

FOOD SAFETY

HEARING
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
ONE HUNDRED TENTH CONGRESS
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SPECIAL HEARING
MARCH 12, 2007—VERONA, WISCONSIN

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CONTENTS

	Page
Statement of Senator Herb Kohl	1
Statement of Dr. Patricia Verduin, Sr., Vice President, Scientific and Regulatory Affairs, Grocery Manufacturers and Food Products Association	3
Prepared Statement of	5
Statement of Thomas E. Stenzel, President and CEO, United Fresh Produce Association	7
Prepared Statement of	10
Statement of Caroline Smith DeWaal, Director, Program on Food Safety, Center for Science in the Public Interest	14
Prepared Statement of	16
History of Produce Outbreaks in the United States	16
Fall 2006 Produce Outbreaks	17
Consumer Confidence	18
FDA's Budget Problems	19
CSPI Proposal	19
Safe Food Act	21
Statement of Michael W. Pariza, Director, Food Research Institute, Madison, Wisconsin	22
Prepared Statement of	25
Statement of Hon. Andrew C. von Eschenbach, Commissioner, Food and Drug Administration, Department of Health and Human Services	32
Prepared Statement of	34
Guidance for Industry	37
Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables	37
Scope and Use	38
Definitions	39
Personnel	40
Building and Equipment	44
Sanitation Operations	47
Production and Process Controls	51
Documentation and Records	56
Traceback and Recall	57
How the FDA Works to Keep Produce Safe	62
FDA Fact—Fresh-cut Fruits and Vegetables Draft Final Guidance	69
FDA News—FDA Issues Final Guidance for Sale Production of Fresh-cut Fruits and vegetables	69
Statement of Robert Brackett, Director, Food and Drug Administration, Center for Food Safety and Applied Nutrition	71
HACCP Approach	72
Imported Fruits and Vegetables	73
Guidance Implementation	74
Grant Program for Research	75
Mandatory Regulations	76
Rapid Response Teams	77
Research	78
Prepared Statement of the Wisconsin Department of Agriculture, Trade and Consumer Protection	84

FOOD SAFETY

MONDAY, MARCH 12, 2007

U.S. SENATE, SUBCOMMITTEE ON AGRICULTURE, RURAL
DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND
RELATED AGENCIES, COMMITTEE ON APPROPRIATIONS,
Verona, WI.

The subcommittee met at 9:10 a.m., at West Madison Agricultural Research Center, Hon. Herb Kohl (chairman) presiding.
Present: Senator Kohl.

STATEMENT OF SENATOR HERB KOHL

Senator KOHL. It's a privilege to be with you and we do appreciate very much your taking the time, folks, to come to this hearing on food safety. I know everybody has busy schedules and I believe our topic demands some thoughtful attention and that's exactly what we're going to give it today. We're also happy to have such a good gathering here this morning.

I especially want to thank our witnesses. Some of you traveled all the way from Washington. We appreciate that very much. Others have traveled all the way across town. Whether you came 1,000 miles or 5, nevertheless, the important thing is to make progress on the thing that we care about very much and that's food safety.

As the chairman of the Senate subcommittee that funds our primary food agencies, both the FDA and the USDA, I think we have not just an opportunity but also an obligation to turn comments and ideas into meaningful actions and accomplishments. We certainly have enough scientific and intellectual heft in this room to make a difference.

By way of introduction, our panels will include the Commissioner of the Food and Drug Administration, Dr. Andrew von Eschenbach, the Director of the FDA Center for Food Safety and Applied Nutrition, Dr. Bob Brackett. Dr. Brackett, I'm happy to say, is returning to his home roots. He is a Wisconsin native and a UW graduate.

We also have with us Dr. Pat Verduin, the Senior Vice President of Scientific and Regulatory Affairs for the Grocery Manufacturers and Food Products Association; Mr. Tom Stenzel, President and CEO of the United Fresh Produce Association, which represents growers, shippers and packers for fresh vegetables and produce; Ms. Caroline Smith DeWaal from the Center for Science in the Public Interest, a group representing consumers and finally; Dr. Michael Pariza, the Director of the Food Research Institute, which is located right here in Madison.

Before we get underway, I'd also like to thank West Madison Agriculture Research Center, especially Mr. Thomas Wright, for let-

ting us use this great facility and for working with us to set up this hearing. We really appreciate that very much.

We're having this food safety hearing here in Wisconsin because this is one of the many places where folks have gotten sick from contaminated foods. In fact, more people got sick in Wisconsin during last September's E. coli spinach outbreak than in any other State.

We're going to go through briefly some food safety numbers because I think they speak clearly and simply about the challenges that we face. Between 1998 and 2004, outbreaks in produce have almost doubled. Since 1990, there have been almost 650 outbreaks caused by produce and over 30,000 people have gotten sick.

The past 6 months have been particularly troublesome. In September, 200 people got sick, including 49 in Wisconsin, and three died from E. coli in spinach. Also in September, almost 200 people got salmonella from tomatoes. In late November and early December, we had two separate E. coli outbreaks from lettuce and 71 people were afflicted in the Northeast and 81 in Minnesota, Iowa and Wisconsin.

A few weeks ago, FDA recalled cantaloupes because of salmonella and we are still in the middle of the peanut butter recall, as you know, because of salmonella, which was first detected in August of 2006.

Against that backdrop, we find another set of numbers that I believe are equally troubling, if not more so. In 2003, there were 870 food inspectors at the FDA. By 2006, that number had dropped to 640. So the FDA lost 230 inspectors in less than 4 years and food inspections dropped nearly in half during that time. Safety tests for food produced in the United States have dropped by nearly 75 percent, and even though some 20 to 30 percent of our fruits and vegetables are imported, less than 1 percent are inspected by the FDA.

These are some sobering numbers and as the morning progresses, I'm sure they will be contrasted against more optimistic statistics. We will hear, probably several times today, that overall food safety in our country is high. That's good for us, good for our country and that's very important. Part of the credit belongs to mature meat and poultry inspection systems that have evolved over decades.

But today we're not here to talk about meat and poultry; we're here to talk about preventing food-borne illness from fruits and vegetable contamination. We're here today to talk about things specifically within FDA's jurisdiction and our question, plain and simple, is can it be better?

I suspect our panelists will say yes and so the next question to each and every one of our panelists is how? What are the specific steps we can take this week, this month, this year, next year and so on? We need to have a sustained commitment and we need to keep on pushing and that's the role that I and others intend to take.

There are, without a doubt, some complex factors involved. We have growing imports of fruits and vegetables, as I pointed out. Produce is moving further and faster than it was a decade or two ago. We don't have inspectors in every processing plant. We have growing consumption and lots of fruits and vegetables, as we know,

are eaten raw. Some of these trends have been very good for consumers, but when it comes to safety, it means that we have yet a bigger hill to climb.

Logic tells us that this hill will be easier to climb if there is collaboration, cooperation and coordination. So we begin this hearing from a mindset of collaboration, cooperation and coordination.

We have with us a representative of growers, a representative of food companies, a representative from a consumer group, a highly knowledgeable food safety scientist, and two of the top government food safety officials. These people are in charge of the process from farm to table. I know and we all know that there is no silver bullet, but we have enough brainpower and political power in this room to make a difference and to come up with something meaningful, something real, something that will prove to Americans that we are serious.

The patience of the American people is not unlimited and neither is mine so I hope that we will seize this opportunity to make a difference.

With this statement, I'd like to turn now to our first panel for their statements. Dr. Verduin, Mr. Stenzel, Ms. Smith-DeWaal and Dr. Pariza, we look forward to what you have to say and I'm hoping that you can start this off with your thoughts on these questions, the questions that I raised a moment ago. Is produce in our country safe? Can it be safer? And how can we do that? Dr. Verduin.

STATEMENT OF DR. PATRICIA VERDUIN, SR., VICE PRESIDENT, SCIENTIFIC AND REGULATORY AFFAIRS, GROCERY MANUFACTURERS AND FOOD PRODUCTS ASSOCIATION

Dr. VERDUIN. Thank you. Thank you for the opportunity to appear before the committee and discuss our current food safety system. The Grocery Manufacturers and Food Products Association represent the world's leading food, beverage and consumer products company. We promote sound public policy that serves to protect the safety and security of the food supply through scientific excellence.

Mr. Chairman, few issues are more critical to the public health than ensuring the safety of the food supply. Food safety is the number one priority for the food industry and without it, really nothing else we do is possible. The entire food industry, from field to fork, is committed to efforts that prevent, detect and resolve food outbreaks. The American food supply is safe, nutritious and wholesome. The American food safety system, which includes combined efforts from the entire food industry and the government, is the most rigorous and respected in the world.

However, the recent outbreaks remind us that while zero risk in our food safety system is always the goal, given the reality and nature of food itself and those who handle it, our food supply will never be totally risk free. At the same time, we must never lose sight of the tremendous obligation we have to provide consumers with the safest food supply possible.

The food industry takes recent outbreaks seriously. These outbreaks had a ripple effect that was felt throughout the entire industry. Many food products use spinach as a key ingredient in processed foods such as soups, dips and frozen products. These products were perfectly safe to eat given the processing steps that

would have destroyed any pathogens. Unfortunately, busy consumers aren't always able to make that distinction and simply choose not to eat any products that contain these ingredients.

This poses an additional risk to overall health. The Federal Government's Food Pyramid is urging consumers to increase their consumption of fresh fruits and vegetables. Outbreaks such as these can cause a consumer to do the exact opposite. In addition to the unfortunate implications these outbreaks have for public health, they immeasurably damage the consumer's confidence in our country's food safety system.

Many dedicated people over several generations have worked collectively to gain this trust. It would be truly unfortunate to lose this hard-earned and well-deserved confidence of the consumers in the food supply.

To reduce foodborne pathogens, a multi-faceted approach from farm to fork is prudent, using the well-proven HACCP approach. The commodities represented in these recent outbreaks are eaten raw and they present specific challenges that will not be addressed in a single kill step. The solution will most likely involve an integrated food safety program that works collectively to reduce the risks of pathogenic contamination. Good agricultural practices, GAPs, must be used to reduce the pathogen load created during growing, harvesting and transportation of these commodities.

While many commodities have GAPs developed, they do not contain validated metrics and procedures to minimize the risk of pathogen contamination. These GAPs should also address packing-houses or the processing plants. Establishing commodity-specific interventions within these plants is critical to the ultimate safety of these products. A single program will most likely not be appropriate due to the wide variation in produce type, farming programs, handling operations, et cetera. Stakeholders are attempting to define the best practices to apply to these GAPs but it is critical that these are science-based, achievable and allow the industry to meet market demand while minimizing risks to consumers.

Another essential tool is the surveillance system, comprised of PulseNet, OutbreakNet, and FoodNet. The system consists of a network of public health laboratory government agencies, including CDC, FDA, and FSIS. Through the network, we are able to more rapidly identify specific strains of pathogens and isolate their origins. We must ensure this surveillance system is fully supported and even expanded.

To ensure proper implementation of any food safety program, regulatory oversight with effective training and inspection is necessary. There must be a means to ensure compliance to existing and/or enhanced GAPs. While there is a role for industry mandated standards and auditing, some level of regulatory oversight will be needed for credibility in the eyes of consumers.

At this time, such an inspection system for the farm does not exist at the Federal level. This dictates the need for a combined and collaborative effort among the Federal and State authorities. We also need a consensus around the control points on the farm and the packing house and then determine how to evaluate their effectiveness. Again, appropriate resourcing is required.

We would like to express some final thoughts on future needs. Currently, there is no one intervention that will eliminate the naturally occurring risks of fresh produce. GMA petitioned the FDA over 6 years ago, to approve irradiation as an appropriate intervention to apply to various ready-to-eat products. GMA is working with FDA to get that irradiation approved, especially for produce, so that the industry can embrace the technology and gain consumer acceptance.

This is only one possible tool. There may be other technologies currently in development that we can consider fast tracking. The science to support the new food safety programs and technologies to control pathogens for fresh produce is lacking. Such knowledge and technology gaps must be filled so new interventions can be properly verified and validated. We believe the land grant university system offers the perfect vehicle for these efforts and money should be dedicated toward this research as well as toward the extension programs that provide outreach to farmers.

At the end of the day, many of the steps that must be taken to enhance our food safety system will require appropriate funding. Congress must be prepared to adequately fund the agencies that play a critical role in the food safety supply and funding for the FDA is especially critical. GMA believes very strongly that FDA's steady decrease in staffing needs to change. That's why as part of the Coalition for a Stronger FDA, we support significant increases to the FDA food programs, starting with the increase of \$115 million in fiscal year 2008. We recognize this is over 10 times the administration's request of \$10 million but we believe the time has come.

PREPARED STATEMENT

Mr. Chairman, no one has a greater stake in the credibility of the food safety system than our member companies. GMA is committed to working with all stakeholders to improve food safety and particularly the safety of fresh produce. Thank you very much for the opportunity to testify and I'll look forward to the rest of my colleagues' testimony.

[The statement follows:]

PREPARED STATEMENT OF DR. PATRICIA VERDUIN

Mr. Chairman and Members of the Committee: Thank you for the opportunity to appear before the committee today to discuss our current food safety system as it pertains specifically to fresh produce. The Grocery Manufacturers/Food Products Association (GMA/FPA) represents the world's leading food, beverage and consumer products companies. We promote sound public policy and champion initiatives that serve to protect the safety and security of the food supply through scientific excellence.

Mr. Chairman, few issues are more critical to public health than ensuring the safety of the food supply. Food safety is the number one priority of the food industry. Without it, nothing else we do is possible. The entire food industry—from field to fork—is committed to and continues to work very closely with Federal and State authorities to prevent, detect and resolve food outbreaks, as well as communicate clearly and concisely with the public in the event of an outbreak.

The American food supply is safe, nutritious and wholesome, and the American system of food safety protection—which includes the combined efforts of the entire food industry and the government—is among the most rigorous and respected in the world. Over the last 10 years, the number of food related illnesses and deaths associated with these illnesses have experienced a steady decline. This is due to improved food handling, technological advances and the vastly improved speed & abil-

ity of food companies and government regulators to identify the source and cause of foodborne outbreaks.

However, the recent foodborne illness outbreaks remind us that while zero risk in our food safety system is always the goal that both industry and government strive for, the reality and nature of food itself and the human dimension of the food safety system, our food supply will never be totally risk free. At the same time, all of us in industry and government must never lose sight of the tremendous responsibility and obligation we have to provide consumers with the safest food supply possible.

The food industry takes very seriously the recent foodborne illness outbreaks involving spinach and cut lettuce and all of the public concern they have generated. While our friends in the fresh produce sector were more directly impacted by these incidents, make no mistake, these outbreaks had a ripple effect that was felt throughout the food industry. In addition to spinach itself, many of our food products use spinach as a key ingredient in processed foods such as soups, dips and a broad range of frozen products such as frozen enchiladas or ravioli. Frozen and canned spinach and many spinach-containing products were perfectly safe to eat given the kill steps involved in their processing that would have destroyed any potential pathogens. Unfortunately, in such situations, busy consumers aren't always able to make that distinction and instead simply choose not to eat any products containing ingredients that were involved in an outbreak. As this case demonstrates, outbreaks involving fresh produce can also have a very negative impact on consumers from a diet and nutrition standpoint. Ironically, as the Federal Government through MyPyramid is urging consumers to increase their consumption of fruits and vegetables, outbreaks such as these can cause a consumer to do the exact opposite.

These outbreaks clearly indicate the need for a focused effort to reduce the risk to consumers. In addition to the obvious implications foodborne illness outbreaks have for public health, they could also do almost immeasurable damage to consumer confidence in our country's food safety system. Even when we take into consideration the recent outbreaks, the U.S. food supply is arguably one of the safest in the world. We have achieved this enviable position not by luck or accident, but through the commitment of the food and agricultural industries and generations of dedicated public servants at the Federal, State and local levels who work for our food safety regulatory agencies. It would be truly unfortunate for us to lose the hard earned and well-deserved confidence of consumers in our food safety system, especially when there are clear steps that can be taken by both industry and government to greatly minimize the risk of future outbreaks.

To reduce foodborne pathogens, a multifaceted approach from farm to fork is prudent using the well-proven HACCP approach. The commodities represented in these recent outbreaks are eaten "raw", presenting specific challenges that will not be addressed with a single "kill step". The solution will most likely involve an integrated food safety program that works to collectively but significantly reduce the risk of pathogenic contamination. Unlike canning where one step in the process is responsible for preserving safety, produce safety will most likely have multiple food safety control points.

Good agricultural practices (GAPs) is the first step in this chain and must be used to reduce the pathogen load created during growing, harvesting and transportation of these commodity products. While most commodities have GAPs developed, they contain appropriate metrics and validated procedures to minimize the risk of pathogen contamination. These GAPs should also address the second step in the chain which is the packing house and/or processing plant. Establishing commodity-specific and appropriate interventions within these plants is critical to the ultimate safety of the product consumed. We understand that a single program will most likely not be appropriate due to the wide variation in produce type, farming programs, handling operations, and other variables. Various concerned stakeholders are attempting to define the best standards to apply to GAPs. These stakeholders include not only growers and industry, but also Federal and State authorities. It is critical that these standards be science-based, achievable and allow farmers, processors and retailers to meet the market demand while minimizing risk to the consumer.

Another essential tool we have at our disposal is our current surveillance system comprised of PulseNet, OutbreakNet and FoodNet. This system consists of a network of public health laboratories, epidemiologists and government agencies including CDC, FDA and FSIS. Through this network, we were able to more rapidly identify the specific strains of the recent foodborne illnesses in question and isolate their origins, thereby minimizing impact on public health and the marketplace. We must ensure that this surveillance system is fully supported and, where appropriate, expanded. Each outbreak identified begins at the local level, and CDC requires ade-

quate funding to ensure State and local jurisdictions have the resources to do the surveillance and investigations needed.

To ensure proper implementation of any food safety program, regulatory oversight with effective training and inspection is necessary. There must be a means to ensure compliance to existing and/or enhanced GAPs. While there is a role for industry-mandated standards, requirements and auditing, some level of regulatory oversight will be needed for credibility in the eyes of the consumers. This oversight and ability to enforce has been in place in processing establishments amenable to Federal and State authority. At this time, such an inspection system for farms does not exist at the Federal level. This dictates the need for a combined and collaborative effort among Federal and State programs. We need to ensure that different standards are not being applied by different States or regions. We need consensus on what the control points are on the farm and in the packing houses and then determine how to appropriately evaluate their implementation and effectiveness. Again, as this integrated system is developed, appropriate resourcing at both the State and Federal levels is essential. Programs on paper do not effect change, people and activities dedicated to this effort are the essential component.

The final step to consider is consumer behavior. Outreach to the consumer is a critical component of food safety. American families continue to spend less and less time in the kitchen preparing food and opt for convenience. Therefore it is equally important that substantive outreach programs be continued and enhanced to emphasize the importance of proper food handling by consumers.

We would also like to express some final thoughts on future needs . . .

Currently, there is no one intervention that will eliminate the naturally occurring risk of fresh produce. GMA/FPA petitioned FDA over 6 years ago to approve irradiation as an appropriate intervention to be applied to various ready-to-eat food products. GMA/FPA is still working closely with FDA to get irradiation approved, especially for produce, so that industry can begin to embrace this technology and work with Federal and State agencies in a consolidated and focused outreach program to gain consumer acceptance and reduce the risk of foodborne disease. This represents only one tool in the toolbox. There may be other technologies that are currently in development to consider fast-tracking evaluation and approval.

The science to support new food safety programs and technologies is lacking in a number of areas, in particular what is most critical and effective to control pathogens on fresh produce. To really minimize the risk of future foodborne disease outbreaks and improve consumer confidence, such knowledge and technology gaps must be filled so that new interventions or operating programs can be properly verified and validated. We believe that the land-grant university system offers a perfect vehicle for these efforts and monies should be dedicated toward this research as well as toward the extension programs that provide outreach and training to growers and their workers.

At the end of the day, many of the steps that must be taken to enhance the safety of our food safety system will require appropriate funding. Congress must be prepared to adequately fund FDA, USDA and the other agencies that are playing critical roles in protecting our food supply.

Mr. Chairman, no one has a greater stake in the credibility of the food safety system than our member companies. GMA/FPA is committed to working with all stakeholders to improve food safety as is evidenced by the leadership we provided in determining effective pathogen lethality in juices to meet FDA performance standards associated with its HACCP regulation and the development of a new risk-based inspection program by FSIS.

Thank you again Mr. Chairman for the opportunity to testify. I would be pleased to respond to questions that you and the other members of the subcommittee may have.

Senator KOHL. Thank you. That was a very good statement. Mr. Stenzel.

STATEMENT OF THOMAS E. STENZEL, PRESIDENT AND CEO, UNITED FRESH PRODUCE ASSOCIATION

Mr. STENZEL. Thank you, Mr. Chairman. Good morning. Let me begin by repeating something that you've heard before and you're going to hear again. Food safety is our industry's top priority. The spinach outbreak last fall was a tragic occurrence and one that struck very hard here in Wisconsin. So many people were affected and it's a testament to the Wisconsin Division of Public Health that

the outbreak was identified here first and communicated to the CDC.

On behalf of our industry, our hearts go out to those who became seriously ill or lost a loved one. We can never forget the real human impact when something goes wrong in our food safety system. That's what drives food safety to be a process of continuous improvement, not a static achievement. We are on a continuum, constantly striving toward perfection while understanding scientifically that perfection or zero risk is simply not possible.

When the spinach outbreak occurred, our entire industry immediately pulled all spinach from shelves nationwide and cooperated fully with the FDA in tracking this problem back to its source. In fact, we now know that the only contaminated product came from one small farm, packaged in one processing plant on one production shift. That's out of more than 300,000 acres of lettuce, spinach and leafy greens grown in that California region known as the Salad Bowl of the World.

But while the source of this outbreak was indeed narrow, our entire industry will learn its lessons, joining together to study ways to reduce all common risk factors and better assure day-to-day compliance with best practices throughout the industry.

Today, an important initiative is underway within our California industry to adopt stringent food safety measurement criteria, which can be enforced and verified. These science-based standards require careful selection of growing fields based on farm history and proximity to animal operations, monitoring of irrigation water and other water sources that can come in contact with crops, prohibition of raw manure with the use of only certified, safe fertilizers, good employee hygiene in fields and handling and of course, strong food safety controls in all processing plants.

But while there is much our industry can and must do, we must also count on the Government to do its job. Today, the Department of Health and Human Services shares a critical public health challenge to increase consumption of fresh produce. The 2005 U.S. Dietary Guidelines call on Americans to literally double our consumption of fruits and vegetables. But I feel that if we do not ensure public confidence in a strong, credible and comprehensive food safety system, we put that goal at risk.

We believe consumers must be able to shop in any grocery store or order fresh produce in any restaurant with confidence that their selection is a safe and healthy choice. Now, I am personally confident in my produce choices today. I know how hard our industry is working, from field to table, on food safety. But no matter how hard our industry works, public confidence will also ultimately depend on Government as the final health and regulatory authority to determine proper food safety standards and ensure that they are being met.

Let me review three key principles we believe are critical to food safety. First, we believe produce safety standards must be consistent for an individual commodity grown anywhere in the United States or imported into this country. Consumers must have the confidence that safety standards are met, no matter where the commodity is grown.

Second, we believe achieving consistent produce safety standards across the industry requires strong Federal Government oversight and responsibility in order to be most credible to consumers and equitable to producers. We believe the FDA must determine appropriate, nationwide safety standards in an open and transparent process, with full input from the States, industry, academia, consumers and all stakeholders.

As science tells us that there is no such thing as zero risk, the public must be able to trust in an independent, objective government body as the ultimate arbiter of what is safe and is not. Industry can't make that call alone.

Finally, we believe produce safety standards must allow for commodity specific food safety practices based on the best available science. In a highly diverse industry that is more aptly described as hundreds of different commodity industries, one size clearly does not fit all.

With our colleagues from FDA here today, let me address several action steps we believe to be necessary. First, we support FDA's broad, good agricultural practices, which are applicable to all producers at farm level. FDA's GAPs guidance continues to provide an effective roadmap for producers, and cooperative agreements with USDA and the States would assure more effective education, monitoring and compliance with these and future guidelines.

Second, we support FDA's approach to developing enforceable, science-based commodity-specific GAPs where there is a demonstrated need based upon outbreak history or specific risk factors. Resources must be focused on the greatest areas of need.

Finally, we support specific, enforceable standards for fresh-cut, ready-to-eat produce and have encouraged FDA to take the important step of completing its draft guide to minimize microbial food safety hazards for fresh-cut fruits and vegetables. We anticipate some discussion of that later from our FDA panel and I'd just like to say, congratulations to FDA for very timely work in moving forward with this particular guidance document.

Let me conclude with just a couple comments about appropriation priorities in this hearing. We believe the most important issue on the table today is whether FDA is adequately funded, has sufficient staff with scientific training and experience in our sector of the food industry, has research dollars available to address key questions, has strong working agreements with the States to support as needed and has the commitment of the President and the Congress.

PREPARED STATEMENT

As a Nation committed to reducing food-borne disease, we all share the important task to adequately fund, staff and support the FDA in carrying out its mission. We as an industry must do all we can to prevent illnesses from ever occurring and we will. At the same time, we pledge our support for government efforts to provide a stronger food safety regulatory framework that assures the public that all appropriate safety standards are in place and are being met. Thank you.

[The statement follows:]

PREPARED STATEMENT OF THOMAS E. STENZEL

Good morning. My name is Tom Stenzel and I am President and CEO of the United Fresh Produce Association. Our organization represents more than 1,200 growers, packers, shippers, fresh-cut processors, distributors and marketers of fresh fruits and vegetables accounting for the vast majority of produce sold in the United States. We bring together companies across the produce supply chain from farm to retail, including all produce commodities, both raw agricultural products and fresh ready-to-eat fruits and vegetables, and from all regions of production.

I mention these characteristics because our organization's views on food safety are shaped by this broad and diverse membership across the entire produce industry, not any one sector or region. Within our industry, there are always diverse and strongly held views on each issue we face. Our association attempts to develop the best overall industry policies and practices to serve the American consumer.

Let me begin by repeating something you've heard many times before, and will hear many times in the future. Food safety is our industry's top priority. The men and women who grow, pack, prepare and deliver fresh produce are committed to providing consumers with safe and wholesome foods.

The spinach outbreak last fall was a tragic occurrence, and one that struck hard here in Wisconsin. So many people were affected, and it is a testament to the Wisconsin Division of Public Health that the outbreak was identified here first and communicated to the Centers for Disease Control. On behalf of our entire industry, let me say our hearts go out to those who became seriously ill or lost a loved one. We can never forget the real human impact when something goes wrong in our food safety system.

That is what drives food safety to be a process of continuous improvement, not a static achievement. We are on a continuum, constantly striving toward perfection, while understanding scientifically that perfection—or zero risk—is not possible. Our overall safety record is good in providing American consumers over a billion servings of fresh produce every day. But, our industry cannot rest when even rare breakdowns in food safety systems can cause such human impact as that felt here in Wisconsin last fall.

Let me allay any concerns that our industry has just now begun to address food safety. In fact, our association published the first Food Safety Guidelines for the Fresh-Cut Produce Industry 15 years ago in 1992, and we are now on our 4th edition. We developed the first industry guidelines in the mid 1990s to minimize on-farm microbiological food safety risks for fruit and vegetables, and worked closely with the U.S. Food and Administration to publish Federal guidelines soon thereafter. Put simply, food safety has been at the forefront of our mission to serve the American public for many years. When a tragedy such as the E. coli O157:H7 outbreak occurs, we are committed to learning all lessons possible and incorporating that knowledge into continuous process improvement.

I want to address two main points today. First, I want to talk specifically about what our industry has done to address this outbreak, and what we are doing now to improve food safety practices from field to table. Second, I want to share with you our association's views on the most appropriate produce safety regulatory framework to protect public health.

When the spinach outbreak occurred, our entire industry immediately pulled all spinach from shelves nationwide, and cooperated fully with FDA in tracking this problem back to its source. That total industry wide shutdown was an unprecedented response, but FDA felt it necessary until they were certain any contaminated product was removed from the market.

In fact, we now know that the only contaminated product came from one 50-acre farm, packaged in one processing plant, and only on one production shift. That's out of more than 300,000 acres of lettuce, spinach and leafy greens grown in the region where this product was grown, and dozens of processing plants around the country. But, when faced with an immediate public health question, we agreed with FDA to err on the side of caution.

Once we learned of the outbreak, our industry also immediately began a comprehensive reevaluation of spinach production, handling and processing to make sure we were taking all appropriate steps to assure safety. This included not only the company directly involved in the outbreak, but companies throughout the spinach growing and processing sector. While the source of the outbreak itself proved to be narrow, the entire industry joined together to make sure we collectively are addressing all the common risk factors that can be associated with fresh leafy greens grown outside in nature and consumed without cooking.

This effort has led to an important initiative spearheaded by the leafy greens industry to adopt stringent food safety measurement criteria which can be imple-

mented and verified across this sector of the industry. The California Department of Food and Agriculture has recently adopted a Leafy Greens Marketing Agreement which will serve as a means of setting rigorous measurements of safety for leafy greens from this major production region. We also believe similar standards must apply nationally and internationally, and I will address this issue specifically in a moment.

These science-based standards include careful attention to site selection for growing fields based on farm history and proximity to animal operations, appropriate standards for irrigation water and other water sources that can come in contact with crops, prohibition of raw manure with use of only certified safe fertilizers, good employee hygiene in fields and handling, and of course, strong food safety controls in all processing plants.

Under the Leafy Greens Agreement, growers will be audited by the California Department of Food and Agriculture to ensure that they are complying with these standards. And, they will face penalties if found not to be in compliance, with the ultimate consequence of not being allowed to sell product if they cannot do so safely.

Taking a step like this toward self-regulation for a private industry sector is not an easy task. But we believe this is a critical step in continuing to assure the public that our industry is doing everything we can to make our products safe. I want to publicly recognize those growers, shippers and processors of leafy greens who have made this commitment.

Stepping out now to a national multi-commodity perspective, I can tell you that many other sectors of our industry are pursuing similar efforts to define, implement and verify best practices from field to table.

For example, the Florida tomato industry is at the forefront of developing good agricultural practices for their sector of the industry, and exploring various means to assure compliance across multiple growing regions outside of the State as well. Just two weeks ago, the tomato industry convened a meeting of some 75 scientists in government, academia and industry to discuss new tomato research initiatives to further reduce risk.

In an effort similar to the leafy greens and tomato good agricultural practices we've discussed, our organization and others have co-published GAP guidance documents for the melon industry, and work is underway on green onions and herbs.

And, of course, many other regional groups are implementing similar efforts. Last month, I met with hundreds of growers in New Jersey where a new food safety task force put together by their Department of Agriculture is looking at specific GAPs and training programs for their growers. And another good example is the Georgia Fruit and Vegetable Growers Association, which has its own GAPs training program to help small growers in that State better understand and apply best practices.

All these efforts represent industry led initiatives to further reduce risk and ensure the safest possible produce for the public.

It is within the context of all of these industry driven efforts that I turn now to discuss what we believe to be the most appropriate regulatory framework for the fresh produce safety. While there is much our industry can and must do, we also have to recognize the important role of the Federal Government.

Today, our country faces a critical public health challenge to increase our consumption of fresh produce. The 2005 U.S. Dietary Guidelines call on Americans to literally double our consumption of fruits and vegetables. And now, our Nation is faced with an obesity crisis that threatens the long-term health of our children unless we radically change eating habits and help them learn to make healthier choices for a lifetime.

I am here today because I fear that if we do not ensure public confidence in a strong, credible and comprehensive food safety regulatory framework, we are putting that goal at risk. It is simply unacceptable for Americans to fear consuming those very fresh fruits and vegetables that are essential to their good health.

Our industry can have but one goal in food safety and it starts with the consumer. We believe consumers must be able to shop in any grocery store, or order fresh produce in any restaurant, with complete confidence that their produce selection is a safe and healthy choice. Fear has no place in the produce department. Whatever low risk that might be present must be viewed as an acceptable risk, based on strong government assurance that proper food safety systems are in place, and that the benefits of consumption far outweigh the low risk.

