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THE RECENT SALMONELLA OUTBREAK: LESSONS LEARNED AND CONSEQUENCES TO INDUSTRY AND PUBLIC HEALTH

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

JULY 31, 2008

Serial No. 110–142

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THE RECENT SALMONELLA OUTBREAK: LESSONS LEARNED AND CONSEQUENCES TO INDUSTRY AND PUBLIC HEALTH

THURSDAY, JULY 31, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, D.C.

The committee met, pursuant to call, at 10:01 a.m., in room 2123, Rayburn House Office Building, Hon. Bart Stupak (chairman of the subcommittee) presiding.

Present: Representatives Stupak, DeGette, Schakowsky, Inslee, Dingell (ex officio), Shimkus, Murphy, Burgess, Blackburn, and Barton (ex officio).

Staff Present: Scott Schloegel, John Sopko, Chris Knauer, Kevin Barstow, Calvin Webb, Alan Slobodin, Krista Carpenter, Whitney Drew, and Kyle Chapman.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This meeting will come to order.

Today we have a hearing titled "The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health." Each member will be recognized for a 5-minute opening statement. I will begin.

Since the 110th Congress began in January 2007, this subcommittee has been investigating the adequacy of the Food and Drug Administration's efforts to protect Americans from unsafe food.

Today we hold the subcommittee's ninth hearing regarding the safety and security of the Nation's food supply. The purpose of today's hearing is to examine the events surrounding a recent Salmonella Saintpaul outbreak. We will consider the implications to public health and industry and will examine what lessons can be learned to better safeguard our food supply.

Since April, at least 1,304 people in 43 States, the District of Columbia, and Canada have been infected with Salmonella Saintpaul. These illnesses have resulted in at least 252 hospitalizations and may have been a contributing factor in two deaths. This outbreak is one of the largest outbreaks of Salmonella ever in the United States, and based on the number of confirmed cases it's the largest food-borne outbreak in the last decade.

The Centers for Disease Control and Prevention, CDC, and the Food and Drug Administration, FDA, have struggled to identify the cause of Salmonella outbreak. Originally CDC and FDA identified tomatoes as the most likely cause of the outbreak. However, as the outbreak continued and the number of illnesses soared the FDA was unable to definitively identify tomatoes as the source of contamination. In late June CDC expanded its epidemiological investigation to include food items that are commonly served in combination with tomatoes. This study found that people who became ill were more likely to have recently consumed raw tomatoes, fresh jalapeño peppers, and fresh cilantro. However, the CDC still could not determine the exact cause of the outbreak.

Finally, on July 21, nearly 2 months after the outbreak was first discovered, the FDA announced a significant break in its investigation when they confirmed the presence of Salmonella Saintpaul in a Mexican-grown jalapeño pepper. The jalapeño had the same Salmonella genetic fingerprint as the strain linked to the outbreak. Despite this discovery in jalapeños, the FDA still refused to rule out tomatoes as the original source of the outbreak, which has angered many tomato growers.

Today we will examine why it took the FDA, CDC and State public health agencies so long to identify jalapeño peppers as a source of Salmonella Saintpaul. Further, we will explore what lessons for industry and government should be garnered as a result of this outbreak. Perhaps most importantly we will try to determine which aspects of this outbreak investigation worked well, and which failed so that regulators, and the affected industry will be better prepared to rapidly respond to future outbreaks.

For example, we will examine a portion of the Bioterrorism Act of 2002 which was designed to ensure the traceability of food. The act directed Secretary of Health and Human Services to issue regulations regarding the establishment and maintenance of records by most people and companies that manufacture, possess, pack, transport, distribute or receive food. Most notably exempt from this requirement are farms and restaurants. The regulation requires that records must be kept to allow federal investigators to identify the immediate previous sources and subsequent recipients of food in order to be able to quickly respond to threats to our food supply.

However, in discussions with committee staff, Dr. David Acheson, FDA's Assistant Commissioner for Food Protection, otherwise known as the Food Czar, stated that the Bioterrorism Act did not function as intended during this outbreak. Because the Bioterrorism Act does not require a particular format for maintaining records, most food companies have their own unique system of recordkeeping which, according to FDA officials, has caused significant delays in FDA's trace-back investigation. While FDA has ultimately been able to trace back commodities associated with this outbreak it has been too time consuming of a process, requiring countless hours trying to link one company's records to the next. Today we will explore what specific problems FDA had in its trace-back investigation and whether alterations to the Bioterrorism Act or other additional regulations are needed to allow federal investigators to quickly trace back suspected commodities during an outbreak.

We will also explore what the industry can do to maintain traceability of its products. While there has been discussion by FDA and the media that loose products, like tomatoes, are difficult to trace due to their complex processing and distribution chain, some of the industry maintain that such commodities are rapidly traceable from the farm to the end user. Indeed, some tomato companies visited by committee staff did provide evidence that tomatoes could be rapidly traced back if the need arose. However, these sophisticated systems appear to conflict with statements by FDA officials who claim that tracing this commodity has often been a time-consuming and daunting task. Today we will discuss whether there are particular systems that can be adapted by industry to enhance traceability, particularly for high risk commodities.

Finally we will also hear a host of criticism from industry directed at the FDA and CDC for the way they conducted its outbreak investigation.

For example, we will hear that the FDA often did not share or solicit critical data and other information from food safety agencies.

We will hear that the way State health agencies interact and share data with key federal agencies such as the FDA and CDC is often inefficient, overly bureaucratic and sometimes even counterproductive.

We will hear that by failing to adequately coordinate with key State agencies both FDA And CDC missed important opportunities to leverage scarce federal resources with State resources to conduct investigation and field work related to the investigation.

We will hear that neither CDC nor FDA worked closely enough with State agencies to understand key produce distribution patterns and, if they had, they would have realized early that based on geographic distribution patterns of the illness the source of the Salmonella was likely not from Florida.

Finally, we will hear that because there were over 3,000 local health departments and 50 State health departments working under different public health laws there is a tremendous variability in the capacity to respond to these outbreaks which can have produced consequences on the ability to pinpoint a contamination source.

These and other troubling issues related to this outbreak continued to be uncovered as we move forward with this investigation. While we understand the FDA's and CDC's investigation into this outbreak is ongoing, it's important to find answers and solutions to the key failures that have been identified up to this point.

At a minimum, the FDA and the CDC must convene and independent post-mortem task force which includes local, State, federal, scientific and industry officials related to this outbreak to study which features of the investigation broke down and how the system can be improved. While this Salmonella outbreak has sickened scores of people and caused great economic damage to the produce industry, we are fortunate that this does not appear to be an intentional contamination of our food supply. If we do not learn from this case and rapidly improve our food safety system we will be doomed to repeat the failures of the current outbreak. The American public deserves better from industry and our State, local, and Federal agencies.

That completes my opening. I will next turn to Mr. Shimkus, the Ranking Member of the subcommittee for his opening statement please, sir.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Mr. Chairman.

I want to welcome this panel and the succeeding panels to follow. This is our ninth hearing we have held on food safety this Congress to identify ways to ensure the safety and security of our nation's food supply. At the beginning of our last hearing in June, grocers and restaurants nationwide had begun pulling tomatoes from the shelves and menus at great economic cost until the cause of the Salmonella outbreak could be identified.

Since then, 2 months after FDA's initial notice, not one contaminated tomato has been found. Instead, the outbreak strain of Salmonella Saintpaul was originally traced back to a jalapeño pepper that was grown in Mexico and imported and distributed through a warehouse in Texas. Yesterday afternoon the FDA learned that the same genetic strain of the Salmonella that was found in the serrano pepper on a different farm in Mexico and in a nearby water reservoir.

Today nearly 1,300 illnesses have been reported in over 43 States, and local State and national public health officials and regulators have been working to protect Americans during the outbreak. Outbreaks of this magnitude cause serious concern and warrant our close attention to help better prepare our nation for the future.

Today we will explore the dynamics of the marketplace in which federal agencies are trying to do the right thing and prevent harm to consumers while their decisions often result in economic losses to the industry. Witnesses from the tomato industry will discuss their frustration of how the outbreak gets handled and explain the effect the government's actions had on consumer confidence and industry revenues.

A question to consider today is: Is there a way to limit unnecessary collateral damage to the industry, and effectively address a food-borne illness outbreak? A lot of the hearing will focus on traceability. Trace-back is an important tool used to rapidly and accurately identify the source of contamination. This issue was supposed to be addressed in the Bioterrorism Preparedness and Response Act of 2002. The act directed the Secretary of Health and Human Services to issue regulations regarding records kept by those who manufacture, process, pack, transfer, distribute, receive, hold or import food. Current regulations required that records must be kept to allow federal investigators to identify the immediate previous sources and subsequent recipients of food. This is known as the one step forward, one step back.

In light of recent outbreaks and events it may be time to evaluate the intent of the act and determine if clarification or additional regulations are needed to improve our trace-back ability. Witnesses today from different states and industry will discuss their current practices and proposals to establish more robust traceability systems. FDA's current traceability system is not without flaws. We

need to identify and understand the system's limitations and explore and implement realistic ways to make it faster and more cost efficient.

A critical part of this hearing is how a contaminated product or commodity is identified in the first place. It seems to me that without reliable information about the contaminated product or commodity, traceability will be ineffective. Among today's witnesses are two epidemiologists and a representative from the Centers for Disease Control. I hope they can explain the process of identifying suspected contaminated commodities and highlight the strengths and the weaknesses of our current system. I want to understand the role epidemiology plays in relation to nationwide food-borne illness outbreaks. If there are gaps in epidemiology that we can avoid and traceability is only as good as the science that is guiding it, we might want to focus our limited resources to improving the science and statistics and not in requiring more regulations. We may not be able to create a perfect system but we must have a more reliable and efficient one.

There is a lot to be learned from this outbreak, and a thorough post-mortem should be conducted by FDA and CDC with input from local and State governments and the affected industries. We need to determine where the breakdown in the epidemiology, and in trace-back, and interagency, and intergovernment communication occurred and then decide how we need to allocate our resources to provide the most protection to Americans against food-borne illnesses.

Finally, if there are legal walls blocking the States, CDC, and FDA from fully communicating and cooperating during an outbreak investigation, then those walls need to be torn down. We have 16 witnesses here to help explore these issues and discuss possible solutions. And I look forward to hearing their testimony. Again, welcome to this panel and the succeeding panels.

Mr. STUPAK. I thank the gentleman.

Ms. DeGette for an opening statement, please.

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

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. Chairman, as a mom I have spent a lot of time with people who are like me, people who are trying to raise their kids and do the right things. And, unfortunately, even though in some prior life they may have been very interested in politics and public policy, they are more interested in the safety of their kids and making sure their families work. But they have been perking up lately because there have been a whole series of threats to their family life and to the safety of their kids.

We dealt with the consumer product safety yesterday and the toy safety, but with food it has just been one thing after another the last few years. First we had the spinach recall, then we had the peanut butter recall, then we had the pet food recall. And the saga of the Salmonella outbreak has been going on now since last spring. And, frankly, this is the kind of thing that people really take notice of because they think that the main job of government

is to protect their families' safety. And, frankly, we could be doing that. We have the technology.

In mid-April people started getting sick in this country. Then in late May the CDC and the State health departments identified that it was Salmonella Saintpaul. But not until June did the FDA warn consumers not to eat red tomatoes. And so consumers all around America quit eating tomatoes. And what that did was that caused tons and tons of tomatoes to be discarded at a cost of millions and millions of dollars to the tomato industry. But now we learn in July, 4 months later, that, oh, it is probably jalapeño and serrano peppers. This makes consumers very nervous, and rightfully so.

And the thing is, it does not have to be this way. Many of you know that I have been working on food traceability issues now for about 6 years. And I have legislation, H.R. 3485, which would require the USDA and the FDA to get moving on a system to track food products throughout the supply chain. For a long time I found a very difficult time trying to convince people that we should have traceability. They said, we cannot afford to do that. And I am here to tell you today with the loss of consumer confidence with the latest outbreak I think we cannot afford not to do traceability.

We have the technology to do traceability for produce, for processed foods, and for other types of foods. In fact, as we will hear today, the tomato industry and many other industries are using traceability right now. We have the technology to trace a tomato from field to fork, but we do not do it in any kind of organized way nationally. So while you might be able to trace a tomato in one particular industry, you cannot do it across industries, and you cannot do it on a national level. And so if we institute simply voluntary trace-backs, those programs will still have cracks and all of the participants will suffer if an outbreak occurs.

On the other hand, if we have a national system of traceability where we might not have just one system in place but the systems are interoperable, that we will be able to effectively trace outbreaks. This will both protect consumers' health and it will protect business because we will not have over-broad recalls and we will not be losing consumer confidence in the system. To me it is an essential part of any food safety legislation that we might do.

Finally, I think all of us up here want to know what we could be doing better from a public health standpoint to trace outbreaks once we identify that there's a problem. Is there some better way we could communicate between health departments and the CDC? Is there some better way we could communicate between the CDC and the FDA and the other various regulatory agencies? This is not rocket science. We have technology to do it. We have the know-how to do it. We simply need to have the will to make it work.

And, Mr. Chairman, I am hoping this investigative hearing will go a long way towards making all of these things work together to protect consumers from unnecessary disease in foods and other consumer products. With that I yield back.

Mr. STUPAK. Thank you.

Ms. Blackburn for opening statement please.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Ms. BLACKBURN. Thank you, Mr. Chairman. I want to thank you for calling the hearing today.

And I would like to recognize Dr. Tim Jones who is an epidemiologist from the Tennessee Department of Health. He is going to be a witness before us today. I am pleased that he is here with us.

As our witnesses can tell, we are fully aware, everybody in America is aware of the food contamination issues that are before us. And this time it is the largest Salmonella outbreak in our nation's history and it has affected tomatoes, it has affected jalapeños and the supply of those. And while the various federal and State agencies work to pinpoint the source of the dangerous bacteria too much time passed at the peril of public health and hundreds of millions of dollars of produce was lost.

And for those of us that have agricultural groups and farms in our districts this is something that we have heard so very much about as we have met with these individuals. Plus, this committee has spent countless hours listening to testimony on FDA's inability to protect the nation's food supply as a result of limited resources, insufficient personnel, lack of interagency communication, and a lack of best practices to streamline safety review efforts. And I am still waiting to hear what those best practices are and looking forward to hearing from the FDA what their best practices are, how they follow these in their communications and their efforts to streamline safety review efforts. I will welcome that information when it makes it to my desk.

I think it is indeed ironic that we are sitting here today for another investigative hearing to scrutinize the nation's food safety review capabilities when yesterday this body, the House of Representatives, took a vote to force the ill-equipped FDA to regulate tobacco products. The FDA is saddled with so many unfunded mandates that placing additional stress on a broken federal bureaucracy will eventually lead to disaster.

And I hope that this is not lost on my colleagues and on those of you that are here. We are talking about an FDA that cannot get information from one division to another and cannot seem to figure out how in the world to police food and drugs and yet, indeed, we are talking about tobacco. For the past few months federal, State and local officials, as well as the industry, were all involved in the Salmonella investigation. I am looking forward to testimony that explains the complex flow of information, or maybe it is the lack of flow of information between all the stakeholders, the lack of clearly-established protocols and lines of communication between different jurisdictions in the industry and the agency seems to be troubling. It is troubling to me. I would think it is troubling to some of you. And as a result from all of this miscommunication and lack of established flow of information the tomato industry was devastated and public panic ensued.

I believe the hearing will be a good opportunity to learn what worked and what changes need to be made to protect consumers in the industry from future outbreaks. It is critical that a coordi-

nated outbreak response further evolve to protect Americans and to ensure consumer confidence. As I have said in the past, the FDA needs to shift its focus from reacting to food safety breaches following contamination and instead implement policies to prevent food safety problems before they occur. The recent outbreak is a clear example of defensive action and a lack of best practices to efficiently solve this issue.

I thank the Chairman and I yield the balance of my time.

Mr. STUPAK. Thank you. Mr. Dingell, Chairman of the full committee, for an opening statement.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, thank you. I congratulate you on the vigor with which you are approaching the problem before us today. I note this is the ninth hearing on the safety and security of the nation's food supply and, interestingly enough, on the inadequacies of Food and Drug and the resources of that agency. There are good people there. There are not enough of them. They do not have the money. They do not have the resources. They do not have the leadership. And they do not have the support of the Administration.

Today's hearing will examine those matters, and in the light of a major food contamination outbreak involving Salmonella Saintpaul. This has again shaken public confidence in Food and Drug and our food industry and has devastated an important industry. Today we are going to learn how important it is not just to the public whose health is at risk but how important it is for the industry because without an adequate way of addressing the problem of ensuring safety of the nation's food supply, confidence in that industry and the costs to that industry are going to be at levels and places that that industry cannot tolerate.

Since April, at least 1,304 people in 43 States, the District of Columbia, and Canada have been infected with Salmonella Saintpaul. These illnesses resulted in 252 hospitalizations or more, and contributed to at least two deaths. This is one of the largest outbreaks of Salmonella in the United States. And based on the number of confirmed cases, the largest food-borne outbreak in the past 10 years.

While it has caused personal and financial tragedy to many, this outbreak should also be another wake-up call to everyone in our system who are responding to unintentional or intentional contamination of the nation's food supply and pointing out that that ability on our national capability is very much at risk and very much wanting.

Our investigation to date has uncovered, among other things: 1) a breakdown in the way the Centers for Disease Control and Prevention, CDC, and the Food and Drug Administration shared critical data with key State agencies; 2) The failure of FDA and CDC to leverage state resources; and 3) More than 3,000 State and local health departments working without any adequate coordination with each other or with the federal government, and with grotesquely limited resources considering the needs of the times. And

they are, I note, supposed to serve as an identifying agent to help bring to our attention the existence and the cause of outbreaks like this.

Finally, Mr. Chairman, we are going to hear today that key sections of the Bioterrorism Act of 2002 which was designed to ensure the rapid traceability of foods in a situation such as this has failed to perform as intended. And I note in good part because the system cannot talk to each other, it does not have resources, and it does not have leadership and proper support from the agencies involved, including the Department of Homeland Security.

This act directed the Secretary of Health and Human Services to issue specific recordkeeping requirements to allow federal investigators to quickly respond to threats to our national food supply.

We have learned, however, that key portions of this act designed to allow for rapid traceability do not work. While the FDA was ultimately able to trace commodities associated with this outbreak, the process was slow and cumbersome. And it reminded me very much of the kind of Keystone Cops situation which we saw when we had the Chilean grapes situation. And this is interesting to note that what should have taken hours or days has taken months or more.

Today we will not only explore the failures of FDA and CDC, but also what industry can and should do to improve the traceability of its products. And we are going to have to explore what we have to do to see to it that the money and the resources are available for this and who is going to pay for that in times of a tight budget. While some in the FDA have argued that loose produce like tomatoes are too difficult to trace, some of our industry witnesses will describe systems currently in place that can rapidly trace their products. And we are going to want to hear why it is that Food and Drug cannot or will not or does not support efforts to get us to the point where we could properly address the traceability of products.

We can and must learn from industry. And rather than be at odds with the government on improved safety, the industry must be our partner. And we are going to find out whether they want to do that today or not. If parts of the tomato industry can develop an efficient traceability system, why cannot other parts of the food industry do likewise? Why cannot FDA mandate it? And why not the industry voluntarily adopt such a thoughtfully crafted and well-done system? Perhaps it is time to revisit what additional changes to existing regulations may be required to achieve this goal.

We have a number of outstanding witnesses today. I want to thank them for coming forward. And I look forward to hearing their views on what needs to be done to prevent more debacles of this sort which seem to occur on a weekly or daily basis. With the help of the industry I believe we can restore public confidence and the safety of our food supply, we can prevent suffering, loss and hurt and death to our people, and we can prevent significant damage to industry at all levels for want of the ability to maintain public confidence and to properly trace and manage our nation's food supply. And we need to see what we have to do to see to it that the regulatory agencies have the resources, the willingness, the enthusiasm and the leadership to protect our Nation's food supply.

I thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Chairman.

Mr. Barton for an opening statement please.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Mr. Chairman. Thanks for the prompt response to this problem and the hearing today and all our witnesses for being here. We have invited 16 witnesses to tell us what went right, and what went wrong in the search for the source of the latest Salmonella outbreak in fresh produce. Nearly everybody seems to think that more went wrong than went right, and I think we need to explore the complex reality if we are really going to try to fix the problem.

First of all we want to know why it took so long to figure out that it was Mexican peppers instead of American tomatoes that were making people sick.Many innocent farmers in the United States lost thousands and thousands of dollars because we at first identified tomatoes, and it hurt their crop. You do not have to be a detective to know that the initial investigation did not really help anybody. As I just said, it did harm to a lot of people. I understand that the investigators followed clues until they found the culprit but it is arguable that our public health agencies should have found the source of contamination much sooner than they did. Identifying tomatoes I believe according to this timeline, Mr. Chairman, in early June, and we did not really begin to look at or identify the jalapeños until late June. And it was not until July that Minnesota authorities actually pinpointed the jalapeños as the source of the Salmonella-induced illnesses. So that is a month that really hurt in terms of the tomato crop situation.The point of doing trace-backs, spending millions of taxpayer dollars is to contain an outbreak quickly and prevent any future contamination. The first response, unfortunately, to this outbreak fingered the tomato industry and caused growers all across America to suffer a devastating loss.

This hearing is also going to examine a portion of the Bioterrorism Preparedness and Response Act of 2002 which required the Food and Drug Administration to establish procedures on trace-back and recordkeeping. The rationale behind passing the act was to enable federal investigators to have access to records that could help trace-back and lead quickly to the source of contamination during an outbreak.

This is important. To meet these regulations the records kept by those who manufacture, process, pack, transport, distribute, receive, hold or import food need to clearly identify the immediate previous source and subsequent recipient of that food. If the records that are kept by industry are not meeting these standards and the trace-back and trace-forward process is not being achieved then industry needs to tell us and the regulators need to find a way to improve compliance. However, if industry is meeting these standards and it is the regulations themselves that are limiting our regulators, then perhaps a change in the law or the regulation may be needed. I am really not interested in trying to find a bad guy in this story. I want to get it right. If the current system is broke, let us figure out what is wrong with it and fix it together. If it just needs a tune-up, then let us start tuning it up.

Mr. Chairman, I have three more pages of specifics but I will submit those for the record. Let me simply say that this is an important hearing, and I know that my folks down in Texas are very interested in this. And as I just said, let us figure what is broke and fix it or let us figure out what needs to be tuned up and tune it up.

Thank you, Mr. Chairman.

[The information follows:]

PREPARED STATEMENT OF HON. JOE BARTON

Thank you, Mr. Chairman. The Committee has invited 16 witnesses here today to tell us what went right and what went wrong in the search for the source in the latest salmonella outbreak in fresh produce. Nearly everybody thinks more went wrong than right, but we need to explore the complex realities if we're going to fix the problem.

For starters, we want to know why it took so long to figure out that Mexican peppers instead of American tomatoes were making people sick that innocent tomato farmers lost their crops and lost their shirts.

You don't have to be a detective to know that the initial investigation here helped nobody and harmed many. I understand that investigators follow clues until they get to the culprit, but our public health agencies should have found the source of contamination much sooner than they did. The point of doing the trace-back and spending millions of taxpayers dollars is to contain the outbreak and prevent future illness. The first response to this outbreak fingered the tomato industry and caused growers all across America to suffer a devastating loss of consumer confidence and revenues. We cannot let this happen each time a food-borne illness outbreak is identified.

This hearing will also examine a portion of the Bioterrorism Preparedness and Response Act of 2002, which required the Food and Drug Administration to establish procedures on trace-back and record-keeping. The rationale behind passing the Act was to enable Federal investigators to have access to records that could help "trace-back" and lead to the source of contamination during an outbreak.

To meet regulations, the records kept by those who manufacture, process, pack, transport, distribute, receive, hold or import food need to clearly identify the immediate previous sources and subsequent recipients of food. If the records kept by industry are not meeting these standards, and the trace-back and trace-forward process is not being achieved, then industry and regulators need to find ways to improve compliance. However, if industry is meeting these standards and it is the regulations themselves that are limiting our regulators, then a change in law or regulation may be needed.

Concerns have also been raised regarding the barriers to and lack of sharing data and information between local, state and federal agencies and industry. I want to know what these barriers are. Are state and federal agencies and governments taking unreasonable positions under the Bioterrorism Act concerning sharing information? Do we need to clarify the law? Do we need to create a carve-out in the regulations to allow for information sharing when a serious public health threat exists? We are in the business of legislating, and we want to pass laws that enable our government to work seamlessly with local, state, and inter-agency personnel to respond, react, and coordinate quickly to contain an outbreak. The communication problems revealed in this outbreak response trouble me greatly as to our preparedness to respond to an intentional act of contamination, tampering, or bioterrorism.

This hearing will also examine the facts of this case and evaluate the success of the agencies and regulators based on what the facts support. It seems to me that one inconvenient fact is that the investigators identified the wrong commodity in the first epidemiological case study. I realize CDC and FDA may take the official position that tomatoes have not been ruled out as a potential source of contamination, but the facts remain that not one contaminated tomato has been identified out of the 1,400 samples taken. On July 21st, a positive sample of the outbreak strain of Saint Paul salmonella was found on a jalapeño pepper and yesterday afternoon, FDA investigators found the same salmonella strain on a Serrano pepper in Mexico and in a nearby water reservoir. How can we measure the performance of a trace-back system in which the original commodity identified may not have been the source of contamination? How do we judge the success of a trace-back and consider the case solved and closed?

One last point about FDA--I would note that at the same time we are having this latest food safety hearing, my staff is continuing to have discussions with Chairmen Dingell, Pallone, and Stupak's staffs about food and drug safety improvement legislation, including the issue of mandatory recall authority for FDA. Given FDA's performance in this instance, and how devastating this has been for our nation's tomato producers, I shudder to think how much more financially devastating it would have been had FDA been given mandatory recall authority. Tomatoes may have been recalled earlier; producers would have lost more money; and people would continued to have gotten sick from tainted peppers. And I think that we need to consider exactly how effective mandatory recall authority would be if it is given to an agency that seems to have a lot of logistical problems communicating with state and local public health officials.

Thank you Mr. Chairman. I look forward to hearing from our witnesses and thank them in advance for being here today.

Mr. STUPAK. Thank you. And I know members will be in and out; there is another hearing going on. So we look forward to your submission and we will put it in the record at the appropriate time.

Mr. Burgess next for opening statement please.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thanks, Mr. Chairman. And I guess I did not realize this was the ninth hearing but I appreciate the Chairman of the full committee bringing that to our attention because I do think it is instructive. I want to thank the panelists for being here with us today. Many have been here with us before and some are new to the process but we welcome you all here to the committee and we are anxious to hear your testimony.

This issue, suffice it to say, has been at the forefront of our nation's consciousness the past few months. And we know that it is impossible to reduce food, there is an irreducible minimum beyond which you cannot go with food-borne illness, but still it is our obligation and it is the FDA's obligation as the premier federal agency to ensure that the products that come to our nation's tables are indeed safe so people can feel safe and secure in the purchases that they make. Now, the Food and Drug Administration has been diligently trying to do the trace-back. And we will hear a lot about trace-back and how perhaps there are some ways that this can be streamlined and improved. And I am anxious to hear from the individuals at the Department of Health in Minnesota because it seems like they got to the root of the problem much more quickly.

In the meantime, of course, our distributors, our retailers, our restaurants have suffered many, many millions of dollars in loss as a result of the public health risk. But the fundamental issue here is that the Food and Drug Administration is in desperate need of help. And this committee, this is the committee that should be helping beyond just holding nine hearings. And we do it over and over again, hearing after hearing. And when, Mr. Chairman, are we going to take some action. And we sit here, we have all the levers of government ahead of us, in front of us that we can pull and all the powers of Congress and the only thing we have managed to do so far is hammer the FDA. And while that may make for good sound bites and that may make for good television on cable, it is not good enough for the American people. As the consequence, the image of the FDA has suffered and I would submit that the image of the United States Congress has suffered as well, and that is something that I think we must stop.

We do need to give the FDA more resources. We need to give the FDA more personnel. We all get that. There has been a small attention, a small amount of attention paid to that as a supplemental. But it is not good enough just to put a bunch of funds down the pipeline and then think we have done our job, there has to be the steady state, there has to be the ongoing appropriations process needs to behave as it is supposed to behave not in this stop and start fashion that we have done the past 18 months. The FDA needs to know that they have a steady supply of funds on which they can depend. And we have not been able to manage even that simple task.

Probably almost 18 months ago we had one of these food safety hearings, and I do not even remember then what we were investigating, but as a consequence of that investigation I see Mr. Hubbard here again and I welcome him back to the committee, he has been very helpful in working with our office in trying to craft legislation that will just simply allow us to stop a problem when we encounter a problem. H.R. 3967 was developed as a consequence of one of the hearings we had in this committee, the Imported Food Safety Improvement Act, and as yet we have had no legislative hearing on that or any other measurable improvement.

The fact remains that after the FDA did their work, after they finally found the problem it is Friday. And on the Lou Dobb's Show when the commentator asked the reporter, well, what is the FDA recommending that consumers do to protect themselves? Well, ask, ask where the peppers were bought? We did not have even the ability to say no more imported peppers for at least this weekend until we figure out this problem. We have to have the ability once we identify where the problem is we have to have the ability to put an immediate stop so the American people will have at least some confidence that, yes, they may still need to ask where this pepper came from if it came into last week but no new sources of contamination are going to come across our borders until we have figured out the problem.

So I am glad we are here today. I am glad we are having a hearing. I wish we would do something concrete. And let us do focus our energies on providing Food and Drug Administration the resources and the authority and the improved processes that it needs to protect our food supply.

So I will continue to work to draft legislation to improve the Food and Drug Administration's ability to stop products from entering the American marketplace. If this committee ever actually gets around to legislating on the issue I would appreciate the opportunity to work with the Chairman so that the fact that one of every four Americans is almost daily touched by the Food and Drug Administration's activities that they can feel safe and secure the Food and Drug Administration has the cops on the beat for them.

And I will yield back.

Mr. STUPAK. Thank you. I thank the gentleman and as the gentleman pointed out, it is the ninth hearing and for the ninth time we do have Mr. Dingell's global drug and food safety act which is being negotiated with all the parties including many of the people in this room and with the minority side.

Mr. BURGESS. If the gentleman would yield.

Mr. STUPAK. Sure.

Mr. BURGESS. My staff and I stand ready to participate in those negotiations but as yet we have not been asked. And I would greatly appreciate the Chairman offering my office the courtesy of participating in that activity. And I will yield back.

Mr. STUPAK. Sure. We have been working with Mr. Barton and the Republican side and we hope to have a bill up as soon as we get back. In fact most of the food provisions have been pretty much negotiated. So it's been an inclusive process, both Democrats and Republicans have been doing it, and they are bringing it up every hearing. And I just wanted to remind you for the ninth time we have been working on it and we will have a bill.

And with that it is Mr. Murphy's turn for an opening statement please, sir.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Thank you, Mr. Chairman. I appreciate these hearings and also look forward to continuing to work with you on these food safety issues.

You know, oftentimes when we are concerned about something the size of a food outbreak the call is for more government. Of course, government has its own problems as well whenever we are working on any issue, we need a system that can constantly learn from itself and adapt from its errors in reviewing problems. And we are immersed in that situation right now.

Families across America want fresh, safe, affordable food year-round. And that is a formidable task. The FDA is tasked with inspecting and ensuring the safety of products, and protecting our citizens from food-borne illnesses and dangerous chemical alterations and acts of terrorism. The number one goal is to prevent this contaminated food from getting to the table. But unfortunately a lot of problems get through.

Some 76 million people contract food-borne illnesses, 325,000 get hospitalized, and 5,000 die. Four hundred to 500 food-borne illness outbreaks are investigated each year by state and local officials. Let's keep in mind a lot of those food-borne illnesses have nothing to do with the food handling industry, many of those are what happens once it's in the consumer's home not properly handled, refrigerated or cleaned.

And to the add to the formidability of this task, some $2 trillion in imports each year, 60 percent of that is food. Eighty percent of our seafood is imported and 40 percent of that comes from China. Many of those have been found with some chemical alterations. And we have had other hearings on some things that are downright poisonous added.

We have passed some bills to help traceability but we need to have Congress and the food industry be able to review these records quickly. I am pleased to hear that some of the private groups are working with the FDA to do that. But the FDA needs to be sufficiently staffed and funded to do this. We have appropriated funding for this purpose. GAO concluded that the FDA did

not reveal any planned process yet by which this plan will be implemented, and we want to see that.

Consumers need to be responsible for their actions. The FDA needs to follow through on the proper epidemiological evidence. And I am hoping that one of the things we can review today is just what happened. My understanding is one of the things that occurred is people who contracted illnesses were interviewed but those who ate the same food were not interviewed. If that is the case, it is a serious epidemiological research issue which we may need to review. I would like to find out if that is the truth.

We also need to find ways to make whole the farmers and those in the food industry who were damaged by this scientific error. And I put "scientific" in quotes. But also let us keep this in mind: our food industry here is among the safest, if not the safest in the world. And what has happened with public health efforts have improved the lifespan of Americans. You know, earlier in the 19th Century when the average person lived to be 40 or so and by the end of the 20th Century living up into the 70's was basically because of public health issues, primarily with clean water and sanitation and some food issues. We need to continue with our history of success in this. But this just shows what happens when you import so much food from around the world that we cannot possibly have an inspector standing at every plant and watching every vegetable and fruit come across the border ever moment of the way. Now I believe only 1 percent of foods are inspected.

We also need better communication with the public when these things get out. I saw signs appearing everywhere when the concern was about tomatoes but, unfortunately, when the things came out about jalapeño peppers I was surprised in a bittersweet way to see the warnings were saying such things as do not feed contaminated food to infants. I cannot imagine many parents of a wise interest who are actually deciding whether or not to feed jalapeño peppers to their infants. I guess they think that spices up the applesauce or something.

But the issues, however, are formidable and ones we have to properly address here. And I want to say this, I certainly believe that the people in the FDA want to do this in the right way. I also believe there are people in the food industry who want to do this in the right way. There are a lot of intelligent people in this who want to fix this system. And my hope is that whatever bill we come out with is a way of opening up a door so we have a system where people with real expertise who are motivated to fix this, because I do not believe anybody wants to hurt consumers. There are no farmers out there that want to see anybody sick. There are no food processors or companies that want to see their own children or grandparents ill from these foods. We are Americans caring about Americans and we are going to fix this problem.

And I want to make sure that we have a bill shaped by the intelligent statements coming from people on these panels today that will make sure we have a good, open process that can learn and evolve as we go on.

And with that I yield back, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Murphy. That concludes the opening statements.

We will have our first panel which is a panel of growers and producers. On my far left is the Honorable Charles H. Bronson who was Commissioner of Agriculture at Florida's Department of Agriculture and Consumer Services; the Honorable A. G. Kawamura, who is the Secretary of California's Department of Food and Agriculture; Mr. Reginald Brown, who is the Executive Vice President of Florida Tomato Growers Exchange; Mr. Ed Beckman, who is President of the California Tomato Farmers; Mr. Parker Booth, who is the President of Ace Tomato Company in California; Mr. Thomas E. Stenzel, who is President and Chief Executive Officer of United Fresh Produce Association; and Mr. William Hubbard, who is a Senior Advisor to the Coalition for a Stronger FDA. Welcome all of our witnesses.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that you have the right to be represented by counsel or advised by counsel during your testimony. Do any of you wish to be represented by counsel during your testimony?

[No response.]

Mr. STUPAK. Everyone is shaking their heads no, so I will take it as a no. Therefore, let me ask you to please rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. Each of you are now under oath.

We will now hear a 5-minute opening statement from our witnesses. You may submit a longer statement for inclusion in the hearing record.

Mr. Bronson, can we start with you, please, sir. Pull that mike up a little bit, turn on that button there, you should get a green light.

And you are on for 5. Thank you.

STATEMENT OF CHARLES H. BRONSON, COMMISSIONER OF AGRICULTURE, DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES, STATE OF FLORIDA

Mr. BRONSON. Thank you, Mr. Chairman, Ranking Member and members of the committee, for allowing us to come today to talk about this issue of the FDA, CDC, and the States working on this issue of trying to get to the bottom of potential contamination of the food supply. I am the elected Commissioner of Agriculture for the State of Florida. Food safety is part of my main function for the people of the State of Florida to protect the people against plant and animal pests and disease from causing any type of problem in the State of Florida.

We have 3,700 employees. We are the largest Department of Agriculture, State Department of Agriculture in the country because I do also have law enforcement and forestry firefighters underneath my office as well as laboratories for food safety and approximately 158 personnel that are food safety specialists with the State of Florida and 50 lab personnel. And we are part of the FERN program with FDA and CDC to test for their particular issues.

I think that I would indicate to you that thanks to the cooperation of the tomato industry and the University of Florida's Institute of Food and Agricultural Science at the University of Florida's land

grant college we put together a program specifically on tomatoes at the request of the industry 3 years ago. And we have the toughest inspection/verification program in the nation for tomatoes. That was a voluntary program the past year-and-a-half. We put into rule July 1 all of those provisions that we had been working under. We made FDA aware of that. And that is why I consistently said over and over that I was 99.99 percent sure that Florida-grown tomatoes was not a part of this problem. As we now find out that not only was Florida-grown but there are no tomatoes that have been shown so far to have Salmonella Saintpaul.

I think if I could get anything out of this meeting today I sit on an advisory group for the National Association of State Departments of Agriculture, one of two members sitting on that group who is working on issues with USDA and Customs/Border Patrol specifically on plant and animal pests and disease brought into our states from offshore which is where I would like this committee to consider is where this all begins, not necessarily with FDA and CDC. However, it starts with USDA inspection, Customs/Border Patrol come into our states and then filtrates throughout the United States.

My point to you would be today that we have 158 inspectors that are just as qualified as any federal inspector out there today. We have lab technicians that are just as qualified with Ph.D.s, our medical teams with our public health are bona fide medical doctors, just as you will find anywhere in the country. We work very closely between our food safety laboratory, our Department of Agriculture inspection teams, and our local health departments and state health department on potential food-borne illnesses.

We also have protracted outbreaks of Avian Influenza and gone through the whole process of how we will handle that, how we will work with the different federal, local, and other State agencies. And I would hope that if we get anything out of this meeting that we can work some type of MOU out since we are using the same process that the federal agencies use, including trace-back and trace-forward, that the use of the personnel that I can call within a moment's notice and put then on the road in the area where the problem may be, not is, but may be. So that we can take inspections of the field, we can take inspections of the produce, we can take inspections of the animals if this happens to be an animal situation, and we can send it to our FERN-approved laboratory that works with the federal government and we can start on it immediately. We do not have to wait for a group at any level of the federal government to decide when we are going to do it, how many people we are going to send, how we are going to react to it. I can do it by a phone call.

On 9/11 at the incident of 9/11 we were sitting in our office or we actually were having a cabinet meeting in the State of Florida, we pulled all of our agricultural leadership together for the State of Florida's department. We were not only taking pictures of people driving hazardous materials at our interdiction stations, which I have 23 of them that we operate in the State of Florida, but we sent our food inspectors out to the grocery stores to make sure no one was tampering with the food supply on the shelf on the day of 9/11. So we have the capabilities of doing these programs in con-

cert with the federal FDA and CDC. We do not want to take over their jobs, what we want to do is do an MOU that says if you do not have the personnel available let us use our people to go get this done immediately so we can clear the State of Florida if that is the case or prove we have a problem.

We do not want people in the State of Florida sick any more than any of the people in your states do. We certainly believe in protecting the public and our tourists that come to the State of Florida. And we want to get to it as quickly as possible. But I think the way this will work the best is if we can work an MOU out so that we can put these people working together on the same issues to protect the people of this country.

Thank you very much.

[The statement of Mr. Bronson follows:]

STATEMENT OF CHARLES H. BRONSON

SUMMARY OF KEY POINTS

FDA did not share or solicit critical information from state food safety agencies. State resources could have augmented FDA's efforts if more information had been shared such as where to target our sampling and laboratory analysis. FDA also failed to ask states to provide them with information we now know they needed such as where were tomatoes being grown at the time and at what stage of harvest. This information would have allowed FDA to immediately target their efforts and potentially lessened the impact on the industry as a whole. States found themselves having to exonerate themselves by asking to be put on the "safe list".

Florida is the only state to have adopted mandatory regulations for the production and safe handling of tomatoes. These were developed as a cooperative effort between the Florida Department of Agriculture and Consumer Services and the Florida tomato industry. FDA dismissed our industry's participation in this program as though it had no bearing on the risk Florida presented in potentially being part of the outbreak.

FDA did not employ a common sense approach to assessing the source of the outbreak.

Florida tomatoes were implicated as much as Mexican tomatoes by FDA in the investigation because our product happened to be in the market at the same time as Mexico's. The number of salmonella cases per state showed that the vast majority were concentrated in the West, with Florida having only three cases (a state of over 18 million people). If Florida grown tomatoes were the source, one would logically expect us to have a high number of cases. While it may have been theoretically possible for Florida to be the source, it was not plausible based upon the geographic distribution of illnesses.

We do need to improve traceability on all levels, but particularly at the re-packing house level. We know that Mexican tomatoes must be labeled as such when they come into the country. Labels, bar codes or some type of additional identifier indicating where the product was grown should have to travel with the product to the final point of sale.

Roles and responsibilities of each governmental agency, both state and federal, in response to food-borne illness outbreaks need to be clearly defined.

Every agricultural producer in this country is familiar with the risk they take every time they put a crop in the ground and there are tools available to mitigate that risk but we never anticipate that our business will be destroyed by an action of the federal government.

TESTIMONY

My name is Charlie Bronson and I am Florida's Commissioner of Agriculture. I want to express my appreciation to the Chairman and Ranking Member for holding this hearing to examine the ongoing salmonella outbreak and the government's response to it. As Florida's food safety regulator, I believe it is critical that we make whatever changes are necessary in the system to protect public health and safety, limit the financial damages that accrue on the industry that is implicated in situations like this and restore consumer confidence that our food supply is safe to eat.

To give you a little bit of background on the Florida Department of Agriculture and Consumer Services (FDACS), we are the largest state department of agriculture in the country with over 3700 employees. FDACS has a broad and varied statutory mission in Florida that covers everything from food safety and forestry to consumer services and aquaculture. These are in addition, of course, to the plant and animal duties borne by most state departments of agriculture. Put another way, we have a great deal of "boots on the ground" that can be activated quickly and efficiently to assist federal agencies during times of crisis.

Florida has quite a bit of experience working cooperatively with federal agencies, sometimes under less than ideal circumstances, notably in the aftermaths of hurricanes. I feel we are well prepared, therefore, to offer great assistance during outbreaks such as this. Unfortunately, if FDA chooses to limit the information they share with states, we are likewise limited in how useful our assistance will be to them. State and federal agencies have got to work together to protect public health and safety whether it be law enforcement officials or food safety officials.

Obviously this outbreak has exposed vulnerabilities in our nation's food safety net which is widely viewed as the best in the world. It has now been over 3 ° months since the first exposure occurred and FDA still does not know the source of the salmonella contamination. In fact, they are stating publicly that they may never know the source. Frankly, as an elected official charged with protecting food safety in Florida, that is an unacceptable outcome in my opinion.

From the very beginning, it was clear to us that FDA was not sharing important information with state regulators. In my department, three people hold FDA commissions, myself included. These commissions should have allowed FDA to share information with us that was not publicly available. Throughout the course of this outbreak, states have not been told much more than what FDA made available to the media. In addition, we also became aware of a disconnect between the information that was being provided to state epidemiologists and state food regulators. Oftentimes, information the CDC was providing on their calls to state public health agencies was more thorough than what FDA was providing to the state food safety regulators. Since these two functions are often in two different state agencies, the information does not always flow quickly between the two. Luckily for Florida, FDACS works very closely with our public health officials and they allowed us to sit in on the CDC calls. However, this is not the case in every state and I believe it is cause for concern. It is important to note that most states have laws that protect information we receive during the course of a food-borne illness investigation. Even Florida, which has one of the broadest public record laws in the country, known as the Sunshine Law, has public records exemptions that protect this type of information. Perhaps a compromise to FDA's confidentiality concerns on information sharing is for FDA to provide more detailed information in a timely fashion to those states that perform inspections and collect samples under contract with them. This will allow us to move more rapidly and coordinate our efforts with our FDA partners to get a mission accomplished.

As I stated earlier, we have many resources at our disposal that could have augmented FDA's efforts yet without information on initial results of their investigation, we didn't know how to target our efforts. FDA also failed to ask states to provide them with information we now know they needed and of course, we had no way of knowing what kind of data that was without them telling us at the time. As an example, in the initial days of the investigation, FDA could have asked states if their producers were even growing the suspect product and what stage of harvest it was in. Having this information would have allowed FDA to immediately focus their efforts and eliminate some states from further scrutiny. FDA would then have been able to target their resources more effectively. I should say that states, including mine, eventually started providing FDA with this information, but for a much different reason. Given the broad brush of the outbreak and the financial impacts associated with consumers avoiding all tomatoes, states provided this information in an effort to get on the FDA "safe list." Had FDA immediately asked for this information, not only would it have helped narrow the focus of their investigation, but providing it to the public might have lessened the financial impacts to the industry as a whole.

Florida was the first, and to my knowledge, is still the only state to have adopted mandatory regulations on Good Agricultural Practices (T-GAP) and Best Management Practices (T-BMP) for the production and handling of tomatoes. The T-GAP's and the T-BMP's are based upon sound scientific research and establishes practices and procedures for the safe handling of tomatoes. It was developed as a cooperative effort between the Florida Department of Agriculture and Consumer Services and the Florida tomato industry. There were many reasons for doing this, but an important consideration was the need to limit or avoid food safety issues associated with

Florida's products, many of which are perishable. Like many of the perishable commodities that Florida produces, tomato growers can't simply hold on to their product until the crisis passes.

Following FDA's announcement that tomatoes were the product suspected of being the source of the outbreak and Florida tomatoes in particular, we reminded FDA that we had this program in place. We thought that this information would allow FDA to more specifically target their resources based on risk as well as keep our growers from being caught up in the dragnet. Unfortunately, FDA dismissed our industry's participation in this program as though it had no bearing on the risk Florida presented in potentially being part of the outbreak.

One of our greatest frustrations is that Florida was as implicated as Mexico from the very beginning of the investigation yet a simple review of the number of salmonella cases per state showed that the vast majority were concentrated in the West. Florida had only three cases in a state of 18 million people. Given the large amount of Florida tomatoes that are consumed in our state, if Florida grown tomatoes had been the source, one would logically expect us to have a high number of cases. Since our tomatoes were in the marketplace at the same time as Mexico it may have been theoretically possible for Florida to be the source. It was not, however, plausible that we were based upon the geographic distribution of illnesses. We have repeatedly raised this issue to FDA yet they continue to maintain that Florida could have been the source out the outbreak and Florida grown tomatoes have yet to be exonerated officially. In fact, Dr. David Acheson, FDA's Associate Commissioner for Foods told the New York Times as late as June 19th that the "tainted tomatoes were probably grown in Mexico or central or southern Florida". A statement like this without strong data to corroborate this allegation is tantamount to a death knell in terms of consumer confidence in an agricultural commodity.

We have learned some lessons from this situation that will help us be better positioned to respond to outbreaks like this in the future. One is that we need to improve traceability on all levels, but particularly at the re-packing house level. Companies, which may have their business operations based in Florida yet grow in both Florida and Mexico, often label their boxes and their invoices with their Florida business address. This resulted in FDA finding invoices in their traceback that indicated a product was from Florida but in fact came from Mexico. We know that Mexican tomatoes must be labeled as such when they come into the country. Labels, bar codes or some type of additional identifier indicating where the product was grown should have to travel with the product to the final point of sale.

We also need to clearly establish the roles and responsibilities of each governmental agency, both state and federal, in response to food-borne illness outbreaks. This could be accomplished through a Memorandum of Understanding (MOU) between the FDA, CDC, state public health agencies and state departments of agriculture. This MOU should outline the expectations and actions that should be taken to timely gather evidence in an investigation.

I would also like to highlight legislation introduced by a member of Florida's Congressional Delegation, Representative Adam Putnam, that would help strengthen the safeguards on our nation's food supply. H.R. 5904, The Safe Food Enforcement, Assessment, Standards and Targeting Act or "Safe FEAST Act", co-sponsored by Representative Jim Costa of California, would put in place new food safety standards throughout the food chain. To ensure the highest level of food safety to American consumers, the legislation requires all domestic and foreign food companies selling food in the 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 food-borne contamination. In addition, 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. This would be accomplished by their completion of a Foreign Suppliers Quality Assurance Program as well as documenting their food safety measures and controls for FDA review. I would respectfully urge you to adopt this legislation.

The losses that have been sustained by this industry are still being calculated. You will hear from Reggie Brown with the Florida Tomato Exchange shortly and he will be able to talk more specifically to those losses. Millions of dollars lost and yet there is still not one shred of evidence suggesting that Florida grown tomatoes were the source of this outbreak. They were implicated simply because they happened to be in the market at the same time as Mexican tomatoes. There has got to be a way to protect public health while minimizing collateral damage to an industry.

Mr. Chairman, as a 6th generation farmer and rancher, I know every time a growers puts something into the ground we take a risk that it may be destroyed

by a weather-related event such as a hurricane or a drought. Pest and diseases can also wreck havoc on a crop, a fact that Florida growers know all too well. But I can tell you we never anticipate that our business will be destroyed by an action of the federal government. As Florida's Commissioner of Agriculture, I don't know how to tell my agricultural producers to prepare for something like that and there is certainly not a crop insurance tool out there to guard against these types of losses.

Again Mr. Chairman, I want to thank you for having this hearing on an issue that you can see I feel very strongly about. Florida stands ready to assist both the FDA and CDC on their efforts to improve the current system in any way we can and I would be happy to answer any questions you may have.

Mr. STUPAK. Thank you.

Mr. Kawamura, your opening statement please. And please pull that mike up a little bit so we get to hear you clearly.

Thank you.

STATEMENT OF A.G. KAWAMURA, SECRETARY, DEPARTMENT OF FOOD AND AGRICULTURE, STATE OF CALIFORNIA

Mr. KAWAMURA. Thank you, Chairman Stupak and members of the committee. It is a pleasure to be here. I appreciate this opportunity to address the committee about the food supply of the 21st Century.

As the leading producer of fruits, vegetables, and nuts, and the leading producer of dairy products, milk, with a farm gate of over $32 billion, California is a diverse supplier of food and other products to this Nation, and we are a leader on food safety programs.

In dealing with human health and the kind of outbreaks that we have seen, human health is always going to be paramount. We recognize that that is a priority when we are looking at any kind of an outbreak. And we know that the focus then also must entail recognizing that this food supply that we enjoy today does come with tremendous balance, tremendous abilities to deliver food, and especially perishable foods in a safe manner.

The difficulty of having a quick and reliable trace-back system I think is one of the main focuses of this committee because by having a trace-back system we are able to quickly identify which products are and which products are not a part of any outbreak. And I think that is one of the focuses that we will have to get to at the end of this session today.

We recognize and understand that the Centers for Disease Control and Prevention and the FDA have been working very hard with their resources to identify the sources of this recent outbreak and others in the past and will undoubtedly initiate more of a full review of their processes as we move forward.

We have directed growers and processors in our State to develop and implement written and scientifically-based guidelines for food safety and food safety prevention. We must also ensure that the public health and regulatory agencies develop and implement their written and scientifically-based procedures for conducting these very complex investigations.

We recognize that it is easy to look for quick fixes. And while we look for someone to blame for the current Salmonella Saintpaul outbreak we must recognize that the complexities of our modern food system are actually quite remarkable. It is a remarkable system that continues to improve with new technologies and advances through research. I would like to mention that I think after every

outbreak, which we would like to prevent in the first place, but after every outbreak this system improves, the system tightens down, we are able to use the technologies of the day to modify, to improve, to eliminate those kind of threats to the food supply. And that process takes place every day.

I think Mr. Barton from Texas mentioned that is this system broken or does it need a tune-up? And I would submit to you today that this system needs a tune-up basically using the 21st Century tools that we have today. And my colleague Mr. Bronson mentioned again the many resources and tools that we can converge to deal with food safety in our nation.

We also recognize that in our State of California good ag practices has been a hallmark of what we continue to provide for this country, whether it was dealing with pistachios years ago, with the challenges of fungus disease that is found with them, whether it is the almond industry and the adopted federal regulations that they put into place requiring raw almonds to undergo an approved pasteurization process. The California tomato industry as well in our State has developed tomato-specific best practices to ensure that their tomatoes are produced under safe guidelines.

These programs also require USDA-trained inspectors to conduct random and continuous audits to ensure compliance with these programs. We recognize that the leafy green marketing agreement which brought together not only spinach but all the different vegetable products that are of the leafy green nature. This was accomplished last year and has completed a successful year of voluntary compliance and audits that involve not only the Departments of Agriculture here and at USDA but FDA, Departments of Public Health and the industry in dealing with solutions using the technologies of today to get to the bottom of these causes of food-borne illnesses.

In closing I would like to mention that we have many next steps that we need to deal with. And let me go through those now.

We must balance then the ability to make sure and ensure public health and a public warning system when we do have an outbreak with also the very important desire to make sure that our producers that are not implicated in an outbreak are not damaged.

We encourage a better dialogue then between the FDA, States, growers, handlers and retailers to identify good ag practices at all levels of the food chain.

Prior to making a food-borne illness announcement FDA should solicit states to provide commodity harvest data. This can minimize the guesswork and can limit the number of growers implicated in any outbreak.

Growers, shippers, and distributors and retailers must agree on a standardized, uniform set of criteria that will follow a product from farm to point of service, enabling quick and accurate identification of the routes and sources of all products and all produce.

We encourage more research dollars be spent on identifying the life cycle of food-borne illnesses, potential points of entry and kill-step technology to ensure safe products. In our state we work closely with the Western Institute for Food Safety and Security as well as the newly established Center for Produce Safety at U.C. Davis to improve methods of growing and safe handling of food products.

Better surveillance of imported products is critical. Consumers are relying more and more on a year-round supply of products that come from outside the United States. Programs must be established to do a better job of monitoring and testing food product imports. By monitoring our points of entry for repeat violators of false import declarations, making changes in import volumes at points of entry, and random sampling of products for contaminants we can more effectively identify sources of potential risk.

We also then urge Congress to support States in the development of programs that result in the implementation and auditing of Good Agricultural Practice.

And lastly, there must be funding to implement a uniform system for epidemiological reporting and investigating outbreaks in all states.

And with that I will submit the rest of my testimony for the record and look forward to continuing with this conversation today.

[The statement of Mr. Kawamura follows:]

STATEMENT OF A.G. KAWAMURA

SUMMARY OF MAJOR POINTS

We must balance warning the public while minimizing the impact to growers.

• 1AWe encourage a better dialogue between FDA, states, growers, handlers and retailers to identify Good Agricultural Practices at all levels of the food chain.

• 1APrior to making a food borne illness announcement FDA should solicit states to provide commodity harvest data. This can minimize the guesswork and can limit the number of growers implicated in an outbreak.

• 1AGrowers, shippers, distributors and retailers must agree on a standardized, uniform set of criteria that will follow a product from farm to the point of service, enabling quick and accurate identification of the routes and sources of all produce.

• 1AWe encourage more research dollars be spent on identifying the life-cycle of food borne illnesses, potential points of entry and kill-step technology to ensure safe products. We work closely with the Western Institute for Food Safety and Security as well as the newly established Center for Produce Safety at University of California at Davis to improve methods of growing and safe handling of food products.

• 1ABetter surveillance of imported products. Consumers are relying more and more on a year-round supply of products that come from outside the United States. Programs must be established to do a better job of monitoring and testing food product imports. By monitoring our points of entry for repeat violators of false import declarations, making changes in import volumes at points of entry, and random sampling of products for contaminants, we can more effectively identify sources of potential risk.

• 1AWe urge Congress to support states in the development of programs that result in the implementation and auditing of Good Agricultural Practices.

• 1AThere must be funding to implement a uniformed system for epidemiology reporting and investigating outbreaks in all states.

STATEMENT

Good morning Chairman Stupak, and esteemed members of the committee. I appreciate the opportunity to address this committee and also I would like to thank Congress for its support of 21st Century agriculture in the 2008 farm bill. As the leading producer of fruits, vegetables and nuts, and the top producer of milk, with a farm gate of $31.4 billion, California is a diverse supplier of food for the nation and a leader on food safety programs.

Human health is paramount in any foodborne illness outbreak. Outbreak investigations are complex and resource intensive, particularly those involving perishable foods such as fresh produce. By the time the surveillance system recognizes clusters of illnesses, 2-3 weeks have passed from the initial exposure. In this timeframe, entire fields or growing areas have been replanted and no samples remain. Epidemiological investigations rely on consumers to remember the foods they ate days or weeks ago and thus include some degree of uncertainty. Trace back investigations depend upon firms providing accurate and complete records in a uniform format to

investigators and may involve detailed assessments of dozens of firms and fields. Agencies must have adequate resources and laboratory surge capacity to conduct these investigations in order to quickly, accurately, and narrowly pinpoint the source of an outbreak.

We recognize and understand that the Centers for Disease Control and Prevention and the Food and Drug Administration have been working very hard with the resources they have to identify the source of the most recent outbreak and will undoubtedly initiate a full review of existing epidemiologic and regulatory approaches to implement needed changes. As we have directed growers and processors to develop and implement written, scientifically based guidelines, we must also ensure that public health and regulatory agencies develop and implement written, scientifically based procedures for conducting these complex investigations.

Unfortunately, a false implication has an impact on the state's commodities and the ability for farmers to sell and market their products. In 1996, an epidemiologic investigation of cyclospora illnesses incorrectly identified California strawberries as the likely source of contamination. Subsequent investigations revealed that the actual source was Guatemalan raspberries. Initial epidemiologic information in the most recent salmonella investigation implicated tomatoes, possibly from California. However, subsequent investigations appear to point to imported peppers.

To be a farmer means to take risks due to weather, pests, market fluctuations, and other influences. Yet there is nothing more devastating to a farmer than to dump a perfectly good crop due to suspicion of contamination. However, public health agencies and regulators may occasionally have to take actions to protect the public without incontrovertible evidence.

Without clear communication, the message to consumers is often misunderstood and the reaction is swift in the marketplace. Retailers, in order to reduce their risk of liability, act to pull products off the shelves despite general advisories that a product is declared "safe" to eat. The economic domino effect is felt all the way down the food chain from the farmers, to the workers, to their families and to the communities.

For all tomato and jalapeño growers in the country, the promise of a successful marketing season is lost for the summer. The consumer who is rightly concerned about the safety of food products has lost confidence in tomatoes in this incident, even if the outbreak was not associated with our state, or any other.

ECONOMIC IMPACT OF ASSOCIATION OF SALMONELLA WITH TOMATOES

The impact to California tomato growers directly and indirectly is significant. According to one commodity group, our tomato growers suffered a 40 to 50 percent drop in retail sales, or $300,000 in a direct loss due to the dumping of good product, a loss of $1 million in product sales right after the announcement, and an estimated nearly $20-24 million in indirect losses due to low demand and poor prices.

While it is easy to look for quick fixes and someone to blame for the current Salmonella Saint Paul outbreak we must recognize the complexities of our modern food systems. It is a remarkable system that continues to improve with new technologies and advances through research. However, the lack of adequate personnel and resources of regulatory agencies charged with protecting public health and our food supply are challenges and weaknesses we must address. There must be funding to implement a uniformed system for epidemiology reporting and investigating outbreaks in all states. Right now, we are relying on what state and local resources are available for gathering data and investigating outbreaks.

AGRICULTURAL FOOD SAFETY PROGRAMSCALIFORNIA HAS IMPLEMENTED VARIOUS FOOD SAFETY PROGRAMS THAT HAVE BEEN INNOVATIVE AND SUCCESSFUL.

The California Leafy Green Marketing Agreement is an example of how federal and state agencies, can work together with industry to create a program that uniformly applies best management practices that are designed to improve safety and quality to handlers throughout the state. Jointly developed by industry, CDFA, USDA and with input from California Department of Public Health and the FDA, the Leafy Green Marketing Agreement was created in 2007 as a response to multiple outbreaks of E. coli O157:H7 illnesses over several years. The leafy greens industry led the effort to craft Good Agricultural Practices and a mechanism for verifying practices through mandatory government audits under the authority of the Agreement.

While membership in the marketing agreement is voluntary, nearly 100 percent of California's leafy green handlers are participants. Once a signatory to the program, compliance with the commodity specific program is mandatory, and violators are subject to discipline. The strength of the Leafy Green Marketing Agreement pro-

gram is the mandatory government inspection program that certifies member companies are complying with the food safety Good Agricultural Practices. These standards were developed by industry, academia and regulators, and reviewed by state and federal government health agencies. Random inspections are conducted by the California Department of Food and Agriculture inspectors who are trained and certified by the USDA. Operators are required to take corrective action on all findings within an audit and follow up audits are required to verify compliance. Handlers that fail to meet the conditions of the program can lose their certification, therefore losing their ability to sell in the marketplace. A service mark assures buyers of California leafy greens that the product bearing the mark has been grown according to the food safety practices accepted by the LGMA.

These Good Agricultural Practices are being mirrored in other commodities.

The almond industry adopted federal regulations requiring raw almonds to undergo an approved pasteurization process, or be labeled as "Un-Pasteurized".

The California tomato industry has developed tomato specific best practices. These programs also require USDA trained inspectors to conduct random and continuous audits to ensure compliance with these programs.

THE CALIFORNIA SET LABELING REQUIREMENTS FOR TOMATO INDUSTRY

California has also implemented tomato-labeling requirements that are unique to handlers in the state. Existing California Food and Agriculture Code provides the authority to require certain labeling and quality standards. All shipping containers of fruits, nuts and vegetables are required to have basic labeling including: Identity (the commodity); Responsibility (name and address of handler or packer or shipper); and Quantity (weight or volume).

In addition to the existing labeling standards, California tomato handlers are required to have the lot and grower ID on the container. This was established in 2006. In the event of violation of this article, a handler shall provide, upon request of the Secretary or his representative, records related to field location, grower, harvest date, pack date, transporter, and purchaser of packed tomatoes. These records shall be maintained for the current marketing year.

This identification provides a better mechanism for traceability of a product in the marketplace. The produce industry is focusing significant attention on the improved traceability of produce. Industry associations have voiced concerns about the inability to track produce in a standardized, electronic format from farm to point of service. Industry groups have been meeting for several months to develop new standards for traceability from farm to table. Growers, shippers, distributors and retailers must agree on a standardized, uniform set of criteria that will follow a product from farm to the point of service, enabling quick and accurate identification of the routes and sources of all produce.

NEXT STEPS

We must balance warning the public while minimizing the impact to growers.

• 1AWe encourage a better dialogue between FDA, states, growers, handlers and retailers to identify Good Agricultural Practices at all levels of the food chain.

• 1APrior to making a food borne illness announcement FDA should solicit states to provide commodity harvest data. This can minimize the guesswork and can limit the number of growers implicated in an outbreak.

• 1AGrowers, shippers, distributors and retailers must agree on a standardized, uniform set of criteria that will follow a product from farm to the point of service, enabling quick and accurate identification of the routes and sources of all produce.

• 1AWe encourage more research dollars be spent on identifying the life-cycle of food borne illnesses, potential points of entry and kill-step technology to ensure safe products. We work closely with the Western Institute for Food Safety and Security as well as the newly established Center for Produce Safety at University of California at Davis to improve methods of growing and safe handling of food products.

• 1ABetter surveillance of imported products. Consumers are relying more and more on a year-round supply of products that come from outside the United States. Programs must be established to do a better job of monitoring and testing food product imports. By monitoring our points of entry for repeat violators of false import declarations, making changes in import volumes at points of entry, and random sampling of products for contaminants, we can more effectively identify sources of potential risk.

• 1AWe urge Congress to support states in the development of programs that result in the implementation and auditing of Good Agricultural Practices.

• 1AThere must be funding to implement a uniformed system for epidemiology reporting and investigating outbreaks in all states. What we learn from this hearing

can set the stage for improved collaboration between the state and federal agencies and farming community. Thank you for inviting me to speak with you today and thank you for your support.

Mr. STUPAK. Thank you.

Mr. Brown, you might want to use that mike right there. We have a large panel. We usually do not have that many people on the panel but there is such great interest from the growers and producers and the commissioners we wanted to give everyone an opportunity. So, Mr. Brown, if you would start your 5-minute opening please, sir.

STATEMENT OF REGINALD L. BROWN, EXECUTIVE VICE PRESIDENT, FLORIDA TOMATO GROWERS EXCHANGE

Mr. BROWN. Thank you, Mr. Chairman, members of the committee.

The producers of tomatoes in Florida represent the largest single State fresh tomato production system in the country. We dominate the supply of fresh tomatoes in the United States from May to November. We have in fact been the primary injured parties in this entire process and we look forward to Congress addressing that concern and our injuries at some point in the future.

We have a few recommendations we would like to pass on to the Committee and to the Congress.

First of all, it is critical to the entire tomato industry that FDA exercise its authority to establish mandatory guidance based on the "Commodity Specific Guidelines for the Tomato Supply Chain." This document was created by the industry in conjunction with science and with FDA. And we would offer that up as a program that could be implemented immediately by the FDA in a mandatory way as a guidance document for tomato production throughout the country and throughout North America.

We also call for the initiation of regulations for mandatory food safety programs for tomatoes throughout the country. This is important that we do not establish a single program that forces programs on various segments of the industries are inappropriate because one size of a regulatory program will not fit all. But we encourage FDA to move forward. And we would encourage the Congress to move forward on bills such as H.R. 5904 to provide basis for those regulations going forward.

We would encourage that the FDA through consulting committees or some other structure create a mechanism for the industry and other representatives to be involved in these outbreaks. These consultants could be integrated early in the outbreak and we can avoid many of the complications and problems that I think we encountered in this unfortunate circumstance. These consulting groups could be constructed to where conflicts of interest and confidentiality could be maintained. And we also have the overriding common interest of the industry and public in making sure that we get this thing right.

We would encourage FDA to expand their current tomato initiative program that they have operated for the last year-and-a-half in both Virginia and Florida. We think those kinds of initiatives are important in giving the experiences and understanding and

knowledge to the agency. It would assist in their understanding the industry. And we would encourage them to incorporate in those tomato initiatives trace-back exercises for small, medium, and large type growers and packers and repackers so they have a very functional understanding of our industry.

We would encourage the FDA and CDC to develop the improved risk communication tools for the future outbreaks that would increase the understanding of the actual risk probability in suspected items and the risks posed to the public. Good risk analysis, informed assumptions and recommendations would facilitate greater understanding for all concerned. Such improved communications would improve public health rather than promote public hysteria.

We strongly urge the formation of a blue ribbon group of experts both inside and outside government to conduct an interview or a review of the handling of the 2008 Salmonella outbreak by state and federal agencies. The purpose of this review would be to improve the effectiveness in handling future outbreaks. Learning from mistakes made is the only way to make the world a better place as a result of our unfortunate experience.

We share the same interest in producing the safest tomatoes possible for consumers. It is a trust that we take extremely seriously in the tomato industry and we look forward to continuing to be leaders in the food safety arena for the American consumer.

Thank you for the opportunity to be here this morning. And I will submit the rest of my testimony for the record in writing.

Thank you.

[The statement of Mr. Brown follows:]

STATEMENT OF REGINALD L. BROWN

SUMMARY

At the time of the salmonella outbreak in April 2008, Florida was the only state in the country growing tomatoes. In early June 2008, the FDA indicated there was a connection between the salmonella outbreak and tomatoes from Florida. It is difficult to challenge the Center for Disease Control's (CDC) and the Food and Drug Administration's (FDA) decision in associating some tomatoes with the outbreak because we are not privy to the information they had before them.

FDA failed its principal task of finding the source of the salmonella and failed to promptly release those areas which were "cleared" by FDA's own testing or by the fact that tomatoes from these areas were not in the marketplace. As a result, the Florida tomato industry has suffered tremendously. Everyone associated with Florida's tomato industry, all the workers, farmers and packers in the designated areas and outside those areas have been harmed. We estimate the loss to the growers and packers to be $100 million, and they will continue to lose sales due the decline in consumer confidence caused by FDA.

The Florida tomato industry has taken the lead position in food safety for fresh tomatoes. Tomatoes from Florida are the only tomatoes in the U.S. subject to government-administered, mandatory food safety regulations. Further, these regulations were established at the request of the industry with the specific purpose of reducing food safety risks and the probability of such an outbreak.

RECOMMENDATIONS

1. Congress should provide relief to growers, packers, and repackers in Florida and throughout the U.S. for real losses suffered to date and those they continue to suffer through no fault of their own.

2. It is critical to the entire tomato industry that the FDA exercises its authority to establish mandatory guidance based on "Commodity Specific Guidelines for the Tomato Supply Chain." We also call on the agency to develop a mandatory food safety requirement for fresh tomatoes throughout the supply chain.

3. We strongly encourage FDA to create consulting committees made up of industry representatives and others. These consultants could then be integrated into outbreak management teams in the event of an outbreak so that experiences such as those suffered in the 2008 salmonella Saintpaul outbreak could be minimized.

4. We encourage FDA to continue to expand their current Tomato Initiative to all points in the tomato supply chain.

5. The development of improved risk communication tools for future outbreaks would greatly increase the understanding of the actual risk probability in "suspected" items and the risk posed to the public.

6. We strongly urge the formation of a "Blue Ribbon" group of experts from both inside and outside the government to conduct a review of the handling of the 2008 salmonella outbreak by state and federal agencies.

STATEMENT

INTRODUCTION

My name is Reggie Brown. I am the Executive Vice president of the Florida Tomato Exchange (the Exchange). We generally harvest from November through May. Almost half of all the fresh tomatoes consumed in the United States year-round come from Florida. During the winter months from October to about the end of May substantially all of the domestically produced fresh tomatoes in the marketplace come from Florida.

Tomato growers have seen major challenges in recent years from hurricanes, invasive pests and diseases, to increased international competition from Mexico and Canada. The fruit and vegetable industry is a critically important sector of Florida agriculture, which is second only to tourism in importance to the state's economy. According to a 2006 University of Florida study, agriculture, food manufacturing, and natural resource industries in Florida directly create more than 400,000 full-time and part-time jobs, with a total employment impact of more than 700,000 full-time and part-time jobs. The direct value-added contribution is estimated at $20.32 billion, with a total impact of $41.99 billion. Florida tomatoes are the largest vegetable crop in the state, with a value of over a half-billion dollars annually.

During the winter, Florida competes in the U.S. marketplace with Mexico and Canada. During the six-to-seven-month harvesting season, Florida's tomato growers employ more than 30,000 tomato workers.

BACKGROUND

At the time of the outbreak of salmonella in April 2008, Florida was the only state in the country growing tomatoes. In early June 2008, the FDA indicated there was a connection between the salmonella outbreak and tomatoes from Florida. It is difficult to challenge the Center for Disease Control's (CDC) and the Food and Drug Administration's (FDA) decision in associating some tomatoes with the outbreak because we are not privy to the information they had before them. However, we do think that decision was highly questionable and that once it was made, FDA failed to take appropriate actions in associating salmonella with tomatoes from a source other than from Florida.

In summary, FDA failed its principal task of finding the source of the salmonella and failed to promptly release those areas which were "cleared" by FDA's own testing or by the fact that tomatoes from these areas were not in the marketplace. As a result, the Florida tomato industry has suffered tremendously. Everyone associated with Florida's tomato industry, all the workers, farmers and packers in the designated areas and outside those areas have been harmed. We estimate the loss to the growers and packers to be $100 million, and they will continue to lose sales due the decline in consumer confidence, caused by FDA. More immediately, FDA 's recent "release" of tomatoes by removing the listing from their website placed Florida's growers in a very difficult position as to planting for next season. It is not an exaggeration to say that the availability of tomatoes from Florida may be reduced for the upcoming season as a result of FDA's actions. Our growers and shippers should be compensated for their losses.

We strongly urge the FDA to develop mandatory trace-back regulations for the entire tomato industry, from the farmer's field to the last retailer, based on the mandatory rules for food safety and trace-back in Florida, the guidelines adopted by the California tomato growers, and the national guidelines for tomatoes prepared by industry leaders (described in more detail below). This course of action will provide the consuming public with additional safety and confidence and will provide the CDC and FDA with the ability to quickly trace back an outbreak involving tomatoes

to the source of the contamination, thereby avoiding injury to innocent tomato growers, packers, and others in the distribution system. Other recommendations are proposed below.

FLORIDA'S TOMATO GROWERS LEAD THE COUNTRY IN FOOD SAFETY AND TRACE BACKS

The Florida tomato industry has taken the lead position in food safety for fresh tomatoes. Tomatoes from Florida are the only tomatoes in the U.S. subject to government-administered, mandatory food safety regulations. Further, these regulations were established at the request of the industry with the specific purpose of reducing food safety risks and the probability of such an outbreak.

The Florida tomato growers, along with University of Florida faculty and state regulators, developed a comprehensive food safety system for growing and packing fresh tomatoes. Details of the program can be found at www.floridatomatoes.org. This program employs the most current good agricultural practices and best management practices and includes third-party audits for packinghouses and for farms and greenhouses. It is a mandatory food safety system for all tomatoes grown in Florida and has been reviewed by the FDA. For many years, Florida's tomato growers have used a trace back system, called "positive lot identification." Using this system, the first buyer of Florida tomatoes can easily obtain the name of the farm and the location of the specific lot where the purchased tomatoes were grown.

We have also been proactive at the national level regarding food safety, working with our counterparts in California, Mexico, and Canada, as well as the United Fresh Produce Association and other groups. We have published the second edition of, "Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain." These guidelines recommend food safety practices to minimize the microbiological hazards associated with fresh tomatoes and fresh-cut tomato products at all points of the fresh tomato supply system.

Certainly, the adoption of Florida's requirements, the trace-back program employed by the California tomato farmers, and the commodity-specific guidelines mentioned above can be adopted for the entire tomato industry. We are strongly supportive of mandatory regulations modeled on these programs as proposed in HR 5904.

ISSUES REGARDING THE HANDLING OF THE SALMONELLA SAINTPAUL OUTBREAK

We believe a number of things went wrong from the beginning of this investigation, and it warrants oversight by this Committee and, we believe, by others as well. We raise the following issues and comments based on incomplete information because complete information was not provided to us by either the CDC or the FDA. While we truly believe mistakes were made, the damage has been done. We hope we can regain our market and convince our consumers that the tomatoes we grow and ship from Florida are among the most wholesome and safest in the world. The food safety system we have adopted is unprecedented in the fresh tomato industry and uses the best practices available. We raise these issues to be constructive so that next time CDC and FDA can make the right association and find the source of contamination in short order. And, there will be a next time for tomatoes and for other perishable commodities because no system is 100% risk free. Risk reduction is the realistic goal of all food safety programs.

We believe the CDC and the FDA incorrectly presumed tomatoes to be associated with the salmonella outbreak. We believe the data reviewed indicated tomatoes and salsa items together were the original problem. Indications that tomatoes and salsa coming from Hispanic outlets were associated with salmonella and that the saintpaul strain of salmonella has not previously been associated with tomatoes should have been given more weight.

We believe the FDA erred in indicating that the outbreak was associated with tomatoes from Florida. While it is easy to suggest that the salmonella came from Florida tomatoes since Florida was the only state in the U.S. producing tomatoes in late April, we believe additional information should have been factored into this decision. Most importantly, it appears the FDA totally ignored the locations of the first outbreaks: the Southwest U.S., New Mexico and Texas. In so doing, it ignored the most likely source of tomatoes and/or salsa: Mexico. In addition, given the cost of fuel, it was most unlikely that tomatoes consumed in New Mexico came from Florida.

We believe the CDC needed to share its first questionnaire and the information that led it away from Mexico as a source.

We believe the FDA erred in not finding the source of this outbreak, and we believe the FDA erred in not promptly "releasing" tomatoes from Florida given the fact that the test done on Florida tomatoes showed no signs of salmonella.

We believe the FDA erred in not bringing experts from the industry to assist with the trace back efforts.

We believe that the FDA erred in not providing and communicating standards used to determine the risks to consumers from the beginning when a warning was issued, when all tests came back negative, when other items (peppers) were added, to the end.

We believe the FDA erred in not exploring the tomato distribution system in the U.S. prior to this outbreak. During this outbreak, an FDA official described the tomato distribution system as "complex." FDA has had prior experience in dealing with trace backs involving tomatoes and should have developed a trace back plan prior to this outbreak as well as a procedure for industry assistance.My industry colleagues on the panel will, or have already, addressed the structure of the industry and the trace back system that exists for tomatoes.

RECOMMENDATIONS

As the group most economically harmed by the salmonella outbreak due to the CDC's and FDA's actions and/or lack of actions in associating fresh tomatoes with the outbreak and in failing to quickly find the source of the outbreak and failure to promptly remove Florida as a source of the outbreak, we have a number of recommendations for this Committee to consider.

1. Congress should provide relief to growers and packers in Florida and throughout the U.S. for real losses suffered to date and those they continue to suffer through no fault of their own. From our perspective, we are in the identical situation as growers of other commodities whose crops were destroyed by natural disasters. The difference is only that our disaster was government driven.

2. It is critical to the entire tomato industry that the FDA exercises its authority to establish mandatory guidance based on "Commodity Specific Guidelines for the Tomato Supply Chain." We also call on the agency to develop a mandatory food safety requirement for fresh tomatoes throughout the supply chain. Such a program could be modeled on the Florida and California programs, allowing for slight modifications to accommodate regional conditions as they exist. A one-size-fits-all approach to food safety is inappropriate. FDA should be encouraged to continue consultations and cooperation with industry groups to accomplish this goal. Current legislative proposals such as HR 5904 call for such regulations, and we fully support them.

3. We strongly encourage the creation of consulting committees by FDA be made up of industry representatives and others. These consultants could then be integrated into outbreak management teams in the event of an outbreak so that experiences such as those suffered in the 2008 Saintpaul outbreak could be minimized. These consultant groups could be structured to avoid concerns about confidentiality and conflict of interest. Everyone has a common interest in identifying and removing the source of any outbreak as quickly as possible.

4. We encourage FDA to continue to expand their current Tomato Initiative to all points in the tomato supply chain. We also encourage FDA to expand their efforts to include trace back exercises that include small, medium, and large growers, packers, and repackers as well as any others who are part of the distribution system. Such efforts would improve the level of knowledge within the FDA and provide experiences designed to expedite future trace back efforts in the event of an outbreak.

5. The development of improved risk communication tools for future outbreaks would greatly increase the understanding of the actual risk probability in "suspected" items and the risk posed to the public. Good risk analysis and informed assumptions and recommendations would facilitate greater understanding for all concerned. Such improved communications would improve public health rather than promote public hysteria.

6. We strongly urge the formation of a "Blue Ribbon" group of experts from both inside and outside the government to conduct a review of the handling of the 2008 salmonella outbreak by state and federal agencies. The purpose of this review would be to improve their effectiveness in handling future outbreaks. Learning from mistakes made is the only way to make the world a better place as a result of our unfortunate experiences.

Thank you for the opportunity to present these comments for your review.

Mr. STUPAK. Thank you, Mr. Brown.

Mr. Beckman, your opening statement please.

STATEMENT OF EDWARD BECKMAN, PRESIDENT, CALIFORNIA TOMATO FARMERS

Mr. BECKMAN. Thank you, Mr. Chairman, members of the subcommittee. California Tomato Farmers Cooperative is the largest producer of fresh tomatoes for all of North America during the summer and fall. Our cooperative was formed in 2006 by 54 growers, large and small, who represent 80 percent of the fresh tomato production in California. And we require production based upon a higher food safety standard.

As noted by the secretary, we require mandatory, random and unannounced food safety audits of all ranches, all packing houses by the California Department of Food and Agriculture. We are also the co-author of the new Commodity Specific Food Safety Guidelines for Fresh Tomatoes. And we support mandatory trace-back at all levels.

Although California was never associated directly with the Salmonella Saintpaul outbreak, our members have indeed lost millions in sales in both domestic and international markets due to the broad warnings related to tomatoes. But our very real concern is that this may happen again, putting the consumer at risk, and that we may see a prolonged investigation that will further weaken trust in our food supply. FDA publicly noted the difficulty of their investigation and we cannot help but ask specifically, Where was the problem? Trace-back should be able to trace fresh tomatoes from point of service to the field in hours, not days or weeks.

Trace-back of fresh tomatoes is based upon lot identification codes which travel with the product. The code is printed on all containers, included on all quality control records, production reports, and forms used in the shipping of the product; it is the foundation of traceability. As you know, we recently hosted a tour for the investigative staff of this committee demonstrating traceability of fresh tomatoes across state lines. The investigative staff directed the case study that I will detail to you today.

In the slides provided to the committee we will be tracing tomatoes from a single restaurant back to the grower through five handling points. And while the tomatoes move in one direction, trace-back requires a two-way flow of information among all who handle the product: the store, the distribution center, the repacker, shipper and grower. There are six steps to this trace-back investigation.

[Slide shown.]

We begin with the quality assurance vice president phoning a restaurant to obtain the date code on a random carton of tomatoes. That date code is relayed to the distribution center.

[Slide shown.]

In step 2, the distribution center uses the date code to learn the product came in on July 7 from a repacker supplier.

[Slide shown.]

In step 3, the supplier is phoned, provided with a purchase order for the shipment. This is the document. Using the purchase order the supplier then determines the origin of the product in a single document.

[Slide shown.]

In the next step the supplier holds the critical document to maintain traceability. It is a single document that documents the pur-

chase order for incoming product and the final lot I.D. for unfinished product. It is this one single document that determines whether not there had been any commingling of product and the source of all tomatoes used in the final product.

[Slide shown.]

In the final slide we look at the role of the supplier who phones the shipper and using the purchase order obtains the original lot I.D. The lot I.D. includes the complete field history and it is passed forward. The supplier, using this document, now has all records they need to pass forward to the food service chain.

[The information appears at the conclusion of the hearing.]

The time required for this trace-back as done for the investigative committee was 35 minutes. Why did this trace-back work? Well, the answer is the use of electronic recordkeeping that is based upon lot identification and also the Bioterrorism Act. What we did was linking one step up and one step back requirements of this act at each level of the supply chain.

We believe that we must learn from this outbreak and investigation to ensure that future investigations do not take months, they should not. And we therefore recommend that Congress require an analysis of the FDA tomato investigation to include individual trace-back records to effectively determine why this investigation of tomatoes was so lengthy, that FDA's tomato initiative be expanded to include tomato repackers, wholesalers and traceability throughout the supply chain, and that FDA establish a pilot project that would establish mandatory food safety production and handling requirements based upon the just-published Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain.

I would like to note this standard is already employed by our members in California and Florida. Together we represent 70 percent of the fresh tomatoes produced in the United States. By taking these already high standards national we would improve preventative measures by all who produce and handle tomatoes, including smaller farms. But we caution, food safety is not limited to the grower in the packing house, it is the responsibility that must be shared by all, including supermarkets and restaurants, if we are to truly protect the consumer.

This concludes my testimony. And I will welcome any questions the committee may have. Thank you very much.

[The statement of Mr. Beckman follows:]

Testimony of Edward Beckman

President

California Tomato Farmers

Before the

Subcommittee on Oversight and Investigations

House Committee on

Energy and Commerce

July 31, 2008

Introduction

My name is Ed Beckman. I serve as president of the California Tomato Farmers (CTF), a cooperative of fresh tomato growers who produce 750 million pounds of fresh tomatoes each summer and fall. Our tomatoes are sold throughout North America and Japan with annual sales greater than one quarter billion dollars. From June through November, we are the largest producer of fresh tomatoes for all of North America.

Thank you, Chairman Stupak, Ranking Member Shimkus and members of this Subcommittee for the opportunity to testify before you on the topic of traceability within the fresh tomato industry.

CTF was formed in 2006 upon a foundation composed of mandated practices in three areas: food safety, social accountability, and sustainability. It was our intent to raise the bar on tomato food safety to protect public health. This was done through the

adoption of new food safety production requirements on the farm including improved standards for water quality, soil amendments and employee hygiene. In addition, CTF members must have trace back procedures beyond what is required under the Bioterrorism Act of 2002. To verify that these standards are being met, CTF requires mandatory government inspections of our members. Today, all ranches farmed by our members and all packinghouses that process our tomatoes are subject to random and unannounced inspections conducted by the California Department of Food and Agriculture. Members who fail to meet these verifiable standards will be removed from the cooperative.

Industry members associated with CTF have been actively working with the U.S. Food and Drug Administration (FDA) on tomato related food safety issues since 2004. As a result, the first commodity specific food safety guidance for fresh tomatoes was published in 2006. In 2007, working with the Florida Tomato Exchange, United Fresh Produce Association and others, the development of a second edition was launched. The finished product has just been released and is now in wide distribution through trade associations and grower organizations. We believe it to be the most comprehensive document related to tomato food safety ever published.

FDA participates in the California Tomato Farmers Advisory Committee comprised of government, academic, trade, and labor advocates whose task is to review all programs of the cooperative and provide input into our policy and food safety initiatives.

The salmonella outbreak of 2008 has and will continue to impact our members. Although never associated with the outbreak, our members have lost sales in domestic

and international markets. Even in California, where we are the "locally grown" tomato, June retail sales of red round and roma tomatoes are down more than 50% according to AC Nielson scanner data. Prices to farmers today (July 24, 2008) as compared to just prior to the outbreak are half what they once were. This is even more concerning based upon recent findings that tomatoes may never have been involved in this outbreak at all.

Our concerns are not limited to the time when tomatoes were the suspect of the FDA investigation. Yes, there were losses but that period of time is not our primary concern.

Our very real concern is that this may happen again. We are concerned that, once again, tomatoes may be cited as a possible source for food borne illness when, in fact, there's no conclusive evidence to support that fact. And, that we will again witness a prolonged investigation that only further weakens the trust in our food supply. Speaking for our growers, this cannot happen again. Regaining trust in our product will take months, if not years.

Even more important is that we learn from this past outbreak and that all parties work together to ensure that investigations such as this do not take several weeks or months. We would ask that consideration be given to an in-depth analysis of the FDA investigation that would include individual trace back records so that we can effectively determine why this investigation of tomatoes was inconclusive. We would ask that officials from the highly respected Minnesota Department of Health be involved in this analysis since in only two weeks time they were able to identify a cluster of illnesses, identify the suspected food item and then successfully trace back that implicated food item, in this case jalapeno peppers. And, we must ask what we can learn from the

efficiencies found in current industry traceability models where product can be traced from store to field in a matter of hours.

Our comments are shared by Dr. Michael Osterholm, an infectious disease specialist and advisor to the government as noted in a July 24 Associated Press report:

> *"We have got to put the appropriate perspective on this outbreak as to what went right and what went wrong so the kind of changes that are going to further foodborne disease (prevention) can be made," said Michael Osterholm, a University of Minnesota infectious disease specialist and frequent adviser to the government.*[1]

While very much in agreement with FDA that their foremost goal must be to protect the public, we cannot help but raise concern with the speed of this investigation and the number of associated illness. Speed of an investigation can be associated with FDA's success in tracing product. It is therefore appropriate to consider the role of traceability - that ability to trace back or forward the identity of a product that may have contributed to this outbreak.

I would like to reiterate, as reported by the Minnesota Star Tribune on July 24, 2008, that the Minnesota Department of Health was able to determine through their trace back methodology that tomatoes were not the source of illness in two weeks time:

> *In less than two weeks, Minnesota Department of Health investigators traced the source of a mysterious salmonella outbreak that had stumped federal health officials for two months and sickened more than 1,200 people in 43 states and Canada. The culprit: jalapeno peppers. Minnesota health officials first learned of*

[1] http://ap.google.com/article/ALeqM5hoVNNMbbTPzpFP_Oaubc_ZXF7I7QD923PDL00

a salmonella outbreak in the state on June 23. By July 9, they were on the phone with their federal counterparts making it "crystal clear" it was not tomatoes but jalapenos that were the likely source, said Kirk Smith, head of foodborne diseases at the Health Department.[2]

Clearly, FDA's handling of this outbreak initially which most likely falsely linked it to fresh tomatoes must be subject to further investigation based upon full disclosure of the trace back procedures from point of service to the field and all points between. The agency should not withhold trace back records from scrutiny. We ask for this investigation not because of the damage done to our farmers, but in the interest of public health. As we have just seen, illnesses continued because people were avoiding the tomatoes but they kept eating the peppers.

Introduction to Tomato Traceability

Tomato traceability is based upon a one up/one down model that is in keeping with The Bioterrorism Act of 2002[3] which is enforced by the FDA Center for Food Safety and Applied Nutrition (CFSAN).

For there to be traceability, there must be a linking of the physical flow of a product from field to the final point of sale/use using a two-way information flow between all who produce, handle or market the product. [4]

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[2] http://www.startribune.com/lifestyle/health/25837094.html?location_refer=Health%20+%20Wellness:highlightModules:2

[3] www.fda.gov/oc/bioterrorism/Bioact.html

[4] www.pma.com/view_document.cfm?docID=148

Traceability is achieved by the tracing and tracking of fresh tomatoes using three components:

- Product, party and location identification
- Recording of information
- Linking of information between parties

Traceability identification may be in the form of a shipper assigned lot ID, where the initial identification is carried throughout the supply chain. Identification may also be transactional, changing with each shipment or transaction. When transactional, there are records kept at each "point of handling" to maintain the original source of the product. Thus, while multiple identifiers may be used as the product moves through the distribution system, each is linked to the prior identifier which maintains product lot identity for the purpose of trace back. As a result, there is the ability to trace product from the point of sale to the field.

Traceability Regulatory Provisions: Federal and State

The Bioterrorism Act of 2002 requires that traceability is maintained from the initial shipper, (commonly referred to as a "packinghouse") to the delivery to the retail or foodservice establishment. Under federal law there is no traceability requirement at the farm or for product sold by a supermarket or foodservice establishment to the consumer. However, the State of California requires that traceability include the farm. The California Tomato Farmers cooperative goes further and requires that farm traceability include all product inputs that are used in the growing of fresh tomatoes.

There is no standard Federal definition for what is to be traced. The item to be traced may be in the form of a shipment, pallet, container or consumer ready package.

Under California's Food and Agriculture Code for fresh tomatoes, the required traceable unit is the original container. The same applies under CTF policy. Containers cannot be reused under California's code or under CTF regulations. Tomatoes from one grower cannot be commingled with that of another grower in the original carton or in a carton repacked in California. In addition, the Perishables Agricultural Commodities Act (PACA) prohibits the sale of any lot of tomatoes in which the state or region of origin is misrepresented, meaning tomatoes labeled as "Product of California" must be grown in California.[5]

Trace back requirements are also part of the California Food and Agriculture Code[6]. The California Department of Food and Agriculture (CDFA) noted in their analysis first published in 2005 the rationale behind amending California's code was to improve food safety and traceability:

> *The California Code of Regulations makes no provision requiring that tomatoes be free from dirt or debris. Salmonella can be vectored by birds or found in the soil. Given the documented illnesses that are the result of salmonella found on field packed tomatoes, the Department is proposing to amend Section 1472(a)(1) requiring tomatoes to be free from dirt and foreign material. The Department is also proposing that tomato containers be stamped with a handler ID number for trace back purposes in the event of product contamination. The proposed changes are intended to provide consumers with safe, good quality tomatoes as well as protect the integrity of the industry.*

[5] U.S. Code 7§499b, 7 CFR 46.45
[6] California Food and Agriculture Code Title 3, Chapter 1, Subchapter 4, Article 43 § 1472(a)(1), 1472.4, and 1472.7.2

Following a review by the California State Office of Administrative Law, the California Code of Regulations was amended on May 18, 2006 to now require tomatoes produced in the state to be free from dirt and other specific contaminants and that all cartons be labeled to assist in trace backs. These regulations are administered by the Inspection and Compliance Branch of the California Department of Food and Agriculture. Under the Agriculture Code, California requires that all individuals or companies who market or distribute tomatoes be able to provide records to enable trace back to the grower and field location.[7]

California also enacted language that regulates the packing of tomatoes requiring that all containers be new and unused[8]. The California Agriculture Code mandates that if tomatoes are repacked that they are returned to the original container of the original packer and that all repackers register with CDFA on an annual basis.[9] As noted previously, this requirement had been unique to California until the recent Florida statute took effect.

California Tomato Farmers

CTF members are required to exceed all state and federal regulations related to trace back and recall. CTF policy incorporates requirements of the State of California and the Bioterrorism Act of 2002. However, CTF also requires members to:

- document their ability to trace back all agricultural inputs used in the production of their tomatoes and all product sold or disposed of;
- identify crews involved in production and harvest;

[7] California Food and Agriculture Code Title 3, Chapter 1, Subchapter 4, Article 43 § 1472.7.2
[8] California Food and Agriculture Code Title 3, Chapter 1, Subchapter 4, Article 43 § 1472.7
[9] California Food and Agriculture Code Title 3, Chapter 1, Subchapter 4, Article 43 § 1472.7 and § 1472.7.1

- successfully conduct mandatory, mock trace back and recall exercises.

All member performance is subject to mandatory government inspections to ensure compliance.

Recordkeeping by members of CTF is largely electronic. Lot identification coding travels with the product. That Lot ID code is unique to that product and provides the means to identify the date that the tomato was harvested and packed; the identity of the ranch that produced it; and, the block or planting number of the field. This code is printed on all containers, included all quality control records, production reports, and forms used in shipping of the product.

Attached as Exhibit A, is the section of the CTF food safety standards that outlines California code requirements along with the additional traceability requirements for CTF members. In part, the policy provides that all levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (next recipient) and one step back (immediate previous supplier). California's Food and Agriculture Code, Article 43 § 1472, provides specific regulations for fresh tomatoes produced in California requiring the traceability of all product.

Non-regulatory Provisions: Food Safety Guidance for Fresh Tomatoes

The North American Tomato Trade Working Group, an ad-hoc coalition of the North American tomato industry, published the first Commodity Specific Food Safety Guidance for the Fresh Tomato Supply Chain. The second edition, published July 2008, was expanded to include specific recommendations for risk reduction in the handling of fresh tomatoes throughout the supply chain – from field to individual supermarkets and

restaurants.[10] Although each section of this document was developed for a specific level of the supply chain (i.e., fresh cut, repacking, retailing, etc), there is one common recommendation – that of mandatory trace back. It was the consensus of everyone involved in the development of this document that all who handle tomatoes must maintain verifiable traceability. This would extend beyond the parameters of the Bioterrorism Act, to include farms and restaurants. For the latter, trace back can begin with nothing more than an invoice for the tomatoes purchased. Thus, the editors of the document, representing all segments of the supply chain, are in agreement that the ability to trace back the origin and handlers of a tomato is critical to all concerned. It is a continuation of industry food safety practices that may begin on the farm but doesn't end until the time of purchase by the consumer.

Attached as Exhibit B, are the requirements set forth by the July 2008 Commodity Specific Food Safety Guidance for the Fresh Tomato Supply Chain to enable trace back at all levels of the supply chain.

Trace Back Beyond the Grower/Shipper: The Role of Tomato Repacking

The challenge of the fresh tomato industry is that retailers and foodservice establishments each have specific standards for color, grade and size. It is not feasible for a farmer to meet the diverse needs of such a customer base. Therefore, tomato repackers play an important role in the movement of product from the field to the end-user. The repacker must be able to pass forward the information as provided by the farmer and shipper. The lot identification code provides the means to maintain product origin at all levels of the supply chain.

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[10] http://www.californiatomatofarmers.com/foodsafety-metrics.asp

Repacking of that product, such as tomatoes, serves an important function in the fresh tomato supply chain. Repacking of tomatoes, if done properly, does not put the traceability of tomatoes at risk. There are two issues to consider:

- Commingling
- Traceability

As noted by FDA's Dr. David Acheson in his press conference of June 18, 2008:

> *"So you know the key point here is not that commingling is a problem. The key point is if you're going to commingle, make sure you can trace them and make sure that the suppliers you're commingling from are using good agricultural practices and preventative control." – Dr. David Acheson.*

We concur with his assessment that the issue of repacking is not commingling of tomatoes per se, but rather, that proper records are maintained.

As an organization, we do not support the commingling of tomatoes from one farmer with those from another. Our position is based upon the production standards of the cooperative and maintaining the integrity of those standards, just as noted by Dr. Acheson. In California, a tomato repacker is not permitted to mix products of multiple growers in the finished container.

Tomato Trace Back Case Studies

During their press conferences, a number of comments were made by FDA related to the difficulty of this trace back investigation. As previously noted, the State of Minnesota was able to successfully complete their investigation using trace back methods not unlike those found in the tomato industry. Trace back of fresh tomatoes using existing industry best practices protocol can enable trace back from point of service to the

field in hours, not days or weeks. Further, if an investigation is focused on the wrong product, trace backs will be both misleading and time consuming.

The following case studies were conducted in July 2008. They are representative of the everyday standard practices of the fresh tomato industry in California as regulated by the contractual provisions of the California Tomato Farmers Cooperative and the California Agricultural Code, as established by the California Department of Food and Agriculture.

History of a Trace Back and Mock Recall by a National Fast Food Chain

Illustrated in the slides attached as Exhibit C and further documented as Exhibit D, in this case study, directed by the Committee on Energy and Commerce Oversight and Investigative staff, a Sacramento restaurant of a national fast food chain was selected at random for a trace back and possible recall of tomatoes. The chain uses tomatoes in salads and sandwiches. The recall originates with the fast food chain and requires all history for the tomatoes used by that restaurant. The supplier to the chain is responsible for the gathering of all information from all sources of the product that was found in that single restaurant.

Slide One

Product Flow:

Grower>Shipper>Repacker>Distribution Center>Restaurant

Information Flow:

Restaurant <>Distribution Center <>Repacker <>Shipper <>Grower

Slide Two

- A single fast food restaurant is selected randomly for a trace back and mock recall by House and Energy Committee staff investigators. A phone call is made by the chain's VP of Quality Assurance to the restaurant to obtain the date code on a carton of tomatoes found in their storage room. The date code is obtained and provided to the VP of Quality Assurance.
- The VP of Quality Assurance informs their distribution center of the need to trace back and recall all tomatoes with that date code. The distribution center uses their computerized system, inputs the date code and learns the product came from ABC Repacker and was received on July 7. 540 boxes were received and distributed to 156 units from the distribution center. ABC Repacker, the supplier, is called and provided with the purchase order code for the shipment. The distribution center can now recall all unused product from all 156 units.
- The general manager of ABC Repacker begins his segment of the trace back. Using the purchase order code on the invoice, he is able to determine that their repacked product originated from XYZ Tomato Shipper in a single shipment of 540 cartons. He calls XYZ Tomato Shipper and reports that he needs to complete the trace back on this purchase order.

Slide Three

- XYZ Tomato Shipper now begins his segment of the trace back. Using the purchase order code, he obtains the original Lot ID from his computer records. This information includes the location of the field, the grower name, variety,

harvest date, pack date, shipping date, and transportation carrier used. This information is provided to the ABC Repacker, who then provides copies of all records to the VP of Quality Assurance for the fast food chain. *The trace-back is complete - Time required: 35 minutes.*

- If there was a need to recall product beyond that of the single unit of this fast food chain or this single shipment this can easily be done since XYZ Tomato Shipper has identified the grower and field. While not required for this specific trace back/recall, using the Lot ID information, the shipper determined that 64,000 cartons were harvested from this field. Under CTF protocol, this Lot ID provides the means to trace forward the destination of all 64,000 cartons and, if product was destroyed prior to shipment, the disposition of that product.
- Under CTF regulations, XYZ Tomato Shipper and the farmer must maintain all records related to the production of the crop including water testing, source of all inputs, pesticide use, names of planting and harvest crews, etc. This is not required under the Bioterrorism Act. This requirement is unique to CTF and allows full field history in the event of a trace back or product recall.
- Codes used in Mock Recall:

  Foodservice chain: *Repacker assigned Date Code and Chain Purchase Order.*

  Repacker: *Chain Purchase Order that includes repacker assigned Lot ID that links to original Lot ID and Purchase Order of the shipper and grower; if product from more than one grower were used, the newly assigned*

Lot ID would link to both growers. Thus, if the tomatoes in this event had been (somehow) commingled using product of two growers, the repacker would maintain Lot ID records for both growers. The trace back would then include two shippers, not one as illustrated. Thus, even if two growers were the source of the product, the ability to trace back is maintained.

Shipper: *Purchase Order and Lot ID*

Grower: *Lot ID*

Note: Names of all parties have been withheld, as this is an actual recall that involved multiple companies, some privately held, other's public.

History of a Trace Back and Mock Recall Conducted by a Buying Cooperative

Mock recalls can be initiated at any point in the distribution system. In the following case study conducted on July 9, a California-based Buying Cooperative (TBC) that purchases product for its members but does not physically handle the product is conducting a recall. The members are large foodservice distribution companies that service both restaurant chains and independent restaurants. TBC requires that all repackers repack tomatoes to their specifications with a trace back code on each container. In this case study, the entire recall is coordinated by TBC's Food Safety Director.

Product Flow:

Grower>Shipper>Repacker>Distribution Center

Information Flow:

Buying Cooperative<>Repacker< >Foodservice Distributor<>Shipper <>Grower

- The Buying Cooperative's (TBC) Food Safety Director at random selects a specific trace back code, X20623. The product was purchased from DEN Repacking in Denver for their member in that market, a foodservice distributor. In the TBC recall, they have asked DEN Repacking to trace forward and back all product linked to the above code, including the location of all distribution centers used, total cases produced under this code, total cases shipped, raw product lot numbers, and the identity of all growers.
- DEN Repacking, using the TBC trace back code, identifies that the product was shipped to SMK Foods (a TBC member foodservice distributor) on July 6. The product had been repacked as follows: 30 cases in TBC label and 16 cases under the DEN label. The repacker also notes that product from the same grower and field was repacked under a second trace back code (shipped on July 4 to the distribution center) with 25 cases using the TBC label and 8 cases using the DEN label. The repacker provides the TBC Food Safety Director with the Lot ID and the Purchase Order (PO) numbers of his supplier, RST Tomato Shipper in California.
- TCB's Food Safety Director, using the Lot ID and PO, asks RST Tomato Shipper to provide information on all cases produced, total cases shipped, raw product lot ID, grower ID and identify harvest crews.
- RST Tomato Shipper, using the Lot ID and PO, is able to document the grower's name and that the product for this order came from two separate lots, but only one field. Lot one produced 37,880 cartons, all but 80 cartons have been shipped. The remaining 80 cartons are still in inventory. The second lot

produced 52,543 cartons; there are 800 remaining in inventory. *Trace back complete – Time required: 5 hours, 11 minutes.* *(Note: The actual amount of product subject to this recall is 79 cartons (46+33). While not required in this specific mock recall, RST Tomato Shipper can identify the destination for all tomatoes produced under this lot order, not only those associated with this recall involving TBC, DEN Repacking, and SMK Foods; As they are a CTF member, they can provide additional documentation as noted under items 5 and 6 in the previous case study.)*

- Codes used in Mock Recall:

  Buying Cooperative: *Repacker assigned trace back code and their own Purchase Order (PO)*

  Repacker: *Cooperative's PO that references repacker assigned Lot ID that links to original Lot ID of the shipper and grower; in this example, product from one grower, but two different lots was used for the final shipment of product. The repacker's own assigned trace back code is linked to the two PO's from the shipper.*

  Shipper: *Purchase Order (PO) and Grower Lot ID*

  Grower: *Grower Lot ID*

Note: *Names of all parties have been withheld, as this is an actual recall that involved multiple companies, some privately held, other's public.*

Trace back Summary

The case studies represent common traceability practices within the fresh tomato industry as they exist today. In each of the illustrations, there is lot identification that travels with the product. There is a two-way flow of information that compliments the physical movement of the product. In each of the illustrations, the time to trace and conduct a mock recall of all associated product was a matter of hours, not days. The current system, when utilized properly, contributes to a rapid flow of information and the documentation of all product in the supply chain. It is a system that, not unlike many other systems, requires recordkeeping that is efficient and effective. Bad data in results in - bad data out. It's a common problem across all industries.

Economies of scale realized by larger growers and their customers provide for electronic recordkeeping. As noted in the case studies, the entire trace back process requires hours, not days or weeks. The challenge to trace back is not the system as outlined. The challenge is that individuals may choose to not properly maintain records. They may choose to violate existing laws, such as the Bioterrorism Act that provides the framework for the trace back and enabled the prompt trace back and recall as noted in the case studies.

Individuals that do not maintain such records put everyone in the supply chain at risk from both a public health perspective as well as an economic perspective.

Trace back is not the means to eliminate food safety illness but it is an essential component that must be mandated on all producers, whether large or small.

Recommendations to the Committee

We are concerned that this could happen again – a product cited as a possible source when there's no conclusive evidence to support that fact. And, that we will again witness a prolonged investigation that only further weakens the trust in our food supply. I have to reiterate that we must learn from this past outbreak and that all parties must work together to ensure that investigations such as this do not take months. Therefore,

We recommend that Congress require FDA, appropriate state health departments and industry conduct an in-depth analysis of the FDA investigation that would include individual trace back records so that we can effectively determine why this investigation of tomatoes was inconclusive or misdirected. We must ask what we can learn from the efficiencies found in current industry traceability models where product can be traced from store to field in a matter of hours, not days or weeks. A comparison of FDA and industry trace back methodology should be considered as the basis for establishing more efficient and effective trace back procedures at FDA.

Although tomatoes were likely not linked to this particular outbreak, we still believe that we should all learn from this outbreak and move food safety initiatives forward. Preventative measures are an important task for consideration. For the tomato industry, the adoption of the just published Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain represents application of the best available science. Provisions of this document include required risk reduction principles and full traceability – from field to point of service – and will enable all to respond to the demand for a higher level of accountability. Therefore,

We recommend that Congress, in the current session, establish a pilot project that would include the adoption of the July 2008 Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain as the baseline for further evaluation of the food safety practices employed in the fresh tomato supply chain. This could be accomplished through the expansion of the current FDA Tomato Initiative that included the evaluation of tomato production methods in Virginia and Florida. This project should extend beyond the farm and packinghouse to evaluate the practices of tomato repackers, wholesalers, and most importantly, the integrity of the traceability of fresh tomatoes throughout the supply chain.

California mandates traceability on all tomatoes produced or handled in the state as does Florida. But, those requirements are limited in scope. Given the needs of the restaurant and supermarket industries are vastly different there must be flexibility in any trace back system that would go beyond that required under the Bioterrorism Act. That does not suggest any segment of the supply chain should be exempt from holding records that enable the ability to trace back or trace forward the movement of fresh tomatoes. Therefore,

We recommend that FDA adopt the July 2008 Guidance Document for the Fresh Tomato Supply Chain as the basis for any regulation of the tomato supply chain, including revised traceability requirements, and such standards apply on all domestic and imported fresh tomatoes.

CTF supports the need for the regulation of the production and marketing of fresh tomatoes. Already, Florida production is governed by statute. In California, nearly 8 of

10 tomatoes produced are now subject to mandated food safety and traceability standards and government inspection under the CTF system. Together Florida and California Tomato Farmers market over 70% of the fresh field-grown tomatoes produced in the United States. Therefore,

> ***We recommend that in any proposed regulation, it must be understood that the reduction of microbial contamination is a responsibility that is not limited to the grower and packinghouse. It is a responsibility that must be shared by all who handle tomatoes. And, that responsibility must also require that transparent traceability be maintained throughout the supply chain, including supermarkets and restaurants.***

As fresh tomatoes are one of the most popular fresh produce items and often subject to cutting, slicing, or dicing in the home we cannot eliminate 100% of the risks associated with the handling of fresh tomatoes. We can, however, ensure that all who commercially handle tomatoes are held accountable for their practices. To exclude any responsible party from such regulation would only lessen the effectiveness of good agricultural practices that are being employed today by our members and many others who strive to provide consumers with the safest supply of fresh tomatoes grown in the United States.

This concludes my testimony and I welcome any questions that the Committee may have. Thank you again for this opportunity to testify before you.

EXHIBIT A

California Tomato Farmers Trace Back Regulations

All levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (next recipient) and one step back (immediate previous supplier). California's Food and Agriculture Code, Article 43 § 1472, provides specific regulations for fresh tomatoes produced in California. In addition, the CTF provides:

1) Documentation of packed tomatoes shall include sufficient information about the source (i.e., grower, production location, lot identification, personnel/crew involved in the harvest of the product) as well as the customer receiving the product to allow for the appropriate tracing of product.

i) The grower shall be able to document the source of agricultural inputs used in each lot of tomatoes handled by the packinghouse.

2) Corrugated containers for the packing of fresh tomatoes shall be new, and accurately labeled with commodity name, member name, and lot identification sufficient to allow for accurate trace back.

3) If using reusable containers, (e.g. Reusable Plastic Containers – RPCs), they shall be clean and sanitized before reuse. Ensure that labels are accurate prior to reusing for packing.

4) A traceability system to track tomatoes back to supply source and forward to customers shall be developed and tested annually. A record of this test shall be kept on file.

i) Traceability records shall be readily available for USDA auditors.

5) Tomatoes that are repacked must be done in compliance with California Agriculture Code, Article 43 § 1472.7.1, and shall maintain traceability established by the original shipper and/or grower.

6) The company shall document the establishment of a recall action team, product complaint log, a flow chart or other means to identify the steps to be taken in the recall process, a plan for product recovery, and annually conducts a successful mock recall.

7) The member maintains adequate record of the sale of product, the disposition of unsold product and the source of all products used in the production and marketing of the member's crop.

Based upon California Agriculture Code Article 43 § 1472.7.1, a repacker or wholesaler doing business in California must maintain lot integrity as established by the grower or shipper.

EXHIBIT B

July 2008 Commodity Specific Food Safety Guidance for the Fresh Tomato Supply Chain – Trace Back Requirements

Grower:

Recordkeeping provide evidence of reviews and evaluations to document those practices. Records shall also be kept to assure traceability of harvested tomatoes.

a. *Records documenting adherence to these practices, such as those addressing pre-harvest assessments, employee training, for the operation must be maintained and producible in a reasonable amount of time.*

b. *Traceability practices shall be utilized to ensure than all tomatoes are traceable to their origin, at least one step forward and one step back.*

c. *Records shall be retained for at least two years, or as required by regulation.*

Packinghouse:

All levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (immediate next recipient) and one step back (immediate previous supplier).

a. *Documentation maintained at the packinghouse shall include sufficient information about the source: (i.e. production location, lot identification, personnel/crew involved in the harvesting) as well as the customer receiving the product to allow for the appropriate tracing of product.*

b. *The packer shall have established procedures to ensure that traceability information about the source is retained with the product as it moves through the packinghouse process to shipping.*

c. *A documented recall system, including a traceability system to track tomatoes forward to customers shall be developed and tested at least annually. A record of this test shall be kept on file.*

d. All records recommended in this section shall be maintained for at least two years and be readily available.

Repacker:

All requirements of the Packinghouse, expanded to include:

a. Establish procedures to maintain lot identify of tomatoes throughout the repacking process.

a. Documentation maintained by the repacking for each lot received shall include sufficient information about the source (i.e. production location, supplier identification, lot identification) as well as the customer receiving the production to allow the appropriate tracing of product.

b. Ensure that the information is retained with product as it moves through the repacking process to shipping.

c. It is preferred the incoming lots are not mixed/commingled during repacking. However, if incoming lots are mixed/commingled, then documentation shall be maintained to identify all included sources.

d. Traceability records shall be readily available.

e. Effectiveness of these procedures shall be tested at least annually. A record of this test shall be kept on file.

b. If tomatoes lots are not mixed/commingled, then tomatoes may be repacked into their original boxes. When containers of a packinghouse supplier are to be used, and the tomatoes are removed and resorted, and returned to that clean and sanitary container, the repacker must labeled the container as being repacked, the commodity, repacker name, and provide lot identification.

c. *If tomato lots are commingled, then tomatoes should be repacked into new boxes that are clean and sanitary and accurate labeled with the repackers information and lot identification that maintains the integrity of traceability information to the include sources. In the event of a call, all lots in the commingled lot are affected*

d. *Used boxes my only be used as secondary shipping containers, provide that the original identification information on the box has been obliterated or otherwise made clear that it is no longer accurate. Use boxes may only be used as primary containers for mixed/commingled lot if they are clean, sanitary, and the original identification information on the box is still accurate to the original source of all of the tomatoes in the box*

Fresh Cut:

a. *All levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (immediate next recipient) and one step back (immediate previous supplier).*

b. *Documentation maintained at the processor shall include sufficient information about the source: (i.e. production location, lot identification, personnel/crew involved in the harvesting) as well as the customer receiving the product to allow for the appropriate tracing of product.*

c. *The processors shall have established procedures to ensure that traceability information about the source is retained with the product as it moves through the processor to shipping.*

d. *Primary and secondary containers shall be accurately labeled with commodity name, processor firm name or identification code, and lot identification sufficient to allow for accurate traceability.*

e. *A documented recall system, including a traceability system to track tomatoes forward to customers shall be developed and tested at least annually. A record of this test shall be kept on file.*

Retail/Foodservice:

a. *All levels of the tomato supply chain shall maintain traceability consistent with record keeping requirement in 21 CFR part 1, subpart J (1.326 – 1.368). Distributors to direct-to-consumer retail and foodservice operations shall maintain traceability to a minimum of one step back (immediately previous supplier) and one step forward (immediate next recipient). Direct-to-consumer retail and foodservice operations shall maintain purchase records that will facilitate traceability.*

b. *Each facilities ability to comply with the above (12.a) shall be verified at least annually. A record of this verification shall be kept on file.*

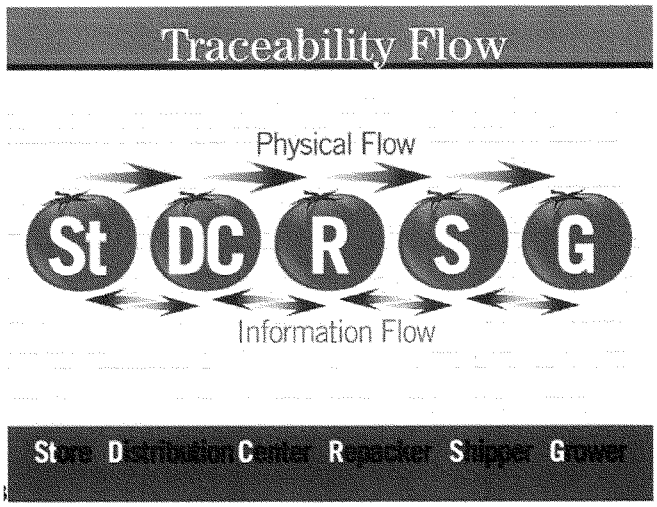
c. *All records recommended in this section shall be maintained for at least six months and be readily available.*

d. *Recognizing that bulk tomatoes may be commingled in a display, in the event of a recall, all lots in the commingled lot are affected.*

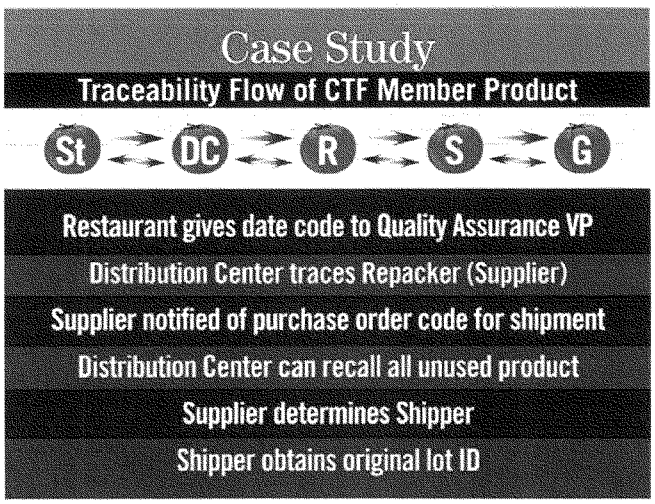
EXHIBIT C

Trace Back Case Study as Conducted for the Investigative Staff

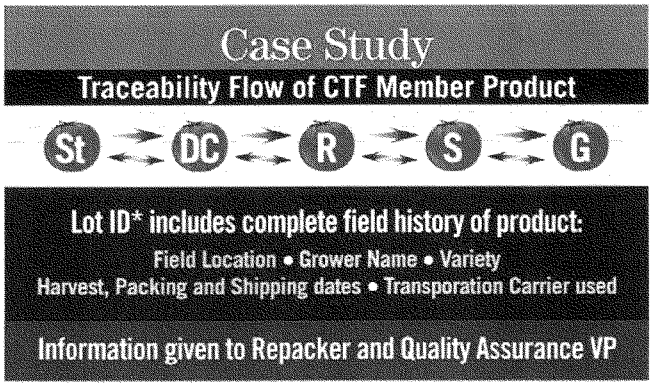
Slide One



Slide Two



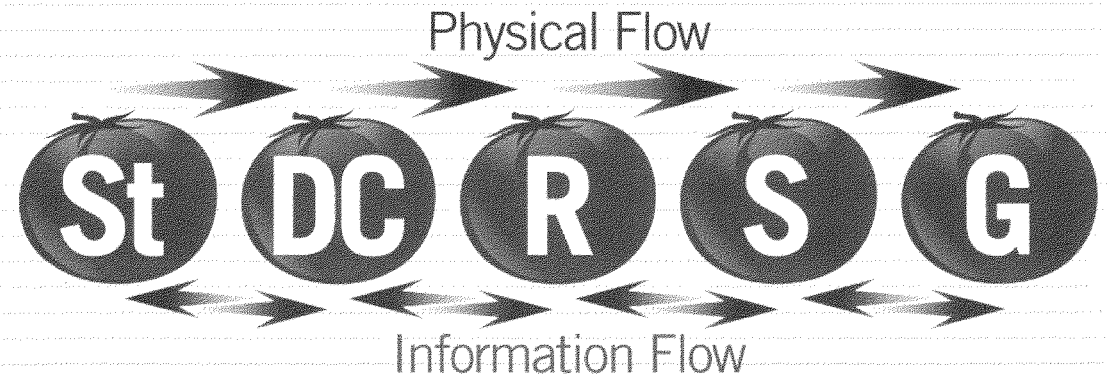
Slide Three



TOTAL TRACE-BACK TIME: 35 minutes

*Lot ID can also trace forward

Traceability Flow



Store **D**istribution **C**enter **R**epacker **S**hipper **G**rower

Case Study

Traceability Flow of CTF Member Product

Restaurant gives date code to Quality Assurance VP

Distribution Center traces Repacker (Supplier)

Supplier notified of purchase order code for shipment

Distribution Center can recall all unused product

Supplier determines Shipper

Shipper obtains original lot ID

Case Study

Traceability Flow of CTF Member Product

St → DC → R → S → G

Lot ID* includes complete field history of product:

Field Location • Grower Name • Variety

Harvest, Packing and Shipping dates • Transporation Carrier used

Information given to Repacker and Quality Assurance VP

TOTAL TRACE-BACK TIME: 35 minutes

*Lot ID can also trace forward

Mr. STUPAK. Thank you, Mr. Beckman.

Mr. Booth, an opening statement please, sir.

STATEMENT OF PARKER BOOTH, PRESIDENT, DELTA PRE-PACK, INC. AND ACE TOMATO CO., INC.

Mr. BOOTH. Thank you. My name is Parker Booth and I am President of Delta Pre-Pack, a repack company, and Ace Tomato Company, Inc., a grower, packer, and shipper of tomatoes. Both entities are part of the Lagorio Family of Companies based in Manteca, California. Today, while farming over 10,000 acres, 3,000 of those acres are planted with a wide variety of tomatoes.

Thank you, Chairman Stupak, Ranking Member Shimkus, and members of this subcommittee for the opportunity to testify before you on the topic of traceability within the fresh tomato industry and the impact this outbreak investigation has had on our two companies.

A critical component of a food safety program is having the ability to trace where the product we pack for our customer comes from all the way back to the field. Trace-back is not a passive process for any company, it must be aggressively managed every step of the way. This process requires a commitment from top to bottom within an organization with a culture of accountability, not matter what the size of the company may be.

Trace-back from our customer to the field can rapidly be completed using existing software programs. As a grower and shipper and also as a repacker we are required to conduct mock recalls that test our ability to trace-back product. Trace-back is not an option, it is a requirement of doing business and it works.

I want to show you an example of a box that we had with our investigator team that came out just last month. And it has on it the markings. You probably cannot see it from your seat there. But the essence is from looking from the left side as the lot number. There is a lot number 23. There is also our State, Federal I.D. code which is the number for our shed which tells us that is who packed it. And finally on the far right-hand side is the date that we actually packed the product.

The lot code which is on the far left, number 23, is the essence of the trace-back. This is the number that starts everything. So when we actually harvest a field we identify and label that particular field with a lot number. And that is what goes through the whole process.

This is information—there is no way you can see this—but this is documentation paperwork that actually supports that, from pallet tags to lot I.D. numbers. And this is the information that will go all the way to a distribution house, all the way to a retail store, or all the way to a national chain distribution with this information.

Although Ace Tomato Company was not in production at the onset of this outbreak, Delta Pre-Pack was marketing fresh tomatoes from both Mexico and Florida. The financial consequences of the inconclusive FDA trace-back increased greatly as the Center for Disease Control expanded their warning beyond the original states into Mexico and Texas. As the warning was expanded to all 50

States our suppliers in Florida and Mexico were considered suspect, as they remained within the scope of FDA's investigation.

We have full confidence in our suppliers as we apply the same standard to the product they grow as we place on our own selves. It is important to note that we work closely each year with our growing partners along with our customers calibrating our food safety standards. This means we are on site in the fields, in the packing sheds verifying protocols we have established in an effort to gain agreement between ourselves and our customers that the supply chain is as safe as possible. But that confidence was not sufficient to retain our customers. Due to blanket warnings by the FDA that Mexico and Florida were not safe our customers were forced to require that we source from other states outside of our normal supply chain. In effect, we moved away from the supply chain that both our customers and ourselves had worked hard to ensure was as safe as possible. In effect, money, the money and resources we invested in our food safety efforts went for naught.

Consequently, in the first week alone we had to dispose of several hundred thousand dollars worth of perfectly good tomatoes, with the total impact from the 2-month outbreak still being tallied.

As a grower, shipper, and repacker of fresh tomatoes, we urge that Congress address the economic significance to all levels of the tomato supply chain that broad-based warnings may have unfairly associated safe tomatoes with food-borne illness. Consideration needs to be given to the development of a more effective warning system that would allow companies to assess their particular positions much further in advance as information from the investigations are being collected.

There is a critical time early in the suspected outbreak where the industry can provide supplemental guidance to the government investigative efforts in order to obtain quicker answers. This industry support could be from a panel of industry advisors whose purpose would be to work closely with the FDA to gain them a better understanding of our industry's distribution system before an outbreak occurs and to provide guidance during any future investigation. As it is, we caused undue alarm to consumers of fresh tomatoes and undue financial hardship on an industry that contributes better than $1 billion in sales to the U.S. economy each year.

This concludes my testimony and I welcome any questions that the Committee may have.

[The statement of Mr. Booth follows:]

Testimony of Parker Booth

President

Delta Pre-Pack, Inc. and Ace Tomato Co, Inc.

Before the

Subcommittee on Oversight and Investigations

House Committee on

Energy and Commerce

July 31, 2008

Introduction

My name is Parker Booth, and I am the president of Delta Pre-Pack Co. Inc. and Ace Tomato Company, Inc. Both entities are part of the Lagorio Family of Companies based in Manteca, California. Today, while farming over 10,000 acres, the Lagorio Family of Companies, still owned and operated by successive generations, is an industry leader for providing safe, fresh and delicious fruits and vegetables in North America and Asia. Of the 10,000 acres farmed, 3,000 acres are planted with tomatoes with the remaining acreage planted with olive trees, walnuts, wine grapes, wheat, and cherries.

Thank you, Chairman Stupak, Ranking Member Shimkus and members of this Subcommittee for the opportunity to testify before you on the topic of traceability within the fresh tomato industry.

I would like to provide insight into how a vertically integrated company handles its food safety program as it relates to traceability. But first I will provide an overview of our two companies.

The primary business of Ace Tomato is the growing, packing and shipping of fresh tomatoes to markets in North America. These tomatoes are grown between the months of July 1st and November 1st in the San Joaquin Valley of California and are of the mature green, vine-ripe, roma and grape varieties. Ace Tomato ships product to various market segments including wholesalers, fresh cut processors, produce distribution companies and repackers while also selling directly to our Delta Pre-Pack operation.

Delta Pre-Pack, in operation since 1985 and also located in Manteca, California, markets an extensive year-round supply of fresh fruits and vegetables. Our Delta Pre-Pack Company is a vertically integrated company that primarily repacks fresh tomatoes into various fruit sizes, pack sizes and stages of ripening. These specifications are dictated by our customers through orders that are given to us prior to packing. Delta Pre-Pack's market segments include export, retail, broadline foodservice suppliers, fresh cut processors, and produce distributors. Delta Pre-Pack sources product from California during the summer months and from Mexico and Florida during the winter months. We have, however, one standard for all tomatoes that we handle whether they are our own or are sourced from other growers in the United States or Mexico. And we employ the same level of traceability on tomatoes that we purchase from others or those we grow in California.

Traceback Protocol

For any trace back program to be effective, there must a strong food safety process in place. Both Delta Pre-Pack and Ace Tomato have a long-established food safety program. We have established dedicated resources to manage and to ensure that we have maximum compliance in all facets of the program. We have a culture within our company that creates and maintains accountability in the maintenance of records both

from within and from our supply chain partners.

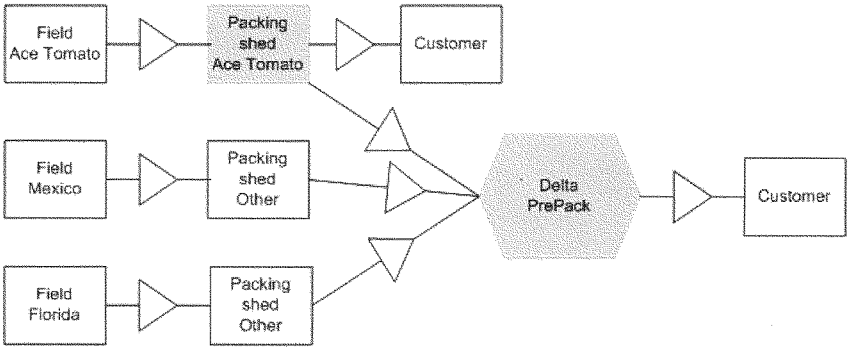
The customer base that we supply our products to today requires that we have a robust system that meets not only government regulations but goes higher in terms of food safety requirements. We are members of California Tomato Farmers (CTF), a producers' cooperative formed in 2006, which has adopted mandatory good agricultural practices and requires government inspections on our farming and packing operations. There is no margin for error under these standards. If at any time any facet of our operations is found by the inspectors of the California Department of Food and Agriculture (CFDA) to not meet the standards set forth by CTF and the audit checklist designed by the United States Department of Food and Agriculture (USDA), we must develop a compliance program to correct any deficiencies and are then subject to re-audit.

We are audited by numerous third party auditors throughout the year to verify our compliance with recognized good agricultural practices and good manufacturing practices. Results are posted and performance levels must be achieved to continue business with our customers. There is total accountability to perform. And failure to perform puts our company and our established history as a supplier of fresh tomatoes at risk. And our efforts to set a higher standard for food safety do not translate into a premium for our product given that the market is largely based upon supply and demand. And we have no input into the price the consumer pays for our product. That is a price determined by our customers. The extra costs we incur on behalf of the safe production and marketing of our product are a cost of doing business – one in which we strongly believe.

Traceability Protocol

A critical component of a food safety program is having the ability to trace where

the product we packed for a customer comes from - all the way back to the field. Trace-back is not a passive process for any company - it must be aggressively managed during every step of the process. This process requires a commitment from top to bottom within an organization with a culture of accountability no matter what the size of the company may be. Figure 1.0 documents the flow of tomatoes through our companies to our customer. Our customer is not the consumer but other wholesalers or distributors.



It is important to note that we purchase product from California, Florida and Mexico, and we treat our growing partners with the same level accountability as our own fields. Our growing partners are some of the best in our industry in terms of food safety practices and the commitment to maintain the highest standards for our customers. All product we handle must meet a common standard, as product may flow from any of a

number of sources, but with the same end point – our customer. In the narrative that follows, I will document recordkeeping requirements of our companies:

Delta Pre-Pack Traceability Requirements

As a repacker, Delta Pre-Pack may repack our own tomatoes or, as noted, during times that Ace Tomato is not in production, we may repack tomatoes produced by other growers. We employ a number of measures to ensure traceabilty:

Date Code Requirements

1. Good Manufacturing Practices require the meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or re-packing activity.

2. The code date is utilized to facilitate positive lot identification and the isolation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

3. Records should be maintained for a period of time beyond the expected shelf life of the product, but need not be retained for longer than two years.

Date Code

1. The unique TAG ID number of between four and six numbers contains the following important information: The date we processed the lot and the information necessary to identify from our purchase order the sellers ID lot and purchase dates.

2. Repacked produce into new containers will have printed stickers or a stamp applied to the container with the unique lot number that can be traced to the shipper and back to the origin.

Placement

1. Every package and/or case of product will be identified with the appropriate I.D. code. It will be legible, easily located so as not to confuse it with any other sequence of

numbers or letters placed on the package and/or carton.

2. The lot number will be entered on all appropriate quality control records, production reports, and shipping forms, so that the product can be traced at a later date if necessary

Ace Tomato Traceability Requirements

Product Date Code Requirements

1. Good Manufacturing Practices require the meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or re-packing activity.

2. The code date is utilized to facilitate positive lot identification and the isolation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

3. Records should be maintained for a period of time beyond the expected shelf life of the product, but need not be retained for longer than two years.

Date Code

1. The product code contains 3 important pieces of information:

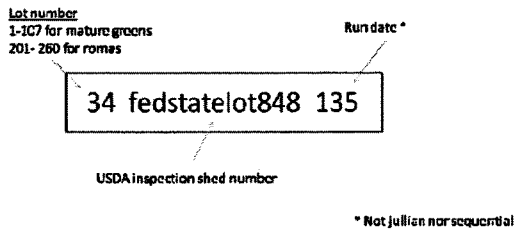
- The date the product was processed. (date code)
- The identity of the ranch that produced it. (lot number)
- Federal State Lot number (packing facility)

2. The Ace Tomato Co. Inc. code date is composed of the pack date that is unique to our company. The first, second and third digits comprise the pack date; 100 for the first run day and 1 will be added for each day packed after and is unique to Ace Tomato Co. Inc.

3. The Ace Tomato Co. Inc. lot number comprises a unique one to three digit number that identifies the ranch, field, planting and variety.

Product Traceability

Ace Tomato Code Label



Placement

1. Every package and/or case of product will be identified with the appropriate code date. It will be legible, easily located so as not to confuse it with any other sequence of numbers or letters placed on the package and/or carton.

2. The lot number will be entered on all appropriate quality control records, production reports, and shipping forms, so that the product can be traced at a later date if necessary.

Steps Taken to Trace and Recall Product

A trace back can be initiated by receiving notification of a potential problem with any box of tomatoes we handle. The entire process can take only minutes using existing software programs. Once the invoice file number is attained from the customer, the following procedures and steps are required to complete the trace back. Access to electronic recordkeeping using *Famous Software*, used extensively in the fresh produce industry, is the basis for illustrating the systems employed by Ace Tomato Company and Delta Pre-Pack.

The following screens are to be accessed:

- Invoicing & Accounts Receivable
- Daily Work
- Order Inquiry

Step One: Enter the invoice number in the order field at the bottom of the order inquiry screen.

Step Two: Select the body option under "view" and details option under "body view". All purchase order numbers will appear for the shipment in question in the middle of the screen. Take the purchase order number and proceed to the purchase order module in *Famous* as outlined below:

- Purchase Orders
- Purchase Order Inquiry
- Enter the six digit Purchase order number at the bottom of the screen and click on order under "show" and order details under "view".
- Print the Purchase Order Inquiry screen, which will provide you with both the supplier of the product as well as their purchase order number representing their shipment to us.
- With the information above you will be able to retrieve from the files the bill of lading and the invoice to us from the shipper from which we received the product.
- Contact the shipper to acquire other requested pieces of information by our end user not previously supplied to us by the shipper (i.e., grower, lot #, location of field, harvest date, pack date, etc.) Once this information is gathered, trace back has been completed.

Trace Back Analysis

Trace back, from customer to the field, can rapidly be completed using existing software programs. As a grower and shipper, and also a repacker, we are required to conduct mock recalls that test our ability to trace back product. Trace back is not an option; it is a requirement of doing business. We are able to efficiently and effectively trace back tomatoes that we repack at Delta Pre-Pack whether the tomatoes are produced in California, Florida, or Mexico. There is no variation in our ability to trace back product based upon the origin of the tomato. In the event of any commingling of product, we are able to use the same system and electronic software to track the origin of all finished product to the original grower.

The length of time required by the United States Food and Drug Administration (FDA) to trace the origin of tomatoes that were initially associated with the current salmonella outbreak is disturbing. As a grower, shipper and repacker of fresh tomatoes, we are keenly aware that traceability of fresh tomatoes is certainly possible using existing technology. If FDA's trace back was delayed due to any individual company failing to comply with the Bioterrorism Act that is a failure of that individual company. It is not indicative of the failure of the tomato industry to maintain traceability. It is not indicative of an already established system failing. It is indicative of an individual failing to maintain accountability. Those individuals should be held accountable for their actions.

As is, the integrity of the trace back systems employed in the fresh tomato industry has been questioned by FDA. We challenge FDA's assessment and would ask that an investigation be held into the practices employed by the agency and whether the agency took into consideration the established systems now employed by the fresh tomato industry. As noted, traceability is a requirement of doing business. It is not an

option for us. And I can only assume we are not alone in our position on traceability, given that our customers demand it. If we cannot meet the demands of our customers, we risk losing that customer to a competitor, and there are many within the fresh tomato industry.

The Financial Implications of FDA's Trace Back

Although Ace Tomato Company was not in production at the onset of this outbreak, Delta Pre-Pack was marketing fresh tomatoes from both Mexico and Florida. The financial consequences of the inconclusive FDA trace back increased greatly as the Center for Disease Control (CDC) expanded their warning beyond the original states of New Mexico and Texas. As the warning was expanded to all 50 states, our suppliers in Florida and Mexico were considered "suspect" as they remained within the scope of FDA's trace back. We have full confidence in our suppliers as we apply the same standard to the product they grow as we place on ourselves. It is important to note that we work closely each year with our growing partners along with our customers calibrating our food safety standards. This means we are on-site in the fields and in the packing sheds verifying the protocols we have established in an effort to gain agreement between ourselves and our customers that the supply chain is as safe as possible. But that confidence wasn't sufficient to retain our customers. Due to the blanket warnings that Mexico and Florida were not safe, our customers were forced to require that we source from other states outside of our normal supply chain. In effect, we moved away from a supply chain that both our customers and ourselves had worked hard to ensure was the safest possible. We had to dispose of several hundred thousand dollars worth of perfectly good tomatoes. And, at a moments notice, we sourced California tomatoes – from a competitor of ours – to fill our customers' needs and at greatly added expense. And now

months later, there's strong evidence to conclude that tomatoes are not the source of this outbreak. While we can appreciate the need to maintain the safety of the food supply, we cannot help but ask what steps will be taken to prevent this from happening again?

Recommendations to the Committee

As a grower, shipper, and repacker of fresh tomatoes, we are mandated to maintain traceability. It is required not only as condition of our membership in California Tomato Farmers but also under the Bioterrorism Act of 2002 and by our customers. We believe that the FDA's public comments related to complex traceability of the fresh tomato industry warrant further investigation by a joint industry/government task force to ascertain what inadequacies were discovered or perceived by FDA.

As a grower, shipper, and repacker of fresh tomatoes, we support the need to maintain traceability throughout the supply chain. Existing technologies are sufficient to maintain traceability, however, this requires recordkeeping by all who handle fresh tomatoes including end-users. There is a need for mandated regulation at all levels not simply directed at the grower and shipper. As a member of California Tomato Farmers, we have already documented our support of mandatory standards. We recommend that Congress consider the mandated food safety programs established by the fresh tomato industry in response to the need to strengthen existing trace back systems.

As a grower, shipper and repacker of fresh tomatoes, we urge that Congress address the economic significance to all levels of the tomato supply chain from broad-based warnings that may unfairly associate safe tomatoes with foodborne illness. Consumption of fresh tomatoes averages nearly twenty pounds per person annually in the United States. In its proper perspective, this means nearly all of us eat one serving of fresh tomatoes each week. As one of the most popular fresh produce items, tomatoes will

always come under scrutiny in any food safety outbreak simply due to the statistical probability that we've all had a tomato to eat. As you know, there has been no conclusive evidence that tomatoes were the source of this most recent outbreak. Steps must be taken to ensure that if tomatoes are not conclusively found to be a source of this outbreak that the tomato industry is cleared of any association with this most unfortunate outbreak. And that in the future, consideration is given to the development of a more effective warning system. As is, we've caused undue alarm to consumers of fresh tomatoes and undue financial hardship on an industry that contributes better than one billion dollars in sales to the United States economy each year.

This concludes my testimony and I welcome any questions that the Committee may have. Thank you again for this opportunity to testify before you.

Mr. STUPAK. Thank you.

Mr. Stenzel, your statement please, sir.

STATEMENT OF THOMAS E. STENZEL, PRESIDENT AND CHIEF EXECUTIVE OFFICER, UNITED FRESH PRODUCE ASSOCIATION

Mr. STENZEL. Good morning, Chairman Stupak, Ranking Member Shimkus, and members of the Committee. My name is Tom Stenzel. I am President and CEO of United Fresh Produce Association, a total supply chain association representing the fresh produce industry, multiple commodities from grower, packer, shipper all the way through retail and restaurant.

Let me broaden my testimony a bit now from specifically the tomato industry but speak on behalf of our entire sector in fresh produce. We are totally committed to food safety and hold ourselves to rigorous standards in growing, handling, packing, and tracing our fresh foods. We strongly support federal oversight, mandatory federal oversight of commodity-specific risk-based rules.

This outbreak also shows us that government and industry alike have not spent sufficient time in the investigation process after an outbreak as we are spending in prevention of those. Today I want to broaden the conversation a bit to some of the lessons I think we can learn from this investigation and hope to engage in a dialogue with the committee about some of these issues.

Number one, there is no one in charge. Throughout the investigation it became clear that no one was in charge, leaving local, State and federal officials blind for leadership, various agencies pursuing different priorities, and well-meaning individuals reacting independently to events rather than part of a coordinated investigation moving forward in a logical and expeditious manner.

We recommend that Congress require a command and control structure with a clear chain of command, take the guesswork out of who is in charge, drive real accountability and authority into this process.

Second, we need better crisis preparedness and transparency in the process. The dispute today over the validity of early work by the states and CDC with food recall surveys in which tomatoes were indicted could have been avoided with properly vetted and peer-reviewed epidemiological tools ahead of time. Instead we find CDC rewriting questions that they asked consumers in the middle of the outbreak and not sharing that data broadly.

Even when FDA tried to do the right thing by creating a cleared list of regional tomato production areas it was responding logically to the fact that many areas were not in production. But the cleared list became problematic and there was no easy way to explain how to get on the cleared list. Individual States were left having to call FDA to advocate for their areas of production. And there is a serious question of equal treatment for all producers.

And there was constant confusion about what data could be shared with industry and what could not. We went weeks asking for simple data such as the onset of illnesses, the geographic patterns of illnesses. We could have used knowledge from our food distribution systems to help in that process and were told the data simply was not available.

Number three, the current system does not use expertise outside of the agencies that is available. Let me first say that industry input needs to be transparent and squeaky clean. We are not asking to run the investigation. But there is an abundance of knowledge in the industry about specific commodities, growing and handling practices and distribution systems, as you have heard from my colleagues, that can help protect public health.

As this outbreak expanded to dozens of states around the country we knew very early that it was highly unlikely that a single contamination point for tomatoes was possible, whether a single farm, packer or repacker. But industry's knowledge was ignored when it could have helped shift attention quickly to some other product, perhaps jalapeños.

The FDA and CDC should also welcome outside expertise not just from industry but also from academia, from USDA and state departments of agriculture.

Number four, we believe government is ill prepared to make complex risk/benefit decisions in the food area. Every health or safety regulatory decision requires an assessment of risk and benefits. Yet in the case of food-borne disease FDA and CDC seemed ill prepared to grapple with risk management other than an all or nothing approach. This leads to the extreme measures of banning all tomatoes or banning all jalapeños in the quest for zero risk. But is it really zero risk when 99.999 percent of the tomatoes available in the market are perfectly safe and we are scaring consumers away from a high-lycopene product that can protect against prostate cancer? There is another part of public health that we have to take into account here as well as the concept of talking about the entire tomato supply.

Finally, the risk communication process that is in use is unacceptable. These are tough issues. They are tough to explain. But how many times have we listened to CDC and FDA media calls where the first 5 minutes was explaining there is nothing new in the investigation and the next 55 minutes are explaining and speculating about what may have happened, what may be happening, what may be plausible, what may be theoretical, but not what the facts are. Yet any risk communication expert would advise precision and care in communicating exactly what you want to say and not speculating beyond what is known.

Mr. Chairman, much of the discussion today I think is going to focus on traceability. I would like to add some perspectives on that perhaps in the question session. My colleagues I think have shown you some of the industry experience with traceability. Frankly, we are confused. We do not understand where some of the problems the FDA is reporting in our system so it is something that we really do want to address.

Thank you.

[The statement of Mr. Stenzel follows:]

Prepared Statement

Thomas E. Stenzel
President and CEO
United Fresh Produce Association
Washington, DC

Before the
U.S. House of Representatives
Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

July 31, 2008

Good afternoon Chairman Stupak, Ranking Member Shimkus, 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 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 safe and healthy produce while failing to properly identify the narrow source of contamination, and damaging, of course, to the entire tomato industry and more recently, the jalapeño pepper sector.

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, and market 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 effectively track fresh produce from the retail store or restaurant all the way back to the farm.

As you also know, our association strongly supports mandatory, commodity-specific good agricultural practices and good handling practices for those items where experience has shown a certain level of risk. Commodity-specific food safety practices are a vital part of preventing contamination in the first place, and our commitment to these principles is well known on Capitol Hill and at the FDA.

Yet, as I look at the flaws in this outbreak investigation, I am left with the bittersweet observation that our priority has been almost exclusively on *prevention* of foodborne disease from the farm up through the distribution chain, rather than management of outbreaks after they occur. Or course that is a good thing, as industry has implemented

best agricultural practices for tomatoes, leafy greens, and other products to prevent contamination, and devoted extensive resources to auditing systems to measure compliance against these standards. What we have *not* done, however, is spend a commensurate amount of time on how best to investigate and manage an outbreak when it does occur.

Let me suggest an analogy to a forest fire. Both government and industry have focused our attention on preventing forest fires, but sometimes lightening strikes and sets off a fire despite our best efforts at prevention. Then, it's just as important that an expert, well-prepared, and well-drilled firefighting team can leap into action and rapidly contain the fire. Judging from our experience in this outbreak investigation, we have all failed to pay as much attention to fire-fighting. It is time for government, industry and all stakeholders to figure out how we can better fight a fire – or a foodborne disease outbreak – to both protect public health and minimize damage to consumer confidence and industry profitability.

Today I want to comment on five lessons that I believe are important for improving outbreak investigations in the future. These observations are not intended to attack any agency or individual personally, or suggest that anyone has not given their best in what has been a frustrating and complex situation. But I do believe the system in which we have all been operating has fundamental flaws, and I want to address those issues directly.

1. There's No One in Charge

Throughout this investigation, it's become clear that no one is in charge, leaving local, state, and federal officials vying for leadership; various agencies pursuing different priorities; and well-meaning individuals reacting independently to events rather than as part of a coordinated investigation moving forward in a logical and expeditious direction.

The diffuse responsibility for public health in outbreak investigations is something that Congress must look at intensely. Local and state governments are usually first to discover illnesses, and are free to draw their own conclusions and issue press releases at any time. We suspect initial state pronouncements about tomatoes being the cause of this illness, even down to suggesting which grocery stores were involved, forced federal hands to jump on board before they were certain. But how can CDC or FDA stand by when a state seems to be "more protective" of its citizens? Yet, not just today's experience but past history shows us that premature mistakes have consequences. When local officials first blamed strawberries for a cyclospora outbreak in the mid 1990s, their advice may have actually pushed consumers to eat more contaminated raspberries that were eventually found to be the cause.

The diffuse responsibility continues at the federal level, even within the Department of Health and Human Services. CDC has the "official" responsibility to determine what food vehicle is the cause of an illness. FDA must wait on the scientists at CDC to make that call, only after which FDA staff are responsible for the traceback investigation. The tension between CDC and FDA in this case has been palpable to most outside observers, only to heighten as it became more and more clear that tomatoes were likely never involved in the outbreak. Lack of a true chain of command brings lack of accountability, and a rush to protect one's own turf or reputation.

Even in the investigation itself, field investigators are all over the map. Some are FDA field staff employees, some CDC, some state, some local. From what I understand from my members, the interaction with these agents is equally across the board. Some are great and know what they're looking for. Others seem to have no idea of what their mission is or how to best go about a traceback.

Suffice it to say, outbreak investigations today do not resemble a well-prepared, well-organized, or well-drilled team of firefighters operating as a cohesive unit to contain a wildfire.

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

2. We Need Better Crisis Preparedness and Transparency

Crisis planning should be done in advance of a crisis, not learned on the job. Let me share three examples.

One of the most important parts of this investigation was the original work by states and CDC with food recall surveys among ill people, CDC's first case control study that showed the strongest association with fresh tomatoes, and its second case control study that showed a greater association with jalapeños. From what we understand, these food questionnaires were adapted for each use, and actually were changed from the first case control study to the second. Did the questionnaire design allow an inaccurate conclusion about tomatoes – which happen to be consumed by 80% of the population at large – and fail to tease out chopped up jalapeños as a sometimes hidden ingredient in tomato-based food dishes? Was the second survey designed better to get at that distinction? Were the food surveys appropriate for the demographics of the ill consumers? Today, these facts are all open to second-guessing, not only because we now know tomatoes were not the sole cause of illness (or perhaps any cause at all), but because no one outside of CDC knows how these studies were conducted. Could there not be consistent food survey protocols set in advance, peer-reviewed by expert epidemiologists outside government, and kept at the ready for a case like this? One might even have a design for Spanish-speaking consumers, or other demographic groups, that are vetted and tested in advance for reliability.

The next example pains me, because it's a case of FDA trying hard to do the right thing, but just not knowing how to do it. When FDA began a "cleared list" of regional tomato production areas, it was responding quite logically to the fact that most tomatoes were not involved in the outbreak. If a farm was not producing tomatoes back in April or May, it could not have been the cause. But the "cleared list" rapidly became problematic as there was no system in place explaining how to get on the list, what geographic boundaries were appropriate and whether there was equal treatment of trading partners, nor even if it was still an appropriate "safe list" as illnesses continued. I'll suggest later that there simply has to be a system to narrow concerns and not effectively ban entire commodity group through public warnings, but those systems need to be well thought out in advance of a crisis, not invented on the fly.

Last, let me talk about data sharing between CDC, FDA and industry. There has been constant confusion about what data could be shared and what could not, as industry has tried to help solve this case. We've been denied data such as the epidemiologic curve showing onset dates of illnesses, the geographic pattern in which illnesses occurred, and the details of CDC's case control studies, citing reasons from state ownership of the data, privacy concerns, or simply that this is an ongoing investigation. Yet, weeks later an official would share the same data we had been denied earlier, or even post it on the CDC website. Could we have helped solve this case with better understanding of how and where people got sick – darn right. But I'm not even arguing that point quite yet. We just want to know

what the rules are for data sharing – in advance – so everyone at CDC, FDA, academia, consumer groups, and anyone else all have a common understanding. That's a matter of being prepared.

Recommendation: Whatever command-and-control structure is put in place for outbreak investigations, plan it, implement it, and test it before a crisis. Take the recommendations from all stakeholders and build a system – in advance – that government and industry alike will follow in the future. Our association teaches workshops on crisis management and our members do recall and traceback drills all the time. We stand ready to cooperate with government in planning and testing overall traceback investigations.

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

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

When this outbreak first began, its concentration in New Mexico and Texas could logically fit with our tomato distribution system that for the most part is regional in nature. Tomatoes are often repacked on a regional basis closer to the point of final consumption to maximize quality. You'll note that none of us yelled, "It's not tomatoes," when the first reports were issued. But when illnesses appeared across many more states, we knew that it was highly unlikely that a common contamination point for tomatoes was possible, whether a farm or packer or repacker. Knowing our distribution systems, it was just not logical that all of these tomatoes could have been contaminated at a common source. FDA's tracebacks were simultaneously also proving that point, although the agency chose to characterize their results as chasing false leads, rather than recognizing the evidence before them. When FDA tracked tomatoes back to multiple farms and packers, they were actually providing strong evidence that tomatoes were not the common food source causing illnesses. Because our industry knowledge was ignored, the investigation dragged on looking for tomatoes, when it might have shifted to jalapeños much sooner. (Incidentally, once FDA began looking for the right food, they traced it back pretty effectively.)

Similarly, after asking for data on onset and location of illnesses for more than a month, finally on July 9 CDC shared some data and asked us to think about jalapeños as a possible source. We looked at the concentration of illnesses in Texas and New Mexico, compared with the relative lack of illnesses westward toward California. With large jalapeño consumption in California, but few illnesses, what did this suggest about a source of contamination? We also looked at the spread of illnesses north and east from Texas, but not so much to the west, as well as a large group of illnesses in the Chicago area but not downstate Illinois. After talking with half a dozen industry members about these distribution patterns, we communicated to FDA and CDC late that same day that if jalapeños were the cause, the distribution pattern would suggest product moving through McAllen, Texas, the eventual location where an identical positive sample was found. Now, industry opinion is not proof and we can get it wrong too, but I see no reason that government should not build that kind of outside expertise into its deliberations.

FDA and CDC should also welcome outside expertise not just from industry, but also from academia, from USDA experts who certainly better understand produce distribution systems, and even from the states themselves. 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." That sounds like the kind of expertise I would want in an investigation.

Finally, industry has other resources that could quickly be brought to bear. For example, many produce companies, wholesalers and retailers have said that when FDA has suspicion about a particular product, they would be willing to take samples from their warehouses to provide to FDA certified labs. A system to ensure the validity of samples and testing protocols would have to be put in place, but I am not aware that anyone has ever considered this type of outside-the-box thinking to help speed investigations.

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

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

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

In this case, it seems that internal agency decisions on when to warn the public, how broadly to make a warning, and what specifically to advise, are based as much on fear of being second-guessed rather than careful risk analysis. That inevitably leads one toward extreme measures – in effect banning all tomatoes or peppers – in the quest for zero risk of immediate illness. But, is such a consumer message truly without risk, when it needlessly scares the public away from a high-lycopene healthy food that may help prevent prostate cancer? If we know that 99.999% of the tomatoes in the marketplace are perfectly safe, is there not a way to craft risk decisions more appropriately.

FDA has shown a willingness to consider a different approach with its initial warning about jalapeño peppers only to the very young or old, and those who are immuno-compromised. Yet, the pressure is always there to revert to a zero-risk approach. FDA eventually felt the need to expand its warning not to consume any jalapeños whatsoever, only to find some states beginning to openly disregard its warning. That is dangerous ground, but a real consequence of losing faith in broad federal government warnings that people know are not based on reality.

We simply must develop risk management systems that can distinguish those producers or distributors who can assure the safety of their produce in the marketplace from those who cannot. FDA must find appropriate ways to advise consumers that the legal responsibility for food safety assurance lies with individual companies who offer food for sale, not the federal government. How can a grower of summer tomatoes in Michigan maintain his livelihood selling to local retailers? How can a fast food chain that knows every detail of where and how its tomatoes are grown maintain the option to keep sliced tomatoes on its burgers? How can a produce company that invests hundreds of millions of dollars in food safety stay afloat when its business is shut down the same as others who never made those investments? The unintended message to industry is don't bother investing in food safety,

if you're going to be tarred with the same brush and face the same costly consequences in every single outbreak.

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

5. Today's Risk Communication Is Unacceptable

These are complex issues indeed, and tough to explain. But I wonder how many of the committee's staff have listened to FDA and CDC media calls that go something like this – the first five minutes are spent explaining that there is nothing new in the investigation, and then the next 55 minutes are spent speculating about how the outbreak may have occurred, theories on why leads may not be panning out, hypothetical questions based on what-if scenarios, and more.

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

This also comes back to our recommendation about a clear chain-of-command – someone has to be in charge of talking with the media. The FDA and CDC speakers on these press calls fluctuate seemingly without reason other than personal availability. People's judgments vary, and they express themselves quite differently. One has the feeling that policy decisions are being made in response to media questions, rather than being well thought out ahead of time and then communicated clearly and concisely.

Even without the changing parts, these calls feature multiple spokespersons from each agency. Often, when FDA has answered a question fully, a CDC representative is invited to answer it again "from their perspective," elaborating further with a different twist. For my members who want to bash the media coverage of this investigation, I often have to remind them that the media don't usually make this stuff up.

Good risk communication is not just an art; it is a science, and a science that needs to be studied in advance and rigorously followed in outbreak investigations.

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

Conclusion

I want to thank the committee again for holding this hearing. I could not cover here every lesson from this experience, but hope I've been able to point in some positive directions. Our goal is to improve the system for the future, and that effort is just beginning.

I do believe that progress will require systemic change, not window dressing. The complex web of local, state and even competing federal agencies is not conducive to effective and efficient identification and management of foodborne disease outbreaks.

When it comes to preventing "fires," I am reasonably confident in the ability of FDA, with proper resources and leadership, to provide food safety oversight for our industry. But when it comes to "firefighting" – the complex local, state and federal effort to identify, manage, track and end outbreaks – I am more concerned about duplicative efforts, lack of system-wide planning, inefficiencies in operation, rivalries between those on the same team, and simply lack of cohesion to drive the most effective process for public health.

There are indeed consequences of our actions. You've heard many of those consequences to the industry today, both in lost income and lost confidence in future sales. But I fear the greatest consequence may be lost faith in government's ability to manage our overall food safety system. That doesn't mean Congress should overreact with knee-jerk actions, but I do believe it is time for Congress to examine these issues fully and thoughtfully to help guide real reform in how government approaches foodborne disease outbreaks.

Mr. STUPAK. Thank you.

Mr. Hubbard, we will turn to you for your opening statement. And we all talked about our ninth hearing, I think you have been here for all nine. We appreciate your work and willingness to work with us and your patience and your insight to this issue. So we look forward to your testimony, please.

STATEMENT OF WILLIAM K. HUBBARD, SENIOR ADVISOR, COALITION FOR A STRONGER FDA

Mr. HUBBARD. Thank you, Mr. Chairman. I do have written comments but I will make just a few oral ones.

It is unfortunate that we are here yet again talking about yet another failure by the FDA. And I am sorry you are having to go through that but I think the public is sorrier.

As you know, I have expressed the view that many of the problems have not been of FDA's doing, that there have been shortfalls other places that have caused FDA to be ineffective. And I think there are many issues for Congress to deal with in this particular outbreak, how the government is organized, how the FDA is organized, how federal/state relations occur, how well the industry can track and otherwise do its job. But I would like to focus my comments, if I could, just on three areas all dealing with FDA's capacities.

First, the agency's food safety resources have not kept up with the responsibility they have been given. And in fact, we have been taking down the food safety system at FDA for several years. We are reducing staff at a time in which we need people even more at the agency. We need more inspections. We need the scientists to deal with these emerging pathogens. And it has been going the other way. So I think that is a tremendous piece of the problem at FDA. By taking down a program at a time it needs to be strengthened we are simply going the other way.

But FDA also needs to be able to acquire a food process to implement a system of preventive control. We need to prevent these things from occurring, not just chase them after the fact. As you know, preventive control is a well-proven mechanism for keeping food safe in the first place from being contaminated. Mr. Dingell's bill attempts to do that. And I certainly wish you well in that effort.

You may know that FDA tried to use its existing authority last year to impose preventive controls over produce. But the Administration rejected the recommendations of the agency scientists to do that. And I think that has proven to be a grievous mistake. Just think, we could be well on our way to having regulations for preventive control for produce in effect today but essentially we are nowhere because of that denial. So I think that was a tremendous mistake. And I urge Congress to proceed with its efforts to establish a system of preventive control.

My third point relates to traceability. When Congress enacted the Bioterrorism Act in 2002 it intended to give the agency the authority to track these products so that you would have a rapid ability to follow up on a potential terrorism attack throughout the supply chain. But instead of having a robust recordkeeping system that allowed for rapid access to complete records by all partici-

pants, the agency got, ended up with delayed access to partial records from only some elements of the supply chain. So we have weakened those regulations tremendously.

And I think the Salmonella incident demonstrates how the weakening of those rules essentially negated the intent of Congress.

So just imagine, Mr. Chairman, if the Salmonella outbreak had been a terrorist attack and thousands or hundreds of thousands of people had been at risk from death and disease how much of a failure those rules, that recordkeeping requirement would have been. And I think we need to look at in that context for future consideration.

Now, the good news is, as Ms. DeGette and others have said, there are effective technologies available to provide for successful trace-back. Some produce firms have demonstrated it. But the problem is we are only as strong as our weakest link. And those small firms that have not been able to do effective trace-back I think need to be addressed. So the means are available to improve the situation. And I hope you will be a strong supporter of those means.

Now in conclusion, Mr. Chairman, we talk a good game about food safety. We say we care about it, we say we are going to do more, but we just have not backed it up, that rhetoric up with necessary support in my view for FDA. I do not believe we can make FDA an effective agency without giving it additional resources and authority. These problems that we are talking about are they going to keep going? We are going to have more of these outbreaks? This is going to be an endless process until we fix the system. So I hope Congress will agree with those and move to make it so.

And thank you for giving me the opportunity, Mr. Chairman, to prevent those views.

[The statement of Mr. Hubbard follows:]

Statement By

William K. Hubbard

Alliance for a Stronger FDA

Before the

Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

United States House of Representatives

Washington, DC

July 31, 2008

INTRODUCTION

Mr. Chairman and members of the Committee, I am William K. Hubbard. Before my retirement after 33 years of Federal service, I served for many years with the U.S. Food and Drug Administration, and for my last 14 years was an FDA Associate Commissioner responsible for, among other things, FDA's regulations and policy development. Today, I serve as an advisor to The Alliance for a Stronger FDA, a consortium of patient, public interest, and industry organizations whose mission is to urge that FDA's appropriations be increased. The Alliance and its constituent members are greatly concerned that FDA's resource limitations have hampered the agency's ability to ensure the safety of our food and drug supply. Today's hearing is focused on the recent salmonella outbreak that been so costly to the public, the produce industry, and the government agencies involved, and is thus an appropriate subject for your attention.

BACKGROUND

As you know, Congress established the Food and Drug Administration in 1906 as a result of concerns about the safety of our food supply. In those days, it was common for foods to be subjected to all manner of problematic practices—filthy, unsanitary conditions were common in food processing facilities; talcum powder, sawdust and many other contaminants were added to deceptively increase the weight or value of foods; and chemical preservatives were used in food that were untested and often highly toxic. As the 20th Century progressed, FDA's scientists and those in the emerging food processing industry slowly built a food safety infrastructure for the United States that enabled us to

claim that we had the safest food supply in the world. And the standards established by the FDA for the production of safe foods became the model for protection around the globe. Throughout the last century, there was steady progress in the food safety system – in learning how to protect food from contamination and in implementing procedures to translate that knowledge into safer food production. But, unfortunately, that progress appears to have largely ground to a halt, at least when it comes to the ability of FDA to effectively oversee improvements in food safety.

And that slowdown in FDA's role –some would even say reversal – has come at the worst possible time. That is because today the need for effective management of food safety is greater than ever before, as evidenced by:

- The emergence of new pathogens, some unknown to science in years past, such as E Coli 0157:H7, that are especially lethal when they contaminate our food;
- The substantial public health and economic costs imposed on our society from the steady – and increasing – numbers of foodborne disease outbreaks in the United States;
- The steady growth in the number of domestic food producers and, even more importantly, the tremendous increase of imported food from other countries -- particularly developing countries in Latin America and Asia, where food safety standards are often lax or unenforced; and

- The increasing desire among our citizens for fresh fruits and vegetables throughout the year, necessitating a complex system of produce production and distribution, often across long distances and through many hands.

THE SALMONELLA SAINTPAUL OUTBREAK

The occasion for this hearing is, of course, the recent (and perhaps ongoing) series of cases of Salmonella Saintpaul linked to fresh produce. With over a thousand illnesses reported, and many more likely not documented; costs to the tomato industry in excess of $100M; and consumer access to one of our favorite foods seriously disrupted, it is a significant event in our national life.

The questions raised by this outbreak are numerous:

1) Is the Federal government properly organized to manage an outbreak of this nature?
2) Is the questionnaire process used by the Centers for Disease Control and Prevention, which led FDA to spend weeks seeking contaminated tomatoes, perhaps in vain, flawed as an outbreak management tool?
3) Are the various government entities involved in foodborne disease outbreaks – Federal, state, and local -- adequately coordinated?
4) Is FDA's management of food safety too fragmented, with no central focus of authority?
5) Are FDA's investigative procedures too outdated to rapidly track a major ongoing foodborne disease outbreak?

6) Did food distributors have adequate records when FDA investigators sought to trace the movement of suspect produce?

7) What are the effects of the recent budget cuts in FDA's food safety program on its ability to respond to foodborne disease oubreaks?

8) Did public health officials have sufficient laboratory capacity and rapid screening technology to quickly analyze samples for Salmonella Saintpaul?

9) Does FDA have sufficient authority to effectively and rapidly identify and control threats to our food? and

10) What if the salmonella outbreak had been the result of intentional contamination of our food supply by forces intent on harming large numbers of our citizens, or if that day does come, will we be prepared for it?

We have, as a nation, simply not demonstrated that we take the threat to our food supply seriously. We talk a great deal about the need to improve food safety, and wring our hands over each major outbreak that occurs, costing lives and industry resources. But our actions have not been consistent with our rhetoric. Let me explain.

FDA FOOD SAFETY PROGRAM DECIMATED BY BUDGET CUTS

First, there is the matter of FDA's capacity to protect the food supply. In 2003, FDA had just over 4000 field investigators to inspect our food facilities and track down problems like the current salmonella outbreak. Entering 2008, that force had been reduced to 3354, a loss of almost 700 inspectors. The cadre of food scientists in FDA headquarters underwent a 20% reduction during that time (from 950 to 782). And this occurred as the

number of major foodborne disease outbreaks more than doubled. These recent trends are part of a larger scenario over many years, in which we have declined to provide the FDA with robust capacity to oversee the safety of our food. Indeed, when I began at FDA in the 1970s, the agency inspected each of the then-70,000 US food processing facilities on average every two years. But today, we give FDA the resources to inspect the now-120,000 domestic facilities at a rate of only every decade or longer. And, of course, that doesn't count the 200,000 foreign facilities making food for our market, which are almost never inspected by the FDA.

FDA DENIED IN ITS EFFORTS TO IMPROVE PRODUCE SAFETY

Second, FDA has not been permitted to act upon its knowledge and desire to improve upon the food safety threats we face. The best recent example is its attempt to have fruit and vegetable producers adopt preventive controls for produce. Early last year, following on successful efforts to require such controls for seafood and fruit juices, agency food scientists presented to the Department of Health and Human Services a comprehensive analysis of the risks posed by contamination from bacterial pathogens on produce, and a proposal to significantly reduce those risks. In essence, they were predicting the very problems we are encountering now with the current salmonella Saintpaul outbreak. Let me describe their thinking.

- First, they listed the enormous public health problems posed by unsafe food, with CDC estimating that there are 76 million foodborne disease cases in the US each year, 325,000 of which result in hospitalization and 5,000 in death.

The economic costs to consumers, industry and the health care industry are believed to range as high as $83 billion annually

- Next, add in the fact that foodborne disease outbreaks are today averaging about 350 in number per year, as opposed to about 100 15 years ago. Then factor in the emergence of the new foodborne pathogens that are especially dangerous to the very young and the elderly.
- Also consider that fresh produce is a particularly vulnerable commodity. It is subject to contamination because it is grown in a natural environment, and further at risk of bacterial contamination via the ways we pack and handle produce. And, of course, it is increasingly attractive to consumers as a healthy product that is eaten raw (and thus not decontaminated through cooking). Tomato outbreaks from several different salmonella strains were described as a particular problem likely to reoccur regularly.
- The agency then argued that the previous voluntary efforts to protect produce had been ineffective and that a national solution, focused on preventive controls, was called for. They estimated that such interventions could cut the toll of death, disease, and economic disruption from produce outbreaks by at least 50%, and probably far more – thus saving not only lives but also hundreds of millions of dollars each year in industry losses.
- But, despite support from major segments of the produce industry, the Administration rejected the proposal, not even allowing the agency to seek public input into whether a preventive controls approach should be considered.

- If FDA's recommendation had been accepted, we would now have a proposed rule published and commented on by industry and the public, with a final rule protecting fruits and vegetables possible this year. Thus, we would have in our sights a major improvement in produce safety. But, instead, we are essentially nowhere, with any solutions years away from implementation.
- In fact, not one single food safety regulation has emerged from the FDA during this Administration (with the exception of a few specifically mandated by Congress).

FDA'S REGULATION IMLPEMENTING THE BT ACT'S RECORDKEEPING REQUIREMENT

The third and last FDA action that I will comment on today deals with the regulations governing recordkeeping by food producers. As you know, after the September 11 attacks seven years ago, Congress was concerned that the food supply could be vulnerable to terrorism, and enacted the Bioterrorism Act of 2002 (formally titled the Public Health Security and Bioterrorism Preparedness and Response Act). One provision of that statute required food firms to establish and maintain records detailing the movement of food through the supply chain, with the intention of giving FDA the ability to rapidly trace sources of contamination; and thereby blunt the potentially devastating effects of intentionally contaminated food.

Unfortunately, the transition from what was believed needed right after 9/11 to what they agency actually got months later when it promulgated its regulations on recordkeeping is

a virtual case study in how to weaken a regulation to the point of being indistinguishable from the original intent. Indeed, if we were to consider the tomato/pepper salmonella search as a test of the recordkeeping rule, I think it's fair to conclude that the grade would be a fairly clear "F." Let me explain, and in so doing describe why the old axiom of not wanting to watch laws or sausages being made can also apply to implementing regulations.

Below is a brief "side-by-side" analysis of some of the key weak points introduced into the original legislation and regulation as it was being reviewed and considered by Administration reviewers:

What FDA wanted/needed	Final Rule Provisions
Records by all sources/recipients	Farms and restaurants excluded
Foreign firms as well as U.S.	Foreign firms dropped
Complete record of a food's movements	Only "one forward, one back"
Lot numbers for each shipment	Denied
Electronic records (for speed)	Denied
Records access within 4 hours	Extended to 24 hours
Consistent record format	Denied
Authority to verify keeping of records	Denied
Authority to enforce requirement	Only (mostly enforceable) "prohibited act"

In sum, the theory after 9/11 was that the agency needed rapid access to complete and useable records of a food's origins and movements, to deter and react to a terrorist attack.

What it ended up with was a requirement for partial records, made available in no particular hurry, from some people but not others, without a requirement that a given shipment be well identified, and in a format that could (and does) include the back of a plain brown paper bag. Further, the word quickly went out among the industry that FDA could only check on a firm's adherence to the recordkeeping requirement if a food connected to the firm was the subject of a serious ("Class I") recall and that the firm was unlikely to be punished if it ignored the recordkeeping requirement entirely.

One reason that the recordkeeping requirements were so watered down was the fear that they would be too costly for the food industry, with some estimates that the rules could cost processors $140 million per year. But, of course, the produce industry lost that much in the 2006 E Coli outbreak and is on track for similar losses in the ongoing Salmonella Saintpaul investigation. While our reluctance to impose regulatory costs is understandable, it may also be contributing to an ineffective regulatory structure and, in turn, the destruction of industries that rely on regulators to make rapid and accurate decisions about public health threats.

ACCURATE PRODUCT TRACING IS ACHIEVABLE

As you may hear today, Mr. Chairman, there are technological solutions that could, if utilized, solve a big piece of the current problem – rapid and accurate traceback of a food's movement through the supply chain. We are all familiar with the fact that FedEx and UPS can tell us in real time where a package has been, is now, and will arrive at its destination. The military is using Radio Frequency Identification (RFID) technology to

track everything from tanks to toilet paper, and Walmart and other major retailers are moving in that direction. The drug industry is slowly adopting RFID tracking for their products, to protect against counterfeiting and illegal diversion. Some U.S. tomato producers are implementing track and trace systems that can track a single tomato back to the farm worker that picked it. Outside the continental U.S., food producers are using or experimenting with a variety of tracking technologies, for example,

- A Dutch pilot program for produce has just been completed, illustrating how fresh produce can be effectively tracked throughout the supply chain using RFID -- not only providing for traceability but also demonstrating how such technology can improve quality and availability of fresh fruits and vegetables.
- The Hawaii Department of Agriculture is beginning an electronic program for tracking tomatoes, onions, mushrooms and other produce that will enable producers to track the movement of their products in real time and, if necessary, to initiate a recall of some foods within minutes.
- The Canadian government has recently begun a "proof of concept" traceability program for beef and pork that will become a national standard for electronic traceability from farm to restaurant or retailer.
- The Japanese have a national traceability law for cattle that uses bar code technology to track every cow and its byproducts from birth to eventual consumption as human food.
- This year, Norway's largest food supplier will begin using an IBM-based RFID tracing system for all poultry and meat products, again, not just for

recall and traceback purposes, but to also introduce operational efficiencies and thus lower costs for producers and consumers.

While the various tracking systems in place or in development use different software and hardware, all should be able to provide the kind of rapid information that is needed to permit rapid traceback in the event of a foodborne disease outbreak. And in doing so, such systems would provide FDA with the records it needs to carry out its responsibilities. There are two keys to success in utilizing technology for effective traceback, in my opinion:

1) One is whether we will give FDA the authority to require adequate traceback information. This should be done using a performance standard approach, rather than asking FDA to choose among various hardware and software vendors, so as to allow the best technologies to be developed and implemented.
2) A second is the need to deal with the cost burden on small producers. We have seen time and gain how large food producers can implement state-of-the-art food safety and information systems. But the system is only as strong as its weakest link, and an outbreak of disease from a small producer that takes weeks to find can seriously harm an entire industry. Currently, FDA is forced to consider the effects of its actions on small producers, and that is certainly understandable, but we need to find a way to assist small producers in adopt the best new technologies for making our food safe and tracking its movement.

A NEED TO MOVE FROM TALK TO ACTION

In conclusion, Mr. Chairman, today's hearing is another in a series that you have held to highlight instances where FDA needs to improve, and I agree with your concerns that FDA is not as effective as it can and should be. In the case of food, we have a real dichotomy between our rhetoric and our action. As I noted earlier, we say we want a strong FDA and a strong food safety system, but our actions belie that stated objective. We have not given FDA the authority and resources it needs to be the agency we want it to be, and then we are critical of it when it fails to meet expectations. When I first arrived at FDA in the 1970s, the food program was one-half of the agency's budget, yet today it is less than one-fourth, despite the fact that the problems on the food side of the agency have grown in numbers and intensity over those years. And the agency's recent experience with recordkeeping and its attempt to improve produce safety demonstrate that the agency is hobbled by decision makers higher up its chain of authority that will not support the agency's efforts to do better. I sincerely hope that you will agree with my conclusions and resolve to act upon them.

Thank you for giving me the opportunity to provide my views on this subject.

Mr. STUPAK. Thank you, Mr. Hubbard.

We will begin questioning. I guess the last 12 hours epitomize how this whole investigation has gone. About 9:00, 10:00 last night we got a release from the FDA about jalapeños in Mexico. And about 10:15 we had a correction. And 8:00, 9:00 o'clock this morning we had another one. So we have had about three releases in the last 12 hours on what is going on with this investigation. Now I do not know if that is the quality of the investigation or the fact we are having this hearing here today.

But let me ask this question of this panel. Now, this investigation started out with Salmonella Saintpaul and detailing tomatoes. Has there been any Salmonella Saintpaul, Salmonella found in any tomatoes in the United States? I take it none; correct?

None? OK.

Then at the time when we started this May 22, the only State I understand that was growing tomatoes at the time would have been Florida; right?

Mr. BROWN. That is correct.

Mr. STUPAK. OK. So any other tomatoes would have had to come either from Florida or I guess Mexico would be the other source; right? OK.

Mr. BROWN. Florida.

Mr. STUPAK. I am sorry, put that up there, Mr. Brown. It would have been Florida?

Mr. BROWN. The primary source, Florida was the primary domestic supplier at that point.

Mr. STUPAK. Right. And then the other one would have been foreign countries——

Mr. BROWN. Other one was primarily Mexico.

Mr. STUPAK [continuing]. Mostly Mexico?

Mr. BROWN. And as a matter of fact, Mr. Chairman, the morning after we were informed there was concern we provided data for a period of 30, 60 days——

Mr. STUPAK. OK.

Mr. BROWN [continuing]. Prior to that where every tomato in the country came from.

Mr. STUPAK. OK. Now, we eventually get to the jalapeños, right, after Minnesota gets there. And believe it or not we got one today, OK. But Florida, Mr. Booth, you mentioned about Florida and, Mr. Brown, you mentioned it, your process you have for tomatoes, the box and all the markings. Did the FDA help you with that? I mean were they aware of your system? Did they help you develop it?

Mr. BROWN. We have had positive lot identity for round tomatoes in Florida for going on close to 20 years under a federal marketing order.

Mr. STUPAK. OK.

Mr. BROWN. We had worked with the FDA in working up on state regulatory program that we were voluntarily implementing and we now have under state regulation.

Mr. STUPAK. OK. But as of today tomatoes are still suspect; correct?

Mr. BROWN. Unfortunately.

Mr. STUPAK. Or as we call it, the vegetable of interest; right? The person of interest, it is still the vegetable of interest?

Mr. BROWN. Yes, sir. We are still indicted and convicted in the media.

Mr. STUPAK. OK. But yet we have never had any. And now we are at jalapeños from Mexico; right?

Mr. MURPHY. Do not touch it.

Mr. STUPAK. OK. I have a double dare with Shimkus, we are going to eat it yet today.

This is a box we got today. There is no markings like you had to show your area; right? All this says is "Produce of the United States, net weight 25 pounds." And just says tomatoes on it. OK, we got it at a local retailer here today.

Now, Mr. Booth, your box had those markings on it. Is it legal to use your box? I mean you ship it to, let us say you ship it up here to Washington, D.C., OK. And can a grower take that box with those markings on put tomatoes in it even it was not from Florida? In other words can you re-use that box again and again and again?

Mr. BOOTH. As long as they maintain the records.

Mr. STUPAK. OK. But they would have to wipe out the coding that you have on it?

Mr. BOOTH. They would have—when a repacker takes that they are going to have to when they repack it they are going to have to take the original lot number——

Mr. STUPAK. OK.

Mr. BOOTH [continuing]. The original information and put their own information on it.

Mr. STUPAK. OK. Now, only California and Florida have that system; right?

Mr. KAWAMURA. Yes.

Mr. STUPAK. So the other 48 States are, they can be sending boxes like this here; correct?

Mr. BROWN. Mr. Chairman, this is why the industry has stepped forward in conjunction with FDA and the——

Mr. STUPAK. Correct.

Mr. BROWN [continuing]. Research community and created this document which would resolve and solve that issue in requiring that every person in the country that grows and handles tomatoes maintains that information, passes it up.

Mr. STUPAK. So you want a federal regulation saying——

Mr. BROWN. Yes, sir.

Mr. STUPAK [continuing]. You must do it this way?

Mr. BROWN. We want a double-phase procedure——

Mr. STUPAK. Whether it is tomatoes, jalapeños, whatever it might be?

Mr. BROWN [continuing]. Because the public trust is so important to us we cannot afford to do it any other way.

Mr. STUPAK. OK. What is the cost of doing that, of putting that code on there and have that trace-backs? Can anyone give me an estimate? Because that is always a question we ask, What is it going to cost us? Mr. Booth?

Mr. BOOTH. Yes, it is——

Mr. STUPAK. Mr. Stenzel?

Mr. BOOTH. I am not sure what the cost is. In the largest——

Mr. STUPAK. Is it minimal or?

Mr. BOOTH. It is minimal.

Mr. STUPAK. It is minimal?

Mr. BOOTH. It is minimal.

Mr. STUPAK. OK.

Mr. BOOTH. Anyway, the point being is that any size firm, large or small, can do this.

Mr. STUPAK. OK.

Mr. BOOTH. It does not have to be fancy and it does not have to be expensive.

Mr. STUPAK. OK. Now, you said, Mr. Beckman, you traced back that tomato that you did in California for the staff and they learned a lot from you guys. That was all within California though; right?

Mr. BECKMAN. It was. But——

Mr. STUPAK. So what if that tomato goes to Michigan where I am from?

Mr. BECKMAN. We actually were able to produce for the investigative staff a number of trace-backs throughout the United States. That included product from California, Florida and Virginia going into multiple states. For example, one of the trace-backs was from California to Colorado.

Mr. STUPAK. How long did that take?

Mr. BECKMAN. That one took about 5 hours.

Mr. STUPAK. OK.

Mr. BECKMAN. But I can give you a story that took place yesterday if you would like?

Mr. STUPAK. OK. But the point is you can do it; right?

Mr. BECKMAN. Yes, we can.

Mr. STUPAK. And there is minimal cost?

Mr. BECKMAN. Cost actually that we can say it is a part of a business culture and it is not significant. The cost that we pay in California to validate our process runs about a penny a box.

Mr. STUPAK. OK. So let us go back to Florida, let us go back to May 22. We have Salmonella, Florida is the only place growing, but Florida has this system, right, to track everything? So if people were getting sick in New Mexico and Texas that seemed to be June 3 is when they put the place out, could they not have gone and said, OK, Florida, have you sent to Texas and New Mexico in this area, wherever it is? Could they have done that?

Mr. BROWN. Yes. They were advised in early conversations that the supply chain or supply system for tomatoes in the country is basically bifurcated by east and west.

Mr. STUPAK. Yes.

Mr. BROWN. Florida dominates the eastern supply system, the Mexican supply source dominates the western supply system. And because of the energy costs we do not move them back and forth very often.

Mr. STUPAK. Right.

Mr. BROWN. And there may have been some minimal amount of tomatoes in that marketplace but they would have been insignificant.

Mr. STUPAK. California then would have been the big supplier to Texas, New Mexico then at that time?

Mr. BROWN. Only when they come into production. And they follow us. We were at a transition zone between.

Mr. STUPAK. When does California go in production?

Mr. KAWAMURA. California had started this year on May 17 was the first field harvest of California.

Mr. STUPAK. OK. So we are on June 3, so they could have possibly been?

Mr. KAWAMURA. No. At that point knowing what the initial outbreaks as they took place we knew that California had not been in production at that time and were able to verify that with FDA at the time.

Mr. STUPAK. So why did we make tomato vegetable of interest then?

Mr. KAWAMURA. It was still a vegetable of interest throughout the rest of the production areas of the state. I know one of the early announcements from FDA was that California was not a part of this outbreak based upon the harvest schedules that we were aware of.

Mr. STUPAK. OK. Could country of origin labeling have narrowed the focus here in your estimation, anyone? Mr. Beckman, anyone, would that have helped?

Mr. BECKMAN. It could perhaps help. But the problem was that the association was with all tomatoes. And so we had a scenario where all tomatoes were suspect. And then as the safe list was produced we are essentially trying to back individual states away from an association of guilt, and that is extremely difficult.

Mr. STUPAK. So the thing we need right now from the FDA is a firm statement that tomatoes are not even vegetable of interest, they have nothing to do with this Salmonella outbreak. Because we still, if I look at the last line here, it says, "FDA announced that it has determined that fresh tomatoes now available in the domestic market are not associated with the current outbreak. As a result, the agency removed its June 7 warning." And my problem is with that is they never cleared tomatoes from the original outbreak.

Mr. BECKMAN. Correct. You are correct, Mr. Chairman.

Mr. STUPAK. So we still have the suspicion over the——

Mr. BRONSON. Well, Mr. Chairman, if I——

Mr. STUPAK. Yes, go ahead.

Mr. BRONSON [continuing]. Might as well enter in this, one of the things that we noticed very early on was when the outbreak took place in Texas and New Mexico and began to go north of there we were selling tomatoes out of Florida all over the southern United States, all over Florida, but we did not have sicknesses in Florida. So we were suspicious right then——

Mr. STUPAK. Right.

Mr. BRONSON [continuing]. That Florida tomatoes, grown tomatoes were not a part of this problem from the very beginning. And I think we need to while we have to follow the scientific method, we also should not throw away common sense and risk assessment that says if you know this is where the outbreak is the most seen there is a good chance it is coming either across the border or from within a state or two of that outbreak because the south had no cases at the time.

And the other issue, Mr. Chairman, that I would like for you to consider, because someone from Florida goes to the doctor with a sickness that ends up being Salmonella Saintpaul they may have gotten it in Texas. They should not be——

Mr. STUPAK. Sure.

Mr. BRONSON. They should not be counted as a Florida sickness because it may have been picked up while they were traveling. And that is the case in a number of these cases.

Mr. STUPAK. Well, I am looking at the CDC investigation outbreak of infections caused by Salmonella Saintpaul, dated July 29. And when you look at it they have the breakdown of 1,319 people, 1,319 people infected, only 11 are from California and 4 from Florida. So with the math of course being Texas with 502 and New Mexico 106, so I guess that proves your point.

One question and my time is way over, and I just want to ask Mr. Hubbard a question. Because we are talking a lot about traceability here and suspect vegetables or not, but let me ask you this one. On July 25 the Associated Press ran an article entitled "Food Industry Bitten by its Lobbying Success. Companies Oppose Electronic Tracking that Could Locate Outbreak Source." The gist of this article is that there were some with the FDA that were advocating a much stronger recordkeeping and trace-back system than what we currently have today underneath the Bioterrorism Act. However, due to heavy pressure from industry many of the requirements were watered down.

Mr. Hubbard, you were an associate commissioner of policy at the FDA at that time. What systems were being proposed? And how did these systems differ from what we are using today or what we have seen in California and Florida?

Mr. HUBBARD. Well, as I said, I think the agency wanted a lot of the things that folks are talking about here now: lot numbers, rapid access, recordkeeping throughout the chain. I will not deny that the industry may have had a "Come to Jesus" moment in recent years, but in 2003 the message from the industry to the Office of Management and Budget which was reviewing the regulation was too expensive, too hard, do not do this.

So again I am very gratified to hear the progress that has been made, but when FDA was doing its regulations it was being literally hammered for proposing things that were viewed by many members of the industry as too much.

Mr. STUPAK. One more. Mr. Beckman, did it not really say, tell our staff that to do that tracing on that box there is it not like a penny a box?

Mr. BECKMAN. It is a penny a box for the verification. The actual costs are, again, insignificant.

Mr. STUPAK. OK. Mr. Shimkus for questions. Thank you, gentleman.

Mr. SHIMKUS. Thank you, Mr. Chairman. Good round of questions. Maybe we should go ten minutes one round or whatever, so. Whatever.

But it is all, you know, I like to talk about on the business end and talk about raising of capital, assumption of risk, return on the investment. And part of this is a payment to lower the risk. And obviously there has been a big loss. Now, the growers have inti-

mated that obviously there should be some recovery. And there could be a debate on takings based upon response. And I do not know if and how that will resolve itself but, you know, the thing I want to focus on to begin with, I had a whole bunch of scribbled notes from the testimony, it is very good.

But first-off for Mr. Bronson. And we have the time line here and so June 3, 2008, FDA warned consumers in New Mexico and Texas not to eat certain types of raw red tomatoes. Now, your opening statement said you were 99.9 percent sure it was not Florida. On June 3, how close to June 3 did you know there is no way it was a Florida tomato?

Mr. BRONSON. Congressman, we, because of our program that we implemented and third party verification which is as close to "HASUP" in most other fields of food safety as you can get the fact that we had no single person in the State of Florida that was showing Salmonella Saintpaul or any other kind of Salmonella that we were aware of because our people in our county and State health departments would have been in touch with us if it had shown up, we had that good a working relationship, and the fact that we were shipping all over the southeast United States and there was no cases.

Mr. SHIMKUS. But what is the date? How close were you to that June 3 time frame you said it is not here? It highlights the communication of the FDA; that is the only reason why I am asking it.

Mr. BRONSON. June, well, I am saying, I am hearing now from my deputy commissioner who is in charge of food safety, around they were very sure by the time we analyzed what we were getting by the 15th of June——

Mr. SHIMKUS. All right.

Mr. BRONSON [continuing]. There was no way Florida was responsible because no Florida tomatoes——

Mr. SHIMKUS. Well, the only thing I am highlighting, we know there are areas to be fixed. One is communication, you all mentioned it, communication across the board with all agencies, transparency. And an early notification of information and acceptance could help limit losses I, you know, I think, and that is an issue.

But I want to highlight, I mean we are all FDA, beat up FDA. Trace-back although it was slow, Mr. Stenzel, trace-back worked in this system, did it not?

Mr. STENZEL. I think, Mr. Shimkus, that you have identified a very key part of our discussion here. The real issue where this started is in the identification of tomatoes at the CDC. Everything in trace-back would prove that tomatoes were not the cause. Everything that was traced back showed tomatoes came from different sources. There was no common point of contamination.

Could that have been done more quickly, more effectively? If it could I want to know how. I want the FDA to show us where they ran into roadblocks. These types of systems that my colleagues have talked about are precisely in place also for many Mexican tomatoes. So many of the tomato products in this industry, because it has been bitten in the past, have done a fantastic job of putting in place extensive traceability. So we do not understand what that slowness was.

But in this case traceability showed tomatoes were not the cause.

Mr. SHIMKUS. 1,400 samples, not one—all right, one positive. And the key, you know, really we ought to have a hearing from the CDC and the State health departments. I mean that is the hearing today ought to be. I mean because that is where in this case the system failed.

Mr. STENZEL. Mr. Shimkus, I think it is very difficult, and this is an issue that I think you have got to grapple with with the agencies, is how do they back away from an initial association? They still will not do it. They are still even in the press releases today clinging to the theoretical plausibility that perhaps tomatoes from near these Mexican farms might have been involved in the early stages.

I guess that is still possible and we will have to hold judgment. But my goodness, we now know that the initial month of activity that said tomatoes are it and, by darn, we are going to prove tomatoes are it; they did not do it. They just found tomatoes were not it.

Mr. SHIMKUS. Mr. Hubbard, you have to agree that as much as we are focused on FDA it is this issue of the CDC and the public health departments and why they did not—I am not a criminal investigator but, you know, when we were doing, I was doing the prep for this it was my understanding they limited the suspects instead of having all the suspects like, you know, everyone in the room instead of they focused on, they focused on a commodity product not all the commodity products?

Mr. HUBBARD. Absolutely. FDA chases the food that the CDC questionnaire process identifies. And epidemiology is an inexact science. And I am sure you will hear that from the CDC folks. I am sure they did the best they could but FDA was chasing down the results of the CDC recommendation.

Mr. SHIMKUS. And let me go to Mr. Beckman real quick because I want to follow up. I think I made my point on the CDC and the public health departments. But this issue that we did on tracing the tomatoes to the retail location which was a Jack In The Box, the Chairman followed up with across state lines. The question I would ask is smaller mom and pop retail locations, family restaurants, or tomorrow is Friday, my American Legion Post 365 does a weekly fish fry. Of course the only way Illinoisans love to eat fish is cod and it is deep fried. So and they will have tomatoes. Can this process that we are talking about, obviously a major retailer, just that whole debate, have the resources, can do the IT, can do all the process. What about my local American Legion Post 365 that really relies on the fish fry to bring in income to help fellow veterans? Can they do that too?

Mr. BECKMAN. Well, first let us look at the State of California and the fact that in the California code all tomatoes must be traceable at all points in the system. That includes the smaller players.

But to answer your question as to outside of California, again referencing the Tomato Supply Chain Guidance document, what we looked at is where are the weaknesses in the Bioterrorism Act? Is there a weakness in the fact that an individual mom and pop restaurant is not required to maintain such a level of documentation?

Trace-back can simply begin with an invoice, an invoice that we recommend in this document be held for at least 6 months so that

way we know where those tomatoes came from. There has to be that initial piece of paper. Right now those outlets are exempt from the Bioterrorism Act recordkeeping requirements.

Mr. SHIMKUS. Let me go to Mr. Booth for a second and talk because you deal with all, you are a grower, you are a supplier, you are a repackager.

Mr. BOOTH. Right.

Mr. SHIMKUS. What about the repacking? Repackaging of the other thing in our research talked about sizing of tomatoes from maybe different growers; does that happen? And then how do you, say you are a repackager and you have a multitude of growers and so they are coming in your facility, you are repackaging by size and weight versus where it came from, so then in that box could there be more than one? And does that code then does it identify that this came from four different locations versus one location? Is that how that works?

Mr. BOOTH. Yes, well maybe I can just take a minute and just give you an example of how that might work. We will buy at any given time from multiple growers. Today this minute Delta, our repack company, is actually purchasing product that we actually grow in multiple different fields. We are going to be purchasing this week product from other growers, competitors to our other baseline company Ace Tomato.

The way we handle and the lot identification is identical whether it is our product coming from our fields or from another grower. And that grower could also come from Mexico. So it is identical.

The product comes in to our repack facility. We run that product to size and spec, specifications that our customers give us, by lot. So that one lot goes all the way through our process. So in a box that I just showed you a few minutes ago you will have one lot of tomatoes in there, just one.

Commingling has been talked about a lot. And I think that has been discussed and it is a little bit confusing as what commingling really is. If you do have multiple lots in one case you need to make sure that you have got the documentation to prove that there are multiple fields, multiple lots in that box. We do not want to do that. We really do not want to mingle a particular box.

As I showed your congressional investigators, on a pallet you may have one case out of 80 that is from a different lot than the other 79 boxes. As long as you have the documentation that shows that that box came from a particular lot you are OK, you can trace that back. And if there is an outbreak or if there is a suspected outbreak of a particular case that goes to that restaurant you can again follow that all the way back to the lot.

Mr. SHIMKUS. My time has expired, Mr. Chairman. Thank you again. I will want to end by saying CDC, state health departments, we have to bring them in the loop and empower them to make some better decisions.

Mr. STUPAK. Ms. DeGette for questions.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

I really want to thank each of you on this panel because you have really, quite thoroughly explained to us that we can do traceability, that it is cost effective and we can do it even with mixed lots.

What I want to talk about is why do we need to have some kind of a national system of traceability? Now, Commissioner Bronson, in your State you have mandatory traceability for tomatoes; correct?

Mr. BRONSON. That is correct.

Ms. DEGETTE. And also, Secretary Kawamura, we have that mandatory traceability in your State as well for tomatoes; correct?

Mr. KAWAMURA. Yes, we do.

Ms. DEGETTE. And, Mr. Beckman, you talked today and also I met with you and you talked to me about how quickly and effectively we can trace tomatoes if we have a traceability system; right?

Mr. BECKMAN. Correct.

Ms. DEGETTE. In fact, the story you wanted to tell Mr. Stupak was you folks bought some sandwiches at Subway and went and ran a trace on those tomatoes at Subway and you were able to do it in a few hours; right?

Mr. BECKMAN. Correct.

Ms. DEGETTE. And that is because Subway requires traceability for its tomatoes; right?

Mr. BECKMAN.

Ms. DEGETTE. I am not sure that the whatever it is the fish fry people might have mandatory traceability. But that——

Mr. SHIMKUS. No, I do not think we do. That is the whole point.

Ms. DEGETTE. Exactly, that is the whole point. And so, Mr. Stenzel, you might be able to answer this broader. We are really clear on what is going on with tomato traceability but part of the problem we have is we do not have national tomato traceability; right, Mr. Beckman? I mean some industry, some producers have it, some industries, some states have it. But it is not a national system; right?

Mr. BECKMAN. It is fair to say that if you are a major tomato grower and shipper and want to do business with major corporations you absolutely must have it. That is not to say that there are not some growers in some areas of this country that do not maintain traceability.

Ms. DEGETTE. But in addition its traceability, it is vertical traceability not horizontal traceability because it is traceability for that grower? It is not a national system of traceability that the national tomato growers have instituted for everybody?

Mr. BECKMAN. Well, traceability begins at the grower/shipper.

Ms. DEGETTE. Well, can you—I am sorry, I do not have a lot of time.

Mr. BECKMAN. OK.

Ms. DEGETTE. Yes or no?

Mr. BECKMAN. Please repeat the question.

Ms. DEGETTE. Is it a national system of traceability that is interoperable for all of the tomato growers?

Mr. BECKMAN. It is not a national system, no.

Ms. DEGETTE. OK. Mr. Stenzel, now you represent broader numbers of growers. And I understand the way you trade a tomato may not be the same way that you would trace green beans or other produce; correct?

Mr. STENZEL. Correct.

Ms. DEGETTE. But there are other types of traceability systems that would work for almost any kind of commodity; correct?

Mr. STENZEL. Yes, ma'am.

Ms. DEGETTE. And so what I have been thinking about is this recent Salmonella outbreak. And it appears that what happened is people, let us step all the way back to the beginning, the public health sleuths talking to people found out that they had eaten probably salsa or something that had tomatoes and chili peppers in it; correct?

Mr. STENZEL. Yes, ma'am.

Ms. DEGETTE. And so if you were trying to do traceability on that it would be really helpful if you could break down the components of that and be able to trace them, whatever the system was; is that right?

Mr. STENZEL. Certainly in any processed food or a mixture of different ingredients it gets much more complex, but you would want to be able to trace the individual ingredients.

Ms. DEGETTE. And that would have helped us in this situation if—I mean it would have helped the tomato industry if the FDA investigators and the CDC would have said, OK, let us trace all of the tomatoes that were involved in this salsa. And if you had had a quick system you could have resolved the tomato problem much more quickly than it was resolved I would assume?

Mr. STENZEL. Well, I think our concern, Congresswoman, is that we believe that across the board there are these systems in place, particularly in the tomato industry and that the trace-back actually showed that it was not the tomatoes.

Ms. DEGETTE. OK.

Mr. STENZEL. This was not a matter of inability to track tomatoes and where they came from.

Ms. DEGETTE. Right.

Mr. STENZEL. It was the confusion with other ingredients that perhaps were in the salsa.

Ms. DEGETTE. Well, let us talk about that. So let us say we had a traceability system, a trace-back system for jalapeño peppers and cilantro and the other ingredients, if that would have moved faster we would have been able to resolve this situation much more quickly to the benefit of the growers of the vegetables that were not contaminated; right?

Mr. STENZEL. Our industry had the highest incentive to resolve these things quickly to protect health and to prevent damage to the industry.

Ms. DEGETTE. Exactly.

Mr. STENZEL. If the CDC scientists had had any concerns about other ingredients they could have been tracked. Once the investigators started looking——

Ms. DEGETTE. Do we have the same kind of system for jalapeños that we do for tomatoes?

Mr. STENZEL. Not nearly as effective. But once they started looking for jalapeños they have tracked them extremely effectively.

Ms. DEGETTE. Right. But if we——

Mr. STENZEL. The fact that the individual farm in Mexico today with today's traceability with one of the most complicated small items that does not have these elaborate systems.

Ms. DEGETTE. Right. But if we had a national system, not maybe one type of traceability but if everybody had to do it and it was interoperable we could have done this much more quickly; would that not be fair to say?

Mr. STENZEL. I am not convinced that the traceability investigation of FDA was the lagging factor in this case.

Ms. DEGETTE. OK.

Mr. STENZEL. We definitely need——

Ms. DEGETTE. You think it was the identification.

Mr. STENZEL. We need to improve our traceability. And that is something the industry is taking very, very seriously.

Ms. DEGETTE. OK.

Mr. STENZEL. And a national program in the tomato industry I should also say is important.

Ms. DEGETTE. OK.

Mr. STENZEL. One key——

Ms. DEGETTE. Excuse me, I am sorry, I do not have much time and I have one more topic I want to talk about with Mr. Hubbard. And welcome back.

Mr. HUBBARD. Thank you.

Ms. DEGETTE. I was just telling staff I feel like we should just put you on the roster every time we have an FDA hearing.

I want to talk to you about the 2002 Bioterrorism Act because some people have said that provides us with the federal tools we need to do traceability. And I know you do not entirely agree with that and I wanted to explore that with you. In your testimony you provide a side-by-side analysis, in you written testimony, of the key weak points introduced into the original legislation and regulation as it was reviewed and considered by administration reviewers. So I want to go through those because I think that kind of gives us some sense why maybe that act is not helping us trace as much as we want.

What you say is what FDA wanted or needed in the final rule, that FDA wanted records by all sources and recipients, but farms and restaurants were excluded; correct?

Mr. HUBBARD. That's correct.

Ms. DEGETTE. And FDA wanted foreign firms as well as U.S. but the foreign firms were excluded from the final recommendation?

Mr. HUBBARD. In the rulemaking process, yes.

Ms. DEGETTE. They wanted a complete record of the food's movement but what ended up, and I think this is maybe the biggest flaw, is only one step up and one step back; correct?

Mr. HUBBARD. That is correct.

Ms. DEGETTE. They wanted lot numbers for each shipment and that was denied in the rulemaking; correct, Mr. Hubbard?

Mr. HUBBARD. Absolutely. I mean the consumer groups pushed very hard for that but the industry view was that lot numbers would be too expensive to maintain.

Ms. DEGETTE. And the FDA also wanted electronic records for speed, and that was denied; correct?

Mr. HUBBARD. Obviously, yes. If you can just go on the computer and punch it up you can do it a lot faster than going through thousands of pieces of paper.

Ms. DEGETTE. They wanted records access within four hours and that was extended to 24 hours; is that correct?

Mr. HUBBARD. Right. Four hours during normal business hours, 8 hours if they asked in the middle of the night, but it got extended to 24.

Ms. DEGETTE. They wanted a consistent record format, and that was denied; correct?

Mr. HUBBARD. Yes. I mean FDA inspectors——

Ms. DEGETTE. Now why is that important?

Mr. HUBBARD. Well, FDA inspectors are now finding they will go into a firm and some of them will have great records and others will have just bills of lading. And I have had anecdotal examples given to me of people have records on a plain paper bag or other, you know, all kinds of different formats where you have got to really search through for the various information you need instead of it all being there rapidly accessible.

Ms. DEGETTE. And that was part of the problem with this recent Salmonella outbreak is the records problem?

Mr. HUBBARD. Absolutely. I mean one anecdote was a Florida tomato packer I am told literally ran out of supply and could not get anymore Florida tomatoes so he bought some Mexican tomatoes. Imagine how that could complicate a trace-back by FDA to have this foreign product enter into the Florida main, into the Florida stream when, you know, that could just be a tremendous fly in the ointment as they say.

Ms. DEGETTE. Furthermore, the FDA wanted authority to verify the keeping of records, and that was also denied; right?

Mr. HUBBARD. I am sorry, I——

Ms. DEGETTE. The FDA wanted the authority to verify keeping of records?

Mr. HUBBARD. Yes, the problem here is the way the rule was set up if an inspector goes in to do a routine food inspection they say, well, let me see your records in case there is ever an outbreak, the firm can say, no, you can only see the records if there is an outbreak. So the inspectors are not able to confirm that the industry is doing what they need to do to prepare for when there is an outbreak. And that is kind of nuts if you ask me but that is the way the rule came out.

Ms. DEGETTE. Now let me ask you this, when you say the FDA wanted or needed, that sounds like a pretty good description of a national traceability system as these gentleman have been describing today, does it not?

Mr. HUBBARD. Oh, absolutely.

Ms. DEGETTE. If we gave them these authorities, let me just ask you in your opinion, would this investigation and further investigations have been expedited so that we could protect public health and also industry?

Mr. HUBBARD. I think that to the extent trace-back was the issue they could have much more rapidly identified that tomatoes were being excluded and then the industry would have been spared a huge expense and they could have gotten to the peppers more quickly and a lot of people would have been saved a lot of distress, absolutely.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

Mr. STUPAK. Thank you.

Mr. Burgess for questions, 10 minutes.

Mr. BURGESS. Thanks, Mr. Chairman.

Mr. Stenzel, I apologize for being in and out but for the other hearing going on. In response to a question by Ms. DeGette of Colorado you said that traceability was not the lagging factor. You started to tell us what that was, so would you tell us what that was?

Mr. STENZEL. Yes, sir, thank you.

The initial identification of tomatoes as the sole source of contamination really sent us down, you know, the wrong path. As Mr. Hubbard said, it is FDA's responsibility then to investigate precisely what CDC has already identified as the villain or the vegetable of interest if you will. In that process we have heard claims that there was slowness or slow in traceability. But as you have heard from other witnesses here on the panel, we do not understand where that slowness would have occurred. We need to see the specific examples, not the anecdotal stories.

It is not uncommon for growers to substitute new product from other regions but they can keep track of that quite well in the systems that are in place. So we do not understand where that slowness would have occurred.

The initial time that FDA did a trace-back from someone who was ill in Virginia and it went to a Florida farm and then they did a trace-back of someone who was ill in Illinois and it went to a Mexican farm, they should have known it was not a common source. That could have happened in the first day, the very first day we could have done trace-backs, I think we did do trace-backs. And I would like to understand what trace-backs were done to confirm that there was not a common source of contamination.

Why did it then take 3 week or 4 weeks? There was a bias, I believe, in terms of we must prove it is tomatoes because that is what CDC has said, that was their epidemiological evidence. Until we got off that horse and realized that there was something else that we had not figured out early enough, by well-meaning scientists but we had not figured it out early enough that it was really something else causing the illnesses.

Mr. BURGESS. We talk a lot up here about things like mandatory recalls. Going down the wrong path like that, had there been a mandatory recall it might have in fact been more deleterious to the industry; is that correct?

Mr. STENZEL. I cannot imagine it would have been worse. We have a mandatory ban of all tomatoes, so we pretty much suffered.

Our industry, the produce industry, supports mandatory recall authority for the FDA. But their press releases are pretty darn effective too.

Mr. BURGESS. OK. Let me, Mr. Hubbard, again, and thank you for being here. Like Ms. DeGette I feel like you are part of the committee you are here so frequently. You mentioned in your testimony, and I was watching it on television upstairs, you said that we are only as strong as our weakest link, and this thing under the Bioterrorism Act, the exception for a company that has 10 or fewer employees keeps coming up. Do you have an opinion as to

how that weak link might be tightened up so that we do not face these problems?

Mr. HUBBARD. Sure. This is an old story at the FDA that small firms tend to drive rulemaking because even though small firms, in this case I imagine 90 percent of the fresh produce is managed by large firms, but there is usually a large number of small firms and they make a powerful argument that a strict regulation could drive them out of business or adversely affect them.

Here I would think with the kind of technology Ms. DeGette's talking about available I would hope there would be ways to identify——

Mr. SHIMKUS. Will the gentleman yield? Off of the record this is Diana DeGette.

Ms. DEGETTE. Thank you.

Mr. HUBBARD. I apologize.

Mr. SHIMKUS. So, my colleague from Texas and Mr. Hubbard. Now we are on the record.

Mr. HUBBARD. I apologize.

Ms. DEGETTE. It kind of sounds more exotic though.

Mr. BURGESS. It does. That is why I used it.

Mr. HUBBARD. There could be off-the-shelf technology or other inexpensive ways to give the smaller firms access to the kind of tracing mechanisms that Ms. DeGette has mentioned as the proper way to do it and reduce some of those costs. But clearly the costs are going to drive decision making here unless we can help the small manufacturers, and in this case the small produce producers.

Mr. BURGESS. Is it an issue of being able to provide them the funding or the back-up for those systems or is it just simply getting them into the process?

Mr. HUBBARD. Well, I think it is more the latter. Imagine you are, you know, you are the small producer and you are not sophisticated in technology, you do not have the funding to have an expert come in an create a system from scratch, but someone says, look, there is established software and hardware that you can purchase and get into the system with the big guys, I would think that that would much, much lower the cost for those if they had easily off-the-shelf access to the technology.

Mr. BURGESS. Let me ask another question. I mean you heard my anxiety about the inability to actually do something definitive on the Friday where this was all finally sorted out that peppers are the culprit. And again on T.V. we are hearing the FDA's recommendation is you ask where the peppers came from. And that seemed like a fairly incomplete response to be delivered.

Is there something better we can do when we find there is a problem? And we talked about mandatory recalls and let us do everything that they do. But at the same time we have to have a way, I think, from stopping that stuff from coming in the country. Our border has to be secure from preventing what we have now identified as a contaminated product from entering in the stream of commerce.

Mr. HUBBARD. Well, first of all, in terms of communication to the public, imagine CDC or FDA had said we are 90 percent certain it is tomatoes, or 80 percent or whatever, and they did not tell anybody because they wanted to be 100 percent, and it turned out it

was tomatoes. You know, you would be having a different hearing but you would still be having a hearing.

Mr. BURGESS. Sure.

Mr. HUBBARD. And it would be really ugly.

Mr. BURGESS. In fact, we had that situation with Heparin in some respects.

Mr. HUBBARD. Sure. So I think that the agencies are in a bind and the key is for them to eliminate a given commodity very rapidly. And that is where things like trace-back and recordkeeping come into play so that these investigations do not run for weeks, they run for days. And then you cut it off and you are done and, you know, and you have solved the problem.

Mr. BURGESS. OK. That point of cutting it off, again Friday they found the problem but there was not really the ability to cut off that product. I mean how do we know how much product came across the border over the weekend? How do we know that by Monday morning we had not had more bushel baskets of contaminated peppers entering the stream of commerce?

Mr. HUBBARD. Well, as we discussed, the import problem is a tremendously problematic one. Conditions on these Mexican farms can be horrendous with farm animals traipsing through. And I understand that one of these farms that is the subject here even though they were told in advance FDA was coming when the inspectors got there they found all kind of problems, animals in the irrigation ditches. They only had two port-a-potties for the entire farm, and one of those had just been stolen. So, you know, you have got fundamental violations of preventive control technology that I would hope we do not see in the United States but we certainly do see in Latin America.

Mr. BURGESS. But as far as securing it at the level of the border is there a authority that the FDA could have that they are lacking at this point?

Mr. HUBBARD. Well, the only authority they have is to examine the product as it comes across the border. And as the committee has found, FDA does very little of that. They need the authority to put preventive controls in place back to the Mexican producer so that they meet the same standards U.S. producers make.

Mr. BURGESS. And I would not disagree with that except that, as you correctly point out, time after time there are violations and the standards do not seem to be where we would want them. It just seems to me that we have to have a way, there has to be a failsafe at the border when we discover we have a problem on a Friday afternoon that we do not just let it run then for the next couple of days until we can get someone down there on the farms and inspect it. There has to be, I think, and I think the American people want us to have the way to stop that from entering the stream of commerce the minute we detect that there is a problem. It may only be temporary. We may have to within a certain time period come back and address that. But we have to have the ability to stop that when we discover there is a problem.

And, Mr. Chairman, in the interest of time I am going to yield back.

Mr. STUPAK. We are shocked but great.

Ms. Schakowsky for questions please.

Ms. SCHAKOWSKY. Thank you. I apologize very much for not being here for your testimony. There are a lot of hearings going on. But through the magic of my assistance from staff I find myself able to ask questions nonetheless.

So let me start with some questions for you, Mr. Stenzel. Let me walk you through a key points of your testimony. Is it true that throughout the outbreak investigation you and your members really could not determine who was in charge of the investigation and this left local, State, federal officials vying for leadership?

Mr. STENZEL. Yes, Congresswoman, in many of our conversations with officials from both CDC and FDA it was unclear who was making the decisions on public advisories, at what point in time which agency had the authority to advise consumers not to eat these tomatoes or this type of tomato. We saw repeatedly concerns between those two agencies.

As far as the State and locals, this is probably more that we have discerned from our members, people doing investigations in the field who said that sometimes they heard from their State health departments a disagreement with the federals in terms of, gosh, we do not think it is tomatoes, I do not know why we are still chasing this.

Ms. SCHAKOWSKY. Is it not also true that as a result of this various agencies related to this investigation, as you say, were—well, I guess you answered that—were pursuing different priorities which added to the confusion. So the priorities were both instructions for consumers, the source of the problem, those kinds of things?

Mr. STENZEL. Yes, that is correct.

Ms. SCHAKOWSKY. OK. Was not one of your chief concerns in this outbreak that field investigators across various agencies were not coordinated so it was difficult for your members to understand what kind of information authorities were seeking and what they could do to help the investigation?

Mr. STENZEL. This is another important lesson I think as we look at trace-back as well. The field investigative staff while doing their best were not experts in produce, certainly not experts in produce distribution. We have anecdotal stories, as Mr. Hubbard told, of an investigator going into a warehouse in Philadelphia who said that they had been investigating heart transplant and heart valves the day before and now they are looking for tomatoes in a warehouse.

We have cases where an investigator on contract to FDA comes in and says, give me all your records. It almost sounded like a "go fish" game. No wonder we cannot trace it with that kind of an approach. But with a very targeted, well-organized effort.

Commissioner Bronson raised an important point I do not want to forget, the ability to task State departments of agriculture who are much more familiar with our systems to help in those investigations might, you know, be a very good lesson out of this hearing.

Ms. SCHAKOWSKY. You suggest that Congress should consider how to put into place a command and control system with a clear chain of command during food outbreak investigations. So you are thinking that we ought to think more broadly and include state ag-

riculture departments or that we should look at that chain of command more broadly as well as more efficiently?

Mr. STENZEL. I think realistically we are going to have to have a collection of different agencies of local, State and federal working together. I do not simply see, you know, a total revolution at hand in change in our public health structure. But there does need to be some type of command structure I would suggest.

I use the analogy of the National Transportation and Safety Board investigating an accident. You know that someone who flies to the scene, that person is in charge. Everything else flows through that investigation. There is one spokesperson to the press. The analogy, this one seems to be going in fits and starts in many directions. How we can pull that together in one more cohesive fashion.

Ms. SCHAKOWSKY. Well, there is also industry expertise. And I know another primary concern of your members was that the government failed to use that expertise during the course of the outbreak investigation. What role should industry experts play?

Mr. STENZEL. We believe that there has to be a very clear precaution taken. We do not suggest that industry run an investigation. But there is a lot of knowledge and expertise. You can hear it from these tomato people. There is expertise in jalapeños out there in the industry. And to be able to bring them in in an appropriate way for FDA and CDC to call on those resources.

An example would be we mentioned the illnesses. There were very few in California, there were very few in some of the Mountain West States. We began to look at the distribution patterns of food distributors and could start to see why and where product may have been coming from. The jalapeños we discerned were probably coming on the east side of Texas, not the west side of Texas just because of the distribution patterns coming up through the Mississippi to Illinois. So that type of expertise.

Ms. SCHAKOWSKY. Are there some legal constraints that regulatory agencies may have in sharing data or that you may have in sharing data?

Mr. STENZEL. There may be. We are not familiar with what those are.

Ms. SCHAKOWSKY. OK.

Mr. STENZEL. But I think it is something the agencies ought to look at. And if there are impediments, is there a way that Congress could help them have a legal means to get that expertise.

Ms. SCHAKOWSKY. I have a few more minutes so let me ask, Mr. Beckman, you communicated to committee staff that you believe in the future the FDA should attempt to use industry to assist in an outbreak investigation because they understand with regard to players and the complex distribution chain, as Mr. Stenzel just said. Let me ask your opinion on how you think industry could help the FDA?

Mr. BECKMAN. Well, to give you an example, within the first 24 hours of our being informed of this outbreak it was brought to our attention by FDA that they were interested in ingredients that went into the production of salsa. There were follow-up discussions that continued.

We did not fully understand though where this investigation was going and what information we provided if it would be acted upon. Really it seemed like there was a greater level of outreach by FDA but we were not able to ask the important questions to help connect the dots. There were some but we tried to shoot blindly——

Ms. SCHAKOWSKY. You were not asked?

Mr. BECKMAN [continuing]. Trying to understand where FDA was going with this investigation. That was part of the problem. And it is my understanding that there are confidentiality issues that prevent them from disclosing specific points of the trace-back during the investigation.

Ms. SCHAKOWSKY. Well, that is what I am wondering in the recommendations, perhaps both of you, because there are statutes, including the Trade Secrets Act, portions of the Federal Food, Drug and Cosmetic Act, even the Freedom of Information Act that makes it difficult to share information with industry. So in the face of those information-sharing limitations that govern the FDA do various associations represented here in conjunction with other produce industries plan to consider ways that would allow more industry assistance during outbreak investigations?

Mr. BECKMAN. We would welcome any form of involvement that would include the restriction of the release of any confidential data. Any involvement that we can possibly have to help move FDA forward on a trace-back investigation. And we would welcome being held to any form of confidentiality law regarding our involvement.

Ms. SCHAKOWSKY. OK. Mr. Stenzel?

Mr. STENZEL. If I may, I suggested the possibility of a security clearance or some type of pre-vetting of industry experts that could be officially authorized and stand at the ready that FDA could call. They have already been preapproved and they would come 24/7 to help in an investigation like this.

Ms. SCHAKOWSKY. Mr. Kawamura, did you want to respond as well?

Mr. KAWAMURA. I would like to add that in my testimony you will note in the written testimony that we mentioned the leafy green marketing agreement which took place in California and now Arizona as well as a nice template for industry working collaboratively with governments both at the State level, as was mentioned earlier, and the federal level, both at USDA and also with FDA as a partnership to look at how we can bring those resources together, create standards and practices that allow for documentation for traceability. And I think that kind of effort shows that I think all parties want to move forward.

Our discussion today continues to be on what happened in the past, but in moving forward on what can happen in the future the diagnostics that we are working with are incredible. To be able to trace genetically these different strains to a source back at a watering hole or in the field, these are the kinds of things that we should really be celebrating in our system. It is not to say that the system is not perfect, but I will continue to submit that this system is getting better because none of the groups that are represented here can sustain these kind of outbreaks and this kind of damage to the growers.

I know we have not talked about compensation today for those growers. When you are unfairly pointed, unfairly implicated or incorrectly implicated in an outbreak I hope that becomes part of the testimony today as well. But I think what we want to do is how do we move forward hand in hand.

I continue to say that for the amazing job that is done domestically in our country, the misunderstanding still comes with the lack of confidence or the collapse of confidence. How do we rebuild confidence with the American public that consumes ever day a billion meals a day, if you will, how do we recapture that confidence and show that the system is moving forward?

Ms. SCHAKOWSKY. And you are suggesting that California may provide some model and some suggestions for us at the federal level?

Mr. KAWAMURA. I believe both California and Florida have some models that can easily be used and put into place.

Ms. SCHAKOWSKY. Thank you so much. I yield back.

Mr. STUPAK. Thank you.

I have called on the FDA to do a post-mortem here on what went right and what went wrong with this investigation. Would you all be willing to serve on that panel if asked?

Mr. BROWN. We would love that opportunity.

Mr. BECKMAN. Absolutely. We are ready to go.

Mr. STUPAK. Let me ask this. It came up and I am still a little confused. Tomatoes is the only one that really has this traceability that we have? Does jalapeños have them? Does spinach have it? Some are shaking heads yes, some are shaking heads no.

Mr. KAWAMURA. In California the leafy green marketing agreement takes all those leafy vegetables and they do have a very comprehensive traceability and identification package.

Mr. STUPAK. OK. So the leafy greens, that would be the spinach that we have had problems with in the past.

Mr. KAWAMURA. And many other, and many other of our products as well from California.

Mr. STUPAK. OK. Florida?

Mr. BRONSON. We do not have a full set yet but we are working on all the leafy greens to match what we are doing in tomatoes.

But let me, Mr. Chairman, if I might let me say to you that even with the new law that has passed on country of origin, where these groups were found and the reason why we began to see that Florida was not a part of this was around a restaurant situation.

Mr. STUPAK. Right.

Mr. BRONSON. You understand that even with the new country of origin labelling it does not have to follow to the restaurant.

Mr. STUPAK. Correct.

Mr. BRONSON. And that is where one of the problems was in this outbreak.

Mr. STUPAK. Country of origin label is really an old law. We are just waiting for it to be implemented by the Administration.

Mr. BRONSON. Florida has had it for 20 years.

Mr. STUPAK. I know. I know.

Mr. BRONSON. That has worked for us.

Mr. STUPAK. I know.

Mr. BRONSON. I am glad it is coming into place.

Mr. STUPAK. I do not know why we cannot get it done up here.

Let me ask this question. Let me ask this question. Because I want to go back to what I said earlier about those three press releases the last 12 hours sort of epitomize this investigation because we still have so many questions. If I am growing a tomato—and I am not a farmer, so bear with me—if I am growing tomatoes to I rotate my crop every other year and put a different crop in there to keep the ground good? I do that. What would be the other crop?

Mr. BOOTH. Absolutely. For tomatoes you will rotate that every two or three years.

Mr. STUPAK. OK. What would I substitute then when I am not growing tomatoes in that field?

Mr. BOOTH. It could be wheat. Wheat is a very good, a very common crop to.

Mr. STUPAK. OK.

Mr. BROWN. In contrasting it, Congressman, in Florida we basically grow tomatoes on the same piece of land year after year after year with the technology we have in place.

Mr. STUPAK. OK. Because going back to these press releases that I mentioned it says, you know, "previously FDA inspectors collected a positive sample of jalapeño pepper from a produce distribution center owned in McAllen, Texas. The FDA continues to work on pinpointing where and how in the supply chain this first positive jalapeño pepper sample became contaminated. It originated from a different farm in Mexico than the positive samples of serrano pepper and irrigation water."

So this tells me, OK, we still have not cleared off tomatoes yet, as we talked about earlier. And the pepper we had one farm, now we have another farm and it could be the irrigation. So it could be all the farms that use that irrigation source or water source; correct?

Mr. STENZEL. That is what it sounds like to us. I think the FDA panel will obviously be able to answer those questions better than us.

Mr. STUPAK. OK. Because it is a different farm in Mexico than what the original positive samples back on, what did we say, July 21. And so, OK.

Mr. Hubbard, you said you had some, what your understanding is this farm that they had had deplorable conditions, sanitary conditions?

Mr. HUBBARD. Yes, but again I think conditions in Latin America in produce operations tend to be fairly consistently substandard. And again, the farm knew they were coming and still there were substandard conditions. So one would suspect that perhaps they were even worse earlier.

Mr. STUPAK. We have inspectors, FDA inspectors in Mexico, do we not, doing produce, looking at the farms?

Mr. HUBBARD. Usually only for cause. There is not, there is not normally a routine.

Mr. STUPAK. Not a normal routine inspection going on?

Mr. HUBBARD. There are lots of attempts to educate though, good agricultural practices, that sort of thing.

Mr. STUPAK. Mr. Booth, you wanted to say something there?

Mr. BOOTH. Thank you. I just want to make sure that we are not painting a broad brush with Mexico and other Latin American countries that they are substandard. There are many, many exceptional growers in Mexico. We deal with those directly.

Mr. STUPAK. Right, and I think some testimony was they have a trace-back system——

Mr. BOOTH. Absolutely.

Mr. STUPAK [continuing]. In some parts of Mexico.

Mr. BOOTH. Absolutely.

Mr. STUPAK. Depending on the grower and who they are working with in the United States?

Mr. BOOTH. Yes, sir, that is right.

Mr. STUPAK. OK. Someone said earlier that a major consumer, let us say like if—who is a major? Jack In The Box, OK, they would have certain requirements for tomatoes which are more towards how they are handled, shipped, grown. Are they different than what you are doing in Florida and California? I mean are you having trouble with corporations saying, do this? You say, well, this is not part of our system. Is that a concern?

Mr. BRONSON. Mr. Chairman, we are not having a problem because we have one of the highest standards, probably the highest standard in America. So we are not having problem with any of our people who are buying, major corporations that are buying our tomatoes.

Mr. STUPAK. Well, some of the farmers are telling us that some of the concerns that some of these corporations are putting on them in order to buy their tomato or jalapeño or whatever it is, are things like benzene and things like that that really has nothing to do with the growing of this tomato. And so I just want to see if you get push-back from corporations who are more geared towards risk assessment from an insurance financial point of view as to risk assessment from a food safety point of view?

Mr. BRONSON. Well, I agree now, now that you have expounded on that, there are certain companies that will say we do not want tomatoes that have a certain product or whatever put on them. And there is usually a third party evaluation of that tomato before that company will buy that particular tomato.

Mr. STUPAK. Sure.

Mr. BRONSON. But we have not had problems in Florida. Whatever the standard is we usually can meet it.

Mr. STUPAK. You think no problem in California like that, Mr. Kawamura?

Mr. KAWAMURA. That is the same. You may know that California provides 50 percent of the fruits, vegetables and nuts that are domestically produced in the United States for the rest of the country.

Mr. STUPAK. Let me ask this question, if you know. I understand that this type of Salmonella Saintpaul is usually associated with poultry; is that right?

Mr. KAWAMURA. Not necessarily.

Mr. STUPAK. Not necessarily, OK.

OK, Mr. Stenzel, you mentioned something about who was in charge, command center. Can you expound a little bit on that? Should we have, like if you have a natural disaster you have a

command center, someone comes in, boom, you know who is in charge, very rigid?

Mr. STENZEL. That is precisely the example, Mr. Chairman, that between CDC and FDA in particular throughout this investigation we have noted tension, rivalries, defensiveness between the two positions of individuals within the agencies. We feel that that is an important thing to look at of putting someone clearly in charge.

Mr. STUPAK. Some kind of an incident command center.

Mr. STENZEL. Where CDC fingers the culprit but then FDA is left to investigate it whether they agree with it or not, it is kind of strange.

Mr. STUPAK. OK. Thank you.

Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. I am going to be brief. As I received the testimony I just want to reiterate we are still looking for this Salmonella-tainted tomato. And once we focused on peppers 18 days to identify the pepper, four days to find the location. And had we identified the right vegetable at the beginning, the losses would have been limited. You still would have had losses.

Go ahead, Mr. Bronson.

Mr. BRONSON. Yes, Congressman, let me say that if we had been given in Florida, and I am sure all the States involved, California including, if we had been given the right information and not withheld information from us we could have gotten to the point very quickly on how to help them in Florida. Every State may be a little different but in Florida if they would have told us what they were looking for, exactly what their suspicions were we could have gone and verified that or denied that we had the problem in Florida which would have cleared it.

Now, I hold a commission with FDA, so does Dr. Brown, so does Dr. Aller in our laboratory. But I am not sure what that commission means because I can hear on national news more than what I was being, we were being told at the state level in these conferences. So we cannot help if we do not know what we are supposed to be looking for.

Mr. SHIMKUS. Mr. Brown, you want to answer in response?

Mr. BROWN. Trace-back works wonderfully and that is an excellent example in the case of the jalapeño. But when you identify the wrong culprit you cannot ever find the trace-back.

Mr. SHIMKUS. Right. And I want to follow-up on this. Because we are going to have a debate about giving the FDA mandatory recall authority. And when this is touched on and also recovery of damages, I am not a lawyer. We have some on the panel. Are any of you all lawyers? What makes a more convincing case, to get cost recovery from a warning or get cost recovery because the government did a mandatory recall that was in error?

I have got to believe that we will be on the hook on a mandatory recall, especially when it was in error. And I think that is one of the problems that we might have in this debate as we move forward.

I think we all are in agreement, transparency, communication, someone responsible and hold them accountable. I mean I am a military guy, that is kind of the way it works. You have to have

a chain of command. And this fusion center we call it in terrorism and connecting the dots, we have heard that numerous times since September 11. We did not do well. The State agencies are getting together where you have people in the same room. That is probably something, Mr. Chairman, we also ought to consider is making sure that we empower everybody to help us solve the case sooner rather than later. And I think we are going to get that in other panels.

So with that I really appreciate it, it is a great panel. We have more to come. And I yield back my time.

Mr. STUPAK. Thank you.

Ms. DeGette, have you got some questions?

Ms. DEGETTE. I just have a couple quick questions, Mr. Chairman, thank you.

Mr. Stenzel, your industry has endorsed mandatory recall; correct?

Mr. STENZEL. Yes, we have.

Ms. DEGETTE. Mr. Beckman, I think your industry has too; correct?

Mr. BECKMAN. Correct.

Ms. DEGETTE. And just so you know, I think most of the industries have endorsed mandatory recall. Most consumers think that we have it now because they read the recall notices and they think they are mandatory.

Mr. Beckman, I just wanted to ask you quickly about your document that you flourished during your testimony which is Exhibit 11 in the notebook. That is someone that your organization helped create called Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain. It is my understanding that this document lays out a number of best practices to be used throughout all the levels of the tomato distribution chain, including traceability requirements. Is that correct?

Mr. BECKMAN. That is correct.

Ms. DEGETTE. And it is also my understanding that you believe that national regulations governing the tomato industry should be enacted. Is that correct?

Mr. BECKMAN. That is correct.

Ms. DEGETTE. And if your document Exhibit 11 were used, then the whole tomato industry, not just bits and pieces, would be required to implement comprehensive systems for tracing their products through the supply chain. Is that correct?

Mr. BECKMAN. That is correct.

Ms. DEGETTE. And I also know that the FDA has seen this document. And you would be in favor of the FDA modeling a national regulation based on the contents; is that correct?

Mr. BECKMAN. That is correct.

Ms. DEGETTE. And, Mr. Stenzel, just to clarify with you, I think a lot of what you said is really important and has some nuance that this committee needs to understand. I just want to clarify one thing. Is it the position of your organization that more stringent traceability requirements should be enacted beyond what is currently required in the Bioterrorism Act of 2002?

Mr. STENZEL. We believe that with traceability as well as preventive food safety controls they need to be commodity-specific and

based on risk. So for the tomato industry we are the co-author of these——

Ms. DEGETTE. Right.

Mr. STENZEL [continuing]. Guidelines and certainly support that in the tomato industry or other products or commodities that FDA would determine to be at higher risk.

Ms. DEGETTE. OK. And you think that those requirements should be more stringent than the Bioterrorism Act of 2002?

Mr. STENZEL. We believe that these requirements in the tomato guidelines would be more stringent.

Ms. DEGETTE. And you would support that?

Mr. STENZEL. Yes, ma'am.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

Mr. STUPAK. Thank you.

Ms. Schakowsky, any questions?

Ms. SCHAKOWSKY. No further questions.

Mr. STUPAK. Well let me thank this panel. It has been most interesting. You have been most helpful. And appreciate your time and your attention to this. And as I said earlier, Mr. Dingell has a bill, most of us are on it, and negotiations are going on between both sides and industry, and hopefully some of the suggestions you made can be part of that.

Mr. SHIMKUS. If the Chairman will yield.

Mr. STUPAK. Sure.

Mr. SHIMKUS. I will now say that we are also in the room and——

Mr. STUPAK. Right.

Mr. SHIMKUS [continuing]. There are negotiations in good faith going on on a bipartisan basis.

Mr. STUPAK. So hopefully we can get something done here yet this Congress. So thank you very much. We will dismiss the panel. Thank you.

[Witnesses excused.]

Mr. STUPAK. Our second panel of witnesses come forward. One our second panel we have Dr. David Acheson, who is Assistant Commissioner for Food Protection in Food and Drug Administration, also known as the Food Czar; Dr. Lonnie King, who is Director of the National Center for Zoonotic and Vector-Borne, and Enteric Diseases at the Centers for Disease Control and Prevention; Dr. Kirk Smith, who is the Supervisor of Foodborne, Vectorborne, and Zoonotic Disease Unit, Acute Disease Investigation and Control Section at the Minnesota Department of Health; and Dr. Timothy Jones, who is a State Epidemiologist for Communicable and Environmental Disease Services at Tennessee's Department of Health.

Welcome, gentlemen. It is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right under the rules of the House to be advised by counsel during your testimony.

Do any of you wish to be represented by counsel during your testimony?

[No response.]

Mr. STUPAK. Everyone is shaking their head no, so I will take that as a no.

So therefore I am going to ask you to please rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect each witness answered in the affirmative. They are now under oath.

And we will start with opening statements. If you would like to submit a longer statement for the record we will include it in the hearing record but we try to hold it to 5 minutes.

Dr. Acheson, do you want to start, please?

STATEMENT OF DAVID W.K. ACHESON, M.D., ASSISTANT COMMISSIONER FOR FOOD PROTECTION, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. ACHESON. My pleasure.

Good afternoon, Chairman Stupak and members of the subcommittee. I am Dr. David Acheson, Associate Commissioner for Foods at the FDA, which is part of the Department of Health and Human Services. Thank you for the opportunity to discuss the recent food-borne 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 assure you that FDA is committed to working with all our food safety partners to expedite trace-backs and to ensure that America's food supply continues to be amongst the safest in the world.

For this outbreak alone we are FDA have conducted nearly 450 inspections or investigations together with our State partners. FDA labs have analyzed nearly 450 samples, including samples of produce as well as environmental samples. To support coordination we have hosted or participated in 40 teleconferences with the States as well as CDC.

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 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 in 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 agents in a variety of foods.

I would now like to provide a brief description of a typical trace-back process. CDC along with State and local officials will through its epidemiological investigations identify possible food or foods associated with an outbreak. And at that point CDC notifies FDA.

From that point FDA begins our trace-back investigation to identify the source of the contamination. We work with industry and with local, State and Federal officials and, when needed, foreign governments to identify the source of the contaminations. 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 right throughout the supply chain. We also obtain information on the practices and conditions under which the product was stored and handled at each point.

The current outbreak investigation which initially focused on certain types of raw tomatoes provides an example of one of the most difficult kinds of trace-back investigations. It was on May 31 that the CDC advised FDA of the significant statistical association between the consumption of certain types of tomatoes and a multistate outbreak of Salmonella Saintpaul infections. Raw tomatoes are a perishable commodity and thus are unlikely to be in a consumer's home after a consumer becomes ill, obtains a diagnosis, and the 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.

A further complicating factor was caused by entities in the supply chain using different terminology to describe the tomatoes.

Since May 31 many FDA employees in the field and headquarters have been working on the outbreak investigation to identify the source. 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 advice, announced that tomatoes currently on the market are not considered to be a possible source of illness.

On July 21 FDA announced it had found a genetic match with an outbreak serotype Salmonella Saintpaul in jalapeño peppers we tested from a distribution center in Texas. This finding of a genetic match was an important break in the investigation. Upon further investigation we determined that the contamination of the pepper occurred in Mexico, not at the plant in Texas and, accordingly, on July 25, updated our advisory, announced that there was no indication that domestically grown jalapeño or serrano peppers were implicated in the outbreak.

Yesterday FDA laboratory analysis confirmed that both a sample of serrano peppers and a sample of reservoir water used for irrigation contained the Salmonella Saintpaul strain that was a genetic match for the outbreak strain. These samples came from a farm in Mexico but not the same farm that produced the first positive jalapeño samples from the distribution center in Texas.

Our current advice is to consumers to avoid jalapeño and serrano peppers grown, harvested or packed in Mexico. In addition, domestically grown raw jalapeño and serrano peppers, canned, pickled and cooked jalapeño and serrano peppers from any and all loca-

tions are not connected with this outbreak. We will continue to refine our consumer message as our investigation continues.

The current trace-back has worked but was slow, requiring review of many paper records. While sectors of the produce industry may keep electronic records, as we have just heard on the previous panel, and be able to do rapid trace-backs, this is not a uniform practice. And many of the plants FDA visited only had paper records, bills of lading or invoices. To better understand the universe of track and trace systems and best industry practices for traceability FDA has reached out to a variety of external entities. We plan to hold a public meeting in the fall to further exchange of information on available technology and best practices for enhanced traceability.

To enhance safety across a range of imported consumer products, last November Secretary Leavitt presented to the President the Action Plan for Import Safety. 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. Both plans build in safety measures across a product's life cycle, from the time a food is produced to the time it is distributed, and encompass the elements of prevention, intervention, and response.

The Food Protection Plan identified ten legislative authorities necessary for achieving full implementation. And we appreciate the work this committee is doing to draft legislation intended to help provide these authorities. We look forward to continuing to work with you to develop this important legislation.

FDA is working hard to ensure the safety of food, in collaboration with our partners. As a result of this effective collaboration, the American food supply continues to be amongst the safest in the world. However, the Salmonella Saintpaul food-borne illness underscores the challenges that we face. We have been making progress and we are moving forward with the implementation of the plans, but more does need to be done. To that end, FDA is exploring used its Science Board to convene a group of State, industry and academic and other experts to examine lessons learned from the outbreak.

I would like to thank you for the opportunity to discuss FDA's continuing efforts to enhance food safety and traceability. And I am happy to answer any questions.

Thank you.

[The statement of Dr. Acheson follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

DAVID ACHESON, M.D., F.R.C.P.

ASSOCIATE COMMISSIONER FOR FOODS

FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

UNITED STATES HOUSE OF REPRESENTATIVES

JULY 31, 2008

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INTRODUCTION

Good morning, Chairman Stupak 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 recordkeeping. 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 educational 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 life cycle, 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. These authorities 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 two 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.

We appreciate the work of this Committee in drafting legislation intended to help provide these authorities. We look forward to continuing to work with you to develop this important legislation.

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.

Mr. STUPAK. Thank you.

Dr. King please, if you will.

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

Dr. KING. Yes. Good afternoon. Chairman Stupak and members of the committee, thank you for this invitation to address this subcommittee today. 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.

First let me offer my sympathies to all the families who have been adversely affected by this outbreak. Also I understand the frustration of many in the food producing and serving industries who work so very hard to produce safe produce that we have heard about today. CDC leads federal efforts to gather data and to investigate food-borne illnesses. Much of what CDC does depends on the critical relationships with a broad range of partners: food safety regulatory agencies, in particular with FDA and USDA, USDA's Food Safety and Inspection Service, and with State and local public health departments.

Salmonella is a group of bacteria with over 2,500 subtypes that is widespread in the intestines of birds, reptiles and mammals. Salmonella is the second most common bacterial cause of food-borne diseases in this country. The current outbreak is called by Salmonella serotype Saintpaul, a relatively uncommon serotype causing only about 1 percent of all reported Salmonella infections each year. This outbreak is the largest food-borne outbreak in the United States in the past decade. This investigation ha been especially complex, difficult and prolonged.

CDC first learned about this outbreak on May 22 in 2008 when New Mexico Department of Health reported illnesses in four persons confirmed with Salmonella Saintpaul. New Mexico posted the information about the unusual number of Salmonella Saintpaul cases through PulseNet, a national network of public health and regulatory agency laboratories used to detect food-borne disease outbreaks. This information allowed State laboratories to compare specific DNA fingerprints found in New Mexico to their own cases of Salmonella that had been reported with matching fingerprints.

The next day Texas and Colorado reported cases of matching fingerprints. Investigators in New Mexico, Texas and CDC began a multi-state investigation. Epidemiologists conducted in-depth interviews with ill persons to collect information about what might be a possible source of infection. Results of this first series of interviews indicated raw tomatoes were the most commonly consumed food, leading to the hypothesis that they were a possible source of this illness.

Following these initial interviews, case control studies comparing what ill and health persons reported eating were then conducted. By May 31 preliminary results of the first case control study showed that the illness was significantly associated with the consumption of raw tomatoes.

On June 4 CDC received the first report of a possible cluster or any restaurant cluster and subsequently learned of additional clusters after that. Between June 18 and June 20 there was a large surge in reported cases in 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 foods in restaurants and the apparent continuation of this outbreak after the alert regarding the tomatoes led to the hypothesis that a food item commonly consumed with tomatoes could also be causing 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 one specific item. After additional epidemiologic investigations of a cluster of illness in Texas, the FDA began their trace-backs on peppers on July 21 and the FDA announced that they had isolated the outbreak strain of Salmonella Saintpaul from serrano peppers and water irrigation samples from a farm in Mexico.

The outbreak investigation unfortunately continues. The active field investigations by CDC, State and local health departments, focusing on identifying clusters of cases and the FDA trace-backs now on jalapeños, serranos, tomatoes and other possible sources are providing new information daily. This outbreak has been particularly challenging. First, there is inherent delay between when persons become ill with Salmonella infection and when results of the testing are reported to PulseNet. For half the cases in this outbreak it took more than 16 days from illness onset to posting the test results on PulseNet.

Second, people 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.

Third, the foods in question are often eaten together so exposure to one item often means exposure to all the items.

And, finally, perishable foods consumed by ill persons were often not available for testing.

As of June 29 at 9:00 p.m., 1,319 cases where Salmonella Saintpaul have been identified in 43 States, the District of Columbia, 255 persons have been hospitalized, and two deaths were possibly linked to this outbreak. At present we believe that jalapeño peppers and serrano peppers are linked to some of these clusters and could be two of several food vehicles, including tomatoes and other possible vehicles, as we continue to explore and investigate. The outbreak is ongoing but there are fortunately fewer illnesses being reported.

In conclusion, this outbreak illustrates the importance of existing public health networks: the laboratories performing PulseNet, fingerprinting, epidemiologists who conduct the investigations, the multi-disciplinary approach to these investigations and the close communication and collaboration among State, local and federal officials. We balance the rapid release of information on sources of illness against the potential negative consequences to consumers,

food growers, producers and industry. CDC is prepared to continue to work with regulatory agencies, State and local partners, food and environmental microbiologists, and certainly the food industry to find long-term solutions to this challenging problem.

I thank you for the invitation to testify and will be happy to answer questions that you may have.

[The statement of Dr. King follows:]

Testimony before the Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

United States House of Representatives

CDC Response to the Multistate Outbreak of *Salmonella* Saintpaul

Statement of
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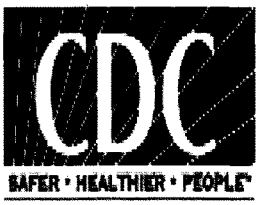

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Introduction

Good afternoon, Chairman Stupak 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, multistate 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, 10 states who participate in CDC's Emerging Infections Program, the Department of Agriculture's Food Safety and Inspection Service (UDSA/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* 0157, 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 4 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 4 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 multistate investigation. Daily multistate 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

[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.

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 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 5 ill persons. Three clusters had more than 10 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 multistate 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 federal 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 jalapeno 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 laboratories 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.

Mr. STUPAK. Thank you.
Dr. Smith please.

STATEMENT OF KIRK SMITH, D.V.M., PH.D., SUPERVISOR, FOODBORNE, VECTORBORNE, AND ZOONOTIC DISEASE UNIT, ACUTE DISEASE INVESTIGATION AND CONTROL SECTION, DEPARTMENT OF HEALTH, STATE OF MINNESOTA

Dr. SMITH. Good afternoon. Chairman Stupak and members of the subcommittee, my name is Kirk Smith, and I am Supervisor of the Foodborne Diseases Unit at the Minnesota Department of Health. Thank you for inviting me to speak on our role in the Salmonella Saintpaul investigation. We were not highly involved in the national investigation early on. Then, from June 23 through June 27 our State Public Health Laboratory received 10 Salmonella Saintpaul isolates from ill Minnesota residents who had gone to the doctor and been tested for Salmonella at a clinical laboratory. Our foodborne disease epidemiology staff immediately began the process of interviewing these patients. By June 30, several patients had reported eating at the same restaurant. That same day, we visited the restaurant to assess illness in foodworkers, determine the exact ingredients in various menu items, and request credit card receipts to identify other potentially exposed individuals to interview.

Ill and non-ill patrons were interviewed in detail about the menu items and ingredients they had consumed. By identifying what ingredients were in each menu item we knew if an individual ate fresh tomatoes, jalapeños, or cilantro, etc., even if they could not discern or recall all of the specific ingredients in a menu item. Then we statistically compared foods eaten by ill people to those eaten by non-ill people.

The ingredient-specific analysis indicated that diced jalapeños were the cause of our restaurant outbreak. We sent our preliminary statistics to CDC on July 3, 3 days after we identified the restaurant as the source through patient interviews. Statistics were updated and provided to CDC daily as the scope of our investigation grew. By July 8, 5 days later, we had interviewed 19 restaurant-associated cases and 52 non-ill controls, and unequivocally implicated jalapeños.

On our first visit to the restaurant on Jun 30, we also requested vendor invoices for produce items served on the implicated meal dates. Those invoices were given to the Minnesota Department of Agriculture, which conducted trace-backs. On July 3, we provided CDC and FDA with information on the possible sources of the jalapeños, all the way back to farms or distributors in Mexico. This part of the trace-back took 3 days.

So why were we able to solve our outbreak so quickly in Minnesota? In short, we have an efficient, rapid, and thorough system. By law, when a clinical laboratory isolates Salmonella or another reportable food-borne bacteria from a patient, the lab is required to submit the isolate to our State Public Health Laboratory. Our lab confirms, serotypes, and DNA fingerprints all Salmonella isolated in real time; and this is not done in many other public health laboratories. There is excellent communication between our lab and epidemiology staff; every day the lab provides us with a report of every isolate they have worked on.

Another reason for our success is that food-borne disease investigations in Minnesota are centralized at the State level. We routinely interview all reported Salmonella cases with a detailed questionnaire, and are able to re-interview patients with specific questions quickly as needed. In many other States, Salmonella cases are not routinely interviewed in a timely manner, and if they are, initial interviews are often done at the county level and may not contain sufficient detail. Centralized surveillance and investigations, coordinated at the level of State or large city health departments, are especially critical during multi-state outbreaks due to commercially distributed food items.

Food-borne disease surveillance and investigation in the U.S. need to be improved. State and federal funding for these activities in public health departments has decreased throughout this decade, and I believe that this affected the national investigation.

State and local health departments need to be able to rapidly confirm and type every Salmonella and E. coli 0157 isolate that is submitted. This is how we can learn that an outbreak is happening as early as possible. But many State public health laboratories cannot currently do this.

Secondly, State and local health departments need to be able to rapidly interview every patient with Salmonella and E. coli 0157 with a detailed questionnaire, and to conduct cluster investigations rapidly. Again, this currently is not being done in most localities.

As we have heard, the trace-back efforts of federal agencies can only be as good as the quality and timeliness of epidemiologic information coming from State and local health departments.

The investment in food-borne disease surveillance will not prevent food contamination from happening, but it will enable outbreaks to be detected and the source identified much earlier. This will help limit the size of outbreaks, minimize the impact on the involved food industry, and identify the types of food products on which to focus our prevention measures.

Thank you.

[The statement of Dr. Smith follows:]

STATEMENT OF KIRK SMITH

Chairman Stupak and Members of the Subcommittee,

My name is Kirk Smith, and I am Supervisor of the Foodborne Diseases Unit at the Minnesota Department of Health. Thank you for inviting me to speak on our role in the Salmonella Saintpaul investigation. We were not highly involved in the national investigation early on. Then, from June 23rd through June 27th, our state Public Health Laboratory received 10 Salmonella Saintpaul isolates from ill Minnesota residents who had gone to the doctor and been tested for Salmonella at a clinical laboratory. My foodborne disease epidemiology staff immediately began the process of interviewing these patients. By June 30th, several patients had reported eating at the same restaurant. That same day, we visited the restaurant to assess illness in foodworkers, determine the exact ingredients in various menu items, and request credit card receipts to identify other potentially exposed individuals to interview.

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Foodborne disease surveillance and investigation in the U.S. need to be improved. State and federal funding for these activities in public health departments has decreased substantially throughout this decade, and I believe that this affected the national investigation.

State and local health departments need to be able to rapidly confirm and type every Salmonella or E. coli O157:H7 isolate that is submitted. This is how we can learn that an outbreak is happening as early as possible. But many state public health laboratories cannot currently do this. Secondly, state and local health departments need to be able to rapidly interview every patient with Salmonella and E. coli O157:H7 with a detailed questionnaire, and to conduct cluster investigations rapidly. Again, this currently is not being done in most localities. The traceback efforts of federal agencies can only be as good as the quality and timeliness of epidemiologic information coming from state and local health departments.

The investment in foodborne disease surveillance will not prevent food contamination from happening, but it will enable outbreaks to be detected and the source identified much earlier. This will help limit the size of outbreaks, minimize the impact on the involved food industry, and identify the types of food products on which to focus our prevention measures.

Thank you.

SUMMARY

A restaurant-associated outbreak of Salmonella Saintpaul infections occurred in late June in Minnesota. The outbreak was quickly identified by the Minnesota Department of Health. Diced jalapeño peppers were implicated and traced back to multiple possible sources in Mexico within 3 days of the identification of the outbreak. This information was provided to the CDC and FDA on July 3. This successful investigation was enabled by a strong, centralized foodborne disease surveillance and investigation system at the Minnesota Department of Health, which collaborated closely with the Minnesota Department of Agriculture.

The large, nationwide outbreak illustrates that foodborne disease surveillance and investigation activities in the United States need to be improved. Effective investigations by federal regulators depend in large part on the timeliness and quality of epidemiologic information provided by state and local investigators. The Minnesota system could act as a model for foodborne disease surveillance and investigation in the United States. All state and local health departments should be able to confirm, serotype (Salmonella) and DNA fingerprint all submitted Salmonella and E. coli O157 isolates in real time, and they should be able to interview all cases with a detailed questionnaire in real time (this currently cannot be done in most localities). This would help identify outbreaks much more rapidly, which would limit

the size of the outbreaks, minimize the impact on the involved food industry, and identify the types of food products on which to focus prevention measures.

Mr. STUPAK. Thank you, Dr. Smith.

Dr. Jones, your opening statement please, sir.

STATEMENT OF TIMOTHY JONES, M.D., STATE EPIDEMIOLOGIST, COMMUNICABLE AND ENVIRONMENTAL DISEASE SERVICES, DEPARTMENT OF HEALTH, STATE OF TENNESSEE

Dr. JONES. Mr. Chairman and members of the subcommittee, thank you for the opportunity to be here today.

The recent nationwide outbreak of Salmonella associated with produce demonstrates challenges and opportunities for improvement in the nation's food safety infrastructure. A typical American meal includes foods from six different countries, and fresh produce travels a mean of 1,500 miles to get to our plates. Dramatic statistics demonstrate the rapidly changing environment in which outbreaks are occurring. Outbreaks increasingly involve multiple States and widely-distributed products, in part reflecting improvements in detection and investigation. Recent remarkable successes have led to high expectations which realistically cannot be met in all investigations.

Epidemiologists, such as those at State and local health departments and CDC, and regulatory agencies, must all work together well for outbreak investigations to be effective. 50 State health departments in the U.S. work under independent public health laws. A handful of States have successfully investigated a disproportionately large number of multi-state outbreaks, reflecting large discrepancies in the resources available to them to respond. Most outbreaks are detected and investigated entirely at the State and local levels. As in the early stages of this Salmonella outbreak, CDC is often in the position of reviewing and integrating results of investigations done by State and local agencies rather than doing de novo investigations.

State and local public health epidemiologist frequently interact directly with the public during outbreak investigations, rapidly assessing data to identify the cause. They do not routinely do things like inspect facilities, perform trace-backs, and do recalls. Federal regulatory agencies have very different missions, legal restrictions and relationships with industry. Investigators must constantly balance the risk of continuing disease due to delays in action with the risk of economic damage to the food industry that might be mitigated by waiting for more specific data. And, clearly, it is impossible to meet all of these expectations.

Faster product trace-backs would clearly have helped bring this outbreak to a more satisfying conclusion. Many epidemiologists I think view federal regulatory agencies as a black box into which data are sent but from which results are received frustratingly late or never. Federal regulatory agencies often must operate under such restrictive legal constraints that they are unable to share important data such as trace-back information, names of facilities, and brand names as quickly and as fully as many of us would like.

In a different outbreak recently, a regulatory agency had information that would have allowed State public health officials to con-

tact consumers at risk of disease but were prohibited from sharing it with us. It is possible for epidemiologists to become commissioned by the FDA to be allowed to receive confidential data, but most of my colleagues have refused to pursue this, specifically to avoid the untenable moral predicament of having access to data which we would then be legally unable to act on.

To their credit, USDA and FDA have recently undertaken a number of regulatory interventions based entirely on epidemiologic data prior to laboratory confirmation of pathogens in a food or production facility. And I hope that these recent experiences will not dissuade those agencies from acting rapidly on strong epidemiologic data in the future.

My message is not all gloom and doom. Americans today have access to one of the safest, most diverse, and cheapest food supplies in the history of mankind. And a variety of groups, such as the Multi-Agency Council to Improve Foodborne Outbreak Response, or CIFOR, are working toward the common goal of food safety. I think there are a number of opportunities for continued improvement of the nation's food safety infrastructure. Solutions require addressing barriers at the local, State and federal levels. Federal regulatory agencies must have the authority and expectation to share actionable information with public health partners promptly and fully to protect the public's health, and that may require changes in the laws governing them.

It is critical to support development of information technology adequate to sustain food safety activities, including improved technology for produce trace-backs, which was available for the recent packaged spinach outbreak, for example, but not necessary for the produce involved in this outbreak. Opportunities for improved coordination with industry should be explored. Industry has access to food testing data and information contained in frequent shopper cards, for example, that is often unavailable to investigators.

And, finally, public health agencies are pitifully under funded. Outbreak response capacity, at least at the State level, has been subsidized heavily by funding for successive waves of high-profile crises from bioterrorism to West Nile Virus, SARS and, recently, pandemic influenza. And funding for these is dropping dramatically. Americans eat a billion meals a day, day in and day out, and 75 million of us fall victim to food-borne illness every year. Adequate and consistent funding and resources must be dedicated to sustain effective public health programs commensurate with the true risks that they address.

Thank you.

[The statement of Dr. Jones follows:]

STATEMENT OF TIMOTHY JONES

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to be before you today.

The recent nationwide outbreak of Salmonella associated with produce, which began in late April, demonstrates challenges and opportunities for improvement in the nation's food safety infrastructure. The global distribution, intensive production, and rapidity of transport of our food supply are markedly increasing the challenges faced during outbreak investigations. A typical American meal includes foods from six different countries, fresh produce travels a mean of 1500 miles to get to our plates, feedlots can hold 300,000 head of cattle, outbreaks involving several hundred

victims no longer shock us. a long list of dramatic statistics demonstrate the changing environment in which outbreaks are occurring. Recognized foodborne disease outbreaks increasingly involve multiple states and widely distributed products, including several recent examples associated with fresh produce. Much of this change reflects improvements in the surveillance and investigation of outbreaks, and the capacity of state and local health departments to successfully identify contaminated foods, prevent additional illness, and subsequently make the food supply safer.

Such outbreaks also highlight the interdependence of multiple agencies at all levels of government in responding to these events. Epidemiologists (such as those at CDC and state and local health departments), environmental health programs, laboratories, and regulatory agencies (such as FDA, USDA and state Departments of Agriculture) at the local, state and federal level must all communicate well and coordinate activities rapidly for outbreak investigations to be effective.

Outbreak investigations typically go through a number of stages, at which various agencies have different levels of involvement. Outbreaks are typically recognized by epidemiologists and laboratories at the state and local levels. Epidemiologists generally work to identify the contaminated food, and regulators then participate in further characterizing the food vehicle and its distribution. Public notification is a critical part of this, at least for outbreaks that may be ongoing, and is usually handled by epidemiologists, regulators or both. It is important to understand that federal agencies (such as the CDC) do not typically initiate investigations of this sort. Thus, CDC is often in the position of reviewing and integrating the results of investigations done by state and local agencies, rather than doing de novo investigations.

The outbreak being discussed today has been particularly frustrating for all involved. It demonstrates the complexity of epidemiologic investigations, difficulties inherent in investigations of novel foods not typically implicated, statistical limitations in identifying one food item which is commonly consumed with other foods (salsa for example), inherent complexities of tracebacks of fresh produce, and challenges in public communication. Recent remarkable successes in investigations of spinach and lettuce-associated outbreaks and a number of other widely distributed products have led to high expectations which realistically can't be met in all investigations.

There are important differences in the "cultures" of the many different agencies that must work together in investigating outbreaks, with widely disparate missions, mandates, legal authorities, and organizational structures. While these are generalizations, state and local public health epidemiologists frequently interact directly with the public during outbreak investigations, rapidly assessing data to allow identification of the cause of an outbreak and make recommendations for preventing additional disease. Federal epidemiologists typically collate information from multiple states, but may not if there are only a few involved. CDC is generally called upon to assess epidemiologic data before federal regulatory agencies will act. Epidemiologists do not routinely do things like inspect facilities, perform tracebacks, or do product recalls. Epidemiologic, laboratory and environmental data are used to inform regulatory agencies, such as the FDA and USDA, in carrying out their functions. These federal agencies have very different responsibilities, priorities, relationships with industry, and legal mandates and restrictions.

Because of the very different "cultures" and working environments of these groups, widely varying perspectives on the challenges and weaknesses in outbreak investigations are inevitable. Consumers might be expected to desire immediate intervention to prevent potential disease, erring on the side of caution by acting on data that may be quite preliminary. On the other hand, many food producers would not want to see their business suffer because of poorly substantiated suspicions, and would expect public intervention to occur only on the basis of comparatively definitive data. Investigating agencies must constantly balance the risk that delays in action might lead to additional preventable disease, with the risk of economic damage to large sectors of the food industry that might be mitigated by waiting for more specific data. Clearly it is impossible to satisfactorily meet all of these demands and expectations, and every outbreak requires making judgments based on unique circumstances and data, quickly and under great pressure.

While there may be room for improvement, it is important to acknowledge that there are no rules, policies, or legal or administrative interventions which will obviate the need for difficult human decision-making in these situations. Moreover, it is important to realize that these decisions are not made by a single federal agency. States can and do act independently when ongoing risks are suspected, though it would be rare for that to happen without notification and consultation with federal agencies, particularly for products that are distributed across state lines. In addition, communication with industry may occur at the state or federal level.

There are over 3000 local health departments in this country, and 50 state health departments working under 50 independent sets of public health laws. Not unexpectedly, there is tremendous variability in the capacity to respond to disease outbreaks among different jurisdictions. A cursory review of outbreaks in recent years will demonstrate that a small handful of states appear to have successfully investigated a disproportionately large number of multi-state outbreaks. This is not an accident, and it is highly unlikely that those states really have more disease than others. Rather, this reflects discrepancies in the resources available, as well as the capacity and inclination to detect and investigate outbreaks. CDC does not in most cases have jurisdiction to come into states and investigate outbreaks without invitation. The large majority of outbreaks are detected and investigated entirely at the local and state levels, without any need for federal agency involvement. State health departments of course have very different thresholds for consulting with federal partners and requesting their assistance. In this recent Salmonella outbreak, for example, the initial disease clusters were recognized and investigated by local and state public health authorities. As the scope of the outbreak grew, CDC was invited in, initially to help evaluate data already collected by other agencies, and subsequently to become increasingly involved in designing and directing the investigations. Likewise, the FDA became progressively more deeply involved as the investigation evolved. At all stages in this fluid continuum, participants are necessarily dependent on data already collected by others previously, and must wait as additional data are collected, which invariably takes more time than any of us would like.

I think that it is safe to say that many public health epidemiologists view regulatory agencies such as the FDA and USDA as a "black box", into which data are sent, but from which results are received frustratingly late, or never. There are many examples of situations in which state health departments have proceeded with their own product testing or limited tracebacks, and gathered important data long before information was available from the federal regulatory agency involved in the investigation. I don't believe that these agencies are purposely withholding critical information from public health partners, but I do think that they are required to operate under such restrictive legal constraints that they are unable or unwilling to share data as fully and as quickly as we would all like, even in urgent situations. Federal regulatory agencies are frequently prohibited from sharing proprietary information and "trade secrets" obtained during the course of their investigations, which can include names of facilities, suppliers, traceback information, brand names, etc. I also acknowledge that tracebacks and regulatory investigations are far more time-consuming and complex than many epidemiologists appreciate, and our expectations of prompt results from an understaffed, underfunded and overworked agency are unrealistic. All that being said, I think it is inarguable that faster product tracebacks and better communication would have helped bring this outbreak to a more prompt and satisfying conclusion. In order for this to be possible, however, investigating agencies must have adequate resources to get the work done, and the legal authority to collect and share their data promptly and appropriately.

I was recently involved in another outbreak which highlights similar limitations. During the investigation of a contaminated product under the FDA's jurisdiction, investigators in that agency had information in their possession that would have allowed state public health officials to quickly identify and contact consumers at risk of serious disease. However, because of policies restricting sharing of proprietary data and information collected through related mechanisms, they were prohibited from sharing it with us. The situation was as frustrating for the FDA personnel involved as it was for us, but we find these types of restrictions during outbreak investigations unconscionable. Of note, it is possible for public health epidemiologists to become "commissioned" by the FDA to be allowed to receive confidential data such as those to which I just referred. Most of my colleagues have refused to pursue this, expressly to avoid the untenable moral predicament of having access to data which they would be legally unable to act upon.

To their credit, it is notable that both FDA and USDA have undertaken tracebacks and regulatory interventions in a number of recent outbreaks, based entirely on epidemiologic data, without first having laboratory confirmation of pathogens in a food or production facility. This has not been the norm in the past, and this growing acceptance of epidemiologic data has led to much prompter interventions to stop outbreaks and prevent additional disease. Clearly, careful consideration of the weight and implications of all data is critical, but I hope that the experience of the outbreak currently under discussion will not dissuade these federal agencies from acting rapidly on strong epidemiological data in the future to protect the public health.

Suspected produce-associated outbreaks are particularly difficult to investigate, from both the public health and regulatory perspectives. Typical produce items pass through a myriad of hands along the "farm to fork" continuum. While large food service corporations and their suppliers often have excellent quality-control programs with impeccable records, many other companies don't, and product tracebacks are susceptible to complete breakdown at the weakest link in the chain. Produce is generally purchased by consumers unlabeled, with no information on its origin. Produce from more than one source is often mixed at different distribution points. Many consumers have difficulty identifying subtle differences in varieties of produce. Such items are frequently consumed as ingredients in other foods (salsa, for example), or in foodservice establishments where consumers can't know a food's origin, and may not even be aware of what they are eating. Even if very detailed information from victims can be supplied by public health investigators to a regulatory agency (which is frustratingly difficult in and of itself), the challenges to performing subsequent tracebacks through such a complex food-handling chain are formidable.

It is important to delineate the jurisdiction and responsibilities of various agencies during outbreak investigations. Food safety is reportedly overseen by 14 federal entities, administering over 35 separate food safety laws, with the involvement of 28 congressional committees. That open-faced sandwiches are regulated by one agency and closed-faced sandwiches another, or jurisdiction differs based on whether a product contains more or less than 2% meat, can be complicated. I have been involved in outbreak investigations in which both FDA and USDA had regulatory authorities within the same production plant, and indeed the same production line, depending on the type of food topping being used that day, and each agency has strikingly different regulatory policies.

A substantial underlying cause of many of the problems I have described is a limitation of resources available to agencies responsible for responding to foodborne outbreaks. We are all familiar with the dramatic statistics describing the FDA's understaffing and responsibilities far exceeding their capacity to meet them, including the fact that only 50 staff are dedicated to inspecting all imported foods, and well under 1% of these products undergoes even cursory examination. CDC suffers from similar underfunding. More than one outbreak was occurring at this time, as is usually the case. Even with excellent staff, the agency simply cannot do its job if overtaxed. State and local public health agencies are likewise pitifully underfunded. Although the front line in outbreak investigations is at the state and local levels, most of those agencies receive the large majority of their funding from federal grants.

Our outbreak-response capacity is in large part supported by funding granted for successive waves of high-profile crises, from bioterrorism and anthrax, to West Nile virus, followed by SARS, then pandemic influenza. These resources have subsidized a wide array of core public health functions, notably disease surveillance and outbreak investigation activities, which otherwise would be impossible to sustain. In recent years "preparedness" funding has been cut repeatedly, leading not only to the obvious direct effects, but also to adverse impacts on our capacity to respond to events like foodborne disease outbreaks, which do not usually attract national attention but occur daily and affect millions of Americans annually. I obviously recognize the importance of disaster preparedness, but also believe that we need to realistically apportion resources to address public health threats in a logical manner. When the "red phone" rings for a bioterrorism attack it is important that we be prepared to respond, but while the likelihood of such an event is impossible to measure, Americans eat a billion meals a day, day in and day out, and 75 million of us fall victim to foodborne disease every year.

My message is not all "gloom and doom". Americans today have access to one of the safest, most diverse and inexpensive food supplies in the history of mankind. Public health, regulatory agencies and industry work remarkably well together toward the common goal of food safety. Huge strides are being made in our capacity to identify, respond to and prevent foodborne disease. FoodNet, a cooperative program among 10 states, the Centers for Disease Control and Prevention, USDA's Food Safety and Inspection Service, and FDA's Center for Food Science and Nutrition, performs internationally-recognized studies of a wide variety of foodborne disease issues. PulseNet, a CDC-based system for sharing of molecular "fingerprinting" data from foodborne pathogens with a variety of agencies has markedly improved disease surveillance and rapid recognition of foodborne outbreaks. OutbreakNet is a CDC-coordinated group of foodborne disease epidemiologists from all 50 states, as well as representatives from other food safety agencies, that is focused on ways to improve communication and response to outbreaks. Outbreak-response training programs are available, including Epi-Ready, which is a national effort to bring environmental health, laboratory, regulatory and epidemiology personnel together for co-

ordinated training. The Food Safety Research Consortium is a non-governmental organization pursuing a variety of projects including a recent report, "Harnessing Knowledge to Ensure Food Safety: Opportunities to Improve the Nation's Food Safety Information Infrastructure". A variety of other academic, consumer-advocacy and industry groups are engaged in similarly important efforts to address many of the issues that have been discussed today.

The Council to Improve Foodborne Outbreak Response (CIFOR) is another important example of successful efforts to address barriers in the food safety infrastructure. CIFOR is a multidisciplinary working group convened in 2006 to increase collaboration among the various public health agencies involved in the investigation, control and prevention of foodborne illness. The Council of State and Territorial Epidemiologists (CSTE) and the National Association of County and City Health Officials (NACCHO) are co-chairing CIFOR with support from the Centers for Disease Control and Prevention (CDC). Epidemiology, laboratory, environmental health and regulatory agencies at the local, state and federal levels are represented. CIFOR is now exploring ways to increase involvement of industry representatives appropriately into its activities. Recent CIFOR projects have included establishment of an online clearinghouse of foodborne-disease response resources, development of guidelines for responding to multi-jurisdictional outbreaks, development of performance indicators for assessment of outbreak-response programs, and writing comprehensive guidelines for multi-agency investigations of foodborne disease outbreaks.

I believe that there are a number of opportunities for continued improvement of the Nation's food safety infrastructure:

-Adequate and consistent funding and resources must be dedicated explicitly to sustain effective public health and food safety programs, commensurate with the true risks associated with the public health threats they address.

-Federal regulatory agencies must have the authority and expectation to share actionable information with public health partners promptly and fully, to the extent necessary to protect the public's health. This may require changes in laws governing those agencies, and trust among public health partners and industry that sensitive and propriety information will be used only for protection of the public's health.

-Though I do not believe that federal public health epidemiology programs should be merged administratively with federal regulatory agencies, there is great potential benefit to reviewing jurisdiction of food types, facilitating improved communication among these agencies, including developing mutually accessible databases, ensuring rapid sharing of data during public health emergencies, and continuing to develop inter-agency training opportunities.

-It is critical to support development of information technology adequate to sustain outbreak detection and response activities. This includes resources for the development of state-based disease surveillance databases that both serve state needs and that allow for the sharing of essential information with other states and federal agencies, electronic laboratory reporting from commercial laboratories to public health agencies, and open data standards that allow data sharing among all food safety and public health agencies.

-Opportunities for improved coordination with food industries should be explored. Many food industries conduct testing which could be valuable in identifying the sources and causes of foodborne illness and outbreaks. Data sharing by industry should be encouraged. In addition, while outbreak investigators require appropriate independence, the food industry has access to data that can be important to investigations. One example is the detailed information often contained in "frequent shopper cards", which can include contact information and precise data on dates and products purchased. A limited number of stores have been very cooperative in sharing such data with public health investigators, but unfortunately this is not currently the norm. Many grocery chains enter into contracts with consumers that they interpret to prohibit unilateral disclosure of sales information to public health agencies.

In summary, I believe that our nation's food safety infrastructure is strong, but substantial barriers to continued improvement remain. Important strides are being made to improve foodborne disease outbreak response, and with adequate support there are many additional opportunities for improvement. I applaud today's meeting as recognition of the importance of pursuing these goals. Thank you for the opportunity to discuss these issues with you today.

SUMMARY

-Improving the nation's food safety infrastructure, and capacity to respond to outbreaks, will require addressing barriers in epidemiology, laboratory, environmental health and regulatory agencies, at the local, state and federal levels.

-Adequate and consistent funding and resources must be dedicated explicitly to sustain effective public health and food safety programs, commensurate with the true risks associated with the public health threats they address.

-Federal regulatory agencies must have the authority and expectation to share actionable information with public health partners promptly and fully, to the extent necessary to protect the public's health.

-Formal mechanisms to facilitate effective communication, sharing of data, and inter-agency training among agencies, and with industry, should be developed.

-An adequate information technology infrastructure is critical to ensuring successful outbreak responses.

-Mechanisms should be developed to support and take maximum advantage of successful efforts, including those of non-governmental, academic, consumer and industry organizations, to improve the food safety infrastructure.

Mr. STUPAK. Well, thank you. And thank you all for your testimonies. Now we will begin questions.

Dr. Acheson, I have been talking about these 3 releases in the last 12 hours because I think it adds more confusion as to what was going on. The first one 9:00 o'clock last night was on jalapeños. The one at 10:15 I think or 10:30 was on cilantro. And then the one today sort of expands and talks a little bit about this farm and the location down there in Mexico. And one of the questions I asked the other one is, the other panel was you still have not cleared the tomatoes. Are tomatoes still a suspect or vegetable of interest as we were calling it on the first panel or are they cleared now?

Dr. ACHESON. FDA has investigated tomatoes. We have done a lot of testing with States and other federal agencies. We have not found a positive sample. We have inspected farms and——

Mr. STUPAK. So why do you not clear the tomato?

Dr. ACHESON. At this point there is nothing for FDA to say that would indicate the evidence that CDC and the States generated early on in this investigation is incorrect. FDA based on that information did its trace-back.

Mr. STUPAK. Right.

Dr. ACHESON. And it is not up to FDA to say that that original case control study was——

Mr. STUPAK. Well, then who clears the tomato then? If it is not up to the FDA you have no Saintpaul Salmonella or Salmonella Saintpaul in any tomato product. We have cilantro suspect and now we have peppers for sure; right?

Dr. ACHESON. Right. Correct.

Mr. STUPAK. Well, so who would clear it then I mean?

Dr. ACHESON. We have made it very clear that there are no tomatoes that are currently available on the market from anywhere in the world that are linked to the outbreak.

Mr. STUPAK. Currently. But how about tomatoes from the original suspect? That is what the last panel was concerned about, that that hangover effect still exists as to tomatoes.

Dr. ACHESON. Are you suggesting that FDA go back and say that that original conclusion was incorrect? Because that is not FDA's role. FDA picks this up at the point——

Mr. STUPAK. OK, so if the FDA makes a mistake you never say, I might have made a mistake?

Dr. ACHESON. Of course we would. But we did not make a mistake. FDA——

Mr. STUPAK. How do you get Saintpaul Salmonella with the tomato then.

Dr. ACHESON. Let me try this again.

Mr. STUPAK. Yes.

Dr. ACHESON. FDA begins its trace-back——

Mr. STUPAK. Correct.

Dr. ACHESON [continuing]. Based on information——

Mr. STUPAK. From the CDC and others, right.

Dr. ACHESON. Right.

Mr. STUPAK. All right.

Dr. ACHESON. We do that in good faith based on the science——

Mr. STUPAK. Right.

Dr. ACHESON [continuing]. That CDC has undertaken.

Mr. STUPAK. And in your trace-back you found nothing to implicate the tomato?

Dr. ACHESON. And we have said that. And we have said that tomatoes that are currently on the market are safe to consume.

Mr. STUPAK. On behalf of the tomato, they want their good name back, I think you should put out something a little more firmer on that.

Let me ask you this. These farms in Mexico that you now suspect with the jalapeños——

Dr. ACHESON. Yes.

Mr. STUPAK [continuing]. Do any of them grow tomatoes?

Dr. ACHESON. Yes, they do. There is at least one farm.

Mr. STUPAK. OK, at least one. Then the irrigation water that is suspect is that irrigation water being used on tomatoes then?

Dr. ACHESON. The farm that grows tomatoes also grows serrano and jalapeño peppers.

Mr. STUPAK. OK.

Dr. ACHESON. That is the farm where the original peppers that were positive in McAllen, Texas, traced back to.

Mr. STUPAK. OK. That's the one that Minnesota had; right? No?

Dr. ACHESON. That is, the Minnesota part is just one piece of this.

Mr. STUPAK. OK. OK. So the farm, there is at least one farm in Mexico that grows jalapeños and tomatoes that we have positive for Salmonella Saintpaul; correct?

Dr. ACHESON. Let me try this again. There is——

Mr. STUPAK. If I am confused the American people are really confused.

Dr. ACHESON. FDA found a positive sample of jalapeño peppers at a distribution center in Texas.

Mr. STUPAK. Texas.

Dr. ACHESON. OK.

Mr. STUPAK. You traced it back to a farm in——

Dr. ACHESON. We traced—can I finish?

Mr. STUPAK. Sure.

Dr. ACHESON. That may clarify your confusion. We traced that positive sample of jalapeño peppers back to a farm in Mexico. That farm grows jalapeños, serranos and tomatoes.

Mr. STUPAK. Tomatoes, OK.

Dr. ACHESON. As part of the investigation in Mexico we were investigating other farms and we took samples on other farms.

Mr. STUPAK. Correct.

Dr. ACHESON. And found the outbreak strain on a different farm that grows jalapeño peppers and serrano peppers but does not grow tomatoes.

Mr. STUPAK. OK.

Dr. ACHESON. Now one question that is out there, which I think you are getting at is, is there a connection between those two farms?

Mr. STUPAK. Well, where is the water source coming from?

Dr. ACHESON. That is a good question and that is part of what we would try to determine while we are there.

Mr. STUPAK. Would these two farms use the same water source?

Dr. ACHESON. Do not know. Do not know. But what I can tell you is that those two farms do send their produce through a single distribution center.

Mr. STUPAK. How far apart are these farms?

Dr. ACHESON. I believe they are about 3 hours drive but I do not know specifically how many miles apart they are.

Mr. STUPAK. OK. Then let me ask this question I asked of the previous panel and they were not real clear on it or did not quite: is Salmonella Saintpaul usually associated with poultry?

Dr. ACHESON. Salmonella, yes, typically with turkey.

Mr. STUPAK. Turkey?

Dr. ACHESON. Yes.

Mr. STUPAK. OK. Are there turkey farms down there near this area in Mexico?

Dr. ACHESON. Not aware of any turkey farms down there.

Mr. STUPAK. OK. Let me ask this: any reason why you could not clear domestically grown tomatoes then?

Dr. ACHESON. We have already stated that domestically grown tomatoes, tomatoes from anywhere are perfectly OK to consume.

Mr. STUPAK. OK, let me ask you this. Let me go to Dr. Smith. You said, and I am going to come right back to you, you said when you did the jalapeño and you nailed it there you traced it back to the farms in Mexico?

Dr. SMITH. There were multiple possible sources of these jalapeños and they were all in Mexico.

Mr. STUPAK. OK. I am sure you gave that information to the FDA.

Dr. SMITH. Yes.

Mr. STUPAK. So are we talking about the same farms then that Minnesota suspected?

Dr. ACHESON. Yes. They crossed into our systems, into what we were tracing back.

Mr. STUPAK. OK. How many farms or possible sources did you find?

Dr. SMITH. Well, we could not get back all the way to the farm level.

Mr. STUPAK. OK.

Dr. SMITH. All of the farms. But we had three different possible trace-back farms.

Mr. STUPAK. OK.

Dr. SMITH. And they all went back to Mexico and one of them only could we get back to a distributor.

Mr. STUPAK. OK. So you found these three farms you have at least two farms about 3 hours apart and the water source we are still not sure about yet; right? Is that correct, Dr. Acheson?

Dr. ACHESON. We found two farms, yes, but we have been—there are many other farm distribution centers that have crossed over in this trace-back. It is not as simple as just two farms in a distribution center.

Mr. STUPAK. OK. How many, if you know, how many farms use this water source that has suspect with Salmonella Saintpaul?

Dr. ACHESON. I do not know.

Mr. STUPAK. OK. OK. Let me ask this question. You mentioned you are going to have a fall conference, Secretary Leavitt has called a fall conference. Will the FDA be running a post-mortem on what went right, what went wrong on this recall? Will you be doing that?

Dr. ACHESON. We are proposing two things: one is a public meeting in the fall that will be focused on issues around traceability. We have had a lot of discussion earlier, it is very important.

Mr. STUPAK. OK.

Dr. ACHESON. What I said is that right now we are exploring using our Science Board as a mechanism to set up a subcommittee of the Science Board that could involve industry, State, federal, academic experts to help——

Mr. STUPAK. Right.

Dr. ACHESON [continuing]. Ask questions about what can we do better? What went wrong? What are the lessons learned?

Mr. STUPAK. Why would you not just use the folks involved in this one because this one is the largest Salmonella outbreak we have had in the last 10 years, last decade? Why would you not use the folks in the first panel to help do it as proposed?

Dr. ACHESON. We very well may. It just needs to be done through the mechanisms of the Science Board. As you have raised earlier or has been raised in terms of information that we can share and the Federal Advisory Committee Act, laws that are around, discussions, etc., it has to be done according to the law.

Mr. STUPAK. Right.

Dr. ACHESON. And doing it through the Science Board is a process that allows us to do that.

Mr. STUPAK. OK.

Dr. ACHESON. The experts——

Mr. STUPAK. OK, last Science Board on review in the FDA though and the things you had there it was limited to they could not talk about budget, so I would hope that this Science Board would be given full review of the information so they can put forth recommendations to help assist with this.

Let me ask you this, with any crisis you learn from your weaknesses in the existing system. What have you learned from this investigation that requires legislative changes? Because in your testimony you said Congress is drafting. We are past drafting, we are actually negotiating between all the parties, and I know the FDA has been involved. So and we are getting, we are on the food part right now on food safety. So what legislative changes have you learned that we need to help you with this kind of investigation?

Dr. ACHESON. Of the 10 legislative proposals that we have discussed previously as part of the Food Protection Plan, probably the

one that is most important is the one that requires preventative controls. I do not think anybody would disagree that the key answer to this is not to react faster but is to prevent the problems in the first place. That is absolutely critical across the board. So that is a very important one.

There are other components in there in terms of the other legislative proposals that would help somewhat. Another one, for example, is the requirement for certification for certain imported products. That is a federal to federal agreement. But that is another example that could help us.

And then I think as the questions around lessons learned unfold here, and we are still focusing on stopping the outbreak as opposed to focusing on what are the lessons learned after, but obviously there needs to be lessons learned and discussion around traceability and whether there needs——

Mr. STUPAK. Right.

Dr. ACHESON [continuing]. To be a legislative fix around that.

Mr. STUPAK. Well, we had the Bioterrorism Act of 2002 which was supposed to give the Secretary of HHS the tools necessary to have rapid trace-back of a food commodity through a distribution chain. Did the Bioterrorism Act work here?

Dr. ACHESON. The Bioterrorism Act worked as written. We rarely ran into a problem where people were not keeping records of people who were supposed to. That did not slow it down. Contrary to what you heard on the first panel, what we learned in this outbreak is that it was many of the small producers, the small restaurants, much like Mr. Shimkus' example of the little restaurant that he goes to on a Friday night that were involved in this, they do not have electronic systems. The vast majority of the information we got was paper, it was invoices, it was bills of lading. That has to be worked through by a person just working their way through, looking for the connectivity.

Mr. STUPAK. Should not the farm be included in the Bioterrorism Act? Right now it is exempt, farms and restaurants. Would that not have really helped you out if they were part of the Bioterrorism Act?

Dr. ACHESON. Currently the Bioterrorism Act does not cover you from farm——

Mr. STUPAK. Right.

Dr. ACHESON [continuing]. All the way through to restaurant.

Mr. STUPAK. Right. Should they not be included?

Dr. ACHESON. It certainly would expedite the process if they were.

Mr. STUPAK. OK, let me go to Dr. Smith, I have a question or two. I read from an Associated Press article, and I want to go back to that, on July 23 Associated Press ran an article entitled, and I am quoting, "A Hot Lead in the Hunt of Salmonella Source: Minnesota Pinpointed jalapeños While Feds Fruitlessly Chased Tomatoes." I presume you have read this article?

Dr. SMITH. Yes.

Mr. STUPAK. OK, then let me ask you this. The article suggests that the State of Minnesota was using certain outbreak investigation techniques that the CDC and FDA were not using. Are there

certain things that you believe that the State of Minnesota did in this outbreak that key federal agencies did not do?

Dr. SMITH. Well, first of all I should say you know the types of things that we do are the types of things that need to be done in other State and local health departments.

Mr. STUPAK. Right. But what about CDC and FDA, should they be using those things too? And what are they?

Dr. SMITH. Well, OK, so what makes I think us so successful is that our laboratory confirms and types all Salmonella isolates that they get right away. It takes 2 or 3 days. And then they give that information to epidemiologists right away. And then we interview these patients right away.

Mr. STUPAK. So that the rapid response from the investigation of the slide to your local health to the interviews?

Dr. SMITH. I think it is the rapid response. But it is also the level of response. We get very detailed information from all of these patients. And I also have epidemiologists who work only on food-borne disease. They are evaluating clusters every day and so they are very experienced.

Mr. STUPAK. So in the first panel when they said, well, yesterday I was working on heart stents, today I am working on tomatoes, that does not lead to good investigative work?

Dr. SMITH. Yes, certainly it is better if you have got people that are just dedicated and focused on one thing. And we are fortunate to have enough resources to be able to have epidemiologists that are dedicated to food-borne disease. And a lot of these resources are from federal programs such as Food Net.

Mr. STUPAK. OK. Just one last question before I turn to Mr. Shimkus. Dr. Acheson, it came up in the first panel, it sort of came up here, Dr. Jones mentioned it, if this were bio-terrorism how would you have acted differently?

Dr. ACHESON. If this was deliberate the process would have been the same.

Mr. STUPAK. So even information sharing would have been the same? There has been complaints about information sharing and whether a person would be commissioned or non-commissioned because there is a concern about information sharing. No command, incident command center, no one was in charge was the other allegation. So you would handle it the same? That is not a good idea.

Dr. ACHESON. There was a lot of information sharing that went on, a lot of work was done. In fact, with the State of Florida, as Commissioner Bronson talked about, we did use Florida labs, we did use Florida inspectors when we were down in Florida. So we actually did what he was suggesting that we did not do.

Mr. STUPAK. But Florida is mad at you for banning their tomatoes when they could provide traceability with a system that FDA helped develop. So I do not think Florida is especially happy with the FDA or the way information was shared. Their traceability would have showed because of the outbreaks that——

Dr. ACHESON. I am pointing out that we did share a lot of information with Florida and we did use the Florida resources, as the Commissioner suggested we should. We did, we used their labs and we used their inspectors.

Mr. STUPAK. Well, I hope if we suspect a bio-terrorism we are not going to treat it the same way, that there would be a little bit more urgency to it.

Dr. ACHESON. The trace-back process would be the same. It is what it is.

Mr. STUPAK. So then it is a major hole in our national safety, whether it is bio-terrorism or Salmonella Saintpaul?

Dr. ACHESON. If somebody has done something deliberate that is involving the same type of products in the same type of restaurants and retailers it would be no different, it could not be different. It is still right now paper, invoices, bills of lading. You have to go and get them, you have to go and pick them up. That is what could be a focus of making it faster if there was a deliberate act.

Now, obviously if this was deliberate there would be different federal authorities involved. Homeland Security would have a lead if it was a bio-terrorism event. It would be run differently. I am simply focusing on FDA's role with the traceability. It is what it is. I mean and it worked, it was just slow.

Mr. STUPAK. Mr. Shimkus please.

Mr. SHIMKUS. Thank you, Mr. Chairman.

I want to go back. I think we are pounding on FDA but FDA spent all this time going after the wrong suspect because it was not identified properly to begin with. And once we got identification with the help of a public health department, 18 days plus 4 to find the location. And so I think there are ways that we think we can make things better. And my questions are going to be in that.

But we have got to keep this in focus. I think the original panel identified that. We just got taken off in the wrong direction and the FDA went. Traceability worked, maybe not as quickly as would like, but it worked. And the reality is, Diana, the reality is tomatoes first time for this disease is infinity. We are still looking, we cannot find it. When it was identified in peppers, 18 days to find the pepper, 4 days to find the location. I think that is a success. What went wrong was that and the issue is the CDC and the public health department.

So I would like to ask first, we have two public health departments, how big is the State of Minnesota population-wise?

Dr. SMITH. About 5 million people.

Mr. SHIMKUS. And, sir, your state?

Dr. JONES. Six million.

Mr. SHIMKUS. And so what is the budget, Dr. Smith, of yours, of the State Public Health Department?

Dr. SMITH. I basically have one food-borne disease epidemiologist for every million people in the State.

Mr. SHIMKUS. One for every million. And, Dr. Jones?

Dr. JONES. Same order of magnitude, yes.

Mr. SHIMKUS. And we do not have to name States, but you probably know States that have one epidemiologist for how many?

Dr. SMITH. Every 24 million people.

Mr. SHIMKUS. Twenty-four million. And I guess Texas, I mean and we are talking about this starting in Texas or New Mexico. I guess Texas was the second point. And I do not want to even ask about my State. So but if we had a bio-terrorism attack it would be identified first by who?

Dr. SMITH. It would be identified in exactly the same way as a natural contamination would, exactly.

Mr. SHIMKUS. And it would go once you had identified the convergence, the commodity, you would then go to the CDC?

Dr. SMITH. Absolutely.

Mr. SHIMKUS. And then in conjunction we would then have to raise a concern to start finding where this thing started from. And again, if we are using this as a case study we just identified it wrong. So I think part of this debate is public health, public health departments get them funded, get them technologically advanced. And then probably, Dr. King, probably working with CDC to get you all fully funded and up to speed and staffing, would you not agree?

Dr. KING. I certainly agree that many of the states are under-resourced when it comes to many public health problems, including food safety. I think that was one of the inherent problems and lessons learned here is that they were poorly resourced and could not respond just because they did not have the resources to put into this.

When you talk about, Congressman, about the States talking to CDC, there is a system in place called PulseNet. And PulseNet is in place. All the States have PulseNet capabilities. There are counties and cities that also have PulseNet. So concurrently and simultaneously we can through the States, local and CDC actually look across the 50 States and even further into those States, into cities, with a system that is standardized to say, oh, this is Salmonella Saintpaul, this is the variety that has caused outbreak over New Mexico and Texas and Illinois. That gives us then the capability to say this is a multi-state outbreak. There is a source here that we did not know about.

The CDC's role then—and by the way, the States can look at this just as quickly as CDC can—CDC then is involved in that coordination when asked. Last year there was 1,260, right, outbreaks that came to CDC's notice. Of those, about 120 CDC was actually involved in giving advice, helping where asked. 12 of those we actually took a lead role. 90 percent of what is happening in the food safety area is at the local and State level. 1 percent of the time CDC actually gets involved in a lead situation. That is why these States need to have proper resources.

Mr. SHIMKUS. And I mean this is a tough position because you make a call, there are people ill. Make the wrong call then you have got the culprit still out there. People are sick, people are dying. It is an honorable profession and we applaud your work, we are just trying to get it better.

Dr. Jones, and this is also in preparation for the hearing, I want to know what are the barriers, these legal barriers, and I want to know some specifics of what are the legal barriers that are limiting our ability to more quickly, clearly identify culprits and the like? Do you have any that you can specifically give me?

Dr. JONES. I am not aware of any legal barriers to sharing epidemiologic data. And I think that that occurs quite rapidly in both directions and goes to the regulatory agencies fairly quickly. I guess the examples that I am familiar with have to do, and again I am not an attorney, have to do with legal restrictions on federal

regulatory agencies not being able to share potentially, you know, proprietary information.

Mr. SHIMKUS. Yes, give me an example. We want to, I would think the committee would want to find out exactly what those are. And as we are doing legislation to say when there is a national public health risk we have to tear these down and we have to ensure that the federal agencies protect the propriety while we are finding information.

So, Mr. Chairman, as we continue this I think this is a key area. And I mean does anyone, can anyone share? Dr. Acheson?

Dr. ACHESON. Part of the problem here is proprietary information that is deemed to be commercial confidential. There is a mechanism through commissioned individuals at the State level that that can be shared with. And we——

Mr. SHIMKUS. Well, we heard about commissioned individuals——

Dr. ACHESON. Yes.

Mr. SHIMKUS [continuing]. In the first panel. And they did not seem to have much power or control or input.

Dr. ACHESON. No, we are able to share information with commissioned individuals, and we do. And I think to that point if a commissioned individual in a State is saying, we think there is something going on and we would like some information, nothing to stop them picking up the phone and saying, can you help us here because we have some questions, if they are commissioned.

Mr. SHIMKUS. Well, we are going to, I know on our side we are going to try to dig in, Mr. Chairman, on this issue because we are the legislative branch. You know, we can—Dr. King, do you want to add?

Dr. KING. There is one piece of information I know the industry was hoping to get and could not get and was critical of it, and that was identification of cases by county. And that is something that through our legal counsel when a State shares information with us first of all the data and information is the State's. When it is shared voluntarily with CDC it becomes part of the federal record. It is also then under the authority of Privacy Act and also under Freedom of Information Act and agency policy. And it has been consistent and the recommendation of our general counsel that when you get down to the county level that that gets too close and patients, to protect patients' rights we will not give that information out.

And so there is a case where you get States with very—not very populated and maybe have one hospital, all right, that is the information then could actually get back. And those patient rights need to be protected. So there is a case.

Mr. SHIMKUS. Yes, again I am going to keep, we are going to keep following up on this line of work because I think where there are some legislative fixes here and where we can protect propriety and carve out provisions because we need information. And I think the first panel talked about transparency when there is a national emergency. If we are talking about bio-terrorism and the risk of millions of people we surely do not want privacy considerations to trump the health and welfare of the nation.

So and the Chairman's position also was if we get sent down the wrong path, as this case is happening, how do we clear the product that has now lost immediate dollars and potentially market share, how do we, who calls it and says lay off the tomatoes? Dr. King.

Dr. KING. Thank you, Congressman. You know, we respectfully disagree that tomatoes were not involved. And so if you give me a little bit of time to talk about what happened in that case control study if you would like for me to explain that, to talk about the science and the epidemiology behind it, that is your call.

Mr. SHIMKUS. Well, my time expired. If the Chairman wants to hear it I would be happy to hear it.

Mr. STUPAK. Well, yes, let us hear it. Because how do you prove a negative? You put a negative out there and you still cannot prove that negative.

Dr. KING. It is an important point to make, so let me go back. And, you know, I apologize for the terms in the epidemiology, I do not apologize for the science.

So initially when we had these cases in New Mexico, New Mexico went ahead and went back to ill people and did what they call hypothesis-generating interviews. And that hypothesis generating, I think your committee had copies of this.

Mr. STUPAK. It is all right here, Yes.

Dr. KING. Absolutely. Was pretty comprehensive. It included at least 200 different sources of food.

Mr. STUPAK. But even at that time you knew tomatoes coming from South Florida does not go to New Mexico. That is the traceability thing that they are arguing with you. And if you will not give them the county they cannot help you.

Dr. KING. Yes, sir. You know, it is what you know at that point in time.

Mr. STUPAK. Right.

Dr. KING. So, you know, at that point——

Mr. STUPAK. Well, you knew that South Florida was the only place that there was producing tomatoes for distribution in the United States, there and Mexico. So if Florida has this great traceability why did you not work with them so they could show that was not Florida tomatoes to we could have protected the domestic tomato industry which has lost $100 million and counting?

Dr. KING. So let me just go back and explain the ep—the trace-backs are part of what FDA does, not what——

Mr. STUPAK. Well, that is part of epidemiology, is it not?

Dr. KING. It informs trace-backs for sure, absolutely. And they go together. So you are absolutely right.

So through the hypothesis-generating interviews and through the case control studies that followed, right, and the case control studies were done by Texas, New Mexico, and the Indian Health Service, and the analysis of the data strongly associated tomatoes as the possible cause of this outbreak. And when I say strongly associated, you have to understand what that is in epidemiologic terms. When we did the calculations, epidemiologist statisticians, right, that means that people that were ill with this form Salmonella Saintpaul that was in this particular pulse field were 7 times more likely to have eaten raw tomatoes.

And when you did further probabilities of the calculation, right, they do what is called a P value. This is the probability that came up with .001. That was 10 times greater in terms of what it would take to publish the scientific data. So with that information in mind and epidemiologists and talking to other people that do this and which we have done for 30 years, right, that is a strong association.

Mr. STUPAK. Agreed. But when you made that strong association, May 22 is when CDC and State health officials identified outbreak of Salmonella Saintpaul, and within a few days you said tomatoes was the probable one; right?

Dr. KING. Had the strongest association.

Mr. STUPAK. Sure, strongest association. OK. But then if it is tomatoes is not the next question where the tomatoes come from? And we know from all the testimony the only place is Southern Florida which has the strongest, as they say, traceable product of tomatoes. And they say you would not work with them. The first line of Mr. Bronson's testimony. Give me the first line of that testimony. His first line of his testimony, written testimony which he gave us was, his first line was, "FDA did not share or solicit critical information from State food safety agencies. State resources could have augmented FDA's effort."

So if you are—and I understand epidemiology, I understand statistics, also understand doing crime scenes. When you got a crime scene everyone is a suspect but the infant probably can be cleared immediately because they do not have the means to cause the harm. So for the tomato industry I guess I am saying if you knew it was South Florida, you knew it was tomato, South Florida's tomatoes were not going there, they could trace that, they could prove that to you, then what went wrong after that? We just kept focusing on the tomato. I understand that but domestically-produced tomatoes?

Dr. KING. Well, CDC does not do the trace-back by the way, so.

Mr. STUPAK. Agreed. But you do the epidemiology; right?

Dr. KING. The epidemiology. We do the lab.

Mr. STUPAK. Correct. And you give it to the FDA then do the trace-back.

Dr. KING. And FDA is informed by what we have with that conversation and it certainly leads them to——

Mr. STUPAK. Correct.

Dr. KING [continuing]. Some indication of best bets in terms of trace-back.

Mr. STUPAK. Well, what would the information would the FDA receive from the CDC on tomatoes to make it think it is domestically-grown tomatoes when we know it is only coming from a very small part of our company which has trace-back laws?

Dr. ACHESON. When we were looking at the clusters and the sporadic cases that the CDC and the locals were investigating in the States, that is our start point. And initially in this outbreak we did not have clusters, we were dealing with sporadic cases and individuals. You are dependent on their memory. And they say, well, we bought our tomatoes at such and such a retail outlet. So we would go there and we would trace it back.

Mr. STUPAK. Correct.

Dr. ACHESON. And then we are, to your point, asking where could those tomatoes have been distributed? This year what we learned from industry was that because of weather or economic conditions Florida tomatoes were going all across the United States, they were going as far as California.

Mr. STUPAK. Well that is not what the first panel said.

Dr. ACHESON. Well, that was what our information.

Mr. STUPAK. And if they are Florida tomatoes would you not think you would have some sick people in Florida about this same time? These were only West, right, New Mexico and Texas was the only two places the first outbreaks were. If it's Florida tomatoes I would think Florida people would be getting sick. What did we have 4, 4 people this whole time out of Florida and 11 in California I think it was, and 500 in Texas and 100-and-some in New Mexico? Anyway, OK, did you want to add anything more on that, on what you did there?

Dr. KING. Yes, Chairman. Thank you.

Mr. STUPAK. Yes.

Dr. KING. Just to put it in a little bit of a context, so I just went back to 2006 and I looked at 10 outbreaks, right: E. coli in spinach, shredded lettuce botulism, Salmonella in tomatoes, E. coli in frozen pizza, Salmonella in peanut butter, Salmonella in——

Mr. STUPAK. Yes, we have done all those hearings.

Dr. KING. Done all of those hearings.

Mr. STUPAK. Yes.

Dr. KING. Let me point out that actions were taken on the basis of epidemiologic investigations on all those in the advance of any product cultures that were done.

Mr. STUPAK. OK.

Dr. KING. So the idea that this one is not different than what we usually find.

Mr. STUPAK. I understand you have a suspect, but you have to put the suspect at the scene of the crime, and you guys sure did not do a very good job I do not think. And I think that is where your problem is.

Mr. SHIMKUS. I will yield back my time here, Mr. Chairman.

Mr. STUPAK. Yes. Ms. DeGette for questions.

Ms. DEGETTE. Dr. Acheson, do you think that the trace-back in this most recent Salmonella outbreak was done in the best and most timely way it could have been done?

Dr. ACHESON. With the system?

Ms. DEGETTE. Yes.

Dr. ACHESON. With the system that we currently have in place, yes.

Ms. DEGETTE. Do you think it is the best system that we could have?

Dr. ACHESON. I think it could be improved in terms of increasing its speed.

Ms. DEGETTE. And if it was improved then would we have if we had a better system, which I will get into, would we have been able to identify, at least eliminate tomatoes as a potential source and move and try to identify the sources more quickly?

Dr. ACHESON. I believe that a faster system, and you could talk about what that would look like, but I believe that a faster system

would allow you to exclude products faster and to get back to potential areas where factors are crossing over to give you a source faster.

Ms. DEGETTE. Now, let me ask you this. We heard on the last panel that there are a number of voluntary industry associations for trace-back and also a number of companies have trace-back systems. Are those going to do the job that you are talking about for speed and efficiency if they do not link up with each other and cross-reference each other?

Dr. ACHESON. No, not entirely. No.

Ms. DEGETTE. And is a voluntary trace-back system in which only some market players participate going to be adequate to give the speed and comprehensiveness that we need in a trace-back system?

Dr. ACHESON. No.

Ms. DEGETTE. Now, I have learned in recent months that many larger companies do have the ability to track their food and probably in a better way than smaller firms because at larger companies brand preservation is almost always a key to survival. So my question is if you have a purely voluntary trace-back system will that be as successful as it could be if some market players, particularly smaller market players, cannot participate in the system?

Dr. ACHESON. Like any system it is as strong as its weakest point. So if you put in a great system and only 99 percent of the industry is using it and you have a problem with that 1 percent, all bets are off, it is not going to work.

Ms. DEGETTE. The whole thing falls apart at that point?

Dr. ACHESON. It does, yes.

Ms. DEGETTE. Now, I would like to know if the FDA currently has the legal authority to do what some of our panelists on the last panel were talking about which would be to use a numerical unique identifier that can travel with the product and instantaneously identify relevant tracking information like location, time, date, etc., vector in the field. Does the FDA currently have that authority to develop that comprehensive system?

Dr. ACHESON. Well, bearing in mind that I am not an attorney but my interpretation of that is that we do not have explicit authority to require the level of detail that you are asking for.

Ms. DEGETTE. OK.

Dr. ACHESON. But it may be better if we get you a written response to that.

Ms. DEGETTE. You betcha. I would love it.

And I also, not to rag on you because you have been very cooperative with my office, but I have made about 10 or 12 requests to the FDA, other parts of the agency, in the last year and I must say I have not gotten responses. So I am sure you will respond to my question.

Dr. ACHESON. I sure will.

Ms. DEGETTE. Now, I wanted to ask a few questions about the other end of this, the identification of the food-borne illness because it seems to me that the problems that we have had in this investigation it is true we do not have the comprehensive traceability system that we could or should have, and it is also true that if we had had a national interoperable system of traceability I believe we

could have identified, we could have eliminated foods in areas that were not affected which would have been financially beneficial to those portions of the industry. And we could have also identified the source of the contamination more quickly which would be good for public health.

But the other, so the traceability is what I have been focusing on in my legislation. But in truth, really the identification of the situation is of great concern to me and the rest of us because people started getting sick in April, and here we are now at the end of July still trying to figure out exactly where that contamination came from. I think some of it does come from the CDC and the State health departments, so I want to focus on that for a few minutes.

And I wanted to ask you, Dr. Jones, is it true that you believe that there are some sizeable communication problems between State agencies, which are often on the frontlines of the outbreaks, and the CDC and the FDA?

Dr. JONES. I do. And I think your point is an important one. You know, the farm to fork continuum has all along that continuum there are places for improvement. And there are States that investigate hundreds of outbreaks every year and there are States that investigate a half dozen. And, you know, I think the food is just as safe in both of those States. And if outbreaks cannot be detected and investigated at the local level then we will never know we have a multi-state issue on our hands and be able to even discuss it with CDC or FDA.

Ms. DEGETTE. And I guess I could ask you, Dr. Smith, and you, Dr. Jones, the same question. Do you think all States have enough resources to do that investigation that they need to do?

Dr. JONES. Absolutely not.

Ms. DEGETTE. Dr. Smith is nodding yes.

Dr. SMITH. I agree 100 percent.

Ms. DEGETTE. And is there something at the CDC, maybe Dr. King you can answer, or somebody, is there some resource management at the CDC that works with those States that have less resources to be able to identify these situations? And if it is incomplete what can we in Congress do to help improve our identification system in this country? Dr. Jones?

Dr. JONES. I think there are a number of things. And, yes, CDC will respond and provide assistance to any State health department that asks for it. And there is obviously wide variability in what, you know, when a State will pull the trigger.

I think there are some very important ways that CDC has provided a lot of support to State health departments. Both of our States are among a group of 10 that are in this Food Net system which gives us, and it all federal resources, it comes through CDC, which supports the half dozen epidemiologists that we talked about. I think that if all 50 States had a system like that that a lot of the problem that we are talking about today would not exist.

Ms. DEGETTE. But, you know, I will say that, I will say that it is all well and good to have the States asking for resources, but when you are talking about identifying either a food-borne disease or a bio-terrorist attack if they do not have the resources to identify

the problem in the first place they do not know, it is a real chicken and an egg kind of a problem. Dr. Smith is again nodding yes.

You are my favorite witness of the day, you just nod in agreement but you do not ramble on, so good work.

Dr. Jones, you mentioned in your testimony that a lot of the reason why critical communication between the federal and the local health agencies is not occurring because of policies that restrict the sharing of proprietary data and information collected in the course of an investigation; is that true?

Dr. JONES. Yes.

Ms. DEGETTE. I am wondering, Dr. King or Dr. Acheson, if you can comment on how much of that proprietary information is hurting your agency's ability to collect data and to find the causes of these diseases?

Dr. ACHESON. Certainly from FDA's perspective we do have a mechanism through commissioned officers at the State level to share that information. But I think as we have addressed, if we can find ways to break down these barriers and these silos, not just with the State partners but with industry because there is no question that they have a significant piece to bring to bear that would be helpful.

Ms. DEGETTE. You know, but part of the problem is, as Dr. Jones states in his written testimony, even though public health epidemiologists can become commissioned by the FDA, he says, "Most of my colleagues have refused to pursue this, expressly to avoid the untenable moral predicament of having access to data which they would be legally unable to act upon."

I am wondering, Dr. Jones or Dr. Acheson or anyone else, if you would have any comment on how we can solve that problem if we are going to be able to more quickly to respond to these issues?

Dr. ACHESON. I would suggest that the way is how do we build these partnerships to be actually successful so that you are not——

Ms. DEGETTE. That is a good paraphrase of my questions.

Dr. ACHESON. And I think that that is the process that we have got to address. I do not know what that is going to be. We have got a process that we are going to begin in August. We are meeting with States and locals, FDA, with CDC to look at how can we better build partnerships around protecting the food supply in the United States. There is a lot to b e done.

Ms. DEGETTE. Does anybody else have an idea how we can break some of those problems? This is not very encouraging to me because it seems to me that one of the keys towards identifying towards having State and federal agencies working together to identify these issues is, is there going to be coordination? If we have barriers right now we need to figure out how to break that. And we sit here as a Congress ready to help you, but you are the experts, so I think that we need to figure out how to break these barriers.

One last question, Dr. Jones. Do you have examples of actual cases where the barriers of data sharing or other forms of communication between State public health agencies and these federal agencies, the CDC and the FDA, made it difficult to rapidly solve a food outbreak case or quickly act in the interests of public health?

Dr. JONES. Yes. and I think I alluded to one fairly generally in my testimony. But, you know, we did have a recent situation where a federal regulatory agency had collected the names of people who had purchased a product which we knew was contaminated. And I know that this frustrated them as much as it did us, but they were not able to hand us the list of the contact information of those patients, victims, for us to be able to call them and talk to them.

Ms. DEGETTE. Thank you very much.

Thank you very much, Mr. Chairman.

Mr. STUPAK. But you were the front line collecting that information; right?

Dr. JONES. Some. This came through a mechanism where——

Mr. STUPAK. Sure.

Dr. JONES [continuing]. Consumers can call in to the FDA hotline——

Mr. STUPAK. Right.

Dr. JONES [continuing]. And ask them questions. And we do not have access to that system.

Mr. STUPAK. Mr. Dingell for questions, please.

Mr. DINGELL. Mr. Chairman, again I thank you for your courtesy and commend you for your labors in this matter.

These questions to Dr. Acheson. These will be yes or no questions. FDA had over 4,000 field investigators in the year 2003 to investigate contamination of food outbreaks and inspect food facilities; true or false?

Dr. ACHESON. In 2003?

Mr. DINGELL. In 2003, had 4,000.

Dr. ACHESON. I would have to check.

Mr. DINGELL. Please check.

And in 2008, FDA's field force of investigators had been reduced to about 3,300 investigators, that is a loss of 700 investigators; true or false?

Dr. ACHESON. I believe that is true.

Mr. DINGELL. Tracking food-borne contamination outbreaks is labor intensive?

Dr. ACHESON. I am sorry, say again?

Mr. DINGELL. Tracking food-borne contamination outbreaks is very labor intensive?

Dr. ACHESON. Yes, agree.

Mr. DINGELL. What level of food-related resources, inspectors, scientists, etc., do you believe that Food and Drug currently needs? You may submit that, the response to that question for the record. But it would be fair to say that the number is rather larger than you have now, is it not true?

Dr. ACHESON. I would agree.

Mr. DINGELL. We are now learning that the probable or possible source of contamination in the jalapeño peppers and tomatoes is Mexico; is that true?

Dr. ACHESON. Correct.

Mr. DINGELL. FDA has minimal resources to inspect food imports at the border?

Dr. ACHESON. It depends how you define minimal.

Mr. DINGELL. Minimal. All right, is Food and Drug's resources in these matters adequate?

Dr. ACHESON. No.

Mr. DINGELL. They can inspect, as I understand it, about 1 percent of——

Dr. ACHESON. That is correct.

Mr. DINGELL [continuing]. The food?

Dr. ACHESON. That is correct.

Mr. DINGELL. Clearly that is not adequate; is that right?

Dr. ACHESON. That is correct. But as we said before, you cannot inspect your way through this. It has got to be a risk-based approach.

Mr. DINGELL. All right. Now, it is also true that Food and Drug has almost no resources that it can dedicate to inspect foreign firms, foreign farms that handle food; is that true?

Dr. ACHESON. In 2007 the FDA conducted about 95 inspections of those types of facilities.

Mr. DINGELL. Do you know how many facilities there are?

Dr. ACHESON. There are a little over 200,000 that are part of the bio-terrorism registration database.

Mr. DINGELL. And you inspected, as I understand, 95 of those 200,000?

Dr. ACHESON. Correct. And do not ask me the percentage because I cannot work that out in my head, please.

Mr. DINGELL. Is a fair comment minimal?

Dr. ACHESON. It depends how you define minimal.

Mr. DINGELL. All right. Now, if Food and Drug had had sufficient resources for inspecting imported produce or actual sources of that produce we could have detected this contaminant much sooner, could we not?

Dr. ACHESON. I suspect not.

Mr. DINGELL. Suspect no?

Dr. ACHESON. No. I think not, because inspections and sampling as a mechanism to ensure that it is safe is not realistic. You just could not sample enough to make it realistic.

Mr. DINGELL. Right.

Dr. ACHESON. The answer is the preventative controls; that is the fix.

Mr. DINGELL. Now, would you agree that FDA needs considerably more resources to conduct foreign and domestic inspection of food processors?

Dr. ACHESON. Yes. And we are getting some of those in 2008 and hopefully 2009.

Mr. DINGELL. Now, does Food, would you agree that Food and Drug needs considerably more resources to inspect actual imports at the border?

Dr. ACHESON. Yes.

Mr. DINGELL. If you turn to page—I am sorry. I guess that constitutes my questions. Mr. Chairman, I thank you for your courtesy. Thank you, sir.

Dr. ACHESON. Thank you.

Mr. STUPAK. Thank you.

Mr. Inslee for questions, please.

Mr. INSLEE. Thank you. I think we all agree that our trace-back and investigatory systems are inadequate. But I want to ask what is more inadequate, our after-the-fact trace-back investigatory sys-

tem or preventative systems of agricultural practices that prevent, and packaging and distribution practices that would prevent these instances from happening? What is sicker? What is more ailing? What is more porous? What is most, what is the most glaring weakness between those two approaches, either pre- or post-injury?

Dr. ACHESON. If I could respond first I would say the most critical is the preventative controls. That is what counts the most, building the safety in up front so whether it be a domestically grown or an imported product, manufactured, whatever it is, build that safety in up front to a standard that is adequate. You have obviously got to have strong reactive capabilities when things do go wrong. But having a reactive system, however well it works, is just not a good way to protect public health.

Mr. INSLEE. Well, I would agree with that. And that is why I hope those who are interested in this subject will be very anxious, as I am, to get legislation through to finally adopt best practices in the industry in the field and in the farm and in the packaging plant to prevent these repeated instances. I have to tell you this is very frustrating to sit at this dais time after time after time to see these incidents and we still have not successfully got the industry totally to agree to standards that will prevent these things from happening.

So I hope that this continued incident will encourage others to work with us as soon as humanly possible to pass practices that will prevent this from happening. We know this can happen. We have had substantial improvement in the meat industry. We have not had improvement in the produce industry in practices in the field. And I just hope that others agree with Dr. Acheson and myself on the importance of those preventative measures so we can move forward.

Dr. Jones, I want to ask you about State measures. I think even a cursory review would show that a relatively small handful of States have been most successful in investigating a disproportionate number of these incidents. And I just want to ask you to, to the extent you can, tell us what do those States have in common, what have they done well? Is it resources? Is it practices? Is it, you know, gubernatorial leadership? What is it and what can we do to get more states to either emulate those efforts or federally remove the necessity of them?

Dr. JONES. Unfortunately I think the basic answer is resources. You know, Dr. Smith has mentioned some other things. I mean States that have a very centralized public health and epidemiology structure tend to get information a little bit faster. Laboratories that are well funded and can do their testing quickly and get their results to epidemiologists quickly help. But all of that requires manpower and resources.

Mr. INSLEE. We were looking for an easier answer actually.

Dr. JONES. Sorry.

Mr. INSLEE. I appreciate that.

Dr. Smith, your team had a relatively rapid identification of jalapeños through genetic systems. And, you know, basically what did they do differently than the FDA? What can we do to replicate that on a federal level?

Dr. SMITH. Right. Well, again I think it needs to be replicated more on the State level because I mean CDC and FDA are kind of limited by the information they are getting from State health departments. And so I think our system or something like it needs to be implemented more at different state levels.

Again, our laboratory is confirming and typing bacteria in real time, giving that information to our epidemiologists right away. And our epidemiologist are interviewing these patients extensively, again in real time. And so we are asking people about what they ate 2 weeks ago. And that is hard to get detailed information at that point. But it is much easier and you get much better information than if you waited until you ask them about 4 weeks ago or 6 weeks ago.

And that is what happens in some States is like some laboratories physically cannot type all the bacteria in real time and so they can only do it once every 2 weeks or once every month. And then by the time they do that and get that information to their epidemiologists, you know, it is 4 or 6 weeks later, you know, when the interviews are being started.

So the whole key is just, you know, it is not really that hard, it is the resources to do stuff right away and to do it in detail and that will get you the detailed interview information that you need to solve an investigation.

Mr. INSLEE. So what would you say to the federal government, the agencies, to match that State input early? Is there something that has to change?

Dr. SMITH. Well, I mean I know for a fact that CDC could use more resources in PulseNet to track all the isolates that are being submitted by State health departments into that. And I also know there are epidemiologists that are helping to coordinate multi-state outbreaks get stretched awfully thin. And so, again, I know that they could use more resources at the federal level to go ahead and assimilate the information that is coming in from the States.

Mr. INSLEE. Anyone else want to add to that?

[No response.]

Mr. INSLEE. With that, thank you very much, I yield back.

Mr. STUPAK. Ms. DeGette had a question?

Ms. DEGETTE. Mr. Chairman, I just had a follow-up question. I am trying to, I am still trying to think about how we could improve our identification of these outbreaks. And, Dr. King, I wanted to ask you in particular about this Salmonella outbreak. Now, patients were given or people who we thought ate the tainted foods were given questionnaires by the State of New Mexico and also the CDC; is that correct?

Dr. KING. Yes.

Ms. DEGETTE. We have been provided copies of these questionnaires by the CDC and I am wondering are these confidential, these forms? I know the ones filled out are confidential. But I am looking at them, I see no reason why these would be confidential in any way.

Dr. KING. The forms?

Ms. DEGETTE. Yes.

Dr. KING. No, not at all.

Ms. DEGETTE. OK. And the first form, which is a very extensive form that was provided by New Mexico to patients, talked about fresh tomatoes and it had a long list of different foods. And it did not highlight jalapeño peppers or serrano peppers, just simply had a space for other peppers.

And then the form that was given out by the CDC, which is a form much more targeted at the salsa that was suspected asked questions about salsa, homemade salsa, store bought salsa. It talked about onions, tomatoes, where you ate tomatoes, a lot of questions about tomatoes. That form never asked one question about peppers. And I am wondering why? Or, for that matter, any other ingredients other than onions that are in salsa.

Dr. KING. There are two different forms. The first one is this hypothesis generating form.

Ms. DEGETTE. It is the larger form provided by New Mexico which has a whole bunch of stuff on it.

Dr. KING. Right. And I think red peppers, green peppers or other peppers.

Ms. DEGETTE. Correct.

Dr. KING. Also, the people doing the interviews it was open-ended so you would also ask people are there other things are not on this list that you could remember that you had. So that is one thing.

Ms. DEGETTE. OK.

Dr. KING. When you get down into case control, which is the second form——

Ms. DEGETTE. OK.

Dr. KING [continuing]. It also was done by the State, actually two States.

Ms. DEGETTE. And that is like a smaller format.

Dr. KING. The difference then is that because the hypothesis has been generated, right, then we are able to focus into this looks like it is food, looks like this type of food. And so the questionnaire then becomes more focused based on that information to try to pinpoint more accurately the different types of foods and ingredients.

Ms. DEGETTE. That makes sense to me. So who develops that second form? And that is like a follow-up set of questions that is asked?

Dr. KING. Yes, ma'am. That is correct, Congresswoman.

Ms. DEGETTE. And who develops that form?

Dr. KING. Well, the States will actually have some changes in those depending on what they do. There is kind of a template that is being used but States will add to those as they——

Ms. DEGETTE. So the State of New Mexico would have developed that second form?

Dr. KING. They would have.

Ms. DEGETTE. OK.

Dr. KING. For the case control study we actually were involved in helping them with that.

Ms. DEGETTE. Well, and the reason I am concerned is this: it may be that after the initial survey that people did not focus in on pepper. However, if you look at this second follow-up form they were focused in on salsa; right? Now, I will tell you as someone who myself is from the Southwest, I never made salsa without put-

ting peppers in it. That is one of the key ingredients of salsa. So if in fact salsa was suspected and you ask the question tomatoes, and extensively tomatoes and onions, why was not the question about peppers asked on that follow-up questionnaire? It may have helped you much more quickly identify the serranos and the jalapeños?

Dr. KING. Now I have to look at the questionnaire. Again it was—no, I understand that you are looking at that. So I would look at the second——

Ms. DEGETTE. I will tell you——

Dr. KING. Yes.

Ms. DEGETTE [continuing]. Without misleading you that peppers are not mentioned whatsoever on this second form. There are many questions about tomatoes. Did you eat any raw tomatoes? Did you eat tomatoes at a restaurant? Where did you purchase them? It seems like what happens was the State of New Mexico and the CDC focused right in laser-like on tomatoes. But yet, if they thought the problem was salsa maybe they should not have, maybe they went off down the wrong road too fast.

Dr. KING. That is, you know, that is part of something we would look at. The second case control study certainly did focus at peppers as we gained more information as we went.

Ms. DEGETTE. OK. I do not think we have that in our—oh here. Here is Mexican food exposure. Then would that have been the next thing after that?

Dr. KING. That is correct.

Ms. DEGETTE. OK. When was that given to them, after the tomatoes were eliminated as a suspect?

Dr. KING. As we gained more information then we were able then to focus more and peppers became something of more concern for us and with stronger association. And consequently the questioning and the questionnaires reflected it.

Ms. DEGETTE. Do you think we might have been better off if we focused on all the ingredients of salsa right at the time that we thought salsa might be a problem rather than just going down the tomato road?

Dr. KING. It may have been. And I can certainly go back and review that.

Ms. DEGETTE. Thank you very much.

Mr. STUPAK. Dr. Acheson, you have indicated then, and I know we have been down this pass before on Heparin and China and all this with the FDA, but you said that the best way to handle these issues is to build up the safety first, in other words make sure the farm is growing a healthy product; correct?

Dr. ACHESON. A safe product, yes.

Mr. STUPAK. Safe product. How many inspectors, full-time inspectors do you have in Mexico then checking farms?

Dr. ACHESON. Nobody is, no FDA employees are permanently stationed in Mexico.

Mr. STUPAK. So then the only chance to make sure that you have the safety of the product coming in is catching it at the border then; right?

Dr. ACHESON. Under the current system, yes. It is based on inspection and sampling at the border. As part of the Food Protection

Plan, FDA beyond our borders, we are looking at establishing FDA presence in a number of countries which would include Central and South America.

Mr. STUPAK. OK. But you are establishing it in China, are you not?

Dr. ACHESON. Yes, we are in the process.

Mr. STUPAK. Did you not have the memorandum that was on the pet food?

Dr. ACHESON. We are in the process of establishing an office in China, that is correct, yes.

Mr. STUPAK. So do you have any food inspectors outside the borders of the United States?

Dr. ACHESON. Not currently, no. Not permanently. Not permanently. They would go out usually for cause. If we know of a problem that needs to be checked on.

Mr. STUPAK. Correct. There has to be a problem first before you will send them off over shores, offshores?

Dr. ACHESON. Typically, yes, there does.

Mr. STUPAK. So but to get to your safety, build up the safety, as you have said——

Dr. ACHESON. Yes.

Mr. STUPAK [continuing]. You really should have the inspectors in other countries, especially like in the winter months we know we get most of our produce at least south of our border.

Dr. ACHESON. It is not all about inspections, it is about building in the preventative controls. So we have got to set the standards, we have got to work with industry to do that, and we have to find a way to ensure that they are meeting those standards. Some of that would be FDA inspections. As I know you are aware, an area that we are exploring as a mechanism here is an FDA-audited third party certification system.

Mr. STUPAK. Correct.

Dr. ACHESON. Simply because, as I said to Congressman Dingell, we are looking at 200,000 foreign manufacturers. And it is like let us focus on those that are high risk and let us leverage every possible mechanism to be able to ensure that they are building the safety in up front.

Mr. STUPAK. OK. Now, Dr. King, if I may ask you, who is in charge of coming up with the source here of the Salmonella, the vegetable of interest if you will, the CDC?

Dr. KING. The original epidemiology CDC is actually, that is our responsibility.

Mr. STUPAK. OK. So CDC told FDA look at tomatoes?

Dr. KING. Yes.

Mr. STUPAK. OK. Then who made the call to change the focus to peppers, CDC or FDA?

Dr. KING. It came through further investigations. By the way, we do not do this kind of by ourselves, we do this through conversations back and forth.

Mr. STUPAK. Correct.

Dr. KING. Our investigations and the epidemiology led us to look more and more toward peppers. And I know Dr. Acheson and folks at FDA. That was from our investigations then that led them to further trace-backs down that track.

Mr. STUPAK. OK. Who is the agency in charge then when you have a food-borne illness outbreak, CDC or FDA?

Dr. KING. It depends on what part of the outbreak. So we do surveillance, we do epidemiology, we do outbreak investigation and the laboratory. We do not do the trace-backs.

Mr. STUPAK. Right.

Dr. KING. So that is the bifurcation. FDA does the trace-backs, the work on the food, or USDA depending on what the product is, and so they are clearly in charge of that part of it. We are clearly in charge of the other part of it. We talk all the time, meet all the time. But that is how the delineation is.

Mr. STUPAK. You say you talk all the time but yet when I hear Dr. Jones talk it sounds like no one talks to the State officials who are really the frontline people, who really do your epidemiology and stuff that Ms. DeGette went over, the forms. Because I am still bemused by the fact that Dr. Jones testified if they have an outbreak you know the names and addresses, or FDA does, of the people who are being sick but they cannot tell the frontline people, Dr. Jones, to warn them or to try to at the local level take care of the issue. I just find that amazing.

Dr. KING. Thank you. And I will talk to Dr. Jones about that. And I am sure he has good reasons to say that.

There are three systems that we have kind of in effect. One is called Outbreak Net where we actually have the epidemiologists in every state and CDC involved. The other are daily conference calls during this outbreak with all the States involved. And the other is CIFOR, which is this council to improve food outbreaks. And that involves States and epidemiologists. So there are three systems in place where I think the dialogue continues fairly readily.

Mr. STUPAK. Three systems in place. So would it not really indicate that you need an incident command center that would include State, local, federal, industry reps, science experts, especially when you get an outbreak as big as this, 43 States, District of Columbia, Canada?

Dr. KING. I think that is something to take a look at. And I appreciate your observation on that.

Mr. STUPAK. Go ahead, Mr. Shimkus.

Mr. SHIMKUS. Yes. And just if this was a bio-terrorism attack and then that is, and this is what we are all, a lot of us are concerned with and you, we have said the system works the same, but as far as the command and incident center does the Department of Homeland Security get involved in that debate then?

Dr. KING. Yes.

Mr. SHIMKUS. Is that the command and control center that we lack here?

Dr. ACHESON. If there is—well, thankfully we have not had to deal with one of those since——

Mr. SHIMKUS. That is true. But I mean we have to be—hopefully we do not—but we need to start, we cannot shy away from the risk and we have to ask these questions.

Dr. ACHESON. Yes.

Mr. SHIMKUS. And this case study is a good case study to help us look at that.

Dr. ACHESON. If it was a deliberate act and we knew it was deliberate, and I want to add that if somebody was putting Salmonella in the food supply the chances are that they would be treated exactly the same as this because it happens, unfortunately, too often. If it was anthrax, which clearly happens never, then it would be, the suspicion would be much higher, law enforcement would be involved very early, and I think the whole thing would be different.

Mr. SHIMKUS. But they would call upon you all for your expertise in the public health departments?

Dr. ACHESON. Oh yes.

Mr. SHIMKUS. In your trace-back?

Dr. ACHESON. Yes.

Mr. SHIMKUS. And CDC.

Dr. ACHESON. But I think your point and Chairman Stupak's point is an incident command type approach for dealing with these is one that seriously needs to be looked at as a mechanism that involves at the very least the regulatory individuals that are seated here, and others. The industry piece is more complex because of the sharing of confidential information. And I would love for us to break down those barriers, it could only help.

Mr. SHIMKUS. And that is what we want to do.

Mr. STUPAK. But following up on that question, if it is a bio-terrorism attack how does—does law enforcement then and security of our country trump those privacy concerns we have? Does it trump the Privacy Act? Does it trump the agency chief counsel who do not allow you to share that information? When reading the Bioterrorism Act I do not see an exception for that. So it would have been done the same way, not sharing information.

Dr. ACHESON. From FDA's perspective I do not think anything changes. It may be different for Department of Justice, law enforcement and FDA. I just——

Mr. STUPAK. But you do not have any opportunity though if it is a bio-terrorism attack to waive the privacy law, the confidentiality, the trade secrets, whatever you want to call it, proprietary interests I think was the words used earlier?

Dr. ACHESON. Not that I am aware of but I will take that back.

Mr. STUPAK. No, I have not seen it either, so.

Dr. ACHESON. And if there is something in the act to that effect then I will obviously get back to you.

Mr. STUPAK. And, Doctor, you quoted a legal opinion. Can you provide that to the committee for the record?

Dr. KING. I would be glad to. That has to do with the county information, yes.

Mr. STUPAK. Right. That is kind of the direction we want to head. So thanks.

Let me thank this panel and thank you again for your time and testimony. And we will continue on this issue.

[Witnesses excused.]

Mr. STUPAK. I would like to invite our third panel of witnesses to come forward.

On our third panel we have Mr. Michael R. Taylor, J.D., who is the Research Professor of Health Policy at George Washington University School of Public Health and Health Services; Mr. Hank

Giclas, who is Vice President for Strategic Planning, Science and Technology at Western Growers Association; Dr. Donna Garren, who is Vice President for Health and Safety Regulatory Affairs at National Restaurant Association; and Dr. Robert Brackett, who is the Senior Vice President and Chief Science and Regulatory Affairs Officer at the Grocery Manufacturers Association.

Thank you all for coming. It is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right under the rules of the House to be advised by counsel during their testimony. Do any of you four wish to be represented by counsel at this time?

[No response.]

Mr. STUPAK. Everyone indicating no. Then I will ask you to please rise, raise your right hand, take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect the witnesses applied in the affirmative. You are each now under oath. We will now hear your opening statement, 5-minute opening statement. You may submit a longer statement for inclusion in the hearing record.

Professor Taylor, let us start with you, sir.

STATEMENT OF MICHAEL R. TAYLOR, J.D., RESEARCH PROFESSOR OF HEALTH POLICY, THE GEORGE WASHINGTON UNIVERSITY, SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES

Mr. TAYLOR. Thank you, Mr. Chairman, I appreciate the opportunity to testify today. I have submitted a written statement, the purpose of which was to demonstrate that we have a system problem here. And I think it is fair to say that the testimony you have heard so far really demonstrates that, I think really demonstrates we need a system solution. And I look forward hopefully this panel can have some time to talk about some of those solutions. But in my written testimony I tick off really 7 elements of preparedness and planning for outbreak response and investigation that are really lacking in the current system. And I think we have heard about all of these today:

And it is focused federal leadership and accountability, it is somebody being in charge.

It is well-defined institutional roles across the system, federal, State, and local, which we really do not have formalized today, it is very ad hoc.

Adequate expertise in capacity, the funding issue that we have talked about; clearly an element of this.

Prompt trace-back. And I think we can talk about some specifics there. This issue of standardized data collection and seamless data sharing I mean I think is really central to being able to manage these outbreaks and also to deal with prevention in a systematic way. And we do not have that provided for.

We have also heard about the need for active industry engagement, which I absolutely agree with. And then coordinated public communication is obviously essential.

I guess one thing I really want to emphasize is that Congress has to act to address these problems. I think these problems are built into our current system, the current fragmentation organizationally

in our food safety system at the national level. It goes beyond outbreak investigation and response, it really goes to the whole way in which we manage our food safety system and it needs to be transformed.

As this committee well knows, we are operating at FDA under a food safety law that is 70 years old that contains no mandate for prevention, it contains no mandate to take an integrated systems approach. I think the legislation you are working on will address that.

The other element, of course, of the broader problem is resources. We have talked about that today.

I would just like to emphasize the organizational issue. And there has been an extensive study of this by the Government Accountability Office, by the National Academy of Sciences, the fragmented structure of the government's food safety system, particularly at the federal level, but then also as we have heard today, State and local agencies. It is health departments at State and local level, it is regulatory agencies, it is Departments of Agriculture, all of whom play roles without any sense of how we or any clear directive. It could be a national leadership role in seeing that entities work in an integrated way.

So Congress really has to address this organizational, this structural issue and really drive the development of an integrated system. I would start that organizational reform at the Department of Health and Human Services personally. Within HHS we have food safety agencies, multiple components really of the Food and Drug Administration as well as CDC, you know, all of which work in their own traditional ways with their own particular charges. They have their own cultures and ways of dealing. None of them have the charge or the stature within the government system to really exert leadership, nationally and internationally for that matter, towards a more integrated preventive approach.

So one of the things I would hope this committee would consider in due course is unifying and elevating within HHS all of the components of HHS working on food safety so that single office, a single official can be in charge and accountable for all HHS food safety activities, including outbreak response and investigation, but going beyond that to include all the things we need to do to build a preventive, integrated food safety system in the country.

So with that I look forward to the opportunity to discuss any of these ideas and solutions to some of the problems that have been identified here today.

[The statement of Mr. Taylor follows:]

Testimony of

Michael R. Taylor*

Before the

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives

Hearing On

"The Recent Salmonella Outbreak:
Lessons Learned and Consequences to Industry and Public Health"

July 31, 2008

Mister Chairman, Ranking Member Shimkus, members of the subcommittee, thank you for the opportunity to testify at today's hearing.

Introduction

This hearing has been convened as the country enters the fourth month of an outbreak of illness associated with *Salmonella saintpaul*. This outbreak has sickened more than 1,250 people in 43 states, the District of Columbia and Canada and has had a devastating impact on the U.S. tomato industry, even as the food vehicle or vehicles responsible for the illnesses remain uncertain.

As the outbreak has continued, the inability of public officials to identify definitively the food vehicle and ultimate source of the contamination has become a matter of great

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* Mr. Taylor is Research Professor of Health Policy at The George Washington University School of Public Health and Health Services and chair of the Food Safety Research Consortium. He served formerly as Administrator of USDA's Food Safety and Inspection Service (1994-96) and as Deputy Commissioner for Policy of the Food and Drug Administration (1991-94).

public concern, and well it should. There is also an understandable tendency to find fault for the perceived failure of the food safety system in this case. And I agree that the management of this outbreak should be carefully examined, both to see if any breakdowns occurred and to learn lessons for the future.

I cannot speak to the details of the ongoing *Salmonella saintpaul* investigation, Mister Chairman, and whether particular agencies or individuals made mistakes. I can, however, speak to the system within which they work, and my message today is this: regardless of whether we find that this outbreak could have been managed better, the fundamental problem is with the system itself, not with how it operated in this case. The sad truth is that we have no system for managing multi-state foodborne illness outbreaks that deserves to be called a system. Many capable people work hard and do the best they can, but they work within a set of institutional arrangements and with tools that are not up to the task.

We are not in this situation for lack of knowing that a system is needed or because we don't know what its basic elements should be. Rather, we simply have yet to make the decision – and the sustained commitment – to have such a system. For reasons I will outline in this testimony, Congress must act to solve this problem.

Before discussing possible solutions, let me share some perspectives on why prompt and accurate outbreak investigations can be very difficult, but also why they are essential to protecting food safety and to achieving the more preventive food safety system to which

we all aspire. I will also describe how the current "system" is simply not designed for success in conducting such investigations.

The Difficulty and Importance of Multi-State Outbreak Investigations

Any outbreak of foodborne illness – defined as two or more cases linked to a common source – is a noteworthy event. It means people have gotten sick and it suggests the existence of a breakdown that could result in making others sick and that could be on-going. Thus, the most immediate need is for prompt response and identification of the common source to prevent further illnesses from that source.

Most outbreaks are relatively small-scale and inherently local in nature. They might involve such breakdowns as poor food handling or employee hygiene practices in a restaurant, cross-contamination during food preparation at home, or the problematic dish at a church picnic. Investigating local outbreaks is a core public health responsibility of local and state health departments. If the root cause is local, local investigators are frequently able to discover it by carefully interviewing people who got sick, analyzing food samples, and gathering other relevant information.

In the past two decades, however, we have seen an increasing number of outbreaks that involve illnesses in multiple states. These have affected most major sectors of the food supply, including meat and poultry, seafood, dairy and produce; and some have been essentially nationwide in scope, such as the current Salmonella outbreak.

This increase in multi-state outbreaks is a result of many factors, including changes in the food system that make it more likely that a problem at one point in the system will radiate out across the system to affect many consumers. These changes include centralized production and nationwide distribution of both fresh and processed foods, convenience-oriented packaging and eating practices, and the increasing volume of imports.

The increase in reported outbreaks of all kinds, including multi-state outbreaks, is also a direct result of investments and improvements in foodborne disease surveillance made over the last decade that have improved our ability to detect outbreaks. These include moving to electronic reporting systems and communications platforms that serve to better connect public health officials in local, state, and federal agencies.

The innovation that deserves specific mention in this context is PulseNet, a collaborative effort of the Centers for Disease Control and Prevention (CDC) and state and local public health laboratories. PulseNet has played a major role in identifying numerous recent outbreaks, including the outbreak due to *E. coli* O157:H7 in spinach in 2006, the Salmonella outbreak associated with frozen pot pies in 2007, and this year's Salmonella outbreak.

Essentially, PulseNet is a shared database of genetic "fingerprints" of bacteria. Public health laboratories throughout the country perform tests to fingerprint bacteria obtained from people sickened by food poisoning in their city, county, or state and then submit these fingerprints to the central database. By analyzing these fingerprints and

discovering matches, individual cases or clusters from multiple locations and states can then be recognized as part of an outbreak rather than isolated local events. PulseNet's success in detecting outbreaks is due to two factors. First, the participating state laboratories use a standardized methodology for fingerprinting the bacteria, which makes data from diverse sources comparable. Second, the system uses modern information technologies for storing, analyzing and sharing data.

While major outbreaks present huge challenges to government and industry alike, it is always better to detect an outbreak than not detect it, for the containment and prevention reasons noted earlier. And this is especially true for large, multi-state outbreaks. Not only are more people at risk, especially if the outbreak is due to a breakdown that is on-going, but multi-state outbreaks also provide the opportunity to draw lessons to help shape preventive interventions of possible system-wide application. It is thus essential not only to detect the outbreak but investigate it promptly and accurately so that the outbreak can be contained and lessons learned.

As evidenced by the impact of the current Salmonella outbreak on the tomato industry, such investigations are important for economic reasons as well.

Unfortunately, our recent advances and growing sophistication in detecting outbreaks has not been matched by corresponding advances and sophistication in investigating them. PulseNet only detects the fact that multiple illnesses are linked to a common pathogen; it does not reveal the common food vehicle(s) responsible for the illnesses or the root cause

of the contamination that led to illness. This requires marshalling the efforts of multiple agencies at federal, state, and local levels of government to conduct case-control studies, traceback investigations, and targeted microbial sampling of food and food environments, and to analyze and act on the information they glean from these efforts.

This is where the difficulty begins, in part because outbreak investigations are inherently difficult and in part because we lack an effective system for conducting them. As outbreaks grow larger and cross state lines, their investigation only becomes more difficult due to the number of parties involved. Moreover, outbreaks associated with fresh produce are particularly difficult to investigate for other reasons.

It typically takes 2-3 weeks for lab results to confirm that a person's illness is part of an outbreak. The short shelf life of fresh produce generally means that, by the time an investigator arrives on the scene, there is no product left to test to see if it is contaminated with the pathogen that made the person sick.

Investigators thus must rely on the indirect, essentially inferential, tools of epidemiology to form hypotheses about what food carried the pathogen that caused illness. This commonly means conducting a case-control study in which investigators use interviews to elicit and compare the recent food consumption of people who got sick with people who did not. In the Salmonella outbreak, CDC reported that 80% of the people who got sick ate tomatoes, while only 50% of those who were not sick ate tomatoes, and

concluded this created a statistically significant association between tomatoes and the *Salmonella saintpaul* illness.

Such an association is not proof of a causal link. However, absent other evidence disproving the link, it is generally considered a sufficient basis for providing public health advice to consumers, notwithstanding recognized methodological uncertainties in case-control studies. The central, inherent uncertainty stems from the fact that the quality of the data on which the studies rely depends on the quality of the subjects' recall of what they ate, perhaps weeks ago – recall that researchers have shown to be of limited reliability. In addition, in large or multi-state outbreak investigations, persons conducting interviews typically come from different state and local health departments, and may or may not conduct interviews and report data consistently due to the lack of nationally standardized food category definitions and interview templates and differences in training and experience.

While a well-conducted case-control study can provide sufficient information about the possible food vehicle to support public health action and advice to consumers, it is not the end of the outbreak investigation. Based on the leads provided by the study, investigators from federal, state and local food regulatory agencies then become involved, often with health department staff, to try to trace the suspect food or foods back to their source in order to find a potential common source of contamination, such as a processing plant or farm. This can be a daunting and labor-intensive task when the suspect food has been found all across the country and passed through many hundreds of processing plants,

wholesalers and retailers. Investigators also collect and test food and environmental samples to see if they can link the pathogen that caused illness directly to the particular food and to possible places where it was produced, processed, or stored.

Such traceback and product testing evidence, coupled with the epidemiological findings, can provide persuasive proof of the casual connection between a particular pathogen-food combination and the reported illnesses, but even that does not, ideally, complete a full outbreak investigation. Once the illness, pathogen, food vehicle, and locations where the food has been have been conclusively linked, multi-disciplinary teams of investigators from federal, state and local agencies can search for the "root cause" of the outbreak by examining what might have gone wrong to result in the pathogen entering the food in the first place and/or not being processed sufficiently to eliminate the pathogen or reduce it to acceptable limits. Information derived from this final "root cause" phase of the investigation can be crucial for both the food industry and food safety regulators in devising future prevention strategies and interventions.

As this brief background illustrates, multi-state outbreaks are inherently complicated affairs that are difficult to investigate – as a function of both technical and scientific complexity and the many different government agencies involved – but they provide absolutely indispensable information for a food safety system that seeks to be preventive, both in the context of the particular outbreak and prospectively. It should thus be a high priority goal of the food safety system to perform prompt, accurate and complete outbreak investigations.

How the "System" for Outbreak Investigations Fails as a System

The very nature of multi-state outbreaks means that high quality response and investigation requires a high level of preparedness and planning. Time is of the essence. Many agencies are involved from all levels of government, with varying degrees of expertise and resources. Data from multiple sources must be compiled and analyzed. And decisions with potentially great public health and economic impact must be made and communicated in the face of unavoidable uncertainty and unrelenting scrutiny.

To perform well under these circumstances, a system for responding to and investigating and multi-state outbreaks should include at least these seven elements:

- **Federal Leadership and Accountability** – Clearly defined responsibility and accountability at the federal level for managing the response and investigation and making key decisions;

- **Well-Defined Institutional Roles** – Clearly defined roles and responsibilities among all the federal, state and local agencies involved in the outbreak response and investigation and established procedures for their interaction and collaboration;

- **Expertise and Capacity** – A consistent and adequate level of expertise and capacity among federal, state, and local agencies to play their key roles in response and investigation efforts;

- **Traceback** – Rapid access to traceback information;

- **Data Collection and Sharing** – Standardized approaches to collecting and analyzing epidemiological and contamination data and seamless systems for sharing data among agencies;

- **Industry Engagement** – Established principles and protocols for engaging the food industry in investigations; and

- **Public Communication** – Established principles and protocols for communicating with the public during investigations.

The current "system" is lacking in every one of these basic elements.

- **Federal Leadership and Accountability** – CDC, the Food and Drug Administration (FDA) and the Department of Agriculture (USDA) (when meat and poultry may be involved) each play important roles in multi-state outbreaks, but no single federal agency or official is clearly in charge and accountable for the overall management of the effort.

- **Well-Defined Institutional Roles** – Federal, state and local agencies necessarily collaborate on multi-state outbreaks, but the collaboration is essentially ad hoc: there are no formally established mechanisms or protocols for such collaboration or even clarity about when responsibility for managing an outbreak properly shifts from the state or local level to the federal.

- **Expertise and Capacity** – The expertise and capacity of state and local agencies vary widely, and, in general, due to chronic under funding and lack of sufficient staff dedicated to outbreak investigations, capacity at all levels of government is thin.

- **Traceback** – There is no effective system for ensuring rapid government access to critical traceback information, which places extra burdens on already strained resources and delays investigations.

- **Data Collection and Sharing** – There are no standardized approaches to collecting and analyzing epidemiological data, which undercuts the scientific foundations of a multi-state investigation scientific, and conflicting interests and policies often obstruct the flow of information among agencies that should be operating as a cohesive team in managing a multi-state outbreak.

- **Industry Engagement** – There are no established mechanisms for tapping the expertise of the food industry on such matters as industry structure, practices, and distribution patterns, which could both expedite and improve the accuracy of investigations.

- **Public Communication** – The lack of clarity about who is in charge of an investigation can result in lack of clarity in communication with the public, as information about an outbreak is commonly made available from multiple government sources.

Mister Chairman, I wish I could say that these observations were new and original, but they are not. The fact is that leaders at a political level and professionals working in federal, state and local agencies have known for a long time that we lack key ingredients of an effective system for managing multi-state outbreaks.

In December 2000, as an outgrowth of President Clinton's Food Safety Initiative, top officials of the Department of Health and Human Services (HHS), USDA and the Environmental Protection Agency entered into a memorandum of understanding to establish an inter-agency body called the Foodborne Outbreak Response Coordinating Group (FORCG). This group, to be co-chaired by the Assistant Secretary of Health at HHS and USDA's Under Secretary for Food Safety and to include representatives of state and local agencies, was intended to address many of the system problems I have outlined, including the need for a high-level federal focal point for managing multi-state

outbreaks, defined roles and responsibilities, and better communication among agencies and with the public.

FORCG was on the right track, but it disappeared with a change in administration.

More recently, professionals working at CDC, FDA, USDA and in state and local agencies came together in 2005 to form the Council to Improve Foodborne Outbreak Response (CIFOR). In June of this year CIFOR issued for public comment a detailed set of draft guidelines for improving response to foodborne outbreaks, including better planning and preparation, model approaches for harmonizing data collection, better coordination and communication, and clearer definition of leadership roles, especially in multi-state and other multi-jurisdictional outbreaks.

Again, CIFOR is on the right track, but the implementation of its draft guidelines will require sustained political-level commitment and leadership, policy change, and new resources.

So, Mister Chairman, the lessons of the current Salmonella outbreak are not new lessons. The challenge now is to act on these lessons and establish a system for managing multi-state outbreaks that really is a functioning, effective system.

In considering how to do that, it is important to be clear about why it hasn't happened before now. There are many reasons, but I see two fundamental underlying obstacles that must be addressed.

The first is the natural centrifugal force that drives government agencies into their separate corners of the bureaucratic landscape, where they focus first and foremost on their particular mission and part of the problem, rather than the system and problem as a whole, and focus too much on defending their turf, prerogatives, and established ways of doing things, often to the detriment of solving the larger problem. FORCG was a top-down initiative, driven by the White House. When the administration changed, the agencies returned to their corners.

Let me be clear. There are many caring and competent people working on food safety in federal, state, and local government and doing their best within the existing institutional framework, but the framework is wrong.

The second underlying obstacle to improving multi-state outbreak response has to do with policies and priorities. Put simply, the political-level commitment to improving outbreak response has been intermittent and inadequate. Outbreak response tends to be seen only as part of the traditional, reactive approach to food safety. Yes, it's important to react well and contain outbreaks, but once that happens, attention shifts elsewhere, and little attention is paid to preparing for the next outbreak, much less learning from the last one.

I believe this is due, at least in part, to the fact that Congress has never given FDA or USDA a modern public health mandate to prevent foodborne illness. If that were the mandate, improving foodborne illness surveillance and investigation of foodborne outbreaks would immediately gain a higher priority. It is simply not possible to do prevention well unless we do surveillance well and learn everything we can from outbreaks. Thus, a mandate for prevention is a de facto mandate for investment in learning about and learning from foodborne illness, through outbreak investigations and other means.

It is right for Congress, through hearings such as this, to examine how well agencies are doing their jobs within the institutional and policy framework that exists today, but only Congress can change the framework.

Let me now outline some specific recommendations concerning a system for managing multi-state outbreaks, but with the caution that these need to be considered as an integral part of the more comprehensive modernization of the food safety system that Congress is considering. I will say more about that at the end of my testimony.

Recommendations for Improving Outbreak Response and Investigation

The creation of an effective system for managing multi-state outbreaks and learning from them will require new authority, new resources, and structural change at the federal level. That is why it is a job Congress must tackle. The starting point for creating such a system

is the recognition by Congress that there is a strong national interest in modern surveillance of foodborne illness, such as through PulseNet, and effective outbreak response and investigation, for the reasons outlined earlier in this testimony.

States and localities have their own important interests and responsibilities when outbreaks occur within their jurisdictions, and they must continue to play a critical frontline role even in the largest multi-state outbreak. Nevertheless, the compelling national interest in containing major outbreaks promptly and using the knowledge that can be gained to be more effective in preventing illness justifies building a national system, of which states and localities are an integral part.

To achieve that goal, Congress should address each of the elements of an effective national system for outbreak response and investigation. The following are my recommendations for reform.

Federal Leadership and Accountability

To address the lack of clarity concerning who is in charge and accountable at the federal level for managing multi-state outbreak investigations and driving planning and preparedness for future ones, Congress should:

- Mandate the designation of a single official and office reporting directly to the Secretary of Health and Human Services and acting on behalf of the Secretary to

be responsible for managing the federal government's role in outbreak response and investigation.

- Require the establishment of a coordinating mechanism, based on the FORCG model, to ensure effective collaboration among all relevant federal agencies (FDA, CDC, USDA and EPA) and with state and local agencies.

- Provide the Secretary the legal mandate and authority to drive development of an effective national system for both preparedness and response and to take charge of multi-state investigations in appropriate cases.

Well-Defined Institutional Roles

To address the lack of clarity in institutional roles and the need for a more cohesive, integrated approach to outbreak investigations, Congress should:

- Direct the Secretary to define and coordinate the roles of CDC and FDA in each phase of an outbreak response investigation.

- Direct the Secretary to establish, in consultation with states and localities, protocols spelling out the roles and responsibilities of federal, state and local agencies in responding to and investigating multi-state outbreaks, including criteria for determining when responsibility for managing an outbreak properly shifts from the state or local level to the federal level.

Expertise and Capacity

In light of the need for adequate expertise and capacity to respond to and investigate outbreaks, Congress should:

- Direct the Secretary to analyze current gaps and disparities in expertise and capacity at federal, state and local levels, and develop a plan for addressing them, including determination of the base level of expertise and capacity that should be in place at federal, state and local levels.

- Appropriate to the Secretary the resources required to have the needed expertise and capacity in place at the federal level.

- Create and fund a program through which the Secretary could provide matching grants to bolster state and local expertise and capacity.

Traceback

Because traceback information is vital in many cases for promptly identifying the food vehicle and getting to the root cause of an outbreak, Congress should pass traceback legislation to:

- Create a duty for food processors, wholesalers, distributers, and retailers to establish systems that enable them to provide FDA and other authorized

investigators with complete traceback information, in accordance with regulations issued by the Secretary.

- Direct the Secretary to establish by regulation commodity-specific performance standards that specify the time within which a firm must be able to provide the required information, taking into account what's feasible with available technology but providing firms flexibility to choose the system that works best in their operation.

- Require that all traceback records be subject to routine inspection and audit by FDA and that firms be required to test regularly the effectiveness of their traceback system and make the test results available to FDA.

Data Collection and Sharing

Because harmonization of data collection and more seamless sharing of information among government agencies are essential to effective outbreak response and investigation, Congress should:

- Authorize and direct the Secretary, in consultation with state and local officials, to standardize, as fully as appropriate scientifically, protocols for collecting and reporting data in the course of an outbreak investigation.

- Establish the goal of eliminating all barriers to the flow of relevant information among federal, state and local agencies in the course of an outbreak response and investigation.

- Direct the Secretary, in consultation with state and local officials, to identify any such barriers to the flow of information and to report regularly on the steps the Secretary is taking to eliminate them.

Industry Engagement

Recognizing that the food industry is both the source of information that could assist outbreak response and investigation and has a critical need for information from the government in outbreak situations, Congress should:

- Direct the Secretary to establish an on-going mechanism for consultation with the food industry on matters related to outbreak response and investigation, including both preparedness and the exchange of information during an outbreak.

Public Communication

Because the clarity, coherence and balance of government communication during an outbreak can have profound impact on both consumers and industry, Congress should:

- Direct the Secretary to devise, in consultation with state and local agencies, protocols for public communication in multi-state outbreak investigations, which

would include the designation of a single focal point for all federal government communications and agreed upon allocation of communication roles among federal, state and local agencies.

- Direct the Secretary to contract with the National Academy of Sciences or other appropriate expert body for a study and recommendations on effective risk communication during foodborne illness outbreaks.

The Bigger Picture of Food Safety Reform

As I discussed earlier, Mr. Chairman, the problems we have today with outbreak response and investigation are just symptoms of more fundamental underlying problems, including (1) the lack of a congressional mandate for the federal agencies to implement a well-integrated risk-based food safety system focused on prevention; (2) chronic under funding of food safety programs; and (3) the well-documented fragmentation of our food safety system at federal, state and local levels.

Thus, while I think the suggestions I have outlined here for improving outbreak management deserve consideration, they will fall short in the absence of congressional action to address these more fundamental concerns. Bills introduced in this and previous Congresses, including the Safe Food Act of 2007 (H.R. 1148), would bring about both the statutory modernization that is needed to have an effective, prevention-oriented food safety program and the unification in a single agency of all federal food safety programs (including those at the Department of Health and Human Services (HHS), USDA, and

EPA). Over the long run, such unification under a modern statutory mandate is the only way to make cost-effective use of all the resources the federal government invests in food safety.

I know the Energy and Commerce Committee is working on legislation to modernize FDA's legislative mandate for food safety, and I agree FDA and its authorizing statute are the right places to start. But I hope the committee and the Congress won't stop there. Successful food safety reform at FDA – and improved outbreak response and investigation – require action on all three fronts of food safety reform: statutory mandate, resources and organizational structure.

I'll summarize briefly needed steps in these three areas as they relate to FDA and the goal of improving outbreak response and investigation.

Modernize FDA's Statutory Mandate

Congress should modernize FDA's food safety mandate to, among other things:

- Explicitly make prevention of foodborne illness FDA's primary food safety mission;

- Establish by law a duty for all those in the food business to implement preventive controls appropriate to their particular operation, subject to FDA's implementing regulations and guidance;

- Direct FDA to establish and enforce performance standards that make companies accountable for implementing effective prevention measures;

- Make importers legally accountable for assuring that foreign producers and processors shipping products to the United States are meeting U.S. standards;

- Provide leadership in building an integrated, national food safety system that is science- and risk-based and makes efficient use of available resources to improve food safety.

A modernized mandate focused on risk-based prevention and a codified duty for food companies to implement science-based preventive controls make improved illness surveillance and outbreak investigation a necessity for government and industry alike. Under the current reactive system, government investigators have little incentive (and even less human and financial resource) to follow through on outbreak investigations, discover root causes, and draw lessons for prevention. A modernized legislative mandate would help change that.

Provide FDA an Adequate and Stable Resource Base

FDA's resources for food safety have been eroding for years as the agency's food safety challenge gets larger. The total operating budget for FDA's Center for Food Safety and Applied Nutrition – the resources available to take action after the staff and rent are paid – is down to around $25 million. This is a paltry sum for an organization charged with

driving food safety progress across 80% of the American food supply, while also regulating dietary supplements and food labeling, ensuring the safety of infant formula and food additives, and attempting to provide food safety leadership internationally.

An agency with all these responsibilities that can't conduct or commission research, adequately equip its staff, or travel simply can't do its job. And it certainly can't drive the substantial efforts that are required to improve both preparedness for and management of large-scale, multi-state outbreaks of foodborne illness.

Congress has a responsibility to act. In addition to meeting FDA's immediate needs through the 2008 and 2009 budget processes, Congress should undertake a serious study of how to establish an adequate and stable funding base for FDA's food safety program for the long-term. Just as it is fair to hold the food industry accountable for doing its food safety job, it is fair to hold FDA accountable for the leadership and effective action we expect from that agency, but only if it has an adequate and predictable resource base.

Congress should explore a range of resource options, including:

- Requiring FDA to prepare for Congress a five-year financial plan and an annual "professional judgment" budget sufficient to implement a modernized statutory mandate.

- Funding that budget entirely through appropriated funds.

- Establishing by law a statutory inspection mandate, with consequences built in for failure to meet it, to serve as an anchor for appropriated resources.

- Authorizing FDA to collect establishment registration fees and import fees to provide a steady base of resources for the food safety program.

Unify and Elevate the Organizational Elements of the FDA/HHS Food Safety Program

The third key ingredient for the success of any agency – after an appropriate statutory mandate and adequate resources – is an organizational framework suitable for its purpose. Action is needed now to create within HHS an effective organizational framework for food safety. HHS needs a framework that enables it to provide national leadership on food safety and run a coherent, well-planned program that makes the best use of available resources to improve food safety. For several reasons, the current structure of FDA does not provide such a framework.

First, within FDA, the food program consistently takes a back seat to the drug and medical device programs in the competition for management attention and resources. This is due in part to the intense interest that drug and device companies, health professionals, and patients all have in FDA's "gatekeeper" role for therapeutic products. It is reflected in the fact that most FDA commissioners come from a biomedical or health care background. This strong tilt toward drugs and devices was exacerbated by the drug

and device user fee laws, which have further focused FDA management attention, accountability, and resources on the therapeutic side of the agency. History has taught that the job of providing effective national leadership simultaneously on both therapeutic products and food safety is too big a job for any one person.

Second, FDA's organizational structure for food safety is fragmented and lacks a clear focal point for leadership. CFSAN ostensibly has the lead on food safety at FDA, but CFSAN actually shares food safety jurisdiction with the Center for Veterinary Medicine, which regulates pet food and animal drug and feed additive residues in human food, and with the Office of Regulatory Affairs, which manages the majority of FDA's food safety resources through its field force of inspectors, compliance officers and laboratory personnel. The recent establishment in the Office of the Commissioner of an Associate Commissioner for Foods only makes this fragmentation more pronounced. The associate commissioner serves as a spokesperson and coordinator but lacks budget or line authority for programs, further clouding responsibility and accountability for food safety within FDA.

Finally, food safety leadership at FDA rests at least two bureaucratic layers removed from the Secretary of Health and Human Services. As decisionmaking in the executive branch continues to be centralized at higher and higher levels, with OMB having enormous influence on regulatory policy, the full time leader of the nation's premier food safety program needs to have the necessary clout in the system that comes from being presidentially appointed and reporting directly to the Secretary.

In my view, the solution to these problems lies in unifying the food-related components of FDA into a single organization and elevating that organization within HHS under the leadership of a presidentially appointed official reporting directly to the Secretary. This official would be responsible and accountable for leading the necessary transformation of the FDA (and HHS) food safety program.

This needed structural reform would also go a long way toward addressing the federal leadership and accountability problem associated with management of major outbreaks. Still, it would not go far enough. It is essential that the food safety epidemiology function now housed at CDC be made directly accountable to the Department's senior food safety official and become better integrated into the national effort to prevent foodborne illness.

Conclusion

Recent events, including the current Salmonella outbreak, provide an enormous learning opportunity, and I hope strong motivation to act to improve our nation's food safety system. I applaud the subcommittee's efforts to drive change. For the most part, we know what to do. The challenge now is to do it.

Thank you again, Mr. Chairman, for the opportunity to testify today. I look forward to your questions.

Testimony of Michael R. Taylor
on
"The Recent Salmonella Outbreak:
Lessons Learned and Consequences to Industry and Public Health"
July 31, 2008

Key Points

- The outbreak of illness associated with *Salmonella saintpaul* illustrates recent improvement in detecting outbreaks through such innovations as PulseNet, but also underscores that our capacity to respond and investigate has not kept up.

- The fact is we have no system for managing multi-state foodborne illness outbreaks that deserves to be called a system. Many capable people work hard and do the best they can, but they work within a set of institutional arrangements and with tools that are not up to the task.

- Multi-state outbreak investigations are inherently difficult due to scientific limitations and the large number of government and private parties involved.

- The inherent difficulty of responding to and investigating multi-state outbreaks demands planning and preparedness that ensures someone is in charge and accountable at the federal level for the overall effort, roles and procedures at all levels of government are clearly defined and coordinated, the right expertise and tools are in place, and pre-planned mechanisms exist for good communication with the industry and the public.

- The current "system" for multi-state outbreak response and investigation is lacking on every key element of planning and preparedness and needs to be fixed.

- The problems with outbreak response and investigation are just a microcosm of long-documented problems with the nation's food safety system as a whole, including: (1) the lack of a congressional mandate for the federal agencies to implement a well-integrated risk-based food safety system focused on prevention; (2) organizational fragmentation of our food safety system at federal, state and local levels; and (3) chronic under funding of food safety programs.

- Only Congress can fix the fundamental problems that impede the effectiveness of the nation's food safety system;

- Congress should act to give the executive branch the prevention-oriented statutory mandate, unified organizational structure, and adequate resource base it needs to be successful and then hold it accountable for delivering the oversight that industry and consumers need and rightfully expect.

Mr. STUPAK. Thank you.
Mr. Giclas please.

STATEMENT OF HENRY GICLAS, VICE PRESIDENT, STRATEGIC PLANNING, SCIENCE AND TECHNOLOGY, WESTERN GROWERS ASSOCIATION

Mr. GICLAS. Thank you, Chairman Stupak, members of the committee. 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. We appreciate the opportunity to speak before you today on our activity and learnings related to food safety.

The industry has a long history of implementing and improving our food safety programs and defense capabilities to protect public health as well as business interests. In the early 1990s we led to develop the first ever Good Agricultural Practices document that recommended key areas and strategies for reducing risk. These guidelines addressed production, harvest, cooling, processing, transportation, and retail and food service handling. They later became the basis for the FDA's Guide to Minimized Microbial Food Safety Standards for Fresh Fruits and Vegetable—excuse me, Hazards. Today that is the baseline for all food safety guidance.

When the Guide was published our emphasis shifted to one of education of extension. A cottage industry of third party food safety consulting and auditing firms began to grow. These programs have driven a high level of implementation as buyers demand audits as a condition of doing business in the marketplace. This benchmark set of guidelines and food safety paradigm has evolved significantly over the last few years for select commodities. Today, commodity-specific guidance has been developed for lettuce and leafy greens, tomatoes as you saw this morning, and cantaloupes. And there is work under way on green onions and herbs. These are each grounded in the FDA Guide and utilize an approach based on hazard identification, assessment and control.

Despite the continuing improvement in guidance there have also been continuing outbreaks. The 2006 outbreak in spinach drove the industry to move far beyond existing paradigms to even more prescriptive sets of best practices. California and Arizona now have established uniform GAPs and a corresponding verification program that requires implementation of food safety measures developed in concert with public health authorities and private sector experts. These newer generation guidelines include specific requirements for risk assessment, sampling and analysis of inputs, safety response measures and requirements for documentation. Compliance with these requirements is verified by government inspectors in the field. And we believe this model should provide direction for broader national and international efforts to improve food safety.

The model program brings together the strengths of State and federal government, the national and international research community and the industry itself in a coordinated fashion to ensure science-based best practices for preventing or reducing the potential for contamination. The Health and Human Service agencies are in a key position to identify the areas that industry must ad-

dress based on the data and information they have gathered and analyzed in epidemiological investigations and trace-back. Addressing these risks in turn becomes the focus for enhanced best practices.

Verification can rely on inspectors who are already in place throughout the country. FDA is exploring this option by evaluating how third parties might assist in providing "boots on the ground" for verification and inspection.

Western Growers firmly believes that prevention is our strongest tool in efforts to reduce food-borne illness associated with produce. But a model program also must address the response to any discovery of contaminated product in the marketplace or outbreak of food-borne illness.

Collaboration is equally important in efforts to respond. The FDA and CDC have an army of industry personnel at the ready. A formal recognition of this industry expertise and a commitment to strengthen communication with industry during an outbreak will both help protect the public and minimize economic damage to the industry.

We believe the time has come to cease operating in silos and work hand-in-hand using the strengths, talents, and expertise of all parties to improve food safety. The program for leafy greens adopted in California and Arizona is moving the industry closer to achieving our common goal of minimizing the incidence of food-borne illness associated with the consumption of fresh product. We encourage this committee to assist the industry to build on and extend the success of these efforts.

I appreciate the opportunity to testify today on behalf of Western Growers. I look forward to any questions you might have regarding our efforts.

[The statement of Mr. Giclas follows:]

Statement of

Henry Giclas
Vice President – Strategic Planning, Science and Technology
Western Growers

before

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives

July 31, 2008

Good morning Chairman Stupak 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 3000 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.

As we enter the 10th week of the salmonella outbreak, Western Growers appreciates the opportunity to speak before you today on our activity and learning related to food safety, particularly with regard to the E.coli outbreak linked to spinach two years ago and the steps that we have taken to develop rigorous food safety programs that may serve as policy models for consideration in the national debate on how to improve the safety of fresh fruits and vegetables delivered to the consumer.

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.

INDUSTRY INITIATIVE

Western Growers has been at the forefront of the efforts to assist the industry in these efforts beginning with our work in the early 1990s to develop the first ever Good Agricultural Practices (GAPs) document to communicate to the industry the key areas of risk within the produce distribution chain and to recommend strategies and practices that could be utilized to reduce those risks. These generic guidelines were the result of an intensive collaboration between public health and agricultural interests aligned around the common goal of making fresh produce safer. The guidelines addressed production, harvest, cooling, processing, transportation, and retail and foodservice handling and became the basis for the FDA and USDA "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" which was published in 1998 and today remains the benchmark or baseline for all food safety guidance in the domestic and international fresh produce industry. After FDA committed the industry work to this formal guidance document our emphasis shifted from the developmental effort to one of education and extension. Produce trade organizations, academic institutions, and individual companies including both suppliers and buyers began efforts to educate and inform the industry as to the importance of implementing these guidelines in their individual operations. Many courses, seminars, guidebooks, and "how to's" were developed and delivered in an effort to secure broad buy-in and adherence to these voluntary guidelines. At the same time, a cottage industry of third party food safety consulting and auditing firms began to grow and with the development of corresponding audits many buyers began requiring their suppliers to have their practices audited before they would qualify as a vendor. These private initiatives resulted in a very high level of

implementation and helped the industry demonstrate to buyers that it was indeed employing the best practices for food safety. It is also important to note that this approach bred a chaotic array of varying standards that often were tied to discrete buyers. This requires individual growers or shippers to undergo multiple audits to supply different buyers each of which adds significant cost to the system without a corresponding return on investment or additional protections of public health.

This benchmark set of guidelines and food safety paradigm, while effective for most fresh produce commodities, has evolved significantly over the last few years 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 the Agency as higher risk including tomatoes and leafy greens. Prior to the publication of the Produce Safety Action Plan, key trade associations including Western Growers met in Washington, D.C. with FDA Center for Food Safety and Nutrition (CFSAN) officials to hear concerns regarding these commodities and receive the charge to develop Commodity Specific Guidelines for these products. The request was to evaluate what might be unique about each of these crops and to develop further guidance based on any factors or practices associated with these crops that might increase their potential for contamination. Today, Commodity Specific Guidance has been developed for lettuce, leafy greens, tomatoes and cantaloupes, and there is work underway on green onions and herbs; in other words, for each of the

produce commodities FDA has determined present a higher risk of contamination. Every set of guidelines is based on the FDA Guide, utilized an approach based on hazard identification, assessment and control and has been thoroughly vetted with both FDA and the industry.

These newer commodity specific sets of Good Agricultural Practices have again been widely disseminated and a corresponding education and extension effort to communicate them has been ongoing since their development. Western Growers believes they are 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 these newer benchmarks.

Despite the continual improvements in guidance there have also been continuing outbreaks. In 2005 and 2006 there were outbreaks in both tomatoes and leafy greens that drove the industry to again move beyond the existing paradigms to even more prescriptive sets of best practices. In very 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. These newer generation guidelines include specific requirements for risk

assessment, sampling and analysis of inputs, safety response measures and requirements for documentation. Compliance with the requirements is verified by government inspectors in the field. These guidelines and formalized verification programs are now the most rigorous prevention programs anywhere in the world and this model is one we believe should provide direction for broader national and international standardized efforts to improve food safety.

The leafy greens model in California issued a report in December of 2007 which highlighted the program's almost 400 audits covering 184 audit points each. They reported in addition to a very high compliance rate that the number of staff dedicated to food safety had more than doubled and that investments in food safety programs had risen by more than 200 percent.

MODEL PROGRAM

This model program, adopted at a national level, would bring together the strengths of the state and federal government, the national and international research community and the industry itself in a coordinated fashion to ensure science-based best practices for preventing or reducing the potential for contamination of fresh fruits and vegetables were developed and then universally implemented throughout the distribution chain.

This type of structure would facilitate and support relevant research and improve communication with producers, preparers, and consumers, help prevent contamination and facilitate rapid and appropriate responses in the face of outbreaks or identification of suspect product in the marketplace.

In advancing this type of model, we believe the HHS Agencies are in a key position to identify the principal areas of concern and risk based on the data and information gathered and analyzed in historical epidemiological investigations and traceback. Those key issues would in turn be the focal points for the development of enhanced food safety best practices to reduce or minimize those risks as well as address any other concerns or risks identified by the Agency or industry. The Agency and industry effort would be done in collaboration with and reviewed by academic experts to ensure that the final set of best practices is science-based, specific and measurable in nature and implementable in the field. If appropriately subjected to a solid scientific peer review these industry standards also could be the basis by which imports are allowed to enter the U.S. food system.

The verification program should rely on inspectors who are already in place throughout the country subject to accreditation by FDA. FDA is currently evaluating the use of third parties to provide their "boots on the ground" for verification and inspection of fresh produce operations. These inspectors could notify the FDA of any violations and appropriate corrective action could be taken by industry and/or agency to protect public health and improve food safety. This step again helps address the goal of p*reventing contamination* which is the most fundamental step we can take together to reduce outbreaks of food borne illness.

Western Growers firmly believes that prevention is our strongest tool in continuing efforts to reduce food borne illness associated with produce. But fresh produce is grown in an open environment, handled by many people and there are many points in the system where contamination can be introduced. We can get better but we can never get to zero risk, as some would hope. This means that a model program must also address the response to any discovery of contaminated product in the marketplace or outbreak of food borne illness.

Collaboration is equally important in our efforts to respond. The FDA and CDC have an army of industry personnel at the ready to help conclude an outbreak as quickly as possible. A genuine recognition of this industry expertise and a commitment to strengthened communication with the industry during an outbreak will help protect the public and minimize the economic damage to the industry. Currently, industry is largely shut out of such investigations. Granted we are given periodic updates, and FDA has sought input on occasion but there is no formal role for industry to assist officials. The integration of industry expertise would assist from the very beginning when CDC and FDA are attempting to identify a possible food vehicle through understanding the scope and distribution of that product and tracing it back to a source(s).

Clear and definitive messaging with the public is also key such that public health is protected and industry collateral damage is minimized. This would be a significant advantage to both agency and industry in the face of a crisis situation and would not only

help protect the public but could be charged to help restore the marketplace upon conclusion of any event.

CONCLUSION

Western Growers believes the time has come to cease operating in silos and instead work hand in hand using the strengths, talents, and expertise of all parties to improve food safety in this country. The program for leafy greens adopted in California and Arizona is moving the industry closer to achieving a goal that we share with FDA; "to minimize the incidence of food borne illness associated with the consumption of fresh produce." It is a program that brought all of the FDA's food safety partners in both the public and private sector together.

We look forward to working with this Committee and with our partners in federal government, industry and the public sector to continue to improve on what is still the safest food supply in the world.

Summary of Statement of Henry Giclas,
Vice President – Strategic Planning, Science and Technology,
Western Growers

before

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives

July 31, 2008

- The produce industry has a commercial interest in ensuring that only safe wholesome fresh fruits, nuts and vegetables are delivered to our customers' tables, and Western Growers has been at the forefront of the efforts to assist the industry in food safety efforts. These efforts have included developing Good Agricultural Practices (GAPs), Commodity Specific Guidance for higher-risk fresh produce commodities, and now uniform GAPs and a corresponding verification program for leafy greens in California and Arizona.
- The way forward involves collaboration, bringing together the strengths of the state and federal government, the national and international research community, and the industry itself in a coordinated fashion to ensure science-based best practices for preventing or reducing the potential for contamination of fresh fruits and vegetables.
- The program for leafy greens adopted in California and Arizona is moving the industry closer to achieving a goal that we share with FDA; "to minimize the incidence of food borne illness associated with the consumption of fresh produce."

Mr. STUPAK. Thank you.

Dr. Garren, your testimony please.

STATEMENT OF DONNA GARREN, PH.D., VICE PRESIDENT, HEALTH AND SAFETY REGULATORY AFFAIRS, NATIONAL RESTAURANT ASSOCIATION

Dr. GARREN. Chairman Stupak and members of the subcommittee, thank you for this opportunity to testify before you today on the recent Salmonella outbreak.

The National Restaurant Association, founded in 1919, is the leading business association for the restaurant industry, which is comprised of 945,000 restaurant and food service outlets and a work force of 13.1 million employees, generating estimated sales of $558 billion in 2008. Nationwide, the industry serves 133 million guests every day.

Food safety is the utmost importance to the restaurant industry. Restaurants have taken the lead in assuring food safety within the four walls of our restaurants. The National Restaurant Association and our members are making multi-billion dollar investments in improving food safety and developing state of the art food safety education programs. We are especially proud of ServSafe, the food safety education program that sets the standard for our industry. More than 3 million food service professionals have been certified through our ServSafe Food Protection Manager Certification exam.

The current Salmonella outbreak is one of the largest in U.S. history. Of particular concern was the over 2-month period of time needed to identify the source of the outbreak and the mid-course change in focus of the cause of the outbreak. We are at a critical time in food safety, and all of us have a road to play.

This highlights, the outbreak highlights the need to re-evaluate our food safety system and implement needed improvements. Of particular concern is the complexity of the food distribution channels for fresh produce and the challenges presented when a finished product served to customers contains a number of ingredients. This complexity presents challenges to the public health officials leading the efforts to resolve this outbreak in timely manner. In moving forward, we need a better approach. We need a farm-to-table approach.

We build confidence by showing people that we are always ready, always vigilant. For the purpose of this hearing we would like to focus on key areas of moving our food safety efforts forward. Adequate funding for FDA, improved collaboration and communication, stronger standards and practices for produce, and additional tools that include recall authority, traceability, improved epidemiological investigations, and private sector certification.

The recent outbreak highlighted the need to provide FDA with adequate resources to do its job. We are encouraged by the Fiscal Year 2008 supplemental increase for FDA of $150 million, further increases recommended for Fiscal Year 2009 budget as well. However, this can only be a down payment on a sustained effort to increase the agency's appropriated base.

This outbreak also highlights the need for increased collaboration and communication between industry and government. The fact that fresh produce is commingled and repacked at various steps in

the chain should not present an insurmountable problem. There are industry experts who specialize in the distribution of these types of products. There should be a mechanism that allows the agency to tap into this expertise to facilitate a more meaningful investigation of the crisis at hand. While we recognize that conducting an outbreak investigation is a governmental function, we would urge a greater level of collaboration and communication between government and industry, as we all benefit from a rapid resolution.

Effective communication guides the public, the news media, healthcare providers, and industry in responding appropriately to outbreak situations. There are certain challenges and hurdles inherent in developing materials to inform and educate the public about potential health and safety risks in an accurate and timely manner. We must overcome these obstacles and improve how we communicate health and safety information.

It would be a serious error to underestimate the importance of developing, by consensus among stakeholders, the final version of risk communication strategy and plan. Communications professionals in the public and private sectors need to ensure strong and well-integrated working relationships that will help sustain communications resources as an outbreak evolves. The planning, preparation, and practice must begin now.

Over the past several——

[Bells.]

Mr. STUPAK. Stop. Soon as we start again.

Go ahead.

Dr. GARREN. OK. Over the past several years, there have been repeated calls for stronger safety standards for fresh produce. This outbreak reinforces the importance and urgency of that task. The produce industry has taken positive, proactive steps to establish standards. Now it is time for the FDA to take the next step.

The first goal of any food safety system must be prevention. FDA's good agriculture practices, developed a decade ago, should be updated and made mandatory. The National Restaurant Association supports the FDA in setting mandatory general standards for produce as well as commodity-specific standards for commodities the FDA deems as posing a higher risk.

Prevention alone cannot guarantee safety and so emphasis must be placed on rapid response when an outbreak does occur. This leads directly to the issue of traceability. The produce industry has made important strides in recent years to improve traceability, yet more can be done. We must apply our best collective knowledge, expertise, and emerging technology so that finding the source of contaminated produce is a matter of hours or days, not weeks or months.

Traceability systems may need to be developed commodity by commodity to address varying supply chains. A one-size-fits-all strategy may not work for all sectors and stakeholders. In addition, any credible traceability system should be effective for all stakeholders and routinely tested to determine potential flaws prior to a crisis event.

The National Restaurant Association supports granting the FDA the authority to recall a food product that poses serious adverse

public health risk and the company refuses to complete a voluntary recall. Enhanced and coordinated recall notification should be developed to better inform the consumer so that the FDA is communicating these notices to the public in a consistent manner.

We also believe that there should be better resources for investigating outbreaks at the State level. The epidemiology of foodborne illness is sophisticated and always changing. Many States lack the manpower and resources to do it well. Poorly managed investigations can be catastrophic, as we most recently demonstrated by this particular outbreak.

We must ensure States have the necessary funding available to access this information and implement better investigations related to food.

Increasingly, our members are relying on private sector to ensure compliance by suppliers with food safety standards. This approach provides consistency of standards and quality across b orders, cost efficiency in the supply chain, and less duplication of certification processes, and simpler buying. We believe the FDA should support the use of third party certification as a way to leverage the agency's limited resources.

In conclusion, the ongoing Salmonella outbreak has been long, costly and frustrating for all concerned. We must do better. This means taking a new look at our food safety system to ensure we have a comprehensive farm-to-table strategy. We must look for ways for government at all levels to collaborate more closely with industry experts during the course of an outbreak investigation. And we must establish stronger standards and practices that move us towards continuous improvement in produce safety.

Thank you for this opportunity to testify.

[The statement of Dr. Garren follows:]

REPRESENTING THE RESTAURANT INDUSTRY
The Cornerstone of the Economy, Career Opportunities and Community Involvement

Written Testimony

of

Dr. Donna Garren
Vice President, Health and Safety Regulatory Affairs

for the hearing

The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health

before the

U.S. House of Representatives
Committee on Energy & Commerce
Subcommittee on Oversight & Investigations

on behalf of the

National Restaurant Association

Thursday, July 31, 2008

1200 SEVENTEENTH STREET, NW • WASHINGTON, DC 20036-3097
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Chairman Stupak, Ranking member Shimkus, and members of the Oversight and Investigations Subcommittee: thank you for the opportunity to testify before you today on the recent salmonella outbreak. I am Dr. Donna Garren, Vice President of Health and Safety Regulatory Affairs for the National Restaurant Association.

Introduction

The National Restaurant Association, founded in 1919, is the leading business association for the restaurant industry, which is comprised of 945,000 restaurant and foodservice outlets and a work force of 13.1 million employees, generating estimated sales of $558 billion in 2008 – an increase of 4.4 percent over 2007 – and a total economic impact of more than $1.5 trillion. Nationwide, the industry serves 133 million guests every day, and every dollar spent dining out generates $2.34 in business for other industries. Seven out of ten restaurants are single unit operators, with 91 percent of eating-and-drinking places having fewer than 50 employees – we are truly an industry of small businesses!

Not only are restaurants the cornerstone of the economy, they are also the cornerstone of career opportunities and community involvement. Nearly half of all American adults have worked in a restaurant and 32 percent of adults got their first job experience in a restaurant. Nine out of 10 salaried employees at table service restaurants – including owners, operators and managers – started as hourly employees. We are also a diverse industry, with eating-and-drinking places employing more minority managers than any other industry. Ownership opportunities for minorities are also growing with 25.2 percent of eating-and-drinking places being owned by women, 15.2 percent Asian-

owned, 7.9 percent Hispanic owned, and 4.1 percent African-American owned. The restaurant industry is the nation's second largest employer outside the government, representing more than 9 percent of the job-base. And we project that the industry will add 2 million new jobs over the next decade.

Furthermore, restaurateurs are active in the lives of their communities with more than nine out of 10 restaurants involved in some type of charitable activity on a local, state or national level – from sponsoring a youth sports team, to raising money for charities, to providing meals to those in need.

Food Safety

Food safety is of the upmost importance to the restaurant industry. Restaurants have taken the lead in ensuring food safety within the four walls of our restaurants. The National Restaurant Association and our members are making multi-billion-dollar investments in improving food safety and developing state-of-the-art food safety education programs. We are especially proud of ServSafe, the food safety education program that sets the standard for our industry. We began our efforts with ServSafe in 1988. More than 3 million foodservice professionals have been certified through our ServSafe Food Protection Manager Certification exam. The industry's leading suppliers, distributors and academic institutions use ServSafe both online and in classrooms, and our exams and certification meet or exceed regulations in all 50 states. Our newest edition – which debuted earlier this year – is the strongest we have produced. Recognizing the demands of a changing workforce, the product is accessible, understandable and industry-leading.

Trust is absolutely essential to what we do. Our nation's 945,000 foodservice establishments feed approximately 133 million Americans a day. Our guests, and those they bring with them - friends, family members - entrust us with serving them safe food. It is a big responsibility and one which we take very seriously. There is no room for error.

Restaurants also depend heavily on food safety systems of suppliers and manufacturers throughout the foodservice supply chain. The fact is, we are also major consumers in the food marketplace. This year, restaurants will spend more than $200 billion purchasing food and beverages to serve our guests. The National Restaurant Association and its members are increasingly involved in driving changes all the way back through the supply chain, to take on a more influential role across the entire life cycle of food.

On behalf of our members, we support risk-based and thoughtful efforts to increase food safety throughout the food chain so that the food received by U.S. restaurants continues to be among the safest in the world.

The recent salmonella outbreak was one of the largest in U.S. history. Of particular concern was the 2-month time period needed to identify the source of the outbreak and the mid-course change in focus of the cause of the outbreak. We are at a critical time in food safety, and all of us have a role to play.

This outbreak highlights the need to re-evaluate our food safety system and implement needed improvements. Of particular concern is the complexity of the food distribution channels for fresh produce and the challenges presented when a finished product served to consumers, like salsa, contains a number of ingredients. This complexity

presented challenges to the public health officials leading the efforts to resolve this outbreak in timely manner. In moving forward, we need a better approach. We need a truly farm-to-table approach.

Outbreaks of this size and magnitude shake the public's confidence in the safety of the food supply. The Food Marketing Institute released its report: U.S. Grocery Shopper Trends, 2007. It confirms what we believe: consumer shopping behavior and attitudes have changed significantly as a result of outbreaks. The number of consumers "completely" or "somewhat" confident in the safety of supermarket food declined from 82 percent in 2006 to 66 percent — the lowest point since 1989 when the issues of pesticides in apples and contaminated grapes were widely reported. Consumer confidence in restaurant food is even lower at 43 percent. It is clear that there is a strong and urgent message in these findings – a message for the entire food industry and government.

We see tremendous opportunities to advance food safety. The increasingly diverse tastes of our consumers and the realities of the food supply chain have created a global food economy, where local ideas and food products are gaining international currency. We are talking about securing a global food chain and that requires a more thoughtful approach to how our companies and our government look at protecting food safety.

Supply-chain collaboration and coordination has taken on a new urgency and new focus. When a restaurant patron sits down to a meal, the food on his or her plate has been through a long and sophisticated process. Keeping a bond of trust with our guests requires every segment of the food industry to collaborate. As allied partners in the process, we work together to ensure safety at every step in the chain and as we have

heard so many times before, we are all as vulnerable – or as strong – as the weakest link in the chain.

The food supply chain has been transformed in a very few years. The Food and Drug Administration (FDA) is facing new and broader demands precisely because the food supply chain is more complex and global. Food safety requires vigilance, surveying the food supply environment and keeping education and practice ahead of the changes we see.

We build confidence by showing people that we are always ready – always vigilant. For the purposes of this hearing, we would like to focus on key areas in moving our food safety efforts forward:

- need for adequate funding to ensure appropriate FDA staffing and expertise
- need for improved collaboration and communication between government and industry during the investigation of a complex outbreak
- need for communication and education strategies to effectively inform consumers in the event of an outbreak or recall
- need for stronger standards and practices for fresh produce
- need for additional tools: recall authority, traceability, improved epidemiological investigations, and private sector certification

Need for Adequate Funding to Ensure Appropriate FDA Staffing and Expertise

The recent outbreak highlighted the need to provide FDA with adequate resources to do its job. We are encouraged by the FY '08 supplemental increase for FDA of $150 million, and further increases recommended for the FY '09 budget. However, this can

only be a "down payment" on a sustained effort to increase the agency's appropriated base. It is important to emphasize that it is not just the number of FDA staff, but their expertise and experience as well. Over the last 5 years, the FDA's Center for Food Safety and Applied Nutrition (CFSAN) has lost over 200 scientific and regulatory experts, including 3 of its most senior and experienced microbiologists. This loss of critical expertise is not easy to replace.

Need for Improved Collaboration and Communication Between Government and Industry

This outbreak also highlights the need for increased collaboration and communication between government and industry. The fact that fresh produce is co-mingled and repacked at various steps in the chain should not present an insurmountable problem. There are industry experts who specialize in the distribution of these types of products. There should be a mechanism that allows the agency to tap into this expertise to facilitate a more meaningful investigation of the crisis at hand. While we recognize that conducting an outbreak investigation is a governmental function, we would urge a greater level of collaboration and communication between government and industry, as we all benefit from a rapid resolution.

Need for Effective Communication and Education Strategies

The National Academy of Sciences defines risk communication as, "an interactive process of exchange of information and opinion among individuals, groups, and institutions." Strategic communications activities should be based on scientifically sound risk communications principles.

Effective communication guides the public, the news media, healthcare providers, and industry in responding appropriately to outbreak situations. There are certain challenges and hurdles inherent in developing materials to inform and educate the public about potential health and safety risks in an accurate and timely manner. We must overcome these obstacles and improve how we communicate health and safety information.

It would be a serious error to underestimate the importance of developing, by consensus among stakeholders, the final version of a risk communication strategy and plan. Communications professionals in the public and private sectors need to ensure strong and well-integrated working relationships that will help sustain communications resources as an outbreak evolves. The planning, preparation, and practice must begin now.

Need for Stronger Safety Standards and Practices for Fresh Produce

Over the past several years, there have been repeated calls for stronger safety standards for fresh produce. This outbreak reinforces the importance and urgency of that task. The produce industry has taken positive, pro-active steps to establish standards. Now it is time for the FDA to take the next step.

The first goal of any food safety system must be prevention. FDA's good agricultural practices, developed a decade ago, should be updated and made mandatory. The National Restaurant Association supports the FDA in setting mandatory general standards for produce as well as commodity-specific standards for commodities the FDA deems as posing a higher risk.

Prevention alone cannot guarantee safety and so emphasis must be placed on rapid response when an outbreak does occur. This leads directly to the issue of traceability. The produce industry has made important strides in recent years to improve traceability, yet more can be done. We must apply our best collective knowledge, expertise, and emerging technology so that finding the source of contaminated produce is a matter of hours or days, not weeks or months.

In the short term, we support the FDA, together with industry, developing traceability guidance for fruits and vegetables that can be voluntarily adopted. These traceability systems may need to be developed commodity by commodity to address varying supply chains. A one-size-fits-all strategy may not work for all sectors and stakeholders. Once guidance is voluntarily adopted then the FDA should move to the development of regulations based upon these guidelines. In addition, any credible traceability system should be effective for all stakeholders and routinely tested to determine potential flaws prior to a crisis event.

Recall Authority

The National Restaurant Association supports granting the FDA the authority to recall a food product when that product poses a serious adverse public health risk and the company refuses to complete a voluntary recall. This authority should only be granted if adequate resources are provided to the agency to implement these new responsibilities. Enhanced and coordinated recall notification should be developed to better inform the consumer so that the FDA is communicating those notices to the public in a consistent manner.

Epidemiological Investigation Resources at the State level

We also believe there should be better resources for investigating outbreaks at the state level. The epidemiology of foodborne illness is sophisticated and always changing - many states lack the manpower and resources to do it well. Poorly managed investigations can be catastrophic, as was most recently demonstrated with this current outbreak.

CIFOR (C4) is the Council to Improve Foodborne Outbreak Response. State officials have pulled together best practices and other resources for state epidemiological investigations. We must ensure states have the necessary funding available to access this information and implement better investigations related to food. This again is important for both the safety and the public trust. We need and the public expects solid investigations when problems arise.

Third-party Certification

Increasingly, our members are relying on private certification to ensure compliance by suppliers with food safety standards. This approach provides consistency of standards and quality across borders, cost efficiency in the supply chain, less duplication of certification processes, and simpler buying. We believe the FDA should support the use of third-party certification as a way to leverage the Agency's limited resources. We believe third-party certification, using consistent, internationally recognized standards, will be more efficient and more successful than seeking to improve food safety through individual cooperative agreements with foreign governments. Such agreements can be useful, but they are often difficult to achieve and difficult to

harmonize given different countries' legal structures. Use of third-party certification can achieve the standardization of food safety processes faster and more efficiently than country-by-country negotiated agreements.

Conclusion

In conclusion, we should not rely solely on government for the safety of our produce, but government has a critical role to play. We must direct our limited resources toward efforts that will have a more significant impact on the safety of our products.

The ongoing salmonella outbreak has been long, costly, and frustrating for all concerned. We simply MUST do better. This means taking a new look at our food safety system to be sure we have a comprehensive farm-to-table strategy. We must look for ways for the government at all levels to collaborate more closely with industry experts during the course of an outbreak investigation. And we must establish stronger standards and practices that move us towards continuous improvement in produce safety.

Food safety is a collective responsibility. If we are to maintain the bond of trust with our guests, it requires every segment of the food industry to collaborate. As an important partner along the food chain, we pledge our best efforts and look forward to working together with all involved to ensure the safety of our food supply chain. Thank you for this opportunity to testify on behalf this nation's restaurants.

Executive Summary

Food safety is of the upmost importance to the restaurant industry. Restaurants have taken the lead in ensuring food safety within the four walls of our restaurants. The National Restaurant Association and our members are making multi-billion-dollar investments in improving food safety and developing state-of-the-art food safety education programs.

The recent salmonella outbreak highlights the need to re-evaluate our food safety system and implement needed improvements. Of particular concern is the complexity of the food distribution channels for fresh produce and the challenges presented when a finished product served to consumers, like salsa, contains a number of ingredients. This complexity presented challenges to the public health officials leading the efforts to resolve this outbreak in timely manner. In moving forward, we need a better approach. We need a truly farm-to-table approach. Supply-chain collaboration and coordination has taken on a new urgency and new focus.

The food supply chain has been transformed in a very few years. The Food and Drug Administration (FDA) is facing new and broader demands precisely because the food supply chain is more complex and global.

For the purposes of this hearing, we would like to focus on key areas in moving our food safety efforts forward:

- need for adequate funding to ensure appropriate FDA staffing and expertise
- need for improved collaboration and communication between government and industry during the investigation of a complex outbreak
- need for communication and education strategies to effectively inform consumers in the event of an outbreak or recall
- need for stronger standards and practices for fresh produce
- need for additional tools: recall authority, traceability, improved epidemiological investigations, and private sector certification

We must direct our limited resources toward efforts that will have a more significant impact on the safety of our products. The ongoing salmonella outbreak has been long, costly, and frustrating for all concerned. We must look for ways for the government at all levels to collaborate more closely with industry experts during the course of an outbreak investigation. And we must establish stronger standards and practices that move us towards continuous improvement in produce safety.

Mr. STUPAK. Thank you, Dr. Garren.

Dr. Brackett, your testimony please, sir.

STATEMENT OF ROBERT E. BRACKETT, PH.D., SENIOR VICE PRESIDENT AND CHIEF SCIENCE AND REGULATORY AFFAIRS OFFICER, GROCERY MANUFACTURERS ASSOCIATION

Mr. BRACKETT. Thank you, Chairman Stupak and other member of the subcommittee.

The Grocery Manufacturers Association represents the world's leading food, beverage and consumer product companies, and the members of GMA share your commitment to ensuring the safety of our nation's food supply. Product safety is the foundation of that consumer trust.

The recent investigation into the food-borne illnesses outbreaks due to Salmonella Saintpaul is the latest event to challenge our whole food safety system. The inability of the current food safety system to rapidly and accurately determine the source of Salmonella Saintpaul in this outbreak is a major contributor to the erosion of consumer confidence in the safety of the nation's food supply.

The topic of this hearing is what we have learned as a result of the Salmonella outbreak. And we have learned three things. Clearly, the first thing we have learned is that FDA is in dire need of additional resources to carry out its mission of protecting the public from food-borne hazards, and not just money but in terms of scientific expertise and IT infrastructure. And all of that goes along with protecting the food supply.

Secondly, we have learned that the ability to trace a product is meaningless if the epidemiological data implicates the wrong product. This highlights the need for more resources at the State and local levels as well so that we can more rapidly and thoroughly investigate these food-borne illnesses if they occur.

Third, we have learned the need to do more to prevent food safety incidents in the first place.

The GMA has led the effort to provide current guidance to the food industry, both domestically and abroad, by issuing the GMA Food Safety Chain Supply Handbook this past April in 2008. And I have a copy of that here for you. This reference manual represents a tool chest for companies in search of examples of successful management practices for suppliers to consider. The GMA Handbook clearly states that at a minimum, suppliers and transporters should consider their ability to trace back and trace forward the movement of ingredients and finished goods through the whole supply chain.

But traceability was not the real issue in the Salmonella Saintpaul outbreak that we are discussing today. We really need to modernize our entire food safety system. GMA continues to propose that Congress modernize our food safety system by making risk and prevention of contamination the focus of our food safety strategies going forward. GMA CEO Cal Dooley and I have testified many times before Congress on the issue of improving food safety. We have consistently proposed the following reforms, many of which are included in legislation already introduced in both the House and the Senate. These include first:

One, that we urge you to give FDA the power to establish mandatory safety standards for fruits and vegetables. In particular, give FDA the power to establish food safety standards for those fruits and vegetables that have repeatedly been involved in food safety incidents.

Two, we urge you to require food companies to have a food safety plan. In particular, every food company selling food in the U.S. should conduct a food safety risk evaluation that identifies potential sources of contamination, identifies appropriate food safety controls, and verifies that those controls are effective, and then documents those controls in the food safety plan subject to FDA review.

Now, with respect to trace-backs, Congress and the FDA should evaluate the trace-back requirements in the Bioterrorism Act to determine whether it should be extended to farms, given these recent developments.

In addition, there is also one inadvertent outcome from the Bioterrorism Act. The law clearly requires food companies to keep the "one up-one down" records that have been discussed so far. However, there appears to be some ambiguity as to whether the law gives FDA the express authority to check during a routine investigation to see if a company is, in fact, keeping such records. We believe Congress should clarify FDA's authority. By expressly granting FDA such authority, FDA can better assess whether companies are properly prepared to trace product when a food-borne incident does occur.

Third, require every food importer to police their foreign suppliers. In particular, Congress should require that all food importers document the food safety measures and controls being implemented by their foreign suppliers and should require food importers to make their foreign supplier food safety plan available to FDA.

And, four, build the capacity of foreign governments and enlist the help of the private sector. In particular, Congress should direct FDA to develop a plan to help build the scientific and regulatory capacity of major exporters to the U.S. and should create a registry of private laboratories that meet FDA standards.

Mr. Chairman, we are grateful for the opportunity to work with you and promote a risk-based approach to food safety regulation and to allow FDA the flexibility to respond to emerging risks in the manner that most efficiently uses the agency's precious resources. We look forward to working with you to develop and implement improvements that will make risk and prevention the focus of our nation's food systems.

This concludes my oral testimony. And my written testimonies have been submitted for the record.

[The statement of Dr. Brackett follows:]

Written Testimony of
Robert E. Brackett, Ph.D.
Senior Vice President and Chief Science and Regulatory Affairs Officer

before

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

July 31, 2008

Thank you, Mr. Chairman. My name is Robert Brackett and I am Senior Vice President and Chief Science and Regulatory Affairs Officer for the Grocery Manufacturers Association (GMA). We represent the world's leading food, beverage and consumer products companies. GMA promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence.

The members of the Grocery Manufacturers Association share your commitment to ensuring the safety of our nation's food supply. The recent investigation into the foodborne illnesses outbreak due to *Salmonella* Saintpaul is the latest event to challenge our food safety system. The inability of the current food safety systems to rapidly trace and accurately determine the source of the *Salmonella* Saintpaul outbreak is a major contributor to the erosion of consumer confidence in the safety of the nation's food supply.

The food industry has an abiding interest in safe food. Maintaining consumer confidence in our products, our brands, and our companies is the single most important goal of the food, beverage, and consumer packaged goods industry. Product safety is the foundation of consumer trust. Food and beverage companies implement a variety of food safety measures and controls to ensure the safety and quality of our products and ingredients. Ensuring the safety of our products is our most important priority. We devote enormous resources toward this goal, and effective regulation and oversight by federal regulatory agencies are critical and complementary elements of the fabric of consumer protection. We agree that steps must be taken to help FDA and the food industry address food safety challenges. We believe that a risk-based approach to prevention of contamination should continue to be the foundation of the nation's food safety strategies.

Current US regulations require product tracing—one step forward and one step back. GMA supports better supply chain management, including responsible recordkeeping as required by the Bioterrorism Act, to ensure the required tracing can be accomplished rapidly when needed. GMA also supports a management program that imposes the same requirements on each step in the supply chain to enable ingredients to be traced back to the source when necessary and to remove products rapidly from the market if a food safety concern arises. We encourage the use of information technology systems that will facilitate more rapid tracing.

The topic of this hearing is what we have learned as a result of the recent *Salmonella* outbreak. Clearly the first thing we have learned is that FDA is in dire need of additional

resources to carry out its mission of protecting the public from foodborne hazards. We are encouraged by the $150 million increase for FDA in the FY08 Supplemental as well as the further increases proposed for FY09 and continue to urge Congress to appropriate the resources FDA needs to protect the public health. Second, we have learned that the ability to trace a product is meaningless if the epidemiological data implicate the wrong product. This highlights the need for more resources at the state and local levels to rapidly and thoroughly investigate foodborne illness if it occurs. Third, we have learned that we need to do more to prevent food safety incidents.

We support the requirement that all food companies have a food safety plan, and we believe food companies should be given the discretion to identify appropriate safety controls including traceability programs. Prescriptive, across-the-board new regulatory requirements will stifle innovation, divert resources from proven food safety measures, and will increase food costs at a time of record food inflation.

We should consider that today's food industry relies upon a web of inter-company relationships. Successful interactions among ingredient vendors, food contact packaging providers, re-packers, co-manufacturers, brokers and other suppliers are the precursors to effective food safety management.

GMA has led the effort to provide current guidance to the food industry both domestically and abroad by issuing the GMA Food Supply Chain Handbook in April 2008. This guidance is publicly available and in 5 different languages. This reference

manual represents a "tool chest" for companies in search of examples of successful management practices for suppliers to consider. It complements the value of third party audits and the need for a publicly owned and internationally recognized set of food safety audit criteria. The GMA Handbook clearly states that at a minimum, suppliers and transporters should consider their ability to trace back and track forward the movement of ingredients and finished goods through the supply chain. Being able to locate where all ingredients, including food contact packaging, came from and where all finished goods were sent may be useful in the event of a recall or crisis. The Bioterrorism Act mentioned above mandates that all members of the food chain shall be able to trace goods one step forward and one step backward, as well as know the shipper or transporter of the goods. But traceability was not the real issue in the *Salmonella* Saintpaul outbreak. We really need to modernize our food safety system.

GMA continues to propose that Congress modernize our food safety system by making risk and the prevention of contamination the focus of our food safety strategies. GMA CEO, Cal Dooley and I have testified many times before Congress on the issue of improving food safety. We have consistently proposed the following reforms, many of which are included in legislation already introduced in the House and Senate. These include:

- One, we urge you to give FDA the power to establish safety standards for fruits and vegetables. In particular, give FDA the power to establish food safety standards for particular fruits and vegetables that have repeatedly been involved

in food safety incidents – when risk and science demonstrate standards are needed and will be effective in enhancing public health. Under this proposal, FDA should be required to work with stakeholders to develop appropriate standards and FDA should be given the power to work with the states to tailor these standards to meet local growing conditions. FDA should be given the power to work with USDA and states to ensure standards are being met.

- Two, we urge you to require food companies to have a food safety plan. In particular, every food company selling food in the US should conduct a food safety risk evaluation that identifies potential sources of contamination, identifies appropriate food safety controls, verifies that those controls are effective, and documents those controls in a food safety plan subject to FDA review. Industry and FDA should focus and allocate resources towards a prioritized list of high risk food products as suggested by the FDA Food Protection Plan.

    a. On traceback, the area of the greatest concern, by far, is fresh produce, as is evidenced by the recent *Salmonella* incident. The problem is that these products are comingled at various points in the supply chain in order to meet customer requirements, and so the original source is easily lost. There is no simple answer to the problem. But you might consider legislation directing FDA to conduct a pilot project with a segment of the fresh produce industry to see what improved practices might be adopted that would expedite traceback but still be cost-effective. Such a pilot

project would explore and evaluate new methods to quickly identify the source of a fruit or vegetable involved in a foodborne outbreak. This pilot project should include at least 3 different types of fruits or vegetables that have been the subject of outbreaks within the past five years in order to address the varying supply chains for different commodities.

b. Congress and FDA should evaluate the traceback requirement in the Bioterrorism Act to determine whether it should be extended to farms, given recent developments.

c. There is also one inadvertent outcome from the Bioterrorism Act. The law clearly requires food companies to keep the "one up-one down" records. However, there appears to be some ambiguity as to whether the law gives FDA express authority to check during a routine inspection to see if a given company is, in fact, keeping such records. We believe Congress should clarify FDA's authority. By expressly granting FDA such authority, FDA can better assess whether companies are properly prepared to trace product when a foodborne incident occurs.

- Three, require every food importer to police their foreign suppliers. In particular, Congress should require that all food importers document, based on FDA guidance, the food safety measures and controls being implemented by their foreign suppliers and should require food importers to make their foreign supplier

food safety plan available to FDA. Food importers who demonstrate that their products pose no meaningful risk should be eligible for expedited entry at the border so FDA can give greater scrutiny to high risk imports. In September of 2007 GMA issued "*Commitment to Consumers: The Four Pillars of Imported Food Safety*" a comprehensive proposal designed to protect consumers by strengthening, modernizing, and improving the system governing food imports. Our proposal envisioned new mandatory requirements for the food industry to assure the adequacy of foreign supplier food safety programs and new responsibilities for FDA. Other elements included a new program to help identify and prioritize imports of potential concern, new efforts by FDA to help enhance the capacity of foreign governments to prevent and detect food safety issues, improvements to FDA's scientific capabilities and its use of information technology, and a significant increase in FDA resources. Underlying this comprehensive set of proposals is a fundamental emphasis on prevention.

- Four, build the capacity of foreign governments and enlist the help of the private sector. In particular, Congress should direct FDA to develop a plan to help build the scientific and regulatory capacity of major exporters to the U.S. and should create a registry of private laboratories that meet FDA standards. In addition, FDA should enlist the help of accredited third party auditors to ensure that high risk imports meet federal safety standards, to verify the contents of foreign supplier safety plans, and to help identify those imports eligible for expedited entry. Such third party audits would not replace FDA inspections, but would

provide FDA with information that could be used to assess where to best place their resources.

Mr. Chairman, we are grateful for the opportunity to work with you to promote a risk-based approach to food safety regulation and to allow FDA the flexibility to respond to emerging risks in the manner that most efficiently uses the agency's precious resources. We look forward to working with you to develop and implement improvements that will make risk and prevention the focus of our nation's food safety systems.

- Executive Summary -
Testimony of Robert E. Brackett, Ph.D.
Senior Vice President and Chief Science and Regulatory Affairs Officer

Food and beverage companies implement a variety of food safety measures and controls to ensure the safety and quality of our products and ingredients. Ensuring the safety of our products is our most important priority. We agree that Congress must take steps to help FDA and the food industry address food safety challenges. We believe that a risk based approach to the prevention of contamination should continue to be the foundation of our nation's food safety strategies.

From the recent *Salmonella* Saintpaul outbreak we have learned that:

- FDA is in dire need of additional resources to carry out its mission of protecting the public from foodborne hazards;
- the ability to trace a product is meaningless if the epidemiological data implicate the wrong product; and
- we need to do more to prevent food safety incidents.

The inability of the current food safety systems to rapidly trace and accurately determine the source of the *Salmonella* Saintpaul outbreak is a major contributor to the erosion of consumer confidence in the safety of the nation's food supply and highlights the need for improvements.

GMA continues to propose that Congress modernize our food safety system focusing on risk and the prevention of contamination. In particular, we urge Congress to:

- One, give FDA the power to establish safety standards for fruits and vegetables.
- Two, require food companies to have a food safety plan.
- Three, require every food importer to police their foreign suppliers
- Four, build the capacity of foreign governments and enlist the help of the private sector.

Mr. STUPAK. Thank you. And thank you all for you testimony.

Unfortunately, as you know, with the bells ringing we have votes. We have 5 minutes left on the floor for us to go vote. We have six votes. I want to say 3:15 we will come back and we will go with questions. I hate to ask you to stay another hour but we want to get the questions in. So let us come back here at 3:15.

OK, the committee will be in recess until 3:15.

[Recess.]

Mr. STUPAK. I thank you for staying with us. And sorry, we thought it was going to be a short deal. There was a special motion on the floor, took a little bit of time, that is why we are an hour late, or for those of us who live in Central Time Zone we are right on time, 3:15. But we will start with some questions here.

Let me ask this, Mr. Giclas, when this outbreak first occurred and tomatoes were named as a possible source of Salmonella, large portions of Florida or in this case the entire State of California were not in production and, therefore, it would have been impossible for Salmonella to be in the tomatoes. Nonetheless, almost the entire growing industry has been broadly painted, and still is today, with the same brush, at least in the eyes of consumers.

Is there anything with respect to CDC or FDA's messaging to the public that can be improved so not to hurt certain parts of industries that are not responsible for outbreaks?

Mr. GICLAS. Mr. Chairman, my response to that would be I think there is a lot of room for improvement in the messaging in a couple of different ways.

First of all, I think that CDC and FDA ought to just tell people what they know when they know it and, you know, not get into a position where they are speculating on what other products or what other commodities or what other regions. I think, I also think that the frequency of communication was problematic in this particular outbreak because there was, you know, a series of media calls that were held over and over and over with really nothing new to report other than an update on the numbers, but no significant findings, if you will.

Mr. STUPAK. OK. Dr. Garren, Dr. Brackett, in the Bioterrorism Act of 2002 both the restaurants and the farms were exempt. Would you now agree that we should put them in the Bioterrorism Act so we can do traceability better? On behalf of the restaurants, Dr. Garren, what would you do, would you agree you should be part of this process?

Dr. GARREN. We definitely believe that there should be a farm-to-table strategy.

Mr. STUPAK. How about restaurants?

Dr. GARREN. Excuse me?

Mr. STUPAK. Restaurants?

Dr. GARREN. We want to work with FDA. Right now we would say that, you know, we represent a very diverse industry that goes from the small, independent operator all the way to the multi-unit operators.

Mr. STUPAK. Agreed.

Dr. GARREN. And in this particular case, you know, I would say in regards to the Bioterrorism Act I would say we already voluntarily comply with it in that we were able to in this particular case

supply information to FDA in a timely manner. It might have been purchasing records for those small unit operators. Those small unit operators that is how they may make——

Mr. STUPAK. Yes, but one of the problems is that you may be, if you are not part of the act maybe the records you are, and we have seen this throughout this whole investigation, records you are providing may be something different than what the distributors gave to you. I think and when we were dealing with the other panels you almost need a seamless form system where we are all using the same systems, otherwise it just burdens everybody. You have paper, they have electronic, they have something else, bill of lading, some are on back of a brown bag they said, that is some of their records.

Dr. GARREN. Right. We would want to work with the stakeholders involved, including government, to come out with an approach that works to integrate commodity to commodity, and incorporate the needs of different stakeholders. I think a one-size-fits-all strategy for traceability might not be working for every particular business type. We need to take into account where we move from here. But we definitely welcome the opportunity to work to move in that direction.

Mr. STUPAK. Dr. Brackett, do you want to add anything on the behalf of the Grocery Manufacturers?

Mr. BRACKETT. Yes, I would make a comment specifically on the farm side of it. This this is in this particular group of products, those that are high-risk products, most of the problems have been in the past the fact that they have not been able to track back to the farms. And so if you are going to have a farm-to-table approach I think they would have to be included. And I think the industry is well on its way to doing that already.

Mr. STUPAK. Mr. Taylor? Professor Taylor, do you want to add anything on that?

Mr. TAYLOR. Well, I think as long as you are in the mode of having a system that is dependent upon government investigation of company records and you want a farm-to-table system you have to extend it to restaurants and farms. I guess I would encourage consideration of a completely different approach though. Because in a public health context it seems to me what FDA needs to be able to do is rapidly get trace-back information that the companies have and give answers to FDA as to where a product came from instead of creating company records that then still rely on FDA to do the investigation. So rather than rely on those internal records, you know, I would suggest, for example, as I did in my testimony, creating a performance standard if you will.

Mr. STUPAK. Right.

Mr. TAYLOR. Having Congress legislate or authorize FDA to do commodity-specific rulemaking that would say based on available technologies everyone in that supply chain should be able to tell FDA within 4 hours, 8 hours, 12, whatever you judge or FDA judges is technologically feasible, the duty is to provide that information within a certain period of time. And then the companies can figure out what specific technology or set of practices work for that commodity or that business model and not get the government

into the business of trying to create the trace-back system but set the performance standard that every company has to meet.

Mr. STUPAK. Or at least some minimum standards that we need for trace-back?

Mr. TAYLOR. Yes.

Mr. STUPAK. And then let the industry by commodity work on it?

Mr. TAYLOR. Yes. And based on an assessment of what is technology feasible and can be done in a cost-effective way but then leave it to the companies to innovate the specific systems that meet that performance standard for timeliness of disclosure of where a product came from.

Mr. STUPAK. Mr. Giclas, you indicate that Arizona and California have standards they have developed together for what, leafy greens, tomatoes?

Mr. GICLAS. Well, the first panel this morning spoke specifically about the standards for tomatoes in California and Florida. My testimony was about the leafy greens program in California and Arizona.

Mr. STUPAK. Could that be replicated throughout the U.S.? I mean you are the only two States that are doing it right now.

Mr. GICLAS. It absolutely can be replicated. And it is one of the things that, you know, we are bringing forward as a potential model. It is very similar to what is being done in tomatoes in both California and Florida on the part of the tomato industry. So it is an example of some of the commodities that have been deemed to have higher risk like leafy greens, tomatoes, cantaloupes, there are some others, where industry is coming forward to put these best practices, if you will, in place. And I think what we need to do is provide that line of sight to FDA and to others.

Mr. STUPAK. I asked the other panel, and I guess it was only I think the other panel said, the first panel, was a penny to print on the box the code. But like to implement this, do you have any cost estimates what would it cost to implement this? I mean that goes out the system I realize from farm to table, but.

Mr. GICLAS. Well, leafy greens there's a couple of different costs that are associated with it. There is a 2 cent per carton assessment levied on the industry to support the verification program and the administration of the leafy greens programs. That cost is borne by everybody but it is not—there are also additional costs for every individual firm in terms of ramping up to meet the requirements of the leafy greens metrics or best practices, if you will. And those have been estimated to be, you know, on the order of 25 cents a carton. There is the significant investment in this program. It has probably tripled through safety investments in California and doubled the number of staff that are focused on food safety. It is a very significant expenditure ultimately.

Mr. STUPAK. Dr. Brackett, do you have any estimates, or Restaurant Association estimates what something like this would cost if we had sort of like uniform standards throughout the nation, had to do it? I would take it you would be in favor of uniform standards maybe promulgated by the federal government, FDA, whatever, but let industry implement it to a minimum standard. And what would the cost estimates be, if you have any costs, Mr. Brackett?

Mr. BRACKETT. Well, Mr. Chairman, I do not know what the cost is. We have been down that. Many of the industry already have systems in place already so they have already bought those costs, those systems already.

But I agree with Mr. Taylor that having a performance-based system where the requirement is what the government expects or what the regulatory agency expects in terms of response in order to trace back and then allowing the industry to adopt to whatever the best technology is at the time is probably what we would support.

Mr. STUPAK. OK. Let me ask this, and whoever can answer it. Industry, like Jack In The Box, they had a problem one year. And they started putting in a system that made demand their growers do certain things. Some of the other, McDonald's I know do, and others. Has that worked? And what is the benefit of that as opposed to having the government put in something? Anyone want to comment on that?

I mean I heard two things: number one, it can work. Even if the tomatoes are being grown in Mexico, if you are McDonald's you are a big enough corporate player you can say, you will do it this way, and get compliance even in a foreign country. And I have heard from other farmers who will say, well, these corporations while they are concerned about the safety of the food but they are putting other restrictions on us which are more risk management like fences and things like that, that have nothing to do with growing or protection. Can you shed a little light on that? Mr. Giclas, you are nodding your head?

Mr. GICLAS. Well, I would be happy to honor or to answer that part of the question. I am sorry. This has been a significant point of frustration for many, many growers. We have worked very, very hard and in close collaboration with the public health community to identify, you know, a set of best practices that we believe are prudent, science-based and feasible and implementable in the field. Those best practices are, you know, part of this program for leafy greens. And yet, there are individual buying companies that will say, for example, if you are estimating an approximate safe distance between a livestock operation and a produce operation, which you should keep separate——

Mr. STUPAK. Right.

Mr. GICLAS [continuing]. We might say that a quarter mile is a safe distance. Or the distance may vary based on the risk; is it uphill, is it downhill, are there barriers in between that might, you know, prevent some escape of. Anyways, I guess the point is if we say a quarter mile and that has been vetted by science, there may be others who say a mile or 2 miles or 3 miles is better. Every single one of those new requirements has a cost to it. It takes valuable production land out of the equation and it jeopardizes people's ability to continue to farm. It may not be science based.

So those are the kinds of things that we are dealing with with these extra requirements.

Mr. STUPAK. Professor Taylor?

Mr. TAYLOR. Yes. Mr. Chairman, I was administrator of the Food Safety and Inspection Service——

Mr. STUPAK. Right.

Mr. TAYLOR [continuing]. For USDA in the aftermath of the Jack In The Box E. coli outbreak and saw what happened in the industry after that and also the efforts we made in the government to try to improve standards. And the first thing I would say is that, I mean Jack In The Box in particular, but also other major retailers went through enormous transformation in terms of their own management of their supply chain putting specifications on suppliers. The beef industry really got with that program and has gone through enormous positive change to bring technology into the processing. And I think they have made real progress, all based on the principle of preventive controls. And so industry innovation has been critical to progress on food safety.

But the other side of that—Go ahead.

Mr. STUPAK. But then what happened to the beef industry? Because we had the largest recall ever, 143 million pounds of beef here. And we had a hearing on that.

Mr. TAYLOR. Yes.

Mr. STUPAK. And I mean did it just get sloppy or what?

Mr. TAYLOR. Part of the, well, one part of the reality is that the E. coli problem is not a problem you solve on one day and it stays solved.

Mr. STUPAK. Right.

Mr. TAYLOR. Because that bacteria changes, it is a very dynamic problem.

But the other point I wanted to make is that while innovation gets driven and really created in food safety by industry practices typically, there is an essential role for government regulation to set standards and ensure that it is not just the good actors who have the market incentive to do that, to make the changes, but that everybody makes. And that you bring the lower performers up to an acceptable, a socially acceptable level. And you also achieve the objective of having a common sense based standard so that their, you know, businesses can plan. And I think it would help probably address some of the concerns that Mr. Giclas raised.

So again I think you have to look to both, you know, industry, private sector innovation to really drive progress, but then government standard setting and hopefully in a performance standard way so that, again, you see what is possible through innovation the industry itself has done and you set government performance standards to ensure that everybody meets that standard that has been demonstrated to be feasible.

Mr. STUPAK. Mr. Giclas, one more and my time is up. But, you know, Salinas Valley we have had, what, 20 outbreaks in 10 years. And why can we not seem to resolve that issue? It seems like every 9 months or so we have a spinach or a leafy problem with E. coli or Salmonella coming out of that particular area. If we have learned from all these different experiences why can we not solve that Salinas Valley problem? Any suggestions? I throw it out to all my panels.

Mr. GICLAS. Well, what I can say is that after the 2006 outbreak in spinach we really as an industry focused in on, you know, looking at these practices, what we could do. And now we have gone a full season without an outbreak. This program is in place. We are

hopeful that this program has resolved these issues and this problem.

As has been pointed out, you cannot get to zero but we can do everything we can to minimize. We think we have the best program in place to do that now.

Mr. STUPAK. All right, thanks. I guess only Dole and Natural Select are the only ones really aggressively doing the program that has been put forth by industry; right? In that spinach area in the Salinas Valley?

Mr. GICLAS. This program is subscribed to by 120 different companies I believe.

Mr. STUPAK. OK.

Mr. GICLAS. Representing 99.9 percent of the volume of——

Mr. STUPAK. The Salinas Valley.

Mr. GICLAS. Yes.

Mr. STUPAK. OK. Mr. Burgess for questions, please.

Mr. BURGESS. I thank everyone's indulgence for what is turning into a very long afternoon.

Professor Taylor, if I could just ask you, again I apologize for being absent for part of your testimony, but on the part where you discuss some of the problems within the food safety program at the FDA, and one of the things you allude to is that because of the bifurcated mission of the FDA, drugs and devices get more attention, and perhaps it is even the presence of a user fee that may drive attention in the direction of drugs and devices.

I know we are going to have at some point the opportunity to discuss a draft here at some level at this committee, and I got a feeling that user fees are going to come up. So what is your feeling about the presence of user fees as it pertains to the food safety side of the FDA's bifurcated mission?

Mr. TAYLOR. Well, I think I mean user fees on the drug side has served a very useful purpose of providing adequate funding for that drug review program. And that is now a program that has demonstrated that with adequate resources FDA can manage efficiently a timely drug review program. So it has worked in that sense.

And my point in the testimony, of course, was that that has had a bit of a distorting effect, unintended, on management attention and the allocation of resources within FDA. And so user fees are a complicated issue and potentially a mixed blessing.

On the food side, you know, I am of the old school that says that ideally we would fund public health programs through appropriated resources. And I think ideally that is what should happen. I——

Mr. BURGESS. Just for the record, I agree with you. That is the fundamental purpose of the Food and Drug Administration and should be the fundamental purpose of our appropriations.

Mr. TAYLOR. And I think philosophically that makes all the sense in the world. I think the issue though is in the world in which we live and in which you live, I mean how, the core issue for food safety is how do we provide an adequate, stable, predictable base of resources for FDA? That need for food safety at FDA, and that need has to be met. And so it may not be an ideal world and maybe there is a fee that could be done that will generate revenues.

And I think I would personally be willing to compromise on the philosophy point if we could find a way to get a base of resources that was fair and not too onerous but would generate a sufficient, you know, core of resource for FDA so that it could do its work and, again, and maintain the independence and all that I think is important for its food safety public health function.

Mr. BURGESS. I will just ask if anyone else on the panel has a feeling about that, about what Professor Taylor just alluded to. I will tell you, philosophically I have difficulty with it. It is almost like we are abrogating our responsibility to provide the protection where it belongs which is within the food safety aspect of the FDA. But does anyone else have an opinion about that?

Dr. GARREN. We do not support user fees. We do, as you mentioned, believe that food safety is a common benefit to all and should be out of the general revenue fund and be appropriate to fund FDA so they can do their job.

Mr. BURGESS. Mr. Giclas, let me just ask you, you talked about a 1 to 2 cent charge for the tracking code on the box. In a sense that is a user fee, is it not?

Mr. GICLAS. It is, sir. It does fund the program. But the program is industry designed. It has industry at the heart of it in the sense of, you know, oversight on funding and spending and administration. ? So it is something that was willingly subscribed to.

Mr. BURGESS. And you can sleep peacefully at night knowing that 1 to 2 cents is not going to grow the government into some other aspect or some other place in your life.

Mr. GICLAS. Absolutely.

Mr. BURGESS. Very good.

Dr. Brackett, let me just ask you a question on the—and we have heard a lot about this today from various sources, but what is the role for the food companies and the importers in the prevention of food-borne illness?

Mr. BRACKETT. Well, it is the food companies that actually provide the safe food to the public. And it is their responsibility to actually make sure that those preventative controls that have been mentioned several times today are actually implemented. And I quite agree with Professor Taylor that it is the role of government to set those standards, and then if you allow the industry to actually meet those standards they will find ways to do that.

Mr. BURGESS. And then what, in the event of an outbreak or in the event of a problem what should the role be?

Mr. BRACKETT. Well, I think the role should be to assist the regulatory agencies as much as they can. And again I would like to repeat what has been said elsewhere that if the regulatory agency and CDC do not have, either do not or do not have the ability to tap into the resources that the industry has in terms of scientific expertise and information I think they are missing the boat.

Mr. BURGESS. Let me ask a question in regards to what we have heard a lot about today in the 2002 Bioterrorism Act. And earlier we heard a lot from the standpoint of the importers. But as far as restaurants are concerned, the ability to opt out of the reporting and the recording requirements, in light of what we have learned with this outbreak and what we have learned today is it still rea-

sonable to allow restaurants to opt out of the requirement when we have 130 people visiting these establishments every year?

Dr. GARREN. Thank you for the opportunity. We, while we are exempt from the Bioterrorism Act I would say that we are voluntarily complying now and that we keep the necessary records to know where we are getting product from. You know, I often say, you know, follow the money. I mean people know who they are buying product from. They have to pay the bills. And, you know, so they know that when FDA comes, even a small independent operator, it may be a paper-based system but they are maintaining those records because they have to financially to know who they are paying product to.

So we would say that, you know, they are supplying the information needed to FDA. We need to come up with an approach and we welcome the opportunity to work with all the stakeholders, including federal and state food safety agencies and all the stakeholders along the supply chain to look at approaches that will work for all stakeholders involved, taking into account different business types, and in some cases taking into commodity types, because one-size-fits-all approach strategy may not work for everyone.

Mr. BURGESS. But in this instance would it not have been better if it was rather than voluntary compliance that it was required compliance?

Dr. GARREN. I would offer that in this particular case that, you know, the restaurants that were involved, even the small operators were able to supply the necessary information to facilitate a rapid response from them. FDA's ability to then go through and assess the amount of paperwork that they had to work through to build a case, you know, in regards to I guess collection of data, evidence and, you know, securing that information made a complicated and frustrating investigation.

Again, we are, you know, willing to work with creating a program that works for all.

Mr. BURGESS. So it was more the FDA's inability to ask the correct question at the correct time of the correct person, not the inability of the small restaurant to provide the needed data when it was requested?

Dr. GARREN. They were supplying the information. And I think the earlier panels did indicate that, you know, we were looking down the wrong path too. So that also made the length of this outbreak, you know, they were supplying information on tomatoes. When asked about jalapeño peppers they quickly were able to supply the information needed to facilitate trace-back.

Mr. BURGESS. But realistically, how burdensome would it be to require the restaurants to participate in a trace-back system?

Dr. GARREN. You know, I do not know what the actual costs associated with that. And again, we would be willing to look at different strategies. I think if we are looking at the diversity of our industry you have a breadth of, you know, small independent operators collecting data on paper all the way through very sophisticated electronic tracking systems through the distribution chain, distributors that supply to our operators as well as large chains that have systems.

We need to make sure that they take into account the different business types and we need to create a new system.

Mr. BURGESS. Mr. Giclas, let me ask you this because it came up during some of our other hearings where we were actually talking about food-borne illnesses in Asian countries. And the statement was made by one of the suppliers that if they found that one of their suppliers was providing a product that was somehow damaged that they didn't feel compelled to report it to other businesses in the area, this was just something they kept to themselves. And in fact they didn't even feel compelled to report it to the FDA who is responsible for ensuring the food safety. And the issue came up around the issue of maintaining a competitive advantage.

Well, do you think members from your organization would be willing to sacrifice some or to provide some leniency on trade secrets, provide information, provide that collaborative role with public health officials in the event of an outbreak or during the course of an investigation? How closely held are those trade secrets and would you be willing to relax those somewhat during the course of an investigation of an outbreak?

Mr. GICLAS. Well, I think in the investigation of an outbreak the industry would comply fully and does comply fully with, you know, the requirements, the law. I mean in terms of learning from an outbreak I think we are all willing to sit down with FDA and others and share information, including what might be confidential business information. That is an individual company decision. But I mean I am certain that people would be willing to collaborate, you know, to improve on trace-back and to improve on those types of things.

The leafy greens program that we have in California and Arizona if you are actually sourcing product from somebody who is not compliant that would be communicated to others so that they would know that there is a non-compliant supplier out there and not be able to—or not go to them to, you know, to source product if you will. So there are some additional preventive steps that are in place in this construct that we have for the leafy greens industry.

Mr. BURGESS. Thank you. And thank you, Mr. Chairman, for your indulgence. I actually if I could submit some questions in writing to the panel, just would like to get some follow-up on the issue of if we are ever able to close our border in the event of an outbreak, again the finding of this problem on a Friday morning and not being able to do anything about it for several days is pretty frustrating to the American people I think.

Mr. STUPAK. Sure, no problem. We will at the end there when we close out this hearing we will leave the record open for 30 days for additional written questions then.

Mr. BURGESS. Thank you.

Mr. STUPAK. Mr. Giclas, in the last question from Mr. Burgess you indicated sure we would like to sit down with the FDA if there was an outbreak and we would all share our records and the proprietary interests would probably be—it would not be burdensome. But I got the impression in listening to the three panels today, and especially Florida and California, like in this whole Salmonella Saintpaul no one ever sat down with the growers or producers to say we have this problem. We referred to it throughout today as

an incident command. Like you think you would sit down with the growers, distributors, the wholesalers, the local health department, State health department and say, OK, where are we going with this? It seems like everything was stovepipe we call it the information was; this one does not talk here and that, and they use these ideas like Privacy Act, proprietary information as not to do that. I think the American people think that when you have an outbreak you are all sitting around a big table like we have in front of us saying, OK, where do we go? How do we do this? Could the tomatoes possibly come from Florida? Was it the growing season?

I take it the industry would be willing to work and sit around a table and get this thing resolved instead of having it go on for a few months like we have now and 1,300 people becoming ill?

Mr. GICLAS. That is absolutely correct. I mean we would very much, and we have encouraged in other testimony and at other times setting up some type of a formal recognition of industry expertise to assist in trace-backs. And I can tell you, now having been involved in trace-backs for numerous commodities for a number of years, we have consistently asked FDA, tell us what went wrong. Tell us what is the obstacle in trace-back. Tell us what information you are missing, what form do you want it in. And we have yet to really get a response to those questions such that we can change our industry systems to meet their needs which is, I mean trace-back is vitally important to use because it minimizes the scope of the economic damages right away.

Mr. STUPAK. Sure. Thanks.

Dr. Brackett, I guess it would only be fair to ask you. I asked some of the other panels on the Associated Press story that we have seen and we have talked a little bit about. And it in the binder there by Mr. Giclas, it is number 5 if you want to see it, but it was the article is entitled, "Food Industry Bitten by its Own Lobbying Success." You were at the FDA at the time during the development of the regulations that resulted in the Bioterrorism Act which is designed to enhance product traceability; is that correct?

Mr. BRACKETT. That is correct.

Mr. STUPAK. OK. In the article referring to the latest Salmonella outbreak investigation you are quoted as saying, "If they," the regulations, "had been broader and a bit more far-reaching it could have helped us." Is that correct?

Mr. BRACKETT. Well, yes. That was the statement. And if I could, I would like to put it in context of what it was.

Mr. STUPAK. Sure.

Mr. BRACKETT. And in fact there were two parts to that, one of which was something that I have said already today which is if it had included the agricultural industry, the farms, that would have helped a lot too.

Mr. STUPAK. Right.

Mr. BRACKETT. And the second half is now, several years later, after technology has changed and the market has changed, if we had the ability to go back in a time machine and change things we could probably think of a way to fit this situation. But we do not have that sort of luxury. But the main part was the fact that the farm-to-table inclusion in the Bioterrorism Act would have been helpful.

Mr. STUPAK. OK. Anything else, Mr. Burgess?

I have no further questions. I want to thank you for coming and thanks for your patience. Once in a while we get pulled out for votes, and I thought we were going to make it. We were pretty close to getting it all completed before the votes. Maybe we will start it earlier than 10:00 o'clock so we can get them in before votes.

But thank you for being here. Thank you for your help. And I know Mr. Burgess will have further questions; we will submit them to you. I am sure other members will too. As I said earlier, there were two sets of hearings going on today besides oversight investigations. So thank you.

That concludes all questions. I want to thank all of our witnesses for coming today and for their testimony. I ask for unanimous consent that the hearing record will remain open for 30 days for additional questions for the record. Without objection the record will remain open.

I ask unanimous consent that the contents of our document binder be entered in the record.

I also ask unanimous consent that the binder containing questionnaires used by the States and the CDC be made available for review at the committee office upon request. Without objection, the documents will be entered in the record and the consent or questionnaires will be in the office.

[The information appears at the conclusion of the hearing]

Mr. STUPAK. That concludes our hearing. Without objection this meeting of the subcommittee is adjourned.

[Whereupon, at 4:50 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Salmonella Saintpaul Outbreak Timeline

- **May 22, 2008**
  - CDC and State health departments identified an outbreak of *Salmonella* Saintpaul infections in New Mexico and Texas.
  - Consumption of raw tomatoes were strongly linked to the illnesses.

Salmonella Saintpaul Outbreak Timeline

- **May 30, 2008**
  - CDC and State health departments first notified FDA.
  - CDC also alerted FDA that raw red Roma, plum, and round tomatoes were identified as being strongly linked to the outbreak illnesses.

Salmonella Saintpaul Outbreak Timeline

- **June 3, 2008**
  - FDA warned consumers in New Mexico and Texas not to eat certain types of raw, red tomatoes

Salmonella Saintpaul Outbreak Timeline

- **June 7, 2008**
  - FDA expanded its alert and warned consumers nationwide not to eat certain types of raw, red tomatoes and products containing those tomatoes unless they were grown and harvested in an area which FDA determined was not associated with the outbreak.
  - At this time, over 100 illnesses had been reported in 16 States.

Salmonella Saintpaul Outbreak Timeline

- **Late June 2008**
  - CDC conducted a new multistate study on people who became ill on or after June 1, 2008.
    - People who became ill were more likely to have consumed raw tomatoes, and/or fresh jalapeños and cilantro.
    - This study found that jalapeños caused some illnesses, but an outbreak source could not be determined.

Salmonella Saintpaul Outbreak Timeline

- **July 9, 2008**
  - FDA advised people in high-risk populations to avoid eating raw jalapeño and serrano peppers.
  - FDA continued to advise consumers not to eat certain raw red tomatoes unless they were grown in an area not associated with the outbreak.

Salmonella Saintpaul Outbreak Timeline

- **July 17, 2008**
  - FDA removed its tomato warning and stated that consumers could eat all types of fresh tomatoes on the domestic market.
  - FDA reiterated its previous warning regarding fresh peppers.

Salmonella Saintpaul Outbreak Timeline

- **July 21, 2008**
  - FDA confirmed the presence of *Salmonella* Saintpaul in jalapeño peppers with same genetic fingerprint as the strain linked to the outbreak (found at a distribution center in Texas, grown from a farm in Mexico).
  - FDA expanded its warning regarding fresh jalapeño peppers and byproducts.
  - Tomatoes were not ruled out as the original source of the outbreak.

Salmonella Saintpaul Outbreak Timeline

- **As of July 23, 2008**
  - 1279 people in 43 States, the District of Columbia, and Canada became infected with *Salmonella* Saintpaul.
  - Illnesses resulted in at least 239 hospitalizations and might have been a contributing factor in two deaths.
  - The largest food borne outbreak in the United States in the last decade.

09/17/08 WED 12:07 FAX 301 443 2567 DHHS FDA OL 002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 1 7 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA) the opportunity to testify at the July 31, 2008, hearing entitled, "The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health," held by the Subcommittee on Oversight and Investigations. Dr. David Acheson, Associate Commissioner for Foods, testified on behalf of FDA. This letter responds to questions for the record which were raised during the hearing. In the enclosed document, we have re-stated each question in bold type, followed by FDA's response.

Thank you again for the opportunity to appear before the Subcommittee. We look forward to continuing to work with you and Committee staff on these important public health issues. If you have any further questions or concerns, please let us know.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosure

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Bart T. Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Diana DeGette, Member
Subcommittee on Oversight and Investigations

The Honorable John D. Dingell

In 2003, FDA had over 4000 field investigators to investigate contamination of food outbreaks and inspect food facilities. True or False? In 2008, FDA's field force of investigators had been reduced to only 3300 investigators, a loss of 700 investigators. True or False?

To clarify, FDA's Office of Regulatory Affairs (ORA) had 4,048 total full-time equivalents (FTE) in Fiscal Year (FY) 2003, of which 1,559 were investigational FTE. The 1,559 investigational FTE perform work such as inspections, investigations, sample collections, and field exams. This work covers both import and domestic activities and covers all program areas including foods, drugs, devices, biologics, and animal drugs and feed.

In FY 2008, ORA had 3,100 total staff FTE, of which 1,218 were investigational FTE. This represents a reduction of 948 staff FTE, of which 341 were investigational FTE, from FY 2003 to FY 2008.

The Honorable Diana DeGette

Does FDA have the legal authority to use a numerical unique identifier that can travel with the product and instantaneously identify relevant tracking information (such as location, time, date, vector in the field)? Does FDA currently have the legal authority to develop such a comprehensive system?

Section 414(b) of the Federal Food, Drug, & Cosmetic Act (the Act), 21 U.S.C. § 350c(b), provides FDA with legal authority to require certain information related to food traceability. Specifically, section 414(b) authorizes FDA to issue regulations to "establish requirements regarding the establishment and maintenance . . . of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed . . . to identify the immediate previous sources and the immediate subsequent recipients . . . in order to address credible threats of serious adverse health consequences or death to humans or animals."

FDA's current regulations (found at 21 CFR §§ 1.337, 1.345) require manufacturers, processors, and packers to record lot or code numbers or other identifiers to the extent this information exists. Under section 414(b), to the extent it is a requirement "regarding the establishment and maintenance of records," FDA may require a unique identifier to travel with food if such a requirement is needed "to identify the immediate previous sources and the immediate subsequent recipients of food . . . in order to address credible threats. . . ." FDA is currently considering what, if any, additional requirements may be necessary in this regard.

Further, the Agency has authority under section 361(a) of the Public Health Service Act (42 U.S.C. 264(a)) (PHS Act) to issue regulations that "are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States. . . or from one State . . . into any other State." This authority potentially could be used to support additional requirements related to traceability, if the necessary factual predicate could be established.

Item #	Description	Date
1	FDA online article, "Fact Sheet on FDA's New Food Bioterrorism Regulation: Establishment and Maintenance of Records."	November 2005
2	FDA online article, "Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL107-188)."	07/17/02
3	FDA online article, "Salmonellosis Outbreak: Questions & Answers for Consumers and Industry."	07/25/08
4	Associated Press article, "A Hot Lead in Hunt for Salmonella Source."	07/23/08
5	Associated Press article by Larry Margasak, "Food Industry Bitten by its Lobbying Success."	07/25/08
6	Letter to FDA Commissioner von Eschenbach from Rep. Wasserman Schultz, et al, re: salmonella outbreak in tomatoes.	06/12/08
7	Florida Tomato Exchange document, subject: "Tomato Good Agricultural Practices & Tomato Best Management Practices."	October 2006
8	Notice of Proposed Rule Making, Florida Department of Agriculture and Consumer Services, "Fresh Tomato Inspection."	09/07/07
9	California Code of Regulations, "Tomatoes, Standards." 3 CCR 1472 (2008)	2008
10	United States Code, 21 USC 350c, "Maintenance and Inspection of Records."	
11	United Fresh Produce Foundation and the North American Tomato Trade Work Group report, "Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain (2nd Edition)."	April 2008
12	Federal Register, FDA Proposed Rule, "Establishment and Maintenance of Records Under the Pubilc Health Security and Bioterrorism Preparedness and Response Act of 2002" (21 CFR Parts 1 and 11).	05/09/03
13	USDA Economic Research Service online brief, "Vegetables and Melons: Tomatoes."	

Protecting the Food Supply

December 2004; Revised November 2005

FDA Actions on New Bioterrorism Legislation

Fact Sheet on FDA's New Food Bioterrorism Regulation: Establishment and Maintenance of Records

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act or the Act) directs the Secretary of Health and Human Services to issue final regulations that establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms, restaurants and certain others) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that must be kept by these regulations are those that are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. This regulation implements the recordkeeping authority in the Bioterrorism Act.

Who must establish and maintain records? Domestic persons that manufacture, process, pack, transport, distribute, receive, hold or import food; foreign persons that transport food in the U.S.; and persons who *place food directly in contact* with its finished container. For these regulations, the term *persons* includes individuals, partnerships, corporations, and associations.

How is food defined for purposes of this regulation? "Food" is defined by reference to section 201(f) of the Federal Food, Drug, and Cosmetic Act. Section 201(f) which defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

Who is excluded entirely or in part from these regulations?

Excluded Entirely
Farms
Foreign persons, except for foreign persons who transport food in the U.S.
Restaurants are excluded entirely. A combination restaurant/retail facility is excluded entirely *if* sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.
Persons performing covered activities with food *to the extent* that the food is within the exclusive jurisdiction of the U.S. Department of Agriculture
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption
Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food packaging (the outer packaging of food that bears the label and does not contact the food), except for those persons who also engage in a covered activity with respect to food (see below)

Excluded From The Requirement To Establish And Maintain Records *But Not The Record Availability Requirements For Existing Records*
Fishing vessels not engaged in processing
Retail food establishments that employ 10 or fewer full-time equivalent employees
Nonprofit food establishments
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to the record availability requirements with respect to its packaging (the outer packaging of food that bears the label and does not contact the food)
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food, except for those persons who place food directly in contact with its finished container

Additional Partial Exclusions
Persons who distribute food directly to consumers (the term *consumers* does not include businesses) are excluded from the requirement to establish and maintain records to identify the immediate subsequent recipients
Persons who operate retail food establishments that distribute food to persons who are not consumers must establish and maintain records to identify the immediate subsequent recipients only to the extent the information is reasonably available

What records must be established and maintained by non-transporters of food? For non-transporters, i.e., persons who own food or who hold, manufacture, process, pack, import, receive, or distribute food for purposes other than transportation, the records have to:

1. Identify the immediate non-transporter previous *sources*, whether foreign or domestic, of all foods received, including the name of the firm; address; telephone number; fax number and e-mail address, if available; type of food, including brand name and specific variety (e.g., Brand X Cheddar Cheese, not just cheese; romaine lettuce, not just lettuce); date received; quantity and type of packaging (e.g., 12 oz. bottles); and identify the immediate transporter previous sources including the name, address, telephone number--and, if available, fax number and e-mail address. *Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.*
2. Identify the immediate non-transporter subsequent *recipients* of all foods released, including the name of the firm; address; telephone number; fax number and e-mail address, if available; type of food, including brand name and specific variety; date released; quantity and type of packaging; and identify the immediate transporter subsequent recipients, including the name, address, telephone number--and, if available, fax number and e-mail address. *Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.* The records must include information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

What records must be established and maintained by transporters of food?

The term *transporters* includes persons who have possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. The term *transporters* also includes foreign persons that transport food in the U.S., regardless of whether the foreign persons have possession, custody, or control of food for the sole purpose of transporting it. For transporters, records have to include names of the transporter's immediate previous source and transporter's immediate subsequent recipient, origin and destination points, date shipment received and date released, number of packages, description of freight, route of movement during the time the food was transported, and transfer point(s) through which the shipment moved.

Do transporters have alternative methods of meeting the requirements of the rule? Persons who have possession, custody, or control of food in the U.S. for the sole purpose of transporting the food, or foreign persons who transport food in the United States, *regardless* of whether they have possession, custody, or control of the food for the sole purpose of transporting that food, have five alternative methods, depending on the mode of transportation, of meeting the requirements of the final rule.

Alternative Methods for Food Transporters
1. Establishing and maintaining the records described above
2. Establishing and maintaining specified information that is in the records required of roadway interstate transporters by the Department of Transportation's Federal Motor Carrier Safety Administration contained in 49 CFR 373.101 and 373.103 as of December 9, 2004.
3. Establishing and maintaining specified information that is in the records required of rail and

water interstate transporters by the Department of Transportation's Surface Transportation Board contained in 49 CFR 1035.1 and 1035.2 as of December 9, 2004.
4. Establishing and maintaining specified information that is in the records required of international air transporters by the Warsaw Convention
5. Entering into an agreement with a non-transporter immediate previous source or immediate subsequent recipient (if located in the United States) to establish, maintain, or establish and maintain the required records in options 1, 2, 3 or 4.

How must the records be maintained? FDA is specifying the information a covered entity must keep but not specifying the form in which the records must be maintained. The records may be kept in any format, paper or electronic, provided they contain all the required information.

Can existing records be used to satisfy the requirements of these regulations? The regulations do not require duplication of existing records, *if* these records contain all the required information.

How long must the records be retained? The rule requires records to be created when food is received, released or transported except to the extent the information is contained in existing records. The period for which the records must be retained depends on the perishability of the food:

Type of food	Record retention period for non-transporters	Record retention period for transporters or persons keeping records on their behalf
Food having significant risk of spoilage, loss of value, or loss of palatability within 60 days	6 months	6 months
Food having significant risk of spoilage, loss of value, or loss of palatability occurring after a minimum of 60 days but within 6 months	1 year	1 year
Food having significant risk of spoilage, loss of value, or loss of palatability occurring no sooner than 6 months	2 years	1 year
Animal food including pet food	1 year	1 year

Where must the records be retained? At the establishment where the activities covered in the records occurred (onsite) or at a reasonably accessible location.

What are the record availability requirements? When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records or other information to which FDA has access must be

available for inspection and photocopying or other means of reproduction as soon as possible, not to exceed 24 hours from time of receipt of the official request. The records requested may be related to the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such an article of food that are maintained by, or on behalf of, an entity subject to the recordkeeping regulation, and at any location.

What records are excluded from these regulations? Recipes, financial data, pricing data, personnel data, research data and sales data are excluded from these requirements. A recipe is defined as the formula, including ingredients, quantities and instructions necessary to manufacture a food product. Therefore, records relating only to the ingredients of a food product and not the other two components of a recipe are *not* excluded.

What procedures does FDA intend to follow before requesting access to records?

FDA has issued guidance for industry and FDA staff regarding records access which details the internal procedures the agency intends to follow (see Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002).

How does FDA intend to make a request to access or copy records under the Bioterrorism Act? Under the guidance, once FDA makes the necessary determination following the specified procedures, an investigator or other FDA personnel, upon presentation of credentials, will submit a written notice, FDA 482 - Notice of Inspection, to the owner, operator, or agent in charge, and inform that person of the records requested and FDA's legal authority to obtain these records. FDA may request additional records related to the implicated food article at a later time under the same authority.

How will FDA maintain the confidentiality of any protected information in records it obtains? Information obtained under the records access provisions of sections 414(a) and 704(a) may include, but is not limited to, a company's non-public confidential commercial or trade secret information. Several statutes (e.g., Trade Secrets Act (18 U.S.C. 1905), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)), and Freedom of Information Act, (5 U.S.C. 552) and the agency's information disclosure regulations at 21 CFR Parts 20 and 21 govern the agency's disclosure of information to the public. FDA personnel will comply with all applicable protections, procedures, and legal requirements against the unauthorized disclosure of non-public information, such as any trade secret or confidential commercial information.

What will happen if the required records are not established and maintained? The Bioterrorism Act makes failure to establish and maintain the required records or failure to make them available to FDA a prohibited act. The Federal government can bring a civil action in Federal court to enjoin persons who commit a prohibited act; the Federal government also can bring a criminal action in Federal court to prosecute persons who commit a prohibited act.

When is compliance with the recordkeeping regulation required? All businesses covered by this rule, must comply within 12 months from December 9, 2004, *except* small and very small businesses. Small businesses (11-499 full-time equivalent employees (FTEs)) must comply within 18 months from this date, and very small businesses (10 or fewer FTEs) have to comply within 24 months from this date. The term, *full-time equivalent employees* or *FTEs,* means all individuals employed by the person claiming the exemption. The number of full-time equivalent

employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks).

For further information: For more details and information on the specific requirements of this final rule, please refer to the final rule. http://www.cfsan.fda.gov/~dms/frrecord.html

July 17, 2002

Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL107-188)

Letter from Center Director
Attachment A: Summary Of Title III, Subtitle A and Subtitle B
Attachment B: Contact Information

Dear Colleague, FDA Foods Community:

The events of September 11, 2001, reinforced the need to enhance the security of the United States food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act" or "the Act") (PL107-188), which President Bush signed into law on June 12, 2002.[1] The Act is divided into the following five titles:

- Title I - National Preparedness for Bioterrorism and Other Public Health Emergencies;
- Title II - Enhancing Controls on Dangerous Biological Agents and Toxins;
- Title III - Protecting Safety and Security of Food and Drug Supply;
- Title IV - Drinking Water Security and Safety; and
- Title V - Additional Provisions.

The purpose of this letter is: (1) to give you an overview of the four provisions in Title III, Subtitle A (Protection of the Food Supply), which require the Food and Drug Administration (FDA) to issue regulations in an expedited time period; (2) to inform you how the Department and FDA will be proceeding; and (3) to solicit comment on areas of concern to you and suggestions for how best to communicate those concerns to us.

A. Provisions Requiring Regulations

Attachment A provides an informal summary of the provisions in Title III, Subtitle A of the Bioterrorism Act. As noted, the Secretary, through the FDA, is required to propose and issue final regulations for the following four provisions:

- Section 305 (Registration of Food Facilities) - requires the owner, operator, or agent in charge of a domestic or foreign facility to register with the FDA no later than December 12, 2003. Facilities are defined as any factory, warehouse, or establishment, including

importers. The Secretary, through FDA, is required to issue final regulations addressing the registration requirements no later than December 12, 2003; however, food facilities must register with FDA by this date even if FDA has not issued final regulations. The Bioterrorism Act exempts farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer; and fishing vessels (except such vessels engaged in processing as defined in 21 CFR 123.3 (k)) from the requirement to register. Also, foreign facilities subject to the registration requirement are limited to those that manufacture, process, pack, or hold food, only if food from such facility is exported to the United States without further processing or packaging outside the United States.

- Section 306 (Establishment and Maintenance of Records) - requires the Secretary, through FDA, to issue final regulations by December 12, 2003, to establish requirements for the creation and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food, (i.e., one up, one down). Such records are to allow FDA to address credible threats of serious adverse health consequences or death to humans or animals. Entities subject to these provisions are those that manufacture, process, pack, transport, distribute, receive, hold or import food. Farms and restaurants are exempt from these requirements.

- Section 307 (Prior Notice of Imported Food Shipments) - requires that prior notice of food shipments be given to FDA. The notice must include a description of the article, the manufacturer and shipper, the grower (if known), the country of origin, the country from which the article is shipped, and the anticipated port of entry. The Secretary, through FDA, must issue final regulations by December 12, 2003. While we fully expect regulations to be issued by this date, if such regulations are not issued, the statute still requires importers to provide no less than 8 hours and no more than 5 days notice to FDA until the regulation takes effect.

- Section 303 (Administrative Detention) - authorizes the Secretary, through FDA, to order the detention of food if an officer or qualified employee finds credible evidence or information indicating an article presents a threat of serious adverse health consequences or death to humans or animals. The Act requires the Secretary, through FDA, to issue final regulations to expedite court actions on perishable foods. No time frame is specified.

Unless exempted, these provisions apply to all facilities for all types of food products regulated by FDA, including dietary supplements.

B. FDA's Regulation Development Plans

While the statute establishes ambitious deadlines for each of the above provisions, I want to underscore that the Secretary has made it clear that he expects FDA to meet them. Our goal is to publish proposed regulations by the end of this calendar year, and we plan to offer at least a 60-day comment period.

We also are committed to receiving and considering the input from stakeholders as we develop the proposed and final regulations. Before issuing these proposed rules, FDA will seek to identify stakeholders' concerns and potential options for addressing them. During the comment period, we plan to hold several public meetings at various locations across the country to

explain the proposed regulatory requirements, answer questions, and receive additional comment.

We also have opened public dockets for each regulation and are ready to receive input from you now. Comments would be most helpful if you not only identify any concerns you may have, but also provide both your recommended solution and any supporting data, if applicable. Also, to the extent feasible, we would appreciate receiving any initial comments you may have by August 30, 2002. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. We request that you submit two copies of any written comments, except that individuals may submit one copy. Please ensure that you include in your submission the docket number that applies to your comment from the list below:

- Section 305 (Registration) Docket No. 02N-0276
- Section 305 (Recordkeeping) Docket No. 02N-0277
- Section 307 (Prior Notice) Docket No. 02N-0278
- Section 303 (Detention) Docket No. 02N-0275

If you would like to review comments FDA has received, you may do so at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Within the FDA, Ms. Linda Skladany, FDA's Senior Associate Commissioner for External Relations, will serve as the focal point for our outreach efforts. The Center for Food Safety and Applied Nutrition (CFSAN) will take the lead for the regulations development process. Mr. L. Robert Lake, CFSAN's Director of the Office of Regulations and Policy, will serve as senior manager of this effort. Ms. Leslye M. Fraser, CFSAN's Associate Director for Regulations, will serve as the overall lead for the regulations workgroups. Additional contact information is contained in Attachment B.

Lastly, many of the remaining provisions in Title III, Subtitle A of the Bioterrorism Act are effective now. Consistent with our good guidance practice (GGP) regulations, 21 CFR 10.115, FDA plans to issue guidance documents for several of these provisions prior to implementing them broadly. Please note that if FDA deems it necessary to use this new statutory authority to protect the public health prior to issuing written guidance, it will do so on a case-by-case basis after consulting with senior officials in the affected District and within Headquarters.

I hope that you have found this information helpful. Again, the Secretary, Dr. Crawford and I are committed to meeting the statutory deadlines required to implement the provisions of the Bioterrorism Act intended to further protect the safety of the food supply.

Sincerely,

Joseph A. Levitt

Director
Center for Food Safety and Applied Nutrition

cc: Dr. Lester Crawford, Deputy Commissioner

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[1]You may obtain a full copy of the Act at http://thomas.loc.gov, and searching with Bill number H.R. 3448.

Attachment A

Summary Of Title III, Subtitle A Of The Public Health Security And Bioterrorism Preparedness And Response Act Of 2002

Title III - Protecting Safety And Security Of Food And Drug Supply

Subtitle A - Protection of Food Supply

Sec. 301. Food Safety and Security Strategy

- Requires the President's Council on Food Safety, in consultation with the Secretaries of Transportation and Treasury, other relevant Federal agencies, food industry, consumer and producer groups, scientific organizations, and the States, to develop a crisis communications and education strategy regarding bioterrorist threats to the food supply. The strategy shall address threat assessments; technologies and procedures for securing food processing and manufacturing facilities and modes of transportation; response and notification procedures; and risk communications to the public.

Sec. 302. Protection Against Adulteration of Food

- Amends Section 801 to direct the Secretary to give high priority to increasing the number of inspections of food offered for import with the greatest priority given to inspections to detect intentional adulteration.

- Directs the Secretary to give high priority to making improvements to the FDA information management systems for imported foods to improve our ability to allocate

resources, detect intentional adulteration, and facilitate the importation of food that is in compliance with the Act.

- Directs the Secretary to improve linkages with other Federal, State and tribal food safety agencies;
- Requires the Secretary to provide for research on development of tests and sampling methodologies to rapidly detect the adulteration of food, with the greatest priority given to detect intentional adulteration, and whose results offer significant improvements over available technology in terms of accuracy, timing, or costs
- Directs the Secretary to give priority to research on the development of tests suitable for inspections of food at ports of entry.
- Directs the Secretary to coordinate as appropriate on the research with CDC, NIH, EPA, and USDA.
- Requires the Secretary to submit an annual report to Congress describing progress made in research.
- Requires the Secretary, through the FDA Commissioner, within 6 months of enactment, to ensure that the threat assessment being conducted on the threat of intentional adulteration of the food supply is completed and that a report describing the findings is submitted to Congress.

Sec. 303 Administrative Detention

- Amends Section 304 to authorize FDA to order the detention of food if an officer or qualified FDA employee finds, during an inspection, examination, or investigation, credible evidence or information indicating the article presents a threat of serious adverse health consequences or death to humans or animals.
- Specifies the detention must be approved by an official at the district director level or higher.
- Specifies period of detention may not exceed 20 days unless a greater period, not to exceed 30 days, is necessary to enable the Secretary to pursue a seizure under Section 304 (a) or to seek an injunction under Section 302. Requires the Secretary to establish regulations for expedited procedures for instituting such actions for perishable foods, such as fresh produce, fresh fish and fresh seafood products.
- Allows the detention order to require that the article be labeled or marked as detained; requires the article to be removed to a secure facility, as appropriate. Specifies that a detained article may not be transferred until released or detention expires.
- Specifies an appeals process which requires the Secretary, after providing for an informal hearing, to confirm or terminate an order within 5 days of an appeal. This confirmation or termination shall be considered final agency action. If the Secretary fails to comply with

the above requirements, the order is deemed terminated. The appeals process terminates if the Secretary institutes action under Section 304(a) or Section 302.

- Amends Section 301 making it a prohibited act to transfer an article of food in violation of a detention order or to remove or alter any required mark or label identifying the article as detained.

- Amends Section 801 to provide for temporary holds at ports of entry. Authorizes an officer or qualified FDA employee to request the Secretary of the Treasury to hold food at the port of entry for a period not to exceed 24 hours. This is to occur when the employee has credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals; and the officer needs more time to inspect, examine, or investigate. The request must be approved at the district director level or higher.

- Directs the Secretary to ask the Secretary of the Treasury to remove a held article to a secure facility, as appropriate. States the article may not be transferred during the holding period.

- Requires the Secretary to notify the State in which the port of entry is located.

- Requires us to issue a regulation to expedite hearing procedures for perishable foods.

- The FDA plans to establish informal hearing procedure.

Sec. 304. Debarment for Repeated or Serious Food Import Violations

- Amends Section 306(b) to establish debarment for persons convicted of a felony for conduct relating to the importation of any food or for persons who have engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

- Amends Section 301 to make it a prohibited act the importing or offering for import of food by, with the assistance of, or at the direction of a debarred person.

- Amends Section 801 to require that food being imported or offered for import by a debarred person be held at the port of entry, at a secure facility as appropriate, and not transferred. The article of food may be delivered to a non-debarred person if that person establishes at their expense that the article is in compliance.

Sec. 305. Registration of Food Facilities

- Amends the Act by adding new section 415 to require registration for food facilities. Requires the owner, operator, or agent in charge of a domestic or foreign facility to submit a registration to the Secretary. For a foreign facility, the registration must include the name of the U.S. agent for the facility.

- The registration shall contain information necessary to notify the Secretary of the name

and address of each facility at which, and all trade names under which, the registrant conducts business and, when determined necessary by the Secretary through guidance, the general food category as identified under 21 CFR 170.3. Requires the registrant to notify the Secretary in a timely manner of changes to such information.

- Requires the Secretary to notify the registrant of receipt of the registration and to assign a registration number to each facility. Requires the Secretary to compile and maintain an up-to-date list of registered facilities. Protects the list and any registration documents from disclosure under Section 552 of Title V, U.S. Code.

- Defines facility as any factory, warehouse, or establishment of an importer that manufactures, processes, packs, or holds food. Specifically excludes farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer; and fishing vessels (except such vessels engaged in processing as defined in 21 CFR 123.3(k). [Note: this covers animal feed and dietary supplement manufacturers.] Limits foreign facilities to those that manufacture, process, pack, or hold food only if food from such facility is exported to the U.S. without further processing or packaging outside the U.S.

- Amends Section 301 making failure to register a prohibited act.

- Amends Section 801 to require that an article of food offered for import from an unregistered foreign facility be held at the port of entry until the facility is registered.

- Authorizes the Secretary to provide for and encourage the use of electronic methods of registration; however, paper registration is allowed.

- Requires the Secretary to promulgate proposed and final regulations within 18 months of enactment. The requirement takes effect upon the expiration of the 18-month period even if the Secretary does not meet the deadline.

Sec. 306. Maintenance and Inspection of Records for Foods

- Amends Chapter IV to authorize the Secretary to have access to certain records when there is a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. It applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of the food. It excludes farms and restaurants. It also excludes information such as recipes, financial data, personnel data, research data, and sales data (other than shipment data regarding sales).

- Requires the Secretary to promulgate proposed and final regulations within 18 months of enactment to establish requirements for the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food. Limits recordkeeping requirement to two years.

- Directs the Secretary to consider the size of a business in promulgating the regulations.

- Directs the Secretary to take appropriate measures to ensure protection from disclosure of sensitive information.
- Amends Section 704 to reflect the requirement to provide the Secretary with access to records.
- Amends Section 301 making it a prohibited act to refuse to permit access to or copying of any required record or to fail to establish or maintain any required record.

Sec. 307. Prior Notice of Imported Food Shipments

- Amends Section 801 to require prior notice of imported food shipments. The notice is required to provide the article, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of entry. States that, if notice is not provided, the article shall be refused admission.
- Requires the Secretary, after consultation with Secretary of the Treasury, to issue regulations that specify the period of advance notice and says that shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification. It states the period may not exceed five days.
- Requires the Secretary to promulgate proposed and final regulations within 18 months of enactment. If the Secretary fails to meet the deadline, the requirement takes effect upon expiration of the 18-month period. In that event, the default period of notice will be no less than 8 hours and no more than five days.
- States that an article of food offered for import and prior notice has not been provided, such article shall be held at the port of entry until the importer, owner, or consignee complies. Directs the Secretary, in carrying out this requirement, to determine whether there is any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.
- Amends Section 301 making it a prohibited act to import of offer for import an article of food in violation of these requirements.

Sec. 308. Authority to Mark Articles Refused Admission into United States

- Amends Section 801 to authorize the Secretary to require the marking of refused food (other than food required to be destroyed). Marking is to be done at owner's expense.
- Amends Section 403 to make food misbranded if it fails to bear the required label when the Secretary has found that the food presents a threat of serious adverse health consequences or death to humans and animals and the Secretary has notified the owner or consignee that the label is required and that the food presents such a threat.
- Provides a rule of construction stating this does not limit the authority of the Secretary of HHS or the Secretary of the Treasury to require the marking of refused articles of food

under any other provision of law.

Sec. 309. Prohibition Against Port Shopping

- Amends Section 402 to deem food adulterated if a food is offered for import that has been previously refused admission unless the person reoffering the food establishes that the article is in compliance.

Sec. 310. Notices to States Regarding Imported Food

- Amends Chapter IX to require the Secretary to notify States when there is credible evidence or information indicating that a shipment, or portions of shipment, of imported food presents a threat of serious adverse health consequences or death to humans or animals. If known, the Secretary must provide notice to the States in which the food is held or will be held and to the States in which the manufacturer, packer, or distributor of the food is located. The Secretary is directed to request the State to take appropriate action to protect the public health.

- Provides a savings clause saying this does not limit the authority of the Secretary with respect to food under any other provision.

Sec. 311. Grants to States for Inspections

- Authorizes the Secretary to make grants to States, territories, and Indian tribes that undertake examinations, inspections, and investigations, and related activities under Section 702.

- Authorizes the Secretary to make grants to the States to assist them with the costs of taking appropriate action after receiving notification under the preceding section.

- Authorizes appropriations of $10 million for FY02 and such sums as may be necessary for fiscal years 03 through 06; however, funds have not been appropriated yet.

Sec. 312. Surveillance and Information Grants and Authorities

- Amends Part B of Title III of the Public Health Service Act to authorize the Secretary to award grants to States and Indian tribes to expand participation in networks to enhance Federal, State, and local food safety efforts. This may include meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

- Authorizes appropriations of $19.5 million for FY02 and such sums as may be necessary for fiscal years 03 through 06; however, funds have not been appropriated yet.

Sec. 313. Surveillance of Zoonotic Diseases

- Directs the Secretary of HHS, through the FDA Commissioner and the CDC Director, and the Secretary of Agriculture to coordinate the surveillance of zoonotic diseases.

Sec. 314. Authority to Commission Other Federal Officials to Conduct Inspections

- Amends Section 702 to authorize the Secretary to commission other Federal employees to conduct examinations and inspections. Requires a memorandum of understanding (MOU) between the Secretary and the head of the other Federal agency. The MOU must address training and reimbursement. It is restricted to facilities or other locations that are jointly regulated by the Secretary and the other department or agency.

- Requires the Secretary and the head of the other Federal department or agency to submit a report to Congress each fiscal year that provides the number of employees that carried out one or more activities, the number of additional articles that were inspected or examined, and the number of additional examinations or investigations that were carried out pursuant to the memorandum.

Sec. 315. Rule of Construction

- States that nothing in this title shall be construed to alter the jurisdiction between USDA and HHS under applicable statutes and regulations.

Subtitle B - Protection of Drug Supply

Sec. 322. Requirement of Additional Information Regarding Import Components Intended for Use in Export Products

- Requires a statement at the time of importation of food additives, color additives, or dietary supplements, that such article is intended to be further processed and exported.

- Requires a certificate of analysis, as necessary, and a bond.

- Requires the article of food to be used in accordance with the submitted statement.

- Requires records to be maintained on the use, destruction, exportation, and compliance, and requires the records to be provided to FDA upon request.

- Authorizes the Secretary to refuse admission of the article if there is credible evidence or information indicating further processing is not intended or not incorporated into the product to be exported.

- Effective September 9, 2002.

Attachment B

Contact Information for Implementing the Bioterrorism Act

Mailing Address for Outreach Efforts:

*(See updated contact information.)

Food and Drug Administration

Mailing Address for Contacting Regulatory Leads:

Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740

Senior Manager

Mr. L. Robert Lake, Esq.
Director of Regulations and Policy
Mail Code HFS-4
Phone: (301) 436-2379
Fax: (301) 436-2637

Overall Lead

Ms. Leslye M. Fraser, Esq.
Associate Director for Regulations
Mail Code HFS-4
Phone:(301) 436-2378
Fax:(301) 436-2637

Day-to-Day Leads for Regulatory Workgroups:

Section 305: Registration Workgroup
Ms. Leslye M. Fraser, Esq.
(Contact Information above)

Section 306: Recordkeeping Workgroup
Dr. Nega Beru
Mail Code HFS-305
Phone: (301) 436-1400
Fax: (301) 436-2651

Section 307: Prior Notice Workgroup
Ms. Mary Ayling
Mail Code HFS-032
Phone: (301) 436-2131
Fax: (301) 436-2605

Section 303: Detention Workgroup
Ms. Marquita Steadman, Esq.
Mail Code: HFS-007
Phone: (301) 827-6733
Fax: (301) 480-5730

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* Updated information: Ms. Cynthia Wise
Food Safety and Security Staff
5100 Paint Branch Parkway HFS-032
College Park, MD 20740
Phone: (301) 436-2125

U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

June 9, 2008; Updated July 25, 2008

Salmonellosis Outbreak
Questions & Answers for Consumers and Industry

Consumer Information and Advice

- What kind of illness does *Salmonella* cause?
- What is *Salmonella*?
- Has the warning against eating certain types of tomatoes been removed?
- Why had the FDA warned against eating tomatoes during this outbreak?
- Why is the FDA lifting the warning against certain types of tomatoes?
- Are jalapeño and serrano peppers being investigated as part of this outbreak?
- UPDATED Have any food samples been found that are contaminated with the outbreak strain, *Salmonella* Saintpaul?
- Does the discovery of the contaminated jalapeños mean the source of the *Salmonella* Saintpaul outbreak has been found and that the outbreak is over?
- UPDATED Should consumers avoid raw jalapeño peppers or foods that contain them during this outbreak?
- NEW How can consumers tell where jalapeño peppers are from?
- What do jalapeño and serrano peppers look like?
- Is it safe to eat canned jalapeño peppers or processed foods that contain them?

Advice for Food Service Providers, Restaurateurs, and Retailers

- What is FDA's advice to retailers, restaurateurs, and food service providers about tomatoes?
- UPDATED What is the FDA's advice to retailers, restaurateurs, and food service providers about jalapeño and serrano peppers during this outbreak?
- In general, what are safe-handling practices for other fresh produce?

About Outbreaks

- What is an outbreak?
- When did the illnesses associated with the current outbreak start?
- How is the cause or source of a *Salmonella* outbreak determined?
- What is the FDA doing to identify the source of this outbreak?
- Why is it taking FDA so long to determine the source of this *Salmonella* outbreak?
- From farm to table, where in the process is fresh produce most likely to become contaminated? What are the most likely sources of

contamination?
- Tomatoes were the first foods investigated in this outbreak. Have there been outbreaks from contaminated tomatoes in the past?

Government Activities Related to Produce Safety

- What steps has the FDA taken to reduce the potential for *Salmonella* outbreaks from tomatoes?
- Does the FDA sample and test domestic and foreign tomatoes?
- Has the FDA conducted outreach/education activities regarding fresh-produce safety?
- What is the FDA's Food Protection Plan?

Consumer Information and Advice

- **What kind of illness does *Salmonella* cause?**
  People who have eaten food contaminated with *Salmonella* often have fever, diarrhea (which may be bloody), nausea, vomiting, and abdominal pain. The bacterium can enter the bloodstream and cause more severe illness, although this rarely happens. Infection with *Salmonella* also may be more serious or fatal in young children, frail or elderly people, and people with weakened immune systems.

- **What is *Salmonella*?**
  Salmonella is a type of bacterium. The type of *Salmonella* causing illness in this outbreak, *Salmonell*a Saintpaul, is relatively uncommon. Fruits and vegetables that come into contact with *Salmonella* may become contaminated with it, causing illness if eaten. *Salmonella* lives in the intestinal tracts of some animals, and can live in soil and water for months. Once *Salmonella* has contaminated something, it can be spread from surface to surface. Fresh produce contaminated with *Salmonella* can spread the bacterium to the hands of a person who cuts the produce and to the cutting board on which the produce is sliced, for example.

- **Has the warning against eating certain types of tomatoes been removed?**
  The FDA has removed the warning to avoid certain types of tomatoes. At this time, there is no reason to believe that tomatoes currently on the market are contaminated with *Salmonella* Saintpaul. For example, tomatoes that were coming into season at the outset of the outbreak are extremely unlikely to still be in the supply chain. Consumers may resume enjoying any type of tomato, including the raw red plum, raw red Roma, and raw red round tomatoes that had been included in the now-removed warning.

- **Why had the FDA warned against eating tomatoes during this outbreak?**
  The first case-control study conducted by the Centers for Disease Control and Prevention (CDC) at the onset of this outbreak did indicate a strong association between the consumption of certain types of raw tomatoes and illness caused by *Salmonella* Saintpaul.

- **Why is the FDA lifting the warning against certain types of tomatoes?**
  Firms that had been producing tomatoes during the onset of the outbreak are no longer doing so, as part of their production cycle. It is very unlikely that any of the batches of tomatoes originally associated with the outbreak are still in the food-supply chain.

- **Are jalapeño and serrano peppers being investigated as part of this outbreak?**

Recently, the CDC reported to the FDA that many, although not all, people who have become ill in this outbreak ate fresh jalapeño or serrano peppers or foods that contained them, such as some types of fresh salsa. Based on this information from the CDC, the FDA expanded its investigation to include jalapeños and serranos.

- UPDATED **Have any food samples been found that are contaminated with the outbreak strain, *Salmonella* Saintpaul?**

  One of the raw jalapeño pepper samples FDA tested was a genetic match with the outbreak serotype, *Salmonella* Saintpaul. The discovery was the result of investigations over the past several weeks by FDA scientists and field investigators. The contaminated sample was obtained during an inspection of a produce distribution center in McAllen, TX. The jalapeños were grown in Mexico. Fresh produce often changes hands many times in the supply chain from farm to table. The complexity of today's food chain is among the challenges of tracing contaminated fresh produce back to its source.

- **Does the discovery of the contaminated jalapeños mean the source of the *Salmonella* Saintpaul outbreak has been found and that the outbreak is over?**

  Although the outbreak appears to have peaked, it is ongoing. Cases of *Salmonella* Saintpaul continue to be reported, and FDA continues its investigation. Epidemiologic data to date suggest that the entire outbreak can **not** be explained by the jalapeño contamination found recently by investigators. However, the discovery of the contaminated jalapeño sample is an important development.

- UPDATED **Should consumers avoid fresh jalapeño peppers or foods that contain them during this outbreak?**

  Jalapeño and Serrano peppers grown in the United States are **not** associated with this outbreak. The FDA advises all consumers to avoid raw jalapeño peppers, and foods that contain them, such as some types of salsa and pico de gallo, if the jalapeños were grown, harvested, or packed in Mexico. FDA also advises consumers who are especially vulnerable to infection, such as infants, the elderly, and people with weakened immune systems, to avoid raw serrano peppers from Mexico, as well as foods that contain them. Consumers are advised **not** to wash, peel, or cook these kinds of raw peppers to try to get rid of *Salmonella* contamination that may be present. These actions are **not** likely to get rid of *Salmonella*, which is very hard to remove by conventional means, and might spread the bacterium to the environment; for example, to hands, sinks, cutting boards, knives, and other foods.

- NEW **How can consumers tell where jalapeño peppers are from?**

  Consumers may ask their retailers or food service providers, such as store or restaurant managers, where the jalapeño and serrano peppers they sell were grown, harvested, and packed.

- **What do jalapeño and serrano peppers look like?**

  See the photos below.

Jalapeño Pepper

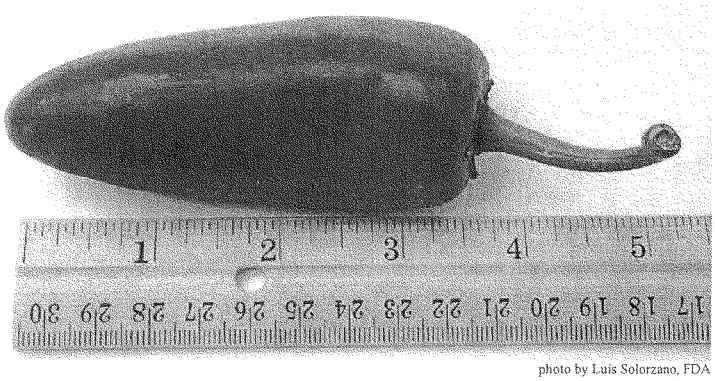

photo by Luis Solorzano, FDA

Serrano Pepper

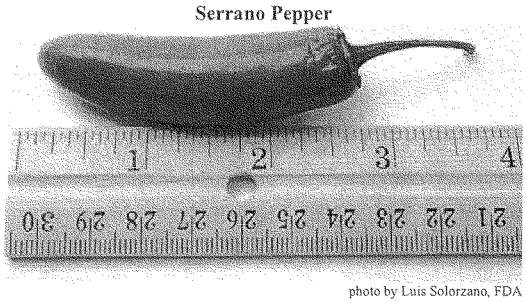

photo by Luis Solorzano, FDA

- **Is it safe to eat canned jalapeño and serrano peppers or processed foods that contain them?**
  All consumers **may continue to eat canned jalapeño and serrano peppers processed in a commercial food-processing facility, or foods that contain them**; for example, the canned processed jalapeños and processed salsas sold in grocery stores.

Advice for Food Service Providers, Restaurateurs, and Retailers

- **What is the FDA's advice to retailers, restaurateurs, and food service providers about tomatoes?**
  Food service providers, restaurateurs, and retailers may resume offering customers any type of tomato, including raw red plum tomatoes, raw red Roma tomatoes, and raw red round tomatoes, from any region.

- UPDATED **What is the FDA's advice to retailers, restaurateurs, and food service providers about jalapeño peppers during this outbreak?**

Food service providers, restaurateurs, and retailers may continue to sell and serve raw jalapeño and serrano peppers grown, harvested, or packed in the United States, as well as foods made with them. These establishments should **not** sell or serve raw jalapeño peppers, should avoid handling them, and should discard them, if they were grown, harvested, or packed in Mexico, and should not sell or serve foods made with them. Attempts to wash *Salmonella* contamination that may be present on these peppers is **not** likely to eliminate the organism, because of *Salmonella*'s physical properties, and is likely to result in cross-contamination. Attempts to peel the peppers is not recommended, as this is likely to introduce any contamination on the exterior of the product into the interior, making elimination of the organism even more unlikely. Attempts to kill *Salmonella* by cooking may result in cross-contamination and likewise is **not** recommended.

- **In general, what are safe-handling practices for other fresh produce?**
  - Wash hands thoroughly with soap and warm running water before and after handling fresh produce.
  - Make sure that food employees are reporting illness and are not working while sick.
  - Purchase food from known safe sources and maintain the foods' safety from time of receiving through purchase.
  - When fresh produce is received, follow supplier recommendations, if provided, regarding handling, storage temperatures, "use by" dates, and other recommendations for the produce. Avoid receiving or using damaged and partially decayed produce.
  - Store raw produce such that it does not contaminate other foods with soil, etc. Store any fresh produce, whole or cut, where other products -- especially raw meat and poultry -- cannot cross-contaminate it.
  - Segregate fresh produce from other refrigerated foods in refrigeration units by using a separate set of storage racks or separate cooler, if possible. Cover and store washed, cut produce *above* unwashed, uncut fresh produce. Store all produce off the floor.
  - Wash, rinse, and sanitize all sinks, utensils, cutting boards, slicers, and food preparation surfaces before each use with fresh produce.
  - Always wash fresh produce under running, potable water before use. Soaking produce or storing it in standing water is not recommended for most types of fresh produce. Commercial, fresh-cut produce has already been washed before processing and should be considered ready to eat, with no further need for washing, unless the label says otherwise.
  - Refrigerate foods prepared with fresh-produce ingredients.
  - Do not re-serve freshly prepared dishes containing raw produce, including dishes made with raw tomatoes, cilantro, and hot peppers, such as salsa and guacamole.
  - More information about handling of fresh produce is available in the Food Code.

About Outbreaks

- **What is an outbreak?**
  An outbreak is defined by the CDC as two or more cases of the same disease that share a common exposure.

- **When did the illnesses associated with the current outbreak start?**
  The illnesses began in mid-April and continue to be reported.

- **How is the cause or source of a *Salmonella* outbreak determined?**
  Once an outbreak is detected and the states and the CDC have determined that two or more cases of the same disease share a common food exposure, and the food is identified, the FDA conducts a "trace-back" investigation to determine the source of the contaminated food. The product is tracked from the point of purchase or service through each point in the distribution chain to find the source of the contamination.

At each point in the distribution chain, an environmental investigation is performed to determine whether the contamination may have occurred at that point and, if so, how it occurred. When outbreak illnesses occur across multiple states, the contamination often occurred at, or near, the original source of the product, such as the growing or packing area. In addition to helping to contain current outbreaks, information gained from trace-back and other investigations can help scientists develop measures to prevent future occurrences.

- **What is the FDA doing to identify the source of this outbreak?**

  The FDA is conducting trace-back investigations. Epidemiological information about the disease serotype (*Salmonella* Saintpaul serotype) is being examined, disease patterns are being linked, and seasonal distribution patterns in the marketplace are being analyzed to rule out sources.

  The federal (principally CDC and the FDA) and state governments continue to work together to analyze samples from ill persons and samples of produce. The strain of *Salmonella* from ill persons is being "fingerprinted" at public health laboratories around the country, as part of PulseNet (the network of public health laboratories that sub-type bacteria). All *Salmonella* strains associated with this outbreak have the same genetic "fingerprint" (DNA pattern).

- **Why is it taking FDA so long to determine the source of this *Salmonella* outbreak?**

  Investigators must track the pathways that the produce associated with illness followed, from multiple consumers who ate it to the multiple retailers or restaurants that sold it; from there to multiple points of supply and distribution; to where the produce was packed, and to where it was harvested and grown. At the points where the produce was sold or prepared, investigators try to determine identifying information, such as packaging, labeling, and lot numbers; when the produce was purchased or prepared, and what the receiving, stock-rotation, inventory, handling, and shipping procedures were. They collect records about suppliers and shipments to retailers or restaurants for the period of the produce's shelf life. Investigators then chart and analyze distribution data, accomplished by tracing lot numbers - if they are available - or by using a shipment-delivery timeline to determine if the produce was useable and "sellable" during the period of infection.

  Distributor interview, data collection, and analysis are repeated for *multiple* levels of distribution until the source of the produce is identified.

  Among the complications that arise for tomatoes in this process is that lot numbers and other information identifying the tomatoes' growers might not be included on receipts and shipping records. In some cases, investigators have to rely on reviewing records and interviewing the personnel who handle such matters, which increases the time and resources needed to trace implicated tomatoes back to their sources. Another complication that delays the investigation is that often there is no package, no product code, no "sell by" date, and no marking on the tomato at the retail level.

  For more information about this process, visit the ***Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations*** that FDA has posted on its web site.

- **From farm to table, where in the process is fresh produce most likely to become contaminated? What are the most likely sources of contamination?**

  Fresh produce can become contaminated at any point along the supply chain, from the field or greenhouse where it is grown to distribution points to food preparation in restaurants and homes.

  The FDA's 1998 Guide to Minimize Microbial Contamination of Fresh Fruits and Vegetables (also referred to as the Good Agricultural Practices (GAPs) guide) describes potential sources of

microbial contamination in the field and packing house environments and makes recommendations for how to reduce or minimize opportunities for contamination.

According to the GAPs guide, areas that should be considered to minimize the potential for the microbial contamination of produce include agricultural water (e.g., for irrigation or crop protection sprays); wild and domestic animals; worker health and hygiene; the production environment (use of manure, previous land use, and use of adjacent land); post-harvest water quality (water used to wash or cool produce) and sanitation of facilities and equipment.

- **Tomatoes were the first food investigated in the current outbreak. Have there been outbreaks from contaminated tomatoes in the past?**
  Since 1990, at least 13 large, multi-state foodborne outbreaks and some small local outbreaks have been associated with different varieties of tomatoes. From 1998 to 2006, outbreaks reported to the FDA that were associated with tomatoes made up 17 percent of produce-related outbreaks. *Salmonella* has been the pathogen of concern most often associated with outbreaks from tomatoes.

Government Activities Related to Produce Safety

- **What steps has the FDA taken to reduce the potential for *Salmonella* outbreaks from tomatoes?**
  On June 12, 2007, the FDA announced a Tomato Safety Initiative, a multi-year effort focusing on the East Coast. The Initiative is a collaborative effort between the FDA and the state health and agriculture departments in Virginia and Florida, in cooperation with several universities and the produce industry. This initiative is part of an ongoing, preventive, risk-based strategy.

  The Tomato Safety Initiative includes identifying practices or conditions that potentially lead to contamination of tomatoes, and what steps producers are taking to address these issues. Information from the Initiative will allow the FDA to continue to improve its guidance and policy on tomato safety. The Initiative also is evaluating the need for additional produce safety research, education, and outreach. The Initiative supports an important goal in the 2004 FDA Produce Safety Action Plan – minimizing the incidence of foodborne illness associated with the consumption of fresh produce – and the prevention activities described in the FDA's Food Protection Plan.

- **Does FDA sample and test domestic and foreign tomatoes?**
  The FDA routinely collects random samples of tomatoes of all varieties, domestic and imported, from various growers, packers and shippers. The samples are sent to a FDA laboratory, to be analyzed for a variety of bacteria, including *Salmonella*.

- **Has the FDA conducted outreach/education activities regarding fresh-produce safety?**
  The FDA has issued a press release to notify the public of the current *Salmonella* outbreak; the press release is updated as information is obtained and evaluated. In addition, the FDA has posted consumer and industry (retailer) warnings and advice related to the current *Salmonella* outbreak on its website.

  The FDA web site also includes a consumers' page about safe handling of fresh produce. In 2006, the FDA issued a publication called Program Information Manual: Retail Food Protection — Storage and Handling of Tomatoes for members of the retail industry. Safe-handling guidelines for the tomato-supply industry are nearing completion.

- **What is the FDA's Food Protection Plan?**
  The FDA has developed a comprehensive Food Protection Plan to address the changes in food

sources, production, and consumption we face in today's world. Building and improving on an already sound food-safety capability, the new plan is a strategy for protecting the nation's food supply. The plan approaches protection of the nation's food supply on three levels: prevention, intervention, and response. This new strategy will help ensure that Americans continue to benefit from one of the safest food supplies in the world.

More information: *Salmonella* Saintpaul Outbreak

See also Information for State Regulatory Agencies June 12, 2008

MSNBC.com

A hot lead in hunt for salmonella source

Minnesota pinpointed jalapeños while feds fruitlessly chased tomatoes

The Associated Press

updated 5:17 p.m. ET, Wed., July. 23, 2008

WASHINGTON - It was a hot lead for detectives on a cold case. People suddenly were getting salmonella at a Minnesota restaurant more than 1,000 miles from the center of the nation's outbreak.

Not my tomatoes, protested the manager. He'd switched his supply to government-cleared fresh tomatoes and even canned ones. But a lot of his menu items had a raw jalapeño garnish sprinkled on top, and that turned out to be a critical clue in the two-month salmonella mystery.

On July 3, Minnesota e-mailed the feds. After tracing credit card receipts — to find what the restaurant's healthy customers didn't eat — there was good evidence that the jalapeños were sickening people. And, officials had a diagram tracing the pepper shipments all the way back to three farms in Mexico.

One of those farms shipped peppers through the same large warehouse in McAllen, Texas, where Food and Drug Administration inspectors weeks later would find a single contaminated Mexican-grown pepper being packed by a neighboring vendor.

How could Minnesota pinpoint hot peppers just days after discovering a cluster of sick residents, when federal investigators had spent weeks fruitlessly chasing tomatoes?

To be fair, "there was already some doubt about tomatoes causing this whole outbreak," cautioned Kirk Smith, foodborne disease chief at the Minnesota Department of Health.

And federal investigators say Minnesota's information came just as they were getting hints from two Texas restaurant clusters that jalapeños might play a role.

"Ours was the first that pointed specifically to jalapeños as an ingredient, not just the salsa," Smith said.

Tomatoes falsely suspected?

It's too soon to know if the Centers for Disease Control and Prevention improperly blamed tomatoes in early June, based on reports from the first people to fall ill in New Mexico and Texas.

"I don't think we can find fault yet," said University of Georgia food-safety expert Michael Doyle. "With tomatoes, if you looked at the initial case-control studies, they really came up high on the list."

The CDC didn't comment Wednesday, but FDA food safety chief Dr. David Acheson told The Associated Press that every part of the system should be scrutinized to see if it can be improved.

Regardless, the way Minnesota unraveled its own cases — speedily comparing the sick and the well and then racing to track food suppliers — offers lessons for a public health system grappling with how to handle increasingly complex outbreaks from tainted produce.

"We have got to put the appropriate perspective on this outbreak as to what went right and what went wrong so the kind of changes that are going to further foodborne disease (prevention) can be made," said Michael Osterholm, a University of Minnesota infectious disease specialist and frequent adviser to the government.

He fears the salmonella mystery may be the "swine flu of foodborne disease," and make federal health officials more reluctant to issue consumer warnings in future outbreaks unless they've found the smoking gun, an actual tainted food.

"That would be the worst legacy of this entire situation," Osterholm said.

A salmonella scare
Reports of salmonella Saintpaul, the rare strain sickening hundreds elsewhere in the country, began dribbling in to Minnesota's state health department on June 23.

Minnesota's system is different from those of many states: Rather than county health departments initially checking outbreaks and reporting to headquarters, Smith's state office handles investigations from the beginning. By Thursday, with six cases reported, he had epidemiologists interviewing the sick: What did you eat in the few days before getting ill? Where?

By Sunday, two people had mentioned the same Twin Cities-area restaurant. Smith ordered that other patients be directly asked about that site. Monday morning, four more people fingered it — and by lunchtime, epidemiologist Erin Hedican was on the scene.

She quickly found seven more ill: employees who ate their own meals at the restaurant and started getting sick after the first customers had. Good to know: That meant the workers weren't the source.

With the manager, Hedican combed ingredients. Any new items added lately? New suppliers? She requested invoices from shipments just before June 14, the first known meal date of one of the sick, and started the hard push to get credit card receipts so she could learn what people who didn't fall ill had eaten.

By Tuesday morning, a garnish made of diced jalapeños and red peppers was topping a list of possible suspects.

"This is not like a sprig of parsley on the edge of your plate. This was sprinkled directly on almost every entree," Smith said.

Still, "a lot of people didn't notice the jalapeños," Smith said, while they were quick to mention tomatoes.

"Recall, that's what makes it tricky. That's why I wonder about all those initial cases" in other states, he added.

Tracking down the culprit
By Wednesday night, Smith's team had interviewed 13 sick people and 28 others who had eaten at the restaurant on the same days but stayed well. The sick were 46 times as likely to have eaten the garnish. The next morning, he alerted CDC and FDA.

Meanwhile, Ben Miller of the Minnesota Department of Agriculture, which regulates food suppliers, was pursuing those invoices. Miller knows traceback: He is credited with following contaminated lettuce blamed for a 2006 E. coli outbreak back to two suspect farms in California, before FDA singled out the culprit.

This time around, Miller knew his colleagues down the hall were suspicious of that garnish. He doubted a red pepper connection; they're used in far more restaurants than jalapeños.

The Twin Cities supplier that delivered to the restaurant led him to a larger distributor, also local. Miller whittled down shipment dates to between June 5 and 9. That distributor had bought from two sources: a shipper in California and another in McAllen, Texas, who in turn got the peppers from three farms in Mexico. Miller later ruled out one farm by further narrowing shipping dates; now he's waiting to hear from FDA if his Texas link panned out.

"A few phone calls and you can work it fairly quickly back to the grower," Miller said.

Federal officials had lots of questions for Minnesota as they matched that data with the clusters in Texas, the outbreak's center.

The Minnesota data "helped us begin to narrow this down," Acheson said, although he wouldn't call it the key cluster.

But Smith's team wasn't done: By July 8, it had a big enough group — 19 sick and 78 healthy customers — to do a statistical comparison of multiple ingredients. The sick were 100 times as likely to have eaten a jalapeño as the well.

The next day, July 9, the CDC issued its first consumer precaution, that people at high risk of salmonella should avoid fresh jalapeños.

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Food industry bitten by its lobbying success

By LARRY MARGASAK
Associated Press Writer
989 words
25 July 2008
12:34 pm GMT
Associated Press Newswires
English
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WASHINGTON (AP) - One of the worst outbreaks of foodborne illness in the U.S. is teaching the food industry the truth of the adage, "Be careful what you wish for because you might get it."

The industry pressured the Bush administration years ago to limit the paperwork companies would have to keep to help U.S. health investigators quickly trace produce that sickens consumers, according to interviews and government reports reviewed by The Associated Press.

The White House also killed a plan to require the industry to maintain electronic tracking records that could be reviewed easily during a crisis to search for an outbreak's source. Companies complained the proposals were too burdensome and costly, and warned they could disrupt the availability of consumers' favorite foods.

The apparent but unintended consequences of the lobbying success: a paper record-keeping system that has slowed investigators, with estimated business losses of $250 million. So far, nearly 1,300 people in 43 states, the District of Columbia and Canada have been sickened by salmonella since April.

Investigators initially focused on tomatoes as a culprit. Now they are turning attention to jalapeno peppers.

A former member of Bush's Cabinet and three former senior officials in the Food and Drug Administration told the AP that government food safety experts did not get the strong record-keeping and trace-back system originally proposed under a bioterrorism law to cope with a major foodborne illness.

"In retrospect, yes, if they (the regulations) had been broader and a bit more far-reaching, it could have helped with this," said Robert Brackett, senior vice president of the Grocery Manufacturers Association. "It wouldn't have hurt, for sure." Brackett formerly was a top safety official at the FDA.

Under pressure in 2003 and 2004, the White House agreed to dilute record-keeping proposals by FDA safety experts.

"If the FDA had been given the resources and authority years ago that it asked for to solve these kinds of problems, I think we would have solved this already," said William Hubbard, a former FDA associate commissioner.

Tommy Thompson, who was health secretary during the industry's lobbying campaign, acknowledged that a more robust food-tracking system -- opposed by business groups as too expensive -- could have helped stem the current illnesses and business losses.

"We went in with the larger package but knew we had to compromise," Thompson told the AP. "I was satisfied with this being the first step. It's always better to be a Monday morning quarterback. We could have ended up with nothing. If we had more, would it help the situation now? Yes."

According to government records reviewed by the AP, business groups met at least 10 times with the White House between March 2003 and March 2004, as the FDA regulations were under debate. Food industry lobbyists successfully blunted proposals using arguments familiar in other regulatory debates: The government's plans would saddle business with unnecessary and costly regulations.

"The FDA's strong proposed bioterrorism rules were significantly watered down before they became final," said Caroline Smith DeWaal, food safety director at the Washington-based Center for Science in the Public Interest. The private advocacy group obtained the White House meeting records under the Freedom of Information Act and provided them to the AP.

Participants in the meetings included companies and trade groups up and down the food chain, including Altria Group Inc. and Kraft Foods Inc., when Altria was Kraft's parent; The Kroger Co.; Safeway Inc.; ConAgra Foods Inc. of Omaha, Neb.; The Procter & Gamble Co.; the American Forest and Paper Association; the Polystyrene Packaging Council; the Glass Packaging Institute; the Cocoa Merchants' Association of America; the World Shipping Council; and the Food Marketing Institute.

The Grocery Manufacturers Association spent $2.6 million on lobbing in 2003 and 2004, the period when the FDA rules were under consideration, according to federal lobbying records. The Food Marketing Institute spent $1.7 million during the period. The figures were for all lobbying by the trade groups and on their behalf.

The grocery group complained during the comment period that the FDA was overstepping authority that Congress had granted under the new bioterrorism law. It said the FDA wanted a "cradle-to-grave record-keeping system" to track every morsel of food delivered to every retail grocery shelf and said more tracking information does not always produce a better result.

The marketing institute said a proposed tracking system as envisioned by the FDA "would be exorbitantly costly."

The food industry now says it will agree to a better tracing system operated by the government, as long as the industry can advise how to design it.

"We support the government requiring industry to have traceability systems that are effective and work," said Jill Hollingsworth, group vice president for food safety programs at the marketing institute. "But industry has to come up with a system that follows products throughout the food chain."

The FDA official in charge of the current salmonella investigation, David Acheson, said the agency slowly is reviewing paper records to help trace tainted produce. But Acheson disputed arguments that an electronic records system would necessarily have helped investigators.

"We still haven't managed to figure out this outbreak," he said in an interview days before the case's biggest break -- discovery of a tainted Mexican-grown jalapeno in a southern Texas warehouse.

The White House Office of Management and Budget defended its meetings with food industry groups in 2003 and 2004, saying it regularly meets with companies and individuals with a stake in proposed government rules.

"Our door is open for anyone -- from non-profits, industry representatives to individual citizens -- who request meetings on regulations," OMB spokeswoman Jane Lee said. "These are listening sessions in conjunction with personnel from the regulating agency."

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Return to Headlines

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Congress of the United States
Washington, DC 20515

June 12, 2008

Commissioner Andrew C. von Eschenbach, M.D.
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Commissioner von Eshenbach:

We write to you today to express our deep concern over the recent salmonellosis outbreak linked to the consumption of tomatoes. As you may know, this emerging health threat is shaking consumer confidence in our nation's food supply and causing havoc within the tomato industry.

We greatly appreciate that the FDA has added 19 Florida counties to the list of areas not associated with the current outbreak. However, we believe the FDA must do more to communicate this information to consumers. As members of Congress representing the state of Florida, we urge the FDA to make every effort to disseminate information on geographic areas with "safe to eat" tomatoes to media outlets and the public. At present, many consumers, including restaurants and grocery stores, are simply not buying <u>any</u> tomatoes because of their uncertainty. If consumer confidence is not restored quickly, the economic consequences could be severe.

Florida is the largest tomato producing state in the nation. During the six to seven month harvest season in Florida, the state employs more than 30,000 workers, with a crop valued at $500-700 million in revenues annually. Almost half of all the tomatoes consumed in the United States each year come from Florida, and this time of year the state provides more than 90 percent of the nation's tomatoes. Currently, there is upwards of $40 million worth of product that is going to waste on docks, in packing plants, and in the fields. While these growers are now free to sell their product, if they do not have buyers, the economic consequences will be equally dire.

Ultimately, until the source of contamination is found, this crisis will cause economic harm not only to tomato growers, but to restaurants, grocery stores and other food operators around the nation that use tomatoes in their daily businesses. And in Florida, which like many states has a climate of economic uncertainty and rising unemployment rates, we can ill afford the collapse of our tomato growing industry. The FDA should use every resource available to quickly determine the source of the contamination, including working with state agencies in the effort.

In the meantime, the FDA should make every effort to identify for the public which states are considered "safe to eat" and which states are still under investigation. We ask that you provide our offices with a detailed written response of your efforts to date to

PRINTED ON RECYCLED PAPER

address this health and safety crisis, your efforts to communicate information to the public, and a timeframe for the swift resolution of this issue.

Sincerely,

Debbie Wasserman Schultz
Member of Congress

Allen Boyd
Member of Congress

Tim Mahoney
Member of Congress

Jeff Miller
Member of Congress

Corrine Brown
Member of Congress

Ginny Brown-Waite
Member of Congress

Tom Feeney
Member of Congress

Ron Klein
Member of Congress

Lincoln Diaz-Balart
Member of Congress

Mario Diaz-Balart
Member of Congress

Alcee Hastings
Member of Congress

Robert Wexler
Member of Congress

Ileana Ros-Lehtinen
Member of Congress

Vern Buchanan
Member of Congress

CC: Dr. Julie Louise Gerberding, Director, Centers for Disease Control and Prevention
Michael O. Leavitt, Secretary, Health and Human Services
Ed Schafer, Secretary of Agriculture, U.S. Department of Agriculture

TOMATO GOOD AGRICULTURAL PRACTICES (T-GAP) & TOMATO BEST MANAGEMENT PRACTICES (T-BMP)

Questions and Answers From the Florida Tomato Exchange

October 2006

Food safety is important for everyone. It is the goal of the entire tomato industry to enhance the safety of tomatoes to the consuming public by the implementation of safer production, handling, and packing practices that will prevent or minimize contamination and will provide the necessary education and training on food safety practices for all levels of the industry.

Over the past two years, the Florida Tomato Exchange has been working with the industry, with the University of Florida's, Institute of Food and Agricultural Sciences (UF/IFAS), with the Florida Department of Agriculture and Consumer Services (FDACS), and with the U.S. Food and Drug Administration (FDA) to capture the food safety practices that many are performing daily and to work toward having consistent food safety practices for all. The document listing these food safety enhancement practices was completed in August, 2006 and is a living document that will change as more knowledge is available.

The Florida Tomato Exchange voted on September 7, 2006 to immediately implement the Tomato Good Agricultural Practices (T-GAP) and Tomato Best Management Practices (T-BMP) for the fresh tomato industry in Florida with the exception of the prohibition of field packing without a microbial reduction treatment. The field packing provision will be implemented in the fall of 2007 provided the legal language has been passed enabling enforcement of the rules and regulations by the Florida Department of Agriculture and Consumer Services.

This action by the Florida Tomato Industry is critical in light of the long-term objective of protecting human health and with the subsequent events of foodborne outbreaks involving spinach and lettuce from California.

What does this mean for you?

Food safety is important for everyone. You need to become very familiar with all the steps you are required to take to enhance food safety and minimize contamination in your operation..

You should obtain a copy of the Tomato Good Agricultural Practices (T-GAP) for field and greenhouse production if you are a grower and follow the recommendations and requirements as closely as possible. The Department of Agriculture and Consumer Services and UF/IFAS can assist in this regard. If you are a packer or involved in any postharvest operations, obtain a copy of the Tomato Best Management Practices (T-BMP) and follow the recommendations and requirements as closely as possible.

Where can I get a copy of the T-GAPs or T-BMPs?

Call the Florida Tomato Exchange at 407-660-1949 and they will provide you a copy. Check the website www.floridatomatoes.org as this document will be there in the near future.

What other documents would help me to better understand the food safety risks and needed good practices for fresh produce?

The U.S. Food and Drug Administration (FDA) has reports on the current foodborne outbreaks everyday on www.fda.gov. The Florida Tomato Growers Exchange will forward pertinent news releases to you on a frequent basis and will point out lessons learned from these situations.

Florida tomato industry representatives were involved in the writing of the Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain and this was adopted under the T-GAP and T-BMP document. This may be found at:
http://www.cfsan.fda.gov/~acrobat/tomatsup.pdf

University scientists are working to distill food safety practices into a brief usable form UF/IFAS EDIS document – "Food Safety on the Farm"
http://edis.ifas.ufl.edu/

Guide to Minimize Food Safety Hazards for Fresh Fruits and Vegetables
FDA/USDA/CDC Published October, 1998
http://www.cfsan.fda.gov/~mow/arprodgu.html

FDA's Produce Safety Action Plan
http://www.cfsan.fda.gov/~dms/prodpla2.html

Safe Handling of Fresh Produce and Fresh –Squeezed Fruit and Vegetable Juices (Consumer Piece)
http://www.cfsan.fda.gov/~dms/prodsafe.html

When will everything in this document take effect?

We are all working together this first season to find the best way to implement these requirements that will give us the maximum benefits to food safety in a common sense

manner. We will continue to work with the industry as a whole, with individual producers, packers and all segments and even with other states.

How do I get registered as a grower or packinghouse?

You are not required to register at this time because the registration process has not been completed. Once complete, you will be sent a notification on effective dates. Registration will be as simple as going on-line on your home or office computer, going to the County Extension office or a simple form submitted to the registration office.

How do I meet the education requirements for this next year?

The only course that has been offered to date was the Sanitation Workshop for Packers offered by UF/IFAS on September 5, 2006 at the Florida Tomato Committee conference. Keep a record of your attendance at this workshop as proof of education and training for packers and repackers. We are working with UF/IFAS, FDA, Cornell and any other providers of effective education and training and we will send you an announcement when training for the other areas of the industry is offered.

We hope to have training modules available for you on the web from your own computer or at County Extension offices where you can go on line, register, complete the training and provide a record of your completion. You are all familiar with the need to document education and training through the pesticide handler programs.

Please send any suggestions of excellent training you may have received to the Florida Tomato Exchange so that it can be considered for this requirement.

How does this affect my current dealings with my third party auditor?

First, the third party that is auditing you currently is probably the same company required by your customers to assure compliance with good practices. The T-GAP and T-BMP will not affect this relationship or your use of this firm. FDACS and UF/IFAS, however, are working with industry and auditors to establish criteria to evaluate third party auditors so that no one could try to se up a third party audit program that is not adequate. FDACS and UF/IFAS through the Methods Evaluation and Research Committee (see page 2 and page 10 of the document) will be completing this process this year.

If your third party auditor does not require an item in the T-GAP or T-BMP, you are still required to meet that section. For instance, some third party audits do not require you to look at irrigation waters yet current events in California with foodborne disease outbreaks show how critical this requirement is to the overall safety of your product.

We are hearing from companies all over the country that some harmonization or consistency is needed in third party evaluations. This can be a long-range goal but cannot be achieved in a short time frame.

What are the current penalties for not complying with T-GAP and T-BMP?

There are no current fines or penalties in place for non-compliance; however, the industry is working with the Commissioner of Agriculture to gain authority to assure compliance with needed food safety practices. The main penalty for non-compliance at the moment would be the potential for a major foodborne disease outbreak, which would have dramatic costs in human health, and economic losses for the entire industry.

Since I'm not a major U.S. grower or packer, aren't I exempt from these requirements?

No, food safety is everyone's responsibility. The only exemptions are if you sell a small amount of tomatoes (not to exceed two 25 lb boxes) from the property on which you grew them to an individual customer or you sell the same maximum 2 boxes yourself to an individual customer at a local farmer's market. If you sell to another party for resale, the tomatoes must meet all the safety provisions. Any greater quantity will have to meet all the food safety requirements. The only other exemption is a charitable donation that is not diverted into other commerce.

It is our hope that everyone will want to enhance the food safety of their tomatoes to the maximum degree possible.

With all this focus on food safety, does that mean the Marketing Order Requirements for tomato quality are no longer in effect?

No, if you produce in the regulated area and are currently under the Federal Marketing Order for tomatoes grown in Florida, all the provisions remain in force.

I've seen other Good Ag Practices documents in the past. Are any of these valuable to help me?

Yes, many of these documents will help you see the reasoning behind the requirements and may help you comply. Many of these documents, along with the web site where you can find these, are listed on page 4-5 of the T-GAP and T-BMP Document. The recently completed guidance in the Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, Edition 1.0, developed by the North American Tomato Trade Working Group composed of the United States, Canada and Mexico has been adopted in its entirety. Our T-GAP and T-BMP document is consistent with this and is written more as a rule to follow.

Questions on Part A – Field and Greenhouse Production
Read the document carefully - These limited Questions and Answers are not meant to cover all areas; merely to address questions that have arisen

How can I be responsible for anything to do with the environment when I am growing in an open field exposed to all the elements?

The environment you use to grow your tomatoes is a critical item for the safety of your product. The recent events with illnesses and deaths from fresh spinach in one packing plant from certain fields in California illustrate the critical need to ensure you know your environment.

Any animal operation adjacent to your tomato field is a potential for danger.

The exact strain of E. coli O157:H7 in the California spinach was found in cattle and wild hog feces in a field adjacent to the spinach field. The October, 2006 lettuce recall was due to finding E. coli O157:H7 in irrigation waters.

Animal and human feces are the source of Salmonella, E. coli and other pathogens on tomatoes. Animal control is critical. Don't have any animal operations next to tomato fields. Don't allow run-off of water from any adjacent land with animals onto your tomato fields. Don't have dogs, cats, pets, etc in tomato fields. Yes, you are in an open environment but control animal entry to the degree possible. If you go in a tomato field and see an increased population of toads, frogs, lizards, etc, this is a high potential for contamination. For any new tomato fields, know the previous land usage. If animals have been grazing on this land or manures spread on this land, check with UF/IFAS scientists on management. A minimum of 120 days is required for tilling in manures and that length of time may not be adequate. Some papers indicate Salmonella survival in soil for 6 months. Remove any piles of debris that can harbor rodents, animals, be an attractant, etc.

Set up an environmental evaluation/assessment record for the land on which you are growing. Record your water source for each crop, what you find on animal species, what controls you are putting in place, what is the use of the adjacent lands, etc. Keep this as a written record. Develop your own checklist. FTE and UF/IFAS will develop a checklist for you to use as a self-audit.

I see that the prohibition of field packing without a microbial reduction step has been delayed. Does that mean if I am field packing that I don't have to apply any of the recommendations at this time?

No, you should carefully read and apply all of the recommendations to the degree possible. For instance, your liability and chance of causing foodborne illness is greatly increased if you harvest from any field adjacent to an animal operation such as pasture with cattle, dairy, etc. You are responsible for knowing the conditions in the field where you are harvesting. You are also responsible for ensuring that all sanitary provisions on facilities, handwashing, cleanliness of harvesting containers, etc. are followed. Although you may not be the grower, you are responsible for ensuring that the actual grower has records of analysis for the irrigation waters and has used properly registered pesticides,

etc. Read the document carefully and question the growers in whose fields you are packing the tomatoes.

Yes, you are correct in that you can continue to field pack this year while we are working with the scientists and regulators to determine a procedure that you can use in the field to reduce the microbial levels on the tomatoes.

Get a copy of Field Pack Questions and Answers from the Florida Tomato Exchange or your County Extension Office.

Am I required to use properly sanitized harvesting containers if I'm field packing?

Yes, everyone is required to use properly sanitized harvesting containers. This issue was not postponed for field packing either. The only delay was the prohibition of field packing until a microbial reduction step was approved. Carefully review the equipment requirements which state that any surfaces or equipment that touches fresh produce is a food contact surface and must be cleaned and sanitized as such. You should establish routine cleaning and sanitizing procedures and maintain these standard operating procedures in writing. You should maintain all equipment and surfaces in such a way as to minimize contamination of and injury to tomatoes. You need to remove debris from the fields and prevent injury to tomatoes you are harvesting in the field.

What other procedures are required of me if I am field packing tomatoes currently?

Carefully review the sections in the T-GAP document about crews, harvesting, water and equipment. You need to instruct your work crews on food safety practices. You cannot use any surface water on the tomatoes you are packing. Do not pack in used, dirty containers. Do not wipe the tomatoes with a rag before packing. This merely spreads more bacteria on the surface and from tomato to tomato.

How can I prove that I am making a good faith effort to comply?

Record all that you are doing. Be certain to write down in a notebook, that you keep with you, all the procedures you are using. Write down when you have verified with the grower that he/she is following proper procedures on irrigation water, fertilizer and pesticide use, animal control.

Why should I be concerned about the water I am using to irrigate? The product will all go to the packinghouse where it will be washed.

It is critical for you to analyze any waters used for irrigation for pathogens. The recent lettuce recall in California was because of finding E. coli O157:H7 in the irrigation water. Well water is less contaminated than surface waters. If you are using ground water (from wells) you may need to test less frequently than for surface water. The recommendations for the frequency for water testing are being evaluated by the scientists and regulators and will be communicated to you. Analyze your irrigation waters now and keep a record of

the testing. If the testing shows any pathogens, immediately contact UF/IFAS and FDACS who can help you with a water treatment procedure to eliminate the pathogens.

Do not use surface water in overhead irrigation once plants are in blossom and fruit stage. Do not use surface water to dilute any pesticide or chemicals applied to a crop. Several studies have shown direct contamination leading to illnesses.

The reuse of waters can be a source of contamination and is a food safety risk. If you are being pressured to reuse irrigation waters, analyze the reused water, and contact FDACS for assistance in resolving any conflicts with the Water Management District. Water conservation measures cannot be in conflict with food safety requirements. Any reuse of water will probably require some type of treatment to eliminate pathogens.

The fresh fruits and vegetables in any flooded field are considered as adulterated by FDA due to the potential for contamination with foodborne disease organisms.

What do I have to do differently on worker hygiene and health?

You are not required to do anything in addition to what you are already required under Department of Health, OSHA and FDA regulations regarding field sanitary facilities, worker hygiene and cleanliness and worker health. Be certain that you follow the current regulations and remember the source of most foodborne pathogens is human and animal feces. In all areas, it is important to document your practices.

What do I need to change on crop production practices under these new guidelines?

You are currently required to follow the fertilizer laws and pesticide laws of the state. Any pesticide you are using has to be registered both by EPA and FDACS and used only in accordance with the label. **You cannot use any surface water out of a pond or canal to dilute a pesticide or ag chemical applied to the crop.** Use only well water or potable water. **No fresh manure should be used on any fresh fruit or vegetable crop.** Properly composted manures may be used but the exact conditions of composting must be known to ensure that all pathogens have been eliminated. Keep accurate up-to-date records of all fertilizers, pesticides and other chemicals applied to crops.

What are important areas when we are haresting?

Everyone who touches a tomato is a potential source of contamination. We all need to ensure that the crews harvesting tomatoes are aware of food safety practices and their importance. We are asking UF/IFAS and FDACS to develop a brief training pamphlet that will help the industry. Debris and culls must be removed to the degree possible. Injured tomatoes are easily contaminated with pathogens if present and once internalized the pathogens cannot be readily killed.

All surfaces that tomatoes touch are considered food contact surfaces and must be cleaned and sanitized as such. Ensure that you are using cleaned and sanitized harvesting containers. See page 7 and 8 of the T-GAP & T-BMP Document.

Where can I go for help?

Everyone in the industry is working together this first year along with UF/IFAS and DACS to make certain we are enhancing the safety of our tomatoes, we are doing all we can do to prevent foodborne illness, yet we are doing this in a common sense way that we can accomplish. Give the Florida Tomato Exchange a call and they can refer someone to you to help you with your operations. Contact your County Extension office. Check the new EDIS document on "Farm Safety on the Farm".

Questions on Part B for Packinghouses and Post Harvest Handling
Read the document carefully - These limited Questions and Answers are not meant to cover all areas; merely to address questions that have arisen

I've run a good packinghouse operation for years. What will be different with the T-BMP?

Basically, nothing should be different if you have been following good sanitary procedures and cleanliness for your packinghouse operation, equipment, tomato handling, worker hygiene, etc. You should be very careful to have written documentation of all procedures, all monitoring of your water, all analytical testing of tomatoes, sanitation of equipment, pest control, chemical usage, etc. Ensure you have adequate procedures for cleaning and sanitizing all areas including storage rooms, ripening rooms, etc.

A chemical company has been telling me they have a new chemical that will be a better sanitizer in my dump tank. Can I use this immediately?

No, at present the only approved method for dump tanks is a free chlorine concentration of 150 ppm for a maximum of 2 minutes with water at pH 6.5 to 7.5, 10 degrees F over pulp temperatures and with careful monitoring to ensure that free chlorine levels, pH and dump tank water temperature are maintained as required during packing. If you want to use any other procedure, supply a file of scientific data showing adequate 3-log reduction of Salmonella and Erwinia in 30 seconds along with your proposed monitoring and the Methods Evaluation and Research Committee will review this to determine if the new method is adequate.

What sanitizers and chemicals can I currently use on equipment in the packinghouse?

Sanitizers and disinfectants are pesticides under the law and have to be registered by both EPA and the state of Florida. FDACS will provide a listing of currently approved

sanitizers for use in packinghouses and if anyone approaches you about using another chemical, call FDACS to verify it is registered. Remember to store all chemicals so they will not contaminate the product.

I ran out of boxes last week during a run and the company down the road refused to sell me some of their boxes saying this was prohibited. Why?

First of all, the current law requires that the name and address on the box be the manufacturer, packer or distributor. **The company with its name on the box is legally liable for what is in that box.** Reused boxes can't be used for final packing of tomatoes. If tomatoes are shipped in bulk they can be packed in a properly sanitized plastic bin. All tomatoes need to have a positive lot identification so that you can traceback any tomatoes that you have packed and shipped.

How can I be responsible for any traceback? What is all this talk about transparency?

If illness occurs or something goes wrong, we have to be able to quickly traceback to the origin of the problem. You may not be able to be responsible for the whole chain, but you certainly know the tomatoes you packed, the growers of those tomatoes, and your customers that received them. Being transparent just means being open about all of your records, your procedures, and how you run your business.

I am following all of these correct procedures but what is to protect me if the processor I'm selling my tomatoes to is mishandling them?

You are correct. You are vulnerable if the regulators don't apply the requirements for safe handling all down the chain. After the past few year's outbreaks from cut/sliced and diced tomatoes, FDA requested the Conference for Food Protection, and the CFP concurred, to classify the cut, sliced and diced tomatoes as a Potentially Hazardous Food which will require careful handling after cutting at 40 degrees F or below. This action should greatly assist and provide protections against microbial growth.

Why all this emphasis on record keeping? I'm doing the right things in my packinghouse.

Regrettably, without a written record you don't have any proof of what you are doing. It is just your word. If something goes wrong, a written record of your procedures and the recorded results of your monitoring is your best insurance.

After doing everything I can, what if something goes wrong? What do I do first?

Our main goal is prevention; however, we must be prepared for crises before they occur. First of all have a written workable plan in place right now as to what you will do in time of a crisis involving your product due to a contamination event, a recall or other crisis. Decide who will communicate for your company in a crisis. Make sure you have after

hour telephone numbers to notify the Florida Tomato Exchange, the local county health department, the local FDACS inspector, and other key officials. Rapid notification and rapid correction limit illnesses and damages.

Second, the other key is cooperation. Quickly and readily meet with any officials that will be working on an investigation and make all records available to them as rapidly as possible.

Again, food safety is everyone's responsibility and the Florida Tomato Industry is proactive in working to enhance the food safety of our crop.

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Division of Fruits and Vegetables

RULE CHAPTER TITLE:	RULE CHAPTER:
Fresh Tomato Inspection	5G-6
RULE TITLE:	RULE NO.:
Purpose	5G-6.001
Definitions	5G-6.003
Inspection	5G-6.005
Annual Food Permit Requirement of Tomato Packers and Repackers	5G-6.007
Tomato Best Practices Manual	5G-6.009
Exemptions	5G-6.011
Enforcement	5G-6.013

PURPOSE AND EFFECT: The purpose of this rule is to establish inspection procedures and best management practices to enhance the safety of fresh tomatoes grown, packed or repacked in Florida and to implement Chapter 2007-67, Laws of Florida, adopted during the 2007 Legislative Session. A set of guidelines have been drafted through a cooperative effort between the FDACS and the Florida Tomato Industry to implement needed practices and procedures for safe production and handling of tomatoes. These guidelines are called the *Tomato Best Practices Manual* and are proposed for adoption by reference into this rule chapter. These rules will have an effect on those establishments permitted by the FDACS in the State of Florida who produce or handle tomatoes from field production through packing.

SUMMARY: This rule development will address inspection, permit requirements, and best practices in the tomato industry for growers, packers, re-packers and workers. This rule development will address the adoption by reference of the *Tomato Best Practices Manual*

guidelines for performing tomato food safety inspections on the farm, in tomato greenhouses and in tomato packing houses.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: No statement of estimated regulatory costs has been prepared. Any person who wishes to provide information regarding the statement of estimated regulatory costs or to provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 500.09(1)(b), (3), (4), 500.12(1) (f), 570.07(6), 570.07(23), 570.481(1)(a), F.S.

LAW IMPLEMENTED: 500.03(1)(j), (n), 500.09(1)(b), (4), 500.12(1)(a), (f), 500.147(6), 570.48(2)(e), 570.481(1)(a), (b), 603.12, 603.13, F.S.

A HEARING WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 2:00 p.m. until 4:00 p.m. on Monday, January 7, 2007.

PLACE: Eyster Auditorium, The Conner Building, 3125 Conner Boulevard, Tallahassee, Florida. Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this hearing is asked to advise the agency at least 48 hours before the hearing by contacting Lee M. Cornman at 850.488.0295. If you are hearing or speech impaired, please contact the agency by calling 1 (800) 955-8771 (TDD).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Lee M. Cornman, Assistant Director, Division of Food Safety, 3125 Conner Boulevard, Mail Stop C-18, Tallahassee, FL 32399-1650; Telephone: 850.488.0295.

THE FULL TEXT OF THE PROPOSED RULE IS:

CHAPTER 5G-6 FRESH TOMATO INSPECTION

5G-6.001 Purpose.

(1) This rule establishes inspection procedures and best management practices to enhance the safety of fresh tomatoes grown, packed or repacked in Florida, as provided by Chapters 500 and 570, Florida Statutes.

(2) The purpose of these procedures and practices is to:

(a) Enhance the safety of tomatoes to the consuming public by the implementation of safer handling, production and packing practices.

(b) Prevent or minimize contamination of tomatoes either in the natural environment in which they are grown or in the handling, packing, repacking or selling of tomatoes once harvested since, once contaminated, removing or killing pathogens is difficult.

(c) Provide the necessary education and training on food safety practices to workers at all levels.

(3) Mandatory compliance with the procedures and practices outlined in this rule will take effect July 1, 2008.

Specific Authority 500.09(1)(b), (3), (4), 500.12(1)(f),570.07 (6), 570.07(23), F.S. Law Implemented 500.09(1)(b), (4), 500.12(1)(f), F.S. History-New

5G-6.003 Definitions.

(1) "Department" means the Florida Department of Agriculture and Consumer Services.

(2) "HACCP" (Hazard Analysis Critical Control Point) means a preventive food safety program used to protect the food supply against biological, chemical and physical hazards.

(3) "T-GAP" means Tomato Good Agricultural Practices.

(4) "T-BMP" means Tomato Best Management Practices.

(5) "Farmers Market" means a market, usually held out-of-doors, in public spaces, where farmers can sell their produce to the public.

Specific Authority 500.09(1)(b), (4), 570.07 (6), 570.07(23), F.S. Law Implemented 500.03(1)(i), 500.09(1)(b), (4), 500.147(6), F.S. History-New

5G-6.005 Inspection.

(1) Regulatory inspections will be performed as frequently as needed to verify adherence to T-GAP or T-BMP for product grown, packed or repacked and will be performed at least once a year in packing houses by the Department.

(2) As specified in Sections 570.48 (2)(e), and 570.481(1)(a)(b), F.S., the industry shall reimburse the Department for regulatory inspections conducted under this program at the rate of $75.00 per hour.

Specific Authority 570.07 (6), 570.07(23), 570.481(1)(a), F.S. Law Implemented 570.48(2)(e), 570.481(1)(a), (b), 603.12, 603.13, F.S. History-New.

5G-6.007 Annual Food Permit Requirements of Tomato Packers and Repackers.

(1) An annual food permit is required for all packers and repackers of tomatoes in Florida. A permit number will be assigned by the Department following receipt of the Annual Food Permit Application, DACS-14306, (Rev. 06/03), herein incorporated by reference, a copy of which can be obtained from the Florida Department of Agriculture and Consumer Services, Division of Fruit and Vegetables, P. O. Box 1072, Winter Haven, Florida 32881-3403.

(2) The annual permit fee shall be $100.00 per applicant and must accompany the Annual Food Permit Application. No establishment shall be issued a food permit until all applicable fees are received by the Department

(3) All fees and fines collected by the Department to cover the cost of providing the inspection service for tomato packinghouses and repackers shall be deposited into the General Inspection Trust Fund.

Specific Authority 500.09(3), 500.12(1)(f), 570.07 (6), 570.07(23), F.S. Law Implemented 500.03(1)(n), 500. 12(1)(a), 570.48(2)(e), 570.481(1)(a), (b), F.S. History-New

5G-6.009 Tomato Best Practices Manual.

(1) The *Tomato Best Practices Manual* (November 2007) is hereby adopted and incorporated by reference in this rule section and contains the specifications of the T-GAP and the T-BMP. Copies of the manual may be obtained by contacting the Division of Fruits and Vegetables, P. O. Box 1072, Winter Haven, Florida 33881-3403, (863) 291-5820.

(2) The following document has been adopted by reference into the *Tomato Best Practices Manual* (November 2007) and is also incorporated by reference into this rule: *The Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, Edition 1.0, developed by the North American Tomato Trade Working Group composed of the United States, Canada and Mexico. A copy may be obtained electronically through the following website: http://research.ifas.ufl.edu/tomato/index.asp.

Specific Authority 500.09(1)(b), (4), 500.12(1)(f), 570.07 (6) ,570.07(23), F.S. Law Implemented 500.09(1)(b), (4), 500.12(1)(f), F.S. History-New

5G-6.011 Exemptions.

The following categories of tomatoes are exempt from the requirements of the T-GAP and T-BMP:

(1) Tomatoes sold by an individual grower to a consumer on the premises on which they are grown not to exceed two twenty-five pound boxes per customer.

(2) Tomatoes grown on premises and sold by the individual grower at a local farmers market not to exceed two twenty-five pound boxes per customer.

(3) Charitable contributions of tomatoes are exempt provided they are not diverted into commercial trade or the market place.

Specific Authority 500.09(4), 500.12(1)(f),570.07 (6), F.S. Law Implemented 500.09(4), 500.12(1)(f), F.S. History-New

5G-6.013 Enforcement.

Any person who violates any provision of these rules is subject to the penalties as provided in Chapter 500, F.S.

Specific Authority 500.09(3), 570.07 (6), 570.07(23), F.S. Law Implemented 500.121, F.S. History-New

NAME OF PERSONS ORIGINATING PROPOSED RULE: Shannon Shepp, Director, Division of Fruits and Vegetables and Dr. Marion F. Aller, Director, Division of Food Safety, Department of Agriculture and Consumer Services.

NAME OF PERSON OR SUPERVISOR WHO APPROVED THE PROPOSED RULE: Terry L. Rhodes, Chief of Staff, Department of Agriculture and Consumer Services.

DATE PROPOSED RULE APPROVED BY AGENCY HEAD:

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3 CCR 1472 (2008)

§ 1472. Tomatoes, Standards

Tomatoes shall be mature, but not overripe, and shall be free from:

(a) The following defects:

(1) Mold, decay, wet or soft rot, dirt, manure, bird or animal droppings that adhere to the surface of the tomato.

(2) Pinworm penetrating beyond the tissue making up the base of the core of the tomato.

(3) Other insect injury which has penetrated or damaged the flesh.

(b) Serious damage due to freezing, blossom end rot, mosaic, alkali spot, sunscald, bruises, catfaces, growth cracks, or other causes. Damage is serious when it wastes 10 percent, by volume, of the individual tomato.

AUTHORITY:

Note: Authority cited: *Sections 407 and 42684, Food and Agricultural Code.* Reference: *Section 42941, Food and Agricultural Code.*

HISTORY:

1. New section filed 1-21-75; effective thirtieth day thereafter (Register 25, No. 4). For former section, See Registers 74, No. 27 and 55, No. 10.

2. Amendment filed 10-5-83; effective thirtieth day thereafter (Register 83, No. 41).

3. Amendment of subsection (a) filed 5-18-2006; operative 5-18-2006 pursuant to *Food and Agriculture Code section 42802* (Register 2006, No. 20).

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3 CCR 1472.1 (2008)

§ 1472.1. Tomatoes, Growth Cracks

Growth cracks generally affect the stem end of the tomato. To determine the amount of waste caused by this defect, the normal method used in preparing the tomato for table use is a practical method of removing the damaged portion. In instances where there are three or more growth cracks, cut or slice under the affected portion from the point of the longest growth crack to remove the damage. The cut may have more depth to include portions of the defect which penetrates more deeply, or less depth where damage is not as deep.

In other instances where there are one or two growth cracks, opposite each other, gouge out the damaged portion. In the case of other combinations of cracks, use the same principle.

Growth cracks may also extend in a complete or partial circle on the top half (stem end or shoulder), in which case the method described in the first paragraph above is suggested.

AUTHORITY:

Note: Authority cited: *Sections 407 and 42684, Food and Agricultural Code*. Reference: *Section 42941, Food and Agricultural Code*.

HISTORY:

1. New sections 1471, 1471.1 and 1472 filed 7-7-55; effective thirtieth day thereafter (Register 55, No. 10).

2. Renumbering from Section 1471 filed 1-26-75; effective thirtieth day thereafter (Register 75, No. 4). For prior history, see Register 71, No. 2.

3. Editorial correction adding NOTE filed 4-27-83 (Register 83, No. 18).

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3 CCR 1472.2 (2008)

§ 1472.2. Tomatoes, Catfaces

Catfaces generally affect the blossom end of the tomato, and they take such varied twists and gnarls that only a general principle is suggested.

In some instances, scarred tissue considered damaged can be removed by slicing it off; if so, such flesh or tissue can be added to determine if 10 percent, by weight, has been damaged from this defect. In other instances when you cannot see the full depth of the catface, it may be necessary to halve the tomato and with a slanting cut (similar in some respects to that suggested for growth cracks), slice off from each half the affected portion and add it to the weight of the defective tissue.

In either method, only include in the defective portion, the pulp or tissue which has the abnormal rough growth characteristic of a catface. Distortion in the shape of the tomato alone cannot be considered as damage.

AUTHORITY:

Note: Authority cited: *Sections 407 and 42684, Food and Agricultural Code.* Reference: *Section 42941, Food and Agricultural Code.*

HISTORY:

1. Renumbering from Section 1471.1 filed 1-21-75; effective thirtieth day thereafter (Register 75, No. 4).

2. Editorial correction adding NOTE filed 4-27-83 (Register 83, No. 18).

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3 CCR 1472.3 (2008)

§ 1472.3. Tomatoes, Tolerances

Not more than 10 percent, by weight, of the tomatoes in any one container or bulk lot may be below the requirements prescribed by this article. Not more than one-half of this tolerance shall be allowed for any one cause.

AUTHORITY:

Note: Authority cited: *Sections 407 and 42684, Food and Agricultural Code.* Reference: *Section 42941, Food and Agricultural Code.*

HISTORY:

1. New section filed 1-21-75; effective thirtieth day thereafter (Register 75, No. 4). For former section, see Register 74, No. 7.

2. Amendment filed 10-5-83; effective thirtieth day thereafter (Register 83, No. 41).

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3 CCR 1472.4 (2008)

§ 1472.4. Tomatoes, Marking Requirements

In addition to basic marking requirements of Section 1359, every nonconsumer container of tomatoes shall be marked with a grower and lot identification code to enable traceback. Every nonconsumer type container of tomatoes of the Roma, "saladette", or "plum" type shall be clearly and conspicuously marked with a weight statement of 25 lbs. accompanied by the words "net weight" or "net wt."

AUTHORITY:

Note: Authority cited: *Sections 407 and 42682, Food and Agricultural Code*. Reference: *Section 42941, Food and Agricultural Code*.

HISTORY:

1. New section filed 5-18-93; operative 6-17-93 (Register 93, No. 21). For prior history, see Register 75, No. 18.

2. Amendment filed 5-18-2006; operative 5-18-2006 pursuant to *Food and Agriculture Code section 42802* (Register 2006, No. 20).

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3 CCR 1472.5 (2008)

§ 1472.5. Tomatoes, Vine Ripened Defined

Tomatoes labeled with the term "vine ripened" shall be considered mislabeled unless the skin surface or the flesh of each tomato has attained some discernible degree of pink or red color at the time of harvest.

AUTHORITY:

Note: Authority cited: *Sections 407, 42681 and 42682, Food and Agricultural Code.* Reference: *Sections 42941 and 42943, Food and Agricultural Code.*

HISTORY:

1. New section filed 7-20-59; effective thirtieth day thereafter (Register 59, No. 12).

2. Amendment filed 1-4-71 as an emergency; effective upon filing. Certificate of Compliance included (Register 71, No. 2).

3. Renumbering from Section 1371.1 filed 1-21-75; effective thirtieth day thereafter (Register 75, No. 4). For former section, see Register 74, No. 27.

4. Amendment filed 10-5-83; effective thirtieth day thereafter (Register 83, No. 41).

5. Amendment of section heading, section and Note filed 8-10-2004; operative 9-9-2004 (Register 2004, No. 33).

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3 CCR 1472.6 (2008)

§ 1472.6. Tomatoes, Standard Container Requirements

All green tomatoes which are not wrapped shall be in standard container numbers 22C, 53, 54, 55, 56, 56A, 57, 57A, 57B, 57C, or 57D.

AUTHORITY:

Note: Authority cited: *Sections 407 and 42682, Food and Agricultural Code*. Reference: *Section 42941, Food and Agricultural Code*.

HISTORY:

1. Amendment filed 6-23-78; effective thirtieth day thereafter (Register 78, No. 25). For prior history, see Register 75, No. 44.

2. Amendment filed 5-19-82; effective thirtieth day thereafter (Register 82, No. 21).

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3 CCR 1472.7 (2008)

§ 1472.7. Tomatoes, New Container Requirements

All tomatoes shall be in new and unused containers. This provision shall not apply to tomatoes that are reconditioned and repacked into the original containers by the original packer of the tomatoes, or to tomatoes that are reconditioned and repacked by a commercial repacker who is registered with the Secretary of the Department of Food and Agriculture as provided in Section 1472.7.1.

AUTHORITY:

Note: Authority cited: *Sections 407, 42681 and 42682, Food and Agricultural Code.* Reference: *Section 42941, Food and Agricultural Code.*

HISTORY:

1. New Sections 1472.1 through 1472.9 filed 1-4-71 as an emergency; effective upon filing. Certificate of Compliance included (Register 71, No. 2).

2. Renumbering from Section 1472.1 filed 1-21-75; effective thirtieth day thereafter (Register 75, No. 4). For former section, see Register 74, No. 27.

3. Repealer filed 10-5-83; effective thirtieth day thereafter (Register 83, No. 41).

4. New section filed 2-2-95; operative 3-6-95 (Register 95, No. 5).

5. Editorial correction of cross reference section number 1472.4.1 to 1472.7.1 (Register 95, No. 6).

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3 CCR 1472.7.1 (2008)

§ 1472.7.1. Tomatoes, Registration of Commercial Repackers

(a) A commercial repacker is a person or firm who is engaged in repacking of tomatoes in used containers, and has facilities for receiving, storing, and grading tomatoes. Every commercial repacker shall register with the Secretary of the Department of Food and Agriculture. Registration shall be on a Department form and shall include only the following:

(1) The name, address (including zip code), and telephone number of the repacking company;

(2) The name of the principal owner(s) of the repacking company.

(3) The address of each location where the tomatoes are being repacked.

(b) Registration shall be valid for one year beginning April 1 and ending March 31 of the following year.

(c) To be approved by the Secretary, repacking facilities shall have the following:

(1) Lighting adequate for inspection by an enforcing officer;

(2) Tables for grading and sorting tomatoes;

(3) A drinkable water supply;

(4) Approved weighing scales for assuring quantity of containers packed to net weight.

AUTHORITY:

Note: Authority cited: *Sections 407, 42681 and 42682, Food and Agricultural Code.* Reference: *Section 42941, Food and Agricultural Code.*

HISTORY:

1. New section filed 2-2-95; operative 3-6-95 (Register 95, No. 5).

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3 CCR 1472.7.2 (2008)

§ 1472.7.2. Tomatoes, Registration of a Handler

(a) For purposes of this section, a handler is any individual or company that engages in the operation of selling, marketing, or distributing tomatoes that have been produced, purchased, or acquired from a producer, and are first marketed on behalf of a producer, whether as an owner, agent, employee, broker, or otherwise, but shall not include retailers or restaurants, and Certified Producers as defined in Section 1392.2.

(b) Prior to commencing packing, handlers shall register with the Secretary of the Department of Food and Agriculture. Registration shall be on a Department form and shall include only the following:

(1) The name, address (including zip code), and telephone number of the handler.

(2) The name of the principal owner(s) of the company.

(c) In the event of a suspected violation of this article, a handler shall provide, upon request of the Secretary or his representative, records related to field location, grower, harvest date, pack date, transporter, and purchaser of packed tomatoes. Such records shall be maintained for the current marketing year.

AUTHORITY:

Note: Authority cited: *Sections 407, 42681, 42802 and 42808, Food and Agricultural Code.* Reference: *Sections 42681 and 42808, Food and Agricultural Code.*

HISTORY:

1. New section filed 5-18-2006; operative 5-18-2006 pursuant to *Food and Agriculture Code section 42802* (Register 2006, No. 20).

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3 CCR 1472.8 (2008)

§ 1472.8. Tomatoes, Greenhouse Grown Defined

Tomatoes labeled with the term "greenhouse grown" shall be considered mislabeled unless tomatoes are grown in a fixed steel structure using irrigation and climate control, in an artificial medium that substitutes for soil.

AUTHORITY:

Note: Authority cited: *Sections 407, 42681 and 42682, Food and Agricultural Code.* Reference: *Sections 42941 and 42943, Food and Agricultural Code.*

HISTORY:

1. New section filed 8-10-2004; operative 9-9-2004 (Register 2004, No. 33).

SEC. 414. [21 USC 350c] Maintenance and inspection of records.

(a) RECORDS INSPECTION. — If the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The requirement under the preceding sentence applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.

(c) Protection of Sensitive Information.—The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.

(d) Limitations.—This section shall not be construed--
(1) to limit the authority of the Secretary to inspect records or to require establishment and maintenance of records under any other provision of this Act;
(2) to authorize the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 USC 601 et seq.), the Poultry Products Inspection Act (21 USC 451 et seq.), or the Egg Products Inspection Act (21 USC 1031 et seq.);
(3) to have any legal effect on section 552 of title 5, United States Code, or section 1905 of title 18, United States Code; or
(4) to extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

SEC. 415 . **[**21 USC 350d**]**. Registration of food facilities

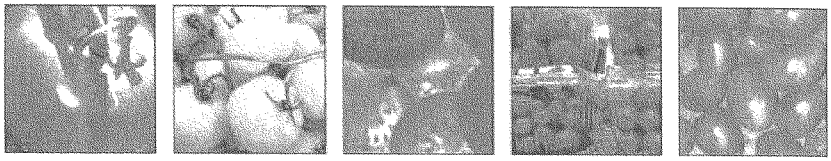
(a) Registration.—
(1) Regulations.— In general.--The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. To be registered--
(A) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary; and
(B) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary and shall include with the registration the name of the United States agent for the facility.

(2) Registration.—An entity (referred to in this section as the `registrant') shall submit a registration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business and, when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations) of any food manufactured, processed, packed, or held at such facility. The registrant shall notify the Secretary in a timely manner of changes to such information.
(3) Notification.—Upon receipt of a completed registration described in paragraph (1), the Secretary shall notify the registrant of the receipt of such registration and assign a registration number to each registered facility.
(4) Records.—The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section. Such list and any registration documents submitted pursuant to this subsection shall not be subject to disclosure under section 552 of title 5, United States Code. Information derived from such list or registration documents shall not be subject to disclosure under section 552 of title 5, United States Code, to the extent that it discloses the identity or location of a specific registered person.

(b) Facility.—For purposes of this section:
(1) The term `facility' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).
(2) The term `domestic facility' means a facility located in any of the States or Territories.
(3)(A) The term `foreign facility' means a facility that manufacturers, processes, packs, or holds food, but only if food from such facility is exported to the United States without further processing or packaging outside the United States.
(B) A food may not be considered to have undergone further processing or packaging for purposes of subparagraph (A) solely on the basis that labeling was added or that any similar activity of a de minimis nature was carried out with respect to the food.

Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain

2ND EDITION



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United Fresh
PRODUCE ASSOCIATION

APRIL 2008

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User's Note

These guidelines provide recommended food safety practices that are intended to minimize the microbiological hazards associated with fresh and fresh-cut tomato products. The intent of drafting this document is to provide currently available information on food safety and handling in a manner consistent with existing applicable regulations, standards and guidelines. The information provided herein is offered in good faith and believed to be reliable, but is made without warranty, express or implied, as to merchantability, fitness for a particular purpose, or any other matter. These recommended guidelines were not designed to apply to any specific operation. It is the responsibility of the user of this document to verify that these guidelines are appropriate for its operation. The publishing trade associations, their members and contributors do not assume any responsibility for compliance with applicable laws and regulations, and recommend that users consult with their own legal and technical advisers to be sure that their own procedures meet with applicable requirements.

Working draft: 6/9/2008

Foreword

The North American Tomato Trade Work Group (NATTWG) published in 2006 the first edition of Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain. In the two years since that document, several initiatives have resulted in significant new learnings about potential risks and control measures at all points in the fresh tomato supply chain. Some of those initiatives include the FDA Tomato Safety Initiative, voluntary efforts by the Florida Tomato Exchange and the California Tomato Farmers to develop USDA-verified audit criteria and programs for tomato production and harvest practices in those states, and several retail and foodservice buyer initiatives to further define tomato safe growing and handling practices. Members of NATTWG and United Fresh Produce Association initiated this second edition to capture those learnings and to include the perspectives of a wider scope of contributors. Significant efforts were made to involve as many associations, agencies, companies and individuals with expertise in food safety practices for one or more steps in the fresh tomato supply chain as possible. All perspectives were considered. Under the leadership of the editors identified in the acknowledgments, over forty contributors collaborated to develop the guidelines presented in this edition.

The guidelines presented in this edition represent a current understanding of conditions and controls that should be considered by every company in the tomato supply chain for their respective operations. In some cases, a company may need to consider the guidelines in more than one module. For example, companies involved in Field Packing should also consider the recommendations in the Open Field Production module, and companies involved in Repacking should also consider the recommendations in the Packinghouse module.

Recently, efforts have been made to more prescriptively define food safety practices for some fresh produce commodities, including the use of quantitative "metrics". While that was considered for this edition, the editors recognize that risks and controls are likely to be different between tomato sub-commodities and between tomato growing regions, and concluded that sufficient science with which to set metrics is currently lacking. Therefore, while the editors believe that this edition provides a comprehensive set of considerations, it is left to a future edition to identify a scientifically-based process for setting quantitative acceptance criteria for those considerations.

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Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain

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Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain

I. Introduction

In 1998, the U.S. Food and Drug Administration (FDA) issued its "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." The practices outlined in this and other documents are collectively known as Good Agricultural Practices or GAPs. GAPs provide general food safety guidance on critical production steps where food safety might be compromised during the growing, harvesting, transportation, cooling, packing and storage of fresh produce. More specifically, GAP guidance alerts the entire supply chain, including fruit and vegetable growers, shippers, handlers, packers, processors and buyers, to the potential microbiological hazards associated with various aspects of the production chain including: land history, adjacent land use, water quality, worker hygiene, pesticide and fertilizer use, equipment sanitation and product transportation. The vast majority of the fresh tomato industry has adopted GAPs as part of normal production operations. Indeed the majority of fresh tomato producers undergo either internal or external third-party GAP audits on a regular basis to monitor and verify adherence to their GAPs programs. These audit results are often shared with customers as verification of the producer's commitment to food safety and GAPs. While the produce industry has an admirable record of providing the general public with safe, nutritious fruits and vegetables, it remains committed to continuous improvement with regard to food safety.

GAPS

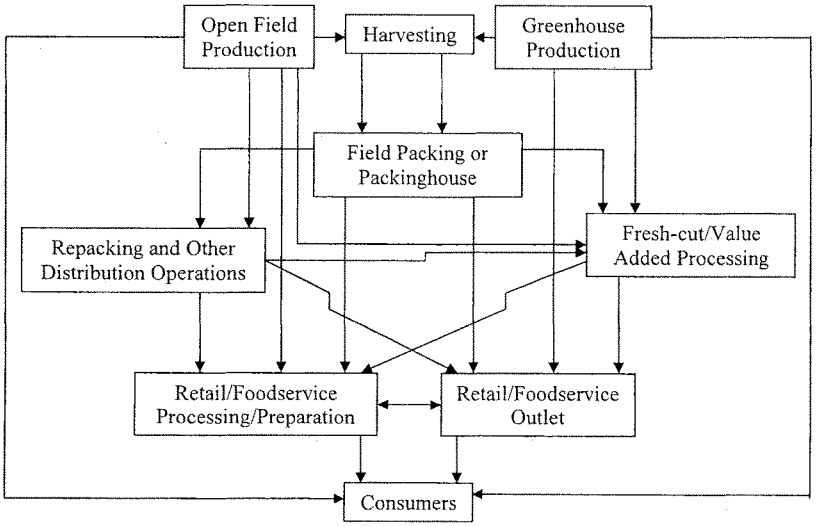
In 2004, the FDA published a food safety action plan that specifically requested produce industry leadership in developing the next generation of food safety guidance for fresh fruits and vegetables. These new commodity-specific guidelines focus on providing guidance that enhances the safe growing, processing, distribution and handling of commodities from the field to the end user. In the last 10 years, the focus of food safety efforts has been on the farm, initial cooling and distribution points and value-added processing operations. Fruit and vegetable processing operations have developed sophisticated food safety programs largely centered on current Good Manufacturing Practices (GMPs) and the principles of Hazard Analysis Critical Control Point (HACCP) programs. Food safety programs for fresh-cut and value added produce have recently been supplemented by FDA's 2008 "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables". As we develop a greater understanding of food safety issues relative to the full spectrum of supply and distribution channels for fruits and vegetables it has become clear that the next generation of food safety guidance needs to encompass the entire supply chain.

II. Scope and Use of Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain

The scope of this document pertains only to fresh and fresh-cut tomato products, and does not include cooked tomato products, tomato juice, or tomatoes intended to be

cooked. This document does not include considerations for products commingled with non-produce ingredients (e.g. salad kits which may contains meat, cheese, and/or dressings), although the tomatoes used in such products should be produced, harvested and otherwise handled in a manner consistent with the recommendations in this document. The distribution chain for fresh tomatoes can be complex, in that tomatoes may be sold direct or indirect to the buyer; tomatoes are often subject to repacking for size and/or quality. As a result, there is no single distribution chain. The distribution chain may be simple or very complex, with tomatoes being handled by a number of entities prior to being offered for sale to the consumer. The model distribution chain for the purpose of this document provides an overview of only a few of the many paths a fresh tomato can take prior to the end user. It is the intent of this document to cover all significant aspects of the tomato supply chain, from production to delivery to the consumer.

Figure 1. General Supply Chain Flow for Fresh Tomatoes



Safe production, packing, processing, distribution and handling of fresh and fresh-cut tomatoes depend upon a myriad of factors and the diligent efforts and food safety commitment of all parties throughout the distribution chain. No single resource document can anticipate every food safety issue or provide answers to all food safety questions. These guidelines are not intended to replace other food safety programs, but are meant to be used in conjunction with them to address food safety hazards known to affect the

tomato supply chain. These guidelines focus on minimizing the microbial food safety hazards by providing actions, based on the best available science, that have been shown to be effective to reduce, control or eliminate microbial contamination of tomatoes in the field to fork supply chain. Because of sub-commodity, regional and operational practice differences, not all of these actions will be applicable to all tomato handling operations. However, it is suggested that all companies involved in the fresh tomato farm to table supply chain consider the recommendations contained within these guidelines in developing their company-specific food safety program. Every effort to provide food safety education to supply chain partners should be made as well, to ensure that opportunities to prevent contamination are not lost as tomatoes pass from one point of the supply chain to the next. Together with the commitment of each party along the supply chain to review and implement these guidelines, the fresh produce industry is doing its part to provide a consistent, safe supply of produce to the market.

For the purposes of this guidance, the tomato supply chain has been divided into eight primary modules:

- open field production,
- harvest practices,
- field packing,
- greenhouse production,
- packinghouse,
- repacking and other distribution operations,
- fresh-cut processing (value-added), and
- foodservice and retail.

Multiple modules will apply to many users of these guidelines. Users should not assume that a single module will cover their entire tomato operation.

Each of these modules contains key considerations for potential sources of pathogen contamination that may be reasonably likely to occur in the absence of control. While not the focus of this document, reference materials for chemical, physical and other food safety hazards and controls, and other resources that may be useful, are provided in the Appendix.

III. Open Field Production

The development of good agricultural practices for field tomato production must consider all the elements of the field production system; field site, land use, adjacent land use, agricultural inputs (e.g., irrigation water, fertilizers), workers and production practices. Microbial contamination can occur from a number of sources; evaluation of these risks, and their management, are essential to proper food safety procedures in the production of fresh tomatoes.

1. Preventing/Minimizing Risks in the Field - Field Management

Field producers must give consideration to the control of microbial contamination in the selection and management of production sites.

a. Tomato growers should determine previous usage of land if at all possible and should assess and mitigate conditions that may pose a food safety risk in and near production fields.
b. Conduct an environmental assessment including topography, land history, risk of flooding, adjacent land use and domestic animal and wildlife presence.
   i. Routinely review field environments and maintain records of assessments and any corrective actions.
   ii. Consider the potential for flooding to create conditions that may pose a food safety risk. Flooding is the uncontrolled introduction of large amounts of water into the production area. Additional guidance related to flood events can be found at in the Appendix.
c. Tomato fields should not be located in any area that can receive runoff or drainage from an animal operation or any other source of contamination.
d. Steps shall be taken to avoid, prevent or mitigate run-off into the field from any animal operation or other conditions that may pose a food safety risk.
e. Areas of tomato fields that have been contaminated by run-off from an animal operation shall not be harvested for fresh or fresh-cut consumption.
f. Procedures used to mitigate risks shall be documented.

2. Animal Exclusion

a. Measures shall be taken to exclude domestic animals and livestock from tomato fields.
b. Measures shall be taken to minimize wildlife presence. These measures may include the use of barriers or other deterrents, minimizing wildlife attractants and opportunities for harborage, redirecting wildlife to non-sensitive areas and/or by other methods identified by wildlife experts.
c. If animal intrusion is detected, measures shall be taken to remove or prevent the harvest of any potentially contaminated product.

3. Adjacent Land Use

a. Assess adjacent land for activities or conditions that may pose a risk to tomato safety. Hazards may include, but not be limited to: livestock, wildlife, landfills, sewage treatment, chemical plants, or other conditions that pose a food safety risk.
b. Appropriate measures shall be taken to mitigate any identified food safety hazards. These measures may include berms, fences, ditches, buffer zones or other strategies to effectively mitigate any hazards.

4. Water Use in the Field

a. Water Source
   i. Document the source(s) of water for each field and agricultural use (e.g., irrigation, crop protection spray).
   ii. Identify potential sources of contamination of agricultural water at its source and during distribution and holding.
   iii. Ensure that any well used is properly designed, located, constructed and maintained in such a way as to prevent contamination.

iv. Ensure any water being utilized for irrigation is not contaminated with animal or human feces and meets the standard for *E. coli* in recreational waters contained in 40 CFR Part 131.41(c), or other standard based on available science.
v. Allow for appropriate water treatment methods and/or identify alternate water sources to ensure water quality is consistent with appropriate standards.
vi. Consider the potential for facilities and equipment used for holding and/or distribution of agricultural water to be a source of contamination.

b. Water Use
i. Any foliar application of water to tomatoes shall meet the microbial standards for potable water contained in 40 CFR Part 141.63.

c. Microbial Monitoring
i. Analyze and maintain records of testing of agricultural waters.
ii. Corrective actions shall be established and taken if standards are not met.
iii. Establish a monitoring frequency for water appropriate to the source and other relevant factors.

5. Hygienic Practices in Tomato Fields

Ensure that production crews, visitors or other field personnel are aware of food safety risk reduction principles and that they agree to adhere to the firm's practices and policies.

a. Written Policies and Employee Training
i. Operations shall develop and implement written GAP and Employee Hygiene Practices.
ii. All employees shall receive mandatory safe product handling and personal hygiene education at time of hire, with periodic reinforcements, at least seasonally.
iii. Training sessions shall be documented, with records kept of topics covered, date, names and signatures of those in attendance.
iv. Routine oversight and periodic self audits shall be used to verify and document compliance with worker hygiene and sanitation policies and practices.

b. Cleanliness/Sanitation
i. Sanitary facilities shall be provided for all field workers and visitors during planting, harvesting or other field activities. Toilet facilities shall be provided with a minimum of one per twenty employees and be readily accessible, located not more than ¼ (0.25) mile of all employees.
ii. Toilet facilities shall be designed, located, operated and serviced in a manner that does not pose a source of contamination of the field.
iii. Toilet facilities shall have appropriate hand washing stations, including collection of gray water.
iv. Toilet facilities shall be maintained in a clean and sanitary condition and properly stocked with soap, water for handwashing that meets the microbial standard for potable water, single use towels, toilet paper, etc. and a written record of cleaning shall be kept.

v. Restroom cleaning equipment shall be labeled and segregated so as not to pose a risk of contamination.
vi. Policies shall require hand washing with soap and water at the appropriate time such as before starting work, after breaks, using the restrooms, sneezing, or coughing.

c. Health
i. Employees, visitors and other field personnel with symptoms of diarrhea, fever, vomiting or other potentially infectious illnesses shall be restricted from working with or in the vicinity of tomatoes or tomato contact surfaces.
ii. Employees, visitors and other field personnel with open sores, cuts, burns, boils, etc., shall report to a supervisor before working or entering the field. The supervisor shall determine if the employee will be allowed to work with or in the vicinity of tomatoes or tomato contact surfaces.

d. Hygiene
i. Employees, visitors and other field personnel shall have designated areas for eating, drinking, smoking, breaks, personal effects, etc.
ii. There shall be a written policy prohibiting eating, drinking, chewing gum, and using tobacco in fields except in clearly designated areas.
iii. Drinking water shall be provided with either fountains or single use containers. Drinking water containers shall be handled in a manner that prevents them from becoming sources of contamination.
iv. There shall be a written policy restricting jewelry in the field.
v. Employees, visitors and other field personnel shall wear clean and suitable outer garments. Consider, as appropriate to the operation, hair restraints, plastic aprons and sleeves, restricting nail polish or false nails, and empty pockets above the waist.
vi. Other good food handling techniques shall be developed as appropriate to the specific operation to prevent cross contamination.

6. Gloves

There continues to be scientific debate as to whether the handling of tomatoes or other foods with bare hands, washed frequently with proper hand washing procedures, is safer than the use of gloves. If tomatoes are handled with bare hands, documentation of hand washing procedures must be made as indicated above. If gloves are utilized, a procedure for glove use must be documented and followed. The following applies to all operators who handle tomatoes in the field.

a. Disposable Gloves
i. The use of single use disposable gloves for hand contact with tomatoes is recommended.
ii. Hands shall be washed before putting on gloves.
iii. Hand sanitizers may be used, but not as a substitute for proper washing of hands.
iv. Disposable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.

b. Reusable Gloves
   i. Reusable gloves are not recommended for hand contact with tomatoes but, if used, the following requirements shall apply.
   ii. The gloves must be made of materials that can be readily cleaned and sanitized.
   iii. It is the responsibility of the production company to ensure that gloves are washed in hot water (≥140°F) and sanitized daily by a procedure validated to eliminate any potential contamination of public health concern. Gloves shall not be permitted to be taken home by workers for cleaning and sanitizing.
   iv. Appropriately cleaned and sanitized gloves shall be issued each day and at such times as needed during the day. Reusable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.
   v. Gloves that have come in contact with the ground or other non-food contact surfaces shall be changed.

7. Crop Production Practices

Assess risk of all production inputs to reduce contamination risk.

a. Chemical Fertilizers
   i. Follow manufacturer's instructions for usage and storage.
b. Fertilizers Containing Manures, Composts or Biosolids
   i. Only properly treated manures and biosolids are allowed for use in tomato fields.
   ii. If treated manures or biosolids are used, records of composition, dates of treatment, methods utilized, application dates and any test results or process verification data demonstrating compliance with microbial standards must be documented.
c. Pesticides (Crop Protection Treatments)
   i. Pesticide chemicals used must comply with all requirements of EPA registration and any federal, state or local regulations.
   ii. Pesticides must be appropriately registered for such use and must be used in accordance with label directions. Pesticide uses shall be documented.
   iii. Pesticides shall be applied by trained, licensed or certified pesticide personnel, as required by regulation.
   iv. Pesticides for foliar application shall only be mixed with water that meets microbial standard for potable water contained in 40 CFR Part 141.63.
d. Chemicals Used on Product
   i. Chemicals used on product that are not registered pesticides may be permitted for food contact use if allowed under regulations of the U.S. Food and Drug Administration (FDA).

8. Equipment and Containers

a. Any surfaces or equipment intended to touch fresh produce is a food contact surface and must be cleaned and sanitized at a frequency sufficient to prevent the surfaces from becoming a source of contamination.
b. Reusable containers and food contact equipment and utensils shall be constructed of materials that can be easily cleaned and sanitized.
c. Clean and sanitize containers, bins, food contact equipment and utensils at least daily during use, or more often as needed, to remove sand, grit, dirt, and other residue.
d. Establish routine cleaning and sanitizing procedures and maintain these sanitation standard operating procedures in writing.
e. Maintain all equipment and surfaces in such a way as to minimize contamination of, and injury to, tomatoes.
f. All containers shall be marked for their intended use (trash, etc.).

9. Record Keeping

Appropriate record keeping provides evidence of operating conditions and practices and facilitates periodic review and evaluation of those practices.

a. Records documenting adherence to these practices, such as those addressing environmental assessments, employee training, water usage, pest control, crop production practices, and any needed corrective actions, for the operation must be maintained and producible in a reasonable amount of time.
b. The source of all agricultural inputs used in the production of the crop (e.g., seeds, transplants, fertilizers, pesticides) shall be recorded.
c. Records shall be retained for at least two years, or as required by regulation.

IV. Harvest Practices

Tomatoes for harvest shall have been produced according to Good Agricultural Practices and the recommendations described in the prior section on Open Field Production.

1. Preharvest Assessment

A preharvest assessment provides a last opportunity to evaluate any safety risks that may impact the potential for the tomatoes to be contaminated. The field man, ranch manager or other responsible person shall ensure that an assessment is performed as close as practical prior to the beginning of harvest, for example, not more than 5 days prior to the beginning of harvest.

a. Conduct an environmental assessment including topography, land history, adjacent land use and domestic animal and wildlife presence.
   i. Review field environments and records of assessments and corrective actions.
b. Tomato fields should not be located in any area that can receive runoff or drainage from an animal operation or any other source of contamination.
c. Domestic animals and livestock have been excluded from tomato fields.
d. Wildlife presence has been minimized.
e. If animal intrusion is detected, measures shall be taken to remove or prevent the harvest of any potentially contaminated product.
f. Run-off from any animal operation has been prevented.

g. The source of water for irrigation for each crop has been documented and criteria have been met.
h. Procedures used to identify risks and mitigate those risks have been documented, followed and are reviewed.

2. Hygienic Practices in Tomato Fields

Ensure that harvest contractors and crews have been trained in food safety risk reduction principles and that they agree to adhere to the firm's practices.

a. Written Policies and Employee Training
   i. Operations shall develop and implement written GAP and Employee Hygiene Practices.
   ii. All employees shall receive mandatory safe product handling and personal hygiene education at time of hire, with periodic reinforcements, at least seasonally.
   iii. Training sessions shall be documented, with records kept of topics covered, date, names and signatures of those in attendance.
   iv. Periodic (e.g., daily, weekly, monthly, quarterly, as appropriate) self audits shall be used to verify and document compliance with worker hygiene and sanitation policies and practices.
b. Cleanliness/Sanitation
   i. Sanitation facilities (i.e., toilet and handwashing facilities) shall be provided for all field workers and visitors during harvest. Toilet facilities shall be provided with a minimum of one per twenty employees and readily accessible, located not more than ¼ (0.25) mile of all employees.
   ii. Toilet facilities shall be located and serviced in a manner to not be a source of contamination of the field.
   iii. Toilet facilities shall have appropriate hand washing stations.
   iv. Toilet facilities shall be maintained in a clean and sanitary condition and properly stocked with soap, water for handwashing that meets the microbial standard for potable water, single use towels, toilet paper, etc. and a written record of cleaning shall be kept.
   v. Restroom cleaning equipment shall be labeled and segregated so as not to pose a risk of contamination.
   vi. Policies shall require hand washing with soap and water at the appropriate time such as before starting work, after breaks, using the restrooms, sneezing, or coughing.
c. Health
   i. Worker health policies shall restrict employees with symptoms of diarrhea, fever, vomiting or other potentially infectious illnesses from working with or in the vicinity of tomatoes or tomato contact surfaces.
   ii. Employees with open sores, cuts, burns, boils, etc., shall report to a supervisor before working. The supervisor shall determine if the employee will be allowed to work with or in the vicinity of tomatoes or tomato contact surfaces.
d. Hygiene

i. Employees shall have designated areas for eating, drinking, smoking, breaks, personal effects, etc.
ii. There shall be a written policy prohibiting eating, drinking, chewing gum, and using tobacco in fields except in clearly designated areas.
iii. Drinking water shall be provided with either fountains or single use containers. Drinking water containers shall be handled in a manner that prevents them from becoming sources of contamination.
iv. There shall be a written policy restricting jewelry in the field.
v. Employees shall wear clean and suitable outer garments. Consider, as appropriate to the operation, hair restraints, plastic aprons and sleeves, restricting nail polish or false nails, and empty pockets above the waist.
vi. Other good food handling techniques shall be developed as appropriate to the specific operation to prevent cross contamination.

e. Harvest crews are trained to recognize and report any food safety risks or hazards observed during the harvest operation.

3. Gloves

There continues to be scientific debate as to whether the handling of tomatoes or other foods with bare hands, washed frequently with proper hand washing procedures, is safer than the use of gloves. If tomatoes are handled with bare hands, documentation of hand washing procedures must be made as indicated above. If gloves are utilized, a procedure for glove use must be documented and followed. The following applies to all harvest operators who handle tomatoes.

a. Disposable Gloves
   i. The use of single use disposable gloves for harvesting of tomatoes is recommended.
   ii. Hands shall be washed before putting on gloves.
   iii. Hand sanitizers may be used, but not as a substitute for proper washing of hands.
   iv. Disposable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.

b. Reusable Gloves
   i. Reusable gloves are not recommended for harvesting but, if used, the following requirements shall apply.
   ii. The gloves must be made of materials that can be readily cleaned and sanitized.
   iii. It is the responsibility of the harvest company to ensure that gloves are washed in hot water ($\geq$140°F) and sanitized daily by a procedure validated to eliminate any potential contamination of public health concern. Gloves shall not be permitted to be taken home by workers for cleaning and sanitizing.
   iv. Appropriately cleaned and sanitized gloves shall be issued each day and at such times as needed during the day. Reusable gloves must be changed after meals, smoking, using toilet facilities, any process involving

handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.

v. Gloves that have come in contact with the ground or other non-food contact surfaces shall be changed.

4. Equipment and Containers

a. Any surfaces or equipment intended to contact fresh produce is a food contact surface and must be cleaned and sanitized at a frequency sufficient to prevent the surfaces from becoming a source of contamination.
b. Reusable containers and food contact equipment and utensils shall be constructed of impervious materials that can be cleaned and sanitized.
c. Any containers used to hold tomatoes that are received back from a packing house must be checked for cleanliness prior to use.
d. Clean and sanitize harvest containers, bins, food contact equipment and utensils at least daily during use, or more often as needed, to remove sand, grit, dirt, and other residue.
e. Establish routine cleaning and sanitizing procedures and maintain these standard operating procedures in writing.
f. Maintain all equipment and surfaces in such a way as to minimize contamination of and injury to tomatoes.
g. Records shall be maintained of cleaning procedures and their implementation.

5. Tomato or Equipment Sanitizing Agents Used During Harvest

a. EPA considers any chemical making an antimicrobial claim, including those used to sanitize equipment and tomatoes, to be a pesticide.
b. Sanitizing chemicals used must comply with all requirements of EPA registration and any federal, state or local regulations.
c. Sanitizing chemicals must be appropriately registered for such use and must be used in accordance with label directions. Sanitizing chemicals uses shall be documented.
d. Chemicals used on product that are not registered pesticides may be permitted for food contact use if allowed under regulations of the U.S. Food and Drug Administration (FDA).

6. Debris Removal

Dirt, stems and leaves should be removed from tomatoes to the degree practical in the field, in a manner that does not pose a risk of contamination.

7. Exclusion from Harvest

a. Tomatoes that have fallen from the plant to the ground (i.e., "drops") shall not be harvested.
b. Tomatoes contacted by any fecal material shall not be harvested.
c. If animal intrusion is detected, measures shall be taken to remove or prevent the harvest of any potentially contaminated product.
d. Damaged, soft or decayed tomatoes should be excluded, to the degree possible.

8. **Culling, Sorting and Removal of Damaged Tomatoes**
   Damaged or decayed tomatoes provides a potential source of contamination.
   a. Damaged, soft or decayed tomatoes should be removed, to the degree possible, to minimize microbial contamination.

9. **Record Keeping and Traceability**
   Record keeping provides evidence of reviews and evaluations to document those practices. Records shall also be kept to assure traceability of harvested tomatoes.
   a. Records documenting adherence to these practices, such as those addressing preharvest assessments, employee training, for the operation must be maintained and producible in a reasonable amount of time.
   b. Traceability practices shall be utilized to ensure that all tomatoes are traceable to their origin at least one step forward and one step back.
   c. Record shall be retained for at least two years, or as required by regulation.

V. Field Packing

Field packing of tomatoes includes any practices to grade, sort, size, clean, pack or palletize tomatoes in the field into containers for commerce. Field packing is conducted in the field and may not include cleaning or washing. Field packed tomatoes are not intended to be transferred to a packinghouse for further handling. Care must be taken to ensure that practices and conditions do not contribute to contamination.

1. **Prerequisites for Field Packing Tomatoes**
   Packing of tomatoes in the field must meet all Good Agricultural Practices (GAPs) included in this document in Section III Open Field Production including field management, site and adjacent land use, water use, hygienic practices, production practices, harvesting procedures and record keeping in addition to the requirements further detailed in this Section on Field Packing.

2. **Field Packing Tomatoes**
   Employees packing tomatoes in the field shall be supervised in order to ensure the safety of the product. Field packed tomatoes may not undergo any further cleaning or sanitizing. If materials such as cloths are used repeatedly for cleaning the tomatoes, steps shall be taken to ensure that they do not become a source of contamination. Hygienic practices for field packing employees shall be followed and verified by supervisors. These hygienic practices shall include frequent handwashing and sanitizing.
   a. Culling
      Packing tomatoes in the field generally occurs with mature ripe tomatoes so extra care to cull and remove any damaged tomatoes shall occur.
   b. Hygienic Procedures
      Minimum legal requirements for field sanitization facilities and procedures

are prescribed in the Occupational Safety and Health Act, 29 CFR, Part 1928.110.

c. Packing tomatoes with bare hands (without gloves) shall require increased handwashing frequency to prevent contamination. This frequency shall be documented and be measured in time or number of units packed, such as "at least every 30 minutes or after the packing of every 20 boxes, and additionally as needed".
d. A written procedure for hygienic practices for field packed operations and records showing compliance must be available.
e. Documentation of employee training on hygienic procedures for the field packing of tomatoes shall be retained and available.

7. Gloves

There continues to be scientific debate as to whether the handling of tomatoes or other foods with bare hands, washed frequently with proper hand washing procedures, is safer than the use of gloves. If tomatoes are packed with bare hands, documentation of enhanced hand washing procedures must be made as indicated above. If gloves are utilized, a procedure for glove use must be documented and followed. The following applies to all field packing operators who handle tomatoes, both picking and packing.

a. Disposable Gloves
   i. The use of single use disposable gloves for field packing of tomatoes is recommended.
   ii. Hands shall be washed before putting on gloves.
   iii. Hand sanitizers may be used, but not as a substitute for proper washing of hands.
   iv. Disposable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.
b. Reusable Gloves
   i. Reusable gloves are not recommended for field packing but, if used, the following requirements shall apply.
   ii. The gloves must be made of materials that can be readily cleaned and sanitized.
   iii. It is the responsibility of the field packing company to ensure that gloves are washed in hot water (≥140°F) and sanitized daily by a procedure validated to eliminate any potential contamination of public health concern. Gloves shall not be permitted to be taken home by workers for cleaning and sanitizing.
   iv. Appropriately cleaned and sanitized gloves shall be issued each day and at such times as needed during the day. Reusable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.
   v. Gloves that have come in contact with the ground or other non-food contact surfaces shall be changed.

4. Exclusion from Harvest

a. Tomatoes that have fallen from the plant to the ground (i.e., "drops") shall not be harvested.
b. Tomatoes contacted by any fecal material shall not be harvested.
c. If animal intrusion is detected, measures shall be taken to remove or prevent the harvest of any potentially contaminated product.
d. Damaged, soft or decayed tomatoes should be excluded, to the degree possible.

5. Cleaning Procedures

The marketplace demands that dirt and debris be removed from a final packing of tomatoes or any fruit or vegetable. The manner in which tomatoes packed in the field are cleaned is of major importance and can be a source of either direct contamination or cross contamination with potentially harmful microorganisms.

a. Cleaning Materials Including Cloths
   i. Firms packing tomatoes in the field must have a written policy for the use and sanitization of cloths used for cleaning.
   ii. If materials, such as cloths, are used repeatedly for cleaning tomatoes, special steps shall be taken to ensure they do not become a source of direct or cross contamination.
   iii. If cloths are moistened to facilitate cleaning, only single use, potable water shall be used. Cloths shall not be moistened by repeated immersion in a bucket.
   iv. Cleaning cloths should be replaced after each box packed.
   v. It is the responsibility of the field packing company to ensure that cloths are washed in hot water (≥140°F) and sanitized before reuse, following a procedure validated to eliminate any potential contamination of public health concern. Cloths shall not be permitted to be taken home by workers for cleaning and sanitizing.
   vi. Documentation of the training of workers in appropriate use of cloths for cleaning must be available.
b. All cleaning procedures shall be documented.

6. Containers for Field Packing Tomatoes

All containers shall be stored in a manner to prevent contamination. Special attention shall be given to contamination risks from rodents, birds and other pests.

a. All packaging material is inspected upon arrival and stored in a clean manner.
b. Containers used for field packing may not be stored in the field unless protected from potential contamination.
c. Picking and packing containers shall be distinguishable from those serving other purposes.
d. Reuse of single use containers, e.g., corrugated, for the field packing of tomatoes is prohibited.

e. Reusable containers, such as reusable plastic containers ("RPCs"), shall be cleaned and sanitized by a documented procedure before reuse, and shall be properly labeled for current use.
f. Containers shall be protected from direct contact with the ground.
g. Containers shall be properly labeled with information sufficient for traceability, including identification of the firm packing the tomatoes. Reusable containers shall have inaccurate labels removed before reuse.

7. Tomato or Equipment Sanitizing Agents Used During Harvest

a. EPA considers any chemical making an antimicrobial claim, including those used to sanitize equipment and tomatoes, to be a pesticide.
b. Sanitizing chemicals used must comply with all requirements of EPA registration and any federal, state or local regulations.
c. Sanitizing chemicals must be appropriately registered for such use and must be used in accordance with label directions. Sanitizing chemicals uses shall be documented.
d. Chemicals used on product that are not registered pesticides may be permitted for food contact use if allowed under regulations of the U.S. Food and Drug Administration (FDA).

8. Equipment and Picking Containers in the Field

a. Any surface that touches tomatoes in the field is a food contact surface and must be clean and sanitary.
b. Harvest containers, food contact surfaces, and utensils shall be cleaned and sanitized at least daily or more often as needed, to remove sand, grit, dirt, and other residue.

9. Reduction of Microbiological Levels on Tomatoes in the Field

a. Tomatoes packed in the field should be washed and sanitized to reduce microbial levels.
   i. Consumer-ready containers shall be labeled to identify when the product has been field packed without washing.
b. The water used for washing tomatoes shall be of microbial quality equivalent to potable water and have sufficient sanitizer to prevent cross contamination. The water antimicrobial shall be monitored at a frequency sufficient to maintain sanitary conditions.
c. Cold water immersion as a cooling technique shall not be done.
d. Water temperature shall be maintained at least 10°F warmer than the pulp temperature of the tomato. Water temperature shall be monitored at least hourly.
e. Products used for sanitization must be appropriately registered by the Environmental Protection Agency (EPA) for such use, and must be used in accordance with label instructions for concentration and contact time.
f. A written procedure for washing and sanitization as well as records of implementation of the procedure shall be maintained.
g. Products for sanitization may include:

i. Hypochlorite
ii. Gaseous ozone
iii. Aqueous ozone (ozonated water)
iv. Peroxyacetic acid
v. Aqueous chlorine dioxide
vi. Other EPA-registered, appropriately labeled agents that have been shown to reduce the level of pathogens such as *Salmonella* or *E. coli* O157:H7 by three logs (99.9%) or more.

10. Transportation of Field Packed Tomatoes

a. Transportation vehicles should be sufficiently clean so as not to be a source of contamination.
b. Inspect transportation vehicles for cleanliness, odors, visible dirt and debris before loading. If needed, the vehicle shall be cleaned or cleaned and sanitized by a documented procedure prior to loading.
c. If non-dedicated vehicles are used for transportation, verify records of prior loads. Should there be any doubt as to previous loads transported or a potential risk from microbial contamination, such as from raw animal proteins, garbage or other refuse, then the vehicle shall be cleaned and sanitized by a documented procedure prior to use.

11. Storage

Any area used to collect or store tomatoes packed in the field must be maintained in a clean and sanitary manner.

12. Traceability, Labeling and Record Keeping

All tomatoes shall be traceable at least one step forward and one step back. This shall include appropriate labeling of each case.

a. Documentation of field packed tomatoes shall include sufficient information about the harvest (i.e., field location and history, grower, personnel/crew involved in the harvesting and packing) as well as the customer receiving the product to allow for the appropriate tracing of product.
b. Containers shall be accurately labeled with commodity name, field packer firm name and information sufficient to allow for identification of grower, ranch and field location, harvest crew and date of harvest/field pack.
c. Labels that are inaccurate shall be removed prior to packing.
d. A documented traceability system to track tomatoes forward to customers shall be developed and tested at least annually. A record of this test shall be maintained and be available.
e. Traceability records shall be readily available.
f. All records recommended in this section shall be maintained for at least two years and be readily available.

VI. Greenhouse Production

For the purposes of this guidance, a greenhouse is presumed to be enclosed. Note that this section does not apply to shade houses or other open structure, which shall

follow recommendations for field production. Harvesting of greenhouse tomatoes shall follow recommendations in Section IV Harvest Practices.

1. **Greenhouse**
   a. The greenhouse shall be enclosed.
   b. A foot dip station or other measure should be used to prevent the introduction of harmful microorganisms or agents and a written record of the sanitizer and maintenance kept.
   c. Soil or other growth medium shall be suitable for its intended purpose.
   d. Adequate hand washing stations shall be available with single use towels. These stations shall be designed to drain or capture all waste water in a manner that does not pose a contamination hazard to the greenhouse.
   e. Signs identifying policies and food safety principles shall be conspicuously posted in appropriate languages.
   f. Trash cans shall be present, adequate in number and location.

2. **Grounds**
   a. The grounds about a greenhouse under the control of the operator shall be kept in a condition that will protect against contamination of tomatoes. The methods for adequate maintenance of grounds include, but are not limited to:
      i. Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
      ii. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where tomatoes are exposed.
      iii. Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
      iv. Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where tomatoes are exposed.
   b. If the greenhouse grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (i) through (iii) of this section, care shall be exercised in the greenhouse by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.
   c. It is recommended that the land adjacent to the greenhouse should not be a significant source of contamination. Hazards may include but not be limited to livestock, wildlife, landfills, chemical plants, etc.
   d. Appropriate measures shall be taken to minimize any food safety hazards from surrounding land use or environment. These measures may include berms, fences, ditches, buffer zones or other strategies to effectively mitigate any hazards. Records shall be kept of the measures used.

3. **Pest Control**
   a. Rodent, birds, amphibians (e.g., tree frogs), reptiles and other facility pests.

i. Effective measures shall be taken to exclude pests from the greenhouse and to protect against the contamination of tomatoes by pests.
ii. The use of insecticides or rodenticides shall be permitted only under precautions and restrictions that will protect against the contamination of tomatoes, food-contact surfaces, and packaging materials.

b. Pesticides (Crop Protection Treatments)
i. Only trained or, where applicable, licensed personnel shall apply crop protection products.
ii. Standard Operating Procedures shall be developed for pesticide applicators, application equipment, storage, and usage (handling, mixing, diluting, etc.).
iii. Application instructions on the pesticide labels shall be followed including but not limited to dilution ratios, time intervals, reentry times, etc. and crop protection records shall be maintained and kept current.
iv. The greenhouse operation shall comply with all federal, state, and local regulations regarding pesticide usage and recordkeeping.
v. Pesticides shall be properly and securely stored. Empty pesticide containers shall be disposed according to the label or regulatory requirements.
vi. Water used for spray applications shall meet the microbial standards for potable water contained in 40 CFR Part 141.63.
vii. Loading, diluting, mixing, etc. of pesticides shall not be done in a manner that will potentially contaminate the water source.
viii. Cleaning of pesticide equipment shall not be done in a manner that will potentially contaminate the water source.

c. No domestic animals or other animals are permitted in areas where tomatoes are packed, handled or stored.

4. Preharvest Agricultural Water

a. Water Source
i. Document the source of water for irrigation for each crop.
ii. Identify potential sources of contamination of irrigation water
iii. Ensure that any well used is properly designed, constructed and maintained in such a way as to prevent contamination.
iv. Water source(s), storage and distribution systems shall be regularly maintained and protected from potential sources of contamination. Any material that may pose a risk of contamination such as trash, plant material, etc. shall be removed.
v. Appropriate backflow prevention devices (e.g., air gaps, backflow valves) shall be used to protect water quality at the source and during distribution and use.
vi. Ensure any water being utilized for irrigation is not contaminated with animal or human feces.
vii. Non-foliar irrigation water shall meet the standard for *E. coli* in recreational waters contained in 40 CFR Part 131.41(c), or other standard based on available science.

viii. Any foliar application of water to tomatoes, whether intentional or unintentional, should meet the microbial standards for potable water contained in 40 CFR Part 141.63.
ix. Allow for appropriate water treatment methods to bring water into compliance with required standards.

b. Microbial Monitoring
   i. Analyze and maintain records of testing of agricultural waters used with tomato production to minimize potential for microbial contamination.
   ii. Corrective actions shall be established and taken if standards are not met.
   iii. Establish a monitoring frequency for water appropriate to the source.

c. Water source(s) shall be protected from cross contamination from fertilizers, pesticides, etc.

5. Fertilizers

Assess risk of all production inputs to reduce contamination risk.

a. Chemical, Non-organic Fertilizer
   i. Follow manufacturer's instructions for usage and storage.
   ii. All fertilizers shall be properly stored and labeled.

b. Fertilizers Containing Manures, Composts or Biosolids
   i. Do not use untreated manure. Only properly treated manures and biosolids are allowed for use in tomato fields.
   ii. All manure should be properly composted and incorporated into the soil no less than 60 days prior to harvest. (California Code of Regulations Title 14, Division 7; and Title 27, Division 2.)
   iii. If treated manures or biosolids are used, records of composition, dates of treatment, methods utilized, application dates and any test results or process verification data demonstrating compliance with microbial standards must be documented.

c. Inert substrates shall be treated in such a way as not to pose a risk of contamination.

d. Fertilizer mixing areas shall not present a contamination hazard to tomatoes.

6. Tomato or Equipment Sanitizing Agents Used During Harvest

a. EPA considers any chemical making an antimicrobial claim, including those used to sanitize equipment and tomatoes, to be a pesticide.

b. Sanitizing chemicals used must comply with all requirements of EPA registration and any federal, state or local regulations.

c. Sanitizing chemicals must be appropriately registered for such use and must be used in accordance with label directions. Sanitizing chemicals uses shall be documented.

d. Chemicals used on product that are not registered pesticides may be permitted for food contact use if allowed under regulations of the U.S. Food and Drug Administration (FDA).

7. Equipment and Containers

a. Any surfaces or equipment intended to touch fresh produce is a food contact surface and must be cleaned and sanitized at a frequency sufficient to prevent the surfaces from becoming a source of contamination.
b. Reusable containers and food contact equipment and utensils shall be constructed of impervious materials that can be easily cleaned and sanitized.
c. Clean and sanitize containers, bins, food contact equipment and utensils at least daily during use, or more often as needed, to remove sand, grit, dirt, and other residue.
d. Establish routine cleaning and sanitizing procedures and maintain these standard operating procedures in writing.
e. Maintain all equipment and surfaces in such a way as to minimize contamination of and injury to tomatoes.
f. All containers shall be marked for their intended use (trash, etc.).

8. Employee Hygiene Policies and Employee Training

a. Facilities shall develop and implement written GAP/GMP and Employee Hygiene Practices.
b. All employees shall receive mandatory safe product handling and personal hygiene education at time of hire and at least annually.
c. Training sessions shall be documented, with records kept of topics covered, date, names and signatures of those in attendance.
d. Periodic (e.g., daily, weekly, monthly, quarterly, as appropriate) self audits shall be used to verify and document compliance with worker hygiene and sanitation policies and practices.

9. Handwashing and Toilet Facilities

a. Restrooms shall be available to all personnel (at least one toilet for every 20 employees) and located in proximity to greenhouse, but should not be a source of contamination. Restrooms should not open directly into greenhouse production areas. Restrooms that do open directly into greenhouse production areas should be equipped with self-closing mechanisms or have a maze-type entrance/exit.
b. Toilet facilities shall be maintained in a clean and sanitary condition and adequately stocked with soap, water for handwashing that meets the microbial standard for potable water (including hot water where available), single use towels, toilet paper, etc.
c. A written record of cleaning shall be kept.
d. Handwashing signs shall be posted in restrooms. Signs should be multilingual or pictorial, as appropriate to the workforce.
e. Other Hand-washing facilities.
   Hand-washing facilities shall be adequate in number and location, and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:
   i. Hand-washing and, where appropriate, hand-sanitizing facilities at each location where good sanitary practices require their use.

ii. Soap and water for handwashing that meets the microbial standard for potable water (including hot water where available).
iii. Single use towels or air drying devices.
iv. Handwashing signs posted at all stations. Signs should be multilingual or pictorial, as appropriate to the workforce
v. Refuse receptacles that are constructed and maintained in a manner that protects against contamination of tomatoes.

f. Provisions shall be in place for capture, disposal or drainage of gray water in a manner that prevents contamination of the environment.

10. Handwashing Practices

a. Policies shall require hand washing with soap and water at the appropriate time such as before starting work, after breaks, visiting the locker rooms, using the restrooms, sneezing, coughing, touching any unsanitary surface or material or anytime hands become soiled.
b. Sanitizers may not be used in lieu of proper handwashing, but should be used in addition to handwashing.
c. If gloves are used when contacting tomatoes or food contact surfaces, policies will clearly communicate that gloves are not a replacement for good handwashing practices, and that single use gloves must be replaced, and reusable gloves must be washed and sanitized, whenever they become soiled.

11. Gloves

There continues to be scientific debate as to whether the handling of tomatoes or other foods with bare hands, washed frequently with proper hand washing procedures, is safer than the use of gloves. If tomatoes are handled with bare hands, documentation of hand washing procedures must be made as indicated above. If gloves are utilized, a procedure for glove use must be documented and followed. The following applies to all greenhouse operators who handle tomatoes, both picking and packing.

a. Disposable Gloves
   i. The use of single use disposable gloves for hand contact with tomatoes is recommended.
   ii. Hands shall be washed before putting on gloves.
   iii. Hand sanitizers may be used, but not as a substitute for proper washing of hands.
   iv. Disposable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.
b. Reusable Gloves
   i. Reusable gloves are not recommended for hand contact with tomatoes but, if used, the following requirements shall apply.
   ii. The gloves must be made of materials that can be readily cleaned and sanitized.
   iii. It is the responsibility of the production company to ensure that gloves are washed in hot water (≥140°F) and sanitized daily by a procedure validated

to eliminate any potential contamination of public health concern. Gloves shall not be permitted to be taken home by workers for cleaning and sanitizing.

iv. Appropriately cleaned and sanitized gloves shall be issued each day and at such times as needed during the day. Reusable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.

v. Gloves that have come in contact with the ground or other non-food contact surfaces shall be changed.

12. Health Policies

a. Worker health policies shall restrict employees with symptoms of diarrhea, fever, vomiting or other potentially infectious illnesses from working with or in the vicinity of tomatoes or tomato contact surfaces.
b. Employees with open sores, cuts, burns, boils, etc., shall report to a supervisor before working. The supervisor shall determine if the employee will be allowed to work with or in the vicinity of tomatoes or tomato contact surfaces.
c. Establish and communicate a clear policy that prohibits workers who report or are observed to have diarrhea or symptoms of illness from activities that may contact tomatoes or tomato contact surfaces.

13. Other Hygienic Practices

a. Employees shall have designated areas for eating, drinking, smoking, breaks, personal effects, etc.
b. There shall be a written policy prohibiting eating, drinking, chewing gum, and using tobacco in fields or facilities except in clearly designated areas.
c. Drinking water shall be provided with either fountains or single use containers. Drinking water containers shall be handled in a manner that prevents them from becoming sources of contamination.
d. There shall be a written policy restricting jewelry in the workplace.
e. Employees shall wear clean and suitable outer garments. Consider, as appropriate to the operation, hair restraints, plastic aprons and sleeves, restricting nail polish or false nails, and empty pockets above the waist,
f. Outer garments and gloves shall be changed after cleaning drains, restrooms or other activities that may result in contamination.
g. Other good food handling techniques shall be developed as appropriate to the specific operation to prevent cross contamination.
h. Glass containers shall not be allowed in the greenhouse.
i. A glass clean up procedure shall be developed and employees trained accordingly.

14. Cleaning and Washing Procedures

When tomatoes are cleaned with cloths or by washing, the manner in which tomatoes packed in the greenhouse are cleaned is of major importance and can be

a source of either direct contamination or cross contamination with potentially harmful microorganisms.

a. Cleaning Materials Including Cloths
   i. Firms packing tomatoes in the greenhouse must have a written policy for the use and sanitization of cloths used for cleaning.
   ii. If materials, such as cloths, are used repeatedly for cleaning tomatoes, special steps shall be taken to ensure they do not become a source of direct or cross contamination.
   iii. If cloths are moistened to facilitate cleaning, only single use, potable water shall be used. Cloths shall not be moistened by repeated immersion in a bucket.
   iv. Cleaning cloths should be replaced after each box packed.
   v. It is the responsibility of the greenhouse to ensure that cloths are washed in hot water (≥140°F) and sanitized before reuse, following a procedure validated to eliminate any potential contamination of public health concern. Cloths shall not be permitted to be taken home by workers for cleaning and sanitizing.
   vi. Documentation of the training of workers in appropriate use of cloths for cleaning must be available.

b. Washing

   Internalization of bacteria into the stem scar has been demonstrated with tomatoes submerged in water that is cooler in temperature than the pulp of the tomato. When the tomato cools, a vacuum is created causing water, and potentially pathogens, to be drawn into pores on the tomatoes. Therefore, water temperature relative to pulp temperature, and water quality, are critical considerations for maintaining the safety of the product.

   i. The water used for washing tomatoes shall be of microbial quality equivalent to potable water and have sufficient sanitizer to prevent cross contamination. The water antimicrobial shall be monitored at a frequency sufficient to maintain sanitary conditions.
   ii. Cold water immersion as a cooling technique shall not be done.
   iii. Water temperature shall be maintained at least 10°F warmer than the pulp temperature of the tomato. Water temperature shall be monitored at least hourly.
   iv. A written procedure for washing and sanitization as well as records of implementation of the procedure shall be maintained.
   v. Products for sanitization of wash water may include:
      (1) Hypochlorite
      (2) Gaseous ozone
      (3) Aqueous ozone (ozonated water)
      (4) Peroxyacetic acid
      (5) Aqueous chlorine dioxide
      (6) Other EPA-registered, appropriately labeled agents that have been shown to reduce the level of pathogens such as *Salmonella* or *E. coli* O157:H7 by three logs (99.9%) or more.

c. All cleaning procedures shall be documented.

15. Packaging Materials

The greenhouse shall minimize the risk of contamination by adopting written plans that address each of the following issues:

a. All packaging material shall be inspected upon arrival and stored in a clean manner.
b. Pallets used to keep finished product off the floor shall be visually clean.
c. Bins, trays, and pallets shall be maintained in clean operational condition according to SSOPs.
d. Bins, trays, and pallets shall be stored in a secure, clean location.
e. Finished produce containers shall be distinguished from those serving other purposes.
f. Storage locations shall be kept free of evidence of pest infestation, including but not limited to rodents, birds or insects.

16. Record Keeping and Traceability

All levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (immediate next recipient) and one step back (immediate previous supplier).

a. Greenhouse Packing
   i. Documentation of greenhouse packed tomatoes shall include sufficient information about the harvest (i.e., greenhouse location and history, grower, personnel/crew involved in the harvesting and packing) as well as the customer receiving the product to allow for the appropriate tracing of product.
   ii. Containers shall be accurately labeled with commodity name, greenhouse firm name and information sufficient to allow for greenhouse identification and date of harvest/pack.
   iii. If using clean and sanitary reusable containers, ensure that labels are accurate prior to packing.
b. Packinghouse Packed Greenhouse Tomatoes
   i. The greenhouse shall maintain supply chain information available to the packinghouse to facilitate accurate traceability; i.e., quantity, greenhouse identification and date of harvest/pack.
c. Customer-ready containers shall be labeled to identify when the product has been greenhouse packed without washing.
d. A documented traceability system to track tomatoes forward to customers shall be developed and tested at least annually. A record of this test shall be kept on file.
e. All records recommended in this section shall be maintained for at least two years and be readily available.

VII. Packinghouse

A well designed and managed packinghouse and food safety program can greatly reduce the risk of chemical, physical and microbial contamination but the risk can

never be totally eliminated. Poor or inconsistent food safety practices can greatly increase this risk. Sanitary conditions and proper food safety practices are critical to product safety.

The needs of each packinghouse may vary due to location, environment, the volume of tomatoes handled, the type of tomatoes handled, local regulations and many other variables but the overall goal of any effective packinghouse food safety program is to minimize risk of contamination. There may be multiple strategies for effectively dealing with individual hazards.

The general requirements for the packing of fresh tomatoes are that facilities shall meet the requirements for packinghouse and grounds, processing, packing, holding and retailing of foods, equipment and utensils, sanitary facilities and controls, sanitary operations and processes and controls as provided for under 21 CFR Part 110 or its equivalent, as appropriate to the facility. This shall extend to all aspects of the packinghouse, including ripening and holding rooms.

1. Grounds

a. The grounds about a packinghouse under the control of the operator shall be kept in a condition that will protect against contamination of tomatoes. The methods for adequate maintenance of grounds include, but are not limited to:
   i. Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
   ii. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where tomatoes are exposed.
   iii. Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
   iv. Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where tomatoes are exposed.

b. If the packinghouse grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (i) through (iii) of this section, care shall be exercised in the packinghouse by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

c. It is recommended that the land adjacent to the packinghouse should not be a significant source of contamination. Hazards may include but not be limited to livestock, wildlife, landfills, chemical plants, etc.

d. Appropriate measures shall be taken to minimize any food safety hazards from surrounding land use or environment. These measures may include berms, fences, ditches, buffer zones or other strategies to effectively mitigate any hazards. Records shall be kept of the measures used.

2. General Maintenance

a. Buildings, fixtures, and other physical facilities of the packinghouse shall be maintained in a clean and sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food contact surfaces or packaging materials.
b. Establish Sanitation Standard Operating Procedures (SSOPs) related to the general cleaning and sanitation of the facility, including maintenance of dump tanks, bump pads, brush rollers, sponge rollers, and other equipment to minimize damage to fruit. While a cleaning schedule is part of SSOPs, the volume of tomatoes handled may require more frequent attention to cleaning. Minor surface injuries such as abrasions that might not result in the culling of a tomato have been shown to promote survival of pathogens, especially in combination with fruit waxes.
c. Cleaning compounds, sanitizers, pesticides and all other chemicals shall be labeled, handled, and stored in a manner that does not pose a risk of contamination to food, food-contact surfaces, or food packaging materials. Food-grade and non-food grade chemicals shall be kept separate in order to minimize the risk of accidentally substituting one for the other. These products shall be used in accordance with manufacturers' label instructions and all federal, state, and local regulations shall be followed.
d. Pest control
   Rodents, birds, amphibians (e.g., tree frogs), reptiles and other facility pests.
   i. A written and implemented pest control program shall be in place to protect the packinghouse from pests.
   ii. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials. Generally, only non-toxic traps and pest control devices are used inside the packinghouse.
   iii. No domestic animals or other animals are permitted in areas where tomatoes are packed, handled or stored.
e. Sanitation of food-contact surfaces.
   i. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned and sanitized in keeping with an established, documented sanitation standard operating procedure (SSOP) to protect against contamination of food.
   ii. Non-food-contact surfaces shall be cleaned and sanitized in accordance to the facility's SSOP or more frequently if necessary to protect tomatoes from contamination.
   iii. Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.
   iv. Sanitizing products shall be registered for their intended use and cleaning and sanitizing products used according to manufacturers' label instructions.

f. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

3. Water Supply and Plumbing

a. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces, intended or unintended, shall meet the microbial standards as set forth by the U.S. Environmental Protection Agency for drinking water.
b. Running water shall be available at suitable temperature and volume where it is needed for packing, cleaning, sanitation, and employee hygiene.
c. Plumbing
   Plumbing shall be of adequate size and design and adequately installed and maintained to:
   i. Supply sufficient quantities of water to required locations throughout the packinghouse.
   ii. Properly convey sewage and liquid disposable waste from the packinghouse in a manner that does not pose a risk of contamination to food, water supplies, equipment, or utensils or create an unsanitary condition.
   iii. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
   iv. Protect against backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing. Appropriate backflow prevention devices (e.g., air gaps, backflow valves) shall be used to protect water quality at the source and during distribution and use.
d. Sewage disposal
   Sewage shall be properly disposed into appropriate sewer, septic or alternative systems that do not pose a risk of contamination.

4. Trash and Tomato Waste Disposal

Trash and tomato waste shall be handled, stored and disposed in a manner that minimizes odors, minimizes the potential for attracting or harboring pests, and minimizes the risk of contamination of tomatoes, food and non-food contact surfaces, and water supplies.

5. Receiving

a. Ensure tomatoes are from suppliers following Good Agricultural Practices or other recognized, similar food safety requirements, and these guidelines.
b. Establish a written procedure for inspecting, accepting or rejecting incoming loads.
c. Ensure that incoming documentation provides sufficient information to facilitate traceability to the source.
d. Records of incoming inspections shall be maintained.

6. Packaging Materials

a. Packaging material shall be inspected upon arrival. The goal is to ensure that packaging material is free from contamination upon arrival and that materials are stored in a means as to prevent contamination.

b. The packinghouse shall minimize the risk of contamination by adopting written plans that address each of the following issues:

   i. All packaging material is inspected upon arrival, stored in a clean manner.
   ii. Pallets used to keep finished product off the floor are visually clean.
   iii. Bins, trays, and pallets are maintained in clean operational condition according to SSOPs.
   iv. Bins, trays, and pallets are stored in a secure, clean location.
   v. Finished produce containers are distinguished from those serving other purposes.
   vi. There is no evidence of rodent, bird, or insect infestations in the storage locations.

7. Postharvest Washing of Fresh Tomatoes

Water quality, both in the field and at the packinghouse, is a critical issue for achieving and maintaining safety. When tomatoes are washed, the quality of post harvest water that contacts fresh produce during postharvest flume transport, cleaning, grading, and surface treatment application is widely recognized as an essential pathogen control point for fresh produce.

a. Water Quality

   Packinghouses shall follow Good Manufacturing Practices (GMPs) to ensure that all water is of adequate quality throughout all packing operations from start-up to the last packed unit. Water used in postharvest operations must be changed as necessary for the given operation; water used in the first dump tank may need to be changed more frequently than water used in subsequent processes.

   i. Follow GMPs to ensure that all water is of adequate quality at start-up and throughout all packing operations.
   ii. Documentation of microbial test results for the source water shall be maintained available for inspection within a reasonable amount of time.
   iii. The dump tank shall be cleaned and the water changed daily and more often as needed.
   iv. Untreated surface waters are not permitted for any uses in packinghouses or other postharvest contact.

b. Water Quality Requirements

   i. While the general consensus is that a packinghouse operator shall use water of appropriate microbial quality for the postharvest processes to be performed, some packinghouses are regulated to ensure that water is in keeping with approved standards. As a matter of reference, those standards are as follows:
   ii. State of Florida and California Tomato Farmers Cooperative
   According to regulations in the State of Florida, only water that meets the

microbial standards for potable water as set forth by the U.S. Environmental Protection Agency in 40 CFR Part 141.63 (<2 MPN generic *E. coli* /100ml) may be used in the packing facility. California Tomato Farmers Cooperative has adopted the same standards.

c. Temperature and Disinfection of Water Supplies Used in Postharvest Applications.
Internalization of bacteria into the stem scar has been demonstrated with tomatoes submerged in water that is cooler in temperature than the pulp of the tomato. When the tomato cools, a vacuum is created causing water, and potentially pathogens, to be drawn into pores on the tomatoes. Therefore, water temperature relative to pulp temperature, and water quality, are critical considerations for maintaining the safety of the product.
   i. The water used for washing tomatoes shall be of microbial quality equivalent to potable water and have sufficient sanitizer to prevent cross contamination. The water antimicrobial shall be monitored at a frequency sufficient to maintain sanitary conditions.
   ii. Cold water immersion as a cooling technique shall not be done.
   iii. Water temperature shall be maintained at least 10°F warmer than the pulp temperature of the tomato. Water temperature shall be monitored at least hourly.
   iv. If water quality maintenance is based on manually monitoring chlorine levels, then free chlorine and pH must be monitored at least at start-up and every hour thereafter, and recorded. Total chlorine measurements do not accurately represent antimicrobial effectiveness. It is critical that pH be maintained in the range of 6.5-7.5 to ensure that chlorine is effective. Measuring devices must have sufficient precision to ensure levels are within established limits and accuracy should be verified periodically.
   v. If water quality maintenance is based on Oxidation Reduction Potential (ORP), maintain an ORP of at least 650 mV.
   vi. Other water disinfectants may be used, but must be registered with U.S. EPA for its intended purposes. If water quality maintenance is based on other water disinfectant treatments, follow manufacturer recommendations for monitoring and limits.
   vii. When monitoring oxidant concentrations electronically, the monitoring should be verified against a chemical test that measures disinfectant levels (and pH where applicable) at start-up and at least every 2 hours thereafter, and recorded.
   viii. Electronic monitoring devices shall be calibrated at a frequency sufficient to ensure continuous accuracy.

d. Removal of Injured/Damaged Tomatoes
Establish procedures to identify and remove injured and damaged tomatoes from dump tanks to reduce microbial contamination. To the degree possible, damaged, soft or decayed tomatoes should be removed whenever detected in order to minimize microbial contamination.

8. Employee Hygiene, Written Policies and Employee Training

a. Facilities shall develop and implement written GMP and Employee Hygiene Practices.
b. All employees shall receive mandatory safe product handling and personal hygiene education at time of hire and at least annually.
c. Training sessions shall be documented, with records kept of topics covered, date, names and signatures of those in attendance.
d. Periodic (e.g., daily, weekly, monthly, quarterly, as appropriate) self audits shall be used to verify and document compliance with worker hygiene and sanitation policies and practices.

9. Handwashing And Toilet Facilities

a. Restrooms shall be available to all personnel (at least one toilet for every 20 employees) and located in proximity to food handling areas, but not so close that they could be a source of contamination. Restrooms should not open directly into food handling areas. Restrooms that do open directly into food handling areas should be equipped with self-closing mechanisms or have a maze-type entrance/exit.
b. Toilet facilities shall be maintained in a clean and sanitary condition and adequately stocked with soap, water for handwashing that meets the microbial standard for potable water (including hot water where available), single use towels, toilet paper, etc.
c. A written record of cleaning shall be kept.
d. Restroom cleaning equipment shall be labeled and segregated so as not to pose a risk of contamination.
e. Handwashing signs shall be posted in restrooms. Signs should be multilingual or pictorial, as appropriate to the workforce.
f. Other Hand-washing facilities.
   Hand-washing facilities shall be adequate in number and location, and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:
   i. Hand-washing and, where appropriate, hand-sanitizing facilities at each location where good sanitary practices require their use.
   ii. Soap and water for handwashing that meets the microbial standard for potable water (including hot water where available).
   iii. Single use towels or air drying devices.
   iv. Handwashing signs shall be posted at all stations . Signs should be multilingual or pictorial, as appropriate to the workforce
   v. Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.
   vi. Sanitizers may not be used in lieu of proper handwashing.
   vii. Provisions shall be in place for capture, disposal or drainage of gray water in a manner that prevents contamination of the environment.

10. Handwashing Practices

a. Written policies shall require hand washing with soap and water at the appropriate time such as before starting work, after breaks, visiting the locker

rooms, using the restrooms, sneezing, coughing, touching any unsanitary surface or material or anytime hands become soiled.

b. If gloves are used when contacting tomatoes or food contact surfaces, policies will clearly communicate that gloves are not a replacement for good handwashing practices, and that single use gloves must be replaced, and reusable gloves must be washed and sanitized, whenever they become soiled.

11. Health Policies

a. Worker health policies shall restrict employees with symptoms of diarrhea, fever, vomiting or other potentially infectious illnesses from working with or in the vicinity of tomatoes or tomato contact surfaces.
b. Employees with open sores, cuts, burns, boils, etc., shall report to a supervisor before working. The supervisor shall determine if the employee will be allowed to work with or in the vicinity of tomatoes or tomato contact surfaces.
c. Establish and communicate a clear policy that prohibits workers who report or are observed to have diarrhea or symptoms of illness from activities that may contact tomatoes or tomato contact surfaces.

12. Other Hygienic Practices

a. Employees shall have designated areas for eating, drinking, smoking, breaks, personal effects, etc.
b. There shall be a written policy prohibiting eating, drinking, chewing gum, and using tobacco in fields or facilities except in clearly designated areas.
c. Drinking water shall be provided with either fountains or single use containers. Drinking water containers shall be handled in a manner that prevents them from becoming sources of contamination.
d. There shall be a written policy restricting jewelry in the workplace.
e. Employees shall wear clean and suitable outer garments. Consider, as appropriate to the operation, hair restraints, plastic aprons and sleeves, restricting nail polish or false nails, and empty pockets above the waist,
f. Outer garments and gloves shall be changed after cleaning drains, restrooms or other activities that may result in contamination.
g. Other good food handling techniques shall be developed as appropriate to the specific operation to prevent cross contamination.

13. Gloves

There continues to be scientific debate as to whether the handling of tomatoes or other foods with bare hands, washed frequently with proper hand washing procedures, is safer than the use of gloves. If tomatoes are handled with bare hands, documentation of hand washing procedures must be made as indicated above. If gloves are utilized, a procedure for glove use must be documented and followed. The following applies to all operators who handle tomatoes in the packinghouse.

a. Disposable Gloves
   i. The use of single use disposable gloves for hand contact with tomatoes is recommended.

ii. Hands shall be washed before putting on gloves.
iii. Hand sanitizers may be used, but not as a substitute for proper washing of hands.
iv. Disposable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.

b. Reusable Gloves
   i. Reusable gloves are not recommended for hand contact with tomatoes but, if used, the following requirements shall apply.
   ii. The gloves must be made of materials that can be readily cleaned and sanitized.
   iii. It is the responsibility of the production company to ensure that gloves are washed in hot water (≥140°F) and sanitized daily by a procedure validated to eliminate any potential contamination of public health concern. Gloves shall not be permitted to be taken home by workers for cleaning and sanitizing.
   iv. Appropriately cleaned and sanitized gloves shall be issued each day and at such times as needed during the day. Reusable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.
   v. Gloves that have come in contact with the ground or other non-food contact surfaces shall be changed.

14. Storage, Ripening Rooms and Distribution Facilities

a. Storage ripening rooms and distribution facilities shall be kept clean and sanitary, with debris minimized. All walls, floors, ceilings and other surfaces shall be systematically and periodically cleaned and sanitized to avoid the build-up of mold or other potential contaminants.
b. Product shall be palletized to avoid direct contact with the floor.
c. A perimeter between pallets and walls shall be maintained to facilitate visual inspection of pest control and sanitation.
d. Product on hold or rejected, shall be clearly identified and segregated from other product.
e. There shall be no storage of trash or waste in the storage or ripening rooms.

15. Transportation

a. Transportation vehicles should be sufficiently clean so as not to be a source of contamination.
b. Inspect transportation vehicles for cleanliness, odors, visible dirt and debris before loading. If needed, the vehicle shall be cleaned or cleaned and sanitized by a documented procedure prior to loading.
c. If non-dedicated vehicles are used for transportation, verify records of prior loads. Should there be any doubt as to previous loads transported or a potential risk from microbial contamination, such as from raw animal

proteins, garbage or other refuse, then the vehicle shall be cleaned and sanitized by a documented procedure prior to use.

16. Record Keeping, Product Labeling and Traceability

All levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (immediate next recipient) and one step back (immediate previous supplier).

a. Documentation maintained by the packinghouse shall include sufficient information about the source (i.e., production location, lot identification, personnel/crew involved in the harvesting) as well as the customer receiving the product to allow for the appropriate tracing of product.
b. The packer shall have established procedures to ensure that traceability information about the source is retained with product as it moves through the packinghouse processes to ~~shipping.~~
c. Corrugated containers shall be new and accurately labeled with commodity name, packinghouse firm name, and lot identification sufficient to allow for accurate traceability.
d. Only containers able to be cleaned and sanitized (e.g., reusable plastic containers, "RPCs") may be reused. If using reusable containers, they shall be cleaned and sanitized before reuse. Ensure that labels are accurate prior to reusing for packing.
e. A documented traceability system to track tomatoes back to supply source and forward to customers shall be developed and tested at least annually. A record of this test shall be kept on file.
f. All records recommended in this section shall be maintained for at least two years and be readily available.

VIII. Repacking and Other Distribution Operations

Everyone in the supply chain that handles tomatoes, including repackers, terminal markets and other facilities, has a responsibility to ensure and maintain the safety and traceability of the product.

1. Prerequisites for Repacking of Tomatoes

Repacking of tomatoes must meet all requirements included in this document in Section V – Packinghouse, including receiving, water supply and plumbing, trash and tomato waste disposal, general maintenance, packaging material requirements, postharvest washing of fresh tomatoes, employee hygiene, written policies and employee training, handwashing and toilet facilities, handwashing practices, health policies, other hygienic practices, gloves, storage and ripening rooms, product labeling/traceability, and transportation, in addition to the requirements further detailed in this Section on repacking.

2. Traceability, Lot Identification

All levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (immediate next recipient) and one step back

(immediate previous supplier). In addition to requirements described in Section VII- Packinghouse, repacking operations shall:

a. Establish procedures to maintain lot identity of tomatoes throughout the repacking process.
   i. Documentation maintained by the repacker for each lot received shall include sufficient information about the source (i.e., production location, supplier identification, lot identification) as well as the customer receiving the product to allow for the appropriate tracing of product.
   ii. Ensure that the information is retained with product as it moves through the packinghouse processes to shipping.
   iii. It is preferred that incoming lots are not mixed/commingled during repacking. However, if incoming lots are mixed/commingled, then documentation shall be maintained to identify all included sources.
   iv. Traceability records shall be readily available.
   v. Effectiveness of these procedures shall be tested at least annually. A record of this test shall be kept on file.
b. If tomato lots are not mixed/commingled, then tomatoes may be repacked into their original boxes. When original containers of a packinghouse supplier are to be reused, and the tomatoes are removed and resorted, and returned to that clean and sanitary container the repacker must label the container as being repacked, the commodity, repacker name and provide lot identification.
c. If tomato lots are commingled, then tomatoes should be repacked into new boxes that are clean and sanitary and accurately labeled with the repacker's information and lot identification that maintains the integrity of traceability information to the included sources. In the event of a recall, all lots in the commingled lot are affected.
d. Used boxes may only be used as secondary shipping containers, provided that the original identification information on the box has been obliterated or otherwise made clear that it is no longer accurate. Used boxes may only be used as primary containers for mixed/commingled lots if they are clean, sanitary and the original identification information on the box is still accurate to the original source of all of the tomatoes in the box.

3. Cleaning Materials Including Cloths

If materials, such as cloths, are used repeatedly for cleaning tomatoes, special steps shall be taken to ensure they do not become a source of direct or cross contamination.

a. Firms repacking must have a written policy for the use and sanitization of cloths used for cleaning tomatoes.
b. If cloths are moistened to facilitate cleaning, only single use, potable water shall be used. Cloths shall not be moistened by repeated immersion in a bucket.
c. Cleaning cloths should be replaced after each box packed.
d. Cloths shall be washed in hot water ($\geq$140°F) and sanitized by the firm before reuse following a procedure validated to eliminate any potential

contamination of public health concern. Cloths shall not be permitted to be taken home by workers for cleaning and sanitizing.

e. Documentation of the training of workers in appropriate use of cloths for cleaning must be available.

4. Cross-docking and Terminal Markets

a. Tomato handling at facilities that primarily redistribute tomatoes, whether or not they repack, sort or otherwise change the contents in the container, are also required to follow the recommendations in these guidelines, as appropriate to their specific operation.

IX. Fresh-cut Processing (Value-Added)

Processing fresh produce into fresh-cut products increases the risk of bacterial growth and contamination by breaking the natural exterior barrier of the produce. The release of plant cellular fluids when tomatoes are cut provides a nutritive medium in which pathogens, if present, can survive or grow. The processing of fresh tomatoes without proper sanitation procedures in the processing environment increases the potential for contamination by pathogens. In addition, the degree of handling and product mixing common to many fresh-cut processing operations can provide opportunities for contamination and for spreading contamination through a large volume of product.

There have been recorded incidents where facilities have received unwashed tomatoes, placed them into ripening rooms, then into ice water baths to firm the tomatoes for processing. Such practices may lead to water infiltration and the microbial contamination of the tomatoes. It is essential processors are familiar with their raw material suppliers, whether the tomatoes have been washed and develop appropriate steps to maintain water quality and minimize the potential for infiltration.

1. Receiving

a. Ensure tomatoes are from suppliers following Good Agricultural Practices and/or Good Manufacturing Practices, as appropriate, or other recognized, similar food safety requirements, and these guidelines.

b. Establish a written procedure for inspecting, accepting or rejecting incoming loads.

c. Ensure that incoming documentation provides sufficient information to facilitate traceability to the source.

d. Records of incoming inspections shall be maintained.

2. Facility Sanitation

Comprehensive sanitation programs, with trained sanitation personnel, reduces the risk of product microbial contamination from equipment, floors and drains. Improper use of chemicals may lead to inadequately cleaned equipment or chemical contamination of equipment. A written pest control program will reduce

the risk of rodent, insect or bird infestations of the facility, which could lead to product contamination.

a. Raw, processing and finished product segregation shall be addressed by using physical barriers or other adequate control separating these areas and the use of disinfectant foam/dip at the entrance to processing area.
b. A documented sanitation program shall be in place that meets regulatory requirements and ensures the cleanliness of product handing equipment and facility, including storage, processing and other rooms.
c. Facilities shall define and maintain cleaning frequencies: include peripherals (walls, ceilings, light fixtures, cooling units, etc).
d. Chemicals shall be registered with U.S. EPA and used in accordance with label instructions for time, temperature, concentration and application.
e. Facilities should establish a sampling program for incoming chemicals at a given frequency that verifies the suppliers' Certificates of Analysis (COA).
f. A written program shall be implemented that monitors adequacy and compliance of the sanitation program.
g. The results of the verification program shall be documented and monitored to identify areas of opportunity for continuous improvement.
h. A program (e.g., color coding) shall be in place to readily identify and segregate food contact vs. non-food contact equipment and utensils used in the sanitation program.
i. Hands shall be cleaned and sanitized prior to handling clean equipment.
j. Product shall be protected or removed during cleaning and sanitizing operations to reduce the potential for cross contamination.
k. Sanitation personnel shall not spray floors or drains with high-pressure hoses (resulting aerosol may contaminate product surfaces).
l. Sanitation personnel shall remove excess water from cleaned equipment.
m. Sanitation personnel shall not place product contact equipment directly onto the floor.
n. Facilities shall properly identify and segregate equipment used to clean drains and floors and shall not use equipment aids with wooden or hollow handles.
o. A program shall be in place that minimizes or eliminates the potential for environmental pathogens. Environmental swabs should be used to verify the effectiveness of the program.
p. A preventive maintenance program shall be in place that identifies areas of opportunities for continuous improvement; e.g., use only food grade lubricants when possible, avoid over-lubricating and wipe off excess, welds should be smooth and sanitary, catch pans shall be placed under motors and bearings which are located over product zones or traffic areas, equipment should be free of rust.
q. Facilities shall develop and implement a written pest control program to include a licensed pest control technician, adequate monitoring frequencies and pest control devices to control the infiltration of rodents and insect monitoring/ control. Pesticides shall be EPA approved for the methods, target pests, and locations where they are used.

3. Employee Health and Hygiene

a. Facilities shall develop and implement written GMP and Employee Hygiene Practices, with mandatory training for all employees at time of hire and at least annually.
b. Worker health policies shall restrict employees with symptoms of diarrhea, fever, vomiting or other potentially infectious illnesses from working with or in the vicinity of tomatoes or tomato contact surfaces.
c. Employees with open sores, cuts, burns, boils, etc., shall report to a supervisor before working. The supervisor shall determine if the employee will be allowed to work with or in the vicinity of tomatoes or tomato contact surfaces.
d. Establish and communicate a clear policy that prohibits workers who report or are observed to have diarrhea or symptoms of illness from activities that may contact tomatoes or tomato contact surfaces.
e. Written policies shall require hand washing with soap and water at the appropriate time such as before starting work, after breaks, visiting the locker rooms, using the restrooms, sneezing, coughing, touching any unsanitary surface or material or anytime hands become soiled.
f. Policies shall require employees working with open products to wear clean outer garments, gloves and hairnets.
g. Plastic aprons and sleeves may also be required.
h. Written procedures shall be developed to define conditions when outer garments and gloves shall be changed, such as after cleaning drains, restrooms or other similar areas.

4. Gloves

There continues to be scientific debate as to whether the handling of tomatoes or other foods with bare hands, washed frequently with proper hand washing procedures, is safer than the use of gloves. If tomatoes are handled with bare hands, documentation of hand washing procedures must be made as indicated above. If gloves are utilized, a procedure for glove use must be documented and followed. The following applies to all operators who handle tomatoes in processing facilities.

a. Disposable Gloves
   i. The use of single use disposable gloves for hand contact with tomatoes is recommended.
   ii. Hands shall be washed before putting on gloves.
   iii. Hand sanitizers may be used, but not as a substitute for proper washing of hands.
   iv. Disposable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.
b. Reusable Gloves
   i. Reusable gloves are not recommended for hand contact with tomatoes but, if used, the following requirements shall apply.
   ii. The gloves must be made of materials that can be readily cleaned and sanitized.

iii. It is the responsibility of the production company to ensure that gloves are washed in hot water (≥140°F) and sanitized daily by a procedure validated to eliminate any potential contamination of public health concern. Gloves shall not be permitted to be taken home by workers for cleaning and sanitizing.

iv. Appropriately cleaned and sanitized gloves shall be issued each day and at such times as needed during the day. Reusable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.

v. Gloves that have come in contact with the ground or other non-food contact surfaces shall be changed.

5. Raw, Intact Product Storage

a. Storage containers as well as storage facilities shall be designed with the proper materials and construction to facilitate cleaning.

b. Containers and product shall be stored in a manner that minimizes the potential for contamination. This may include, but is not limited to, protecting stored containers and product with liners/covers and ensuring storage areas are clean and devoid of pests.

c. Storage temperature of whole, intact tomatoes is critical to maintaining the quality of the product. Tomatoes stored at refrigeration temperatures for extended periods of time may result in decreased quality of raw product, increasing the likelihood of damaging the product during processing. Storage temperatures should also be maintained at sufficient temperatures to ensure required finished product temperatures are achieved.

6. Sorting

Use of damaged product or further damaging tomatoes with poor handling practices could provide openings for colonization and growth of pathogens. It is important to remove damaged or decayed raw material and maintain gentle handling practices to reduce the risk of contamination.

a. Secondary containers used for packing sorted tomatoes shall be maintained in clean and sanitary condition.

b. Tomatoes that show signs of physical damage such as skin breaks or decay shall be culled from processing. Culled tomatoes shall be disposed of properly so as not to serve as a contaminant.

c. The sorting process shall be performed in a manner ensuring that further damage to the tomato is minimized.

d. Lot identity shall be maintained throughout the sorting process.

e. Preventive measures shall be implemented to remove foreign/extraneous materials.

7. Whole Tomato Wash

Internalization of bacteria into the stem scar has been demonstrated with tomatoes submerged in water that is cooler in temperature than the pulp of the tomato.

When the tomato cools, a vacuum is created causing water, and potentially pathogens, to be drawn into pores on the tomatoes. Therefore, water temperature relative to pulp temperature, and water quality, are critical considerations for maintaining the safety of the product.

a. The water used in processing shall be of microbial quality equivalent to potable water and have sufficient sanitizer to prevent cross contamination. The water antimicrobial shall be monitored at a frequency sufficient to maintain sanitary conditions.
b. Whole tomatoes should be pre-cooled by air in a cold room prior to processing.
c. Cold water immersion as a cooling technique shall not be done.
d. Water temperature shall be maintained at least 10°F warmer than the pulp temperature of the tomato. Water temperature shall be monitored at least hourly.
e. Water antimicrobials shall be registered with U.S. EPA and used in accordance with manufacturer's label instructions, particularly for concentration and contact time. Tomatoes shall not be submerged in more than one foot of water for more than two minutes total time.
f. If water quality maintenance is based on manually monitoring chlorine levels, then free chlorine and pH must be monitored at least at start-up and every hour thereafter, and recorded. It is critical that pH be maintained in the range of 6.5-7.5 to ensure that chlorine is effective. Total chlorine measurements do not accurately represent antimicrobial effectiveness. Measurements must have sufficient precision to ensure levels are within established limits.
g. If water quality maintenance is based on Oxidation Reduction Potential (ORP), the wash water shall be maintained at an ORP sufficient to assure a level of at least 650 mV [see Appendix].
h. If water quality maintenance is based on other water disinfectant treatments, follow manufacturer recommendations for monitoring and limits.
i. When monitoring oxidant concentrations electronically, the monitoring should be verified against a chemical test that measures disinfectant levels (and pH where applicable) at start-up and at least every 2 hours thereafter, and recorded.
j. Electronic monitoring devices shall be calibrated at a frequency sufficient to ensure continuous accuracy.
k. If spray systems are utilized in place of whole tomato immersion, the processor shall design the line so that the entire tomato surface is rinsed.

8. Cutting

Blade condition relating to sharpness and damage should be monitored regularly. Improperly maintained blades can result in damaged and bruised tissue, which can make the product more susceptible to support microbial growth during the shelf life.

9. Cut Tomato Washing

Appropriately utilized, antimicrobial chemicals help minimize the potential for

microbial contamination of the processing water, reducing the risk of cross-contamination of the product. Processors may refer to 21 CFR 173.315 for information about approved wash water chemicals.

a. The water used in washing shall be of microbial quality equivalent to potable water.
b. Sufficient sanitizer with adequate dwell time shall be used to prevent microbial build-up over time. The sanitizer shall be monitored at a frequency sufficient to maintain sanitary conditions.
c. Wash water temperature shall be monitored to assure finished products do not exceed refrigerated temperatures (≤41°F).

10. Packaging

a. An effective system shall be maintained to prevent the use of contaminated, damaged, or defective cartons, trays and totes in order to prevent microbial contamination of the fresh-cut tomatoes during packing operations.
b. Packaging materials coming into direct contact with the fresh-cut tomatoes shall be appropriately identified, including traceability to their source.
c. Packaging containers and cartons shall be used for their intended purpose only.
d. Packaging materials shall be stored in a manner to protect them from contamination, such as away from pests, dirt, cleaning chemicals, and water condensation from overhead equipment and structures.
e. Primary or secondary finished fresh-cut tomato product containers shall be labeled with recommended storage instructions (e.g., "Keep Refrigerated") and storage temperature to inform all persons handling the product of the recommended storage conditions.
f. Primary and secondary packaging shall be coded to ensure traceability.

11. Storage Rooms and Distribution Facilities

a. Finished products shall be stored at refrigerated temperatures not to exceed 41°F.
b. Storage rooms and distribution facilities shall be kept clean and sanitary, with debris minimized. All walls, floors, ceilings and other surfaces shall be systematically and periodically cleaned and sanitized to avoid the build-up of mold or other potential contaminants.
c. Product shall be palletized to avoid direct contact with the floor.
d. A perimeter between pallets and walls shall be maintained to facilitate visual inspection of pest control and sanitation.
e. Product on hold or rejected, shall be clearly identified and segregated from other product.
f. There shall be no storage of trash or waste in the storage rooms.

12. Transportation

Finished products transported in sanitary and refrigerated coolers and vehicles reduce the risk for physical, chemical and microbial contamination.

a. Finished products shall be transported at refrigerated temperatures not to exceed 41°F.
b. Finished products shall be transported in pre-cooled vehicles equipped with a calibrated temperature recording device.
c. Transportation vehicles should be sufficiently clean so as not to be a source of contamination.
d. Inspect transportation vehicles for cleanliness, odors, visible dirt and debris before loading. If needed, the vehicle shall be cleaned or cleaned and sanitized by a documented procedure prior to loading.
e. If non-dedicated vehicles are used for transportation, verify records of prior loads. Should there be any doubt as to previous loads transported or a potential risk from microbial contamination, such as from raw animal proteins, garbage or other refuse, then the vehicle shall be cleaned and sanitized by a documented procedure prior to use.

13. Traceability and Labels

All levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (immediate next recipient) and one step back (immediate previous supplier).

a. Documentation maintained by the processor shall include sufficient information about the source (e.g., production location, packer/repacker, lot identification, as appropriate to the source of tomatoes) as well as the customer receiving the product to allow for the appropriate tracing of product.
b. The processor shall have established procedures to ensure that traceability information about the source is retained with product as it moves through the processes to shipping.
c. Primary and secondary containers shall be accurately labeled with commodity name, processor firm name or identification code, and lot identification sufficient to allow for accurate traceability.
d. Traceability records shall be readily available.
e. A documented traceability system to track tomatoes back to supply source and forward to customers shall be developed and tested at least annually. A record of this test shall be kept on file.

14. Record Keeping

Food processors are required to keep records on file to verify processes.

a. All processing, receiving and shipping records shall be maintained on file for a minimum of one year from processing.
b. A document control program should be established to ensure customer confidentiality of specifications and proprietary documents.
c. Records to be maintained shall include:
   i. Sanitation records
   ii. Pest Control records
   iii. Maintenance records
   iv. Facility inspection records
   v. Employee training records

vi. Incoming inspection records
vii. Customer complaint records
viii. Incoming water quality records
ix. Water treatment and monitoring records
x. Equipment calibration records
xi. Temperature control records
xii. Finished product inspection records
xiii. Microbiological records (environmental, product)
xiv. Distribution records

X. Foodservice and Retail

1. Purchasing

a. Ensure tomatoes are from suppliers following Good Agricultural Practices and/or Good Manufacturing Practices, as appropriate, or other recognized, similar food safety requirements, and these guidelines. Practices can be verified through documented self-inspections, audits done by qualified government or private sector food safety auditors, and/or other appropriate mechanism of assurance.

2. Receiving – Whole and Fresh-cut Tomatoes

a. Establish written procedures for inspecting, accepting or rejecting incoming loads. Procedures should include the condition of transportation vehicles as well as incoming product requirements.
b. Ensure that incoming documentation provides sufficient information to facilitate traceability to the immediate prior supplier.
c. Records of incoming inspections shall be maintained.
d. Cut tomatoes (i.e., sliced, diced or chopped) shall be received at $\leq$41°F, and requires continuous temperature control during transport.
e. Cut tomatoes >41°F at receipt shall be rejected.

3. Storage – Whole and Fresh-cut Tomatoes

a. Whole tomatoes shall be maintained at the temperature recommended for the variety and the particular stage of ripening.
b. Cut tomatoes shall be maintained at $\leq$41°F, in accordance with recommendations in the current edition of the Food Code or appropriate state and local regulations.
c. Tomatoes shall be raised off the floor and stored in a manner to prevent cross contamination from raw food products, chemicals, or unsanitary conditions.

4. Facility Sanitation

a. Sanitation of retail and foodservice facilities shall be in compliance with the current edition of the pertinent federal, state or local Food Code.

5. Employee Health and Hygiene

a. Employee health and hygiene policies and practices at retail and foodservice facilities shall be in compliance with the current edition of the pertinent federal, state or local Food Code.

6. Preparation within Foodservice/Retail Establishments

a. Facility
   i. A facility preparing tomatoes shall be designed consistent with the current edition of the Food Code and appropriate State and local regulations, including but not limited to:
      (1) Floors, walls and ceilings that can be effectively cleaned and sanitized.
      (2) Closing external doors and windows.
      (3) Water that is adequate and suitable for product and product contact surfaces.
      (4) Sufficient hot water for intended use.
      (5) Adequate storing of cleaning and sanitizing chemicals and supplies to prevent cross contamination.
      (6) Adequate hand-wash facilities.
      (7) Adequate provisions to wash sanitize and dry equipment and utensils.
      (8) Maintain an effective pest control program with no signs of insect or rodent activity.
b. Equipment
   i. When preparing or further handling tomatoes at retail, follow the Food Code or state/local requirements regarding facilities and equipment, temperature control, cleaning and sanitizing, and personal hygiene.
   ii. Equipment and utensils used to hold, cut, dice or slice tomatoes should be designed for that purpose. Equipment shall be easily cleaned, free from damage that prevents proper cleaning, and stored in a manner that will not contribute to product contamination. Examples of equipment include but are not limited to:
      (1) Cutting boards
      (2) Thermometers
      (3) Utensils
      (4) Disposable gloves
      (5) Safety gloves
      (6) Finished product containers
c. Employees preparing cut tomatoes shall adhere to safe food handling practices as directed by the most current edition of the Food Code. Employees shall:
   i. Be adequately trained in safe food handling procedures.
   ii. Be free from symptoms or diagnosed transmissible diseases as defined within the most current edition of the Food Code.
   iii. Implement and practice good hand washing procedures, such as at the start of the shift, after breaks, visiting restrooms, sneezing, coughing, handling trash or money, or anytime hands become soiled.
   iv. Not eat, drink or use tobacco products while in the food preparation or storage areas.
   v. Wear clean uniform and/or outer clothing.

vi. Minimize bare hand contact with tomatoes to be sold as ready-to-eat. Options may include clean and sanitary utensils or disposable gloves.
vii. Utilize hair and beard nets when appropriate.
viii. Practice good retail practices and food handling techniques to prevent cross contamination.

7. Gloves

There continues to be scientific debate as to whether the handling of tomatoes or other foods with bare hands, washed frequently with proper hand washing procedures, is safer than the use of gloves. If tomatoes are handled with bare hands, documentation of hand washing procedures must be made as indicated above. If gloves are utilized, a procedure for glove use must be documented and followed. The following applies to all food service/retail operators who handle tomatoes.

a. Disposable Gloves
   i. The use of single use disposable gloves for hand contact of tomatoes is recommended.
   ii. Hands shall be washed before putting on gloves.
   iii. Hand sanitizers may be used, but not as a substitute for proper washing of hands.
   iv. Disposable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.
b. Reusable Gloves
   i. Reusable gloves are not recommended for hand contact of tomatoes but, if used, the following requirements shall apply.
   ii. The gloves must be made of materials that can be readily cleaned and sanitized.
   iii. It is the responsibility of the food service/retail company to ensure that gloves are washed in hot water (≥140°F) and sanitized daily by a procedure validated to eliminate any potential contamination of public health concern. Gloves shall not be permitted to be taken home by workers for cleaning and sanitizing.
   iv. Appropriately cleaned and sanitized gloves shall be issued each day and at such times as needed during the day. Reusable gloves must be changed after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes or when the gloves have become torn, soiled or otherwise contaminated.
   v. Gloves that have come in contact with the ground or other non-food contact surfaces shall be changed.

8. Tomato Washing and Culling

To prevent exterior microorganisms from infiltrating the interior of the tomato during washing, ensure the wash water temperature is at least 10°F warmer than the internal tomato pulp temperature.

a. To prevent the growth of bacteria during the cutting, slicing or dicing operation, the following precautions should be taken:
   i. Whole tomatoes should be free of obvious signs of filth, and skin damage such as punctures, cuts or breaks.
b. Washing tomatoes before cutting shall be performed by either:
   i. Continuous running water or
   ii. If chemicals are used to wash tomatoes, they must conform to 21 CFR 173.315 and be used according to the manufacturer's label instructions for recommended concentration and contact time.
   iii. Soaking tomatoes or storing them in standing water is not recommended.

9. Storing Cut/Sliced/Diced or Repackaged Tomatoes

a. After cutting, tomatoes shall be chilled to and maintained at ≤41°F.
b. Cut tomatoes must be stored in a covered container and above other items that may cause contamination.
c. Tomatoes must be stored off the floor and in a manner to prevent cross contamination from raw food products, or unsanitary conditions.
d. Cut tomatoes that are held longer than 24 hours must indicate the date or day by which the food shall be consumed on the premises, sold, or discarded.

10. Displaying Cut Tomatoes for the End Consumer

a. Maintain cut fruit at ≤41°F during display.
b. If time only is used as a public health control and allowed by your licensing regulatory authority, written procedures shall be prepared in advance, maintained in the food establishment and made available to the regulatory authority upon request. Refer to the current edition of the Food Code for details of displaying cut/sliced/diced tomatoes without temperature control.
c. Packaged cut fruit may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water.

11. Displaying Whole Tomatoes for the End Consumer

a. Whole tomatoes should be free of obvious signs of filth, and skin damage such as punctures, cuts or breaks.

12. Traceability and Record Keeping

a. All levels of the tomato supply chain shall maintain traceability consistent with record keeping requirements in 21 CFR part 1, subpart J. Distributors to direct-to-consumer retail and foodservice operations shall maintain traceability to a minimum of one step back (immediate previous supplier) and one step forward (immediate next recipient). Direct-to-consumer retail and foodservice operations shall maintain purchase records that will facilitate traceability.
b. Each facility's ability to comply with the above (12.a) shall be verified at least annually. A record of this verification shall be kept on file.

c. All records recommended in this section shall be maintained for at least two years and be readily available.
d. Recognizing that bulk tomatoes may be commingled in a display, in the event of a recall, all lots in the commingled lot are affected.

XI. Appendix

- A Notice to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products on How to Dispose of Contaminated Food. Updated September 7, 2006. http://www.cfsan.fda.gov/~dms/fsdisas3.html
- A Notice to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products About the Safety of Food Affected by Hurricanes, Flooding, and Power Outages. Updated September 7, 2006. http://www.cfsan.fda.gov/~dms/fsdisas1.html
- Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables. 2008. http://www.cfsan.fda.gov/~dms/guidance.html
- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. 1998. http://www.cfsan.fda.gov/~acrobat/prodguid.pdf
- Suslow, Trevor V. Oxidation-Reduction Potential (ORP) for Water Disinfection Monitoring, Control, and Documentation. Univ. California Publication 8149. http://postharvest.ucdavis.edu/datastorefiles/234-406.pdf
- Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, Edition 1.0. 2006. http://www.cfsan.fda.gov/~dms/tomatsup.html
- Code of Federal Regulations. http://www.gpoaccess.gov/cfr/index.html

Federal Register

Friday,
May 9, 2003

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 11

Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 11

[Docket No. 02N–0277]

RIN 0910–AC39

Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations that would require the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States. In addition, these requirements apply to certain foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. The proposed regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and are necessary to properly address credible threats of serious adverse health consequences or death to humans and animals. FDA expects that the requirements the agency is proposing in these regulations, if finalized as proposed, would result in a significant improvement in FDA's ability to respond to and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

DATES: Submit written or electronic comments by July 8, 2003. Written comments on the information collection provisions should be submitted by June 9, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1400.

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I. Background and Legal Authority

A. Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The events of September 11, 2001, reinforced the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act") (Public Law 107–188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 306 (21 U.S.C. 335a), which amends the Federal Food, Drug, and Cosmetic Act (the act) by adding section 414, Maintenance and Inspection of Records (21 U.S.C. 350(c)). Section 414(b) of the act provides, in part, that the Secretary of Health and Human Services (the Secretary), may by regulation establish requirements regarding the establishment and maintenance, for not longer than 2 years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that must be kept by these regulations are those that are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. In section 306(d) of the Bioterrorism Act, Congress directed the Secretary to issue proposed and final regulations establishing recordkeeping requirements under section 414(b) of the act no later than 18 months after enactment of the Bioterrorism Act, that is, by December 12, 2003.

In addition, the Bioterrorism Act adds a new section 414(a) to the act that

414(a)

provides records inspection authority to FDA. Section 414(a) of the act provides that when the Secretary has a reasonable belief that a food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, persons who manufacture, process, pack, distribute, receive, hold, or import food must provide access to records related to the food that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. Section 306 of the Bioterrorism Act also amends section 704(a) of the act (21 U.S.C. 374(a)) to specifically authorize FDA inspections of all records and other information described in section 414 of the act, when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. Also, section 301 of the act (21 U.S.C. 331) is amended to make it a prohibited act to refuse to permit access to, or copying of, any record as required by section 414 or 704(a) of the act; or to fail to establish or maintain any record as required by section 414(b) of the act or to refuse to permit access to or verification or copying of any such required record; or for any person to use to his own advantage, or to reveal, other than to the Secretary or officers or employees of the Department of Health and Human Services, or to the courts when relevant in any judicial proceeding under this act, any information acquired under authority of section 414 of the act.

In addition to section 306 of the Bioterrorism Act, which amends the act as described above, FDA is relying on sections 701(a) of the act (21 U.S.C. 371(a)) in issuing this proposed rule. Section 701(a) of the act authorizes the agency to issue regulations for the efficient enforcement of the act.

B. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent an open letter to the members of the public interested in food issues outlining the four provisions in Title III of the Bioterrorism Act that require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them. In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held meetings with representatives of industry, consumer groups, other Federal agencies, and foreign embassies after sending out the July 17, 2002, letter, to solicit stakeholder comments. In response to these solicitations, FDA received a number of comments regarding section 306 of the Bioterrorism Act.

FDA has considered all the comments received by August 30, 2002. FDA will consider all comments we received so far with the comments we receive during the public comment period on this proposed rule in developing the final rule. Some of the significant comments FDA received on or before August 30, 2002, include:

- The regulations should be performance-based. There is no need to specify the form or manner in which the information must be kept by a person subject to the regulations;
- The regulations should provide flexibility for using existing recordkeeping systems;
- The regulations should give businesses the flexibility they need to store records in the manner they find most efficient;
- The regulations should divide food products into two categories, perishable and nonperishable, and establish separate recordkeeping requirements for each;
- The regulations should not have a 2-year time period for maintenance of records for fresh fruits and vegetables;
- The regulations should not require retailers to maintain records to identify which consumers bought specific food products;
- The regulations should make clear that the transporter of the food and its packaging between sources and recipients should not be considered the "immediate previous source" or the "immediate subsequent recipient" under the Bioterrorism Act;
- The regulations should make the actual physical location of the food the key to identifying the source and recipient, which may differ from ownership (i.e., corporate headquarters);
- The regulations should exclude as farms those engaged in shellfish growing and harvesting in the farm exemption;
- The regulations should define the exemption for restaurants as businesses that prepare food at the same location where such food is sold to individual consumers, and where such food may be eaten;
- The regulations should provide a phase-in period of at least 6 months to allow all businesses to make any needed adjustments to their current practices before implementation of new regulations;
- Although the regulations must take size of business into account, the regulations should not have a general exemption for small businesses;
- The regulations should allow for phasing-in of the requirements based on the size of regulated companies.

C. Highlights of the Proposed Rule

This proposal is just one of several rulemaking activities currently underway as part of the overall implementation of Title III of the Bioterrorism Act that enhance FDA's ability effectively and efficiently to respond to bioterrorist threats and other food-related emergencies in a way that promotes and protects the public health. Our intent in developing these proposed regulations is to provide the proper balance between ensuring that FDA has information it needs to complete a tracing investigation and ensuring adequate and reasonable flexibility for industry to comply with these requirements.

Section 414(b) of the act, as added by section 306(a) of the Bioterrorism Act, provides that the Secretary "may" by regulation establish recordkeeping requirements. Section 306(d) of the Bioterrorism Act, however, provides that the Secretary "shall" issue proposed and final regulations no later than 18 months from the date of enactment. FDA believes that Congress has directed the agency to exercise the authority in section 414(b). However, the agency recognizes that the use of the term "may" in one section of the statute and "shall" in another section creates an ambiguity. We request comments on our interpretation that we are required by section 306(d) of the Bioterrorism Act to exercise the authority in section 414(b) of the act.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (NAFTA). For example, FDA believes this proposed rule is not more trade-restrictive than necessary to meet the objectives of the Bioterrorism Act. FDA has endeavored to make the establishment and maintenance of records process as simple as possible for both domestic and foreign facilities.

FDA is proposing to describe the specific information a covered entity must keep, but not specify the form or type of system in which those records must be maintained. Some of the key provisions we are proposing include: (1) Requirements to establish and maintain records to identify the immediate previous source of all food, (2) requirements to establish and maintain records to identify the immediate subsequent recipient of all food, (3) requirements to establish and maintain

records to trace the transportation of all food, (4) record retention requirements, (5) record availability requirements, and (6) compliance dates. Following is an overview of the proposed regulations, which is intended to highlight the content of certain sections and request comment on those sections specifically, including comment on whether certain requirements should be included in the final regulations.

Proposed requirements to establish and maintain records to identify the nontransporter and transporter immediate previous sources of all food (§ 1.337) would require specific persons ("you") to establish and maintain records that identify the sources of all food you receive. The information that we propose as necessary to identify the nontransporter immediate previous sources includes: (1) The name, address, and phone number of the nontransporter immediate previous source; (2) the type of food received; (3) the date you received the food; (4) the lot number or other identifier of the food if available; (5) the quantity; and (6) the name, address, and phone number of the transporters who transported the food to you.

Proposed requirements to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients of all food (§ 1.345) would require that you keep records that identify the nontransporter recipients of all food you release. The information that we propose as necessary to identify the nontransporter immediate subsequent recipients is similar to that required to identify the nontransporter immediate previous sources.

Proposed requirements to establish and maintain records to trace the transportation of all food (§§ 1.351 and 1.352) would require that you keep records that trace the transportation process of all food you transport. The information that we propose as necessary to trace the transportation process includes: (1) The name, address, and phone number of the person who had the food immediately before you (the transporter's immediate previous source), and the date you received it from that person; (2) the name, address, and phone number of the person who had the food immediately after you (the transporter's immediate subsequent recipient), and the date you delivered it to that person; (3) the type of food transported; (4) the lot number or other identifier of the food if available; (5) the quantity; and (6) identification of each and every mode of transportation used (e.g., company truck, private carrier, rail, air, etc.) from the time you first received the food until the time you delivered it.

Proposed record retention requirements (§ 1.360) would require records for perishable foods not intended to be processed into nonperishable foods to be retained for 1 year after the date the records were created. FDA seeks comment on whether a person subject to these proposed regulations always or usually knows at the time perishable food is released whether or not it is intended to be processed into nonperishable food. For all other food, you would be required to retain the records for 2 years after the date the records were created. You would be required to retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location. The maintenance of electronic records would be acceptable. FDA is proposing to exempt electronic records established or maintained to satisfy the requirements of this subpart from the requirement to comply with part 11—Electronic Records; Electronic Signatures (21 CFR part 11) and proposing to amend part 11 to reflect this exemption.

Proposed records availability requirements (§ 1.361) would require that records be made available within 4 hours of an FDA request if the request is made between 8 a.m. and 6 p.m., local standard time, Monday through Friday, or within 8 hours of a request if made at any other time.

In § 1.368, the agency is proposing that firms be in full compliance with these regulations within 6 months of publishing the final regulations. However, these proposed requirements would not be effective for small businesses (those employing fewer than 500 but more than 10 full-time equivalent employees) until 12 months after publishing the final regulations. Very small businesses that employ 10 or fewer full-time equivalent employees would have 18 months to comply.

The Bioterrorism Act directs the Secretary to take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary under the new regulations. FDA is planning to reemphasize in instructions to FDA personnel the importance of current protections and legal requirements against the unauthorized disclosure of any trade secret or confidential information that is obtained.

Section 306 of the Bioterrorism Act expressly states that FDA has authority to require recordkeeping as to "food, including its packaging." FDA interprets this section as authority to require persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records to allow for the identification of the immediate previous sources and immediate subsequent recipients of food packaging as well. FDA interprets packaging in section 306 of the Bioterrorism Act to mean the outer packaging of food that bears the label. FDA is not interpreting packaging to include food contact substances, which are included in the definition of "food." Outer packaging would include, for example, the outer cardboard cereal box that bears the label of the cereal, but would not include the inner lining that holds the cereal. Outer packaging would also not include the outer shipping box in which the cereal boxes are shipped.

FDA has tentatively concluded that the risk to human and animal health from contamination of outer food packaging is relatively small compared to the risk from contamination of the immediate packaging that comes in direct contact with food. Therefore, FDA is proposing not to require covered persons to keep records regarding outer food packaging. However, the agency also recognizes that there may be instances where it may be necessary for FDA to be able to investigate agents that could lace outer packaging and could thereby contaminate a food for which the immediate food contact packaging may not provide an adequate barrier. In addition, outer packaging could be intentionally diverted and used to package food that has been tampered with. FDA seeks comment on whether the level of risk to human and animal health from potential contamination of outer packaging is high enough to warrant inclusion of outer packaging in the final regulations.

In addition to the above, we seek comment on all other provisions in the proposed regulations, such as the proposed definitions and exclusions. We also invite comment on whether the final rule should include additional provisions, such as a model form that can be used to record all the required information.

II. Description of the Proposed Regulations

A. General Provisions

1. Who is subject to this subpart? (Proposed § 1.326)

Proposed § 1.326(a) describes the scope of the rule. As required by the Bioterrorism Act, proposed § 1.326(a) would require domestic persons who

manufacture, process, pack, transport, distribute, receive, hold or import food intended for human or animal consumption in the United States to comply with the regulations in this subpart, unless you qualify for one of the exclusions proposed in § 1.327. In addition, foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are subject to these regulations, unless you qualify for one of the exclusions proposed in § 1.327.

However, even if you qualify for one of the exclusions proposed in § 1.327, if you conduct more than one type of activity at a location, and some of that activity is not exempt, you would be required to keep records with respect to the statutorily covered activities. For example, in addition to selling food to consumers, a retail facility may have an onsite restaurant or counter that prepares food it sells to consumers. The restaurant activity is exempt from all of the regulations in this subpart; however, the retail activities are covered by § 1.336. Similarly, a retail facility may sell both food and nonfood products, and may even sell primarily nonfood products. Regardless of what proportion of the retail facility sells nonfood products, these proposed regulations would require the retail facility to keep records of the immediate previous source for all food it receives that is not exempted by an exclusion. The regulations do not apply to the nonfood products the retail facility receives.

Proposed § 1.326(b) would require compliance by persons who engage either in interstate or in intrastate activities involving food. The Bioterrorism Act does not limit the establishment and maintenance of records requirement only to persons directly engaged in interstate commerce. To the contrary, the Bioterrorism Act provides FDA with the authority to require the establishment and maintenance of records by all "persons" who engage in specified activities involving food. Therefore, FDA tentatively concludes that the statute allows FDA to require domestic persons to keep records, whether or not they engage in interstate commerce. Because a bioterrorist threat involving food or other food-related emergency would have the same effect on the public health regardless of whether the food had originated from an out of state source, FDA is proposing in § 1.326(b) that all persons who manufacture, process, pack, transport, distribute, receive, hold, or import food be subject to these regulations, whether or not they directly engage in interstate activities involving food. Nonetheless, because FDA recognizes that this is an important and controversial issue, the agency is seeking comment on whether its tentative conclusion that it has authority to require recordkeeping by persons engaged in only intrastate commerce is correct. FDA also seeks comment on how many intrastate persons are not covered by one of the exemptions from the recordkeeping requirement (e.g., the farm or retail exemption) and we invite recommendations on what screening questions the agency could ask to enable a person to easily determine whether the person is engaged in interstate or intrastate commerce.

Proposed § 1.326(a) would also require compliance by foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States unless the facilities qualify for an exclusion under proposed § 1.327(f). FDA is proposing that the foreign facilities that are required to register under section 305 of the Bioterrorism Act also be required to establish and maintain records under section 306 of the Bioterrorism Act. (The foreign facilities that would be excluded from both the proposed registration and recordkeeping requirements are described in the discussion of proposed § 1.327(f).) FDA believes if these foreign firms were not required to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food, trace back of food products from outside the United States would be severely compromised. FDA believes that this approach provides the most efficient and effective strategy for obtaining needed information on food from foreign countries. FDA plans to take the appropriate steps and work closely with foreign governments to obtain access to the needed records if a threat of serious adverse health consequences or death to humans or animals from adulterated food necessitates inspection of records in foreign countries.

The provisions of this proposed rule apply to records of both human food and animal food. FDA believes that some recordkeeping requirements are necessary for food intended for food-producing animals, as well as for certain food for nonfood-producing animals (e.g., pet dogs and cats, horses, and zoo and circus animals). We define food for nonfood-producing animals as pet food. FDA believes, however, that the consequences of a potential terrorist attack or food-related emergency are greater for human food than for animal food. FDA also believes that the consequences of a potential terrorist attack or food-related emergency are greater for food for food-producing animals than for pet food. FDA addressed certain animal food risks in our regulation for animal proteins prohibited in ruminant feed (21 CFR 589.2000), also referred to as the bovine spongiform encephalopathy (BSE) rule.

Although FDA acknowledges that the risk to humans from an attack on the animal food supply is lower than the risk to humans from an attack on the human food supply, there is some risk to both humans and animals from an attack on the animal food supply. Contaminated animal food can be a link to human foodborne illness. (Ref. 32). People could be at risk through direct contact with animal food or through unintentional cross-contamination of cooking surfaces or utensils. Animals may also become infected and serve as a reservoir for exposing other animals and humans. For example, in 1996, an organochlorine pesticide was intentionally introduced into an ingredient used in animal food, including pet food. In 2002, dog chew treats were contaminated with Salmonella and became a vehicle to transmit Salmonella into homes. As a consequence, many pet owners became ill and one person died.

We propose that (1) All entities that manufacture, process, pack, transport, distribute, receive, hold, or import food for food-producing animals must keep records under this proposed rule; and that (2) those entities that manufacture, process, pack, transport, distribute, receive, hold, or import pet food that must keep records under the BSE rule also keep records under this rule. Because of the concern that some pet food is diverted for use for food-producing animals, the BSE rule recordkeeping requirements apply to pet food. We believe this proposal to require recordkeeping under the Bioterrorism Act by pet food entities covered by the BSE rule will provide important safeguards needed to limit the impact of contamination of pet food while minimizing additional costs to industry.

As discussed below, we are proposing to exempt pet food entities that are not subject to the recordkeeping requirements of the BSE rule from the recordkeeping requirements of this proposed rule. We propose that all entities involved in animal food, including the pet food entities exempt from the recordkeeping requirements, remain subject to the proposed records access and availability requirements.

FDA is interested in comments on whether or not the proposal provides adequate tools to trace animal food affected by a terrorist attack or other food related emergency and whether an

alternative approach should be used. Specifically, FDA is soliciting comments on the following questions: (1) Should we exempt all types of animal food entities from all or part of this proposed rule? (2) Should we exempt all pet food entities from all or part of this proposed rule? (3) Should we treat pet food the same as other types of animal food by requiring all pet food entities to meet the recordkeeping requirements under this regulation, not just those subject to the BSE rule? (4) Should we use criteria other than the scope of the BSE rule to determine which pet food entities should be exempt? If so, what should those criteria be?

2. Who is excluded from all or part of the regulations in this subpart? (Proposed § 1.327)

Proposed § 1.327(a) codifies the exemption for farms. This exemption is consistent with and required by the express language of the Bioterrorism Act.

Proposed § 1.327(b) codifies the exemption for restaurants. This exemption is consistent with and required by the express language of the Bioterrorism Act.

Proposed § 1.327(c) would exclude certain fishing vessels from all of the regulations in this subpart, except §§ 1.361 and 1.363. These vessels include those that not only harvest and transport fish, but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. The Bioterrorism Act is silent with respect to exempting fishing vessels in section 306, the "Maintenance and Inspection of Records for Foods" provision, although the "Registration of Food Facilities" provision, section 305, expressly exempts fishing vessels, except such vessels engaged in processing as defined in § 123.3(k) (21 CFR 123.3(k)).

FDA has tentatively concluded that the records of fishing vessels as defined in § 123.3(k), like those of farms, are not a necessary component of an effective traceback investigation. Nevertheless, because the records of "fishing vessels otherwise engaged in processing fish, which for purposes of this subsection means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding" are necessary to an effective traceback investigation, these would still be subject to all of the regulations in this subpart.

Proposed § 1.327(d)(1) would exclude retail facilities from the regulations in § 1.345 of this subpart. This limited exclusion is only from the requirement to establish and maintain records of the immediate subsequent recipients of food when the food is sold directly to consumers. The Bioterrorism Act expressly states that the Secretary may require the establishment and maintenance of records by persons who "distribute" food, and therefore retail facilities could be subject to all other regulations in this subpart if FDA required it. FDA has tentatively concluded that to require retail facilities to keep records of each individual recipient consumer would be too burdensome and not necessary in order to address credible threats of serious adverse health consequences or death to humans or animals.

Proposed § 1.327(d)(2) would exclude retail facilities, such as roadside stands, located in the same general physical location as farms, as defined in proposed § 1.328, that sell unprocessed food grown or raised on those farms directly to consumers. This exclusion only applies to those retail facilities that employ 10 or fewer full-time equivalent employees, which is consistent with the way FDA is proposing to define very small businesses in proposed § 1.368(a)(2). This exclusion applies only to unprocessed food, including fresh fruits and vegetables and other raw agricultural commodities for use as food, such as honeycomb. The exclusion also applies to fish raised on farms. Unprocessed food grown or raised on locations other than farms, or on farms not located in the same general physical location, are not excluded.

This exclusion does not apply to processed food, even if it is sold directly to consumers from a retail facility in the same general location as a farm, unless all of the ingredients in that processed food were grown or raised on that farm. Processed foods include, for example, baked goods, jams, jellies, and maple syrup. Retail facilities would be required to establish and maintain records of the immediate previous sources under proposed § 1.337 for processed food sold directly to consumers if any of the ingredients of that processed food were not grown on that farm.

FDA believes that the burden placed on these retail facilities to establish and maintain records for unprocessed food grown or raised on a nearby farm and sold directly to consumers would likely outweigh the risk to the public health that follows from this proposed exclusion. FDA has tentatively concluded that such records are not needed in order to address credible threats of serious adverse health consequences or death to humans or animals. FDA believes it is necessary to narrow this exemption only to those retail facilities that remain close to the source farm in order to not compromise FDA's ability to trace adulterated food that has been transported over a distance greater than the same general physical location. The agency solicits comments on this proposed exemption.

FDA also is proposing in § 1.327(e) to exempt from all of the regulations in this subpart persons who manufacture, process, pack, transport, distribute, receive, hold, or import food that is regulated exclusively by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). This section complies with section 306(d)(2) of the Bioterrorism Act, which states that section 306 should not be construed to authorize FDA to promulgate regulations for records governing foods within the exclusive jurisdiction of USDA. It also complies with section 315 of the Bioterrorism Act, which states that nothing in Title III of the Bioterrorism Act, or an amendment made by Title III, shall be construed to alter the jurisdiction between USDA and the U.S. Department of Health and Human Services under applicable statutes and regulations.

This exemption is for food within the exclusive jurisdiction of the USDA. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food that is jointly regulated by FDA and USDA would be required to keep records with regard to the food regulated by FDA. An example of food that is jointly regulated by FDA and USDA is frozen T.V. dinners containing both meat and fish.

Proposed § 1.327(f) would exclude foreign facilities that are also excluded from the requirement to register under section 305 of the Bioterrorism Act. As discussed previously in this document, FDA believes that requiring foreign facilities that must register to also establish and maintain records would be the most efficient and effective way to obtain information on food from foreign countries. Therefore, foreign facilities would not be required to establish and maintain records "if food from these facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States." In other words, foreign facilities involved in the initial stages of manufacturing/

processing food are not required to establish and maintain records if another facility further manufactures/processes or packs the food produced at that facility outside the United States.

This exclusion would not apply to facilities if the "further manufacturing/processing" at the subsequent facility is of a de minimis nature, such as adding labeling to a package or adding plastic rings to the outside of beverage bottles to hold them together. In that case, both the facility conducting the de minimis activity and the facility immediately prior to it would be required to register and, therefore, would also be subject to these regulations. FDA seeks comment on the requirement for facilities conducting de minimis activities to keep records. The following are examples of which foreign facilities would be subject to, or excluded from, these regulations based on the activities they perform. As stated previously, the foreign facilities that are subject to these regulations are the same facilities that would be required to register under section 305 of the Bioterrorism Act.

- A foreign facility would be subject to these regulations if it prepares a finished food and places it into packages suitable for sale and distribution in the United States.
- A foreign facility distributing food to food processors outside the United States for further manufacturing/processing before the food is exported for consumption in the United States would not be subject to these regulations, unless the further manufacturing/processing entails adding labeling or other de minimis activity. If the further manufacturing/processing is of a de minimis nature, both the facility conducting the de minimis activity and the facility immediately prior to it would be subject to these regulations.
- The last foreign facility that manufactures/processes an article of food before it is exported to the United States would be subject to these regulations, even if the food subsequently is held or stored at a different facility outside of the United States.
- Facilities located outside the United States that take possession, custody, or control of finished foods for holding, packing, and/or storage prior to export to the United States are subject to these regulations.

Proposed § 1.327(g) provides that persons who manufacture, process, pack, transport, distribute, receive, hold, or import pet food who are not subject to the recordkeeping provisions of the animal proteins prohibited in ruminant feed regulation (21 CFR 589.2000) would be excluded from the recordkeeping requirements of this proposed rule. However, these entities, like all entities involved in animal food, remain subject to the proposed records access and availability requirements in proposed § 1.361 and § 1.363.

3. What definitions apply to this subpart? (Proposed § 1.328)

Proposed § 1.328 states that the definitions of terms in section 201 of the act (21 U.S.C. 321) apply to such terms when used in this subpart. Section 201 of the act defines various terms that appear throughout the act, including "food" (see section 201(f) of the act). The definitions of such terms apply when we use those terms in these regulations. In addition, proposed § 1.328 defines specific additional terms used in the proposed rule.

Proposed § 1.328 defines "act" as the Federal Food, Drug, and Cosmetic Act.

FDA is proposing in § 1.328 to define "domestic person" consistent with the definition of "State" in section 201(a)(1) of the act. That is, FDA is proposing to define a domestic person as one that is located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

FDA is proposing in § 1.328 to define a "foreign facility" as a facility other than a domestic person that manufactures, processes, packs, or holds food for consumption in the United States.

Proposed § 1.328 defines "farm" as a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. A farm may consist of contiguous parcels of land, ponds located on contiguous parcels of land, or, in the case of netted or penned areas located in large bodies of water, contiguous nets or pens. The term "farm" includes: (a) Facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and (b) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. "Farm" includes such facilities because they are activities incidental to farming that most farms engage in (e.g., holding and packing of harvested crops). Facilities that engage in manufacturing/processing, packing, or holding of food that is not described in the definition of "farm" are subject to these regulations because such activities are not activities that most farms engage in and are thus not included in the definition of "farm." Some examples of farms include: Apple orchards, hog farms, dairy farms, feedlots, and aquaculture facilities.

Persons that engage in more than one type of activity may meet the definition of farm as to some of those activities while not meeting the definition of farm as to other activities. Persons that grow crops and raise animals and also manufacture/process food that is sold for consumption off the premises are not farms for purposes of this subpart and are not exempt. For example, a person who grows oranges and manufactures/processes them into orange juice for sale to a distributor would need to keep records under this subpart of both the immediate previous sources and the immediate subsequent recipients of the orange juice. However, establishing and maintaining records of the immediate previous sources would only be required when persons manufacture/process food from ingredients obtained from other sources than that farm.

Similarly, persons who manufacture/process food from ingredients obtained from other sources only meet the definition of farm if all the food used in such activities is consumed on that farm or another farm under the same ownership. If a person combines oranges grown on his farm with oranges obtained from another source, processes them into orange juice on his premises, and consumes all of the orange juice on those premises, he would not need to keep records regarding those oranges. However, if the person sells that orange juice at a roadside stand directly to consumers, that roadside stand would not meet the definition of farm but would fall within the partial retail exclusion provided in proposed § 1.344. Retailers need only keep records identifying the immediate previous source.

Proposed § 1.328 defines "food" as having the meaning given in section 201(f) of the act, which is: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." FDA also is proposing to include some examples of products that are considered food under section 201(f) of the act. Examples listed in the proposed rule include: Fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods;

snack foods; candy; and canned foods. "Substances that migrate into food from food packaging" include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food.

The provisions of this proposed rule apply to records of both nontransporters and transporters. Section 414(b) of the act provides that FDA may require recordkeeping with regard to records that are needed for inspection to allow the agency to identify the immediate previous sources and the immediate subsequent recipients of food. The proposed rule establishes two sets of immediate previous sources and immediate subsequent recipients, one for nontransporters and one for transporters. For nontransporters, the proposed rule defines immediate previous source as the nontransporter from which the company received the food. The immediate subsequent recipient for nontransporters is the nontransporter to which the company sent the food. The definition of nontransporter immediate previous source and immediate subsequent recipient describes them as persons who own food or who hold, process, pack, import, receive, or distribute food for purposes other than transportation. Nontransporters are also expected to keep records of the transporters that they receive food from and send food with. Nontransporters will thus be required to keep records on both transporters and nontransporters for both previous sources and subsequent recipients.

With respect to transporters (persons who have possession, custody, or control of food for the sole purpose of transporting it), the proposed rule provides for the company to establish and maintain records about its own transportation activities and the person from whom it received the food and the person to whom the food is delivered. The person from whom the food is received by the transporter is the immediate previous source. This could be a nontransporter as described previously or another transporter. The person to whom the food is delivered by the transporter is the immediate subsequent recipient. This person could be another transporter or a nontransporter. These records allow FDA to follow the chain of custody of the food through each transportation step, which may include a variety of forms of transportation (e.g., plane, train, and truck).

Because it is critically important for FDA to have the ability to trace back and trace forward quickly in the event of a terrorist event or other food-related emergency, FDA has defined for nontransporters the immediate previous source and immediate subsequent recipient as the previous nontransporter or next nontransporter. This will allow FDA in most cases to efficiently and effectively determine where the food was contaminated and to locate where the contaminated food was sent. However, the contamination could occur during the transportation process as well. The records of transporters will ensure that FDA has the potential in all cases to determine the source of contamination and trace the food back and forward through the transportation chain. FDA recognizes that requiring nontransporters to keep records on both previous and subsequent transporters and nontransporters is potentially burdensome. FDA is mandating this in order to facilitate the efficient investigation of food related emergencies (records on nontransporters) and to increase the likelihood of a successful traceback by ensuring all those who handle the food are examined (records on transporters).

We also recognize that there could be other interpretations of the statute. The statute could be read to provide that at every step of the movement of the food, the immediate previous source is the person who had the food before they delivered it to the next person. That next person would be the immediate subsequent recipient. Under that reading, if company A processes the food and sends it to company B via several modes of transportation, the chain of custody would be as follows: (1) Company A; (2) Red Truck Co.; (3) train; (4) Blue Truck Co.; and (5) company B. In this scenario, the immediate subsequent recipient for company A is Red Truck Co. The immediate previous source for Red Truck Co. is company A and the immediate subsequent recipient is the train. The immediate previous source for the train is Red Truck Co. and the immediate subsequent recipient is Blue Truck Co. The immediate previous source for Blue Truck Co. is the train and the immediate subsequent recipient is company B. If it is discovered at company B that the food is contaminated, since company B only has records to identify Blue Truck Co. as its immediate previous source, FDA would have to trace back from company B to Blue Truck Co. and from there to the train, then to Red Truck Co., until FDA finally arrives at company A, the source of the contamination. This type of tracing would not allow the agency to efficiently and effectively trace back from company B to company A or get to company A quickly to trace forward other food sent out by company A.

We are requesting comments on whether the approach with two sets of immediate previous sources and immediate subsequent recipients in this proposed rule is a reasonable interpretation of the statute. We also request comments on whether all transporters, including small independent transporters, have the capability to maintain records for the 1 and 2 year record retention periods. FDA also requests comment on the extent to which the recordkeeping burden on nontransporters (previous and subsequent transporters and nontransporters) creates new burdens for firms. We are also interested in suggestions for alternative recordkeeping arrangements that would allow for the complete and efficient investigation of food-related emergencies. In addition, we request comments on whether an approach different from the proposed rule that would require or create incentives for nontransporters to obtain and keep records on all the transporters that transport food between the nontransporters, by obtaining the records from the transporters, would be a reasonable interpretation of the statute.

Proposed § 1.328 defines "manufacturing/processing" as making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Some examples of manufacturing/processing include, but are not limited to, cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. FDA is defining "manufacturing" and "processing" together because the meanings of the terms overlap. For example, combining two materials into a finished product, such as macaroni and cheese, could be considered "manufacturing," "processing," or both. Since both manufacturers and processors are subject to these regulations, FDA does not believe it is necessary to distinguish between manufacturing and processing in the proposed rule.

Proposed § 1.328 defines "nontransporter" as a person who owns food or who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Proposed § 1.328 defines the "nontransporter immediate previous source" as a nontransporter who last had an article of food before transferring it to another nontransporter. Nontransporter immediate previous source includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity. Government entities include school systems, public hospitals, prisons, commissaries, etc.

Proposed § 1.328 defines "nontransporter immediate subsequent recipient" as a nontransporter who acquires an article of food from another nontransporter. Nontransporter immediate subsequent recipient also includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity.

Proposed §§ 1.337(a)(1) and 1.345(a)(1) would require the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source and nontransporter immediate subsequent recipient, respectively, whether domestic or foreign. We propose these requirements to mean the address and information of the specific location of where the statutorily covered activity occurred, and not that of a corporate headquarters at another location than where the activities took place. For example, a food product may be processed at a manufacturing plant, shipped to a packing facility, and then transported to a retail store all owned by the same corporation. The proposed requirements would apply to each individual location that received or released the food, even if each facility is owned by the same corporation. This would mean that firms would need to establish and maintain records accessible at each specific plant, packing facility, and retail store. FDA's intention is that these requirements identify the physical location of the food at each step of the way as it travels through the chain of distribution, from the farm or sea to the consumer. FDA requests information on whether this requirement to keep records on intra-corporate transfers will impose new burdens upon firms or whether firms keep these records currently.

Proposed § 1.328 defines "perishable food" as food that is not heat-treated, not frozen, and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions.

The "perishable food" definition has been modeled after the current Regulatory Procedures Manual definition of "perishable commodity" for purposes of this proposal. Examples include, but are not limited to, fluid milk (but not ultrapasteurized), live fish, lobster, crab, other crustaceans, shellfish, fresh fruits and vegetables. The agency is seeking comment on whether we have best defined "perishable food" for purposes of these regulations.

In addition, FDA is defining "perishable foods" for the purposes of establishing a shorter record retention time for those foods as opposed to nonperishable foods. FDA seeks comments on the proposed definition of perishable foods and whether the agency should use that definition as the basis for establishing record retention times.

Proposed § 1.328 defines "pet food" as food for nonfood-producing animals. Nonfood-producing animals include household pets, such as dogs and cats, and also include other nonfood-producing animals such as horses and circus and zoo animals.

Section 306 of the Bioterrorism Act does not extend to recipes. Proposed § 1.328 defines "recipe" as the quantitative formula used in the manufacturing of the food product, but not the identity of the individual ingredients of the food. If finalized as proposed, FDA would have access to the records containing the ingredients used in a food product, but would not have access to the quantities of the ingredients used to make a product. The act currently requires manufacturers to disclose to the public the ingredients they use on the labels of their food products. It is critical to a tracing investigation that the ingredients and the sources of the ingredients are identified.

Proposed § 1.328 defines "restaurant" as a facility that prepares and sells food directly to consumers for immediate consumption. As with farms, persons who engage in more than one type of activity may meet the definition of restaurant as to some of those activities while not meeting the definition of restaurant as to other activities. Those persons would be required to keep records as to those activities covered by this subsection that do not meet the definition of restaurant.

Some examples of restaurants as defined in the proposed regulations include: Cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens.

Due to possible ambiguity in the term "catering facilities," FDA states in the proposed restaurant definition that facilities that provide food to interstate conveyances, such as airplanes, passenger trains, and cruise ships, rather than directly to consumers, are not restaurants. Facilities that provide food to interstate conveyances are not considered restaurants because they do not serve food directly to consumers for immediate consumption. For example, a facility that provides sandwiches to a passenger train for eventual sale to passengers would not be considered a restaurant. However, the snack bar on the train that sells the sandwiches to consumers would be considered a restaurant. FDA has historically inspected these facilities that provide food to interstate conveyances and considers them processors, rather than restaurants.

Because the proposed regulations also apply to persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for animal consumption in the United States, by analogy, the term "restaurant" also includes pet shelters, kennels, and veterinary facilities in which food is provided to animals.

Proposed § 1.328 defines "retail facility" as a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries. The limited exclusion from establishing and maintaining records of the immediate subsequent recipient applies only to food sold directly to consumers. A facility that sells food to wholesalers and/or other retailers, in addition to consumers, would have to keep records of the immediate subsequent recipients because wholesalers and retailers are not considered consumers for purposes of these proposed regulations.

Proposed § 1.328 defines "transporter" as a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food. A person who owns food or who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation is not a transporter.

Proposed § 1.328 defines "transporter's immediate previous source" as the person from whom a transporter receives food. This source can be either another transporter or a nontransporter. The transporter's immediate previous source includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity.

Proposed § 1.328 defines "transporter's immediate subsequent recipient" as the person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter. A transporter's immediate subsequent recipient includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity.

Proposed § 1.328 defines "you" as a person or facility subject to this subpart under § 1.326. FDA is proposing to use "you" throughout the proposed rule for easier readability.

4. Do other statutory provisions and regulations apply? (Proposed § 1.329)

Proposed § 1.329 would require that in addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods. Regulations in this subpart are in addition to existing recordkeeping regulations, such as the regulations for low acid canned foods, juice, infant formula, color additives, bottled water, animal feed, and medicated animal feed. (See 21 CFR 113.100(d); 21 CFR 120.12; 21 CFR 106.100(g); 21 CFR 80.39; 21 CFR 129.35; § 589.2000; and 21 CFR 225.102 & 225.110, respectively).

5. Can existing records satisfy the requirements of this subpart? (Proposed § 1.330)

Proposed § 1.330 states that the regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a person subject to the regulations keeps records of all of the information as required by this subpart in compliance with other Federal, State, or local regulations, or for any other reason, e.g., as a result of its own business practices, then those records may be used to meet these requirements. Such records may include, but are not limited to, purchase orders, bills of lading, invoices and shipping documents. Some current FDA regulations require records, including those for low acid canned foods, juice, infant formula, color additives, bottled water, animal feed, and medicated animal feed. (See 21 CFR 113.100(d); 21 CFR 120.12; 21 CFR 106.100(g); 21 CFR 80.39; 21 CFR 129.35; 21 CFR 589.2000; and 21 CFR 225.102 & 225.110, respectively). However, none of the existing FDA regulations are sufficient alone to meet the requirements we are proposing in these regulations. A person who has been complying with these regulations only would have to add records addressing the new elements. The burden is on the person subject to these regulations to ensure it keeps all applicable records. Our intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these proposed regulations. We are proposing the specific information a covered person must keep, but we will not specify the form or type of system in which those records must be maintained.

B. Establishment and Maintenance of Records to Identify the Nontransporter and Transporter Immediate Previous Source of All Food

What information is required in the records established and maintained to identify the nontransporter and transporter immediate previous source? (Proposed § 1.337)

The Bioterrorism Act authorizes FDA to require by regulation the establishment and maintenance of records "needed" by the Secretary for inspection to allow the Secretary to "identify" the immediate previous sources of food. Based on FDA's interpretation of this statutory authority and what is "needed" to "identify" the immediate previous source, proposed § 1.337(a) would require that you establish and maintain records for all food as follows:

- Proposed § 1.337(a)(1) would require the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;
- Proposed § 1.337(a)(2) would require an adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);
- Proposed § 1.337(a)(3) would require the date you received the food;
- Proposed § 1.337(a)(4) would require the lot or code number or other identifier of the food (to the extent this information exists);
- Proposed § 1.337(a)(5) would require the quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle); and
- Proposed § 1.337(a)(6) would require the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the transporters who transported the food to you.

Proposed § 1.337(a) would require that you include information reasonably available to you to identify the specific source of each ingredient that was used to make every lot of finished product, so that incoming ingredients can be linked to the outgoing finished products. If FDA cannot immediately narrow the trace back to a specific source, tracing becomes much more difficult, there is an increased risk to consumers, and some food sources are unfairly implicated. FDA believes this is a necessary and beneficial requirement for consumers, and will help conserve FDA's limited resources, by focusing our investigation only on those entities who handled the at-risk food. FDA's investigation of the unaffected sources is time consuming and may have a negative business impact on the incorrectly implicated sources. These sources should not be penalized by exposure to unwarranted scrutiny and perhaps unwarranted adverse publicity because of inadequate recordkeeping by others in the distribution chain. In addition, in a recall situation, a business could limit the economic impact by being able to limit its recall to only a specific group of products instead of having to conduct a broader recall. What is reasonably available may vary from case to case.

FDA recognizes that the food industry often relies on multiple sources of ingredients to make food products, and that it is common practice to commingle ingredients from different sources prior to incorporating them into a finished product. For example, some food processors commonly store raw materials like corn syrup and flour in tanks and silos. In some instances, these tanks and silos are not dedicated by suppliers, but are topped off as supplies run low, resulting in routine commingling of raw ingredients from a number of suppliers. Moreover, it is FDA's understanding that flour or grain silo crowns do not uniformly dissipate, resulting in uneven distribution of ingredients. FDA acknowledges that changing this longstanding system to require dedicated supplier storage to facilitate source specific recordkeeping would involve significant financial costs.

It is not FDA's intent to require the reconfiguration of each manufacturing plant. These proposed regulations, however, would require you to capture the information that is reasonably available to you to connect finished products with the immediate previous source of each of the food products used to make that finished product. FDA understands that in some multiple sourcing contexts this information only may allow for a reduction in the number of potential sources for a specific food product, but may not necessarily

identify one specific source of the food product.

For example, a company that bakes cookies may source flour from five different companies rather than depend on a single company as its supplier. The flour from the five companies may be stored in one common silo prior to being used in the manufacture of the cookies. In this scenario, the manufacturer could identify, depending on the date the flour was received from each company and placed in the silo and when the silo was emptied, the various companies that were the sources of the flour. Under this situation, the information is not reasonably available to determine a single source of the flour used in a particular lot of cookies. In this case, the information reasonably available to you would be the identity of all of the potential sources of the flour for each finished lot of cookies.

Conversely, if the manufacturer did have dedicated silos for each supplier of flour, then the information would be reasonably available to the manufacturer to specify the specific source of the flour for each finished product.

Proposed § 1.337(a)(4) would require maintenance of the lot or code number or other identifier of the food (to the extent this information exists) to allow FDA the capability to limit its investigation to the implicated food. For instance, if a company repeatedly and consistently orders a particular food from a supplier, and the threat is associated with a single shipment or some shipments but not others, it is important to have the capability to isolate the shipment or shipments in question from others. This would be more cost effective and less burdensome to FDA. In addition, if the threat affects the transporter, identifying information such as lot numbers or other identifiers would facilitate the location and isolation of the conveyance that may have become contaminated by the implicated food. This cannot readily be done without information that specifically identifies the food.

Proposed § 1.337(a)(5) would require you to record the quantity of the food and how it is packaged to assist FDA in identifying the implicated food and also allow FDA to determine the scope of the threat. With this information contained in the records, FDA would be able to determine the quantity of the potentially adulterated food that is in the stream of commerce, i.e., whether it is one crate or 1,000 crates of tomatoes. In addition, as part of a tracing investigation, FDA would be able to identify at each location whether all of the potentially adulterated food has been accounted for or whether any part of a shipment had been diverted. Both the immediate previous source and immediate subsequent recipient would be required to keep records of the quantity of food received or released to allow FDA to determine that the quantity of food sent was the quantity received. This would ensure that FDA is best able to protect public health by being able to identify and locate adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

Proposed § 1.337(a)(6) would require you to keep in your records information to identify the transporter who transported the food to you. This requirement to identify the transporter is in addition to proposed § 1.337(a)(1), which requires you to keep in your records information that identifies the nontransporter immediate previous source.

C. Establishment and Maintenance of Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipient of All Food

What information is required in the records established and maintained to identify the nontransporter and transporter immediate subsequent recipient? (Proposed § 1.345)

The Bioterrorism Act authorizes FDA to require by regulation the establishment and maintenance of records "needed" by the Secretary for inspection to allow the Secretary to "identify" the immediate subsequent recipient of food. Based on FDA's interpretation of this statutory authority and what is "needed" to "identify" the immediate subsequent recipient, proposed § 1.345(a) would require that you establish and maintain records for all food you release that identifies information that is substantially similar to that discussed in the requirements to identify the nontransporter immediate previous source.

D. Requirements to Establish and Maintain Records to Trace the Transportation of All Food

1. Who is required to establish and maintain records for tracing the transportation of all food? (Proposed § 1.351)

The Bioterrorism Act expressly states persons who transport food are subject to these regulations. Proposed § 1.351 would require you, if you are a domestic person, to establish and maintain records for tracing those immediately before (transporter's immediate previous source) and immediately after you (transporter's immediate subsequent recipient) in the transportation process if you transport food.

2. What information is required in the transportation records? (Proposed § 1.352)

Proposed § 1.352(a) would require that you establish and maintain the following records for each food you transport:

- Proposed § 1.352(a)(1) would require the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the person who had possession, custody, or control of the food immediately before you, and the date you received it from that person;
- Proposed § 1.352(a)(2) would require the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the person who had possession, custody, or control of the food immediately after you, and the date you delivered it to that person;
- Proposed § 1.352(a)(3) would require an adequate description of the type of food, including brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);
- Proposed § 1.352(a)(4) would require the lot or code number or other identifier of the food (to the extent this information exists);
- Proposed § 1.352(a)(5) would require the quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle); and
- Proposed § 1.352(a)(6) would require the identification of each and every mode of transportation (e.g., company truck, private carrier, rail, air, etc.), and the individual responsible, from the time you first received the food until the time you delivered it.

The proposed requirements are intended to provide the necessary information to allow FDA to trace the transportation of all food. In proposed § 1.352(a)(1) and (a)(2), the required information would consist of whoever had the food before you and after you. This person could be either a nontransporter or another transporter. In a multiple transporter situation, you may be receiving the food from another transporter and/or delivering it to another transporter. The proposed requirements in § 1.352(a)(1) and (a)(2) are intended to capture this information regardless of whether you receive food from a nontransporter or another transporter, or deliver it to a nontransporter or another transporter. You would only be responsible for maintaining a record of the required information with respect to the person

from whom you received the food from and the person to whom you gave it. You would not be required to maintain records of transactions to which you were not a party.

Proposed § 1.352(a)(6) would require transportation companies that use several modes of transportation within their company to record when the food was put on which kind of vehicle and who was responsible for it during that leg of the trip. For example, Yellow Transportation Co. may use two different Yellow trucks and a Yellow plane. This section would require Yellow Transportation Co. to keep records of each and every mode of transportation and the individual responsible, from the time the food was first received until the time it was delivered. The "individual responsible" should be the person within the transportation company who is responsible for that vehicle and the food being transported. FDA seeks comments on whether "individual responsible" should be the operator of the conveyance or whether it can be someone within the corporation who has overall responsibility for the vehicle and the food being transported. FDA understands that it is common practice for one transportation company to use several different modes of transportation within that company throughout its possession and control over the food. The food is potentially subject to tampering at each phase of the transportation process. If the transportation company responsible for the food does not have complete records identifying the mode of transportation and who was responsible for the food throughout the entire time that company had possession and control over the food, the tracing chain is broken and it becomes more difficult and time consuming to determine if that shipment of food has been diverted or tampered with. FDA believes this detailed information regarding the food transportation would be necessary to expedite the tracing investigation in situations when FDA has a reasonable belief that food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

E. General Requirements

1. What are the record retention requirements? (Proposed § 1.360)

Proposed § 1.360(a) states the records required by these regulations are to be created at the time the statutorily covered activities take place. Proposed § 1.360(b) would require records for perishable foods not intended to be processed into nonperishable foods to be retained for 1 year after the date the records were created. Although perishable foods have a relatively short shelf life, FDA is proposing a 1 year record retention period for these foods. In some situations, the health hazard may not be immediately apparent but may emerge months after the food has been consumed. In other situations, the harm may have been caused by novel contaminants or novel vehicles for known contaminants, and it may take months to identify the sources of contamination. As an example, in 1995, there was an investigation of an outbreak of cyclosporiasis. At the time, FDA did not know that Cyclospora could contaminate raspberries. An investigation concluded that water was the likely vehicle. In 1996, there were numerous additional cyclosporiasis outbreaks in the United States and the link was made to raspberries from Guatemala. Fresh raspberries had been served at the site of the 1995 outbreak and then, a year later, FDA needed to determine their source. The distributor had no records to facilitate the traceback.

The proposed 1-year period would not apply to perishable foods that are intended for processing into nonperishable foods, e.g., jams and jellies made from fruits. In those instances, the longer record retention period of 2 years is needed to ensure the recordkeeping chain for finished food products made using perishable foods is available during tracing investigations. If you are uncertain whether a perishable food is destined or intended for processing into a nonperishable food, the 2-year record retention period applies. FDA seeks comment on the impact of this provision.

Proposed § 1.360(c) would require that you retain records for all foods (except animal foods as discussed below) not covered by proposed § 1.360(b) for 2 years after the date the records were created. This proposed requirement is consistent with the authority given in the Bioterrorism Act. Based on information provided to FDA by the food industry, the minimum time for processed food products to clear the food production and distribution/retail system is 3 years. In addition, the average distribution time between harvesting and final retail sale of frozen fruits and vegetables is approximately 3 to 24 months. These are average times, and individual products may be in commerce for a longer period. FDA believes that allowing anything less than a 2-year record retention period for nonperishable food, as well as perishable foods intended to be processed into nonperishable food, would severely compromise a tracing investigation.

Proposed § 1.360(d) would require that you retain records required by these regulations for animal food, including pet food, for 1 year after the date the records are created. Food for food-producing animals tends to have a faster turnover rate than many kinds of human food. In addition, since pet foods are typically the sole source of food for pets, such foods tend not to be stored as long as many human foods. Therefore we propose that records for all animal food, including pet food, be retained for only one year after the date the records are created. This is consistent with the BSE rule.

Proposed § 1.360(e) would require that you retain all records required by these regulations at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location. We recognize that there may be more records than available storage space at the location where the covered activities occur. We are therefore proposing that records may be stored offsite, provided you can comply with the record availability requirements in proposed § 1.361.

Proposed § 1.360(f) provides that the maintenance of electronic records is acceptable. In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA issued regulations at part 11 that provide criteria for acceptance by FDA of electronic records under certain circumstances. To minimize the burden of this proposed rule, FDA proposes to exempt electronic records established or maintained to satisfy the requirements of this subpart from the requirement to comply with part 11. FDA believes that a requirement that records kept under this subpart comply with part 11 would hinder the ability of persons subject to these regulations to utilize existing systems and records to satisfy the requirements of these proposed regulations as contemplated in proposed § 1.330. If the agency decided to require all electronic records to satisfy part 11 before they could satisfy these proposed recordkeeping requirements, large numbers of already existing electronic records and recordkeeping systems would have to be recreated and redesigned. This provision would require that records kept for some other statutory or regulatory purpose, but which also may be used to meet the requirements of this subpart, must comply with part 11 as required.

2. What are the record availability requirements? (Proposed § 1.361)

Proposed § 1.361 states that when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records or other information accessible to FDA under section 414 or 704(a) of the act must be readily available for inspection and photocopying or other means of reproduction. Although the statutory requirements in section 414 and amended section 704(a) of the act regarding records access are self-executing and are currently in effect, FDA is issuing regulations to further refine some aspects of the food records access requirements. Because section 306 of the Bioterrorism Act includes two records inspection authorities, one of which, section 704(a), cross refers to records described in section 414, we request comment on the interconnection between the records access provisions in sections 414 and 704(a) of the act.

Proposed § 1.361 would require records to be made available within 4 hours of a request if the request is made between 8 a.m. and 6 p.m. (local standard time), Monday through Friday, or within 8 hours of a request if made at any other time, by an officer or employee duly designated by the Secretary who presents appropriate credentials and a written notice. In the event of a threat of serious adverse health consequences or death to humans or animals, FDA believes these time limits are necessary to effectively and efficiently perform a tracing investigation.

The most common problem encountered by the FDA in a tracing investigation has been a lack of ready access to records. Records are often stored offsite or are stored in a database where the records are difficult to retrieve. In FDA's experience, rarely do firms make records available within 24 hours. The usual timeline is 2 to 3 days. This delay severely reduces the speed at which FDA can perform a traceback. If every firm were to take 2 days to give FDA the needed records, even with a short traceback (e.g., 3 firms), it could take FDA up to 2 weeks to trace the product to its source, taking into account time for record review and travel to the firms. This time may be increased if the records are incomplete and FDA has to wait for missing records to be retrieved. This possible delay would be a substantial concern if FDA were attempting to remove adulterated food that presents a threat of serious adverse health consequences or death to humans or animals from commerce.

Proposed § 1.361 would also require that if you store the records required by these regulations offsite, you must be able to retrieve and provide the records onsite within the specified time period. Electronic records are considered to be onsite if they are accessible from an onsite location.

3. What records are excluded from this subpart? (Proposed § 1.362)

Proposed § 1.362 would exclude from the proposed regulations recipes for food as defined in proposed § 1.328, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales). These exclusions are consistent with the express language in the Bioterrorism Act.

4. What are the consequences of failing to establish or maintain records or make them available to FDA? (Proposed § 1.363)

Consistent with the express language in the Bioterrorism Act, proposed § 1.363 states (a) the failure to establish or maintain records as required under section 414(b) of the act or to refuse to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act (21 U.S.C. 331) and (b) the failure to make records or other information available to FDA as required by section 414 or 704(a) of the act is a prohibited act under section 301 of the act (21 U.S.C. 331).

5. What are the compliance dates for this subpart? (Proposed 1.368)

Under sections 414 and 704(a) of the act, FDA may have access to and copy all records and other information related to an article of food if the Secretary has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The basic requirement that access to records and other information be given under these circumstances is currently in effect and does not require implementing regulations. FDA has chosen to further define access requirements in regulations, but can use its inspectional authority prior to the effective date of these regulations.

FDA carefully considered the size of a business when developing these proposed regulations. FDA found that most products and ingredients pass through at least one small business when moving through the distribution process (see Initial Regulatory Flexibility Analysis discussion in section III.B. of this document). If FDA were to exempt small businesses from these regulations or to permit shorter record retention times for them, the effectiveness of the regulations would be severely compromised due to the breaks in the recordkeeping chain during tracing investigations. Thus, FDA cannot propose totally exempting any business based on size from these requirements. However, FDA does propose to provide small and very small businesses additional time to come into compliance with these regulations.

Thus, proposed § 1.368(a) would require that firms that do not qualify as small businesses be in full compliance with these regulations within 6 months after the publishing date of the final rule. Proposed § 1.368(a)(1) would require that small businesses employing fewer than 500 but more than 10 full-time equivalent employees be in full compliance with these regulations within 12 months after the publishing date of the final rule. Proposed § 1.368(a)(2) would require that very small businesses, defined as those employing 10 or fewer full-time equivalent employees, be in full compliance with these regulations within 18 months after the publishing date of the final rule.

III. Analysis of Economic Impact

A. Benefit-Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

Need for the regulations: The purpose of these proposed regulations is to enable FDA to respond to, and help contain, adulterated food that presents a threat of serious adverse health consequences or death to humans or

animals. The benefits of these proposed regulations would be realized by accomplishing this purpose.

Reason for the regulations: FDA is proposing several regulations that will work in harmony to improve food safety. Food safety is mostly a private good. Establishments have powerful incentives to ensure that the ingredients they purchase are not contaminated and that their production processes are protected from unintentional and intentional contamination. Deliberate (intentional) contamination of food linked to a particular product or plant—particularly if the plant is considered negligent—would be extraordinarily costly to a firm. Indeed, the private incentives to avoid deliberate contamination should be similar to the private incentives for food safety. Deliberate food contamination events nonetheless differ from ordinary outbreaks of food-borne illness in that they are more likely to be low probability events with severe public health consequences.

Although private incentives lead to the private efforts to protect against deliberate contamination at the plant level, there are external effects associated with privately produced protection. The most important external effect of protection against deliberate contamination is information. Getting food from the farm or sea to the plate involves a complex system of production and distribution. The system works using local knowledge and information; each participant needs to know only as much about the overall system as is necessary for his or her business. Market prices convey most of the information necessary for the ordinary production and distribution of food. In the event of an actual or suspected contamination of the food supply, however, more complete information is needed where it can be centrally used. The suspect food must be traced backward and forward through the distribution chain, both to protect consumers and to find the source and cause of the event.

No individual firm or organization has sufficient financial incentive to establish a central information system relating to food safety for the entire economy. The nation's food producers and importers as a whole would benefit from such a system because it would be easier to uncover and solve problems, but the private costs to create the system would probably be prohibitive for any single firm or third party organization.

We estimate that an effective system of information would require several hundred thousand participants to gather information and provide it to a central system. The private transaction costs to bring all the participants together voluntarily and get them to agree to create such a system would be extraordinarily high. No single organization could capture additional revenue sufficient to cover the cost. Also, because the provision of information by some participants makes it available for all, there would be a tendency for establishments to try to be free riders in the information system. But the more information and participation in the system, the more effective it is.

Another way of looking at the problem of participation is in terms of marginal private benefits and marginal social benefits. By gathering and providing the information used in a food safety system, an individual establishment receives additional private benefits from enhancing the safety of its own food. In addition, participating in the system increases the effectiveness of the entire information system. In other words, the system works better the more establishments participate in it. The individual establishment does not capture this additional social benefit. The marginal private benefit (enhanced safety for individual establishments) is less than the marginal social benefit (the marginal private benefit plus the increased effectiveness of the entire information system). The difference between private and social benefit reduces the incentive for establishments to participate in a voluntary private system.

The events of September 11, 2001, led Congress to conclude that public creation and provision of an information system is necessary. The Bioterrorism Act and its implementing regulations would establish an information system that would allow FDA to have an integrated picture of the food distribution system. This particular regulation addresses one important aspect of this information system: The need to keep product and ingredient distribution records. However, as stated above, FDA is proposing several regulations to address these needs so the costs and benefits of any one regulation will be closely associated with related provisions in other proposed rules. With the regulations in place, the agency would have the additional tools necessary to help deter and respond to deliberate threats to the nation's food supply as well as to other food safety problems.

Baseline: FDA considers the baseline for this analysis the current state of the world, and we assume this baseline has zero costs and benefits. We also consider having no new recordkeeping requirements as option 1 in our analysis. Section 414(b) of the act, as added by section 306(a) of the Bioterrorism Act, provides that the Secretary "may" by regulation establish recordkeeping requirements. Section 306(d) of the Bioterrorism Act, however, provides that the Secretary "shall" issue proposed and final regulations no later than 18 months from the date of enactment. FDA believes that Congress has directed the agency to exercise the authority in section 414(b) of the act, so the current state of the world as considered in option 1 is not legally viable. The agency recognizes, however, that the use of the term "may" in one section of the statute and "shall" in another section creates an ambiguity. We request comments on our interpretation that we are required by section 306(d) of the Bioterrorism Act to exercise the authority in section 414(b) of the act. However, the Office of Management and Budget (OMB) cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity costs of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. Option 1 will serve as the baseline against which other options will be measured for assessing costs and benefits.

Options: The following section analyzes regulatory options that address the need for the recordkeeping regulation:

1. No recordkeeping requirements. Take no new regulatory action.

2. Require all persons that manufacture, process, pack, hold, receive, distribute, transport, or import food destined for consumption or use in the United States to establish and maintain records identifying the immediate previous source and the immediate subsequent recipient of the food, and its outer packaging. Also require all persons that manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging destined for use in the United States to establish and maintain records identifying the immediate previous source and the immediate subsequent recipient of that outer food packaging. The records requirements apply to both foreign and domestic persons. For domestic persons, this includes those who engage in the specified food-related activity whether or not those activities occur solely intrastate. Persons engaging in more than one type of activity, some of which is covered by this proposed

regulation, would be required to keep records pertaining to the covered activity even if they are not required to keep records relating to exempt activity. Records must include information reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product. Required times for record-retention would be 1 year for perishables destined for final consumption in their perishable state, and 2 years for all other foods or food packaging. Upon a written request, records must be made available to FDA in 4 hours, if the request is made during the normal business hours of 8 a.m. to 6 p.m., or 8 hours otherwise.

3. Require all elements of option 2, except exclude persons that manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging.

4. Require all components of option 3 but do not require persons that are required to establish and maintain records on food to establish and maintain records on the food's outer packaging.

5. Require all components of option 4, but change the required time for responding to an FDA records request to 24 hours.

6. Require all components of option 4, but exempt intrastate businesses.

7. Require all components of option 4, but exempt persons who operate farms, and persons who operate restaurants, who also perform a covered activity.

8. Require all components of option 4, but change the record retention requirement to 1 year for all products.

9. Require all components of option 4, but change the record retention requirement to 2 years for all products.

10. The proposed rule. Require all components of option 4, but only cover foreign facilities also covered by the proposed registration regulation published at 68 FR 5377 (February 3, 2003).

11. Require all components of option 4, but only cover foreign facilities that are the final holder of the product before export to the United States.

12. Require all components of option 4 but cover only domestic persons.

13. Require all components of option 4, but the required information would include the records necessary for facilities to be able to link specific raw ingredients to specific outgoing finished products for all raw ingredients and all products. This option is to analyze the costs and benefits of requiring records that link specific raw ingredients to specific finished products, including ingredients from different sources that are currently commingled before being incorporated into finished products.

In order to clearly identify the marginal cost of each provision specified in the codified, most options represent only one modification of a provision in another option. Option 4 is appropriate to use for comparison with the other options, since it differs by only one provision from almost all other options considered. As the Analysis of Economic Impact section will reflect, FDA has examined the economic implications of this proposed rule by analyzing several regulatory options that address the need for the recordkeeping regulation. FDA is proposing option 10. FDA believes that this option would require creation and maintenance of the records needed to address credible threats of serious adverse health consequences or death to humans or animals while providing adequate flexibility and minimizing industry burden. FDA requests comments on other viable options not considered by this analysis. Note that additional options designed to lower the regulatory burden on small businesses are considered in the initial regulatory flexibility analysis below.

Cost assumptions: The total cost of each of these options will depend on the number of facilities affected and the extra burden these options place on facilities. For all options, FDA would only specify the information a covered entity must keep, but not specify the form or type of system in which those records must be maintained; we expect that for all options, if possible, firms will choose to collect the additional information not currently included in their existing records. Furthermore, FDA assumes that firms will choose to comply with any new requirements by modifying shipping or purchase records such as Bills of Lading, Invoices, or Purchase Orders. In its cost computations, FDA does not take into account other Federal, State, or local regulations that require similar recordkeeping practices for small sectors of the food economy (e.g., "the BSE rule", § 589.2000) because of the relatively large amount of uncertainty in our knowledge of existing State and local recordkeeping requirements, and because the effect on the cost computations from their inclusion is likely to be very small. For this reason the analysis does not distinguish among entities that may be covered by the recordkeeping requirements in "the BSE rule" which may result in a small overstatement of the costs of the proposed rule. The following discussion of facility counts and per facility costs is not tied to any specific option, but describes the data and assumptions we use to analyze the cost of each option.

Number of facilities and number of firms affected: FDA assumes that for the options that do not consider exemptions, approximately 1,230,000 facilities owned by approximately 960,000 firms would be covered. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food or food packaging, and foreign facilities performing any of these activities on food or food packaging destined for consumption or use in the United States. Table 1 contains a summary and breakdown of this estimate.

TABLE 1.—AFFECTED FACILITY AND FIRM DETAILS

Type	Facility Estimate	Facility to Firm Adjust. Factor	Firm Estimate	North American Industry Classification System (NAICS) Codes if Applicable
Domestic				
Manufacturers	43,376	1.17	36,948	3111–3119, 3121
Wholesalers/Warehouses	95,745	1.24	76,952	4224, 4225, 4228, 49312, 49313
Packaging[1]	73,813	1.07	69,266	32221, 32222, 326111, 326112, 326130, 326140, 326150, 326160, 3272, 331315, 331316, 332431, 332439, 42261, 323110, 323111, 323112, 323113, 323114, 323115

TABLE 1.—AFFECTED FACILITY AND FIRM DETAILS—Continued

Type	Facility Estimate	Facility to Firm Adjust. Factor	Firm Estimate	North American Industry Classification System (NAICS) Codes if Applicable
Transporters/Packers	16,773	1.11	15,171	481112, 481212, 483111, 483113, 483211, 4841, 48422, 48423, 488320, 488510, 488991
Retail Grocery and Specialty Food	207,657	1.35	153,277	44511, 445220, 445230, 44529, 445310, 446191,
Convenience Stores	128,985	1.87	68,866	44512, 447110
Mixed-Type Facilities that Have Farms	30,497	1.25	24,397	—
Importers	5,036–32,768	1.25	4,029–26,214	—
Total Domestic	601,883–629,615		448,905–471,090	
Foreign				
Final Holders	77,427	1.25	61,942	
Manufacturers	125,450	1.17	106,858	
Other Facility Types	457,836	1.25	366,269	—
Total Foreign	660,713		535,068	

[1] Includes both outer packaging and food contact substances.

Data sources for the number of facilities and firms affected: Except for the firm-to-facility adjustments explained below, the unit of observation for all data used for this analysis is the number of establishments performing a particular activity. To estimate the number of establishments, FDA uses several sources: The 2000 County Business Patterns (Ref. 1) and the 1999 Nonemployer Statistics from the U.S. Census Bureau (Ref. 2), the FDA Field Accomplishments and Compliance Tracking System (FACTS), the FDA Operational and Administrative System for Import Support (OASIS), and the 1997 National Agricultural Statistics Service (NASS) Survey (Ref. 3). All datasets used in this analysis were the latest available as of the time of writing.

The Census Bureau creates the 2000 County Business Patterns (CBP) by analyzing data from the Business Register, the Census Bureau's file of all known single and multiestablishment companies with at least one employee. Data for single-location firms are obtained from the Economic Censuses, the Annual Survey of Manufacturers, Current Business Surveys, and administrative records from the U.S. Internal Revenue Service, Social Security Administration, and the Bureau of Labor Statistics.

Facilities not included in the CBP are counted in the Nonemployer Statistics, also from the Census Bureau. Nonemployer businesses are companies with no paid employees. The Census Bureau primarily obtains data about nonemployer businesses from business income tax returns filed with the Internal Revenue Service.

The FDA FACTS tracking system is an online database designed to monitor compliance related information for each facility that is regulated by FDA. The database contains an updated list of regulated facilities. FACTS and the Census Bureau use different categories for facilities, making a direct comparison of FACTS with the CBP and Nonemployer Statistics difficult. In our estimates, FACTS facility counts are the primary source of data on importers and foreign facilities, and interstate manufacturers, wholesalers, and warehouses.

Manufacturing, warehouses, wholesalers, and packaging facilities: The primary source for the total (both intrastate and interstate) number of manufacturers, warehouses, wholesalers, and packaging facilities is the 2000 CBP and 1999 Nonemployer Statistics for the NAICS codes identified in table 1 of this document. The NAICS codes identify industry groups and subgroups. Often the data are more aggregated in the 1999 Nonemployer Statistics than in the CBP; when the nonemployer statistics only exist for an aggregated NAICS code, we adjust the total number of facilities identified in the aggregated nonemployer category by the ratio of CBP counts in the relevant subcategory and aggregated category. For example, the 1999 Nonemployer Statistics identified 4,700 facilities under code 4931, but does not break the total down further. Our adjustment changes the 4,700 facilities to 964 [4,700 x (1,461/7,123)] facilities in subcategories 49312 and 49313. The sum of the number of facilities under the codes 49312 and 49313 in the CBP is 1,461, and 7,123 is the number of facilities under the aggregated code 4931 in the CBP.

The term "packaging" described by the data used in this analysis varies from FDA's interpretation of "packaging" in section 306 of the Bioterrorism Act because it is broader and includes food contact substances, which fall within the act's definition of food. In this economic analysis, we use the term "manufacturer and distributor" of outer packaging to refer to all persons who manufacture, process, pack, hold, receive, distribute, transport, or import "packaging" as that term is used in the Bioterrorism Act. FDA was unable to find any data that discriminated between outer packaging manufacturers and distributors and those that manufacture or distribute materials that FDA currently regulates as food contact substances, including plastic beverage bottles and inner cereal box liners. The data used for the analyses include the number of manufacturers and distributors of the following types of packaging: Paperboard containers, paper

bags and treated paper, plastic bags, bottles, laminated plastics and other plastic materials, polystyrene and urethane foam products, glass products, and metal and aluminum can, sheet, plate, and products. Furthermore, printing services and label producers are included such as lithographic, gravure, flexographic, screen, digital, and quick printing services.

Transporters and packers: Although the CBP and Nonemployer statistics distinguish passenger and nonpassenger transport, they do not separately identify establishments engaged in the transport of food. Based on a comment received through our preliminary outreach activities, FDA assumes that 20 percent of the specialized freight transport industry is engaged in food transport. FDA requests comments on this assumption. The largest category in transport and packing is trucking.

Mixed-type facilities that engage in farming: Firms engaged in covered activities would be required to keep records on these activities as discussed above, even if those firms were mixed-type facilities that engage in farming. Covered activities conducted on mixed-type facilities that engage in farming potentially comprise a large percentage of the activity conducted at these facilities. For example, manufacturing or processing for farms includes canning, freezing, cooking, pasteurization, homogenization, irradiation, milling, grinding, chopping, slicing, cutting, coloring, waxing, shelling of nuts, peeling, labeling, and packaging. Facilities with farms will be considered mixed-type facilities if they alter the general state of the commodity, use any ingredients obtained from another source, and then sell or transfer the product for final use offsite.

To estimate the number of mixed-type facilities that engage in farming that would be affected by this rule, FDA uses the 1997 USDA NASS Census of Agriculture and data obtained from various county level Cooperative Extension Service (CES) offices. The Census of Agriculture provides the total number of farms producing specific commodities. To estimate the number of farms that are part of mixed-type facilities, FDA used a sample of counties with information from their respective CES offices. CES offices from Clay County, Kansas; Monterey, Sonoma, Marin, and San Diego counties in California; Jackson County, Wisconsin; Gillespie and San Saba counties in Texas; Carol County, Maryland; and Berks County, Pennsylvania provide data on the percentage of farms producing specific commodities that could be considered mixed-type facilities (Ref. 4). Table 2 presents the estimated number of mixed-type facilities that engage in farming by type of farm. While some of the facilities described in table 2 may qualify as roadside stands for some of the products that are sold from these facilities (and would not be subject to recordkeeping requirements for those products), we were not able to distinguish between facilities that would qualify as roadside stands and mixed-type facilities that engage in farming. The numbers of mixed-type facilities that engage in farming listed in table 2 may be overstated to the extent that they qualify as roadside stands. The estimated total is 30,497. FDA requests comments on the methods used to estimate the numbers of mixed-type facilities that engage in farming and for identifying the number roadside stand facilities.

TABLE 2.—MIXED-TYPE FACILITIES THAT ENGAGE IN FARMING

Commodity	Total No. of Farms	Percent Mixed-Type	No. of Mixed-Type Facilities that Engage in Farming
Pig Farms (Feed Mixing)	46,353	1.5%	695
Cattle (Feed Mixing)	785,672	1%	7,857
Poultry (Feed Mixing)	36,944	1%	369
Other Animal Production (Feed Mixing)	110,580	1%	1,106
Dairy	86,022	1.1%	903
Grain, Rice, and Beans	462,877	1%	4,629
Apples	10,872	1.5%	163
Oranges	9,321	1.5%	140
Peaches	14,459	1.5%	217
Cherries	8,423	1.5%	126
Pears	8,062	1.5%	121
Other Fruit	29,413	1.5%	441
Nuts	14,500	2%	290
Berries	6,807	1.5%	102
Grapes	11,043	10.5%	1,160
Olives	1,363	3.5%	48
Vegetables and Melons	31,030	0.5%	155
Organic vegetables	6,206	50%	3,103

TABLE 2.—MIXED-TYPE FACILITIES THAT ENGAGE IN FARMING—Continued

Commodity	Total No. of Farms	Percent Mixed-Type	No. of Mixed-Type Facilities that Engage in Farming
Honey	7,688	50%	3,844
Syrup	4,850	100%	4,850
Herbs	1,776	10%	178
Total			30,497

Importers: FDA bases the number of importers on a database collected from shipment records that list all companies that were listed as importers or consignees for a covered product in 2001. These data were collected through FDA's OASIS system, which is an automated system for processing and making admissibility determinations for shipments of FDA-regulated products seeking to enter U.S. domestic commerce. Many of these facilities are of a type that would already be counted in the FDA FACTS or CBP (or nonemployer statistics) data. In order to avoid double counting, FDA assumes the following: (1) Any facility that identifies itself through its name as being a facility type covered by the CBP will already be counted in the CBP; (2) any facility that is a consignee only will already be counted in the CBP since its main business is not simply importing; (3) any facility self-identified as an importer only is not in the CBP; and (4) all other facilities will be considered in an uncertain range of facilities affected. Since it is uncertain whether these facilities would already be counted in the CBP, we will use a uniform distribution to assign a probability of double counting in all of our cost estimates. For example, if the uniform distribution generates a probability of 0.5, then we will assume that half of these unclassified facilities are already in the CBP. A uniform distribution implies that any probability from zero to 100 is equally likely. FDA requests comments on these assumptions.

Foreign establishments: FDA estimated the number of foreign manufacturing establishments that will be affected by the regulation from a count of foreign manufacturers identified in the OASIS system. We were unable to find reliable data on the number of foreign nonmanufacturing establishments and made the following assumptions to estimate their numbers: For the final holders of the article before the food or food packaging is imported into the United States, we assumed the same number of facilities as on the domestic side of the importation process, for a total of approximately 77,000 foreign final holders. For other firm types, we assumed that the ratio of foreign to domestic facilities of other types is approximately equal to the ratio of foreign to domestic manufacturers. We also assumed that the facility to firm ratio is the same for both foreign and domestic establishments. We request comments on the assumptions used to arrive at these estimates, as well as on reliable sources of data that would improve these estimates.

Firm adjustment: Even though recordkeeping requirements apply to each facility within a firm, some of the overall burden will be estimated at a firm level in order to better capture the true burden of the regulation. In order to estimate the number of firms affected, we used the 1999 Statistics of U.S. Businesses, also from the U.S. Census Bureau (Ref. 5). This dataset is based on the CBP and Nonemployer Statistics, but calculates both the number of establishments and the number of firms for each NAICS code. The Census Bureau has not updated this dataset for the latest 2000 CBP, so we use the 1999 ratio of establishments to firms to adjust the 2000 CBP and 1999 nonemployer establishment count numbers to firm numbers.

Costs per facility or per firm: Some costs of the regulatory options apply to firms, while other costs apply to individual facilities. FDA assumes that the costs to facilities are the same for transfers within firms as for transfers between firms. We request comments on this assumption. Costs fall into several broad categories:

Additional record information: Any possible new regulation may require more information on the input, output, or source ingredients than is kept in existing food facility records. A limited amount of new information could be accommodated by a simple redesign of existing records, whereas requiring more new information may require a completely new design and collection. The extreme version of this requirement is explored under option 13: requiring all raw ingredients to be connected through records to all final products would cause a substantial change in recordkeeping and other business practices for many commingled commodities.

Information Collection and Maintenance: The burden of maintaining extra information is a direct function of the amount of information required by this proposed regulation that is not normally collected by industry. This burden estimate will be substantially correlated with the redesign burden described previously.

Storage time: A longer storage time may place more of a burden on industry, but will also increase the probability of having records available should an outbreak occur. The major determinant of the impact on costs of storage time requirements is whether the proposed storage times will be longer than normal industry practices. FDA believes that the storage times proposed in option 2 are within normal industry practices. Requiring longer retention times than those proposed in option 2 for records on perishable foods might impose an additional burden. This issue is discussed in more detail below and in options 2, 8, and 9.

Records access time: As in storage time, the major determinant of the impact of any required response time for records access is what firms would reasonably be able to achieve in an emergency situation with current business practices.

Data sources and cost estimates common to options:

Labor costs: For all labor costs, FDA used a wage rate for an administrative worker of $25.10 from the Bureau of Labor Statistics occupational wage rates for the year 2000 (Ref. 6), doubled to include overhead costs. We assume that all labor for all options is by administrative workers. FDA lacks wage data specific to each of the foreign countries that export to the United States, so we used the wage rate for an administrative worker in the United States for the foreign wage rate. We

assume that the nature of the worker and the worker's wage would be about the same in foreign countries as in the United States. In open markets where trade takes place, real wage rates tend to be equal for similar work and productivity across countries.

Learning costs: Foreign and domestic facilities will incur administrative costs in order to learn how to comply with any new regulation. Because most of the facilities covered by the proposed registration rule would be covered by this proposed rule, the administrative costs will be shared between the registration and recordkeeping rules. Those establishments covered by both regulations will probably search for information on both regulations at the same time and find information in the same places. Therefore, the learning cost estimates presented here probably overestimate the costs actually incurred by firms covered by both rules since there is the potential for double counting. The potential for double counting occurs in estimates of costs for firms covered by both rules. These include domestic manufacturers, wholesalers, warehouses, mixed-type facilities that engage in farming, foreign final holders, foreign manufacturers, and importers in any of these categories.

Facilities will become aware of these requirements through normal business activities: Reading trade press, reading industry news, FDA outreach, or conversation with other business operators. Because facility operators or owners must be aware of the requirement to change their activity, we assume that becoming aware of the regulations will occur as part of normal business practice and so have no economic costs for the facility. There may be costs incurred, however, by FDA or trade organizations to undertake the outreach.

Once the owner or operator of the facility becomes aware of the regulations, he or she will need to research the requirements of the regulation, which will require searching for a copy of the requirements and reading and understanding them. Owners or operators may search for a copy of these requirements on the Internet or at a library. FDA received comments indicating that many businesses might not have access to the Internet. Searching costs will be higher for facilities that do not have access to the Internet and have to write to FDA or find other sources of information. In the United States, 59.1 percent of the population accessed the Internet at least once in the 3 months prior to being surveyed (Ref. 7). A Small Business Administration (SBA) report cites two studies that report 40 and 47 percent of small businesses had Internet access in 1998 (Ref. 8). An updated report from Dunn and Bradstreet in 2002 reports that 71 percent of small businesses have Internet access (Ref. 9). Therefore, FDA assumes that 71 percent of domestic facilities will search for the requirements for both regulations electronically. FDA estimates it will take domestic facilities with Internet access 1 hour to search for the requirements, and domestic facilities without Internet access 2 hours to search for the requirements. FDA requests comments on these assumptions.

FDA expects foreign establishments to go through the same searching, reading, and comprehending steps as domestic establishments. Costs for searching, reading, and comprehending the regulation requirements will be higher for some foreign establishments than for domestic establishments due to distance and language differences. Costs for searching, reading, and comprehending for some foreign establishments may be so high that, rather than become informed about the requirements before shipping, they learn about the requirements after shipments to the United States have been made. Costs for searching, reading, and comprehending for foreign facilities will vary depending on: (1) Whether the worker researching the regulatory requirements or the person who manufactures, processes, packs, transports, distributes, receives, holds, or imports food or food packaging can read and write in English; and (2) the level of Internet access available in exporting countries.

The percent of foreign facilities with Internet access will be lower than in the United States. