bottling of Bottled Drinking Water. Available: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=129&showR=1> [accessed June 24 2009].

FDA (U.S. Food and Drug Administration). 2009. Bottled Drinking Water Standards. Sec: 410. [21 USC §349] Available: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCAActChapterIVFood/ucm107854.htm> [accessed June 12 2009].

- GAO (Government Accountability Office). 1991. Food Safety and Quality: Stronger FDA Standards and Oversight Needed for Bottled Water RCED-91-67. Available: <http://www.gao.gov/products/RCED-91-67> [accessed June 10 2009].
- Health Waters, inc. 2009. Mountain Valley Spring Water. Available: <http://www.healthwatersinc.com/ourhistory.html> [accessed July 5 2009].
- Nestlé (Nestlé Waters North America). 2009a. Ice Mountain. Available: <http://www.nestle-watersna.com/Menu/OurBrands/Ice+Mountain.htm> [accessed July 5 2009].
- Nestlé (Nestlé Waters North America). 2009b. Poland Spring heritage. Available: <http://www.nestle-watersna.com/Menu/OurBrands/PolandSpring/Poland+Spring+Heritage.htm> [accessed July 5 2009].
- NRDC (National Resources Defense Council). 1999. Bottled water. Pure drink or pure hype? Available: <http://www.nrdc.org/water/drinking/bw/exesum.asp> [accessed July 5 2009].
- Philadelphia Water Department. 2009. 2008 Annual Drinking Water Quality Report. Available: http://www.phila.gov/water/Drinking_Water_Qual.html [accessed June 24 2009].
- Poland Spring. 2009. Poland Spring - Be Assured. Available: <http://www.polandspring.com/KnowH2O/Be-Assured.aspx> [accessed June 24 2009].
- Rodwan JG Jr. 2009. Confronting challenges. U.S. and international bottled water developments and statistics for 2008. Bottled Water Reporter. April/May 2009.
- Tampa Water Department. 2009. 2008 Tampa Water Department Water Quality Report. Available: http://tampaf1.gov/dept_Water/information_resources/Water_Quality.asp#Water_Quality_Reports [accessed June 24 2009].
- Volvic. 2009. Clean taste crisp finish. Available: <http://www.volvic-na.com/> [accessed July 5 2009].

Mr. STUPAK. Thank you.

Mr. Doss, your opening statement, please, sir.

TESTIMONY OF JOSEPH K. DOSS

Mr. DOSS. Chairman Stupak, Ranking Member Walden and members of the subcommittee, my name is Joe Doss. I am president and CEO of the International Bottled Water Association. I appreciate very much this opportunity to discuss the regulation of bottled water.

Bottled water, whether in retail-size packages or in larger containers used in home and office water coolers, is a safe, healthy, convenient beverage. It is comprehensively regulated as a packaged food product at both the federal and State level, and as with other packaged food and beverages, bottled water must meet FDA's general food regulations which include extensive labeling requirements for ingredients, the name and place of business of the manufacturer, packer or distributor, the product's net weight, and if required, nutrition labeling. In addition, FDA has promulgated separate standards, as we have heard, separate standards of identity including labeling requirements that identify the type of bottled water, standards of quality and good manufacturing practices specifically for bottled water. Federal law requires FDA bottled water regulations to be as protective of the public health as EPA standards for public drinking water systems, and to that end, FDA has established bottled water standards for quality for more than 90 substances. Most FDA bottled water quality standards are the same as EPA's maximum contaminant levels for public water systems. The few differences in regulated substances are because they are not found in bottled water or they are regulated under another provision of law such as FDA's food additive program.

If a container of bottled water has a contaminant that exceeds an FDA standard, this fact must by law be disclosed on the label. Failure of a bottled water container to meet the standards of quality and to be properly labeled can subject it to recall by the company and enforcement action by FDA. If a bottled water product source is a public water system and the finished bottled water product does not meet the FDA standard of identity for purified or sterile water, that product label must disclose the fact that it comes from a public water source.

It is also important to note that the courts have held that FDA's jurisdiction over food and beverages extends not only to those products that move in interstate commerce but to those products sold within a single State if they are using packaging materials that have moved in interstate commerce such as the bottle, the caps or the labels, and that is the case for almost every bottled water sold in the United States. In addition, Congress has created a statutory presumption of interstate commerce for all FDA-regulated products including bottled water.

Now, while the current laws regulating bottled water products protect the public health, IBWA members and others in the food industry have recently worked with the Energy and Commerce Committee to update the food safety laws. IBWA supports a risk-based inspection system that would require inspections of all food facilities every 6 months to 3 years, a requirement for all food man-

ufacturers to conduct a hazard analysis and establish and maintain preventive controls which all IBWA members already do as a condition of membership in granting FDA authority to mandate recall under circumstances where a food product presents an imminent threat of serious adverse health consequences or death.

IBWA supports a consumer's right to clear, accurate and comprehensive information about the bottled water products they purchase. As I mentioned, all packaged food and beverages including bottled water are subject to extensive FDA labeling requirements that provide consumers with a great deal of product quality information. In addition, virtually all bottled water products include a phone number on the label that consumers can use to contact the company. In fact, IBWA petitioned FDA in 2001 to require all bottled water labels to include a phone number on the label. IBWA believes that the most feasible way to consumers to obtain information not already on the label is through a request to the bottler. In addition, consumers can go to the IBWA Web site to obtain contact information or water quality information for all IBWA member brands.

Consumers have many options when choosing which bottled water brand to drink. If a bottled water company does not provide them with the information that they want, he or she can choose another brand of bottled water. That is not the case with tap water. Consumers cannot choose which public water system is piped into their homes, and that is a fundamental issue: consumer choice.

Unfortunately, many people want to make this out to be a bottled water versus tap water issue. We just don't see it that way. If people are drinking water, whether it is tap or bottled, that is a good thing and consumers should be free to choose. In fact, 75 percent of consumers who drink bottled water also choose to drink tap water. IBWA supports investments to improve the U.S. public drinking water system in order to maintain the highest quality of water for all citizens. And with the increase in diabetes, obesity and heart disease rates in the United States, any actions that would discourage consumers from drinking bottled water are not in the public interest. Throughout the years, bottled water companies have always responded to the need for clean, safe drinking water after natural disasters such as hurricanes, floods and forest fires, and in emergency situations such as terrorist attacks and boil alerts. However, the bottled water industry cannot exist only for disaster response. The vast majority of bottled water companies in the United States are primarily family owned and operated small business that depend on a viable commercial market to provide the resources necessary to respond in emergency situations. In fact, 90 percent of IBWA's members have gross sales of less than \$10 million a year.

In summary, bottled water is a safe, healthy, convenient good product that is comprehensively regulated at the federal and State level. IBWA stands ready to assist the subcommittee as it considers this very important issue. Thank you for considering our views.

[The prepared statement of Mr. Doss follows:]



Written Testimony of
Joseph K. Doss
President and CEO
International Bottled Water Association
Before the
Subcommittee on Oversight and Investigations
of the Energy and Commerce Committee
United States House of Representatives
Hearing on Bottled Water Regulation
July 8, 2009

Chairman Stupak, Ranking Member Walden, and Members of the Subcommittee, my name is Joseph K. Doss. I am President and CEO of the International Bottled Water Association (IBWA)¹ in Alexandria, Virginia. Thank you for the opportunity to provide the bottled water industry's perspective on the regulation of bottled water, particularly as compared with public drinking water regulation.

I. Overview of the Bottled Water Industry

Background

IBWA appreciates the opportunity to provide the Subcommittee with our views on the very important issues being considered at this hearing. Bottled water is a safe, convenient, healthful, regulated food product that consumers find refreshing and use to stay hydrated. People choose bottled water for several reasons, including taste, quality, and convenience. Bottled water is also an alternative to other packaged beverages when consumers want to eliminate or moderate calories, caffeine, sugar, artificial flavors or colors, alcohol and other ingredients from their diets. The consumption of water, whether from the bottle or the tap, is a good thing, and any actions that discourage people from drinking bottled water are not in the public's interest.

The bottled water industry is the second largest commercial beverage category by volume in the United States. Nearly all bottled water sold in the United States is sourced domestically. Only approximately two percent of the total volume is comprised of imported bottled water.

¹ IBWA is the trade association representing all segments of the bottled water industry, including spring, artesian, mineral, sparkling, well, groundwater and purified bottled waters. Founded in 1958, IBWA member companies include United States and international bottlers, distributors and suppliers. Bottled water companies produce a packaged food product that is comprehensively and stringently regulated by the United States Food and Drug Administration (FDA). IBWA is committed to working with state and federal governments to establish and implement stringent standards for assuring the production and sale of safe, high-quality bottled water products. In furtherance of this objective, IBWA has developed and published a Code of Practice (available at IBWA's website: http://www.bottledwater.org/public/policies_main.html), which establishes standards of bottled water production, quality, and distribution that must be met by IBWA members. In some cases, the IBWA Code of Practice is even more stringent than state and federal regulations. As a condition of membership, IBWA bottlers must submit to an annual plant inspection by an independent third party to determine compliance with the Code of Practice and all applicable FDA regulations.

According to the Beverage Marketing Corporation, in 2008 the total volume of bottled water consumed in the United States was 8.7 billion gallons, a one percent decrease from 2007. That translates into an average of 28.5 gallons per person. Sales revenues for the United States bottled water market in 2008 were approximately \$11.2 billion (in wholesale dollars), a 3.2% decrease over the previous year. Bottled water consumption is about half that of carbonated soft drinks (CSD's) and only slightly ahead of milk and beer.

The United States bottled water market is truly consumer driven. This is, in large part, because people are making healthier beverage choices. The strength of this consumer self-generated demand is illustrated by the relatively modest amount spent on bottled water advertising. The 2007 bottled water advertising expenses totaled only \$54.5 million.² For comparison purposes, \$803 million was spent on advertising carbonated soft drinks (nearly fifteen times that for bottled water), and advertising expenses for beer totaled \$1.187 billion (approximately 20 times that for bottled water).

Bottled Water Industry Profile

The bottled water industry has two primary business models. The first model is home and office delivery (HOD) of the three and five gallon bottles used with water coolers, which accounts for about 20% of the bottled water market. This segment of the bottled water market has been providing consumers with safe, quality products for over one hundred years in the United States. The second model is retail sales of bottled water to consumers in 2 ½ gallon, 1 gallon, and smaller sized bottles (e.g., half liter and one liter), generally through retail, convenience, and grocery stores, as well as vending machines. Retail business accounts for about 80% of the bottled water market and is the largest and fastest growing segment of the United States bottled water industry.

The sources for bottled water products that comprise the United States market can be divided into two fundamental categories, which are aligned with the Food and Drug Administration's (FDA) standards of identity. The largest segment of the bottled water industry – the natural waters -- is sourced from groundwater. They are artesian, mineral, sparkling, spring and well water. The remainder of the market is processed water, such as purified, sterile or drinking water. Groundwater sources, which are used by an estimated two-thirds of bottled water companies, are exclusively from underground aquifers, while processed water sources can be from either groundwater or municipal water systems.

Bottlers of natural waters have made extensive investments in developing groundwater sources, and have been at the forefront of legislative and regulatory efforts to encourage states to enact groundwater management programs that help ensure the sustainability of this important resource. From the source, the water is moved to the bottling plant, whether by tanker truck or pipe, where, if needed for added safety, it is disinfected. The water is then placed in a sealed sanitary container in the filling room of the bottling plant. A similar process is followed if the source is a public water system, with the exception of the added processing steps mandated by the United

² Beverage Marketing Corp.

States Food and Drug Administration (FDA) that must be employed to meet the purified or sterile standard of the U.S. Pharmacopeia 23rd Revision, e.g., distillation, reverse osmosis, or de-ionization.

Bottled water companies in the United States are primarily family owned and operated small businesses. Over 60% of the IBWA bottler members have annual sales of less than \$1 million and 90% have sales less than \$10 million. Almost all bottled water brands are sold on a local or regional basis, with the exception of imports and purified waters.

II. Regulatory Framework

A. Bottled Water is a Regulated Food Product

Bottled water is comprehensively and stringently regulated in the United States at both the federal and state levels, which helps ensure its safety and quality. At the federal level, bottled water is regulated as a packaged food product under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301 *et seq.*, and several parts of Title 21 of the Code of Federal Regulations (CFR). There are four pillars that support the federal bottled water regulatory framework: general food regulations, specific bottled water Good Manufacturing Practices, bottled water Standards of Identity, and bottled water Standards of Quality.

First, as a packaged food product, bottled water must comply with the general food provisions under FFDCA and accompanying regulations. The FFDCA defines “food” as “articles used for food *or drink* for man or other animals”³ Thus, all food and beverage products are regulated under the same statutory regime, and bottled water is no different in this respect than juice, carbonated soda, or energy drinks. Bottled water is subject to the same general FFDCA prohibitions against adulteration and misbranding as other beverage products, and is subject to the same general requirements for ingredient labeling, nutrition labeling, and product claims as other beverage products, as well as good manufacturing practices. From a market and legal perspective, bottled water is regulated the same as other beverages such as soft drinks, teas, and juices, which have water as their primary ingredient.

Bottled water containers, as with all food packaging materials, must be made from FDA-approved food contact substances. Thus, the plastic and glass containers that are used for bottled water products have undergone FDA scrutiny prior to being available for use in the market place. FDA has determined that the containers used by the bottled water industry are safe for use with food and beverage products, including bottled water, and that they do not pose a health risk to consumers. FDA is continually reviewing published scientific studies on food contact substances and also working with other federal and international agencies in research on health impacts for a variety of subsets of the general population. FDA has rigorous standards for research and evaluation of risk for food contact substances. The bottled water industry and others in the food industry rely on FDA to evaluate and determine which substances are safe to be used in contact

³ 21 U.S.C. § 321(f) (emphasis added).

with food. All of the bottled water industry's packaging containers have been determined to be safe by FDA.

B. Bottled Water Good Manufacturing Practices

The second pillar in the federal bottled water regulatory framework can be found in FDA's bottled water good manufacturing practices. FDA's testing frequency and other parameters are specified in 21 C.F.R. Part 129, as part of the Good Manufacturing Practices (GMP) for bottled water. Bottled water is one of only a few food products with its own specific GMP regulations. Indeed, 21 C.F.R. Part 129 contains GMP's specific to bottled water. This section entitled "Processing and Bottling of Bottled Drinking Water" sets guidelines for:

- Bottled Water Plant Construction and Design [including separation of the bottling room (a fill room), protection of processing operations, adequate ventilation and enclosure of washing and sanitizing operations]. These requirements are very specific in the construction of a bottled water facility and must be met by every producer of bottled water, regardless of size or volume.
- Sanitary Facilities.
 - Source water must be obtained from an approved source and conform to applicable state and local laws and regulations.
 - Operations water, if different from source water, must also be obtained from an approved source and conform to applicable state and local laws and regulations.
 - Required testing of source water and finished product includes testing for chemical parameters once a year, rather than over a number of years as with public water systems; radiological testing once every four years; and microbiological testing once a week.
 - Sampling and analytical methods used must be those recognized and approved by the government agency of jurisdiction.
- Sanitary Operations.
- Equipment Design and Construction.
- Production and Process Controls (including water analysis, sampling and analytical methods, sampling and inspection of containers and closures, and record keeping).

Disinfection and Treatment

FDA's bottled water regulations establish stringent standards of quality but do not mandate any particular type of treatment techniques to meet those standards. Bottled water products - whether from groundwater or public water sources - are produced utilizing a multi-barrier approach. From source to finished product, a multi-barrier approach helps prevent possible harmful contamination to the finished product as well as storage, production, and transportation equipment. Measures in a multi-barrier approach may include one or more of the following: source protection, source monitoring, reverse osmosis, distillation, micro-filtration, carbon filtration, ozonation, ultraviolet (UV) light or other safe and effective methods. Many of the steps in a multi-barrier system may be effective in safeguarding bottled water from microbiological

and other contamination. The piping in and out of plants, as well as storage silos and water tankers, are also maintained through regular sanitation procedures. In addition, bottled water products are bottled in a controlled, sanitary environment to prevent contamination during the filling operation.

In addition to a multi-barrier approach, members of IBWA are required to employ a Hazard Analysis Critical Control Point (HACCP) approach to quality assurance. (FDA does not currently require a HACCP program for most food products, including bottled water, but it is mandated by the IBWA Code of Practice). This practice scrutinizes the steps involved in the production process – from source to finished product – that are critically important to the safety of the product and puts in place systems to help ensure that those safety and quality control processes are functioning effectively. Identification of risk and severity of health effects and control measures for specific biological, chemical and physical agents are included. Widely used in the food and pharmaceutical industries, FDA considers HACCP a comprehensive method for assuring product safety. IBWA supports the provisions of HR 2749, the Food Safety Enhancement Act, which would require all food manufacturers to conduct a hazard analysis and establish and maintain preventive controls. Such pro-active procedures will assist producers in managing the risk of contamination and reduce the need to recall food products.

Differences Between Bottled Water and Public Drinking Water Monitoring

The FDA Standards of Quality for bottled water as contained in 21 C.F.R. § 165.110 (b) apply to all containers of bottled water sold in the United States. There are no waivers, or averaging of test results, or exemptions to the standards. Since the FDA bottled water standards of quality apply to each container of bottled water, anyone is able to have an analysis done on any specific bottle of water and determine if it meets those standards. This is very different from public water systems. You cannot take a sample from your faucet and have it analyzed to determine compliance with the public drinking water standards because most public water system testing standards apply to the point of distribution and not the point of consumption. In addition, public water systems are permitted to average test results for many contaminants over a 12 month period to determine compliance. They are often subject to reduced monitoring requirements, and are often granted testing waivers. Both bottled water and public drinking water regulatory requirements for testing and monitoring are required by law to be equally protective of public health. In addition, IBWA's Code of Practice is even more stringent than the FDA requirements for testing and monitoring.

Bottled water is frequently tested throughout its production. To get an accurate picture and comparison of the frequency of testing between bottled water and public water systems, one should examine volume produced, or better yet, consumed. The entire bottled water industry in the United States annually produces approximately the same volume of water as a city of 150,000 people uses in the same time period. In addition, bottled water companies do not have waivers or exceptions available to them, as public water systems do.

For coliform testing, for example, the City of New York produces 1.086 billion gallons of tap water per day and is required to perform a minimum of 480 microbiologic tests, which represents

one test per 67.875 million gallons produced. If coliform testing for bottled water was done on a volume basis, a large bottler producing 250,000 gallons per day would be required to perform at least one microbiological test per 1.875 million gallons or over 30 times as many tests per gallon of water than a public water system.

A comparison of chemical testing yields similar conclusions when frequency in terms of volume of water is considered. The National Primary Drinking Water Regulations (NPDWRs) provide a public water system that uses groundwater with opportunities for monitoring waivers and reductions in testing frequency. FDA does not permit reduction of testing frequency to less than once per year, unless a state having jurisdiction over bottled water specifically issues such a waiver or reduction in monitoring. For example, for inorganic chemicals such as arsenic, cadmium, chromium, and mercury, a municipal water system with a groundwater source may receive permission from a state for a reduction in monitoring from every year to once every three or even nine years. Ironically, the only time that the same public water system source monitors for these chemicals more frequently than a bottled water source is when the municipal water system exceeds the MCL for any of the chemicals, at which time the NPDWRs require four consecutive quarters of testing for the chemical to demonstrate compliance with the MCL before a reduction can be considered again. Bottled water must be tested for these same chemicals annually, without any opportunity to request a reduction in testing frequency from FDA. In terms of comparing volumes, a municipal water system that distributes 5 million gallons of water per day and tests for inorganic chemicals every three years would test one sample for every 5.475 billion gallons of water. If the frequency is reduced to every nine years, the municipal water system would test one sample for every 16.425 billion gallons of water. The bottled water facility described above would test for the same inorganic chemicals every 91.25 million gallons, or over 50 times as many test per gallon of water, with no reduction in monitoring frequency under FDA's regulations.

Most states have issued statewide or use waivers for certain synthetic organic chemicals (SOCs) for municipal water system source waters. Therefore, they do not test source water for chemicals such as glyphosate, endosulfan, or 2,3,7,8-tetrachlorodibenzo-p-dioxin ("Dioxin"). Bottled water sources must be tested for these chemicals annually, unless a state drinking water agency has specifically issued a waiver for the bottled water company's ground water source. However, this does not occur frequently, as most bottled water sources are regulated by state agencies that regulate food products, not public water systems, and these agencies have no authority to issue those exemptions or waivers under FDA's regulations. Bottled water finished products are not eligible for waivers, and must be tested annually. In contrast, a public water system groundwater system must collect only one or two post-treatment samples (depending on populations served) at the entry point into the distribution system for SOC analysis during each three-year monitoring period.

Radiological testing is required for both public water system and bottled water ground water sources. But, once again, there is a difference in testing frequency. Municipal water systems must test most radiological parameters once every four years. FDA, on the other hand, requires source water testing every four years, but finished product water must be tested annually.

C. Standards of Identity

The third pillar in the federal bottled water regulatory framework is the Standards of Identity. FDA has promulgated Standards of Identity regulations that define what a given food product is, its name, and ingredients that must be used, or may be used in the manufacture of the food. In 1995, FDA established standard of identity regulations for bottled water. The Standard of Identity encompasses (1) a general description of bottled water; (2) names that may be used to identify bottled water products and what the terms mean (e.g., “bottled water,” “drinking water,” or alternative terms such as “purified water” or “spring water”); and (3) FDA requirements for “other label statements” specific to bottled water products. 21 C.F.R. § 165.110 (a) contains the standard of identity for bottled water. It provides uniform definitions for the following bottled water classifications: bottled, drinking, artesian, groundwater, distilled, deionized, reverse osmosis, mineral, purified, sparkling, spring, sterile and well water.

The FDA definition of bottled water is “water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents.” Fluoride may be optionally added within the limitations established in § 165.110(b)(4)(ii).⁴

Labeling

The current system of federal labeling laws and regulations protects the public health (including providing consumers with useful product information) and permits bottled water companies to sell their products in an efficient and cost effective manner in interstate commerce. All packaged foods and beverage products, including bottled water, have extensive labeling requirements, including a statement of identity, compliance with the applicable definitions in the Standards of Identity, ingredient labeling, name and place of business of the manufacturer, packer or distributor, the product’s net weight, and if required, nutrition labeling. Any other information FDA may wish to require by regulation must be considered a material fact, the absence of which will result in misleading labeling for failure to reveal a material fact. Thus, if consumers are interested in more information about their choice of bottled water, they have the means to contact the manufacturer or distributor and request it.

FDA **does** require that the source be included on bottled water labels in a very specific instance. If a bottled water product’s source is a municipal water system and the finished bottled water product does not meet the FDA Standard of Identity for purified or sterile water, it must indicate on the label that it comes from a public water system source.⁵ Bottled water from a public water system source that is minimally treated to meet the bottled water quality standards would likely be labeled “drinking water.” Since public water systems are not likely to meet the bottled water standards for purified water (United States Pharmacopeia 23rd Revision) or any other standard of identity, the source becomes a material fact, the absence of which would make the product misbranded. The FDA Standards of Identity provide consumers with a clear and concise

⁴ 21 C.F.R. § 165.110 (a)

⁵ 21 C.F.R. § 165.110 (b)(3)

description of what type of bottled water they are purchasing. All spring water, purified water, mineral water, and other types of bottled water must all meet the same standards in order to claim a specific type of bottled water. Thus, consumers can have confidence that all products labeled “purified water” must meet the same FDA Standard of Identity and all products labeled “spring water” must be able to document a hydrological connection of the bottled water’s source with a spring that must continue to flow to the surface from an underground aquifer.

A bottled water product must meet the appropriate Standard of Identity and bear the required name on its label or it may be deemed misbranded under the FFDCFA.⁶ By law, FDA’s standards of identity regulations pre-empt state laws that are different from the FDA regulations.⁷ In promulgating the standards of identity and the labeling requirements for bottled water, FDA solicited, received and responded to numerous recommendations and suggestions on bottled water nomenclature and regulatory requirements. In fact much of the pre-amble to the final rule discusses the standards of identity and labeling issues.⁸ The issue of whether or not to require the source of the main ingredient (water) to be listed on the label was considered and rejected specifically by FDA. IBWA concurs with the FDA conclusion, as follows:

“Therefore, the agency concludes that the absence of information concerning the exact water source (e.g., specific municipal source, the well number, spring’s legal name, address of the source) is not a material omission that would render the labeling misleading because bottled water must meet FDA’s requirements which provide the consumer with assurances as to the safety, quality, and type of source. While the agency recognizes that some States require the geographic source identity, FDA simply is not persuaded that the additional information is a material fact that must be disclosed.

The brand name and the name of the manufacturer distinguish bottled waters as much as specific source labeling would. According to § 101.5(a), the label of a food in packaged form must specify conspicuously the name and place of business of the manufacturer, packer, or distributor. This labeling requirement provides consumers with the necessary information to contact the firm and obtain information (e.g., the name and location of the source, the well number, or the spring’s legal name) that is not provided on the label if they are interested. Therefore, FDA concludes that there is no basis on which to require that information concerning the specific source of bottled water appear on the label.”⁹

D. Bottled Water Quality

The fourth pillar of the federal regulatory framework for bottled water is the standards of quality. FDA establishes standards of quality regulations that set the allowable levels of substances that may be in a given food product. 21 C.F.R. § 165.110(b) contains the FDA Standards of Quality for bottled water. This regulation goes on for many pages and establishes quantifiable limits for microbiological, physical, chemical, and radiological substances for both source water and

⁶ 21 U.S.C. § 343 (g)(1).

⁷ 21 U.S.C. § 343-1 (a)(1)

⁸ Beverages: Bottled Water: Final Rule, 60 Fed. Reg. § 57076 (November 13, 1995)

⁹ 60 Fed. Reg. § 57104 – 57105 (November 13, 1995)

finished bottled water products. FDA has established standards for more than 90 substances pursuant to the Standards of Quality for bottled water. As FDA explained in its final rule amending the Standard of Quality for arsenic, the Standards of Quality regulations for bottled water are issued under the authority of the Standards of Identity and, therefore, pre-empt state laws that conflict with the FDA Standards of Quality.¹⁰

Most FDA bottled water quality standards are the same as EPA's maximum contaminant levels (MCL) for public water systems. The few differences are usually the result of the substance not being found in bottled water or the substance is regulated under another provision of law such as FDA's food additives program.¹¹ And, in some instances, FDA bottled water Standards of Quality are more stringent than EPA's public drinking water standards (e.g., copper, fluoride, lead, nickel and phenols).

DEHP (Di(2-ethylhexyl) phthalate, or Bis 2-ethylhexyl phthalate) is an example of a substance for which EPA has issued a regulation for tap water but FDA has not promulgated a similar standard of quality for bottled water. The three principal materials used in plastic containers in the bottled water industry -- polyethylene terephthalate (PET), polycarbonate, and high density polyethylene (HDPE) -- do not contain DEHP or any other phthalate chemical. Therefore, DEHP is not likely to be found in bottled water products. The EPA MCL for DEHP in tap water is 6 parts per billion (ppb). In an effort to maintain parity with the EPA tap water standards, IBWA adopted an identical standard in our Code of Practice prior to 1998, which all members must meet as a condition of membership.

(Note: A complete list and a comparison of the FDA standards of quality for bottled water, the EPA maximum contaminant levels (MCL), and the IBWA standards of quality can be found in the attached Appendix A of the IBWA Code of Practice. In addition, attached is a Comparison of US FDA SOQs and US EPA MCLs with IBWA Code of Practice SOQs - revised 7/2007)

Equivalency with Public Drinking Water Standards

Section 410 of FFDCA requires FDA to review all U.S. Environmental Protection Agency (EPA) National Primary Drinking Water Standards (NPDWS) for public water systems to determine their applicability to bottled water. If FDA determines that the NPDWS is applicable to bottled water, it must establish standards of quality for bottled water that are as stringent and protective of public health as the EPA's standards for public drinking water. If FDA fails to act within 180 days of the effective date of any new EPA NPDWS for public water systems, FDA must then apply the new NPDWS to bottled water.

¹⁰ Beverages: Bottled Water, 70 Fed. Reg. § 33694, 33699- 33700 (2005).

¹¹ FDA did not establish an allowable level for acrylamide and epichlorohydrin because EPA determined that establishing MCLs for these chemicals (used as flocculents in public drinking water) was not feasible, and because FDA regulations issued under the Food Additives Amendment of 1958 (Pub. L. 85-929) prohibit unsafe use of acrylamide and epichlorohydrin (as flocculents) in the production of bottled water. Regulations governing food additives can be found in 21 C.F.R. §§170-180. See 21 U.S.C. §§ 348(c)(3)(A).

As noted, Section 410 of the FFDCA was enacted by Congress to ensure that FDA's regulation of bottled water is at least as protective of the public health as EPA's regulation of public water systems.¹² Key elements include:

1. Under Section 410, whenever EPA issues a primary drinking water regulation under section 1412 of the Safe Drinking Water Act that establishes a "maximum contaminant level" (MCL) or "treatment technique" for a contaminant, FDA is required to either: (a) publish a standard of quality for that contaminant for bottled water; or (b) make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems but not in water used for bottled drinking water.
2. FDA is required to publish either the standard of quality or the finding that such regulation is not necessary not later than 180 days before the EPA regulation becomes effective. If FDA fails to act within that time, then the MCL's and/or treatment techniques established by the EPA become applicable to bottled water as a matter of law. If this happens, FDA – not EPA – would be responsible for enforcing the EPA standard or treatment technique made applicable to bottled water by operation of law.
3. As noted above, the purpose of Section 410 is to ensure that bottled water is regulated at least as stringently as public water systems. If EPA sets an MCL, and FDA determines that such MCL is applicable to bottled water, then FDA is required to set an allowable level that is "no less stringent" than the MCL set by EPA. Similarly, if EPA establishes a treatment technique, and FDA determines that such treatment technique is applicable to bottled water, then FDA is required to set requirements "no less protective of the public health" than the treatment technique established by EPA.

Examples of how Section 410 has operated are as follows:

1. FDA establishes a standard of quality regulation. FDA promulgated a regulation establishing a standard of quality for arsenic of 10 ppb on June 9, 2005,¹³ which became effective on January 23, 2006. This was in response to EPA's issuance of a revised arsenic standard for public water systems – at the same level of 10 ppb - that also became effective on January 23, 2006.¹⁴

On May 29, 2009, FDA promulgated a regulation establishing a zero tolerance for *E. coli* in the sources for bottled water, as well as in finished product. The rule becomes effective for bottled water on December 1, 2009.¹⁵ The regulation provides a standard

¹² Federal Food, Drug, and Cosmetic Act § 410, 21 U.S.C. § 349 (2005).

¹³ Beverages: Bottled Water, 70 Fed. Reg. § 33694 (2005)

¹⁴ National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. § 6976 (2001)

¹⁵ 74 Fed. Reg. § 25651 (May 29, 2009)

of quality as protective of public health as the EPA's Ground Water Rule that also becomes effective on December 1, 2009.¹⁶

2. FDA determines EPA action not applicable to bottled water. After reviewing EPA's Interim Enhanced Surface Water Treatment Rule (IESWTR), FDA concluded in a *Federal Register* notice on July 5, 2001,¹⁷ that it would not apply to bottled water, since bottled water is produced either from groundwater sources that are not under the influence of surface water or from municipal water systems that would have already complied with the IESWTR.
3. FDA takes no action. Following EPA's issuance of MCL's and monitoring requirements for nine contaminants, FDA did not amend its Standard of Quality regulations before the statutory deadline. In that case, Section 410 operated and the MCL's established by EPA, as well as, the monitoring requirements, became applicable to bottled water, as a matter of law.¹⁸ This is the only occasion where FDA has not acted within the statutory timeframe.

Total Coliform and *E. Coli*

As mentioned above, FDA has just recently established a zero tolerance standard of quality for *E. Coli* in bottled water. However, since 1995, FDA has had a microbiological standard of quality for coliform in bottled water (21 C.F.R. § 165.110 (b)(2)) that requires bottled water to meet the following standards, depending on the type of analysis being done:

- “i) Multiple-tube fermentation method. Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or
- (ii) Membrane filter method. Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.”

On May 29, 2009, FDA published additional microbiological requirements rule that require bottled water manufacturers to test both source and finished product for the presence of total coliform bacteria. This new rule is effective December 1, 2009.¹⁹

The new rule establishes a “zero tolerance” standard for *Escherichia coli* (*E. coli*) for source and finished product. It mandates that if a bottled water source tests positive for total coliform, every total coliform-positive sample must be confirmed for presence or absence of *E. coli*. The rule

¹⁶ 71 Fed. Reg. § 65574 (November 8, 2006)

¹⁷ Beverages: Bottled Water, 66 Fed. Reg. § 35439 (2001).

¹⁸ Bottled Water: Monitoring Requirements, 63 Fed. Reg. § 42199 (1998).

¹⁹ 74 Fed. Reg. § 25651 (May 29, 2009)

also provides specific detail on what must be done to correct and return a source into service after a positive *E. coli* result.

Bottled water manufacturers that obtain their source water from a natural source (e.g., spring or artesian well) or any other source other than a public water system (PWS) must test their source water at least weekly for total coliform. If that source water is total coliform positive, the bottled water manufacturer must conduct follow-up testing to determine whether any of the coliform organisms are *E. coli*. Source water found to contain *E. coli* will not be considered water of a safe, sanitary quality as required by FDA for use in bottled water. FDA's decision to include this provision is based primarily upon the legislative and regulatory requirements under Section 410 of FFDCa to demonstrate that the rule provides at least equivalent protection of public health when compared to the USEPA Ground Water Rule, which also becomes effective on December 1, 2009.

In 2001, IBWA adopted a zero tolerance standard of quality for *E. coli* for its members and provided clear guidance in how to confirm the presence or absence of this more accurate indicator of fecal contamination. IBWA has urged FDA to establish a zero tolerance for *E. coli* for several years and fully supported the adoption of the new rule.

The EPA rule for public drinking water requires that a ground water-based PWS follow up *E. coli*-positive test results or possibly other fecal indicators with a series of actions, including additional testing and corrective action (such as an alternate source, remedying the deficiency or providing treatment to achieve 4-log virus inactivation). However, the EPA rule does not prohibit such a contaminated source from being used again in the future as long as corrective action has been implemented. To achieve at least an equal level of public health protection, while not having to rely on a "reactive" set of measures, FDA simply established an absolute standard of quality at both the source and for finished product. As a result of this strict approach, any non-PWS bottled water source shown to be positive for *E. coli* is considered unsuitable for use for bottled water production. In order to resume use of the same source for bottled water production, FDA mandates that appropriate corrective actions be implemented and followed by a defined testing regime showing the absence of *E. coli*.

Before a bottler can use water from a source that has tested positive for *E. coli*, the bottler must take appropriate measures to rectify or otherwise eliminate the cause of *E. coli* contamination of that source in a manner sufficient to prevent its recurrence. This provision is intended to eliminate microbial risk to the product from a contaminated source that relies solely on the bottling process to eliminate the contaminant. While FDA permits bottlers to remove certain compounds ("undesirable elements") prior to bottling the product, this new rule does NOT permit treatment as an acceptable means to "rectify" the problem. A source previously found to contain *E. coli* can only be considered again for bottled water production when:

- a. Corrective actions have been implemented
- b. Five samples collected over a 24-hour period from the same sampling site are *E. coli* negative.

This new regulation is *more protective* of public health than the corresponding rule for public drinking water, because it does not permit the continued use of a contaminated source for bottling purposes.

Microorganisms

If pathogenic microorganisms are present in bottled water and potentially injurious to public health, FDA has authority to classify the product as adulterated²⁰ and subject it to enforcement action, such as seizure of the product.²¹ This would apply to such microorganisms as *Cryptosporidium*, *Legionella*, *Giardia lamblia*, and other pathogens that are generally found in surface water. However, the Agency has not established standards of quality for these three microorganisms because bottled water is produced from either groundwater sources that, by definition, must not be under the influence of surface water,²² or from municipal water systems that are already compliant with EPA's Surface Water Treatment Rule.²³

III. Oversight and Inspections

Inspections

In recent years, FDA has increased the frequency of inspections of all food facilities and is working with state agencies with jurisdiction over food products through contracts to augment the FDA Office of Regulatory Affairs inspectors with state personnel. In addition, 24 states require out-of-state bottlers to be either licensed or permitted to do business in the state and as a condition of obtaining a permit, they require proof of inspection. The 26 states that do not require out-of-state bottlers to be permitted regulate the in-state bottlers and use either state or county inspectors to ensure compliance with the federal and/or state bottled water regulations.

Beyond these government inspection programs, IBWA requires its member bottlers to submit to an annual inspection by an independent, third party organization as a condition of membership. IBWA members are inspected for compliance with the IBWA Code of Practice, which includes all FDA regulations as well as several more stringent requirements. The current inspection companies are Underwriter Laboratories (UL) and NSF International (NSF). IBWA bottler members must agree to a third party inspection by one of these two companies when they join or renew their membership.

IBWA members have embraced inspections as a method of enhancing a company's compliance and quality programs through the IBWA Code of Practice and its annual independent third party inspection program. This IBWA program has evolved (and continues to do so) as the industry and technology have changed, and new scientific developments have provided new information that will improve the safety and quality of bottled water.

²⁰ 21 U.S.C. § 342.

²¹ 21 U.S.C § 334.

²² 21 C.F.R. 165.110 (a)(2)(ii)

²³ National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule, 71 Fed. Reg. § 653 (2006).

For many of our members, the IBWA inspection program is just one of many to which their facilities are subjected each year. FDA has included bottled water in many of its efforts to secure the food and agriculture critical infrastructure. Bottled water has been classified by FDA as warranting increased scrutiny to guard against security risks. In addition, state and federal agencies have inspected bottled water facilities with increased regularity. Within the private sector, retailers and distributors have also increased their oversight of their supplier network, as have manufacturers and processors have for their suppliers. IBWA welcomes this oversight, and is working with its members, customers and suppliers to better coordinate, manage and standardize the quality and quantity of inspections. IBWA is looking to such programs as the Global Food Safety Initiative, which is a world-wide effort to enhance food safety standards, to assist us in this effort.

HR 2749, as amended, would provide for risk based frequency for inspections by FDA. IBWA supports this approach because it should provide a better allocation of FDA resources to be dedicated to higher risk food categories than lower risk food categories. Increased frequencies of inspections would be welcomed by IBWA members. IBWA members are currently required, as a condition of membership to undergo annual inspections by an independent third party. Unfortunately, not all bottled water companies in the United States are subjected to this standard. Inspection frequency would be particularly important as FDA implements the hazard analysis and preventative controls provisions of HR 2749.

FDA Enforcement

The FDA Standards of Identity and Standards of Quality apply to each container of bottled water. If a bottled water product contains a contaminant that exceeds an FDA “Standard of Quality”, the product must be labeled to reflect this substandard condition (e.g., “contains excessive _____”).²⁴ Failure of a bottled water container to meet the standards of quality and to be properly labeled may subject it to recall by the company and removal from the market place. Further, and most importantly, if a bottled water product contains a contaminant that exceeds the Standard of Quality and it may be injurious to health, such product may be considered adulterated under the Federal Food, Drug, and Cosmetic Act (FFDCA) and subject to FDA enforcement action even if its label discloses the contaminant. The following tools are available to FDA in its enforcement of bottled water regulations:

- Pursuant to section 704 of the FFDCA (21 USC § 374), FDA may inspect any food manufacturing facility, including a bottled water plant.
- In the event a product is deemed misbranded or adulterated, FDA generally seeks voluntary compliance through the use of warning letters and requests for voluntary recalls.
- If the company declines to comply with applicable requirements or declines to take action to correct the violation, FDA may take civil action through either seizure or

²⁴ 21 C.F.R. § 165.110(c), 21 U.S.C. § 343(h)(1)

injunction. Depending on the circumstances, a criminal prosecution may also be warranted.²⁵

- FDA may also use its authority to warn the public (e.g., press releases) or to publicize a product recall.
- Finally, under a new law passed just last year creating a reportable food registry, all food and beverage companies will be required to report to FDA whenever they have evidence showing a reasonable probability that their product may cause serious adverse health consequences or death, and FDA may take enforcement action if a company fails to do so.

IBWA supports granting FDA authority to mandate a recall under circumstances where an article of food presents an imminent threat of serious adverse health consequences or death. IBWA supports the provisions of HR 2749, which provide due process protections and limitations on FDA's authority to issue recalls, subpoenas, civil penalties and quarantine orders. These new enforcement authorities, along with the ability to suspend a facility's registration, would provide FDA with a wide choice of options to assist them in enforcing the U.S. food safety laws and substantially improving compliance by food companies.

FDA Has Jurisdiction Over Intrastate and Interstate Commerce

FDA's jurisdiction over bottled water products (and any other product regulated by FDA) extends not only to those products that move in interstate commerce, but to those products sold within a single state that are enclosed in packaging materials that have moved in interstate commerce. Known as the component theory of FDA jurisdiction, courts have long held that if a component of a food product moves in interstate commerce, FDA has jurisdiction over the finished product, regardless of whether the finished product itself moves in interstate commerce. This is because it is a violation of the FFDCA to adulterate or misbrand a food while it is held for sale after shipping in interstate commerce.²⁶ This position is well established by judicial opinion.

For example, in United States v. An Article of Food, 752 F.2d 11 (1st Cir. 1985), FDA brought a seizure and condemnation action against three lots of bottled soft drinks on the premises of a beverage producer in Puerto Rico. FDA contended that the beverages were adulterated because they contained an unapproved food additive (i.e., potassium nitrate). The bottler conceded that the beverages contained potassium nitrate but argued that FDA lacked jurisdiction because, although the potassium nitrate had been shipped in interstate commerce before addition to the beverages, the beverages had not. The court quickly disposed of the argument, commenting that "the 'shipment in interstate commerce' requirement is satisfied when adulterated articles held for in-state sale contain ingredients shipped in interstate commerce."²⁷

²⁵ 21 U.S.C. § 333(a). Indeed, responsible officials of a food company may face criminal penalties for any violation of the FFDCA by the company, even if there was no "intent" to violate the law. *United States v. Park*, 421 U.S. 658 (1975).

²⁶ 21 U.S.C. § 331(k).

²⁷ An Article of Food, 752 F. 2d at 15 (citations omitted). This is only one in a long series of federal court decisions concluding that interstate shipment of a component of a food subjects the finished food to FDA jurisdiction. See also U.S. v. Sullivan, 332 U.S. 689 (1948) (labeling requirements of the Act apply to druggist who obtained drug product

The necessary interstate commerce element would likewise be satisfied based only on a component of a food product where the component is not edible, such as food packaging.²⁸ Indeed, IBWA is confident, based on the judicial precedent discussed above, that a court, if asked, would likely conclude that FDA has jurisdiction over bottled water if the bottle or other material used to package the water had been shipped in interstate commerce, even if the bottled water itself was processed and sold exclusively within the boundaries of a particular state.

Moreover, the FFDCRA was amended in 1997 to create a statutory presumption that all FDA-regulated products have traveled in interstate commerce. Thus, FDA no longer needs to establish the interstate commerce element to assert jurisdiction. 21 U.S.C. § 379(a) states, “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.”

IV. Consumer Access to Bottled Water Information

IBWA supports a consumer’s right to clear, accurate and comprehensive information about the bottled water products they purchase. IBWA agrees with the conclusion in FDA’s 2000 Final Study Report, titled “*Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water*” (the “Feasibility Study Report”) that placing on bottled water labels all of the information contained in the Consumer Confidence Reports (CCRs) provided by public water systems is not feasible for many reasons, including limited space available.²⁹ IBWA believes the most feasible mechanism for consumers to obtain this information is through a request to the bottler or distributor.

The FDA Feasibility Study Report looked at various ways that bottled water information could be communicated to consumers, including company contact information on the label, placing specific contaminant and other information on the label, distributing pamphlets at the point of

in bulk and repackaged it for intrastate sale where bulk product had previously moved in interstate commerce); U.S. v. Dianovin Pharmaceuticals, Inc., 475 F.2d 100 (1st Cir. 1973) (injectable form of vitamin K constituted drug held for sale after shipment in interstate commerce where components had moved in interstate commerce; United States v. Cassaro, Inc., 443 F.2d 153 (1st Cir. 1971) (finding bakers who sell bread and rolls made from flour shipped in interstate commerce are subject to prosecution for placing the flour in insect-contaminated equipment, thereby adulterating it); U.S. v. Detroit Vital Foods, Inc., 330 F.2d 78 (6th Cir. 1964) (finding misbranded tablets constituted drug held for sale after shipment in interstate commerce because ingredients had been shipped in interstate commerce); United States v. 40 Cases, More or Less, of Pinocchio Brand . . . Oil, 289 F.2d 343 (2d Cir. 1961) (concluding FDA has authority to proceed against misbranded or adulterated cans of vegetable oil that were mixed entirely within New York state from properly labeled oils shipped in interstate commerce); United States v. Varela-Cruz, 66 F. Supp. 2d 274 (D. Puerto Rico 1999) (rejecting defendants’ contention that FDA lacked authority to prosecute milk adulteration case because the salt used to economically adulterate milk had traveled in interstate commerce, thereby providing necessary interstate commerce element).

²⁸ Cf. Baker v. U.S., 932 F.2d 813, 814, 816 (9th Cir. 1991) (finding that “shipment in interstate commerce” occurs “even when only an ingredient is transported interstate” and that “whether the ingredient is a main one or a minor one . . . is inconsequential”); U.S. v. Miami Serpentarium Lab., Food Drug Cosm. L.J. (CCH 38, 164 (S.D. Fl. 1982) (finding federal jurisdiction even when the “interstate constituent comprises only a minute fraction of the article” and that “it is immaterial whether the ingredient is characterized as ‘active’ or ‘inactive.’”).

²⁹ 65 Fed. Reg. § 51833-51839 (2000)

purchase and providing information via the internet. With regard to the feasibility of providing the same information on a bottled water label that is contained in CCRs provided by public water systems, FDA concluded that:

“We agree with comments that stated it is not feasible to provide all of the information that is analogous to that contained in a CCR on a bottled water label. Such information would be excessive in limited label space, particularly on the small, single serving bottles. In addition, information that requires frequent changes due to changing test results may result in a misbranded product. Costs of frequent label changes that are necessary to ensure accurate information on the contents of a bottled water product, due to frequently changing information, may present an economic hardship to companies. Moreover, even annual updates that represent the contaminant history would need information to put the history for all such CCR-type information in context for the consumer and would be excessive in limited label space.”³⁰

IBWA believes that consumers should have timely and easy access to information about their bottled water products. To help ensure that consumers have access to useful and meaningful bottled water product information, the IBWA Code of Practice requires all members to comply with the following:

- All proprietary brand products must include a telephone number on their labels so consumers can easily contact the company and request product information. (In 2001, IBWA submitted a petition to FDA requesting that the Agency require a phone number to be listed on the label of all bottled water products.)
- IBWA maintains an online member database, which also contains a specific link to a member company’s water quality information and/or contact information that may be used to secure a company’s water quality report.

IBWA offers counsel to bottlers as to how to prepare and present water quality reports. Such assistance is provided one-on-one with bottlers; in educational sessions at national, regional, or local bottled water industry meetings; and in monthly, weekly, and targeted publications. IBWA makes available to its members an online Water Quality Reporting Template, which users may download and enter extensive water quality reporting information based on analytical testing results for all regulated parameters. IBWA provides either company contact information, a link to the company website for contact purposes or a direct link to water analysis data by brand on the IBWA website: www.bottledwater.org

Disclosures, such as those required by EPA in Consumer Confidence Reports for public water systems, are not required of any food or beverage product. These products must meet the safety standards and must be manufactured according to FDA regulations. However, bottled water companies voluntarily provide consumers with easy access to information about their products.

³⁰ 65 Fed. Reg. § 51836 (2000)

As mentioned earlier, consumers have a plethora of choices in brands of bottled water. That is not the case with their public water system. Consumers cannot make a choice of which municipal water is piped into their homes. If a bottled water company does not satisfy a consumer's request for more information, that consumer is free to make other brand choices. Such requests are not a matter of consumer safety because a bottled water product that does not meet the FDA Standards of Quality, which are the health-based standard for bottled water, may not stay in the market place and is subject to enforcement action by the FDA.

V. Environmental Impact of Bottled Water

The bottled water industry is strongly committed to stewardship of the environment. Whether it is developing groundwater protection areas, supporting state groundwater management programs or developing new technology to reduce the plastic needed for its containers, the bottled water industry has been on the forefront of innovation in the food and beverage industry in developing policies and technology to promote environmental stewardship. IBWA is dedicated to the comprehensive management of bottled water packaging to provide the highest quality, cost effective and environmentally responsible containers possible. IBWA and its members approach packaging issues in a manner emphasizing the most effective and efficient solutions to reduce the impact on the environment, while taking into account the equal responsibility of all solid waste generators. Consideration must also be given to behavioral solutions, such as public education and enforcement of existing recycling and litter control laws.

Packaging

IBWA and its members believe a comprehensive approach must be utilized, emphasizing efficient and effective solutions that address the broad array of solid waste and treat all solid waste, including waste from all food and beverage products, in an equitable manner. IBWA believes the following set of principles should be a guide in addressing solid waste, recycling and litter:

- Education and awareness - Behavioral approaches to solid waste reduction and litter control must be a part of any good public policy.
- Efficient, yet effective, solutions - Programs that more properly balance cost and convenience with effectiveness should be given a higher priority.
- Curbside recycling programs – Improvements and expansion of curbside recycling and venue recycling opportunities need to be addressed.
- Equitable treatment for all waste producers - In order to effectively address the total municipal solid waste stream, proper solutions must look beyond just beverage containers.

Bottled water is one of thousands of food and beverage products that are packaged in plastic containers. Members of IBWA recognize their responsibility for their containers and are taking steps to mitigate its environmental impact. These steps will be outlined later in this testimony. However, the issue of environmental impact of plastic containers and the impact of those containers on community landfills is not solely to be borne by the bottled water industry, but

rather the producers of all consumer products. In addition, the debate must also include how do we, as a nation, increase the recycling rates and capture more of the plastic packaging for reuse. Plastic bottles that enter the recycling stream provide a valuable, sought after feedstock for numerous other consumer products.

The bottled water industry has one segment that has a uniquely positive story on reuse and recycling. The home and office delivery segment of the bottled water industry uses primarily three and five gallon plastic containers that are routinely returned, sanitized and reused from 20 to 40 times. The bottles are then sent by the bottler to be recycled. Almost 100% of these containers are first reused, and then recycled, and the processed plastic is made into a wide variety of different products. As indicated earlier in this testimony, the home and office delivery segment of the bottled water represents about 20% of the industry. IBWA is not aware of any other industry that experiences this incredible reuse and recycling rate.

For the retail market segment of the bottled water industry, the most common plastic used is PET, although HDPE and other plastics are used as well. These containers are fully recyclable and the value of the recycled plastic has been steadily increasing. However, bottled water is only one of many consumer products that use PET plastic in the production of the product. To put the issue in perspective, in 2006 a total of 244 billion units of ready-to-drink beverages were sold, and only 33% of those units were packaged in plastic (see attached Chart I). A total of 36 billion units of bottled water were sold in 2006, amounting to only 15% of all beverage units sold. That means that 85% of all the beverage units sold in 2006 were for products *other than* bottled water.

With regard to the lack of recycling of beverage units, bottled water critics claim that our products are filling up municipal landfills. Beverage containers are recycled at an overall rate of approximately 25%, a much higher rate than other food containers, and that rate continues to increase. Bottled water containers, as a subset of all beverage containers, has a recycling rate of approximately 23%. However, bottled water containers make up only 0.3% of the entire municipal waste stream in the United States (see attached Chart II). Clearly, bottled water containers are not significantly contributing to municipal landfills. Significant overall progress with recycling and the management of municipal waste streams cannot be made unless the public policy net is cast much more broadly than just bottled water. Efficiently capturing and recycling of *all* plastic products should be a priority.

The national recycling rate for PET plastic bottled water containers (.5 liter or 16.9 ounce size) has improved by 16.42%, according to new data from two new studies: “2008 Post Consumer PET Bottle Bale Composition Analysis” and “2007 Report on PET Water Bottle Recycling,” both produced by the National Association for PET Container Resources (NAPCOR). According to data from an earlier 2006 bale content study for all beverages, the number of PET bottles counted per pound was approximately 12. In 2008, the total number of PET bottles increased to 13.78, a reflection of the dramatic increase in water bottle collection, as well as the continued lightweighting of other plastic containers. The 2007 NAPCOR study on water bottle recycling has determined that the recycling rate for water bottles is 23.4%, representing a significant 16.42% increase over the 2006 recycling rate of 20.1%.

With data compiled during an extensive bale composition study in 15 locations in 14 states, the 2008 NAPCOR PET analysis states: “Water bottles are now the most recycling container in curbside programs by weight, and overwhelmingly by number.” PET water bottles now account for 50% of all the PET bottles and containers collected by curbside recycling. This trend was consistent in all curbside bales sampled nationally, with no major shifts observed in any other plastic container category. The biggest jump in water bottle collection for recycling was in California, where a state-funded consumer education campaign, emphasizing that water bottles are recyclable, seems to be having the desired effect.

In tandem with the new NAPCOR data, IBWA tracked the average amount of plastic used in .5 liter (16.9 ounce) PET bottles, using published data from the Beverage Marketing Corporation (BMC) to determine the light-weighting trend currently being seen in many brands of bottled water. In the year 2000, the average weight of a plastic water bottle was 18.90 grams. It has declined consistently on an annual basis and by 2007, the last year BMC has complete data (as of this date), the average weight of a PET water bottle was 13.83 grams – a 26.7% decline.

The bottled water industry recognizes that the recycling rate for bottled water containers is not satisfactory. IBWA has joined with the American Beverage Association, the Food Marketing Institute, the Grocery Manufacturers Association and the National Recycling Coalition in the National Recycling Partnership to fund a pilot project in Hartford, Connecticut. The pilot project will measure the impact of having single stream collection with consumer financial incentives to recycle. The pilot project is utilizing Recycle Bank. Recycle Bank provides monetary credits on individual debit cards to each participating household for the amount that they recycle. We are hopeful that this project will demonstrate a means to increase community recycling rates, while lowering the impact on landfills. The project was launched in May of 2008, and the preliminary results have been very promising: volumes recycled by the pilot households more than doubled from the pre-pilot volumes and the average quantity of recycled material also doubled. In addition, the Partnership joined with the United States Environmental Protection Agency (EPA) in funding research on rebranding recycling. This is just one of many efforts in communities throughout the United States to increase the recycling rates.

More still needs to be done. In 1999, almost 1000 communities around the country provided their citizens with curbside recycling. However, less than 900 communities offer this service today. Rather than fewer communities providing curbside recycling, more communities should be encouraged to establish curbside programs and promote recycling within their jurisdictions. We all can play a role in making this happen and the bottled water industry stands willing to work with others to enhance community recycling. Many of IBWA members donate bottled water to community events, such as fundraising efforts or community promotional events. They often condition the donation on the event sponsor providing recycling opportunities at the event.

As part of the environmental stewardship of the bottled water industry, innovations and new technologies are being developed to reduce the environmental impact of the industry. Examples of such innovation can be seen in the container, itself. As discussed above, the PET bottled water container is produced using far less plastic than it did 10 years ago. This innovation is readily apparent to consumers as they can actually feel the difference in their bottled water container.

Second, many bottled water companies are using some recycled PET material when making their plastic bottles. This reduces the amount of virgin material necessary to make these containers. And third, new technologies are being developed to allow bottlers to use a “compostable” container made from corn. Bottled water is one of only a few food products that have begun to be packaged in this type of container, and a few IBWA members now use this type container for bottled water. Since it is relatively new to the market, the use of this new technology may increase over the next few years.

The bottled water industry should be recognized and supported in its efforts to innovate and find solutions to reducing the environmental impact of its product. Like all manufacturers of consumer goods, the industry is finding new ways to reduce the amount of petroleum used to deliver its product to market, whether using hybrid trucks or configuring delivery routes. These efforts are ongoing and vital to the continued economic health of the industry.

VI. Water Stewardship

Groundwater is the primary water source for bottled water products sold in the United States. Because a long-term sustainable supply of high-quality water is literally the foundation and “lifeblood” of bottled water companies, IBWA member bottlers recognize the critical importance of environmental conservation and stewardship of all water resources. Bottled water companies perform hydro-geological assessments, monitor the quality and quantity at source wells, purchase surrounding land for protection and recharge of their source and participate in local and regional water stewardship partnerships on aquifer protection.

Groundwater is a renewable natural resource that is replenished through the hydrologic cycle. The duration of the replenishment cycle is influenced by weather patterns, recharge areas and characteristics, geologic settings and other site-specific factors. When developing and using water resources, it is essential that use is balanced with the replenishment cycle and the requirements of the regional demand for the resource. IBWA supports groundwater management policies, laws and regulations that are comprehensive, science-based, multi-jurisdictional, treat all users equitably, and balance the rights of current users against the future needs to provide a sustainable resource.

The bottled water industry uses minimal amounts of ground water to produce an important consumer product—and does so with great efficiency. According to a 2005 study by the Drinking Water Research Foundation (DWRF), annual bottled water production accounts for less than 2/100 of one percent (0.02%) of the total groundwater withdrawn in the United States each year.³¹ Additionally, based on information gathered in the DWRF study, in 2001, 87% of the water withdrawn by bottled water companies, on average, was actually bottled for consumption by humans, so the bottling process is a very efficient one.³²

³¹ Drinking Water Research Foundation, 2005, *Bottled Water Production in the United States: How Much Groundwater Is Actually Being Used?*

³² *Id.*

VII. Bottled Water Plays a Vital Role in Disaster Response

Clean, safe water is a critical need for citizens and first responders immediately following a natural disaster or other catastrophic event. Unfortunately, the availability of water from public water systems is often compromised in the aftermath of such an event. During these times, bottled water is the best option to deliver clean safe drinking water quickly into affected areas.

The bottled water industry has always been at the forefront of relief efforts during natural disasters and other catastrophic events. Throughout the years, bottled water companies have immediately responded to the need for clean water after natural disasters, such as Hurricanes Andrew, Charlie, and Katrina, the earthquakes and forest fires in the West, or the terrorist attacks on the Pentagon and World Trade Center. Our companies also provided bottled water to those in need last year in the aftermath of the spring flooding in the Midwest and to the victims of Hurricanes Gustav and Hanna.

The bottled water industry looks to IBWA to help coordinate activities with state and federal government agencies and organizations, such as the American Red Cross and Salvation Army. Working together, we determine the quickest and most effective way to deliver safe bottled water into affected areas to augment other relief efforts.

An example of this experience was the bottled water industry's response to the September 11, 2001, attacks on the Pentagon and World Trade Center. IBWA worked with the Salvation Army in identifying a staging area in Northern Virginia for bottled water being delivered to the Pentagon. The industry began shipping product to that staging area in the afternoon of September 11, 2001. In addition, IBWA identified one of its member companies' facilities on the western shore of the Hudson River as a staging area for bottled water being delivered across the river to "ground zero" in New York City. IBWA then notified its member bottlers of this location and they began shipping bottled water to the facility before the end of the day. IBWA also worked with the Federal Emergency Management Agency (FEMA) and National Guard so that bottled water and other goods could be staged at the facility and transported into New York City.

Another example is Hurricane Katrina, a tragic disaster that impacted millions of Americans. IBWA and its members were actively involved in responding to this monumental disaster. From IBWA members personally driving truckloads of bottled water and other relief supplies into affected areas, to shipments of multiple truckloads to remote communities—in many cases as the first responders on the scene—to the execution of staff/member partnerships to help identify and make arrangements with stricken communities for direct relief deliveries, the bottled water industry stepped up to the plate to donate products to those in need. IBWA members provided tens of millions of bottled water servings, ranging from 16-ounce bottles to five gallon bottled water cooler containers in the aftermath of Hurricane Katrina. This is in addition to the tankers of bulk drinking water supplied by IBWA bottlers and the tens of millions of servings provided through the relief organizations, state emergency management agencies and the Federal Emergency Management Agency.

Bottled water companies have also worked with municipal water systems to provide the public with clean, safe bottled water when the public drinking water infrastructure is compromised or when the water does not meet state and federal health standards. An example of such a situation occurred last year in Washington, DC, when lead levels in some parts of the public water supply exceeded the action level set by the United States Environmental Protection Agency (EPA). Bottled water and point-of-use systems were used to meet the drinking water needs in the affected area until the Washington Area Sanitation Commission was able to reduce the lead levels to meet EPA standards.

The efforts of the industry to provide crucial drinking water to citizens afflicted by disasters are contingent on a viable commercial market. The commercial market provides them with the capital and resources to respond when needed. The industry cannot exist only for disaster response as some industry critics would have people believe. The need for such philanthropic efforts can only be seen when people need it the most. To discourage the use of bottled water or question the safety of bottled water does a disservice to an industry that is called upon every year to provide much needed drinking water.

VIII. Conclusion

Bottled water provides consumers with a convenient, healthy beverage choice. The standards of quality for bottled water are as protective of public health as those for public drinking water by law and practice. Such standards for bottled water are applied to each container and failure to meet those standards may result in a recall or FDA enforcement action. If a consumer is interested about what is in their bottled water, they have multiple methods of obtaining it, e.g., from the company website, contacting the company directly, researching state websites which post the information or IBWA's website. If they are not satisfied with the response or the information provided, they have many choices among bottled water brands.

IBWA appreciates the opportunity to provide the Subcommittee with this overview of the bottled water industry. If you would like more information or have further questions, please feel free to contact us.

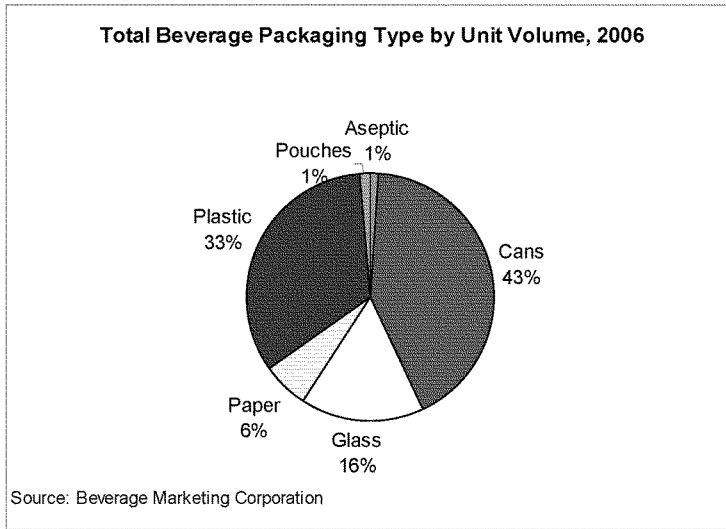


Chart I

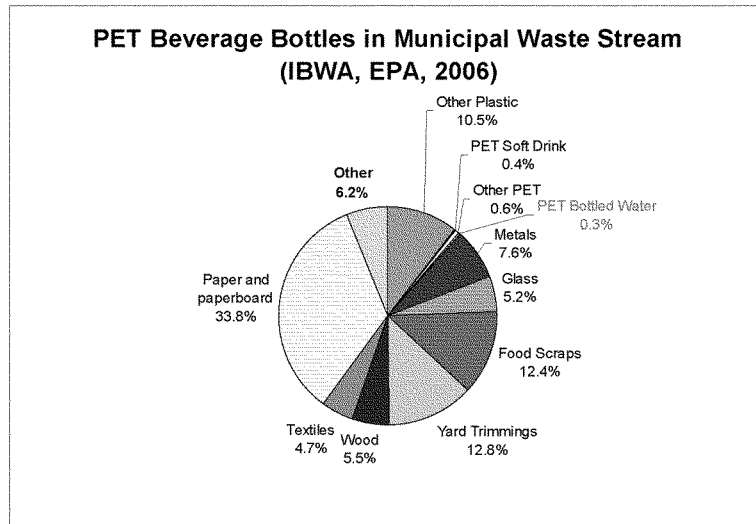
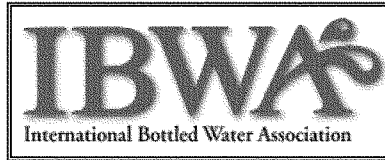


Chart II

Model Code



Bottled Water Code of Practice

Revised January, 2007

International Bottled Water Association
1700 Diagonal Road, Suite 650
Alexandria, VA 22314
(703) 683-5213
<http://www.bottledwater.org>

Appendix A
2007 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP	MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
<i>Individual Group Analytes</i>				
Inorganic Chemicals (IOCs)	ANNUALLY	IBWA SOQ	FDA SOQ	EPA MCL
	(Product and Source)			
Antimony (1)		0.006	0.006	0.006
Arsenic		0.01	0.05	0.05
Barium	For items with footnote (2), see FDA D/DBP Rule Monitoring Requirements on page 21.	1	2	2
Beryllium (1)		0.004	0.004	0.004
Bromate (2)		0.010	0.010	0.010
Cadmium		0.005	0.005	0.005
Chlorine (2)		0.1	4.0	4.0
Chloramine (2)		4.0	4.0	4.0
Chlorine dioxide (2)		0.8	0.8	0.8
Chlorite (2)		1.0	1.0	1.0
Chromium		0.05	0.1	0.1
Cyanide (1)		0.1	0.1	0.2
Fluoride		(3)	(3)	4
Lead		0.005	0.005	0.015 AL
Mercury		0.001	0.002	0.002
Nickel (1)		0.1	0.1	
Nitrate-N		10	10	10
Nitrite-N		1	1	1
Total Nitrate + Nitrite		10	10	10
Selenium		0.01	0.05	0.05
Thallium (1)		0.002	0.002	0.002
Secondary Inorganic Parameters	ANNUALLY	IBWA SOQ	FDA SOQ	SMCL (4)
	(Product and Source)			
Aluminum		0.2	0.2	0.2
Chloride (5)		250	250	250
Copper		1	1	1 AL
Iron (5)		0.3	0.3	0.3
Manganese (5)		0.05	0.05	0.05
Silver		0.025	0.1	0.1
Sulfate (5)		250	250	250
Total Dissolved Solids (TDS) (5)		500	500	500
Zinc (5)		5	5	5
Volatile Organic Chemicals (VOCs)	ANNUALLY	IBWA SOQ	FDA SOQ	EPA MCL
	(Product and Source)			
1,1,1-Trichloroethane		0.03	0.2	0.2
1,1,2-Trichloroethane		0.003	0.005	0.005
1,1-Dichloroethylene	For items with footnote (2), see FDA D/DBP Rule Monitoring Requirements on page 21.	0.002	0.007	0.007
1,2,4-Trichlorobenzene		0.009	0.07	0.07
1,2-Dichloroethane		0.002	0.005	0.005
1,2-Dichloropropane		0.005	0.005	0.005
Benzene		0.001	0.005	0.005
Carbon tetrachloride		0.005	0.005	0.005
cis-1,2-Dichloroethylene		0.07	0.07	0.07
trans-1,2-Dichloroethylene		0.1	0.1	0.1
Ethylbenzene		0.7	0.7	0.7
Methylene chloride (Dichloromethane)		0.003	0.005	0.005
Monochlorobenzene		0.05	0.1	0.1
o-Dichlorobenzene		0.6	0.6	0.6
p-Dichlorobenzene		0.075	0.075	0.075
Haloacetic Acids (HAA5) (2)		0.06	0.06	0.06
Styrene		0.1	0.1	0.1

(1) Included in FDA's 9 contaminant regulations.

(2) Included in FDA's D/DBP rule. See D/DBP monitoring requirements section on page 21 in Appendix A for details.

(3) SOQ dependent upon temperature and other factors. See fluoride section on page 22 of Appendix A for details.

(4) SMCL = Secondary maximum contaminant level. SMCLs are guidelines established by the USEPA for use in evaluating aesthetic, non-health-related properties in water. SMCLs are not enforceable for public water systems.