Now, I personally am confident in my produce choices today. I know many of the people who are growing and processing fresh produce, and I trust them to be doing their very best to market safe products. I know a lot about these many industry efforts across the country to develop best agricultural practices and implement strong standards and controls. And I know how hard our own team is working to make sure every corner of our industry is focused on food safety.

But, no matter how hard our industry works, public confidence also ultimately depends upon government as the final health and regulatory authority to determine proper food safety standards and ensure that they are being met.

Let me review three key principles we believe to be critical for our Nation's food safety regulatory framework.

Consistent Produce Food Safety Standards

First, we believe produce safety standards must be consistent for an individual produce commodity grown anywhere in the United States, or imported into this country. Consumers must have the confidence that safety standards are met no matter where the commodity is grown or processed. Because of the variation in our industry's growing and harvesting practices in different climates and regions, flexibility is very appropriate and necessary. For example, some production areas use deep wells for irrigation while others use river water supplied from dams. Some farms use sprinkler irrigation, others use a drip system laid along the ground, and still others use water in the furrows between rows of produce. But the common factor must be that all uses of water for irrigation must meet safety standards that protect the product. That must be true whether the produce is grown in California, Florida, Wisconsin or Mexico.

We strongly applaud industry groups in different States and regions that are working to enhance local practices. Their work demonstrates the industry's commitment to do all we can to enhance safe growing and handling practices. But to build consumer trust, strong scientific standards we're developing for one region can only be successful if applied consistently across the industry.

Federal Oversight and Responsibility

Second, we believe achieving consistent produce safety standards across the industry requires strong Federal Government oversight and responsibility in order to be most credible to consumers and equitable to producers.

We believe that the U.S. Food and Drug Administration, which is the public health agency charged by law with ensuring the safety of the Nation's produce supply, must determine appropriate nationwide safety standards in an open and transparent process, with full input from the States, industry, academia, consumers and all stakeholders. We are strong advocates for food safety standards based on sound science and a clear consensus of expert stakeholders.

But in a situation where science tells us there can be no zero risk, and there is no cooking step for our product, the public must be able to trust in an independent, objective government body as the ultimate arbiter of what is safe enough. In the future, we must be able to stand side-by-side with government to reassure the public that together, we have done everything necessary to implement and comply with strong mandatory government standards to protect public health.

Let me say a word here specifically about USDA's role in helping our industry enhance safety. USDA is a strong ally and offers a number of means to assist the produce industry in safely growing, handling and processing fresh produce. First, as a diverse agricultural industry, marketing orders have been an extremely useful means of setting quality standards, conducting research and promoting specific commodity groups. These orders fall under the Agricultural Marketing Service of USDA, and are increasingly being looked at as a potential means to stimulate good food safety practices as well. Growers of a commodity can come together and vote to require specific practices that then become mandatory for all growers of that commodity.

In addition, USDA through AMS offers several auditing programs that assist the industry in measuring good agricultural practices, good handling practices, and HACCP programs in processing plants. These are good education and training programs, as well as a means to measure individual operators' understanding and implementation of food safety practices.

We believe these programs can be very helpful, and are an important element in enhancing food safety systems. Yet, while these programs are an important means for specific sectors of the industry to enhance performance, long-term public trust requires that FDA set the most appropriate regulatory safety standards. That is simply a call that industry cannot make alone.

And, FDA must have the ultimate responsibility to ensure that industry is complying with these standards. That does not mean that FDA has to hire 5,000 new inspectors to visit every farm in America and travel around the world. But it does mean that FDA must have relationships with other governments, USDA, and State agriculture and regulatory officials to ensure that compliance is taking place. Cooperative agreements between FDA and the States have been extremely effective in providing oversight of food safety standards.

Our analysis is that FDA has the regulatory authority today to promulgate any needed rules and regulations, issue guidance that compels industry action, enter into agreements with States to support field investigations, and generally set all necessary standards to protect the public health.

Commodity-Specific Scientific Approach

Finally, we believe produce safety standards must allow for commodity-specific food safety practices based on the best available science. In a highly diverse industry that is more aptly described as hundreds of different commodity industries, one size clearly does not fit all.

For example, the food safety requirements of products grown close to the ground in contact with soil are far different from those grown on trees. And, the large majority of produce commodities have never been linked to a foodborne disease. Every produce commodity is different, and our food safety regulatory approach must contain needed scientific flexibility to address specific commodities differently based on their unique production and handling practices.

This will be an extremely important point in looking at produce safety. Government and industry alike must be careful that broad strokes do not result in requirements that should not apply to specific commodities, and do nothing to enhance safety. Taking a general approach would be far too easy to add regulatory costs and burdens to sectors where those requirements are unneeded, without doing anything to enhance safety where most critical.

We support the approach currently taken by FDA to establish broad Good Agricultural Practices (GAPs) applicable to all producers at farm level. FDA's 1998 GAPs guidance continues to provide an effective roadmap for producers, and cooperative agreements with USDA and States can assure compliance with these guidelines based on today's science and as they are modified by FDA in the future to reflect increasing knowledge.

We also support FDA's scientific approach to develop commodity-specific GAPs where there is a demonstrated need. This must be a scientific process, looking at outbreak history and potential risk factors to ensure that resources are not diluted trying to address hundreds of commodities that have never been linked to illnesses. These principles are embodied in commodity specific guidance documents that are being developed for tomatoes, melons, leafy greens and green onions, as well as FDA's already published guidance document for fresh sprouts.

Finally, we support FDA's approach to address specific standards for fresh-cut processing, as contained in the agency's proposed Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables. We strongly support HACCP food safety programs in all fresh-cut processing plants. Although research has not yet identified a kill step such as pasteurization for fresh-cut ready-to-eat produce, we must apply strict processing controls to minimize any risk that might be introduced from incoming raw agricultural product or at the processing level.

Together, these three principles I've discussed help define a food safety regulatory policy that we believe will most help our industry enhance produce safety, concurrent with establishing the highest level of public trust in fresh produce. We strongly support a U.S. regulatory framework for the fresh produce industry that incorporates these principles.

Let me conclude with a few comments about appropriations priorities. We believe one of the most important issues at this hearing is whether FDA is adequately funded, has sufficient staff with scientific training and experience in our sector of the food industry, has research dollars available to address key questions, has strong working agreements with the States to provide support as needed, and has the commitment of the President and full support of Congress.

Now that's a big commitment, but we believe it is essential to have a strong and effective Federal regulatory framework for the produce industry. As a Nation committed to reducing foodborne disease, we all share the important task to adequately fund, staff and support the FDA in carrying out its mission.

Finally, let me address the subject of research. Our industry is doing everything we know today to reduce the risk of foodborne disease, but there are many scientific questions literally begging for research. We need better understanding of ways to reduce E. coli O157:H7 in cattle; we need better ways to prevent potential contamination from pathogens that might be present at field level; and we need to develop more effective microbial reduction and elimination techniques after harvest and in processing. While there's no obvious silver bullet around the corner, developing a "kill step" akin to pasteurization while still protecting the natural texture and flavor of our product would be a critical advancement in preventing even rare future illness outbreaks.

We ask for the committee's support in boosting produce safety research as a vital part of reducing risk in the future. Specifically, we support an additional appropriation for fiscal year 2008 of \$10 million for USDA's Agricultural Research Service, \$10 million for the USDA Cooperative State Research, Education and Extension Service, and \$6.5 million for the FDA Center for Food Safety and Applied Nutrition, for produce safety research. We also ask the committee for its support as we discuss significantly greater research needs in the 2007 Farm Bill.

In conclusion, let me return to the important role fresh fruits and vegetables play in public health. Of course any reasonable person in the food industry would want to produce only the safest possible product. But for us, somehow it seems even more important because of the healthfulness of fresh produce.

With that public health imperative, we simply cannot allow fears of food safety to become linked with fresh produce.

We as an industry must do all we can to prevent illnesses from ever occurring, and we will. To those who became ill from last year's outbreak or have loved ones who did, we pledge to do our very best to prevent this from happening in the future.

At the same time, we pledge to support government efforts to provide a strong food safety regulatory framework that assures the public that appropriate safety standards are in place and are being met by the industry.

Together, we can help consumers enjoy an ever increasing array of safe, healthy and nutritious fresh fruits and vegetables.

Senator KOHL. That's very good, Mr. Stenzel. Thank you very much. Ms. DeWaal.

STATEMENT OF CAROLINE SMITH DE WAAL, DIRECTOR, PROGRAM ON FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Ms. DEWAAL. Thank you, Senator. This is an important hearing. It's an important hearing both for the citizens of Wisconsin but also the citizens of the United States. So I appreciate the fact that you're having it.

The Center for Science in the Public Interest is a consumer organization. We represent over 900,000 consumers, both in the United States and Canada. The Centers for Disease Control and Prevention estimates that 76 million consumers get ill each year from something they ate and 5,000 die.

According to CSPI's database, we have a 5,000 outbreak database spanning 15 years, fruits and vegetables and the dishes with salads prepared from them cause 13 percent of food-borne illness outbreaks and 21 percent of associated illnesses. Food-borne illnesses from produce surpass those of all other single food categories, including beef, chicken, and seafood. Produce sickens more people each year than these categories. The average size of the outbreaks is larger in produce than in any other food category.

The bottom line here is that consumers want to eat fresh vegetables and fruits and we love the convenience that the industry has brought forward with these bagged products and ready-to-eat products that allow us to have salads on the table in just a few minutes. But consumer confidence in these bagged products has certainly declined since the fall. The spinach outbreak had as many fatalities as the Jack-in-the-Box hamburger outbreak in 1992, and it may well prove to be the tipping point for consumer confidence unless the industry and the government act quickly to provide solutions to the risks.

In my written testimony, we do have data supporting this with a Rutgers University study of consumer confidence. Many consumers were confused about whether canned or frozen products were impacted. Also, they were never really sure when the recall

or the warning ended and whether it also extended to other bagged greens for a large percentage of consumers.

For us, though, last fall's produce outbreaks were just the latest symptom of an agency, FDA, that is overwhelmed by responsibility but lacks the staff and resources to function effectively. In fact, since 1972, inspections conducted by FDA have declined 81 percent and just in the last 3 years there was a 47 percent drop in Federal inspections. FDA's food program is facing a critical shortfall, around \$135 million, just for a current functioning budget and overall, this means that consumer confidence in FDA has really plummeted. A Harris poll has documented that those who thought FDA was doing an excellent or good job dropped dramatically since just 2000. Sixty-one percent of consumers rated the government as doing an excellent or good job in 2000 and only 36 percent believed that in 2006.

Equally important is the fact that the Federal agency's food safety expenditures are widely disproportionate to the risks between the foods that they regulate. The U.S. Department of Agriculture regulates 20 percent of the food supply, meat and poultry, and these products caused about 32 percent of the outbreaks, yet its food safety appropriations have doubled that given to the Food and Drug Administration. The Bush administration's 2008 budget proposal gives USDA around \$270 million in new appropriations. The FDA, which regulates 80 percent of the food supply, including produce, was only given a \$10.6 million increase.

Senator, this is a food safety budget that defies logic and we really hope that you can help to correct this inequity. CSPI has petitioned FDA to take action right away. Fresh fruits and vegetables are the center of a healthy diet so it is critical that immediate steps are taken. CSPI has petitioned the FDA to require all fresh fruit and vegetable producers and processors to develop written plans to identify where contamination is likely to occur and how to prevent it. We believe the farmers themselves hold the key to the solution. These plans should apply first to high-risk products, such as leafy green vegetables and more gradually to other areas.

Specifically, we're asking for a three-pronged approach. The FDA should require all growers and processors to have written food safety plans designed by the farmers themselves. The FDA should develop standardized criteria for farmers to use for such items as the use of manure, water quality and worker sanitation. Worker sanitation, by the way, is critically important to protecting food safety. Finally, the written plan should be audited at least once per growing season by FDA, the States and the buyers and FDA should review these audits.

Senator, you asked us very specifically to talk about specific steps that could be taken this year. We think you could help out dramatically by equalizing the budget, the food safety budgets that are already in the President's budget for 2008, between USDA and FDA. The money is there. It needs to be more equitably distributed and in addition, we urge you to get FDA to understand that consumers can't fix this problem. We can't tell them to wash it to eliminate it. We could urge them to cook it. Cooking it would destroy the hazard but who wants cooked salad? I certainly don't and I know most consumers don't want to go that level. People ask me,

do we need chlorine? Should we wash it in chlorine? We hope not. We hope that we're not going to get to that point. But voluntary standards don't work. They've been tried. We have a history of outbreaks and it's not working. It definitely won't work with imports as well and a lot of our produce is coming from foreign countries.

PREPARED STATEMENT

So the guidance documents FDA has put out are not enough and if you could urge them and demand that they put in place the same systems that Mr. Stenzel has been asking for and we're asking for. We're all at the same place on this. Thank you.

[The statement follows.]

PREPARED STATEMENT OF CAROLINE SMITH DEWAAL

My name is Caroline Smith DeWaal, and I am director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 900,000 subscribers to its Nutrition Action HealthLetter and by foundation grants. We accept no government or industry funding.

The Center for Disease Control and Prevention (CDC) estimates that 76 million Americans get sick and 5,000 die from foodborne hazards each year in the United States. Many health-conscious Americans consume fresh produce as part of a balanced diet, but in the last decade, produce is too frequently the cause of major outbreaks, resulting in deaths, illnesses, both mild and severe, and great market disruptions.¹

According to CSPI's database of 5,000 foodborne illness outbreaks spanning 15 years, fruits and vegetables caused 13 percent (639) of these outbreaks with nearly 21 percent (31,496) of the associated illnesses. Norovirus, Salmonella and E. coli O157:H7 illnesses have been traced to a wide variety of produce, including lettuce, salads, melons, sprouts, tomatoes, and many fruit- and vegetable-containing dishes.² In fact, foodborne illnesses from these produce outbreaks surpassed those from all other foods, including beef, chicken and seafood. Equally troubling is that the average size of these outbreaks is larger than outbreaks from other foods, thus affecting more people.

HISTORY OF PRODUCE OUTBREAKS IN THE UNITED STATES.

Produce outbreaks in the United States have been documented from both imported produce and domestically grown produce. Imported fruits and vegetables have caused numerous large and sometimes deadly outbreaks. Here are several examples:

- Both in 1996 and 1997, thousands of people became ill in both the United States and Canada from a parasite, *Cyclospora*, on raspberries grown in Guatemala.³ *Cyclospora* infects the small intestine and typically causes watery diarrhea, loss of appetite, substantial loss of weight, and persistent fatigue. If untreated, illness may last for a month or longer, and may follow a remitting-relapsing course.⁴
- In 1997, over 256 cases of Hepatitis A were associated with the consumption of frozen strawberries. The strawberries were harvested in Mexico and processed and frozen in southern California before they were distributed by U.S. De-

¹ Center for Science in the Public Interest, *Outbreak Alert* (Revised and updated—2006). This database of foodborne illness outbreaks is maintained by CSPI. It contains 15 years of data, from 1990–2004. Outbreaks are classified by both food vehicle and disease-causing agent. Food is classified by which agency regulates the product. During the years 1990–2004, there were 3,323 foodborne illness outbreaks from FDA-regulated foods (e.g. seafood, produce, eggs, milk); USDA regulated-foods (e.g. beef, poultry, pork) caused 1,344 outbreaks.

² Center for Science in the Public Interest, *Outbreak Alert* (Revised and updated—2006).

³ J Hoffman et al (1996). "Update: Outbreaks of *Cyclospora cayetanensis* Infection—United States and Canada, 1996." July 19, 1996. MMWR 45(28): 611–612.

⁴ CDC Division of Parasitic Diseases (2004). *Fact Sheet: Cyclospora Infection—Information for Healthcare Providers*. April 19, 2004. March 5, 2007. <http://www.cdc.gov/ncidod/dpd/parasites/cyclospora/healthcare_cyclospora.htm>.

- partment of Agriculture (USDA) to school lunch programs in several States, including Michigan, Wisconsin, Louisiana, Maine and Arizona.⁵
- Three multistate outbreaks of Salmonella serotype Poona infections associated with eating cantaloupe imported from Mexico occurred in the spring of consecutive years during 2000–2002. FDA conducted traceback investigations and determined that the cantaloupes were from farms in Mexico. FDA conducted on-farm investigations in Mexico and found many possible sources of contamination, included irrigation of fields with water contaminated with sewage; processing (cleaning and cooling) with Salmonella-contaminated water; poor hygienic practices of workers who harvest and process the cantaloupe; pests in packing facilities; and inadequate cleaning and sanitizing of equipment that came in contact with the cantaloupe.⁶
 - In 2003, a major Hepatitis A outbreak linked to raw green onions used in restaurant salsa sickened 555 people in Pennsylvania, killing three of them. Preliminary traceback by FDA indicated that green onions supplied to the restaurant were grown in Mexico under conditions where contamination with human waste was likely. Other onions from this area were linked to outbreaks in Georgia, Tennessee, and North Carolina that occurred earlier in the fall.⁷
- But problems with domestic produce are also widespread:
- In February 2004, following fourteen outbreaks linked to lettuce and tomatoes, FDA sent a letter to firms that grow, pack, or ship fresh lettuce and/or fresh tomatoes reminding them to review their current operations in light of the agency's guidance.⁸ FDA sent another letter specifically to California lettuce firms in November 2005 expressing concern over continuing outbreaks of foodborne illness and outlining actions the industry should take in order to ensure lettuce safety.⁹
 - At a June 2004 public meeting to discuss the proposed Produce Action Plan, Dr. Robert Gravani of Cornell University's Food Science Department reported that a Good Agricultural Practices Survey of Farm Workers in New York State showed that approximately 30 percent of producers were unaware of Good Agricultural Practices (GAPs) for their particular crop. The numbers show the need for a mandatory regulatory program for fresh produce and the same should go for fresh-cut produce.
 - A qualitative study examining food safety practices used by Iowa produce growers was conducted by researchers from Iowa State University. Observational and in-depth interview techniques were used to assess current food safety practices at each operation. Producers were conscious of product safety, but levels of awareness about risk varied. Areas that needed improvement included improved hand washing facilities and practices; provision of employee training; and the development of cleaning and sanitizing protocols for both products and food contact surfaces.¹⁰

FALL 2006 PRODUCE OUTBREAKS

The 2006 spinach outbreak hit Wisconsin the hardest. The State had 49 confirmed cases, 24 hospitalizations, nine individuals with Hemolytic Uremic Syndrome (HUS) resulting from their E. coli poisoning, and one death.¹¹

On September 5, 2006, the Wisconsin Department of Health and Family Services was notified of several cases of E. coli O157:H7 in the State. Two days later the State health department contacted the Centers for Disease Control and Prevention (CDC) and the Wisconsin State Laboratory about this suspected outbreak. On September 8, the Wisconsin State Laboratory "DNA fingerprinted" the specific E. coli

⁵Centers for Disease Control (1997). "Hepatitis A Associated with Consumption of Frozen Strawberries—Michigan, March 1997." *MMWR*, 46(13): 288–295.

⁶SM Anderson et al. (2002). "Multistate Outbreaks of Salmonella serotype Poona Infections Association with Eating Cantaloupe from Mexico—United States and Canada, 2000–2002." November 22, 2002. *MMWR*, 51(46):1044–1047.

⁷V Dato et al. (2003). "Hepatitis A Outbreak Associated with Green Onions at a Restaurant—Monaca, Pennsylvania, 2003." *MMWR*, 52(47): 1155–1157.

⁸FDA, CFSAN (2004). *Letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes*. Feb. 5, 2004. March 5, 2007. <<http://www.cfsan.fda.gov/dms/prodltr.html>>.

⁹FDA, CFSAN (2005). *Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce*. November 4, 2005. March 5, 2007. <<http://www.cfsan.fda.gov/dms/prodltr2.html>>.

¹⁰J Ellis, et al. (2005). "Assessing On-farm Food Handling Practices of Iowa-grown Produce and Eggs in Regard to Food Safety." *Food Protection Trends*, 25(10): 758–61.

¹¹Wisconsin Department of Health and Family Services. "Disease Outbreaks and Investigation." 2006. October 3, 2006. March 5, 2007. <<http://dhfs.wisconsin.gov/communicable/outbreaks/index.htm>>.

strain and posted the information for the CDC and other State laboratories. This posting allowed the CDC to match the genetic fingerprint of the Wisconsin E. coli O157:H7 to victims of an outbreak in Oregon and the multi-State outbreak investigation of E. coli began. Investigations by the CDC, the Wisconsin health department, and the Oregon health department identified fresh spinach as the likely culprit.¹² On September 14, the FDA issued a warning for consumers to avoid eating fresh spinach.¹³ But the warning came after much of the produce was distributed and consumed. Overall, during August and September, E. coli O157:H7 in fresh spinach sickened 204 people in 26 States, killing at least three.

While many produce outbreaks occurred prior to 2006, this outbreak provided the smoking gun that sourced the cause all the way to the farm. FDA traced the exact strain of the E. coli bacteria to a California spinach farm, finding it in nearby manure piles, in a creek and even in a wild pig.¹⁴ These findings definitively proved that the E. coli contamination that sickened so many people started right on the farm.

This spinach outbreak was the first of a series of produce outbreaks that swept the Nation in the closing months of 2006. In late September, Salmonella found in tomatoes sickened restaurant patrons throughout the Nation. This time 183 people fell ill in 21 States. E. coli O157:H7 appeared in produce once more before the year's end when shredded iceberg lettuce at Taco Bell and Taco John Restaurants sickened 152 individuals.

Rapid investigations and the quick release of information to consumers are important to lessen the public health impact. In September, FDA's nationwide consumer notification to avoid spinach likely reduced the illness and death toll, and its continual updates meant that many additional consumers heard the news.¹⁵ Thorough¹⁶ investigations are also essential to prevent reoccurrences of outbreaks. But it is time to do more. Consumers want FDA to put in place a regulatory system that will prevent these outbreaks from occurring.

CONSUMER CONFIDENCE

Consumers want to eat fresh vegetables and fruits and we love the convenience of bagged salads that allow us to have a salad on the table in few minutes. But consumer confidence in the safety of these bagged products has certainly declined since the fall. The spinach outbreak had as many fatalities as Jack in the Box hamburger outbreak of 1992. It may prove to be a tipping point for consumer confidence unless the industry and the government act quickly to provide solutions to the risks that are now so evident.

In November 2006, the Food Policy Institute at Rutgers University conducted a telephone survey of 1,200 adults to see if consumers had heard about the FDA advisories and the subsequent recalls of spinach and to understand how the outbreaks would affect their future consumption of fresh spinach.¹⁷ The majority of Americans knew about the recall (87 percent) and most learned of it from television reports (71 percent). Many Americans were unsure which spinach products were affected; only 68 percent knew that, in addition to bagged fresh spinach, bulk spinach was also recalled. Twenty-two percent incorrectly identified frozen spinach as recalled. The survey also documented that public notice is sometimes not enough to warn people off a high-risk food item. In fact, more than one-in-eight Americans (13 percent) who were aware of the recall continued to consume fresh spinach during the recall.

Many consumers were confused about when the recall ended; at the time of the survey in November 2006, 6 weeks after the FDA's initial warning, 45 percent were unsure if the spinach recall had ended. Many consumers surveyed were also avoiding other fresh greens: 18 percent had stopped buying other bagged produce. At the

¹² Wisconsin Department of Health and Family Services. "Disease Outbreaks and Investigation." 2006. October 3, 2006. March 5, 2007. <<http://dhfs.wisconsin.gov/communicable/outbreaks/index.htm>>

¹³ States Food and Drug Administration. (September 14, 2006). *FDA Statement on Foodborne E. coli O157:H7 Outbreak in Spinach*. Press Release. September 14, 2006. March 5, 2007. <<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01450.html>>

¹⁴ ProMED-mail. E. coli O157, spinach—USA (multistate)(20). ProMED-mail 2006; 27 October: 20061027.3067. February 23, 2007. <<http://www.promedmail.org>>

¹⁵ United States Food and Drug Administration. (September 14, 2006). *FDA Statement on Foodborne E. coli O157:H7 Outbreak in Spinach*. Press Release. September 14, 2006. March 5, 2007. <<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01450.html>>

¹⁶ United States Food and Drug Administration. *Spinach and E. coli*. November 15, 2006. March 5, 2007. <<http://www.fda.gov/oc/opacom/hottopics/spinach.html>>

¹⁷ Cutie, Cara Ph.D., et al, *Public Response to the Contaminated Spinach Recall of 2006*. Food Policy Institute, Rutgers University. (February 5, 2007).

time of the survey 44 percent of consumers resumed eating fresh spinach and 20 percent said they “definitely will eat spinach in the future.” Five percent of Americans who ate spinach before the recall said they “definitely will not eat spinach in the future.” Nearly one in five reported (19 percent) that they will now avoid spinach grown in particular areas of the country and 15 percent said they would avoid specific brands of spinach.

FDA’S BUDGET PROBLEMS

Last fall’s produce outbreaks are just the latest symptom of an agency that is overwhelmed by responsibility, but lacks the staff and resources to function effectively. The agency responds to crisis after crisis rather than preventing them. Current FDA funding shortfalls have reached a critical level and budget cuts have left the agency with fewer inspectors, even as their workload continues to increase. In fact, since 1972 inspections conducted by the FDA declined 81 percent. Since 2003, the number of FDA field staff dropped by 12 percent and between 2003 and 2006, there was a 47 percent drop in Federal inspections.¹⁸

FDA’s food program has a current funding shortfall of \$135 million, which an FDA budget official described as equivalent to a 24 percent budget cut. This means that many other parts of the agency’s responsibilities are just not getting attention—things like obesity, dietary supplements, and appropriate oversight of new technologies. Overall consumer confidence in FDA has plummeted. A Harris Poll has documented that those who thought FDA was doing an “excellent” or “good” job went from 61 percent in 2000 to 36 percent in 2006.

Equally important is the fact that the Federal agencies’ food safety expenditures are disproportionate to the risk posed by the foods they regulate. USDA regulates 20 percent of the food supply, which causes 32 percent of outbreaks, yet its food safety appropriations are double that given to FDA.¹⁹ This means that while USDA has the resources to inspect meat and poultry plants daily, the FDA inspects food facilities it regulates on average just once every 5 to 10 years.

The Bush Administration’s 2008 budget proposal brings no relief to the ailing agency. The recent budget proposal gives USDA \$270 million in new money for food safety and security. The FDA, on the other hand, regulates 80 percent of the food supply, including produce, but will only get \$10.6 million in new food safety money. It is a food safety budget that defies logic.

CSPI PROPOSAL

Fresh fruits and vegetables are at the center of a healthy diet, so it is critical that immediate steps are taken to improve their safety. CSPI has petitioned the FDA to take action to require that all fruit and vegetable producers and processors develop written plans to identify where contamination is likely to occur and how to address it. This approach is appropriate for both large and small growers and processors. It targets resources to critical areas and reduces risk by using prevention. These plans should apply first to the highest-risk products—such as leafy green vegetables that have been repeatedly linked to illness outbreaks and more gradually to other segments of the industry.

Specifically, CSPI proposes a three-prong approach to improve the safety of fresh fruits and vegetables:

- First, FDA should require all growers and processors to keep a written food safety plan, designed by the farmer to address the specific environmental conditions on the farm.
- Second, FDA should develop standardized criteria for use by the farmers for such items as water quality, manure use and management, and worker sanitation.
- Finally, the written plans should be audited at least once per growing season by FDA, the States, or the buyers, and FDA should review these audits.

FDA’s standards should include the following areas:

Manure.—The grower must manage the application of manure to ensure that it does not contribute to the contamination of crops, including limitations on the crops where and the times when it may be applied. The use of raw manure on produce during the growing season should be prohibited as currently required under USDA’s

¹⁸Waxman, Henry. *Fact Sheet: Weaknesses in FDA’s Food Safety System*. Representative Henry Waxman. (October 30, 2006); Andrew Bridges, Seth Borenstein, “AP Investigation: Food Safety Inspections Lanquish,” Associated Press, February 29, 2007.

¹⁹Center for Science in the Public Interest, *Outbreak Alert* (Revised and updated—2006).

Organic Certification Program.²⁰ Composting of manure intended for use on food crops should be monitored and records should be maintained to ensure effective controls are used to destroy pathogens. Domestic animals should be excluded from fields and orchards during the growing and harvesting season, and growing areas should have wildlife deterrents. Farmers and producers should ensure that animal waste from adjacent fields, pastures, or waste storage facilities do not contaminate growing areas. Manure treatment and storage sites close to fresh produce fields increase the risk of contamination; livestock producers should be required to move or otherwise control these sites.

Water.—Growers and producers should ensure that the water supply used for irrigation and in food processing plants is suitable for its intended use. The internationally agreed-upon Codex Code of Hygienic Practice for Fresh Fruits and Vegetables Processors says that growers should assess the microbial and chemical quality of the water used in primary production.²¹ Vegetable processors should use only potable water in processing or for cleaning or sanitizing the facility and equipment. Facilities should have an environmental monitoring program that includes sampling for pathogens to detect areas of harborage and to verify the effectiveness of cleaning and sanitizing programs in preventing cross-contamination. Sanitizers used for washing vegetables should be approved by FDA and continuously monitored by the facility to ensure they remain at effective levels in the wash water. If effective sampling programs can be developed, water used for washing produce should be monitored for the presence of pathogens at a rate adequate to ensure highly contaminated batches are identified and eliminated.

Hygiene.—Growers and processors should ensure that employees have close access to bathrooms and that handwashing facilities are visible to supervisors. Employees with direct and indirect access to the production areas should be trained in preventive controls that will help to eliminate or minimize contamination of produce.

Sanitation.—Processors should establish mandatory sanitation standard operating procedures, including cleaning procedures for equipment, storage areas, air systems, and water storage areas. Facilities should be designed to facilitate maintenance and good sanitation practices so that contamination may be controlled throughout receiving, cooling, processing, packing, and storage operations. There should be limited access to the facility and to its processing areas; adequate space for operations; adequate drainage of processing and wash water; food contact surfaces that are easy to clean and maintain; and areas and structures designed to protect the product and equipment from contamination.

Traceback.—Processors should mark packaging to ensure easy traceback when fruits and vegetables are implicated in an outbreak. Package markings should be specific enough to extend all the way back to the farm/farms of origin. The ability to identify the source of a product is a critical component of food safety programs intended to prevent the occurrence of microbial contamination. Information gained from a traceback investigation can help limit the impact of an outbreak of foodborne illness and help to identify and eliminate conditions that may have contributed to product contamination.

Written food safety plans would help farmers to focus on hazards associated with their products and the steps taken to address those hazards. These plans are the essential first step in preventing a reoccurrence of the outbreaks from last fall. The plans should be reviewed during random third party and State auditing based on consistent standards. Seasonal audits would allow FDA to monitor that the regulations are being fully implemented and enforced. If States or third party auditors are relied on, FDA should periodically conduct on-sight audit reviews to ensure that auditors provide consistently reliable services. Whenever auditors inform FDA or if the agency finds violations, it should bring enforcement actions, including product seizure and criminal sanctions.

Foodborne illness outbreaks related to fresh produce are a major public health problem. Prevention, early detection, and control measures must be in place at every step of fresh produce production to help minimize food safety risks. Voluntary guidelines are not an effective public health response to address the food safety problems related to fruits and vegetables. And while FDA can likely cobble together the authority it needs to regulate on the farm from existing statutes, there is no clear mandate from Congress that ensures food safety oversight all the way from

²⁰ National Organic Program. 5 CFR pt.205.203(c).

²¹ United Nations Codex Alimentarius Commission (2003). Codex Code of Hygienic Practice for Fresh Fruits and Vegetables. Section 3.2.1.1. March 5, 2007. <http://www.codexalimentarius.net/download/standards/10200/cxp_053e.pdf>. See also: Beuchat LR (1998). "Surface decontamination of fruits and vegetables eaten raw: A review." Food Safety Issues. World Health Organization.

the farm to the table. Food safety is critically important to consumers' health and to the health of the industries that produce food; yet, it is governed by laws that are 100 years old. It is time to modernize food safety.

SAFE FOOD ACT

While we believe that FDA has authority to implement these improvements under both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act, neither of these laws give the agency clear authority from farm-to-table when it comes to food safety. The FFDCSA sets up a reactive structure, in which the agency is truly empowered only when food is found to be adulterated or misbranded. This is very different from the Federal Meat Inspection Act, for example, that requires government inspectors to approve every meat product before it can be sold.

In order to bring these disparate food safety laws together, on February 15, 2007, Senator Richard Durbin and Representative Rosa DeLauro introduced The Safe Food Act to streamline food safety at the Federal level. This bill creates a strong, science-based Food Safety Administration, ending the current tug-of-war between agencies.

The Safe Food Act would create a system of risk-based inspection, "determined by the type of food handled and the type of processing to which the food is subjected."²² Food establishments would receive a rating (1-5) to determine the number and the time between inspections, based on public health considerations and strong scientific evidence. The risk-based inspection program would continue the "carcass-by-carcass" inspections at slaughterhouses and perform daily inspections of other high-risk products. All food processors would be inspected at least annually, with many inspected much more often. This system of risk-based inspection would allow for the best use of department resources while still ensuring the safety of the entire "farm-to-fork" process.

The Safe Food Act addresses imported foods as well. The FDA currently inspects only about 1 percent of food entering the United States, due to its limited resources and does little to evaluate foreign food safety systems or inspect foreign plants.²³ The Safe Food Act gives the Food Safety Administration the authority to evaluate and certify a country's food safety program to ensure that it is "at least equivalent to the food safety program in the United States."²⁴ Food coming from uncertified countries or plants will not have an "open visa" to enter the United States without inspection or regulation as they do today, while food that are properly certified would move quickly.

When food safety problems do occur, it is vital that the Food Safety Authority has sufficient tools to respond in an emergency. According to the World Health Organization "tracing systems and market recalls are thus critical in responding to food contamination, whether deliberate or inadvertent."²⁵ Today, however, the USDA and the FDA rely on voluntary company tracking and recall systems. The Safe Food Act mandates the establishment of a national system for "tracing food and food producing animals from point of origin to retail sale."²⁶

The Safe Food Act works to prevent foodborne illness and bioterrorism without grand schemes or an inflated budget. Instead, it ensures a strong national program, outbreak surveillance, and effective, honest public communication. The food industry is the first line of defense, but recent outbreaks demonstrate that effective industry programs require government monitoring and oversight.

Senator KOHL. That's great, very good. Dr. Pariza.

²² DeLauro, Rosa L. Summary: *The Safe Food Act of 2005, H.R. 1507* Congresswoman Rosa L. DeLauro's Website. March 5, 2007. <http://www.house.gov/delauro/safe_food_act_109.html>

²³ General Accounting Office (GAO), Food Safety. *Overview of Food Safety and Inspection Service and Food and Drug Administration Expenditures* (GAO/T-RCED-00-300T). (September 20, 2000) (statement of Lawrence J. Dyckman, Director, Food and Agriculture Issues, Resources, Community, and Economic Development Division, GAO). March 5, 2007. <<http://www.gao.gov/archive/2000/rc00300t.pdf>>

²⁴ United States. Congress. House of Representatives. 110th Congress, 1st Session. H.R. 1148, *The Safe Food Act of 2007*. [introduced in the House of Representatives 16 February 2007]. 110th Congress. Congressional Bills, GPO Access. March 5, 2007. <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h1148ih.txt.pdf>

²⁵ Food Safety Dept., World Health Org., Terrorist Threats to Food: Guidance for Establishing and Strengthening Prevention and Response Systems, Food Safety Issues 4 (2002). March 5, 2007. <<http://www.who.int/foodsafety/publications/general/en/terrorist.pdf>>

²⁶ United States. Congress. House of Representatives. 110th Congress, 1st Session. H.R. 1148, *The Safe Food Act of 2007*. [introduced in the House of Representatives 16 February 2007]. 110th Congress. Congressional Bills, GPO Access. March 5, 2007. <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h1148ih.txt.pdf>

STATEMENT OF MICHAEL W. PARIZA, DIRECTOR, FOOD RESEARCH INSTITUTE, MADISON, WISCONSIN

Dr. PARIZA. Thank you. I really appreciate the opportunity to speak here this morning and I want to begin by commending you, Senator Kohl, for holding this extraordinary meeting here in Badger Capitol, where we know that the most important reason for having a belt line is to transport excited sports fans from all over the State to Kohl Center.

Seriously, Senator Kohl, it is almost impossible to fully express our gratitude to you for your unfailing dedication and support, both public and personal, to the State of Wisconsin and to the University and we really feel that you exemplify the highest principles of public service.

We are here this morning to consider a serious issue, the apparent increase in food-borne illness associated particularly with fresh produce. I say apparent because we are not really sure how much is due to a true increase as opposed to increased awareness and reporting. Of course, either way, it's important news and we know that important news can be both good and bad.

The good news is that the public and Congress are focusing on food related issues that are true risks rather than distractions like the Carcinogen of the Week headlines that used to occupy an inordinate amount of FDA's energy and resources. I am pleased to say that we were able to work with former Congressman Scott Klug to revise the so-called Delaney clause to bring it in line with current scientific understanding.

This revision permitted resources to be re-directed to food-borne illness, which is a real issue that we can actually address with the tools of science. We can really reduce the risks, the economic loss, the morbidity and the mortality caused by food-borne pathogens and toxins.

There is bad news, too. There are critical gaps in our knowledge base. The limiting factor is lack of research funds rather than lack of good ideas. Perhaps even worse is the realization that our regulatory agencies, in particular, the FDA lack of resources to apply to what we already do know and of course, we've heard that from other panelists.

On the morning of September 11, 2001, Americans got a wake-up call that continues to reverberate. Funds were quickly allocated to, among other things, food security, which was certainly appropriate. UW Madison is a major partner in the Department of Homeland Security's National Center for Food Protection and Defense, which is currently headquartered at the University of Minnesota. However, funds that had previously been allocated for traditional food safety research and regulatory activities were also re-directed to the defense against food bioterrorism and that trend should be reversed. The prospect of food bioterrorism is very scary and could have catastrophic consequences but in fighting this demon, we should not lose sight of the more mundane and very real risks of food-borne illness in more familiar corners.

You've asked whether the current system is working or broken. The answer, in my opinion, is yes and yes. One might argue that the system works, at least sort of because food-borne illness, when it happens, particularly on a large scale, is still news. If the system

were completely broken, food-borne illness would be commonplace and that certainly is not the case.

The safety of fresh produce is very important and the focus of this hearing. Illnesses and deaths associated with fruits, vegetables and herbs are unacceptable. Of course, fresh produce is not the only type of food that can harbor risks, like pathogens, so it is important that funds are not simply redirected to fresh produce safety from other important areas. We need an overall increase, in other words, is what I'm getting at here.

UW Madison's Food Safety Program is designed to enhance the safety of all foods consumed in the United States. We've found that knowledge coming from one area can often be applied to other areas. At the risk of sounding immodest, I should tell you that a substantial amount of the information used by the processed food industry and its regulators to ensure safe food was discovered or developed at FRI. Especially noteworthy examples of research by FRI faculty and staff that affect virtually every consumer included the development of the methodologies that are used worldwide to ensure that processed cheese spreads are safe and methods for producing microbiologically safe low-nitrite bacon.

You may have noticed holes in the plastic wrap around fresh mushrooms. Those holes are there because FRI researchers discovered that allowing air to enter freely into the package eliminates the threat of botulism from that product.

FRI faculty and staff isolated the toxins that produce staphylococcal food poisoning, known euphemistically as the two-bucket disease. They also developed the reagents needed to detect these toxins and used them to save a small cheese company in Green Bay, Wisconsin from bankruptcy. Today you know that company as Schreiber Foods.

More recently FRI personnel studied the transmission on farms of *E. coli* O157:H7, which you've heard a lot about. No one ever wants *E. coli* because it causes bloody diarrhea and it can be fatal, especially for children. This critically important work led to a simple solution. Keep manure out of the water that cows drink. Now that may sound obvious but imagine how difficult it is to implement on a large dairy farm. One needs knowledgeable, dedicated individuals and capital investment into the required equipment. This research was initiated to enhance our understanding of the ecology of *E. coli* O157:H7 and reduce the risk of that pathogen in ground beef. But the discoveries from the project have wider impact that includes reducing the contamination of fresh produce from farm runoff and the use of manure as fertilizer.

Other current FRI research is aimed at helping the State and national dairy and meat processing industries develop safe formulations, reduce mold toxins in grain, eliminate thin layers of microbial pathogens from food processing equipment, control acrylamide formation in fried potato products, and understand botulinum toxin. The last, incidentally led to the development paradoxically of botulinum.

Yes, that's right. The first Botox ever approved by FDA for human drug use was purified right here in Madison at the Food Research Institute.

Wisconsin Alumni Research Foundation known as WARF, has patented discoveries made at FRI involving conjugated linoleic acid, which is now the sixth most financially successful technology in WARF history and it earns more than \$1.5 million annually from the royalty income book, which goes back to the university-supported research.

FRI faculty and staff also collaborate with the broader UW Madison community, for example, the College of Engineering. Projects include using nano-technology to develop novel sensors for detecting microbial pathogens and toxins, and procedures for disposing of the food that was intentionally contaminated with a biological agent. We are discussing other major collaborative efforts to utilize our collective expertise in food safety, risk analysis, risk perception and applied economics to study the spread of microbial contamination from farm fields to consumers in the fresh produce industry.

The ultimate goal of this project is to assess the effectiveness of potential risk reduction measures and identify cost effective strategies for improving the safety of fresh produce.

I've discussed how the current National Food Safety Program sort of works. The system is also sort of broken. To be clear, the system needs repair, not a major overhaul and in this regard, you can help us with one big matter, the need for increased funding requires that you direct it to food safety research and regulatory activity without, of course, compromising the equally important, complimentary efforts aimed at preventing food bioterrorism.

With regard to fresh produce, we need improvements in pre-harvest practices and post-harvest intervention. These are particularly crucial. The term pre-harvest encompasses all that happens while a crop is growing in the field or orchard. By contrast, post-harvest encompasses what happens between the harvest of a crop and the transport to a supermarket and may include washing, cutting and packaging.

In this country, the most important pathogens associated with fresh produce are enteric pathogens, particularly *E. coli* O157:H7 and salmonella. These microorganisms are commonly found in the intestines of mammals and birds and they find their way into fresh produce because of fecal contamination.

Birds fly over orchards, rodents run between crop rows, cows graze near fields and so forth. You can reduce the impact through improved fencing and cover, and cultivation that minimizes contamination from runoff, but we would have to grow all of our crops in sterile greenhouses to ensure the complete absence of contamination and this is where so much additional research is helping us.

PREPARED STATEMENT

I'm running way over time so I'm just going to bring it to the end. In summary, the U.S. food safety system is not really broken but it is also not working as well as it could and a critical missing component is sufficient funding for research and regulatory activities. Thank you.

[The statement follows:]

PREPARED STATEMENT OF MICHAEL W. PARIZA

Good morning. I'm Mike Pariza, Director of the UW-Madison Food Research Institute (FRI) and Wisconsin Distinguished Professor of Food Microbiology and Toxicology. I appreciate the opportunity to speak this morning and will begin by commending Senator Kohl for holding this extraordinary meeting here in Badger Capital, where we know that the most important reason for having a beltline is to transport excited basketball fans from all over the State to the streets that go to the Kohl Center.

Seriously, Senator Kohl, it is almost impossible to fully express our gratitude for your unflinching dedication and support, both public and personal, to the State of Wisconsin and UW-Madison. You exemplify the highest principles of public service.

We are here this morning to consider a serious issue: the apparent increase in foodborne illness, associated particularly with fresh produce. I say "apparent" because we are not really sure how much is due to a true increase, as opposed to increased awareness and reporting. Of course either way it's important news, and as we know important news can be both good and bad.

The good news is that the public and Congress are focusing on food-related issues that are true risks, rather than distractions like the "carcinogen-of-the-week" headlines that used to occupy an inordinate amount of FDA's energy and resources. I'm pleased to say that we were able to work with former Congressman Scott Klug to revise the so-called "Delaney Clause" and bring it in line with current scientific understanding. This revision permitted resources to be redirected to foodborne illness, which is a real issue that we can actually address with the tools of science. We really can reduce the risks, the economic loss, the morbidity and mortality caused by foodborne pathogens and toxins.

But there is bad news too. There are critical gaps in our knowledge base. The limiting factor is lack of research funds rather than lack of good ideas. Perhaps even worse is the realization that our regulatory agencies, in particular FDA, lack the resources to apply what we already do know.

On the morning of September 11, 2001 Americans got a wake-up call that continues to reverberate. Funds were quickly allocated to among other things food security, which was certainly appropriate. UW-Madison is a major partner in DHS's National Center for Food Protection and Defense, which is currently headquartered at the University of Minnesota.

However, funds that had previously been allocated for traditional food safety research and regulatory activities were also redirected to defense against food bioterrorism, and that trend should be reversed. The prospect of food bioterrorism is very scary and could have catastrophic consequences, but in fighting this demon we should not lose sight of the more mundane but very real risks of foodborne illness from more familiar corners.

You've asked whether the current system is working or broken. The answer, in my opinion, is yes and yes. One might argue that the system works, at least "sort of," because foodborne illness, when it happens particularly on a large scale, is still news. If the system were completely broken foodborne illness would be commonplace, and it certainly is not that.

The safety of fresh produce is very important and the focus of this hearing. Illnesses and deaths associated with fruits, vegetables and herbs are unacceptable. Of course fresh produce is not the only type of food that can harbor risks from microbial pathogens, so it is important that funds are not simply redirected to fresh produce safety from other important areas.

UW-Madison's food safety program is designed to enhance the safety of all foods consumed in the United States. We've found that knowledge gained from one area can often be applied to other areas. At risk of sounding immodest, I should tell you that a substantial amount of the information used by the processed food industry and its regulators to ensure safe food was discovered or developed at FRI. Especially noteworthy examples of research by FRI faculty and staff that affect virtually every consumer include the development of the methodologies that are used worldwide to ensure that processed cheese spreads are safe, and methods for producing microbiologically safe low-nitrite bacon. You may have noticed holes in the plastic wrap around fresh mushrooms; those holes are there because FRI researchers discovered that allowing air to enter freely into the package eliminates the threat of botulism from the product.

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More recently FRI personnel studied the transmission, on farms, of *Escherichia coli* O157:H7, also known as hemorrhagic *E. coli* because it causes bloody diarrhea that can be fatal, especially for children. This critically important work led to a simple solution: keep manure out of the water that cows drink. That may sound obvious but imagine how difficult it is to implement on a large dairy farm. One needs knowledgeable dedicated individuals, and capital investment in the required equipment. This research was initiated to enhance our understanding of the ecology of *coli* O157:H7 and reduce the risk of the pathogen in ground beef, but the discoveries from the project have wider impact that include reducing the contamination of fresh produce from farm runoff and the use of manure as fertilizer.

Other current FRI research is aimed at helping the State and national dairy and meat processing industries develop safe formulations, reduce mold toxins in grain, eliminate thin layers of microbial pathogens (called biofilms) from food processing equipment, control acrylamide formation in fried potato products, and understand botulinum toxin which led, paradoxically, to the development of botulinum toxin as a drug. Yes, that's right, the first BOTOX ever approved by FDA for human drug use was purified right here in Madison at FRI. The Wisconsin Alumni Research Foundation (WARF) has patented discoveries made at FRI involving conjugated linoleic acid (CLA). CLA is now the 6 most financially successful technology in WARF history, and earns more than \$1.5 million annually in royalty income, the bulk of which goes to support research at UW-Madison.

FRI faculty and staff also collaborate with the broader UW-Madison community, for example the College of Engineering. Projects include using nanotechnology to develop novel sensors for detecting microbial pathogens and toxins, and procedures for disposing of food that was intentionally contaminated with a biological agent. We are discussing a major collaborative effort to utilize our collective expertise in food safety, risk analysis, risk perception, and applied economics to study the spread of microbial contamination from the farm fields to consumers in the fresh produce industry. The ultimate goal of this project is to assess the effectiveness of potential risk-reduction measures, and identify cost-effective strategies for improving the safety of fresh produce.

I've discussed how the current national food safety system "sort of" works. But the system is also "sort of" broken. To be clear, the system needs repair, not a major overhaul. In this regard you can help us with one big matter: the need for increased funding directed to food safety research and regulatory activity, without of course compromising the equally important complementary efforts aimed at preventing food bioterrorism.

With regard to fresh produce, the need for improvements in pre-harvest practices and post-harvest intervention is crucial. The term "pre-harvest" encompasses all that happens while a crop is growing in a field or orchard. By contrast "post-harvest" encompasses what happens between the harvest of a crop and its transport to a supermarket, and may include washing, cutting and packaging.

In this country the most important pathogens associated with fresh produce are enteric pathogens, particularly *E. coli* O157:H7 and *Salmonella*. These microorganisms are commonly found in the intestines of mammals and birds, and they find their way onto fresh produce because of fecal contamination—birds fly over orchards, rodents run between the crop rows, cows graze near fields planted with food crops, and so forth. You can reduce the impact through improved fencing and cover, and cultivation practices that minimize contamination from runoff. However we would have to grow all our crops in sterile greenhouses to ensure the complete absence of contamination.

Accordingly, there is great need for improved pathogen surveillance tools and detection methodologies. Typically one is dealing with small levels of pathogen contamination against a much larger backdrop of harmless, mundane bacteria that are commonly found in soil. Quickly identifying the pathogens and differentiating them from their harmless relatives is no easy task, and we don't have optimal tools for this yet.

Post-harvest intervention focuses on treating fresh produce so that the inevitable pathogens are destroyed while at the same time protecting the fresh quality that consumers want.

Traditional post-harvest methods for killing pathogens and preserving vegetables and fruit, for example canning, are not the solution because no matter how safe canned vegetables are they don't taste fresh. Rinsing fresh produce helps but effectiveness is limited because pathogens can sometimes hide within the cellular structures of the plant, where the rinse cannot penetrate. Other methods, for example irradiation and the use of high-pressure pasteurization, appear to work very well in many applications. However both of these are expensive, and in the case of irradiation unfairly maligned. Accordingly there is urgent need for novel processing and

disinfection methodologies that are effective and economically viable across a wide range of products and applications.

Post-harvest intervention is an area that truly needs more research. We will not solve the problem of fresh produce safety until we master post-harvest intervention.

Finally, education is critically important to maintaining a safe food supply. While there is a lot we do not yet know, it is equally true that there is a lot about food safety that we do know, and that is where educational programs focused on food and food safety at research universities like UW-Madison come in. Some of our former students go into the private sector where they often make crucially important contributions. An example is the late Dr. Howard Bauman, who received his Ph.D. at UW-Madison under the direction of Professor Mike Foster, FRI's last Director and one of the principals involved in moving the Food Research Institute from the University of Chicago to UW-Madison in the 1960s. Dr. Bauman spent his career at the Pillsbury Company, where he invented a procedure called HACCP, the acronym for Hazard Analysis Critical Control Point. HACCP is a method used to identify and control the vulnerable steps in a process where contamination may occur. It has become the backbone for food safety analysis worldwide and is mandated by USDA. If you operate a food plant in the United States, you must have a HACCP plan. HACCP is also applied to agricultural practices, to identify and control the most vulnerable areas for pathogen contamination.

We're also very proud that some of our food safety program graduates choose careers in the public sector, for example Dr. Brackett who you will hear from next, and Dr. Don Burr who is in the audience. Both Dr. Brackett and Dr. Burr manage key programs to help ensure that our food remains safe and secure.

In summary, the U.S. food safety system is not really broken, but it is also not working as well as it could. A critical missing component is sufficient funding for research and regulatory activities.

Senator KOHL. Thank you very much, Dr. Pariza. A couple questions, Dr. Verduin. In your statement, you talked about the need for regulatory oversight but you noted the differences in commodities, farm programs, etcetera. Are there basic standards, in your opinion, that could be implemented for all commodities as a Federal baseline?

Dr. VERDUIN. Yes. I believe there are. I believe there are some basic farm practices and standards relative to water irrigation systems, manure—certain standards that would apply to all farms and commodities. Then what we would believe would happen is, depending upon the commodity, as Mr. Stenzel said, you would then get down to much more specific standards relative to that commodity's practices, how it is cut, how it is harvested. So we believe there are overarching guidelines that can be established that are science-based and specific.

Let me just comment on science-based. There is a lot of stuff that we don't know. There are a lot of things that are going to be built into these standards initially that may prove out to be ineffective, that are our best guess or our best judgment on all the expertise, and that's okay for a time, but we also need the science to support and put in those things that really do matter and strengthen them as much as possible.

So we would like guidelines put in place, over all commodities, with underpinnings for specific commodities and then we would like, at the same time, research being done to make sure those guidelines represent the best science and the best interventions and the best limits to date.

Senator KOHL. Okay. Do you think that the FDA currently has the ability to make these improvements within their authorities and their funding levels?

Dr. VERDUIN. We believe they have the authority to make these improvements. We believe they have the authority to make these

guidelines and to also work with the States. They have the authority to work collaboratively and to get into cooperative agreements with the States.

Having said that, and I know you're going to hear this again, they need the money to do it and we also believe that Congress expressly asking them to do it is also important.

Senator KOHL. Good. Could you talk a little bit about irradiation? We keep hearing about it. In your opinion, is it safe? Would it work on everything? And what other technologies do you think are on the horizon? Do we need to do more research?

Dr. VERDUIN. I think irradiation is a tool in the toolbox. I think it is a potential—obviously, we know that the science is there that supports the fact that it kills pathogens. On fresh produce, we know that it's applicable to certain types of produce and not to others, not from a safety perspective but from a quality of product eaten perspective, how consumers perceive the product. Is it crispy at the end of the day? So we know that the science works. We know that it is one tool that we can potentially apply to certain products. We believe that that tool should be allowed to be used.

Having said that, it's not the only tool. There is modified atmosphere packaging, there are sanitizers that we could use that also need to be further investigated and further researched at hopefully the land grant universities like the University of Wisconsin and should we continue to pursue these and continue to make them available to farmers and to processors.

Senator KOHL. Thank you. Mr. Stenzel, what economic effects have the recent outbreaks had on your members?

Mr. STENZEL. Well, Senator, clearly there has been a huge economic impact. I hesitate to even answer the question, though, in equating economic impact with the human impact of the food-borne illness itself. So please don't misjudge that.

In looking at the impact of the spinach outbreak in particular on our industry, as I stated in my testimony, this proved to be a very narrow outbreak, one company and one particular bag produced in one processing plant on one day. But the impact was across the entire industry. It's one of the reasons why I think you have seen an unusual phenomenon occur. CSPI and the industry is sitting side by side and asking the FDA to do the same thing, and that is because our industry has had such impact from this loss of consumer confidence, across many people who did not cause the outbreak, and that's something that we've come to grips with, that we either have to restore public confidence in our overall food safety system or else our industry may not be able to fulfill that public health challenge of increasing consumption of fruits and vegetables.

Senator KOHL. Thank you. You said that the FDA does not need to go out and hire 5,000 new inspectors in your statement or to be on every farm and in every plant. I certainly agree that's not feasible nor would it be responsible, but do you think FDA has all of the people it needs, both in the field as well as at the FDA?

Mr. STENZEL. As Dr. Verduin stated in response to your question to her, I do believe it is a resource question for FDA. It is not a question of authority. It's not a question of intent. We have the greatest respect for the scientists in the Center for Food Safety and Applied Nutrition but they simply don't seem to have the resources

to tackle this job as quickly and as effectively as we think they could, despite best efforts.

Now when you look at the inspection force, I know that there has been a drop in that area as well. That's something that needs to be tackled at the same time, but I think it is a little bit of a different issue than simply the scientific staff within the center itself that need even more resources at that Federal level in addition to the Office of Regulatory Affairs.

When it comes to on farm inspections, we see a great potential for Federal/State cooperation. Every State has its own department of agriculture, departments of health and they really have their boots on the ground, if you will, in order to be able to go to do some of the farm inspections that we're talking about. But it needs to be still under FDA's authority and FDA's direction as to what they should be looking for.

Senator KOHL. Mr. Stenzel, tracing back to a source after the outbreak is obviously important in order to see what went wrong and learn lessons to prevent future incidents. But I'm sure you'd agree it's even more critical to detect an outbreak early when something does go wrong, in order to keep more people from getting sick. How can we better detect food-borne disease quickly to prevent further spread of the illness?

Mr. STENZEL. Well, Senator, that's absolutely a top priority, I think, for everyone in the public health community, certainly within the industry as well. When an outbreak occurs, and it doesn't matter what product it is, whether it is fresh produce or a packaged, processed product, that product is being consumed and we only learn about it after the fact. In our case, we were 3, 4, 5 weeks after the product had been consumed in that spinach outbreak, so early detection is something that is extremely important to minimize the likelihood of additional people becoming ill.

Dr. Pariza mentioned that clearly, in terms of the importance of that early detection process. Let me give you one example of something that you'll hear more about and that's shelf life and the amount of time the product is being consumed. In the spinach outbreak in particular, 25 to 30 percent of the people who became ill consumed the product after the use by date that was stamped on the back. We've simply got to do a better job also of teaching people that that's not a wise practice, either. So we've got to look at the total supply chains and make sure that we have the strongest public health detection systems in place as well.

Senator KOHL. Thank you very much. Ms. DeWaal, it seems like many of the standards that you talk about regarding hygiene, sanitation, et cetera, wouldn't require a significant test. You could simply walk onto a farm or processing plant and see if the standards were, in fact, being met. But they would require FDA or State inspectors to show up much more often. Do you agree with that?

Ms. DEWAAL. Yes. The model that we're working off of is one that actually has been tried in the meat area and with quite a bit of success. It's one where the plants themselves design the safety systems but it's got to meet certain hazards. We know the use of manure around produce can be a hazard. It's already regulated with respect to organic but it's not regulated for general produce. We know that water quality is vital, critically important. We know

that farm worker hygiene and the ability to wash your hands is very important to the safety of these products. About 40 percent of the produce outbreaks in our database come from norovirus, which is transmitted from an infected human onto the food.

So there are things that we know and that you could go onto a farm and say, let me see your records of manure use or composting records. You could actually see the hygiene facilities sitting right there. You could see if the hand washing sinks are visible. These kinds of things don't take fancy tests. Tests can be very important, especially in processing, to check the water to ensure that you don't have a highly contaminated batch of lettuce or spinach coming in, for example, but tests in the field, I think, will not be the key here. It is good old-fashioned inspection, which is someone going on the farm.

Let me talk for one minute about the issue of who should inspect. Do we need 5,000? Do we need an army of inspectors like we have over in the meat area, for meat and poultry inspection? I think that we could do with less if we utilize not only the States but also the buyers. The buyers have every bit of interest in ensuring the safety of those products and so if you have auditing that is done, both at the State level or at the level of the Wal-Marts or the Costcos who are going to be buying the products, that auditing system could be consistent and it could be something that FDA could double-check.

It's critical though, that this also be capable of being enforced. If FDA has a problem on a farm, that they can walk in on the basis of a State audit or a third-party, independent audit and take enforcement action.

So we have to work on it. It's not the good, old-fashioned USDA inspectors like we have in meat who can take action right away. It's a new model but I think it's one that could be very effective.

Senator KOHL. Very good. You stated that the average size of an outbreak of food-borne illness from produce is larger than it is from other foods. Why is this so?

Ms. DEWAAL. In our database, the average size of a produce outbreak is about 49 people. This is over a span of 15 years and this is almost double the size of outbreaks from beef or chicken and four or five times that of seafood. So it's really distinctive.

Part of what's going on is I think for a long time, produce was the last thing they suspected when they saw a salmonella or an E. coli outbreak, they thought it was chicken or beef long before they suspected the produce. Although produce is consumed very quickly—so you buy the lettuce, you eat it very quickly, sometimes compared to the meat or poultry, so the outbreaks simply take longer to identify and the food source takes longer to identify and to trace back. Oftentimes, FDA doesn't even recall the product because they say the product is all gone by the time they know enough to recall it.

So that's what we've observed and I think the public health departments are getting better at identifying produce but the trend is still there.

Senator KOHL. Thank you very much. Dr. Pariza, you mentioned several discoveries by the talented faculty and staff at FRI. Can you talk a little bit about how, for example, in the mushroom packaging you mentioned, you get from the question to the answer?

How long would research like that take when you are trying to answer a specific question?

Dr. PARIZA. Yes, thank you very much. That particular finding, actually I don't know how long it took exactly but I'm sure it didn't take very long. That's because when you have an awful lot of information already about an item and about what was happening inside of the package. So that was not a very—that particular finding, we were able to apply previous information very quickly to come to a solution. I guess that it probably didn't take more than a few months at the most. So there is a range of how long things might take and it's really dependent on the nature of the question.

Senator KOHL. In your opinion, Dr. Pariza, if there were a pool of funding that FDA dedicated to new food safety research to answer some of the questions that you mentioned in your statement, how long would it take, in your opinion, to yield us some real results?

Dr. PARIZA. Well, yeah, I think some results could come fairly quickly. Other results might take longer. I could imagine certain things with regard to better applying an understanding, for example, of how E. coli is transmitted on farms, could be applied fairly quickly if you have the resources. There may be other things, like trying to develop better tests, that could take quite a bit more time. I do have to say that I believe testing is extremely important because an inspector can't see a pathogen. You really have to have tools to do this; you have to be able to detect the pathogens on produce in order to have meaningful impact on all of this.

Senator KOHL. Very good. Well, I think you all are a great panel and you're a great resource of information and suggestions and recommendations. I'm going to use your expertise so that in this hearing, listening to you talk and having the opportunity, as we do today, to have the top dogs from Washington here, Dr. von Eschenbach and Dr. Brackett. I'm sure you feel that this is an unusual opportunity we have to not only have them in our presence but to talk to them a little bit.

So after they make their statements, instead of maybe me questioning them or making a suggestion or making a request, I'd like to give you all an opportunity to pose one or two questions to Dr. Brackett or Dr. von Eschenbach to get the kind of answers that you'd like to get right here on the ground, as well as myself, from people who you can hope will make a difference. So we'll do that after they make their statement. Thank you so much.

First of all, I'd like to thank you both again for taking the time and putting forth the effort to be here with us today. As the panel that we've just heard have aptly illustrated, FDA's food safety programs deserve some very specific attention and I'm grateful that you are here today to give it and give us your attention.

I've scheduled you to appear as the second panel so you could have the benefit of hearing the witnesses before you, who I'm sure you would agree have done an outstanding job and I hope you consider that a blessing rather than a curse. It's a blessing because now you have a chance to make some real replies and illustrate how the FDA, under your leadership, can make progress on these important topics.

There are some who suggest that the FDA's food systems are not up to the task. Some might have called those systems somewhat broken and I want those critics to be convinced otherwise. I suggest that we need to convince them not just with words—both myself and yourself—but with deeds and accomplishments and I, of course, want to work with you in the years to come to do exactly that.

I said before and I want to repeat, outbreaks of food-borne illness caused by produce have doubled since 1998. During this time, the FDA's food budget has suffered. The number of people getting sick is going up but the number of inspections and food safety tests are going down. So too, are the number of food inspectors and overall staff at the FDA's Center for Food Safety. As we know, imports have risen dramatically over the years but the agency is only able to inspect less than 1 percent of imported product.

I know the arguments and we all understand the arguments. I know that your ability to ask for additional funding is limited, that you have to support the President's budget request. I don't envy your position. However, the job of the FDA is to protect the public as I'm sure we would agree and not just a budget request.

We all know that more needs to be done. We've talked about this multiple times. I know that you are truly committed to protecting the public and of course, it's my job to help you to do just that. I want to help you put more people on the ground in the right place, people who not only react when an outbreak occurs but more importantly, people who are in place to prevent more outbreaks. I want to help you accomplish the research to be more efficient, to have faster tests, to enhance the FDA's capacity for preventing contamination as well as to trace as quickly as possible when contamination does occur.

We all understand these things cost money and you cannot do them all by yourself. But there are things that we can do, things that we can do now. We can require farmers and processors to implement and maintain good safety practices. You've been asked to do so by two of the witnesses that we have here today and I know that you are considering this. I hope that you will speak to some of these ideas today and respond to what you've already heard. We're looking forward to your statements and thank you again for being here. Dr. von Eschenbach, we'd like to hear from you first.

**STATEMENT OF HON. ANDREW C. VON ESCHENBACH, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH
AND HUMAN SERVICES**

Dr. von ESCHENBACH. Thank you very much, Mr. Chairman. Let me begin by thanking the entire subcommittee that you chair for the tremendous support that has been provided to the Food and Drug Administration. I know this staff is here as well and is testimony to the tremendous support that you have provided to us. I want to thank you personally for your national leadership, not only in the support of the food component of FDA but for the tremendous leadership you've provided addressing many of the challenges we face with regard, for example, to your vision of generic drugs. I think your leadership is manifested here today and it's a great opportunity for us to be in Wisconsin and specifically to be accompanied by one of Wisconsin's finest, Dr. Brackett, and I think the

fact that he is born and bred in Wisconsin and now leads the Center for Food Safety and Applied Nutrition is again testimony to the important role that we recognize is being played here in this conference room.

You take great pride in this State's contributions to the American food supply and clearly, you are unsurpassed with regard to contributions of cheese and cranberries, so feeding the American people is an important part of Wisconsin's commitment. We're blessed in this country to be unsurpassed with regard to our food, both in terms of its nutrition and with regard to the choices that are provided to us and in fact, with regard to food safety. But the world is changing around us and we've noted, for example, as has been pointed out, an increase in the consumption of fresh fruits and vegetables. We noticed important changes in production and rapidly moving from farm to table. And that has provided new challenges to us.

So it is also fitting to be here in Wisconsin, where, as has been pointed out, the Wisconsin Department of Health and Family Services was the first to detect the outbreak of *E. coli* and to fingerprint that particular pathogen so we were able to determine that it was not just a sporadic illness but in fact, a food outbreak.

We must, as you have pointed out, Mr. Chairman, together and collectively recognize that no matter how nutritious, no matter how safe, no matter how good our food is in this country, we must do better and FDA is committed to working with you and others because even one death is one death too many.

You have my written testimony, Mr. Chairman, which I'll submit for the record and the Food and Drug Administration has provided a number of materials for this particular hearing that I would also like to have included. One of them describes the steps that occur in the anatomy of an outbreak so that there is an opportunity to understand the sequential events that all typically result in FDA intervening in a food outbreak, taking appropriate steps, as we did with regard to both the recent outbreak of *E. coli* and salmonella.

We've also provided an edition of FDA Consumer and in this recent edition, it defines the specific steps that FDA is taking to continue to enhance the safety of produce, especially fresh produce. We will be providing also in the handout and the materials, a new FDA Guidance that we are announcing today for the safety of fresh produce.

You asked us, Mr. Chairman, how we can make it better. FDA will commit to you and to the American people, our ongoing effort toward a multi-step, multi-disciplinary campaign to improve food safety. It is a part of an overarching continuous quality improvement of products initiative so that food, along with drugs, devices and biologics, will all be enhanced with regard to not just their effectiveness but their safety, by focusing on the life cycle of the product, from production to consumption and the FDA's important role and multiple steps with multiple partners in that continuum.

With regard to food, it will be an effort from farm to fork. A few of the initiatives that we believe are important to address food safety are to look at the protection that can be provided by enhanced detection and enhanced remedies. One particular initiative that I think should be significant into this effort is our current Of-

office of Regulatory Affairs reorganization that we have currently proposed to Congress. Within that reorganization, we will provide opportunities to significantly enhance the efficiency of our field operations to be able to provide a shift from laboratory efforts that are centralized to laboratory opportunities that we can take into the field and also enhance the number of trained investigators that will be available to that field force.

We will also be enhancing our ability to coordinate our food safety efforts by greater integration of our food defense efforts. We have a focus in that regard, across that continuum, on risk management and risk mitigation strategies. Some of those opportunities will allow us to enhance greater cooperation with State laboratories, particularly through the CFSAN Network and especially with regard to our interactions with academia, including a very significant opportunity we've had with the University of Wisconsin, to address many issues with regard to the protection of our food supply.

We will continue our efforts with regard to coordination with other Federal agencies. We have currently an effort that was fully supported by Secretary Johanns and Secretary Leavitt that will be announced that will bring USDA and the Department of Health and Human Services to a much closer level of integration around food safety.

This past week, Julie Gerberding, head of the Centers for Disease Control and Prevention and I have announced the commitment to a joint leadership task force between FDA and CDC that will be specifically focused on enhancing our data integration networks as well as our enhanced communications strategies. So as we go from diligence to outbreak, the relationship between the CDC and the FDA will be much more seamless and much more efficient.

We will also be increasing our efforts with regard to enhancing the safety, the science of safety, particularly with focused research efforts not only in CFSAN but also in our National Center for Toxicological Research and our Center for Veterinary Medicine, all of which will be able to provide an opportunity for us to focus on the science that is necessary to understand the anatomy of an outbreak.

PREPARED STATEMENT

In particular today, we are pleased to announce a further effort to enhance our collaboration with industry by approaching an initiative of building quality in to the production process. I'd like to this opportunity with your permission, Mr. Chairman, to turn the microphone over to Dr. Brackett to give you specific reference to that new initiative of collaboration with industry.

[The statement follows:]

PREPARED STATEMENT OF DR. ANDREW C. VON ESCHENBACH

Good morning, Chairman Kohl. Thank you for the opportunity to appear today to discuss food safety and the safety of fresh produce. I appreciate your commitment to the work of FDA and I commend you for your special interest in the safety of America's food supply.

Appearing with me today is Dr. Robert Brackett, Director of FDA's Center for Food Safety and Applied Nutrition. We appreciate the opportunity to discuss FDA's

current processes as well as planned improvements for food safety, particularly the safety of fresh produce.

In the past decade, fresh produce consumption has increased, and fresh-cut produce¹ represents a particularly fast-growing segment of the fresh produce market. These foods are an important part of a healthy and nutritious diet, and Americans expect them to be safe. The 2006 outbreaks of *Escherichia coli* (E. coli) O157:H7 infection linked to fresh spinach and lettuce emphasize the need for continued efforts to protect the public health from foodborne illnesses associated with fresh produce. We at FDA are committed to doing everything we can to help ensure that these and all other FDA-regulated foods are safe.

Therefore, FDA has requested an increase of \$10.6 million for food safety activities in fiscal year 2008. This increase will bring the total FDA investment for food safety to \$391 million in fiscal year 2008. This investment will help FDA reduce risk across the lifecycle of produce production. FDA will use these resources to develop better methods to detect and attribute foodborne illness outbreaks related to produce, increase sampling and traceback, develop and update guidance to prevent and reduce outbreaks, obtain additional expertise in the production and processing of fresh produce, and enhance our response to foodborne outbreaks.

Fresh vegetables and fruits pose particular food safety challenges. Because most produce is grown in an outdoor environment, it is vulnerable to contamination from pathogens that may be present in the soil, in agricultural or processing water, and in manure used as fertilizer, or due to the presence of animals in or near fields or packing areas. It is also vulnerable to contamination due to inadequate worker health and hygiene protections, environmental conditions, production safeguards, and sanitation of equipment and facilities. The fact that produce is often consumed raw or with only minimal processing, without any type of intervention that would reduce or eliminate pathogens prior to consumption, contributes to its potential as a source of foodborne illness. Consequently, controlling the way fresh produce is grown, harvested, and moved from field to fork is crucial to minimizing the risk of microbial contamination.

For the past 100 years, FDA has established and maintained the gold standard for food safety. Americans have one of the safest food supplies in the world. But the production, distribution, and importation of foods, the public's consumption practices, and our ability to track and identify foodborne pathogens have changed significantly, and FDA must respond to those changes. Fresh produce serves as a good example of the changes we are witnessing. Consumption of fresh produce—especially items like spinach and lettuce implicated in recent outbreaks of foodborne illness—has increased significantly since 1999. According to USDA, per capita consumption of leafy green lettuce and spinach grew by 59 percent and 130 percent respectively, between 1999 and 2006.

Therefore, reducing the risk of foodborne illness requires strong science capable of identifying both the sources of risk and effective control measures. We are using molecular technology to improve our ability to identify foodborne illnesses and their causes by tracking the fingerprints of the suspected contaminants. We must address some of these risks as food is produced and other risks as food is processed and distributed. We must also enhance our ability to detect and contain outbreaks. Reducing the risk of foodborne illness also requires effective partnerships with other parties interested in food safety. Finally, reducing the risks of foodborne illness also requires FDA to strategically deploy inspection resources in a manner that addresses the greatest risks to the food supply. FDA has focused its food safety efforts in three key areas, and I elaborate on these here.

Strengthening the Scientific Basis for FDA's Program to Improve Food Safety

Strengthening the scientific basis for FDA's program to improve food safety is key to improving FDA's effectiveness at protecting public health. For the past decade, FDA has worked closely with USDA's Agricultural Research Service (ARS) and Cooperative State Research, Education, and Extension Service (CSREES) to coordinate and mutually support our respective research efforts related to produce safety. This relationship allows FDA to augment its research resources and gain access to facilities and expertise we do not have. In this spirit, we collaborated with ARS and CSREES to look for sources of E. coli O157:H7 in California's Salinas Valley, to analyze water samples from the Salinas watershed for E. coli O157:H7, and to relate

¹ Fresh-cut is defined as fruits and vegetables that have been minimally processed and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. Minimally processed fruits and vegetables have not undergone steps designed to kill pathogens that may be present.

the location of bacteria to geographical, seasonal, or rainfall variation. FDA will use the information obtained from this study to inform produce growers about strategies to prevent pre-harvest microbial contamination.

We strengthen the scientific basis for our program by collaborating and learning with others, such as participating in many scientific and technical meetings on food safety. Last month we participated in a forum sponsored by the Western Institute for Food Safety and Security to share information on assessing industry approaches to address the safety of lettuce and leafy greens on the farm and at packing, cooling, and processing facilities. In February 2007, the FDA-affiliated Joint Institute for Food Safety and Applied Nutrition and the University of Florida sponsored a workshop to improve understanding of how tomatoes become contaminated with *Salmonella* and other pathogens. In May 2007, FDA, the National Center for Food Safety and Technology, and the University of Georgia's Center for Food Safety will co-sponsor a workshop on microbial testing to reach a consensus on the role of microbial testing to ensure the safety of produce.

To seek additional input from the public, we are holding two public hearings (March 20 in California and April 13 in Maryland) concerning the safety of fresh produce. We will share information about recent outbreaks of foodborne illness related to fresh produce and solicit comments, data, and other scientific information about current agricultural and manufacturing practices, risk factors for contamination, and possible measures by FDA to enhance the safety of fresh produce.

Enhancing Effective Partnerships

To succeed in our science-based efforts to promote food safety, we need to enhance our collaborations with stakeholders interested in food safety, particularly with respect to fresh produce. Fresh produce is produced on tens of thousands of farms, and contamination at one step in the growing and processing chain can be amplified at the next step. FDA has worked with the public and private sector to encourage industry to follow the recommendations and standards contained in FDA guidances. After enlisting the help of the scientific community and the industry, FDA published the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guide, published in 1998, recommends good agricultural practices and good manufacturing practices that growers, packers, and shippers can take to address common risk factors in their operations. We have worked with the domestic and foreign fresh produce industry since the release of this Guide to promote its recommendations and to advance the scientific knowledge to enhance the safety of fresh produce.

The example of fresh sprouts illustrates how successful these efforts can be. In 1999, there were 390 reported illnesses associated with eating contaminated fresh sprouts. FDA published two guidance documents for sprouts that year. We believe that the subsequent decline in sprout-associated illnesses was in large part due to industry adhering to recommendations in those guidances through our outreach and inspection efforts. In 2004, only 33 illnesses were reported associated with fresh sprouts, and in 2005 and 2006 there were none.

FDA's efforts in this area are ongoing. I am pleased to report that this morning FDA issuing a draft final version of its "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (the Fresh-cut Guide). This guidance is intended for all fresh-cut produce firms, including, among others, fresh-cut spinach and lettuce/leafy greens, to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards. In addition, FDA worked with the Delegation of the United States to the international Codex Alimentarius Commission to request, at the earliest possible date, an expert consultation on the microbiological safety of fresh produce to support the development of commodity-specific annexes to the hygienic code. In August 2006, FDA launched its "Lettuce and Leafy Greens Initiative," which assesses practices and conditions at select farms and facilities in California, in collaboration with California's Department of Health Services and its Department of Food and Agriculture. We will continue to work with Federal, State, local and international food safety partners and with industry to develop guidance, conduct research, develop educational outreach materials, and initiate other commodity- or region-specific programs to enhance the safety of fresh produce.

Improving Risk-Based Targeting of Inspection Resources

FDA is significantly improving its ability to target its inspection resources at the greatest risks to public health. However, inspections cannot and will not identify every potential contaminant. Improving the processes and operations of all participants in the food production and distribution process offers the greatest protection for American consumers, and inspections are only one component of this activity. To make best use of available resources, FDA uses a targeted, risk-based approach

to inspections. FDA conducted 17 percent more import field exams in 2006 than in 2003. In addition, the FDA/USDA Food Emergency Response Network increased its laboratory participation to 134 laboratories in fiscal year 2007, compared to 30 participating laboratories in March 2004 (near FERN's inception), integrating the Nation's food testing capability for microbiological, chemical and radiological threat agents.

FDA's ability to reallocate resources based on risk was tested when peanut butter was recently implicated in an outbreak of Salmonella Tennessee. FDA issued a warning to consumers within 24 hours of receiving notification by CDC, and swiftly deployed inspectors to the plant. ConAgra recalled the products and ceased production in the implicated processing plant. FDA is working to identify the root source of the contamination in order to prevent similar foodborne illness outbreaks from recurring.

Conclusion

FDA is working hard to ensure the safety of food, in collaboration with its Federal, State, local, and international food safety partners, and with industry and all its other stakeholders. The American food supply continues to be among the safest in the world. We have made progress, and we will continue to strive to reduce the incidence of foodborne illness.

Thank you for the opportunity to discuss FDA's continuing efforts to improve the safety of fresh produce. I am happy to answer any questions.

GUIDANCE FOR INDUSTRY

GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF FRESH-CUT FRUITS AND VEGETABLES

INTRODUCTION

The Federal Government provides advice on healthful eating, including consuming a diet rich in a variety of fruits and vegetables, through the Dietary Guidelines for Americans and the related MyPyramid food guidance system (Ref. 1, 2). In response, per capita consumption data show that Americans are eating more fresh produce (Ref. 3). With \$12 billion in annual sales in the past few years (Ref. 4), the fresh-cut sector of the produce industry is its fastest growing segment. As the fresh-cut produce market continues to grow, the processors of such produce are faced with the challenge of processing an increasing variety and volume of products in a manner that ensures the safety of this produce. From 1996 to 2006, seventy-two foodborne illness outbreaks were associated with the consumption of fresh produce. Of these produce related outbreaks, 25 percent (18 outbreaks) implicated fresh-cut produce (Ref. 5). Many factors may play a role in the incidence and reporting of foodborne illness outbreaks that implicate fresh produce, such as an aging population that is susceptible to foodborne illness, an increase in global trade, a more complex supply chain, improved surveillance and detection of foodborne illness, improvements in epidemiological investigation, and increasingly better methods to identify pathogens (Refs. 6 thru 12).¹

Processing fresh produce into fresh-cut products increases the risk of bacterial growth and contamination by breaking the natural exterior barrier of the produce (Ref. 6). The release of plant cellular fluids when produce is chopped or shredded provides a nutritive medium in which pathogens, if present, can survive or grow (Ref. 6). Thus, if pathogens are present when the surface integrity of the fruit or vegetable is broken, pathogen growth can occur and contamination may spread. The processing of fresh produce without proper sanitation procedures in the processing environment increases the potential for contamination by pathogens (see Appendix B, "Foodborne Pathogens Associated with Fresh Fruits and Vegetables."). In addition, the degree of handling and product mixing common to many fresh-cut processing operations can provide opportunities for contamination and for spreading contamination through a large volume of product. The potential for pathogens to survive or grow is increased by the high moisture and nutrient content of fresh-cut fruits and vegetables, the absence of a lethal process (e.g., heat) during production to eliminate pathogens, and the potential for temperature abuse during processing, storage, transport, and retail display (Ref. 6). Importantly, however, fresh-cut produce processing has the capability to reduce the risk of contamination by placing the preparation of fresh-cut produce in a controlled, sanitary facility.

¹This guidance has been prepared by the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

This guidance is intended for all fresh-cut produce processing firms, both domestic firms and firms importing or offering fresh-cut product for import into the United States, to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards. This guidance does not set binding requirements or identify all possible preventive measures to minimize microbial food safety hazards. We recommend that each fresh-cut produce processor assess the recommendations in this guidance and then tailor its food safety practices to the processor's particular operation. Alternative approaches that minimize microbial food safety hazards may be used so long as they are consistent with applicable laws and regulations.

This guidance primarily addresses microbiological hazards and appropriate control measures for such hazards. However, some chapters in the guidance discuss physical and chemical hazards.

FDA's guidance documents, including this document, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidance means that something is suggested or recommended, but not required.

SCOPE AND USE

Fresh-cut Produce.—This guidance covers fresh-cut fruits and vegetables that have been minimally processed (e.g., no lethal kill step), and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. Examples of fresh-cut products are shredded lettuce, sliced tomatoes, salad mixes (raw vegetable salads), peeled baby carrots, broccoli florets, cauliflower florets, cut celery stalks, shredded cabbage, cut melon, sliced pineapple, and sectioned grapefruit.² Fresh-cut produce does not require additional preparation, processing, or cooking before consumption, with the possible exception of washing³ or the addition of salad dressing, seasoning, or other accompaniments. As the fresh-cut produce market continues to evolve, the scope of this guidance may need to be modified to address new or novel types of products.

Fresh-cut Produce and Current Good Manufacturing Practice Requirements for Foods (CGMPs) (21 CFR Part 110).—FDA's regulations⁴ in 21 CFR Part 110 establish CGMPs in manufacturing, packing, or holding human food. However, raw agricultural commodities (RACs), as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (the Act), are not subject to the CGMP requirements by virtue of the exclusion in 21 CFR 110.19. Section 201(r) defines a raw agricultural commodity as any food "in its raw or natural state . . ." Fresh-cut fruits and vegetables are not RACs because they are no longer "in [their] raw or natural state" and instead have become "processed food" as that term is defined in the Act. Section 201(gg) of the Act defines a "processed food" as "any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydrating, or milling." Under 21 CFR 110.3, the definitions in section 201 of the Act apply to Part 110. Thus, fresh-cut fruits and vegetables are appropriately considered "processed foods" and are subject to the CGMPs in Part 110. The conclusion that fresh-cut produce are not RACs is consistent with the preamble to the proposed revisions to the CGMP regulation (44 FR 33238 at 33239, June 8, 1979), which states, when discussing the exclusion for RACs, that such products may be excluded because "food from those commodities is . . . brought into compliance with the Act at the later stages of manufacturing, processing, packing, or holding." The CGMPs establish food safety practices applicable to processors who manufacture, process, pack, or hold processed food. FDA believes that the recommendations in this guidance complement the CGMPs by suggesting more specific food safety practices for processors of fresh-cut produce.

²Fresh sprouts are raw agricultural commodities and thus, their production is not governed by 21 CFR Part 110. FDA does, however, recommend that sprouting firms employ current good manufacturing practices. Also, FDA has published specific guidance for the production of sprouts. We recommend that producers of sprouts refer to this guidance, "Reducing Microbial Food Safety Hazards for Sprouted Seeds" (Ref. 13) and "Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" (Ref. 14).

³For information regarding re-washing of fresh-cut produce, go to <http://www.dhs.ca.gov/fdb/>, click on "Food Safety Program" and scroll down to the Produce section to obtain a link to the Recommendations from Fresh-cut Produce Re-wash Panel, April 4, 2006.

⁴A copy of the CGMPs in 21 CFR Part 110 may be accessed on the internet at <http://www.gpoaccess.gov/cfr/index.html>.

Fresh-cut Produce and HACCP Systems.—A Hazard Analysis and Critical Control Point (HACCP) system is a prevention-based food safety system designed to prevent, reduce to acceptable levels, or eliminate the microbial, chemical, and physical hazards associated with food production (Ref. 6). One strength of HACCP is its proactive approach to prevent food contamination rather than trying to identify and control contamination after it has occurred.

Although HACCP is not currently required for the processing of fresh-cut produce, the United Fresh Produce Association recommends use of HACCP principles, and according to the association, many segments of the fresh-cut produce industry have adopted HACCP principles.⁵

FDA encourages fresh-cut produce processors to take a proactive role in minimizing microbial food safety hazards potentially associated with fresh-cut produce. We recommend that fresh-cut processors consider a preventive control program to build safety into the processing operations for fresh-cut fruits and vegetables. Awareness of the common risk factors discussed in this guidance and implementation of preventive controls determined by a firm to be appropriate to its individual operations will enhance the safety of fresh-cut fruits and vegetables. FDA also recommends that processors encourage the adoption of safe practices (See Chapter IV) by their partners throughout the supply chain, including produce growers, packers, distributors, transporters, importers, exporters, retailers, food service operators, and consumers, to ensure that the processor's efforts will be enhanced.

This guidance begins with a discussion of primary production and harvesting of fresh produce in Chapter IV and continues with recommendations for fresh-cut processing in four areas—(1) personnel health and hygiene, (2) training, (3) building and equipment, and (4) sanitation operations. Following this discussion, the guidance covers fresh-cut produce production and processing controls from product specification to storage and transport. The final chapters provide recommendations on recordkeeping and on recalls and tracebacks.

DEFINITIONS

The following definitions apply to this guidance.

Adequate Quality Water.—The determination of adequate quality water is based on its use, where adequate quality water for one purpose is not necessarily adequate for another purpose. (1) Where the water does not become a component of the fresh-cut produce, adequate quality refers to water that is safe and sanitary, at suitable temperatures, and under pressure as needed for all uses; and (2) where the water is used in a manner such that it may become a component of the fresh-cut produce (e.g., when such water contacts components, fresh-cut produce, or any contact surface), adequate quality water refers to water that complies with applicable Federal, State, and local requirements.

Fresh Fruits and Vegetables.—Fresh produce that is likely to be sold to consumers in an unprocessed (i.e., raw) form. Fresh produce may be intact, such as whole strawberries, carrots, radishes, or tomatoes, or cut from roots or stems during harvesting, such as celery, broccoli, lettuce, or cauliflower.

Fresh-cut Fruits and Vegetables or Fresh-cut Produce.—Fresh fruits and vegetables for human consumption that have been minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing, prior to being packaged for use by the consumer or a retail establishment (e.g., pre-cut, packaged, ready-to-eat salad mixes). Fresh-cut produce does not require additional preparation, processing, or cooking before consumption, with the possible exception of washing or the addition of salad dressing, seasoning or other accompaniments.

Food Hazard.—A biological, chemical, or physical agent that is reasonably likely to cause human illness or injury in the absence of its control.

Pathogen.—A microorganism capable of causing human illness or injury.

Processing Water.—Water that is used for post-harvest handling of produce, such as washing, cooling, waxing, or product transport.

Standard Operating Procedures (SOPs).—Procedures established by an operator for the day-to-day activities involved in the production of safe and wholesome food.

Sanitation Standard Operating Procedures (SSOPs).—Procedures established by an operator for the day-to-day sanitation activities involved in the production of safe and wholesome food.

⁵United Fresh Produce Association: <http://www.unitedfresh.org/>.

IV. Primary Production and Harvesting of Fresh Fruits and Vegetables

In general, anything that comes into contact with fresh produce has the potential to contaminate it. Fresh produce may become contaminated at any point along the farm-to-table continuum. The major source of microbial contamination of fresh produce is indirect or direct contact with animal or human feces. Once fresh produce has been contaminated, removing or killing the microbial pathogens is very difficult. Prevention of microbial contamination at all steps in the farm-to-table continuum is preferable to treatment to eliminate contamination after it has occurred.

On the farm, potential contamination avenues include contact with untreated manure used as a soil amendment, contaminated water, infected workers, or conditions in the field or packing facility such as unclean containers and tools used in harvesting and packing, and the presence of animals. In transport, conditions such as unclean floors and walls of the transport vehicle and unclean containers can contribute to contamination with pathogens. Thus, it is important that fresh-cut produce processors be aware of the conditions under which their fresh produce is grown, harvested, packed, and transported. Furthermore, knowing your suppliers and what they are doing to minimize risk of contamination is prudent.

To reduce potential contamination, FDA's 1998 "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (GAPs Guide) (Ref. 15) provides recommendations for growers, packers, and shippers to use good agricultural and good manufacturing practices in those areas over which they have control to prevent or minimize microbial food safety hazards in fresh produce. Potential sources of contamination identified in the GAPs Guide are biosolids and manure, water, field workers, equipment, and containers.

We recommend the following practices to ensure that incoming fresh produce is safe and suitable for processing into fresh-cut product:

- Becoming aware of practices used by your suppliers (i.e., growers, packers, coolers, transporters, etc.)
- Evaluating the practices of your suppliers by a knowledgeable food safety expert
- Accepting produce from suppliers who use GAPs, GMPs or other appropriate practice from the farm to the processing facility
- Using a mechanism to verify the use of food safety practices by your suppliers (e.g., letter of certification or guarantee from a supplier)

PERSONNEL

This section provides recommendations regarding personnel of an establishment that processes fresh-cut produce. The recommendations address two major areas: worker health and hygiene, and training.

Worker Health and Hygiene

Workers can carry microbial pathogens on their skin, in their hair, on their hands, and in their digestive systems or respiratory tracts. Unless workers understand and follow basic food protection principles, they may unintentionally contaminate fresh produce and fresh-cut produce, food contact surfaces, water supplies, or other workers, and thereby, create the opportunity to transmit foodborne illness. Basic food protection practices related to worker health and hygiene fall into two categories, disease control and cleanliness.

Disease Control

FDA recommends that employees with direct access (such as processing, storage, and transport workers) and indirect access (such as equipment operators, buyers, and pest control operators) to the production areas of fresh-cut fruits and vegetables follow good hygienic practices for maintaining personal health and hygiene in order to protect the product from contamination.

FDA recommends the following practices to prevent food, food contact surfaces, and food packaging materials from becoming contaminated with microbial pathogens from an employee with an infectious illness or wound:

- Establishing a company policy that requires employees to report any active case of illness to supervisors before beginning work
- Training supervisors to know the typical signs and symptoms of infectious disease

We recommend that firms train employees to report to their supervisor any information about personal health status or activities relating to diseases transmitted through food. Such information would include reporting an active case of illness. FDA recommends that supervisors be trained to recognize the symptoms of active infectious disease; these symptoms are vomiting, nausea, diarrhea, and abdominal cramps. We recommend that employees with these symptoms be excluded from any operations which may be expected to result in con-

tamination of fresh or fresh-cut produce or food contact surfaces, including equipment and utensils, until the medical condition is resolved.

—Covering cuts and wounds with a suitable water proof dressing when workers with such injuries are permitted to continue working.

We recommend that firms maintain an adequate supply of bandages that provide protection from any wound. A wound containing pus (such as an open and draining boil or other infected wound) that is located on a part of the body that could contact fresh produce or fresh-cut produce, processing equipment, or tools, presents a risk of contaminating fresh-cut produce. When a worker in the processing area needs a bandage, we recommend that the firm consider using a bandage that is detectable by a metal detector if there is a metal detector in the processing line. Using detectable bandages will allow the facility to detect when a bandage has fallen into the processing line so that corrective action can be taken. We also recommend that a worker with a wound that cannot be covered to prevent contact with fresh produce or fresh-cut produce, processing equipment, or tools not work with any aspect of fresh produce or fresh-cut produce, processing equipment or tools until the wound has healed.

Cleanliness

FDA recommends that employees use the following food protection practices to prevent fresh or fresh-cut produce or food contact surfaces including equipment or utensils from becoming contaminated as a result of poor employee hygiene or inappropriate employee conduct:

—Maintaining adequate personal cleanliness

—Washing hands frequently and effectively and sanitizing hands if needed

FDA recommends that employees wash their hands before beginning work and after engaging in any activity that may contaminate their hands. FDA's recommendations regarding when employees should wash their hands are reflected in the following list:

Before beginning work, especially if the employee has direct contact with fresh produce

Before putting on a new pair of disposable or non-disposable gloves and after removing the gloves

After touching human body parts or anything other than food or food contact surfaces

After using the toilet; after coughing, sneezing, or using a handkerchief or tissue

After using tobacco, eating, or drinking

After engaging in any activity that may contaminate hands, such as handling garbage, cleaning chemicals, or incoming produce before it has been washed

After caring for or touching animals

Before returning to a workstation

—Washing and sanitizing non-disposable gloves before starting work, and as needed

—Changing disposable gloves whenever contamination is a possibility

Improperly used gloves may become a vehicle for spreading pathogens. The use of gloves does not lessen the need for, or importance of, hand-washing and other proper hygiene practices. We recommend that if gloves are used in a facility, the firm develop guidelines for their safe use, sanitation, and changing.

—Wearing appropriate attire on the job

FDA recommends that employees wear clean clothes and any additional outer items (e.g., hairnets and beard covers, lab coats, aprons, and appropriate footwear) that will help protect fresh and fresh-cut produce from inadvertent contamination during processing.

—Not engaging in certain activities where food may be exposed or utensils are washed

FDA recommends that employees in food processing areas not engage in activities that could contaminate food, such as eating, using tobacco, chewing gum, or spitting.

Training

Training every employee about the CGMPs and preventive controls will help to eliminate or minimize contamination of fresh-cut produce. We recommend that education and training programs be designed to help employees understand what is expected of them and why what is expected is important. We also recommend that company expectations for proper employee hygiene and food protection techniques be clearly communicated to new employees before starting employment and reaffirmed during periodic training programs. There are many materials available to

firms to support employee training. We recommend that firms consider whether the language of the training and training materials is appropriate for the employees. Useful materials and information may be found at the USDA/FDA Foodborne Illness and Education Information Center (<http://www.nal.usda.gov/foodborne/index.html>), the Fight BAC!® campaign of the Partnership for Food Safety Education (<http://www.fightbac.org/main.cfm>), and Government Food Safety Information (<http://www.foodsafety.gov/>).

Training employees before they begin work with fresh or fresh-cut produce, at regular intervals, and at a minimum annually provides employees with important information about food safety best practices and company policies. We recommend that firms consider teaching, in the same training session, only a small number of employees at or near their workstation, if the environment permits it, for short periods of time, such as 10–15 minutes per session. The sessions could cover only one topic at a time and could be targeted to specific food safety concerns of that workstation. For example, washing station employees could be trained about appropriate antimicrobial chemical usage, and packaging station employees could be trained about proper handling and cleanliness of boxes and totes. We recommend refresher or follow-up training to reinforce the initial training. Training a few employees at a time can be an effective way to provide refresher training with the least disruption to work.

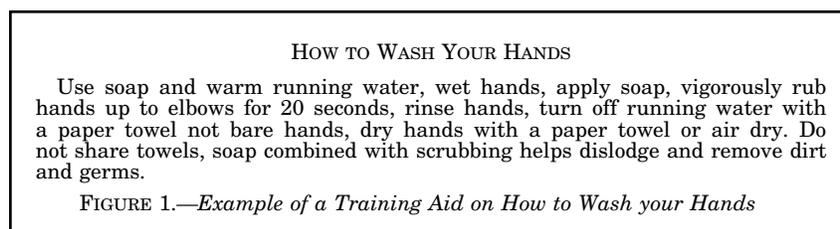
A firm may wish to post signs and pictorial representations of good practices covered in training as an additional way to reinforce training. We recommend that signs be multilingual and posted in areas close to where the practice is performed. We also recommend that the training provided to employees be documented so there is a record of the training topics covered and which employees completed it.

A well-designed training program provides information to help employees apply CGMPs while on the job. We recommend that a fresh-cut produce firm's training program for employees (including temporary, seasonal, and full time employees) include training on the CGMPs for production, maintenance, quality assurance, and quality control with an emphasis on worker health and hygiene; employee roles and responsibilities; and sanitation principles and sanitary practices.

Training for Worker Health and Hygiene

We recommend that employees be trained to follow good personal hygiene practices, including the use of proper hand washing techniques, wearing clean clothes and any additional outer coverings (e.g., hairnets and beard covers, disposable gloves, aprons), and appropriate conduct on the job. FDA also recommends that employees be trained on how, when, and to whom to report illness. Hand washing training is particularly important. We recommend that employees be trained about how, when, and why they must properly wash their hands and exposed portions of their arms. We also recommend that employees be taught to wash and sanitize their hands before entering areas where fresh or fresh-cut produce is present.

Figure 1 is an example of an aid that could be used to train employees on the proper technique to use in washing hands:



Training on Employee Roles and Responsibilities

We recommend that employees be trained consistent with the level of complexity of their jobs and that additional training be provided as needed to ensure current knowledge of equipment and process technology.

One goal of a training program is to help workers understand the importance of the tasks for which they are responsible, particularly those tasks that are important to minimizing microbial food safety hazards (such as monitoring the disinfectant level in wash water). We recommend that employees be trained about how to perform these tasks; to be aware of the microbial food safety hazards associated with them; to understand the procedures for monitoring conditions such as the disinfectant level, pH, and the temperature of the wash water, and any associated record-

keeping that the firm chooses to implement; to know the actions that are needed to minimize contamination of the product; and to consult with their supervisors if the established limits (such as the appropriate level of disinfectant in the wash water) are not met.

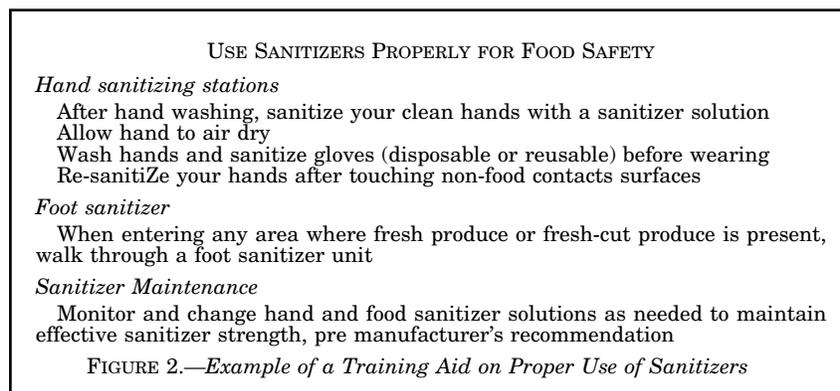
We recommend that personnel responsible for maintaining equipment that may have an impact on food safety be trained to understand the importance of their role in the production of safe food. Equipment maintenance jobs that may have an impact on food safety include changing water filters, maintaining refrigeration units, treating processing water, and calibrating equipment. We recommend that employees be trained to identify deficiencies that could affect product safety, to take the appropriate corrective actions (e.g., in-house repairs, contract repairs), and to be able to understand how indirect cross-contamination may occur when proper equipment controls are not maintained.

Training on Sanitation Principles and Sanitary Practices

We recommend that employees with cleaning and sanitation duties be trained to understand the principles and methods required for effective cleaning and sanitation, especially as those methods relate to food safety. We recommend that supervisors be trained to identify and promote good sanitary practices.

We also recommend that employees be trained in the proper use of sanitizing agents (sanitizers) and foot foam, foot baths, or spray systems, in proper cleaning and sanitizing steps of the equipment and facility, in proper use of equipment in the production environment, such as hoses and tools, and in the proper use, handling, and storage of chemicals used in sanitation.

Figure 2 is an example of an aid that could be used to train employees on the proper use of sanitizers:



Equipment (whether fixed or free standing), fixtures, floors, walls, and other structures in a processing facility can become a source of microbial contamination if not adequately maintained in sanitary condition. The high humidity and structural niches in a fresh-cut produce processing facility encourage microbial build-up. To prevent fresh-cut produce from becoming contaminated by equipment or other structures in the facility, we recommend that employees be trained on proper cleaning and sanitizing steps within the processing areas.

Figure 3 is an example of an aid that could be used to train employees on the cleaning and maintenance of processing equipment and facilities:

CLEANING AND SANITIZING STEPS

Remove heavy debris from floors with brooms or shovels and dry clean processing equipment, if needed
 Pre-rinse the equipment with adequate quality water
 Clean remaining debris from floor
 Rinse floor and drains with adequate quality water using a low pressure hose
 Use dedicated brushes to scrub floor and drains with an effective cleaner, applying adequate quality water as needed
 Foam and scrub the equipment with an effective cleaner and scrub using dedicated brushes
 Thoroughly rinse the equipment, floors, and drains with adequate quality water using a low pressure hose
 Remove excess water from floors
 Sanitize (according to manufacturer directions) the equipment and floors

FIGURE 3.—*An Example of a Training Aid on Cleaning and Sanitizing Steps Within Processing Areas*

In addition to using sanitizers¹ appropriately and cleaning and sanitizing the equipment and facility regularly, proper use of equipment, such as hoses, can also reduce the risk of contamination of fresh and fresh-cut produce. For example, keeping hose nozzles off the floor can help prevent nozzles and employee hands from becoming a source of contamination. We recommend that sections of hose that touch the floor or other unclean surface not make contact with fresh produce, food-contact surfaces, or packaging materials. A retractable hose suspended from the ceiling may help to prevent such contamination. In addition, allowing hose ends to sit in standing water or to be submerged in water tanks could allow back siphonage of water, thereby contaminating the water distribution system.

Further, we recommend that employees be trained to avoid use of high-pressure water hoses to clean floors, walls, and equipment in the processing and packaging areas during production or after production equipment has been cleaned. This practice will help prevent aerosols from contacting processing equipment and food-contact surfaces, product, or packaging materials. Therefore, we recommend that employees be trained on the proper use of cleaning equipment.

BUILDING AND EQUIPMENT

FDA recommends that the processing facility and its structures (such as walls, ceilings, floors, windows, doors, vents, and drains) be designed to be easy to clean and maintain and to protect the product from microbial, physical, and chemical contamination. For example, designing food contact surfaces to be smooth, non-absorbent, smoothly bonded, without niches, and sealed would make these surfaces easier to clean and thus, would prevent the harborage of microbial pathogens.

Building

Both direct contamination and cross-contamination of produce can be minimized by giving proper attention to physical design, emphasizing proper product flow, using appropriate construction materials, managing facility traffic, and ensuring proper airflow. We recommend that facilities and staging areas be designed to facilitate maintenance and good sanitation practices so that contamination may be controlled throughout receiving, cooling, processing, packing, and storage operations. We also recommend that buildings, fixtures, and equipment be maintained in a condition that will protect fresh-cut produce from potential microbial, chemical, and physical contamination.

External/Internal Structures

In general, we recommend limiting access to the facility and to its processing areas, providing adequate space for operations, ensuring adequate drainage of processing and wash water, installing food contact surfaces that are easy to clean and maintain, and designing areas and structures to protect the product and equipment from contamination.

In addition, we recommend the following practices:

¹Work from top down for cleaning and sanitizing activities. Some equipment may need to be disassembled before cleaning and sanitizing followed by reassembly.

- Adequately screening open windows, vents, fans, and similar features to prevent pest (insect, bird, rodent, reptile) entry
- Closing all exterior doors and entrances when not in use and ensuring an adequate seal when exterior doors and entrances are closed
- Properly constructing all walls, ceilings, windows, doors, floors, and overheads (e.g., pipes, air vents, and lights) and maintaining them in good condition (e.g., no cracks, rust, breakage, missing parts, or dips allowing puddles to form) so that they do not harbor pests or pathogens
- Designing properly sloping floors to drains ($\frac{1}{4}$ inch per foot), and sealing and keeping them in good repair so as to provide adequate drainage
- Designing floor drains to prevent the accumulation of water in or around the drains and making drains accessible for cleaning
- Fitting floor drains with seals and grates capable of preventing pest entry
- Using floor flumes with caution due to the potential for water aerosol contamination of the room air and nearby equipment surfaces

We recommend against the use of a floor flume transfer from the produce cooling and packing operation into or across an area housing fresh-cut produce operations.

- Constructing trench drains for automatic flushing
- Using under-floor drains in fresh-cut produce processing areas
- Designing collection areas for waste stream water to prevent product and equipment contamination
- Designing pipelines to avoid pipe and wall condensation from becoming a source of contamination

Where overhead condensate cannot be prevented, we recommend that catch pans be utilized, and be cleaned and sanitized on a regular basis.

- Avoiding wood construction materials wherever possible

If wooden equipment is used (including pallets), we recommend that the equipment be in good condition and well maintained so it is not a source of physical or microbial contamination. Non-wooden construction materials, such as plastic or stainless steel, are preferable for use in processing areas because they reduce the risk of microbial harborage and cross-contamination of final product.

- Using protective guards for light fixtures to prevent broken glass from falling into product

Facility Layout

We recommend that a fresh-cut fruit or vegetable processing facility be designed so that incoming raw products never cross paths with or are commingled with finished fresh-cut produce products. Similarly, we recommend maintaining separate raw incoming product, in process, and finished product areas so as to prevent the potential for microbial cross-contamination. Adequate food safety controls, operating practices, and facility design can reduce the potential for contamination by using location and/or flow of humans, product, equipment, and air.

We recommend the following practices that use location to reduce the potential for contamination:

- Having rest rooms that open into a location other than a processing area
- Locating the door to the outside in an area other than into a processing area
- Having a microbiology lab that opens into an area other than into a processing area
- Storing in-process and raw produce materials in different rooms
- Establishing dedicated cold rooms for raw product and processed product
- Locating hand washing and sanitizing facilities to facilitate regular and appropriate use by employees
- Locating a disinfectant foot foam, foot bath, or foot spray at all entrances and exits to all production and finished product storage areas.

We recommend the following practices that use flow of personnel, product, equipment, or air to reduce the potential for contamination:

- Having short direct routes for both product and personnel flow
- Designing the plant for one direction of personnel traffic, product, and air flow
- Designing product areas to have traffic patterns that separate raw and finished product using either linear product flow (raw to finished product) or by physical partition (Figure 7 in Appendix E is an example of product and personnel flow patterns in a fresh-cut processing plant.)
- Using an air filtration system for central air distribution and airflow that is counter to product flow, so that filtered air moves with a positive pressure from the cleanest areas (e.g., from packaging and finished product storage) toward less clean areas (e.g., the receiving area)

We also recommend that air intake for the facility be located to minimize contamination of the intake air by:

- Keeping the number of entrances and exits to the processing areas to a minimum
- Restricting the movement of lift trucks, bins, totes, maintenance tools, cleaning implements, clothing, and people from receiving and storage zones to processing and packaging areas
 - Color coding bins, totes, clothing, cleaning implements, maintenance tools, and other items (e.g., blue aprons for receiving zones and red aprons for processing and packaging areas) may help achieve separation of traffic and thereby, minimize cross-contamination.

Equipment Design, Construction, and Maintenance

We recommend that the processing equipment be designed and constructed to be easy to clean and maintain and to avoid microbial contamination of the fresh-cut product.

Equipment Design and Construction

We recommend the following to facilitate cleaning and to help ensure that fresh-cut produce is not contaminated during the processing operation:

- Using smooth, non-absorbent, sealed, and easily cleanable food contact surfaces that are sloped to drain freely and made of durable, non-corrosive, nontoxic materials

Food contact surfaces include items such as knives, conveyors, belts, chutes, product totes, gloves, tools including shovels and racks, cutting boards, tables, dryers and spinner baskets, and packing scales. We recommend that all food contact surfaces be smoothly bonded (e.g., free of pits, folds, cracks, crevices, open seams, cotter pins, exposed threads, and piano hinges) to avoid harboring pathogens. Where two food contact surfaces meet, we recommend use of a cover over the juncture to prevent food debris from collecting in the crevice and creating an area that is difficult to clean.

- Locating catwalks with open grating so they do not pass over areas of exposed fresh or fresh-cut produce or food-contact surfaces
- Designing equipment in the processing area to prevent water collection

We suggest cautious use of hollow structures, such as catwalk framework, table legs, conveyor rollers, and racks, because they may collect water and debris, and thus, harbor pathogens.

- Elevating food-contact surfaces sufficiently above the floor (with accessibility for cleaning) to prevent contamination from floor splashes
- Installing stationary equipment away from floor drains to allow accessibility to drains for cleaning and to prevent contamination of the equipment

Equipment Maintenance

Establishing a preventive maintenance program helps to ensure that all equipment functions as intended. Equipment failure requiring maintenance activities during production may increase the risk of microbial contamination, particularly from *L. monocytogenes* (Ref. 16). Preventive maintenance includes periodic examination and maintenance of equipment such as valves, gaskets, o-rings, pumps, screens, filters, and heat exchanger plates. We recommend that a firm develop appropriate plans of action in case important equipment, such as refrigeration equipment, disinfectant delivery systems, power systems, or alarm systems, malfunctions. We also recommend the following practices:

- Performing maintenance and calibration of equipment by appropriately trained personnel

We recommend that maintenance personnel who work in the processing or packaging areas comply with the hygiene requirements for production employees.

- Installing, calibrating, and maintaining temperature measuring or recording devices as necessary to ensure accuracy
- Frequently sharpening knives, if used, including retractable knives, and disinfecting before use

We recommend that knives be replaced if damaged or if they cannot otherwise be maintained in a sanitary condition.

- Frequently inspecting cutting blades and belts during processing operations for damage, product residue build up, or cleaning needs

We recommend that blades be removed and cleaned separately, and remaining equipment parts disassembled (if possible) and cleaned on a regular basis.

- Operating metal detectors in accordance with the manufacturer's instructions and checking for proper functioning at least daily to ensure effective detection of metal and removal of affected product

We recommend that procedures be in place, such as the use of metal detectors during packaging operations, to minimize the possibility that metal ends up in finished product packages.

- Calibrating safety control devices that are essential for maintaining the proper level and activity of wash water disinfectant, at a frequency recommended by the manufacturer and documenting this activity on the instrument calibration forms/logs
- Examining air filters for both intake air and compressed air and changing at least as often as the manufacturer specifies, or more frequently if a problem is indicated, such as evidence of filter fouling or perforation

SANITATION OPERATIONS

Pathogenic microorganisms may be found on floors, in drains, and on the surfaces of sorting, grading, processing, and packaging equipment. Without appropriate sanitation practices, these surfaces may be a source of microbial contamination.

Sanitation Program

We recommend the use of a comprehensive sanitation program developed by a trained employee such as a certified sanitarian to avoid microbial contamination of the product in a fresh-cut processing facility.

We recommend that fresh-cut processors consider using the following practices for their sanitation program:

- Establishing sanitation standard operating procedures (SSOPs), including a cleaning and sanitizing procedure with a regular schedule for all equipment, storage areas, fresh and fresh-cut produce production areas, air systems, and water storage areas

An example of such a schedule is included in Figure 4. When visual inspection or environmental monitoring results for equipment or the facility reveal dirt, food residues, or other debris, we recommend a more frequent cleaning and sanitizing schedule relative to what is shown in Figure 4.

FIGURE 4.—AN EXAMPLE OF A PROCESSING PLANT ENVIRONMENTAL SANITATION MASTER SCHEDULE ^{6 7}

Area	Cleaning/Sanitization Method	Tools	Cleaning Materials	Frequency
Walls	Foam, brush, rinse	Soft nylon brush and High Pressure Hose (when appropriate).	Chlorine-Quaternary ammonium ("quat")-based cleaner.	Once/Month Walls adjacent to processing equipment should be cleaned daily
Ceiling	Foam, brush, rinse	Nylon brush, high pressure machine	Chlorine-quat-based cleaner	Once/Month
Floors	Wash, rinse	Hard bristle broom (not straw), floor scrubbers, low pressure hose.	Chlorine-quat-or iodine based cleaner.	Daily
Doors	Foam, scrub, rinse	Scouring pad, cloth	Chlorine-quat-based cleaner	Once/Week
Plastic curtains	Foam, rinse	Foam and Rinse	Chlorine-quat-based cleaner	Once/Week
Overhead pipes, electrical conduits, structural beams	Foam, brush	Brush, bucket, high water pressure machine.	Chlorine-quat-based cleaner	Once/Month
Hoist, overhead light fixtures	Wipe, clean	Cleaning pad	Water, light detergent	Once/Quarter
Refrigeration coils	Rinse, sanitize	High pressure hose	Water, sanitize with quat	Once/Quarter
Chillers	Scouring	Scouring pad	Acid cleaner	As Needed/Audit
Air distribution filters	Soak	Plastic bins	Chlorine-alkaline detergent	Once/Quarter
Drains, trench	Clean, flood, rinse	Soft Nylon brush, 50 gallon container.	Chlorine-alkaline detergent, quat or iodine based sanitizer.	Daily
Grids	Brush, rinse	Nylon brush, high water pressure machine.	Chlorine-alkaline detergent	Daily
Waste, dumpster areas	Foam, brush, rinse	Nylon brush, high water pressure machine.	Heavy duty chlorine-based cleaner	Daily
Employee break rooms/bathrooms	Wash, rinse	Nylon brush, sanitary brushes	Chlorine-based soap or quat	Frequently throughout the day
Maintenance areas	Scrub, rinse	Nylon brush	Degreasing agent	Once/Month

⁶ Used with permission from the United Fresh Produce Association (UFGA). Food Safety Guidelines for the Fresh-cut Produce Industry, 4th Edition, 2001.

⁷ Also, as noted previously in section V.B.3., we recommend that employees be trained to avoid use of high-pressure water hoses to clean floors, walls, and equipment in the processing and packaging areas during production or after production equipment has been cleaned. This practice will help prevent aerosols from contacting processing equipment and food-contact surfaces, product, or packaging materials.

- Including as part of the sanitation schedule the name of the employee (and alternate when primary employee is absent) responsible for the activity, the equipment to be cleaned and how to disassemble it, the frequency of cleaning, procedures for cleaning (including type and concentration of cleaning compound and sanitizer), time and temperature requirements, cleaning solution flow rate (pressure) if applicable, and the name of an employee responsible for verifying the program effectiveness by inspection
- Cleaning the condenser unit, drip pans, and hoses of refrigerators
- Keeping cold storage as dry as possible
- After cleaning and sanitizing, visually inspecting the area cleaned for product residue and conducting routine microbiological tests (conventional or rapid microbiological methods, such as total count or bioluminescence) to verify effectiveness of the cleaning and sanitizing program
- When reassembling sanitized equipment, placing the equipment parts on a sanitary mat and not on the floor
- Cleaning and sanitizing all processing equipment, facility utilities (e.g., air system, water system), and food-contact surfaces after maintenance work and prior to use in production
- Cleaning and sanitizing processing equipment and food-contact surfaces between the processing of different commodities, if appropriate based on risk
- Avoiding cleaning and sanitizing equipment during processing operations to prevent contamination
- Minimizing splashing during the cleaning of floor drains by using an appropriate brush, such as a ¼ inch smaller brush than the diameter of the drain opening, or a splash guard
 - For cleaning drains, we recommend using dedicated utensils (color coded and used for cleaning drains only) to minimize the potential for contamination. We also recommend that floor drains not be cleaned during processing operations and that the person who cleaned drains not clean fresh-cut produce food contact surfaces without changing outer garments, and washing and sanitizing his or her hands.
- Regularly inspecting tools for cutting, slicing, and shredding for damage that could impair cleaning and sanitizing them
 - We recommend replacing a tool if it cannot be fixed so that it can be adequately cleaned.

Cleaning and Sanitizing Chemicals

Cleaning and sanitizing chemicals may be toxic, and should be stored in dry, secure, and ventilated areas away from facility traffic and processing operations. They should be handled by employees trained in the use of such chemicals.

We recommend the following practices in using cleaning and sanitizing chemicals:

- Using adequate quality water for cleaning and sanitizing at temperatures appropriate for the chemicals used
- Using toxic chemicals for cleaning operations in accordance with the manufacturer's instructions and in accordance with relevant Federal, State, and local government regulations
- Clearly labeling toxic chemicals
- Storing toxic chemicals and pesticides in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials and in accordance with relevant Federal, State, and local government regulations
- Monitoring the effectiveness of cleaning and sanitizing chemicals by visual inspection and environmental testing (especially grooves and niches) for microbial growth

Pest Control

We recommend a pest control program be implemented throughout the entire processing facility to eliminate pests (such as rodents, birds, reptiles, and insects) that may harbor or be a vector for a variety of pathogens. As part of the plant's pest control program, consider frequent monitoring of affected and treated areas to assess accurately the effectiveness of the program. Some helpful physical and chemical controls are recommended below.

- Using window screens, screen doors, and weather stripping for all doors, and air fans at all doorways
- Keeping all exterior doors closed when not in use
- Removing waste products to, and storing waste products in, a location outside the facility
- Removing old, unused equipment from the facility

- Maintaining the exterior grounds surrounding the facility in a manner that will control pest harborage
 - Properly storing ingredients, finished product, and food packaging
 - Cleaning up spills and produce debris in a timely manner
 - Using pesticides, traps, bait, and chemicals that are acceptable for use in a food processing facility and that will not contaminate foods, food ingredients, or food packaging
- Chemical controls should be applied by a licensed pest control operator or according to local regulations.
- Maintaining a map to identify by numbered locations all rodent traps and bait boxes used both inside and outside the processing facility.

Sanitary Facilities and Controls

Employee Changing Facilities and Toilets

We recommend that changing facilities and restrooms be adequate and located in proximity to processing areas, but not so close that they could be a source of contamination. We recommend that restrooms not open directly into processing areas and doors be equipped with self-closing mechanisms or have a maze-type entrance/exit.

Hand Washing Facilities

FDA recommends the following practices for employee hand washing facilities:

- Providing a sink, hot and cold running water of adequate quality, effective hand cleaning preparations (e.g., liquid soap), sanitary hand drying devices (such as disposable paper towels), and a waste container
- Installing water control devices (such as knee, foot, or elbow faucet controls) that will protect against contamination of clean hands
- Posting signs that show proper hand washing procedures

We recommend that these signs be posted near the facility entrance, in restrooms, near all hand washing stations, and wherever employees may handle produce, food packaging materials, or food-contact surfaces. We further recommend that these signs be multilingual where some of the workers in the facility are not native English speakers or pictorial where literacy is a concern.

Air Quality

Air inside a processing plant can be a vehicle for contamination of food by mold, yeast, dust, or pathogens if not properly controlled. Where fresh and fresh-cut fruits and vegetables are exposed to open air, we recommend that air quality be monitored to ensure that it is of suitable quality.

We also recommend that fresh-cut processors consider the following to maintain appropriate air quality:

- Using positive, negative, and ambient air pressure differentials to direct potential airborne contaminants away from microbially sensitive areas. For example, negative air pressures in raw product areas, microbiology laboratories, and rest rooms may help to keep air from those areas from flowing into the processing areas. Similarly, positive air pressure can be maintained in areas such as the processing and packaging area.
- If air filtering equipment is used in a fresh-cut processing facility, filters should be performing at manufacturer specified levels of performance.
- Filtering compressed air (such as oxygen (O₂), nitrogen (N₂), and carbon dioxide (CO₂) used in modified atmospheric packaging) when such air contacts fresh produce using a 0.3 micron filter (with an efficiency of approximately 75 percent)

Water Supply

Water can be a carrier of microorganisms including pathogens. Adequate quality water is critical in a fresh-cut processing facility because of the absence of a step lethal to pathogens (kill step) in processing the product as well as the presence of factors such as the high degree of product handling, the damage to product during cutting, shredding, etc., and the potential for temperature abuse in processing and storage. We recommend that the water supply in a food processing plant be sufficient for the operations intended and be derived from an adequate source. We recommend that water for operations in the processing facility, such as cleaning and sanitizing the facility and equipment as well as preparing the product for processing, processing the product, and manufacturing ice, be of adequate quality. Where water does not become a component of the fresh-cut produce, we recommend that water be safe and sanitary, at suitable temperatures, and under pressure as needed for all uses. For water that is used in a manner such that the water may

become a component of the fresh-cut produce (such as when such water contacts components, fresh-cut produce, or any contact surface), we recommend that water comply with applicable Federal, State, and local requirements.

See Section VIII.C., which provides our recommendations for maintaining water quality used from preparation for processing through processing operations.

We recommend the following practices regarding the water used in a processing facility:

- Complying with applicable Federal, State, and local requirements for water that contacts fresh-cut produce or food-contact surfaces, including water used to make ice

We recommend that processors protect sources of water and ice from contamination and that ice be manufactured, transported, and stored under sanitary conditions.

- Testing well water, if used, at the site of the well and at the point in the plant most distant from the well on a regular basis to ensure compliance with Federal, State, and local requirements

- Maintaining and inspecting on a routine basis any water charcoal filtering system to prevent it from becoming a source of microbial or physical contamination of water

- Reviewing on a periodic basis water systems to ensure that no cross-connections exist between systems carrying water that is of adequate quality and systems carrying water that is not.

- Ensuring that the volume, temperature, and pressure of water is adequate for all operational and clean up demands

Environmental Monitoring

FDA recommends an environmental monitoring program designed to detect areas of pathogen harborage and to verify the effectiveness of cleaning and sanitizing programs in preventing cross-contamination. We recommend the following practices:

- Performing environmental sampling on both food contact and non-food contact surfaces (e.g., drains)

- Determining the appropriate target pathogen, test locations, and frequency of sampling.

We recommend that the appropriate target pathogen be the most resistant microorganism of public health significance that is likely to occur in fresh-cut produce.

- Focusing environmental monitoring on an indicator organism, such as *Listeria* spp., which indicates microbial contamination but is nonpathogenic and more easily detectable than a target pathogen, such as *L. monocytogenes*

- Establishing a plan for action in the event that a microbiological test indicates the presence of a target pathogen or indicator organism

- Documenting corrective actions and follow-up for all positive microbial test results

PRODUCTION AND PROCESS CONTROLS

To minimize the potential for the growth of microorganisms and for the contamination of fresh-cut produce, FDA recommends that control measures be in place to prepare, process, package, and store the product.

Product Specifications

We recommend that food processors consider developing specifications and controls for all ingredients and components (including raw fruits and vegetables, packaging materials, and gases) that are necessary for production of safe finished product. Specifications provide standards by which a food processor can assess the acceptability of ingredients and components and thus, minimize microbial, chemical, and physical hazards. We recommend, for example, that the fresh-cut processor know as much as possible about the production practices and conditions for the firm's incoming product. The "Guide to Minimize Microbial Food Safety Hazards in Fresh Fruits and Vegetables" (Ref. 15) provides useful guidance when reviewing primary production practices.

Receipt and Inspection of Ingredients

Opportunities for contamination of fresh produce occur from the field to the processing facility. Loading, transporting, and unloading produce may introduce contaminants. Damaged produce, soil, debris, and pests may all arrive with the produce when it is delivered to the facility. To help ensure the quality of incoming fresh produce, we recommend that the processor carefully inspect the produce upon receipt at the processing facility. We also recommend the following practices:

- Transporting the produce from the field to the processing, packing, or cooling facility as soon as practical after harvest
 - Inspecting delivery vehicles carrying fresh produce and other components of the finished product, e.g., cartons, packaging materials, for cleanliness
 - Visually inspecting incoming fresh produce for damage, filth, and infestation according to a predetermined sampling plan and rejecting products that do not meet established specifications
 - Removing all damaged, moldy, or decomposed product and extraneous matter (such as metal or other foreign material) from in-coming raw ingredients to a designated area
 - Retaining information about all incoming ingredients, such as the identity of the grower or supplier, date of harvest, the field, and linking the information on the incoming product with the operation's production records (e.g., when processed, date, shift) for finished product
- This information will be useful in the event a traceback is conducted. See section X in this guide for more information on tracebacks.

Specific Processing Steps

Preparation for Processing

Appropriate preprocessing of incoming produce can help minimize microbial, chemical, and physical hazards. We recommend that fresh-cut produce processors consider the following activities to help minimize microbial, chemical, and physical hazards in in-coming produce:

- Inspecting fresh produce throughout the processing stream for field contaminants that may not have been noticed during the incoming produce inspection
- Removing from the processing stream damaged or decomposed produce, extraneous matter, and produce that appears to be contaminated by animal feces, fuel, machine grease, or oil
- Removing as much dirt as possible from incoming produce

We recommend, when appropriate, washing incoming RACs prior to further processing (such as cutting or chopping) to reduce the overall potential for microbial contamination from the surface of intact fruits and vegetables.

Processing Water

Water is used extensively in almost all aspects of processing fresh-cut fruits and vegetables, including during cooling, washing, and conveying of produce. Although water may be a useful tool for reducing potential contamination, it may also introduce or spread contaminants. When used for washing, cooling, rinsing, or conveying food, we recommend that water comply with applicable Federal, State, and local requirements.

In a fresh-cut processing operation, water quality changes as the water is used and, thus, maintaining the quality of processing water should be considered. Reusing processing water may present a risk of new or increased number of microbial populations, including human pathogens.

We recommend the following practices:

- Where water is reused in a series of processes, arranging water flow to be counter to the movement of produce through different operations, with the result that as produce is further processed, it is exposed to the cleanest water
- Monitoring and treating processing water for level of disinfectant chemical to ensure the water is maintained in a condition suitable for the application (e.g., washing, cooling, or transporting) and does not become a source of microbial contamination
- Routinely inspecting and maintaining equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, to ensure efficient operation

We recommend that ice used on fresh or fresh-cut produce be included in routine water quality testing.

Maintaining Water Quality

When used appropriately with adequate quality water, antimicrobial chemicals help minimize the potential for microbial contamination of processing water and subsequent cross contamination of the product. The effectiveness of an antimicrobial agent, as well as the amount that should be used, depends on the treatment conditions, such as water temperature, acidity [pH], water hardness, contact time, amount and rate of product throughput, type of product, water to product ratio, amount of organic material, and the resistance of pathogens to the particular antimicrobial agent. For example, the antimicrobial activity of a chlorine-based disinfectant depends on the amount of hypochlorous acid (also called "free chlorine")

present in the water. The amount of hypochlorous acid in the water depends upon the pH of the water, the amount of organic material in the water, and, to some extent, the temperature of the water. If the amount of hypochlorous acid is not maintained when the amount of organic material increases, the antimicrobial agent may lose effectiveness in maintaining water quality. If a fresh-cut processor uses a chlorine containing compound as a disinfectant, we recommend that the processor monitor the processing water for free chlorine or hypochlorous acid concentrations. As another example, the measurement of Oxidation-Reduction Potential (ORP) is used as an indicator of the activity of any antimicrobial agent that is an oxidizer and as a measure of the agent's effectiveness during processing. Variables that affect antimicrobial activity during processing directly affect the ORP value and may also be used to determine the effectiveness of these oxidizers such as hypochlorous acid, hypobromous acid, chlorine dioxide, ozone, and peroxides.

We recommend that fresh-cut processors consider options for maintaining the quality of water most appropriate for their individual operations. Producers may wish to contact a local agricultural extension agent, their chemical supplier, or a food safety consultant for help in deciding what water treatment chemicals to use. In addition, processors may refer to 21 CFR 173.315, "Chemicals used in washing or to assist in the peeling of fruits and vegetables," for additional information about chemicals approved for use in wash water.

We recommend that fresh-cut processors also consider the following regarding water quality maintenance:

- Following the manufacturer's directions for correct mixing of antimicrobial agents to obtain effective concentrations and to minimize safety hazards
 - Manufacturers' suggested or allowable levels of antimicrobial chemicals in wash water should not be exceeded.
- Monitoring disinfectant levels frequently in water used for various processing operations to ensure appropriate concentrations are maintained
 - Test strips or test kits may be useful for monitoring some disinfectant levels.
- Minimizing the build up of organic material in wash water
 - For some operations, filtering recirculating water or using a net to scoop plant material or other debris from tanks may help reduce the build up of organic material.
- Following contact between produce and processing water containing antimicrobial chemicals with a clean water rinse of adequate quality to remove any treatment residues where appropriate and consistent with the manufacturer's directions

Washing Fresh Produce

Prior to arriving at the processing facility, RACs may be washed in the field or in a place such as a cooling facility. RACs may also go directly from the field to the processing facility to be washed after receipt. Regardless of where the initial washing of the produce takes place, washing produce can reduce the overall potential for microbial food safety hazards because most microbial contamination is on the surface of the produce. If pathogens are not removed, inactivated, or otherwise controlled at this initial stage, they can potentially spread the contamination to additional produce during processing. Washing RACs before any processing of the produce occurs may reduce potential surface contamination. However, washing, even with disinfectants, can only reduce, not eliminate, pathogens, if present. Washing has little or no effect on pathogens that have been internalized in the produce.

A number of post harvest processes, such as hydrocooling, use of dump tanks, and flume transport utilize a high degree of water-to-produce contact. We recommend that fresh-cut processors use practices to maximize the cleaning potential during these processes and to minimize the potential for cross-contamination.

We recommend the following practices:

- Using a series of washes, if appropriate
 - For some operations, a series of washes may be more effective than a single wash. An initial wash treatment may be used to remove the bulk of field soil from produce followed by an additional wash or washes containing an antimicrobial chemical.
- Using appropriate wash methods
 - Vigorous washing of produce not easily bruised or injured increases the likelihood of pathogen removal. Different methods may be used to wash different types of produce, including submersion, spray, or both. Regardless of the method used, maintaining the quality of the wash water (see section 2.a. above) is important in order to minimize the potential for contamination.
- Maintaining the efficacy of wash treatments
- Using wash water of an appropriate temperature

Produce is susceptible to infiltration of wash water if warm produce is placed in water that is cooler than the produce. Such infiltration occurs when the temperature difference creates a pressure differential causing air spaces inside the fruit or vegetable to contract, thereby allowing water to be pulled into the fruit or vegetable. If pathogens are present in the cooling/wash water, they may infiltrate the produce, and subsequent washing will not reduce levels of these pathogens (Refs. 6, 14). Therefore, water used for washing or cooling produce should contain sufficient levels of disinfectant to reduce the potential for pathogens to persist in such water. When it is not practical to reduce the temperature differential between the wash/cooling water and the produce, it is especially important that processors follow practices to minimize pathogens in the water or on the surface of produce. Such practices may include using antimicrobial chemicals in the wash water or using spray type wash treatments instead of submerging produce. Alternatively, produce may be cooled by means other than hydrocooling and then washed with water that is warmer than the produce.

Precooling and Cold Storage

Sanitary cold storage of RACs and fresh-cut produce is important to reduce the risk of microbial contamination and potential for subsequent growth. However, most current temperature recommendations for both whole and fresh produce are based on temperatures that maintain quality attributes.⁸ Although we recognize that more research needs to be done to identify the types of whole and fresh-cut produce that will support the growth of human pathogens and the temperatures at which this pathogen growth will occur, certain practices can reduce the potential for pathogen growth and contamination during precooling and cold storage. We recommend the following practices to reduce this risk:

- Holding RACs and fresh-cut produce at appropriate cold storage temperatures to reduce the potential for microbial growth
- Preventing condensate and defrost water from evaporator-type cooling systems (e.g., vacuum cooling, cold storage) from dripping onto fresh and fresh-cut produce
- Designing and maintaining forced air cooling to avoid contaminating fresh produce
 - In most instances, vacuum cooling or use of fans poses the lowest risk of microbial contamination
- Holding cut melons and any other fresh-cut product determined to need temperature control for safety at $\leq 41^{\circ}\text{F}$ ($\leq 5^{\circ}\text{C}$)
- Locating temperature monitoring devices in the warm area of the refrigerator unit (e.g., near the door) and calibrating them on a regular basis
- Inspecting all refrigeration units on a regular basis and keeping them in good operating condition
- Storing similar commodities together (unprocessed product next to unprocessed product and finished product next to finished product) to avoid cross-contamination
- Using an appropriate inventory system to ensure first in first out (FIFO) use and FIFO shipment of raw materials and finished products

Washing Fresh-cut Produce: Post-processing Controls

Final washing of fresh produce after cutting, slicing, shredding, and similar fresh-cut processes helps remove some of the cellular fluids that could serve as nutrients for microbial growth. Monitoring the quality of water used in such operations and replacing it at an appropriate frequency as indicated by such monitoring may help prevent the build up of organic material in the water and reduce or prevent cross-contamination of processed produce. We have the following additional recommendations for use after the final wash of processed produce:

- Where appropriate for the product, removing as much excess water as possible from processed produce through draining methods such as spin drying
- Keeping containers used to hold produce (e.g., spin baskets) from direct contact with the floor and away from containers that have had direct contact with the floor (e.g., in cold storage)

Packaging

Anything that touches fresh-cut produce has the potential to contaminate it, including the materials used in packaging the finished product.

⁸An exception is Chapter 1 of the FDA Food Code (2005), which defines potentially hazardous food (PHF) and identifies specific fresh produce (among other foods) that is considered PHF and therefore requires refrigeration at 41°F. Cut melons are considered a PHF. See website at <http://www.cfsan.fda.gov/dms/foodcode.html>.

We recommend the following practices:

- Maintaining an effective system to prevent the use of contaminated, damaged, or defective cartons and totes in order to prevent microbial contamination of the fresh-cut produce during packing operations
- Overseeing incoming materials and gases used in packaging to confirm that they are not damaged or defective and are in appropriate working order
- Rejecting packaging materials that are damaged or contaminated
- Determining the appropriate gas mixtures for products
- Using containers and cartons for their intended purpose only. For example, we recommend against using a carton designated for holding fresh-cut produce to hold tools.
- Storing packaging containers and other packaging materials in a manner so as to protect them from contamination, such as away from pests, dirt, cleaning chemicals, and water condensation from overhead equipment and structures
- Maintaining a program to identify and correct situations where damage to containers may potentially occur
- Labeling all finished fresh-cut produce products with recommended storage instructions (e.g., “Keep Refrigerated”) or storage temperature to inform all persons handling the product of the recommended storage conditions

Modified Atmosphere Packaging (MAP)

Some packaging controls used for fresh-cut produce affect the environment within the package by reducing the levels of oxygen. Low oxygen levels help maintain the quality of fresh produce and extend shelf-life by slowing respiration and senescence in plant tissues. Oxygen can be reduced passively by using gas permeable films in packaging that result in the natural development of the desired atmosphere; the desired atmosphere is a consequence of the products’ respiration as gas diffuses through the film (Ref. 6). Oxygen can also be reduced actively by displacing the mixture of gases in a package with a gas mixture that has a low concentration of oxygen (1–5 percent). Microorganisms respond differently to the surrounding gases depending on their tolerance. While reduced oxygen and elevated carbon dioxide retard the growth of spoilage microorganisms such as *Pseudomonas* spp., the same gas conditions may provide growth opportunities for pathogenic microorganisms. At extremely low oxygen levels (< 1 percent), anaerobic respiration can occur, resulting in tissue destruction that affects product quality and creating the potential for growth of foodborne pathogens such as *Clostridium botulinum* (Ref. 6). It is generally believed, however, that fresh-cut produce will spoil before the toxin becomes a concern (Ref. 6). Non-pathogenic aerobic and facultative microorganisms are present at the time of packaging and persist after packaging.

MAP is only effective in extending shelf-life if used in conjunction with good refrigeration. Elevated temperatures can promote the growth of spoilage organisms and pathogens that may be present. Thus, we recommend that food processors using MAP adhere to strict temperature controls and appropriate shelf-life parameters. Because refrigeration temperatures may not be maintained during distribution of the products or while they are held by retailers or consumers, we also recommend that controls be in place to either prevent increases in temperature, as feasible, or to alert the processor, retailer, or consumer that the product may not be safe to consume. Processors may wish to consider providing product handling guidelines on temperature control and washing to the distributor, retailer, and consumer. Another potential source of contamination of fresh cut produce packed in MAP occurs when the gases, equipment, or packaging materials are not properly maintained. As with any type of packaging, we recommend that controls be put in place to ensure that the process of packaging the product and the packaging materials themselves do not cause the product to become contaminated.

Shelf-life

Fresh-cut fruits and vegetables can cause illness due to contamination with a variety of microorganisms because these products do not undergo any processing to ensure the total elimination of microorganisms that might be present. Some packaging and storage techniques for fresh-cut produce (e.g., MAP, refrigerated storage) may slow the rate of physical deterioration by slowing respiration of the produce. However, if packaging and storage are not properly controlled, pathogens may grow to levels that could render the product unsafe for human consumption. The rate of respiration of fresh produce is inversely related to product shelf-life, which means that a higher respiration rate decreases shelf-life (Ref. 6). Fresh fruits and vegetables that have been cut or otherwise physically altered will have increased respiration, and thus, a shorter shelf-life. To address the risks of increased respiration, we recommend the following practices:

- Communicating (through product labeling) that the consumer should refrigerate the product to prevent product spoilage and the potential for growth of pathogens
- Ensuring that any “use by” date on the product package is validated by studies of the product with respect to microbiological safety
 - We recommend that records of these data and studies be maintained to document the reliability of the “use by” labeling.

Transportation and Storage

We recommend that finished fresh-cut product be stored and transported under conditions that will protect the food against physical, chemical, and microbiological contamination. We recommend, if feasible, that raw whole produce not be stored with finished product and finished product be transported in clean, sanitary vehicles. We also recommend the following practices:

- Keeping finished products refrigerated at temperatures appropriate for the product during storage, transportation, and display for sale to minimize the potential for growth of microbial pathogens
- Equipping refrigerated transportation vehicles and storage rooms with accurate temperature measuring devices, preferably including a temperature recording function
 - If a recording temperature device is not used, we recommend that a min/max thermometer, i.e., a thermometer that shows the range of temperatures attained over a set time period, be used.
- Shipping fresh-cut produce products on a FIFO basis to minimize storage time
- Ensuring that the equipment in refrigeration vehicles is designed to circulate cold air uniformly throughout the vehicle while taking the load layout into consideration
- Placing fresh-cut produce products in storage facilities and transportation vehicles in a manner that allows for proper air circulation
- Transporting and storing fresh-cut produce products in vehicles and containers that are dedicated to carrying food products and have been treated by a process that is effective in destroying vegetative cells of microorganisms of public health significance
- Inspecting transportation vehicles and containers for debris, soil, and off-odors prior to loading to increase their suitability for transporting fresh-cut produce
- Loading and unloading fresh-cut produce in a manner that minimizes the potential for damage and for microbial contamination

DOCUMENTATION AND RECORDS

We recommend as a general practice that food processors maintain records sufficient to reflect important product information and practices. Such documentation can be helpful to the processor in several ways. First, such records help ensure consistency of processing operations and end-product quality and safety. They are more reliable than human memory, and they are a useful tool to identify operational areas where inconsistencies occur and further employee training may be needed. Second, maintaining adequate documentation and records of processing operations is important if a traceback investigation of product is ever needed. We recommend that records be retained at the processing plant for at least six months after the date that the products were prepared unless a longer retention time is required under a relevant law or regulation. Records are most useful when they begin by including the date and time, name of person(s) who completed the record, and the activity or production station being recorded.

Records that may be kept for most food processing operations include the following:

- Water quality and supply records
- Water treatment and monitoring records
- Employee training records
- Temperature control records
- Equipment monitoring and maintenance records
- Calibration records
- Sanitation records
- Product processing batch records
- Corrective action records
- Pest control records
- Distribution records
- Inspection records (e.g., incoming product, facility, production area)
- Microbiological contamination records (e.g., food contact surfaces, equipment)

TRACEBACK AND RECALL

Traceback is the process of tracking food items, such as fresh-cut produce, back to their source (growers, packers, processor, field and when harvested). The ability to identify the source of a product can serve as an important complement to food safety programs intended to prevent the occurrence of microbial contamination. Information gained from a traceback investigation may also be useful in limiting the impact of an outbreak of foodborne illness and in identifying and eliminating conditions that may have resulted in the produce becoming contaminated. We recommend that fresh-cut processors establish and maintain written traceback procedures to respond to food safety hazard problems when they arise.

We also recommend that fresh-cut processors establish and maintain a current written contingency plan for use in initiating and carrying out a recall. Having procedures in place will enable the recall of any lot of product that may have been implicated in an outbreak or that tested positive for a pathogen and help provide detailed information to assist the investigation of any foodborne illness associated with the product. Recall procedures usually include the name of the contact persons responsible at all times; the roles and responsibilities for the coordination of a recall; the methods to identify (e.g., use of lot codes), locate, and control recalled products; requirements to investigate other possibly affected products which could subsequently be included in the recall; and procedures for monitoring the effectiveness of the recall.

Because a recall may extend to more than one lot of product, we recommend that processors develop a coding system to help identify incoming product sources, individual production lots and to whom each lot is distributed. Use of package and date codes can help link product packages with production times, equipment, and raw ingredient sources and may facilitate recovery of products during a recall.

In the event of a firm-initiated recall, if a firm believes its product is adulterated or otherwise violates the Act, we request that the firm immediately notify the appropriate FDA district office in the State where the processing facility is located. District office locations are provided in 21 CFR 5.115. (See Appendix A for information to include in the notification.)

Produce growers and packers, fresh-cut produce processors, and shippers are encouraged to work with their partners in growing, transporting, distributing, packing, and processing, and with retail sectors to develop technologies that allow identification of fresh-cut produce from the grower to your operation, to the retailer, and to the consumer.

ADDITIONAL INFORMATION

The following are additional resources for information on how to handle food products safely.

On the web

FDA/Center for Food Safety and Applied Nutrition www.cfsan.fda.gov
 Fight Bac!TM www.fightbac.com
 Gateway to Government Food Safety Information www.foodsafety.gov
 USDA/FDA Foodborne Illness Education Information Center www.nal.usda.gov/fnic/foodborne
 Centers for Disease Control and Prevention (CDC) www.cdc.gov
 USDA/Food Safety and Inspections Service (FSIS) www.fsis.usda.gov
 NACMCF HACCP guidelines <http://www.cfsan.fda.gov/comm/nacmcfp.html>

Other resources

Ednet: a monthly electronic newsletter for food safety educators. To subscribe, send an email message to Listserv@foodsafety.gov with the message, "Subscribe EDNET-L first name last name."
 Foodsafe: An online electronic discussion group. Go to www.nal.usda.gov/fnic/foodborne to join.
 FDA's Outreach and Information Center: 1.888.SAFEFOOD
 Code of Hygienic Practices for Fresh Fruits and Vegetables (CAC/RCP 53-2003)
 General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)

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- (2) U.S. Department of Agriculture, "MyPyramid," April 2005. See website at <http://www.mypyramid.gov/>(accessed 2/27/07).

- (3) U.S. Department of Agriculture, Economic Research Service, U.S. per Capita Food Consumption of Fruits and Vegetables, 2005. See web site at <http://www.ers.usda.gov/Data/FoodConsumption/> (accessed 2/27/07)
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APPENDIX A

Notifying FDA of a Recall

In the event of a firm-initiated recall, if a firm believes its product is adulterated or otherwise violates the Act, we request that the firm immediately notify the appropriate FDA district office and that the notification include:

- the identity of the product involved (i.e., an adequate description of the type of food to include brand name and specific variety, date of releasing the food, the lot or code number or other identifier of the implicated product, the quantity and how the food is packaged);
- the reason for the recall and the date and circumstances under which the product deficiency or possible deficiency was discovered;
- an evaluation of the risk associated with the product;
- the total amount of implicated product units processed and the time span of processing;
- the total amount of product in inventory and the total amount of product distributed;
- the distribution information including the number of direct accounts and, where necessary, the identity of the direct accounts;

- a copy of the firm’s recall communication, if any has issued, or the proposed communication if none has issued;
- the proposed strategy for conducting the recall; and
- the name and telephone number of the firm official who should be contacted concerning the recall

For further FDA guidance on recalls, see 21 CFR sections 7.40–7.59.

APPENDIX B

Foodborne Pathogens Associated with Fresh Fruits and Vegetables

The U.S. Public Health Service has identified a number of microorganisms associated with foodborne illness that are notable either because of the severity or because of the prevalence of the illness they cause. Foodborne microbial pathogens associated with the consumption of fresh fruits and vegetables include *Cyclospora cayetanensis*, *Escherichia coli* O157:H7, hepatitis A virus, *Listeria monocytogenes*, Norovirus, *Salmonella* spp., and *Shigella* spp.⁹

Cyclospora.—Infections (cyclosporiasis) are caused by the protozoan *Cyclospora cayetanensis*. The infections are spread by ingestion of food or water contaminated with infected stool. Direct person-to-person transmission is unlikely because excreted oocysts require days to weeks under favorable environmental conditions to become infectious (i.e., sporulate). The natural host for this parasite has not been identified; however, contaminated water used for irrigation and pesticide application and poor worker hygiene have been suggested as the most likely routes of contamination. The infection (cyclosporiasis) is commonly characterized by watery diarrhea, loss of appetite, weight loss, abdominal bloating and cramping, low-grade fever, nausea, vomiting, and fatigue. Relapses and asymptomatic infections can occur. Outbreaks of cyclosporiasis have been linked to fresh raspberries, mesclun lettuce, and basil or basil-containing products. (For more information: www.cfsan.fda.gov/~mow/intro.html)

E. coli O157:H7.—Is a bacterium and one of the enterovirulent strains of *Escherichia coli*. Most *E. coli* strains are nonpathogenic, found in the intestines of all animals, including humans, and function by suppressing harmful bacterial growth. However, there are a minority of strains such as serotype O157:H7 that may cause human illness. *E. coli* O157:H7 is a life-threatening bacterium that produces large quantities of potent toxins that can cause severe damage to the lining of the intestines. Human illness associated with *E. coli* O157:H7 infection may include nonbloody diarrhea, hemorrhagic colitis, hemolytic uremic syndrome (HUS), or thrombotic thrombocytopenic purpura (TTP). Hemorrhagic colitis progresses from abdominal cramps to nonbloody diarrhea to bloody diarrhea. HUS largely affects young children and is the leading cause of acute renal failure in children. TTP is a rare syndrome of *E. coli* O157:H7 infection, which largely affects adults and resembles HUS histology. *E. coli* O157:H7 outbreaks have been associated with meat (especially undercooked or raw hamburger), fresh produce, raw milk, unpasteurized apple juice, coleslaw, and contaminated water (For more information: www.cfsan.fda.gov/~mow/intro.html).

Hepatitis A Virus.—May cause a serious, and sometimes fatal, disease. Hepatitis attributed to hepatitis A virus is characterized by sudden onset of fever, malaise, nausea, anorexia, and abdominal discomfort, followed in several days by jaundice. Hepatitis A virus is excreted in fecal material and is transmitted by the fecal-oral route, which include consumption of contaminated food. The most common food sources of Hepatitis A are shellfish and salads, but it may also be transmitted through drinking water. (For more information: www.cfsan.fda.gov/~mow/intro.html)

Listeria Monocytogenes.—Is a bacterium¹⁰ that causes listeriosis, a serious disease in pregnant women, the elderly, and those with weakened immune systems. *L. monocytogenes* is widespread in the environment (i.e., in soil, water, and decaying vegetation) and has been isolated from domestic animals, humans, raw produce, food processing environments (particularly cool damp areas), and home refrigerators. Outbreaks of listeriosis in the United States have been associated with the consumption of hot dogs, deli or luncheon meats, pate, salami, Mexican-style soft cheeses and butter made with raw milk, and raw vegetables (Ref. 16). (For more information: www.cfsan.fda.gov/~mow/intro.html)

⁹More information about these and other microbiological pathogens can be found in FDA’s Bad Bug Book (<http://vm.cfsan.fda.gov/~mow/intro.html>). See Ref. 17.

¹⁰For additional information, FDA, the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture (USDA) have developed a *Listeria* Action Plan (Ref. 18) and a *Listeria* risk assessment (Ref. 16).¹¹ Used with permission from UPPA, Food Safety Guidelines for the Fresh-cut Produce Industry, 4th Edition, 2001.

Noroviruses.—Are a group of related, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans. Norovirus was recently approved as the official genus name for the group of viruses provisionally described as “Norwalk-like viruses.” Norovirus is transmitted by the fecal-oral route most commonly via contaminated water or contaminated foods. Shellfish and salad ingredients are the foods most often implicated in norovirus outbreaks. (For more information: www.cfsan.fda.gov/~mow/chap34.html and <http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus.htm>)

Salmonella.—Is the second most common cause of foodborne illness (salmonellosis) in the United States and is responsible for millions of cases of illness each year. Typical symptoms of salmonellosis are nausea, vomiting, abdominal cramps, fever, mild diarrhea, and headache; these symptoms usually last 6–48 hours. Salmonella outbreaks have been associated with the consumption of raw and undercooked eggs, undercooked poultry and meat, dairy products made with unpasteurized milk, shrimp, fresh produce, and unpasteurized fruit juice. (For more information: www.cfsan.fda.gov/~mow/intro.html)

Shigella spp.—Humans are a natural reservoir for *Shigella spp.* The primary means of transmission of the shigella organism is by the fecal-oral route. Most cases of infection by shigella (shigellosis) are attributed to the ingestion of food or water contaminated with fecal matter. Contamination has often been associated with poor personal hygiene of food workers. Typical symptoms include abdominal pain, cramps, diarrhea, fever, vomiting, and blood, pus, or mucus in stools. Shigellosis outbreaks have been associated with shredded lettuce, potato salad, green onions, parsley, cheese, seafood, and poultry (Ref. 19). (For more information: www.cfsan.fda.gov/~mow/intro.html)

APPENDIX C

Pathogens Often Transmitted by Food that Has Been Contaminated by Infected Employees

A wide range of communicable diseases may be transmitted by infected employees to consumers through contaminated food or food utensils. We recommend that fresh-cut produce firms establish an ongoing program to identify employees who present a risk of transmitting foodborne pathogens to fresh produce or to other employees. Below is a list of the most common pathogens that may be transmitted through food and their associated symptoms.

Pathogen	Symptoms
Hepatitis A virus	fever, jaundice
Salmonella typhi	fever
Shigella species	diarrhea, fever, vomiting
Norwalk and Norwalk-like viruses	diarrhea, fever, vomiting
Staphylococcus aureus	diarrhea, vomiting

Diarrhea, fever, and vomiting are also symptoms of several other pathogens that could be transmitted by food contaminated by infected employees.

Please refer to this CDC web site for further information on foodborne diseases, pathogens, and toxins: <http://www.cdc.gov/foodsafety/disease.htm>.

APPENDIX D

POTENTIAL SOURCES OF MICROBIAL CONTAMINATION

- Ingredients
 - Raw produce
 - Fresh-cut produce
- Packaging materials
 - Containers, films, lids, trays
- Processing aids
 - Compressed air
 - Untreated or inadequately treated wash water
 - Ice
 - Reused processing water
- Facility environment
 - Ceilings, overhead structures, catwalks
 - Rubber seals around doors (especially coolers)
 - Drains
 - Walls

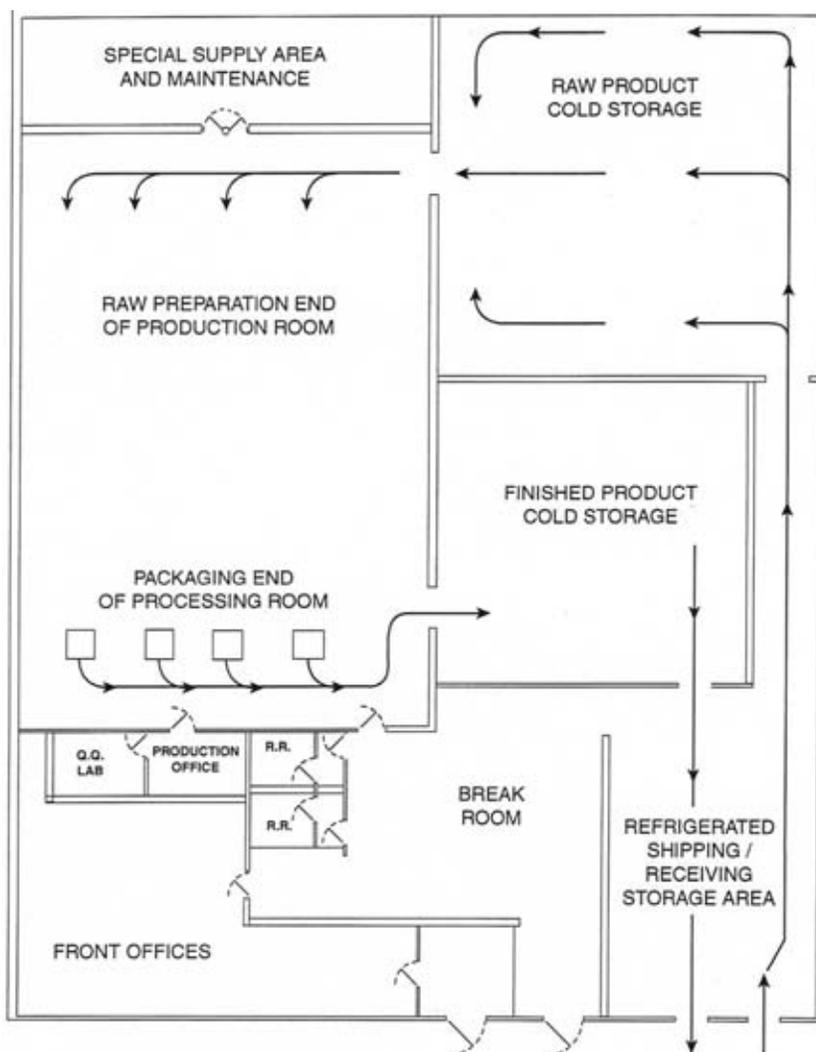
- Standing water
- PWet insulation in walls or around pipes and cooling units
- Condensate
- Vacuum cleaner contents
- Hand washing areas (sinks) and restrooms
- Food contact surfaces
 - Fibrous or porous type conveyor belts
 - Filling or packaging equipment
 - Equipment cleaning tools
 - Slicers, dicers, shredders, blenders,
 - Belts, peelers, collators
 - Containers, bins, tubs, or baskets
 - Hands, gloves, and outerwear
 - Ice makers
 - Utensils
- Nonfood-contact surfaces
 - In-floor weighing equipment
 - Hollow rollers for conveyors
 - Trash cans and other such ancillary items
 - Visible bearings within equipment
 - Condensate drip pans
 - Maintenance tools (wrenches, screw drivers, etc.)
 - On/off switches
 - Cracked hoses
 - Equipment framework
 - Wet rusting or hollow framework
 - Poorly maintained compressed air filters
 - Motor housing
 - Forklifts, hand trucks, trolleys, racks
 - Vacuum cleaners and floor scrubbers

EXAMPLES OF SCENARIOS THAT MAY CAUSE MICROBIAL CONTAMINATION OF THE
PRODUCT

1. A processing line is moved or modified significantly.
2. Used equipment is brought in from storage or another plant and installed into the process flow.
3. An equipment breakdown occurs.
4. Construction or major modifications are made to a fresh-cut produce processing area (e.g., replacing refrigeration units or floors, replacing or building walls, modifications to sewer lines).
5. An employee unfamiliar with the operation and microbial controls has been hired or assigned to work or clean equipment in the processing areas.
6. Personnel who handle fresh produce and fresh-cut produce touch surfaces or equipment that are likely to be contaminated (e.g., floor, trash cans) and do not change gloves or follow other recommended procedures before handling product.
6. Periods of heavy production make it difficult to change processing water or clean food contact surfaces at the facility as scheduled.
7. A drain backs up.
8. Product is caught or hung up on equipment for an extended period and is not removed during equipment clean-up. Microorganisms may grow in stagnant product and can be a major source of contamination during production. FDA recommends that equipment be modified to eliminate areas where product stops moving along or through a processing line and cannot be readily removed during cleaning.
9. There are frequent product changes on a packaging line which necessitate changing packaging film, labels, forming pockets or molds, line speeds, etc.
10. Personnel are used interchangeably for handling unprocessed produce and finished fresh-cut product.
11. There is increased production requiring wet cleaning of down lines in the same room as lines running product.
12. Equipment parts, tubs, screens, etc. are cleaned on the floor.
13. Waste bins in the processing areas are not properly maintained, cleaned, and sanitized. Personnel handling product may come into contact with these items and then contaminate product and/or product contact surfaces.

APPENDIX E

AN EXAMPLE OF PRODUCT/PERSONNEL FLOW PATTERNS IN A FRESH-CUT PROCESSING PLANT ¹¹



HOW THE FDA WORKS TO KEEP PRODUCE SAFE

The contamination of fresh spinach with the bacteria *Escherichia coli* (*E. coli*) O157:H7 during the fall of 2006 led to one of the largest and deadliest outbreaks of foodborne illness in recent years.

Most of the illnesses due to *E. coli* occurred from August 26, 2006, to Sept. 16, 2006. Illnesses from spinach were confirmed in 26 States, and one case was con-

¹¹ Used with permission from UFPA, Food Safety Guidelines for there Fresh-cut Produce Industry, 4th Edition, 2001.

firmed in Ontario, Canada. In all, nearly 205 cases of illness were recorded during the outbreak, including 31 involving a type of kidney failure called hemolytic uremic syndrome (HUS). More than 100 people were hospitalized, and three deaths were recorded, including a 2-year-old boy in Idaho. “One foodborne illness is too many,” says Robert Brackett, Ph.D., director of the Food and Drug Administration’s Center for Food Safety and Applied Nutrition (CFSAN). “We’ve seen that there is no such thing as a small error when it comes to produce safety. Even what may be perceived as a small error can have disastrous consequences.”

Fresh produce is especially vulnerable to contamination—because it’s grown in a natural environment. It may be grown in a field or orchard, and it is often consumed raw, without cooking or other treatments that could destroy bacteria and other pathogens.

The FDA works with many partners to prevent contamination, but it’s impossible to eliminate all problems through prevention. “When there is a problem, we want to catch it early and contain it through efficient outbreak response,” says David Acheson, M.D., director of food safety and security in the CFSAN. “In this case, the FDA mounted a collaborative effort with public health authorities throughout the country to identify the source of the problem and prevent its spread.”

The CFSAN has the lead responsibility for ensuring food safety, regulating everything except meat, poultry, and processed egg products, which are regulated by the U.S. Department of Agriculture (USDA). The Centers for Disease Control and Prevention (CDC) has a complementary role, serving as the lead Federal agency for conducting disease surveillance and outbreak investigations. Surveillance systems coordinated by the CDC, in collaboration with the States, provide an essential early-information network to detect dangers in the food supply.

Detecting an Outbreak

When a patient is diagnosed with *E. coli* O157:H7, a sample of the bacterial strain is sent to a participating PulseNet lab, says Christopher Braden, M.D., chief of outbreak response and surveillance at the CDC. PulseNet is a national network of public health laboratories that perform genetic fingerprinting on foodborne bacteria that result in human illness. Scientists use a process called pulsed-field gel electrophoresis (PFGE), a technique that subtypes bacteria.

“After the bacterial strain is subtyped or “DNA fingerprinted” at a lab, the fingerprint is then uploaded electronically to the national PulseNet database where it can be compared with other patterns in other States,” Braden says. “This gives us the capability to rapidly detect a cluster of infections with the same pattern occurring in multiple States. The strength of this system is its ability to identify patterns even if the affected people are geographically far apart.”

Epidemiologists in Wisconsin were the first to alert CDC officials about a small cluster of *E. coli* O157:H7 infections on Sept. 8, 2006. At that time, the source of the problem was unknown. Wisconsin posted the bacterial strain to PulseNet to alert the entire network. PulseNet confirmed that *E. coli* strains from infected patients in Wisconsin had matching PFGE patterns and identified the same patterns in other States. “Once a cluster of cases with the same DNA pattern is identified, epidemiologists interview patients to determine whether cases of illness are linked to a food source or what other exposures they have in common,” Braden says.

Oregon’s State health department also had noted a small cluster of cases and began interviewing patients. On September 13, 2006, Wisconsin and Oregon health officials both notified the CDC that eating fresh spinach was reported. Most of those interviewed reported eating prepackaged raw spinach that came from a bag. That same day, the CDC Director’s Emergency Operations Center notified the FDA’s Emergency Operations Center (EOC) of the possible association of prepackaged raw spinach to the illnesses. The FDA’s EOC is the agency’s focal point for coordinating and managing all emergencies involving products regulated by the FDA.

Alerting the Public

After learning from the CDC that fresh spinach was confirmed as the source of the outbreak, the FDA immediately took action to prevent further illness by alerting the public. On Sept. 14, 2006, the FDA and the CDC held a conference call with the States and issued a public alert, advising consumers not to eat bagged spinach at that time. Neither frozen nor canned spinach was implicated in the outbreak.

Those who had become ill reported eating various brands of bagged spinach, processed by Natural Selection Foods LLC of San Juan Bautista, Calif. One week after Wisconsin officials notified the CDC, Natural Selections, which bags spinach under several brand names, announced a voluntary recall. The company recalled all spinach products with a date code of October 1 or earlier. Five more companies issued recalls between September 15 and September 22. “These secondary recalls occurred

because Natural Selections had shipped spinach to other companies that repackaged it,” Acheson says.

The companies that issued secondary recalls were RLB Food Distributors, L.P., of West Caldwell, N.J. River Ranch Fresh Foods LLC of Salinas, Calif.; Kenter Canyon Farms Inc. of Sun Valley, Calif.; Triple B Corp., doing business as S.T. Produce of Seattle; and Pacific Coast Fruit Co. of Portland, Ore.

On September 16, the FDA expanded its warning and advised consumers not to eat any fresh spinach or fresh spinach-containing products. “We expanded the advisory when we learned that bagged spinach was sometimes sold in an un-bagged form at the retail level,” Brackett says. The FDA advised retailers and food service operators that they should not sell raw spinach or blends that may contain raw spinach.

“We were also concerned about fresh spinach products that could still be in consumers’ refrigerators,” Brackett says. “At that point, the priority was to prevent further illnesses. We wanted to get the word out and get fresh spinach off the shelves while we conducted an investigation to narrow down the source. The number of illnesses was increasing daily, which was alarming. And the reach was nationwide. We also knew that there were a significant number of severe illnesses and hospitalizations.”

E. coli O157:H7 causes diarrhea, often with bloody stools. Though most people recover in a week, some are more vulnerable, especially very young children and older people. Of the 95 cases that had been reported by Sept. 15 2006, almost half had been hospitalized, and 15 percent had NUS, a condition that can cause kidney damage and death.

The FDA’s advice to not eat any fresh spinach remained in effect until Sept. 22, 2006, Brackett says, when the FDA became confident that the source of the tainted spinach was restricted to three California counties. On that day, the FDA advised the public that fresh spinach implicated in the outbreak was grown in Monterey, San Benito, and Santa Clara Counties. At the same time, the FDA said that spinach grown elsewhere was not implicated in the outbreak and could be consumed.

The Trace-Back Investigation

From the first indications that fresh spinach was the culprit in the fall 2006 outbreak, investigators from the FDA, the CDC, and the States worked together to trace the implicated spinach back from consumption to the fields. The fact that illnesses were reported in multiple States suggested that contamination likely happened early in the distribution chain.

“Traceability to the farm is absolutely critical,” says Jeff Farrar, D.V.M., Ph.D., chief of the Food and Drug Branch in the California Department of Health Services (CDHS). “We have seen many processors in the past who believed they had state-of-the-art traceability systems and when outbreaks occur, they realize their systems are not nearly as good as they thought.”

On September 14, 2006, Erica Pomeroy, an investigator in the San Francisco District of the FDA’s Office of Regulatory Affairs, was already in the Salinas Valley with James Sigl, a senior investigator with the CDHS. The Salinas Valley is in the central coast region of California, about 55 miles south of San Jose and 20 miles northeast of Monterey.

“We were there conducting an assessment of a grower when we got a call that we needed to go to Natural Selections to start an investigation,” Pomeroy says. They were in the area as part of the FDA’s Lettuce Safety Initiative, which calls for assessments of growing and harvesting practices in major growing areas of leafy greens during September and October—months when outbreaks have occurred in the past. It took Pomeroy and Sigl about 45 minutes to drive to Natural Selections, where they reviewed the spinach washing and packaging process and collected documents from the company to determine which fields should be investigated.

Serving as team leaders for the investigation, they set up a command center at a hotel near the Salinas Valley. They were soon joined by other members of the California Food Emergency Response Team (CaIFERT), a collaboration between the FDA’s Pacific Region and the CDHS. CaIFERT includes a diverse team of investigators, food scientists, environmental scientists, microbiologists, and chemists.

“Having the right people with the right skills available on site is critical to any successful investigation,” says Barbara Cassens, the FDA’s San Francisco district director. “By training the CaIFERT staff together and offering them an opportunity to develop a working relationship prior to an emergency, we were able to move quickly in this outbreak response.”

Pomeroy says the command center served as a place where they could have computer access and convene to share information, review findings, and plan strategies. “By focusing on fields associated with certain production lots, we were able to nar-

row the search to nine different ranches in the area,” Pomeroy says. We interviewed harvesters and growers about growing practices, irrigation practices, and their workers. We collected samples in and around the suspect fields from every possible source of contamination—water, soil, and domestic and wild animal feces.” Labs of the FDA, the CDHS, and the USDA were able to process about 900 samples in a relatively short time.

And while investigators were conducting investigations on the farm level, other experts continued to analyze data collected in spinach questionnaires of people who had gotten ill. “The FDA collaborated with CDC to design a spinach questionnaire, a tool used to elicit a detailed history of spinach consumption from people who became ill,” says Karl Klontz, M.D., a medical officer in the CFSAN. “We worked with CDC to analyze data collected using information such as brand name, date of purchase, Universal Product Code (UPC) code, and lot numbers.”

A Break in the Case

On September 20, 2006, a big break came when New Mexico’s public health laboratory announced that it had isolated the outbreak’s strain of *E. coli* O157:H7 from an open package of spinach that came from the refrigerator of a patient who had become ill. “The package of spinach that tested positive was Dole baby spinach best if used by August 30,” Klontz says. This was a tremendous help in tracing back to the fields. Later, the strain implicated in the outbreak also was isolated from open packages of fresh spinach consumed by ill people in several other States, including Utah, Pennsylvania, Colorado, Ohio, and Wisconsin.

In the end, the focus of the trace-back investigation narrowed to four fields on four different ranches. On September 29, 2006, the FDA announced that all spinach implicated in the outbreak traced back to Natural Selection Foods.

Possible Routes of Contamination

The investigation into how the spinach may have become contaminated included sample collection in facilities and a review of animal management practices, processing practices, and water use. Richard Gelting, Ph.D., an environmental engineer from the CDC’s National Center for Environmental Health, was deployed to California at the FDA’s request to join in the investigation of possible environmental sources of contamination. He investigated irrigation well structure, ground water movement, and water management practices in the implicated farm regions.

On Oct. 12, 2006, the FDA and the State of California announced test results. The field investigation, discovered the same strain of *E. coli* O157:H7 involved in the illnesses in environmental samples collected at one of four implicated ranches that supplied spinach to Natural Selection. The samples included water from a stream and cattle feces taken from pasture areas on the ranch outside the crop fields. The *E. coli* O157:H7 isolates from these samples were matched to the outbreak strain by their PFGE patterns. Wild pig feces collected by investigators on the ranch were also found to contain this same strain of *E. coli* O157:H7.

“One unusual finding on the ranch was a high population of wild pigs,” says Farrar. “But we haven’t determined conclusively that wild pigs were the source of the contamination. Finding an exact-matching *E. coli* strain on an implicated farm is a first in California, and it directly reflects the CALFERT approach. But we still don’t know how the pathogen came into contact with the spinach.”

Fencing around the cow pastures nearby appears to keep the cows from going into the spinach fields. But Gerald Wiscomb, an expert on the team from the USDA’s Wildlife Services, observed during his behavioral studies that pigs go into the crop fields on the ranch. “There are many possibilities,” Pomeroy says. “It could be that the pigs rooted around the cow feces, contaminating themselves, and then later defecated in the spinach fields.” Another possibility is that surface contamination from pig and cow feces in the pasture areas got into the ground water.

More research is needed to better understand how *E. coli* O157:H7 is introduced into the environment, says Farrar. “We need a better understanding of how the organism survives, whether it grows in certain conditions, exactly how it comes into contact with ready-to-eat products, and how it’s affected by current processing practices,” he says.

History of Outbreaks in the Salinas Valley

Produce-related outbreaks have been a continuing problem in recent years. Since 1995, there have been 20 outbreaks involving leafy greens, most traced to California. Many, but not all, were traced to the Salinas Valley. But there aren’t definitive answers as to why many of these outbreaks are linked to the Salinas Valley, according to experts.

“Some have speculated that the reason other areas have not been implicated is simply because of the difference in the volume of production,” Farrar says. “The Sa-

linas Valley produces much more leafy greens than any other area in the country so we may be more likely to see outbreaks from this area. Others believe there are one or more unidentified geographic, topographic, or environmental risk factors unique to Salinas Valley that result in systemic contamination with *E. coli* O157:H7.”

In a recent multiagency investigation project, the CDHS discovered many *E. coli* O157:H7 positive findings in agricultural ditch water in many area locations. This is the runoff water originating in the hills surrounding the Salinas Valley. Although none of these isolates have matched any known outbreak strains, these findings have resulted in a grant from the USDA’s Agricultural Research Service to the University of California at Davis (UC-Davis) and the CDHS to look further into environmental sources of contamination in this area.

Industry and FDA Action

In 2004 and 2005, the FDA wrote to industry to express both the agency’s concerns with continuing outbreaks and its expectations for industry to improve produce safety. One letter to the lettuce and tomato industries in February 2004 encouraged industry to review practices in light of the FDA’s Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) guidance. Another letter, sent in November 2005, reiterated this concern and focused on fresh-cut lettuce and other leafy greens.

After the most recent spinach outbreak, the FDA and the State of California asked the produce industry to develop a comprehensive plan to minimize the risk of another outbreak due to *E. coli* in spinach grown in California.

The Grower-Shipper Association of Central California, the Produce Marketing Association, the United Fresh Produce Association, and the Western Growers Association pledged their commitment and submitted a draft plan to the FDA.

Implementation of this plan is voluntary, but the FDA and the State of California may institute regulatory requirements if it is determined that they are needed.

The Public Health Service Act authorizes the FDA to make and enforce regulations to prevent the introduction, transmission, or spread of communicable disease. And the Federal Food, Drug, and Cosmetic Act provides a broad statutory framework for Federal regulation to prevent adulterated foods from entering commerce, and to ensure that human food will not be hazardous to health.

Farrar says that industry also has proposed the creation of a statutorily based “Marketing Order and Marketing Agreement” on the State level for growers and processors as a possible avenue. “We are familiarizing ourselves with this proposal for mandatory and uniform standards for leafy greens industry in California that would be administered under the California Department of Agriculture’s statutory authority,” he says.

The FDA and the State of California have reiterated previous concerns and advised firms to review their operations in light of the FDA’s guidance for minimizing microbial food safety hazards, as well as other available information regarding the reduction or elimination of pathogens on fresh produce.

Charles Sweat, chief operating officer of Natural Selection Foods, announced that his company will require a number of measures be taken by growers that supply their company with the fresh-cut produce that they pack. These measures include working with growers from seed to harvest, inspecting the seed, irrigation water, soil, plant tissues, and wildlife. The company also indicated that sanitation protocols for farm equipment and packaging supplies will be enhanced and monitored, and that a “firewall” will be set up to test all the freshly harvested greens before they enter the production stream.

“Clearly things have to change throughout the leafy greens industry and the changes need to occur quickly,” Farrar says. “We have relayed to industry that the solution must include specific, measurable, enforceable on-farm food safety practices that are based on the best science that’s available now.”

According to PAP guidelines, areas that should be considered to minimize the potential for microbial contamination of produce include:

- agricultural water used for irrigation or crop protection sprays
- wild and domestic animals
- worker health and hygiene
- the production environment, which includes the use of manure, previous land use, and use of adjacent land
- post-harvest water used to wash or cool produce
- sanitation of facilities and equipment.

The Produce Safety Plan

The FDA instituted a Produce Safety Action Plan in 2004. The action plan builds on previous guidance and addresses microbial food safety hazards and good agricultural and management practices common to growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or raw (minimally processed) form.

The plan contains four objectives: preventing contamination of fresh produce with pathogens; minimizing the public health impact when contamination of fresh produce occurs; improving communications with producers, preparers, and consumers of fresh produce; and facilitating and supporting research relevant to fresh produce.

“A significant change is that we’ve gone from a broader-scope guidance in the past to more commodity specific guidance,” says Nega Beru, Ph.D., director of the CFSAN’s Office of Plant and Dairy Foods. “Certain commodities account for most of the foodborne outbreaks associated with produce.”

As part of the plan, the FDA has provided technical assistance to help industry develop food safety guidance for five commodity groups: cantaloupes, lettuce and leafy greens, tomatoes, green onions, and herbs. The guidelines for cantaloupes, tomatoes, and lettuce have been finalized and are available. With FDA assistance, industry work on guidances for herbs and green onions is ongoing.

In March 2006, the agency released draft guidance for the fresh-cut produce industry. The agency is working to finalize its “Draft Guidance to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables.” The Lettuce Safety Initiative, developed in August 2006, supports the produce safety plan and covers lettuce and other leafy greens, including spinach.

In August 2006, the FDA met with Virginia officials to discuss outbreaks associated with tomatoes produced on the Eastern shore of Virginia. The FDA worked with the Florida Tomato Exchange and the University of Florida’s Institute of Food and Agricultural Sciences to arrange a forum, held in November 2006, to discuss improving tomato safety. Also in November 2006, the FDA announced results of an investigation by State and CDC investigators which found that consuming tomatoes in restaurants was the cause of illnesses of *Salmonella* Typhimurium. Twenty-one States reported 186 cases of illness to the CDC.

“Produce safety is the number one priority in CFSAN right now,” Brackett says. “Our role is to serve as a leader in providing direction for industry and to apply the best science-based approaches toward building an even safer food supply. As a result of effective collaboration with our public health partners, the American food supply continues to be among the safest in the world. But we also know that we must continue to work on reducing the incidence of foodborne illness to the lowest level possible.”

E. COLI OUTBREAKS AT TACO BELL AND AT TACO JOHN’S

On December 14, 2006, the Centers for Disease Control and Prevention (CDC) announced that the *Escherichia coli* (E. coli) O157:H7 outbreak linked to Taco Bell Restaurants in northeastern States appeared to be over. Based on a number of factors, shredded iceberg lettuce is considered overall to be the single most likely source of the outbreak at this time. The FDA announced that it continues to narrow its investigation by focusing efforts on finding the sources of shredded iceberg lettuce served at the restaurants.

The peak of the outbreak occurred from the last week of November until the beginning of December. A total of 71 cases in five States were reported to the CDC (Delaware (two cases), New Jersey (33 cases), New York (22 cases), Pennsylvania (13 cases), and South Carolina (one case—this person ate at a Taco Bell in Pennsylvania). Fifty-three hospitalizations and eight cases of hemolytic uremic syndrome (HUS) have been reported. HUS can cause permanent kidney damage and death.

FDA investigators reviewed Taco Bell’s records in order to trace the distribution channels of the iceberg lettuce and identify the farm or farms where the lettuce was grown, as well as all the firms and facilities that handled the product. This outbreak has been traced to California’s Central Valley.

In January 2007, the agency also announced that it had moved closer to identifying the source of illness for an outbreak of E. coli O157:H7 at Taco John’s Restaurants in Iowa and Minnesota. The FDA and the State of California, working with State health officials in Minnesota, Iowa, and Wisconsin, have DNA-matched the strain of E. coli O157:H7 bacteria associated with the outbreak with two environmental samples gathered from dairy farms near a lettuce-growing area in California’s Central Valley. The outbreak sickened 81 people in November and December 2006. Illnesses were reported in Minnesota (33), Iowa (47), and Wisconsin (one).

Twenty-six people were hospitalized, and two suffered from HUS. No deaths have been associated with the outbreak.

PRODUCE SAFETY TIPS

In light of recent contaminated produce outbreaks, the FDA is emphasizing advice to consumers on how to reduce the risk of foodborne illnesses from fresh produce.

Buying

Purchase produce that is not bruised or damaged.

When selecting fresh-cut produce—such as half a watermelon or bagged mixed salad greens—choose only those items that have been refrigerated or surrounded by ice.

Bag fresh fruits and vegetables separately from meat, poultry, and seafood products when packing them to take home from the market.

Storage

Strawberries, lettuce, herbs, mushrooms, and other perishable fruits and vegetables can best be maintained by storing in a clean refrigerator at a temperature of 40 degrees F or below. If you're not sure whether an item should be refrigerated to maintain quality, ask your grocer.

All produce that is purchased pre-cut or peeled should be refrigerated within two hours to maintain both quality and safety.

Keep refrigerators set at 40 degrees F or below. Use a refrigerator thermometer to check!

Preparation

Many pre-cut, bagged produce items like lettuce are pre-washed. If so, it will be stated on the packaging. This pre-washed, bagged produce can be used without further washing.

As an extra measure of caution, you can wash the produce again just before you use it. Pre-cut or pre washed produce in open bags should be washed before using.

Begin with clean hands. Wash your hands for 20 seconds with warm water and soap before and after preparing fresh produce.

Cut away any damaged or bruised areas on fresh fruits and vegetables before preparing or eating. Produce that looks rotten should be discarded.

All unpacked fruits and vegetables, as well as those packaged and not marked pre-washed, should be thoroughly washed before eating. This suggestion includes produce grown conventionally or organically at home, or produce that is purchased from a grocery store or farmer's market. Wash fruits and vegetables under running water just before eating, cutting, or cooking.

Even if you plan to peel the produce before eating, it is still important to wash it first.

Washing fruits and vegetables with soap or detergent or using commercial produce washes is not recommended.

Scrub firm produce, such as melons and cucumbers, with a clean produce brush.

Drying produce with a clean cloth towel or paper towel may further reduce bacteria that may be present.

Separation

Keep fruits and vegetables that will be eaten raw separate from other foods, such as raw meat, poultry, or seafood, and from kitchen utensils used for those products.

Wash cutting boards, dishes, utensils, and countertops with hot water and soap between the preparation of raw meat, poultry, and seafood products and the preparation of produce that will not be cooked.

For added protection, kitchen sanitizers can be used on cutting boards and countertops periodically. Try a solution of one teaspoon of chlorine bleach to one quart of water.

If you use plastic or other nonporous cutting boards, run them through the dishwasher after use.

For More Information

Safe Handling of Raw Produce and Fresh-Squeezed Fruit and Vegetable Juices
 FDA Issues Final Guidance For Safe Production of Fresh-Cut Fruits And Vegetables (Press Release, March 12, 2007)

The FDA page on E. coli Outbreaks

The CDC page on E.coli Outbreaks www.fightbac.org

—www.foodsafety.gov

FDA FACT—FRESH-CUT FRUITS AND VEGETABLES DRAFT FINAL GUIDANCE

The Food and Drug Administration announces the availability of the draft final fresh-cut guidance, entitled “Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables” (the Guide). The purpose of the Guide is to minimize the potential for microbial contamination during the processing of fresh-cut produce by providing recommendations to fresh-cut processors.

Fresh-cut produce is produce that is minimally processed (no lethal kill step) and altered in form by peeling, slicing, chopping, shredding, coring or trimming with or without washing or other treatment prior to being packaged for use by the consumer or a retail establishment. Examples of fresh-cut products are shredded lettuce, sliced tomatoes, salad mixes (raw vegetable salads), peeled baby carrots, broccoli florets, cut melons and sectioned grapefruit.

The fresh-cut produce sector is the fastest growing sector of the produce industry. As the fresh-cut sector grows, a larger volume and greater variety of fresh-cut products have become available. From 1996 to 2006, 26 percent of all outbreaks associated with fresh produce implicated fresh-cut produce.

If pathogens are present, the processing of fresh-cut produce by peeling, slicing, shredding, coring, or trimming may increase the risk of bacterial contamination and growth by breaking the natural exterior barrier of the produce thereby supplying nutrients for pathogens to grow. In addition, the high degree of handling common in fresh-cut operations may increase the risk of cross-contamination if adequate controls (e.g., adequate levels of free chlorine in a dump tank) are not in place.

The Guide is a continuation of existing programs such as the good agricultural practices (GAPs) program and covers the processing of fresh produce into fresh-cut produce, the next link in the supply chain. In FDA’s 2004 Produce Safety Action (PSAP), the issuance of the Guide was identified as an action that could help achieve the PSAP’s first objective, to prevent contamination from occurring.

The Guide complements FDA’s Current Good Manufacturing Practice regulations for food (21 CFR 110) and provides a framework for identifying and implementing appropriate measures to minimize the risk of microbial contamination during the processing of fresh-cut produce. Specifically, it discusses the production and harvesting of fresh produce and provides recommendations for fresh-cut processing in the following areas: (1) personnel health and hygiene, (2) training, (3) building and equipment, (4) sanitation operations, and (5) fresh-cut produce production and processing controls from product specification to packaging, storage and transport. The Guide also provides recommendations on recordkeeping and on recalls and tracebacks.

In the Guide, FDA recommends that processors encourage the adoption of safe practices by their partners throughout the supply chain, including produce growers, packers, distributors, transporters, importers, exporters, retailers, food service operators, and consumers.

The Guide also recommends that fresh-cut processors consider a preventive control program such as the Hazard Analysis and Critical Control Points (HACCP) system to build safety into their processing operations. HACCP is a system designed to prevent, eliminate, or reduce to acceptable levels the microbial, chemical, and physical hazards associated with food production.

FDA will hold two public hearings concerning the safety of fresh produce including fresh-cut produce on March 20, 2007, in Oakland, CA and April 13, 2007, in College Park, MD (Wiley Building).

FDA NEWS—FDA ISSUES FINAL GUIDANCE FOR SALE PRODUCTION OF FRESH-CUT FRUITS AND VEGETABLES

The Food and Drug Administration (FDA) today published a draft final guidance advising processors of fresh-cut produce how to minimize microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables, which are often sold to consumers in a ready-to-eat form.

The document—“Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables”—suggests that fresh-cut processors consider a state-of-the-art food safety program such as the Hazard Analysis and Critical Control Points (HACCP) system, which is designed to prevent, eliminate, or reduce to acceptable levels the microbial, chemical, and physical hazards associated with food production.

The guidance complements FDA’s regulations of manufacturing practices and incorporates comments received in response to its draft issued in March 2006. The current version will not be final until the White House Office of Management and Budget completes an authorization step required by the Paperwork Reduction Act, and the agency announces that the guidance is final.

“Ensuring the safety of the American food supply is one of this Agency’s top priorities,” said Andrew C. von Eschenbach, MD, Commissioner of Food and Drugs. “Americans are eating more fresh-cut produce, which we encourage as part of a healthy diet. But fresh cut-produce is one area in which we see food borne illness occur. Offering clearer guidance to industry should aid in the reduction of health hazards that may be introduced or increased during the fresh-cut produce production process.”

Dr. von Eschenbach will testify before a hearing by the Agriculture, Rural Development, and Related Agencies Subcommittee of the Senate Committee on Appropriations, which will address the processes in place and improvements being made regarding food safety, specifically the safety of fresh produce and vegetables. The hearing will take place in Madison, Wisconsin, on March 12, 2007.

Processing produce into fresh-cut product increases the risk of bacterial contamination and growth by breaking the natural exterior barrier of the produce by peeling, slicing, coring, or trimming the produce with or without washing or other treatment before the produce is packaged for consumers. Examples of fresh-cut products are shredded lettuce, sliced tomatoes, salad mixes (raw vegetable salads), peeled baby carrots, broccoli florets, cauliflower florets, cut celery stalks, shredded cabbage, cut melons, sliced pineapple, and sectioned grapefruit.

Consumers can reduce their risk of illness from fresh-cut produce by following safe handling practices such as refrigerating the product after purchase; using only clean hands, utensils or dishes in preparing the product; and discarding the product when the “use by” date has expired.

The Guide complements FDA’s Current Good Manufacturing Practice regulations for food (21 CFR 110) and provides a framework for identifying and implementing appropriate measures to minimize the risk of microbial contamination during the processing of fresh-cut produce.

Specifically, it discusses the production and harvesting of fresh produce and provides recommendations for fresh-cut processing in the following areas: (1) personnel health and hygiene, (2) training, (3) building and equipment, (4) sanitation operations, and (5) fresh-cut produce production and processing controls from product specification to packaging, storage and transport. The Guide also provides recommendations on recordkeeping and on recalls and tracebacks.

The Guide also recommends that processors encourage the adoption of safe practices by their partners throughout the supply chain, including produce growers, packers, distributors, transporters, importers, exporters, retailers, food service operators, and consumers. These practices include:

- Establishing a company policy that employees report any active case of illness to supervisors before beginning work and training;
- Training supervisors to recognize typical signs/symptoms of infectious disease; maintain the proper first aid to protect and cover any wound; and not allow an employee to work with any aspect of fresh or fresh-cut produce, processing equipment or tools until the wound has healed and/or the infectious disease has been treated.

FDA believes awareness of the common risk factors discussed in this guidance and implementation of preventive controls determined by a firm to be appropriate to its individual operations will enhance the safety of fresh-cut fruits and vegetables. More information on safe handling practices of produce can be found at <http://www.fightbac.org/>.

Written comments on the Guide are acceptable at any time and should be sent to FDA’s Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Comments on the Guide-specific to issues involving the Paperwork Reduction Act should be faxed within 30 days of the publishing date of the Federal Register notice to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

The Guide is accessible on the FDA Website at: <http://www.cfsan.fda.gov/guidance.html>

Additional Information about the Guidance

Fact Sheet: “Fresh-Cut Fruits and Vegetables Draft Final Guidance”
Federal Register Notice (March 13, 2007) [PDF, 67KB]

Dr. von Eschenbach’s Statement before the Agriculture, Rural Development, and Related Agencies Subcommittee of the Senate Committee on Appropriations

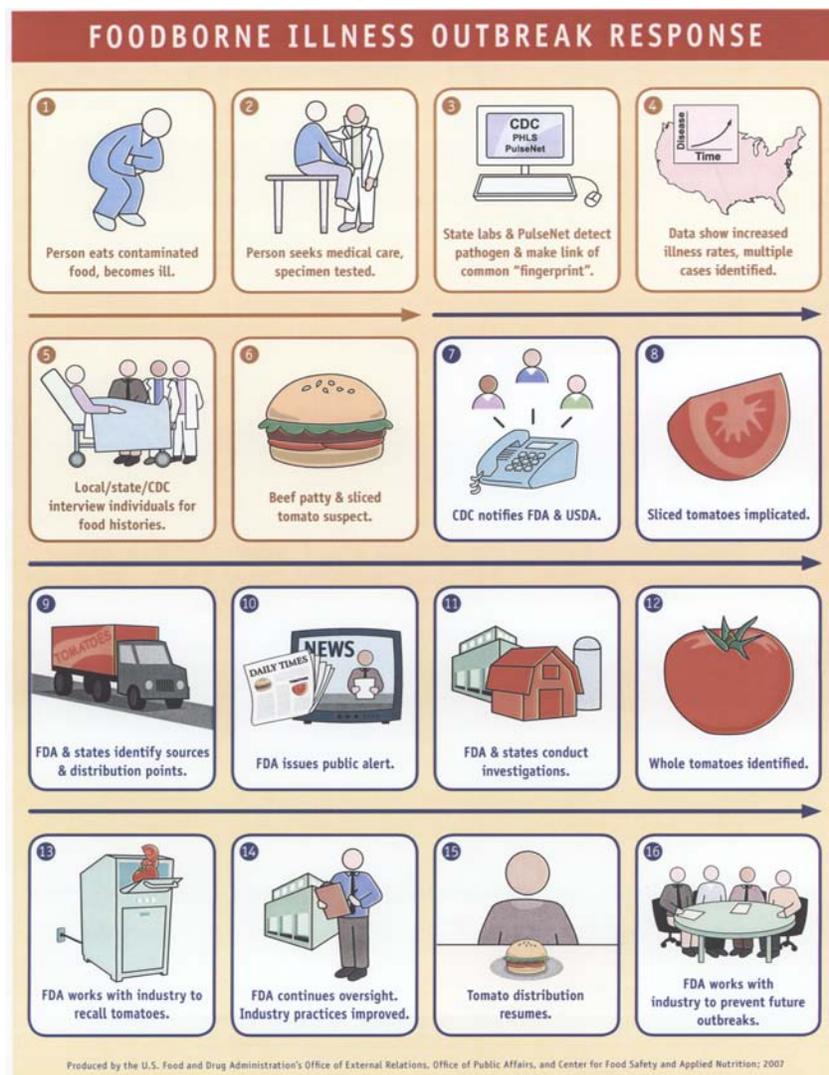
Relevant Food Safety Information: “How the FDA Works to Keep Produce Safe”
www.foodsafety.gov

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Senator KOHL. Dr. Brackett.

STATEMENT OF ROBERT BRACKETT, DIRECTOR, FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

Dr. BRACKETT. Thank you, Senator Kohl and thank you, Dr. von Eschenbach. I am pleased this morning to announce that as we speak, a new important tool in produce safety is being announced at this time and posted and that is something that Mr. Stenzel alluded to during his testimony, which is a guidance to minimize mi-

crobial safety of fresh fruits and vegetables. This is a document that was first published in draft in March 2006 and specifically addresses the cut-fresh growth produce industry and focusing on, as was mentioned by some of the panelists, a complement to the more general Good Agricultural Practices that we've published that really focuses and provides much more focused guidance on that particular industry.

It addresses such things as personal health and hygiene, which is important, as Ms. DeWaal mentioned, the building and equipment and the best practices that can be used there, sanitary operations and what controls could be used in the fresh produce industry, fresh-cut produce industry and perhaps some recommendations for records, which the industry might use. Many of the recommendations are based on similar principles of what we call HACCP in other industries so we're encouraged that this is going to be something that the industry can use in a great way.

Also, I want to re-emphasize that we are anxious to have consumers regain confidence to complete their diets with more fresh fruits and vegetables and we're hoping that this is one way that we can again, encourage consumers to be more healthful in their diets.

Senator KOHL. Thank you very much. Consistent with what I said just a few minutes ago, what I'd like to do at this time is to give the first panel an opportunity to make a suggestion, comments, get some answers directly from the source. Who would like to stand up first and get shot down?

Senator KOHL. Mr. Stenzel, go ahead.

HACCP APPROACH

Mr. STENZEL. Thank you, Senator. This is quite an opportunity. I commend you and I appreciate your participation in this as well. Dr. Brackett, could you give us a sense of—we're looking at a number of regulatory options in the produce industry and you have so much experience beyond produce as well—the seafood HACCP approach and how that has worked in the seafood industry and then also, a second issue, closer to produce, the Sprout Guidance document that FDA published a number of years back, both of which we believe have been very effective in addressing risks in the food supply. So your perspective on those and applicability in produce?

Dr. BRACKETT. Well, thank you. I think what you've listed are two different models that we've used in food safety, both of which are actually considering with respect to produce. The first was seafood HACCP has specific points during the production of seafood at which the manufacturers are required to take interventions to make sure that the product is not contaminated or not made less safe, a good example of which would be is proper refrigeration as they catch them on the boat so that when it gets to the dock, there hasn't been any microbial contamination. That is in the form of a regulation and that's something that we have used. It has worked in other industries, including meats and poultry, quite well.

Now, the second one had to do with sprouts. Sprouts was an example of something where we had unacceptable numbers, a lot of illnesses associated with particularly alfalfa sprouts and when our researchers went and looked to find out where this was occurring,

we found the specific points in sprout production and that allowed us to write some guidance that would tell the manufacturer, if you do these certain things, specifically testing at certain points, you can really reduce the risk that you have. We have had good adoption of those guidelines and in fact, the sprout illnesses have dropped to the point where they were none reported in the last few years after points where there were hundreds before that.

So both of those mechanisms can work but I think the important part is to have a good understanding of the science underlying the advice so that you can actually tailor it.

IMPORTED FRUITS AND VEGETABLES

Senator KOHL. Ms. DeWaal.

Ms. DEWAAL. Thank you. One of the challenges in this issue is that so much of our produce is imported from other countries and one of our great concerns is that the use of guidance may be somewhat effective for our domestic industry and have absolutely no impact on the people growing in foreign countries. In fact, we've had a large number of outbreaks from imported produce, both fruits and vegetables. How will your latest guidance help in preventing outbreaks associated with imported fruits and vegetables?

Dr. von ESCHENBACH. I'm going to ask Dr. Brackett to speak specifically to the science but I do want to comment on the more global issue of our relationship outside of our borders. Our Office of International Foods is very actively engaged in multi-lateral discussions. I personally have committed to continue to enhance that so that we work to disseminate these good agricultural practices into those areas and into those regions so that we're able to enhance the ability of them to be creating and bringing into this country, quality products. We have, as part of an integration with the Food Defense Program, the ability for prior notice so that as imports are coming into this country, they are already recognized and know the source from which they're coming so we can identify those sources according to areas of risk and therefore, direct our inspection efforts to those areas in which we do have concerns that have the quality of production, whereas those other areas in which we have very close collaborative interactions and working relationships that are assured of quality at the site of production, we could then mitigate those kinds of efforts in terms of our import strategies. So we are protecting the border, we're working outside of our borders to enhance their practices and then using the kinds of guidance that are being developed here as a foundation for that kind of sharing of vital information.

Dr. BRACKETT. One of the first things in the foundational sort of ways that we deal with this, because we have different regs for importing products versus our domestics. We have some different tools, is to really engage both the industry and the governments at the other half of the exporting countries and telling them what our expectations are, which is we expect the products that they send us are as absolutely safe as what we get in this country or we will take assertive action and I'll get to that in a moment.

But part of one of the requests we get is, they will say, well, this is fine. What would you like us to do? And that's where documents such as the guidance documents or some of the other good agricul-

tural practices is very important, because we will go to them and tell the governments, this is what our expectations are. We also, of course, have an educational role and this we do through partners like the Joint Institute for Food Safety and Nutrition at the University of Maryland, which actually has a program that goes out to producing countries to educate their governments, local governments as well as their industry, in application of good agricultural practices and now with the fresh-cut guidance.

Having said that too, we've worked directly with the governments and I see us doing more of this in the future, in such programs as we have with Mexico. We have an MOU with Mexico under the Federal Recognition Program, that basically tells them how we expect cantaloupe to be produced because we've had salmonella outbreaks with cantaloupe and in those cases where a particular farm or a particular company is not meeting our expectations, we need to go down there and audit these. They are removed from our list of companies that can import into this country and so that's been important.

In the past, many of the outbreaks that you alluded to, such as raspberries from Guatemala, we work very closely with the country and with the industry but we never were able to get rid of that parasite, which was a spore and in fact, so through our import alerts, we basically stopped shipment in this country and that's one of the most powerful tools we have with those countries, is if they are not living up to our expectations, they simply can't ship to us.

GUIDANCE IMPLEMENTATION

Senator KOHL. Dr. Verduin.

Dr. VERDUIN. I have a two-part question. Number one is, you have this new guidance, which I congratulate you on, but, do you see a regulatory framework that helps make sure that guidance gets implemented throughout the industry? That's number one and then number two, is what do you see the role of industry and I think Ms. DeWaal—she commented on that—hard data. Do you see that helping FDA at all and is there a way that you think if the auditing practices and the testing that the customers of fresh produce require get implemented, and get incorporated into the data that you—will use that data to regulate the industry, the growers?

Dr. BRACKETT. I'll answer the second part first. I think that any kind of data that we get from the industry is absolutely helpful to us. It helps us make real life sort of decisions, practical decisions on where the outbreaks are actually occurring and why they are occurring. Many of the data that CSPI has provided for us has helped us sort of target where the outbreaks are happening and as was mentioned, in upcoming sources of infection are the viral, particularly with norovirus and in many cases, that is a people-person problem where someone is actually touching the product, either in the field or in many cases, in the point of preparation, such as restaurants. It's important for us not to forget that that part happens. It does happen. It can be a farm to table approach and so we have to focus resources appropriately on that.

With respect to how we're going to implement the guidance, I think that's—one of the things we're going to do is look at the in-

dustry and we hope that will work with trade associations to make sure that these are implemented. But we'll go look again, as we did with our Leafy Greens Initiative last summer in the Salinas Valley to actually assess if they are being implemented.

One of the other things that we'll be doing is having several public meetings, one of which is going to be on March 20 in Oakland, California. Another one, is April 15 in Washington, to get the best knowledge that we can both from the industry as well as the scientific community, as to what the best regulatory approach is, given this industry, as diverse as it is and as important as it is to public health.

Dr. von ESCHENBACH. If I could just add to that somewhat, I think the chairman has pointed out very well, the importance of collaboration and cooperation and clearly, we've heard this morning, not just the concern that the industry has on the impact on public health but it's also true to point out that there are great motivations on the part of the industry from both a legal perspective, an economic perspective, in addition to the commitment to public health.

I view that the opportunities to go from the continuum of statute to regulation to guidance is that there are really tremendous opportunities given that spirit of cooperation and collaboration, to really enhance the guidance mechanism and guidance opportunity. It allows us to continue to adapt to the rapidly changing environment, new science, new insight to what our best practices are. I think, in your testimony, you pointed out many times, we need to learn and understand and the guidance gives us the flexibility to continue that rapid learning process and changing process, which doesn't necessarily encourage statute or from a regulatory point of view.

As Dr. Brackett has pointed out, if it is not working, then we need to move to a more stringent type, a much longer and laborious type of process like regulation or statute. But I think guidance has really given us an opportunity for flexibility and the ability to integrate, coordinate and adapt knowledge of your understanding and when you refine it, it's really going to be an efficient plan.

Ms. DEWAAL. Thank you.

GRANT PROGRAM FOR RESEARCH

Senator KOHL. Dr. Pariza.

Dr. PARIZA. Thank you. One of the most successful and really economically successful as well programs that we've had in this country in the way of the research has been through the National Institutes of Health, where investigators put in research proposals in areas that they think are important. They are peer-reviewed and then scored and ultimately, you find out who is funded and not funded based on that scoring. FDA used to participate in this 25 or 30 years ago. FDA was a participant that had funding, which was allocated for this and so if you submitted a proposal to NIH in some area that related to FDA's program, and it was approved, the FDA would fund it. What I'm wondering is if you were able to provide FDA with some sufficient new funding, would they be interested in maybe reinitiating this program?

Dr. BRACKETT. Well, that's an interesting question and I'll let Dr. von Eschenbach too, answer this as well but since he has much

more experience in NIH than I do but one of the important questions of mine with funding would be research, and we certainly have had a program like that, is in this particular case, we think that we need some very focused, very applied research and that's something that some organizations are better at than others. And I think one of things we want to make sure is that whatever research document, whoever funds it, that it is targeted so that it really answers somebody's critical questions, whatever the method.

Dr. von ESCHENBACH. I feel, having spent 4 years as Director of the National Cancer Institute and having had the perspective of NIH, I believe it is extremely important for there to be a very solid core of research within the Food and Drug Administration, independent of the research that occurs at the National Institutes of Health and in academia. But I don't believe that the FDA should stand apart. We need to create much more collaboration and interactions with those other sources of research that are very, perhaps basic and developmental as FDA's core research effort is much more applied.

This is going to be particularly important as we go forward with regard to CFSAN, as we look not just at food safety and food defense, but even more important, at the issue of nutrition and the important role that fruit must play in promoting our health. So I see the importance of the integration but I don't believe that the FDA needs to duplicate the research structure that currently exists at NIH with regard to investigator initiated, hypothesis-driven research. I think we can complement that and we must have a very strong research base with a continuum that moves much more to the applied.

MANDATORY REGULATIONS

Senator KOHL. Several members of our first panel talked about the need for FDA to publish mandatory regulations for produce instead of what we have now, voluntary guidance. You could do this with no money, and setting a minimum safety standard seems to be a simple and a good idea. I know the FDA has resisted that effort thus far. Could you comment on that?

Dr. von ESCHENBACH. Mr. Chairman, as I indicated in my follow-on question, I believe the sense, as we look at our options, it isn't a matter of resisting regulation as much as it is trying to fully utilize the opportunities that guidance has provided to us in terms of flexibility, in terms of the abilities which we could rapidly, more rapidly implement them instead of the regulatory process itself. So I believe, as Dr. Brackett has pointed out, for example, even in the sprouts experience, how effective those guidances can be in eradicating and eliminating threats to our food supply. So I would, at this point, use the opportunity to fully utilize the guidance mechanism and the guidance process as opposed to regulation. We'd certainly accept regulatory processes—an issue of focusing on guidance.

Senator KOHL. Well, we have mandatory regulations in the meat industry and the poultry industry in respect to safety and inspection and we understand our produce is not exactly the same by any means. But the public has come to accept and expect that the meat and the poultry, mandatory safety processes will occur.

So maybe, Dr. Brackett, why is produce so different that you might suggest that we cannot even begin to approach it in this way? Several members of the panel believe that we should at least make that attempt and that some of the things that we can do with respect to requiring certain sanitation procedures on the farm to occur should be universal and should be subject to mandatory kinds of rules and regulations. What is your thought and your comment?

Dr. BRACKETT. Well, I think that in order for any kind of regulation to be successful, it has got to answer the question or solve the problem that it is intended to ask. I think a big difference between meat and poultry and where produce is, is simply the state of scientific knowledge at this time. One of the things that people immediately want us to do is to implement actions on the farm level or anywhere else, just because they think they might have something mandatory. But we want to make sure that whatever we tell the industry actually works so that this doesn't cause any undue economic burden on them, to make sure that if it doesn't solve the problems, so that the illnesses continue, which is one of the things we are concerned about. We are in a stage now, in a phase where I think the scientific knowledge is going to increase dramatically in the next few years and we hope to apply that to any kind of regulatory strategy but especially regulations that are much more difficult to change down the line.

RAPID RESPONSE TEAMS

Senator KOHL. I have to ask about a rapid response team approach. I know you're trying to focus and target resources and we all agree that trying to blanket the country with 5,000 additional inspectors just is not feasible. But I believe and others have suggested that one way to improve where we are right now is to create five or six rapid response, FDA Rapid Response Teams and put them around the country in strategic locations. The purpose would be to respond to an outbreak at the very inception so that it does not spread. And when they are not doing that, they could do things like sample, inspect, and do other work however you direct them. Each of these teams might have five or six or seven people, depending on your wisdom and judgment as applied members. This would be a more economical way and I think that the right people out in the field can contain outbreaks when they do occur. Do you have some response to that thought, which I know you've heard before and we've discussed it. Dr. von Eschenbach.

Dr. von ESCHENBACH. Well, Mr. Chairman, as a matter of fact, I'm greatly appreciative for the kind of guidance that you've given us with regard to the importance of a rapid response team and in fact, we're looking at that issue and your suggestion. One of the things that Dr. Brackett can comment on is the lessons learned in the spinach outbreak and in fact, by virtue of having close collaboration between our Office of Regulatory Affairs, CFSAN and the States, particularly in this case, the State of California, because they had initiated this concept of a rapid response team around the issue of addressing problems with regard to lettuce, that enabled us to really effectively be able to intervene in the spinach outbreak and one of the lessons learned is the importance of having these

rapid response teams ready to be deployed and on the ground. So expansion of that program and creating more rapid response teams is certainly now an important part of our strategic agenda going forward. I think it is an important lesson learned and your direction in that regard has been very well taken. Do you want to comment?

Senator KOHL. Dr. Brackett.

Dr. BRACKETT. The team that Dr. von Eschenbach was referring to was called CALFERT and this is a team that we put together with the State of California, both agriculture and their public health officials, and the term CALFERT is another acronym meaning California Food Emergency Response Team. They were meant to work as a team. They were trained together on farm investigations, on food breakout breaks, as a group. So that whenever an outbreak occurred, they were able to quickly go into action and go investigate and so that team sort of has the—been the model for how things should be done. An important component of that, again, is to have the flexibility to be out there and to respond quickly, which is the point that you made. But the other part was, what do they do when there is not an outbreak? And they were the same group, for instance, when we had our Leafy Greens Initiative, to go out to the farms in California in August to make sure that the good agricultural practices were being enforced or adopted and to look at the level of education that was needed among the farmers. This was the group that was actually doing that.

When the spinach outbreak occurred, they were in the field doing that, so they were the ones that were immediately able to respond to that. That's probably one of the reasons why we were able to identify this outbreak to the level that it was, something we had never been able to do before. So it's a very good model.

RESEARCH

Senator KOHL. Dr. Brackett, are there other promising areas of research that are going on right now within your area of responsibility?

Dr. BRACKETT. There are many different types of research that are going on, not only within our own agency but within USDA and the private sector.

This includes, as Dr. Pariza mentioned, better detection methods. One of the things that help in a response is if you are able to identify the organism and trace it back in a much faster way. That helps the public health as well. Being able to look at some of the new technologies such as irradiation, such as high pressure, many other food technologies. People haven't even thought about how that could be applied to products where consumers want them fresh, a more fresh-like taste in something, not unlike salads. That's another area of interest that we have.

But another part that people sometimes forget about is the research that is on consumer behavior and why people make the choices they do, what they are hearing to make sure that when we have a message, which was a very important lesson learned in the spinach outbreak, to make sure that we communicate clearly and often with the consumer so that they can know what the true risk is and what it isn't. We want to make sure that when the con-

sumers come out of one of these outbreaks, they are confident again, and that takes some consumer behavior research. So that's one that is often forgotten about.

Senator KOHL. Let me just talk about imported produce. Of the produce we're eating now, 20 to 30 percent of the total is imported and the importation inspection system is—I won't say it's non-existent, but it really is small. It's really amazing, if you think about it, why we don't have more outbreaks when so much of what comes in from foreign countries is not inspected and it winds up in our stores and it winds up in our stomachs without any real inspection taking place. What can we look forward to? What might be the state of the art in that whole system 5 years from now, 10 years from now? Is there any hope that we can bring to the American people in some reasonable period of time, some kind of an inspection system on imported produce that will give them some sense of safety? Dr. von Eschenbach.

Dr. von ESCHENBACH. At least at the outset, the short term, Mr. Chairman. What we are approaching this from is the perspective of risk management and risk mitigation. I already alluded to the ability to have prior notice, for example, and then to be looking at how we are building quality in before that product ever even comes to our shores. Tools that we will enable to do that are more sophisticated information technologies that would enable us to manage that data, manage that information, would be an important part of the developmental process and an important part of our effort.

Detection methodologies that we could use, that we would be able to deploy in the field, so to speak or at the point of inspection would be opportunities for enhanced safety and those are very important research questions. Someone, I think it was Dr. Pariza, alluded to, for example, what role nano-technology has, what role some molecular technologies might play in being able to sample and test at the point of contact, especially when you're dealing with perishable items that need to move very rapidly. So I can see a continuum with regard to further research that are on very disparate ends of the spectrum, from very fundamental, basic, to really technologies that we have to manage risk. I don't know if Bob has a specific plan in terms of what he sees as research opportunities and importance but I see it as just a part of the continuum.

Dr. BRACKETT. Yes, I think whatever the research results that we, or the rules that we get, we would absolutely want to export to our trading partners to make sure that they are using the same things. And I think it is important to realize that we are in a growing global economy where we are going to be trading back and forth and we want to make sure that, especially in the area of fresh produce, that the expectations and the standards that are being used are international, not just our own. So one of the things we've done in terms of trying to promote this is introduced produce safety as one of the items that will be addressed in the Codex Elementarious discussions on international food standards of fresh produce. I think just for us to have standards and not have the expectation that every other country will have those same high standards, I think would be self-defeating for us.

So that's one important area that is a little more long-term but the other part again, is to continue our collaborations with groups

such as CFSAN and make sure that they are out and doing the education that is needed with the trading partners, to make sure that we support whenever there is an action taken by the FDA for a product that is coming to this country, that we get back with that country and know why their product is being held at the border so that they can correct the action. They want to correct it and we want to have safe food.

Then the adoption of technologies at the border so as Dr. von Eschenbach mentioned, we could really address the highest risk products as quick as we can and not wait until they get into the consumers' mouths before we find out there was a problem.

Senator KOHL. Does the panel have any other follow-up thoughts or questions you want to ask? Ms. DeWaal.

Ms. DEWAAL. I always have more questions.

The thing that concerns me a bit is the issue again, going o back to imports, which I think you covered very, very well. But we still have no mechanism to enforce those standards on importers, to the extent that they are using simply guidance as your approach suggests. There is no mandatory requirement for our domestic industry, who is now calling for one, and there is simply no way to enforce those standards for importers. So I guess, Dr. von Eschenbach, I'm wondering if you would consider the issue of how you will enforce, not after the outbreak happens but before the outbreak happens, the standards that you are proposing. Because under USDA, they approve the country before they import, they approve individual meat plants before they import, and they inspect 20 percent of imported meat and poultry products. Do you need a system like that? And without such a system, how can you enforce guidance documents that aren't even mandatory for our own country?

Dr. BRACKETT. Sure. I think the biggest tool we have as far as our experience at the border, is to be able to stop products if we know that there has been a problem in the past. Now, that pre-supposes that we have identified a problem in the past, but again, one of the challenges that we have with any kind of requirements is being able to make sure that what we tell them to do is, in fact, making a difference in that country. One of the areas of research that is critical to understand in this is, for instance, the survival and growth of E. coli O157, the same in the soils in Salinas Valley as it is in Montello, Wisconsin as it is in Oaxaca, Mexico. And without that understanding, what we have as standards in this country may not at all apply in that country. We have to make sure that we're much more focused.

Dr. von ESCHENBACH. I think the point that Dr. Brackett is making and why I wanted him to make it is to make it clear that it isn't as if the borders are totally letting just about anything comes in. We do have standards, we do have prior notice, we do have the ability to interdict and stop something from coming into the United States when we have concerns.

The issue, I believe, this again goes back to the point that the chairman made, is that this is a problem that I believe we will solve best by our ability to work collaboratively and cooperatively from the level of the farm all the way through to the point that the product gets on someone's table. In a variety of places along the

way, we have opportunities to continue to enhance that process and that system, clearly building quality in at the very beginning, is the way to ensure everything downstream being approved and the guidances that we're creating and the relationships that we're creating, both within this country with producers as well as what we're creating outside of this country, I think, will lead us to that kind of an outcome, as the science and as we're evolving and developing the knowledge that we need, not to just do the right thing but due to the right plans. So I don't see it at this point as being our failure is simply we don't have the power to do something like that. I think the focus is much more on creating the systems and the opportunities to do more, not just simply creating a regulation. I don't see that as the solution to the problem by itself.

Dr. BRACKETT. A couple things that I neglected to say are when we look at products at the border, it's not the produce standards that we're looking at. In many cases, we apply appearance standards where if the product looks like it's been mishandled, we can lock it at that point without even having to do microbiological testing. But microbiological testing is going to be important and in fact, we have changed the way that we've done testing, which actually led to some of the recalls that you mentioned in cantaloupe—not because anyone had gotten ill but because our ability to detect it at a much, much lower level was much better and it had gotten to that point and in fact, some of the new techniques that we use—we're actually bringing investigators in from the industry from Mexico into the United States to teach them actually how we're doing it so they can get it before it even is sent out.

Senator KOHL. I'd like to ask you, gentlemen, how important is it to get back to the former level of inspectors and to increase the number of inspections? Dr. Brackett, would you like to respond to that?

Dr. BRACKETT. Sure. I think what—one of the difficulties in answering that directly because the food system is changing and the way we do business and the technology is changing. Rather than just getting back to a certain number, what we really have to do is back to the point where each individual investigator is actually having a bigger impact than they might have had in the past. So we need to be flexible enough and nimble enough in this agency to be able to respond to changing technology and societal changes in products they eat so that we can apply those inspections at the right point and it makes a difference.

Dr. von ESCHENBACH. One of the other strategies, Mr. Chairman, that we want to pursue is to amplify the impact of respecting field force, for example, much more collaboration and interaction with the States and enhancing the number of inspections that are done by State officials so that we're creating, if you will and multiply that, that will enhance our ability to continually expand this network of protection and interdiction. So we've talked about not just the number of investigators but we've talked about the kind of investigators, the different skill sets that now we need to develop within that field force, the creation of teams of inspectors and these rapid response teams, for example, is one dimension of that, to multiply their impact by giving them more modern tools of science and technology with which to work and by having them work col-

laboratively and cooperatively with others who are engaged in the same effort, including industry. All which results in a rapidly enhanced inspection process within this country, not just simply a matter of counting the number of inspectors or the number of inspections and then also having that entire platform be based on a risk management strategy, whether it is a HACCP model or a modifications of a HACCP model but for us to begin to understand where to focus those inspections, both by product because certain products carry with them inherent risks that don't exist in another product and today, of course, we recognize the inherent risks of fresh-cut produce and fresh-cut vegetables going from soil to table.

And also as we talked about on multiple times throughout this hearing, not just in terms of products but source. There will be differences and risk depending upon the source of that product and not just the source in terms of the soil or not or what process it's going through but even in terms of whether it's coming from one country or another country, etcetera.

So I hope that what the audience and what the subcommittee will appreciate is that the FDA, in addition to being collaborative and cooperative, is really taking a strategic approach to the issue of protecting our food, both its safety and protecting it from intentional contamination and doing that in the context of a real overarching strategy that is multi-factorial.

Senator KOHL. I'm going to ask the question to you, Dr. Brackett, you work with the amount of money that you get every day and you make it go as far as you can. How constrained are you by your budget from doing the things that you really, really believe need to be done?

Dr. BRACKETT. Well, I think anytime you ask someone, especially a former researcher about what could be done, the sky is the limit. But I think we can—we address the things that need to be done today. Where I think we are more constrained is, as has been mentioned before, in the generation of new knowledge, in some cases, where we either don't have the capacity, internally, to do that and it's appropriate to have that funding go either through us or as it has done in the past, or some other direction to make sure that those actions, those projects, those research proposals, would be done to the outside, to make sure. So even if we had a whole boatload of money dumped on us right now, that wouldn't necessarily get us to where we want to be unless that was applied and managed the right way to people that could actually give us the answers that we want to get.

Senator KOHL. Any other questions from the panel, from the audience? Some ideas, some thoughts, anything on your mind, folks?

Ms. DEWAAL. Can I just ask one last question on the issue of raw manure and the fact that in the organic industry, USDA has very specific requirements for the application of raw manure for products labeled organic? Why aren't those applied to our agriculture and isn't farm worker sanitation such a basic issue of not only human rights but also food safety that those—don't we know enough already that farm workers should be washing their hands before they touch the food? Aren't there things we know already that could really make a difference in protecting fruits and vegetables from making us sick?

Dr. BRACKETT. Yeah, there are a lot of things and we've had these cultural practices and their good manufacturing practices in the plants ever since we've had those documents out. We could apply a mandatory, for instance, hand washing, much as you would in a restaurant. In many cases, actually they are under those jurisdictions in local health departments where they have to do that on the farm anyway, through local health. So that's actually being done. A bigger challenge is how do you get these people to actually do it without having someone stand there and watch? And that again, is a communications problem that we have to—and a cultural problem in many cases, that we have to address.

With respect to the organic, yes, there are specifications for raw manure on organic and that, I think, was done specifically because people had the impression that if it was organic, that it would be using raw manure and so really, it was a way to assure the consumers that they did have standards for that, where the conventionally grown products have not traditionally used raw manure and in those cases where you have chemical applications or if you have compost and manure, the assurance was that the organic product was as safe as a conventionally grown product.

Senator KOHL. Are you comfortable with that answer?

Ms. DEWAAL. No. Senator, with all due respect, I believe that they know that there are certain minimum standards for the use of manure, for farm worker hygiene, for water quality that they know enough about to implement standards.

Senator KOHL. What did you say with respect to organic?

Ms. DEWAAL. There are specific standards for organic. If you want to label a product organic, they can't apply raw manure within a certain amount of time of planting or harvesting these products. There are some requirements also for composting. These are already in place for the organic industry and are not applied to traditionally grown. I mean, I'm from a dairy State just like Wisconsin. I'm from Vermont. Farmers all over that State apply raw manure to the land. It's used all the time and it's an appropriate use of manure but it's got to be done within some restrictions based on what's going to be grown on that land. So I'm not comfortable yet that we're getting a straight answer. I'm sorry.

Dr. BRACKETT. Do you want me to respond to that? No, you're quite right. People should be washing their hands, people should not be using raw manure on produce, there's no question about that. In many cases, in local application, this is already applied. In our investigations, though, we haven't seen where raw—I'm sure it does happen, just like people disobey the speed limit—but we haven't seen an overall use in the raw manure across the industry. The application usually is with compost and in some cases, grazed with what they call green manure, which is not animal waste, which is really treated to kill the pathogens that are there. Now, in some cases, for instance, with the new marketing agreement in California, there are some standards there being proposed of some network for the people in that State to produce that would actually have testing of the compost and manure to make sure that it didn't have organisms.

Now, there is still some debate on whether the metrics that are being used are right ones but at least they're making a good at-

tempt to try to, in their own industry, adopt those. We have to make sure they are science based before we really apply those in a stronger way, though.

Mr. STENZEL. Sir, if I could jump into this?

Senator KOHL. Yeah, go ahead.

Mr. STENZEL. Discussing this a little bit, oddly enough, Dr. Brackett identifies one of the reasons that we are so interested in a uniform, national approach. The commercial production of spinach and lettuce and leafy greens, which is dominantly focused in that area of California, is now holding itself to the standards of not using raw manure and yet we hear in Vermont that perhaps some of the product that is being grown just for local markets may not have the same standards. So we do need to move toward a national, uniform approach.

That can be achieved in a number of ways but I think that's one of the things that the commercial vegetable industry is increasingly concerned about, that we want to make sure that the same standards are equitably applied to growers across the country.

Senator KOHL. All right. Well, I think this has been a great hearing, very illuminating and certainly have brought many of the most important questions to the table and gotten responses from you. I think we all understand and agree that we can and must do better. We will do better, working together, finding ways that we can collaborate and move the process forward to make our produce safer. Again, we need greater levels of confidence from the public. This is our goal. And I think there have been several ideas that I think have come forth today that I particularly feel might be productive and useful. So on behalf of all of us, I want to thank you, you guys for coming out today and giving us the benefit of your knowledge and your authority and your ideas and things that you would like to get done. I think you would agree, you learned a lot from this panel. These are experts who are also people who work on the ground and are ready and comfortable and knowledgeable about what's happening and as such, I think you've got to give information and thought to this hearing. So we thank you for being here and I thank you guys for coming and we thank you all for being here.

ADDITIONAL SUBMITTED STATEMENT

The Wisconsin Department of Agriculture, Trade and Consumer Protection has submitted a statement that will be placed into the hearing.

[The statement follows:]

PREPARED STATEMENT OF THE WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

Dear Honorable Subcommittee Members: As Secretary of the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP), I would like to enter these comments into the record of the March 12, 2007 hearing, held by the Senate Subcommittee on Agriculture Appropriations.

Recently there have been several high profile food illness outbreaks. Two of the most devastating outbreaks involved E. coli in bagged spinach and E. coli contamination of Taco Bell products. These incidents have put the spotlight on the Nation's food safety system. Much discussion has centered on how USDA and FDA can improve their inspection activities and put forth a more unified surveillance system.

Lost in the discussion however is the important role the States play in surveillance, inspection, regulation and enforcement, and outbreak response.

States are the backbone of our Nation's food safety system, providing a network of inspectors who are on the job in a variety of food-related venues. Over 80 percent of the food safety regulatory work done in this country is performed by employees of State or local government.

This regulatory work is comprised of activities that respond to incidents where food is contaminated as well as activities that seek to prevent significant food safety problems (e.g., routine facility inspections). Whether food becomes contaminated by accident, intent, or act of nature, States are in the frontlines protecting the public.

The Association of Food and Drug Officials (AFDO) conducted a survey of State activities in 2001 that showed State and local governments performed:

- More than 2.5 million inspections of food establishments
- More than 3,000 food borne illness investigations
- Investigation of over 46,000 consumer complaints
- Response to over 2,800 emergencies or disasters involving food products
- More than 128,000 emergencies or disasters involving food products embargos, seizures and stop sales; injunctions; criminal prosecutions; warning letters; informal hearings; and food recalls; and collection and analyses of over 328,000 food samples, including more than 252,000 microbiological samples.

The Department of Agriculture, Trade and Consumer Protection (DATCP) serves in the frontlines ensuring food safety in Wisconsin. Our Division of Food Safety is responsible for the safety and wholesomeness of the State's food supply, from the point of production through processing, packaging, distribution, and retail sale. The division also protects consumers from fraud and the misbranding of food products.

The division licenses and inspects more than 14,000 dairy farms, 370 dairy plants, 192 certified laboratories, 3,400 bulk milk tankers and more than 6,800 other food processing businesses, meat slaughter and processing plants, food warehouses, grocery stores and other food businesses. Food and meat inspectors regularly inspect processing facilities and sample food and meat products.

Also, State food laboratories play a crucial role in surveillance activities, and they play the primary role in responding to outbreaks by bringing expertise to bear in an emergency. Take the E. coli spinach outbreak in September, 2006: Our DATCP food laboratory was the second laboratory in the Nation to isolate and identify the disease causing E. coli in spinach. Our effort was critical to the national response to this illness.

A study by the Scripps-Howard News Service indicates that Wisconsin has the Nation's best record in diagnosing the causes of food illness (The Detroit News, November 24, 2006). This excellent record is the result of a strong public health and food safety system in Wisconsin. The factors that contribute to this strong system are evident in a review of the chronology of the events in the State response to the E. coli spinach outbreak:

September 5, 2006—Wisconsin's Division of Public Health (DPH) is notified of several E. coli cases in the State.

September 7, 2006—Wisconsin notifies the U.S. Centers for Disease Control (CDC).

September 8, 2006—Wisconsin's State Laboratory of Hygiene posts the "DNA fingerprint" of the causative organism to a national data base. State public health professionals believe the evidence points to bagged spinach as the source of illness.

September 14, 2006—Based upon data provided by Wisconsin and other States the U.S. FDA and the USDA issue a national alert, warning people not to eat bagged spinach.

September 25, 2006—Wisconsin's State Department of Agriculture Laboratory, having worked through the weekend, detects and confirms the presence of E. coli O157 in spinach samples collected from patients by local health sanitarians.

September 26, 2006—The State Agriculture Laboratory provides the E. coli O157 cultures isolated from food to the State Laboratory of Hygiene for further comparison testing.

September 27, 2006—The State Laboratory of Hygiene confirms the strain isolated from food has an identical "DNA fingerprint" to the strain isolated from clinical samples.

States are clearly indispensable partners to USDA and FDA—especially since FDA food safety inspections dropped 47 percent between 2003 and 2006, according to a database analysis of Federal records by the Associated Press. The analysis also shows there are 12 percent fewer FDA employees in field offices who concentrate on food issues.

In fact, response efforts begin and may end at the State level. States have inspection and surveillance systems in place; the State systems employ highly skilled pro-

professionals such as epidemiologists, food inspectors, public health sanitarians, and laboratory chemists and microbiologists who work within the system on a daily basis.

As seen in the bagged spinach E. coli outbreak, the States are often the first responders in a food emergency. The Federal Government acted as a facilitator for the national response, and offered technical support to the States when needed. The better the response at the State level, the quicker the response will be at the national level.

That's why strengthening our Nation's food safety system, means strengthening the State-Federal partnership by:

- Providing more financial support to on-going cooperative agreements with the States for food surveillance and inspection activities.
- Providing additional financial support to the USDA–AMS Microbiological Program (MDP), and assuring that this important program that strengthens Agriculture Laboratories on the frontline of outbreak response continues to be funded in future years.

Eight select State Agriculture Laboratories are the backbone of the MDP. Using sophisticated techniques and technology, the primary role of MDP is to provide surveillance data by testing produce for the presence of disease causing organisms, such as E. coli, Salmonella, and Listeria.

Techniques and technologies developed or fine tuned by the state labs within MDP were utilized in Wisconsin's response to the bagged spinach outbreak. However, MDP funding for fiscal year 2007 and beyond is in serious jeopardy, potentially costing DATCP \$170,000.

- Similarly, in fiscal year 2006, USDA's Food Safety and Inspection Service (FSIS) failed to provide full 50 percent funding for our State Meat and Poultry Inspection program for the first time in 38 years. The fiscal year 2006 short fall was approximately \$170,000. If funding remains at this diminished level, we anticipate the State will be under funded by \$570,000 in fiscal year 2007.

Wisconsin's meat safety and inspection program—and the consumers and 360 small processors who depend on it—need USDS–FSIS to provide at least 50 percent of the program's funding needs. State meat inspection programs are a bargain for the Federal Government, which pays only half of the costs. If a State drops its meat inspection program, the Federal Government by law would need to take it over—and assume 100 percent of the costs.

- Providing additional financial support to the Food Emergency Response Network (FERN), and assuring that those funds are allocated to support all the labs within the network.

As we review our Nation's food safety system, it is essential that we also look to the States for ideas that work. The Wisconsin system works because there is a high degree of collaboration throughout the system; there is a great deal of expertise and dedication throughout the system; there is an independent inspection and surveillance infrastructure in place that provides routine inspection and testing activities. What we're doing here in Wisconsin is a great example of what can be done across America to protect our food supply.

Thank you for coming to Wisconsin and for considering these comments. Please keep these thoughts in mind as you work to strengthen our national food safety system.

CONCLUSION OF HEARING

Senator KOHL. This hearing is recessed.

[Whereupon, at 11:10 a.m., Monday, March 12, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]