

**QUALITY AND ENVIRONMENTAL
IMPACTS OF BOTTLED WATER**

HEARING

BEFORE THE

SUBCOMMITTEE ON TRANSPORTATION SAFETY,
INFRASTRUCTURE SECURITY, AND WATER QUALITY

OF THE

COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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SEPTEMBER 10, 2008
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ONE HUNDRED TENTH CONGRESS
SECOND SESSION

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C O N T E N T S

| | Page |
|--|------|
| SEPTEMBER 10, 2008 | |
| OPENING STATEMENTS | |
| Lautenberg, Hon. Frank R., U.S. Senator from the State of New Jersey | 1 |
| Inhofe, James M., U.S. Senator from the State of Oklahoma | 16 |
| WITNESSES | |
| Lloyd, Emily, Commissioner, New York City Department of Environmental Protection | 3 |
| Prepared statement | 4 |
| Wu, Mae, J.D., MPhil, Staff Attorney, Natural Resources Defense Council | 18 |
| Prepared statement | 21 |
| Responses to additional questions from Senator Boxer | 34 |
| Hauter, Wenonah, Executive Director, Food and Water Watch | 36 |
| Prepared statement | 38 |
| Responses to additional questions from Senator Boxer | 43 |
| Edberg, Stephen C., PhD., A.B.M.M., Professor, Laboratory Medicine, Internal Medicine, Chemical Engineering, Yale University School of Medicine, and Director, Clinical Microbiology Laboratory, Yale-New Haven Hospital | 47 |
| Prepared statement | 49 |
| Doss, Joseph K., President and CEO, International Bottled Water Associa- tion | 77 |
| Prepared statement | 80 |
| Responses to additional questions from Senator Boxer | 132 |

QUALITY AND ENVIRONMENTAL IMPACTS OF BOTTLED WATER

WEDNESDAY, SEPTEMBER 10, 2008

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON TRANSPORTATION SAFETY,
INFRASTRUCTURE SECURITY, AND WATER QUALITY,
Washington, DC

The subcommittee met, pursuant to notice, at 3 p.m. in room 406, Dirksen Senate Building, Hon. Frank Lautenberg (chairman of the subcommittee) presiding.

Present: Senators Lautenberg, Inhofe

OPENING STATEMENT OF HON. FRANK LAUTENBERG, U.S. SENATOR FROM THE STATE OF NEW JERSEY

Senator LAUTENBERG. Good afternoon. The Subcommittee will come to order. We expect other Senators to join us, but I caution the witnesses, don't think that a quiet room up here is anything other than a reflection of other things to do, and not lack of interest in this hearing, because there is a lot of interest, as we all know, in this hearing.

I would invite our witnesses to take the stand, please. We thank all of you for being here with us. There is a lot of mythology attached to drinking water, and what its value is. We know one thing, we know what its prices are. So as I call the hearing to order, I welcome everyone to today's hearing as we look into the quality of the bottled water that Americans are drinking and the impact that bottled water has on our environment.

Bottled water has become so popular, so much a part of our culture, that more than half of all Americans drink it. About a third drink it with regularity. People keep bottled water everywhere. It is in their cars, their gym bags, in their homes. By the way, this Senator is also a participant in the consumption of bottled water. I look around my children's houses, they all have bottled water, and I hope they are listening today.

Americans spend more than \$8 billion a year on bottled water, and that amount is only expected, based on history, to grow. With people spending that much money, they have a right to expect that their water is safe and clean. That is what they expect what they turn on the faucet at home, as well. That is what they should expect when they turn the cap on a bottle of water.

I want to be clear. Bottled water serves some important purposes. But in this case, we can't say what you don't know won't hurt you. What you don't know deserves close review. The need for

clean bottled water is magnified during an emergency, such as Hurricane Gustav, which just passed through the Gulf Coast, when people are evacuated from their homes or in their homes but without basic utilities. It certainly is healthier to purchase water from a vending machine rather than soda.

But what many Americans don't know is that almost 40 percent of bottled water on the market is actually tap water, fresh from the tap. They don't say that, but we know that that's the case. Some bottlers use additional treatments to clean it, with others it is merely tap water in a fancy container. In addition, water bottles that are discarded in the trash have a lasting effect on our environment and the Country's continuing energy crisis. Americans use 2.7 million tons of plastic each year for water bottles. The amount of oil that it takes to produce those water bottles would power more than 1 million cars and trucks for a year. And only 14 percent of plastic bottles are recycled, according to one study. The rest languish in our landfills, and the plastic is not biodegradable.

One solution is to encourage Americans to drink more tap water, either right from the tap or with a filter. American tap water is the cleanest in the world, and by drinking it, people can save money and save a growing environmental problem at the same time. Earlier this year, the U.S. Conference of Mayors passed a resolution to encourage the use of tap water in their cities. New York City, which we will hear from today, and cities in New Jersey across the Country played an important part in that resolution.

But knowing that Americans are still going to drink bottled water, we can also act to give American consumers the facts about what they are drinking. That is why I am going to soon be introduced the Bottled Water Right to Know Act, which will provide consumers information about where their bottled water comes from and the quality of the water that they are drinking. We should never be in a situation where we don't have access to clean, safe water. And bottled water plays a role in that safety net.

But Americans deserve to know what it is that they are consuming and the full effects of their decision. So I thank the witnesses at the table and look forward to hearing from all of you. I would welcome each one. Emily Lloyd, Commissioner with the New York City Department of Environmental Protection. New York City has been working on a new program to reduce bottled water use. I look forward to learning about their efforts.

Mae Wu, an attorney with the Health and Environment Program, at the NRDC, the Natural Resources Defense Council. They have focused on bottled water issues for more than a decade.

Wenonah Hauter, the Executive Director of Food and Water Watch, a think tank that has focused on bottled water.

Dr. Stephen Edberg, a professor from Yale University School of Medicine, a well-respected microbiologist with expertise on health and quality of water.

Mr. Joseph Doss, the President and CEO of the International Bottled Water Association, which is the industry association that represents bottled water producers.

I want to thank all of you for coming today and for lending your expertise to this hearing. Your full statement will be included in

the record, so I ask you to present a 5-minute summary of your testimony.

Ms. Lloyd, if you will, please begin.

STATEMENT OF EMILY LLOYD, COMMISSIONER, NEW YORK CITY DEPARTMENT OF ENVIRONMENTAL PROTECTION

Ms. LLOYD. Thank you. Good afternoon, Chairman Lautenberg. I am Emily Lloyd, Commissioner of the New York City Department of Environmental Protection. I greatly appreciate the opportunity to testify on drinking water.

As you may know, one of New York City DEP's most important responsibilities is to manage the surface water system that provides potable water to approximately 9 million people, or half of the population of New York State, including of course New York City. Thanks to the foresight of my predecessors, the surface water system we operate today continues to provide extremely high quality water at very moderate costs, which unfortunately are increasing rapidly, due to unfunded mandates and rising construction costs.

There are two simple reasons for the historically low cost of our drinking water. First, until the Surface Water Treatment Rule was promulgated in 1989, New York City's water required no treatment beyond chlorination and at times of high turbidity, the addition of alum. Second, it flows downhill from reservoirs in the mountains, down to New York City, throughout the city, with one or two exceptions, and all the way to the sixth floor in city buildings purely by gravity. That means no energy costs and no greenhouse gases from mountaintop to tap.

Without sounding boastful, I hope, I think I can say safely that the quality and taste of New York City's drinking water is widely admired by both water quality professionals and by average New Yorkers and our guests. Most recently, at this year's New York State Fair, New York City's water emerged victorious in a tasting competition sponsored by the State Department of Health in the New York section of the American Water Works Association. The event raised awareness of the importance of clean, high quality drinking water and also of the massive investment it takes to maintain our system and keep our watershed clean.

Our Federal regulators have also acknowledged the quality of our drinking water. We are especially proud that last year we were granted a 10-year renewal of EPA's filtration avoidance determination for 90 percent of our water supply, double the length of time of all previous exemptions. New York is one of only five large cities in the Nation that is not required to filter its drinking water.

The 10-year filtration avoidance determination demonstrates how investment in watershed protection assures the continued delivery of safe, clean drinking water. Watershed protection is one of the highest priorities in Mayor Michael Bloomberg's PlaNYC 2030, the blueprint for making New York City an even more sustainable city. Nineteen initiatives in the plan address water quality and the maintenance and upgrade of our water network.

Of course, supplying 9 million people with high quality drinking water comes at an ever-increasing cost. Aging infrastructure and evolving regulations are requiring a huge reinvestment in our water system. From 1972 until 1986, Federal programs supplied

some support. But for many years now, municipalities have been on their own financially. We hope that the growing awareness of the high quality of our drinking water and the importance of tap water as a natural resource will encourage renewed Federal interest in water infrastructure.

Returning to the subject of your bill, Senator Lautenberg, establishing standards for bottled water at least as protective as drinking water, I believe it highlights the differences between tap and bottled water. In June, Mayor Bloomberg signed on to a resolution of the U.S. Conference of Mayors that you referred to, supporting municipal water systems. The resolution draws some striking contrasts between tap water and bottled water. Bottled water can cost a thousand to ten thousand times what tap water costs the consumer. Tap water is subject to more stringent testing requirements and still costs a fraction of bottled water. Plastic water bottles are an ever-growing component of municipal waste, and their production and distribution consume tremendous amounts of energy.

The resolution recognizes that there are going to be circumstances where municipalities, New York City included, will not have alternatives to bottled water, particularly in emergency situations. But we hope the resolution will erode the misperception that public water supplies are somehow less desirable than commercial bottled water. In fact, public water supplies are one of society's greatest assets, and tap water is superior to the quality of bottled water at a fraction of the cost, both direct and indirect. Aggressively promoting tap water raises citizens' awareness of the importance and quality of this resource.

I know the Subcommittee is interested in efforts taken by New York City to promote tap water consumption. Last year, DEP, in conjunction with the New York City Department of Health and Mental Hygiene, conducted a public awareness campaign on the benefits of drinking tap water. The multimedia campaign included posters on public transit, I brought an example here, radio spots in Spanish and English and the distribution of more than 50,000 reusable water bottles. Again, I brought one of those for people to see.

One of the goals of the campaign was to address the myth that tap water is somehow not as safe or desirable as bottled water or sweetened beverages. Part of our challenge is that for many of our foreign-born residents and visitors, it is not a myth. The reality is that finding a safe and reliable source of potable water is a problem in many areas of the world. Recent immigrants and their children may needlessly spend money on bottled water or opt for a cheaper can of sugary soda if they don't know that tap water is the cheaper, healthier alternative.

Working again with sister agencies, we are now preparing a renewed campaign to expand awareness of the benefits of New York City tap water. Making the healthier choice, we believe, should be everyone's right. Making the choices, personal and governmental, that support the environment and public drinking water infrastructure we think is everyone's responsibility.

[The prepared statement of Ms. Lloyd follows:]

Statement of Commissioner Emily Lloyd
New York City Department of Environmental Protection
before the Senate Environment and Public Works Subcommittee on
Transportation Safety, Infrastructure Security and Water Quality

**Dirksen Senate Office Building, Washington, D.C.
Wednesday, September 10, 2008**

Good afternoon, Chairman Lautenberg, Ranking Member Vitter and Members of the Subcommittee. I am Emily Lloyd, Commissioner of the New York City Department of Environmental Protection (NYCDEP).

I greatly appreciate the opportunity to testify on drinking water. As you may know, one of NYCDEP's most important responsibilities is to manage the surface water system that provides potable water to approximately nine million people, or half of the population of New York State. Thanks to the foresight of my predecessors, the surface water system we operate today continues to provide extremely high-quality water at very moderate costs which, unfortunately, are increasing rapidly due to unfunded mandates and rising construction costs.

There are two simple reasons for the historically low cost of our drinking water: First, until the Surface Water Treatment Rule was promulgated in 1989, New York City's water required no treatment beyond chlorination and, at times of high turbidity, the addition of alum. Second, it flows downhill to New York City from reservoirs at a higher elevation upstate, thereby saving enormously on energy costs, since pumping is, for the most part, not needed to get water to customers in the first six stories of New York City's buildings.

Without sounding boastful, I think I can safely say the quality and taste of New York City's drinking water is widely admired by both water quality professionals, and by average New Yorkers and our guests. Most recently, at this year's New York State Fair, New York City's water emerged victorious in an unscientific -- but impartial -- competition sponsored by the State Department of Health and the New York Section of the American Water Works Association. The event raised awareness of the importance of clean, high-quality drinking water and also of the massive investment it takes to maintain our system and keep our watershed clean.

Our federal regulators have also acknowledged the quality of our drinking water. We are especially proud that last year, we were granted a ten-year renewal of the EPA Filtration Avoidance Determination (FAD) for the Catskill/Delaware Watershed, the two largest watersheds comprising our reservoir system. The FAD renewal doubled the previous five-year renewal, and New York is one of only five large cities in the nation that is not required to filter its drinking water. The FAD demonstrates EPA's confidence that our robust watershed protection will assure the continued delivery of safe, clean drinking water for years to come.

Watershed protection is one of the imperatives of New York City Mayor Michael Bloomberg's PlaNYC 2030, the blueprint for making New York City "greener and greater." Nineteen initiatives in the plan address water quality and the maintenance and upgrade of our water network, which will enable us to continue to reliably provide high-quality drinking water.

I know the subcommittee is interested in efforts taken by New York City to promote tap water consumption in preference to commercial bottled water or other beverages. Last year, DEP in conjunction with the NYC Department of Health and Mental Hygiene (DOHMH) conducted a public health awareness campaign on the benefits of drinking tap water. The multi-media campaign included posters on public transit, radio spots in Spanish and English, and the distribution of 50,000 reusable water bottles.

One of the goals of the campaign was to address the myth that tap water is somehow not as safe or desirable as bottled water or sweetened beverages. Part of our challenge is that for many of our foreign-born residents and visitors, it isn't a myth: the reality is that finding a safe and reliable source of potable water is a problem in many areas of the world.

Working again with sister agencies, we are now preparing a renewed campaign to expand awareness of NYC Water. Particularly since tap water is so often considered a default choice - something consumed when alternatives aren't available - the campaign emphasizes the true distinction between bottled water - environmentally deleterious, expensive and of variable quality - and tap water, particularly NYC Water - a superior product that is cheap, healthy, environmentally sound, safe and excellent tasting.

Of course supplying nine million people with high-quality drinking water comes at a significant cost, which is borne by our ratepayers. From 1972 until 1986, when the federal government was actively funding environmental work through grants, property owners had some relief from

rising water and sewer rates. Municipalities upgraded and federal assistance waned; now the primary means of federal support for wastewater and drinking water infrastructure is subsidized loans generated by grants from USEPA to State Revolving Funds. While the funds leverage bonds issued at lower interest rates, subsidizing the interest payments on capital expenditures does not have the same impact on reducing costs as grants. Furthermore, the amount of subsidized loans available is relatively small. An enhanced federal program of investment in water infrastructure could help relieve pressure for rate increases or permit acceleration of projects that must be deferred to out years, given the ever-increasing costs of project budgets.

If I may return to the subject of your bill, Senator Lautenberg – establishing standards for bottled water at least as protective as for drinking water – I believe it highlights the differences between tap and bottled water.

In June, Mayor Bloomberg signed on to a resolution of the U.S. Conference of Mayors supporting municipal water systems. The resolution draws some striking contrasts between tap water and bottled water: bottled water can cost 1,000 to 10,000 times what tap water costs the consumer; tap water is subject to more stringent testing requirements and still costs a fraction of bottled water; plastic water bottles are an ever-growing component of municipal waste; and their production and distribution consume tremendous amounts of energy. The resolution recognizes that there are going to be circumstances where municipalities, New York City included, will not have alternatives to bottled water, particularly in emergency situations. But we hope the resolution will erode the misperception that public water supplies are somehow less desirable than commercial bottled water. In fact, public

water supplies are one society's greatest assets; and tap water is superior to the quality of bottled water at a fraction of the costs, both direct and indirect. Aggressively promoting tap water raises citizens' awareness of the importance and quality of this resource. We then tell their legislators that tap water is better quality and a better deal than bottled water, and that public water supplies are renewable national resources if we steward them properly.

Great with a twist

Zero calories

Healthy

Delicious

Zero sugar

Clean

NYC Water
Get Your Fill

NYC Health

The New York City Department of Health and Mental Hygiene, Thomas F. Frist, M.D., M.P.H., Commissioner
The New York City Department of Environmental Protection, Robert J. Pollina, Commissioner
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DEP

Zero sugar

Great on the rocks

Healthy

Clean

Refreshing

Fat free

NYC Water
Get Your Fill

NYC Health

The New York City Department of Health and Mental Hygiene, Thomas H. Koppe, R.D., M.P.H., Commissioner
The New York City Department of Environmental Protection, John J. Sweeney, Commissioner
Richard A. DiGirolamo, Mayor

DEP

Great straight up

Zero sugar

Healthy

Clean

Zero calories

Refreshing

NYC Water
Get Your Fill

NYC
HEALTH

The New York City Department of Health and Mental Hygiene • Thomas R. Frieden, M.D., M.P.H., Commissioner
The New York City Department of Environmental Protection • John L. Satterly, Commissioner
Michael R. DeStefano, Mayor

DEP

Cool

Great on the go

Healthy

Clean

Zero calories

Zero sugar

NYC Water
Get Your Fill

NYC Health

The New York City Department of Health and Mental Hygiene | Licensed to Health, LLC, L.P. - Distribution
The New York City Department of Environmental Protection | 480 Canal Commerce
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DEP

Delicious

Healthy

Refreshing

Clean

Stain free

Zero sugar

NYC Water
Get Your Fill

NYC Health

The New York City Department of Health and Mental Hygiene, Division of Environmental Health, 112-10 Queens Blvd., 11th Floor, Rego, NY 11106
The New York City Department of Environmental Protection, 100 East 42nd Street, New York, NY 10017

DEP

NYC WATER BOTTLE DESIGN:



Front



Back

Senator LAUTENBERG. Thank you, Ms. Lloyd. I don't want anybody to think that I am prejudiced to New York City's side of the issue. We will try to allow others fairness in watching the clock.

Ms. Wu, we thank you for being here with us.

Senator Inhofe.

Senator INHOFE. I am sorry, Mr. Chairman, while I am the Ranking Member of the whole Committee, Senator Vitter from Louisiana is the Ranking Member of this Subcommittee. He has an amendment on the floor, so I told him I would sit in at the beginning.

Senator LAUTENBERG. Please forgive me. I would ask Senator Inhofe, please, Ms. Wu, to make his opening statement.

**OPENING STATEMENT OF HON. JAMES M. INHOFE,
U.S. SENATOR FROM THE STATE OF OKLAHOMA**

Senator INHOFE. Thank you.

First of all, thank you for having this hearing. I think we in the United States are privy to the very best quality of both tap water and bottled water. It is something that does deserve attention at this time.

Due to Senator Vitter's absence, he wanted me to say to the bottled water industry how much he appreciates the help that you have been all during the disasters that they have had to incur down in Louisiana. He said you have really come in and done an excellent job.

Recently certain NGO's, non-governmental organizations, have argued that bottled water poses health risks to humans and is extremely harmful to the environment, spurring some public concern and spurring this hearing, I might add. These issues, however, are not new. They have been studied for quite some time and needless public concern should be taken into consideration.

The safety of bottled water is comprehensively regulated at the Federal, State and the local industry levels. In fact, both the Natural Resources Defense Council and the Centers for Disease Control note that illness from bottled water has only been a result of rare, isolated instances, which suggests that the current framework works and further regulation may not be necessary. The bottled water industry, in recognition of environmental concern and shifting consumer preferences, has led industry efforts to significantly enhance their sustainability efforts to minimize environmental impact.

The production of bottled water, however, does share many of the same environmental impacts as other consumer goods. How many of my colleagues have walked down the supermarket aisles lately to find that many products are now packaged as a disposable good. Society has driven the market to produce more disposable goods, putting extreme pressures on municipal waste sites. It is important to note that the proliferation of bottled water and other consumer goods is a consequence of shifting consumer lifestyles.

As a former mayor, I sympathize with the concerns of increased pressures on the holding capacity of our counties' municipal waste facilities. We as a Country need to become more conscious of what we buy and toss into our garbage cans.

We will hear testimony today from our distinguished witnesses. We will also hear testimony on both sides of this issue. I hope this issue will provide clarity to the status of bottled water, which is already comprehensively regulated at the Federal, State and local level. I thank you, Mr. Chairman, for holding this hearing.

[The prepared statement of Senator Inhofe follows:]

STATEMENT OF HON. JAMES INHOFE, U.S. SENATOR
FROM THE STATE OF OKLAHOMA

Mr. Chairman, thank you for calling this hearing today on the quality and environmental impacts of bottled water. I'm sure you would agree that Americans are privy to the best drinking water and bottled water available in the world. There is undoubtedly growing popularity of bottled water and consumers and the general public are justified to ask whether bottled water in America is safe and sustainable. I believe the answer to both of those questions is yes, as we will hear in testimony today.

Due to Senator Vitter's absence, I would first like to mention how grateful we all are for the bottled water industry's service to our country in recent catastrophes. The State of Louisiana I'm sure is grateful for the continued assistance. America's recovery efforts would be severely hindered if it weren't for their generosity.

Recently, certain Non-Governmental Organizations or NGO's have argued that bottled water poses health risks to humans and is extremely harmful to the environment, spurring some public concern and this hearing. These issues, however, are not new but have been studied for quite some time. Nevertheless, public concern should not be discounted.

The safety of bottled water is comprehensively regulated at the Federal, State, Local and Industry levels. In fact, both the Natural Resource Defense Counsel and the Center for Disease Control note that illness from bottled water has only been the result of rare and isolated incidents, which suggests that the current framework works and further regulation is unnecessary.

The bottled water industry in recognition of environmental concern and shifting consumer preferences have led industry efforts to significantly enhance their sustainability efforts to minimize environmental impact. The production of bottled water, however, does share many of the same environmental impacts as other consumer goods. How many of my colleagues have walked down the supermarket aisles lately to find that many products are now packaged as a disposable good. Society has driven the market to produce more disposable goods, putting extreme pressures on municipal waste sites. It is important to note that the proliferation of bottled water and other consumer goods is a consequence of shifting consumer lifestyles. As a former mayor, I sympathize with the concerns of increased pressures on the holding capacity of our countries municipal waste facilities and we as a country need to become more conscious on what we buy and toss into our garbage can.

We will hear testimony today from Dr. Stephen Edberg, Professor Laboratory Medicine and Director of Microbiology at Yale University, whose extensive research is focused on bacteria that are found in the environment that may cause infection in human beings. He will explain to the Committee that concerns over the potential harm to human health are unwarranted and that U.S. bottled water is indeed safe for human consumption.

We will also hear testimony today from Joseph Doss, President and CEO of the International Bottled Water Association, here to discuss industry efforts to ensure consumers receive a safe and sustainable product. He will discuss how they have addressed contamination, mislabeling and waste stream concerns by going above and beyond the requirements imposed under current law through their Model Code, which applies to the overwhelming majority of bottled water sold in the United States.

I hope this hearing provides clarity to the status of bottled water, which is already comprehensively regulated at the Federal, State, Local and Industry levels in order to ensure its safety and sustainability.

Senator LAUTENBERG. Thank you very much, Senator Inhofe.
Now, Ms. Wu, we will hear from you.

**STATEMENT OF MAE WU, J.D., MPHIL, STAFF ATTORNEY,
NATURAL RESOURCES DEFENSE COUNCIL**

Ms. WU. Good afternoon, Senator Lautenberg and members of the Committee. Thank you for this opportunity to testify on the quality and environmental impacts of bottled water.

I am Mae Wu, a staff attorney in the health and environment program at the Natural Resources Defense Council. My testimony today will highlight a few of the important differences between EPA's and FDA's regulation of tap water and bottled water, and the environmental issues associated with the production and transport of bottled water.

As the members of this Committee are probably aware, bottled water consumption in the United States is growing at a tremendous pace, quadrupling since 1990. Ironically, even though we have one of the best and safest public drinking water systems in the entire world, the U.S. consumes the largest volume of bottled water in the world.

One of the driving forces behind this thirst for bottled water is the belief that it is safer than tap water. Unfortunately, this belief is largely unfounded. The public should not assume that water purchased in a bottle is better regulated, more pure or safer than most tap water.

Tap water and bottled water are regulated separately in the U.S. EPA regulates tap water under the Safe Drinking Water Act, and it establishes health-based standards limiting the amount of certain contaminants that can be present in tap water. EPA requires water utilities to regularly test their water for contaminants and to report the results to the EPA. These results are also available to the public.

FDA regulates bottled water under the Food, Drug and Cosmetics Act. By law, FDA is required to set health standards of quality for bottled water at least as protective as health standards set by EPA. However, FDA has not adopted some of EPA's standards. Two of the most significant for public health are e-coli and DEHP.

EPA requires that no e-coli can be confirmed in any tap water sample. However, while FDA does regulate a broader category of bacteria which includes e-coli, it has no corresponding prohibition on e-coli, as EPA has. A 1993 proposal by FDA to prohibit e-coli in bottled water languished at the agency until 2004 when it was withdrawn altogether from further consideration.

The chemical DEHP is a potent hormone disrupter which interferes with the production of testosterone and is associated with birth defects of the genitals, testicular cancer and poor sperm quality. It has been widely used as a sealant in bottled water and other packaged foods. EPA limits the amount of DEHP in tap water, but FDA does not for bottled water.

In 1996, FDA proposed setting a standard equal to EPA's but has deferred final action on a DEHP standard for the past 12 years. Over that time, the scientific evidence about the potential health risks of DEHP has grown significantly.

There are other important differences besides standards for specific contaminants. FDA's testing and reporting requirements for bottled water are weaker than EPA's, and EPA has many fewer re-

sources dedicated to regulating bottled water than EPA. Perhaps the greatest discrepancy is that the public does not have access to the same information about bottled water that it does about tap water.

EPA requires water utilities to report to customers annually about the quality of their tap water over the past year. But FDA has no such reporting or labeling requirement for bottled water. FDA's minimal oversight over the industry, combined with a lack of publicly available information, makes it much less likely that if a problem exists it will be identified.

Furthermore, FDA's regulations exclude water bottled and sold within the same State, which constitutes a significant amount of bottled water, as well as several types of bottled water, including sparkling water and tonic water. Regulation of these waters is left to the States who are also under serious resource constraints and are under no legal obligation to adopt the FDA standards or any standards at all.

There are also significant environmental issues connected to the production and distribution of bottled water. Consumption of bottled water produces billions of plastic bottles each year, most of which are not recycled. As a result, tens of billions of plastic bottles are sent to landfills that are already overburdened.

In addition, in contrast to tap water, bottled water gets to us on ships and trains and trucks that all use oil and come in bottles made from oil. A Swiss study found that bottled mineral water is responsible for more than 175 times more primary energy consumption, almost 170 times more crude oil use and over 200 times more greenhouse gas emissions than tap water. There is also growing concern that bottling water can produce scarcity problems in certain areas, which is becoming a more common problem in the U.S.

In short, a significant amount of resources are used and pollution and waste is created in the production and distribution of bottled water which could be avoided by a greater use of tap water. In conclusion, NRDC offers the following recommendations. Congress should enact bottled water labeling legislation like what Senator Lautenberg has introduced that ensures the public's right to know about the quality, treatment and source of bottled water. FDA should adopt EPA's health standard for DEHP, prohibit the presence of e-coli and increase monitoring and reporting requirements. To the extent that FDA does not have or does not believe it has authority to undertake these actions, Congress should clarify that it does. Congress should further clarify that all bottled water sold in the United States is federally regulated.

To maintain improved protection for the Nation's drinking water, Congress should increase funding for water infrastructure and establish strong, health-protective standards for contaminants of concern. The long-term solution to drinking water problems is to fix tap water, not to switch to bottled water. Most of the time, plain old tap water is just as good for you as bottled. It costs a lot less and it does not consume as much energy to produce or leave as much waste.

Thank you again for inviting me to testify before you today. I would be happy to answer any questions.

[The prepared statement of Ms. Wu follows:]

TESTIMONY OF
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NATURAL RESOURCES DEFENSE COUNCIL

ON BEHALF OF:
NATURAL RESOURCES DEFENSE COUNCIL

BEFORE THE U.S. SENATE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON TRANSPORTATION SAFETY, INFRASTRUCTURE
SECURITY, AND WATER QUALITY

AT HEARING ENTITLED:
QUALITY AND ENVIRONMENTAL IMPACTS OF BOTTLED WATER

September 10, 2008

Good morning Senator Lautenberg, Senator Vitter, and members of the committee. Thank you for this opportunity to testify on the quality and environmental impacts of bottled water. I am Mae Wu, a staff attorney in the Health Program at the Natural Resources Defense Council (NRDC). I have a law degree from Duke University, a policy degree from the University of Cambridge, and a chemical engineering degree from Rice University. NRDC is a national, nonprofit organization of scientists, lawyers and environmental specialists dedicated to protecting public health and the environment.

NRDC's Health program focuses on toxic chemical pollutants in air, water, food, and shelter, including successful efforts to substantially reduce diesel air emissions from trucks and buses, for example, and to take a number of dangerous and outdated pesticides off the market. There are more than 70,000 chemicals in commerce, but some are much more toxic than others, and we can make great progress in environmental health protection if we focus on the chemicals pollutants that pose the greatest threat to human and ecological health.

NRDC's Health and Environment Program has worked for many years to strengthen health protections and right to know requirements for tap water and bottled water. On the tap water side, we have led the efforts to establish strong health-protective standards for both well-known contaminants, such as arsenic, perchlorate, cryptosporidium and pesticides, and "emerging contaminants" such as pharmaceuticals. We strongly support increased investment in our nation's water infrastructure, under both the Safe Drinking Water Act and Clean Water Act. Our nation's water system, although it faces many problems, is rightly the envy of many countries around the world.

At the same time, NRDC has also worked extensively on issues pertaining to bottled water, emphasizing that that the long-term solution to our drinking water problems is to improve tap water – not to switch to bottled water. This work includes publishing a 1999

report “Bottled Water: Pure Drink or Pure Hype?” which tested more than 103 brands of bottled water. Among other things, our report found that we cannot assume that all bottled water is more pure and safer than most tap water, because although most bottled water appeared to be of good quality, some contained contaminants exceeding regulatory standards. This finding may not be a significant issue for the average person, but it may be extremely serious for vulnerable subpopulations such as people with a weakened immune system, people with health problems, cancer patients, the very young, and the elderly. Our report also found that the federal regulation of bottled water could be improved in ways that would provide better assurance for the quality of bottled water including stronger health standards for some contaminants, requiring more frequent monitoring, better federal oversight, and mandating public disclosure of key information. These recommendations are just as important today.

The issues of whether bottled water is generally safer than tap water, whether consumers are provided sufficient information about the quality of their bottled water, and whether the federal and state resources being expended are sufficient to ensure the safety and quality of bottled water, are just as relevant nearly a decade later, especially so since bottled water consumption has doubled. In addition, over the past few years, awareness and concern has grown over the environmental and health implications of the enormous consumption of bottled water, including the contribution of solid waste to landfills from the bottles, the effect on water scarcity in some source areas, and the large amount of oil expended in the production and transport of bottled water across the country and around the world, including its contribution to greenhouse gas emissions.

We welcome an examination of these issues by this Subcommittee.

My testimony today will highlight some of the important discrepancies between the two separate regulatory systems that govern the nation’s tap water and bottled water. I will also address some of the unique health risks posed by a plasticizer – known as DEHP – that can leach into the water from the bottles themselves, and the environmental issues arising with production and transport of bottled water. Much remains to be done to improve public protection and consumer awareness of the public health issues and environmental impact of bottled water consumption.

Use of Bottled Water Grows Every Year

As the members of this Committee are probably aware, bottled water consumption in this country continues to grow every year. The number of gallons of bottled water sold in the U.S. has more than quadrupled since 1990. The industry now brings in \$15 billion and sells over 8 billion gallons of water annually to Americans. Ironically, despite one of the best and safest public drinking water systems in the entire world, the U.S. consumes the largest volume of bottled water in the world. Conservative estimates show that at least 15 percent of water used for drinking comes from bottled water,¹ and almost a decade ago, 9 percent of children received the majority of their drinking water from bottled water.² According to a 2003 Gallup Poll, three out of four Americans drink bottled water and one out of five drink *only* bottled water.³ Survey after survey, and article after article

highlight one of the driving forces behind Americans' seemingly unquenchable thirst for bottled water as the belief that bottled water is safer than tap water.

Unfortunately, this belief is largely unfounded. No one should assume that water purchased in a bottle is necessarily any better regulated, any more pure, or any safer than most tap water. In fact, tap water is tested for safety more frequently than bottled water because our municipal water systems must meet strict requirements set by the U.S. Environmental Protection Agency (EPA) under the Safe Drinking Water Act (SDWA), whereas bottled water falls under less proscriptive regulations promulgated by the Food and Drug Administration (FDA) under the Food Drug and Cosmetic Act (FDCA). Moreover, while nearly all drinking water systems are covered by EPA standards, only an estimated 40 percent of bottled water products are regulated by the FDA.⁴ And, as it turns out, in many cases – perhaps as much as 25 percent or more – bottled water is nothing more than tap water in a bottle – sometimes further treated, sometimes not.⁵ This is not to say that bottled water is dangerous, although we are concerned that weaker oversight could let problems pass undetected. But there is no reason to assume it is any better for you either.

There are various reasons to use bottled water. In emergencies when tap water supplies are not available – either because of natural disasters such as hurricanes or contamination of tap water, people use bottled water as the only available source of drinking water. Also, aside from health concerns, some people choose to use bottled water because of taste and smell or for convenience. These latter concerns could be addressed at less expense and with less environmental harm by using home filters and convenient stainless steel reusable water bottles to carry tap water. Furthermore, given the environmental impacts of bottling water, as well as the significant expense to consumers, the vast majority of people in the United States who are drinking safe, clean water from their tap should reconsider their choice of voluminous consumption of bottled water.

Bottled Water is Not Necessarily Safer Than Tap Water

Consumers often have the mistaken impression that bottled water is always more pure, although little information is provided upon which they can base their decisions about drinking water. Studies conducted comparing the quality of bottled water to tap water underscore the fact that not all bottled water is as pure as the public may believe. In 1999, NRDC completed a four-year study of over 1,000 bottles of water. Of the bottles we tested, the majority proved to be good quality and relatively free of contaminants. The quality of some brands was spotty, however; 33 percent violated an enforceable state standard or exceeded microbiological-purity guidelines, or both, in at least one sample. Thus, a significant fraction of our bottled water samples from 1999 did pose a possible health risk, primarily for people with weakened immune systems (such as the frail elderly, some infants, transplant and cancer patients, or people with HIV/AIDS). Some of the contaminants that were detected – such as arsenic, nitrate, and trihalomethanes – have been associated with cancer or other illnesses in both laboratory and human population studies. Additional studies have confirmed NRDC's findings. For example, in 2000, a study comparing Cleveland tap water to various brands of bottled water found that some

were more pure, some were less pure and some were the same as tap. Those that were less pure were found to have higher levels of bacteria than the tap water.⁶ Similarly, a simple comparison of Boston tap water to various bottled water brands found that bottled water quality is not necessarily better than tap water quality.⁷

People who assume that the FDA sets additional standards for contaminants in bottled water beyond what EPA sets for tap water are mistaken: if EPA has not set a standard for a contaminant in tap water, FDA has not set one for bottled water. In at least two instances (discussed below) – *E. coli* and DEHP – FDA has done less than EPA. In addition, weaker oversight and limited resources at the federal agency leave the bottled water system vulnerable to potentially undetected contamination.

Federal Regulation Of Tap Water Is More Stringent Than Its Regulation Of Bottled Water

Tap water in the U.S. is regulated by the EPA under the SDWA. Pursuant to the SDWA, EPA has established over 80 health-based standards for contaminants which may be present in drinking water and mandates that levels of those contaminants cannot exceed those standards (called Maximum Contaminant Levels or MCLs). Furthermore, EPA has a list of 25 unregulated contaminants for which many public water systems are required to monitor, which may be considered for future regulation.

By contrast, Congress has delegated limited authority to the FDA under the FDCA to regulate bottled water. The FDCA regulates bottled water as a food and prohibits the introduction of “adulterated” bottled water into interstate commerce, meaning bottled water that is “injurious” to health. The FDCA requires the FDA Secretary to establish “standard of quality” regulations based on the contaminants regulated by EPA that are no less stringent than the EPA tap water standards (or explain why it chose not to adopt those standards). FDA’s failure to adopt health standards set by EPA within the statutory deadline led Congress to amend the FDCA as part of the SDWA Amendments of 1996 so that any new MCLs adopted by EPA would automatically become the FDA standards of quality if the deadlines were not met; however, some of the standards set by EPA prior to 1996 have still not been adopted by FDA. Two of the most significant for public health are *E. coli* and DEHP.

Escherichia coli refers to a category of bacteria with many strains – many of which are harmless, but some of which can be very dangerous or deadly. Depending on the strain, the health effects from exposure to *E. coli* can range from diarrhea, urinary tract infections, respiratory illness, pneumonia, and even death.⁸ In light of these potential effects, EPA mandates that municipal tap water cannot have any confirmed *E. coli* bacteria. The International Bottled Water Association (IBWA) – the trade association representing bottled water manufacturers – has established a model code that also prohibits the presence of *E. coli* in its members’ water.⁹ However, while FDA does regulate coliforms (a broader category of bacteria, which includes *E. coli*) in bottled water, the agency has set no corresponding prohibition on *E. coli* as EPA and IBWA have. Fortunately, the NRDC report found no *E. coli* in its tests. But an outright

prohibition by FDA would better ensure that all bottled water (not just the ones we sampled) are likely free of *E. coli*. An October 1993 proposal by FDA to consider a prohibition on *E. coli* in bottled water languished at the agency until November, 2004 when it was withdrawn altogether from further consideration.¹⁰

One of NRDC's most serious concerns with FDA's current standards for bottled water is the agency's failure to set a standard for the presence of a particular, toxic plasticizer that is used as a gasket for the plastic caps. DEHP (di(2-ethylhexyl) phthalate) is one of the most toxic phthalates – it is a potent endocrine disruptor which interferes with the production of the male hormone, testosterone. In animal studies, DEHP has been associated with a wide range of health outcomes including birth defects of the genitals, testicular cancer, poor sperm quality and abnormal hormone profiles.¹¹ Humans, especially baby boys, who have been exposed to DEHP have similarly been found to have alterations in the development of their genitals.¹² Likewise, adult men with poor sperm quality have been found to have higher levels of DEHP in their bodies.¹³ The State of California has recognized the toxicity of DEHP and has listed it on their Proposition 65 list of chemicals known to cause cancer and cause developmental or reproductive harm. Because bottled water may also be used to reconstitute powdered formula, this FDA inaction raises special concerns about exposures in infants.

The Centers for Disease Control has found the majority of Americans carry residues of DEHP in their bodies.¹⁴ DEHP has also been found in cord blood,¹⁵ amniotic fluid¹⁶ and breast milk.¹⁷ Exposures are especially of concern for children whose reproductive organs are still developing and vulnerable to hormonal disruption from chemicals like phthalates. The National Toxicology Program has expressed concern for the reproductive toxicity of DEHP in young children.¹⁸

In fact, in 2002 FDA, based only on evidence of reproductive harm in animal studies, issued a public health notification advising healthcare providers about reducing exposure to DEHP from medical devices.¹⁹ The notification stated

Exposure to DEHP has produced a range of adverse effects in laboratory animals, but of greatest concern are effects on the development of the male reproductive system and production of normal sperm in young animals. We have not received reports of these adverse events in humans, but there have been no studies to rule them out. However, in view of the available animal data, precautions should be taken to limit the exposure of the developing male to DEHP.²⁰

In light of the human studies that have been published since that notification was released, this precaution has become even more pertinent.

Even without these recent studies to support its decision, but recognizing that DEHP occurs in drinking water and that there are health effects associated with it, in 1992 EPA established a MCL under the SDWA for DEHP in tap water, prohibiting any tap water to have more than 6 parts per billion (ppb) of DEHP.

However, despite all of the concerns with DEHP (including its own), FDA has not set a standard to limit the amount of DEHP that is in bottled water. In 1996, FDA *considered* setting a standard for DEHP in bottled water at the same level as EPA's standard for drinking water.²¹ During that proposal period, some bottlers and members of the plastics manufacturing industry vigorously opposed a phthalate standard, arguing that it would cause some bottled water to be in violation after storage for long periods.²² As one company put it, "bottled water tested immediately after packaging would meet the 6 ppb [FDA proposed] limit but with storage it is possible that levels might exceed this requirement . . . [so] the proposed amendment . . . [would] effectively ban the use of DEHP in closure sealants for bottled water"²³

In fact, in a different set of regulations promulgated over 20 years ago, FDA explicitly *permitted* the use of DEHP in food-packaging material when it migrates into food with high water content.²⁴ Specifically, DEHP is allowed in the gaskets that seal the plastic caps on bottles. FDA itself has noted that this use of DEHP "may result in levels of [DEHP] migrating into water that exceed" the EPA standard.²⁵ Facing the potential conflict between its existing regulations and EPA's health standard, FDA deferred final judgment on whether to issue a standard for DEHP in bottled water, and has yet to act – for the past 12 years.

In light of the extensive scientific evidence that has emerged about the potential health risks posed by DEHP since it last considered this issue in 1996, the FDA should move expeditiously to adopt the EPA tap water standard for bottled water.

Testing and Reporting

FDA's failure to set a standard equivalent to EPA's MCL for DEHP is only one way in which the regulation of bottled water is less thorough than for tap water. The FDA's requirements for testing what is in bottled water (usually referred to as monitoring) and reporting those results to government agencies and the public are also weaker than those for tap water.

For example, the frequency at which bottling companies must monitor their product is less than what public water systems must do. EPA regulations require small public water utilities to monitor for bacteria at least 20 times a month and large utilities to monitor hundreds of times a month. In contrast, FDA requires that bottled water manufacturers test for bacteria only once a week. Similarly, EPA requires public water systems to test for synthetic organic chemicals (like vinyl chloride) four times a year, while FDA only requires bottled water manufacturers to test for them one time a year.²⁶

Furthermore, municipal tap water must be tested by a government-certified lab, while no certification is required for those testing bottled water. FDA relies on bottled water companies to self-test for contaminants, rather than ensure that independent laboratories use approved water quality test methods as EPA does.

Another important difference in testing and reporting concerns public disclosure; FDA does not require that bottled water testing results be submitted to the government or made available to the public. EPA on the other hand requires that municipal water providers publicly report their monitoring results and any violations to EPA or the state (if the state has EPA-approved enforcement authority). Serious violations must be reported within 48 hours. EPA posts all violations on the Web for easy public access. EPA also requires public water systems to keep bacteria testing results for 5 years and chemical tests for 10 years, to allow effective EPA and state inspections.

In contrast, FDA does not require bottlers to notify anyone of test results. Furthermore, FDA requires that test results be retained for only two years. Since FDA inspections occur, at best, every four to five years, many contamination problems may never come to FDA's attention.

FDA does have the ability to initiate court actions to prevent the sale of bottled water that is injurious to health, but the Agency largely relies on voluntary recalls by manufacturers to protect the public from contaminated bottled water. FDA provides unenforceable guidance to help manufacturers establish recall procedures, but has no immediate authority to mandate recalls.²⁷

In 1991, the GAO recognized these problems as major areas where FDA could work to adequately ensure the safety of bottled water.²⁸ The largest problems identified – self-testing by bottlers, lack of reporting requirements, and failure to require laboratories to be certified – meant that FDA could not ensure that tests were actually conducted or that the results are accurate. Now, 17 years after the GAO's report, FDA still has not improved its regulation of bottled water in these areas.

Furthermore, FDA continues to assign a low priority to bottled water. In 1999, NRDC learned that FDA had dedicated just one half of one staff person to bottled water regulation and less than one to ensuring bottled water compliance. Since then, very little has changed at FDA – with estimates around the same amount of staff dedicated to bottle water regulation at the agency.²⁹ The lack of resources dedicated to overseeing the bottled water industry suggests that even if problems exist, it is less likely that such problems would be identified. In stark contrast to FDA, EPA headquarters in Washington, D.C. alone has over 150 FTEs working on drinking water.³⁰

FDA claims that because the public health threat of bottled water contamination is low, there is reason not to devote scarce agency resources to overseeing the industry. While the agency is undoubtedly stretched thin, its failure to conduct adequate oversight prevents the agency from identifying real problems that may exist. In addition, such a significant lack of resources may contribute to not addressing even the most immediate and significant needs for ensuring the safety of bottled water, such as by establishing a standard for DEHP.

Many types of bottled water are not regulated by FDA

FDA regulations have other troubling limitations that pose problems for large scale consumption of bottled water. Specifically, the definition of bottled water excludes large categories of products generally considered by consumers to be bottled water, such as sparkling water, tonic water, soda water, carbonated water, seltzer water, and others.³¹

Also, FDA has interpreted its statutory mandate of regulating only water shipped in “interstate commerce” to exclude a great amount of the bottled water sold in the United States. FDA’s position thereby excludes a significant amount of bottled water sold in the U.S. that is bottled and sold within the same state, constituting *intrastate* commerce as opposed to *interstate* commerce.³²

As a result, regulation of a large amount of bottled water is left to state public health authorities, who also are under serious resource constraints. In addition, states are under no legal obligation to adopt the FDA bottled water standards, and FDA has no formal system to track the adequacy of state regulations, inspection results, enforcement, source-water approvals, or other aspects of state bottled water programs. To the contrary, in 1991, the GAO identified the inadequate regulation of intrastate bottled water as a significant problem in its 1991 report to Congress.³³ NRDC’s 1999 survey of state regulations found that 13 states had no resources, staff or budgetary allotments specifically earmarked to implement the state bottled water programs. In addition, 26 states reported having less than one full time staff equivalent dedicated to running the state’s bottled water program. Some states have weaker regulations than FDA, and in fact, three states (Kansas, Delaware and Indiana) and the District of Columbia have no regulations for intrastate bottled water. These gaps leave the public unprotected from potential problems in bottled water from these areas.

Voluntary standards

IBWA has established a model code for its members.³⁴ While this voluntary industry effort contains some valuable elements including strong protections for contaminants (including *E. coli*) and some good source water protection and monitoring guidelines, they are not an effective substitute for a strong and enforceable federal regulatory program. In addition, voluntary standards only apply to IBWA members – and almost 20 percent of the industry – including giants Coca-Cola and Pepsi, manufacturers of Dasani and Aquafina respectively – are not members.³⁵ Furthermore, these voluntary standards are only applicable to those covered under the narrow definition of bottled water established by FDA. While some states (more than a dozen, according to IBWA) have adopted their standards as binding and enforceable, most states have not done so.

Right to Know

Perhaps the greatest difference between the regulation of bottled water and tap water is the public does not have access to the same information about bottled water that it does about tap water. EPA requires that municipal water utilities produce annual right to know reports – termed “Consumer Confidence Reports” under the Safe Drinking Water Act – to inform the public about their tap water including what types of contaminants

have been found, and at what levels, in the past year. The reports are also intended to help their customers understand the potential health effects associated with the presence of any regulated contaminant found in the tap water. These reports must contain, among other things, information on the source of the water, information about the detection of any regulated contaminant in violation of a maximum contaminant level, and the health concerns associated with that exceedance, and information on the levels of unregulated contaminants for which monitoring is required.³⁶ FDA requires no such reporting or labeling for bottled water.

Given the gaps in the federal regulation of bottled water, and the fact that most people who drink bottled water do so under the mistaken belief that it is more pure and safer than tap water – consumers must have access to information about the actual quality of the water they are drinking. Because consumers should not assume that bottled water is safer than tap water, they should be given the information they need to make smart decisions about the water they choose to drink.

For that reason, NRDC petitioned FDA in 1999 to, among other things, require labels on bottled water that list the following: any contaminants of potential concern found in the water and any health goals or advisories for them, the potential health effects of contaminants found, any violations by the bottler of state or federal rules in the past year, the precise source of the water, any treatment used, whether the water meets the CDC/EPA criteria for *Cryptosporidium* safety, the bottling date, and the FDA website and addresses or phone numbers for further information.³⁷ To date, the Agency still has not established consumer right-to-know standards or set standards for DEHP, thus falling short in two critical areas for public health protection in this industry.

FDA's failure to act is a clarion call for congressional action to ensure the public has full information about bottled water, equivalent to what it is provided for tap water. As such, we believe that legislation along the lines of the right to know bill introduced by Senator Lautenberg in 1999 (S.790) to require bottled water manufacturers to provide annual reports and to label their bottles is needed. Such legislation would be an important step towards ensuring that consumers can make fully informed choices about the water that they drink.

Environmental Impacts of Bottled Water

Even if there were no direct health concerns posed by the consumption of bottled water, there are significant environmental issues posed by the production and distribution of bottled water that point to a wasteful use of our limited, precious resources.

Start with 60 *billion* plastic bottles a year – almost a billion bottles a week, or almost 160 bottles per year for every man, woman and child in America. Almost 90 percent of water bottles are not recycled and the plastic will likely never decompose.³⁸ Food & Water Watch has estimated that PET plastic water bottles create two million tons of trash in U.S. landfills each year.³⁹ Overall, plastics created 30 million tons of municipal solid waste, representing 11.7% of the total in 2006.⁴⁰ That means that every year 45 billion

plastic bottles (which is the equivalent of \$1 billion worth of plastic) are sent to landfills that are already over burdened.

Next, consider that in contrast to tap water, bottled water gets to us on *ships and trains and trucks* that all use oil and comes in *bottles made from oil*. The Earth Policy Institute estimated in 2006 that the manufacture of water bottles for U.S. consumption required more than 10 million barrels of oil annually.⁴¹ And those bottles are increasingly coming from the farthest corners of the earth. Not just France, but Fiji, in the middle of the South Pacific.

In 2005, the Swiss Gas and Water Association commissioned a study to compare the environmental impacts of tap water against those from bottled mineral water. The study found that bottled mineral water is responsible for more than 175 times more primary energy consumption, almost 170 times more crude oil use, and over 200 times more greenhouse gas emissions.⁴² These findings were based on an entire life cycle assessment of the bottled water and tap water – from extraction to serving the water in a glass. The assessment calculated the environmental impacts from water extraction and treatment, bottling (including packaging, distribution, and transportation), and distribution via water pipes). The report considered various metrics to analyze the different variations of water including cumulative primary energy consumption, crude oil equivalent, and greenhouse gas emissions. For every metric, tap water consistently rated lower environmental impacts than bottled mineral water. Relatively speaking, non-refrigerated, non-carbonated bottled water contributes a very large environmental footprint compared to non-refrigerated, non-carbonated tap water.

The results of this study support what is probably common sense for most people who consider the issue: a significant amount of resources is used, and pollution and waste is created, in the production and distribution of bottled water, which could be avoided by a greater use of tap water. Given that tap water in the United States is, by and large, safe; that there is little basis to assume that bottled water is generally safer than tap water; and that the cost of bottled water is vastly greater than that of tap water, consumers should seriously consider whether extensive consumption of bottled water is the best choice.

There is also growing concern that bottling water can produce scarcity problems in certain areas. Water scarcity issues are becoming more common in the U.S. and the extraction of water from some areas for bottled water could exacerbate some of these problems. Anecdotes about the effects of extracting water for bottling on small communities abound – from Mecosta County, Michigan to McCloud, California to Barrington, New Hampshire.⁴³ In addition to these extraction issues, estimates indicate that for every one liter bottle of water, it takes 9 liters of water just to make that bottle, from extraction of the oil to refining to production of the plastic.

Recommendations for Bottled Water

Given the disparity in regulation of tap water and bottled water, and the lack of sufficient information available to the public regarding the contents of bottled water, NRDC offers the following recommendations:

Congress should enact bottled water labeling legislation that ensures the public's right to know about the quality, treatment, and source of bottled water.

FDA should harmonize its regulations with EPA's – particularly including the adoption of EPA's health standard for DEHP, prohibition on the presence of *E. coli*, and increased monitoring and reporting requirements. To the extent that FDA does not have or does not believe it has the authority to undertake these actions, Congress should clarify that it does.

All bottled water sold in the United States should be federally regulated, whether it is carbonated or not. Congress should introduce legislation to make this clear if FDA believes it lack the authority, to ensure that all bottled water sold in the United States is federally regulated.

In addition, Congress may also want to consider whether, given their lack of resources devoted to the issue, jurisdiction over bottled water regulation should be transferred from FDA to EPA.

Recommendations for Tap Water

Congress needs to continue to maintain and improve protection for the nations' drinking water, including increasing funding for water infrastructure under both the Safe Drinking Water and Clean Water Acts; and establishing strong health-protective standards for prevalent and dangerous contaminants including perchlorate and TCE.

Conclusion

The long term solution to drinking water problems is to fix tap water – not to switch to bottled water. There are many holes in the regulation of bottled water, and the public should not assume that water purchased in a bottle is necessarily any better regulated, any more pure, or any safer than most tap water. Some bottled water is not of the highest quality. It is likely that some bottled water is being consumed without having been subjected to proper and adequate quality testing, potentially putting consumers' health at risk. Most of the time, plain old tap water is just as good for you as bottled. It will cost a lot less and it does not consume as much energy or leave as much waste.

Thank you again for inviting me to testify before you today. I would be happy to answer any questions from the panel.

¹ Using the assumption that every person drinks 8 glasses of water a day.

² Flaitz CM, Hill EM, Hicks MJ. A survey of bottled water usage by pediatric dental patients: implications for dental health. *Quintessence Int.* 1989; 20:847-852.

³ U.S. Environmental Protection Agency, "Analysis and Findings of The Gallup Organization's Drinking Water Customer Satisfaction Survey" available at http://www.epa.gov/safewater/ccr/pdfs/tools_survey_gallup_customersatisfaction2003.pdf, last visited 5 September 2008.

⁴ This estimate is based on FDA testimony from 1991. Changes in the bottled water market, including the introduction of Aquafina and Dasani brand waters after 1991, may have affected these percentages. However, based on personal communications with FDA staff, the agency is not tracking the percentage of intrastate bottled water.

⁵ International Bottled Water Association. "Bottled Water Regulations." Available at <http://www.bottledwater.org/public/BWFactsRegHome.htm>, last visited 8 September 2008.

⁶ Lalumandier, JA, Ayers, LW. "Fluoride and Bacterial Content of Bottled Water vs Tap Water." *Arch Fam Med*, vol. 9, March 2000.

⁷ Whittier, J. "The Value of Tap Water: A Comparison of Bottled, Filtered and Tap Water Using the MWRA as a case study." 19 December 2007. available at www.mwra.state.ma.us/01news/2008/WaterPaper.pdf last visited 3 September 2008.

⁸ Centers for Disease Control and Prevention. Division of Foodborne, Bacterial, and Mycotic Diseases (DFMBD). Fact sheet on *Escherichia coli*. Updated March, 2008. available at http://www.cdc.gov/nczved/difbmd/disease_listing/stec_gi.html, last visited 6 September 2008.

⁹ International Bottled Water Association, Bottled Water Code of Practice, available at <http://www.bottledwater.org/public/pdf/2008-code-of-practice.pdf>, last visited 5 September 2008.

¹⁰ 69 Fed. Reg. 68831 at 68837 (November 26, 2004).

¹¹ Parks LG, et al. The plasticizer diethylhexyl phthalate induces malformations by decreasing fetal testosterone synthesis during sexual differentiation in the male rat. *Toxicol Sci.* 2000 Dec;58(2):339-49. Voss C, et al. Lifelong exposure to di-(2-ethylhexyl)-phthalate induces tumors in liver and testes of Sprague-Dawley rats. *Toxicology.* 2005 Jan 31;206(3):359-71.

¹² Swan SH, et al. Decrease in anogenital distance among male infants with prenatal phthalate exposure. *Environ Health Perspect.* 2005 Aug;113(8):1056-61. Erratum in: *Environ Health Perspect.* 2005 Sep;113(9):A583.

¹³ Hauser R, et al., DNA damage in human sperm is related to urinary levels of phthalate monoester and oxidative metabolites. *Hum Reprod.* 2007 Mar;22(3):688-95

¹⁴ Silva MJ, et al., Urinary levels of seven phthalate metabolites in the U.S. population from the National Health and Nutrition Examination Survey (NHANES) 1999-2000. *Environ Health Perspect.* 2004 Mar;112(3):331-8. Erratum in: *Environ Health Perspect.* 2004 Apr;112(5):A270.

¹⁵ Latini G, et al., In utero exposure to di-(2-ethylhexyl)phthalate and duration of human pregnancy. *Environ Health Perspect.* 2003 Nov;111(14):1783-5.

¹⁶ Silva MJ, et al. Detection of phthalate metabolites in human amniotic fluid. *Bull Environ Contam Toxicol.* 2004 Jun;72(6):1226-31

¹⁷ Zhu J, Phillips SP, Feng YL, Yang X. Phthalate esters in human milk: concentration variations over a 6-month postpartum time. *Environ Sci Technol.* 2006 Sep 1;40(17):5276-81. Frederiksen H, Skakkebaek NE, Andersson AM. Metabolism of phthalates in humans. *Mol Nutr Food Res.* 2007 Jul;51(7):899-911.

¹⁸ Kavlock R, et al. NTP-CERHR Expert Panel Update on the Reproductive and Developmental Toxicity of di(2-ethylhexyl) phthalate. *Reprod Toxicol.* 2006 Oct;22(3):291-399. Kavlock R, et al. NTP Center for the Evaluation of Risks to Human Reproduction: phthalates expert panel report on the reproductive and developmental toxicity of di(2-ethylhexyl) phthalate. *Reprod Toxicol.* 2002 Sep-Oct;16(5):529-653.

¹⁹ FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP, July 12, 2002.

<http://www.fda.gov/cdrh/safety/dehp.html>

²⁰ *Ibid.*

²¹ 61 Fed. Reg. 13258 (March 26, 1996).

²² Comments of Grace Container Products, dated May 11, 1995, FDA Docket 93N-0085, Document C11.

²³ *Ibid.*

²⁴ 21 C.F.R. 181.27.

²⁵ 61 Fed. Reg. 13258 (March 26, 1996).

²⁶ Citation

²⁷ U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Industry Affairs Staff Brochure, “FDA Recall Policies” June 2002, available at <<http://vm.cfsan.fda.gov/~lrd/recall2.htm>> last visited 7 September 2008.

²⁸ U.S. Governmental Accountability Office, “FDA Could Do More To Ensure the Safety of Bottled Water.” Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, April 10, 1991, available at <<http://archive.gao.gov/d38t12/143588.pdf>>, last visited 5 September 2008.

²⁹ Personal communication between Henry Kim, FDA and Dylan Atchley, NRDC. 4 September 2008.

³⁰ Personal communication with EPA staff, U.S. EPA on 5 September 2008.

³¹ 21 C.F.R. 165.110(a)(1).

³² However, the bottled water industry, by and large, has a significant effect on interstate commerce and many of the products used in the bottling plants – such as the bottles, the labels, the caps – move through interstate commerce even if the source of the water may be intrastate. Given the prevalence of moving plastic bottles through interstate commerce, most, if not all, bottled water should fall under FDA’s watch.

³³ U.S. Governmental Accountability Office, “FDA Could Do More To Ensure the Safety of Bottled Water.” Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, April 10, 1991, available at <<http://archive.gao.gov/d38t12/143588.pdf>>, last visited 5 September 2008.

³⁴ International Bottled Water Association Bottled Water Report, 2008 Media Kit, <<http://www.bottledwater.org/public/downloads/2008ibwamediaokit.pdf>>, last visited 4 September 2008.

³⁵ <http://www.bottledwater.org/public/whatis_main.htm> last visited 3 September 2008.

³⁶ 42 U.S.C. §300g-3(c)(4).

³⁷ Cite to petition; the studies showing that more chemicals can leach into bottled water over time and after exposure to elevated temperatures underscore the importance of labeling water with bottling dates, as well as information about the proper storage.

³⁸ Container Recycling Institute, available at <<http://www.container-recycling.org/images/plastic/graphs/PETrecsale-units-96-06.gif>>, last visited 8 September 2008.

³⁹ *Take Back the Tap: Why Choosing Tap Water Over Bottled Water is Better for Your Health, Your Pocketbook, and the Environment*, Food & Water Watch, June 2007 (p. 7) <http://www.foodandwaterwatch.org/water/pubs/reports/take-back-the-tap>

⁴⁰ United States Environmental Protection Agency, Municipal Solid Waste (MSW), Plastics, January 29, 2008, available at <<http://www.epa.gov/garbage/plastic.htm>>, last visited 8 September 2008.

⁴¹ Earth Policy Institute, Bottled Water: Pouring Resources Down the Drain (2006), available at <www.earth-policy.org/Updates/2006/Update51.htm> last visited 8 September 2008.

⁴² Jungbluth, N. “Comparison of the Environmental Impact of Drinking Water vs. Bottled Mineral Water.” Prepared for the Swiss Gas and Water Association. 2005. available at <www.fern.org.uk/researchLib/PDFs/bottled%20water%20lca.pdf> last visited 3 September 2008.

⁴³ See generally “Assessing The Environmental Risks of the Water Bottling Industry’s Extraction of Groundwater,” Hearing in the Committee on Government Oversight and Reform, Domestic Policy Subcommittee.

**RESPONSES OF MAE WU,
STAFF ATTORNEY,
NATURAL RESOURCES DEFENSE COUNCIL**

**ON BEHALF OF
THE NATURAL RESOURCES DEFENSE COUNCIL**

**TO QUESTIONS FROM
SENATOR BOXER ON BOTTLED WATER**

October 15, 2008

Question #1

Your testimony says that “perhaps the greatest difference between the regulation of bottled water and tap water” is the lack of public Right-to-Know requirements for bottled water, while tap water utilities are required to send annual Right-to-Know reports disclosing contaminant levels to all of their customers.

Why do you believe that it is important for there to be a mandatory Right-to-Know requirement for bottled water?

Answer to Question #1

With so many Americans drinking bottled water and doing so under the mistaken belief that the water they buy in a store is always safer than tap water, it is important for consumers to be given the right information to make informed choices. More than ten years ago, recognizing that everyone deserves to know when they turn on their taps where the water comes from, whether it meets federal standards, the likely source of any contaminants and their potential health effects, Congress mandated that public water systems provide annual right-to-know reports to their customers. The same principle holds for bottled water; consumers deserve to know whether the quality of the water they are purchasing meets federal standards and is as safe and pure as they assume it is.

Voluntary standards established by groups like the International Bottled Water Association, while commendable, are no substitute for strong, enforceable federal regulations. Although companies following best practices may choose to display the quality of their water, others may not, especially those with the processes most vulnerable to contamination problems. Mandatory disclosure requirements would ensure that every bottle of water is labeled so that consumers will know whether the product they choose to buy is as safe as they assume it is. The requirements for consumers’ right-to-know about the quality of their tap water must extend to consumers’ right-to-know about the quality of bottled water.

Question #2

You mentioned that NRDC's extensive testing showed that bottled water is not necessarily any safer or purer than tap water, and that limited subsequent testing by others confirmed this.

As I understand it, you are not saying that most bottled water has quality problems, but rather that just because you buy water from a store shelf is no guarantee that it is any safer or purer than tap water. Is that right?

Answer to Question #2

That is exactly right. Based on our findings in 1999, our report concluded that "[m]ost bottled water apparently is of good quality, but some contains contamination; it should not automatically be assumed to be purer or safer than most tap water." The less stringent regulation of bottled water compared to tap water leaves gaps that could result in undetected contamination of bottled water. Even if the occurrence of contamination is not high, without mandatory labeling regulations requiring companies to inform customers about those occurrences, customers will not know whether the water they are purchasing is safe or not. Simply put, consumers cannot assume that when they purchase water in a store, that is a guarantee that it will be safer or more pure than tap water.

Question #3

You raised the issue of DEHP, a Phthalate, which is regulated under the Safe Drinking Water Act in tap water, but which the FDA decided not to regulate in bottled water. You mentioned that some in industry strongly opposed regulation of this phthalate in bottled water, admitting that it can leach over time from certain plastic bottle components and could cause violations of a standard if one were established.

Would you please describe your concerns about phthalates in bottled water and whether there are feasible alternatives to phthalates?

Answer to Question #3

We are concerned about the health effects associated with a category of chemicals called phthalates. Phthalates are known hormone disrupting chemicals which interfere with the production of sex hormones such as testosterone or estrogen. If this interference occurs during critical periods of development or function, fertility and reproduction could be affected. Phthalate exposure has been associated with changes in hormone levels, birth defects of male genitals, testicular cancer, and poor semen quality.

In bottled water, we are mostly concerned with one phthalate – DEHP – which has been associated with reproductive harm and is commonly used as a plasticizer in PVC plastic.

Senator LAUTENBERG. Thank you, Ms. Wu.

We now have a different standard than we started with. We are now engaged in a 6-minute standard, and that is made possible by the lack of the presence of others here. So Ms. Hauter, here you go, and you have 6 minutes, not seconds over, but 6 minutes, to present your testimony, and we invite you to do so at this point.

**STATEMENT OF WENONAH HAUTER, EXECUTIVE
DIRECTOR, FOOD AND WATER WATCH**

Ms. HAUTER. Good afternoon, Chairman Lautenberg. Thank you for the opportunity to testify.

My name is Wenonah Hauter. I am Executive Director of Food and Water Watch, a consumer organization in Washington, DC. We are very concerned that consumers have been misled about the benefits of bottled water, because it is a product that is very poorly regulated by the FDA. In fact, the FDA has less than one full-time employee devoted to bottled water oversight. The rules that the FDA has for bottled water apply only to bottled water packaged and sold across State lines, which leaves out about 60 to 70 percent of bottled water that is sold within a single State.

Also, one out of five States do not have bottled water laws, and some State regulations mirror FDA's standards. Some are more stringent and some fall far short of ensuring consumer safety. For the 30 to 40 percent of bottled water that the FDA does regulate, the companies do not have to test the water after bottling or storage. The agency requires that companies test four empty bottles every 3 months for bacterial contamination. They must test a sample of water after filtration and before bottling for bacteria once a week. And when it comes to physical, chemical and radiological contaminants, a sample of water must be checked only once a year. And the FDA does not monitor industry records to make sure that there is compliance.

Meanwhile, tap water is regulated under the Safe Drinking Water Act by the Environmental Protection Agency. EPA requires that water systems serving more than one million people test 300 water samples per month, while utilities serving three million people or more must collect and test 480 samples monthly. Unlike the bottled water industry, that does not have to inform consumers of testing results, utilities are required to make their testing results available to consumers.

Yet, because of the aggressive advertising of the bottled water industry, consumers believe that they are getting a better product when they purchase bottled water. And with the downturn in the economy, many consumers are spending their hard-earned money on a product that is inferior or no better than tap water. A person who buys the equivalent of one gallon of water in 20 ounce bottles will likely pay anywhere from \$8 to \$10 compared to the going rate of almost \$4 a gallon for gasoline.

And it is not just consumers who are paying too high a price for bottled water. So is the environment. Here are just a few of the statistics. More than 26 billion plastic water bottles are sold each year in the U.S. Eighty-six percent of the empty plastic water bottles end up in landfills or are incinerated. More than 17 million barrels of oil, not including fuel for transportation, are used in bot-

tled water production. Producing the bottles themselves creates about 2.5 million tons of carbon dioxide, and it uses, to create a 20 ounce bottle of water uses 60 ounces of water.

Another environmental cost of bottled water is the loss of groundwater. And there are communities all over the Country who are fighting the bottled water industry because of water mining that affects their springs, wetlands, streams and rivers. We think that there should be some kind of reporting of the impact on localities and regions.

Another recommendation is, we believe that every society should offer its citizens safe and affordable water. Unfortunately, we have new generations of young people who have had bottled water and believe that tap water isn't good to drink. We are concerned about the continuing commitment to fund infrastructure in the future for drinking water and for sewage. We would like to see Congress pass a clean water trust fund that would help close the \$22 billion gap for clean infrastructure.

We are also very enthusiastic about the Bottled Water Right to Know Act, and we intend to help work to pass that. We hope that it is a stepping stone to require the bottled water industry to actually label the bottled water product with the source of the water, how and whether it was treated, the presence of regulated and unregulated contaminants. We think that testing results should be public.

Thank you very much.

[The prepared statement of Ms. Hauter follows:]

Testimony of
Wenonah Hauter, Executive Director
Food & Water Watch
Senate Committee on Environment and Public Works
Subcommittee on Transportation Safety,
Infrastructure Security, and Water Quality

Hearing on Quality and Environmental Impacts of Bottled Water

September 10, 2008

Good morning Chairman Lautenberg, Ranking Member Vitter and members of the subcommittee. I'm Wenonah Hauter, executive director of Food & Water Watch, a Washington, D.C.-based non-profit consumer organization that works on food policy and water infrastructure issues.

I welcome this opportunity to testify today about the impact on consumers of bottled water. Unfortunately, consumers have been misled about the benefits of bottled water, a product that is poorly regulated and that has negative environmental consequences. They have bought into the myth created by the beverage industry's marketing magic that water in a plastic bottle is safer and healthier than tap water. A 2003 Gallup survey commissioned by the Environmental Protection Agency (EPA) found that about 74% of the 1,000 survey respondents reported that they purchased and drank bottled water; 20 percent drank bottled water exclusively. Thirty-three percent of respondents cited health and safety concerns. In another poll, 56% cited safety and health as the primary reason they sought out an alternative to tap water.

This industry has grown explosively over the last 20 years since the beverage industry realized its potential. As the former chairman of Perrier was quoted saying, "It struck me...that all you had to do is take the water out of the ground and then sell it for more than the price of wine, milk, or, for that matter, oil." Today Americans spend approximately \$8.8 billion dollars for the 8.3 billion gallons they drink each year.

Unfortunately, consumers have been misled about the benefits of bottled water, a product that is poorly regulated and that has negative environmental consequences. Bottled water is no cleaner or more healthful than tap water. Regulated under the Federal Food, Drug and Cosmetic Act, the Food and Drug Administration (FDA) has less than one full-time employee devoted to bottled water oversight.

The rules apply only to bottled water packaged and sold across state lines, which leaves out the 60 to 70% of water bottled and sold within a single state. In fact, anywhere from 25 percent to 40 percent of all bottled water is nothing more than purified tap water. The FDA regulations also exempt carbonated bottled water. One out of five states do not have bottled water laws. Some state regulations mirror FDA standards, some are more stringent, and some fall far short of ensuring consumer safety.

For the 30 to 40 percent of bottled water that FDA does regulate, the companies do not have to test the water after bottling or storage. The agency requires that companies test

four empty bottles every three months for bacterial contamination. They must test a sample of water after filtration and before bottling for bacteria once a week. When it comes to chemical, physical, and radiological contaminants, a sample of water must be checked only once a year.

Meanwhile, tap water is regulated under the Safe Drinking Water Act by the Environmental Protection Agency. EPA requires that water systems serving more than one million residents test 300 water samples per month, while utilities serving three million people or more must collect and test 480 samples monthly. Unlike the bottled water industry, which does not have to inform consumers of testing results, utilities are required to make their testing results available to consumers. All water utilities are required to prepare an Annual Water Quality Report, also called the Consumer Confidence report. This report provides information about any contaminant violations in the water system. Also, EPA posts many of these results on its web site.

Yet, because of the aggressive advertising of the bottled water industry, consumers believe they are getting a better product when they purchase bottled water. Unfortunately, with the downturn in the economy, many consumers are spending their hard earned money on a product that is inferior or no better than their tap water. This means they have fewer dollars to spend on food and the other necessities of life. A person who buys the equivalent of one gallon of water in 20-ounce bottles likely will pay anywhere from \$8 to \$10, compared to the going rate of nearly \$4 for a gallon of gas. The price of gas is taking a toll on consumers' pocketbooks, but when it comes to the cost of bottled water, they're getting soaked.

It is not only consumers who are paying too high a price for bottled water. For example, Nestle, with its introduction of a lighter bottle, claims to be a steward of the Earth. But are Nestle and other bottled water companies really green? People in the United States dispose of some 30 billion empty plastic water bottles annually. Extrapolating from Nestle's control of about 32 percent of the U.S. bottled water market, we can determine that approximately 9 billion of those empty bottles come from Nestle. That amounts to about 13 billion pounds of plastic waste each year.

And after the production of billions of plastic bottles for multiple bottled water companies and the national and international travel of bottled water, billions of empty bottles remain. About 86% of the empty plastic water bottles in the United States land in the garbage instead of being recycled. That amounts to about two million tons of PET plastic bottles piling up in U.S. landfills each year. Single serve water bottles and other beverage containers, often used on the go, are recycled at a lower rate than containers typically used at home.

The bottled water industry's environmental and economic cost, including a huge carbon footprint and toxic emissions from plastic production, are externalized onto society:

- More than 25 billion plastic water bottles are sold each year in the United States.
- More than 17 million barrels of oil (not including fuel for transportation) were used in plastic bottle production.
- Bottling water produced more than 2.5 million tons of carbon dioxide.
- Approximately 60 ounces of water are required to fill a 20-ounce bottle.

- The total amount of energy used to produce, transport, refrigerate and dispose of a plastic bottle of water may be as high as the equivalent of filling a 33-ounce bottle one-quarter full of oil.

Another environmental cost of bottled water is the loss of groundwater when bottlers enter communities to mine water. When the flows and levels of a region's springs, wetlands, lakes, streams and rivers are materially affected from extraction for bottling, the entire local and even regional environment suffers, and this extends to the activities that depend on the water –agriculture, individuals, businesses, tourism and recreation. No one knows how much water is being mined for bottled water because there is no universal requirement for bottled water companies.

Many communities across the country develop water management plans that take into account such issues as population and climate, including drought. The people and businesses living and operating there have to live within the rules set forth in those plans, but bottling companies too often get a nearly free pass, even though they are permanently removing water from a rural community's aquifer.

McCloud, California, provides a good example. Nestle planned to build a bottling plant and extract about 500 million gallons of the town's water annually. Concerned citizens learned that the proposed contract, which Nestle now wants to renegotiate, between the McCloud water provider and the transnational beverage giant would give the company preference over the town's ratepayers because the company could draw the maximum amount of water it wants, regardless of drought or water shortage. What is more, the local water district would bear all the responsibility for the wellbeing of the springs and the water infrastructure. The plan would have had Nestle paying only \$300,000 a year for access to the water and leave the town with only a PENNY for every 17 gallons. In the face of citizen and political opposition, Nestle has backed off its original plan.

The extraction of any community's water for sale has the potential to create a crisis. The people and businesses in a watershed have the right to use it reasonably for drinking, growing food and other activities in the community. Over the long term, as communities enter into contracts with companies that extract water, it could become difficult for states and local governments to regulate water removal.

The recently passed Great Lakes Compact agreement among the eight states of the Great Lakes Basin exemplifies the difficulty of preventing the removal of water. The agreement lays out takings guidelines from major water supplies in that area for use by large-scale projects and private enterprise. Yet many of the exceptions outlined in the Compact are bad for consumers and the environment. Unless some of the loopholes are closed, the bottled water industry could gain access to Great Lakes community water.

Without adequate money, communities are lured into 50- or 100-year contracts that seem lucrative in terms of what the bottler will pay. But studies have shown that the companies are not really covering the various costs to the community or what happens when the water is gone. The jobs created by these bottling plants are seasonal, low paying and often go to people outside of the community. The constant roar of trucks leaving and entering the bottling plant has an impact on the quality of life of these communities and

on the transportation infrastructure. Most rural roads have not been designed for extremely heavy 18-wheelers.

Recommendations

One of the most important services a society can provide its citizens is safe and affordable water. But as the nation's population grows and its infrastructure ages, our public water systems are facing some grim realities. Even though tap water is safe today, if the infrastructure is not repaired for both drinking and sewage water, we could see many problems in the future. We also need to address emerging problems like pharmaceuticals and other contaminants in water. We need to restore the American people's faith in our drinking water by funding the gap for water infrastructure—approximately \$22 billion a year. Congress should pass and the president should sign into law a clean trust fund that would provide a solid, consistent stream of money to the states for improving our drinking water and waste water infrastructure, including rural water systems. Renewed investment in public water infrastructure through dedicated funding, like a federal trust fund, would ensure that communities have the financial resources necessary to keep their pipes upgraded, their water safe and their natural resources in their community. As we at Food & Water Watch stated in our report water, *Clear Waters: Why America Needs a Clean Water Trust Fund*, it also would create more long-term, sustainable jobs; for example, one billion dollars invested creates about 47,500 jobs.

We recommend that Congress require labels on all bottled water that include:

- The source of the water,
- How and whether it was treated,
- The presence of regulated and unregulated contaminants and
- Information about the high environmental and economic cost of bottled water.

In the interim, we support passage of Senate Bill 790, which amends the Federal Food, Drug, and Cosmetic Act to require manufacturers of bottled water to submit annual reports about contamination. The bottled water industry should be held to the same standard that our water utilities must meet in terms of testing and reporting. Citizens have a right to know about the bottled water that they are purchasing.

But just as importantly, we believe that there must be some regulation or standard, preferably at state and local levels, addressing how much water bottling companies can extract from states. At the federal level, we need to provide federal funding to the United States Geologic Service to map water resources and to keep this information updated. Today this is only done piecemeal because of a lack of resources.

Thank you for your attention. I would be happy to respond to any questions.

October 21, 2008

Food & Water Watch
1616 P Street, N.W., Suite 300
Washington, D.C. 20036

Heather Majors
Senate Committee on Environment and Public Works
410 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Ms. Majors:

Attached are my answers to the follow up questions from my September 10, 2008 testimony.

I thank the Committee for the opportunity to testify and for inviting me to answer these questions.

Sincerely,

Wenonah Hauter
Executive Director
Food & Water Watch

**Answers to Follow-Up Questions
Environment and Public Works Committee Hearing
September 10, 2008**

Question #1

In your opinion, what are the most serious environmental problems with the bottled water industry here in the United States?

Answer:

Bottled water harms the environment in a variety of ways, ranging from pollution to climate change to ecosystems left parched because of water extraction for bottling.

Annual U.S. plastic bottle production requires more than 17 million barrels of oil, enough to fuel one million vehicles on our roads each year. But what happens when all that energy is used, is burned? It creates pollution. In fact, bottling water produces more than 2.5 million tons of climate-changing carbon dioxide gas annually. However, those figures on energy use and CO₂ emissions apply to just the bottling.

The energy used to pump, process, transport and refrigerate bottled water amounts to 50 million barrels of oil, enough to run 3 million cars for a year. That ends up emitting an additional 9.75 million tons of carbon dioxide gas into the atmosphere.

But that's not the end of the story. A domino effect can ensue. The climate change caused by bottled water production and distribution in turn can affect groundwater in communities across the country. In 2005, the journal *Nature* published a study showing how climate change could diminish water sources dependent on melting snow. With warmer periods, earlier snowmelt could mean "much of the winter runoff will immediately be lost to the oceans." The answer is to address climate change, protect our source water from pollution AND address the removal of water, be it groundwater or municipal, from communities.

Unfortunately, the bad environmental news doesn't stop there. About 86 percent of the empty plastic water bottles in the United States land in the garbage instead of being recycled. That amounts to about two million tons of PET plastic bottles piling up in U.S. landfills each year. Ultimately, many plastic bottles of all types and sizes will be incinerated, which releases toxic byproducts such as chlorine gas and ash laden with heavy metals.

Mining water also directly harms ecosystems. Removing too much groundwater can reduce the level and raise the temperature of water in an ecosystem's lakes, streams and rivers, which can damage fish and plant populations. This includes harm to breeding grounds for native fish.

In addition, excessive water extraction can raise the salinity of an area's surface water enough to affect its ability to support the organisms and species living there. According to an article in *The Journal of Land Use*, "If a spring is overpumped, there is a potential for a great reduction in the habitat of plants and animals in the area surrounding the spring. Kurt Cuffey, assistant professor of geology at the University of California-Berkeley, explained that 'tapping springs and aquifers even on a small scale can alter the movement of sediment in nearby streams, which can in turn disrupt the food supply for fish and other wildlife.'"

Question #2

You noted the lack of public Right-to-Know requirements for bottled water, and urged that bottled water disclose certain information about the source of the water, the presence of contaminants in it, and how it was treated, among other information.

Why do you believe that it is important for there to be a mandatory Right-to-Know requirement for bottled water?

Answer:

First of all, bottled water falls under FDA oversight of food products. And the agency's mission statement reads, in part, that it is "...responsible for protecting the public health by assuring the safety, efficacy, and security of our nation's food supply..." We believe that public health and safety can be assured only if consumers know exactly what they are consuming.

After all, the public has a right to know about the tap water it consumes. EPA requires public drinking water utilities to disclose contaminant levels in municipal drinking water. We believe it is only right, just and fair for water bottling companies to label their products with contaminants the water contains and the source.

We also believe that companies should inform consumers about the environmental "health" implications – the carbon or eco footprint – of producing and distributing bottled water, just as cigarette makers are required to label their products with information about the health implications of smoking.

Question #3

What are the short- and long-term potential implications, including for communities, jobs, and agriculture, of large industries going into the arid West and other locations

around the country where water scarcity is or may become a problem, and setting up bottled water facilities that withdraw large amounts of water?

Answer:

As we mentioned earlier, extracting water for bottling can decrease the flow and level a region's springs, wetlands, lakes, streams and rivers. That in turn can affect a variety of activities, including agriculture.

For example, many farmers increasingly are trying to improve their soil's water absorbency and health. But they still have to have water to grow food that local and regional residents depend on. Unfortunately, their job is made harder when a corporation removes the area's groundwater for bottling. Farmers and everyone else are left with less water.

A 2007 report by the non-profit Ground Water Protection Council, pointed out that, although much is not known about exactly how groundwater moves through geological formations, it "typically moves very slowly" and is recharged by rain or other surface water very slowly. Mining the water can alter the "pattern and speed of natural flows."

Indeed, agriculture and other businesses and activities have been subject to laws governing the management of water in streams, lakes and rivers. Groundwater, however, long had a distinct hydrological and legal classification. But that is now changing with increased mining of water for bottling.

The Journal of Land Use found numerous issues with removing groundwater from an area.

Allowing for millions of gallons of water from a community or region to be bottled "conflicts with the establishment of local water resource protection plans put in place to conserve local water resources. Many areas developed water resource plans in response to increasing populations, decreasing municipal water resources, and several years of drought conditions. As a result, it is illegal for local residents to use water at certain times for specified activities, such as lawn irrigation. However, pumping gallons of water away to factories to be bottled and sold across the country directly conflicts with the goals of these programs."

Extracting too much water from an aquifer can reduce its levels to such a degree that nearby water sources and wells cannot be replenished. This could include drinking water for a town or city.

The article goes on to say that some proponents of bottled water have said that extracting water for local use is no different than bottling it. But that's not quite true. In many cases, irrigation and agriculture actually return much water to the aquifer, "while the removal of water for bottling simply acts to reduce the aquifer's supply without replenishing it for use in the future."

What is more, allowing bottling companies to mine away too much groundwater can actually reduce the water table. That can lead to water wells drying up and requiring new, deeper wells and, of course, more energy to draw up the water. In short, regional drinking water suppliers, farmlands and wetlands feel the consequences of excessive water removal.

McCloud, California and its fight to keep Nestlé from mining the area's groundwater provides an example of some these problems.

An independent report evaluating Nestlé's proposed bottling plant found that its removal of water "would reduce the availability of water for competing uses—municipal, industrial, agricultural, and environmental—over the period of 50 to 100 years."

-end-

Senator LAUTENBERG. Thank you very much.
 And now we will hear from Dr. Edberg. Thank you, Ms. Hauter,
 you beat the time clock.
 [Laughter.]
 Senator LAUTENBERG. That is not a requirement, but noteworthy.
 Thank you.

STATEMENT OF STEPHEN C. EDBERG, PHD., A.B.M.M., PROFESSOR, LABORATORY MEDICINE, INTERNAL MEDICINE, CHEMICAL ENGINEERING, YALE UNIVERSITY SCHOOL OF MEDICINE, AND DIRECTOR, CLINICAL MICROBIOLOGY LABORATORY, YALE-NEW HAVEN HOSPITAL

Mr. EDBERG. Thank you very much for inviting me. It is a distinct honor to be here.

This year I won the lifetime achievement award in medical microbiology and the title of my talk was From PF70: the Bronx to Yale. Now I can say I have testified in front of Senator Frank Lautenberg. I have many relatives in New Jersey and we know you as a person of great respect.

I am here representing Yale University School of Medicine. I have been involved in drinking water research for approximately 25 years. I have been a consultant to virtually every drinking water organization there is, including the Groundwater Association, the World Health Organization, American Water Works Association, EPA and IBWA.

I have at least 75 papers and peer-reviewed journals concerning health issues related to drinking water. It turns out that actually I invented this standard drinking water test used throughout the world and in 45 of the 50 States for bacteria, which are total coliforms and e-coli. That has been the standard throughout the world since 1992.

So that is what I am bringing to the table today.

The purpose of my talk, which is outlined, is to basically review the essential differences between tap water and bottled water from an objective point of view. Quite simply, bottled water is a sealed food product. Once you put the water in the bottle and you seal it, that is it, nothing else happens. It may seem fairly obvious, but it is essential to actually compare that with municipal water.

One of the reasons is, municipal water has a terrific challenge. Municipal water, first of all, can't choose its own source and has to deal with where it is. As a result, all sorts of different treatment parameters have to take effect or have to be used. The major difference is, of course, that in bottled water, it is sealed, that is it, nothing else happens. Tap water has to pass through a distribution system. I think it is fair to say that the EPA and many of the public health people now view the distribution system as injecting potential great variability into the process.

The average American city loses 18 to 44 percent of its drinking water actually through leaks in the pipes. And leaks are going both ways, the leaks go in and the leaks out. As a result, there can be intrusion of soil and often drinking water pipes are in the same trench as sewage pipes. So it is a great challenge. I would like to echo what Commissioner Lloyd said. I think that certainly I would very strongly support, as probably one of the major public health

agendas in this Country, financing for particularly distribution system upgrades and maintenance. I think that is absolutely essential.

As I mentioned, bottled water is a sealed food product. One of the other differences is, bottled water is actually highly regulated, meaning there are a lot of regulations that apply to bottled water. Now, because it is a very low-risk item, there is not a lot of individuals at FDA necessarily spending their time on it. The regulations of bottled water by FDA, I think it should be clear, mirror that of EPA. We have already heard that. In fact, there is a hammer provisions. If EPA passes a new regulation, FDA has a certain period of time to apply that to bottled water, otherwise it automatically applies to bottled water.

Now, some things that are regulated in municipal water don't apply to bottled water, things related to distribution system or storage, for example. But if they apply, FDA has to do it. It is as regulated as EPA is.

The third major differences are treatment parameters. Basically, bottled water gets to choose its sources. Regardless of whether it is municipal water, as you mentioned, or protected aquifers or what have you, virtually or if I am not mistaken all bottles then undergo further treatment. There is a principle in engineering, and I originally had an engineering background, called the multiple barrier concept. What that means is that there are barriers established horizontally along the treatment train. Filtration is one such barrier. Ozonation is a barrier. Reverse osmosis is a barrier.

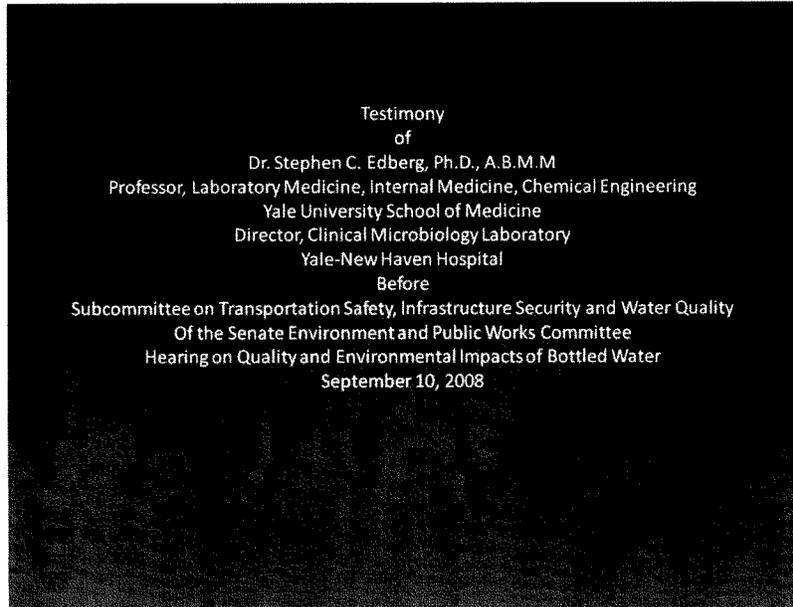
So bottled water companies have the ability to choose and mix what they need for that particular water source. Municipal water can do the same. But certainly bottled water adds additional multiple barriers to the process.

Essentially, from the medical point of view, and the CDC agrees with this, it is on their website, in a bottle of water, you can call the company up and find out what is in it. There is almost invariably an 800 number, and you should be able to do that. If you can't, I wouldn't use that bottled water. It is free choice. Municipal water, again, goes through a distribution system, and that individual glass can or can't have something in it. Municipal water, as you heard, is actually tested fairly infrequently, for a million people, 300 tests a month or so is, considering the size, not that much. New Haven has a square mile of about 30 by 20, and we are only mandated to perform 400 water tests a month.

So in summary, I don't want to go over, there are differences. It is to me, as the CDC says, an individual choice of whether you want to pay or not pay for a product which you can call up and identify. It is that simple to me.

So I would be happy to take any questions, and you have my e-mail address.

[The prepared statement of Mr. Edberg follows:]



Dr. Stephen C. Edberg is a professor in the Department of Laboratory Medicine and Internal Medicine at the Yale University School of Medicine, and the director of the Clinical Microbiology Laboratory at Yale-New Haven Hospital. He has received the following degrees: B.A. Lehigh University, Bethlehem, Pennsylvania, 1967, Major in Biology, Minor in Chemical Engineering; M.A. Hofstra University, Hempstead, New York, 1968, Major in Bacteriology, Minor in Chemistry; Masters thesis entitled: "The Effect of Calcium and Strontium on the Heat Resistance of *Bacillus subtilis* and *Bacillus megaterium*"; Ph.D. State University of New York at Buffalo Medical School, 1971, Department of Microbiology and Immunology, Dissertation entitled: "The Valency of IgM and IgG Antidextran Antibody"; Post-doctoral, University of Washington, Seattle, Washington, 1972, Medical Microbiology under Dr. J. Sherris and Dr. F. Schoenkecht; M.A. (Honorary), Yale University, New Haven, Connecticut, 1989.

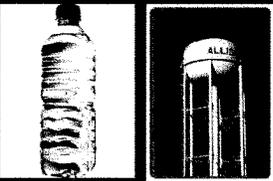
Among Dr. Edberg's research activities that have found their way into usage in clinical microbiology laboratories are constitutive enzyme testing for rapid identification of gram-negative species, the refinement of immunoglobulin coating of latex particles for the direct detection of antigens, and the use of hydrolysable substrates to directly identify bacterial and mycotic isolates within one hour. His most significant contribution to global well-being was his development of the "Colilert" test for the detection and enumeration of *Escherichia coli* in drinking water.

Dr. Edberg has received the Becton Dickenson (BD) Award for Research in Clinical Microbiology. This award, which has been supported by BD Diagnostic Systems for 30 years, recognizes a distinguished scientist for research accomplishments that form the foundation for important application in clinical microbiology.

Americans Need to Drink More Water....

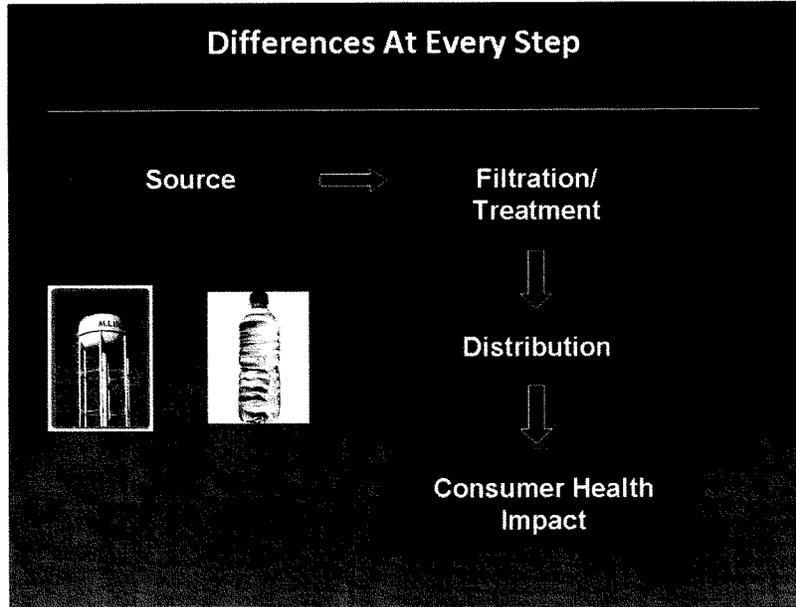
What Are The Differences?

- *Tap/Municipal*
- *Bottled*



There are fundamental differences between bottled water and water from a municipal water system and the regulatory framework that governs them. These regulatory frameworks are properly tailored to the particular production of drinking water. In the case of bottled water, it is regulated by FDA as a food product, similar to other beverages. The production, labeling, standards of quality and standards of identity are all prescribed in FDA regulations. As a food product, the bottled water quality requirements apply to each container. Violations of the regulations, including standards of quality, can lead to product recalls and FDA enforcement action.

Municipal water systems are regulated by the Environmental Protection Agency, which has promulgated regulations that prescribe the production and quality of the drinking water that they produce. There are substantial differences between bottled water and municipal water systems in compliance with the quality standards. For example, municipal water systems may average the monthly tests for disinfection by-products. Thus, public drinking water may exceed the maximum contaminant level (MCL) in some months, but be substantially lower in other months and not be in violation. If there are violations for exceeding the MCL, the water continues to flow, but corrective action and public notice are required. This is appropriate because much of the water produced by municipal water systems is not consumed by humans and is vital to the economic health of the communities they serve.



There are substantive differences from sources to treatment to distribution and most importantly to consumer health. Although there are a number of differences, consumers in the United States have access to the best drinking water in the world.

Water Sources

- **Municipal Sources**
 - 75% of U.S. population served by surface waters
 - Limited choice of source

- **Bottled Sources**
 - Approx. two-thirds groundwater and one-third municipal
 - Springs protected by law
 - Springs selected based on sustainability, quality, flow and taste
 - Purified water can be municipal/tap or wells

Municipal Water Sources

Approximately 75% of the population is serviced by municipal water systems that have surface water as their source. Surface water is subject to run-off and other pollution intrusion into the water source that are not as abundant, difficult to manage or present in groundwater sources. Micro-organisms, such as *Cryptosporidium*, *Legionella*, *Giardia*, and viruses can be present in surface water, but are not present in groundwater. In addition, municipal water systems are limited by their geography on potential water sources that can be used.

Bottled Water Sources

Two thirds of bottled water sources are groundwater and one third is purchased from municipal water systems. If a source becomes contaminated or the aquifer becomes stressed during a drought period, bottled water companies can locate new sources or purchase bulk water from another company. Spring sources are selected on the basis of quality, sustainability, flow, stability and taste, which is a function of the composition of the water source. By law, springs must continue to flow naturally to the surface in order for the bottled water product to be labeled as spring water.

Filtration & Treatment Processes

▫ Municipal/Tap

Less specialized, most common treatment involves sand filtration and chemical treatments including chlorine as disinfectant to provide safety for large volumes of water

▫ Bottled Spring, Artesian and Mineral

Highly specialized processes typically include filtration, microfiltration, ultraviolet light, low concentrations of ozone.

▫ Bottled Purified

Same treatments as spring, plus reverse osmosis or distillation, Meets US Pharmacopeia Standard R23.

The primary differences in the filtration and treatment processes between municipal water systems and bottled water are related to scale. Municipal water systems must be designed to produce large quantities of water every day to satisfy the demand on their systems. They commonly use sand filtration and chemical treatment, including chlorine, to disinfect water, both in the treatment plant and through the distribution system.

Bottled water production is done on a much smaller scale and as a result can be more specialized. The average bottled water plant produces less than 100,000 gallons per day. The common multi-barrier approach employed in most bottling facilities is source protection, filtration, microfiltration, ultraviolet light and low dose ozonation in a closed environment. For purified or sterile water, the additional treatment of reverse osmosis or distillation or de-ionization or de-mineralization is used to meet the U.S. Pharmacopeia 23rd revision standards. Although many purified bottled waters use a municipal water system as the source, the finished bottled water produced is a very different composition than the source. There is not one municipal water system in this country that meets the standard USP standard for purified water.

Distribution to Consumer

- Municipal/Tap
 - One of the best systems in the world
 - Low cost
 - Delivery through pipes
 - Susceptible to lead contamination
 - City water loss between 18% and 44% of water from leaking pipes
 - Pressure changes can cause environmental intrusion
 - Open system is vulnerable to environmental contamination

The United States has one of the best drinking water production and distribution systems in the world that delivers quality water at a low cost to citizens of communities throughout the country. However, one stark difference between municipal water systems and bottled water is the distribution system. Municipal water is distributed through miles of pipe, some of which is centuries old. These pipes are susceptible to leaking and municipal water systems lose between 18% and 44% of the water they produce through these pipes.

Drinking water pipes are often buried near waste water pipes, which are also susceptible to leaking. Because of pressure changes within the drinking water system, the drinking water pipes are vulnerable to intrusion from the surrounding environment. This has been shown in a study by Mark W. Lechevallier that highlights the risk to the distribution systems because of pressure changes and environmental intrusion. Thus, drinking water may be fully compliant when it leaves the municipal water treatment plant, but can be subject to change as it travels through the distribution systems. The water delivered to the tap may contain contaminants that entered through the distribution system. Such vulnerability places consumers at a much greater health risk than from the production process of drinking water. The infrastructure of our municipal water systems needs to be improved to help ensure the reduction of health risks to the citizens of communities around the country.

Distribution to Consumer

- Bottled Spring & Purified
 - Bottle hygienically seals in the quality
 - Each bottle is coded to ensure tracking for quality assurance and safety – recallable

Bottled water is distributed in sealed containers that are made of materials approved by FDA for food contact. During the bottling process, the containers are sanitized, filled and immediately sealed with FDA approved closures. The containers help ensure that there is no contamination and quality is not compromised after production.

As a food product, there is the added benefit of being able to tracking products to permit them to be recalled because of the coding required of all food products. If a container of bottled water is found to exceed the Standards of Quality that FDA has established, the lot (production run) of products can be tested. If it is found to be out of compliance, it can be removed from the market place. This safeguard minimizes the health risk to consumers. Depending upon the circumstances, the recall notice can go to consumers notifying them that a particular lot is a health risk and should not be consumed. We have seen such notices on a variety of food products.

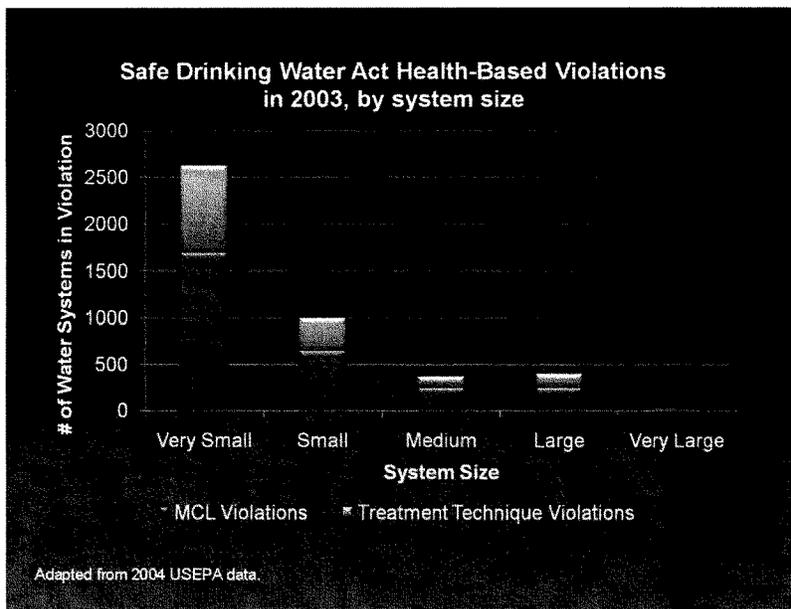
Consumer Health Impact

- EPA researchers estimate 16.4 million cases of acute gastro-intestinal illness in 2006 associated with tap water contamination *
- CDC has associated bottled water with less than 10 incidents resulting in possible cases of illness in the past 35 years

*Messner, et al., J Water Health. 2006 ;4 Suppl 2 :201-40 16895092

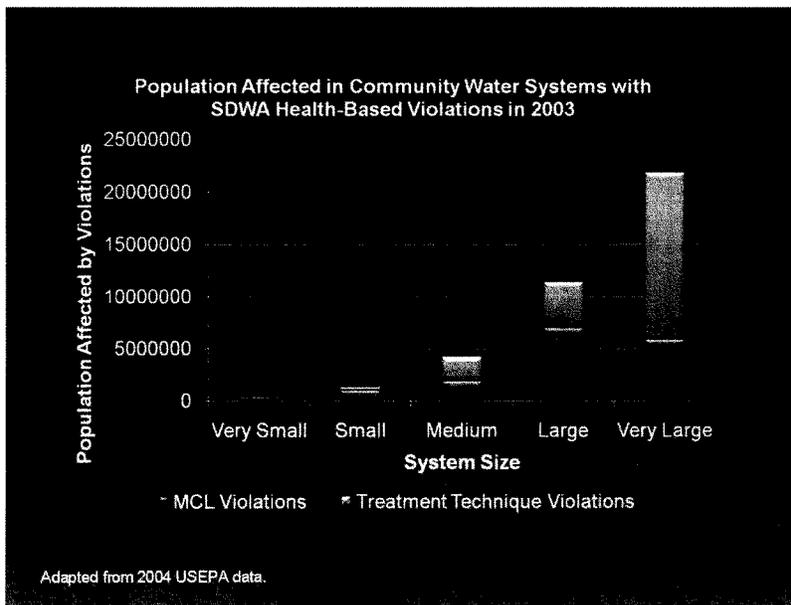
As stated earlier, the healthiest means of hydration is the consumption of water and public policy should encourage consumers to choose water to drink. However, there are differences in the health impact between bottled water and water from a municipal water system. There were an estimated 16.4 million cases of acute gastro-intestinal illnesses in 2006 associated with tap water. On the other hand, there have been less than 10 incidents resulting in possible illness from the consumption of bottled water in the past 35 years.

This difference is primarily related to the issues of source, treatment and distribution between municipal water systems and bottled water.



The challenges faced by small municipal water systems are substantial, particularly in lowering of MCL's. The expense incurred to meet those standards often exceeds the financial resources of the system. However, it is important to understand the assumptions used in establishing MCL's by the EPA. They assume a consumption of two liters per day over a 70 year life span.

Also, it is important to note that under Section 410 of the Food, Drug, and Cosmetic Act, FDA is required to review all EPA National Primary Drinking Water Standards for their applicability to bottled water and to regulate bottled water as stringently and as protective of public health as public drinking water. Some bottled water recalls are related to exceeding the FDA Standards of Quality, which are applied to each container.



As you saw in the previous chart, small systems have a numerically higher number of MCL violations, than larger systems, but the populations affected by larger systems' violations is far greater.

Consumer Health Impact

- Bottled water has absolute standards – no averaging of contaminant levels
- FDA recalls and enforcement actions for bottled water, 1998 - 2008*
Approx. one per year over the past decade

*<http://www.fda.gov/oc/ohrt/water.html>

As I indicated earlier, exceeding the FDA Standard of Quality for bottled water subjects the product to recall or FDA enforcement action. The FDA Standards are an absolute standard that is applied to each container. Bottled water companies are not granted waivers or allowed to average, as municipal water systems are permitted to do. For example, FDA and EPA have established standards for disinfection by-products. Most bottled water companies use ozone as a disinfection and some municipal water systems are also using it. When ozone interacts with bromide (a naturally occurring compound in water), it converts it to bromate. The FDA Standard of Quality and the EPA MCL for bromate is 10 ppb. If a bottled water container has more than 10 ppb, it is violation of FDA regulations and subject to recall and enforcement action by FDA. If a public water system has a 25 ppb level for two months, the municipal water system has not exceeded the MCL, so long as the 12 month average is below 10 ppb. Thus, the consumers of that public water system can be consuming much higher levels of bromate than if they were drinking bottled water.

The true public policy question should be: "How do we encourage more people to drink more water?" With obesity and diabetes a true public health concern, drinking more water can be very beneficial to a healthier diet. Water, whether from a municipal water system or in a bottle, is one of the best options for people to meet their hydration needs. If people would drink more water, their health will be improved, particularly if they reduce the number of calories consumed and exercise. People have available to them some of the best drinking water in the world, even with the challenges the municipal water systems and bottled water face to improve the quality.

I would be glad to answer any questions from the Committee. My email address is:
Stephen.Edberg@yale.edu.

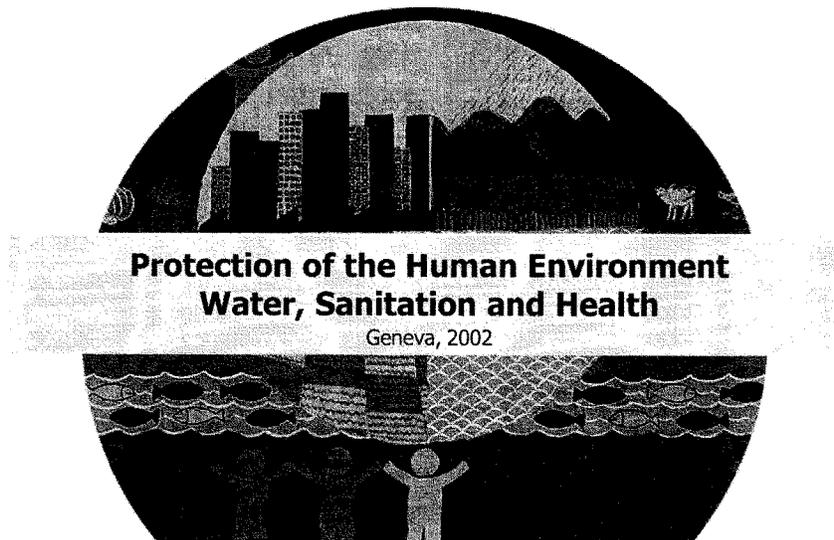


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Heterotrophic Plate Count Measurement in Drinking Water Safety Management

Geneva 24-25 April 2002



**Protection of the Human Environment
Water, Sanitation and Health**

Geneva, 2002

**HETEROTROPHIC PLATE COUNT MEASUREMENT
IN DRINKING WATER SAFETY MANAGEMENT**

Report of an Expert Meeting
Geneva, 24-25 April 2002

Water, Sanitation and Health
Department of Protection of the Human Environment
World Health Organization
Geneva

Heterotrophic Plate Count Measurement in Drinking Water Safety Management

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TABLE OF CONTENTS

| | Page |
|--|-------------|
| Background | 1 |
| Introduction..... | 1 |
| Agenda to the meeting..... | 1 |
| Conclusion of Meeting | 1 |
| 1. Definitions and Scope | 1 |
| 2. Applications in piped water supplies | 3 |
| 3. Applications/uses in non-piped and other water supplies | 4 |
| 4. Health aspects | 5 |
| 5. Outstanding questions and Research..... | 6 |
| 6. Bibliography | 7 |
| ANNEXES | |
| Annex 1 List of participants | 8 |
| Annex 2 Agenda | 13 |

The Role of HPC Measurement in Drinking Water Quality Management

Background

A group of microbiology and public health experts including regulatory and medical expertise was convened in Geneva, Switzerland, 25-26 April 2002 to consider the utility of Heterotrophic Plate Count (HPC) measurements in addressing drinking water quality and safety. The group was convened following the NSF International/World Health Organization Symposium on HPC Bacteria in Drinking Water Public Health Implications?.

The meeting was attended by 31 participants from Australia, Canada, France, Germany, Italy, Japan, the Netherlands, South Africa, Switzerland, UK and USA (see Annex 1).

Introduction

Dr Jamie Bartram opened the meeting and thanked Health Canada, Centers for Disease Control and Prevention, US Environmental Protection Agency and American Water Works Association Research Foundation for providing financial support. Dr Martin Exner was elected Chairman and Drs Joseph Cotruvo and Axel Glasmacher as joint Rapporteurs.

This report provides an assessment of the public health significance of "heterotrophic plate count" (HPC) measurements in drinking-water quality management, based on a review of presently available information and experience by an international group of experts. It deals with evidence concerning:

- The relationship of HPC to health risk for the general public.
- The role of HPC as an indirect indicator or index for pathogens of concern in drinking-water.
- The role of HPC in assessing the efficacy and proper functioning of water treatment and supply processes.
- The relationship of HPC to aesthetic acceptability of drinking water.

The scope of the report deals with safe water supply, extending from source to consumer, including plumbed-in devices, domestic and building environments, and water supplied in bottles or packages. The different uses for which drinking water may be used in the home are considered and specific concerns in higher risk settings and populations at increased risk are addressed.

Agenda to the meeting

The agenda of the meeting is included in Annex 2.

Conclusion of Meeting

1. Definitions and Scope

1.1 Drinking water

WHO considers that 'drinking water' should be 'suitable for human consumption and for all usual domestic purposes including personal hygiene'. Diverse regulatory agencies adopt similar definitions. Drinking water should therefore be suitable for consumption, washing/showering and domestic food preparation. In human health terms, exposure to water and its constituents can occur through ingestion, contact and aerosol inhalation.

Drinking waters should be safe for lifetime use, taking account of differing sensitivities that occur across life stages, but all are not necessarily suitable for individuals suffering from certain specific immune compromising disorders.

Piped drinking water supplies typically involve source abstraction, treatment and distribution. The latter may include ancillary devices at domestic or institutional levels such as softeners, activated

carbon treatment, vending machines, dispensers etc. Drinking waters also include those obtained from non-piped sources such as springs and community wells, in bottles and as ice.

The control of faecal contamination in drinking water systems and sources where it occurs, is of primary importance. Faecal- specific indicator bacteria such as *E. coli* are the parameters of first importance in monitoring faecal pollution.

1.2 Heterotrophic plate count

Heterotrophs are broadly defined as microorganisms that require organic carbon for growth. They include bacteria, yeasts and moulds. A variety of simple culture-based tests which are intended to recover a wide range of microorganisms from water are collectively referred to as "heterotrophic plate count" or "HPC test" procedures. Accordingly, the terms "heterotroph" and "HPC" are not synonymous.

There is no universal 'HPC measurement'. Although standardized methods have been formalised, HPC test methods involve a wide variety of test conditions that lead to a wide range of quantitative and qualitative results. Temperatures employed range from around 20° to 40° C, incubation times from a few hours to 7 days or a few weeks, and nutrient conditions from low to high. The test itself does not specify the organisms that are detected.

Only a small proportion of the metabolically active microorganisms present in a water sample may grow and be detected under any given set of HPC test conditions, and the population recovered will differ significantly according to the method used. The actual organisms recovered in HPC testing can also vary widely between locations, seasons and between consecutive samples at a single location.

Microorganisms recovered through HPC tests generally include those that are part of the natural (typically non-hazardous) microbiota of water; in some instances they may also include organisms derived from diverse pollutant sources.

1.3 Microbial growth in water

Microorganisms will normally grow in water, and on surfaces in contact with water as biofilms. Growth following drinking water treatment is normally referred to as 'regrowth'. Growth is typically reflected in higher HPC values measured in water samples. Elevated HPC levels occur especially in stagnant parts of piped distribution systems, in domestic plumbing, in bottled water and in plumbed-in devices such as softeners, carbon filters, and vending machines. The principal determinants of regrowth are temperature, availability of nutrients, and lack of residual disinfectant. Nutrients may derive from the water body and/or materials in contact with water.

1.4 Use of HPC in water management

HPC testing has a long history of use in water microbiology. At the end of the 19th century HPC tests were employed as indicators of the proper functioning of processes (and of sand filtration in particular) and thereby as indirect indicators of water safety. Use as a safety indicator declined with the adoption of specific faecal indicator bacteria during the 20th century.

HPC measurements nevertheless continue to figure in water regulations or guidelines in many countries. HPC measurements are used:

- to indicate the effectiveness of water treatment processes, thus as an indirect indication of pathogen removal;
- as a measure of numbers of regrowth organisms that may or may not have sanitary significance; and
- as a measure of possible interference with coliform measurements in lactose-based culture methods. This application is of declining value as lactose-based culture media are being replaced by alternative methods that are lactose-free.

2. Applications in piped water supplies

2.1 Water Safety Plans

There is an increasing trend toward application of a comprehensive 'Water Safety Plan' (WSP) approach to drinking water supply safety management. This approach is applicable throughout the water supply from catchment to consumer.

It has been proposed that WSP approach be included in the next edition of the WHO Guidelines for Drinking-water Quality and that this would entail five components:

1. Water quality targets based upon public health protection and disease prevention.
2. System assessment to determine whether the water supply chain (up to the point of consumption) as a whole can deliver water of a quality that meets the defined targets.
3. Monitoring of the steps in the supply chain which are of particular importance in securing safe drinking water.
4. Management plans documenting the system assessment and monitoring; and describing action to be undertaken from normal conditions to extreme events, including documentation and communication.
5. Systematic independent surveillance that verifies that the above are operating properly.

Piped water systems of large buildings may incur greater growth than encountered elsewhere (because of storage tanks and extensive internal distribution networks, and temperature-related growth). The principal health concerns in these networks are cross connections, and growth of *Legionella* bacteria, that are not detected by the HPC test procedures. General water safety is assured by maintenance protocols, regular cleaning, temperature management and maintenance of a disinfectant residual. For these reasons authorities responsible for building safety should provide advice and require specific water management safety plans.

2.2 Water quality targets

There is no evidence that HPC values alone directly relate to health risk either from epidemiological studies or from correlation with occurrence of waterborne pathogens. They are therefore unsuitable for public health target setting, or as sole justification for issuing "boil water" advisories. Abrupt increases in HPC levels might sometimes concurrently be associated with faecal contamination; tests for *E.coli* or other faecal-specific indicators and other information are essential for determining whether a health risk exists.

2.3 Validation and verification

Experience suggests that HPC monitoring can be used in drinking water supplies along with other information for validation and verification of treatment process performance and other applications. These may include:

- Monitoring of performance of filtration or disinfection processes.
- In piped distribution systems HPC measurements are assumed to respond primarily to (and therefore provide a general indication of) distribution system conditions. These arise from stagnation, loss of residual disinfectant, high levels of Assimilable Organic Carbon (AOC) in the water, higher water temperature, and availability of particular nutrients. In systems treated by chloramination or that contain ammonia in source waters, measurement of a variety of parameters including HPC, but especially nitrate and nitrite (which are regulated for health protection), can sometimes indicate the possible onset of nitrification.
- HPC values are also used in verification (and by some authorities also for validation) of efficacy of cleaning in diverse applications including drink vending machines, food processing and

preparation facilities and medical devices. These applications of HPC have not been considered in this review.

2.4 *Aesthetic quality*

Drinking water must be aesthetically acceptable as well as safe. Aesthetic acceptability is directly relevant to health since rejection of safe, but unacceptable (undesirable) water, may lead users to consume acceptable but potentially unsafe alternative waters. HPC testing may be used in investigating aesthetic quality and it is used by some authorities as a marker for some of the underlying causes of some aesthetic problems.

3. *Applications/ uses in non-piped and other water supplies*

3.1 *Bottled water*

Bottled ("packaged") water is considered drinking water under some regulatory schemes and as a food in others. Some authorities distinguish natural mineral water from other bottled waters. WHO *Guidelines for Drinking-water Quality* are referred to directly in international norms (Codex Alimentarius Commission) and are considered applicable to bottled waters.

Bottled waters represent a specific growth situation for microbial flora. Bottled waters may derive from 'pristine' sources ('natural mineral water') or from processed waters. They may contain or have added carbon dioxide that will restrict regrowth potential, but typically no long-lasting disinfectant residual is present. The finished product will often be exposed to elevated (room) temperatures over a period of days to weeks before consumption.

Microorganisms naturally occurring in water are a normal part of the microbiota of bottled waters that meet appropriate safety norms. Levels of HPC recovered from bottled water post-distribution may therefore sometimes be significantly higher than those found in municipal water supplies in distribution.

Microbial safety for bottled waters is best pursued by a Water Safety Plan approach (as summarized in Section 2.1). *Pseudomonas aeruginosa* and HPC counts are used by some as process management indicators in bottled water production and not as health risk indicators.

3.2 *Plumbed-in Devices*

Bacterial growth occurs in plumbed-in domestic water devices (including water softeners, carbon filters etc.) and plumbed-in commercial devices such as beverage vending machines. HPC values in water samples typically increase in such devices. Increases of HPC (due to growth) in these devices therefore do not indicate the existence of a health risk, so long as the entry water meets acceptable water microbial quality norms (e.g. WHO *Guidelines for Drinking-water Quality*). Appropriate maintenance of these devices is required for aesthetic reasons (see section 2.4) e.g. per manufacturers' recommendations. Plumbed-in devices in health care facilities are considered in section 4.

3.3 *Conveyances*

Water systems on conveyances such as ships and aircraft present specific challenges to water safety management. These include both physical characteristics (extensive complex piping in confined space, physical movement) as well as organisational issues, such as multiple responsible parties in different locations and at different stages of delivery.

In general, the potential roles for HPC in water safety management in conveyances are similar to those elsewhere (see Section 2.1). HPC measurements alone are unsuitable for use in independent surveillance by, for example, Port Health Authorities where series results are unavailable; faecal indicator bacteria measurements are essential in this role. This issue is dealt with in the WHO *Guide*

to *Ship Sanitation and Guide to Hygiene and Sanitation in Aviation*, which are presently in revision.

When drinking water is stored in tanks in conveyances microbial growth invariably occurs. If HPC testing is conducted, the counts measured will often exceed those normally found in piped distribution systems. Obtaining a high count by the HPC test may indicate the need to examine procedures for taking on water, maintenance of the system and disinfection.

3.4 Other water exposure media

Swimming pools and spas are outside the topic of this report. They are dealt with in *WHO Guidelines for Safe Recreational Water Environments*. The role of HPC in humidifiers and air cooling is also outside the scope of this report.

4. Health Aspects

4.1 Exposure

Exposure to general HPC microbiota is far greater through foodstuffs than through drinking water. Levels of exposure regarded as acceptable from foods are much greater than those regarded as acceptable from drinking water. Limited data are available with which to characterise exposure to specific microorganisms through these two routes. Exposure to HPC microbiota also occurs through air and other environmental sources.

4.2 Epidemiology

Some epidemiological studies have been conducted into the relationship between HPC exposures from drinking water and human health effects. Other studies relevant to this issue include case studies, especially in clinical situations and compromised animal challenge studies using heterotrophic bacteria obtained from drinking water distribution systems. The available body of evidence supports the conclusion that, in the absence of faecal contamination, there is no direct relationship between HPC values in ingested water and human health effects in the population at large. This conclusion is also supported indirectly by evidence from exposures to HPC in foodstuffs where there is no evidence for a health effects link in the absence of pathogen contamination.

There is a small number of studies that have examined possible links between HPC and non-intestinal outcomes in general populations. The conclusions of these studies do not support a relationship.

4.3 Health Effects - Specific organisms

Information on the association of specific HPC microbiota with health effects may be derived from epidemiological studies, including outbreak investigations, or from risk assessments.

Bacteria typically described as "opportunistic pathogens" that may be recovered amongst HPC microbiota include strains of *Pseudomonas aeruginosa*, *Acinetobacter* spp., *Aeromonas* spp., *Klebsiella pneumoniae* etc. There is no evidence of association of any of these with gastro-intestinal infection through the water-borne route among the general population.

There are opportunistic pathogens which may regrow in water but which are not detected in HPC measurements including strains of *Legionella* and non-tuberculous Mycobacteria. The public health significance of inhalation exposure to some legionellae has been demonstrated.

There is no evidence that HPC levels *per se*, as measured by established procedures, have a direct relationship to the likely presence of, or act as indices for the numbers or presence of regrowth organisms such as legionellae, *P. aeruginosa* and non-tuberculous mycobacteria.

4.4 Populations at increased risk (including sensitivity through life stages)

Specific strains of microbial species that may be a part of HPC microbiota can cause infection in certain vulnerable people (e.g. the immunocompromised and those with in-dwelling urinary catheters, intravenous catheters, continuous ambulatory peritoneal dialysis, etc.). Most infections due to these organisms are from non-water sources (endogenous microbiota, cross-infection from other persons in health care wards or the general environment). However, there have been a number of outbreaks reported where the investigations may implicate the water supply. The implication for infections of immunocompromised patients in the general community is unclear.

There are increasing numbers of persons who are immunocompromised to various degrees and types living in communities, including some patients discharged to 'home care'. Normal "drinking water" is not always suitable for all such individuals for all uses (e.g. wound irrigation). This relates to water safety in general and not to growth of HPC organisms in particular. Advice should be provided by public health authorities to at-risk groups in general and by practitioners responsible for individuals discharged to home care.

Where the drinking water supply meets international norms such as WHO Guidelines for Drinking-water Quality, only those people with severe changes from normal as determined by their physicians or medical agencies (e.g. an absolute neutrophil count < 500/ μ l) are considered immunosuppressed to the extent that they may require specially processed drinking water.

4.5 Health Care Facilities

Health care facilities include hospitals, health centres, dialysis facilities and dental facilities. These facilities represent a general area of concern for infection control because of the potentially increased susceptibility of the associated population, and their risk of infection from organisms growing in their environment.

Health care facilities should have general water safety plans as part of their infection control strategy. Such plans may be generic (e.g. applicable to health centres in general) or specific when applied to a larger built environment (e.g. many hospitals and nursing homes). Such plans should address microbial growth in addition to control of external contamination by *Pseudomonas aeruginosa*, and *Legionella*, and should include ancillary equipment such as shower heads, and medical devices such as dialysis units and dental water dispensing equipment that involve patient contact.

5. Outstanding Questions and Research

The state of the evidence indicates that any further research on HPC in general should focus on its use for process management and control applications as described in section 2, and is not a high priority for public health protection.

Because of ongoing interest, further research in this area is likely to occur. It may usefully focus on: specific heterotrophic organisms of potential concern for human health, along with developments of future molecular techniques that may provide additional public health information;

- the immunocompromised (especially infection control in healthcare facilities and susceptible persons in the public at large);
- non ingestion exposures (including aerosol exposure and hypersensitivity reactions), and roles of amoebae in biofilms;
- *Pseudomonas aeruginosa* bacteria which are common in the environment and occasionally are found in drinking water - they are sometimes associated with wound and other infections in high-risk populations;
- additional research on conditions and routes of exposure, control methods (when appropriate);
- susceptible populations of relevance to exposure from drinking water would be appropriate.

The potential role of heterotrophic bacteria in preventing or reducing colonisation of water system components by organisms of human health concern also merits further research.

6. *Bibliography*

WHO Guidelines for Drinking Water Quality (Vols. 1, 2, Microbiology addendum) Fewtrell and Bartram, Water Guidelines, Standards and Health Water Safety Plan Report.

WHO Guidelines for Safe Recreational Waters

Volume 1 – Coastal and Fresh Waters

Volume 2 –Swimming Pools, Spas and Similar Recreational Water Environments

WHO Guide to Ship Sanitation.

WHO Guide to Hygiene and Sanitation on Aircraft.

General Standard for Bottled/Packaged Drinking Water (other than Natural Mineral Water).

Standard Methods for the Analysis of Drinking Water and Wastewater- APHA, AWWA, WEF.

The Microbiology of Drinking Water (2002) – Part 1-Water Quality and Public Health (Standing Committee of Analysts, Environment Agency, (London).

The Microbiology of Drinking Water (2002)- Part 7- Methods for the enumeration of heterotrophic bacteria by pour and spread plate techniques (Standing Committee of Analysts, Environment Agency, (London).

International Standard ISO 6222:1999. Geneva: International Organization for Standardization.

EU 98-83-EG Quality of Water for Human Consumption (3 November 1998 (ABLEG no. 330).

Guidelines for Disinfection and Sanitation of Water Treatment Equipment, 3rd Edition, 2000, Publ. No.E2, The Water Quality Association, Lisle, Illinois 60532-1088, USA www.wqa.org.

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Agenda

1. Definitions and Scope
2. Applications in piped water supplies
3. Applications/ uses in non-piped and other water supplies
4. Health aspects
5. Outstanding questions and research

Annex 1 – Participants

Annex 2 – Meeting Agenda

Senator LAUTENBERG. Thank you very much.

Mr. Doss, you are in quite a position here, representing the industry. I want to say, before your testimony, the purpose of this hearing is not intended to criticize or vilify bottled water. That is a choice people make. We hope they make it with some forethought, but knowledge is important in this case. That is what we are looking for. We welcome your testimony.

**STATEMENT OF JOSEPH K. DOSS, PRESIDENT AND CEO,
INTERNATIONAL BOTTLED WATER ASSOCIATION**

Mr. DOSS. Thank you, Mr. Chairman. Good afternoon, Chairman Lautenberg. My name is Joe Doss. I am President and CEO of the International Bottled Water Association. I appreciate this opportunity to discuss the quality and environmental impact of bottled water.

Bottled water, whether in retail size packages or in the larger containers used in home and office water coolers, is a safe, healthy, convenient beverage product. It is comprehensively regulated as a packaged food product at both the Federal and State level. At the Federal level, bottled water must meet FDA's general food and beverage regulations in addition to standards of identity, standard of quality, good manufacturing practices and labeling requirements specifically promulgated for bottled water.

In 1996, Congress enacted legislation that requires FDA bottled water regulations to be as protective of public health as the EPA standards for public drinking water systems, which we have heard a couple of the witnesses refer to previously.

Contrary to the statements made earlier, it is also important to note that the courts have held that FDA's jurisdiction over foods and beverages, which includes bottled water, extends not only to those products that move in interState commerce, but to those products sold within a single State if they use 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 and every food product sold in the United States. In fact, FDA amended the law in 1997 that provides a presumption that all foods move in interState commerce.

IBWA supports a consumer's right to clear, accurate and comprehensive information about the bottled water products they purchase. All packaged food and beverages, including bottled water, are subject to extensive FDA labeling regulations 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.

IBWA believes that the most feasible mechanism for consumers to obtain information not already on the label is through a request to the bottler. In addition, consumers can go to the IBWA website to access contact information or water quality information for all IBWA member brands.

Consumers have many options when deciding which bottled water brand to drink. If a bottled water company does not provide the information that a consumer requests, he or she can choose another brand. And that is the fundamental issue: consumer choice.

Unfortunately, many people want to make this a bottled water versus tap water issue. But we just don't see it that way. If people are drinking water, whether it is tap water or whether it is bottled water, that is a good thing and consumers should be free to make that choice. In fact, 75 percent of consumers who drink bottled water also choose to drink tap water.

Furthermore, IBWA agrees with the others on this panel and supports investments to improve the U.S. public drinking water system in order to maintain the highest quality water quality for all citizens. The bottled water industry strongly supports comprehensive environmental conservation and stewardship policies. Bottled water companies have been taking actions to reduce their environmental footprint. For example, the bottled water industry is using much lighter weight plastics for its containers, utilizing more fuel-efficient means of transportation, and developing new technologies and product packaging, such as the use of recycled content.

All bottled water containers are 100 percent recyclable. While the recycling rate for beverages, including bottled water, is better than other foods and consumer products, we know that more needs to be done, and we have taken steps in that direction. IBWA supports comprehensive curbside recycling programs and is working with the National Recycling Partnership to increase consumer awareness about the importance of recycling and to find new and innovative ways to increase recycling rates.

While the bottled water industry supports effective environmental conservation policies, we strongly believe that any efforts to reduce the environmental impact of packaging must focus on all consumer goods and not just target any one industry. Because bottled water containers make up just one-third of 1 percent of the entire waste stream in the United States, any proposed solutions must cover all consumer goods or they will be ineffective in dealing with the environmental issue.

Throughout the years, bottled water companies have immediately responded to the need for clean, safe drinking water after natural disasters such as Hurricane Katrina and the earthquakes and forest fires in the west, and in other emergency situations, such as terrorist attacks at the Pentagon and World Trade Center. Most recently, our companies provided bottled water to those in need after the spring flooding in the Midwest and in just the past few weeks, to the victims of Hurricanes Gustav and Hanna. With Hurricane Ike fast approaching the Texas coast, our members have already begun preparations to provide bottled water if needed.

Bottled water is always there when it is needed; however, the bottled water industry cannot exist only for disaster response. Bottled water companies in the United States are primarily family owned and operated small businesses that depend on a viable commercial market to provide the resources necessary to respond in emergency situations. Over 60 percent of IBWA members have annual gross sales of less than \$1 million. And 90 percent have annual gross sales of less than \$10 million.

In summary, bottled water is a safe, healthy, convenient food and beverage product. The bottled water industry, while a very small part of the overall waste stream, is working hard to reduce its envi-

ronmental footprint. With the increase in diabetes, obesity and heart disease rates in the United States, any actions that would discourage consumers from drinking this safe, healthy beverage are not in the public interest.

Thank you for considering our views. IBWA stands ready to assist the Subcommittee as it considers this very important issue.

[The prepared statement of Mr. Doss follows:]

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

Chairman Lautenberg, Ranking Member Vitter, 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 present this testimony on the quality of bottled water and the environmental impacts of bottled water.

Overview of the Bottled Water Industry

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 packaged beverage product that consumers find refreshing and use to stay hydrated. In many instances, consumers choose bottled water because it does not have the calories, caffeine, or other ingredients that they may wish to eliminate or moderate in their diets. And with the rise in obesity and diabetes in the United States, any actions that discourage the consumption of bottled water are not in the public 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 U.S. is sourced domestically. Only 2.1% of the total volume is comprised of imported bottled water. According to the Beverage Marketing Corporation, in 2007, the total volume of bottled water consumed in the United States was 8.8 billion gallons, a 6.9% increase over the 2006 volume level. That translates into an average of 29.3 gallons per person, which means U.S. residents now drink more bottled water annually than any other beverage except carbonated soft drinks (CSDs). Sales revenues for the United States bottled water market in 2007 were approximately \$11.7 billion (in wholesale dollars), a 7.8% increase over the previous year. Although bottled water is currently the second most consumed

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, unannounced plant inspection by an independent third party to determine compliance with the Code of Practice and all applicable FDA regulations.

beverage in the United States, the consumption volume is about half that of carbonated soft drinks (CSDs) and only slightly ahead of milk and beer.

Based on this data, it is apparent that consumers are choosing bottled water in greater and greater numbers. The U.S. bottled water market is truly a consumer driven market, in which consumers are making healthier choices in the beverage category. The strength of consumer self-generated demand is illustrated by the relatively modest amount spent on bottled water advertising. The 2006 bottled water advertising expenses totaled only \$52 million.² For comparison purposes, \$637 million was spent on advertising for carbonated soft drinks (over ten times that for bottled water) and advertising expenses for beer totaled \$1 billion (approximately 20 times that for bottled water).

Bottled Water Industry Profile

The bottled water industry can be divided into two primary business models. The first model is the 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 liter), generally through 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 types of bottled water 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 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 waters are either groundwater or water from municipal water systems.

Bottlers of natural waters have extensive investments in developing groundwater sources and have been on the forefront of advocating for states to enact groundwater management programs to provide sustainability of the 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. This process is also similar, if the bottling source is a public water system, with the exception of the added processing steps that are employed to meet the purified or sterile standard of the U.S. Pharmacopeia 23rd Revision, i.e. distillation, reverse osmosis, or de-ionization.

² Beverage Marketing Corp.

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.

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 by the FDA 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). It must meet FDA's general food regulations as well as standards of identity, standards of quality, good manufacturing practices and labeling requirements specifically promulgated for bottled water.

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 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 the same as other beverages such as soft drinks, teas, and juices, which also have water as their primary ingredient.

FDA regulations define 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 optionally contain safe and suitable antimicrobial agents.” Fluoride may be optionally added within the limitations established in § 165.110(b)(4)(ii).⁴ As a result, bottled water is subject to the general Good Manufacturing Practices (GMP) and labeling regulations for all food products,⁵ as well as the specific bottled water GMPs in 21 CFR 129, and the FDA-established Standards of Quality and Identity in 21 CFR Part 165. Bottled water is one of only a few food products that must follow additional, product-specific GMPs in addition to the general food GMPs, as well as product-specific Standards of Quality and 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

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

⁴ 21 C.F.R. § 165.110 (a)

⁵ 21 C.F.R. § 110.3 *et seq.*

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. 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 FFDCA.⁶ By law, FDA's standards of identity regulations pre-empt state laws that are different from the FDA regulations.⁷ If a bottled water product's source is a municipal water system and it 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.⁸

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

Bottled Water 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 finished bottled water products. FDA has established standards for more than 90 substances pursuant to the Standard of Quality for bottled water. As FDA explained in its final rule amending the Standard of Quality for arsenic, the standard 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.⁹

Most FDA bottled water quality standards are the same as EPA's maximum contaminant levels (MCL) for public water systems. In fact, by law, unless FDA determines that controlling for a particular contaminant is not applicable to bottled water (because, for example, the contaminant is not found in bottled water sources), FDA's Standard of Quality for any given contaminant must be as stringent and as protective of the public health as the corresponding EPA regulation for tap water. The few differences are usually the result of the substance not being found in

⁶ 21 U.S.C. § 343(g)(1).

⁷ 21 U.S.C. § 343-1(a)(1)

⁸ 21 C.F.R. § 165.110 (b)(3)

⁹ Beverages: Bottled Water, 70 Fed. Reg. § 33694, 33699- 33700 (2005).

bottled water or the substance is regulated under FDA food additives program.¹⁰ 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).

(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.)

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.

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.¹¹ Key elements include:

- a) 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.
- b) 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.
- c) 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 a 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

¹⁰FDA 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).

¹¹ Federal Food, Drug, and Cosmetic Act § 410, 21 U.S.C. § 349 (2005).

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.

Three examples of how Section 410 has operated follow:

- a) FDA establishes a standard of quality regulation. FDA promulgated a regulation establishing a standard of quality for arsenic of 10 ppb on June 9, 2005,¹² 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, 2006.¹³
- b) FDA takes no action. Following EPA’s issuance of MCL’s and monitoring requirements for nine contaminants (antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and 2,3,7,8-TCDD (dioxin), FDA did not amend its Standard of Quality regulations before the statutory deadline.¹⁴ 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.¹⁵ This is the only occasion where FDA has not acted within the statutory timeframe.
- c) 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, 2001,¹⁶ that it would not apply to bottled water, because 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.

If pathogenic microorganisms are present in bottled water and potentially injurious to public health, FDA has authority to classify the product as adulterated¹⁷ and subject it to enforcement action, such as seizure of the product.¹⁸ This would apply to such microorganisms as *Cryptosporidium*, *Legionella*, *Giardia*, and other micro-organisms and viruses 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,¹⁹ or from municipal water systems that are already compliant with EPA’s Surface Water Treatment Rule.²⁰

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

¹² Beverages: Bottled Water, 70 Fed. Reg. § 33694 (2005)

¹³ National Primary Drinking Water Regulations: Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. § 6976 (2001)

¹⁴ 63 Fed. Reg. § 25764

¹⁵ Bottled Water: Monitoring Requirements, 63 Fed. Reg. § 42199 (1998).

¹⁶ Beverages: Bottled Water, 66 Fed. Reg. § 35439 (2001).

¹⁷ 21 U.S.C. § 342.

¹⁸ 21 U.S.C. § 334.

¹⁹ 21 C.F.R. 165.110 (a)(2)(ii)

²⁰ National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule, 71 Fed. Reg. § 653 (2006).

test results, or exemptions to the standards. Since the bottled water standards of quality apply to each container of bottled water, anyone is able to have an analysis done on bottled water and determine if it meets those standards. This is very different from public water systems, where you cannot take a sample from your faucet and have it analyzed to determine compliance with the public drinking water standards. 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 most contaminants over a 12 month period to determine compliance and are often granted waivers.

Monitoring Regulatory Differences Between Bottled Water and Drinking Water

Bottled water is frequently tested throughout its production. To get an accurate picture and comparison of the frequency of testing between bottled water and municipal 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 exemptions 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 municipal 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, endothall, 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 municipal 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 municipal water system ground water sources and for bottled water ground water sources. But, once again, there is a difference in 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.

Enforcement and Inspections

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 _____”).²¹ 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

²¹ 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.²²

- 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.

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 to 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 unannounced, independent third party inspection as a condition of membership. IBWA members are inspected for compliance with the IBWA Code of Practice, which include 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. These third party inspection companies cannot participate in IBWA committees or policy development.

FDA Jurisdiction

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.²³ 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

²² 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).

²³ 21 U.S.C. § 331(k).

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.”²⁴

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.²⁵ 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 FFDCA 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.”

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 FDA’s conclusion that placing all this information on the product label is not feasible for many reasons including limited space

²⁴ 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 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).

²⁵ 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.’”).

available.²⁶ IBWA believes the most feasible mechanism for consumers to obtain this information is through a request to the bottler or distributor.

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.
- 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 counsel 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

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 Standard of Identity, ingredient labeling, name and place of business of the manufacturer, packer or distributor 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.

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. . Bottled water has gone further than any other food or beverage product—including those beverages whose primary ingredient is water-- by voluntarily providing consumers with easy access to information about their products.

²⁶ 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.

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 21%. 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 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 we should see preliminary results before Thanksgiving. 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 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. Two examples of such innovation can be seen in the container, itself. First, the PET bottled water container is produced using far less plastic than it did 10 years ago. The gram weight of plastic in a PET bottled water container is one of the lowest in the food industry. The lightest beverage container on the market is a bottled water container with less than 12.5 grams for a 500 ml container, as compared to many other beverage containers with over 20 grams of plastic. This has resulted in substantial decrease in plastic per container in the industry. This innovation is readily apparent to consumers as they can actually feel the difference in their bottled water container.

Second, 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.

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 “lifeline” 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.²⁷ 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.²⁸

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. More recently, our companies provided bottled water to those in need in the aftermath of the spring flooding in the Midwest, and in just the past two weeks 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

²⁷ Drinking Water Research Foundation, 2005, *Bottled Water Production in the United States: How Much Groundwater Is Actually Being Used?*

²⁸ *Id.*

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.

Conclusion

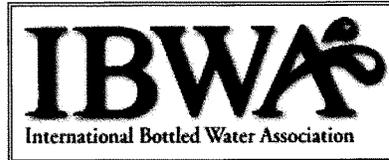
IBWA appreciates the opportunity to provide the Subcommittee with this overview of the bottled water industry. Bottled water provides consumers with a convenient, healthy beverage choice. The standards of quality for bottled water are as protective of public health as those for public drinking water 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, etc. If they are not satisfied with the response or the information provided, they have a plethora of choices among bottled water brands.

IBWA and its members are working with others to improve the recycling rates for plastic containers. The bottled water industry is committed to innovation and to reducing its environmental impact. IBWA will continue to work to increase the recycling rates for bottled water products. Finally, the near 100% reuse and recycling rate in the HOD segment of the bottled water industry is one of the "best kept secrets" that warrants broader awareness and recognition.

IBWA appreciates this opportunity to provide information on bottled water. If you would like more information or have further questions, please feel free to contact us.

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 (ICs) | ANNUALLY | IBWA SOQ | FDA SOQ | EPA MCL |
| Antimony (1) | (Product and Source) | 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) |
| Aluminum | (Product and Source) | 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 |
| 1,1,1-Trichloroethane | (Product and Source) | 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 | 0.001 | 0.005 | 0.005 |
| Vinyl chloride | Monitoring Requirements on page 21. | 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 ⁻⁹ | 3x10 ⁻⁸ | 3x10 ⁻⁶ |
| 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 (TTHMs).
- (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

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 butyl ether (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. ME: <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 (β) | 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

| *Annual average of maximum daily air temperatures (°F) | Fluoride concentration in milligrams per liter |
|---|--|
| 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

| *Annual average of maximum daily air temperatures (°F) | Fluoride concentration in milligrams per liter |
|---|--|
| 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.

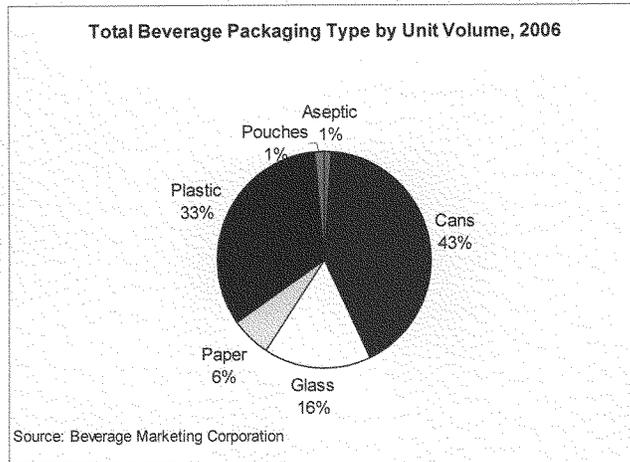


Chart I

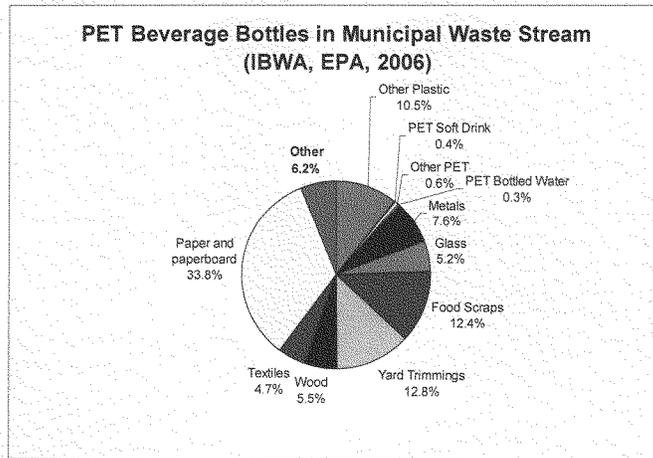


Chart II

Exhibit A

DEHP has been approved by the FDA as a food additive and food has been estimated to be a major source of exposure to DEHP. Specifically, we are concerned about the use of DEHP in the lining of bottled water gaskets found in the lid. The possibility exists that DEHP can leach into the bottled water from this use. There may be other phthalates that are being used in the packaging of bottled water that we are not aware of. In general, the use of phthalates in the packaging of food and bottled water (as well as in pesticides) needs greater public transparency, oversight, and regulation.

Although I am unable to identify specific alternatives for this use of DEHP, generally, there are alternatives to the use of DEHP and other phthalates that may be relevant to its use in the sealants for bottled water caps.

One possible option may be to use a plastic other than PVC for the bottled water caps. Since DEHP is used to soften PVC plastic, if a softer plastic (such as polyolefins or silicone) were used in the gasket, this could eliminate the need to use a plasticizer like DEHP.

Furthermore, a number of phthalate alternatives have been developed. These include citrate-based products and soybean-based products which have been used for food contact applications. Unfortunately, we do not have information on whether these phthalate alternatives are currently being used or have been tested for use in bottled water. The article "The plasticizer market: an assessment of traditional plasticizers and research trends to meet new challenges" by Mustafizur Rahman and Christopher S. Brazel, attached as Exhibit A, provides a useful list of alternatives to phthalates that merit greater research and consideration.



The plasticizer market: an assessment of traditional plasticizers and research trends to meet new challenges

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Abstract

Plasticizers have long been known for their effectiveness in producing flexible plastics for applications ranging from the automotive industry to medical and consumer products. The plasticizer industry has grown with the use of plastics worldwide. Recent plasticizer research has focused on technological challenges including leaching, migration, evaporation and degradation of plasticizers, each of which eventually lead to deterioration of thermomechanical properties in plastics. Human exposure to certain plasticizers has been debated recently because di(2-ethylhexyl) phthalate, used in medical plastics, has been found at detectable levels in the blood supply and potential health risks may arise from its chronic exposure. The current paper presents a brief history and an overview of the traditional plasticizers currently available in the world market, discusses some of the problems associated with the end uses of these plasticizers and reviews recent scientific approaches to resolve these problems. The definition of an ideal plasticizer changes with each application; thus, this paper addresses technical issues first from a broad perspective, and then with a focus on leaching, migration, evaporation and degradation issues. Several approaches to reduce leaching and migration of plasticizers are discussed, including surface modification of plasticized polymers and the application of alternative plasticizers and oligomers to meet technological requirements. New approaches to reduce evaporation and degradation of plasticizers are discussed, with the aim of formulating long-lasting flexible plastics and minimizing the ultimate environmental impact of these chemicals. The development of fire-retardant plasticizers and novel plasticizers for use in biodegradable plastics are also included.

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Keywords: Plasticizer; Leaching; Migration; Degradation; Health risk; Surface modification; Alternative plasticizers; Fire-retardant plasticizers

Contents

| | |
|-----------------------|------|
| 1. Introduction | 1224 |
| 2. Background | 1225 |

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| | |
|--|------|
| 2.1. Attributes of plasticizers | 1225 |
| 2.2. Evolution of plasticizers | 1225 |
| 2.3. Trends in plasticizer production | 1226 |
| 2.4. Current industrial plasticizers | 1226 |
| 3. Technical challenges for the plasticizer industry | 1227 |
| 3.1. Aspects of leaching and migration of plasticizers | 1227 |
| 3.2. High temperature flexibility | 1229 |
| 3.3. Low temperature lubricity | 1230 |
| 3.4. Health and environmental effects of plasticizers | 1231 |
| 3.4.1. Government regulation of phthalates | 1232 |
| 3.5. Flammability concern regarding phthalates | 1233 |
| 3.6. Compatibility with new polymers | 1233 |
| 3.7. Stability when exposed to ultraviolet rays | 1233 |
| 3.8. Plasticizers for biodegradable polymers | 1233 |
| 3.9. Improved material lifetime | 1233 |
| 4. Approaches to meet plasticizer challenges | 1234 |
| 4.1. Approaches to reduce plasticizer leaching and migration | 1234 |
| 4.1.1. Surface modification | 1234 |
| 4.1.2. Polymeric plasticizers and oligomers | 1236 |
| 4.1.3. Alternative plasticizers | 1238 |
| 4.1.4. Alternative polymers | 1239 |
| 4.2. Thermal aging and evaporation of plasticizers | 1240 |
| 4.3. Low temperature lubricating plasticizers | 1241 |
| 4.4. Improving health and environmental issues | 1241 |
| 4.4.1. Reducing exposure | 1241 |
| 4.4.2. Lower toxicity plasticizers | 1242 |
| 4.5. Flammability | 1243 |
| 4.6. Ultraviolet stability | 1244 |
| 4.7. Plasticizers for biodegradable polymers | 1244 |
| 5. Conclusions | 1246 |
| Acknowledgements | 1246 |
| References | 1246 |

1. Introduction

In the past century, engineering plastics have progressed from novel invention to a major component in numerous industries. In recent years, engineering plastics have penetrated markets once dominated by metals and continue to grow in popularity with an average annual consumption growth rate of 5.09% [1]. The continuous use and growth of plastics depend on finding materials with unique and dependable properties that can be used efficiently and produced economically. Because of

the nearly limitless polymer structures and formulations that can be designed, the field of plastics is continually marked with technical innovations.

Both technically and economically, additives form a large and increasingly significant part of the polymer industry. Plasticizers account for about one third of the global plastic additives market in terms of consumption [2]. Used to increase structural flexibility, plasticizers have recently been scrutinized for environmental and health related problems. The expansion of plasticizing compounds to meet new material challenges, has also led to significant

technical advances. This paper highlights plasticizer research and development over the past 20 years.

2. Background

2.1. Attributes of plasticizers

The primary role of plasticizers is to improve the flexibility and processability of polymers by lowering the second order transition temperature [3]. Plasticizers are actually low molecular weight (MW) resins or liquids, which form secondary bonds to polymer chains and spread them apart. Thus, plasticizers reduce polymer-polymer chain secondary bonding and provide more mobility for the macromolecules, resulting in a softer, more easily deformable mass.

Plasticizers are incorporated in the amorphous parts of polymers while the structure and size of any crystalline part remains unaffected [4]. Plasticizers are expected to reduce the modulus, tensile strength, hardness, density, melt viscosity, glass transition temperature, electrostatic chargeability and volume resistivity of a polymer, while at the same time increasing its flexibility, elongation at break, toughness, dielectric constant and power factor [5]. Ideal plasticizers should be highly compatible with polymers, stable in both high and low temperature environments, sufficiently lubricating over a wide temperature range, insensitive to solar ultraviolet (UV) radiation, leaching and migration resistant, inexpensive and should fulfill health and safety regulations. The current market offers numerous choices of plasticizers with a range of attributes that can be selected for specific applications to meet critical material requirements.

Plasticizers can be either internal or external, where external plasticizer molecules are not attached to polymer chains by primary bonds and can therefore be lost by evaporation, migration or extraction. On the other hand, internal plasticizers are inherently part of the plastic and remain part of the product [6]. For both types of plasticizers, there is often a marked temperature dependence of material properties, though this is more pronounced with internal plasticizers. Internal plasticizers also have problems with retaining dimensional stability at elevated temperatures.

Plasticizers may also be divided into primary and secondary types [7]. Primary plasticizers are used as the sole plasticizer or as the major component of plasticizer, while secondary plasticizers are typically blended with primary ones to improve certain performance properties and/or to lower cost.

2.2. Evolution of plasticizers

The first man-made plastic known was manufactured in 1862 by Alexander Parkes in London, but it was not until the late 19th century when the concept of plasticizers was first introduced [8]. In the early days, manufacturers of celluloid or celluloid lacquers used natural camphor and castor oil for plasticization purposes, but those were unsatisfactory for many end uses. The discovery of triphenyl phosphate in 1912, later used as substitute for camphor oil, was a significant turning point that ushered in the era of ester plasticizers. The most important product that resulted from this early discovery was tricresyl phosphate which is still in use today. For some time, tributyl phosphate was highly regarded for cellulose derivatives, but it was eventually replaced by less volatile products. At the same time, glycerin acetates were developed but suffered the same fate due to their volatility. Phthalic acid esters found applications as plasticizers for the first time in 1920 and continue to be the largest class of plasticizers in the 21st century. Dibutyl phthalate (DBP) gained a dominant position amongst plasticizers which it held for many years and continues to hold today for polyvinyl acetate dispersions. Di(2-ethylhexyl) phthalate, DEHP, was introduced in 1930 and has been the most widely used plasticizer since the 1930s.

The driving forces for development of specialty plasticizers come from the extensive use of plastics in a wide range of applications, increased quality requirements, the need for materials that meet increasing rigorous product specifications and compatibility problems relating to particular products. Food legislation, health and industrial safety and commercial aspects play an important role and, over last 50 years, have led to the development of the vast range of plasticizers currently available. Initially a few fatty acid esters, benzoates, tartrates and chlorinated hydrocarbons were available to meet the new safety requirements. They were soon joined by esters

of adipic, azelaic and sebacic acid. These latter three immediately attracted interest because they considerably improved the cold fracture temperature of plasticized poly(vinyl chloride), PVC, the third most consumed polymer worldwide [9]. A large number of high performance plasticizers are produced now by systematic esterification of aliphatic or aromatic carboxylic acids.

2.3. Trends in plasticizer production

As the plastic industry continues to grow, so does the plasticizer industry. In the early 1990s, the annual US production of plasticizers averaged 2 billion pounds, of which 1.25 billion pounds were phthalates [10]. By 1999, the global demand for plasticizers had increased to 10.1 billion pounds, worth about US \$7 billion, while the total plasticizer demand in North America was 2.2 billion pounds [2]. Europe, North America, and Japan are currently the major consumers of plasticizers, and account for 28, 22, and 10% of the global demand, respectively. The current overall growth rate for production of plasticizers, as estimated in early 2000s, is about 2.8% per annum [2].

2.4. Current industrial plasticizers

The most frequently plasticized polymers include PVC, poly(vinyl butyral) or PVB, poly(vinyl acetate) or PVA, acrylics, cellulose molding compounds, nylon, polyamides and certain copolyamides. On average, PVC accounts for about 80% of all plasticizers consumed [11] (88% in Europe and 85% in North America [2]). The degree of plasticization of polymers is largely dependent on the plasticizer's chemical structure, including chemical composition, MW, and functional groups. Plasticizers that have low MW and a small number of polar groups generally provide higher flexibility and plasticization [12]. Plasticizers are generally chosen on the basis of the following criteria [8]:

- compatibility of a plasticizer with a given polymer,
- processing characteristics,
- desired thermal, electrical and mechanical properties of the end product,
- resistance to water, chemicals, solar radiation, weathering, dirt, microorganisms,

- effect of plasticizer on rheological properties of polymer,
- toxicity, and
- volume-cost analysis.

The most commonly used plasticizers worldwide are esters of phthalic acid (e.g. DEHP, diisodecyl phthalate or DIDP, diisotridecyl phthalate or DITDP, and diisononyl phthalate or DINP). With more than 30 different phthalates on the market, DEHP is by far the most widely used one. Phthalate esters have been used extensively in thermoplastic cellulose ester molding compounds, PVC and other vinyl chloride copolymers for over 60 years. Phthalates account for 92% of plasticizers produced worldwide while DEHP represents 51% of the phthalates [1]. In general, phthalates combine most of the desirable properties of a plasticizer such as [8]:

- minimal interaction with resins at room temperature,
- good fusion properties,
- satisfactory insulation for cables,
- produce highly elastic compounds with reasonable cold strength,
- relatively nonvolatile at ambient conditions, and
- low cost.

With phthalates, the polarizable benzene nucleus is highly effective with respect to compatibility with PVC, affording great flexibility to the polymer chains. However, compatibility decreases with the increasing length of the disubstituted alkyl esters. Shorter chain phthalates are easier to formulate because they diffuse faster, but have the drawback that they are more volatile [8]. The plasticizing effectiveness is reduced by branching and this effect is stronger the nearer the branches are to the polar group and the shorter the main chain becomes due to branching. This is paralleled by an increase in viscosity so that viscosity and plasticizer effectiveness are closely related. Terephthalates, oligoesters of *o*-phthalic acids and solid phthalate esters (e.g. dicyclohexyl phthalate and diphenyl phthalate) have some plasticizing properties, but are seldom used because of their high cost.

Phthalate esters were initially found to be benign to human beings [13] and therefore have been used in various products such as children's toys and medical

plastics where they may come in close contact with the human body. However, more recent reports have criticized these petroleum-derived products because of their suspected endocrine-disruption activity in laboratory rats, especially after phthalate plasticizers have been found to leach out of medical plastics such as intravenous (IV) bags and dialysis tubing [14]. A further discussion of medical issues is included later in this paper.

Phosphates are among the earliest known PVC plasticizers. They are also important for their additional flame retardant properties. They are less flammable than the phthalates probably because they form polyphosphoric acids by condensation reactions on heating and these cause charring reactions to occur in the polymer formulation [15]. Depending on their basic molecular structure, commercial phosphate esters can be grouped into three main categories: trialkyl, triaryl and alkyl/aryl phosphates. The triaryl phosphates improve the flammability properties of polymer formulations in which they are present but at the expense of increased smoke production. The alkyl and aryl phosphates also improve the flammability properties but unlike the triaryl derivatives, they do not increase smoke production when burnt in the air.

Other than phthalates and phosphates, there are several classes of plasticizers commercially available in the market, which offer different end properties to polymeric materials. Aliphatic dicarboxylic acid esters (adipates, azelates, sebacates) have high plasticizing effectiveness with PVC and PVA, and provide excellent low temperature flexibility. However, they are only effective in a narrow MW range. These types of esters with MW of 300–350 tend to be too volatile for many applications, while those with MW over 400 tend to be incompatible with polymers [16]. Monocarboxylic acid esters of polyols show good plasticizing properties too. Epoxidized fatty acid esters have been used as plasticizers and also as stabilizers for PVC due to their ability to form bonds with the hydrogen chloride that results from the decomposition of PVC. Trimellitates, paraffinic sulfonic acid and phenyl esters, polyesters, chlorinated hydrocarbons, aliphatic/aromatic monocarboxylic acid esters such as benzoates, and a variety of elastomers have also been used as plasticizers for years.

Plasticizers continue to evolve with the demand of specialty applications. This evolution has recently been spurred by the controversy over the safety of many traditional plasticizers [14]. This has led to the emergence of novel plasticizers including citric acid esters, oligomers and polymeric plasticizers, epoxidized soybean oil, PVC/EVA (ethylene vinyl acetate) graft polymers and terpolymers, many of which have become commercially available over the past two decades. Thus, a plethora of plasticizers is available to choose from, depending on the processability and end-use requirements. Table 1 summarizes the major categories of plasticizers giving specific examples and some common end uses for the plasticized materials, while Fig. 1 shows the structures of some commercially available plasticizers.

3. Technical challenges for the plasticizer industry

As the plasticizer industry has matured, a number of technical challenges have been addressed to improve formulations, solve technical end-use problems or meet new requirements. Some of the problems include evaporation or degradation of traditional plasticizers due to their volatility or UV susceptibility, leaching of plasticizers to polar and nonpolar liquid media, migration of plasticizers to other polymeric substances and surroundings, insufficient lubrication at subzero temperatures and suspected carcinogenic effects on a number of living organisms. Table 2 summarizes some of the current technical challenges for the plasticizer industry. The fundamental bases for these problems are chemical in nature; many are related to molecular thermodynamics, transport properties and interfacial phenomena. Current plasticizer research focuses on these technical issues from different perspectives.

3.1. Aspects of leaching and migration of plasticizers

Leaching and migration of plasticizer molecules from polymers is a critical issue that determines a material's usable lifetime. Leaching, by definition, refers to the removal of a substance from a solid via a liquid extraction media. Migration, on the other hand, refers to any method by which a component leaves a material—to a gas, liquid or solid phase. In this paper,

Table 1
Properties and applications of some commercial plasticizers [1,6,8,10,16–19]

| Plasticizer type | Main characteristics | Common examples | End uses |
|---|---|---|--|
| Phthalates | Excellent compatibility, high gelling capacity, low volatility, water resistant, inexpensive *terephthalates have high migration resistance | DEHP, DIDP, DINP, DITDP, DBP | Medical plastics (IV bags and tubing), kitchen floors, vinyl wall coverings, carpet backing, wires and cables, toys, hoses, shower curtains, food packaging, automobile parts |
| Phosphates | Flame retardant, heat resistant, highly solvating for vinyl resin, lower fusion temp. than DEHP, but accelerates thermal degradation of PVC, not suitable for low temp. and food-contact applications | Triphenyl phosphate, tris (2-ethylhexyl) phosphate, tricresyl phosphate, Kronitex [®] | Flame retardant plasticizer in calendared goods, extrusions, plastisol-derived products with nylon, sulfonamides and other highly polar compounds, PVC, polyacrylates, cellulose derivatives, synthetic rubbers |
| Adipates | Low viscosity, higher gelation and fusion temp. than DEHP, cause less brittleness than phthalates, relatively volatile and extractable, but give superior low temp. flexibility | Dibutyl adipate, bis(2-ethylhexyl) adipate or DEHA, diisodecyl adipate | In combination with phthalates, improved low temp. (even arctic) flexibility for automobile parts and aircraft interiors |
| Azelates | Improve low temp. flexibility, less water sensitive than adipates | Bis(2-ethylhexyl) azelate | With cellulosic resins and elastomers, food-contact applications with PET and polyester |
| Sebacates | Excellent low temp. performance | Dibutyl sebacate, dioctyl sebacate | Dibutyl sebacate used specially for polyisoprene; food contact, medical, and pharmaceutical plastics |
| Epoxidized fatty acid esters | Impart cold strength, very low volatility, pigment dispersing agents in plasticized PVC, synergistic thermostabilizing effect with Ca–Zn stabilizers, can stabilize other plasticizers by offering migration resistance | Butyl epoxystearate, cyclohexyl epoxystearate | Low temp. applications of PVC and its copolymers |
| Benzoates | Highly solvating, low moisture sensitivity, excellent resistance to organic extraction, excellent stain and UV resistance, good gelation properties, desirable environmental, health and safety profiles, high viscosity (limits application) | Benzoplast [®] , Benzoflex [®] | Vinyl flooring, PVA adhesives, PU castable and sealants, latex caulks, coatings, plastisol formation, processing aids, inks, hot melt adhesives |
| Polyesters/polymeric plasticizers (MW between 850–3500) | Very low volatility, highly resistant to extraction and migration, extend lifetime of flexible articles, improve weathering resistance, highly viscous and usually blended with lower viscosity plasticizers | Poly(1,3 butyleneglycol adipate), poly(ethylene glycol) PEG, Admex [®] , Paraplex [®] | Compatible with PVC, cellulose acetate butyrate and cellulose nitrate, used in vinyl dispersions, films, sheet, floor coverings, cable insulation and sheathing resins only where oil and fat resistance is required |
| Trimellitates | Low volatility, good water resistance, high temp. stability, similar to phthalates in compatibility and plasticizing effectiveness, less migration tendency, extraction by oils and hydrocarbons as high as phthalates, high price | Trioctyl trimellitate (TOTM), octyl dibenzyl trimellitate | PVC tubes, blood storage bags, haemodialysis tubing, catheters |
| Sulfonic acid esters and sulfamides | Less volatile than phthalates, tend to discolor, weather resistant, sulfonic acid esters have slightly better gelation effectiveness than DEHP, good hydrolytic resistance in alkaline solution, arylsulfonamides not compatible with PVC | <i>n</i> -Butyl benzenesulfonamide, toluenesulfamide | Sulfonic acid esters used with PVC, sulfonamides used specially with polyamide and cellulose based molding resins |

(continued on next page)

Table 1 (continued)

| Plasticizer type | Main characteristics | Common examples | End uses |
|-----------------------------|--|--|--|
| Monocarboxylic acid esters | Esters with low alkanols are too volatile, sensitive to water, and show poor gelation properties, longer chain esters of fatty acids are not too compatible with polymers | <i>n</i> -Butyl formate, ethyl lactate | Important as low temp. secondary plasticizers and as lubricants in processing rigid and plasticized PVC |
| Epoxidized vegetable oils | Heat and light stability, resistant to extraction, epoxidized soy bean oil has high MW (~1000) and bulky structures which resist migration | Epoxidized soy bean oil (ESO), epoxidized linseed oil, tallates | Primarily as heat stabilizers |
| Chlorinated hydrocarbons | Somewhat flame retardant, limited compatibility, often colored, have odor; aromatic—high viscosity, fairly good compatibility, poor heat and light stability; aliphatic—low viscosity, may exude from aged fused products | Polychlorinated biphenyls (PCBs), polychlorinated 1-dodecene, 1-tetradecene, 1-hexadecene | Mainly used as secondary plasticizers; for cost reduction in blends and to achieve some flame retardancy |
| Citrates | Good solvating power for PVC and cellulose acetate, high efficiency, non-toxic, non-acetyl citrates are relatively volatile and water sensitive compared to DEHP, good for medical plastics if not exposed to high lipid media | (acetyltri- <i>n</i> -hexyl citrate) Citroflex [®] A-6, (<i>n</i> -butyryltri- <i>n</i> -hexyl citrate) Citroflex [®] B-6 | With cellulose, PVC, PVA, and other polymer films and flexible tubings used in medical plastics and food-contact plastics |
| Oligomers (low MW polymers) | Offer better extraction and migration resistance, lower volatility, weathering resistance and reduced odor, may exude particularly at high temp. and humidity | (recorinol bisdiphenyl phosphate) Fyrolflex [®] RDP-B, poly (butadiene dimethacrylate) | Automotive, marine and aeronautical applications |
| Polymerizable plasticizers | Polymerize at elevated temp. during the gelling of PVC | Allyl phthalate, acrylic esters, monochlorostyrene | Toys, shoe heels and certain industrial articles that must have high stiffness |
| Elastomers | Used instead of or together with low MW plasticizers for PVC to improve resistance to migration, saponification, low temp. flexibility, mechanical and oxidative stability at high temperatures | Nitrile rubber, ethylene/vinyl acetate copolymers, acrylonitrile/butadiene/styrene terpolymers | Coverings of instrument panels, cushion covers, shoe soles, insulations for cables, tubes and articles for aircraft interior |

leaching will be used to refer to any liquid extraction of a plasticizer while migration will refer to any gas or solid-phase transfer of plasticizer.

Plasticized polymers are often in contact with stationary or flowing fluids, or in contact with some other solid material. In the course of time, plasticizers tend to diffuse down the concentration gradient to the interface between the polymer surface and the external medium. In many instances, the interfacial mass transport to the surrounding medium has been found to be the limiting step rather than diffusion of plasticizer through the matrix to the surface. This rate is usually a function of temperature and initial plasticizer concentration while the rate of migration (permeation) is a product of solubility and diffusion coefficients [20]. Whether the plasticizers leach out to a liquid, or migrate to gaseous or solid substance,

polymers fail to retain their flexibility while the loss of plasticizers leaves the polymers inappropriate for the desired application. In addition, the plasticizers coming out of the polymers often pose health and environmental risks, as described in a later section. Leaching and migration issues are indeed one of the toughest challenges regarding research in the plasticizer industry today.

