

**Prepared Statement**

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**Before the**  
**U.S. Food and Drug Administration**

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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 majority of produce grown and imported into 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 understand all viewpoints and advocate for the best overall industry policies and practices to serve the consumer.

Let me begin this morning by thanking the Food and Drug Administration for holding this hearing, and your ongoing commitment to enhancing produce safety. We in the industry look to FDA as our most important and credible partner in assuring the American public that the produce industry and government alike are taking all needed measures to assure a safe supply of fresh fruits and vegetables. After all, FDA's mandate to *protect* public health requires an equal commitment to *promote* public health through increased consumption of fruits and vegetables to meet the U.S Dietary Guidelines. Public fear of consuming fresh, healthy and safe produce – even with the inevitability of some small level of risk – cannot be an acceptable outcome to the public health mandate of the Department of Health and Human Services.

Let me quote from the federal register notice announcing today's hearing. "FDA is responsible for ensuring the safety of all domestic and imported fresh and fresh-cut fruits and vegetables consumed in the United States." We believe that responsibility is at the very core of our discussion today. FDA has the legal responsibility to assure American consumers that their produce meets all acceptable safety requirements. Our industry must and will do all we can to grow, pack and process the safest possible products. But no matter what steps we take as an industry, the law requires, and the public demands, that FDA as an independent, public health agency be the final arbiter of what is safe enough.

It is in that spirit that I will address the rest of my remarks.

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The spinach outbreak last fall was a tragic occurrence. 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 excellent 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 occurred 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. Bagged salads and fresh-cut produce are not new, but were developed over the past two decades to enhance not only convenience but also safety standards from what was significant variability in back-room or store-level food preparation.

We developed the first industry Good Agricultural Practices (GAPs) in the mid 1990s to minimize on-farm microbiological food safety risks for fruit and vegetables, and worked closely with FDA as the agency published its overarching GAPs document in 1998. Put simply, food safety has been at the forefront of our industry's commitment to serve the American public for many years.

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 industrywide shutdown was an unprecedented action, and one from which I hope we all have learned many lessons.

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 nation's most productive growing region that was unnecessarily impugned last fall. But, when faced with an immediate public health question, we readily accepted FDA's public health advice to err on the side of caution, at a cost of millions of dollars to growers and companies who were never related to the outbreak but destroyed truckloads of healthy foods and plowed under acres of safe production. Our commitment to public confidence in all of our foods demanded nothing less, but it is also clear that neither government nor consumers are well-served by generating such broad fear about wide swaths of a safe food supply. We clearly must study the science of risk communications, and do a better job in communicating with the public on these complex matters.

In the future, it is critically important to isolate a specific, real public health threat of contaminated food in the marketplace from other safe foods. Consumers know that when there is a peanut butter outbreak associated with one brand, they can have confidence in choosing another brand to feed their children. FDA must be committed to this same standard for fresh produce, aggressively addressing specific threats if they occur, without implicating other sources of safe products.

But when a tragedy such as this occurs, we also recognize that it is critical that our industry learn all lessons possible and incorporate that knowledge into continuous improvement in our overall food safety systems. We have and will continue to do just that.

As soon as we learned of the outbreak, our industry immediately began a comprehensive evaluation 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 implemented and verified across this sector of the industry. The California Department of Food and Agriculture has recently certified 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 testing 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. I would like to submit the attached copy of these Commodity Specific Food Safety Guidelines for the hearing record today.

Under the Leafy Greens Agreement, growers, shippers and processors will be audited by the California Department of Food and Agriculture to ensure that they are complying with these standards. 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.

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 tomato industry is at the forefront of developing best agricultural practices for their sector of the industry, and exploring various means to assure compliance across multiple growing regions. Similar efforts are underway in the melon sector and many other commodity groups.

And, of course, many regional groups are implementing similar efforts. Earlier this year, 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. Another good example is the Georgia Fruit and Vegetable Growers Association, which has its own GAPs training program to help 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 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 in setting that regulatory framework.

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 consumer health at risk by exacerbating fears of those very same fresh fruits and vegetables that are essential to 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.

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.

**1. Geographically Consistent Produce Food Safety Standards**

First, we believe produce safety standards must be consistent for an individual produce commodity grown or packaged 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 produced. 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, or Mexico.

We strongly support groups within our industry in different states and regions that are working to enhance food safety. Their work demonstrates the industry's commitment to do all we can to enhance safe growing and handling practices. But to build consumer confidence in the grocery store or restaurant, strong scientific standards developed for one region can only be successful long term if applied consistently across the industry.

**2. 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 FDA has the legal mandate to 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 forged in an open and transparent process.

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. I assure you that the produce industry will be strong scientific advocates in the regulatory process, but industry alone cannot be the final arbiter of safety standards if we want to maximize consumer trust in our products.

It is also FDA's ultimate responsibility to ensure that industry is complying with the standards it sets. 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. I am confident that with adequate funding and direction from Congress, FDA, USDA and state and local partners working together can provide a high level of consumer assurance that compliance is indeed taking place.

### **3. 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 vines or trees. And, the large majority of produce commodities have never been linked to a foodborne disease. In the federal register notice announcing this hearing, FDA confirms that five produce commodities have been associated with 80% of all foodborne disease outbreaks in the past 10 years, and that is where we must direct our resources.

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.

Let me now turn from general principles to three specific regulatory actions under FDA's purview.

First, 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.

Neither the public nor government should underestimate the power of these guidelines to truly minimize risk when well understood and implemented by growers, packers and processors. Strong attention is needed today on greater education and implementation of these GAPs across the entire produce supply. This need calls out for a well-funded intergovernmental effort between FDA, USDA and the states to assure that producers across the country and internationally understand GAPs and are implementing proper controls.

Second, we also support FDA's scientific approach to develop commodity-specific GAPs where there is a demonstrated need. The principle of developing commodity-specific food safety standards is the best way to tackle specific risks associated within such a diverse produce supply. 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.

To date, FDA has published commodity-specific GAPs only for fresh sprouts. Alternatively, the agency has asked the industry to develop commodity specific GAPs for leafy greens, tomatoes, melons, green onions, and herbs. The industry has taken this challenge seriously, and worked diligently to bring scientific leaders from academia, government and industry together in formulating these best practice documents. Today, the leafy greens GAPs are in their 2nd edition; GAPs for tomatoes and melons are in the 1st edition, and work on green onions and herbs is nearing completion.

While we will continue to work on implementing best practices as an industry, we believe it is important for FDA to pursue the regulatory model used with fresh sprouts and publish its own commodity specific GAPs where warranted, rather than simply provide technical input to industry-prepared documents alone. FDA must *endorse, embrace and defend* these standards as sufficient to allow public confidence in the safety of the food supply, based on the best science available.

Again, do not underestimate the power of FDA published commodity specific GAPs such as the fresh sprouts document. In this text, FDA specifically states the following:

*The following recommendations identify the preventive controls that the FDA believes should be taken immediately to reduce the risk of raw sprouts serving as a vehicle for foodborne illness and ensure sprouts are not adulterated under the food safety provisions of the Food, Drug, and Cosmetic Act (the act). Failure to adopt effective preventive controls can be considered insanitary conditions which may render food injurious to*

*health. Food produced under such conditions is adulterated under the act (21 U.S.C. 342(a)(4)). FDA will consider enforcement actions against any party who does not have effective preventive controls in place, in particular, microbial testing."*

Producers of fresh sprouts do not consider this voluntary guidance or an option that they may choose or not choose to follow.

We believe this same approach should be taken with specific commodity groups in which FDA determines there is a need for specific preventive controls for food safety. It is time for FDA to publish its own commodity specific guidance documents where needed, rather than write letters to industry. I would add, as well, that FDA's administrative process of public notice and comment on draft and eventual final guidance documents offers the most equitable way to receive broad input on such standards, from industry members with differing views as well as all other stakeholders.

Finally, we strongly support FDA's approach to address specific standards for fresh-cut processing, as contained in the agency's *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables* published just last month. 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.

Again, consider the legal power of this guidance document. FDA has provided its interpretation of what is required to comply with mandatory GMPs to which all fresh-cut processors must adhere. This carries serious liability both in terms of government inspection and product liability. If a processor does not follow the specific requirements outlined in this document, he must demonstrate and justify a different approach that provides equal or greater assurance of safety. That would be no easy task, and holds the processor to deliver the same or greater level of safety as that mandated in the guidance document.

Let me conclude with a few comments about funding and spending 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.

In the past several months, I have testified at both House and Senate Appropriations hearings in support of increased funding for FDA for both senior scientific staff and research in the area of produce safety. I would ask that today's hearing record also cite the full hearing records of the House Agricultural Appropriations Committee on February 8, 2007 and the Senate Agricultural Appropriations Committee on March 12, 2007.

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 Administration's support in boosting produce safety research and FDA's leadership in this area as a vital part of reducing risk in the future. Unfortunately, this is one of the four parts of the FDA's Produce Safety Action Plan which has received the least attention.

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. At the same time, we pledge to support a strong federal 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.