HEARING TO REVIEW THE LEGAL AND TECHNOLOGICAL CAPACITY FOR FULL TRACEABILITY IN FRESH PRODUCE

HEARING

BEFORE THE

SUBCOMMITTEE ON
HORTICULTURE AND ORGANIC AGRICULTURE

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

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CONTENTS

HEARING TO REVIEW THE LEGAL AND TECHNOLOGICAL CAPACITY FOR FULL TRACEABILITY IN FRESH PRODUCE

WEDNESDAY, JULY 30, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HORTICULTURE AND ORGANIC AGRICULTURE,
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The Subcommittee met, pursuant to call, at 1:33 p.m., in Room 1300 of the Longworth House Office Building, Hon. Dennis A. Cardoza [Chairman of the Subcommittee] presiding.

Members present: Representatives Cardoza, Etheridge, Mahoney, Childers, Costa, Neugebauer, and Foxx.

Staff present: Nathan Fretz, Alejandra Gonzalez-Arias, Tyler Jameson, Keith Jones, April Slayton, John Goldberg, Pam Miller, Pete Thomson, and Jamie Weyer.

OPENING STATEMENT OF HON. DENNIS A. CARDOZA, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

The CHAIRMAN. We will call this hearing to order. I would like to welcome everyone in the audience and all our panelists. This hearing of the Subcommittee on Horticulture and Organic Agriculture is to review the legal and technological capacity for full traceability in fresh produce, and it will now come to order. What we will do is follow the agenda. We are going to start with opening statements by myself and my Ranking Member, Mr. Neugebauer of Texas, and then we will proceed to our first panel. We have a very distinguished panel with us today. I want to start by thanking you all for attending this hearing and taking your very busy time to be here with us.

This hearing, as I said, is on the traceability of fresh produce. We are holding this hearing in the midst of one of the most costly and disruptive food illness outbreaks in recent memory. Since April, almost 1,300 Americans in 42 states and the District of Columbia have been infected with *Salmonella* Saintpaul. This outbreak was first identified May 21 by the New Mexico Department of Health. As the number of cases mounted, state officials alerted the CDC of the outbreak. Meanwhile, but unbeknownst to New Mexico officials, authorities in Texas also alerted the CDC that similar cases had emerged in their state.

The investigation faltered almost from the beginning as health officials in both states began asking patients what they ate before

they became ill. They used standard questionnaires which list the major but not all food items that the patients may have consumed. The questionnaires listed peppers but not specifically jalapeño peppers, a food commonly consumed in the Southwest. But a number of those infected remembered eating tomatoes, so with little else to go on, the FDA issued a nationwide warning linking consumption of certain raw red tomatoes to the outbreak of *Salmonella* Saintpaul.

Hundreds of miles away, however, a different conclusion was being reached in Minnesota. A cluster of *Salmonella* Saintpaul cases emerged in connection with a local Mexican restaurant. Among the customers and employees sickened, jalapeños were the common thread. So over 2 months after the first outbreak began, over 1,000 illnesses reported and hundreds of millions of dollars in losses to tomato farmers later, jalapeño peppers were implicated by FDA as the source of the current outbreak. This missed connection between jalapeños as the ultimate source of the outbreak is extremely troubling. Clearly, serious flaws continue to exist in the methodology used by some states to collect primary epidemiological data. Furthermore, the process used by CDC to verify and redefine the collected data calls into serious question the effectiveness of communications between states, the CDC and the FDA. I want to note for the record that both Texas and New Mexico Departments of Health were invited to serve here as hearing witnesses but unfortunately both declined due to scheduling conflicts.

Given the FDA's reversal on the source of the outbreak, I am extremely interested today to hear from FDA and CDC regarding the performance of the survey instruments, the methodology employed in interviewing the patients and the sampling protocols. Frankly, I would just like to hear what went wrong. We all sat here a little more than a year ago and had nearly the same conversation about spinach. Was nothing learned from that experience? Were we any better prepared this time around?

What was particularly troubling to me as I watched the *Salmonella* investigation drag on and the illnesses and losses mount is the government's continued inability to effectively and accurately trace products from the retail level back through the supply chain to its origin. Some food safety experts that we will hear from today assert that these traceback efforts have been hampered by a lack of uniform record-keeping or product descriptions or that traceback requirements within the 2002 Bioterrorism Act have been both poorly implemented and poorly enforced by FDA. But industry officials on the other hand claim that traceback efforts in this current outbreak have worked well and as expected.

As we can see, there is a disagreement, but, hopefully today we can stop the rhetoric that has been circulating around this investigation and start working on a solution because there is no disagreement about one thing: the *status quo* simply cannot and must not continue. Poor handling of this outbreak has confused consumers, damaged producers and led to just mass confusion in the public. You could describe our current food safety system as outbreak roulette: one spin of the outbreak wheel and your industry may be bankrupt, your loved ones sickened. This is unacceptable and we need to take steps to improve the response of our govern-

ment and industry to foodborne illness outbreaks. We must stop being reactive and wasting precious time pointing fingers as soon as an outbreak occurs.

In the House-passed version of the farm bill, I and several of us tried to take steps in this direction by allowing marketing orders to include food safety protocols. I strongly supported this provision and with the hope that the growers could fill the void of food safety while Congress debated the merits of overhauling our current tracking systems because tracking only solves the mystery after the health problem has broken out. That is always helpful but the marketing order approach helps improve grower and shipper practices before consumption and before a possible outbreak. Unfortunately, that provision lost out in a strange dance we call around here the conference committee process, and as such, the *status quo* for food safety remains in place.

But strengthening marketing orders and cultural practices are only part of the story. Today we are here to take a closer look at the legal and technological capacity for traceability in fresh produce. We have four very distinguished panels to hear from today. This hearing is purposely structured to include Members of Congress, and we have two of the best here before us from different parts of the country. It includes agencies, industry, scientists as well as consumer interests. We all have a role to play in re-examining and reshaping this country's food safety system.

[The prepared statement of Mr. Cardoza follows:]

PREPARED STATEMENT OF HON. DENNIS A. CARDOZA, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

Thank you all for attending this hearing and taking time from your very busy schedules to testify today on traceability in fresh produce.

We are holding this hearing in the midst of one of the most costly and disruptive food illness outbreaks in recent memory.

Since April, almost 1,300 Americans in 42 states and the District of Columbia have been infected with *Salmonella* Saintpaul.

This outbreak was first identified May 21 by the New Mexico Department of Health. As the number of cases mounted, state officials alerted the CDC of the outbreak. Meanwhile, but unbeknownst to New Mexico officials, authorities in Texas also alerted the CDC that similar cases had emerged in their state.

The investigation faltered almost from the beginning as health officials in both states began asking patients what they ate before they became ill. They used standard questionnaires which list the major—**but NOT all**—food items that patients may have consumed.

The questionnaire listed peppers, but not specifically jalapeño peppers—a food commonly consumed in the Southwest. But a number of those affected remembered eating tomatoes. So with little else to go on, FDA issued a nationwide warning linking consumption of certain raw red tomatoes to the outbreak of *Salmonella* Saintpaul.

Hundreds of miles away, however, a different conclusion was being reached in Minnesota. A cluster of *Salmonella* Saintpaul cases emerged in connection with a local Mexican restaurant. Among the customers and employees sickened, jalapeños were the common thread.

So over TWO MONTHS after the first outbreak began, and over a thousand illnesses reported and hundreds of millions in losses to tomato farmers later, jalapeño peppers were implicated by FDA as the source of the current outbreak.

This missed connection between jalapeños as the ultimate source of the outbreak is extremely troubling.

Clearly serious flaws continue to exist in the methodology used by some states to collect primary epidemiological data. Furthermore, the process used by the CDC to verify and refine the collected data calls into serious question the effectiveness of communications between the states, CDC and FDA.

I want to note for the record that both the Texas and New Mexico Department of Health were invited to serve as hearing witnesses, but unfortunately both declined due to scheduling conflicts.

Given the FDA's reversal on the source of the outbreak, I am extremely interested to hear from FDA and CDC regarding the performance of the survey instruments, the methodology employed in interviewing the patients and the sampling protocols.

Frankly, I would just like to hear what in the heck went wrong??

We all sat here, a little more than a year ago and had nearly the SAME conversation about spinach. Was nothing learned from that experience? Were we any better prepared this time?

What was particularly troubling to me as I watched *Salmonella* investigation drag on and on and the illnesses and losses mount, is the Federal Government's **continued** inability to effectively and accurately trace products from the retail level back through the supply chain to its origin.

Some food safety experts that we will hear from today assert that these traceback efforts have been hampered by a lack of uniform record-keeping or product descriptions. Or that traceback requirements within the 2002 Bioterrorism Act have been both poorly implemented and poorly enforced by FDA.

But industry officials on the other hand claim traceback efforts in this current outbreak have worked well and as expected.

As we can see, there is disagreement but hopefully today we can stop the rhetoric that has been circulating around this investigation and start working on solutions. Because there is no disagreement that the ***status quo*** **can not and MUST NOT continue.**

The poor handling of this outbreak has confused consumers and damaged producers. You could describe our current food safety system as "outbreak roulette". One spin of the outbreak wheel and your industry may be bankrupt, your loved ones sickened. This is unacceptable, and we need to take steps to improve the response of government and industry to foodborne illness outbreaks.

We must stop being reactive and waste precious time pointing fingers as soon as an outbreak occurs. The House-passed version of the farm bill tried to take a step in this direction by allowing marketing orders to include food safety protocols.

I strongly supported this provision, with the hope that growers could fill the void of food safety while Congress debated the merits of overhauling our current tracking systems. Because tracking only solves the mystery after a health problem has broken out. That's helpful, but the marketing order approach helps improve grower and shipper practices before consumption and before a possible outbreak.

Unfortunately, that provision lost out in the strange dance we called "Conference". And, as such, the *status quo* for food safety remains in place.

But strengthening marketing orders and cultural practices are only part of the story. Today we are here to take a closer look at the legal and technological capacity for traceability in fresh produce, we have four very distinguished panels to hear from today. This hearing is purposely structured to include Members of Congress, agencies, industry, scientists and consumer interests.

We *all* have a role to play in re-examining and reshaping this country's food safety system.

With that, I now yield time to Ranking Member Neugebauer for his opening statement.

The CHAIRMAN. With that, I would now like to yield the floor to my Ranking Member, Mr. Neugebauer, for his opening statement.

OPENING STATEMENT OF HON. RANDY NEUGEBAUER, A REPRESENTATIVE IN CONGRESS FROM TEXAS

Mr. NEUGEBAUER. I thank you, Chairman Cardoza, and I appreciate you calling this hearing. Obviously this is a subject that a lot of people have a lot of interest in. We see a lot of folks here, and it is an important subject as well, and I appreciate the opportunity to review the recent events with the *Salmonella* outbreak that has been tentatively associated with fresh vegetables.

This was a tragic event. It is one that we hope that we can work together both with the industry and this Committee and the government to come up with ways in the future to prevent these kinds of episodes from happening. One of the things we do know is by

and large Americans have enjoyed the safest food in the world. We need to continue to work on that and make sure that process happens. Can we get better? I think we must. I think the real fine line that we are all going to be walking here is, are there things that we can do, for example, on traceback to ensure that when we do identify that there is a problem that we can quickly resolve that with the least amount of disruption to the marketplace and to the consumers. I think it is going to be a cooperative effort because no one knows more about the supply chain than the individual companies and producers themselves. We must integrate the information that they have along with what the regulatory entities in charge of food safety can provide for us and work together to look at the overall system and say where are the weak links in this process so that we can indeed make them stronger. And certainly the traceback is one of those issues that we have had now, I believe, two different jalapeño peppers that now have been identified as the potential source for that.

But what we do know, as the Chairman alluded to earlier, that tomatoes were originally named as the culprit and so we did a widespread ban and took millions and millions of dollars worth, maybe even billions of dollars worth of produce off the market as a preventative measure. As it turns out at this particular point in time, it was not necessary to do that. And so I think that also brings up the other issue as we go down this road of making sure that American people have safe food and the processes that we might implement and the policies that we may make. What we also don't want to do is cause unnecessary processes that drive up the cost of food to the ultimate consumer. We have already seen a fairly substantial increase in food prices for Americans. Their gasoline prices are increasing. Their food prices are increasing. And so what we will make sense of as we listen to the testimony of those that have interest and have knowledge about this, we are going to be looking for common sense solutions of using the technology that we have available to us today. We will be looking at some of the different places in the supply and the food chain where the cases of contamination are more likely to happen and see what we can do in order to make that process better.

So I appreciate the Chairman holding this hearing. I think it is going to be very important. I think the American people are anxious to see what we can and are going to do about this. With that, Mr. Chairman, I look forward to hearing from our panel today.

The CHAIRMAN. Very good. I thank the gentleman from Texas. He has been a great partner in working on the issues in this Committee. I would like to also say that I wholeheartedly concur with him. I should have made this point at the outset of my opening statement as well, that I believe that the produce and the food that the farmers of this country grow and produce for consumption is the safest in the world. This isn't a question about indicting all of our farmers. It is a question of making sure that when we do have a problem, that we can figure out how to correct that problem and that we continue to strive for the safest possible food that we can produce. And so I thank the Ranking Member for making that point.

Now, we are going to recognize, if they come in, Mr. Peterson and Mr. Goodlatte as the *ex officio* Members, Mr. Peterson being the Chairman and Mr. Goodlatte being the Ranking Member of the full Committee, if they show up later throughout the hearing, and of course, they can participate as well. The chair would request that other Members submit their opening statements for the record so the witnesses may begin their testimony and we ensure there is ample time for questions.

[The prepared statement of Mr. Peterson follows:]

PREPARED STATEMENT OF HON. COLLIN C. PETERSON, A REPRESENTATIVE IN CONGRESS FROM MINNESOTA

Thank you, Chairman Cardoza for recognizing me to speak and for holding this hearing on this serious issue. As we have watched the situation involving cases of *Salmonella* Saintpaul unfold over the past several months, many of us in Congress have become more and more concerned about the ability and agility of government and industry to respond to foodborne disease outbreaks. I also want to thank the witnesses who have joined us today. There are some serious questions that need to be asked, and their answers will help us better understand what needs to be done to respond better to the next outbreak.

There are several issues related to the current outbreak that this and other panels in Congress will be taking a close look at. First is the information provided by different states to the CDC during the effort to identify the cause of the outbreak. Information from New Mexico and Texas suggested tomatoes as a culprit, but in Minnesota, officials found a cluster of illnesses that started after suspect tomatoes were removed from the menu. Now, the source appears to be jalapeño peppers, but some people question how sure FDA can be about this source after first implicating, then exonerating another.

Beyond these serious questions about availability and quality of information received by CDC and FDA from the states, there are questions about why it took so long to rule out tomatoes as the source. It is vitally important both for consumer confidence and public health purposes that we can identify the source of food products quickly and effectively. This is particularly important when we're trying to stop the spread of a foodborne disease outbreak.

This is a serious problem that we seem to come back to after every serious outbreak. Traceability must be a priority—it is critical not only to ensure public health, our top priority, but also to ensure that consumers can feel confident that when there is a problem with a food product, we can quickly find the source and prevent additional illnesses.

Looking at the current outbreak of *Salmonella* Saintpaul and other recent incidents, there is plenty of blame to go around—government and industry have made mistakes and have failed to address the flaws that have been highlighted in recent outbreaks. But what is more important is that we work together to find solutions that will help government and industry do a better job next time. I hope that today's hearing will be a step in that direction.

Chairman Cardoza, thank you again for holding this timely and important hearing, and I look forward to the testimony from the witnesses.

We are going to start out with two of the best, as I said, Congresswoman Diana DeGette from Colorado and Congressman Putnam from Florida. Thank you both for being here. You have been leaders in this question, and the floor, Ms. DeGette, is yours for your statement.

STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman and Members of the Committee. My urban constituents were a little bemused when they found out that I was testifying in front of the Agriculture Committee but I reminded them that they are all con-

sumers too, and certainly we have an important topic today with the recent foodborne disease outbreaks that we have seen.

Mr. Chairman, you mentioned in your opening remarks about *déjà vu* all over again with the spinach outbreak and now the tomato/jalapeño outbreak, which we feel the same way in the Energy and Commerce Committee where we have had a series of food safety hearings. While it is absolutely true that we have the safest food growing and distribution system in the world, we can still do better and I think that is all of our hope as we fashion legislation going into the fall. This is an important hearing and it is an important topic and I think that we can well address it.

As you may know, I have been working on traceback legislation for almost 6 years now. H.R. 3485, the TRACE Act, would require the USDA and the FDA to set up a food product traceability system that would track foods all along the supply chain. Now, obviously our primary focus needs to be on continuing to build quality into the system and avoid outbreaks all together. Being able to fully trace tainted food is not the ideal situation because by then the tainted food is in the stores and in the households and on the plates of Americans. But the fact remains that we also must have procedures in place to deal with an emergency to get food off store shelves quickly, to avoid the kind of mass panic we saw in the most recent outbreak of *Salmonella* and most importantly to prevent more people from getting sick. If we did, businesses, Mr. Neugebauer so aptly pointed out, would save millions of dollars in avoiding overreaching recalls as well.

To a certain extent, we have limited traceability right now. Most food companies know their own suppliers and customers and the Bioterrorism Act requires companies to have the ability to trace one step up and one step back. While this is a good start, it is not enough because it does not fully trace food from field to fork, as we have seen all too painfully in the most recent outbreak. In that case, the FDA sifted through boxes and boxes of paper to determine who the suppliers and customers were. In the meantime, over 14 weeks went by and over 1,200 people got sick, not to mention the endless news stories, tons and tons of spoiled food and entire industries destroyed unnecessarily. This one outbreak has shown us that the system is agonizingly slow and simply incapable of keeping up with a globalized food distribution system. And it is not over yet because despite the discovery of a tainted jalapeño pepper recently and now another one just this week in my home State of Colorado, the FDA cannot say with any certainty whether or not tomatoes were ever to blame and it still does not know where the contamination occurred. Given the new warning that consumers should not eat jalapeños despite their origin, it is obvious that we still have no idea where the tainted peppers came from or were distributed.

Mr. Chairman, there really is a better way. As I mentioned before, H.R. 3485 would require the USDA and FDA to set up a system to trace foods throughout the supply chain. Not only is this legislation technologically feasible, it is absolutely critical. Now, I am not saying that the government should be in the business of mandating certain technology. There are many ways of electronically tracking foods and tracking is already being done by some

companies and some industries all over the world using labels, barcoding, wireless RFID readers, lasers and even GPS. What I do think is that the government's role is to standardize and coordinate. What we need is an integrated system rather than a patchwork of incomplete and incompatible traceability systems. Because of the valuable public health and economic benefits of full traceability, I think that the Federal Government must mandate these systems.

Now, Mr. Chairman, I will put the rest of my statement in the record but let me say and let me be on record, I don't want to create a system that is overly burdensome for business or to put a whole new set of costly regulations in place that would burden food distributors or small farmers. Quite the contrary. In fact, right now I am being approached by businesses from around the country that tell me they want to get going right now because they want to avoid the kinds of losses that we saw in the tomato industry just with this latest outbreak. If you meet with the FDA, if you meet with the business groups, you know we do have the technology in place.

In the Energy and Commerce Committee, Chairman Dingell has put together a Chairman's markup of a food safety bill. This bill does not yet include traceability but I would hope as we move forward in that Committee as well as in the other Committees of jurisdiction, we would seriously look at having our Federal Government put together traceability systems that are interoperable and that can help us trace from field to fork where this food came from.

So, Mr. Chairman, I look forward to answering the questions of the Committee, and with that, I suppose I will yield to my distinguished colleague. Thank you.

[The prepared statement of Ms. DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM COLORADO

Thank you, Chairman Cardoza and Members of the Subcommittee. I would like to start by thanking you for giving me the opportunity to testify before this distinguished Subcommittee.

I also want to commend you for taking up such an important topic at such a critical time. The events over the past few months have crystallized the need for a comprehensive food traceability system in this country, particularly with regard to fresh produce.

I have been working on traceback legislation for about 6 years. H.R. 3485, the "TRACE Act," would require the USDA and FDA to set up a food product traceability system that would track foods at all points along the supply chain.

In my opinion we cannot begin to address updating our nation's food safety laws without looking at the ability to track our food.

Obviously our primary focus needs to be on building quality into the system and avoiding outbreaks altogether. Being able to fully trace tainted food is not an ideal situation.

But the fact remains that we must have procedures in place to deal with an emergency, to get food off store shelves quickly, avoid the kind of mass panic we saw in this most recent outbreak of *Salmonella*, and most importantly prevent more people from getting sick.

To a certain extent, we have limited product traceability right now. Most food companies know their own suppliers and customers, and in fact the Bioterrorism Act requires companies to have the ability to trace one step up and one step back. While this is a good start, it is *not* enough, and we need to find out whether these requirements are even being enforced. And I think we can all agree that whatever traceability system that exists today certainly did not work in the tomato/pepper *Salmonella* outbreak.

In this case, the FDA sifted through boxes and boxes of paper records to determine suppliers and customers. In the meantime, over 14 weeks went by and over 1,200 people got sick—not to mention the endless news stories, tons and tons of spoiled food, and entire industries damaged unnecessarily.

It has become clear that this system is agonizingly slow and simply incapable of keeping up with a globalized food distribution system.

And it's not over. Despite the discovery of a tainted jalapeño pepper recently, the FDA cannot say with any certainty whether or not tomatoes were ever to blame, and it still does not know where the contamination occurred. And given the new warning that consumers should not eat jalapeños, despite their origin, it's obvious that they have no idea where the tainted peppers were distributed.

Mr. Chairman, there is a better way.

As I mentioned before, H.R. 3485 would require the USDA and FDA to set up a system to trace foods throughout the supply chain. Not only is this legislation technologically feasible and cost effective, but it's absolutely critical.

I am *not* saying that we should be in the business of mandating certain technology. There is a whole host of ways to electronically track foods, and it is already being done by certain companies and certain industries all over the world, using labels, bar coding, wireless RFID readers, lasers, even GPS.

Where I think the government can be useful is to help coordinate. What we need is an integrated system, rather than a patchwork of different traceability systems. And because of the valuable public health and economic benefits to full traceability, I feel the FDA and USDA have a responsibility to help.

We must ensure systems are interoperable and can talk to each other, so food can be continually tracked along the distribution system, especially when there is a transfer of ownership.

What I don't want to do is create a system that is overly burdensome for business, or to put a whole new set of costly regulations on our nation's food distributors or small farmers. Quite the contrary. In fact, I am being approached by businesses from across the country that want to get going now.

Full traceability is going to be good for business. IBM Consulting has written a report that recommends its clients develop full traceability to improve consumer confidence, which has eroded in recent years due to recall after recall.

As we have seen in the latest *Salmonella* outbreak, as well as previous recalls in spinach and other products, when contamination happens at even a single facility, an entire *industry* can be devastated. Despite the fact that nearly all spinach was harmless in 2006, and the vast majority of jalapeños are probably safe now, and the distinct possibility that not a single tomato was ever contaminated, growers and distributors suffered catastrophic losses.

Nationwide, blanket recalls and generalized consumer warnings with no connection to actual distribution chains create mass panic, causing customers to avoid certain products and altogether. In an industry where brand preservation is everything, we can't allow this to continue.

A comprehensive traceback program would allow for targeted recalls; if an outbreak occurs we will know exactly what lots were potentially contaminated instead of targeting the entire universe of products like we did with spinach, tomatoes, and peppers.

We can find out within seconds where tainted food was sent and where it originated, and have an orderly process of notifying affected consumers and pulling products from shelves. Therefore the 99.9% of businesses selling perfectly safe food from perfectly sanitary facilities will be protected against contamination that occurs elsewhere.

And electronic traceability has benefits to business that go beyond brand preservation and insurance against recalls caused by other parts of the market. Traceability brings better inventory control and supplier/customer monitoring practices, and is a good marketing technique to attract and retain customers.

To be sure, the outbreaks of foodborne illnesses in recent years have spurned action in the private sector. Traceability systems are being implemented by industries as diverse as fresh produce and alcohol, from processed food to fast food, just to name a few.

But the USDA and FDA need to play a key role. My legislation will build upon this important work that is already happening by linking all of the pieces together without being overly burdensome.

Mr. Chairman, we cannot waste any more time postponing food safety reform. Why wait for the next outbreak, the next 1,200 illnesses, the next mass panic that devastates our farmers, before we act?

There is much to be done. It is time to create a unitary food agency, so 12 different agencies aren't sharing the jurisdiction yet passing the buck. We need to pro-

vide the USDA and FDA with mandatory recall authority. And we have to start rebuilding the FDA and USDA to be able to better operate in a 21st Century, globalized food distribution system.

But the latest *Salmonella* outbreak has shown that food traceability must be a part of the mix. Consumers want to know where there food is coming from, businesses need insurance against risk, and as policymakers our first priority must be public health.

Thank you so much for the opportunity of appearing before this Subcommittee.

The CHAIRMAN. Thank you, Ms. DeGette.

Mr. Putnam.

STATEMENT OF HON. ADAM H. PUTNAM, A REPRESENTATIVE IN CONGRESS FROM FLORIDA

Mr. PUTNAM. Thank you very much, Mr. Chairman. It is great to be back in the Agriculture Committee. I was explaining to my colleague here that when I arrived, I was the next to bottom chair here at the kids' table embarking on that farm bill discussion back in 2001.

I appreciate the opportunity to be before this Subcommittee on which I used to serve, and like you, Mr. Chairman and Mr. Neugebauer, Ranking Member, I am very interested in hearing what the other panels have to say in terms of what went wrong. Clearly there was a very serious breakdown and we need to improve the system as we move forward, recognizing that Americans are still blessed with the safest, cheapest and most abundant food supply.

I want to spend just a little bit of time talking about the recent outbreak of *Salmonella* and then talking about a bill that I have filed with Mr. Costa, who is also a Member of the Committee, from California and the work that we have done based on the work that each of our states have done, California and Florida, to really produce a seamless food safety net, especially for the produce aspect of agriculture.

The outbreak of *Salmonella* Saintpaul, which is now estimated to have impacted over 1,300 people in 43 states, not only called into question the integrity of the system designed to protect our food supply and the security and safety of our consumers, but also significant disruptions to the network that produces those agricultural goods. The aftermath, the damage that was caused to the early publicly suspected commodities though lasts far longer than the impact of this illness. There is permanent damage done to the markets, which is something that is an important aspect of this discussion, that as a result of early errors in the investigation, there were early public statements that inaccurately identified particular commodities. That is damage that transcends this discussion, that transcends the illness and is permanent to those producers and to the market brand or image of those crops. This incident demonstrated that our governing food safety authorities are outdated. They must be reformed and enhanced to reflect modern scientific standards and industry practices as well as sound and strong policies implemented to prevent future food contamination.

The bill that Mr. Costa and I have introduced is called the Safe Food Enforcement, Assessment, Standards and Targeting Act, or the Safe FEAST Act, H.R. 5904, we believe it would help to provide the highest level of food safety protection both for goods produced

domestically and those that are imported from abroad. As I said earlier, it is based on the success from our laboratories of democracy in the states where this has been tried real-time, and implemented, and it is functioning well.

The comprehensive measure would modernize our food safety network and put into place new food safety standards all along the food chain from farm harvest, processing, packing and distribution, to the retail outlet and finally to the consumer to identify and prevent potential sources of foodborne illness. The bill calls for balanced, science-based food safety requirements for farm and food companies, domestic and abroad, implementing the principles of risk assessment and risk management, to improve safeguards in our food supply as well as mitigate unwarranted market disruptions to agricultural suppliers.

To ensure the highest level of food safety for the American consumer, the bill requires all domestic and foreign food companies selling food in the United States to conduct a food safety risk analysis that identifies potential sources of contamination, outlines appropriate food safety controls and requires verification that those controls that are implemented are adequate to address those risks of foodborne contamination.

Similarly, to ensure that food products coming into the United States from international sources are safe, those imported goods would also have to adhere to the same safety and quality standards as set by the FDA for what is grown in the United States. It specifically establishes new standards for fresh produce, putting into place for the first time mandatory food safety regulations for high-risk produce and voluntary good agricultural practice guidelines for the safe production of all fruits and vegetables.

For those produce items that are deemed to pose the highest risk by FDA, the bill calls for the issuance of mandatory science-based regulations to prevent the occurrence of foodborne illness at all potential points of hazard from the farm to the table. It calls on FDA to establish standards for the safe production, harvesting and packaging of those types of fruits and vegetables for which the Secretary has determined are necessary to minimize the risk of serious adverse health consequences.

These food safety initiatives have the support of the produce industry. I think that that is an important piece of this. This is not something that is being foisted on an industry that is either technologically incapable of for various reasons in the supply chain or the production of these commodities are unable to implement these new regulations. It has the support of the industry, which has a stake in ensuring the safety and security of their food products.

This issue, the spinach issue, other issues prove the growers, the farmers have as much at stake as anyone in making sure this doesn't happen again. I mean, your public health officials and your farmers are of one mind in being committed to prevent this from being a future problem. It is in no one's interest to continue to undermine public confidence in the safety and sanctity of the nation's food supply.

This bill strengthens the relationship between Federal, state and foreign government agencies by increasing cooperation to better control food safety threats, calling on the expertise and resources

of these partners to respond to the food safety occurrences in a more timely and efficient manner.

This is the second point that I would like to make. Just as our bill, which was drafted long before the Saintpaul *Salmonella* outbreak, built on the success at the state level, one of the failures, frankly, in this recent outbreak was the breakdown in communication between not only industry experts and public health officials but state public health officials, people who are charged by their state legislatures under state statute with implementing food safety guidelines for their states. I don't believe that in this investigation we fully utilized all the resources that were out there in government, in public health, in the industry to deal with this in a timely way. As time went by, more and more people got sick because we weren't using all the tools in our toolbox to track down or traceback the source of the contamination. Time is of the essence and the industry and our state and local health and agricultural officials are on the frontline and can narrow that knowledge gap and close the time window when people are still getting sick.

Collaboration with state and industry partners is key, and in our home State of Florida, they have adopted mandatory regulations on good agricultural practices and best management practices for the production and handling of tomatoes through all channels of commerce. It was developed as a cooperative effort between the Department of Agriculture, the Florida Department of Agriculture, the Florida tomato industry and the FDA and they are based on sound science. They provide traceability and they establish practices and procedures for the safe handling of tomatoes. These state efforts should be broadened through vehicles such as this legislation, the Safe FEAST Act, to provide greater protection and traceability in our food network both at the domestic level and at the international level.

So, Mr. Chairman, I applaud your willingness to hold this hearing. I appreciate all of the Members' work in jumping on this issue and attempting to get something into the law that modernizes our food safety network and system. I just want to reiterate, it is in all of our interests to have a high consumer confidence in the food supply in the United States. There have been a series of incidents both in fresh produce, in processed foods, in dog food and in toys, essentially in every aspect of the consumer's world, there have been incidents over the last 2 years that have continued to undermine that level of confidence. It ought to be our challenge to restore the faith and confidence of the American consumer and reiterate again that American produce is the safest, cleanest and healthiest in the world.

With that, I appreciate the opportunity and look forward to your questions.

[The prepared statement of Mr. Putnam follows:]

PREPARED STATEMENT OF HON. ADAM H. PUTNAM, A REPRESENTATIVE IN CONGRESS FROM FLORIDA

I am Representative Adam H. Putnam, representing Florida's 12th Congressional District, and it is my privilege to provide testimony to the House Subcommittee on Horticulture and Organic Agriculture on an issue of national significance, protecting the safety and security of our country's food supply.

Thank you again for the opportunity to testify, and I also look forward to the statements of those witnesses here today that serve "on the front line" in ensuring the safety of the American food supply for the public, as well as the testimony of those critical to providing food resources for our country.

While our nation's food supply continues to be the safest in the world, recent incidences of foodborne illness have highlighted deficiencies in our food safety system that must be addressed.

The outbreak of *Salmonella* Saintpaul, said to be associated with foodborne illness affecting in an estimated 1,284 persons, not only called into question the integrity the system designed to protect our nation's food supply for the safety and security of consumers, but also caused significant disruptions to the food supply network and those that produce agricultural goods for our nation.

This incident demonstrated that our governing food safety authorities are outdated and must be reformed and enhanced to reflect modern scientific standards and industry practices, as well sound and strong policies implemented to help prevent food contamination.

The *Safe Food Enforcement, Assessment, Standards and Targeting Act* "Safe FEAST Act", H.R. 5904 which I am proud to have cosponsored with my colleague from California and Member of the House Agriculture Committee, Representative Jim Costa, would help ensure the highest level of food safety protection for our nation's food supply, both for goods produced domestically and those imported from abroad.

The comprehensive measure would modernize our food safety network and would put into place new food safety standards all along the food chain—from farm, harvest, processing, packing, distribution to retail outlet, and finally to consumers—to identify and prevent potential sources of foodborne illness.

The Safe FEAST Act calls for balanced, science-based food safety requirements for farm and food companies, domestically and abroad, implementing the principles of risk assessment and risk management, to improve safeguards in our food supply as well as mitigate unwarranted market disruptions to agricultural suppliers.

The bill focuses on strengthening preventative measures, building upon existing regulations with tough—but common sense standards, while expanding the tools of the Food and Drug administration (FDA) to more effectively respond to food safety incidents in this nation.

This bipartisan bill strengthens the relationship between Federal and state agencies to better control food safety threats, and for the first time, and grants FDA new authorities powers to recall contaminated food in the case of adulteration.

By reinforcing the public-private partnership, the Safe FEAST Act improves FDA's role in safeguarding and overseeing the safe production of food, while drawing upon the strengths of industry to meet the highest food safety standards.

To ensure the highest level of food safety to American consumers, H.R. 5904 requires all domestic and foreign food companies selling food in U.S. to conduct a food safety risk analysis that identifies potential sources of contamination, outlines appropriate food safety controls, and requires verification that the food safety controls implemented are adequate to address the risks of foodborne contamination.

Similarly, to ensure that food products coming into the United States from international sources are safe, imported goods would have to adhere to the same safety and quality standards as set by the FDA, through completing a Foreign Suppliers Quality Assurance Program, documenting the food safety measures and controls for FDA review.

H.R. 5904 also establishes key new standards for fresh produce. It improves and expands upon FDA's *Good Agricultural Practices* for the safe production of fruits and vegetables. For those produce items that are deemed to pose the highest risk, the bill calls for the issuance of mandatory science-based regulations to prevent the occurrence of food borne illness at all potential points of hazard, from farm to table.

While putting into place mandatory food safety standards for high-risk produce, and voluntary guidelines for all other produce—the bill and allows for variances in FDA regulations to meet local growing conditions. It also directs FDA to collaborate with the U.S. Department of Agriculture regarding agricultural practices in the issuance of regulations.

The Safe FEAST Act strengthens the relationship between, Federal, state and foreign governments agencies by increasing cooperation to better control food safety threats, calling on the expertise and resources of these partners to respond to food safety occurrences in a more timely and efficient manner.

Collaboration with state and industry partners is key, as for example my home State of Florida has adopted mandatory regulations on Good Agricultural Practices (T–GAP) and Best Management Practices (T–BMP) for the production and handling of tomatoes through all channels of commerce. Developed as a cooperative effort be-

tween the Florida Department of Agriculture and Consumer Services, the Florida tomato industry, and the FDA, these best practices based upon sound scientific research, provide traceability, and establish practices and procedures for the safe handling of tomatoes.

These state efforts should be broadened, through vehicles such as the Safe FEAST Act, to provide greater protection and traceability in the food supply network at the national and international level.

Finally, to better control food safety threats, the Safe FEAST Act directs the FDA to adopt a risk-based approach to inspections, grants the FDA statutory power to recall contaminated food in the case of adulteration, and gives FDA authority to access food safety production records during foodborne emergencies.

The Safe FEAST Act is endorsed by several state, national and international produce, food manufacturing and retail organizations which have a high stake in maintaining safety and quality standards for American consumers.

Thank you again for the opportunity to testify, and I appreciate the Subcommittee's attention to this most important issue.

The CHAIRMAN. Thank you to both of you for being here. We are going to engage in something somewhat unusual today. Typically it is not the protocol of Members of Congress to ask questions of their colleagues but both of our witnesses have said that it would be okay with them for the Committee to ask questions. In fact, I have talked to both of them about it in advance, so I would just remind the Committee that you will be recognized for questioning in order of seniority for Members who were here at the start of the hearing. After that, Members will be recognized in order of arrival. I appreciate the Members' understanding.

I will start the questioning with my colleague, Ms. DeGette. We spoke yesterday with regard to the farm bill that had a marketing order approach. You have a tracking approach. And the reality is, we don't see those as being out of sorts with each other, that one can possibly help the other. In our discussion yesterday, we discussed that a bit and I would like you to share with the Members of the Committee your views, since you have worked on this so long and so hard.

Ms. DEGETTE. Mr. Chairman, I think the real key role for the Federal Government is to have a traceability system that when there is evidence of a foodborne outbreak, then we have some systems in place that allow immediate traceability. My bill, 3485, does not legislate what that system will be, and furthermore, I don't think that you would necessarily have the same system for each segment of the food industry. As Mr. Putnam wisely said, we have fresh produce, we have prepared foods, we have meat, we have many other types of processes by which food enters our economy, and so my view would be rather that the FDA or the USDA should by working with industry to develop systems of traceability that will take us from field to fork and then make sure that those systems are interoperable. I don't envision one size fits all. I don't envision necessarily one system, but part of the problem we have had is that our agencies have not—we have such spotty traceability throughout our food system that we don't have an ability to quickly trace foods. This is exactly what we have seen with the latest foodborne outbreak and I don't think that that is in any way at odds with what you are concerned with or what the legislation envisioned.

The CHAIRMAN. Exactly. And Mr. Putnam, you raised, and I would like you both to comment on this, that there is wide variability between states and the capacity that each state has. Cer-

tainly in California, I feel that California and frankly in your State of Florida that the departments of agriculture in those two states probably surpass the Federal Government's capability of determining foodborne illness in a very rapid fashion. I tried to get former Secretary of Agriculture Bill Lyons from my district to testify here today. He wasn't able to make it. But because he jumped on an outbreak of illness in poultry, he was able to resolve the situation before it affected the commercial flocks. And if you want to comment both of you about the disparities between the states and how you see those working in with your bills.

Mr. PUTNAM. I agree with you, Mr. Chairman, and I think that is a reflection that these state departments of agriculture recognize the importance not only to the consumer but also to the producer of avoiding these types of outbreaks and building consumer trust and confidence in the products that are being grown in those states. Because of the substantial economic loss that occurs when you have these types of illnesses and you have these types of scares and the damage, the economic damage lasts a lot longer than the life of the *Salmonella* Saintpaul bug. And so, it proves the point that I think both of us are making here, which is that the industry recognizes that they need a robust risk assessment, risk management system. They have, in many cases, in these individual states pressed their legislature for a more robust regulatory system that was also workable, that was practicable and technologically feasible. This is an area where the grower and the consumer are entirely overlapping in their interests and that is why the states that tend to be large specialty crop-producing states, fresh produce-producing states have invested heavily in that type of a modern food safety system.

Ms. DEGETTE. And just to add, I think that is the point I was going to make. States like California and Florida and others have really instituted very sophisticated systems, but those systems are not interoperable with each other across the states. If a tomato from southern California is sent to Colorado and there is an identification by the Colorado Health Department of a foodborne outbreak, the Bioterrorism Act only gives us one step up and one step back. So, you can't trace that tomato all the way back to the field in California, which is why we need a national system putting together all these state systems. And just quickly let me add, an additional problem that we are looking at in Energy and Commerce as well, it is not just the food traceability systems, it is also the public health systems where there is a real patchwork of ability to identify the contamination from the beginning that we need to deal with at a Federal level.

The CHAIRMAN. Thank you very much.

Mr. Neugebauer.

Mr. NEUGEBAUER. Thank you, Mr. Chairman, and I thank both of our panelists.

One of the things that Mr. Putnam—and I want to thank both of you, and I know Mr. Putnam has been a huge advocate for food safety and represents a very large state that has a lot of production of citrus and fruits and vegetables for our country. In your bill, as I understand it, you talk about things that can be done from an agricultural perspective and then also what happens to some of

those agricultural products. You talk about some of the authority in your bill would be given to the Secretary of Health and Human Services, and then I heard both of you saying what is important here is communication, of tying the network all together, the states when there is a traceback event. One of the concerns I have had is where we are dividing food safety responsibilities between, in some cases, two agencies, and then when you bring the CDC in, you bring another agency in there, is this an issue, is this part of the problem? In other words, that you are relying on agencies, you want states to communicate, you want agencies to communicate, you want state agencies to communicate with Federal agencies. I guess the question I have, is the loop too big and would making this food safety issue under one umbrella be something this Committee should consider?

Mr. PUTNAM. Is that one for me?

Mr. NEUGEBAUER. Either one of you.

Ms. DEGETTE. Let me say that ultimately I think we need to have a conversation about whether it would make sense for us to have a unitary food safety agency. This is an issue Congresswoman DeLauro and I have been working together on for a number of years. For example, why is it that the FDA has jurisdiction over cheese pizzas and the USDA has jurisdiction over pepperoni pizzas? That has never made a lot of sense to me. But I think that would be a long and important discussion to have.

In the short term, we can use our current system and improve it by increasing technology and communication, and I will give you an example. The CDC and its related health departments and reporting agencies in the public health arena actually communicate pretty well right now on identification of foodborne diseases and they get the information in. The problem is though, and we saw this with the most recent outbreak—I hate to harp on that because I could really pick almost any of the outbreaks—once they figured out that there was a foodborne vector and what it was, then they reported to the FDA, which is the chain of command. Then what happened was, the FDA was unable to target exactly was it peppers or was it tomatoes, and where did they come from, and using the Bioterrorism Act, it just failed completely. So if we had a system in place that you could trace those tomatoes all the way back to the field or the peppers, that would help us go a long way in having very quick traceability. That would help us at least minimize the extent of the business damage because we would be having big recalls and it would also help us quickly identify where that contamination came from so we could minimize the disease.

Mr. PUTNAM. Thank you, Mr. Neugebauer. For as long as I have been here and long before I got here, there has been a discussion about a single food safety agency or not. The cheese pizza example is sort of the classic example of what is regulated by USDA, what is regulated by FDA, *et cetera,* and in theory, you probably—I mean, you do look at this Byzantine structure of food regulation and you say well, if we were going to do it all over again, that is probably not how we would do it. That is exactly how we approached the merger of all the different agencies into the Department of Homeland Security, and I hadn't been too thrilled with how that turned out. My experience from bringing that same vision

to Homeland Security where we said, "Gosh, it really doesn't make sense that you have one agency looking for stuff and one agency looking for people and one agency looking for bugs, and so we are going to make it all into this really nice, neat, simple flow chart", and it just hasn't turned out the way we all hoped it would. I think that the same would be true if we were to disrupt the existing food safety and regulatory system that we have today.

But the same bureaucratic cultures and barriers that led us to create the Department of Homeland Security exist today in the food safety system where, for whatever reason, people are reluctant to pick up the phone and say, "Hey, we happen to know a lot about tomatoes, I know you guys do public health, I know that you can spot anthrax or you can spot smallpox or you know that the West Nile virus is increasing in intensity. But, maybe you don't understand the difference between the supply chain of cilantro *versus* jalapeño peppers *versus* tomatoes *versus* green peppers *versus* red peppers." Maybe we ought to kind of break down this cultural aversion to seeking out people who actually have the information about how the real world really works. And in doing so, whether that involves bringing in industry expertise or in bringing in state and local health and industry expertise, I think all of those things will help give us a more well-rounded system. It is not fair for Congress to expect the FDA or the CDC to know everything there is to know about the supply chain of every commodity grown in the United States. It is not right for us to expect that of them. I think it is appropriate for us to put in place a system that allows them to rapidly tap into the expertise that is there.

It is cynical to believe that asking for industry expertise is allowing them to be in charge of their own regulation. I think that is a very cynical view because as we have seen, it is in their best interest more than almost anyone else's to get to the facts, to get to the truth, to end the spread of the disease as quickly as possible and limit the damage. What is not in their best interest is for government agencies to flail around publicly speculating about which commodity it may or may not be while people change their purchasing habits based on that public speculation.

The CHAIRMAN. I as usual agree with both of you. Thank you for being here.

It is come to my attention that we can be expecting a vote any minute, so I am going to try and switch to the next panel and try to get the testimony of the next two panelists in as soon as possible. Thank you both for being here. You testimony was as enlightening as I thought it would be.

The next panel of witnesses we would like to invite up is Dr. Acheson, Associate Commissioner for Food Protection of the U.S. Food and Drug Administration, Rockville, Maryland, and Dr. Lonnie King, Director of the National Center for Zoonotic, Vector-borne and Enteric Diseases, ZVED, of the Centers for Disease Control in Atlanta, Georgia.

Dr. Acheson, I would call on you to give your testimony first. You will probably hear the bells ring midway through your speech but we will sit here and listen to both of you give your testimony. And then hopefully we will ask you to stay while we vote and we can

come back and reconvene to ask questions. Dr. Acheson, the floor is yours.

STATEMENT OF DAVID W.K. ACHESON, M.D., F.R.C.P., ASSOCIATE COMMISSIONER FOR FOOD PROTECTION, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, D.C.

Dr. ACHESON. Thank you. Good afternoon, Chairman Cardoza and Members of the Subcommittee, I am Dr. David Acheson, Associate Commissioner for Food Protection at the Food and Drug Administration, which is part of the Department of Health and Human Services. Thank you for the opportunity to discuss the recent foodborne illness outbreak associated with fresh produce contaminated with *Salmonella* Saintpaul and the measures FDA is taking to enhance the safety of fresh produce and to enhance traceability.

There is no question that the *Salmonella* Saintpaul outbreak investigation has been one of the most complex in recent memory. I want to assure you that FDA is committed to working with all of our food safety partners to expedite tracebacks and to ensure that America's food supply continues to be among the safest in the world. The number of illnesses associated with fresh produce is a continuing concern for FDA and we have worked on a number of initiatives to reduce the presence of pathogens in these foods. Some of these activities include: working with industry to develop guidance on ways to prevent or minimize potential contamination; conducting educational outreach to consumers on safe food handling practices; sampling and analyzing both domestic and imported produce for pathogens; and working with industry and foreign countries to promote the use of good growing, harvesting, packing, transporting and processing practices. We are also conducting research to improve the identification and detection of disease-causing bacteria in a variety of foods.

I would like to provide a brief description of the typical traceback process. Once CDC and the state and local health authorities, through their epidemiological investigations, identify a possible food or foods associated with an outbreak, CDC notifies FDA. At that point, we at FDA start our traceback investigation to identify the source of the contamination. We work with industry and the local, state and Federal officials and, when needed, foreign governments, to identify the source of the contamination. We do this by tracing the food suspected of being the vehicle for transmitting the pathogen back through the supply chain from the retailer or restaurant and inspecting or investigating points throughout that supply chain to determine where the contamination most likely occurred.

Tracing food requires us to find and examine documentation such as bills of lading and invoices for the product throughout the supply chain. We also obtain information on the practices and the conditions under which the product was stored and handled at each of those points.

The current investigation, which initially focused on certain types of raw tomatoes, provides an example of one of the most difficult kinds of traceback investigations. On May 31, the CDC ad-

vised FDA of the significant statistical association between consumption of certain types of tomatoes in a multi-state outbreak of *Salmonella* Saintpaul. Raw tomatoes are a perishable commodity and thus are unlikely to be in the consumer's home after a consumer becomes ill, obtains a diagnosis and an outbreak is identified. Further, raw tomatoes are often sold loose without any form of packaging. In the current investigation, we learned that many tomatoes had been shipped to washing, packing and repacking facilities where they were or might have been commingled with other tomatoes from different sources.

Since May 31, many FDA employees in the field and at headquarters have been working continuously on the outbreak to identify the sources of the illness. To help the public distinguish tomatoes not associated with the outbreak, FDA adopted the policy of specifically designating the types of tomatoes implicated in the outbreak as well as listing growing areas that were not part of the outbreak. On July 17, FDA updated its consumer advisory and announced that tomatoes currently on the market are not considered to be a possible source of illness.

On July 21, a genetic match with the outbreak strain of *Salmonella* Saintpaul in jalapeño peppers we had tested from a distribution center in Texas was determined. This finding of a genetic match was an important break in the investigation, and upon further investigation, FDA determined that the contamination of the peppers occurred in Mexico and not at a plant in Texas. Accordingly, on July 25, FDA updated its consumer advisory and announced that there was no indication that domestically grown jalapeño or serrano peppers are implicated in the outbreak.

To illustrate that point, I brought a chart with me that demonstrates what we learned.

What I would like to point out here on this chart is over on the left-hand side, a firm was identified that is in the red box. That was the site which we found the positive pepper sample in the McAllen, Texas, distribution center. Through our investigations in Texas, we were able to trace that back through the red dotted line to the facility at the center of the diagram, which was in Mexico, and from there up to another facility in Mexico and finally to the red box on the far side, which is the grower where that pepper was grown. The rest of this diagram illustrates what we were learning during that process of the complexity of the potential tracebacks of peppers in the State of Texas.

Two hours ago, we learned that we had gotten breaking news in this regard. We have had our investigators in Mexico and they had been investigating a specific farm taking samples, looking for signs of the *Salmonella* Saintpaul outbreak, and 2 hours ago we learned that we had gotten a positive sample in both the water used for irrigation and a sample of serrano peppers from the same farm that matched the outbreak strain of *Salmonella* Saintpaul. So this is a key breakthrough, and Dr. Solomon is going to illustrate on here which farm that was. So that is a key breakthrough.

Now, the other thing that we have learned today from the investigation with our investigators in Mexico today——

Mr. COSTA. Mr. Chairman?

The CHAIRMAN. Yes?

Mr. COSTA. Could he move a little either on the other side or move that around and——

The CHAIRMAN. Would it be possible to bring the easel up forward, or do you have—oh, we do have documents.

Mr. COSTA. That would be nice.

The CHAIRMAN. Thank you.

Mr. COSTA. I am sorry to interrupt but——

Dr. ACHESON. No, sure, please.

Mr. COSTA.—my eyes aren't what they used to be.

Dr. ACHESON. No, I apologize for taking a few extra moments but this is breaking news and I wanted you to be current.

The CHAIRMAN. We love breaking news here. We like to get it right as well. Thank you.

Dr. ACHESON. So what we have learned is that the box there with the new red square around it is where we found these two positive samples. We have learned also that that farm is distributing to a number of other places. You can see one arrow already on there, and Dr. Solomon is going to draw three more where we have now learned that this farm is distributing to a variety of other places.

This is obviously critical information that is fresh off the press as of, as I say, 2 hours. One of the key things that we are learning is where the product from that farm has gone to and what the investigators in Mexico are going to be doing right now as the days move forward is identify where else might those products have been distributed within the country of Mexico before coming into the United States. And that will eventually allow us hopefully to narrow this down to a specific place.

Obviously one of the questions is, if we have contamination on that farm but the pepper traced back to another farm, is there a connection between the two? Is one shipping to the other? Is there a common water supply? We know that the contamination was in the water so is there a common water supply or is there some other common point? And you can see there again in the middle of that diagram, there is a distribution center—Dr. Solomon, if you could point to that, down one, there—where the peppers on the top part of the diagram and the positives are passing through the same distribution center.

Based on this, we are right now expanding our message to consumers. We found a positive in serrano peppers and we are recommending that consumers in the United States not only not consume jalapeño peppers imported from Mexico but also serrano peppers.

The CHAIRMAN. So is that a new advisory that will be going out today?

Dr. ACHESON. It is a new advisory as of right now, yes, indeed, because we have now gotten a confirmed positive in serrano peppers as well as jalapeño peppers, so both kinds of peppers have tested positive for the outbreak strain. So the message will be to consumers to avoid those kinds of peppers or products made from fresh—these are fresh peppers. As before, if they are processed, cooked or pickled, then they are not of concern.

So that essentially is an update. I have already gone way over my time. I recognize that, so I would be happy to take any questions when you are ready.

[The prepared statement of Dr. Acheson follows:]

PREPARED STATEMENT OF DAVID W.K. ACHESON, M.D., F.R.C.P., ASSOCIATE COMMISSIONER FOR FOOD PROTECTION, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, D.C.

Introduction

Good afternoon, Chairman Cardoza and Members of the Subcommittee. I am Dr. David Acheson, Associate Commissioner for Foods at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). I am pleased to be here today with my colleague, Dr. Lonnie J. King, from the Centers for Disease Control and Prevention (CDC), which is also part of HHS. FDA appreciates the opportunity to discuss the recent foodborne illness outbreak associated with fresh produce contaminated with *Salmonella* Saintpaul and the measures we are taking to enhance the safety of fresh produce and to enhance traceability.

FDA is the Federal agency that regulates almost everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at the United States Department of Agriculture (USDA). FDA is committed to ensuring that America's food supply continues to be among the safest in the world.

There is no question that the *Salmonella* Saintpaul outbreak investigation has been one of the most complex investigations in recent memory. I assure you that FDA is committed to working with all our food safety partners to examine ways to remove or mitigate some of the complicating factors to expedite tracebacks. In my testimony, I will discuss some of the factors that made this investigation so complex. I will also describe some of the challenges we face both in preventing fresh produce from becoming contaminated in the first place and in investigating outbreaks associated with fresh produce. I will also discuss some of the specific measures FDA is taking to enhance the safety of fresh produce and other foods to prevent future outbreaks and to improve traceability when an outbreak occurs.

Food can become contaminated at many different steps—on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, we have done a great deal to prevent both intentional and unintentional contamination of food at each of these steps. FDA has worked with other Federal, state, local, tribal, and foreign counterpart food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry, consumer groups, and academia to significantly strengthen the nation's food safety and food defense system across the entire distribution chain.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports posed challenges that required us to adapt our current food protection strategies and to develop the Food Protection Plan and the Action Plan for Import Safety, which I will discuss later in my testimony.

Challenges of Fresh Produce

The number of illnesses associated with fresh produce is a continuing concern for FDA, and we have worked on a number of initiatives to reduce the presence of pathogens in these foods.

Fresh produce presents special challenges. For example, consumption of produce, particularly "ready-to-eat" products, has increased dramatically during the past decade. This is a positive development from a nutrition perspective, but also a new dynamic that challenges our food safety efforts.

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, in manure used as fertilizer, or due to the presence of animals in or near fields or packing areas. Produce also may be vulnerable to contamination due to inadequate worker health and hygiene protections, environmental conditions, inadequate production safeguards, and inadequate sanitation of equipment and facilities. Fresh produce is produced on tens of thousands of farms, and contamination at one step in the growing, packing, and processing chain can be amplified throughout the subsequent steps. The fact that produce is often consumed raw or with only minimal processing, without any type of intervention that would eliminate pathogens (if they are present) prior to consumption, contributes to its potential as a source of foodborne illness.

Consequently, addressing the way fresh produce is grown, harvested, and moved from field to fork is crucial to minimizing the risk of microbial contamination. In recent years, FDA has initiated several activities to address safety concerns associated with the production of fresh produce. Some of these activities include: working with industry to develop guidance on ways to prevent or minimize potential contamination, conducting educational outreach to consumers on safe food handling practices, sampling and analyzing both domestic and imported produce for pathogens, and working with industry and foreign countries to promote the use of good growing, harvesting, packing, transporting, and processing practices. For example, just last month, FDA provided training in good agricultural practices in Costa Rica.

Research is also a critical element of our efforts to improve the safety of fresh produce. Our current research agenda is focused on improving the identification and detection of disease-causing bacteria and toxins in a variety of foods. More rapid and precise testing methods to identify contaminants are important for detecting contamination if it is present and minimizing the spread of foodborne disease once it occurs. In addition, we are working with academia, industry, other Federal agencies, and state governments to develop both risk-based microbiological research programs and technology transfer programs to ensure that the latest food technology reaches the appropriate end users along the supply chain.

I would now like to provide a brief description of the typical traceback process.

Traceback Process

Once CDC, through its epidemiological investigation which involves working with state and local governments, identifies the possible food(s) associated with a foodborne illness outbreak, CDC notifies FDA. At that point, we start our traceback investigation to identify the source of the contamination. We work with industry and with local, state, and Federal officials, and, when needed, with foreign governments, to identify the source of the contamination. We do this by tracing the food suspected of being the vehicle for transmitting the pathogen back through the supply chain from the retailer or restaurant and inspecting or investigating points throughout the supply chain to determine where the contamination most likely occurred. Tracing food requires us to find and examine documentation (such as bills of lading and invoices) for the product throughout the supply chain. We also obtain information on the practices and conditions under which the product was stored and handled at each point to better determine shipments of interest and whether contamination may have occurred at each point.

Traceback investigations involving fresh produce are more difficult because the food is perishable and is usually no longer available for testing by the time consumers become ill. In addition, fresh fruits and vegetables are often sold loose without any packaging that could provide information about its source. Further, practices such as packing or repacking produce from multiple sources add complexity to traceback investigations. As each traceback investigation is different, I would like to mention three recent examples which illustrate the different degrees of difficulty.

Peanut Butter

In 2007, CDC notified FDA of a multi-state outbreak of *Salmonella* Tennessee infections associated with the consumption of peanut butter. In this case, because it was not a perishable food, consumers who had become ill still had jars of peanut butter available for testing. This enabled investigators to confirm the presence in that food of the contaminant associated with the outbreak. Further, because the food was packaged, the investigators were able to identify the manufacturer through the information on the jars. This is an example of a rapid traceback in which the necessary information was readily available.

Fresh Spinach

In 2006, CDC informed FDA of a multi-state outbreak of illnesses associated with the consumption of fresh spinach contaminated with *Escherichia coli O157:H7*. Although this outbreak involved a perishable food, the food was sold in a package. The traceback investigation was facilitated because several consumers who had become ill still had packages of fresh spinach in their refrigerators. The information on those packages ultimately led investigators to the spinach processors. By looking at the processor's records, the investigators were able to identify the implicated farms associated with the identified production lot of bagged spinach. This is an example of a traceback of medium complexity that took a little longer than the peanut butter example but which was aided by the information on the package.

Salmonella *Saintpaul*

The current outbreak investigation, which initially focused on certain types of raw tomatoes, provides an example of one of the most difficult traceback investigations.

On May 26, CDC informed FDA of the hypothesis of a possible association between ill persons and the consumption of raw tomatoes. On May 31, CDC formally notified FDA of a significant statistical association between consumption of certain types of tomatoes and a multi-state outbreak of *Salmonella* Saintpaul infections, and FDA decided to initiate investigations attempting to trace the tomatoes reported to have been eaten by ill persons back to their sources. Raw tomatoes are a perishable commodity and, thus, are unlikely to be in the consumer's home after the consumer becomes ill, obtains a diagnosis, and a foodborne illness outbreak is identified. Further, raw tomatoes are often sold loose, without any form of packaging. In this case, we learned that many tomatoes had been shipped to washing, packing, and repacking facilities where they were or might have been commingled with other tomatoes from many different sources. This commingling has the potential to multiply the quantity of food that is contaminated. It also increases the difficulty in determining which tomatoes were the source of the illnesses. A further complicating factor was caused by entities in the supply chain using different terminology to describe the tomatoes. For example, one party might describe the tomatoes as "hothouse" or "greenhouse" tomatoes while the next party in the chain might describe them simply as "tomato bulk." Yet another party might use a descriptor such as "green six-by-six." This lack of consistency in nomenclature makes it more difficult and more time-consuming to connect the links in the chain and to identify the source of the tomatoes.

***Salmonella* Saintpaul Outbreak Investigation**

Since May 31, many FDA employees in the field and at headquarters have been working continuously on the outbreak investigation to identify the source(s) of the illnesses. To help the public distinguish tomatoes not associated with the outbreak, FDA adopted the policy of specifically designating the types of tomatoes implicated in the outbreak as well as listing growing areas that were not part of the outbreak. Based on information provided by CDC, state officials, and from our own investigations, FDA has been regularly updating the information on its website, conducting media calls, and updating our Federal, state, and local partners, along with the affected industries.

As is our usual course, FDA's recommendations for consumers were focused on protecting public health and were based on epidemiological information from the state agencies and CDC.

From them we learned initially that illness was statistically linked to consumption of raw tomatoes. Ill persons reported consuming red round, red plum, and red Roma tomatoes. Because few ill persons had reported consuming other types of tomatoes, we advised consumers that these other types of tomatoes had not been implicated. We also had information from our ongoing traceback investigation that a limited number of geographic regions were being identified as possible sources of the tomatoes that were associated with the outbreak. A number of states informed FDA that growers within their jurisdictions either were not shipping tomatoes during the period of concern or they would not have shipped tomatoes as widely as would have been required to account for this multi-state outbreak. This aggregated information allowed us to advise consumers that they could eat certain types of tomatoes and all tomatoes from a number of countries and states (or from certain regions within a state) with confidence that they were not from the sources that were identified in the traceback investigation.

On June 30, CDC advised FDA that their epidemiological data from the ongoing outbreak indicated that jalapeño and Serrano peppers also might be implicated in the outbreak. Accordingly, on July 1, FDA expanded its investigation into peppers as well and advised consumers at increased risk of complications from infection (elderly persons, infants, and persons with impaired immune systems) not to consume raw Serrano and jalapeño peppers.

On July 17, FDA lifted its warning to consumers to avoid certain types of raw tomatoes. FDA announced that tomatoes currently on the market are not considered to be a possible source of the continuing *Salmonella* Saintpaul illnesses because the tomatoes coming to market now are harvested from different growing areas than those initially implicated. We also reiterated our recommendation to consumers at increased risk of infection to avoid eating Serrano and jalapeño peppers while the investigation continues.

On July 21, FDA announced that one of the jalapeño pepper samples we tested is a genetic match with the outbreak serotype, *Salmonella* Saintpaul. This finding is strong evidence that jalapeño peppers were involved in the outbreak; however, it does not exonerate other foods. While this one positive sample does not provide the whole story, this genetic match is an important break in the case that we hope will help us pinpoint the source of the contamination. FDA obtained the jalapeño pepper

sample during an inspection of the Agricola Zaragoza produce distribution center in McAllen, Texas. The company voluntarily issued a recall. The pepper was grown in Mexico, but that did not mean the pepper was contaminated in Mexico. We continued to investigate the source of the contamination.

Based on this finding, on July 21, FDA advised consumers to avoid eating fresh jalapeño peppers and foods made with them. This advisory did not include cooked or pickled jalapeño peppers. As the traceback investigation continued into the source of the pepper's contamination, the review of the current traceback investigation and harvesting dates, matched with the dates that people became ill, combined to indicate that the contaminated jalapeño pepper originated in Mexico and not at the plant in Texas. Therefore, on July 25, FDA announced that there was no indication that domestically grown jalapeño or Serrano peppers are implicated in the outbreak. We updated our consumer advisory to indicate that our advice to avoid raw jalapeño and Serrano peppers now applies only to peppers grown, harvested, or packed in Mexico. In addition to domestically grown raw jalapeño and Serrano peppers, canned, pickled, and cooked jalapeño and Serrano peppers from any and all geographic locations also are not connected with this outbreak. Serrano and jalapeño peppers are often grown together, are often served in the same foods, and often travel along the same distribution routes. The finding of the contaminated jalapeño pepper does not mean that Serrano peppers were not also associated with the outbreak.

We are working with state regulatory agencies and the food industry, including restaurants, grocery store chains, and wholesalers to ensure that this new, more narrowly focused advisory is clearly understood by everyone. Our investigation into the source of the contamination is ongoing. We will continue to refine our consumer guidance as our investigation continues.

I would now like to describe some of our recent activities to improve traceability of fresh produce.

Recent FDA Activities To Improve Traceability of Fresh Produce

The ability to trace pathways of any food, including tomatoes and other fresh produce, through every point in the supply chain is crucial for limiting foodborne illness in an outbreak, for preventing future outbreaks, and for reducing the impact on the segments of the industry whose products were not associated with the illnesses. The pathways that fresh produce travels from field to consumer have become increasingly complex, with items sometimes changing hands many times in the supply chain.

FDA formed an internal multi-Center group to meet with external entities (such as industry, consumers, and Federal, state, local, and foreign governments) to better understand the universe of track and trace systems that are currently in use or being developed. FDA has reached out to various organizations, including trade associations and consumer groups, to gain a better understanding of best industry practices for traceability, including the use of electronic and other technologies that speed and enhance the traceback process and the use of systems that connect all the links in the produce supply chain. FDA is using this information to develop recommendations for the fresh produce industry to use to improve its internal traceback systems. We plan to hold a public meeting in the fall to further the exchange of information on available technology and best practices for enhanced traceability.

We have been working extensively with states and the fresh produce industry to encourage incorporation of traceability procedures and technology. For example, FDA assisted the Florida Tomato Commission and the University of Florida/Institute of Food and Agricultural Sciences in the development of Florida's Tomato Best Practices Manual. This Manual incorporates Good Agricultural Practices, Good Handling Practices, and traceability recommendations for industry. The Manual formed the basis of the State of Florida's tomato safety rule.

Another recent example is the final guidance for the fresh-cut produce industry, which FDA issued this year. The guidance includes a section on tracebacks and a section on documentation and record-keeping. FDA also has provided industry its "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations," which is used by our investigators.

Last month, FDA issued a Request for Applications to provide funding to six states to establish Food Protection Rapid Response Teams to investigate multi-state outbreaks of foodborne illness. Enhancing the infrastructure of state food protection programs and strengthening joint Federal/state responsiveness at a local level are an important way to protect consumers by expediting traceback investigations.

We will continue to work with Federal, state, local and international food safety partners and with industry to develop guidance, conduct research, develop edu-

cational outreach materials, and initiate other commodity-, practice-, or region-specific programs to enhance the safety of fresh produce.

Action Plan for Import Safety and Food Protection Plan

To enhance safety across the range of imported consumer products, last November, Secretary Leavitt presented to the President an Action Plan for Import Safety (Action Plan) which reflects the input of twelve Departments and Agencies and provides recommendations to enhance the safety of imported products. In conjunction with the Action Plan, FDA released the Food Protection Plan, which provides a framework to identify and counter potential hazards with respect to both domestic and imported food. Achieving the food safety enhancements identified by these plans will require the involvement of all our food safety partners—Federal, state, local, tribal, and foreign governments; industry; academia; consumers; and Congress. Both Plans build in safety measures across a product's lifecycle, from the time a food is produced to the time it is distributed and consumed. They encompass three core elements: prevention, intervention, and response.

The Food Protection Plan identified ten legislative authorities necessary for achieving full implementation. We encourage Congress to provide these authorities, which would:

- Allow FDA to require preventive controls against intentional adulteration at points of high vulnerability in the food chain;
- Authorize FDA to issue additional preventive controls for certain high-risk foods;
- Require food facilities to renew their FDA registrations at least every 2 years and allow FDA to modify the current food product categories for purposes of registration;
- Authorize FDA to accredit highly-qualified third parties for voluntary food inspections;
- Require a new reinspection fee from facilities that fail to meet current Good Manufacturing Practice (cGMPS) requirements;
- Empower FDA to require electronic import certificates for shipments of designated high-risk products from countries with which FDA has concluded an agreement on a certification program that provides a level of safety sufficient to meet FDA standards;
- Allow FDA to charge export certification fees for food and animal feed to improve the ability of U.S. firms to export their products;
- Authorize FDA to refuse admission of imported food if FDA inspection access is delayed, limited or denied;
- Empower FDA to issue a mandatory recall of food products if voluntary recalls are not effective; and
- Give FDA enhanced access to food records during emergencies.

Last month, the Secretary announced that the Administration is increasing its Fiscal Year (FY) 2009 budget request for FDA by $275 million. This increase brings the Administration's total proposed increase in FDA's budget, including user fees, for FY 2009 to $406.3 million, a 17.9% increase over FY 2008. A large portion of this increase ($125 million) will be used for food safety and will allow FDA to intensify actions to implement the Food Protection Plan. This is in addition to the $42.2 million increase proposed for food protection in the budget announced in February 2008.

On June 30, the President signed the FY 2008 Supplemental Appropriation into law. This appropriation act provided $150 million for FDA, and these resources will allow FDA to accelerate its transformation of its regulatory strategies to meet the challenges of the evolving global marketplace for food and medical products. The funds in the supplemental appropriations act will allow FDA to further implement the Food Protection Plan, the Action Plan for Import Safety, and important medical product priorities. It will specifically allow FDA to expand its food safety activities, such as increasing inspections, performing research on mechanisms of food contamination, establishing offices overseas to build capacity with our foreign partners, developing and validating more rapid detection tools, enhancing our information technology systems to support interoperable databases, and enhancing FDA's ability to identify and target the greatest threats from intentional and unintentional contamination.

Conclusion

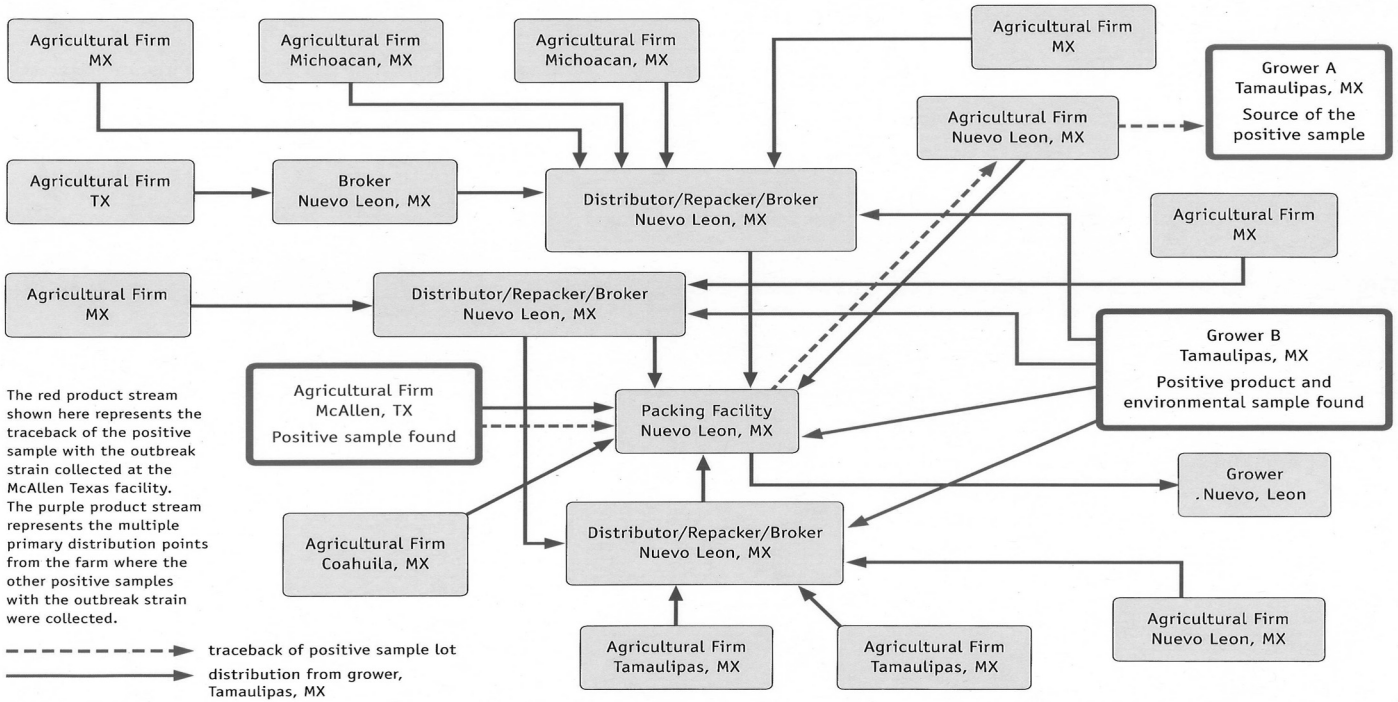
FDA is working hard to ensure the safety of food, in collaboration with its Federal, state, local, tribal, and international food safety partners, and with industry, consumers, and academia. As a result of this effective collaboration, the American food supply continues to be among the safest in the world. However, the *Salmonella* Saintpaul foodborne illness outbreak underscores the challenges we face. Once our investigation has determined the cause of the *Salmonella* contamination, we will examine what other measures are needed.

In the meantime, we have been making progress and are moving forward to implement the Plans. We recently issued 6 month updates that demonstrate the specific actions we have been taking to implement the Plans. For example, we have formed a Risk-Based Steering Committee with the charge of ensuring that a comprehensive risk-based approach is taken with regard to food protection. We are holding a 50 state meeting in August to share information and develop strategies for implementing the Food Protection Plan and to enhance future collaborations between Federal, state, and local partners. Progress also has been made in identifying food vulnerabilities and mitigation strategies; for example, FDA has identified several natural plant bacteria that are effective in preventing contamination of tomatoes with *Salmonella* Newport. FDA scientists received training and instruments to rapidly detect and accurately identify *Salmonella* serovars using a new molecular method. We have strengthened the response to food safety threats by providing incident command system training to our FDA offices around the country and to states and by developing templates to enhance communication during a food recall. We will continue to strive to reduce the incidence of foodborne illness to the lowest level possible.

Thank you for the opportunity to discuss FDA's continuing efforts to enhance food safety and traceability. I would be happy to answer any questions.

Salmonella Saintpaul Outbreak Traceback & Distribution

Partial view of the traceback & distribution of peppers from Mexico: July 16 – July 30, 2008



The CHAIRMAN. I am sure the Committee will have a series of questions. We have just gotten called for a vote. I would like Dr. King to be able to present his oral testimony before questions, and we will take that at this time and then we will come back, because I know the Committee as do I have a number of questions with regard to the announcement you have just made as well as how consumers can protect themselves as well as if you know the cause of the water contamination in Mexico.

Dr. King, please proceed now.

STATEMENT OF LONNIE J. KING, D.V.M., DIRECTOR, NATIONAL CENTER FOR ZOONOTIC, VECTOR-BORNE AND ENTERIC DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, D.C.

Dr. KING. Thank you very much, Mr. Chairman. Good afternoon. I am Lonnie King. I am the Director of the National Center for Zoonotic, Vector-borne and Enteric Diseases at the CDC. Thank you for the invitation to address the Subcommittee today.

First, let me offer my sympathies to all families who have been adversely affected by this outbreak and also I understand the frustration of many of the food-producing and serving industries who work so very hard to produce and serve safe produce.

CDC leads Federal efforts to gather data and investigate foodborne illnesses. Much of what CDC does depends on the critical relationships with a broad range of partners, food safety regulatory agencies, in particular with the FDA, the USDA's Food Safety Inspection Service and with the state and local public health departments.