3.2. High temperature flexibility

Most flexible plastics are limited in their end use because plasticizers are generally low-to-medium MW chemicals with measurable vapor pressure below their boiling points. This often causes the plasticized materials used in high temperature environments to be replaced frequently, as they become brittle and tend

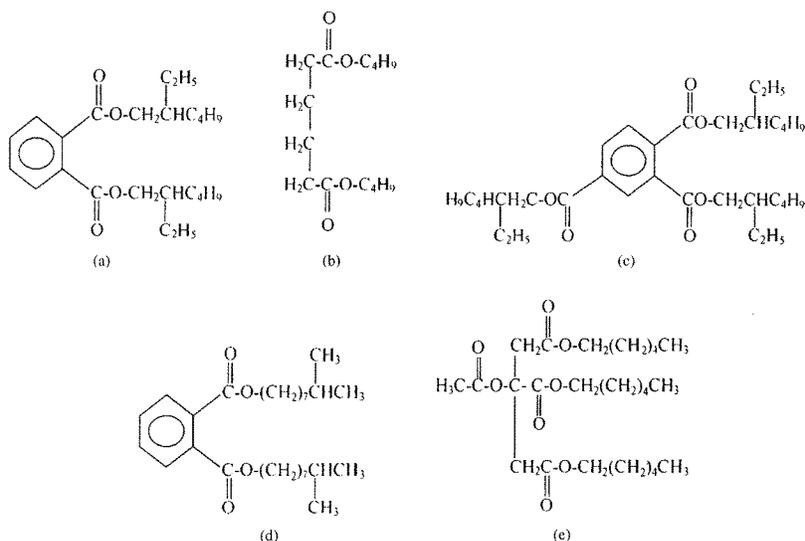


Fig. 1. Structures of some traditional plasticizers: (a) di(2-ethylhexyl) phthalate, (b) dibutyl adipate, (c) trioctyl trimellitate, and (d) acetyltri-n-hexyl citrate.

to crack owing to evaporation or degradation of plasticizers. In addition to degradation of plasticizers, some polymers, e.g. PVC, are also susceptible to high temperature environments. The thermal degradation and dehydrochlorination of PVC have been widely studied since the 1940s [21]. Thermal dehydrochlorination of PVC begins with internal allylic chloride

Table 2

Plasticizer-related technical challenges

1. Migration out of plastic
 - a. Solid–solid migration
 - b. Evaporation
 - c. Liquid leaching
2. High temperature flexibility
3. Low temperature lubricity
4. Health and environmental effects (cytotoxicity)
5. Flammability concern regarding plasticizers
6. Compatibility with new polymers
7. Stability to ultraviolet rays
8. Biodegradability
9. Improved material lifetime

and tertiary chloride structural defects formed during polymerization [22]. The initial stage of thermal degradation of PVC involves sequential loss of hydrogen chloride accompanied by the generation of conjugated polyene sequences and followed by a series of polyene growth steps through an ion-pair or quasi-ionic route. Phthalate esters, in addition to plasticization, have been found to reduce the rate of dehydrochlorination of PVC by inhibiting the growth of polyene sequences. Hence, when they evaporate from the PVC host, discoloration, tackiness and embrittlement result. The development of new plasticizers that are not subject to thermal aging will allow the use of flexible polymers at temperatures higher than what is currently possible.

3.3. Low temperature lubricity

The low temperature performance of plasticizers can cause problems with sealing plastics such as

gaskets, which may become brittle and crack in cold environments. Plasticizers work effectively to lower the glass transition temperature of the host polymer, but the degree to which the T_g is reduced depends on the thermodynamic compatibility of the plasticizer with the polymer (the greater this compatibility, the more plasticizer can be added to the formulation, which increases lubricity). An additional problem at low temperatures is that many plasticizers have melting points close to room temperature, and they may freeze (solidify) before the polymer passes through a T_g . Therefore, low temperature lubricating plasticizers can provide polymeric materials with new and improved applications.

3.4. Health and environmental effects of plasticizers

Human and environmental exposure to plasticizers can occur in different ways. The most prevalent causes of these exposures include point-source pollution from plasticizer manufacturing or plastic formulation, and leaching, migration and evaporation of plasticizers.

Phthalate plasticizers have been a target of worldwide scrutiny in the past two decades from consumer and environmental groups on the grounds of potential carcinogenicity and possible endocrine modulating effects [14]. PVC-based medical plastics have received the most attention partly because medical uses constitute 10% of the phthalate plasticizer market [23]. The PVC used in IV and blood storage bags typically contain 30–40 wt% DEHP and medical tubing such as dialysis tubing may contain as much as 80 wt% DEHP [24]. This DEHP has been shown to leach out of PVC depending on temperature, amount of plasticizer present, agitation of the device, storage time while in contact with medical solutions, and the type of medium being stored in or moving through the medical device.

DEHP leaching from medical plastics was first observed in late 1960s when Jaeger and Rubin found that one pint of blood and its anticoagulant solution may contain 6 mg of DEHP after being stored in PVC blood bags for 21 days at 4 °C [25]. Another study by the same authors in 1972 showed that DEHP was extracted from PVC blood bags by human blood at a rate of 2.5 mg/l per day at the typical blood bank storage temperature of 4 °C [26]. Extensive research began after the International Agency for Research on

Cancer classified it as 'possible carcinogenic to humans' in 1980 based on early studies on rodents [1]. Subsequently, numerous experiments were conducted to examine the testicular and ovarian toxicity, as well as the embryotoxicity, nephrotoxicity, cardiotoxicity, pulmonary toxicity, and hepatotoxicity of DEHP in mammals [24]. Results proved it to be a possible carcinogenic substance, but it has been found that the maximum safety limits required for consumer products are at least 75 times lower than a hazardous concentration.

Leaching of DEHP from plasticized PVC has been observed in soapy water, cottonseed oil, and also in high humidity environments [24]. While losses in aqueous solutions are small, these percentages are not insignificant especially considering the lifetime exposure and bioaccumulation of DEHP. Particular concern has been raised in neonatal care applications because newborns receive among the highest doses of DEHP from blood transfusions, extracorporeal membrane oxygenation and respiratory therapy [27,28]. Using the typical PVC-DEHP tubing and EVA bags with PVC-DEHP connections, it has been found that infants and children receiving intravenous total parenteral nutrition (TPN) infused through PVC-administration sets potentially receive considerable amounts of DEHP every day. DEHP is extracted from the bags and tubing due to the high solubility of DEHP in lipids and DEHP extraction by TPN depends on the lipid content of each TPN preparation and the flow rate [29]. Table 3 shows the amount of DEHP received by a 2 kg baby in 24 h with different amounts of TPN solutions, using typical DEHP-plasticized PVC infusion lines [28].

Adults can also be subjected to DEHP exposure from medical plastics. Kambia et al. [30] studied the leachability of DEHP from PVC haemodialysis tubing during maintenance haemodialysis of 10 patients with

Table 3
Daily doses of DEHP received by a 2 kg baby during TPN infusions

| Solution | Amount (ml) | DEHP load (μ g) |
|---------------------|-------------|----------------------|
| Aminoacid/glucose | 140 | 116.2 |
| Lipid emulsion, 20% | 24 | 10,185.6 |
| Midazolam | 24 | 26.4 |
| Fentanyl | 28.8 | 132.5 |
| Propofol 1% | 10 | 6561.0 |

chronic renal failure. The patient blood obtained from the inlet and the outlet of the dialyzer was analyzed during a 4 h dialysis session. An average DEHP quantity of 123 mg was extracted from tubing during a single dialysis session, of which approximately 27 mg was retained in the patient's body.

Phthalates are also used in baby-care products and toys which represent around 1% of the phthalate plasticizer market [23]. Since young children put the plastic-toys in their mouth, the plasticizers can leach out and be swallowed, which has led to the investigation of low toxicity plasticizers. Fortunately, DEHP exposure in this way is considerably less than the critical limit of 69 mg/kg per day [1].

Human exposure to DEHP also occurs through inhalation of air due to off-gassing from PVC products such as flooring and car dashboards, drinking water contaminated with DEHP, and through the ingestion of food containing DEHP that has leached out of packaging. Contact between food and plastic packaging may often cause reciprocal transfer between the material and the surrounding medium. In the case of PVC-based commercial wrap films or containers, various processing aids like plasticizers may exude from the packaging material or can be extracted by the foodstuff [31]. Apart from the alteration in chemical and physical properties of the plastic material, this phenomenon causes contamination of the packaged food which eventually ends up inside human body.

Oral LD₅₀ values for DEHP have been reported as 25 g/kg in rats and 30 g/kg in mice [24]. As mentioned earlier, a detrimental dose for humans has been estimated at 69 mg/kg per day whereas the average daily exposure to DEHP is much lower (2.3–2.8 µg/kg in Europe and 4 µg/kg in the US) [1]. Because this figure does not include workplace air exposures or indoor air exposures from off-gassing of building materials, there is a possibility that some people could be at a greater risk, especially with an estimated 500,000 pounds of DEHP released to the environment from US manufacturing facilities in 1997 alone [24]. Also, daily exposure to DEHP in medical settings may exceed general population exposures by up to three orders of magnitude [14].

In addition to toxicity-related problems, application of DEHP as plasticizer was found to have adverse effects on the biocompatibility of the plastic materials used in medical devices. Upon contact with

blood, albumin is instantly absorbed on the polymer surface, followed by globulin [32]. Penerovski et al. [33] have established that the surface of a polymer material that has already absorbed a layer of albumin attracts thrombocytes to a greater extent. Elsewhere, it was found from both in vitro and in vivo studies that in plasticized PVC, an increase in DEHP content leads to deterioration in the material's biocompatibility [34]. In addition to the increased protein deposition found on PVC surfaces with increasing DEHP content, blood coagulation time and hemoglobin concentration in blood were found to decrease during storage of blood in DEHP plasticized PVC bags. This is probably due to the higher concentration of DEHP that migrated onto the surface of the samples.

Beyond the concerns over the use of phthalates in the medical field and other household applications, these plasticizers have also been noted to have an adverse environmental impact on plants as cellulose acetate filters plasticized with diethyl phthalate (DEP) showed severe phytotoxicity in Ashley cucumbers when exposed to UV-B rays ($\lambda = 290\text{--}320\text{ nm}$) [35]. Hence, preventing leaching and migration of plasticizers will have considerable impact on the environment as well as human health.

3.4.1. Government regulation of phthalates

The regulation of phthalates as plasticizers has undergone scrutiny with the concerns over the toxicity and carcinogenic behavior of DEHP. Because these compounds have been used safely for an extended period, there are some disagreements among the different regulating agencies over the urgency to find suitable replacements to DEHP as plasticizers. The European Union Scientific Committee of Toxicity, Ecotoxicity and the Environment announced in 1998 that there were safe migration limits for phthalates [1]. In a scientific opinion, the committee stated that the phthalate plasticizers can safely be used in production of soft PVC-based toys, provided that migration limits are observed. Parallel to the European conclusions, the American Council on Science and Health convened a scientific panel of health experts, which concluded that the phthalate plasticizers used in PVC medical devices are neither carcinogenic nor have any harmful effect at the levels to which consumers are exposed [1]. Also, a scientific panel convened by the US Consumer Product Safety Commission concluded

that DINP, the most used plasticizer in PVC-based toys, does not pose a health risk to children at the typical level of exposure [36]. However, the concern over DEHP has led the US Food and Drug Administration (FDA) to suggest that manufacturers either label certain devices with their DEHP content or consider the feasibility of replacing PVC containing DEHP with alternative materials or different plasticizers, or using coatings that may minimize patient exposure to DEHP [37]

3.5. Flammability concern regarding plasticizers

Traditionally-used plasticizers are generally hydrocarbons and often make the polymers more susceptible to fire hazards. The aliphatic components of plasticizer molecules, especially if they are linear, have better plasticizing properties than aromatic compounds but they are, in general, more flammable [15]. Because of the flame-retardant properties of chlorine atoms, PVC usually requires much less flame-retardant additives than do other polymers. However, since PVC is frequently used in plasticized forms, the flammability of the plasticizers is a major concern. Phthalate plasticizers such as DEHP, when compounded into PVC formulations, increase smoke production, ease of ignition and the burning rate. Application of less or nonflammable plasticizers is therefore one of the main foci of current plasticizer research.

3.6. Compatibility with new polymers

As novel polymers are developed and new applications require the plasticization of polymers that have not been used in flexible plastics, plasticizers must evolve to be compatible for a range of new formulations. As has already been discussed, the plasticizing efficiency and thermodynamic compatibility of plasticizers with polymers depend on a number of properties such as chemical structure, MW, functional groups, alkyl chain length and diffusion and solubility parameters of the plasticizers. Therefore, plasticizers must have sufficient thermodynamic compatibility with the host polymers in addition to providing desired flexibility and other end-use properties to the polymeric materials.

3.7. Stability when exposed to ultraviolet rays

Apart from leaching, migration and thermal aging, degradation of polymeric materials by UV rays may also cause a reduction in plasticizing efficiency. Plastics are often subjected to harsh environments that can cause evaporation of plasticizers, as often observed in automotive dashboards. Many dashboards lose plasticizers and crack over years of exposure to UV rays from sunlight and temperature cycles. Degradation of PVC is particularly important for this discussion as it has been found that plasticized PVC degrades more rapidly than unplasticized PVC in the near UV region ($\lambda > 290$ nm) [16].

3.8. Plasticizers for biodegradable polymers

Biodegradable polymers have gained much attention for environmental and biomedical applications. When disposed in biologically active environments, biodegradable polymers are completely converted to biological products (biogas, humic matter, biomass, etc.) within a certain period of time. These polymers, as well as their degradation products, must cause no deleterious effects on the environment. Fully biodegradable synthetic polymers such as poly(lactic acid) or PLA, polycaprolactone, and polyhydroxybutyrate-valerate have been commercially available since 1990 [38]. Plasticizers are used for biodegradable plastics as well. There are more stringent requirements on these plasticizers, though, since by definition they will be released to the environment during normal product use. Health and safety issues dominate the research in this field, with benign, often natural substances having nearly as great importance as the ability to lower the T_g of the polymer. Because of the prevalence and commercial applications of biodegradable polymers, recent research has focused on developing compatible plasticizers that also biodegrade.

3.9. Improved material lifetime

By preventing plasticizer loss and degradation, and by improving thermodynamic compatibility of plasticizers with polymers, the lifetime of flexible plastics can be increased. This results in reduced costs and fewer plastics that must be landfilled annually.

4. Approaches to meet plasticizer challenges

Current research trends in the plasticizer industry represent approaches to solve the technical issues discussed in Section 3. Many of the issues are interrelated; thus, novel plasticizers and material modification often seek to solve multiple shortcomings. While the plasticizer industry grows, these technical challenges are dealt with from different perspectives in terms of the diversified applications of plastic materials.

4.1. Approaches to reduce plasticizer leaching and migration

Several approaches have been developed to reduce the leaching of plasticizers into physiological fluids as well as different organic and inorganic solvents and also to reduce the migration of plasticizers into solid and gaseous media. These techniques vary in level of complexity and also cost. Some methods that have successfully reduced leaching are broken down in Table 4.

4.1.1. Surface modification

Surface modification of polymers has attracted great attention in biomaterial research because it can improve the biocompatibility of a polymer without compromising the mechanical properties. This technique has also been employed to reduce or prevent leaching and migration of plasticizers from polymers.

4.1.1.1. Surface crosslinking. Surface crosslinking is one of the most common techniques studied to prevent leaching and migration of plasticizers. The cross-linked polymer-surface actually acts as a barrier to

Table 4
Major methods investigated to reduce plasticizer leaching and migration

| |
|---|
| 1. Surface modification |
| a. Surface crosslinking |
| b. Modification of surface hydrophilicity/lipophilicity |
| c. Surface coating |
| d. Surface extraction |
| 2. Use of polymeric plasticizers and oligomers |
| 3. Use of alternative plasticizers |
| 4. Alternative polymers |

interfacial mass transport of plasticizer molecules. Audic et al. [39] investigated the effect of plasma-induced surface crosslinking of PVC-based flexible films to limit plasticizer leaching from packaging into fatty foodstuffs. Leaching tendencies of DEHA and ESO from PVC films to isooctane were monitored by supercritical fluid chromatography. Simultaneously, the effect of replacing DEHA with an elastomeric terpolymer, poly(ethylene-co-vinyl acetate-co-carbon monoxide) or EVACO, Elvaloy 742[®], was observed. It was found that the percentage leaching of plasticizers decreased with increasing plasma-treatment time. Best results were shown with Argon plasma (Fig. 2). Argon plasma-treated PVC films showed significant leaching resistance which can be attributed to the high degree of crosslinking during plasma treatment and further formation of oxygen-based functional groups when the samples were re-exposed to air. Partial replacement of DEHA by EVACO led to higher migration of DEHA, but it was reduced considerably after the plasma-treatment. Surface crosslinking of polymer to reduce leaching and migration is often employed along with other surface modification techniques, as will be shown later in this chapter.

4.1.1.2. Modification of surface hydrophilicity/lipophilicity. The nature of polymer surface often governs

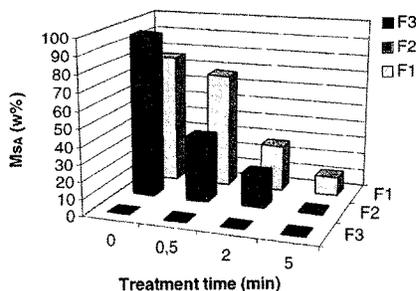


Fig. 2. Percentage-leaching of DEHA from PVC films to isooctane with increasing Argon plasma-treatment time. F1 films contain 28 phr DEHA and no EVACO, F2 films contain 10 phr DEHA and 40 phr EVACO, and F3 films contain no DEHA and 60 phr EVACO. Reprinted from Ref. [39], © (2001), with permission from John Wiley and Sons, Inc.

the interaction of the polymer with certain liquid media. Leaching of plasticizers from polymer into a liquid can therefore be controlled by regulating surface characteristics. Among a variety of surface modification techniques, grafting of water soluble polymers to the surface of biomaterials has been attempted by a number of researchers. For example, Krishnan et al. [40] grafted *N*-vinyl pyrrolidone onto flexible PVC sheets used in medical applications using ionizing radiation from a ^{60}Co source. The leaching of the plasticizer DEHP into a strong organic extractant, *n*-hexane, was significantly reduced in different grafted PVC systems at 30 °C. Incorporation of ethylene dimethacrylate as a crosslinking agent during grafting further reduced the plasticizer leaching.

Leaching resistance of flexible PVC has also been improved by grafting PEG, which is often used in biomaterials to prevent biological recognition and protein adhesion [41]. Surface-modified plasticized PVC sheets and tubes were formed by the classical Williamson ether synthesis reaction where PVC was treated with an excess of Na-PEG. Leaching of DEHP from PVC to petroleum ether, cottonseed oil and paraffin oil was reduced considerably for PVC grafted with Na-PEGs with MW 400 and 4000. The decrease in plasticizer leaching after PEG-grafting is presumably due to the hydrophilic PEG surface acting as a barrier to the diffusion of DEHP from the PVC matrix. Fig. 3 shows the reduced leaching of DEHP into cottonseed oil and paraffin oil due to grafting of PVC with PEG 400 at 70 °C.

Another surface modification technique that has been found to be effective in preventing leaching of plasticizer is the nucleophilic substitution of chlorine in plasticized PVC by sodium azide in aqueous media and using tetrabutyl ammonium bromide as the phase transfer catalyst [42]. The azidated PVC surface was then irradiated using UV rays with a 125 W lamp for various time periods to crosslink the surface. Leaching of DEHP from the surface-modified PVC into hexane was reduced considerably depending on the extent of azidation of the PVC surface and the irradiation dose. However, there was pronounced change of color of the PVC samples due to substantial dehydrochlorination that occurred during the grafting process and 35% reduction in elongation at break resulting from the surface crosslinking of PVC.

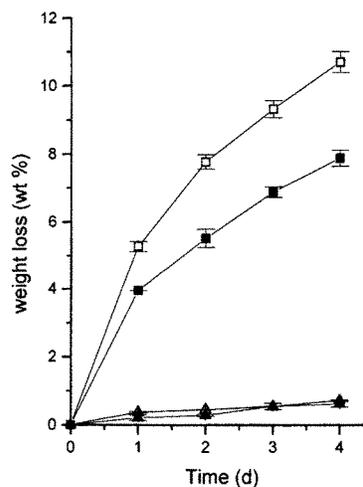


Fig. 3. Kinetics of leaching of DEHP from DEHP-plasticized PVC tubes to cottonseed oil and paraffin oil at 70 °C. [unmodified PVC tubes in cottonseed oil (-□-), and in paraffin oil (-■-), and PEG 400-grafted PVC tubes in cottonseed oil (-△-), and in paraffin oil (-▲-)]. Reprinted from Ref. [41], © (1998), with permission from Blackwell Publishing Ltd.

Nucleophilic substitution to surface-crosslink plasticized PVC was also studied by replacing chlorine atoms in medical grade PVC tubes with thiosulfate anions in aqueous media in the presence of a phase transfer catalyst, tetrabutylammonium hydrogen sulfate [43]. Tubes were then sterilized by autoclaving and by gamma irradiation. This treatment resulted in a hydrophilic polymer surface, which showed significant leaching resistance for DEHP in hexane (Table 5). This can be attributed to the presence of hydrophilic sulfonate and thiosulfate groups on the surface acting as a barrier to diffusion of the plasticizer as well as to some extent the surface crosslinking, caused by chain scission during gamma sterilization. However, the surface-modified PVC showed accelerated leaching of DEHP in cottonseed oil and PEG 400. This modified PVC surface was also found to be cytotoxic in nature and therefore cannot be used in contact with living tissue.

Table 5
Amount of DEHP leached out into hexane at 30 °C from thiosulfate-substituted PVC tubes subjected to different modes of sterilization [40]

| Sample | Mode of sterilization | Incubation time in hexane | DEHP migrated ^a (wt%) |
|------------------------------|-----------------------|---------------------------|----------------------------------|
| Unmodified PVC | Unsterilized | 24 h | 27.07 ± 0.8 |
| Unmodified PVC | Autoclaved | 24 h | 27.32 ± 0.9 |
| Unmodified PVC | Gamma | 24 h | 25.88 ± 0.4 |
| Thiosulphate substituted PVC | Unsterilized | 30 days | 0.14 ± 0.002 |
| Thiosulphate substituted PVC | Autoclaved | 30 days | 0.18 ± 0.005 |
| Thiosulphate substituted PVC | Gamma | 30 days | 0.02 ± 0.008 |

^a Average of three determinations.

4.1.1.3. Surface coating. Leaching and migration of plasticizers from polymer surface can be reduced by coating the polymer surface with some non-migrating material. But these coatings are usually thick and may often cause a reduction in flexibility of the polymeric materials. However, a surface modification technique that could be useful to prevent leaching and migration of plasticizers is chemical vapor deposition (CVD), which is generally used to coat complex substrates like fibers or the inner surfaces of tubes. Usually, CVD requires high coating temperatures, which make it impossible to coat temperature-sensitive materials like polymers with titanium (Ti)-based layers. But a new plasma-assisted chemical vapor deposition (PACVD) process was developed to coat polymers at very low temperatures with Ti-based layers [44]. PVC and five other commercial polymers were coated using the precursor $Ti[N(C_2H_5)_2]_4$ with the carrier gases hydrogen (H_2) and nitrogen (N_2). The coating was found to be an effective diffusion barrier to prevent leaching of DEHP from PVC. Additionally, the Ti–C–N coatings have the potential to improve the blood compatibility of polymers. Besides medical applications, this new coating makes it possible to improve the wettability, corrosion stability or electrical conductivity of polymers.

4.1.1.4. Surface extraction. The removal of plasticizer from the polymer surface by surface extraction is another method proven successful at reducing diffusion and leaching in polymer systems [45,46].

In surface extraction, a material is briefly exposed to a solvent for the plasticizer, and then dried. This leaves the polymer with a non-uniform distribution of plasticizer and a rigid surface which blocks interfacial mass transfer of the plasticizer. However, this rigid surface affects the flexibility of the polymer to some extent. Fugit et al. [47] proposed this technique to resist the leaching of plasticizer from plasticized PVC. Plasticized materials were first briefly soaked in *n*-heptane and then dried. Both the extraction and drying times and temperatures were varied to find the optimum result. This treatment reduced the leaching of DEHP from plasticized PVC into liquid food or a stimulant by more than 50%, and also introduced a significant lag time for leaching, as shown in Fig. 4. While this technique may be useful for sporadic exposure to a solvent, it is not a solution that prevents leaching permanently.

While different surface modification technique discussed in this section were found to successfully prevent leaching of plasticizers into different solvents, there are a number of trade-offs that can change other polymer properties such as flexibility, thermal stability, surface characteristics and appearance. These properties, along with the added expense of any of these treatments, must be considered so that optimal materials can be designed for each application.

4.1.2. Polymeric plasticizers and oligomers

Polymeric plasticizers have a great advantage in their inherent low volatility and are now being studied as replacements for traditional plasticizers. They can be designed so that they are highly compatible with the host polymer, and leaching and volatility issues have been significantly improved over traditional plasticizers. However, polymeric plasticizers are usually expensive and have lower plasticizing efficiency than most traditional plasticizers.

In a long-term study, medical grade PVC, plasticized with a 58 phr polycaprolactone-polycarbonate (PCL-PC) blend of $M_n \sim 32,700$, experienced negligible leaching while samples were kept in water or phosphate buffer at 37 °C for 98 days [48]. Only a trace amount of 6-hydroxyhexanoic acid, the final hydrolysis product of PCL-PC, was detected in the leachate and there was no notable weight loss. Even when the aging temperature was raised to 70 °C, only a minor increase in the amount of 6-hydroxyhexanoic

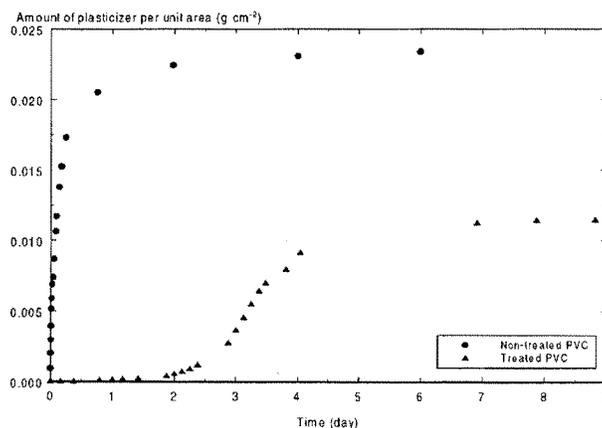


Fig. 4. Amount of DEHP (per unit surface area of PVC samples plasticized with 35 wt% DEHP) leached out into *n*-heptane from surface-extracted and non-extracted PVC sheets at 30 °C. Reprinted from Ref. [47], © (2003), with permission from John Wiley and Sons, Inc.

acid was observed and the weight loss after 98 days was less than 1%.

While the observation that polymeric plasticizers can reduce leaching is not surprising, the MW of polymers incorporated as plasticizers plays an important role in determining the properties of the end product. It has been found that the flexibility of the polymeric material as well as diffusion and migration of plasticizer within the host polymer is directly related to the MW of the polymeric plasticizer used. The polymeric plasticizer poly(1,3-butylene adipate), PBA, was found to have better migration resistance than DEHA and DEHP, plasticizers typically used in PVC-based cling films [49]. Shah et al. [50] also studied the effect of replacing DEHP by the polymeric plasticizer PBA ($M_n = 1200$), in PVC. It was found that PBA induced significant resistance to leaching in petrol and kerosene (Fig. 5) and migration resistance to silica (Fig. 6). PBA's extraction resistance was attributed to its higher MW. A study of the leaching of different MW PBA plasticizers from a PVC film into olive oil indicated preferential leaching of the lower MW species [51]. The oligomers with MW between 300 and 1100, which comprised 24% of the parent plasticizer, accounted for more than 90% of

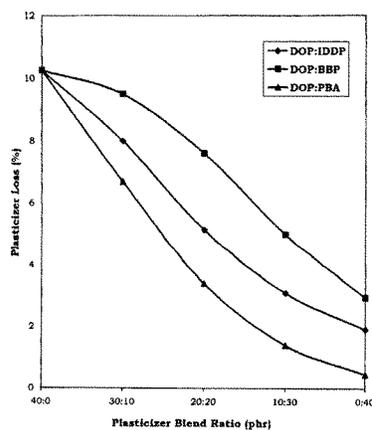


Fig. 5. Leaching of plasticizers from PVC in kerosene at room temperature for 24 h, obtained by systematic replacement of diethylhexyl phthalate (DOP) by isodecylidiphenyl phosphate (IDDP), butylbenzyl phthalate (BBP) or poly(butylene adipate) (PBA) as plasticizers. Reprinted from Ref. [50], © (2003), with permission from John Wiley and Sons, Inc.

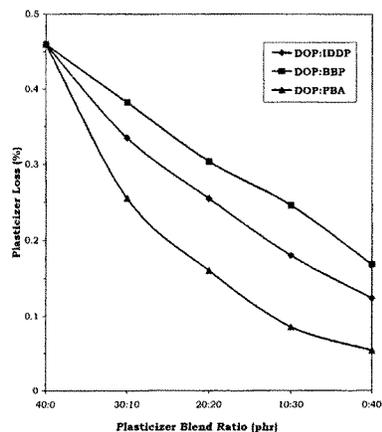


Fig. 6. Solid-migration of plasticizers from 50 mm diameter PVC discs to two 30 ml layers of finely divided silica, obtained by systematic replacement of diethylhexyl phthalate (DOP) by isodecylidiphenyl phosphate (IDDP), butylbenzyl phthalate (BBP) or poly(butylene adipate) (PBA) as plasticizers. Reprinted from Ref. [50]. © (2003), with permission from John Wiley and Sons, Inc.

the plasticizer leaching. The smallest oligomers leached out 90-fold more readily than the bulk plasticizer.

While polymeric plasticizers may cause a reduced flexibility in plastic materials, they can also be used in combination with traditional plasticizers to improve leaching resistance of the latter. A terpolymer of ethylene, vinyl acetate and carbon monoxide (EVACO), with reported MW of 240200, was used to plasticize food grade PVC along with DEHA [52]. EVACO was able to reduce the leaching of DEHA, in the organic extractant isooctane, literally to zero. Plasticizers of this type might allow us to prevent leaching of plasticizers as well as formulate plastics with desired mechanical properties.

Polymeric plasticizers and oligomers are now being produced commercially. A wide variety of these plasticizers are available to provide desired properties to different polymers. Manufacturers including P.A.T. Products, Inc., Environmental Protection Inc., and Velsicol Chemical Corp. are engaged in producing low viscosity polymeric plasticizers

and these innovations are being introduced to the current plasticizer market. For example, Bayer Chemicals recently started producing a new polymeric plasticizer, Ultramoll[®] VP SP 51022, which is a low-viscosity polymeric plasticizer based on phthalic acid [53]. This particular plasticizer is characterized by good migration resistance and high thermal stability. Plastic moldings, cable sheathing and cords with a wide range of hardness and elasticity can be produced using this plasticizer.

4.1.3. Alternative plasticizers

Extensive research is going on to find alternative plasticizers for medical and other commodity plastic materials. Several alternatives have been suggested so far. Some offer better compatibility with polymers, while some show less migration and leaching tendency. However, the toxicological information about many of them are unknown. Also many are expensive and the mechanical properties offered are different than those offered by the traditional plasticizers. So the quest for novel plasticizers continues.

Morflex, Inc., set out to find a suitable, less toxic replacement for DEHP and developed Citroflex[®] A-6 and Citroflex B-6 based on citric acid esters which are bio-based and biodegradable. Initial toxicity tests conducted by the Pfizer Drug Safety Evaluation Department proved citrates to be safe through acute dermal toxicity and ocular irritation tests in rabbits, and acute oral toxicity tests in mice and rabbits [17]. Also, the citrate-based plasticizers did not induce gene mutation when tested in microbial cells and mammals. However, in later animal studies, citrates were found to cause respiratory irritation, nervous system effects, and effects on blood pressure and calcium metabolism [24]. Tests conducted by Morflex, Inc., showed that Citroflex B-6 was an ideal candidate replacement for DEHP since it provided similar properties to PVC, when combined with ESO [17]. Yet it had poor oil extraction properties compared to DEHP. So, citrates are best suited for medical plastics not exposed to high lipid media. They are being used as plasticizers in packaging and medical devices for years. However, health effects arising from long-term exposure to citrates in medical devices have not been widely studied.

Bayer Chemicals invented phenol alkyl sulfonate plasticizers and is producing them under the trade

name Mesamoll[®] [54]. These sulfonates have been proven to be effective for a number of polymers including PVC and polyurethanes. This class of plasticizers has outstanding gelling capacity which offers reduced processing time and temperature. Their main advantage is that they have significantly greater saponification resistance than phthalate plasticizers and display a much reduced tendency to leach out, which is particularly important for biomedical plastics exposed to warm, aqueous media for an extended period of time. Also, PVC plasticized with Mesamoll has shown improved tear strength and resistance to weathering and light. These plasticizers are typically used in sealing and adhesive systems, swimming pool covers, shower curtains, rain-wear and in automotive industries.

Ionic liquids (ILs) are a relatively new class of compounds that have been investigated as plasticizers for PVC and poly(methyl methacrylate), PMMA, and were found to be compatible with both the polymer systems [55–57]. Fig. 7 shows the structures of some ILs studied as plasticizers for the abovementioned polymer systems. ILs have already gained wide recognition as potential environmentally-benign solvents [58]. ILs have low volatility, low melting points (as low as -96°C has been reported), a wide (often $\sim 400^{\circ}\text{C}$) liquid range, are high-temperature stable, nonflammable

and are compatible with a wide variety of organic and inorganic materials. It was found that a number of imidazolium-, ammonium- and phosphonium-based ILs are capable of producing flexible PVC as does DEHP [57]. Leaching of plasticizers from 20 wt% plasticized PVC samples to water was studied at 50°C for 5 days [59]. An ammonium-based IL, tetrabutylammonium dioctylsulfosuccinate [$\text{tbam}^{+}][\text{doss}^{-}]$, showed much less leaching tendency than the widely used plasticizer DEHP. In a study of migration of plasticizers, phosphonium- and ammonium-based ILs showed excellent migration resistance. Further research is being conducted to examine the leaching resistance of a wide number of ILs in aqueous and saline solutions, when used as plasticizers in PVC.

4.1.4. Alternative polymers

While many researchers have investigated the approach of using alternative plasticizers to minimize leaching of plasticizers, some researchers have focused on replacing PVC-DEHP systems with alternative polymers. Polyolefins are currently popular because of their ease of processing, low cost and durability [24]. Metallocene polyolefins have been especially popular due to their narrow MW distribution and flexible nature that requires only a small amount of additives. Hence, they are not readily subjected to problems like leaching

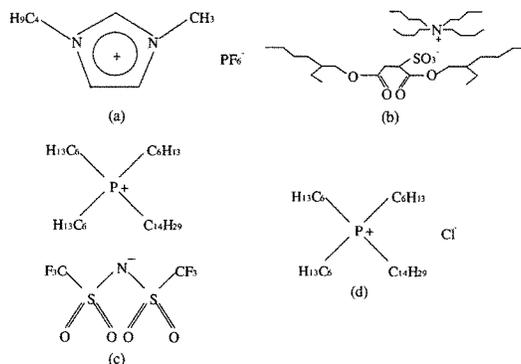


Fig. 7. Structure of some ILs studied as plasticizers for PVC and PMMA: (a) 1-butyl-3-methylimidazolium hexafluorophosphate, (b) tetrabutylammonium dioctylsulfosuccinate, (c) trihexyl(tetradecyl) phosphonium bis(trifluoromethyl)sulfonylimide, and (d) trihexyl(tetradecyl) phosphonium chloride.

and migration. They also produce materials with good mechanical properties. These polyolefins have already started pushing PVC out of the IV bag market. EVA also competes with PVC due to its capability of ranging from a thermoplastic to an elastomeric state depending on the vinyl acetate content in the polymer. It does not need plasticizer and retains its mechanical properties well over time. However, there are instances where the use of PVC plasticized with DEHP is actually favorable and does not need a replacement. For example, in red blood cell storage bags, DEHP has been shown to bind to the cells and stabilize them, extending their shelf life [24]. Polyesters, polyurethane, and silicone are some of the other competing technologies in medical plastics.

4.2. Thermal aging and evaporation of plasticizers

Current research is focused on analyzing the mechanisms of plasticizer evaporation, finding new high temperature stable plasticizers, and implementing measures to inhibit loss of plasticizer at high temperatures. Since some polymers are unstable at elevated temperatures (notably PVC, which begins to degrade above 100 °C) [5], improved plasticizers are not going to be able to impart high temperature stability to every polymer. However, for specialty applications, especially flexible plastics that operate near moving parts or are subjected to rapid extension and contraction cycles, improved plasticizers may offer significant benefits in longer material lifetimes as well as the possibility of working with flexible materials at temperatures well above the range of today's plastics.

Mrklic et al. [60] studied thermal aging DEHP-plasticized PVC systems and suggested that the rate of evaporation of plasticizers can be represented by a linear first order differential equation. Different kinetic parameters were also analyzed. Values of activation energy were found to rise with increasing plasticizer content. Interfacial mass transport in the surrounding medium was detected as the rate-controlling step in the physical process of plasticizer loss. Later on, the same researchers did a comparative study between a number of phthalates and other commercial plasticizers [61]. All of the plasticizers showed the same kinetic behavior earlier observed with DEHP, while Reofos[®], a phosphate plasticizer,

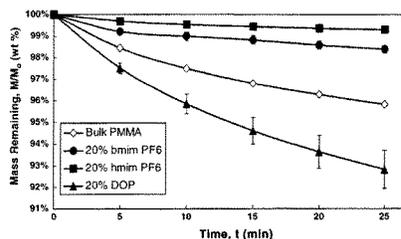


Fig. 8. Short-term thermal stability of bulk PMMA and samples containing 20 wt% 1-butyl-3-methylimidazolium hexafluorophosphate [bmim⁺][PF₆⁻], 20 wt% 1-hexyl-3-methylimidazolium hexafluorophosphate [hmim⁺][PF₆⁻], and 20 wt% di(2-ethylhexyl) phthalate (DOP) at 250 °C. Reprinted from Ref. [56], © (2003), with permission from Elsevier.

showed the highest activation energy barrier to evaporation.

Some new carboxylate esters containing one or more sulfhydryl groups have been found to be remarkably effective as both plasticizers and thermal stabilizers for PVC [62]. These esters function well as primary stabilizers in the absence of metal-containing additives and also lubricate the polymer significantly. In addition to the fact that sulfhydryl groups are effective in removing poisons and toxins, they have the advantage of not having any heavy metal

Table 6

Long-term thermal stability of bulk PMMA and samples plasticized with 1-butyl-3-methylimidazolium hexafluorophosphate [bmim⁺][PF₆⁻] and di(2-ethylhexyl) phthalate (DOP) at 170 °C for 21 days [53]

| Plasticizer and content | Sample mass loss (wt% of initial plasticized polymer) (%) | Plasticizer mass loss (wt% of initial plasticizer) ^a (%) |
|---|---|---|
| None (bulk PMMA) | 2.3 | 0 |
| 10% [bmim ⁺][PF ₆ ⁻] | 2.9 | 8.3 |
| 15% [bmim ⁺][PF ₆ ⁻] | 3.4 | 9.6 |
| 20% [bmim ⁺][PF ₆ ⁻] | 4.6 | 13.8 |
| 30% [bmim ⁺][PF ₆ ⁻] | 5.7 | 13.6 |
| 35% [bmim ⁺][PF ₆ ⁻] | 6.7 | 14.9 |
| 40% [bmim ⁺][PF ₆ ⁻] | 6.9 | 13.8 |
| 20% DOP | 15.2 | 66.8 |
| 30% DOP | 24.2 | 75.3 |

^a Assuming 2.3 wt% of the polymer mass in each sample decomposed at 170 °C.

component which brings about the debate concerning toxicity of the typical heat stabilizers.

ILs, when studied as plasticizers, were also found to increase the thermal stability of polymers [55,56]. Imidazolium-based hydrophobic ILs were incorporated into PMMA and were found to be compatible with PMMA up to 50 vol% as plasticizers. In addition to lowering the T_g of PMMA ($\sim 120^\circ\text{C}$ when unplasticized) as low as $\sim 20^\circ\text{C}$, and producing polymer samples with mechanical properties similar to those produced by DEHP, the ILs offered far better high temperature stability when compared to DEHP in both short-term (Fig. 8) and long-term (Table 6) experiments. As a plasticizer for PVC, a phosphonium-based IL, trihexyl(tetradecyl) phosphonium bis(trifluoromethane)sulfonylimide, showed superior short-term high temperature stability compared to DEHP [57].

While higher MW polymeric plasticizer PBA was able to produce flexible PVC, it also offered better thermal stability by increasing the onset temperature for degradation when 40 phr DEHP was completely replaced by 40 phr PBA [50].

4.3. Low temperature lubricating plasticizers

Developing new plasticizers that maintain lubricity at temperatures under subzero conditions would provide new materials with reduced low temperature failure, and can be used in such areas as space exploration, and storage of liquefied gases. When more and more plasticizer is added to a polymer, the T_g drops and usually tends to level out when the plasticizer reaches a maximum solubility. But with imidazolium-based ILs as plasticizers for PMMA, the T_g of PMMA showed no sign of leveling out even after being lowered by 100°C from the original value at 50 vol% plasticizer concentration [56]. ILs are known to have melting points as low as -96°C [58] and therefore have the potential to offer satisfactory lubrication to polymers at subzero temperatures.

4.4. Improving health and environmental issues

While point-source pollution can be approached in traditional ways, there are a number of techniques which could help minimizing health and environmental problems owing to the use of leachable plasticizers. One simple way to do this is the use of

alternative flexible polymers (e.g. polyolefins), which require less or no plasticizers [24]. Health and environmental issues can also be improved by reducing the exposure of plasticizers through different surface modification techniques and by using plasticizers that have less volatility and leachability, or by using lower toxicity plasticizers.

4.4.1. Reducing exposure

In Section 4.1, a number of surface modification techniques have been described by which leaching and migration of plasticizers from plastic to adjacent solid, liquid and gaseous media can be reduced. Research to prevent leaching of plasticizers by polar media was instigated by the need for benign biomedical plastics which have less probability of adverse health and environmental effects. Much of the early work on reducing leaching focused on organic extractants, as the plastics were used in various industrial applications. Likewise, early research on biomaterials focused on the biocompatibility of plastic surfaces by minimizing interactions between biomaterial surfaces and biological tissues or blood. Several approaches have been used to enhance the biocompatibility of flexible plastics, especially to prevent protein deposition on plastic surface caused by leaching of DEHP. In the early 1980s, leaching of DEHP during platelet storage in glow discharge-treated and then silicone-coated PVC bags was studied [63]. Glow discharge treatment can introduce different functional groups, cause chain crosslinking or chain scission at the polymer surface. DEHP leaching from PVC bags to blood during platelet storage was reduced from 150 to 200 $\mu\text{g}/\text{ml}/\text{day}$ in untreated PVC to 10–20 $\mu\text{g}/\text{ml}/\text{day}$ in treated PVC bags.

When grafting of PEG on plasticized PVC surface successfully reduced leaching of plasticizer DEHP in three different organic solvents [41], the blood compatibility of the PEG-grafted and ungrafted PVC sheets was evaluated by open-static platelet adhesion studies with platelet rich plasma and this treatment was actually found to reduce the interaction between blood and the polymer surface. The improved blood compatibility of PEG-grafted PVC can be seen in the scanning electron micrographs of platelet adhesion on ungrafted and PEG 4000-grafted PVC sheets (Fig. 9), where the bare PVC surface promoted extensive adhesion of platelets leading to a rough and

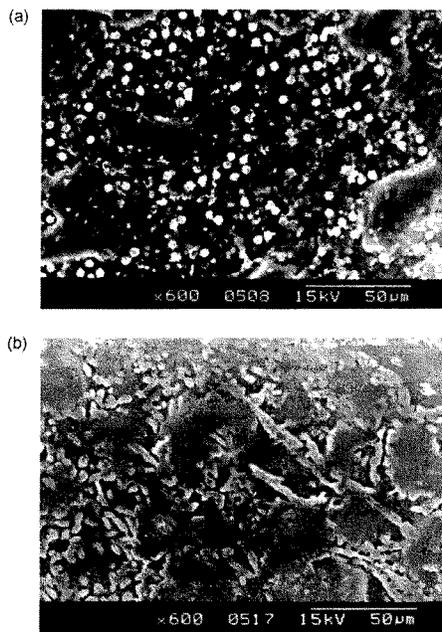


Fig. 9. SEM micrograph of (a) ungrafted and (b) PEG 4000-grafted PVC sheets after being incubated in platelet-rich plasma for 1 h at 37 °C. Reprinted from Ref. [41], © (1998), with permission from Blackwell Publishing Ltd.

nonuniform surface. On the other hand, the plain surface of the PEG 4000-grafted samples is a clear indication of the anticoagulant nature of the graft-modified surface. It was further confirmed by the whole blood clotting time measurements, with ungrafted samples showing much less clotting time compared to the PEG-grafted ones. Grafting PVC with PEG did not alter the mechanical properties of PVC samples in any significant way. Blood compatibility of plasticized PVC was also found to improve with PACVD technique mentioned earlier [44].

Kicheva et al. [34] found that paraffin and complexon coatings can improve the biocompatibility of PVC by providing complete resistance to protein deposition while providing a barrier to DEHP leaching. However, both of these materials have

drawbacks. Complexon coatings are likely to be washed away by flowing blood, while paraffin may crack on bending and therefore is not recommended for long-term use in drain tubes or other biomaterials.

As has already been mentioned, polymeric plasticizers, due to their high MW, have been found to offer good leaching and migration resistance to a number of solvents [48–53], and so did the ILs [59]. These plasticizers have low volatility which also reduces the possibility of off-gassing, thereby reducing the possibility of environmental exposure and offering less health and safety concern regarding plasticizers.

4.4.2. Lower toxicity plasticizers

The use of environmentally-benign plasticizers is another way to improve the health and environmental

issues concerning plasticizers. Among the number of factors that decide the feasibility of a substance to be used as a plasticizer, toxicological information is an increasingly important one. If the plasticizers used have less toxicological effects on living beings, they are obviously less likely to pose health risks upon exposure.

To address the toxicity issue of phthalates, a joint effort by the Ohio Soybean Council and Battelle led to the development of a new plasticizer derived from modified soybean oil [64]. In the past, commercial soybean oil-based plasticizers were not compatible with PVC at the levels needed for primary plasticizers such as phthalates and benzoates. The newly developed environmentally-friendly plasticizer has been found to be fully compatible with PVC, offers more stretching ability than its petroleum-based counterpart, and is also capable of providing high thermal stability unlike many synthetic plasticizers (e.g. DEHP). Being highly effective and based on a renewable agricultural resource, this soy-based plasticizer offers many benefits over existing products. Toxicology and leaching studies are currently in progress.

A new benzoate plasticizer, Benzoflex[®] 2888 (a blend of diethylene glycol dibenzoate, triethylene glycol dibenzoate, and dipropylene glycol dibenzoate), has been developed by Velsicol Chemical Corporation to account for the leaching problems associated with application of leachable plasticizers in children's toys [65]. Benzoflex has been found to be a good alternative of phthalates as plasticizer when used in flexible toys due to its ease of processing, final product performance, low toxicity and fast biodegradation. Toxicity tests performed according to EU protocols yielded low acute toxicity with an oral LD₅₀ value of 3–5 g/kg in rats, and no evidence of reproductive toxicity. Recent risk assessments conducted by the Toy Manufacturers Association proved the extreme unlikelihood of Benzoflex[®] 2888 to pose an adverse health risk and therefore it is currently being used in the toy industry.

Toxicity evaluation can be done on whole organisms, with the LD₅₀ values reported for each route of administration (e.g. oral, ocular, transdermal) and species (e.g. mouse, rabbit) tested. More recently, cytotoxicity studies using cell culture instead of whole organisms have been used in screening for the toxicity of materials. For example, Lampen et al. [66] introduced two new in vitro test systems to detect the carcinogenic and teratogenic effect of certain

compounds on mammals. The experimental protocol monitored F9 teratocarcinoma cell differentiation and activation of peroxisome proliferator-activated receptor (PPAR)-ligand-binding domain in the ovary-reporter cells of Chinese hamsters. A series of phthalate esters and their metabolites including two diphthalate and nineteen monophthalate esters were studied. Only five of them were found to induce F9 cell differentiation (or mutagenesis). The same five esters activated the δ type of PPAR (PPAR δ), while most of others activated PPAR α and PPAR γ . Since three of those five esters were already known teratogenic compounds, the combined result of the differentiation and activation assays actually helped detecting possible teratogenic phthalate esters and derivatives. Thus, these two in vitro experiments can be useful as a screening test in the development of new plasticizers.

4.5. Flammability

Knowing that fire hazards concerning plastic materials can be reduced by reducing the flammability of the plasticizers incorporated in the polymers, a number of researchers have tried alternative plasticizers as replacements. A newly developed alkyl diaryl phosphate plasticizer originally marketed by Monsanto Company under the trade name SAN 2148 was studied as a plasticizer for chlorinated PVC (65% Cl) and results were compared to those with DEHP [15]. Two standard flammability parameters were determined: limiting oxygen index (LOI) and smoke density measurement (flaming mode). With the incorporation of equal amounts of either plasticizer, SAN 2148 gave higher LOI and char values. More significantly, SAN 2148 lowered smoke density values in many of the formulations studied. Another benefit of using SAN 2148 as a direct replacement of DEHP is that the phosphate plasticizers appear to stabilize the formulations against thermal decomposition, especially in those systems containing mixtures of flame-retardant and smoke-suppressant.

Another newly developed environmentally-friendly plasticizer, ethylenedioxysephenone (EDOS), was studied as an alternative plasticizer to DEHP [67]. PVC was plasticized using either DEHP or EDOS, which is a mixture of 1,3 dioxane derivatives. EDOS matched the ability of DEHP to

produce flexible PVC, and was less toxic, cheaper and reduced the amount of dioxin-equivalent incineration product formed during burning.

Polymeric plasticizer PBA, which offered good leaching and migration resistance and high temperature stability, also improved the flammability characteristics of PVC by increasing the limiting oxygen index [50]. This was probably due to the higher flash point of the plasticizer used.

ILs represent another viable approach to reduce flammability concern regarding plasticizers. All the commercial plasticizers, even the phosphate esters, are known to lower the LOI of the compound with increasing plasticizer concentration [68]. ILs have been proposed to be flame-retardant plasticizers, because they are known for their nonflammability [58].

4.6. Ultraviolet stability

In many cases, UV stabilizers are added to plastic formulations, but the development of plasticizers that have the added capability to delay or halt UV-induced polymer degradation could minimize the need for stabilizers. Rahman et al. [57] investigated the stability of PVC plasticized with ILs and traditional plasticizers under UV rays at $\lambda = 254$ nm. After a short-term (1 min) exposure, sample moduli were increased for all the samples probably due to crosslinking effect. The samples containing trihexyl(tetradecyl) phosphonium bis(trifluoromethane)sulfonylimide, a phosphonium-based IL, as plasticizer went through minimum change in moduli and were able to retain original properties most effectively. Stability of plasticized PVC under UV irradiation of different intensities is currently being studied.

4.7. Plasticizers for biodegradable polymers

One of the most important factors in designing biodegradable polymers is the rate of degradation of the product. A number of plasticizers have been investigated to be used with biodegradable polymers. Citrate plasticizers, being biodegradable esters, gained much attention. PLA, which has been extensively studied in medical implants, suture, and drug delivery systems since the 1980s due to its biodegradability, was plasticized with four

commercially available citrate plasticizers: triethyl, tributyl, acetyltriethyl and acetyltributyl citrate [69]. The plasticizing effects on thermal and mechanical properties of PLA were satisfactory in that the citrate esters produced flexible materials. The high MW citrates also reduced the degradation rate of PLA. However, a considerable amount of plasticizer loss was encountered during processing, especially with the lower MW citrates. Elsewhere, citrate esters were used to plasticize cellulose acetate, and the biodegradation rates increased dramatically with an increase in plasticizer content [70].

Polyols are another class of compounds which have been studied as plasticizers for biodegradable polymers. Glycerol, which is often used with biodegradable polymers, was found to reduce degradation of thermoplastic starch (TPS). Starch, a polysaccharide found abundantly in plants, is not a thermoplastic material itself. But at moderately high temperatures (90–180 °C), under pressure and shear stress, starch granules melt and flow to give an amorphous material called TPS, which can be processed just like a thermoplastic synthetic polymer. The utilization of TPS for the production of biodegradable plastics has increased and has been the object of several studies in the last decade. One of the problems associated with TPS processing is degradation of starch. The effects of glycerol in preventing degradation of TPS, reinforced with cellulosic fibers, were observed [71]. An increase in glycerol content reduced chain degradation considerably. However, an increase in the fiber content amplified it.

In another experimental study, glycerol, ethylene glycol (EG), propylene glycol (PG), diethylene glycol (DEG) and triethylene glycol (TEG) were tested as plasticizers for a biodegradable polymer based on a sunflower protein and aging properties were observed [72]. Films with high-quality mechanical properties were formed which had shear strength similar to that of the low-density polyethylene used in agricultural mulching. They were also sufficiently impermeable to water vapor. An aging study showed that the relatively lighter plasticizers (PG, EG, DEG) were lost over time. However, there was no marked loss of glycerol or TEG over the 3-month aging period. These two plasticizers have the advantage of being suitable for use in the food industry as they are on

the FDA's Generally Regarded As Safe (GRAS) list. Glycerol was found to be an excellent plasticizer for starch [73] and edible gellan films too [74], while PEG 400 was found to be effective at imparting flexibility to methylcellulose [75].

The group of Boutevin investigated two new amine-based plasticizers for biopolymer films made of wheat gluten, which is used for food-packaging [76]. Glycerol is the most used plasticizer for wheat gluten films. But glycerol causes the film to have high water-vapor permeability and often migrates from gluten films due to its high sensitivity towards moisture. Diethanolamine and triethanolamine were studied as plasticizers which did not change water vapor barrier properties of gluten films, but significantly increased extensibility and elasticity at moderate relative humidity, RH (Table 7). However, at high RH, the effects of plasticizers were overshadowed by the large amount of moisture absorbed by the polymer films.

Tarvainen et al. [77] studied the effectiveness of two *n*-alkenyl succinic anhydrides (ASAs), 2-octenyl succinic anhydride (OSA) and 2-dodecen-1-ylsuccinic anhydride (DYA) as plasticizers for the film-forming polymer ethyl cellulose (EC). OSA is typically used to increase drug dissolution properties of starch and also in the chemical and paper industries, as an oil-phase corrosion inhibitor. The principle of the experiment was to investigate the plasticizing

effectiveness of the long hydrocarbon chains with accessible carbonyl groups. Triethyl citrate (TEC) and dibutyl sebacate were used as reference plasticizers. Due to the excellent mechanical properties (a tough film structure with considerable flexibility) and low permeability of the plasticized films, both the *n*-ASAs, especially OSA, proved to be ideal plasticizers for EC-based coatings at 30 wt% or higher concentrations.

Methylparaben (methyl-*p*-hydroxybenzoate), which is GRAS and is used in the cosmetics industry and as a preservative in the pharmaceuticals industry, was studied as a solid-state plasticizer for a thermally stable pharmaceutical grade acrylic polymer, Eudragit[®] RS PO, during a hot-melt extrusion process [78]. The T_g , melt viscosity and rheological properties of the extrudates containing methylparaben were compared with the extrudates containing traditional plasticizers. It was found that methylparaben was as effective as traditionally used TEC in reducing torque during the extrusion process. Solid state NMR spectra indicated a change in the chemical shift of Eudragit RS PO plasticized with methylparaben, which could be ascribed to an interaction between the hydroxyl group of the methylparaben and the ester group of the Eudragit RS PO polymer. The results of this study demonstrated that methylparaben could be used as a solid-state plasticizer for the Eudragit RS PO

Table 7
Effects of plasticizer concentration and relative humidity on the mechanical properties of gluten films [72]

| Plasticizer | | σ_R (MPa) | ϵ_R (%) | E (MPa) |
|------------------------------------|----------------------------|------------------|------------------|------------|
| Compound | Concentration (g/100 g dm) | | | |
| <i>Panel A: results at 58% RHs</i> | | | | |
| Glycerol | 10 | 12.1(2.3) | 4(1) | 5.7(1.9) |
| | 20 | 2.6(1.1) | 22(10) | 2.6(1.1) |
| Diethanolamine | 10 | 7.5(2.9) | 9(5) | 2.3(1.6) |
| | 20 | 4.1(1.9) | 125(8) | 0.1(<0.1) |
| Triethanolamine | 10 | 10.1(1.5) | 6(2) | 0.1(0.1) |
| | 20 | 5.3(1.2) | 114(8) | 0.1(0.1) |
| <i>Panel B: results at 98% RHs</i> | | | | |
| Glycerol | 10 | 0.4(0.1) | 11(4) | 0.1(<0.1) |
| | 20 | 0.9(0.2) | 30(6) | 0.1(<0.1) |
| Diethanolamine | 10 | 1.0(0.1) | 61(11) | <0.1(<0.1) |
| | 20 | 0.8(0.3) | 58(11) | <0.1(<0.1) |
| Triethanolamine | 10 | 1.3(0.9) | 103(10) | <0.1(<0.1) |
| | 20 | 0.8(0.2) | 54(9) | <0.1(<0.1) |

σ_R , tensile strength at break; ϵ_R , elongation at break; E , Young modulus.

polymer when a hot melt extrusion technique is employed in the preparation of sustained release tablets.

The extensive use of polymers in short-term packaging and disposable applications, and in food and pharmaceutical industries, has stimulated research interest in biodegradable plasticizers as an alternative to the conventional nondegradable ones. This is one of the major research interests in the plasticizer industry now. With the expansion of biodegradable plastic industry, owing to the growing global concern about the environmental impact of persistent plastics, biodegradable plasticizer research continues to grow.

5. Conclusions

Plasticizers form a major part of the plastic industry. The diversified applications of plastics in numerous fields of applications largely depend on the performance of the plasticizers incorporated. In the past century, the plasticizer industry came across a number of technical challenges. Leaching and migration of plasticizers have been reduced by methods including surface crosslinking, grafting, and surface extraction, the use of alternative and novel plasticizers and also the use of alternative polymers which do not require plasticizers. Many of these methods to prevent leaching and migration of plasticizers have been developed on a case-by-case basis, where different methods were successful for particular solvents or plasticizers. Research is being carried out worldwide in both academic and industrial laboratories to provide tunable solutions to the leaching and migration issues. Also, plasticizers are being sought to improve the biocompatibility of flexible plastics since they are widely used in medical applications.

High temperature stable plasticizers are under investigation to provide materials that meet demanding work environments. New and modified plasticizers have also been developed to impart nonflammable properties to polymers. With the extensive growth in the biodegradable polymer market, a major portion of plasticizer research is now focused on materials which are GRAS and are capable of providing flexibility to polymers. As

the plastic industry continues to expand, new challenges arise for the plasticizer industry. Thus, different approaches to resolve the shortcomings of traditional plasticizers for use in a multitude of plastic materials have led to the continuing quest for specialty plasticizers.

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References

- [1] Murphy J. Additives for plastics handbook, 2nd ed. New York: Elsevier; 2001.
- [2] Lerner I. Plasticizers to reach \$8 billion by 2004. Look Smart. Ltd; 2003. http://www.findarticles.com/cf_dls/m0FVP/9_258/65462810/p1/article.jhtml
- [3] Rosen SL. Fundamental principles of polymeric materials, 2nd ed. New York: Wiley; 1993.
- [4] Fedorko P, Djurado D, Trznadel M, Dufour B, Rannou P, Travers JP. Insulator–metal transition in polyaniline induced by plasticizers. *Synth Metals* 2003;135–136:327–8.
- [5] Matthews G. PVC: production, properties and uses. London, England: Institute of Metals; 1996.
- [6] Frados J, editor. Plastics engineering handbook. 4th ed. New York: Van Nostrand Reinhold; 1976.
- [7] Krauskopf LG. Monomeric plasticizers. In: Wickson EJ, editor. Handbook of PVC formulating. New York: Wiley; 1993.
- [8] Gachter R, Muller H, editors. Plastics additives handbook. 3rd ed. New York: Carl Hanser; 1990.
- [9] VERIS Consulting LLC. APC Plastics Industry Producers' Statistics Group; October 20, 2003. <http://www.american-plasticscouncil.com/benefits/economic/economic.html>
- [10] Modern Plastics Magazine, editor. Plastics handbook. New York: McGraw Hill; 1994.
- [11] Stevens MP. Polymer chemistry—an introduction, 3rd ed. New York: Oxford University Press; 1999.
- [12] Moreno R. The role of slip additives in tape casting technology. 2. Binders and plasticizers. *Am Ceram Soc Bull* 1992;71:1647–57.
- [13] Phthalate Information Center, American Chemistry Council, Inc., 2003. <http://www.phthalates.org/whatare/index.asp>
- [14] Tickner JA, Schettler T, Guidotti T, McCally M, Rossi M. Health risks posed by use of di-2-ethylhexyl phthalate (DEHP) in PVC medical devices: a critical review. *Am J Ind Med* 2001;39(1):100–11.
- [15] Carty P, White S. Flammability studies on plasticized chlorinated poly(vinyl chloride). *Polym Deg Stability* 1999; 63(3):455–63.

- [16] Krauskopf LG. Plasticizers: types, properties and performance. In: Nass LI, Heiberger CA, editors. Encyclopedia of PVC, 2nd ed, vol. 2. New York: Marcel Dekker; 1988.
- [17] Edenbaum J, editor. Plastics additives and modifiers handbook. New York: Van Nostrand Reinhold; 1992.
- [18] Haim J, Hyatt D, editors. International plastics handbook. 3rd ed. New York: Carl Hanser; 1995.
- [19] Wypych G. Plasticizer types. In: Wypych G, editor. Handbook of plasticizers. Toronto, Ont.: ChemTec Publishing; 2004.
- [20] Foldes E. Study of the effects influencing additive migration in polymers. *Die Angewandte Makromolekulare Chemie* 1998; 261/262(1):65–76.
- [21] Marvel CS, Horning EC, editors. Organic chemistry. 2nd ed. New York: Wiley; 1943.
- [22] Starnes WH. Structural and mechanistic aspects of the thermal degradation of poly(vinyl chloride). *Prog Polym Sci* 2002; 27(10):2133–70.
- [23] Tullo AH. Plastics additives' steady evolution. *Chem Eng News* 2000;78(49):21–31.
- [24] Tickner JA, Rossi M, Haiama N, Lappe M, Hunt P. The use of di(2-ethylhexyl) phthalate in PVC medical devices: exposure, toxicity and alternatives. Center for Sustainable Production, Lowell, MA; 1999. <http://www.sustainableproduction.org/downloads/DEHP%20Full%20Text.pdf>.
- [25] Jaeger RJ, Rubin RJ. Plasticizers from plastic devices: extraction, metabolism and accumulation by biological systems. *Science* 1970;170:460.
- [26] Jaeger RJ, Rubin RJ. Migration of phthalate ester plasticizer from poly(vinyl chloride) blood bags into stored human blood and its localization in human tissues. *N Engl J Med* 1972;287: 1114–8.
- [27] Sjoberg P, Bondesson U, Sedin E, Gustaffson J. Exposure of newborn infants to plasticizers: plasma levels of di-(2-ethylhexyl) phthalate and mono-(2-ethylhexyl) phthalate during exchange transfusion. *Transfusion* 1985;25(5):424–8.
- [28] Loff S, Kabs F, Witt K, Sartoris J, Mandl B, Niessen KH, Waag KL. Polyvinylchloride infusion lines expose infants to large amounts of toxic plasticizers. *J Pediatr Surg* 2000; 35(12):1775–81.
- [29] Kambia K, Dine T, Gressier B, Bah S, Germe AF, Luyckx M, Brunet C, Michaud L, Gottrand F. Evaluation of childhood exposure to di(2-ethylhexyl) phthalate from perfusion kits during long-term parenteral nutrition. *Int J Pharm* 2003; 262(1–2):83–91.
- [30] Kambia K, Dine T, Azar R, Gressier B, Luyckx M, Brunet C. Comparative study of leachability of di(2-ethylhexyl) phthalate and tri(2-ethylhexyl) trimellitate from haemodialysis tubing. *Int J Pharm* 2001;229(1–2):139–46.
- [31] Startin JR, Sharman M, Rose MD, Parker I, Mercer AJ, Castle L, Gilbert J. Migration from plasticized films into food. I. Migration of di-(2-ethylhexyl) adipate from PVC films during home-use and microwave cooking. *Food Addit Contam* 1987;4(4):385–98.
- [32] Baier RE. The role of surface energy in thrombogenesis. *Bull NY Acad Med* 1972;48:2.
- [33] Penerovski E, Chazova I, Andreeva SV, editors. Basic principles of the synthesis of thromboresistant implantable polymer materials. Current problems of hemostasiology molecular biological and physiological aspects. 12th supplement ed. Moscow: Nauka; 1981. p. 310–25.
- [34] Kicheva YI, Chichovska M. In vitro and in vivo studies of the effect of the concentration of plasticizer di(2-ethylhexyl) phthalate on the blood compatibility of plasticized poly(vinyl chloride) drain tubes. *Biomaterials* 1995;16(7).
- [35] Krizek DT, Mirecki RM. Evidence for phytotoxic effects of cellulose acetate in UV exclusion studies. *Environ Exp Botany* 2004;51(1):33–43.
- [36] Hileman B. Panel concludes phthalate is safe. *Chem Eng News* 2001;79(26):12.
- [37] Hileman B. FDA suggests replacing DEHP in plastics. *Chem Eng News* 2002;80(37):6.
- [38] Sun XS. Biodegradable plastics from wheat starch and polylactic acid (PLA) *Grain Sci Ind.* 2004;March:xxhttp://www.mindfully.org/Plastic/Biodegradable-Wheat-Starch-PLA.htm.
- [39] Audic JL, Epailard FP, Reyx D, Brosse JC. Cold plasma surface modification of conventionally and nonconventionally plasticized poly(vinyl chloride)-based flexible films: global and specific migration of additives into isooctane. *J Appl Polym Sci* 2001;79(8):1384–93.
- [40] Krishnan VK, Jayakrishnan A, Francis JD. Radiation grafting of hydrophilic monomers on to plasticized poly (vinyl chloride) sheets: II. Migration behaviour of the plasticizer from *N*-vinyl pyrrolidone grafted sheets. *Biomaterials* 1991; 12(5):489–92.
- [41] Lakshmi S, Jayakrishnan A. Migration resistant, blood-compatible plasticized polyvinyl chloride for medical and related applications. *Artif Organs* 1998;22(3):222–9.
- [42] Jayakrishnan A, Sunny MC. Phase-transfer catalyzed surface modification of plasticized poly(vinyl chloride) in aqueous media to retard plasticizer migration. *Polymer* 1996;37(23): 5213–8.
- [43] Lakshmi S, Jayakrishnan A. Synthesis, surface properties and performance of thiosulphate-substituted plasticized poly(vinyl chloride). *Biomaterials* 2002;23(24):4855–62.
- [44] Breme F, Buttstaedt J, Emig G. Coating of polymers with titanium-based layers by a novel plasma-assisted chemical vapor deposition process. *Thin Solid Films* 2000;377–378: 755–9.
- [45] Lee PI. Initial concentration distribution as a mechanism for regulating drug release from diffusion controlled and surface erosion controlled matrix systems. *J Cont Release* 1986;4(1): 1–7.
- [46] Huang X, Chestang BL, Brazel CS. Minimization of initial burst in poly(vinyl alcohol) hydrogels by surface extraction and surface-preferential crosslinking. *Int J Pharm* 2002;248(1–2):183–92.
- [47] Fugit JL, Taverdet JL, Guavrit JY, Lanteri P. Treatment of plasticized PVC to reduce plasticizer/solvent migration: optimization with an experimental design. *Polym Int* 2003; 52(5):670–5.
- [48] Hakkarainen M. New PVC materials for medical applications—the release profile of PVC/polycaprolactone–polycarbonate

- aged in aqueous environments. *Polym Deg Stability* 2003; 80(3):451–8.
- [49] Oriol-Hemmerlin C, Pham QT. Poly 1,3-butylene adipate Reoplex[®] as high molecular weight plasticizer for PVC-based cling films-microstructure and number-average molecular weight studied by ¹H and ¹³C NMR. *Polymer* 2000;41(12): 4401–7.
- [50] Shah BL, Shertukde VV. Effect of plasticizers on mechanical, electrical, permanence, and thermal properties of poly(vinyl chloride). *J Appl Polym Sci* 2003;90(12):3278–84.
- [51] Castle L, Mercer AJ, Gilbert J. Migration from plasticized films into foods. 5. Identification of individual species in a polymeric plasticizer and their migration into foods. *Food Addit Contam* 1991;8(5):565–76.
- [52] Audic JL, Reyx D, Brosse JC. Migration of additives from food grade poly(vinyl chloride) films: effect of plasticization by polymeric modifiers instead of conventional plasticizers. *J Appl Polym Sci* 2003;89(5).
- [53] New plasticizer joins Bayer's range. *Addit Polym* 2003; 2003(8):2.
- [54] SpecialChem Newsletter. PVC plasticizer adds value to waterbeds. *Plastics Additives and Compounding*; July 25, 2003 <http://www.specialchem4polymers.com/resources/articles/article.aspx?id=1293>
- [55] Scott MP, Benton MG, Rahman M, Brazel CS. Plasticizing effects of imidazolium salts in PMMA: high temperature stable flexible engineering materials. In: Rogers RD, Seddon KR, editors. *Ionic liquids as green solvents: progress and prospects*. American Chemical Society Symposium Series, vol. 865, 2003. p. 468–77.
- [56] Scott MP, Rahman M, Brazel CS. Application of ionic liquids as low-volatility plasticizers for PMMA. *Eur Polym J* 2003; 39(10):1947–53.
- [57] Rahman M, Brazel CS. Effectiveness of phosphonium, ammonium and imidazolium based ionic liquids as plasticizers for poly(vinyl chloride): thermal and ultraviolet stability. *Polym Preprints* 2004;45(1):301–2.
- [58] Huddleston JG, Visser AE, Reichert WM, Willauer HD, Broker GA, Rogers RD. Characterization and comparison of hydrophilic and hydrophobic room temperature ionic liquids incorporating the imidazolium cation. *Green Chem* 2001;3(4): 156–64.
- [59] Shoff HW, Rahman M, Brazel CS. Leaching and migration resistance of phosphonium-based ionic liquids as PVC plasticizers: a comparative study of traditional phthalate and citrate plasticizers with ionic liquids. *Polym Preprints* 2004; 45(1):295–6.
- [60] Mrklic Z, Kovacic T. Thermogravimetric investigation of volatility of dioctyl phthalate from plasticized poly(vinyl chloride). *Thermochim Acta* 1998;322(2):129–35.
- [61] Kovacic T, Mrklic Z. The kinetic parameters for the evaporation of plasticizers from plasticized poly(vinyl chloride). *Thermochim Acta* 2002;381(1):49–60.
- [62] Starnes WH, Du B, Zaikov VG. Heat stabilization and plasticization by 'plasticizer thiols', a remarkable new class of nonmetallic additives for PVC. *Polym Preprints* 2001; 42(2):881.
- [63] Ishikawa Y, Honda K, Sasakawa S, Hatada K, Kobayashi H. Prevention of leakage of di-(2-ethylhexyl)phthalate from blood bags by glow discharge treatment and its effect on aggregability of stored platelets. *Vox Sang* 1983;45:68–76.
- [64] Soy-Based Plasticizer Makes the R&D 100. Ohio Soybean Council; August 15, 2003 <http://www.soyohio.org/news/press/news.cfm?id=188>
- [65] SpecialChem Newsletter. Benzoate plasticizer for flexible PVC injection moulded toy applications. *Plastics Additives and Compounding*; July 23, 2001 <http://www.specialchem4polymers.com/resources/articles/article.aspx?id=449>
- [66] Lampen A, Zimmik S, Nau H. Teratogenic phthalate esters and metabolites activate the nuclear receptors PPARs and induce differentiation of F9 cells. *Tox Appl Pharm* 2003;188(1): 14–23.
- [67] Gotlib EM, Grinberg LP, Chakirov RR. Composition of incineration products of plasticized PVC materials. *React Funct Polym* 2001;48(1–3):209–13.
- [68] Touchette NW. Flame-retardant plasticizers. In: Wickson EJ, editor. *Handbook of PVC formulating*. New York: Wiley; 1993.
- [69] Labrecque LV, Kumar RA, Dave V, Gross RA, McCarthy SP. Citrate esters as plasticizers for poly(lactic acid). *J Appl Polym Sci* 1997;66(8):1507–13.
- [70] Ghiya VP, Dave V, Gross RA, McCarthy SP. Biodegradability of cellulose acetate plasticized with citrate esters. *J Macromol Sci—Pure Appl Chem* 1996;33:627–38.
- [71] Carvalho AJF, Zambon MD, Curvelo AAS, Gandini A. Size exclusion chromatography characterization of thermoplastic starch composites. I. Influence of plasticizer and fibre content. *Polym Deg Stability* 2003;79(1):133–8.
- [72] Orliac O, Rouilly A, Silvestre F, Rigal L. Effects of various plasticizers on the mechanical properties, water resistance and aging of thermo-moulded films made from sunflower proteins. *Ind Crop Prod* 2003;18(2):91–100.
- [73] Zhai M, Yoshii F, Kume T. Radiation modification of starch-based plastic sheets. *Carbohydr Polym* 2003;52(3):311–7.
- [74] Yang L, Paulson AT. Mechanical and water vapor barrier properties of edible gellan films. *Food Res Int* 2000;33(7): 563–70.
- [75] Park JS, Ruckenstein E. Viscoelastic properties of plasticized methylcellulose and chemically crosslinked methylcellulose. *Carbohydr Polym* 2001;46(4):373–81.
- [76] Mangata JI, Bauduin G, Boutevin B, Gontard N. New plasticizers for wheat gluten films. *Eur Polym J* 2001;37(8): 1533–41.
- [77] Tarvainen M, Sutinen R, Peltonen S, Mikkonen H, Heikkilä KV, Lehto VP, Paronen P. Enhanced film-forming properties for ethyl cellulose and starch acetate using *n*-alkenyl succinic anhydrides as novel plasticizers. *Eur J Pharm Sci* 2003;19(5).
- [78] Wu C, McGinity JW. Influence of methylparaben as a solid-state plasticizer on the physicochemical properties of Eudragit[®] RS PO hot-melt extrudates. *Eur J Pharm Biopharm* 2003;56(1):95–100.



By Messenger and E-Mail

October 15, 2008

The Honorable Barbara Boxer, Chairman
The Honorable James Inhofe, Ranking Member
United States Senate
Environment and Public Works Committee
410 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senators Boxer and Inhofe:

The International Bottled Water Association (IBWA) appreciated the opportunity to testify at the September 10, 2008, hearing on "Quality and Environmental Impact of Bottled Water." Provided below are IBWA's answers to the follow-up questions submitted by Senator Boxer.

Question #1: Public Right to Know

Mr. Doss, you testify that IBWA "believes that consumers should have timely and easy access to information about their bottled water". My staff has searched each IBWA member websites linked to your website and many do not have detailed water quality reports, and many reports that are available omit important information. Also, big bottlers like Aquafina and Dasani are not members of your association, and do not appear to post water quality reports on their websites.

Does this constitute "timely and easy access to information about their bottled water"?

Do you agree that people have a right to know about the quality of their water?

If you believe customers do have a right to know about the quality of their water, then do you also agree that providing simple to understand information about water quality directly to the consumer so they can compare products is the best way to ensure informed consumer choice and accountability for the bottled water industry?

Answer to Question #1

IBWA supports a consumer's right to clear, accurate and comprehensive information about the bottled water products they purchase. All packaged foods and beverages, including bottled water, are subject to extensive U.S. Food and Drug Administration

(FDA) labeling requirements that provide consumers with a great deal of product information. In addition, virtually all bottled water products include a phone number on the label that consumers can use to contact the company and request product information. IBWA believes that the most feasible mechanism for consumers to obtain information not already on the label is through a direct request to the bottler or distributor.

As you noted, IBWA also maintains an online member database, which contains a specific link to our member companies' water quality information and/or contact information that may be used to obtain a particular company's water quality report. In those instances when a water quality report is not included on an IBWA bottled water company's website, there will be a phone number or e-mail address on that website, or on the IBWA website, that a consumer could use to request such information. We believe that these various options provide consumers with timely and easy access to information about their bottled water.

As I mentioned in my written testimony, consumers have many choices in brands of bottled water. If a bottled water company does not satisfy a consumer's request for more information, that consumer is free to make other brand choices. That is not the case with their public water system. Consumers cannot choose which public water system provides the water that is piped into their homes.

Question #2

Mr. Doss, the IBWA put out a press release on March 11, 2008 stating that unlike city tap water, "Experts and Bottled Water Industry Confident that Technical and Safety Measures Used to Produce and Process Bottled Water are Effective in Protecting From Pharmaceutical Contamination." Is all bottled water sold on the U.S. market tested for pharmaceutical contamination?

If not, what percentage is tested for pharmaceuticals, and what are the test results? Please provide documentation supporting your statements to the committee.

Is all bottled water sold on the U.S. market treated with reverse osmosis or other treatment that has been certified to remove pharmaceutical contamination? If not, what percent of bottled water is so treated?

Answer to Question #2

Testing for pharmaceuticals in bottled water is not presently required by the FDA, nor is it required for public drinking water regulated by the U.S. Environmental Protection Agency (EPA).

The IBWA Press Release to which you refer points out that the technical and safety measures used to produce and process bottled water are very effective in protecting

*IBWA Response to Committee Questions
October 15, 2008
Page 3 of 3*

against pharmaceutical contamination should these substances be present in the source water. Bottled water companies use a multi-barrier approach to bottled water safety, which includes source protection, source monitoring, reverse osmosis, distillation, filtration and other purification techniques, ozonation or ultraviolet (UV) light. The combination of FDA and state regulations, along with a multi-barrier approach and other protective measures, reduces the likelihood that bottled water products would contain pharmaceuticals.

Not all bottled water sold in the U.S. is treated by reverse osmosis. However, approximately 35% of all bottled water sold in the U.S. is "purified water," which means that it has been treated using reverse osmosis (RO) or distillation. The remaining types of bottled water are treated using a multiple barrier process that usually includes one or more of the following treatment techniques:

- Granular activated carbon (GAC) filtration.¹
- Ultraviolet light (UV) (advanced oxidation).²
- Ozonation.³

Studies of these treatments have found that pharmaceutical products in water are either removed or reduced by these processes. Many bottled water facilities employ combinations such as GAC, UV, and ozonation to treat waters for bottling.⁴

Thank you again for the opportunity to testify and provide IBWA's perspective.

Sincerely,


Joseph Doss
President

¹ Removal of Antibiotics from Surface and Distilled Water in Conventional Water Treatment Processes; J. Envir. Engrg., Volume 128, Issue 3, pp. 253-260 (March 2002)

² Occurrence and Fate of Antibiotics and Other Pharmaceutically Active Compounds During Transport to and During Drinking Water Treatment *Howard S. Weinberg, Mark D. Sobsey, Philip C. Singer, Embrey L. Bronstad, Vanessa J. Pereira, Katherine M. Stauffenberg, Zhengqi Ye, and Joshua D. Huneycutt University of North Carolina, Chapel Hill, NC 08/23/05*

³ Oxidation of pharmaceuticals during ozonation and advanced oxidation processes; Huber et al; Environ Sci Techn; 2003 Mar 1; 37 (5) 1016-24

⁴ Keeping Drugs out of Drinking Water; Environmental Science & Technology; September 4, 2002

Senator LAUTENBERG. Thank you very much.

Now I would like to turn to some questions. I would ask Commissioner Lloyd, why did New York City spend nearly a million dollars to reduce bottled water use? Are there reasons other than the environmental impact of the accumulation of waste material that caused the city to begin this initiative?

Ms. LLOYD. Yes. It was a dual project that we undertook with our New York City Department of Health, as I mentioned. Our real goal was to encourage drinking water. The Department of Health was very focused on diabetes, obesity, high blood pressure, those problems, and particularly getting young people to drink water.

One of our concerns was that we have a very significant immigrant population in New York City. We were concerned that those people might feel that they had to purchase bottled water in order to drink water, and that would be a financial barrier. So we really wanted to make it clear that tap water was a healthy alternative that was available.

Senator LAUTENBERG. Has bottled water use decreased in New York City since the marketing plan began?

Ms. LLOYD. We don't have any numbers that would indicate that. But I would be surprised if that were the case, because of course, it continues to be extremely popular. But we have seen a couple of things that we think are really encouraging. First of all, there was a tremendous interest in our bottles. We are going to do another generation of those and continue to distribute them. Also, there has been very visible increase in the sale of reusable water bottles in lots of places where, grocery stores and that sort of thing, as well as sports stores.

The other thing is that many restaurants in New York City now are encouraging the use of the drinking of tap water, even though it is more profitable for them to sell high value bottled water. So we really appreciate that.

Senator LAUTENBERG. Ms. Wu, the statistics show that plastic bottles are usually not recycled and typically then wind up in landfills. While plastic bottles still make up a relatively small percentage of landfills, as was noted by Mr. Doss, does their increasing use pose a more significant environmental threat?

Ms. WU. Yes, it does. As you mentioned, we have landfills that are overburdened right now and sending plastic bottles into these overburdened landfills is definitely an environmental problem, as well as the fact—

Senator LAUTENBERG. Does that small percentage suggest that doesn't really matter?

Ms. WU. Well, there are other problems, too, which is that sometimes they don't go to landfills, they are incinerated. There are a lot of toxic chemicals that are released into the atmosphere from the incineration of plastic. That is a problem.

As I mentioned, we have some concerns about chemicals that are used in the plastic bottles leaching into the water and the effect that might have on the quality of the water.

Senator LAUTENBERG. Is there any dissolution of plastic bottles? Do they ultimately survive forever?

Ms. WU. Generally, we think it will probably take thousands of years for them to degrade once they get in that landfill.

Senator LAUTENBERG. So it continues, in your view, to be a threat that lasts a long time?

Ms. WU. Yes.

Senator LAUTENBERG. I will ask Mr. Doss a question, and that is, would it help, and this is personal experience, would it help to make recycling a more attractive part of the process, glass bottles with deposit? Does that get any response? Or just the note that says, this product should be recycled for the well-being of future generations, or something? That is probably not the best wording. Because honestly, you have to hunt, I am not sure whether a particular product is recyclable or not, I don't know whether milk cartons are or they are not, plastic bottles. I don't see anything that really calls attention to the fact that recycling is a good idea, as opposed to just throwing it in the trash.

Mr. DOSS. You make a very excellent point, Chairman. I think we do need to make it more attractive. And the bottled water industry has worked hard, two things. First of all, I think we need to educate consumers about the importance of recycling. We have been part of the National Recycling Partnership to do just that. So I think that is an important part of it.

I think we need to look at it, though, as I was sort of mentioning, and a more comprehensive approach is needed. When you go to your kitchen cabinet or when you go to open up your refrigerator door, you see so many different products that are made out of plastic containers. As I mentioned, the bottled water industry is only .3 percent of all waste in the United States.

Now, we want to do our part, and we are working hard to try to reduce our environmental footprint. But to your point, with regard to the National Recycling Partnership, we are involved in a pilot program right now in Hartford, Connecticut. Part of that effort in Hartford, Connecticut is to try some new and innovative ways to get consumers to recycle. One of those is to perhaps provide a bit of an incentive to do so. There is something called the Recycle Bank up there that they are trying. Basically consumers will be putting the recyclables in a single stream, and that is important to your point of making sure that is easy for consumers, to your point. You don't know if this or that. In this pilot program, a single stream, everybody, you can throw your cardboard, you can throw your newspapers, you can throw everything into one bin and it is taken away and recycled, at curbside. That is very important. You don't have to separate it, you don't have to worry, well, does this go here, is this recyclable. So I think that is very important.

And the incentive there is that if consumers, the more they recycle, they are able to get a financial incentive, I think up to \$400 per year on a debit card that they can go spend at local shops around that area in Hartford. So I think that all of these things need to be looked at, but I think we need to take a comprehensive approach to it, to make it attractive, to give incentives.

Senator LAUTENBERG. Do you think the industry does, well, that is not a fair question, enough? Because even though it is only .3 percent, you put it all in containers, that is a lot of containers, that is a lot of space. A lot of the trash that is picked up burns without too difficult an effect or too serious an effect. But apparently, plastic bottles give off toxic emissions or what have you. So I think

there is little solace, really, in the fact that it is only a small percentage. When you think about it, how many items in landfills are more than .3 percent? I don't think there are a lot. Old bed parts and things like that may consume a lot more space, but ultimately—

Mr. DOSS. I didn't mean to diminish that. I think we obviously think it is very important for all industries, and we are doing what we can. But if it is to be effective, it has to be a more comprehensive approach.

By the way, on your point, I think a lot of bottled waters do now, and a lot of other products that are made out of plastic, do try to put on their label, please recycle, some message to try to encourage consumers to recycle.

Senator LAUTENBERG. It would be good if they could use large type.

[Laughter.]

Senator LAUTENBERG. Ms. Hauter, many people are surprised, maybe even shocked, when they learn that 40 percent of bottled water is actually tap water. Does the marketing of water bottles tend to mislead, do you think?

Ms. HAUTER. Yes, we think it is very misleading. Our concern is for consumers, especially today with the downturn in the economy, people have only so many dollars to spend at the grocery store. If they are spending that money on bottled water instead of perhaps a fruit or vegetable for their family, then we think that is probably not the best decision. In most places, more than 90 percent of public water systems met the requirements last year, the EPA requirements. So generally, tap water is very safe and affordable.

Senator LAUTENBERG. Only 60 percent met?

Ms. HAUTER. More than 90 percent.

Senator LAUTENBERG. More than 90. It is a hard statistic to come by. By you are satisfied that is reliable?

Ms. HAUTER. Yes, that is from the Environmental Protection Agency. And utilities are required to post their results for testing, and to do a water quality report once a year. So most consumers can go onto their local utilities' website, or if it is a small utility, they can call and get the testing results. Utilities also mail out the testing results.

If there is a problem with the drinking water, then the most efficient and safest way to deal with the problem is to match a filtration system with the contaminant. Then they can be certain. Even in a bottle, a sealed bottle, there is very little scientific research being done on the plastic leaching and the chemicals leaching into the water after it has been on the shelf for a long time. That is one of the reasons we think the bottled water industry should use some of the new testing that is available and make that information available.

If the product is good, then there shouldn't be a problem with more testing and more transparency.

Senator LAUTENBERG. One of the things that obviously my legislation is intended to do is to get some kind of a uniform standard out there that things can be measured by. I would ask you, Mr. Doss, when there is a picture of a mountaintop, frosty at the top,

and snow, is that designed to imply that is the derivation of the water that is in that bottle?

Mr. DOSS. I would say that is something that has to be dealt with on an individual by individual case. Obviously, I don't know which exactly you are referring to. I think you would have to look at it. But obviously, I think that is a matter for State law, Federal law, if there is misleading advertising going on, misleading marketing going on, then obviously that product should be held accountable.

We are not here to defend companies that might be making misrepresentations on the label, either in words or in pictures. That would have to be dealt with, I think, on a sort of individual case.

Senator LAUTENBERG. Because it won't say that this water comes from an altitude above 6,000 feet, just the awful pretty mountain-top, and you think of purity. Again, I think there is a place for bottled water. Those communities where aquifers, which we typically in New Jersey use, dry up or turn brackish or what have you, there is not always supplies available. And I am not suggesting that the only value to bottled water is emergency.

But I can see situations where bottled water is perhaps not only a good substitute but an essential one. But that case has to be made by, I think, the industry and in fairness, once again, to the consuming public, we have to make sure that they understand when things are as tight as they are, budgets are difficult, people can't afford things, it is suggested that bottled water, a gallon of water can cost more than a gallon of gas.

But if people will sooner give up the bottled water than the gallon of gas, it doesn't have dual purpose. You can't drink it, thank goodness. But the fact of the matter is that budgeting is very difficult for working families today. So that is a test that obviously the industry has to look at as well.

Mr. DOSS. Certainly. Again, I guess it comes down to choice, and consumers do have a choice, whether they want to purchase it or not. I will address the issue of advertising, since it has been brought up.

Senator LAUTENBERG. That, recycling and I think it is an industry with significant economic power. A lot of the product is produced by very large, reliable companies. But I still think that the test has to be passed as to whether or not alternating with public water supply is essential. People are now, I believe, for the most part, saying, oh, don't drink the public water. I know that New York City has been very successful in creating good tasting water, and people feel good about it. But that can't be said in every place. So we have the consumer choices.

I would ask the panel your views, do you believe that bottled water manufacturers should be giving, it is almost rhetorical, the public the detailed information, source of water, level of contaminants and so forth? How much more information do you think might be given that puts the public at ease with knowing that the water that they buy is strictly a choice between good water from the tap or good water in a bottle? What do you think the industry ought to do? By the way, they are not necessarily going to listen.

Mr. EDBERG. Could I make a brief comment?

Senator LAUTENBERG. Dr. Edberg.

Mr. EDBERG. I am a practicing medical microbiologist, I am head of medical microbiology at Yale. We have a very large cancer program, we have a very large HIV program. I am asked that question all the time by people who are taking all sorts of immunosuppressives.

One of the common therapies for rheumatoid arthritis is an immunosuppressive. And at least in New Haven, all the water that is sold has an 800 number on it. You can call them up and say, where does the water come from, how are you treating it and exactly what is in it. That is my answer to the question. I have done that myself, by the way.

Senator LAUTENBERG. But do you think the average person is sophisticated enough to know that—

Mr. EDBERG. I think the average person is more sophisticated to call an 800 number than if you list the amount of boron in the water, in the natural water. Even in the medical field, we don't necessarily even report out individual numbers to the doctors. We report out things like susceptible intermediate resistance for antibiotics.

So I think it is more important to have somebody on the phone to explain actually what is in the bottle than to have a number that very few people are actually going to be able to interpret. That has been my personal experience, because I get those phone calls.

Senator LAUTENBERG. Do you disagree?

Ms. HAUTER. I disagree. What we are saying is that very few bottles have the information necessary for a consumer to actually call and get a live person. You can go down to Giant and get their local brand. Very little information.

The big water bottlers, Nestle being the largest, with many, many different brands, the 800 numbers, if it is on the package simply says that they are basically meeting standards. It is very difficult to get any real information. And that would be voluntary information, probably provided by somebody with a \$7 an hour paycheck. Much better to have the industry required to provide that to the public. And if it is not a problem, I am not sure why the bottled water industry opposes it so much.

The same with recycling. When we have been involved in battles at the State level over recycling, the beverage industry is usually the biggest opponent of having recycling laws. So I think we need to have some accountability and we need to have consumers provided the information easily so that they can make the choice for their household, not having to call an 800 number and be basically dependent on the goodwill of a company.

Senator LAUTENBERG. Dr. Edberg, do you think that someone might make the call and get an answer, oh, we fill these bottles from a water tap in Bedford, New York, or Bayonne, New Jersey or wherever, and say that this is where we get our water supply, but it is good water, we check that out first? Would you think, Mr. Doss, do you think that—

Mr. EDBERG. It has been my experience, and the experience of my patients, that when they call an 800 number and they ask to speak to the plant manager or somebody, they get all that information. And my family is from Bayonne, and the water is perfectly fine. And I have no idea if they bottle water in Bayonne.

[Laughter.]

Mr. EDBERG. But it has been my experience that information is available, the source of it. Bottled water is a packaged food product, so it has a lot number on it. It says when it is made, where it is made, you can trace it back. If it turns purple, you can call up and say, why is the water purple. I haven't seen that, but the fact is, it has a trail of accountability. And I have never been disappointed in following that trail back, neither have my colleagues who are actively involved in the clinical treatment of patients.

Senator LAUTENBERG. Mr. Doss, what do you think about an information requirement? You have already said that numbers do not necessarily reflect knowledge that is consumable by the persons who might make the phone call. What else? Is there anything you would recommend to the industry that would clarify this dilemma that we are reviewing here now, that is whether we go into legislation and say, OK, there is a right to know, that is a favorite view of mine, all kinds of things, people have a right to know what is stored chemically, people have a right to know about safe products, et cetera.

Mr. DOSS. I don't think we disagree that consumers have a right to know what is in their water. I think the real question comes down to how we best can effect that. I think for us, as I have said before, we think the best way to achieve that, the most feasible way to achieve that, is for consumers to be able to contact the company. There is information on the label right now where they can contact the company and get information that they need. If they don't get it, they should choose another bottled water.

There is scarce label space right now for the information that is already required. FDA several years ago did a feasibility study on whether or not the consumer confidence reports required for the EPA tap water would be feasible for bottled water. Their recommendation is that there is just too much information, obviously, on a consumer confidence report to be able to get it on a bottle label. You just can't do it. So the question then is, and so much of that information might change from source to source, might cause that product to be mislabeled and misbranded because of changes in terms of what source you might use. So there are some problems that FDA identified with doing that.

Senator LAUTENBERG. But you wouldn't obviate the rules because there might be, it might be misunderstood by a water bottler? The rule says this is what the bacterial content might be, or the things that you folks are aware of that might be a health threat.

I understand that there was, and I saw an attempt at this being done, and that is, there was a system shown to me that said, through light beams, purify the water after it was bottled. And I have known there have been several attempts to do that. Has there ever been a system devised that would further cleanse water after it has been packed and bottled?

Mr. DOSS. I am not familiar with that technology, no.

Senator LAUTENBERG. By the way, the company went bankrupt. [Laughter.]

Senator LAUTENBERG. Ms. Wu, do you have a view?

Ms. WU. Not on that technology, but I wanted to go back to the labeling question that you had asked, and how Mr. Doss had talked

about how it wasn't feasible. From our perspective, we think that there needs to be, on the label, information about the contaminants that were detected, what the potential health effects are, what the real, precise source of the water is, whatever treatment happens to it. And the reality is that information could be put on a label. We have done a really kind of rough mock-up of what that would look like. Something like this would have all the information that we think could go on a label. It would inform a consumer right away as they are looking at the bottle, rather than expecting them to call up.

Senator LAUTENBERG. So you would use that numerical equivalence or things of that nature, a broad statement that nothing in this water can injure your health or something like that?

Ms. WU. It would be basic information about what the maximum allowed limits are, whether the water has violated that number or not. And it could be something as simple as just saying, an annual label that has to be changed, so it doesn't have to be changed every time they do testing.

Senator LAUTENBERG. So a dated label might do?

Ms. WU. Yes, exactly. There are many ways to make it feasible.

Senator LAUTENBERG. Ms. Lloyd.

Ms. LLOYD. I am just thinking two things. One is, we do send out a very complete report every year on all the cumulative findings of all the testing that we do. We test thousands of locations a week in New York City, and distribution. I think it is right that the water does have to be monitored closely in distribution.

But it is very interesting, because we also do get people who call up 311, which is the general information number in New York City, and ask to be sent that information. So there certainly is some interest about that. I think having it readily available over the phone would be a real plus to people. I was also just thinking, I noticed on a package of chewing gum the other day that there was a very long bit of information about what the contents were, including that there was a content that people who took a certain medication might be sensitive to. So I really think that, I find it hard to believe that packaging couldn't be devised that would give some basic information that would be helpful to people about, and I think in particular of how difficult it can be to maneuver the telephone and 800 numbers for some people, and that it would be much easier just to be able to get it off the label.

Senator LAUTENBERG. Well, if you judge it by airline response, there wouldn't be any room for other telephone calls. But I have some other questions.

I would ask this of you, that it is obvious that we need to increase funding for water infrastructure, to continue to provide safe and healthy tap water to our communities. Mr. Doss, does the increased use of bottled water call for some infrastructure funding in the rest of our system to say, OK, there is more consumption, thus, we can see more consumption of bottled water and so forth? Is bottled water gaining market share in your organization's view?

Mr. DOSS. Are we gaining market share against tap water?

Senator LAUTENBERG. Of usable water, yes.

Mr. DOSS. I don't believe we are gaining market share over tap water. I think if anything we are gaining market share over the

other carbonated soft drinks, fruit juices, teas, on the marketplace. I think consumers are more health conscious these days. They are trying to eat and drink more healthfully. So I don't think we are taking anything away from the tap water. As a matter of fact, as I understand it, there is about 1 percent of tap water in the United States that is consumed, only 1 percent.

So we don't consider ourselves to be in competition. As I say, it is not a tap water versus bottled water issue. Our competition in the marketplace is the fruit juices, the carbonated soft drinks, and the teas. So we are not trying to gain market share over tap water. And to the advertising point, this industry only spends \$52 million to advertise during the course of a year. That is Beverage Marketing Corporation's statistics. If you look at carbonated soft drinks, that figure is about \$600 million. If you look at beer, that is about \$1 billion. If you look at milk, it is about—

Senator LAUTENBERG. So that says that your industry doesn't have to, that people just run to it.

Mr. DOSS. It is market-driven, it is a consumer-driven growth, and we are not advertising against tap water. We are basically trying to provide a healthy product for consumers when they want to drink it.

Senator LAUTENBERG. So I come to the conclusion from your commentary, not to put words in your mouth, that there wouldn't be any objection to having a standard established that could be easily understood by the public that says, OK, this bottle has some of these and none of these, or whatever, that has to be reported in order to protect health. Would that be OK with you? One standard for the whole industry?

Mr. DOSS. I think the fundamental difference here is that we are trying to, in this discussion, compare bottled water to tap water and compare bottled water labeling, which is a food product, to tap water consumer confidence reports. There is a big difference there.

Senator LAUTENBERG. I was thinking of more specifically, we have tap water standards that have to be met. And even there we don't have enough inspections being done. We are short of people and short of motivation from some of the agencies.

But I just wondered whether a uniform standard by which, and it allows for advertising, but would be a good idea to give the public some confidence that what they think they are getting is what they are getting. Is that of value? Would you say source of water is of value?

Mr. DOSS. We think the information that is currently required is sufficient on the label. FDA has made determinations, for instance, about source labeling, that it is not a material fact. Some manufacturers put it on the label. Some do not. And again, I think we are getting into a situation where we are trying to compare a food product with consumer confidence reports. There is a big difference.

The difference is this. With regard to the consumer confidence reports, consumers have no choice about what tap water is piped into their homes. Consumers do have a choice about what bottled water they drink.

Senator LAUTENBERG. Is there frequent enough inspection of bottled water quality, do you think, to properly guard the public at this point?

Mr. DOSS. I think so.

Senator LAUTENBERG. Do you think so, Ms. Hauter?

Ms. HAUTER. We are concerned, because just look at the study that NRDC did a few years ago that looked at 1,000 bottles of bottled water. They basically found that a quarter of the brands had bacterial contamination, a fifth of the bottles had some kind of man-made chemicals. So there is an issue out there, and we shouldn't have public interest groups having to do this research. We know that the FDA is under-staffed and under-resourced. They are not even able to inspect the food that they are responsible for. So they view bottled water as low risk.

But there is a chemical load that people have. So even if there is just a very small percentage of chemicals in a brand that somebody is drinking on a regular basis, that has an effect on a person's chemical load. So we think there should be testing, and if there is testing going on as the bottled water industry says, even though the FDA doesn't have the staff to check the results, then they should be willing to make that public and transparent.

And I will tell you, these 1,000 bottles, the problems that those brands had, they weren't giving the public that information when they called the 800 number.

Senator LAUTENBERG. Thank you.

We are going to close. Ms. Wu.

Ms. WU. The other thing I wanted to say is that studies show that people are buying bottled water because they think that it is better regulated and better tested and more pure than tap water. So the fact is that consumers shouldn't assume that is the case, but they need the information to be able to make the choices, and the right choices.

Senator LAUTENBERG. I am going to close with a note here. I used Bayonne as an example. There is no suggestion that Bayonne, Bayonne happens to be, I have roots in Bayonne. Bayonne is a terrific city, very well managed. By the way, growing in attraction.

Mr. EDBERG. Chuck Lefter was a personal hero of mine.

Senator LAUTENBERG. Yes. Barney Frank comes from Bayonne.

Mr. EDBERG. That is right.

Senator LAUTENBERG. I thank all of you. I am sorry I have kept you so long, but the fact is that without colleagues here, it was so nice——

[Laughter.]

Senator LAUTENBERG. Oh, I mean, what an accident——

[Laughter.]

Senator LAUTENBERG. Thank you all for being here.

[Whereupon, at 4:20 p.m., the subcommittee was adjourned.]