(5) Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

All SOQs, MCLs, SMCLs, and guidelines in mg/L (ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

Appendix A
2007 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP	MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
<i>Individual Group Analytes</i>				
Volatile Organic Chemicals (VOCs) (Continued)	ANNUALLY	IBWA SOQ	FDA SOQ	EPA MCL
Tetrachloroethylene	(Product and Source)	0.001	0.005	0.005
Toluene		1	1	1
Trichloroethylene	For items with footnote (2), see FDA D/DBP Rule Monitoring Requirements on page 21.	0.001	0.005	0.005
Vinyl chloride		0.002	0.002	0.002
Xylenes (total)		1	10	10
Bromodichloromethane		(6)	(6)	(6)
Chlorodibromomethane		(6)	(6)	(6)
Chloroform		(6)	(6)	(6)
Bromoform		(6)	(6)	(6)
Total Trihalomethanes (2)		0.01	0.08	0.08
Semivolatile Organic Chemicals (SVOCs)	ANNUALLY	IBWA SOQ	FDA SOQ	EPA MCL
Benzo(a)pyrene	(Product and Source)	0.0002	0.0002	0.0002
Di(2-ethylhexyl)adipate		0.4	0.4	0.4
Di(2-ethylhexyl)phthalate		0.006	NA	0.006
Hexachlorobenzene		0.001	0.001	0.001
Hexachlorocyclopentadiene		0.05	0.05	0.05
Total Recoverable Phenolics		0.001	0.001	NA
Synthetic Organic Chemicals (SOCs)	ANNUALLY	IBWA SOQ	FDA SOQ	EPA MCL
2,4,5-TP (Silvex)	(Product and Source)	0.01	0.05	0.05
2,4-D (Dichlorophenoxy acetic acid)	(unless otherwise noted)	0.07	0.07	0.07
Alachlor		0.002	0.002	0.002
Aldicarb		0.003	NA	0.003
Aldicarb sulfone		0.003	NA	0.003
Aldicarb sulfoxide		0.004	NA	0.004
Atrazine		0.003	0.003	0.003
Carbofuran		0.04	0.04	0.04
Chlordane		0.002	0.002	0.002
Dalapon		0.2	0.2	0.2
Dibromochloropropane (DBCP)		0.0002	0.0002	0.0002
Dinoseb		0.007	0.007	0.007
Dioxin (2,3,7,8-Tetrachlorodibenzo-p-dioxin) (1)(7)	Product: Every 3 years Source: Annually	3x10 ⁻⁸	3x10 ⁻⁸	3x10 ⁻⁸
Diquat (1)(7)		0.02	0.02	0.02
Endothall (1)(7)		0.1	0.1	0.1
Endrin	ANNUALLY	0.002	0.002	0.002
Ethylene dibromide	(Product and Source)	0.00005	0.00005	0.00005
Glyphosate (1)(7)	Product: Every 3 years Source: Annually	0.7	0.7	0.7
Heptachlor	ANNUALLY	0.0004	0.0004	0.0004
Heptachlor epoxide	(Product and Source)	0.0002	0.0002	0.0002
Lindane		0.0002	0.0002	0.0002
Methoxychlor		0.04	0.04	0.04
Oxamyl (vydate)		0.2	0.2	0.2
Pentachlorophenol		0.001	0.001	0.001
Picloram		0.5	0.5	0.5
Polychlorinated biphenyls (PCBs)		0.0005	0.0005	0.0005
Simazine		0.004	0.004	0.004
Toxaphene		0.003	0.003	0.003

(1) Included in FDA's 9 contaminant regulations.

(2) Included in FDA's D/DBP Rule. See D/DBP monitoring requirements section in Appendix A for details.

(6) No SOQs or MCLs established for individual trihalomethane contaminants. The sum of the 4 THMs is regulated as total trihalomethanes (THMs).

(7) FDA requires that the four synthetic organic chemicals (SOC) listed must be tested quarterly for four consecutive quarters for each type of finished bottled water (e.g., spring, purified, etc.). If none of the SOCs are detected, then once every three years for each type of finished product. If SOCs are detected, maintain monitoring for four consecutive quarters in each three-year period. New products and new companies must do an initial round of quarterly monitoring in the first year of operation.

All SOQs, MCLs, SMCLs, and guidelines in mg/L (ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

* Denotes FDA Regulation

Page 3

IBWA Code of Practice
Revised 01/07

Appendix A
2007 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP	MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
<i>Individual Group Analytes</i>				
Additional Regulated Contaminants	ANNUALLY (Product and Source)	IBWA SOQ	FDA SOQ	EPA MCL
Methyl tertiary butylether (MTBE)		0.07	NA	NA
Naphthalene		0.3	NA	NA
1,1,2,2-Tetrachloroethane		0.001	NA	NA
Microbiological Contaminants		IBWA SOQ	FDA SOQ	EPA MCL
Total coliform / <i>E. coli</i>	SOURCE: at least once each week (21 CFR §129.35(a)(3)) PRODUCT: at least once each week (21 CFR §129.35(g)(1))	No <i>Escherichia coli</i> detectable in a 100 ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by resampling. NOTE: Confirmation AND validation of all positive total coliform results in finished product required. See Appendix C of the Model Code.	MPN: <2.2 organisms per 100 ml. MF: <4 CFU per 100 ml.	No more than 5% of monthly samples valid for total coliform.
Radiological Contaminants	SEE BELOW	IBWA SOQ	FDA SOQ	EPA MCL
Gross Alpha Particle Radioactivity	SOURCE: Annually	15 pCi/L	15 pCi/L	15 pCi/L
Gross Beta Particle and Photon Radioactivity (B)	PRODUCT: Every 4 years	50 pCi/L	50 pCi/L	50 pCi/L
Radium 226/228 (combined)	SOURCE: Annually PRODUCT: Every 4 years	5 pCi/L	5 pCi/L	5 pCi/L
Uranium	SOURCE: Annually PRODUCT: Every 4 years	0.030	0.030	0.030
Water Properties	ANNUALLY (Product and Source)	IBWA SOQ	FDA SOQ	GUIDELINE
Color		5 Units	15 Units	5 Units
Turbidity		0.5 NTU	5.0 NTU	0.5 NTU
pH (9)		5-7/6.5-8.5	NA	6.5-8.5
Odor		3 T.O.N.	3 T.O.N.	3 T.O.N.

(8) If the gross beta particle activity exceeds 50 pCi/l, an analysis of the sample must be performed to identify the major radioactive constituents present. Compliance (with § 141.16) may be assumed without further analysis if the average annual concentration of gross beta particle activity is less than 50 pCi/l and if the average annual concentrations of tritium and strontium-90 are less than those listed in table A. *Provided*, That if both radionuclides are present the sum of their annual dose equivalents to bone marrow shall not exceed 4 millirem/year. Consult with your testing laboratory for more information.

(9) The Model Code guideline for pH in purified water is 5.0-7.0 (see Appendix B for definition and requirements for purified water). The guideline for source water and other product waters is 6.5-8.5. NOTE: This guideline is not enforceable.

All SOQs, MCLs, SMCLs, and guidelines in mg/L(ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

Appendix A
2007 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

FDA D/DBP Rule Monitoring Requirements

Public Water System (PWS) Source Water

If current PWS D/DBP data is available, no source water analysis is required.

If current PWS D/DBP data is NOT available, ANNUAL testing for the following is required:

- Disinfectants: Chlorine, Chloramine, Chlorine dioxide
- Disinfection Byproducts: Bromate, Chlorite, Haloacetic acids (HAA5), and Total Trihalomethanes (TTHMs)

Natural Water Sources

If no disinfection is applied at the source, including use in bulk water hauling, no source water analysis is required.

If disinfection is applied at the source, including use in bulk water hauling, ANNUAL testing for the following is required:

- The residual disinfectant used (chlorine, chloramine, or chlorine dioxide)
- Ozone: Bromate, Haloacetic acids (HAA5), Total Trihalomethanes (TTHMs)
- Chlorine-based disinfectants (chlorine, chloramine, or chlorine dioxide): Haloacetic acids (HAA5) and Total Trihalomethanes (TTHMs)

ALL FINISHED PRODUCTS

ANNUAL testing is required for ALL of the following in each finished product type:

- Chlorine
- Chloramine
- Chlorine dioxide
- Bromate
- Chlorite
- Haloacetic acids (HAA5)
- Total Trihalomethanes (TTHMs)

Appendix A
2007 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

FDA Requirements for Fluoride in Bottled Water

Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

<u>*Annual average of maximum daily air temperatures (°F)</u>	<u>Fluoride concentration in milligrams per liter</u>
53.7 and below	2.4
53.8–58.3	2.2
58.4–63.8	2.0
63.9–70.6	1.8
70.7–79.2	1.6
79.3–90.5	1.4

Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 2

<u>*Annual average of maximum daily air temperatures (°F)</u>	<u>Fluoride concentration in milligrams per liter</u>
53.7 and below	1.7
53.8–58.3	1.5
58.4–63.8	1.3
63.9–70.6	1.2
70.7–79.2	1.0
79.3–90.5	0.8

Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

**Comparison of US FDA SOQs and US EPA MCLs With
IBWA Code of Practice SOQs *
(revised 7/2007)**

MONITORING PARAMETER GROUP	IBWA MONITORING FREQUENCY	SOCs, MCLs, SMCLs, and Guidelines		
<i>Individual Group Analytes</i>				
Inorganic Chemicals (IOCs)	ANNUALLY	IBWA SOQ	FDA SOQ	EPA MCL
Barium		1	2	2
Chlorine		0.1	4.0	4.0
Chromium		0.05	0.1	0.1
Lead		0.005	0.005	0.015 AL
Mercury		0.001	0.002	0.002
Nickel		0.1	0.1	
Selenium		0.01	0.05	0.05
Secondary Inorganic Parameters	ANNUALLY (Product and Source)	IBWA SOQ	FDA SOQ	EPA SMCL
Silver		0.025	0.1	NA
Volatile Organic Chemicals (VOCs)	ANNUALLY (Product and Source)	IBWA SOQ	FDA SOQ	EPA MCL
1,1,1-Trichloroethane		0.03	0.2	0.2
1,1,2-Trichloroethane		0.003	0.005	0.005
1,1-Dichloroethylene		0.002	0.007	0.007
1,2,4-Trichlorobenzene		0.009	0.07	0.07
1,2-Dichloroethane		0.002	0.005	0.005
Benzene		0.001	0.005	0.005
Methylene chloride (Dichloromethane)		0.003	0.005	0.005
Monochlorobenzene		0.05	0.1	0.1
Tetrachloroethylene		0.001	0.005	0.005
Trichloroethylene		0.001	0.005	0.005
Total Trihalomethanes		0.01	0.08	0.08
Semivolatile Organic Chemicals (SVOCs)	ANNUALLY (Product and Source)	IBWA SOQ	FDA SOQ	EPA MCL
Di(2-ethylhexyl)phthalate		0.006	NA	0.006
Total Recoverable Phenolics		0.001	0.001	NA
Synthetic Organic Chemicals (SOCs)	ANNUALLY (Product and Source)	IBWA SOQ	FDA SOQ	EPA MCL
2,4,5-TP (Silvex)		0.01	0.05	0.05
Aldicarb		0.003	NA	0.003
Aldicarb sulfone		0.003	NA	0.003
Aldicarb sulfoxide		0.004	NA	0.004
Additional Regulated Contaminants	ANNUALLY (Product and Source)	IBWA SOQ	FDA SOQ	EPA MCL
Methyl tertiary butyl ether (MTBE)		0.07	NA	NA
Naphthalene		0.3	NA	NA
1,1,2,2-Tetrachloroethane		0.001	NA	NA
Microbiological Contaminants	DAILY / WEEKLY AT APPROVED LAB	IBWA SOQ	FDA SOQ	EPA MCL
Total coliform / <i>E. coli</i>	NOTE: Confirmation AND validation of all positive total coliform results required. SEE APPENDIX C OF THE MODEL CODE	No <i>Escherichia coli</i> detectable in a 100 ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by resampling.	MPN: <9.2 organisms per 100 ml. ME: <4 CFU per 100 ml.	No more than 5% of monthly samples valid for total coliform.
Water Properties	ANNUALLY	IBWA SOQ	FDA SOQ	GUIDELINE
Turbidity		0.5 NTU	5.0 NTU	0.5 NTU
pH		5-7/6.5-8.5	NA	6.5-8.5

*The above is a list of contaminants for which IBWA has more stringent standards of quality than either FDA or the USEPA.

Mr. STUPAK. Well, thanks. We will start with questions, and thank you all for your comments.

Mr. DOSS, let me ask you this. Is it true 80 percent of the water bottlers are part of your organization, about 80 percent?

Mr. DOSS. I am sorry?

Mr. STUPAK. Water bottlers in this country, they belong to your organization?

Mr. DOSS. I would say we probably represent 75 percent of the actual facilities.

Mr. STUPAK. Is Dasani, Coca-Cola, are they part of your—

Mr. DOSS. Dasani is not a member of the association.

Mr. STUPAK. How about Nestle?

Mr. DOSS. Nestle is a member.

Mr. STUPAK. OK. And how about Aquafina? That is Pepsi, right?

Mr. DOSS. That is not a member.

Mr. STUPAK. So are those the three biggest, Coke, Pepsi and Nestle?

Mr. DOSS. The largest companies.

Mr. STUPAK. So two of the three are not part of your organization?

Mr. DOSS. That is correct.

Mr. STUPAK. Your standards, which track many of the things we recommended and GAO and the others, that is voluntary standards you try to have your member comply with?

Mr. DOSS. IBWA has always tried to, you know, have the highest possible safety standards so we have a mandatory requirement for our member, and if they don't meet those standards, then they cannot be a member of the International Bottled Water Association.

Mr. STUPAK. Do you do anything on the advertising then? I mean, we have seen these crazy—

Mr. DOSS. No, advertising is not an issue that we deal with. Obviously that is a case-by-case situation where there are State and federal laws that would allow companies to be—action to be brought against them for deceptive or misleading advertising, so we don't do anything in that regard.

Mr. STUPAK. OK. So like Aquamantra about these mantras inherently penetrate the molecular structure of the water, you guys don't condone any of that?

Mr. DOSS. It is not something—the association does not deal with advertising issues. That is something that would be left to the State and federal authorities.

Mr. STUPAK. Well, the company went on to say that it consulted, and I use the word “consulted” because that is what it said on the Web site, with a Dr. Marura Emoto who wrote a book called Hidden Messages in Water, and the company said that he showed us the basic principles of quantum theory whereby the molecular structure of water was changed by a Zen Buddhist monk's thoughts. Based on this premise, Aquamantra uses the design on its labels to affect the molecular structure of California natural spring water to make it more refreshing and wholesome. Is there any water studies that a Zen monk can change the molecular structure of water?

Mr. DOSS. Well, I can't speak to what that company has found. I just can't speak to that. I don't know that they are a member of

IBWA so I can't comment on what information they may have about what they say on their label or other materials.

Mr. STUPAK. Dr. Sharfstein, have you seen anything quite like this? Do you think those should be part of the labeling of bottled water, Zen Buddhist monks' thoughts that can change the structure of water?

Dr. SHARFSTEIN. I would be highly skeptical.

Mr. STUPAK. But, you know, we have seen it, and Ms. Houlihan pointed out and a couple others, these are just sort of like fantastical claims. Are they legal? Can they do it underneath your misbranding or false advertising?

Dr. SHARFSTEIN. Well, we will definitely look into this case. In general, misbranding pertains to whether people are claiming to treat disease. That is the big one. That is where we put our priority. If people are saying you drink this water and it cures your cancer, then people may not pursue cancer treatment.

Mr. STUPAK. So like Mr. Ricker of Poland Springs who had a miraculous recovery and lived nearly 52 years and it is good for liver and kidney diseases, is that—

Dr. SHARFSTEIN. Well, there were two that you—you know, the one with historical fable. I don't know if that is exactly—

Mr. STUPAK. That is Mr. Ricker.

Dr. SHARFSTEIN. But the other one where you said used in clinical—

Mr. STUPAK. Clinical tests, Philadelphia, St. Louis.

Dr. SHARFSTEIN. That one I think we would like to see. I mean, that to me strikes me as pretty, you know, worth our evaluating. I am not familiar with that. But I think that would definitely fall into something we would look closely at.

Mr. STUPAK. How about the other one? The makers of H2OM claim that they play music and sounds at their bottling facility that charge the water with special vibratory frequencies? Would that be misadvertising?

Dr. SHARFSTEIN. I am not a musician but I would still express skepticism about that one, and I think that, you know, we have—the misbranding provision is really about things that we focus on we really think are going to pose a public health threat, a claim like that, and you know, the issue about whether it treats kidney or liver disease, this really does raise that issue.

Mr. STUPAK. You know, in tab 13 is that chart again, and we might want to put it back up on the board there. And the two reports by GAO and Environmental Working Group talk about the regulations, and you mentioned a little bit in yours too. If the bottlers discovered dangerous contaminants of water, they don't have to alert the public. Unlike municipalities, bottlers don't have to use certified labs. Water bottlers generally are not required to provide information about test results, the source of their products. You know, take Dasani here. We mentioned them today, and I have this bottle that was put on the airplane when I fly back and forth so I grabbed it with me as I was reading my testimony. When I go through and read it, you know, their claims aren't too outrageous. It is enhanced with minerals for a pure, fresh taste that can't be beat, and then you go to www.makeyourmouthwater.com. That is out there a little bit but it says bottled by CCDA Waters

LLC, Millersburg, Pennsylvania, but then underneath it they have CT and then the symbol for number, 992, then they have NV 07354, NYSHD certificate 173 and then they have another one, L, but CT, would that be Connecticut? NV, would that be Nevada? New York State Health Department, I take it, would be New York. It doesn't say anything about sources or anything, so you don't know where this water really came from, Nevada, Connecticut, New York or Pennsylvania.

Dr. SHARFSTEIN. I could not decipher that for you.

Mr. STUPAK. Mr. Doss, can you help out on that, these markings?

Mr. DOSS. I can't say for sure because I obviously don't—I am not familiar with that brand but it may be that all of those states require the product to be registered like other food products do within the State. If you are going to sell products within a State, I think all food products tend to have those registration information on the bottles.

Mr. STUPAK. So you would have to figure out—the last one is probably a lot number. You would have to go through and figure out your lot number to try to figure out where it came from, right, and whether Nevada, Connecticut, New York or Pennsylvania, or Coca-Cola in Atlanta, Georgia, because that address is on there too. Really, a consumer has no way of knowing, and this is one of the big bottlers.

Mr. DOSS. Again, I can only tell you I think that is what that refers to.

Mr. STUPAK. Mr. Walden.

Mr. WALDEN. Thank you very much, Mr. Chairman.

Just like any food product regulated by the FDA, if dangerous contaminants are in the bottled water, it is considered adulterated by the FDA, correct, Doctor?

Dr. SHARFSTEIN. That is correct.

Mr. WALDEN. And it violates the law if it is sold to consumers?

Dr. SHARFSTEIN. People can go to jail if they do it.

Mr. WALDEN. And if we are worried about some of these claims on the label, isn't that really also under the jurisdiction of the FTC, the Federal Trade Commission, on false advertising and labeling?

Dr. SHARFSTEIN. You know, I will have to get back to you. I don't know if I can answer that. I think we do have certain jurisdiction there and I am not sure about the FTC.

Mr. WALDEN. I would assume that they would but I don't know that for a fact but it is something we ought to look at because it would be helpful if they were here today and the EPA was here today and perhaps somebody from Coca-Cola as well since they are not represented on this panel but we are singling them out.

Dr. SHARFSTEIN. One thing I might want to mention is, in just a couple of months FDA is going to launch—

Mr. WALDEN. Is your mic on, by the way?

Dr. SHARFSTEIN. Yes.

Mr. WALDEN. OK.

Dr. SHARFSTEIN. In just a couple months, FDA is going to launch the reportable food registry that was part of legislation that Congress passed, and when that happens, we are anticipating September, companies will have to notify FDA if there is a product release that could pose a serious risk to health. So some of the gap

will be filled by that but we really think, you know, the passage of the food safety legislation is necessary to really close that.

Mr. WALDEN. Yes, we are hopeful that that can be brought up on the—Mr. Chairman, has that been scheduled for House Floor consideration yet?

Mr. STUPAK. Not yet. We are still working on the final touches.

Mr. WALDEN. OK. In your testimony, Doctor, you discussed new FDA testing requirements for bottled water to include testing source water for total coliforms and establish a zero tolerance for E. coli. Does the EPA require testing for coliforms in tap water and did the EPA establish a zero tolerance level for E. coli?

Dr. SHARFSTEIN. Give me one second. I have some information on that right here. I was curious about that also.

Mr. WALDEN. Because I think you made the case on lead, that you have zero tolerance for lead in bottled water but EPA allows a certain—

Dr. SHARFSTEIN. I think it illustrates the point that it is just a little different, the systems. My understanding is that public water systems are required to collect monthly total coliform samples throughout their distribution systems and that if they are positive they must be tested for E. coli. For a system collecting more than 40 samples per month, if more than 5 percent are positive, that triggers a violation. If it less than 40 samples per month, then one positive sample triggers a violation. So, you know, for FDA, bottled water, if there is any violation that kicks in for municipal, it has to be certain percentage of the tests violative for it to trigger a violation. So the standards are slightly different. I hope I was able to explain that clearly enough. They do a whole bunch of tests—

Mr. WALDEN. Are they more stringent under your regulations or the EPA regulations?

Dr. SHARFSTEIN. It is—

Mr. WALDEN. Or is it just different?

Dr. SHARFSTEIN. They are different. I mean, you know—

Mr. WALDEN. Because I know here in the District of Columbia, I think I am correct in saying this, that we all went many years drinking the tap water believing it to be safe only to discover that they hadn't really fully disclosed the amount of lead that was coming into the water through the pipes, and so I don't know if you ran into that in Baltimore when you were health commissioner there, but as I recall you advocated to people to buy it and it would be safer to drink bottled water.

Dr. SHARFSTEIN. Well, not for the population of Baltimore because the municipal water supply in Baltimore we felt very comfortable with but—

Mr. WALDEN. But for public school children?

Dr. SHARFSTEIN. Public school children. That is right. In fact, I advised the school superintendent to turn off all the drinking fountains in the Baltimore City public schools because of problems that they were having with lead.

Mr. WALDEN. And to go to bottled water.

Dr. SHARFSTEIN. And to go to bottled water across the system. It turned out to be cheaper also, given the expense of testing the municipal water because of the old buildings and the problems they had with the pipes in the school. So, you know, I certainly as a

health commissioner, I think there are certain scenarios where, for example, after certain types of disruptions of the water supply, the water can be unsafe for a period of time and we recommended that people buy bottled water or boil it.

Mr. WALDEN. Thank you.

Mr. DOSS, a question about this notion that consumers are wanting to know what it is in their bottled water. While I want to know that it is safe when I drink it, I am not sure I am going to chase down what spring it came out of or well, as long as I know it is safe. How many inquiries do you get through your association of people who say I want to know the ingredients, I want to know—I mean, when I take water out of my place here in D.C., there is no label on the tap that tells me all this stuff. I wouldn't know where to go in the D.C. system to even find out, and frankly, as long as it is safe, I don't care. How much of this is the case? How many people are rushing to you and calling your folks saying hey, I demand to know where this water came from?

Mr. DOSS. At IBWA, the association has hardly gotten any comments, any questions from consumers. I have talked to some of my members including our large members and our small- and mid-sized members, and they get very few requests. Now, I will say—

Mr. WALDEN. And how do they handle those requests?

Mr. DOSS. They provide them with the information.

Mr. WALDEN. Do they disclose?

Mr. DOSS. If they want testing results, if they want source information, whatever they ask for, you know, in our opinion, that is what they should provide, and that is, our bottom line is, that if a consumer has a question, we believe they have the right to have that information. The real issue is how to best provide that information. I think that is the distinction here and that was related a minute ago. These are two different systems. Bottled water is a packaged food product in a very different distribution system than tap water. So there are necessarily some differences in the way you might want to provide the information, and as far as the overall safety is concerned, again, they both have to be safe. There are different ways that you get to that goal.

Mr. WALDEN. Because I don't think in a soft drink bottle they disclose where the liquid source comes from, right? Because they put water in a cola beverage, right? Is that right, Doctor?

Dr. SHARFSTEIN. Yes.

Mr. WALDEN. Isn't that the number one ingredient, is water, in these beverages we all drink? And the last time I checked, nobody is saying tell me where the water came from that is in there. It is not required to be on those labels, is it?

Mr. DOSS. And that is why—

Mr. WALDEN. So you are kind of being singled out.

Mr. DOSS. Bottled water is a food product so we follow the rules that are in place.

Mr. WALDEN. Is cola a food product?

Dr. SHARFSTEIN. Cola is a food product and it is not subject to the Good Manufacturing Practices that exist specifically for bottled water, so there is a—

Mr. WALDEN. So is there less oversight on our soda drinks from the FDA's perspective?

Dr. SHARFSTEIN. Maybe I wouldn't use the word "oversight" but I would say there is definitely more regulations and——

Mr. WALDEN. On which?

Dr. SHARFSTEIN. On bottled water.

Mr. WALDEN. Than on cola products? And I am not picking on cola versus uncola versus, you know, the new cola versus whatever. I am just talking soft drinks.

Dr. SHARFSTEIN. That is correct.

Mr. WALDEN. So there is less oversight—well, I will use the term "oversight" but in terms of food safety issues——

Dr. SHARFSTEIN. Right, and there are Good Manufacturing Practices that apply to foods generally that apply to colas, and someone will tap me if I am getting this totally wrong, but I understand that the bottled water has a whole set of regulations that are really just for bottled water, and it relates to the fact——

Mr. WALDEN. Commodity-specific——

Dr. SHARFSTEIN. Right.

Mr. WALDEN [continuing]. Regulations which don't exist for soft drinks?

Dr. SHARFSTEIN. Right.

Ms. HOULIHAN. Can I also say that one difference between bottled water and soda is also that people choose bottled water because they think it is healthier and safer than——

Mr. WALDEN. Yes, but that is not——

Ms. HOULIHAN [continuing]. In a lot of cases, and that is not the reason they are choosing colas. So I think that——

Mr. WALDEN. Yes, but the question—whether they choose it or not, the question I thought you were getting at is, consumers have the right to know the source of the ingredients in the bottle, the labeling and all that. I mean, I want to know if—I may think a soda product is better than bottled water.

Ms. HOULIHAN. Water is very different from other kinds of food products. It makes up more than half of our body and we are advised to drink at least eight——

Mr. WALDEN. Right, because it helps remove toxins and everything else.

Ms. HOULIHAN. Exactly, and so people are choosing bottled water in particular, not colas, because there is a perception that it is safer and healthier than tap water, and I think that is why it is being singled out here over other foods because of the special place that it holds in people's minds. Also, because it is almost 2,000 times more expensive than tap water and people——

Mr. WALDEN. How much more expensive is a soda drink over tap water?

Ms. HOULIHAN. Maybe a similar amount, but people are making really tough choices right now about their budgets and so bottled water is part of that.

Mr. WALDEN. And I have almost doubled over my time.

Mr. STUPAK. No, that is all right. We will come back another time but I want to get to Mrs. Christensen for questions.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. I just want to go over the contaminant disclosure issue again so I am clear. According to the new reports released today, it appears that consumers have access to a lot more information about contaminants in tap

water than they do about contaminants in bottled water in answer to some of the questions previously asked.

Mr. STEPHENSON, under current law, municipal water authorities have to notify the public within 24 hours when they detect contaminants such as E. coli above prescribed levels in tap water. Is that correct?

Mr. STEPHENSON. That is right.

Mrs. CHRISTENSEN. And they have to send that notice over broadcast media or in warnings posted in conspicuous locations?

Mr. STEPHENSON. Yes, there are very specific requirements on how you report those.

Mrs. CHRISTENSEN. But if a bottled water company ran the same tests on its water and found the same level of E. coli, a level that both EPA and FDA say is dangerous to human health, they don't have to tell the FDA or EPA or the public?

Mr. STEPHENSON. Or the State. Well, some States require it but not the FDA.

Mrs. CHRISTENSEN. A few States require it but generally no?

Mr. STEPHENSON. Excuse me?

Mrs. CHRISTENSEN. Generally they don't have to report it?

Mr. STEPHENSON. Generally, they don't.

Mrs. CHRISTENSEN. Now, under current law, municipal water systems are also required to issue annual consumer confidence reports that disclose any contamination problems, the likely source of that contamination, potential health effects of that contamination and information about the system's susceptibility to future contamination, correct?

Mr. STEPHENSON. Yes.

Mrs. CHRISTENSEN. But bottled water companies are not required to make similar disclosures to the public?

Mr. STEPHENSON. That is true. We currently don't have the authorities to make that requirement.

Mrs. CHRISTENSEN. Dr. Sharfstein, this is a striking disparity in the information available to consumers. We learn about dangerous contaminants in our tap water through broad public announcements within 24 hours but we may never learn about the dangerous contaminants in bottled water. Did you say that you supported a requirement to have the bottled water companies disclose test results showing contamination above the federal levels?

Dr. SHARFSTEIN. Actually, starting in September, we think, that requirement will take effect for contamination that poses a risk to the public.

Mrs. CHRISTENSEN. Is it enough to have the companies report their lab reports or should there be certified labs and should the labs be required to tell FDA when a positive result is found? Isn't that more reliable?

Dr. SHARFSTEIN. I think it is a very important question. I think there are two questions there, the certified lab and then whether labs should be required to report.

Mrs. CHRISTENSEN. Right.

Dr. SHARFSTEIN. So for certified labs, I think FDA would like to have authority to require labs if we think that that is important for a particular product, and I think that because of the broad pre-

ventive authority that this new legislation that has been moving through the House would give, we would be able to do that.

The second question of requiring labs to report to FDA is a little bit more complex because there are so many tests that are done.

Mrs. CHRISTENSEN. Just the positive ones.

Dr. SHARFSTEIN. Right. I understand. The concern that is expressed there is whether or not it inhibits the private sector from testing at all. If they have a good testing program in place where there are identifying and keeping things out of the system, you know, should they be reporting every single positive, which ones should get reported. Those are questions that are a little bit more complex because you could be drowning, and if you are thinking not just for water but all the different foods, all the different tests, we don't want to inhibit companies from doing their own testing if they have good preventive plans in place. We want to not be missing the forest for the trees in terms of all the information coming to us. So that question of how much to require, where to get it from is sort of more complex issue that we would probably look at, you know, in a particular industry, a particular situation like, you know, certain types of tests we probably would want to know because they would be so serious.

Mrs. CHRISTENSEN. And earlier this year, the subcommittee held two oversight hearings on salmonella poisoning in peanut products that caused multiple deaths and dozens of illnesses, and we learned that the Peanut Corporation of America received positive tests for salmonella and was not required to disclose them to anyone, and FDA didn't have the access to those results and couldn't access them until people fell ill by invoking another law, the bioterrorism law, and so the same legal loophole applies to bottled water companies. Although the municipal water authorities are required to disclose their test results, FDA cannot compel bottled water companies to disclose theirs.

So Ms. Houlihan, if a bottled water company tests its water and finds dangerous levels of E. coli, as far as you understand, is that required to disclose those results to the public?

Ms. HOULIHAN. As far as I understand, that is the case. We found a lot of bottled water brands that are posting, 18 percent of the brands that we looked at that are posting full water quality test reports online, and we think 100 percent of companies should be doing that and letting people know right away about contamination.

Mrs. CHRISTENSEN. I am not really—even though I made a reference to peanut butter, I am not in any way suggesting that the water issue is similar. But one important lesson that we learned is that sometimes disreputable companies have warning signs long before major problems arise because the systems are faulty, and if federal or State officials had access to that testing data, they might be able to flag small problems before they become big ones.

Mr. Doss, your organization represents, I think you said about 75 percent of the bottled water industry. Do you support a requirement that bottled water companies make their test records available to the FDA during routine inspections?

Mr. DOSS. We do.

Mrs. CHRISTENSEN. And I am sure Dr. Sharfstein already answered that question. I guess I am out of time right now and I will just hold for a second round.

Mr. STUPAK. Thank you.

Mr. BURGESS for questions, 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman. I apologize for being gone during your testimony and the earlier questioning. Can anyone tell me, if bottled water has a certain standard, what about our cola drinks? Are those bottles held to the same standard as bottled water?

Dr. SHARFSTEIN. So cola drinks are considered food and there are food Good Manufacturing Practices that they are held to but cola drinks are not held to the bottled water Good Manufacturing Practices which are sort of in addition to the general Good Manufacturing Practices.

Mr. BURGESS. To the best of anyone's knowledge, there is no difference in the way any of these compounds would leach out of the plastic into liquid phase whether it be water or cola drinks. Is that correct?

Dr. SHARFSTEIN. Yes, I don't know if I know enough to answer that question. I do think that the point that is there, you know, from a food safety perspective. You know, there is not a—from a food safety perspective, water has a whole additional set of regulations compared to cola. It really depends on—and, you know, public health, you are saying compared to what. If you compare bottled water to cola, it has got a whole additional set of regulations. If you compare bottled water to municipal water, then there are certain disclosure requirements of municipal water that don't apply to bottled water. So it is sort of just your vantage point, but from a food safety perspective, you know, there is a whole additional set of regulations that apply to bottled water compared to cola.

Mr. BURGESS. Well, what about the water that is manufactured and sold with caffeine added to the water? Does that fall under the foodstuff or is that a water?

Dr. SHARFSTEIN. That is not a water.

Mr. BURGESS. That is not a water?

Dr. SHARFSTEIN. Yes, I think—and somebody is going to tap me if I get this wrong but I am pretty sure that it is not a water. It depends. I think some of those may be—people may be attempting to market them as dietary supplements and other things but what they are actually marketed as is a whole separate discussion, but I don't think they are considered a water if you put extra caffeine in.

Mr. BURGESS. It just really underscores the complexity of the process that you have to deal with.

Now, let me ask the GAO, on the report that two people to inspect the \$11 billion water industry, and 4 years ago the FDA changed the risk assessment for bottled water from low risk to high risk, so the question then comes, how many inspectors should be required? If two are not enough, what is our limit? We will be doing the agriculture appropriations bill this afternoon which will have the funding for the Food and Drug Administration in it. How do we know that we have got the right number of inspectors so

that we can then know that we have the right appropriation attached to the FDA?

Mr. STEPHENSON. That is a good question, and we don't have a precise number just for this segment of FDA's overall responsibility. We have said designating food safety a high-risk area over the past 2 years that the resources are inadequate to do the job right now, and we have pointed out from a broader standpoint that food safety is spread over a number of different agencies and of those agencies, FDA seems to get the smallest proportion of the budget yet it has 80 percent of the responsibility. So I don't know whether two is right or four is right or six is right just for bottled water. All we are just doing is stating a fact, that that is how many FTAs are currently dedicated to inspecting bottled water facilities.

Mr. BURGESS. And that in fact does not seem to be a sufficient number?

Mr. STEPHENSON. It does not seem to be a sufficient number, given the number of bottled water facilities.

Mr. BURGESS. Also in your testimony, you note that three-quarters of the water bottles produced in the United States in 2006 were recycled. Do we know about the rates of recycle for other beverages?

Mr. STEPHENSON. I think it is probably similar for all plastic bottles. With bottled water being a growing share of the market, there are more bottles dedicated to water than soda percentage-wise.

Mr. BURGESS. So numerically, there are more in the environment—

Mr. STEPHENSON. Right, and this isn't a volume problem, as we noted. It is less than 1 percent of what is going into a landfill. Nevertheless, they never decompose and they stay there forever, and recycling is a good thing in general.

Mr. BURGESS. And I would agree with that.

Dr. Sharfstein, in the GAO report it states that the FDA currently assigns two people yet 4 years ago the Food and Drug Administration changed the risk assessment from low to high risk, so again, I would ask the question, how many inspectors should now be assigned to oversee the Code of Federal Regulations as it relates to bottled water?

Dr. SHARFSTEIN. I am not sure that is right, that we changed it to high risk. I think that in general compared to other foods, we considered bottled water in the lower risk side. I think that there are two issues. One is the frequency of inspection and the other is all the things that go with inspections, and one of the key things we talked about is just knowing who is making bottled water, and we have a hard time under the current food safety laws really understanding that because by law, people can register on paper and the category is called soft drinks and waters, so everyone is sort of thrown in together so we don't have a very good idea—we don't have as good an idea as we would like to have or we should have exactly who is making it. That is sort of the first step to have, like, you know, a solid system. And then we would like the ability to require preventive plans and, you know, all the key basic steps there, and then you put inspections as part of that strategy. But just thinking of inspections alone with the rest of the way it is, it is probably going to leave some opportunities for strengthening the

system off the table if you are just thinking of inspection alone which is why we would like the parts of the law giving us access to records, giving FDA the ability to require preventive plans, certified labs if we think necessary, other things like that.

Mr. BURGESS. Let me ask you a question in the time I don't have remaining, and it is not fair to ask you this but I will do it anyway. We are going to vote on the agriculture appropriations bill today or tomorrow. Is the number we have in the bill for the Food and Drug Administration, do we have the right number there?

Dr. SHARFSTEIN. Yes. The President's budget and what came out of committee is a historic increase and I think there is no question the Administration responded very strongly to GAO's finding this would be a high risk and putting a lot more resources into food safety, and if we get that combined with additional authority, I think we will be able to strengthen the system considerably.

Mr. BURGESS. And just for the record, Mr. President, the beautiful campus that they occupy is actually part of the GSA budget so none of your food safety dollars are going to build that lovely campus which we are all so proud of. I will yield back.

Mr. STUPAK. Thanks, Mr. Burgess.

Let us go another round of questions. Dr. Sharfstein, if we do testing and if they have to report their positive results, wouldn't after a while if you see a continued positive results for E. coli or something from a plant that indicates you have a problem, we have to get there or at least increase inspections, like the peanut butter one with the salmonella. We had report after report of problems but no one ever received a report and no one ever knew, at the FDA, at least, what was going on there.

Dr. SHARFSTEIN. I agree with you. FDA has to respond to problems very aggressively and has got to be able to follow up with manufacturers that aren't meeting standards and if necessary shut them down, and, you know, in recent weeks we have taken action against some firms—

Mr. STUPAK. But you wouldn't know unless you received positive results, I mean, unless you received the results. Somewhere, someone at the FDA has to receive results and look at them, right?

Dr. SHARFSTEIN. Well, it could be that we got a complaint and we investigated. It could be testing that FDA does, and FDA does do some testing. So we can find out problems. We could have somebody call us and say there is a problem with this company, and so that leads us to investigate. But once we find the problem, I think it is important to really follow up until that problem is clearly resolved.

Mr. STUPAK. Well, how about for those bottlers who use municipal water as their source? Wouldn't it make sense to require them to post a link to the required EPA testing results because they have to do it once a year? Wouldn't that make sense to require them to—25 percent, I think, Ms. Houlihan was in your report, 25 percent of the bottlers use tap water, so why wouldn't we just require them to post their Web site?

Dr. SHARFSTEIN. Right. I can totally understand why that would make sense, why consumers might be interested in that. But the thing for FDA is, the standard that we have for putting something on the label is that it would have to be misleading without it, and

so we can't—you know, we use that to say that, you know, something has got to be there or it is misleading without it, and that is a hard thing to put that, you know, to kind of file that in that category. So that is not to say we wouldn't support it but whether we could do it under our misleading, you know, authority, that we think is questionable and that it might require a different authority.

Mr. STUPAK. It is misbranding authority that you have?

Dr. SHARFSTEIN. Yes, the misbranding authority. The basic—if we were to do it, and this would—you know, what standard would we have to meet, and it would be that it is misleading without it, and, you know, we don't require it for other types of foods. You know, would it really be misleading consumers not to have that, and that is a hard standard for us to reach. There may be a better way for Congress to achieve that.

Mr. STUPAK. Mr. Stephenson, if I may, on page 22 of your report you referred to a poll conducted by Water Research Foundation that approximately 56 percent of bottled water drinkers cite safety and health as the primary reason they sought an alternative to tap water. So is it fair to say that the number one reason people are buying bottled water is because they think it is safer and healthier than tap water?

Mr. STEPHENSON. Well, there is that poll and several other research studies that have concluded that, although convenience is a top reason as well.

Mr. STUPAK. Well, what bothers me about that is the perception that bottled water is healthier than tap water, in many instances, bottled water is nothing more than tap water. The Natural Resources Defense Council, they estimated, as I said, 25 percent of bottled water is just tap water in bottles. Sometimes it is treated, sometimes it is not. So I guess my question is, and Ms. Houlihan, I think you cited in your report, is that accurate that 25 percent of the bottled water is just tap water in a bottle?

Ms. HOULIHAN. Those are the numbers that are publicly available, and I think it is a big question as to whether it is even more than that because in so many cases we just don't have the information on what the source actually is and we found almost a third of all bottled waters have no information on their label.

Mr. STUPAK. But if they take it from tap water and do something like reverse osmosis or something, then they don't have to claim it is tap water, right?

Ms. HOULIHAN. That is right, and there is a provision that requires that bottled waters be labeled as from a municipal supply if they have not undergone any additional treatment, but any treatment that is, according to FDA, quote, suitable, allows that bottled water manufacturer not to use that label and just to call it this is a purified water without giving people information on what the treatment processes actually were.

Mr. STUPAK. Well, like I said, I got this on the airplane yesterday. Does Coca-Cola use municipal water for its Dasani bottled water?

Ms. HOULIHAN. You can't tell from the label. There is no information at all on the water source for that product.

Mr. STUPAK. How about Pepsi there that Dr. Burgess is drinking, the Aquafina bottled water? Does that come from a municipal source?

Ms. HOULIHAN. Aquafina, we have that label in one of the examples, if you could pull that up. So on the label, it is labeled as from a municipal supply for Aquafina. It doesn't name the municipal supply, which is what so many other bottled waters are choosing to do.

Mr. STUPAK. But do we know if they do any further treatment or anything of it? Would it have to be on there?

Ms. HOULIHAN. It doesn't have to be labeled at all, and we found 44 percent of all labels don't provide any information on treatment.

Mr. STUPAK. Mr. Doss, if Aquafina was part of your organization, I understand it is not, but if it was, would they have to put on there whether they further treated or would they just put down municipal source?

Mr. DOSS. No, they wouldn't, and I think the issue here is one maybe of misunderstanding. Purified bottled water, which is what Dasani is and what Aquafina is, is not just tap water in a bottle.

Mr. STUPAK. Correct. Something else happens to it.

Mr. DOSS. When water comes in from a municipal source, it goes through reverse osmosis, it goes through UV light, it goes through ozonation and then in a sanitary condition is placed in a bottle. Now, those purified waters must meet the U.S. pharmacopoeia standard for purified or sterile water. If it does not, then that label must disclose in that bottle that it comes from a municipal source. So in that case, that water because it doesn't list it as from a municipal source, meets the U.S. pharmacopoeia standard for purified or sterile water, and that is the big difference, and that goes to the sourcing of the water. It would be not—to list that this source was the Dayton whatever county municipal water, that water is quite different once it gets in that bottle than when it started out, and that is the distinction here.

Mr. STUPAK. OK, let me ask you this. Let us go back to Dasani then. And again, I am reading the label right here on what I got here. It says "noncarbonated, crisp, fresh taste. Dasani is filtered through a state-of-the-art purification system and enhanced with minerals for a pure, fresh taste that can't be beat." And then if you go on the other side of the label, it says purified water, magnesium sulfate, potassium chloride, salt, and then it has an asterisk, "adds a negligible amount of sodium," then it has a cross on it and it says "minerals added for taste, purified by reverse osmosis." So to get that clean, crisp taste, are the chemicals they are adding then magnesium sulfate, potassium chloride, salt and sodium or is it other chemicals?

Mr. DOSS. I can't speak to Dasani specifically but what is done sometimes is that the water comes in from a municipal source, it is purified by reverse osmosis and other treatments and then minerals are added back for taste. That is what they are disclosing. Again, I can't speak to that specific label but in general that is oftentimes what happens.

Mr. STUPAK. OK. I guess my time is up.

Mr. WALDEN, questions?

Mr. WALDEN. Thank you.

First of all, what the chairman cited, are those chemicals or minerals?

Mr. DOSS. I believe they are minerals that have been added for taste, and that is why they disclose it on the label. They are meeting the labeling requirements. They are making sure that they are informing those who buy it that this is a purified water with minerals added back.

Mr. WALDEN. And if they added other things into the water, would they have to disclose that?

Mr. DOSS. I believe they would. It then is a question of the standard of identity for bottled water, which we talked about which specifically says if you are spring water, you have to do this, if you are purified water, you have to do that. So what—

Mr. WALDEN. So there are already rules that say that?

Mr. DOSS. There are rules that say exactly what you must do if you want to say you are a purified water, a spring water, an artesian water, well water.

Mr. WALDEN. All right.

Mr. DOSS. If you then add something else to the water, then for labeling purposes you would probably—and this is where FDA—I will have to make sure we can get back to you on this specifically but I think in that case, FDA would say you need to then make sure you are saying this is purified water with minerals added back, and I think that is why they do it.

Mr. WALDEN. Dr. Sharfstein, do you know or do your folks know if that is correct?

Dr. SHARFSTEIN. The question is, what you are allowed to put back in?

Mr. WALDEN. Not what you are allowed to put back in but that which you put back in, do you have to disclose on the label?

Dr. SHARFSTEIN. I am getting a yes, it is required.

Mr. WALDEN. So it is already required? If I am a bottler of water and if I go through reverse osmosis and the UV and all that and then I add things back in, I have to put that on the label?

Dr. SHARFSTEIN. That is what I am understanding.

Mr. WALDEN. OK. I want to ask about the DEHP issue. In your testimony, you state the FDA has decided to move forward on making a decision on DEHP. Can you elaborate on this and tell us when we can expect a ruling? That is actually what I hear. If I hear anything about bottled water, it is about this discussion about what is in the plastic.

Dr. SHARFSTEIN. This is where it gets a little bit confusing, but basically in the mid-1990s when this was originally done and this particular chemical was deferred. The reason it was deferred is because it had been marketed prior to 1958 and had a special grandfather-like provision as a food additive, and it was thought that it was in plastic and therefore this provision of the law that we are talking about conflicted with another provision of the law. Our understanding has changed since that time. In fact, we don't believe that it is being used in water bottles or water caps right now, and as a result of that, the concern that existed—and I am a pediatrician and not a lawyer—basically the legal conflict that was of concern in the mid-1990s is not of concern now and that we can move forward and basically testing whether or not there is a reason to—

there has to be an affirmative reason not to have the same standard as municipal water so, you know, my presumption would be that we will move forward with the standard for DEHP like we have for all the other contaminants. What held it up before was really the grandfather legal issue, and I think that that may not apply anymore and we can move forward.

Mr. WALDEN. But I want to get to sort of the heart of the matters for the people I represent. You are telling me that plastic in the cap here doesn't have the phthalate?

Dr. SHARFSTEIN. In our communications with industry, as I understand, we do not believe that this is regularly used in—

Mr. WALDEN. Mr. Doss, can you speak to this issue?

Mr. DOSS. I can. It is my understanding that none of the plastic containers used for bottled water contain DEHP at all, not the PET, not the polycarbonate, not the HDPE. So none of the bottled water containers contain any DEHP. However, the International Bottled Water Association for purposes of parity several years ago, we have a standard in our model code that is exactly the same as the EPA, more for parity reasons, but none of the plastic containers used for bottled water contain DEHP.

Mr. WALDEN. From your knowledge, does that apply also to Dr. Burgess's Pepsi bottle there and other bottles used for sodas?

Mr. DOSS. If they are using PET, which I believe most are, if they are using polycarbonate or HDPE, which are the three primary uses for all beverage products, then there is no DEHP in them.

Dr. SHARFSTEIN. So the DEHP issue is really, is it in the water separately just because it is in the environment and, you know, that—

Mr. STUPAK. Is there a number that you use for DEHP like PET has a number 1 on it, and that is what this one is here. But there is usually a symbol. Is there a symbol that if you use DEHP in a plastic—

Dr. SHARFSTEIN. I will have to get back to you on that.

Ms. HOULIHAN. Can I also add—

Mr. WALDEN. Go ahead. I actually have another question, though, I want to get to.

Ms. HOULIHAN. The food contact notifications that EPA has approved show at least 100 different other kinds of plastic additives that could leach into the water, so this is a problem that is much bigger than DEHP.

Mr. STUPAK. Go ahead, Mr. Walden.

Mr. WALDEN. I just wanted to get to another point because we are so focused, and I realize that is the focus of the hearing is on bottled water and where that water comes from and all of that, but I am sitting here thinking, if I buy orange juice in a carton that is made from concentrate, what percent of that is water? It has to be a huge percent, right? Because we are adding water in and then the concentrate. And if the issue here is the quality of the water and the source of the water going into what we consume, then it seems to me we are kind of myopic here just looking at bottled water because somebody doesn't like bottled water or presumes that it has a higher sort of threshold in our minds about purity. I would suggest that a lot of us drink orange juice thinking that

is better than perhaps bottled water because you get other—no offense, but you get other things with it, and yet I am thinking 80 percent, 90 percent of what I am getting in the carton of orange juice unless it is, you know, fresh squeezed only, not from concentrate, is probably water. And so from the FDA's standpoint, do you look at the water that goes into that?

Dr. SHARFSTEIN. That is part of what makes food safe is the water and they need to meet food safety requirements, and—

Mr. WALDEN. And that is the same thing you apply to the bottled water, right?

Dr. SHARFSTEIN. It is more we apply to the bottled water because we—

Mr. WALDEN. OK.

Dr. SHARFSTEIN. So as I was saying before, a lot of this is compared to what—if you are comparing bottled water to other foods or other foods that contain water, there are additional regulations that apply. If you are comparing it to municipal water, then there is more disclosure on municipal water than there is on bottled water.

Mr. WALDEN. Well, I—

Dr. SHARFSTEIN. It is just your point of comparison.

Mr. WALDEN. Yes, but I guess the question would be, where is that disclosure? I mean, I have never even—at least there is something on this label. In my hometown of Hood River, we have it out of a spring but I don't get a notice on my tap or on my water bill, or here in the District of Columbia, for heaven's sake, I mean, what it runs through to come out of my tap is scary. That is why I put a filter on the end and then refilter it in another deal and, you know, all of that. So anyway, I am over my time. I am done. Thank you.

Mr. STUPAK. So you get from a municipal water supply and you don't get a notice every year? We get a letter, seriously.

Mr. WALDEN. Probably. And I rush out to my mailbox to read it.

Mr. STUPAK. OK.

Mr. WALDEN. And, you know, it is like the sewer notice I get here. It tells me that when it rains they inflate these inflatable things to keep the sewage from rushing out into the Potomac unless it rains too much and then they deflate them because they cause too much problems. But that is a whole other issue.

Mr. STUPAK. No, we don't want them releasing untreated sewage in our waters, that is for sure.

Mrs. Christensen.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

Mr. Stephenson, I note that in your report the surveys were done in the 50 States and the District of Columbia. Any reason why the territories are not included or are they generally not included in surveys done by GAO?

Mr. STEPHENSON. No, no particular reason, just the methodology we chose.

Mrs. CHRISTENSEN. But they are not generally excluded just—

Mr. STEPHENSON. No.

Mrs. CHRISTENSEN [continuing]. That in this particular—

Mr. STEPHENSON. No, a limited amount of time, a limited amount of resources dictated 50 States and the District of Columbia.

Mrs. CHRISTENSEN. And Dr. Sharfstein, in your testimony you say that FDA has broad authority over food that is introduced or delivered in interstate commerce. So if it is just within a state or within a territory, FDA doesn't have any jurisdiction or do you work with the States then and the territories?

Dr. SHARFSTEIN. That actually is a pretty broad statement because if the bottle comes from outside the State or the cap comes from outside the State, even if it is just sold within the State, it counts as interstate, and there is a presumption, I understand, that it would be interstate, but in theory there might be products that could be challenged, our authority over them, although I am not aware that we heard about a problem that we haven't been able to get to either directly or through the State.

Mrs. CHRISTENSEN. Mr. Stephenson, we have talked a lot about whether bottled water is safer and healthier and there is disagreement on that but there is no disagreement on the fact that bottled water uses more energy to produce and deliver. On page 26 of your report, there is a quite amazing statistic where you refer to a study by the Pacific Institute which examined how much energy it takes to bring bottled water from different locations throughout the world to L.A., and in your report this is what it says. "The Institute estimated that the total energy required to bring a typical one-liter bottle of water weighing about 38 grams to a consumer in Los Angeles would typically range from about 1,100 to 2,000 times the energy cost of producing tap water.

Mr. STEPHENSON. That is true.

Mrs. CHRISTENSEN. So if I drink a single bottle of Evian or Fiji or some other bottled water, which I may not ever drink again, from overseas, I could be using up to 2,000 times more energy than if I just walked over to my sink and filled up a glass?

Mr. STEPHENSON. That is true. The import bottled water accounts for a very small percentage of the total bottled water but that is true.

Mrs. CHRISTENSEN. I see. OK. The study cited in the GAO report also describes how transporting these bottles can be the single biggest cost. According to that study, transportation energy costs can be as high as 57 percent of the total energy costs for spring water bottled in France, transported overseas by cargo ship and transported by rail from the eastern United States to Los Angeles.

Mr. STEPHENSON. That is correct.

Mrs. CHRISTENSEN. Your report also has some other findings related. For example, you concluded that most plastic water bottles are discarded rather than recycled.

Mr. STEPHENSON. Yes, we estimate 25 percent are recycled, so 75 percent are discarded.

Mrs. CHRISTENSEN. So Ms. Houlihan, how did we get here? Why do consumers pay so much, hundreds of times more for bottled water, taking thousands of times more energy to produce?

Ms. HOULIHAN. You heard some of the marketing claims that are used by the industry and I think a lot of people are under a misperception that bottled water must be safer than tap water. A

lot of people believe that it is free of contaminants. In fact by law, it is not required to be any safer than tap water. When we tested 10 major brands of bottled water, we found 38 different pollutants, everything from disinfection byproducts to radioactive isotopes, even traces of Tylenol and fertilizer residues. So one thing that we need when it comes to the bottled water industry is just more daylight, information for consumers on where that water comes from, how it is treated and what is in it.

Mrs. CHRISTENSEN. I think it is really important for the information to be there so that people can make knowledgeable judgment.

I certainly understand that bottles are convenient, but if we are going to use them, isn't there a better way than going into the landfill. This bottle of water is bottled in Virginia and is transported just a few miles from here to the Capitol and it is biodegradable. Mr. Doss, you represent the bottled water companies. How many of them are using biodegradable bottles?

Mr. DOSS. I am not sure exactly how many are using biodegradable bottles but I will say that as a general statement that bottled water companies like other food industry companies are trying to do whatever they can to reduce their environmental footprint. Obviously, going to bottles such as those is one way of doing it. We have made significant efforts to lightweight the bottled water containers. Anyone who drinks bottled water knows these days they are much lighter weight which uses less plastic. We also have some of our companies that are using recycled content, less virgin materials. So bottled water is trying to do what it can to reduce the environmental footprint, but I think it is important to recognize that bottled water is just one of thousands of food products on the market in plastic, and in fact, we are only one-third of 1 percent, as reported in the GAO report, of the entire waste stream in the United States so I think that any efforts to reduce the environmental impact of packaging has to focus more broadly on all consumer goods.

Mrs. CHRISTENSEN. Absolutely. Thank you for your answers.

Mr. STUPAK. Thank you.

Mr. Burgess, let us get 5 minutes in before we have to go for votes.

Mr. BURGESS. Great. Thank you.

Dr. Sharfstein, just to follow up a little bit on what Mr. Walden was talking about on the lawsuit with the phthalate DEHP that has been held up. I think Mr. Stupak referenced it has been 15 years in the making. You are now prepared to issue a ruling in September. Do I understand that correctly, on DEHP? The FDA is prepared to go ahead with that ruling now or is that—

Dr. SHARFSTEIN. So there is questions whether we set a standard for bottled water, and our intent is to proceed with setting a standard for bottled water. That is just a matter of preparing the standard, getting it going. If we come across some reason why this doesn't apply to bottled water at all, we are permitted to make the statement that it doesn't apply to bottled water at all but it is not obvious to us there is such a compelling reason at this point, so we would anticipate then going forward and setting a standard. So at that point is just as long as it takes to do. What is in the law, and this gets, you know, there is a 180-day standard in the law which

is that if EPA sets the standard, FDA needs to set a standard at least 180 days before so that it can take effect at the same time as the EPA standard. But with this one where they waited so long because of this legal thing, that is sort of out the window. It doesn't really apply because the EPA's standard went into effect so long ago. So really, we would just like to do it in a reasonable time frame.

Mr. BURGESS. And at this point, any preview, any look ahead as to what that standard may be?

Dr. SHARFSTEIN. Sure. It would just be the—if we were to do it, it would be the same standard that EPA has unless we had a really good reason otherwise, but that would be the assumption, just like we have done for almost all the other contaminants, the same standard as EPA.

Mr. BURGESS. Mr. Chairman, on the issue of the high risk, low risk, apparently there was a ruling issued by the FDA in 2005 in the risk assessment, and I have a copy of that. With your permission, we will make that available to the committee for its consideration and adding it to the record.

And then finally, let me just ask a question about recycling, and really this is for everyone on the panel, about the compounds leaching out of the plastic in greater amounts in recycled materials than native or first-run materials. So is that a real concern for us to have? Are there going to be different standards for the recycled bottles or should there be different standards? Do consumers need to be aware of any difference between a recycled bottle and a first-run bottle?

Ms. HOULIHAN. We looked at FDA reviews of additives in plastic and found that there are over different compounds that could leach out of plastic, so the question you have raised is a very important question and we think not only do recycled bottles need to be more closely inspected and tested with regard to that but also new bottles, what is coming out of the plastic into waters, and that kind of testing is not required. We fully support the greater rates of recycling in industry. That is just a smart move overall.

Mr. BURGESS. Is there another secondary use for the recycled plastic water bottle other than re-creating another plastic water bottle? Can they be used in building materials or is there any other use for these bottles?

Ms. HOULIHAN. That is a fabulous question, and I think we are creative enough in this country to come up with other uses that don't involve direct contact with water.

Mr. BURGESS. Mr. Doss, do you have an opinion?

Mr. DOSS. I don't know anything specifically about the issue you just raised but I do know that FDA has to clear all contact packaging materials. So if FDA clears it, then the manufacturer is able to use it and they have made the determination that they are safe to use.

Mr. BURGESS. So we come to Dr. Sharfstein.

Dr. SHARFSTEIN. There has got to be a standard of safety. Whether it is recycled or not recycled, there has got to be a standard of safety, and so that is what FDA enforces, and understanding in light of, you know, new evidence that comes out about the particular substances and the latest science and the different concerns

people have, FDA's job is to weigh that, but at the end of the day, it has to be a standard of safety and it has got to apply no matter what is in the package.

Mr. BURGESS. So where are we right now with the issue of recycling? Should consumers be concerned about buying bottled water in a recycled product? Are you testing these products currently, or even are there any available?

Dr. SHARFSTEIN. Well, we test the water, you know. When we test water, it could be from a recycled bottle or not, but I am not aware of any special concerns for recycled plastic but I think if there are concerns people have they should share them with the agency.

Mr. BURGESS. And I guess I don't really even know enough to know whether these recycled materials are then broken down and reconstituted or do we just simply wash out the bottle and put a new cap on it. But, I mean, obviously the push is to recycle so we are going to be seeing more of these products on our shelves and in our stores.

Dr. SHARFSTEIN. I think you are illustrating why the job is so challenging because products change and FDA has to be up on them so we can enforce the same basic safety standards.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. STUPAK. Thanks, Mr. Burgess.

Just one last question and we will close the hearing. Mr. Stephenson, in your GAO report that we talked about today about consumer confidence reports, and in 1996 Congress directed the FDA to assess the feasibility of providing bottled water to consumers with the functional equivalent of a consumer confidence report, and according to your GAO report that is released today, on August 25, 2000, FDA concluded that it would be feasible to provide consumers with some of the information contained in the consumer confidence report directly on a bottle label and access the remaining information through an address or phone number, and that is tab number 3 there in the document. Is that correct?

Mr. STEPHENSON. Yes, that is right.

Mr. STUPAK. So Mr. Doss, any reason why your organization would object to that or do you think we should have a consumer confidence report for bottled water?

Mr. DOSS. Well, as I think was reported in their study, they did say it was feasible. They didn't exactly say what was feasible to put on the label. I think they were quite skeptical of putting some of the contaminants, et cetera on the label because it would just clutter the label. Now, as I said before, I think that the bottom line for us that consumers ought to be able to get information and we think that a telephone number, call the company and request that information is the best way to do it and almost all bottled waters currently as well as other food products have a phone number at least that a consumer could call the company and say could you send me the information and that information should be sent, and if it isn't, I would say go find another product to buy.

Mr. STUPAK. So you don't mind the phone number but you don't want any other information?

Mr. DOSS. We don't.

Mr. STEPHENSON. Mr. Chairman, I think there needs to be some specificity in what is going to be required in those confidence reports. When we were checking labels and Web sites, it was very difficult to get the kind of information we were——

Mr. STUPAK. Sure. Your report didn't say put the whole report on the bottle.

Mr. STEPHENSON. It doesn't have to be on the label.

Mr. STUPAK. Just that some information should be on there and there should at least be a phone number to back it up if you want further information.

Mr. STEPHENSON. That is right.

Mr. STUPAK. Well, that concludes all of our questioning. I want to thank all of our witnesses for coming today and for your testimony.

The committee rules provide that members have 10 days to submit additional questions for the record. That concludes our hearing. This meeting of the subcommittee is adjourned.

[Whereupon, at 12:00 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**CONGRESSWOMAN DONNA M. CHRISTENSEN'S STATEMENT
BEFORE THE HOUSE SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
ON
THE CURRENT REGULATION OF BOTTLED WATER**

July 8, 2009

Thank you Chairman Stupak, and thank you and Ranking member for continuing the badly needed oversight on products that we use and ingest – this time on the current federal regulation of bottled water—an issue that is of concern to us all.

When millions of Americans across the Nation purchase and drink bottled water, they do so with the confidence that it is safe, pure, and contaminant free and with the assurance that their government and the industry have taken the necessary steps to protect them.

Some consumers purchase bottled water because they feel that it is “safer” than tap water; others choose bottled water for its convenience. Regardless of the reason, we have a commitment to our constituents and the Nation’s citizens to continue to make certain that the necessary regulations are in place to ensure its safety for human consumption.

As bottled water sales have exponentially grown, so has the public's concern for what producers market as high quality, great tasting products.

When one looks at FDA, it appears that existing regulations at the federal, state and local level seek to ensure that bottled water is regulated by standards of quality and integrity, but FDA staffing levels and several surveys of bottled waters lead us to question the presumed safety of these products.

While many bottled waters producers work avidly to ensure that their product is of superb quality and standard, we must work collaboratively to guarantee consistency across the industry.

To date, bottled water has been regarded as a traditional food product and regulated as such. It is my hope that stronger regulations if needed, and where applicable and more robust funding and staffing of the agency will ensure that quality standards are set and maintained so as to safeguard our public's health and peace of mind. We must continue to take responsibility for bottled water regulations and work to close any regulatory gaps that exist.

I am pleased that this committee has brought this issue to the forefront of our legislative agenda as it is a critical one.

I would like to welcome our panelist to today's hearing. I look forward to your testimony and to working with you on this very important issue.



United States Government Accountability Office
Washington, DC 20548

August 10, 2009

The Honorable Henry Waxman
Chairman
Committee on Energy and Commerce
House of Representatives

Attention: Earley Greene

Dear Mr. Chairman:

Enclosed is our response to questions submitted for the record by the Honorable Greg Walden regarding our July 8, 2009, testimony regarding the regulation of bottled water. If you should have any questions, you may contact me on (202) 512-3841 or my Assistant Director, Steve Elstein, on (202) 512-6515.

Sincerely yours,

John B. Stephenson
Director, Natural Resources
and Environment

Enclosure

1. The June 2009 GAO report on bottled water made only one recommendation concerning an FDA standard of quality for bottled water that was not as stringent as the EPA regulation for public water systems and that was for DEHP. Since FDA does not currently have a DEHP standard, you recommended that FDA establish a standard for this substance or publish a rationale for not doing so. Are you aware of any bottled water bottled that contain DEHP? Are you aware of any instances where FDA's regulation of bottled water is more stringent or protective of public health than EPA's regulation of municipal water systems?

GAO is not aware of any bottled water that contains DEHP. According to the North American Metal Packaging Alliance, Inc. (NAMPA), an industry association, DEHP is not used in bottled water packaging. A NAMPA representative stated that at one point, DEHP may have been used in the closures for glass water bottles, but its use has been phased out. Aside from packaging, FDA officials stated that they do not expect to find DEHP in bottled water from other sources because bottled water comes from groundwater sources, which are generally protected, or from municipal sources, which are already required to meet EPA's maximum contaminant level for DEHP. However, in the absence of a standard of quality and monitoring requirements, we cannot be assured that bottled water does not contain any DEHP. Moreover, the NAMPA representative with whom we spoke stated that, in his view, it would not be problematic for the industry if FDA set a quality standard for DEHP in bottled water. If FDA concludes that it is not necessary to establish a standard of quality because DEHP is unlikely to be found in bottled water, the agency should publish its rationale in the Federal Register, as required.

GAO is aware of several instances where FDA's regulation of bottled water is more stringent or protective of public health than EPA's regulation of municipal water systems. As noted in Appendix II of our report, FDA's standards of quality for lead and copper are more stringent than EPA's maximum contaminant levels because leaching of these contaminants from distribution systems and residential plumbing is not a factor for bottled water. In addition, FDA has a standard of quality for nickel and total phenols in the absence of an EPA standard for these substances.

2. According to the U.S. Government Accountability Office's (GAO) recent survey of 50 States and the District of Columbia, there has been no conclusive evidence that bottled water has caused any illnesses in the past five years. The Centers for Disease Control (CDC) estimates that there are anywhere from 4 million to 33 million cases of gastrointestinal illness associated with public drinking water systems each year. (See the following information on the CDC website: <http://www.cdc.gov/ncidod/dpd/healthywater/estimate.htm>) Is the CDC estimate accurate? Does EPA have information concerning the number of illnesses or death caused each year from consuming public drinking water?

The estimates on acute gastrointestinal illness were derived by the Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA) through a joint effort to develop a national estimate of waterborne disease as part of the 1996 amendments to the Safe Drinking Water Act. The joint study attempts to estimate acute gastrointestinal illness based on past reported instances and other available epidemiological data. On the other hand, the results of our survey of the 50 states and the District of Columbia focused on collecting information from state regulatory agencies about cases that were reported. Since not all cases would be reported to state regulatory agencies and because a direct link to an illness as a result of bottled water consumption may not always be accurately identified when a case is reported, the results of our survey are not comparable with the results of the joint CDC/EPA study.

With regard to the accuracy of the estimates made by the CDC and EPA, and the information available to EPA concerning drinking water-related illnesses, we would have to understand both the reliability of the data and the statistical models used to link drinking water consumption with acute gastrointestinal illness or other illnesses. To conduct such an assessment would require substantially more time than what is available to respond to this question for the record and would require a separate request to conduct a review that is consistent with GAO's internal controls related to data reliability and statistical estimates.

www.ewg.org

August 10, 2009

Honorable Greg Walden, Ranking Member
Oversight and Investigations Subcommittee
House Energy and Commerce Committee
22322A Rayburn House Office Building
Washington, DC 20515

Dear Ranking Member Walden,

Thank you for your attention to the issue of a consumer's right to know about the source and quality of bottled water. I appreciate the opportunity to testify before the Oversight and Investigations subcommittee at the "Regulation of Bottled Water" hearing on July 8, 2009. We hope that the subcommittee will continue focusing on this issue, so that consumers will ultimately get the information they need.

As you may recall, our recent bottled water investigation (EWG 2009) found that:

- 30% of bottled waters surveyed failed to label their products with any information on the source of the water;
- 44% failed to include any information on the label about how or if the water is treated;
- Only 18% published current water quality test reports on their websites.

In a separate independent review of bottled water labels and water quality reports, the General Accountability Office (GAO) found that "additional information about bottled water would be beneficial to consumers" (GAO 2009).

Please see the attached answers to the questions you submitted to Environmental Working Group (EWG) subsequent to my testimony at the July 8, 2009 bottled water hearing.

Thank you again for your attention to this important issue, and for your thoughtful questions and comments.

Sincerely,

A handwritten signature in cursive script that reads "Jane Houlihan".

Jane Houlihan
Senior Vice President for Research
Environmental Working Group

cc: Honorable Bart Stupak, Chair, Subcommittee on Oversight and Investigations, House Energy and Commerce Committee

Honorable Greg Walden
August 10, 2009
page 2 of 2

WRITTEN RESPONSE OF JANE HOULIHAN, SENIOR VICE PRESIDENT FOR RESEARCH
ENVIRONMENTAL WORKING GROUP
REGARDING "THE REGULATION OF BOTTLED WATER" HEARING BEFORE
THE HOUSE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
HOUSE ENERGY AND COMMERCE COMMITTEE ON JULY 8, 2009

Question #1: *"Your July 2009 report on bottled water labels states that the label samples that you used in your survey were obtained from volunteers responding to your e-mail and website requests. What was the total number of unique bottled water labels that you reviewed? What was the total number of states from which you collected bottled water labels? Was this a representative sample of all bottled water brands sold in the United States? Are your survey results statistically valid?"*

Answer: We reviewed labels from 188 unique bottled waters sent from 38 states altogether. Of note, the number of labels we analyzed was 2.3 times greater than the 83 labels reviewed by GAO (GAO 2009). The labels in EWG's survey include top domestic and important brands as well as a wide cross-section of local brands available, thus covering a broad range of a diverse market. A census of labels for all bottled water products available to consumers was not possible, since as noted by GAO (2009), "FDA's database of registered food firms does not capture data that would identify all U.S. firms manufacturing bottled water" or the various labels under which the water is sold. The statistics we present in our investigation are derived from the pool of labels we reviewed, and are a valid representation of that sample.

Question #2: *"In your July 2009 report on bottled water labels, were any labels found to be in violation of State or Federal laws?"*

Answer: Our study did not include an investigation of the bottled water industry's compliance with state and federal labeling laws.

References

EWG (Environmental Working Group). 2009. Is your bottled water worth it? Accessed August 10 2009 at <http://www.ewg.org/health/report/bottledwater-scorecard>.

GAO (U.S. Government Accountability Office). 2009. Bottled water. FDA safety and consumer productions are often less stringent than comparable EPA protections for tap water. GAO-09-610. June (2009).