Salmonella is a group of bacteria that is widespread, mostly in the intestines of birds, reptiles and mammals. There are some 2,500 subtypes, or serotypes. *Salmonella* is the second most common bacterial cause of foodborne illness in this country. The current outbreak of *Salmonella* caused by the serotype Saintpaul is relatively uncommon as a serotype, causing only about one percent of all reported *Salmonella* infections each year. This outbreak is the largest foodborne outbreak in the United States in the past decade. Its investigation has been especially complex, difficult and, unfortunately, prolonged.

CDC first learned about the outbreak on May 22, 2008, when the New Mexico Department of Health reported illnesses in four individuals confirmed as *Salmonella* Saintpaul. New Mexico posted the information about this unusual number of *Salmonella* Saintpaul cases to PulseNet, a national network of public health and food regulatory agency laboratories used to detect foodborne disease outbreaks. This information allowed state laboratories to compare the specific DNA fingerprint found in New Mexico to their own cases of *Salmonella* and to report any cases where there may be matching fingerprints. The very next day, Texas and Colorado reported cases with matching fingerprints. Investigators in New Mexico, Texas and CDC began a multi-state outbreak investigation. Epidemiologists conducted hypothesis-generating interviews with ill persons to collect information about many possible sources of infection. Results of this first series of interviews indicated raw toma-

toes were the most commonly consumed food, leading to the hypothesis that they are possible source of illness. Following these initial interviews, case control studies comparing what ill and healthy persons reported eating were conducted. By May 31, preliminary results of the first case control study showed that illnesses were significantly associated with the consumption of raw tomatoes.

On June 4, CDC received the first report of a possible restaurant cluster and subsequently learned of additional clusters. Between June 18 and June 20, there was also a large surge of reported cases from Texas. The geographic concentration of illness in the Southwest and in Native American and Hispanic persons along with a strong association with the consumption of Mexican-style food in restaurants and the apparent continuation of this outbreak after the alert regarding tomatoes led to the hypothesis that a food item commonly consumed with tomatoes could also be producing this illness.

Investigations then focused on the recently identified clusters and a second multi-state case control study of persons who became ill after June 1 was initiated. The results of the case control study indicated a strong link to fresh produce items used in Mexican cuisine but did not point clearly to a specific item. After additional epidemiologic investigations of a cluster of illness in Texas, the FDA began their tracebacks on peppers, and on June 21, the FDA announced they had isolated the outbreak strain of *Salmonella* Saintpaul from a sample of jalapeño peppers, and we now know that other information has come forward. This outbreak continues as does the investigation. The active field investigations by the CDC, state and local health departments focusing on identifying clusters of cases and the FDA's tracebacks on jalapeños, tomatoes and other possible sources are providing new information almost on a daily basis.

This outbreak has been particularly challenging. First, there is an inherent delay when a person becomes ill with *Salmonella* and when results of the tests are reported to PulseNet. For half the cases in this outbreak, it took more than 16 days from onset of illness to posting the test results on PulseNet. Second, people have difficulty remembering exactly what foods they ate and remembering specific ingredients in those foods was even more difficult, especially in dishes that were prepared by someone else. Third, the foods in question are often eaten together, so exposures to one item often means exposures to all the items. Finally, perishable foods consumed by ill persons were often not available for testing.

As of July 29 at 9 p.m., 1,319 persons infected with *Salmonella* Saintpaul have been identified in 43 states, the District of Columbia and Canada. At least 255 persons have been hospitalized with two deaths possibly linked to this outbreak. At present, we believe that jalapeño peppers are the cause of some of these clusters and could be a major vehicle that we need to look at as part of this outbreak. Fresh serrano peppers, with this new information today from FDA, not only remain under investigation but now we have a smoking gun, it appears.

It also appears likely that more than one food vehicle has been involved in this outbreak. I think that has been confirmed by FDA

today. By themselves, tomatoes cannot explain this entire outbreak nor do jalapeño peppers explain all of the clusters. The outbreak is ongoing but fortunately fewer new illnesses are reported each day.

In conclusion, the outbreak illustrates the importance of existing public health networks: the laboratories that use and perform PulseNet fingerprinting; the epidemiologists conducting the investigations; the multidisciplinary approach to the investigation and the close communication and collaboration among state, local and Federal officials. We balance the rapid release of information on the sources of illness against the potential negative consequences to consumers, food growers, producers and industry. CDC is prepared to continue to work with its regulatory authorities, state and local partners, food and environmental microbiologists and the food industry to find long-term solutions to this very challenging problem.

I appreciate being here today, and your kind invitation to testify. After your vote I would be happy to answer any questions you may have.

[The prepared statement of Dr. King follows:]

PREPARED STATEMENT OF LONNIE J. KING, D.V.M., DIRECTOR, NATIONAL CENTER FOR ZOONOTIC, VECTOR-BORNE, AND ENTERIC DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, D.C.

Introduction

Good afternoon, Chairman Cardoza and Members of the Subcommittee. I am Dr. Lonnie King, Director of the National Center for Zoonotic, Vector-borne, and Enteric Diseases, at the Centers for Disease Control and Prevention. Thank you for the invitation to address the Subcommittee on CDC's activities related to the prevention of foodborne disease and CDC's role in the response to the current outbreak of *Salmonella* Saintpaul infections associated with fresh produce. First, let me offer my sympathies to all the families who have been adversely affected by this outbreak. Second, I understand the frustration of many in the food producing and serving industries, who work very hard to produce and serve safe produce. This investigation has been especially difficult and prolonged. We have faced many challenges with this particular foodborne outbreak. I will discuss these challenges in more detail after describing the CDC's response to the *Salmonella* Saintpaul outbreak.

Background

Foodborne disease presents a continuing challenge to public health. CDC estimates that approximately 76 million U.S. residents get sick, 325,000 are hospitalized, and 5,000 die each year from foodborne illness. Overall, foodborne diseases appear to cause more illnesses but fewer deaths than previously estimated in the 1980's. More than 250 different foodborne illnesses have been described. Most are caused by a variety of bacteria, viruses, and parasites. Some foodborne illnesses are caused by toxins or chemicals.

As an agency within the Department of Health and Human Services (HHS), CDC leads Federal efforts to gather data on foodborne illnesses, investigate foodborne illnesses and outbreaks, and monitor the effectiveness of prevention and control efforts. CDC is not a food safety regulatory agency but works closely with the food safety regulatory agencies, in particular with HHS's Food and Drug Administration (FDA) and the Food Safety and Inspection Service within the United States Department of Agriculture (USDA). CDC also plays a key role in building state and local health department epidemiology, laboratory, and environmental health capacity to support foodborne disease surveillance and outbreak response. Notably, CDC data can be used to help document the effectiveness of regulatory interventions.

Much of what CDC does depends on critical partnerships with state and local public health departments who collect surveillance data and investigate most outbreaks themselves. CDC has worked with the Association of Public Health Laboratories (APHL) and the Council of State and Territorial Epidemiologists (CSTE) to strengthen networks for foodborne disease surveillance. For example, PulseNet, the

national network for molecular subtyping of foodborne bacteria coordinated by CDC, empowers every state health laboratory to test strains of bacteria from sick persons in that state, and to compare them with DNA "fingerprint" patterns in the national database at CDC. This has greatly improved the ability to detect clusters of illness that may be related, even if they are dispersed across multiple states.

OutbreakNet is the group of public health officials at state health departments and CDC who regularly investigate foodborne outbreaks. The OutbreakNet team at CDC coordinates the investigation of the large, multi-state clusters and works with the foodborne disease epidemiologists in each state to evaluate clusters that PulseNet detects. The OutbreakNet team at CDC also manages the electronic Foodborne Outbreak Reporting System (eFORS). Established in 2001, eFORS is a web-based outbreak surveillance system through which state and local health departments voluntarily submit completed reports of foodborne disease outbreak investigations to CDC.

CDC's Environmental Health Specialists Network (EHS-Net), a collaborative effort with FDA and nine states, assists state health departments in their efforts to improve the practice of environmental health service programs; participants assess policies and practices of retail foodservice establishments that could lead to or prevent foodborne outbreaks. FoodNet is a network that is a collaborative effort among CDC, ten states who participate in CDC's Emerging Infections Program, the Department of Agriculture's Food Safety and Inspection Service (USDA–FSIS), and FDA; it provides the most accurate surveillance data for determining the burden of infections, conducts scientific studies to better understand the sources for the many illnesses that occur outside the outbreak setting, and monitors trends in infections as new control measures are instituted. We have PulseNet to detect possible outbreaks, OutbreakNet to investigate and report them, and FoodNet to track general trends and define where more effective prevention strategies are needed.

CDC also works with a broad range of other partners to improve capacity and knowledge regarding foodborne disease control and prevention. In collaboration with the National Environmental Health Association (NEHA), CDC conducts team training programs for local and state health department officials including specialists in environmental health, laboratory, and epidemiology. CDC works with the World Health Organization (WHO) and a variety of other international partners to conduct similar training programs in other countries through the WHO Global *Salmonella* Surveillance program. CDC supports the Council to Improve Foodborne Outbreak Response (CIFOR) which was created to help develop model programs and processes that will facilitate the investigation and control of foodborne disease outbreaks. CSTE and the National Association of County and City Health Officials (NACCHO) are co-chairing CIFOR, and it includes representatives from CDC, FDA, USDA, APHL, NEHA, the Association of State and Territorial Health Officials, and the Association of Food and Drug Officials.

Salmonella

Salmonella is a group of bacteria that is widespread in the intestines of birds, reptiles, and mammals. *Salmonella* bacteria have been known for over 100 years to cause human illness. *Salmonella* is the second most common bacterial cause of foodborne diseases in the country, causing 15 reported laboratory-confirmed infections per 100,000 population in 2007, as measured in FoodNet. There are many different kinds, or serotypes, of *Salmonella* bacteria. Serotyping is a classification system based on differences in structures on the surfaces of bacteria or other disease-causing agents. Serotyping divides *Salmonella* into more than 2500 different serotypes, some common and some rare. For example, during 1996–2006, *Salmonella* serotype *Typhimurium* and *Salmonella* serotype *Enteritidis* typically caused 41% of reported *Salmonella* illnesses each year in the United States. *Salmonella* serotype Saintpaul is relatively uncommon, causing only 1% (about 400) of all reported laboratory-confirmed *Salmonella* infections each year. Each serotype can be further sub-divided into many more subtypes based on their DNA.

Salmonella infections have often been associated with meat, poultry, eggs, and raw milk; these products are derived from animals that can carry *Salmonella*. *Salmonella* has also been associated with fresh produce and other plant-derived foods. Fresh produce can be an important source of other types of foodborne infections as well; for example, *Escherichia coli O157*, another bacterial agent, caused a large outbreak of illness linked to spinach in 2006. *Salmonella*, like other pathogens that are commonly foodborne, can also be transmitted in other ways, such as from contact with reptiles or other animals or between children at a child care center.

Many foodborne infections, including *Salmonella*, occur in persons without obvious connections to each other. These are called sporadic cases; determining the source of a single sporadic case can be very difficult. Cases of similar infections can

also occur as a group or "cluster." Epidemiological investigation of clusters of possibly related cases permits public health officials to determine if the cases were connected and, specifically, if they were linked to food. A cluster of foodborne illnesses is considered an outbreak if an investigation demonstrates that two or more infections caused by the same agent are linked to the same food.

In general, for a foodborne illness to be recognized by the public health surveillance system, a patient must seek medical attention, the physician must decide to order diagnostic tests, and the laboratory must conduct the test using the appropriate procedures and report the results to a health department. Many ill people do not seek medical attention, and of those who do, many are not tested. Therefore, many cases of foodborne illness are neither diagnosed nor reported. For example, *Salmonella* infection has been estimated to cause about 1.4 million foodborne illnesses annually, however, only about 40,000 laboratory-confirmed cases of *Salmonella* are reported to CDC each year.

Regular reporting about detection of *Salmonella* serotypes from ill persons is critical in determining whether a change in incidence has occurred signaling a possible outbreak. Each serotype can be further divided by DNA analysis into subtypes. The subtypes are distinguished by different DNA fingerprint patterns. The fingerprint pattern is determined with a test known as pulsed-field gel electrophoresis (PFGE). PFGE is a very good method for discriminating between epidemiologically unrelated isolates of this serotype. Public health laboratories determine the serotype and PFGE patterns for *Salmonella* strains and share the patterns through PulseNet. PulseNet plays a vital role in surveillance for and investigation of widely dispersed foodborne illness outbreaks that were previously difficult to detect. The laboratories participating in PulseNet are in state health departments, some local health departments, USDA, and FDA. When a clinical laboratory detects *Salmonella* from an ill person, a sample is sent to a state or local PulseNet laboratory where it is serotyped and DNA fingerprinted. The laboratory compares the fingerprint pattern to that of other *Salmonella* strains from people in that area and uploads the pattern electronically to the national PulseNet database maintained at CDC, where it can be compared with the patterns from all over the country. This gives us the capability to detect an unusual number of *Salmonella* cases with the same pattern in a single area or in multiple states. The system can identify patterns even if the affected persons live far apart, which is important given the widespread U.S. food distribution systems. The pattern causing the current outbreak is usually quite uncommon, and was identified only 25 times in 2007, among the 400 *Salmonella* Saintpaul infections that were reported.

It is important to recognize there is an inherent delay between when a person becomes ill with *Salmonella* infection and when the results of testing are reported to PulseNet. In the current *Salmonella* Saintpaul outbreak, the median number of days between when the illness began and when the fingerprint pattern was reported to PulseNet has been 16 days. It takes time for a person to become ill, seek medical care, submit a sample for testing; it then takes time for the clinical laboratory to detect *Salmonella* and send the strain to the public health laboratory; it then takes time for the public health laboratory to perform serotyping and DNA fingerprinting.

The *Salmonella* Saintpaul Outbreak

On May 22, 2008, the New Mexico Department of Health contacted CDC to report that they were investigating illness in four persons with *Salmonella* Saintpaul strains that had the same DNA fingerprint pattern, and that *Salmonella* strains from 15 more persons were still being characterized. The DNA fingerprint determined by PFGE was rare. It usually occurs no more than 2–3 times a month in the whole United States, so four or more in one location was unexpectedly high. New Mexico posted the information about the unusual number of *Salmonella* Saintpaul cases to the PulseNet web board on May 22, so that all state laboratories could quickly compare the DNA fingerprint pattern with that of their own strains, and CDC requested that states report any strains that matched the DNA fingerprint pattern. That next day, Texas and Colorado reported cases with this PFGE pattern, and investigators in the New Mexico Department of Health, the Navajo Nation, the Indian Health Service, the Texas Department of State Health Services, and CDC began a multi-state investigation. Daily multi-state conference calls began and continued through July, with states being added to the calls as their cases were identified. The investigation was initially coordinated by the New Mexico State Health Department, because most identified cases were in that state. On June 3, after more states in different regions of the country reported cases, CDC assumed this role of the investigation.

The initial steps in an epidemiological investigation are to collect information from which hypotheses can be generated about the possible source of the outbreak.

As cases with the same DNA fingerprint pattern were identified, epidemiologists interviewed patients to determine what specific foods or other exposures they may have had in common. The New Mexico Department of Health, Texas Department of State Health Services, and the Indian Health Service conducted hypothesis-generating interviews from mid to late May among 19 ill persons from whom *Salmonella* Saintpaul with the DNA fingerprint matching the outbreak strain had been isolated during May 2008. These interviews collected information about possible sources of infection, including attendance at gatherings, travel, daycare contact, contact with reptiles and/or other household pets, contact with farm animals, sources of drinking water, history of swimming, eating at restaurants, and specific food consumption history for approximately 200 food items; the interviews also included open-ended questions about what ill persons had eaten, meal by meal, in the days before they became ill. The preliminary results of this first series of interviews indicated raw tomatoes were the most commonly consumed food item (reported by 84% of ill persons) leading to the hypothesis that they were a possible source of the illnesses. CDC informally advised the FDA on May 26 of the hypothesis of a possible association between ill persons and the consumption of raw tomatoes.

In the next steps of the investigation, analytic epidemiologic studies were conducted to test the hypotheses generated by case finding. These studies compare the frequency with which ill persons report exposure to a particular food item to the frequency with which healthy persons (or controls) report that exposure. If the ill group is more likely than the well group to report exposure to a particular food, a statistical test can show how likely this finding would have occurred by chance alone. Additional information about the likelihood of that particular food actually being contaminated, the biological plausibility of it causing the illnesses, the fit of the cases with the distribution of the food, and other factors may enter into the professional judgment of whether the food with a statistically significant association with cases is likely to explain the outbreak. Preliminary findings from these types of studies guided subsequent next steps of the investigation while additional statistical analyses are being conducted on the data gathered. It is important to keep in mind at this stage of investigation, as analyses are conducted and interpreted, that initial findings and hypotheses may change. As is common in outbreak investigations but especially true for foodborne outbreaks, the process of case finding, hypothesis generating, and hypothesis testing is an iterative process; each step informs subsequent steps and often leads to new investigative avenues.

In the next phase of the investigation, in late May, the New Mexico Department of Health, the Texas Department of State Health Services, and the Indian Health Service, in consultation with CDC, conducted a multi-state case-control study. The data from the earlier 19 hypothesis generating interviews were used to identify which foods were most frequently consumed by the ill people. The questionnaire used in this case-control study included the 14 foods[1] reported by half or more of the ill people in the hypothesis-generating interviews. These questionnaires were administered to approximately 150 people. By May 31, preliminary results of the case-control study demonstrated that illness was significantly associated with consumption of raw tomatoes (88% of cases consumed raw tomatoes compared with 64% of the controls, a very strong statistical difference). FDA was formally notified of this significant association between tomatoes and infection. Statistical analysis of these data showed that illness was associated with consumption of raw tomatoes independent of consumption of tomatoes in salsa, guacamole, or pico de gallo.

The next step in the investigation was to trace the implicated food back to its sources, looking for points where contamination might have occurred, and to determine if there is a single farm, processing location, or other point in distribution system that could explain all the illnesses providing additional evidence supporting the food item as a cause of the outbreak. Tracing the implicated food back from consumption through preparation, to distributors, and source can also help determine how the contamination occurred, stop distribution of the contaminated product, and prevent further outbreaks from occurring. On May 31, 2008, FDA decided to initiate investigations attempting to trace the tomatoes reported to have been eaten by ill persons back to their sources. Tracebacks began on June 1, 2008. Throughout the investigation there has been ongoing communication between CDC and FDA regarding these traceback investigations.

On June 4, CDC received the first report of a possible restaurant cluster. Four cases in Illinois appeared to be related to exposure to a single restaurant. Such clusters were otherwise absent in the early part of the outbreak. The outbreak continued and expanded. Over the next few weeks, hundreds more cases were reported

[1] Food items examined included tomatoes, eggs, ice cream, potatoes, milk, tortillas, cold breakfast cereal, raw onions, salsa, avocado, guacamole, ground beef, chicken, and lettuce.

from an increasing number of states. The average number of persons who became ill between May 20 and June 10 was 33 per day. New information emerged as each case was reported and interviewed by local or state health department authorities.

On June 16, CDC learned about the first recognized large cluster linked to a single restaurant, approximately 30 illnesses, in Texas. Between June 18 and June 20, Texas reported an additional 134 cases. This surge in the number of cases from Texas highlighted the geographic concentration in the Southwest and in Native American and Hispanic persons, which did not have a clear explanation. This information, along with the strong association between illness and consumption of Mexican-style foods in restaurants coming from continued analysis of the case-control studies, and the apparent continuation of the outbreak after the alert regarding tomatoes, led to the hypothesis that a food item commonly consumed with tomatoes could be causing illnesses. Epidemiologists decided to focus the investigations on the recently identified clusters and to conduct a case-control study of persons nationwide who became ill in June. CDC offered assistance to the Texas Department of State Health Services; a CDC Epi-Aid team arrived in Texas on June 19.

By July 7, 32 clusters of *Salmonella* Saintpaul infections with the PFGE pattern of the outbreak strain had been identified in 13 states and the District of Columbia. Twenty-six were associated with Mexican-style restaurants. Most clusters had fewer than five ill persons. Three clusters had more than ten ill persons, and analytic studies have been conducted on these. In one of these larger restaurant clusters, illnesses were linked to consumption of an item containing fresh tomatoes and fresh jalapeño peppers. In the other two, illnesses were linked to an item containing fresh jalapeño peppers but neither raw tomatoes, nor fresh cilantro. Among the 22 smaller clusters with data on the presence of food items in the venue, four did not serve jalapeño peppers. Together, these investigations indicated that jalapeño peppers caused some illnesses, but did not appear to explain all illnesses. Raw tomatoes, fresh serrano peppers, and fresh cilantro also remained under investigation. We were strongly considering the probability that more than one food item caused illness.

CDC and state and local health departments conducted a second case-control study to investigate the possibilities that illness was related to consuming foods in Mexican-style restaurants, and that illness was associated with consuming, in a restaurant, event, or home, a range of produce items that are often served with tomatoes, including freshly made salsa, fresh jalapeño peppers, and fresh cilantro. This was a large multi-state study, with over 400 interviews, with 141 interviews from persons who had become ill on or after June 1 and 281 interviews from healthy controls available for preliminary analysis. The study showed that illness was strongly associated with eating at a Mexican-style restaurant. In a preliminary statistical analysis that considered the entire dataset, consumption of fresh tomatoes, jalapeño peppers, and cilantro were each shown to be risk factors in subgroups but no single suspect exposure statistically dominated the others in explaining all cases. Thus, this study indicated a strong link to fresh produce items used in Mexican cuisine but did not point clearly to one specific item.

As new restaurant-associated clusters were reported, CDC and state health departments investigated them aggressively. By July 16, CDC investigators were assisting state and local health officials in field investigations of restaurant clusters in North Carolina, Missouri, Texas, and New York City. In addition, another CDC team was investigating illnesses in New Mexico.

As the epidemiological investigation expanded, the FDA also expanded their traceback and sampling efforts. FDA began their tracebacks on peppers identified by the outbreak investigations conducted by the states and CDC. CDC sent two medical epidemiologists to FDA to directly participate in analyzing findings from the tracebacks and connect them with the CDC epidemiologic data. On July 21, the FDA announced that they had isolated the outbreak strain of *Salmonella* Saintpaul from a sample of jalapeño peppers. The epidemiologic data from a Texas cluster of ill persons led to this specific traceback investigation. In most *Salmonella* outbreaks that are linked to a particular food, however, *Salmonella* is never detected in the food. Detection of *Salmonella* in a food item that was implicated in an epidemiologic study provides strong evidence that this food item caused illnesses, though it does not exclude other foods as possible causes of illness.

Throughout the investigative process, to ensure that information was disseminated to the public as accurately and quickly as possible about health threats and other information related to this outbreak, CDC and FDA coordinated their communication strategies and messages and discussed these strategies in daily calls with state health officials. We balance the rapid release of information on sources of illness against the potential negative consequences to consumers, food growers, producers, and industry. Continued collaborations and communications between Fed-

eral agencies, state and local health departments, and all relevant stakeholders are essential.

Challenges Confronting the Outbreak Investigation

Every outbreak response is a challenge for everyone involved. This outbreak was particularly challenging in a number of ways. As already mentioned, it takes time for a case to be reported to public health authorities and then investigated. For half the cases in this outbreak, it took more than 16 days from when the person became ill to the when the DNA fingerprint of their *Salmonella* was added to the PulseNet database. The resulting delay sometimes prevented interviews from occurring while memories were still fresh. The precision of interviews by epidemiologists depend on the observations and memories of people about what they ate and what ingredients the dishes contained. People often have difficulty remembering exactly what foods they ate, and remembering specific ingredients in those foods is even more difficult, especially if the dish was prepared by someone else, or eaten in a restaurant. Another challenge has been that the foods in question are often eaten together—many salsa, guacamole, and pico de gallo recipes contain tomatoes, jalapeño peppers, and cilantro, so exposure to one item often means exposure to all three. When food items are mixed together and consumed in the same dish, all the items may be statistically linked to illness. In that case, it can be difficult or impossible to separate out the risk from individual foods without additional information such as microbiological culture or traceback of the foods. Although laboratory testing of foods might help identify the source of an outbreak, perishable foods that were consumed by ill persons were often not available to test. This is in contrast to outbreaks from frozen or processed foods which may still be present in someone's freezer or pantry weeks later. Finally, the traceback of fresh produce, such as tomatoes, through the supply chain can be very difficult and labor intensive. Doctor Acheson will be able to say more about this.

Status of Investigation

As of July 27, 1304 persons infected with *Salmonella* Saintpaul with the same fingerprint have been identified in 43 states, the District of Columbia, and Canada. At least 252 persons were hospitalized. Two deaths were possibly linked to the outbreak: A man in his eighties who died in Texas from cardiopulmonary failure had an infection with the outbreak strain at the time of his death. A man in his sixties who died in Texas from cancer had an infection with the outbreak strain at the time of his death.

Three larger clusters were intensively investigated as of July 7. In one, illnesses were linked to consumption of an item containing fresh tomatoes and fresh jalapeño peppers. In the other two, illnesses were linked to an item containing fresh jalapeño peppers and no other of the suspect items. Since then, detailed investigations of three other clusters indicate that jalapeño peppers do not explain all illnesses. In two of these more recent investigations, illnesses were linked to an item containing fresh serrano peppers and tomatoes, but not jalapeño peppers. In a third, illnesses were linked to an item that contained fresh jalapeños and tomatoes. Other clusters are under active investigation. At present, the information indicates that jalapeño peppers and serrano peppers grown, harvested, or packed in Mexico are the cause of some clusters and could be a major food vehicle for the outbreak. The U.S. Food and Drug Administration is advising consumers that jalapeño and serrano peppers grown in the United States are not connected with the current *Salmonella* Saintpaul outbreak and consumers may feel free to eat them without concern of illness. By themselves, tomatoes cannot explain the entire outbreak, nor do jalapeño peppers explain all the clusters. The outbreak appears to be ongoing, but with fewer new illnesses each day. New, very active field investigations by CDC in collaboration with state and local health departments, and FDA tracebacks on jalapeño peppers and tomatoes are providing new information almost daily. It appears likely that more than one food vehicle is involved. Although rare, more than one food has been implicated in foodborne outbreaks in the past, as observed in a group of 1998 outbreaks traced to imported parsley and cilantro from a single farm.

Conclusion

The current outbreak investigation of *Salmonella* Saintpaul is the largest foodborne outbreak in the United States in the past decade. The investigation has been especially complex, difficult, and prolonged. The outbreak appears to be slowing, but we are not able to say with confidence that the outbreak is over because of the reporting delay. The event illustrates how a large and widespread outbreak can occur, appearing first as individual cases, then as small clusters, and finally with large numbers of persons becoming ill if a widely consumed food is contaminated. It also illustrates the importance of existing public health networks: the lab-

oratories performing PulseNet fingerprinting; the epidemiologists conducting the investigation; the environmental health aspects of the outbreak; the multi-disciplinary approach to the investigation; and the close communication and collaboration among local, state, and Federal officials.

CDC is prepared to continue working with regulatory authorities, state and local partners, food and environmental microbiologist scientists, and the food industry to find long-term solutions to this challenging problem.

Thank you again for the invitation to testify before you today. I will be happy to answer any questions you may have.

The CHAIRMAN. Thank you, Dr. King. As you said, we do need to go vote now. I think both of you have said something very important, and that is that there is somewhat of a breakdown in the public health arena oftentimes.

My wife is a family doctor, and every time we have one of these outbreaks in the country, she laments the fact that so many of our states have had had a breakdown in their public health functions from budget cuts and other things. We now rely on the Federal network more than ever, and that isn't the purview of this Committee but it is certainly a problem for this Congress.

The Members will be back to ask questions right after we vote. I think there are two votes and so it should not be too long. We will reconvene this Committee right after the beginning of the second vote. We are temporarily in recess.

[Recess.]

The CHAIRMAN. We will reconvene this hearing. We don't have any Members of the Minority here at the present time but we do have their staff and I am sure they will be coming in and out as we proceed. I don't want to delay the questioning, however, any longer.

Dr. Acheson, as you have submitted this as part of your testimony, we will make this chart part of the official record of the hearing today.

Dr. ACHESON. Thank you.

The CHAIRMAN. Dr. Acheson, I would like to begin my questioning with you. Do your agencies measure the *Salmonella* contamination of tomatoes or any product on a regular basis to determine what the incidence rate, the background incidence rate of contamination is?

Dr. ACHESON. The FDA does what we call assignments in which we will, over a period of time, sample certain types of produce and other foods to develop data and information, particularly if it is foods that we have had concern about. We do not have an ongoing approach or process for gathering baseline data for different types of food items or fresh produce so it is targeted, depending on areas where we have seen problems in the past typically.

The CHAIRMAN. So say we have now called out tomatoes, as we have, and it was an erroneous callout, we believe, or was it an erroneous callout by your agency?

Dr. ACHESON. No. I think that is a very important point. As Dr. King pointed out, there was a very clear, methodical, scientific process by which CDC and the states reached a conclusion statistically that it was tomatoes at which point——

The CHAIRMAN. Let me stop you for just a second, if I might. You reached a statistical conclusion but you never found any direct evi-

dence, you have never found a contaminated tomato. Is that correct?

Dr. ACHESON. FDA has not found a contaminated tomato but we have now, as you have heard, found contaminated jalapeño and serrano peppers, so that is two food commodities, and we have also found places where serrano, jalapeño peppers and tomatoes have all passed through, distribution centers where they have all——

The CHAIRMAN. They have common distribution points?

Dr. ACHESON. Yes, common distribution points, and we have also identified a farm where all three are grown. So the possibility certainly exists that this was on more than one commodity. We now know it is on two, so it could very readily have been on three.

The CHAIRMAN. Well, I guess my point is, in future testimony that we are going to hear today, we are going to hear about risk-based inspection. Certainly certain commodities are going to be at higher risk for certain pathogens than others. Wouldn't it be good to sample and to know if we are having higher incidence from different areas? Wouldn't that be a good idea to do if we could?

Dr. ACHESON. Our whole approach of inspections and sampling and testing is based on risk. That is the whole philosophy. That is the philosophy of the intervention part of the Food Protection Plan, and likewise, where do you put your preventative strategies based on risk. I mean, that is just logical, common sense, good food safety practices, in our opinion. I suspect what you are wondering is, should we be doing some routine baseline sampling? If that is what you are asking me of certain types of higher risk produce, and it is certainly something that we have discussed internally, but it is very resource-intensive. Certainly as new resources are coming online in 2008, 2009, I think that is something that we would seriously look at being able to do. But to do that on an ongoing basis, to make it meaningful, it is resource-intensive.

The CHAIRMAN. I understand that, Dr. Acheson, but I think that is one of the things that we are going to delve into more and more as the hearing goes on today. Just this one outbreak, it is reported in testimony that I read that is going to be given here later in the afternoon, just this outbreak has caused the tomato industry over $300 million in losses. It caused 1,300 people to be off their job for an extended period of time. Two or three have lost their lives. That deserves a significant amount of the government's resources.

And so my question, I guess, is, is it not beneficial to sample the products that we grow, find out regions, for example? You know, we import an awful lot of our food from other places these days. It is important to note there are certain regions of Mexico that produce more outbreaks than others. We have to start getting a handle on this, I would suspect. So I invite your comment.

Dr. ACHESON. Well, thank you. I couldn't agree more that when you look at the societal cost of an outbreak like this, which is really what you are discussing in terms of the economic impact on the industry, and more importantly, the economic impacts on human health and life sometimes in an outbreak. Then when you ask those sorts of questions, clearly FDA would wholeheartedly agree with you that that is an important priority. Within the resources that we currently have, we are not able to do the level of baseline testing that you are suggesting. It is not that I am saying it is not

a good idea, it just simply isn't possible with the resources that we currently have available to set up the type of risk-based baseline testing of foods, both domestic and imported from areas of concern or foods of concern based on public health risk. It makes all kinds of sense to do that.

The CHAIRMAN. And so you agree that if the resources are available, it would make sense to conduct some food-based risk assessment throughout the food supply?

Dr. ACHESON. Absolutely, and that is one of the things that we are targeting to do in the Food Protection Plan from a risk-based approach.

The CHAIRMAN. Mr. Mahoney.

Mr. MAHONEY. Thank you, Mr. Chairman.

Dr. Acheson, Dr. King, thank you very much for being here today. Let me start out by thanking Dr. Acheson for the time that you spent with me updating me on this complex situation. It was very illuminating. I think that what has happened is that with the focus on national security and food security, I think people are now starting to see that they are very related to one another, and so I think the nation is very concerned. I also think the nation is very concerned about the fact that we need to protect our food, make sure that the product that is being put on our family's table is safe, and part of that is, how do we keep track of all this. But with the exciting news that you just gave us, the breaking news, I didn't see it on CNN but I am sure it is going to be soon, my first question is, are we at a point now where FDA feels they can clear tomatoes and take the overhang, the cloud off of tomatoes? Because as you know, we haven't found tomatoes to be a problem, but at the same time, you haven't exonerated tomatoes. And as a result, there continues to be economic damage because there has not been a clear statement on the part of the FDA that it is safe to eat tomatoes again.

Dr. ACHESON. What FDA has clearly stated, I hope, and if not, I will state it again, is that tomatoes that are currently being grown anywhere in the world, there is no evidence that they are linked to the outbreak, whether they are Mexican tomatoes or domestically grown tomatoes.

Mr. MAHONEY. And so with this information, you are not prepared to say that tomatoes weren't part of the problem?

Dr. ACHESON. Not at all. No, I think that we did not find a positive in tomato, as we have already heard, we have already discussed, but there are plausible explanations of how the *Salmonella* Saintpaul strain could have cross-contaminated both tomatoes and peppers. As I said just a moment ago, we found at least one farm that is growing serrano peppers, jalapeño peppers and tomatoes, and we know there are other distribution centers that they are going through.

Mr. MAHONEY. Okay. Well, I think you understand that there is a big difference between making a very clear statement as opposed to saying it is okay to eat tomatoes today. Because I think informed consumers are going to say, "Well, it is only safe to eat tomatoes today because we are not seeing the incidents and the problem could still exist out there."

Anyway, next question I have for you, the source of the positive sample, what kind of standards do these growers have down in Mexico? I mean, what food safety requirements do they have?

Dr. ACHESON. They, in order to import foods into the United States, should be practicing good agricultural practices. That is not a requirement, as I am sure you are aware; it is a guidance. But it is the standard that we hold farmers, growers, and packers to. If, when we inspect, we find that they are not doing that or we find other evidence of problems, then we would resort to putting them on an import alert.

Mr. MAHONEY. When is the last time you inspected this farm?

Dr. ACHESON. I don't believe we have ever inspected this farm.

Mr. MAHONEY. Is there a requirement for anybody to inspect, the Mexican Government, any other agency within the U.S. Government should be inspecting this farm?

Dr. ACHESON. There is not a requirement that I am aware of legally for us to inspect those farms. They essentially have an obligation to produce safe food, and when they don't and we find out about it, then the consequences are significant.

Mr. MAHONEY. Now, when it got to the packing facility in Nuevo León and then got packaged and went to McAllen, Texas, was there any testing or is there any requirement to do any testing when that food came into the United States?

Dr. ACHESON. On a routine basis, no.

Mr. MAHONEY. Okay. Are there any standards that people operating in McAllen, Texas, the agricultural firm, has to meet when they take that product in?

Dr. ACHESON. Well, they need to be operating under whatever good manufacturing practices or good agricultural practices, depending where you are on the distribution chain of agriculture *versus* manufacturing process and packing. So yes, there are standards that they should be following.

Mr. MAHONEY. Well, it is very clear to me, talking to my growers, that one of the problems we have here is that the U.S. growers have very exacting requirements, they have state officials coming, checking out to make sure that they are in compliance. But, people that are competing with them down in Mexico are basically in this particular case, Mexico or anyplace overseas, they are basically operating without any oversight and they are shipping the same product competitively into the United States. Am I correct to say that the only time we get concerned about it is when we have a situation like this and it goes back to a foreign source?

Dr. ACHESON. Not at all, no. Last November, FDA put out a series of legislative proposals, one of which is the requirement for preventative controls for high-risk foods. Fresh produce and, I have said before, tomatoes, leafy greens, would fall under that very clearly because a high-risk food to us is one that is repeatedly associated with serious illness.

Mr. MAHONEY. And let me ask one last question. The costs associated with the investigation in Mexico and our work down there, who is paying for that?

Dr. ACHESON. For our investigators? We are.

Mr. MAHONEY. So there is no requirement on the part of the Mexican Government or no interest on the part of the people that are selling it in this country to help defray the cost of this?

Dr. ACHESON. All I can tell you is that the people down in Mexico, the FDA investigators are under——

Mr. MAHONEY. They are coming to work for you.

Dr. ACHESON. Yes, absolutely.

Mr. MAHONEY. And how many staff do you have in Mexico?

Dr. ACHESON. Currently, I think there are three there. We had a team of—it generally is a team of three or four each time we have a visit but it varies.

Mr. MAHONEY. And what are they doing down there? Are they checking farms, or what is their purpose?

Dr. ACHESON. This is now their third visit. They essentially will go down there based on the traceback that we got——

Mr. MAHONEY. They are not headquartered there, they are not located there?

Dr. ACHESON. No, not at all.

Mr. MAHONEY. I understand. Thank you.

The CHAIRMAN. Thank you. I anticipate that we will have a second round of questions for this panel, so you will have an opportunity for more questions.

Mr. Neugebauer, I would like to give the floor to you.

Mr. NEUGEBAUER. Thank you, Mr. Chairman.

One of the things that we are talking about traceback in this hearing, but traceback is an event that occurs after we have a problem. One of the things that I think we have to look at here as we address this issue is, what resources need to be allocated for the prevention piece as well as building the infrastructure for the traceback piece. Because if you are focusing all of your resources on the traceback, you are really not doing anything for food safety. I think that is one of the things we need to stress to people that are watching this hearing, traceback doesn't necessarily make the food safer because traceback is about looking for the problem once it happens. Obviously traceback does help us mitigate future problems hopefully. In your estimation, what is the appropriate allocation of resources? At the same time that we are discussing this traceback, should we also be talking about the structure of the testing and supervision and the measures that we have in place to try to catch these problems before they happen; but more importantly what are the things we can do to mitigate them in the future?

Dr. ACHESON. You made excellent points, and we recognized some time ago the importance of prevention, which I think is essentially what you are suggesting. You are far better at preventing the problem in the first place then reacting to it when it happens, and that just makes all kind of sense. To that end, in November, we published a Food Protection Plan that emphasizes prevention, intervention and response, the importance of building in preventative controls up front, understanding where the risks are, making sure that industry understands what its responsibilities are, what sort of mitigation strategies can be put in place, where those risks exist. We requested new legislative authority to require preventative controls for high-risk foods, to require preventative controls for certain types of foods that were particularly vulnerable to delib-

erate attack, and there were eight other legislative proposals that are in there, not all focused on prevention but certainly three of them are. Combined with that, you are absolutely correct, the focus in past has been heavily on reaction, of essentially reacting when something bad happens. We have to get better at that. It is not like we can ignore that. But there has been a deliberate shift of focus with the new assigned food safety money for FDA in 2008 and what is in the President's budget for 2009 towards prevention, and it is all about understanding how you build in those preventative controls.

To that end, with tomatoes, we began last year something called the Tomato Safety Initiative that we work with the State of Florida and the Commonwealth of Virginia. It is still ongoing. But we have learned things from that about growing practices about potential problems, many of which have been picked up by the industry, addressed and fixed. But there are lessons learned in there for all of us because it is not just Florida and Virginia that are growing tomatoes. We have talked about tomatoes being grown in other countries. What we learn from our domestic situation could easily be applied, and it is all down to prevention. So the goal is for much more effort, energy and resources to be put into prevention, it has to be combined with a risk-based inspection and sampling process, a system for early detection of problems and then a rapid and effective response system when something does fall through the cracks.

Mr. NEUGEBAUER. Dr. King, do you have a reflection on that?

Dr. KING. I would certainly agree with that, and it is about the farm to the table, that public health emphasis needs to be across that whole spectrum. You did talk about resources and I think it is very important the states are well resourced. I think in some instances, their public health systems are not as well resourced as they should be and that adds to the difficulties that they have.

Mr. NEUGEBAUER. One quick question: When we have these occurrences and we are beginning that traceback period, what is the appropriate amount of information that we can give to consumers? Not to cause this panic that we saw where just basically unilaterally taking tomatoes completely out of play when we, A, didn't know whether it was tomatoes, and B, we didn't know where they were coming from. What do we need to do better about that so that we can address the issue but not cause this fairly substantial monetary loss for the industry, plus the lingering effects of such a wide—I think what probably scared the market more than anything was that we just took the product almost completely off the market, if not entirely. That is a pretty big statement.

Dr. KING. Yes, sir, that is a great question. It is all about balance. It is about a balance of when do you give information to the public to make good decisions. We talked about 1,319 cases. We know obviously that there are many more. There are thousands of cases involved here. How quickly do we need to get out to the public some good information to inform them so they can make good decisions about what they eat to prevent further illnesses or possible deaths. So that is the balance that we deal with. Unfortunately, in many of these foodborne outbreaks, we don't find the etiology or the exact cause of the infection during the outbreak. So early on when we want to give warnings to consumers, that would

be most helpful. More often it is the rule rather than the exception that we won't necessarily have a positive culture from a product. So what we want to do is then rely on good epidemiology, good surveillance, good statistical analysis that would say there is a strong association with this food and this illness and try to balance that with the messaging to the public.

Mr. NEUGEBAUER. I see my time has expired.

The CHAIRMAN. Thank you, Mr. Neugebauer.

Mr. Etheridge.

Mr. ETHERIDGE. Thank you, Mr. Chairman. Let me thank you for holding this hearing and thank our witnesses for being here.

As you probably know, North Carolina is a state that produces an awful lot of produce, and one of the expanding markets we have on the East Coast of growers and our folks suffered tremendous adverse effects with the tomato, really almost like an embargo really. So my question, Dr. Acheson, to you is, during the traceback investigation, how frequently did the FDA reach out to farmers and producers, and the second part of that question, what kind of communication does FDA have between FDA and the industry, folks who grow it here in the United States?

Dr. ACHESON. Yes, I understand what you are saying. One of the things that we have learned from the recent outbreaks, and particularly in some of the opening statements was the importance of learning lessons from these situations. We learned from the spinach outbreak that continuous, regular communication with industry was not only helpful to us but it was helpful to them and it was important. In this outbreak, we have attempted to maintain regular conference calls with industry leaders. Now, obviously we can't communicate with every single grower, farmer in the United States. That is simply not practical.

Mr. ETHERIDGE. No, I don't mean that, but that is a very general question with not much of an answer, because I can say industry, that says one thing. I would kind of be interested to know whether or not you contacted the states that are primary growing states, California, Florida, Texas, North Carolina, New Jersey, a host of other states. Did you interact with them? Did we interact with those farmers?

Dr. ACHESON. Yes.

Mr. ETHERIDGE. Or did we just talk to someone who imports? I guess my broader question should have been more specific.

Dr. ACHESON. Well, the interaction with the industry, *per se,* is typically with the trade associations, and that is the way that we have operated, and if that is not adequate, then we need to learn a lesson from that. That is on the industry part. With regard to the states, we hold regular calls with departments of health and we invite departments of agriculture to be on those calls with us so we can share the information. They are not just essentially a data dump, they are an opportunity for Q&As, and every time we go out with these, we ask if anybody has any questions, and it is not like somebody can't pick up the phone if they think we have some really important information and we don't think FDA has it, they are not asking us for it. That may be just our ignorance that they have something that could really help, and I would advocate for them,

pick up the phone, call us rather than saying well, you never asked me.

Mr. ETHERIDGE. Who would they call? Do you have an ombudsman where you can call? Is there a number that they are given or just call FDA?

Dr. ACHESON. There are many numbers. I mean, almost anybody in the agency who——

Mr. ETHERIDGE. I hate to interrupt you, but that is sort of my point. If there is not an entrance point where you could call, it would be helpful for folks to know that because they may have good information that would help.

Dr. ACHESON. There are a number of direct avenues through the Center for Food Safety and Applied Nutrition, through the Office of the Commissioner. A lot of people call me directly. In fact, the Commissioner of Agriculture for North Carolina called me directly and I have spoken to him a number of times. He had specific concerns much along the lines that you are suggesting and said, "Okay, Dr. Acheson, what is going on, can you tell me what is happening," and we had a good conversation and he had some good ideas and some suggestions for the future. That is what I am talking about. He was able to find me without much trouble.

Mr. ETHERIDGE. Dr. King, does the CDC have any procedure in place in order to ensure that local and state agencies are reporting the data in the same accurate and consistent way, so that all of it comes in in a form that can be used?

Dr. KING. Yes, sir. All the states now and some of the counties and the cities actually use a system called PulseNet, to post on the web results of pulsed-field gel electrophoresis (PFGE) testing. PFGE is a standardized system where you actually can take a sample of a bacteria that has been cultured from a person and go through a procedure, put it in gel and electrify it and get the DNA patterns and then put the results on PulseNet where all the other states can see it at one time, and so we have algorithms and we look at those. Last year we had over 60,000 reports of cases from the states in which we were able to do that, so states then are able to compare their outbreak samples or their cultures collectively across the country.

Mr. ETHERIDGE. One follow-up, Dr. King. We talked a lot about traceback. Is there any way within the data you are collecting that you have an effective and consistent traceback across the reporting data—where you can have an effective traceback procedure?

Dr. KING. Sir, that is really not in our purview. The CDC is working in surveillance, it is working in outbreak investigation, laboratory and analysis. A lot of what we do is the epidemiology, obviously we share with FDA now on a daily basis. That really helps inform them in terms of helping them with traceability but that's really the FDA's job.

Mr. ETHERIDGE. Dr. Acheson, do you have that kind of data collection across the board that is consistent enough where that traceback could be effective?

Dr. ACHESON. Yes, our traceback system is very consistent. I mean, it is FDA inspectors doing it, often with the assistance of the states. We have activated the Food Emergency Response Network, which is heavily driven by the states for sampling, inspection. The

states have done a lot of the inspection part of this whole outbreak investigation.

Mr. ETHERIDGE. Thank you, Mr. Chairman.

The CHAIRMAN. We are going to turn the floor over to Mr. Costa, but Mr. Etheridge's question just begs, isn't there wide variability between the states? California and Florida do amazing jobs. Some states, I don't want to impugn anyone's state so I am not going to say which ones I think are the bad actors, but some states do a very poor job, don't they, Dr. Acheson?

Dr. ACHESON. Well, I am not going to impugn one state over another either; but, what I can tell you is, when they are doing inspections for FDA, they are doing them under contract with us and they are doing them to a standard——

The CHAIRMAN. But do you then do those inspections in those states that don't have an apparatus?

Dr. ACHESON. Yes. I mean, essentially we are using states to leverage resources because they are on the ground.

Mr. ETHERIDGE. Mr. Chairman, I want to follow that up. How many states do you have contracts with?

Dr. ACHESON. I think it is 42.

Mr. ETHERIDGE. Forty-two of the 50? Thank you.

The CHAIRMAN. Congressman Costa, thank you so much for being patient with us when we did additional follow-ups. The floor is yours, sir.

Mr. COSTA. Thank you very much, Mr. Chairman. I appreciate your and the Subcommittee's efforts on this very important issue to ensure that American consumers have the very safest food possible, and I believe by and large we do. You have a very difficult job as implementers of the policy because you deal every day in the venue of risk assessment *versus* risk management and trying to determine how we can minimize the risks to the degree possible, but realizing that you cannot make it entirely risk free. I mean, there are the variables on people's eating habits. Certain people prepare food improperly, not cooked properly. Sometimes people eat foods that are beyond the "okay on the shelf" credibility and they are consuming foods that are way beyond their shelf life. So as you wear your hat of risk assessment *versus* risk management, I have a series of questions and I would like to focus with regards to the Food and Drug Administration, and if the CDC would like to chime in, you are welcome, but let us be quick because of my time.

I am very familiar, and of course, I have my own view on how we ought to do this and improve it. It is H.R. 5904. Congressman Putnam testified about it earlier on and we are working with a lot of different interest groups to try to see if we can get the sort of support to give you the additional tools to ensure safety. When the tomato industry, which I think has a pretty sophisticated traceback system, it was my understanding that the FDA was reluctant to disclose too much information on their investigation to the industry but you navigated the distribution chain blind. Do you think that played a role in prolonging the tracking process?

Dr. ACHESON. No. First of all, we are bound by law in terms of what we can share with industry.

Mr. COSTA. So there is a statute that restricts the information that can be shared with industry during an investigation?

Dr. ACHESON. Yes.

Mr. COSTA. Okay. The tomato industry has developed very detailed food safety guidelines for the entire supply chain in coordination with FDA. You call it, I guess, CFSAN or whatever the acronym is. The frontline investigators had little or no knowledge about these standards and systems, I have been told, that the coordination in there between CFSAN and your brain trust, so to speak, and the actual investigators. What sort of training do you give your investigators?

Dr. ACHESON. In terms of their investigational capacity, they get extensive training. In terms of investigating a problem and what they are going to do out in the field, they get a lot of training.

Mr. COSTA. Do you think it would make sense to have some additional training and oversight done by CFSAN to ensure that the investigators are informed before they do a search?

Dr. ACHESON. The Center for Food Safety and Applied Nutrition, which is CFSAN, is involved in the training of investigators and they work with the——

Mr. COSTA. I understand it is not to the degree that it should be.

Dr. ACHESON. Certainly if you are raising a point that could training be more extensive, it is certainly something that we could look at.

Mr. COSTA. In the recent traceback drill that you guys performed in California or that was performed, it is my understanding that they went from Jack in the Box to a farm to be able to trace in 35 minutes where tomatoes had come from. Five other drills they ran, the longest traceback took 5 hours. Why do you think it took you folks so long to do your own FDA traceback?

Dr. ACHESON. One of the interesting things about this outbreak was that to start with, there were many sporadic cases. They weren't clusters so there was no clear focus for traceback. Then what we were learning is that in fact it was not the major chains and the major industries, it was small Mexican-style restaurants very often.

Mr. COSTA. Of all your tracebacks nationwide that you attempted, how many were unsuccessful in each step of the supply chain? Do you have that number? If you don't, could you provide the Subcommittee with that information?

Dr. ACHESON. Certainly, I will. A number of the sporadic ones that we were doing initially for tomatoes were unsuccessful.

Mr. COSTA. As you went through this chart earlier, there was a contamination in jalapeños and then serrano peppers on July 1. Why did it take until July 17 to remove the warning from tomatoes, even though you thought the samples from the jalapeño were a genetic match? It doesn't exonerate other foods.

Dr. ACHESON. Tomatoes were never exonerated from that perspective.

Mr. COSTA. So then it is proven guilty? You are guilty until proven innocent?

Dr. ACHESON. There isn't a question of guilt or innocence here. We were operating——

Mr. COSTA. When the bottom drops out of the market, it is a real problem.

Dr. ACHESON. Our mandate is to protect public health, sir.

Mr. COSTA. I believe that.

Dr. ACHESON. And we were responding to solid, scientific, epidemiological data through a tried and trusted source from professionals whose job it is to do that, and FDA was taking that data, initiating the tracebacks. No question that they were complex, that they were difficult, largely because it wasn't the big chains, it was many small people who are not big producers, not big suppliers. You have to go to every single one of them, you have to get the records. They are often not maintained electronically. You just simply cannot do the whole thing in 5 hours when you are dealing with that kind of level.

Mr. COSTA. Well, but the industry was able in the case of the tomato industry in California, they were able to traceback over five drills. The longest took 5 hours.

Dr. ACHESON. I don't question that certain sections of the tomato industry are capable of doing that, but I do question whether all sectors of the tomato industry from the largest to the smallest are capable of doing that. What I am trying to say here is that some of the smaller players were some of the ones that we were dealing with here. It was not necessarily the big guys, who can do it all in 5 hours.

Mr. COSTA. My time has expired, Mr. Chairman. I will save the questions for the next round.

The CHAIRMAN. I have a housekeeping piece of business that I have been told by counsel I have to do. I have to ask unanimous consent of the Committee assembled that you be allowed to ask questions since you are a Member of the full Committee but not a Member of the Subcommittee, so without objection, Mr. Costa will be allowed to ask questions at this hearing.

Mr. COSTA. Can I ask my questions now?

The CHAIRMAN. And, Mr. Costa, your time has expired.

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

The CHAIRMAN. You are welcome. Thank you for the excellent line of questions.

Dr. Acheson, I want to follow up. I spent 6 years in the legislature, three of which were as Chairman of the Agriculture Committee there, and I spent the entire 6 years on that Agriculture Committee in the legislature and now my 6 years here in Congress. In that period of time, I have asked a number of questions about imports from other countries and how we can in fact determine that they are safe for our public. Why do other countries not have to abide by the same protocols that our farmers here in the United States have to comply with? Many times during those hearings, I have been told that there is sampling done at the border. Today you have indicated to me that there is no sampling done at the border.

Dr. ACHESON. No, that is not what I said.

The CHAIRMAN. Okay. Would you like to elaborate on that, please?

Dr. ACHESON. Please. I didn't say there was no sampling done at the border. If I said that, it was a misrepresentation. There is limited sampling based on risk, based on those food commodities where we have seen previous problems.

The CHAIRMAN. Do you do sampling for pesticides?

Dr. ACHESON. Yes.

The CHAIRMAN. How much of the product that goes through the border would you estimate is sampled on a percentage basis?

Dr. ACHESON. A hundred percent of what is coming through the border is examined electronically in terms of where it has come from, whether we have concerns. About one percent of that is physically examined by an inspector and about, I think about half of that, a sample may be taken or maybe a little less in terms of actually taking a sample to do some testing.

The CHAIRMAN. And of that ½ of 1 percent that actually get sampled, what things do you sample for, and would you sample for everything that is known? I mean, would you be sampling for *E. coli,* for pesticides, for DDT, for things that are banned here in the United States?

Dr. ACHESON. It is very much driven by the commodities and the risk. There are certain types of foods where we know pesticides have been a problem so they get sampled for that. A case in point, we know we have had problems with inappropriate use of antibiotics and other antimicrobials in shellfish and other kinds of seafood, so for those, we would sample for that typically. We have ongoing assignments sampling cantaloupe for *Salmonella* because we have repeatedly seen problems with that. So we don't look for everything in everything. It is targeted and it is risk-based.

The CHAIRMAN. Sir, can you tell me, you said this is the worst outbreak this decade. How long has your agency been monitoring food safety in the United States? Let us start with that first.

Dr. ACHESON. Just a little over 100 years.

The CHAIRMAN. Okay. So you have been doing this a while.

Dr. ACHESON. I haven't been doing it the whole 100 years.

The CHAIRMAN. So in your experience, say, in the last 20 years, we have encountered a number of food safety crises and outbreaks in this country. You are saying this is the worst one in the last decade. Can you tell me, of the foodborne outbreaks that we have seen with different pathogens, whether they be pesticide-related—I think Alar was a pesticide that we had a problem with a few years ago. We have had several *Salmonella* cases. We have had several *E. coli* cases, and your agency doesn't do meat but that has been one of the areas of problems, so both you and USDA and have had challenges with regard to the areas of jurisdiction. Can you tell me how many, on a percentage basis, would you suspect come from Mexico or other countries *versus* domestically grown products?

Dr. ACHESON. In terms of outbreaks?

The CHAIRMAN. In terms of outbreaks.

Dr. ACHESON. Yes. That is a question that I would ask Dr. King to help me answer because the CDC tracks outbreaks more than FDA. But my experience is that I am aware of maybe two or three that have come from south Central America. We had hepatitis A on green onions. We have had *Cyclospora* on raspberries. That was not from Mexico, that was from another country. Not that many.

The CHAIRMAN. We had strawberries, that I remember.

Dr. ACHESON. Well, it was originally thought to be strawberries and then it turned out to be raspberries.

The CHAIRMAN. But that wasn't from Mexico?

Dr. ACHESON. No, Guatemala.

The CHAIRMAN. Okay. Dr. King, can you elaborate on that question?

Dr. KING. We don't have too much information internationally. What we are trying to do is have standardization in some of the sampling internationally. We have this PulseNet system that I have talked to you about that is now becoming more global. China is looking to put it in. Mexico has it. We also have a system called Global Salm-Surv, which is also looking internationally so that we can see these products. It would be good to know, are they having outbreaks in other cities, in other parts of the world, and can we actually compare those outbreak strains with what we are seeing in the United States. A multi-state outbreak may be a multi-country outbreak. We are not there yet but that is something we are looking at down the road.

The CHAIRMAN. Dr. King, what was the substance of the communications that CDC had with local officials conducting the investigations?

Dr. KING. Early on, New Mexico was the first source. That was May 22 when they actually contacted us about 19 potential cases with the same PulseNet identification. From that point on, we talked to them frequently. Texas was involved. The Indian Health Service was involved. We helped them design——

The CHAIRMAN. We are running over my time so let me further define my question that might bore into exactly what I am trying to get to. PulseNet has without question improved the ability of scientists to identify foodborne illnesses and outbreaks, no question about it. Scientists today can identify outbreaks that never would have been identified a decade ago, and people who thought they were just having the stomach flu, we now know have been sick or whatever it is. However, it seems to me that for PulseNet to work efficiently, a state should input such information immediately rather than wait until they think they have a cluster. I think we can all agree here today that 2 months delay is quite a significant period of time. An awful lot of folks can get ill, as we have seen, in that 2 month period of time. How is it supposed to work with PulseNet, and during your daily calls with these public officials, did any states question the hypothesis that tomatoes were the vehicle for the outbreak, or can you provide data implicating any other food product, and if so, when?

Dr. KING. We have conversations with the states almost on a daily basis. Certainly the 43 states were involved. We constantly have communications with them through conference calls. We have an "OutbreakNet" system where we talk to epidemiologists across the country, where we compare notes, we talk about hypotheses, we question each other, I think which is healthy, in a rigorous way. Part of what the states need to do in these case control studies where they are actually talking to cases and match controls, that information needs to come forward. Many states do that themselves. Over 90 percent of these outbreaks that we see are all done by the states themselves. We only are involved in a small percentage of those. We are able to help them where we can. We are able to send people in in large outbreaks like this where we had so many clusters. There is variability in terms of the reporting from the states. That is one of the areas that we would like to be able

to cut down on. How quickly states will put results up on PulseNet, how quickly you get specimens from clinical laboratories, how quickly they are able to handle them, doing serotyping, do they save them and do them in lumps or do they do them right away.

The CHAIRMAN. Well, I think that is part of the question we are trying to bore in on, Dr. King, because in earlier testimony, I can't recall if it was you or Dr. Acheson who indicated to us that there was standardization amongst the states. But now you are indicating that some states report very quickly and some states don't, that there is not in actuality uniformity in the protocols that the states comply with.

Dr. KING. Yes, sir, there is standardization in terms of the process of using PulseNet. Some states are able to report it more quickly. Some delay in that. Some of them will not run the samples quickly, they will do it in a bulk way.

The CHAIRMAN. That is exactly my point, sir.

Dr. KING. But the procedure is the same in terms of PulseNet. The amount of time that it takes them to do it is the variability.

The CHAIRMAN. Well, that is my point, is that in California or Florida, you might get that overnight. In another state, Texas or Minnesota, it may take—and I don't know. I am not an expert so I am not saying which ones and I certainly don't want to offend a state, but since they are not here to represent themselves, we will use them as an example. They might take a longer period of time in which case people continue to get sick and we really don't have the information that we need.

Dr. KING. And I agree with you, and we talk to states and ask them if they can decrease this amount of time. It is very important. We can't stay 2 and 3 weeks behind in order to do these outbreak investigations. I agree with you that we are pushing states to try to do that in as rapid a way as possible.

The CHAIRMAN. Well, not only are we not being fair with the public, who is becoming ill when there is an outbreak that should have been reported but wasn't. We are not being fair to the farmers for 3 weeks who are losing their potential to provide their products to the market, but are being implicated in something where they are absolutely innocent possibly.

Dr. KING. I agree with that, Mr. Chairman.

The CHAIRMAN. Mr. Mahoney.

Mr. MAHONEY. Thank you, Mr. Chairman.

Just a follow-up question to both of you. Has there been any indication, have you found anything in your investigation that would indicate that any tomato grower in the United States had done anything that would warrant at this stage of the game that there was any problem with what they had done as far as growing tomatoes, packing tomatoes and delivering tomatoes? Have you found anything?

Dr. ACHESON. No.

Mr. MAHONEY. So you haven't found any indication?

Dr. ACHESON. No. As part of the process, we went down and we inspected the farms in Florida. By the time we got there, they were no longer in production, but we did not find anything——

Mr. MAHONEY. That there is a problem with contaminated water supply or something like, I mean.

Dr. ACHESON. We didn't find any problems. That is all I can say. But they were not in production.

Mr. MAHONEY. I mean, you understand that crop insurance doesn't cover this loss. I mean, the estimate in my State of Florida is about a $47 million direct loss to the growers. I think $300 million is probably light in terms of what the total impact is, but again, the biggest casualty here is consumer confidence in our tomato industry. It appears from this testimony I have heard today that what we have is a situation where we have a two-tiered system. We have foreign growers that operate under a completely different set of standards and oversight than our domestic producers. I won't spend any time talking about the inequality of that as far as cost and competitiveness but certainly for public health, there has got to be a lot of concern, which gets to my last question.

I think that it is clear that given the resources that you have available to both of you at this point in time in your respective organizations, I am confident that you did the very best you could possibly do. But, I also am hearing that there is potentially more that we could be doing. So my question is, in a perfect world, given the expertise that you have, do we need to take action? Is there more that we could be doing; should we be doing more; do we need to give you more resources? I mean, from your experience, Dr. Acheson and Dr. King, what would you recommend to this Committee that we do to fix this problem?

Dr. ACHESON. There is unquestionably more that we need to do. I think your point about the economic impact needs to be addressed. The urgency of public health needs to be addressed. The Food Protection Plan has a lot of suggested authorities that we think we need and we don't have those. It is going to require resources and clearly that is being addressed and it is going to be ongoing. But it is not all about response. If you are thinking about response from FDA's perspective, then clearly examining ways to improve traceback, make it faster and not just with the big producers but with everybody. It has to be uniform. You talked about standards for domestic *versus* imported. The requirement for preventative controls would go some way toward that, and you know, frankly, we need to hold everybody to the same standard whether they are domestic or a foreign grower.

Mr. MAHONEY. And do you have the resources necessary within the FDA to do that, to implement that and to do that today?

Dr. ACHESON. No, we don't. The new resources that we have gotten will go a long way to begin to develop those once we have the authorities. But, to actually implement them and assure that they are being maintained, whether it be through direct FDA inspection or third-party inspection with FDA audit and oversight, that is not part of the current——

Mr. MAHONEY. Do you feel that the FDA has the expertise and the ability to implement such a system and to operate it successfully?

Dr. ACHESON. Yes, I do. I believe FDA has the knowledge, has the system, but we need to do more. We need to hire more experts, particularly in certain specific areas, produce being one of them. We do have some produce experts. We need to hire more.

Mr. MAHONEY. Dr. King, do you have any thoughts in terms of the CDC?

Dr. KING. Yes, thanks. One of the things I wanted to reiterate in terms of resources would be for the states. One of the reasons that they were slow is not because they are incompetent, it is because they went really flat out, and when you have a lot of cases and all that work to do, they just couldn't keep up. So there are resource issues within the states. There is no question about that. I think this idea of what we call infectious disease ecology, understanding how agriculture and public health need to be linked over a continuum and how the outcome is very positive that we both try to achieve. We don't want to just look at cases in controls. We want to be able to move upstream and we need industry support to do that. We need their help. We need their understanding. And I think one of the lessons learned for us that would come out of this would be to have that kind of expertise as part of putting this whole integrated strategy together and we would look very much forward to doing that.

As far as CDC goes, we would like a better electronic system where we could actually have data from the states that would come in, do it quickly, for data from case control studies to come in, where the analysis could be done more quickly, could be done on a Web-based system. We would look at that and potential iterations of PulseNet which would look at microarrays, Luminex kind of platforms where it is more accurate and quicker. That technology is available and we would look forward to adopting that down the road.

Mr. MAHONEY. Thank you, Dr. King.

The CHAIRMAN. We are going to have to move on. Thank you, Mr. Mahoney.

Mr. Costa, if you have a couple burning questions since you have been so patient sitting here, I would like to give it to you. We have two witnesses that have flights to catch and so we are short on time, and I also have to get two or three things on the record for the staff. So I will turn it over to Mr. Costa and ask for brevity.

Mr. COSTA. I will try to be quick. Does the FDA currently have the authority to institute mandatory regulations for high-risk products or do you believe that Congress needs to give you that authority?

Dr. ACHESON. Do you mean mandate preventative controls? We do not have authority to do that.

Mr. COSTA. Okay. Because it seems to me, the problem where you have very sophisticated industries like the tomato industry in California or Florida is really—and you have the traceability technology in place, that what we are really talking about is the small truck farmer that maybe delivers to a restaurant. Unless you have a receipt or some traceability, you have no ability to—I mean, the larger producer that goes through a wholesaler, goes through a co-op, a processing plant, traceability there is pretty good, would you not agree?

Dr. ACHESON. Yes, but you need to hold everybody to the same standard. I think that is what you are suggesting.

Mr. COSTA. And you believe we ought to do that?

Dr. ACHESON. Right, for preventative controls, absolutely.

Mr. COSTA. There are other questions, but for the sake of time, I will defer and thank you again, Mr. Chairman.

The CHAIRMAN. Congressman Costa, maybe we could submit them in writing and get a response.

Mr. COSTA. Yes, I will do that.

The CHAIRMAN. Thank you very much.

Dr. Acheson, We need to clarify, because we think there is confusion in the testimony, whether or not you have found tomatoes on the farms where the peppers have been implicated, whether they actually grow those on those same farms as the peppers that have been implicated.

Dr. ACHESON. Okay. If we could go back to the diagram, I will try and explain it. The red box that is furthest away from me is a farm where the pepper that we found in McAllen, Texas, pepper samples. That is where that went back to when we traced it back, so the positive pepper samples went back to that farm. That farm grows tomatoes and peppers. The farm that I talked about today is a different farm. It is lower down on the chart. That farm grows just serrano and jalapeño peppers, it does not grow tomatoes. Both of those farms are going through their distribution system through one distribution center that is in the middle of the chart with a circle around it. So there is at least one farm that is growing all three and there is at least one distribution center that all three are passing through.

The CHAIRMAN. Let me bore in on that question. In the farm that has grown all three, did you find positive samples at the farm or at the distribution center?

Dr. ACHESON. We found the positive sample in a jalapeño pepper at a distribution center in Texas. We visited that farm and there are samples that are pending in the lab from that farm.

The CHAIRMAN. Okay. So to date, we don't have a positive implication directly to a tomato on either one of those properties? There were tomatoes grown on that property. That property shipped to a distribution center and you have found contamination at that distribution center?

Dr. ACHESON. We have not found contamination at the distribution center in Mexico. We found contamination at the distribution center in Texas, and I think your point is that have we found a positive *Salmonella* Saintpaul isolate on the farm that is growing all three. To this point, no, but those samples right now are in the lab being analyzed, so that could change.

The CHAIRMAN. The Committee will be very interested in that outcome.

Dr. ACHESON. Absolutely.

The CHAIRMAN. Thank you. Go ahead.

Mr. MAHONEY. Just to clarify, I thought you said that in the box furthest away from you, that you had found contamination or *Salmonella* in the water. Did I misunderstand that?

Dr. ACHESON. The box in the middle of the chart that has a hand-drawn red circle around it, that is the farm where we found contamination in the irrigation water and in a sample of serrano peppers.

The CHAIRMAN. Dr. Acheson and Dr. King, I am going to have to fast-forward because we have other panelists who have to testify

and catch planes, but I am going to ask you to submit to some requests. Would you please provide the Committee with the criteria and communications procedures used by your agencies to communicate risk and issue alerts? And second of all for Dr. Acheson, would you please provide the Committee, when did you first learn that jalapeños were being considered by CDC as a potential source for the outbreak? And finally, for Dr. King, could you please submit to the Committee the criteria used by CDC in conducting the epidemiological and traceback investigations? Those three things, the Committee needs further clarification on the exact procedures. We won't take up Committee time to do that today but I want to thank you both for your testimony and I appreciate you being here with us today.

Dr. ACHESON. Thank you.

Dr. KING. Thank you very much.

The CHAIRMAN. Now, we are going to deviate a little bit again and we are going to ask that a panelist from the fourth panel join panel number three. Would Dr. Michael Osterholm please join panel number three? And I will call that panel up for questioning now.

We would like Mr. Anthony J. DiMare, Vice President of DiMare Homestead Inc., DiMare Ruskin Inc. and DiMare Johns Island, Inc., of Ruskin, Florida, to come forward; Mr. Henry Giclas, Vice President of Strategic Planning, Science and Technology for Western Growers Association of Irvine, California; Mr. Bryan Silbermann, President of the Produce Marketing Association, Newark, Delaware; and Mr. Thomas E. Stenzel, President and CEO of United Fresh Produce Association, Washington, D.C., to please come forward. I am sorry if I butchered your names. I typically do that.

Dr. Osterholm, I know you are blazing a trail to a plane. We are going to let you testify and then if you need to go, we will excuse you after your testimony. If you can stay, we are happy to have you.

Dr. OSTERHOLM. Mr. Chairman, I can stay for another hour.

The CHAIRMAN. Dr. Osterholm, please go ahead and proceed with your testimony and then we will go next to Mr. DiMare and down the line as I read your names off today.

STATEMENT OF MICHAEL T. OSTERHOLM PH.D., M.P.H., DIRECTOR, CENTER FOR INFECTIOUS DISEASE RESEARCH AND POLICY; DIRECTOR, MINNESOTA CENTER OF EXCELLENCE FOR INFLUENZA RESEARCH AND SURVEILLANCE; PROFESSOR AND ADJUNCT PROFESSOR, DIVISION OF ENVIRONMENTAL HEALTH SCIENCES, SCHOOL OF PUBLIC HEALTH, MEDICAL SCHOOL, UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MN

Dr. OSTERHOLM. Thank you, Mr. Chairman. My name is Dr. Michael Osterholm. I am the Director of the Center for Infectious Disease Research and Policy at the University of Minnesota, and for almost 30 years I have been involved in the area of foodborne disease epidemiology, having served many of those years as the State Epidemiologist at the Minnesota Department of Health and have

led a number of complex large foodborne disease outbreaks including that involving produce over that time.

Today I have submitted my written comments in detail to you about the issues that we believe are relevant to this discussion you are having today. I think the discussion we have had to date here this afternoon has been very helpful. With that, let me make a couple of specific comments that I am sure the rest of the panel will address and I think really go the heart of some of the issues that you have.

Some of you are aware that as early as the first part of June, I raised questions about the conduct of the investigation that was undergoing examination at that time in terms of the *Salmonella* Saintpaul. Let me make it clear that at no time was I challenging the issue that tomatoes might be involved but if we in fact would ever find the source of those using the techniques that we are. I would submit to you today and having been involved with outbreaks with multiple vehicles from over multiple periods of time from the same farms that it is very likely that this could represent multiple vehicles. I think that statements today suggesting tomatoes are not involved are very premature, and that in fact this very well could be an outbreak that involved multiple vehicles over multiple periods of time which made it much more confusing. I believe those answers will be forthcoming. I believe that we will learn specifically whether or not there were three, two or four different vehicles involved and I would urge that all of us take a breath in the sense of saying we need the information. Clearly public health owes that to all of us here but that in fact you have to be very careful about making the conclusions that it is just peppers.

I would add that I must, Mr. Chairman, at the risk of a friendly amendment to your comments, I come from the great State of Minnesota. Our health department has pioneered many of the techniques used today, and in fact, we have the fastest turnaround of any state in the country for both interviews and pulsed-field gel electrophoresis submission, and I would daresay that we are very proud of that point.

The CHAIRMAN. The Chairman of the Committee and all the rest of the delegation probably would admonish me as well, and I accept it.

Dr. OSTERHOLM. I am sure Representative Peterson will be very pleased to hear that, sir.

Having said that, I also want to point out to you though that I think that given this cause issue, we have more to do, but I don't think that this outbreak has necessarily provided any wrong information yet. It may have provided incomplete information but I think we are going to learn more about that.

The next thing I would address here, and I heard this comment made multiple times today. As someone who has spent the better part of their career in the area of foodborne disease epidemiology, I just have to say I don't know where we come off or where we have the data to support that we have the safest food supply in the world. I would suggest we have the world's food supply, and the fact being is today if you look at any item, whether it is processed or non-processed foods, your Nutragrain bar that you think of as a domestically produced item in any one day may have ingredients

from ten different countries in it. I could go through a whole laundry list of products. So the point being today is that we do have an international food supply. I think you have heard already here in this hearing that the FDA has a very limited ability to address the ingredients or food products coming into this country relative to what they can do of what is processed or grown within our borders. I think this is an important consideration that we all need to talk about.

Having said that, also I think we have to talk about the industry. As someone who has been very involved with foodborne outbreaks and has actually worked closely with the industry, I don't know if it is the 95–9 rule or the 99–1 rule or the 99.1.01 rule but I have never seen any food commodity produced yet for which everyone within that particular domain has a stellar operation. There are many organizations in this country that have suffered because the least of their producers was the one that caused the outbreak. I think one of the things we have to address is not just a blanket statement that the industry has done this or the industry has done that. I actually represent a company that is a major supplier of bagged produce, lettuce and so forth, and to date, they have never had a documented foodborne outbreak in 20-some years of production. They are an example of a company that has done it very well and done it right. But just down the road, one of their competitors was responsible for the spinach outbreak that occurred 2 years ago. So I think we have to be very careful about this, and I know our industry representatives will make that point, I am sure, that we have to assure that the least of us have the standards that are very important.

The next area of comment here is, I think we have some confusion going on with the difference between what we call an epidemiologic association and traceability. This outbreak is not about traceability. It is not. This outbreak was about an association, meaning the public health agencies, the state and local health departments together with the CDC, did they do the appropriate investigation to determine this is the likely source of this, meaning this food item as a class, as a category. Once that is established, or if it is not established in the minds of reasonable people you can argue it wasn't established, then that information goes to the FDA, and I have seen a constant discussion of the failures of the FDA in this outbreak investigation. I just want to point out that if this product really isn't associated with tomatoes, which again I think we all have to reserve judgment on, that is a failure of the up-front part of the investigation of the CDC and the state and local health departments. That is not an FDA issue. Our own Minnesota Department of Health, which was the group that found the first major association with jalapeño peppers and the large restaurant outbreak in the Twin Cities, and actually fingered the location of where that ultimate positive came from and did determine jalapeño peppers were involved, basically did that entire investigation a little short of 10 days, tracing it back to one of three farms in Mexico in addition. So in fact, that is the kind of information that is very important. Once that is established, then we go to traceability. Then we say okay, if we do in fact have peppers, where do they come from. My original criticism of this outbreak investigation as

our group, the investigations I led, actually determined that in the first three outbreaks in this country due to tomatoes and all of them were locally and domestically grown tomatoes, required us to not only look at the tomatoes where the cases brought them but the people or the controls, because tomatoes do get repackaged and resorted, and that has changed over time. All we were pointing out was, you have to trace them all back to basically then find out where the preponderance of tomatoes came from. And so I just want to point that out because I keep hearing that this is about traceability. I have yet to see an outbreak investigation where we could not determine the source when we had an association because of a lack of traceability capability. Some, we have had a much harder time doing. Some, we haven't had the greatest clarity, meaning it was an absolute perfect bull's-eye hit, but on a whole, this is not about traceability, this is about can we find it in the first instance and associate it.

The next issue is risk-based testing. We cannot test our way out of this problem. Testing a product to a certain degree isn't meaningless but almost, and the reason I say that is because testing is based on the statistical probability you are going to find it in a product. We have oftentimes implicated a product epidemiologically, meaning that the data were clear that people were getting sick eating this product, people not getting ill were not eating the product, and it still took us weeks and weeks to find it. I remember one particular example which had nothing to do with produce but some years ago, because I got really panned in the media by the dairy industry——

Mr. MAHONEY [presiding.] Dr. Osterholm, you are going to have to speed it up.

Dr. OSTERHOLM. I know. I am looking at my clock here. I just have 1 minute left.

The point being is that we actually implicated cheese in an outbreak of *Salmonella* infection and they couldn't find it in this cheese for a period of 5 weeks and then one day a laboratory in Canada happened to be testing some of the cheese and found it. The point being is testing doesn't necessarily tell you it is there or doesn't tell you it is there.

And the finally, the last point I just want to make, the real issues around this is what happens at the state and local health departments with the CDC, and this is about disease surveillance and outbreak investigation. Today less than a quarter of the clusters that we find through PulseNet, these clusters of cases, do we ever find a source of why they occurred. Today we have a system out there that is largely broken at the state and local health department level where this disease surveillance occurs. In my written testimony, we provide great detail how we can fix that at a cost that would be just a small percentage of any one of these large outbreaks for the country. I think if I would urge you of anything today, one of the great services you could do is help forward that part of the agenda. Then the gentlemen sitting to my right would very rarely find themselves in this position of we have a possible situation but we don't know what it is, therefore, everybody is in limbo. What they need, what they deserve, what the public deserves are quick answers with quick identification of what the

problems are and then rectifying those problems in such a way as to have a minimal impact on both the food supply but most of all meaning that there is an unsafe food in the distribution center.

Thank you very much.

[The prepared statement of Dr. Osterholm follows:]

PREPARED STATEMENT OF MICHAEL T. OSTERHOLM PH.D., M.P.H., DIRECTOR, CENTER FOR INFECTIOUS DISEASE RESEARCH AND POLICY; DIRECTOR, MINNESOTA CENTER OF EXCELLENCE FOR INFLUENZA RESEARCH AND SURVEILLANCE; PROFESSOR AND ADJUNCT PROFESSOR, DIVISION OF ENVIRONMENTAL HEALTH SCIENCES, SCHOOL OF PUBLIC HEALTH, MEDICAL SCHOOL, UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MN

Chairman Cardoza and Members of the Subcommittee, my name is Dr. Michael Osterholm; I am the Director of the Center for Infectious Disease Research and Policy and professor at the University of Minnesota. Prior to my current position, I served for almost 25 years in various roles at the Minnesota Department of Health (MDH), including 15 years as State Epidemiologist. In that role, I led some of the largest and most complex foodborne outbreaks in our country during the past several decades and helped pioneer some of the cutting-edge epidemiology and laboratory techniques in use in this area today. In addition I'm joined in my testimony today by coauthors Drs. Craig Hedberg and John Besser. Dr. Hedberg served with me at the Minnesota Department of Health and is now a professor in the School of Public Health at the University of Minnesota. He is an internationally recognized expert in surveillance and outbreak investigation of foodborne disease. Dr. Besser is a leading expert in the laboratory aspects of foodborne disease agent identification and is at the MDH.

Today we are pleased to share with you our perspective on the current outbreak of *Salmonella* serotype Saintpaul, particularly given the role the MDH has played in identifying jalapeño peppers as a vehicle for this outbreak; the significant problems in our food delivery systems that can and should be addressed, such as insufficient product traceability, inadequate food protection planning, and inadequate inspection and traceback capacity at the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA); the problem with the epidemiological methods used by state and local health departments and the Centers for Disease Control and Prevention (CDC) to determine what specific foods or other exposures are responsible for outbreaks; and finally, what we must do to address these critical issues if we are to change our current and inadequate foodborne disease surveillance and outbreak investigation systems.

First, let us share our perspectives on the current outbreak. On June 2, 2008, the CDC announced that it was collaborating with public health officials in several states, the Indian Health Service, and the FDA to investigate an ongoing multi-state outbreak of human *Salmonella* serotype Saintpaul infections. At the time, they reported that an epidemiologic investigation comparing foods eaten by ill and well persons had identified consumption of raw tomatoes as the likely source of the illnesses in New Mexico and Texas. Results of this investigation could not identify a specific type and source of tomatoes. The extent of the outbreak, as it was then recognized, included approximately 87 cases in nine states.

Almost 2 months, more than 1,300 confirmed cases in 43 states, the District of Columbia and Canada and two positive jalapeño peppers later, we appear to be moving towards the end of the outbreak. We are just now beginning to understand how this unprecedented event occurred and why new case illnesses continued for so long.

There has been a great deal of discussion during these past 2 months regarding the difficulties in tracing the source of tomatoes and an increasing concern that the epidemiological investigation may have implicated the "wrong" food item. There will be a proper time and place for all of the details of this investigation to be thoroughly reviewed to determine what we might have known when, and how we might more effectively use this knowledge to improve our investigation the next time. If there is one clear message today to the public health foodborne disease professionals of our country, it is that our other public health colleagues, government leaders, the food and agricultural industries and the public are expecting us to answer with some clarity, "What happened?" The one great certainty of recent years' experience in investigating large, multi-state foodborne illness outbreaks is that there will be a next time and it could be as soon as tomorrow.

We are not here to point fingers as to what worked and what didn't work in this outbreak, but rather to point out that there are effective models for the investigation of complex foodborne outbreaks that can be adapted to improve our ability to rapidly detect and respond to these events now and to build our capacity to prevent such outbreaks well into the future. The fundamental questions we all need to ask ourselves are how much do we really care about foodborne illness and what are we willing to do to change our current approaches in both the public and private sectors? Are the public and private sectors willing to invest in a public health system that can more readily detect and effectively respond to these outbreaks? Why are we not using available food safety technology, such as irradiation, to effectively pasteurize our fresh food supply? While we don't expect to answer these questions today with great definition, we must begin to address them head on.

In light of the current outbreak-related recommendations to avoid certain kinds of tomatoes, there will no doubt be extensive debate about how quickly and with how much certainty public health recommendations such as this should be made. The Council to Improve Foodborne Outbreak Response (CIFOR) is a multidisciplinary working group convened to increase collaboration across the country and across relevant areas of expertise in order to reduce the burden of foodborne illness in the United States. The Council of State and Territorial Epidemiologists (CSTE) and the National Association of County and City Health Officials (NACCHO) are cochairing CIFOR with support from the CDC. CIFOR represents an important new effort to improve our foodborne disease surveillance system by actively engaging local public health agencies in the discussion with state and Federal counterparts. Because the effectiveness of our national surveillance efforts depends on the actions of local agencies, their participation in evaluating the performance of foodborne disease surveillance and addressing its weaknesses is critical. As noted in outbreak investigation guidelines being prepared by CIFOR, "While releasing premature and incorrect conclusions to the public can be a disaster, and sounding the alarm bell too often can lead to warning fatigue, it is a mistake to withhold or delay the release of information that the public may need to protect themselves. Public health agencies have an obligation to get information to the public or others who need to know as quickly as possible."

We believe that there are significant problems in our food delivery systems that can and should be addressed, such as insufficient product traceability, inadequate food protection planning, and inadequate inspection and traceback capacity at the FDA and USDA. However, in our opinion this outbreak primarily highlights serious shortcomings with our foodborne disease surveillance system and initial epidemiologic investigations. As the name implies, foodborne disease surveillance is the part of our food safety system involved with gathering of data from people who have become ill with diseases that may be due to contaminated food.

Foodborne disease surveillance is the single most powerful tool at our disposal for the detection of unrecognized problems in our food and water supplies, and yet it remains largely out of the public eye and conspicuously underrepresented in national food safety planning. In a sense, our surveillance system has become crippled by its own success. Most of the foodborne disease outbreaks that have come to national attention in the past few years would not have been detected at all 15 years ago. This has largely been due to the development of PulseNet, the nation's molecular subtyping network. PulseNet was created by the CDC in 1998 to track disease-causing bacteria such as *Salmonella* by "DNA fingerprinting," using similar methods to those used to identify people in criminal investigations. Unfortunately, PulseNet cannot identify the source of an outbreak by itself. Its principle role is to identify clusters of cases that have a high likelihood of having been infected by a common source, such as a mass-distributed food item. Another critical aspect to maximizing the effectiveness of PulseNet is the time it takes to actually get patient bacteria isolates into the public health laboratories and the time until the results are in the hands of trained surveillance epidemiologists. In Minnesota, this typically takes less than 3 days; in many states it takes up to 5 or more weeks.

Once a cluster has been identified, an epidemiological investigation is then required to determine if the cluster truly represents an outbreak and to identify the cause or causes. The essential problem with our current national system in our opinion is that the epidemiological methods to determine the specific foods or other exposures responsible for these outbreaks have not kept pace with our ability to detect significant clusters of disease through PulseNet. There are a variety of reasons for our limitations in this area. While PulseNet is centralized and standardized, epidemiological investigations occur at multiple jurisdictional levels, and there is no generalized agreement on best practices. As such, there are great differences in the ability of states to collect and analyze the basic information needed to resolve outbreaks, which places intrinsic limitations on the ability of CDC to investigate multi-

state outbreaks. This in turn limits the ability of FDA or USDA to pinpoint the sources of contamination and to break the chain of transmission. It is at the core level of exposure data gathering that we will focus our testimony today.

The challenges of foodborne disease surveillance in the U.S.

Jurisdiction for foodborne disease surveillance in the U.S. is based on individual state reporting rules. Across 50 states, more than 3,000 local health departments act with varying degrees of autonomy. Last year at the Annual OutbreakNet/CSTE meeting, C.P. Kanwat from South Carolina and Bill Keene from Oregon presented the results of a survey of the states regarding the structure and practices of foodborne disease surveillance programs. Results of this survey found that gastrointestinal disease surveillance was the responsibility of local agencies in approximately half of the states and was centralized in a single state office in approximately a quarter of the states. Surveillance was conducted by regional state offices in approximately 20% of states. The multiplicity of different models for conducting foodborne disease surveillance makes it difficult to standardize surveillance activities across the country. Imagine what it would be like if our U.S. Weather Service was a hybrid system of local, state and Federal agencies of varying resources and expertise and all using different methods and models to predict, document and interpret our weather. It would be a mess; to certain degree that is the system we have for foodborne disease surveillance and outbreak response.

CDC aggregates surveillance on a national level and provides consultation and coordination for multi-state outbreak investigations. However, CDC lacks authority to independently investigate outbreaks within a state, and while encouraging states to be active participants in multi-state outbreaks, has limited resources to directly support outbreak investigations. The primary mechanism that CDC has to respond to outbreaks is the initiation of an EpiAid request by a state health department. In response to an EpiAid, CDC can mobilize resources and dispatch an Epidemic Intelligence Service (EIS) officer, or small group of EIS officers to the state making the request. EIS officers are epidemiologists in training. Over the years this has been a tremendous resource for states investigating unusual outbreaks, outbreaks caused by an unknown agent or in states lacking adequate resources or basic expertise to conduct such investigations. However, the logistics of dispatching one or a few EIS officers to a field location do not address the primary need to rapidly conduct a large number of interviews as part of the investigation of an outbreak of foodborne illness. While participating in outbreak investigations is an important part of EIS training, EIS officers do not always have the experience and skills needed to lead a complex foodborne disease outbreak investigation.

Because CDC has primary relationships with the states, it is also limited in its ability to directly interact with the more than 3,000 local health agencies that in many states have primary responsibility for conducting patient interviews. The result is that in many outbreak investigations, local agencies are left out of the loop and may not fully appreciate the importance of their individual efforts (or lack thereof) to the overall outbreak investigation. Establishing effective means of integrating local agencies into large, multi-state investigations that are detected and coordinated on a national level is a major concern.

From 2002–2005, 40% of *E. coli O157:H7* outbreaks and 25% of *Salmonella* outbreaks reported to CDC were multi-jurisdictional in occurrence. Increasingly, these outbreaks are detected by the identification and investigation of clusters of cases with identical pulsed-field gel electrophoresis (PFGE) profiles. These profiles are the fingerprint of the infectious agent that allows us to determine their similarity and serve as the key data used in PulseNet. The development of standardized PFGE protocols and the ability to transmit and store digitized PFGE patterns has put PulseNet at the forefront of pathogen-specific surveillance for *Salmonella*, *E. coli O157:H7* and *Listeria*. No longer do states have to send living cultures to CDC for the purposes of comparison. Electronic image files can be uploaded to a central server and shared with public health officials instantly, around the country.

The active participation of public health laboratories can be seen from the result of surveillance in 2005, when over 5,000 *E. coli O157:H7* patterns and almost 30,000 *Salmonella* patterns were uploaded to PulseNet. These data and the subsequent analysis resulted in the detection of 36 multi-state *E. coli O157:H7* clusters and 152 multi-state *Salmonella* clusters. The CDC was involved in 19 multi-state *E. coli O157:H7* investigations and 30 multi-state *Salmonella* investigations. However, the food items responsible for transmitting the infectious agent, known as a vehicle, were identified for only four *E. coli O157:H7* investigations (or 21%) and eight *Salmonella* investigations (27%) (CDC data presented at 2008 OutbreakNet/CSTE meeting by Dr. David Warnock).

The relatively low yield of these investigations is disappointing. While some of these clusters may have represented the co-incidental occurrence of organisms with a similar pattern from multiple unrelated sources, others were almost certainly outbreaks for which the source could not be identified. There are many reasons why an investigation may fail to identify a common source. The first is the length of time between when patients got sick and when the outbreak was recognized. In a study of enteric disease timelines, known as the EDITS study and led by Dr. Hedberg and conducted on behalf of CSTE, the average time interval between onset of illness and subtyping by PFGE was 15 days for *E. coli O157:H7* and 18 days for *Salmonella*. Because a cluster is defined as the occurrence of multiple cases caused by strains with matching PFGE patterns, clusters may not be recognized until 3–4 weeks after onset of illness. If interviews of cases are not initiated until after the cluster is identified, these further delays mean cases are being interviewed about exposures that may have occurred 4–6 weeks earlier. Longer delays reduce the likelihood that cases will accurately recall important details of where and what foods they may have eaten before they became ill. Since the incubation period for *E. coli O157:H7* and *Salmonella* infections may be up to a week, this represents a considerable challenge to identifying the contaminated food item.

A final challenge to identifying the source of contamination is that many public health agencies do not use a standardized exposure questionnaire or collect detailed source information about food items during initial interviews. It is very common to identify from which restaurants and grocery stores food was obtained and also to ask about consumption of food items such as chicken, ground beef or lettuce and tomatoes. However, these are not always cross-referenced in a way that would link a specific tomato to a meal at a specific restaurant—information that is critical to tracing the source of contamination. Systematically collecting detailed exposure information during early interviews with cases is a critical need to improve the effectiveness of our surveillance and outbreak investigation efforts.

Opportunities for improving foodborne disease surveillance.

The challenges we face in improving our foodborne disease surveillance have been becoming increasingly apparent for some time. The CDC, FDA and the CSTE have been working for a number of years to define the problems and seek solutions. In 2001, the National Food Safety System (NFSS) Project, Outbreak Coordination and Investigation Workgroup published guidelines for improving coordination and communication in multi-state foodborne outbreak investigations. These were specifically developed to address the challenges of coordinating large and complex foodborne outbreak investigations among multiple states and Federal public health and food regulatory agencies.

While these guidelines targeted communication and coordination "at the top" of the investigation, they appear to not have increased our ability to engage local public health agencies in multi-state outbreak investigations and to rapidly develop the critical exposure information "at the base" of the investigation.

While we fully support the effort of CIFOR, the multidisciplinary working we discussed previously, we want to submit that there is a natural conservatism in any large and complex system that resists the adoption of the types of new practices we believe may be needed to make effective use of the tools we now have available for foodborne disease surveillance in the U.S., and to respond to the challenges posed by our rapidly changing food systems. The tension between holding onto the methods of the past and using effective new methods of the present are seen in much of the discussions within CIFOR, and the development of guidelines for investigating outbreaks. Drafts of these guidelines are currently available for review and comment on the CIFOR website (*http://www.cifor.us/documents/CIFORGuidelines-draft.pdf*).

Chapter 4 of these guidelines on foodborne disease surveillance and outbreak detection contains a very thorough overview of foodborne disease surveillance methods, strengths and limitations. This chapter also describes model practices for routine surveillance and cluster evaluation—the actions that led to the early detection of outbreaks such as the recent outbreak caused by *Salmonella* serotype Saintpaul. The reality of the current situation is that the practices used may vary based on pathogen priority, the needs of a particular outbreak, and on an agency's resources. These determinations are made on a state-by-state and agency-by-agency basis. However, there are a series of practices described that provide a more aggressive approach to surveillance that we believe give us the best chance to rapidly detect outbreaks and identify the source of exposure. Many of these are practices have been successfully used by the MDH. These include interviewing all laboratory-diagnosed cases when they are first reported using a standardized form to collect detailed exposure information when recall is the greatest, and as possible new expo-

sures are suggested during case interviews linked to an outbreak, to systematically re-interview initial cases to uniformly assess these exposures. We believe these should be adopted as best practices, and that where resources limit the adoption of these practices, we must find a way to build the infrastructure of our public health system to make it possible.

Another key to the success of foodborne disease surveillance in Minnesota has been the use of a dedicated group of eight to ten public health students (four to five FTE's), known as "Team Diarrhea", to serve as a primary resource for interviewing cases as part of routine surveillance and outbreak investigation. The use of Team D fits very nicely into the centralized system of foodborne disease surveillance that exists in Minnesota. Moreover, since conducting interviews in a timely manner is one of the rate-limiting steps in outbreak investigations, we believe a series of regional Team Ds or a national Team D would go a long way to providing precisely the real-time support for outbreak investigations at the state and local levels that is so sorely needed.

The benefits of Team D go far beyond providing a dedicated group of interviewers. Because members of Team D are public health students at the University of Minnesota, they receive valuable experience in conducting surveillance that enriches their academic training immeasurably. The graduates of Team D are now moving into important food safety roles in public health and food regulatory agencies across the country.

We believe the time is right to build on the success of Team D in Minnesota and to invest in a major Masters of Public Health-level training program that should include epidemiology and surveillance methods, risk assessment and risk management, and overviews of the food system from farm to fork. This training program should include service on National Team D, to conduct interviews and support outbreak investigations at state and local levels.

The model for such a training program currently exists at the University of Minnesota, School of Public Health. In addition to our academic tracks in Infectious Disease and Food Safety, the University has a post-graduate certificate program in Food Protection that defines the key curriculum for food safety, with course offerings available through a 3 week public health institute, or online.

We bring this to your attention to demonstrate that we have the capacity to rapidly scale up this training program and establish both a National Team D to provide an immediate resource to rapidly conduct interviews to support multi-state outbreak investigations, and a long-term program to develop a new generation of food safety specialists with applied training in outbreak investigations to work in public health and food regulatory agencies and food-producing industries.

To accomplish this effort quickly and with expertise, we propose that the University of Minnesota can be designated as the lead academic institution to develop this new food safety training initiative and that a consortium of other schools of public health be established to replicate this training program under the University's leadership. Within 1 year this program can be established and prepared to support outbreak investigations across the country. Within 5 years it will transform foodborne disease surveillance at all levels.

A frequent objection to the "Minnesota Model" has been the additional resources needed to interview all cases of foodborne diseases with a sensitive and specific questionnaire, conduct laboratory testing on a "real time" basis, and routinely investigate all clusters of disease. We don't know how much money is currently being spent on foodborne disease surveillance nationwide, but a CIFOR cost-benefit study is underway to answer that question. Our understanding is that most of the nation's capacity is funded by the CDC Epidemiology and Laboratory Capacity Cooperative Agreement, which has had level or declining funding for the past several years. Many states do not have any dedicated foodborne disease epidemiologists, and some states have only a single part time laboratory worker to conduct PFGE analysis. We believe that the amount of funds needed to improve this situation nationwide is small compared to the consequences of maintaining the *status quo*. The MDH, serving a population of more than five million people employs four to five student FTE's to interview all reported cases of foodborne disease in a timely and systematic manner at a cost of approximately $100,000 per year. Minnesota has made a greater investment in epidemiologists and laboratory workers than most states and we believe the stellar record of disease detection and outbreak response is a direct result. Extrapolating from the Minnesota experience, we estimate that enhanced nationwide surveillance for *Salmonella, Shigella, Campylobacter,* and *E. coli O157:H7* disease would cost between $25 million and $50 million additional per year nationwide. To put this number in perspective, a single case of hemolytic uremic syndrome, the direst consequence of *E. coli O157:H7* infection, costs between $½ to $1 million in medical costs alone, and a single death has been estimated to cost society approxi-

mately $6.2 million. Based on these estimates, it would take very few prevented cases per year to justify the entire investment.

We don't know how many cases of foodborne disease are being prevented by our current system, or how many cases could be prevented with enhanced surveillance. We do know that since 1998, hundreds of millions of pounds of contaminated food have been removed from the marketplace and destroyed or discarded as the result of these activities and have included such varied vehicles as peanut butter, ground beef, breakfast cereal, almonds, frozen pizza, and stuffed chicken products. Surveillance has allowed us to identify unrecognized problems in our food and water delivery systems that might continue for years if not detected. Therefore, we believe it's safe to say that the number of cases of disease prevented by our current surveillance system is a very large number. Nevertheless, the consequences of these outbreaks remain high, and as we have described most outbreaks are probably not recognized or resolved. As we have seen during the past several months and during the 2006 outbreak associated with fresh spinach, industry suffered extraordinary losses during protracted outbreak investigations. The cost of fixing our system is only a fraction of what industry loses in a single outbreak caused by delayed or inadequate investigation.

In conclusion, we do know how to greatly reduce foodborne diseases. We believe that most food producers and distributors place high priority on delivering safe food to our tables. Furthermore, quality foodborne disease surveillance and outbreak investigation fundamentally changes the economics of food production, leveling the playing field between those that work hard to produce safe food and those that cut corners. We must continue to improve food safety through better design and implementation of our food safety systems, promoting the use of food irradiation and improving the traceability of implicated products when inevitable problems occur. With a minimal investment in foodborne disease epidemiology resources and disease surveillance infrastructure, we can greatly improve our ability to detect and respond quickly and correctly to unexpected problems such as the *Salmonella* serotype Saintpaul outbreak we are discussing today.

Thank you Mr. Chairman for this opportunity to share with you and the other Subcommittee Members our experience and perspectives on this important issue. I'm happy to answer any questions you or the Subcommittee may have.

The CHAIRMAN [presiding.] Thank you, Doctor.

Next up we have Mr. Anthony DiMare, Vice President of DiMare Homestead Inc., from Ruskin, Florida. Mr. DiMare, welcome. Thank you. The floor is yours for your testimony.

STATEMENT OF ANTHONY J. DIMARE, VICE PRESIDENT, DIMARE HOMESTEAD INC., DIMARE RUSKIN INC., AND DIMARE JOHNS ISLAND INC.; MEMBER, BOARD OF DIRECTORS, FLORIDA FRUIT & VEGETABLE ASSOCIATION; PRESIDENT, FLORIDA TOMATO EXCHANGE; MEMBER, BOARD OF DIRECTORS, UNITED FRESH PRODUCE ASSOCIATION, RUSKIN, FL

Mr. DIMARE. Thank you, Mr. Chairman. Good afternoon, Members of the Subcommittee. My name is Tony DiMare. I am Vice President of DiMare Homestead Inc., DiMare Ruskin Inc. and DiMare Johns Island Inc. in South Carolina. I am pleased to have this opportunity today to address this group.

The DiMare Company is an 80 year old family-owned produce company that grows, packs and ships tomatoes and other vegetables from seven states across the United States. And I must say, in the 80 year history of our company, we have not had any foodborne illness relating back or tracing back to any one of our farms in that time period.

I represent the third generation of my family to carry on our produce business. I am a past Chairman of the Florida Fruit and Vegetable Association and currently serve on its executive committee and Board of Directors. I recently was elected to the United

Fresh Produce Association Board of Directors. I also serve as President of the Florida Tomato Exchange and I am former Chairman of the Florida Tomato Committee and the Florida Tomato Growers Exchange. I was also appointed in 2002 to the inaugural USDA Fruit and Vegetable Industry Advisory Committee.

Today I want to speak to you about our company's food safety program, Florida's new mandatory food safety regulations for tomato production and how DiMare Company was affected when the CDC and FDA singled out tomatoes in the *Salmonella* Saintpaul outbreak.

Food safety is at the forefront of everything we do day in and day out at the DiMare Company. Not only do our customers demand it, today's consumers expect that fresh produce they buy at the supermarket or eat in a restaurant is safe and nutritious. Simply put, ensuring food safety is the right thing to do. From our farms to our packing facilities and distribution centers, the food safety team at the DiMare Company works diligently to ensure all products are maintained in a food-safe environment at every stage of the process.

Our stringent internal food safety program includes monthly facility audits and mock recalls throughout the year. Audits by third-party companies ensure our program exceeds industry standards. All DiMare fresh locations are audited twice a year by the American Institute of Baking and have received the highest scores possible. Each of our farms is audited by Primus Labs and Davis Fresh. In addition, we routinely test our fields, facilities and all water sources for pathogens. We follow good agricultural practices in our fields and best manufacturing practices in our packing facilities.

Our company has invested significantly in technology and personnel to ensure product traceability. All DiMare Company produce can be traced back to the grower and all produce originates from either DiMare farms or growers who participate in our food safety program.

Not only is the DiMare Company an industry leader in food safety, the State of Florida is as well. On July 1 of this past year, Florida became the first state in the country to adopt a comprehensive food safety program with mandatory government inspection and audits for tomato handling, production and packing. Other states have inquired about the program as a model. The program includes annual registration of all producers, packers and repackers of tomatoes in Florida. It also requires regulatory inspections and audits by state inspectors from the Florida Department of Agriculture and Consumer Services.

Our industry was shaken to the core in June when the CDC announced that tomatoes were a suspected source of the *Salmonella* outbreak and the FDA issued a broad advisory for all consumers to avoid eating certain types of tomatoes. Shipments ground to a halt. Tomatoes were left in the fields, in the packinghouses and on trucks that were turned away by our customers. More than a week went by before the FDA cleared 19 Florida counties to ship tomatoes. By then, however, consumers were too confused and were reluctant to resume buying tomatoes. Severe losses were incurred all along the distribution chain. Early on, our sales were down as

much as 60 percent and business has been slow to pick up. Today our repack operations are still off by approximately ten to 20 percent.

Adding to our frustration during the traceback was the FDA and CDC's reluctance to turn to industry for help in understanding and identifying distribution channels, knowledge they clearly lacked. Tapping into industry expertise early on would have gone a long way in speeding up the traceback. More cooperation is clearly needed in the future.

In conclusion, even though the FDA has announced that all tomatoes are safe to eat and has focused its attention on other produce, we urge both FDA and CDC to completely clear Florida tomatoes as a potential source of the outbreak. In addition, we are calling on these agencies and others to sit down with industry to determine how the investigation and traceback process can be improved. Hard questions need to be asked and lessons must be learned from this outbreak so that a similar situation never happens again.

Looking ahead, we don't know how long it will take for consumer confidence in fresh tomatoes to rebound. What has transpired over the past 2 months is sure to affect our business into next season. As an industry, we are strongly committed to taking whatever proactive steps are necessary to ensure Americans know they are consuming the safest, healthiest and most nutritious fresh produce possible.

I want to again thank the Committee and Chairman Cardoza for this opportunity to speak to you today.

[The prepared statement of Mr. DiMare follows:]

PREPARED STATEMENT OF ANTHONY J. DIMARE, VICE PRESIDENT, DIMARE HOMESTEAD INC., DIMARE RUSKIN INC., AND DIMARE JOHNS ISLAND INC.; MEMBER, BOARD OF DIRECTORS, FLORIDA FRUIT & VEGETABLE ASSOCIATION; PRESIDENT, FLORIDA TOMATO EXCHANGE; MEMBER, BOARD OF DIRECTORS, UNITED FRESH PRODUCE ASSOCIATION, RUSKIN, FL

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Today I want to speak to you about our company's food safety program, Florida's new mandatory food safety regulations for tomato production, and how DiMare Company was affected when the CDC and FDA singled out tomatoes in the *Salmonella* Saintpaul outbreak.

Food Safety and Traceability

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Florida's Food Safety Program

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The program includes annual registration of all producers, packers and repackers of tomatoes in Florida. It also requires regulatory inspections and audits by state inspectors from the Florida Department of Agriculture and Consumer Services.

The Outbreak

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Adding to our frustration during the traceback was the FDA and CDC's reluctance to turn to industry for help understanding and identifying distribution channels—knowledge they clearly lacked. Tapping into industry expertise early on would have gone a long way in speeding up the traceback. More cooperation is clearly needed in the future.

Conclusion

Even though the FDA has announced that all tomatoes are safe to eat and has focused its attention on other produce, we urge both the FDA and CDC to completely clear Florida tomatoes as a potential source of the outbreak.

In addition, we are calling on these agencies and others to sit down with industry to determine how the investigation and traceback process can be improved. Hard questions need to be asked, and lessons must be learned from this outbreak so that a similar situation never happens again.

Looking ahead, we don't know how long it will take for consumer confidence in fresh tomatoes to rebound. What has transpired over the past 2 months is sure to affect our business into next season. As an industry, we are strongly committed to taking whatever proactive steps are necessary to ensure Americans know they are consuming the safest, healthiest and most nutritious fresh produce possible.

Thank you again for the opportunity to address the Subcommittee today.

The CHAIRMAN. Thank you, Mr. DiMare.

Next up we have Mr. Giclas, Vice President of Strategic Planning, Science and Technology for Western Growers.

STATEMENT OF HENRY L. "HANK" GICLAS, VICE PRESIDENT—STRATEGIC PLANNING, SCIENCE AND TECHNOLOGY, WESTERN GROWERS ASSOCIATION, IRVINE, CA

Mr. GICLAS. Good afternoon, Chairman Cardoza, Members of the Subcommittee. I am Hank Giclas, Vice President for Strategic

Planning, Science and Technology at Western Growers, a trade association representing growers, shippers and handlers of fresh fruits, nuts and vegetables in California and Arizona. Our 3,000 members produce approximately half of the United States total production of fresh fruits, nuts and vegetables. We appreciate the opportunity to speak before you on the *Salmonella* outbreak and its consequences for tomato growers.

The industry has a decades-long history of implementing food safety improvements and has a commercial interest in ensuring that only safe, wholesome, fresh produce is delivered to our customers' tables.

The issuance of a consumer alert relating to red round tomatoes has cost the California tomato industry millions of dollars to date. The nature of the alert has precluded industry from accessing established avenues of recourse such as insurance programs to help with recovery. In addition, the lack of an effective, timely "all clear" message from public health authorities, a formalized restorative campaign for the commodity and the continuing implication of additional commodities have eroded consumer confidence such that losses are likely to increase. Keep in mind, these negative impacts are from growing regions that have not been implicated during this outbreak.

On June 3, 2008, the FDA alerted consumers in New Mexico and Texas that a *salmonellosis* outbreak appeared to be linked to certain types of raw red tomatoes and products that may contain them and warned consumers not to eat these products. A few days later, the FDA expanded its warning to consumers nationwide. They did communicate that several areas had been excluded as a potential source for suspect tomatoes but this nuanced message was largely lost on buyers, who avoided purchasing all tomatoes.

In a survey of Western Growers' tomato-producing members, individual losses ranged from $400,000 to $3.4 million. They are mostly due to lower market prices related to poor demand. To date, our members have experienced nearly $13 million in early season losses at the farm gate related to this advisory on tomatoes. The grower-level losses multiply as you add the economic losses sustained at other points along the supply chain.

Consumer polls surveying attitudes about food safety found that ⅔ of consumers had stopped purchasing tomatoes and that many consumers have changed their eating and buying habits over the past 6 months because they are afraid they could get sick by eating contaminated food.

Grower losses and waning consumer confidence are our principal rationale for being here today. When FDA takes action to issue a broad consumer warning, it is, for all practical intents and purposes, an international recall for that commodity, regardless of production area or variety. It calls into question the offerings of all producers, handlers, retailers and food service providers and causes immediate and long-term damage to the marketplace. Today, months after the outbreak began, we still have no conclusive food items identified as the source of these illnesses, and for every speculation as to potential products, there is a negative marketplace reaction.

FDA has access to expertise that can help guide the agency through the complexities of the produce supply chain quickly and efficiently. It is imperative for FDA to establish an incident command process, an outbreak team, if you will, that includes industry experts that would be formally engaged from the very beginning to assist the agency in their investigations. True reforms, improvements and enhanced protection of both public health and industry cannot occur in a siloed fashion. We must work together. The declaration of outbreaks, the management of traceback, the communication with industry and the public must be reviewed and examined using this outbreak and others as examples. We must look at effective models such as the Minnesota effort that recently outpaced FDA in the traceback on jalapeños.

Western Growers is here to ask that impacted growers be made whole and for changes to be made in the way FDA and CDC investigate and communicate during outbreaks. The industry adopts measures constantly to improve the safety of our produce for the protection of our customers, but what about our protection? To exclude the industry from the investigative procedures ignores knowledge and expertise that can be brought to bear to help bring outbreaks to swifter conclusions. Instead, our industry is left in ruins. We must be made whole and a new, more transparent, more participatory communications and investigative process must emerge from FDA and CDC.

I thank you for the opportunity to testify and look forward to the questions.

[The prepared statement of Mr. Giclas follows:]

PREPARED STATEMENT OF HENRY L. "HANK" GICLAS, VICE PRESIDENT—STRATEGIC PLANNING, SCIENCE AND TECHNOLOGY, WESTERN GROWERS ASSOCIATION, IRVINE, CA

Good afternoon Chairman Cardoza and Members of the Subcommittee. I am Hank Giclas, Vice President for Strategic Planning, Science and Technology at Western Growers. Western Growers is a trade association representing growers, shippers and handlers of fresh fruits, nuts and vegetables in California and Arizona. Our 3,000 members produce approximately half of the United States total production of fresh fruits, nuts and vegetables and are committed to ensuring that these products are delivered safely to consumers, here in the United States and abroad.

Western Growers appreciates the opportunity to speak before you on the *Salmonella* outbreak and its consequences for our tomato growers. We also want to highlight the status of ongoing efforts within the produce industry to ensure safe food reaches the American table.

The industry has a decades-long history of implementing food safety improvements to prevent both deliberate and unintentional contamination of produce as it makes it way from the field to the retail store or restaurant. We have a commercial interest in ensuring that only safe wholesome fresh fruits, nuts and vegetables are delivered to our customers' tables. As a result, industry is driven to constantly improve and refine its own food safety programs and food safety defense capabilities.

In addition, there are historical legal requirements, such as the Perishable Agricultural Commodities Act and the Bioterrorism Act as well as new governmental mandates and calls for industry action, for example, the Produce Safety Action Plan and the more recent Food Protection Plan, that have spurred industry improvements in the areas of prevention and traceback; each integral parts of comprehensive food safety programs. These efforts, conducted in cooperation and consultation with FDA, DHS, USDA, state departments of health and agriculture and food safety experts have resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, and the ability to respond more quickly to outbreaks of food borne illness.

Despite these ongoing and significant improvements in industry food safety programs and practices, the U.S. Centers for Disease Control and the Food and Drug Administration appear to maintain a "guilty until proven innocent" approach to the

regulation of select commodities that has manifested itself recently in sweeping "consumer advisories" that confuse consumers and wreak havoc in both domestic and export markets. The result is significant losses at all levels of the supply chain with no demonstrable positive impact on consumer food safety. It is very likely that the public health impact has been just the opposite, as confused consumers abandon fresh fruits and vegetables in their diet in response to FDA and CDC alerts.

The June 2008 issuance of a consumer alert relating to red round, roma and plum tomatoes has cost the California tomato industry an estimated 30 million dollars to date and has precluded industry from accessing established avenues of recourse such as insurance programs to help with recovery. In addition, the lack of an effective, timely "all clear" message from public health authorities, a formalized restorative campaign for the commodity, and the continuing implication of additional commodities have eroded consumer confidence such that losses are likely to increase. Keep in mind that these negative impacts are from growing regions that have not been implicated at any time during this outbreak. Nonetheless they have been painted with the same brush by CDC and FDA.

