

Prepared Statement

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Committee on Energy and Commerce**

Subcommittee on Health

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Introduction

Good morning Chairman Pallone, Ranking Member Deal, and Members of the Committee. My name is Tom Stenzel and I am President and CEO of the United Fresh Produce Association. Our organization represents more than 1,500 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. In the area of science and food safety, our association works to develop industrywide consensus on the best overall 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.

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. Because our products are enjoyed by consumers in their fresh and natural state without cooking, we have to be right every single time – not one in a million, or even one in a billion. But as

long as there is the potential of even one individual getting sick, we will do all we can to prevent that from happening.

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 that their results are overwhelmingly successful, with the actual incidence of illness extremely low. Just look at the numbers.

- Over a billion servings of fresh produce are eaten every day.
- More than 5 million bags of fresh salads are sold every day.
- And, out of the hundreds of fruits and vegetables offered in a typical supermarket, only a very few have been implicated in illness outbreaks, and then rarely as compared with their volume of consumption.

But, we also know that consumers today are walking into grocery stores and restaurants with new concerns, new doubts, and sometimes fears about produce. They don't understand those statistics; they don't know what farmers and processors are doing to protect the safety of their produce; and equally important, they do not have complete confidence that government is doing all it should to protect their health.

Most importantly, we cannot lose sight that health experts are unanimous that Americans must increase our consumption of fruits and vegetables for better health. That's the juxtaposition we face today on food safety – it is simply unacceptable for Americans to fear consuming fresh fruits and vegetables that are essential to their good health.

How We Got Here

Let me first state that our industry has worked to address food safety for many, many years. In fact, our association published the first *Food Safety Guidelines for the Fresh-Cut Produce Industry* 17 years ago, 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 fruits and vegetables, and worked closely with the U.S. Food and Drug Administration to publish federal guidelines soon thereafter. Food safety has been at the forefront of our mission to serve the American public for many years.

When the spinach outbreak occurred in 2006, 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 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 being grown, with salads being prepared in dozens of processing plants around the country. Yet today, two and half-years later with no further outbreaks, spinach consumption is still down with many consumers shying away from one of the healthiest vegetables they could be eating.

Our mission following this outbreak was twofold –

- 1) First, we undertook a comprehensive reevaluation of leafy greens production, handling and processing to enhance every possible step we could take in assuring safety. Even though the problem was isolated to one small farm, the entire leafy greens industry has adopted the most rigorous scientific principles to minimize risk, and developed compliance

protocols and audits that are now conducted by the California Department of Food and Agriculture.

2) Second, our broad industry had to address the role of federal government oversight of food safety. In January of 2007, six months after the spinach outbreak, our Board of Directors adopted a series of policy principles calling for mandatory, science-based regulation by the federal government.

To protect public health and ensure consumer confidence, produce safety standards:

- *Must allow for a commodity-specific approach, based on the best available science.*
- *Must be consistent and applicable to the identified commodity or commodity sector, no matter where grown or packaged in the United States, or imported into the country.*
- *Must be federally mandated with sufficient federal oversight of compliance in order to be most credible to consumers.*

Put simply, we concluded that we had to work to rebuild public confidence in our system of food safety government oversight, such that when another outbreak occurs, the public can have confidence that it is the result of an isolated breakdown in one situation, not an endemic problem causing them to question the safety of all the produce they eat. With an analogy of the airline industry, we must have rigorous government oversight and strong industry compliance with the clear, scientifically vetted safety practices. But, when an isolated tragedy occurs, we must get back on the an airplane knowing that next flight is inordinately safe – just as spinach from thousands of farms was safe on the day of the tragedy in our industry, and the next day, and the next day.

Let me explain each of these principles.

- Must allow for a commodity-specific approach, based on the best available science. 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 fact, a recent FDA federal register notice in 2007 confirmed 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.

In addition, 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. Finally, as part of this commodity specific approach, FDA must develop a rule-making procedure that establish risk and science-based regulations for the production, handling and distribution of those types of fruits and vegetables for which the Secretary determines such standards are necessary to minimize the risk of microbial illness.

- Must be consistent and applicable to the identified commodity or commodity sector, no matter where grown or packaged in the United States, or imported into the country. 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.
- Must be federally mandated with sufficient federal oversight of compliance in order to be most credible to consumers. 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.

Together, these three policy principles provide a direction for food safety regulatory policy that we believe would most help our industry enhance produce safety, concurrent with establishing the highest level of public trust in our industry and in our fresh produce offerings. It is our goal to support a U.S. regulatory framework for the fresh produce industry that incorporates these principles.

With this hearing and others conducted over the last several years, it is clear that Congress and the Administration will be looking closely to overhaul of our food safety laws. We support that effort and want to work closely with this committee and others in the design of strong and credible laws that would help rebuild public confidence in food safety.

In this context, our Board of Directors has expanded on the policy principles above to adopt a *Food Safety Policy White Paper* to provide specific policy recommendations for food safety legislation. I have attached this policy paper to my written statement (see Appendix 1) as it reinforces my comments here.

Outbreak Investigations

While most of my testimony today is rightly focused on what we can do to prevent illness associated with our products, I must also include comments about the current management of outbreak investigations by federal, state and local government.

In testimony I presented last summer to the House Energy and Commerce Oversight and Investigation subcommittee (July 31, 2008) on the *Salmonella* Saintpaul outbreak associated with jalapeño peppers, I called on Congress to develop policy that will address the then current failures and lack of leadership in managing outbreak investigations. Since then, the peanut paste fiasco has only provided more fuel to my comments, unfortunately this time affecting thousands more consumers and tearing down another whole industry.

In that testimony, I highlight five fundamental flaws that I believe must also be addressed in reform of food safety laws.

1. There's No One in Charge

The diffuse responsibility for public health in outbreak investigations is something that Congress must look at intensely. It was clear in last summer's *Salmonella* outbreaks that no one was in charge, leaving local, state, and federal officials vying for leadership; various agencies pursuing different priorities; and well-meaning individuals reacting independently to events rather than as part of a coordinated investigation moving forward in a logical and expeditious direction.

Recommendation: We suggest Congress consider how to put in place a command-and-control structure with a clear chain of command. Take guesswork out of who's in charge, and drive real authority and accountability into the process. Whether this can be achieved in a multi-agency cooperative agreement, or requires new government structures, is something that Congress must ask. We suggest looking at other agencies for insights, such as National Transportation and Safety Board investigations. From afar, such a system seems designed for a 24-7 immediate response, with clear authority and command leadership, supported by a team of well-prepared experts.

2. We Need Better Crisis Preparedness and Transparency

Crisis planning should be done in advance of a crisis, not learned on the job.

Recommendation: Whatever command-and-control structure is put in place for outbreak investigations, plan it, implement it, and test it before a crisis. Take the recommendations from all stakeholders and build a system – in advance – that government and industry alike will follow in the future.

3. The Current System Doesn't Use the Expertise Available

The government's failure to use industry's expertise in outbreak investigations is one of our most important lessons. Let me first say that this needs to be transparent, supported by consumer groups, and squeaky clean. But there is an abundance of knowledge in the industry about specific commodities, growing regions and handling practices, and specific distribution systems that can be used to protect public health in an outbreak.

Recommendation: Congress and the agencies should find a proper and transparent way to bring industry and other outside expertise into its outbreak investigations. We specifically recommend that a group of experts in major produce commodities be selected and vetted by government well ahead of time, perhaps through a process similar to gaining a security clearance. Then, at a moment's notice, these pre-cleared experts could be assembled with government investigators to provide counsel in their areas of expertise.

4. Government Is Ill-Prepared To Make Complex Risk-Benefit Decisions

Every health or safety regulatory decision requires an assessment of risks and benefits. Agencies make risk management decisions every day that attempt to balance risks and benefits broadly to society, whether in automobile design, toy manufacturing, airline safety, or even FDA approval of food additives. Yet in the case of foodborne disease, FDA and CDC seem ill-prepared to grapple with any risk management approach other than "all or nothing."

Recommendation: Congress needs to empower FDA and CDC to look at risk management decision-making in advance of an outbreak, and develop transparent guidelines for when to take specific action. The broad brush approach taken with tomatoes, then jalapeños, is not an appropriate risk management strategy to best protect public health, either in the short- or long-term.

5. Today's Risk Communication Is Unacceptable

These are complex issues indeed, and tough to explain. The principle of timely and candid communication with the press and public cannot be compromised. Yet, any risk communications expert would also advise precision and care in communicating exactly what you want to say, and not speculating beyond what is known. Consider again the example of a National Transportation and Safety Board press conference investigating an airline accident. There's no speculation about whether a crash might have been caused by pilot error, or bad hydraulics, or a flaw in wing design. Those are precisely the things under investigation and are NOT discussed until there's a conclusion by the experts.

Recommendation: Risk communication must be a central part of any crisis management structure, and well planned in advance. As the agencies develop overall management plans, one single office must have authority and accountability for public communications, with one single officer designated as the media spokesperson for the investigation.

Conclusion

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. The very Department of Health and Human Services that regulates our safety has the dual responsibility to promote the importance of eating more fruits and vegetables to prevent chronic diseases such as cancer, heart disease, stroke, and more. And now, our nation is faced with an obesity crisis that threatens the long-term health of our children and out-of-control escalation in health care costs unless we radically change eating habits to consume more fruits and vegetables.

With that public health imperative, fears of food safety have no place in the fresh produce department. We, as an industry, must do all we can to prevent illnesses from ever occurring, and we will.

But because science tells us there is no such thing as zero risk, government must also be able to assure the public that even if something does go horribly wrong in an isolated case, consumers can continue to have confidence in fresh produce. We must all be able to trust the overall system of government oversight and industry responsibility, working together to produce the safest possible supply of fresh, healthy and nutritious fruits and vegetables.



Appendix 1

United Fresh Produce Association Food Safety Policy White Paper

Approved by the Board of Directors
January 25, 2009

Introduction

Food safety is the produce industry's top priority. The men and women who grow, pack, and market fresh produce are committed to providing consumers with safe and wholesome foods. We are constantly working to enhance and improve our performance in growing crops in the field, carefully harvesting and handling them for distribution, packaging and processing commodities into convenient, ready-to-eat products, and maintaining the safest possible delivery chain all the way to the consumer's table.

In addition to our own efforts, the produce industry also supports a strong role by the federal government in ensuring that produce sold in the United States is grown, packed and distributed in accordance with appropriate science-based safety standards. It is critical that American consumers have confidence that the federal government is exercising diligent and appropriate oversight of food safety standards and compliance for all foods, including fresh produce. For fresh fruits and vegetables, any breakdown in consumer trust of either government or industry in our mutual food safety responsibilities will lead to a loss of confidence in the very foods that we should all be eating more of to improve public health.

KEY FOOD SAFETY POLICY ISSUES

PRODUCE SPECIFIC PROVISIONS

OVERVIEW

First and foremost, the fresh produce industry has been at the forefront of developing comprehensive food safety programs for many years. In fact the first *Food Safety Guidelines for the Fresh-Cut Produce Industry* were published 16 years ago in 1992, and was just updated by FDA in February 2008. The industry also developed 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. More recently, we have worked with scientists from government, academia and industry to develop extensive commodity-specific food safety guidelines for tomatoes, melons, sprouts, and leafy greens, and have implemented strong compliance systems based on state inspections and audits by government personnel. Put simply, food safety has been at the forefront of our industry's commitment to serve the American public for many years.

In addition, it is clear under current law and regulation, that 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 the discussion

today with Congress. 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. In that vein, we believe FDA already has strong regulatory authority by statute to achieve these goals. In particular, FDA has the authority to promulgate rules and regulations, issue guidance that compels industry action, enter into agreements with states to allow for field investigations, and generally set standards to protect the public health.

Lastly, we believe one of the most important issues for produce 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.

POLICY STATEMENT

Any new food safety legislation affecting the fresh produce industry should be based on the best available science, be risk based, and consider that fresh produce is a raw agricultural commodity. In that regard, any new legislation should aim at reducing the incidence of foodborne illness by minimizing the risk of adulteration. It is imperative that it is understood that most fresh produce is not sold as ready-to-eat commodities and should not be held to RTE standards. Any food safety effort should, however, encompass the entire supply chain regardless of size, location or operation type.

SPECIFIC POLICY RECOMMENDATIONS

- Must allow for a commodity-specific approach, based on the best available science. 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 fact, a recent FDA federal register notice in 2007 confirmed 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.

In addition, 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. Finally, as part of this commodity specific approach, FDA must develop a rule-making procedure that establish risk and science-based regulations for the production, handling and distribution of those types of fruits and vegetables for which the Secretary determines such standards are necessary to minimize the risk of microbial illness.

- Must be consistent and applicable to the identified commodity or commodity sector, no matter where grown or packaged in the United States, or imported into the country. 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.

- Must be federally mandated with sufficient federal oversight of compliance in order to be most credible to consumers. 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.

We also believe 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. In particular, USDA has been a strong ally and has offered a number of means to assist the produce industry in safely growing, handling and processing fresh produce. For example 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.

However, HACCP is not the equivalent of a food safety program, as HACCP is merely a component of an overall food safety program and cannot be established without prerequisite programs such as GAPs, cGMPs, and sanitation standard operating procedures (SSOPs) being in place. Conversely, it is unclear if HACCP can or should be used as a component of a food safety program for production agriculture as these types of programs are well defined and may function well within the control environment of a food processing plant. This does not mean that process hazards should be ignored but simply that the risks and hazards associated with a process need to be dealt with via an alternative mechanism. For production agriculture, in particular produce, risk reduction and mitigations programs such as GAPs, are considered an essential element in controlling and minimizing food safety risk.

THIRD-PARTY CERTIFICATION

OVERVIEW

Currently, most third-party certification programs do not ensure compliance with FDA requirements specifically, but rather with their own sets of audit standards. The basic reason that current programs do not ensure compliance with FDA requirements is that FDA has not clearly established the standards that it believes must be audited against. This

leaves open to interpretation to a wide range of competing interests – market players, auditing companies, etc. – to develop their own standards. Also, many produce audits currently overemphasize documentation and testing, which seems designed more to satisfy private commercial liability concerns than compliance with FDA food safety standards. Finally, most other third-party certification programs measure a wider range of practices that might be of interest to the person requiring the audit. For example, many audits measure procedures and practices outside of FDA food safety requirements, thereby diluting the assessment of a facility's compliance with those requirements.

POLICY STATEMENT

We believe there may be potential benefits to FDA, the industry and consumers by use of certain 3rd party certifiers under specific conditions. However the process must overcome many obstacles we see in implementation of such programs today, as well ensure a consistent, science-based, and credible certification system in the future that garners the widespread confidence of consumers, industry and government. Because of these concerns, we propose three specific policy recommendations for third-party certification programs currently being considered by Congress.

SPECIFIC POLICY RECOMMENDATIONS

- FDA must retain a definitive role in setting fair and appropriate audit fees initiated by third-party certification programs to demonstrate compliance with FDA standards. Currently, produce industry food safety certification programs range in cost (auditor/certification fees alone) from a few hundred dollars per audit (generally by the not-for-profit organizations) to tens of thousands of dollars (generally by the more complex certification bodies like SQF or ISO). Yet, we do not have evidence that the increased costs of some audits result in better evidence of compliance with standards or better evidence of safer food. The tremendous range in audit fees can have a significant impact on the ability of particularly small businesses to participate. If exorbitant audit fees were required, we fear that many producers would be financially challenged to comply with these requirements.
- A third-party certification program should be based on a harmonized set of FDA endorsed standards, and have industry-wide public recognition to preempt additional redundant audits. Today, the produce industry faces multiple, redundant audits, which in most cases are not interchangeably acceptable to different buyers. Most buyers will only accept the results and certification of certain certification bodies, thus leading to proliferation of different audits for different buyers. In some cases, the same auditor will visit a facility multiple times to perform different audits to verify compliance with different and potentially conflicting standards. In addition, inconsistencies in audit standards among the different certification bodies have created frustration and confusion, have unnecessarily increased operational costs, and may create an obstacle to training in food safety practices. To date, every effort to create a harmonized set of produce food safety audit standards has only added another set of standards to the list. If third-party certification programs are to be successful, there must be a system in place that requires buying companies to recognize and approve the results of these audits without requiring their own duplicative audits to recognize the same results.
- USDA/state department of agriculture GAP audits should be designed to certify against FDA standards. Most current audit programs do not ensure compliance with FDA requirements specifically, but rather with their own sets of standards. If given authority, training and adequate oversight, we believe that USDA/state department

of agriculture GAP audits could be designed to certify against FDA standards, although most would be considered more educational and benchmarking tools for individual growers at present. Perhaps the one audit program that most closely ensures compliance with FDA standards today is the California Leafy Greens Marketing Agreement (LGMA).

TRACEABILITY AND OUTBREAK INVESTIGATIONS

OVERVIEW

The produce industry is committed to the capability of effectively and quickly tracking the source of our products from retail stores and restaurants back to their original farm source.

The Bioterrorism Act of 2002 requires mandatory record-keeping 'one-step-up' and 'one-step back' of all foods, with the ability to provide such records within 24 hours. The industry is committed to full compliance with these requirements, and urges FDA to rigorously enforce the requirements of this law. We know of no instances where FDA has taken any regulatory action to cite a produce company or its customer for failure to provide adequate records as required by the Act. Rather, we hear generalized concerns about adequacy of records, without specific examples with specific companies where compliance is inadequate. The produce industry stands ready to work with the Agency to ensure full and total compliance with these requirements.

In addition, outbreak investigations are multi-disciplinary processes, with tracking of product records only one element of successful investigations. FDA, CDC and the states must enhance their epidemiological work to identify which foods are associated with illness; must enhance their understanding of and/or access to expertise on produce industry distribution patterns; and must enhance the expertise of individual investigators. The produce industry has publicly committed to work cooperatively with FDA to help the agency better understand existing industry traceability and recordkeeping practices, and to better understand any areas where the agency believes we could improve those practices.

Concurrently, a number of produce companies throughout the entire distribution chain have begun to adopt a standardized system of case coding for all produce sold in the United States, including bar codes that contain source information and lot numbers, which will then be scanned and stored by subsequent buyers through the distribution chain. This Produce Traceability Initiative is a multi-year effort to standardize the broad adoption of state-of-the-art processes across the industry. As more in the industry adopt this initiative, it will maximize the effectiveness of industry's current traceability procedures, improve our internal efficiencies, and assist the Agency greatly in its work.

POLICY STATEMENT

Strong FDA enforcement of existing record-keeping laws, together with work by industry to ensure full compliance today while continuing to enhance the efficiency of tracking systems, provides the public with assurance that produce items can be effectively tracked in an outbreak investigation. Therefore until the current federal law is proven to be deficient, we oppose any additional mandatory legislative or regulatory requirements for traceability as premature and unwarranted.

SPECIFIC POLICY RECOMMENDATIONS

- Congress should consider how to put in place a command-and-control structure for outbreak identification and management, with a clear chain of command. Take

guesswork out of who's in charge, and drive real authority and accountability into the process. Whether this can be achieved in a multi-agency cooperative agreement, or requires new government structures, is something that Congress must review. The diffuse responsibility for public health in outbreak investigations is something that Congress must look at intensely. Local and state governments are usually first to discover illnesses, and are free to draw their own conclusions and issue press releases at any time. The diffuse responsibility continues at the federal level, even within the Department of Health and Human Services. CDC has the "official" responsibility to determine what food vehicle is the cause of an illness. FDA must wait on the scientists at CDC to make that call, only after which FDA staff are responsible for the traceback investigation. Lack of a true chain of command brings lack of accountability, and a rush to protect one's own turf or reputation. Even in the investigation itself, field investigators are all over the map. Some are FDA field staff employees, some CDC, some state, some local. Suffice it to say, outbreak investigations today do not resemble a well-prepared, well-organized, or well-drilled team operating as a cohesive unit.

- A stronger crisis preparedness and transparency needs to be developed by FDA and CDC. One of the most important parts of an investigation is the original work by states and CDC with food recall surveys among ill people. However, as we saw in the *Salmonella* Saintpaul outbreak this summer, CDC's first case control study showed an association with tomatoes, but its second more detailed case control study showed a greater association with jalapeños. Today, these facts are all open to second-guessing, not only because we now know tomatoes were not the continuing cause of illness (or much more likely never the cause at all), but because no one outside of CDC knows how these studies were conducted with the state of New Mexico who did the initial work. Could there not be consistent food survey protocols set in advance, peer-reviewed by expert epidemiologists outside government, and kept at the ready for a case like this?

Whatever command-and-control structure is put in place for outbreak investigations, plan it, implement it, and test it before a crisis. Take the recommendations from all stakeholders and build a system – in advance – that government and industry alike will follow in the future. Many in the private sector hold workshops on crisis management and many in the produce industry do recall and traceback drills all the time. The industry stands ready to cooperate with government in planning and testing overall traceback investigations.

- Congress and the agencies should find a proper and transparent way to bring industry and other outside expertise into its outbreak investigations. The government's failure to use industry's expertise in outbreak investigations is one of our most important lessons today. First and foremost this needs to be transparent, supported by consumer groups, and completely open to all interested parties. There is an abundance of knowledge in the produce industry about specific commodities, growing regions and handling practices, and specific distribution systems that can be used to protect public health in an outbreak. FDA and CDC should also welcome outside expertise not just from industry, but also from academia, from USDA experts who certainly better understand produce distribution systems, and even from the states themselves

We recommend a broad group of stakeholders be convened to look at all potential options and provide recommendations to Congress and the agencies. We also specifically recommend that a group of experts in major produce commodities be selected and vetted by government well ahead of time, perhaps through a process

similar to gaining a security clearance. Then, at a moment's notice, these pre-cleared experts could be assembled with government investigators to provide counsel in their areas of expertise.

- Congress needs to empower FDA and CDC to look at risk management decision-making in advance of an outbreak, and develop transparent guidelines for when to take specific action. Every health or safety regulatory decision requires an assessment of risks and benefits. Agencies make risk management decisions every day that attempt to balance risks and benefits broadly to society, whether in automobile design, toy manufacturing, airline safety, or even FDA approval of food additives. Yet in the case of foodborne disease, FDA and CDC seem ill-prepared to grapple with any risk management approach other than "all or nothing." We simply must develop risk management systems that can distinguish those producers or distributors who can assure the safety of their produce in the marketplace from those who cannot. FDA must find appropriate ways to advise consumers that the legal responsibility for food safety assurance lies with individual companies who offer food for sale, not the federal government. How can a grower of summer tomatoes in Michigan maintain his livelihood selling to local retailers? How can a fast food chain that knows every detail of where and how its tomatoes are grown maintain the option to keep sliced tomatoes on its burgers? How can a produce company that invests hundreds of millions of dollars in food safety stay afloat when its business is shut down the same as others who never made those investments? The unintended message to industry is don't bother investing in food safety, if you're going to be tarred with the same brush and face the same costly consequences in every single outbreak.
- Risk communication must be a central part of an overall crisis management structure, and well planned in advance. As the agencies develop overall management plans, one single office must have authority and accountability for public communications, with one single officer designated as the media spokesperson for the investigation. The principle of timely and candid communication with the press and public cannot be compromised. Yet, any risk communications expert would also advise precision and care in communicating exactly what you want to say, and not speculating beyond what is known. This also comes back to our recommendation about a clear chain-of-command – someone has to be in charge of talking with the media. Good risk communication is not just an art; it is a science, and a science that needs to be studied in advance and rigorously followed in outbreak investigations.

IMPORT REQUIREMENTS

OVERVIEW

Food imports in general and fresh produce imports in particular have increased in recent years where there have been dramatic changes in the volume, variety, and complexity of FDA-regulated products arriving at U.S. ports. The United States trades with over 150 countries/ territories. In the last decade, the number of food imported items has tripled. According to the USDA Economic Research Service, approximately 15 percent of the overall U.S. food supply by volume is imported. However, in certain food categories, a much higher percentage is imported with imports of fresh produce varying seasonally.

FDA primarily relies on an electronic screening process to review imported produce -- typically only inspecting foreign produce firms for cause, such as a potential link to an outbreak of foodborne illness. The basic import process consists of two stages--prior notice

and food safety evaluation. In the first stage, FDA must receive prior notice before a food shipment arrives in the United States. Prior notice information is screened electronically by FDA's import database, the Operational and Administrative System for Import Support (OASIS), for potential risks associated with intentional contamination. Once the prior notice review has been completed, the food safety evaluation is conducted. For this evaluation, OASIS screens each entry line--or portion--of the shipment for risk factors associated with unintentional contamination to determine whether the shipment may proceed automatically or whether it requires further review.

According to FDA officials, import alerts are the agency's primary mechanism for keeping products with a history of violations out of the country, and they use them regularly. Through the use of import alerts, the agency may detain potentially adulterated products at the border without a physical exam. Additionally, import alerts place the burden on the importing firm to demonstrate that the product is safe.

POLICY STATEMENT

We believe produce safety standards must be consistent for an individual produce commodity grown anywhere in the United States, or imported into this country. In particular, imports must be treated equitably in all areas of food safety regulation, including similar and equal assessment of imports and domestic production in all areas such as Good Agriculture Practices and Good Manufacturing Practices. Consumers must have the confidence that safety standards are met no matter where the commodity is grown or processed.

SPECIFIC POLICY RECOMMENDATIONS

- Food importers should be required to ensure their foreign suppliers meet all U.S. food safety requirements. In particular, Congress should require that all food importers, subject to FDA guidance, document the food safety measures and controls being implemented by their foreign suppliers and should require food importers to make their foreign supplier food safety plan available to FDA. Food importers who demonstrate their products pose no meaningful risk should be eligible for expedited entry at the border so FDA can give greater scrutiny to high risk imports.
- Build the capacity of foreign governments and enlist the help of the private sector. In particular, Congress should direct FDA to develop a plan to help build the scientific and regulatory capacity of major exporters to the U.S. and should create a registry of private laboratories that meet FDA standards. In addition, FDA should provide for the possibility that official controls and certification are used instead of, or in combination with, third party systems. It would be more efficient for FDA to enforce an appropriate level of protection through administrative collaboration with governments rather than third parties in some cases. Finally, FDA should consider accredited third party certification programs for imports when foreign government food safety oversight capacity is limited. Under these types of programs, third party certification should be able to verify compliance with federal safety standards, foreign supplier safety plans, and identify those imports eligible for expedited entry.

MANDATORY RECALL AUTHORITY

OVERVIEW

Many in industry have long held that regulatory agencies do not need recall authority, since companies almost never refuse to conduct a recall when asked. Moreover, the regulatory

agencies have the “power of the press” to issue a public warning indicating the product is adulterated or otherwise harmful AND the company is not cooperating with the agency in getting the product off the market (which can be much more harmful to a business than a recall). The agencies can go to court to seize adulterated product, which takes time, but under the Bioterrorism Act, FDA can also “detain” product to allow time to process a seizure action, or can ask states to “embargo” the product. Moreover, because companies generally do not refuse to conduct a recall, mandatory recall authority is more of a perceived gap in the food safety system than a real one.

One of the biggest food industry concerns has been the criteria to be used by FDA to determine the need for a recall. The key issue is where to draw the line between protecting public health and preventing the unintended consequences of unjustified recalls (should FDA elect to take precautionary action “in the interest of public health”). Congress recently passed new legislation amending the Food Drug and Cosmetic Act, establishing a reportable food registry, which requires reporting of foods for which there is a reasonable probability that consumption will cause “serious adverse health consequences or death” (the same standard incorporated into the Bioterrorism Act and the basis for a class I recall) within 24 hours of determining that a food meets the criterion.

Policy Statement

Although food companies routinely recall contaminated products, we believe Congress should give the FDA the power to order a recall, subject to due process protections, when a product poses the risk of severe health consequences or death and the company has refused to conduct a recall. In addition, Congress should consider a mechanism to ensure that if FDA issues unsubstantiated recall notice, that impacted companies or producers have an appropriate mechanism for redress.

FUNDING

OVERVIEW

One of the key components to modernizing our food safety laws is the ability to fund these new requirements. The produce industry strongly opposes any food tax related to growers, food facilities or food importers. All Americans are the beneficiaries of enhanced food safety oversight. Food safety is a public health issue affecting our entire society and, accordingly, the cost of federal regulatory oversight should be borne by U.S. general revenues for both equity and overall trust and credibility.

Moreover, a governmental policy of recouping inspection costs based on some type of user fee system would tend to shift fruit and vegetable production in favor of larger, more complex farming operations and away from many smaller, traditional, and local family truck-farms, groves, and orchards. This shift could work against product diversity and support for local agriculture, and act as a barrier to entry for smaller operations that today already contribute substantially to the safe and wholesome supply of fruits and vegetables. Additionally, fees specifically targeting imported produce or facilities handling imported produce will likely be viewed as duties, import taxes or trade barriers and invite retaliatory measures by foreign governments and harm exports of fresh produce to these countries.

POLICY STATEMENT

We believe the costs of FDA inspections and research should be financed from general tax revenue, not from taxes imposed on food importers or facilities. While we support increased resources for FDA, we strongly oppose food taxes and fees that are not tailored to provide a government service to our industry and that will likely compound food costs at a

time of record food inflation. As a matter of public policy, it is much preferred to have direct governmental oversight of such critical matters as the safety of the nation's food supply paid by the general treasury—as opposed to the private commercial companies subject to inspection.

FOOD FACILITY REQUIREMENTS

OVERVIEW

FDA oversees the vast food industry that includes about 46,000 U.S. food processors and warehouses, and comprises a significant segment of the nation's economy. FDA regulated products account for about two-thirds of consumer spending on food, with an annual retail value of \$430 billion. Every year, U.S. food processors spend \$1.4 billion on research and development and introduce 15,000 new products.

Food facilities impose a variety of food safety measures and controls such as Good Manufacturing Practices to ensure the safety and quality of products they process. These regulations cover the basics of producing food under clean and sanitary conditions. The following is just a partial list of matters of concern to the public that are addressed by FDA's food facility regulations:

- Pathogens (bacteria, viruses, parasites)
- Chemical contaminants (pesticides, natural toxins, heavy metals, animal drug and antibiotic residues)
- Loss of wholesomeness (molds, decomposition)
- Mislabeling (false nutrition information or other misleading statements)
- Economic deception (violation of standards, counterfeit foods)
- Safety of food and color additives

POLICY STATEMENT

While we support the requirement that all food companies have a food safety plan, we believe food facilities should be given the discretion to identify appropriate safety controls and measures beyond those controls and measures already required by regulation. Prescriptive, across-the-board new regulatory requirements will stifle innovation, divert resources from proven food safety measures, and will increase food costs at a time of record food inflation.

MISCELLANEOUS PROVISIONS

Export Certification Programs – Several bills introduced in the 110th Congress provided FDA with the authority to issue export certificates as the Secretary determined appropriate, and on a fee-basis. This new authority, if adopted by the new Congress, could help some raw agricultural commodities (and processed food) exporters access markets that are currently closed due to sanitary-related concerns by the importing country, e.g., dairy imports to India. FDA certification should be safeguarded, however, so that it does not become a customary requirement by our trading partners, and instead is granted only under special circumstances supported by technical justification. This will help to control costs for our exporters and help ensure that certification does not become a convenient trade barrier.

Food Safety Research – In recent years, federal funding for food safety research has been woefully inadequate, with little to no research focused directly on mitigating risk factors associated with potential field contamination of fresh produce, or to developing 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. As a nation, we need Congress to fund scientific research to help prevent future outbreaks. Specific produce safety research at FDA that is field oriented and implemented to find practical solutions is critically important, and we urge Congress to include a robust research agenda when considering reforming our nation's food safety laws. We believe that boosting produce safety research is a vital part of reducing risk in the future.