Need for Indemnity and Improved Regulatory Processes

First let me explain specifically why Western Growers asked for this hearing. On June 3, 2008—The Food and Drug Administration alerted consumers in New Mexico and Texas that a *salmonellosis* outbreak appeared to be linked to consumption of certain types of raw red tomatoes and products containing raw red tomatoes and warned them not to eat certain types of raw red tomatoes. The bacteria causing the illnesses are *Salmonella* serotype Saintpaul, a relatively uncommon type of *Salmonella*. Four days later on June 7, 2008 the Food and Drug Administration expanded its warning to consumers nationwide that a *salmonellosis* outbreak had been linked to consumption of **certain** raw red plum, red Roma, and red round tomatoes, and products containing these raw, red tomatoes and warned consumers not to eat these products unless they could be effectively identified as being from one of several states or countries that had been excluded as a potential source for the suspect tomatoes.

This nuanced message was largely lost on consumers and to a certain extent industry buyers who instead avoided purchasing all raw red, red Roma and red plum tomatoes. As a result, growers on the okayed list experienced severe restrictions in demand and depressed pricing.

One of our members, a Central California tomato grower, lost $1.4 million in revenue due to lower market prices related to poor demand. Other members including Central Valley and Central Coast tomato growers have reported losses ranging from $400,000 to $1.5 million. And suffering perhaps the greatest damage among our membership, another Central California member has sustained losses of nearly $3.4 million. In addition to revenue losses in the market, several of our members have had to disc up their tomato acreage because there are simply no buyers.

To date, our members have experienced nearly $13 million in losses at the farm gate related to the FDA advisory on tomatoes. It's important to note that this $13M figure reflects only early season losses. The growing season for tomatoes in California doesn't peak until late July and August. As indicated earlier, the losses are expected to increase. It is also important to note that these numbers are calculated at the grower level, and do not include economic losses sustained at other points along the supply chain, including shippers, packers, processors, and retailers and food service.

In addition, two consumer polls were conducted recently surveying attitudes about food safety and the potential to avoid commodities that have been implicated in recent media stories. The first was a Produce Marketing Association survey, conducted June 13 to 19, which found that while 88 percent of those surveyed indicated they were regular consumers of fresh tomatoes, ⅔ of consumers had stopped purchasing tomatoes. Remember, at this time only a few production areas in Florida and Mexico had been implicated by FDA. But in the market, it didn't matter that most of the country's tomatoes were deemed safe to eat. The second survey, which has implications well beyond tomatoes, was an Associated Press-Ipsos poll, conducted July 10 to 14, which found that 46 percent of people surveyed were worried they might get sick from eating tainted products, such as tomatoes. In fact, these consumers have changed their eating and buying habits over the past 6 months because they are afraid they could get sick by eating contaminated food.

Grower losses and waning consumer confidence underlie our principal rationale for being here today. We have stated publicly that these sweeping generalizations and speculations in the public arena cannot go unquestioned and that the protocol for making a decision to implicate an entire commodity generically must become transparent to the public and subjected to fair and balanced scrutiny. When FDA

takes action to issue a broad consumer warning it is for all intents and purposes an international recall for that commodity, regardless of production area, or variety. A recall that calls into question the offerings of all producers, handlers, retailers and food service providers causes immediate and long-term damage to the marketplace.

Western Growers asks that the impacted growers be made whole, and for changes to be made in the way FDA and CDC investigate outbreaks and communicate outbreaks to consumers. The FDA and CDC have an entire industry army at the ready to assist with any food borne illness outbreak, but we are left largely out of the process. We have a common goal: safety of the food supply.

To advance this common goal it is imperative that both industry and government work together. True reforms, improvements and enhanced protection of both public health and industry cannot occur in a siloed fashion or by pointing fingers of blame. We must talk openly and candidly about the declaration of outbreaks, the management of traceback, and the communication with industry and the public including examining CDC criteria for connecting a food source to an outbreak (as well as the criteria for clearing it), FDA operating procedures, internal policies, experience in tracing product in the fresh produce industry, and the desperate need for improved messaging to industry and consumers.

We are here today, a full 2 months after the outbreak began, with no definitive idea as to what food item(s) is (are) responsible for the illnesses. FDA has speculated in calls with the media that the outbreak "could be" attributed to tomatoes *or* "foods commonly served with tomatoes" "such as" jalapeño and serrano peppers, cilantro, onions *or* "foods where these are common ingredients" like salsa, pico de gallo, guacamole. For every speculation there is a negative marketplace reaction.

It borders on reckless for CDC and FDA to operate seemingly without clear definitive criteria for when they can and cannot name or intimate a commodity as a public health risk. We firmly believe that a structured problem analysis must occur to quickly identify what is and is not implicated by the epidemiology and that levels of confidence must be established prior to impugning an entire commodity. While CDC and FDA may conduct this analysis today, the analytical process has not been effectively communicated to industry or others who could possibly review and refine the approach. There must also be a specific timeframe established to communicate at each stage of the analysis such that it is clear at what stages information is released and or shared with all parties. FDA has access to industry expertise that can help guide the agency through the complexities of the produce supply chain quickly and efficiently. It's imperative for FDA to establish an incident command process—an outbreak team, if you will—that includes industry experts and would be formally engaged from the very beginning to help the agency in its investigations.

In protecting public health it is important to ensure FDA is able to respond from a relevant position. World class manufacturing organizations turn their inventories over 18 to 25 times a year. Produce companies turn their inventories over 100s of times per year. In the time it takes the system to identify an outbreak (up to 2 weeks) growers may have turned their inventory over dozens of times. This lag time coupled with the rapid movement of industry product puts FDA in an "after the fact" or "reactionary" position. We must look at the entire system with an eye towards reducing this lag in order to improve the overall ability of all parties to respond.

Industry Activity and Capability

Good Agricultural Practices (GAPs)

The fresh produce industry has a long history of activity in the area of food safety. Much of the activity has centered on the development and dissemination of guidelines to prevent contamination from the field throughout the supply chain to the consumer. This work has been and continues to be critical to the first element of FDA's integrated strategy to protect the food supply (as outlined in the Food Protection Plan of 2007) which is to "prevent" contamination in the supply chain.

Western Growers has been integrally involved since our lead in the development of the first ever "good agricultural practices" document in the mid 1990's. This landmark industry work laid the foundation for FDA and USDA to develop and publish in 1998 the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" which today remains the benchmark utilized by FDA and USDA in gauging the adequacy of prevention programs employed by the fresh produce industry.

That benchmark, while effective for most fresh produce commodities, has evolved significantly for select commodities that have been deemed a higher risk because of their continuing association with key pathogens. In the last few years, beginning as a response to the Produce Safety Action Plan issued by FDA in 2004, industry has

developed much more specific guidance for several commodities that continue to be identified by FDA as higher risk including tomatoes, leafy greens and cantaloupes.

These newer more specific sets of good agricultural practices have again been widely disseminated and closely adhered to by producers of these commodities. Adherence has typically been overseen by the marketplace in the form of buyers who will not purchase from parties that have not been rigorously audited to ensure they meet or exceed the benchmark.

Driven by more recent outbreaks, both the tomato and leafy greens industries have moved beyond the commodity specific guidelines to more prescriptive sets of best practices. In close collaboration with the FDA CFSAN and CDC scientists and with other public health and academic partners, newer specific guidelines were developed driving the adoption of more rigorous best practices by the industry to reduce or mitigate potential risks.

With regard to leafy greens in particular, California and Arizona have established uniform GAPs and a corresponding verification program that requires implementation of food safety measures developed with the FDA, CDC, state health authorities and private sector experts. Compliance with the requirements is verified by government inspectors.

As a result of these newer generation guidelines, risk assessment procedures, sampling and analysis of inputs, safety response measures and requirements for documentation can now be verified in the field. These guidelines have become the foundation for formalized verification programs in which government inspectors audit production and handling practices for compliance. They are a food safety lynchpin, for helping FDA and industry advance efforts to prevent contamination.

Traceability

While efforts to improve our abilities to prevent contamination have long been the focal point of industry activity, it is also clearly evident that efforts to "intervene" and "respond" in the event of food borne illness or positive identification of a contaminated product are critical to protecting public health as well as important to improving food safety systems. One element of key importance is traceability. It is critical that producers, handlers and others within the supply chain be able to quickly and efficiently identify where product was sourced and to whom it was delivered so as to limit the scope of any event.

In today's business environment, there are many requirements for record keeping that facilitate tracing product from its point of service to its origin. The legal requirements of the Perishable Agricultural Commodities Act, the Bioterrorism Act and state standardization and marketing laws all require documentation about the entity to whom the product was sold, and from whom the product was received.

These documents can be maintained in a variety of formats but when handlers are asked to identify from where they sourced product and to where they shipped product they can readily provide that information today. Current industry approaches employed by shippers and processors, associate a product with a number that conveys information on harvest date, harvest crew, field location and grower, in other words, traceback to the field.

In the recent investigation of tomatoes we have been repeatedly told that industry's traceback capabilities have made it difficult for investigators to follow the trail from a point of service to a production field but we have received no information on where this traceback breaks down. Is it a function of some entity not maintaining required records? Are the records in a format that cannot be utilized by FDA? Is FDA actually getting back to the handler level before traceability is lost? Western Growers is firmly committed to leading the industry to improving our own and FDA's ability to intervene and respond but we must understand the challenges faced by FDA in this arena.

During the current *Salmonella* outbreak, we have asked repeatedly for this information, first when the investigation was focused on tomatoes, and now, as the investigation has shifted to jalapeños.

Please don't misunderstand our frustration. We are not saying that the industry could not improve its timeline for traceback. In fact, we are participating in such an initiative underway that will be based on a common language and uniform data requirements. But we have no evidence that delayed traceback is to blame for the ongoing outbreak.

Conclusion

The industry adopts measures constantly to improve the safety of our produce for the protection of our consumers. But what about our protection? To exclude the industry from investigative procedures ignores knowledge and expertise that only industry can bring to bear to help bring outbreak to swifter conclusion. Instead, our

industry is left in ruin. We cannot sit by any longer. We must be made whole, and a new, more transparent, more participatory communications and investigative process must emerge from the FDA and CDC.

The CHAIRMAN. Thank you very much, sir.

Next up, we have Bryan Silbermann, President of the Produce Marketing Association, and I am going to admonish all our witnesses, I know you have come a long way to testify. I have read every one of our prepared testimony. We are getting very long in the day here. We have other folks and we have other meetings that I am missing to be here today. This is very important to our country, so I have no problem with that, but whatever you can do to summarize your testimony and get the most salient points, I would appreciate it. Mr. Silbermann.

STATEMENT OF BRYAN SILBERMANN, C.A.E., PRESIDENT, PRODUCE MARKETING ASSOCIATION, NEWARK, DE

Mr. SILBERMANN. Chairman Cardoza, Members of the Subcommittee, my name is Bryan Silbermann, President of the Produce Marketing Association and I will briefly summarize my written comments.

PMA is the largest worldwide association of companies that market fresh fruits and vegetables. We represent 3,000 companies and their subsidiaries spanning the entire produce supply chain. Since our start nearly 60 years ago, PMA has pioneered packaging concepts for produce and served as a clearinghouse for standardization. Over the past 2 decades, this Association and I personally have been at the center of developing standards to improve the flow of information from produce packinghouses to the consuming public. Mr. Chairman, that includes those small stickers on the fruit and other items shipped from your district as well as standard barcodes on packaged produce. This involvement combined with our members' commitment to provide fresh and wholesome fruit and vegetables compel us to appear here today.

It has been said many times that food safety is the top priority for all our members and it has been that way for many years. The deeply troubling spinach *E. coli* outbreak and the recent *Salmonella* outbreak are tragedies that shake the public's trust. Rather than casting blame, we want to and need to work on solutions. We all have a shared responsibility to protect public health.

The produce industry has already changed rapidly to avoid the introduction of risk into the food system. This paradigm shift brings with it new responsibilities, not just for us but also for government. We cannot as an industry reflexively oppose regulation but government action must recognize and harness the ingenuity of the private sector to improve food safety and to gain back the full confidence of our consumers. At the same time, it is not our role as the private sector to wait passively for government to regulate. We must act and we are already doing so.

Today's hearing is recognition that traceability is one key to the food safety process, and I would like to applaud Dr. Osterholm's comments about how it is a second step in the process that must follow associations done by public health authorities. Unlike other food industries, the produce marketing chain has been required to maintain records since the 1930 passage of the Perishable Agricul-

tural Commodities Act. The Bioterrorism Act added the "one up, one back" concept, but the requirement for comprehensive record-keeping has been a longstanding legal obligation. Focusing exclusively on this legal requirement misses the advancements we have made to improve not just the retention of records but also the tracking of fresh produce.

Our companies have internal systems to track produce. However, the very handling needs of hundreds of different fresh fruits and vegetables and the diversity of systems needed to manage them made us look to common elements to enhance and speed up the link between these diverse approaches.

Last year PMA, United Fresh and CPMA launched a traceability initiative to reach across the entire supply chain. This proposes that these three common elements use an existing, standard, global format. I want to stress the words "global" and "standard" because the solution we develop must work for all fresh produce, no matter where it is grown or shipped. The three comments simply are, number one, a global trade item number which identifies the supplier as well as the item in the case, number two, the lot number, and number three, the harvest or pack date. These three pieces of information will be on each case in human readable form. By reading the label, one will know the supplier of the product and the lot number assigned. The information is also encoded in a barcode each company can scan, giving every handler a record of when the case entered and left his facility. Think of these three pieces of information as a baton that is passed by one runner in a relay race to the next. That common information then travels and can be tracked from start line to finish. I also want to stress, Mr. Chairman, that we have reached out as an industry to brief both FDA and USDA officials on this work.

In less than a month, the initiative steering committee will be meeting to approve an action plan and a timeline for implementation. First, you will see produce suppliers begin labeling cases with both human-readable and machine-readable information. Next, companies will begin reading and storing this electronically. Through this process, we will have faster enhanced traceability across our supply chain.

As an industry, we take seriously our obligation to develop solutions, not just the traceability initiative I have described. We also must help determine what went wrong in the *Salmonella* investigation. That is why during this crisis, Mr. Stenzel and I jointly wrote to Secretary Leavitt to offer our assistance in uncovering the source of the pathogen by lending industry's unique knowledge of distribution and handling processes. We wrote again when our first letter went unanswered and only recently did we hear that we will eventually meet with FDA and CDC on this. We want to participate in jointly and transparently learning lessons and improving regulators' process of traceback.

Just as we recognize our obligations, it is our profound hope that any future legislative and regulatory changes will be fashioned to work with the industry to fulfill our shared responsibility, which is to protect public health by providing safe, wholesome and nutritious food, every bite, every time.

Mr. Chairman, thank you for the opportunity to appear before you today. I look forward to answering your questions.

[The prepared statement of Mr. Silbermann follows:]

PREPARED STATEMENT OF BRYAN SILBERMANN, C.A.E., PRESIDENT, PRODUCE MARKETING ASSOCIATION, NEWARK, DE

Chairman Cardoza, Ranking Member Neugebauer and Members of the Subcommittee, I am Bryan Silbermann, President of the Produce Marketing Association (PMA). I am honored to appear before you to address the topic of this hearing: the legal and technical capability for full traceability in fresh produce.

PMA

PMA is the largest worldwide trade association of companies that market fresh fruits and vegetables. We represent 3,000 companies and their affiliates across the produce supply chain, ranging from grower-shippers and supermarket retailers to hotel and restaurant chains, as well as other buyers of produce worldwide. Within the United States, PMA members handle more than 90 percent of fresh produce sold to consumers. Reflecting the global nature of our industry, we also have members in over 50 countries.

PMA serves the industry on the issues that are important to it. Since our start nearly 60 years ago, PMA has pioneered packaging concepts for produce and served as the clearinghouse for standardization of these issues. Over the past 2 decades, the association—and me personally—have been at the center of developing standard systems to improve the flow of information from produce packinghouse to the consuming public. This work includes the advent of those small identification stickers that are so ubiquitous on tree fruit and other produce shipped from your district, Mr. Chairman, as well as standard bar coding on produce packages sold in supermarkets. This involvement, combined with our members' commitment to provide fresh and wholesome fruits and vegetables, compel us to appear before you today on this important topic.

The Way Forward

One illness linked to the products our members grow and market is one too many. Food safety is the top priority for our members, now as it has been for many years. The deeply troubling spinach *E. coli* outbreak in 2006 and the recent *Salmonella* outbreak are tragedies that shake the public's trust, and cause us to review all actions by industry and by those who regulate us. Rather than casting blame we need to work toward solutions. Speaking today before Congress, with my industry colleagues, Federal regulators and experts, I want to talk about our shared responsibility to protect public health.

Clinging to old ways is not an option. Because consumers rightfully expect safe food, our buyers—retail and foodservice—demand exacting food safety standards, and assurances they are being met; in turn, suppliers are evaluated in light of this new reality of the marketplace and on their ability to ensure the safety of their product. Turning the page on the past, the produce industry has already rapidly changed to avoid the introduction of risk into the food system. This paradigm shift brings with it new responsibilities for industry, and for the government. Industry cannot reflexively oppose regulation—but governmental action must recognize and harness the ingenuity of the private sector to improve food safety and to gain back the full confidence of our consumers. At the same time, it is not the private sector's role to wait passively for government to regulate; we must act.

Reflecting the will of our members, PMA has already taken considerable action on food safety. We have contributed $2 million to the creation of the Center for Produce Safety at the University of California at Davis. My organization also provides funding for and volunteer leadership of the public-private Partnership for Food Safety Education, which educates consumers on safe handling practices in the home. We have endorsed the idea of mandatory good agricultural practices based on risk specific to certain commodities and have recently advised FDA that we support the concept of certification of food safety by third parties. Further, PMA with our colleagues have launched an industry-wide effort on traceability.

Traceability

Today's hearing is recognition of the importance of traceability to the food safety process; that is, the ability to determine the origin of suspect product and its path from the farm to the consumer. Over the next several months, we need to learn lessons from the *Salmonella* investigation to understand what went wrong and why the investigation took the path it did. It is very early in that process, and we have

numerous questions that should be answered in a searching review that must include all stakeholders. It is our common duty to protect the public. If that process identifies gaps in the current system, the Food and Drug Administration should close those gaps—but such actions should not be based on rumors or speculation; they should be based on science.

Unlike other food industries, the produce marketing chain has been required to maintain records since the 1930 passage of the Perishable Agricultural Commodities Act. The Bioterrorism Act added the "one up, one back" concept, but the requirement for comprehensive record-keeping is a longstanding legal obligation in our industry.

Critics have said the *Salmonella* event demonstrates the limitations of the industry's current traceability system, and that current regulations do not go far enough. Focusing exclusively on the legal requirements misses the advancements the private sector has made to improve not just the retention of records, but also the tracing of fresh fruits and vegetables. Many companies have already implemented internal systems to track produce, but this multiplicity of systems caused industry leaders to see the need to create a common platform to link the disparate approaches. PMA joined with the Canadian Produce Marketing Association to develop an *Implementation Guide to Fresh Produce Traceability* that was first published in 2004.

Last year, PMA, CPMA and United Fresh Produce Association began a traceability initiative to reach across the entire supply chain. At that time, I said:

> "Our food safety system is not complete without a more robust and quicker ability to rapidly recall our products and trace their history. The issue of how to have improved traceability is not about technology; it's about changing our business practices. Effective traceability must be a business imperative for everyone in our industry. Consumers and regulators demand it."

These words are even more true today. The initiative has moved quickly to create a standard methodology for maintaining key information. Comprised of more than major 50 produce buyers, sellers, brokers, terminal markets, distributors and wholesalers, the Produce Traceability Initiative's Steering Committee acknowledges that each member of the supply chain will have its own traceability system. However, these systems must be adapted so that important information can flow through the supply chain in a common format that uses existing global information standards. I want to stress the word global, because the solution we have developed must work for all fresh produce, no matter where grown or shipped. I also want to stress that from the initiative's beginning, we have briefed FDA and U.S. Department of Agriculture officials and others on our work.

As developed by the initiative, the process uses three pieces of information: (1) a Global Trade Item Number (GTIN), which will identify the "manufacturer" of the product and the produce that is in that specific case; (2) the lot number; and (3) the harvest or pack date. These three pieces of information will be on each case so that the numbers are intelligible to the human eye. Immediately, by reading that case's label, you will know the origin of the product and the lot number assigned to it.

What is more, the information will also appear in machine-readable form on that label, in a barcode each member of the supply chain will be required to scan so that the information will be maintained in its computer system. Having the specific lot number and pack or harvest date, each handler will have a record of when that particular case entered and left its facility. Think of these three pieces of information as a baton that is passed by one runner in a relay race to the next; that common information then travels—and can be tracked—from the start to the finish lines.

The Produce Traceability Initiative's process avoids a bloated and unworkable central computer system to warehouse all of the data for an entire industry that ships in this country alone more than five billion cases of produce annually. Because the three pieces of information will be standard, and because each link in the supply chain will scan that information into its computer systems, each link will be able to determine with a quick computer search the origin of the produce and its destination. These searches can be done simultaneously rather than sequentially—so we can get answers faster.

The process works the same when a commodity is "repacked." When repackers commingle produce from multiple growers into one case or simply repack the case, they become the new "manufacturer." As such, they will be responsible for assigning a new GTIN (now showing them as the new "manufacturer") to that new case, as well as the corresponding lot number and pack date. They must also establish a link between the new GTIN and the original GTINs and associated lot numbers and pack or harvest dates.

In less than 1 month from today, the steering committee for the initiative will meet to approve and release to industry an action plan along with a timeline for implementation throughout the industry. First, produce suppliers will be directed to have the capacity to label cases with both human-readable and machine-readable information; next, everyone in the supply chain will be expected to read and store that information—and chainwide traceability will have been achieved.

The Produce Traceability Initiative relies on several elements that will be the keys to its success. It relies on core pieces of information that are consistent across the supply chain, and are maintained on the case itself. Each participant in the supply chain retains that consistent information electronically. The initiative builds on the individual traceback systems that currently populate the marketing chain, by knitting a common thread among them.

Conclusion

Whole-chain traceability, we believe, is our responsibility to the public and the produce industry takes seriously its obligations to develop traceability solutions. These solutions include not just the Produce Traceability Initiative I have described today; it also includes helping to determine what when wrong when the tomato industry was apparently wrongly fingered as the culprit in the *Salmonella* outbreak. During this crisis, PMA and United Fresh jointly wrote to Secretary Leavitt, of the Department of Health and Human Services, to offer our assistance in uncovering the source of the pathogen by lending the industry's unique knowledge of distribution and handling processes. This information could and should serve as the key to unlock the *Salmonella* mystery. We wrote again when our first letter went unanswered, and only recently did we get an assurance that we would eventually get to meet with FDA on these matters. In the coming months, we also want to participate in learning lessons and in improving regulators' traceback in light of ongoing industry efforts.

Just as we recognize our obligations, it is our profound hope that any future legislative and regulatory changes will be fashioned to work with the industry to fulfill our shared responsibility to protect public health by providing safe, wholesome and nutritious food, every bite, every time.

I thank you for the opportunity to appear before you today, and I look forward to answering any questions you may have. Thank you.

The CHAIRMAN. Thank you, sir.

Mr. Stenzel, welcome to the Committee again and thank you for being here and sharing your information with us.

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

Mr. STENZEL. Thank you very much, Mr. Chairman and Members of the Committee. It is a pleasure to be here. We appreciate you holding this hearing. United Fresh Produce Association represents the total supply chain in the fresh produce industry, concentrated here doing business in the North American market but also globally as well.

I am going to summarize my comments at this late hour. I submitted an extensive written testimony for the Committee. Let me start with prevention. That is where it all starts. We in the produce industry hold ourselves to rigorous standards in growing and handling fresh foods and we support strong Federal oversight of commodity-specific risk-based rules. We have worked closely with Mr. Costa and Mr. Putnam in the development of their legislation and urge the Committee to lend its support to those efforts.

We are also committed to compliance with the traceability rules of the Bioterrorism Act in ensuring our industry's ability to track fresh produce from the retail store or restaurant all the way back to the farm. I want to say that this is true also for all produce sold in the United States, not just grown in the United States. We in the produce industry have an obligation that whenever consumers go to their grocery store or restaurant, it doesn't matter where it

is grown, it is not "safe in one place and not safe in another." It is our responsibility to assure no matter where produce is being consumed by American citizens, it is safe.

Now, in this particular outbreak, I want to make one thing very, very clear. Traceability worked. I thank Dr. Osterholm for making this point so it is not just an industry point of view. FDA was in fact able to trace tomatoes back that had been eaten by sick consumers all the way to the farm. The only problem was that those tracebacks kept pointing to different farms. But those aren't false leads. Those aren't tracebacks that didn't work. Those are tracebacks that pointed to the fact that there was not a common point of contamination for all those tomatoes. Very, very early in this investigation, we should have known that tomatoes were not the sole cause of all of those illnesses across 43 states. Perhaps there is yet judgment to be made as to any plausible explanation of tomatoes having been involved at all. We don't think so but we will hold our judgment as well. But early on everyone should have known that tomatoes were not the sole cause of this outbreak.

We hear complaints about traceability and how difficult it is, but the stories about FDA having to pour through boxes and boxes of records just don't ring true to those of in the industry, to Mr. DiMare, who can track his tomatoes up and down the supply chain, and even to investigators such as those in Minnesota, who were able to describe tracking product back very quickly. Even in the Minnesota case, I might add, from a very small restaurant, not a national chain; but the ability to find out where that product came from, go all the way back and, as Dr. Osterholm said, finger the exact tiny distribution center on the border of McAllen, Texas, and eventually get back to the farm. The fact that we now have positive identical samples on jalapeño peppers from these facilities is just remarkable. In fact, this would be my exhibit for traceability working, that Dr. Acheson showed you, this chart. Look at that ability. Once they started looking for jalapeños, they got there very, very quickly.

The produce industry understands better than anyone that we have the most to gain from isolating produce that may be part of a problem, and that goes to the initial identification of what is the food vehicle involved. In this particular case, it is clear that CDC did not have the right story from the beginning. Whether they were 100 percent wrong, we do not know yet. But clearly when they issued a broad warning that tomatoes were that cause of this outbreak, there was no mention of jalapeños. They had missed something in the early outbreak identification. That is something that we just have to look at, not so much the traceability back but look at that initial identification of product.

This past Friday, FDA concluded that jalapeños grown in the United States were not associated with this outbreak, and that is indeed very good news. We have growers now who are once again shipping truckloads of jalapeños from North Carolina and Georgia, and that is important. But you know what? It is also important that there are a lot of Mexican producers of jalapeños who also are not involved in this outbreak either. We have to narrow the suspicion down to the ultimate source. We can never let geographical boundaries, whether national or state or county borders, be short-

hand for food safety, and I remind the Committee that in the spinach outbreak, we went through this exact same problem when three counties in California were all labeled under suspicion equally when we know that there was only one place where there was contaminated product. So geography is not shorthand for food safety.

Mr. Chairman, let me conclude my remarks with a brief comment about compensation. We would like to thank Congressman Mahoney for your efforts to step up with the bill to provide disaster assistance. What a true disaster this has been, as much as any hurricane or flood in our industry, but it is a disaster that struck our entire industry. It struck the entire tomato supply chain, whether our growers who were plowing under fields or others in wholesale and upstream had to take product out to the dump. As you consider potential support for the tomato industry, I ask you to think about both the growers we represent but also their customers who had already paid for that produce and also took losses in having to throw it away unnecessarily.

Thank you.

[The prepared statement of Mr. Stenzel follows:]

PREPARED STATEMENT OF THOMAS E. STENZEL, PRESIDENT AND CEO, UNITED FRESH PRODUCE ASSOCIATION, WASHINGTON, D.C.

Good afternoon Chairman Cardoza, Ranking Member Neugebauer, 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.

Thank you for holding this hearing to begin a detailed examination of what has been one of the most frustrating and damaging investigations ever of a foodborne disease outbreak. This investigation has been damaging to consumer confidence in our food safety system, damaging to consumer health in scaring the public away from healthy produce while failing to properly identify the source of contamination, and damaging, of course, to the entire tomato industry.

Let me state again for the record 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. And let me add, they are also committed to compliance with the traceability requirements of the Bioterrorism Act and ensuring our ability to track fresh produce from the retail store or restaurant back to the farm.

As today's hearing is focused on traceability, let me begin with this—I believe that traceability worked in this outbreak. Despite some hurdles which I will address later, FDA in fact was able to trace tomatoes eaten by sick consumers back to the farm. The only problem was those tracebacks kept pointing to different farms. Rather than complaining about the complexity of the tomato industry and so-called false leads sending the search to myriad farms across two countries, the evidence was staring government in the face. There was no common point where all of these tomatoes could have been contaminated, whether at the farm or in repacking at the wholesale level. Traceback worked; it just didn't confirm the hypothesis that the Centers for Disease Control had advanced, and that we now know was most likely wrong.

For weeks and weeks, investigators were on the trail of the wrong product. That speaks to a fundamental need to reassess how CDC conducts its initial assessment of potential foods that might be linked to an outbreak, the degree of certainty they affix to inexact science, how decisions are made on when to warn the public and what to say, and when to admit a mistake and find the real culprit rather than fear for embarrassment in changing course. These are questions for another day, but we urge this and other Committees to seriously tackle each of those issues.

Let me turn specifically to a discussion of traceability in our industry. As context, let me suggest that an individually packaged food item with a UPC code and lot number provides about the most complete traceability possible. You simply punch in that code and the company can tell you when the item was packed, in what facility, and usually even whether it was packed on the morning or afternoon shift. Ironically, that's the specific case with the *E. coli* outbreak associated with spinach 2 years ago. The only contaminated spinach ever in the marketplace was bagged on one shift, on one day, in one processing plant, with the same lot code appearing on every bag.

Yet, who can forget the 4 week nightmare for consumers and industry with FDA first saying to avoid all spinach, then supposedly narrowing the focus to "counties of concern" where spinach may have been grown? Never mind that 95% of the spinach in the marketplace was grown in these counties. Here we had the most immediately traceable food product individually labeled with a lot code, and it took weeks before FDA finally began to tell consumers they could eat spinach again. Contrast that with the peanut butter *Salmonella* outbreak. After months of investigation, a recall of certain lot codes from one manufacturer was launched, and consumers merely switched to a different brand the next day. No intense search for where the peanuts were grown, and whether potentially contaminated peanuts were elsewhere in the distribution system or other products.

My point is this—even with perfect traceability with an individually packaged produce item with a lot code on the bag, there is still a flaw in the way in which CDC and FDA are going about produce investigations. They just do not seem to understand what can admittedly be a complicated sourcing and distribution system required to assure the quality of fresh perishable foods to consumers. But broad brush warnings not to consume an entire commodity group make no sense when a better understanding of produce distribution systems and the traceability systems in place today can effectively narrow the point of concern. FDA should work much more closely with industry, and with USDA, to better understand produce distribution systems. Today, each investigation seems a totally new learning experience rather than the execution of a well-prepared and well-drilled crisis plan.

I mentioned in the beginning that produce industry members are committed to full compliance with the Bioterrorism Act and its "one-step-up; one-step back" requirements. Industry members take that responsibility seriously. While produce often changes hands between farm and table, industry members are able to track a majority of produce from retail back to farm source. Stories in the press about having to pore through reams of paper records and mysterious spider webs in the supply chain just don't ring true to industry members who track produce pretty efficiently everyday. And, that's not just industry talking. One of the more interesting developments in this outbreak investigation was the report from Minnesota health officials that they quickly identified jalapeños as the real culprit, not tomatoes, and then quickly traced the peppers back from a small restaurant in Minneapolis, to the distributor, wholesaler and farm. The Minnesota investigator is quoted in the media saying it takes "a few phone calls and you can work it fairly quickly back to the grower."

So why is this proving so difficult for FDA? In my conversations with both FDA and with member companies who have had FDA field investigators in their facilities, it appears that the demand for paper records may be FDA's doing. Even when a wholesaler can tell FDA where a product came from, it seems that FDA is dependent upon a legal trail of paperwork, seeking to make sure that all the details such as number of boxes, brand names, lot codes, ship/receive dates, *etc*. correlate exactly on invoices, bills of lading, etc. I'm told of field staff faxing hundreds of pages of records to FDA headquarters for someone to try to read through and connect the dots. No wonder they complain about that process. This overly legalistic approach may be appropriate to build a court case 2 years from now, but it is not conducive to rapid protection of public health. Perhaps that's one explanation why most industry members throughout the distribution chain can report who they've received produce from, and keep tracking back to the farm.

Before there is a knee-jerk reaction to pass new laws or requirements for traceability, we urge the Congress to fully examine how FDA today conducts tracebacks, and whether those systems are appropriately designed to protect public health and get back to the farm as quickly as possible. We have asked FDA to show us specifics where they've run into problems, so industry can help. We also urge the Committee to ask the agency for specific examples and answers to these questions, rather than a theoretical discussion or generic statement of frustration. This is too important to gloss over the details.

Nevertheless, the produce industry understands better than anyone that we need the most efficient and quickest traceability systems possible. We have the most to

gain from isolating produce that may be part of a problem as quickly as possible. The fewer people who get sick, and the quicker a problem is contained, the better off we are. I read one recent news report where someone suggested the industry might not want to trace a problem back to a farm and thus avoid responsibility. Are you kidding? Does anyone remember the angry mob with torches chasing the Frankenstein monster? This industry would storm the barricades to quickly identify the real source of contaminated food, no matter where that finger points.

And that brings me to the other incentive we have to continuously enhance traceability—we have the most to gain by ruling out concerns about produce that is clearly not related to a problem. This past Friday, FDA concluded that jalapeños grown in the United States were not associated with this outbreak, and narrowed their consumer advice accordingly. That was a critically important step, especially for one of our Georgia growers who went from shipping six truckloads of jalapeños a day to nothing. Incidentally, he's testifying before the Agriculture Appropriations Committee today. But we also urge FDA to narrow their investigation within Mexico as quickly as possible. Clearly, many Mexican producers are not associated with the outbreak either. We should never accept geographical boundaries, whether national, state or county borders, as shorthand for food safety. Our goal in every case of a foodborne disease outbreak must be to find the specific source as quickly as possible, and free the rest of the industry from suspicion.

That's why United Fresh Produce Association joined with the Produce Marketing Association and Canadian Produce Marketing Association last year to launch an initiative to build a common framework and nomenclature for case labeling, better transparency, and streamlined connectivity across the supply chain. That initiative is guided by a Steering Committee of more than 50 produce retailers, wholesalers, distributors, packer-shippers and growers. The committee has met four times this year—before this outbreak—and is now finalizing action plans and timelines for industry adoption.

The Produce Traceability Initiative will help connect the internal traceability systems of each member of the supply chain. This whole-chain connectivity is based on three pieces of information that will be labeled on every case of produce: (1) a Global Trade Item Number (GTIN), which will identify who the originator of the case is and the type of product that is inside; (2) a lot number specifically identifying the produce; and (3) the pack or harvest date. This information will be labeled on each case so that the numbers may be read and understood universally throughout the supply chain. Labels will also carry a barcode, which each member of the supply chain will be able to scan so that the information can be stored.

This system also works when produce must be re-packed or commingled to ensure the best quality to consumers. When repackers commingle produce from more than one grower into one case, they become the new "manufacturer". As such, they will assign a new coding number to the new case, but will also maintain a link between the new case number and the original incoming cases. In fact, systems to keep track of different incoming product sources are used widely in the tomato repacking business today.

One the key reasons industry is pursuing this approach is to harmonize standards for efficiency. With one common set of standards for case labeling, product tracking can be performed simultaneously in different stages of the supply chain, rather than sequentially.

This is an exciting and important development for industry efficiency, and the best example I know of an industry committed to constant improvement in traceability. But I want to repeat for the Committee that traceability was not the problem with this outbreak investigation. And, this or any other traceability system is not the solution to the problems identified over the past 2 months.

Produce traceability worked in this outbreak. It provided tremendous evidence that tomatoes were not the cause of the outbreak, as there was no single point where contamination may have occurred. And, once investigators began looking for the right commodity, tracebacks from Minnesota and from the FDA led to the warehouse of a small produce distributor where an identical sample of the outbreak strain was found. And, FDA even knows which farms supplied this small distributor.

If I may Mr. Chairman, let me conclude with a brief comment about compensation. We all know the error in CDC's initial assessment that fresh tomatoes were the sole cause of this outbreak. While CDC has not yet stepped away from its suspicion that tomatoes might have caused some of the earlier illnesses, this is neither a likely nor plausible position without some real evidence. The fact that consumers didn't know that they had eaten jalapeños chopped up in salsas, garnishes, or other foods is no reason for CDC to cling to the accuracy of their initial food surveys just out of pride. Even good scientists can make a mistake, and there's no shame in ad-

mitting that consumers apparently were just unaware of this hidden ingredient in their foods.

There can be no doubt that this has been a disaster for the tomato industry, and we support Congressman Mahoney's H.R. 6581 as a step toward providing disaster assistance to our agricultural sector just as vital as any hurricane or flood. It's also a fact that this disaster struck every company in the tomato supply chain whether they had to discard full warehouses of perfectly healthy tomatoes, haul product to the dump, watch fruit rot on the vine, or plow fields under. I know well that this is the Agriculture Committee, but I ask you to think about both the growers we represent, and also our growers' customers who had already paid for their produce, but were forced to discard millions of dollars of product.

Our supply chain for fresh perishable foods is truly an interdependent agricultural industry, and now is the time for all of us to stand together for what's right.

Thank you for your time and attention.

The CHAIRMAN. Thank you, Mr. Stenzel.

I would share with you that your last point is well taken. Mr. Etheridge and I have had significant discussions already about how we deal with whether or not crop insurance could be made the risk holder for this. Certainly compensation is a concern if you look to FDA or someone who is actually making the adjudication for compensation. While in my opinion they have made some errors or potentially have made some errors, how would compensation affect their future judgments to make the same kind of calls? Frankly, we need them to be able to make calls that are not based upon whether they have to take money out of their agency for compensation.

So Mr. Etheridge, Mr. Peterson, other Members, and I have been talking about how we go about looking at the compensation that should somehow come back to this industry that has been implicated but not necessarily indicted. I know the growers in my area have been devastated and it is nothing they have done of their own doing. So I can't imagine any other businessman who would subject themselves to the vagaries of the weather, to pestilence, to all the rest and then also submit themselves to the regulatory agencies; farmers are certainly a hearty breed and they keep doing it. I often ask myself why they do. I know the answer, because they love what they do, but they ultimately have to make a profit at the end of the day, and we have seen an industry just be devastated here, and I thank you and Mr. Giclas and Mr. DiMare, all of you for your testimony.

I have a number of questions. I want to start out with Dr. Osterholm. What did Minnesota do differently from other states in their investigation that led to the implication of peppers directly?

Dr. OSTERHOLM. Mr. Chairman, first of all, they had the bad or good luck, I guess, depending on how you look at it, of actually having cases occur that were all associated with one of two restaurants, local restaurants in the Twin Cities that made it easier to investigate. But the most important reason is that Minnesota has dedicated foodborne disease surveillance and outbreak investigation as a very high priority, and as such, they actually have a team of graduate students known affectionately as Team Diarrhea, that literally on a real-time basis are interviewing case reports that are coming in on a daily basis. Our turnaround time for the pulsed-field gel electrophoresis and the analysis is less than 3 days every time so that in fact this group has solved many outbreaks. Last year we had an outbreak of a rare kind of *Salmonella* that had been occurring in the United States for the better part of 6 months.

When the first three cases occurred in Minnesota, within literally 1 week, Minnesota fingered the potpies and broke open the entire national investigation that had gone nowhere for 6 months.

So I think what it is, is a system. In my written testimony to you, I actually lay out what we do, how we do it. It is not rocket science. It is commitment. It is willingness to do it. It is not accepting a state like Texas that takes 5 weeks to get their pulsed-field gel electrophoresis results done. It is the fact that we don't wait for a county health official to decide they are not going to go ahead and interview a patient. It is all done centrally. We believe that this entire system could be replicated across all 50 states for somewhere between $50 million and $100 million annually. When you think about the cost of one of these outbreaks getting missed, that seems like a small amount of money to put forward. I tell you this at the time when the Federal resources for this are being cut so that just as we are talking about this right now, the very support that has happened over the 4 years for all the states is being cut. So I think that is the big distinction. Minnesota made it a priority. They have done it. They showed it can be done and we just have to hold all the other 49 states to the same standard.

The CHAIRMAN. I totally agree with you.

To all our panelists, prior to and during the recent warnings concerning tomatoes, what input were you asked for by the CDC and the FDA and what input did you give these agencies, either solicited or unsolicited? Mr. Stenzel, we will just go down the line and start with you. Since you spoke last, we will give you the first shot and go the other direction.

Mr. STENZEL. Prior to the issuance of the warnings, no input whatsoever. We were not asked or consulted. In fact, there was a very quick notification by FDA to the industry that New Mexico believed that tomatoes had been associated with this outbreak and quickly CDC was going to be issuing a public statement. So no input there. During the course of the investigation, I appreciate and would thank Dr. Acheson for his efforts to keep the industry informed. They did reach out and share information with us, but one of the most frustrating things about this process is, there was a lot of information they either couldn't share or wouldn't share and they were very slow to take any kind of input back from the industry, and I have to be specific. Specifically, one of my concerns is with CDC. We repeatedly were asking for data on how the illnesses had occurred, in what order, what geographic locations.

For us in the industry, we can look at the spread of an illness, and if it is moving from Texas to New Mexico and then up to Illinois, we can look at our own distribution patterns for tomatoes. Quickly, once we got past about ten or 15 states, we knew this was not all related to tomatoes. There is no single point, there is no one farm, there are no repackers who would process all of those tomatoes to all of those geographies yet they didn't really listen to that point of view.

Mr. SILBERMANN. Mr. Chairman, I would agree with everything Mr. Stenzel has said. I would thank Dr. Acheson for his outreach once the announcements were made and the way in which FDA briefed us, but I would draw a parallel. Imagine that you are an orthopedic surgeon and you are being asked to do surgery with an

arthroscopic device and you can't see down that arthroscopic device to see what is inside the body. That is the way we felt, quite honestly at PMA, giving a lot of information, not seeing the endpoint, not seeing the picture but being asked to comment on it. That is the way we felt in this process.

Mr. DIMARE. We at the DiMare Company were contacted by FDA at a couple different levels. One of our repack locations in Houston was contacted through one of the tracebacks with tomatoes. One of the problems I had with FDA was I felt first of all that some of the people from FDA that did the investigation had no experience on the food side. We had a person that was from the drug side that was in the operation. Also, we had, I think it was about a week-long process of a full audit of our facility without again any relation or tracing back of any positive evidence that any of the tomatoes that we were distributing contained the *Salmonella* Saintpaul outbreak. From a grower packing level, we were contacted by FDA in both our Ruskin and Homestead operations, again from a traceback that led back to some of the customers that we supplied—had supplied in this one case a retailer actually in Georgia led the traceback back to our two packing facilities and it happened to be specifically on plum and Roma tomatoes, not round tomatoes.

The investigator in our Homestead operation who I had spoken to on the phone personally several times, it was a very frustrating process. It was frustrating in the sense that he really didn't know what he was asking for, a lower-level FDA person that was being given directives from the higher ups above within FDA. In fact, the questioning started out when he first contacted me as he wanted to see information and all information on all tomatoes in all our operations. I said are you sure you want to see information on all types of tomatoes in all the operations, that is a lot of information you are asking for, I prefer that you name something specifically. Is it Romas, is it rounds, which location are you looking for. I was then contacted by an official from FDA out of the Tampa office that did the follow-up in our Ruskin location. She was very specific in what she wanted and I asked her, do you want to see information on all round and Roma tomatoes or just one type specifically. She stated very clearly we are looking at specifically Roma tomatoes and we are looking at it for this particular window. It was about a week or 10 day period of shipment that they were looking for. That is a heck of a lot different from the information I got from the other investigator——

The CHAIRMAN. Mr. DiMare, let me stop you because we are going over, but this is really important to the Committee. You have indicated in your testimony that you do over-sampling much greater than maybe—you do a lot of sampling for pathogens in your company.

Mr. DIMARE. Yes, sir.

The CHAIRMAN. Did you share that information with FDA or CDC?

Mr. DIMARE. Yes. In fact, in the Houston case, some of the product that they were looking at was product actually of our own. In other words, it actually came from our own farm packing operations, which is not unusual. In this particular case, it was product

that we actually grew and packed, and in those instances, we had done pathogen testing specifically for *Salmonella*.

The CHAIRMAN. Thank you. I am going to have to move you along, and there is a rationale why I am asking this question. When you passed on that information, did it have any impact on their investigation?

Mr. DIMARE. I am not sure it did. The only comment I got back from the investigator in Homestead was to the extent that it is good that you did that, but as Dr. Osterholm said about testing is that we are not going to test our way out of this.

The CHAIRMAN. No, I understand. I have a follow-up I am going to ask you all, but I want to hear from Mr. Giclas and then we are going to ask you a follow-up.

Mr. GICLAS. Mr. Chairman, I don't have much to add. Mr. Stenzel and Mr. Silbermann outlined the type of communication between trade associations and the agency during the outbreak. I can tell you that the types of questions that we got were not very constructive questions. They were, what can you tell us about distribution patterns, and we had to ask additional questions about well, distribution patterns need to be outlined a little bit more specifically before we can really answer those. But we tried to answer any kind of question that was raised by the agency during the course of the investigation. What I can also tell you is that some of the questions that we asked have been put off until this outbreak investigation is concluded and behind us and we have an opportunity to sit down, but they are important questions like what is failing in traceback. We have heard over and over and over that traceback systems are failing and we have asked for people to show us where, how. If that is actually the case, industry wants to fix that as quickly as possible because it is in everybody's best interest to have those programs——

The CHAIRMAN. That is my understanding and experience as well, sir, so that is my follow-up question is, oftentimes from my colleagues, I get well, it is the industry, they just want to protect their profits. They don't understand that protecting their profits means not having outbreaks because the minute you have an outbreak, you are devastated. It is the death sentence for many of these farmers. And so my point is, how do we communicate back from industry to FDA and CDC more effectively. What I am told is, you are pretty much kept in the dark, asked questions that sometimes may apply but your experience may be much greater than the FDA's experience. What I found, is state departments of agriculture oftentimes have much more experience than the Federal Government either at USDA or at FDA. Can any of you comment on that? And Dr. Osterholm, we will start back and we will let you sum up.

Mr. GICLAS. Well, I will be very brief. We would welcome that. I think there are models, perhaps the Minnesota model where there are state departments of agriculture that are fundamentally involved. I know in California, they also involve state departments of agriculture and those are the two states that I know of that have the most robust traceback programs today.

The CHAIRMAN. Mr. DiMare, quickly.

Mr. DIMARE. Your question again?

The CHAIRMAN. What inputs and what methods could you better provide FDA and CDC with information that they are not asking the right questions?

Mr. DIMARE. Well, in this case here, to me, go back to the initial outbreak of April 10 and you look at the timeframe and look at where tomatoes were coming or being produced at that time of the year. You look at the initial outbreaks in New Mexico and Texas, which seemed to have the most outbreaks, and then Illinois. Knowing the distribution channels, knowing where products come from for that particular time of the year. There is no doubt in my mind the product didn't come from Florida, whether it be tomatoes or jalapeños now. Again, you look at those distribution channels where product is flowing from, that is the thing that was frustrating for me.

The CHAIRMAN. If they are not ripe there, they are probably not coming from there. That is your point?

Mr. DIMARE. Yes.

The CHAIRMAN. That is pretty much common sense.

Mr. Silbermann.

Mr. SILBERMANN. Mr. Chairman, the letters that Mr. Stenzel and I have written to Secretary Leavitt laid that out. I think we really have to have a standing type of communication system so that it is not just dealing with each crisis when it comes up, and our written testimony deals with that too.

The CHAIRMAN. That is one thing that troubles me, sir, and I know I am going way over my time. But, that is one of the things that troubles me because I thought we had gotten past some of this with the leafy green protocols, and we are going to get to in just a moment Mr. Stenzel and Dr. Osterholm, then I am going to turn it over to my colleagues.

Mr. STENZEL. I thought a lot about this. FDA is a regulatory agency. They are the cops and they treat industry like you are being investigated, like you did something wrong, and maybe one person did but they are treating the entire industry that way. I am going to suggest to the Energy and Commerce Committee a new system to bring industry expertise into the process ahead of time, to perhaps have a security clearance, something by which the agencies could vet and clear people who are experts. There are experts in jalapeño peppers in growing and production and distribution that we still haven't heard from, and we have to find a way to bring that expertise in a way that the cops still feel comfortable with.

Mr. COSTA. Would the gentleman yield?

The CHAIRMAN. Sure.

Mr. COSTA. This precisely points to the question that I asked the FDA spokesperson in the first panel, whether or not they had people in the field that had expertise. I think it is very clear that they don't have people, Mr. Chairman, in the field that have expertise. They are spread too thin and this most recent round of investigations points very clearly to that. Your point, I think makes the most amount of sense.

First of all, all of these growers here are consumers. They eat tomatoes. Their families and friends eat tomatoes. Number two, if they send out products that are not good quality products, healthy

products, the market drops. I mean, they have a vested interest. And so when I asked the FDA witness earlier what regulations that prevented, as you said, a surgeon trying to do surgery on a knee using arthroscopic and not being able to see, you are being asked to provide information. You can provide help. You want to get to the bottom of it. The quicker you get this cleared, the better chance you restore confidence of the American consumers to resume purchasing the product. This is not rocket science. And so I appreciate your yielding, but I think that clearly we have pointed out this afternoon where the breakdown in this whole traceback process is that needs to be fixed.

The CHAIRMAN. Well, Mr. Costa, I think you are absolutely right, and the problem we are having, you, Mr. Mahoney, and I, a lot of us have spent time on a farm. We spent time on a farm and we spent time in the coffee shops and we hear the farmers complaining about the fact that they can solve some of these mysteries that sometimes happen very quickly because it is common sense to them because they deal with it every day. But that information is not percolating back to the bureaucrats in Washington and it is what frustrates the heck of the American population all the time. They are both being afflicted by an outbreak, the industry is being destroyed and they are not being able to help their government make the right call. That is the problem that we are facing here.

Dr. Osterholm.

Dr. OSTERHOLM. Mr. Chairman, I think that all the points made are getting to a central point but I think they are missing the point. The point is, the information that needs to be added at a critical time like that critical ingredient in the chocolate chip cookie dough is not the FDA. At the time that you are trying to track back the product, you have already identified a trend. You have identified a geographic set of cases. You identified a time sequence. You have identified a kind of restaurant or a location where it is purchased. That is state and local public health at the CDC. That is where I think the critical input is needed. In Minnesota, when I was State Epidemiologist, every time we had an outbreak of any kind, the first thing I did was assemble a group of local business experts in that particular commodity whether it was red meat or produce. More often that not, they helped solve it. By the time this gets to the FDA for the traceback, in a sense the footprint has already been set.

So I think I would support your point very much that this input is needed. I think the industry folks are absolutely right. In fact, many of the people down this table I have talked to in past outbreaks where I was actually leading them. I think the FDA, to follow up one point, has learned some issues around traceback with this outbreak and I give them great credit. I think the last days of the outbreak, they have taken some different approaches and sped up their process and actually I think to their credit have done quite a good job.

And let me just last comment, being a government bureaucrat is obviously a tough job when you are in the crossfire, and I do want to give Dr. Acheson great credit because I have had great access to him to give my input and comments. I think that he is trying but he has a whole system he has to deal with. I think today that

as much as we all want to find the reason why things went wrong, it is not Dr. Acheson and I think we are very fortunate to have him.

The CHAIRMAN. I hope I haven't given that impression. In fact——

Dr. OSTERHOLM. You haven't. I just want to be sure everyone knows that.

The CHAIRMAN. Thank you, Dr. Osterholm. I agree with everything you have said and what you have done. I am getting ready to turn it over to Mr. Mahoney, but I have to say one last thing. Early on in this hearing, I indicated that my wife, the family doctor, said that public health is the fundamental thing that we need to shore up in America, and I think you have just made it even more clear that my wife was right again.

Mr. Mahoney.

Mr. MAHONEY. And Mr. Chairman, you are always right.

I just have a couple of comments and questions. I mean, unfortunately, I don't get to live in Minnesota so we are not blessed to have this wonderful capability across the country. I do agree with Dr. Osterholm in one perspective, and that is, I think that the issue that is coming out today is really not traceback, it is making sure that we are implementing the right procedures and standards to make sure that the food is grown in the proper way and being delivered properly to begin with. I think traceback will happen if we implement a uniform system. And it is also clear to me that unfortunately in this particular example in the testimony given today by Dr. Acheson, is that when we go down to Mexico and we are taking a look at what is happening down there and the standards under which produce is being grown, that there is a big inequity between domestic production and foreign production and our ability to keep track of it. So I think that that is something I will walk away with.

One of the other things now I am concerned about, and I guess I am going to start with Mr. DiMare, is that when I met with my growers, and none of them were tomato growers, but when I met with my growers in my district, I was asking them about standards. It appeared to me that one of the things we are dealing with is that the bigger producers are dealing with a whole range of standards, some from the State of Florida, others from big resellers, big buyers. Is that true? I mean, how many—you know, you are operating in multiple states. I mean, how many different sets of standards are you working towards in terms of what you have to produce and what you have to report?

Mr. DIMARE. Well, you are right. There are many, depending on what customer you are dealing with. Right now, we are getting a lot of pressure because of this with customers wanting to do preharvest pathogen testing, but there is no scientific base or parameters right now to go by. This is part of the problem I have with all of the testing is, you don't have any true standards in place for industry to follow. And, different customers are demanding different things at different levels and that is very frustrating and——

Mr. MAHONEY. Also very costly.

Mr. DIMARE. It is very, very costly, and I guess that is what we are trying to do through the associations is trying to come up with standardization that is unified across the board. So that, we are all complying with the same standards of whatever the food safety audit, whether it is going to be Primus based, whether it is going to be Davis Fresh, whether it is going to be AIB, that the standard level be the same for all producers across the board.

Mr. MAHONEY. Let me ask another question to all of you, and that is, I had the pleasure, I guess, now that I am no longer involved in it, of being a small cattle rancher, never made any money because all of my cows had first names, so I was at a disadvantage. But when we were talking about immigration of cattle and trying to understand how that works, I know that in the cattle industry, a disproportionate amount of the cattle produced in this country comes from small ranchers. One of the concerns that I have as we move down this path in terms of traceback, in terms of implementing systems of accountability, is the small producer. One of the questions I would have for you is, that if there are all of the different regulatory aspects, whether imposed by the state, the Federal Government or by large customers, what is your experience? What is the ability for American agriculture to be able to deal with that, not from just the perspective of the big producers but the small farmer? And why don't we start with Mr. Giclas.

Mr. GICLAS. Thank you, Mr. Chairman, Congressman Mahoney. I think the industry is capable. Smaller growers tend to have a relationship with their receivers. Larger growers tend to have the more robust record-keeping and traceback programs in place. There are legal requirements for everybody, going back to Mr. Silbermann's comment about PACA, which is in the grower's best interest to keep those records because that is how they ensure that they are paid for their products. They have a motivation to maintain and keep those records.

Mr. MAHONEY. Mr. Silbermann.

Mr. SILBERMANN. I would just add that anyone who is packing a vegetable product, let us say, in a box, would have the capability of attaching the kind of label that we are talking about, the standard label that has the three pieces of information fairly easily. If they are going to have a packing line, they certainly would be able to do that. But it is definitely an issue for very small local growers who might be delivering just to one or two stores. That is clearly an issue that needs to be looked at.

Mr. MAHONEY. By the way, I will just point out that one of the things that I was just working with Wal-Mart on is the fact that they are now having a new program where they are going to reach out to local growers. I can tell you that in these tough economic times, going to these farmers' markets, there is a lot of people now that have decided that they are going to turn their back 40, if you will, their half-acre, into an alternative income source by growing vegetables and trying to sell them. So I am seeing that happening.

Mr. Stenzel.

Mr. STENZEL. Two quick things on that. I think the small producer is going to be able to put the information on the case. For now, most of them do. It may be the company's name of the farm's name, that type of thing, but as I said, anybody who is packing a

box of produce. The standardization effort that we are trying to lead from an association standpoint just gets everybody on the same numbering system. So there is an education part of that, an outreach, but it is no more costly than just putting information on the case. We think that would go a long way.

I do want to mention one other thing though, when you talk about a lot of small farmers coming in. One of the toughest things we are going to have to do is help them as well with the good agricultural practices to prevent illness because they may not be part of other organizations and have had the education. We have to make sure that anybody who is going to be growing produce, even on a very small scale, meets those same food safety standards and prevention.

Mr. MAHONEY. One last question. Do we need to have more aggressive oversight and making sure that foreign producers are meeting our standards? Dr. Osterholm?

Dr. OSTERHOLM. Congressman, can I just quickly answer the last question too?

Mr. MAHONEY. No.

Dr. OSTERHOLM. Okay, because that is a key piece. You are onto a very important issue beyond what you realize. I want to answer.

Mr. MAHONEY. I get in trouble if I go too long. I am a freshman, so they only give me so much time.

Dr. OSTERHOLM. Well, let me just tell you, that is an important point because I think the small producer is going to be a critical problem with food safety, and we have to understand that right now, so I will just say that and leave it at that.

Mr. MAHONEY. Okay.

Dr. OSTERHOLM. As far as the issue of the—I am sorry, your second question?

Mr. MAHONEY. Foreign producers.

Dr. OSTERHOLM. Foreign producers. I think we have to be very careful about that in the sense that yes, we do have outbreaks with foreign producers. They have been a problem. But again, if you are big and you can actually make the investment into food safety, you can do it safely wherever you are at. What I worry about is, as I said in my testimony. It is the 99.1 *versus* .9 percent rule, whatever. When you have the industry, be careful how you label that. There are always a few out there who are going to take and cut corners for costs. They are the ones that more often than not have become the problem.

Mr. MAHONEY. I have to tell you, I disagree with you, because what I heard today from the FDA is the fact that they are underfunded, under-sourced. They are not checking to make sure that the growers are doing their job overseas and there is very little oversight or inspection when these things are coming in.

Dr. OSTERHOLM. I don't disagree. What I am saying is——

Mr. MAHONEY. And I am just saying, I take a look at my tomato growers in Florida and I take a look at what the State of Florida requires these folks to do and I think that it is an alarming situation.

Mr. Stenzel.

Mr. STENZEL. Congressman, exactly what the State of Florida and the tomato growers are being required is a self-motivated proc-

ess. Our tomato industry, and I don't want to speak for Mr. DiMare or others here in the hearing room, has gone out of its way to build those new processes and have the state inspect. But that is precisely what we all want across all tomato production regions including Mexico. It is not a matter of one *versus* the other. Congressman Costa's bill and Congressman's Putnam's bill would do precisely that, get to a common platform for preventive control for all production. So I really think it is important that the industry itself is asking for that including the Mexican producers.

Mr. SILBERMANN. I would also add, Congressman, that many large American producers are also producing products in Mexico and taking some of the best practices to Mexico and requiring that Mexican product is produced with exactly the same standards. They have their own brand identity to protect when their product is shipped, whether it is in Mexico or the United States.

Mr. MAHONEY. I don't think that is the problem. I think it is the local producer.

Mr. DIMARE. I would agree with that. I think it behooves us as an industry to implement a program that is standardized, whether it is domestically or in Mexico, because in this case, as you can see, even if it wasn't a relation to your operation tied to the outbreak, we all suffered fairly equally. So I think it behooves us to make sure those standards are not only passed on to the rest of this nation but certainly to all imports coming into this country.

Mr. GICLAS. I really don't have anything to add other than to reinforce Mr. DiMare's point. We are only as strong as our weakest link, and we would like to see everybody on the same level playing field.

Mr. MAHONEY. Can I ask one last question quickly?

The CHAIRMAN. Let me let Mr. Costa, and then we will give you a whole other round if we need to. Mr. Costa.

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

Mr. Stenzel, what percentage of your members would you say today have electronic records to trace their products through the distribution chain?

Mr. STENZEL. Gosh, I am going to have to estimate. I will go back and try to get a better estimate for you. Electronic interchange, the ability to have a computer record somewhere, I would say more than 50 percent would have those records. I think something earlier that was said, the PACA really has produced a greater recordkeeping for produce companies and produce traders than most people realize. What we are lacking in some areas is the ability for those computer systems to talk to each other but the ability for an individual to do it is there.

Mr. COSTA. So a mandatory tracing effort, your industry could adjust to it?

Mr. STENZEL. Well, adjust to and find a particular program that makes the most sense. We have heard already today that traceability was not the problem in this outbreak.

Mr. COSTA. Right.

Mr. STENZEL. We know we can traceback. We can traceback within, relatively, a matter of hours or days. The question that will come is, what type of system and to what cost and what benefit.

Mr. COSTA. And that is why that is very important to all of us because you had actually answered the question a moment ago. I was going to ask, is there any legislation out here that has been proposed that you think would address these issues that we are talking about today. The answer was?

Mr. STENZEL. The answer is no.

Mr. COSTA. There is no proposed legislation that has been introduced that——

Mr. STENZEL. Well, with a little bit of encouragement——

Mr. COSTA. That is a leading question.

Mr. STENZEL. I said a couple times that obviously the Safe FEAST Act that you and Congressman Putnam have introduced we believe takes care of that. It doesn't have the traceability provision that Congresswoman DeGette's bill does but we don't necessarily feel that that is the critical factor.

Mr. COSTA. In terms of maximizing risk assessment *versus* risk management to ensure public safety of health.

Mr. STENZEL. Absolutely. To ensure public safety, we have to prevent the illnesses from ever occurring. Traceback is not the problem.

Mr. COSTA. Mr. DiMare, the tomato industry has made some major advances, and the last time your industry had an implicated food safety issue I believe was 2004. Would you like to talk about the differences today between 4 years ago?

Mr. DIMARE. Yes.

Mr. COSTA. Very quickly, because I have one more question.

Mr. DIMARE. Sure. What the Florida tomato industry has implemented has been unprecedented in the produce industry. We voluntarily as a group adopted a food safety program that is going to be mandated by the State of Florida Commissioner of Agriculture's office, and it covers all producers of tomatoes, big and small.

Mr. COSTA. So you think it is a model we ought to look at?

Mr. DIMARE. I think it certainly is a model and other states are currently looking at it.

Mr. COSTA. Dr. Osterholm, I concur with you about the impacts of, again it gets to be, and I have many of them in my district and there are many cases of immigrants trying to live the American dream, growing on a couple acres. But, they go and there isn't the sort of safety requirements and standards and I do think it is a potential problem when they drop off a load in a small restaurant. The accountability and the thoroughness is a question, at least for me, even though I certainly support their efforts. As it relates to that, there has been discussion about the epidemiology studies, and it is my understanding that there aren't any standards for the questions that are asked of individuals who got sick. How can you compare in terms of the possible food eaten to find any commonality if you don't have any uniformity in the data that is being collected? I think, is at least in my mind, there seems to be an issue there.

Dr. OSTERHOLM. Congressman, you are exactly right on target, and that is part of what we propose to require of this national system. There are efforts underway right now to help improve upon that, an organization called CIFOR, which is a combination of public health agencies trying to come up with standards for this kind

of investigation for when you move that forward, and so I think you are exactly right.

Mr. COSTA. So uniformity in the information required by the states is something that we ought to be looking at in any proposed legislation?

Dr. OSTERHOLM. Well, uniformity to the extent that, think of a criminal investigation. There is no one form you fill out, there is no one set of pictures you take but there are certain standards of how you gather evidence at a crime scene. Each one is going to be different, whether it is in a building, whether it is outside, whether it is in the middle of the summer or the winter. The same thing is true with foodborne outbreaks. Each one will be a little different but there should be uniformity of standards and approaches that could be replicated whether that happens in California, Minnesota, Texas or New York, the same approaches would be taken, and that is what is being attempted to be put in place now but it is not done.

Mr. COSTA. Okay. That is very helpful.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Costa. I appreciate your questions.

I have asked this question a couple different ways throughout the day, and that is, how the fact that we have now traced it back to Mexico, how many outbreaks there have been. We are waiting for more of that information and we will be compiling that information. But I think, Mr. Stenzel, I believe it was your testimony, and I want to make this point as well, that American farmers weren't the only ones that were affected here, that there may be a lot of places in Mexico that grow jalapeños or serranos. But, it was only one farm and all those other farms in Mexico were implicated by regional name, but weren't necessarily any worse than the American farmers on this side of the border. So while I object when the protocols aren't the same south of the border as they are north of the border and where there are different pesticide regulations and there are all the different issues that I have complained so vigorously about other countries competing with our farmers on a different playing field, different levels. How I believe that our folks are subjected to the most rigorous standards, and I support those standards, but how others may not have to do that. I want to make the point very clearly and let you comment, that Mexican farmers have been affected in a way as well, that they have been affected by this recall the same way as others have.

Mr. STENZEL. Thank you, Mr. Chairman. The bottom-line message I would leave is that food safety is the responsibility of the individual producer and they can get it right and they can get it wrong and it doesn't really matter where they are. We have to look at equivalent systems. We have to look at the fair playing field and the same rules but ultimately food safety is the responsibility of that individual producer.

The CHAIRMAN. Thank you.

Now, another question very briefly to Mr. Silbermann and Mr. Stenzel, if the current traceback system works, what is the rush on the part of industry players in moving forward with its produce traceability initiative? Second, what is the timing of implementa-

tion of that initiative? And third, Representative DeGette's bill requires FDA to mandate traceability systems that enable the Secretary to retrieve history use and location of an article. I would like you to briefly comment on those three questions.

Mr. SILBERMANN. Thank you, Mr. Chairman. Number one, the produce traceability initiative began long before this current outbreak, so please don't see this as a reaction to this outbreak. It has been underway since the end of last year and we have a desire to do this because it is going to take several years to have complete implementation of this. I mean, it is a long process because people have to get numbers from the standards bodies, apply numbers and then build the system, so we must get started. We understand that.

As far as a timeline for implementation, that will be decided at the meeting on August 20 of the steering committee, and we will make that available publicly once that has been approved.

Finally, we believe that the degree of record-keeping that already exists in the industry when married to this electronically scannable information on every box will in fact be in the best interests of the industry to require and buyers have already committed that they are going to ask their suppliers for this. Major buyers have already said we want to have this information on the box. So I believe that industry, the force of the market will drive adoption of this. I do not believe at this time that regulation is required. I think that regulatory authority already exists whether in PACA or in the Bioterrorism Act.

The CHAIRMAN. Thank you.

Mr. Stenzel.

Mr. STENZEL. Quickly, we believe FDA already has the authority to mandate any kind of traceability systems they believe without legislation. Look at enforcement of the Bioterrorism Act. What cases have been brought in any of the concern about traceability that people were not complying? We just don't see that as an issue. Why are we moving forward? Standardization, efficiency across the industry. We think that is important. We talked about the little stickers on the fruit. At one time every grocery chain had a different numbering system. They still could look up the cost of the produce. It still worked. But we moved as an industry to standardize that and that is what we are trying to do here, get all of our case labeling on the same standard format.

The CHAIRMAN. I am going to actually turn it back to Mr. Mahoney. You had one more question?

Mr. MAHONEY. Well, no, I was just going to thank everybody for coming because I recognize how difficult it is, and I guess the last thing I was just going to ask is, I think it was Mr. Stenzel that pointed out the fact that it has been an effort with me and several of the Members to do some compensation. My concern, of course, is that I believe that food safety and national security are synonymous. We are down to two percent of the population feeding the other 98 percent. This has been the most expensive year in history to plant a crop and we need to be figuring out, and one thing I love about the Agriculture Committee is that we go to work every day trying to figure out how to make agriculture stronger in this country and profitability is one of the things.

So given the fact that crop insurance doesn't cover this, is it a general consensus among the Members that there needs to be some form of compensation or that would be justified in this situation? Whether or not we can get it is another issue, but we have to convince other Members to do this and I guess the President at some point. But do you feel from an industry perspective that this is warranted or merited? Why don't we start with Mr. Giclas?

Mr. GICLAS. We are here specifically to raise that issue so we are very supportive of that, and I also agree wholeheartedly that we need to look at mechanisms like crop insurance for events like government action.

Mr. MAHONEY. Mr. DiMare?

Mr. DIMARE. Certainly from the producer's side, and I can speak from a company standpoint, our losses as a total company are approaching about $18 million, so again, as it was stated earlier, this is not an action that was caused by us and producers so there has got to be some accountability and compensation.

Mr. MAHONEY. Mr. Silbermann? Yes?

Mr. SILBERMANN. Yes.

Mr. MAHONEY. Mr. Stenzel?

Mr. STENZEL. Yes, sir.

Mr. MAHONEY. And Dr. Osterholm, you get the last word.

Dr. OSTERHOLM. I don't have any comment except if we don't fix the system, we are going to keep coming back, so help fix the system and hopefully we can prevent these future needs for additional compensation.

Mr. MAHONEY. Good comment. Thank you very much. Thank you.

The CHAIRMAN. We really have to get to our next panel. Thank you all for being here. Just as we are transitioning to our next panel, I would like to say that Mr. Etheridge has allowed me to say that he will be holding a hearing on compensation and the questions in September when we come back.

Next up, with the patience of Job, I will call up, because they have been waiting an awful long time, James Gorny, Ph.D., Executive Director, Postharvest Technology Research and Information Center at the University of California at Davis, and Ms. Jean Halloran, Director of Food Policy Initiatives, Consumers Union, Yonkers, New York. Thank you so much for both of you being here. It has taken a long time to get to your testimony but that makes it no less important to me. So please proceed with your verbal statement, Dr. Gorny.

STATEMENT OF JAMES R. GORNY, PH.D., EXECUTIVE DIRECTOR, POSTHARVEST TECHNOLOGY RESEARCH & INFORMATION CENTER, UNIVERSITY OF CALIFORNIA-DAVIS, DAVIS, CA

Dr. GORNY. Thank you, Mr. Cardoza. Thank you for the opportunity to be here. As you said, I am Dr. Jim Gorny. I am with the Postharvest Technology Research and Information Center at the University of California at Davis. Our center's mission is to reduce postharvest losses and enhance the quality, safety and marketability of fresh horticultural crops.

First and foremost, I want to express my sympathies to all who have been adversely affected by this foodborne illness outbreak and to say I hope to provide at least some small assistance to this Subcommittee to enhance the consumer and marketplace confidence in our nation's food supply.

I am going to echo a lot of the themes that were heard earlier today. First and foremost, enhanced produce traceability may certainly play an important role as a means of bolstering the safety of our food supply but by no means should it be seen as a panacea. Traceability and recall procedures must be viewed as the last line of defense, not the first line of defense, in preventing foodborne illnesses.

Today I would like to address current industry practices and possible means of enhancing the health and safety of our food supply in America in general. First and foremost, with regard to current handling practices, we have heard a lot today about the Bioterrorism Act. Both in the *Code of Federal Regulations* and specific provisions of the Bioterrorism Act require traceability by everyone up and down the food supply chain. The rules promulgated by FDA regarding the Bioterrorism Act do require that everyone in the supply chain within a reasonable amount of time, meaning less than 24 hours, be able to tell who they received product from and who they subsequently shipped product to. These rules promulgated by FDA do not specify a uniform reporting format, they do not require electronic record-keeping and they do not prohibit commingling of food products. As has been mentioned earlier, while FDA has reported numerous difficulties in the recent traceback investigation, to my knowledge, no enterprise has been found to be in violation of the Bioterrorism Act provisions regarding record-keeping.

Now, commingling of food by various suppliers is not unique to the produce industry. It happens also, for instance, in lots of baking flour which may be commingled in storage silos, so why does the produce industry commingle produce? For example, tomatoes are picked at a mature green stage and basically they are shipped off in long distances to the marketplace for ripening and size sorting before being shipped to grocers and restaurants. Green tomatoes simply ship much better. They bruise less easily and there are less postharvest losses. The ripening and size sorting of tomatoes does occur at repacking operations and it offers a real value-added service to retailers and restaurateurs because no consumer wants to eat a small green tomato on their sandwich or on their hamburger.

Now, because tomatoes are often not uniform in size and ripeness when they are picked, there may be insufficient quantities in any given lot to meet customer demands or needs so there will be commingling at the repacking facility to meet grocer and restaurateur needs.

We also talked a lot about epidemiology today and I would like to discuss that in a little bit of detail. Epidemiology is all about finding commonalities to ultimately determine where tainted food came from, how it got contaminated and prevent occurrences in the future. Undoubtedly, tomato commingling can confound an investigation, but in this case, it seems to be imperative as we move forward to determine if produce traceability did work or didn't work.

Was the lack of commonality or patterns in the tomato traceability investigation simply indicated that tomatoes were not the tainted food causing the illnesses.

Now, in fact, we know that it is jalapeños and again, I would like to address how the Minnesota Department of Public Health broke this case. They used different agencies. They used the Department of Agriculture in Minnesota, and it points out the benefits of public health agencies collaborating with other agencies.

Can traceability be improved? Yes, absolutely, and we heard from the industry today talking about their GTIN initiative with regard to electronic records. It will certainly provide a common electronic language for produce traceability.

Last but not least, with regard to protecting public health and some recommendations, the food industry, government and the public should be very concerned about public health officials' lagging response time and inability to quickly identify what food is making people sick. Broad advisories by the FDA to consumers not to consume certain foods should be a regulatory tool of last resort to protect public health. It is a huge disincentive for private enterprises to invest in robust food safety programs and traceability systems if they offer no protection to industry-wide shutdowns by broad public health advisories. In short, a focused approach is what is needed, and more resources and cooperation are what is needed.

I am going to sum up a few specific recommendations. First and foremost, I think we have heard today we need increased understanding by public health officials regarding how specific food industry sectors produce, process and handle and distribute foods. The University of California at Davis stands ready to assist CDC and FDA in helping them understand how the produce industry works. We need development of a harmonized approach to foodborne illness outbreak investigations among the various agencies at the Federal and state level. An agency should engage academia and industry personnel as well as government who have specialized working knowledge about industry segments. We need increased capacity building at FDA and CDC, as Dr. Osterholm talked about. We need increased transparency to understand and have confidence in the CDC and FDA's decision-making process regarding foodborne illness outbreak investigations. And last, we need accelerated harmonization of the traceability initiative by the industry.

In conclusion, it is imperative that we all work together to ensure the safety of fresh produce because these foods play such an important and central role in maintaining good health of our population.

I would like to thank you for the opportunity to address the Subcommittee and provide my professional perspectives. Thank you.

[The prepared statement of Dr. Gorny follows:]

PREPARED STATEMENT OF JAMES R. GORNY, PH.D., EXECUTIVE DIRECTOR, POSTHARVEST TECHNOLOGY RESEARCH & INFORMATION CENTER, UNIVERSITY OF CALIFORNIA-DAVIS, DAVIS, CA

My name is Dr. Jim Gorny and I am Executive Director of the Posharvest Technology Research & Information Center at the University of California in Davis, California. The Postharvest Technology Center is made up of a multi-disciplinary team of researchers and extension educators, with a common mission to reduce

postharvest losses and enhance the quality, safety and marketability of fresh horticultural crops. The Center specializes in providing research-based information to stakeholders to assist them in making informed decisions about produce handling practices.

The foodborne illnesses recently associated with produce are a tragic occurrence and my sympathies go out all of those who have become ill. We can never forget the real human impact when something goes wrong in our food safety system. I am glad to be here to assist in developing solutions to enhance consumer and marketplace confidence in our nations food supply.

I would like to address two issues today.

First, I want to address current produce industry handling practices and their implications for traceability in the event of a foodborne illness outbreak.

Second, I want to share with you views regarding possible means of protecting public health in the future.

Enhanced produce traceability may certainly play an important role as a means of bolstering the safety of our food supply, but it is not a panacea as other issues also need attention. Traceability and recall procedures are the last line of defense in preventing foodborne illnesses.

1. Current Industry Handling Practices

Legal Requirements: The Bioterrorism Act of 2002 and other provisions of the *Code of Federal Regulations* require food product traceability. Specifically the Bioterrorism Act of 2002 requires that records be kept for one step forward and one step back product traceability by everyone in the supply chain.

Rules promulgated by FDA regarding the Bioterrorism Act:

- Do require that everyone in the supply chain be capable in a timely manner (within 24 hrs of notice) of identifying suppliers of food products and/or ingredients and to know to whom product has been subsequently shipped;
- Do not specify a uniform reporting format;
- Do not require electronic record-keeping;
- Do not prohibit commingling of food products or ingredients.

While FDA has reported numerous difficulties and specifically tomato commingling, in this recent traceback investigation, to my knowledge, no enterprise has been found by the FDA to be in violation of Bioterrorism Act provisions regarding record-keeping.

Commingling of food from various suppliers is not unique to the produce industry, another example would be lots of flour for baking which may be commingled in storage silos. The practice of commingling tomatoes has been reported by the FDA to be particularly problematic in hampering their recent investigations to identify the cause of the recent *Salmonella* Saintpaul foodborne illness outbreak. So why does the produce industry commingle produce.

Current Industry Practices: Tomatoes are commonly picked when they are at the mature green stage of ripeness. These green tomatoes are then shipped, often long distances near to the marketplace for ripening and sizing sorting before being shipped to grocers and restaurants. This is done because green tomatoes ship much better than ripe tomatoes that are very susceptible to bruising and postharvest losses. Ripening and repacking operations which ripen and size sort tomatoes offer a very real value added service because no consumer wants to purchase of consume a small green tomato on their sandwich or hamburger.

Because tomatoes are not uniform in size and shape and there may be insufficient quantities of tomatoes from any one lot, different lots of products may be commingled and then sent to grocers and restaurants.

Salmonella *Saintpaul Foodborne Illness Investigation*

Determining in an epidemiological investigation where tainted food came from (which store, then which distributor, then which grower/shipper/packer) by identifying commonalities among where ill individuals purchased their food, is critical to ultimately identifying the most likely root cause of contamination and thus providing the possibility of making sure such contamination never occurs in a similar manner again.

Epidemiology is all about finding a common thread and traceback is only a part of the epidemiological investigation.

Undoubtedly, commingling as in the case of tomatoes has the potential to confound and hamper traceback investigations. In this case it will be important to determine if produce traceability did or did not work and if the lack of commonality or patterns in the tomato traceback investigation simply indicated that tomatoes were not the tainted food causing the illnesses.

Epidemiologists when investigating a foodborne illness outbreak must be extremely careful in assuring that the link between what ill persons ate and where they purchased that food item from is factually correct. If a false assumption is made early in the investigation process (i.e., wrong food product or wrong point of purchase) it leads the epidemiological investigation down the wrong distribution chain, thus wasting time, resources and ultimately delaying the identification of the true cause of the illnesses.

It has now come to light, that in fact jalapeño peppers are the most likely food product responsible for this recent almost nationwide *salmonellosis* outbreak, through epidemiological evidence gathered by the Minnesota Department of Public Health and jalapeño peppers samples testing positive for the presence of *Salmonella* Saintpaul with a similar genetic fingerprint to the outbreak strain.

It is interesting to note is that in an AP news report on July 24, 2008, reporting about how jalapeño peppers were identified as like cause of this foodborne illness outbreak Ben Miller of the Minnesota Department of Agriculture said, "A few phone calls and you can work it fairly quickly back to the grower". This seems to point out the traceability does seem to be working in the produce industry and it also points out the benefits for public health agencies to use allied agencies with complimentary expertise during investigations.

Can traceability in the produce industry be improved? Absolutely yes, the produce industry does have an opportunity to more effectively aid public health investigations into foodborne illness outbreaks by having a uniform format of electronic records. This task developing and adopting a harmonized format of electronic records for traceability has actually already been initiated by a joint task force of produce industry trade associations. This group is working on development and use of what is called Global Trade Item Numbers (GTIN) which provides a common electronic language for traceability for the produce industry.

2. Protecting Public Health

The food industry, government and the public should be concerned about public health officials lagging response time and inability to quickly identify what food is making people ill.

First and foremost public health agencies are currently fragmented and underresourced to effectively monitor and respond rapidly to developing public health issues. Each and every foodborne illness outbreak investigation is an opportunity to enhance investigation team response time.

Broad advisories by FDA to consumers not to consume certain foods should be a regulatory tool of last resort to protect public health. It is a huge disincentive for private enterprises to invest in robust food safety programs and traceability systems, if they offer no protection against industry wide shut downs by broad public health advisories. A more focused approach is needed to protect public health and commerce. This recent foodborne illness outbreak has tarnished FDA's reputation and credibility with consumers and businesses alike, many of whom continued to sell and consume jalapeño peppers despite FDA's blanket advisory against their consumption. This is simply unprecedented and paradigm shift in how people perceive the FDA's public health recommendations.

Simply put more resources and cooperation are needed to adequately protect public health and commerce.

Specific recommendations include,

- Increased understanding by public health officials regarding how specific food industry sectors produce, process, handle and distribute food products.
- Development of a harmonized approach to foodborne illness outbreak investigations among various Federal and state public health agencies. Agencies should also consider engaging academia and industry personnel whom have special working knowledge about food industry segment practices during an investigation.
- Increased capacity building at FDA, CDC and state public health agencies, in terms of trained professions to respond to foodborne illness outbreaks.
- Increased transparency to understand and have confidence in the CDC and FDA decision making process regarding foodborne illness outbreak investigations.
- Accelerated adoption of a harmonized traceability format Global Trade Item Numbers (GTIN) electronic traceability format for the produce industry.

In conclusion, it is imperative that we all (academia, industry and government) work together to assure the safety of the fresh produce supply because these foods play such an important and central role in maintaining good health.

Thank you for this opportunity to address the Subcommittee and provide my professional perspectives on this issue.

The CHAIRMAN. Thank you, sir.

Ms. Halloran.

STATEMENT OF JEAN HALLORAN, DIRECTOR, FOOD POLICY INITIATIVES, CONSUMERS UNION, YONKERS, NY

Ms. HALLORAN. My name is Jean Halloran and I am Director of Food Policy Initiatives for Consumers Union, the nonprofit publisher of *Consumer Reports,* and I suppose there is always something to be said for having the last word.

The CHAIRMAN. My kids always try and get it, so I know it is important.

Ms. HALLORAN. This foodborne illness outbreak involving *Salmonella* Saintpaul in produce, which has now been linked to peppers grown in Mexico, shows quite clearly that traceability offers a way to protect consumers better, use our regulatory resources more efficiently and effectively, and limit the losses of produce growers.

We believe that had a good traceability system been in place for tomatoes 4 months ago, and I would like to say that traceability is something supported by 86 percent of consumers in a recent AP-Ipsos poll, had that been in place, FDA would have gotten to the bottom of this problem much more quickly. With traceability, investigators could more quickly have followed what people were eating back trough the distribution chain and all its repacking and remixing stages, could more quickly have sampled along that chain, and could more quickly have understood that tomatoes were most likely not the primary source of the problem. This could have helped FDA and CDC turn their attention sooner to foods eaten in association with tomatoes and thus to the jalapeños that we are now considering so seriously.

We see two options for upgrading traceability. At a minimum, we believe that products should have labels on the packages and boxes and where possible on the product itself that show the country, facility, date and time where the product was first processed and shipped. I was very encouraged by the testimony of the Produce Marketing Association that they have such a scheme in process. It is essential that this be mandated for everyone and not just be voluntary because it is the gaps that will cause the problem and slow down a traceback process. This can be implemented on the very same stickers that will show a product's country of origin, which is going to be mandatory for imported produce in October of this year.

Even more effective is what we call the FedEx model in which each product gets a code on it that can be read as the product moves through the process and will enable it to be tracked through the distribution system. Then if you come up with a contaminated pepper, you could look back and see all the places it has been and all the places it might have been contaminated or contaminated something else. We know that there are important issues to resolve here including ensuring that all handlers log in and log out shipments and also whose computer will process all this tracking data. But, we do believe that Congress should mandate full traceability

on the FedEx model, and unless it is mandated, you will not get compliance with foreign producers and small producers. I would say for very small producers, this is not really an issue because if something goes direct from the producer to a farmer's market, you don't need traceability. There is nothing to trace. You are buying from the producer.

The CHAIRMAN. Both the consumer and the producer know who did it, right?

Ms. HALLORAN. Yes. The alternative to these options is the present situation with the consequences we have just been discussing. I would like to emphasize that FDA has no choice but to inform the public when it has strong suspicions about contamination. Consumers need to be able to take precautionary actions to protect themselves in such situations and FDA cannot withhold information from them that would better allow them to take precautions for themselves and their loved ones. Therefore, we must learn to prevent these situations and to not have the investigations drag on.

In addition to traceability, we feel that other preventive measures are really important, as others have stated. One is a substantial increase in resources for FDA. Another is FDA should be required to develop standards for processing facilities. A third is that FDA should be required to enforce clear performance standards for contaminants in produce. USDA data, a recent study shows that there are higher levels of pesticides in imported salad vegetables than in domestic, so we need enforcement of standards. FDA is not enforcing sufficiently at the border. They said only one percent was being looked at. They visit facilities only once every 5 to 10 years, foreign facilities even less frequently, although we believe they need it more. Finally, they should have mandatory recall authority and disclose the stores that carry recalled products.

This Congress has much to do and little time to do it in but we think these issues are urgent and we urge you to tackle these issues now. Thank you.

[The prepared statement of Ms. Halloran follows:]

PREPARED STATEMENT OF JEAN HALLORAN, DIRECTOR, FOOD POLICY INITIATIVES, CONSUMERS UNION, YONKERS, NY

Thank you for the opportunity to testify today on traceability and its potential use in fresh produce. My name is Jean Halloran and I am Director of Food Policy Initiatives for Consumers Union, nonprofit publisher of *Consumer Reports.*

This is a timely and important hearing because we are still in the midst of a serious foodborne illness outbreak involving *Salmonella* Saintpaul in produce, which has now been linked to peppers grown in Mexico.[1] This outbreak shows quite clearly that traceability offers a way to protect consumers better, use our regulatory resources more efficiently and effectively, and limit losses of produce growers when food safety problems emerge.

We are now in an era of a globalized food supply. Food products move around the United States and are imported from other countries as never before. Unfortunately our systems for insuring the safety of food have not kept up with the changes in production and distribution systems. Congress can and should address the need to modernize FDA to deal with these new challenges. We urge you to require full traceability as part of this much needed overhaul. Consumers overwhelmingly like

[1] FDA Statement, "U.S. Grown Jalapeño and Serrano Peppers Not Connected to *Salmonella* Saintpaul Outbreak," July 25, 2008.

this concept: an Associated Press-Ipsos poll shows that 86 percent of consumers support traceability.[2]

Food Safety Incidents

We are now facing significant problems as to the safety of our food. The current tomato/jalapeño *Salmonella* Saintpaul outbreak is just latest example. This foodborne illness outbreak has sickened more than 1,200 people, sent more than 200 to the hospital, and contributed to two deaths. As is usually true in such disease outbreaks, the deaths tend to affect the very young, the very old and those with compromised immune systems, and in this case the *Salmonella* contributed to the deaths of two elderly gentlemen.[3]

This outbreak follows several others in the last 2 years that have involved significant numbers of illnesses, including *Salmonella* in peanut butter,[4] where the problem originated in a Georgia processing plant, and *E. coli* in spinach, where the contamination apparently occurred on a California farm.[5] There have also been problems with prohibited chemicals in seafood, stemming from use of the chemicals at aquaculture facilities in China.[6]

The tomato/jalapeño case is still not resolved, in that the Food and Drug Administration and the Centers for Disease Control have so far not traced the problem back definitively to its source or sources. Until they are able to do that, we cannot be sure that the outbreak is over, or that it will not start up again. Although some 1,200 cases have been officially reported to CDC, it is likely that many more people have been and could still be affected. Experts estimate that for every reported case in an outbreak of this type, three to ten times as many people may be affected, but are not counted because they don't see a doctor, or their doctor doesn't seek to identify the bacterium causing their problem.

This case in particular has highlighted the need to establish traceability systems in produce. FDA's original hypothesis, based on case control analyses by CDC of what victims ate, was that tomatoes were the problem food. FDA then began the extremely labor intensive process of trying to traceback the tomatoes that the people had eaten, hoping to find the source of their *Salmonella* infection. Unfortunately they found that tomatoes go through many hands and are mixed and repackaged often. Thus trying to traceback one person's tomato became an enormous task, with trails branching again and again. The mystery dragged on for weeks, resulting in confusion for consumers and hundreds of millions of dollars in losses for our nation's tomato growers.

We believe that had a good traceability system been in place for tomatoes 4 months ago, FDA would have gotten to the bottom of this problem much more quickly. With traceability, FDA investigators could much more quickly have followed what people ate back through the distribution chain, could much more quickly have sampled along that chain, and could much more quickly understood that tomatoes were most likely not the source of the problem. This would have helped it turn its attention earlier to foods eaten in association with tomatoes, and thus to jalapeños where last week the *Salmonella* strain was identified.

Options for Traceability

We currently have very limited traceability for food, which are not sufficient. The current system, wherein those in the produce industry keep paper records that indicate one step forward and one step back in the supply chain, creates an enormous amount of work for any regulatory agency trying to follow a trail.

We see two options for upgrading traceability at this time. One would be relatively easy to implement. We believe that at a minimum, we should have labels or marks on produce packages and boxes, and where possible on the product itself (such as with fruit), that show country, facility, date and time where the item was first processed or shipped. The label or mark should allow the product to be traced all the way back to the farm. This can be implemented in the form of a numerical or bar code on the very same sticker that will already show the product's country of origin—which is mandatory for imported products in October of this year. Such facility/date/time of processing information was present on the packages of bagged

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[2] *http://www.latimes.com/news/nationworld/nation/wire/ats-ap-ap-poll-food-safetyjul20,0,428028.story.*

[3] *http://www.cdc.gov/salmonella/saintpaul/.*

[4] FDA News, "FDA Warns Consumers Not to Eat Certain Jars of Peter Pan Peanut Butter and Great Value Peanut Butter Product May be Contaminated With *Salmonella*," February 14, 2007.

[5] FDA News, "FDA Finalizes Report on 2006 Spinach Outbreak," March 23, 2007.

[6] FDA News, "FDA Detains Imports of Farm-Raised Chinese Seafood; Products Have Repeatedly Contained Potentially Harmful Residues," June 28, 2007.

spinach that were found to contain dangerous *E. coli* in 2006, and it allowed FDA to quickly—within a couple of weeks, instead of months—identify and isolate the source of the contaminated spinach.

An even more effective option, though somewhat more difficult to implement, is what we think of as the "FedEx model." In this model, each lot being shipped would get a label like that on a FedEx package that would enable its progress to be tracked throughout the food distribution system. Then if you had a contaminated pepper, you could look back and see all the places it had been, and therefore all the places it could have been contaminated. We do understand that there would be many issues to resolve to implement such a system, including how to ensure that all handlers log in and log out their shipments, and whose computer would process all the tracking data on shipments in process. Still, if FedEx can do it, why not the tomato industry?

The alternative to implementing one of these options is the present situation where it is enormously difficult for FDA in certain cases to pinpoint the source of an outbreak. This has unfortunate consequences for consumers, the regulators and the industry. First, FDA wastes enormous financial resources getting to the bottom of the problem. Second, FDA has no choice but to inform the public when it has strong suspicions about contamination—as it did in the case of tomatoes—even though we know that an initial hypothesis, no matter how sensible and justified, may turn out to be incorrect. FDA must do this because not to do so would be irresponsible. *Salmonella*, *E. coli* and *Campylobacter* infections can all result in deaths, particularly of the most vulnerable such as young children, the very old, and the sick. Consumers need to be able to take precautionary actions to protect themselves in such situations, and FDA cannot withhold information from them that would better allow them to protect themselves and their loved ones. But consumers may needlessly discard good produce and avoid healthful foods as a result, and growers may experience enormous financial losses.

To prevent such precaution-taking from having a devastating impact on an industry, FDA must be able to get to the bottom of a problem quickly and efficiently. To do this we need product traceability.

Additional Reforms Needed

As much as traceability will help, however, the ability to traceback in response to a disease outbreak is not the whole solution. FDA should be acting proactively to prevent these outbreaks from occurring in the first place. FDA also needs other enhancements to its resources and authority to be able to prevent as well as respond to food safety problems effectively. We urge Congress provide the following so that FDA can function as a 21st century food safety agency:

- **A Substantial Increase in Resources:** Significantly increasing appropriations for the agency is essential. Registration fees can also provide revenue, although they should not substitute for appropriations.
- **Process Controls:** Companies should build safe practices directly into production. Production facilities should be required to develop and use written food safety plans to identify hazards likely to occur in their facilities, and then implement measures to reduce those hazards. FDA should be required to develop standards for process controls in areas like tomatoes and leafy greens that have caused disease outbreaks.
- **Strong Food Safety Standards:** Contamination can occur at many points along the food chain, including production, processing, shipping, or handling. Such contamination can include bacteria, illegal antibiotic residues, heavy metals, and pesticides. FDA must establish and enforce clear performance standards for food products to reduce the risk of contaminated food being released into the marketplace.
- **Traceability:** As the recent *Salmonella* outbreak has demonstrated, we desperately need to be able to trace our food throughout the supply chain when an outbreak occurs.
- **Food Facility Inspection:** Between 2003 and 2006, FDA domestic food safety inspections decreased 47 percent.[7] On average, domestic food production facilities are inspected once every 5 to 10 years, foreign facilities even less frequently. Congress should require FDA to create a risk-based system of routine inspections, based on the type of food produced, how it is processed, and history of the plant and region or country where it is located, among other factors. All

[7] Associated Press, "Risks of tainted food rise as inspections drop; Amid high-profile scares, FDA safety testing has fallen by half since 2003" February 26, 2007.

facilities regulated by the FDA, foreign and domestic, should be subject to mandatory, regular inspection by officers of the FDA. Higher-risk facilities should be inspected on a more frequent basis—at a minimum once a year—and all facilities must be inspected at least once every 2 years.

- **FDA Border Inspections:** FDA inspects less than one percent of food imports at the border. This must be significantly increased, especially for high-risk foods. For example, the European Union physically inspects either 20 percent or 50 percent of all imported seafood shipments, depending upon the risk of the individual product.[8]
- **Mandatory recall authority and disclosure of retail consignees:** When FDA discovers a problem, it is forced to ask companies to voluntarily recall an unsafe product. It is important that FDA be able to act quickly in such situations and order a mandatory recall. FDA should also be required to inform consumers of all retail outlets, schools, nursing homes, etc. that are involved in a recall.

Although this Congress has much to do and little time to do it in at this point, this problem is urgent. We urge Congress to tackle it now, and require full traceability as part of a significant overhaul of FDA's regulation of food safety.

The CHAIRMAN. Thank you, Ms. Halloran. Thank you very much to both of you. I have a couple of questions that I want to ask.

First of all for Dr. Gorny, do you believe adoption of the Global Trade Item Number, GTIN, electronic traceability format, should be accelerated? You also have acknowledged that one of the most difficult aspects of creating that traceability program is dealing with the issue of commingling of produce at different stages along the way. Does this format provide appropriate level of granularity to address the current risks and concerns?

Dr. GORNY. First and foremost, I believe that the GTIN standard that is being put forward by the trade groups in produce will be a huge step forward, a great leap forward with regard to the ability to trace product. The reason being that it puts it on a common format and an electronic format, exactly what FDA has said has been a huge problem with regard to these traceback investigations. The second part of your question is, I think if we provide—you are never going to get away from commingling of produce. You are never going to get away from commingling of all food products. You just have to deal with that at a most appropriate level, and it is at a per-box level so you know that potentially two potential suppliers may have put product into that potential box, and I think it is possible to closely segregate, so I think it is a huge step forward.

The CHAIRMAN. Thank you.

Ms. Halloran, your recommendations for traceback systems, do you envision establishing a single traceback system for all food products or do you see different systems for different products?

Ms. HALLORAN. I am not certain of the most appropriate method. I think it may well be for different industries you need different systems and they may need to be maintained by industry associations or other entities, but you need a uniform framework. There needs to be uniform criteria for how this is done so that there are certain minimum criteria and that FDA can use them simply and don't have to learn a new system every time.

The CHAIRMAN. During the farm bill discussion, I had serious conversations with the Chairman of the Senate Agriculture Committee, Mr. Harkin. We tried to figure out how we were going to

[8] Food & Water Watch, "Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections," FWW report, May 2007, at 6.

do this and there is a genuine commitment on his part to wanting to move along these lines. We had a method in the House bill that he didn't feel comfortable with. One of the arguments that I made to him was, there are 350-some commodities in the food world but within those there are so many subsets, different types of varietals, and to develop different protocols for each one of those on food safety measures is very difficult. The industries that do that though can individually can come up with it. So we were having a very difficult time. My question for Ms. Halloran is, should FDA start by establishing a traceback system for high-risk products or handle all products simultaneously, knowing that it is very complex and the record of agencies developing regulations and protocols is not that great in this country? It takes a long time. I think the quickest one we have ever seen is 18 months to 2 years, and you multiply that times 350 and you are looking at the next century before we will finally get to food safety by that criteria. I think we can do it another way but I would like to hear your testimony.

Ms. HALLORAN. Yes, I think that to have FDA try to micromanage this would be probably a mistake, and that some of the basic—the three things that the produce manufacturers were talking about—we were thinking, basically four facts, the country of origin, the facility of origin, the date and the time of the shipment for the original product. If that ended up on that sticker that annoyingly we are always pulling off as the consumer, that would be a huge leg up on the traceback process, would be very simple to do and all you need is a numerical system that is common to everyone which obviously the produce industry is already well in the process of developing.

The CHAIRMAN. Thank you. I appreciate your acknowledgement of that. Frankly, I think that our farmers and our distributors in this country have done a miraculous job producing the volumes they do at the costs. Even at the higher costs that we are now seeing in the supermarket, we are certainly lower than most parts of the world and pay less for our food than most parts of the world do, and it is, in my opinion, safer than many parts of the world. It is not always safe but it is safer than what is typically, in my opinion, available in many parts of the world. But that is my editorial comment.

Ms. HALLORAN. I really have to say, I think we can say we have one of the safest food supplies in the world. I really do think that, for example, many countries of the European Union are now ahead of us, if you look at the statistics, so we really don't want to lose our edge on that area and we have some work to do to keep up.

The CHAIRMAN. Thank you. At this point, I want to thank you both for your testimony. I want to thank all our panelists. I want to thank the audience. I want to give a special thanks to the staff, both the Minority and the Majority staff, who have done a fabulous job preparing this hearing and getting all our witnesses here today.

Under the rules of the Committee, the record for today's hearing will remain open for 10 days to receive additional material and supplementary written responses from the witnesses to any question posed by a Member of the panel. This hearing of the Subcommittee on Horticulture and Organic Agriculture is hereby adjourned.

[Whereupon, at 5:40 p.m., the Subcommittee was adjourned.]
[Material submitted for inclusion in the record follows:]

SUBMITTED TESTIMONY OF JESSE DRISKILL, PRESIDENT, FRESH PRODUCE ASSOCIATION OF THE AMERICAS

August 1, 2008

Hon. DENNIS A. CARDOZA,
Chairman,
Subcommittee on Horticulture and Organic Agriculture,
Committee on Agriculture,
Washington, D.C.

Re: Written Hearing Testimony Submitted for the Record on Behalf of the Fresh Produce Association of the Americas; House Agriculture Committee, Subcommittee on Horticulture and Organic Agriculture Held on July 30, 2008

Dear Chairman Cardoza,

On behalf of the Fresh Produce Association of the Americas, a trade association representing more than 125 member importers of produce located in Nogales, Arizona, we would like to submit this written testimony for the record. FPAA was founded in 1944 to represent the U.S. importers of produce from Mexico, an industry that is a vital part of the U.S. border and regional economy, the port of Nogales imports $1.5–$2.5 billion annually. Our industry provides jobs and contributes significantly to the U.S. economy, particularly in the southern border region of the United States, but also down the supply chain including distributors, retailers and restaurants. In the context of this hearing, it should be noted that FPAA also represents the majority of the distributors and importers of tomatoes from Mexico. With all due respect, we would like to suggest that for future hearings on food safety for produce that FPAA be included as a witness. Based on our long history in the business, we have many facts and practices to share about food safety from the unique importer position in the market.

At the outset, we would like to thank Chairman Cardoza for holding this balanced, fair and positive hearing seeking solutions and improvement in the area of food safety for produce. In this important area, where confidence of the U.S. food supply is at issue, we cannot indulge in finger pointing but must move forward together to ensure consumer confidence in our products. Produce is a healthy product, essential for a healthy diet. At a time when obesity and related illnesses are costing consumers and the U.S. taxpayers as much as billions of dollars annually in healthcare costs, we must not discourage consumption of fresh produce. In the recently passed farm bill, the Congress wisely funded the U.S. school snack program at a level of about $1 billion annually to provide fresh produce to under-privileged children with the goal that child nutrition and long-term eating habits would be established for the U.S. population in years to come. We cannot let unwarranted fears undermine this progress toward improved nutrition. For these reasons, it is important that we improve the FDA–CDC response to outbreaks and ensure balance in communication about risk.

With regard to produce, we view the industry as the North American industry. The produce industry, whether in the United States, Canada or Mexico operates in an integrated manner. Our products share supply chains and distribution points and there is substantial cross ownership of production by multiple entities across national lines. As you are aware, for example, California-based produce companies in many instances have growing operations in California and in Mexico as well. With the increasing difficulty obtaining agriculture laborers in the United States, the trend on the part of U.S. companies to expand across the border to Mexico will only continue. Another driver in this integration is the globalization of supply as mandated by the larger retailer purchasers. These large purchasers demand high quality, reliable and safe product all year round. During the winter months, Mexican fresh produce accounts for as much as 25 percent of U.S. produce consumption. More than 4 billion pounds of produce enters the U.S. at Nogales, Arizona to meet the U.S. consumer demand for year-round, high-quality fresh produce. Evidence of this approach and integration of the industry was clear in the course of the recent investigation of *Salmonella* Saintpaul in tomatoes where it was found that many distributors sourced from U.S., Canada and Mexico at the same time.

For food safety, this globalization of the market and the advent of large purchasers means that more and more all producers are being held to one food safety standard—the standard set by the purchaser. As any large retail outlet can validate, products are all held to the same food safety standard regardless of the source of the product. For a retailer, their brand and reputation is at issue. The purchaser will remember where they purchased the product and not where the product was

produced. As a result, when there is a food safety incident, consumers will stop purchasing the product regardless of the source. We have learned this in the two biggest recent outbreaks: spinach from California and now peppers from Mexico. We have learned that consumers stop eating the product broadly—regardless of source. When there is a food safety issue, the entire product category suffers a reduction in sales and severe economic loss.

Another lesson that we have learned from recent outbreaks is that while we "are only as strong as our weakest link" when it comes to food safety that at the same time it is not always the small producer that is the weakest link. In the case of spinach the failure did not occur within a small operation; whereas for peppers this appears to be the case. What we know is that is regardless of geographic region or size of an entity that food safety failures can occur. It is common sense backed up by science that risk cannot be reduced to zero. This points to a fundamental principal that should be adopted in regulating food safety: the cause of an outbreak is the failure in the system of one specific entity—and *not* a failure of a geographic region or particular type of entity. There should not be pre-conceived biases against particular products, particular size of entity or particular geographic region. The only focus should be to quickly track, based on the facts at hand, to a specific entity in order to pinpoint and close out that source.

In food safety, speed of an investigation is absolutely critical. Once there has been an outbreak, the priority must be finding the source of the contamination immediately. Undoubtedly, traceback is one (but not the only) critical element of the investigation. From the importer perspective, we would like to note that in the recent tomato and chili pepper investigations, traceback did work across the border into Mexico. There was no blackout of information or end of the trail at the border with Mexico. Tomatoes and peppers were traced from consumer to farm in both instances. This is a very important point because some have suggested that whenever there is an outbreak that the borders should be shut down, as if there is something different about traceback at the border. But this is not the case, as shown in the tomato and chili peppers investigations the traceback across the border occurred successfully and with no slow up. Under the Bioterrorism Act, foreign entities are required to register with the Department of Health and Human Services, Food and Drug Administration and are required to keep records one step up and one step back just as domestic entities.

Further, with all due respect, in response to the misguided suggestion, by several at the hearing, that a response to an outbreak should be closing of U.S. borders to imports, we would like to point out that with regard to produce, imported products have not accounted disproportionately for outbreaks. While including imports in the solution is essential, it would not be sensible to target or single out imports as the problem for a different approach. The approach should be to continue to harmonize and standardize requirements so that all producers are subject to the same standards and requirements.

A further point on standardization of requirements in the produce sector is that U.S. produce is not more highly regulated than Mexican or Canadian produce at the Federal level at this time. Good Agricultural Practices for produce in the U.S. are not mandatory. Therefore, making such requirements mandatory on imports would be holding imports to a higher standard than domestic products and there is no scientific justification for a difference in treatment. Any such effort to hold imports to a higher standard than domestic products would be a violation of U.S. international obligations under the WTO. In the past, mandatory GAPs for imports only has been made and been vetoed when reviewed by the United States Trade Representatives legal counsel. It is a very important principle of international trade agreements that domestic and imported products be regulated in an equivalent manner so as to prevent an illegal trade barrier. The U.S. subscribes to these international agreements so that U.S. products (including U.S. produce exported to Mexico, for example) will not be subject to trade barriers going into Mexico.

Another clarification to make clear is that FDA does have extensive authority to regulate imports of produce and to stop imports on a company-specific basis. Under its system of Detention Without Physical Examination and Import Alerts, the FDA has the authority (which it regularly and frequently uses) to prevent imports of a specific shipment, product, region or exporter. DWPE is based on past history or other information indicating the product may be a hazard. A product may then be subject to a detention until the shipper or importer proves that the product meets FDA standards. See *http://www.foodsafety.gov/~lrd/imp-info.html* In other words, the system for stopping even suspicious products at the border is well-established. FDA, in effect, does have "mandatory recall" with regard to imports. Based on some of the testimony and Member questions at the hearing, we are concerned that the Members of Congress were not properly informed on how food safety is enforced

with regard to imports. We would be pleased to meet with, answer questions and brief any Member or staff interested in understanding this issue and how it operates at the border from an operational perspective.

Whenever the issue of food safety is addressed, it is stated that "we cannot sample/inspect our way out of this problem" and we would like to agree with and explain this view. First, this reality applies equally to domestic production and to imports. It is not a theoretical statement but rather a statement of fact. The volume of produce consumed in the U.S. compared to the level of contamination is so small that it is just not possible to always identify a 100 percent of the contaminations through inspections. When there is an outbreak, FDA does not begin testing every piece of produce in the U.S. because this would be impossible. Instead, FDA initiates a traceback, a process of pinpointing where to test in order to increase the odds of finding the contamination. Unfortunately, in hearings on food safety, we do not seem to be able to move beyond this red herring quickly, and important time is often wasted reviewing again this point.

It is because 100% testing and inspection (not based on any targeting or risk response) is not the answer, that the industry recommends preventative measures such as preventative controls (food safety workplans) that are verifiable. As you have heard in every recent hearing on food safety, the majority of the produce industry already has verifiable food safety plans in place. Many of these are based on established and scaleable practices that are verified by third parties. Some of these standards established by industry groups with wide input and are published by FDA on its website. These are adhered to by almost all producers of the covered products. With regard to imports, we would suggest the idea of "pushing the border back" which means that the focus should not be increased inspection at the border but rather preventative and verifiable controls on the farms.

Following are some specific suggestions to FDA for improvement with regard to imports:

(1) Sampling time must be shortened

The lengthy delays in sampling by FDA are another unintended source of potential food safety problems for imports. In those situations where FDA decides to sample and analyze fresh produce, it currently takes as long as 72 to 96 hours to obtain the analytical results and a release from FDA. Nearly 24 hours of that delay is consumed by the sampling and shipping process alone—delivering the sample to the FDA laboratory. However, another 18 hours of delay occurs when FDA laboratory analysts, with flexi-time schedules, arrive for work in the lab at 6:00 a.m., and leave by 2:00 p.m. When a sample of fresh product arrives at the laboratory for analysis at 11:00 a.m. or noon (or later), the analyst will wait until the next day to set up and run the sample. This additional delay compounds the damage to produce caused by increased time and less-than-optimum storage conditions. In too many cases, by the time clean laboratory results are received and reported, the fresh produce has already passed a quality point requiring it to be discarded. In this regard, FDA's testing processes, which are intended to ensure that an imported shipment is safe, ironically contributes substantially to the tested food being of such a lower level of quality that it is no longer marketable—and yet FDA releases the shipment because of the clean analytical results.

(2) Regulations and requirements must be updated through a transparent process

FPAA deals at the border with a range of U.S. regulating agencies, including CBP and FDA. It is our experience that FDA appears to be under-funded and not in control of its border function resulting in arbitrary, unpredictable and non-uniform practices. This encourages exporters and importers to engage in "forum shopping" among ports and weak links in the food safety activities at the border. In our experience FDA is somewhat a "black box." The FDA has historically operated its import operations on the back of antiquated agency policies and procedures, which were created in the 1970s. Chapter 9 of FDA's Regulatory Procedures Manual, a few regulations promulgated in the last century, and the more recent Bioterrorism Act regulations (relating to prior notice of imported foods and registration of food facilities) together represent the total sum of FDA policies and procedures for managing as much as half of all of FDA's regulated commodities in interstate commerce. FDA operates according to many unpublished internal procedures, and some districts have promulgated local policies and procedures to address certain isolated problems in the importation process. However, the vast majority if FDA policies and requirements are not published. Therefore Many of FDA's published procedures (the RPM, the Investigation Operations Manual, Compliance Policy Guides and Compliance Program Manual Guides) have no legal effect whatsoever; however, they are imple-

mented as if they are regulations promulgated under the Food Drug and Cosmetic Act.

These and other incongruities could be resolved if FDA would operate with a level of transparency similar to Customs and Border Protection. Customs' local port offices also issue local procedures, but they do so after entering into open and public dialogue with the affected industry. FPAA recommends FDA enter into a public dialogue with the fresh produce industry to revise its procedures and policies relevant to the agency's import operations.

(3) Recognition of point of origin testing

Many Mexican fresh produce growers and packers already conduct routine tests of product prior to shipment. FPAA urges that FDA begin recognizing and incorporating into its own import risk screening process the routine, scientifically sound, and reliable laboratory testing being conducted at the point of origin. FPAA believes this will assist the Agency in focusing its limited import inspection resources on those shipments that have not been tested or that pose some additional and identifiable risk factor. Many Mexican growers also implement routine and rigorous water analyses and Good Agricultural Practices to ensure their products are safe for consumption. Although each of these components should eventually be considered in developing a dynamic risk-based imported food safety program, point of origin sampling and analysis—whether the analysis is conducted in Mexico or in the U.S.—can quickly be incorporated into FDA's current decision making process when product arrives at the port of entry.

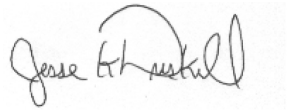
(4) FDA should work to develop a program for small entities

Finally, we would like to agree that the additional food safety requirements will be hard for small companies, whether they are entities located in the United States or in Mexico. The expense of developing a food safety plan that is certified by third parties is significant. We must all work together to make sure that the small growers and importers are treated fairly and perhaps subsidized in some way with regard to the expense of certification and compliance.

* * * * *

We appreciate all of your effort on behalf of the produce industry and we look forward to working with you in the months and years ahead.

Sincerely,



JESSE DRISKILL,
President.

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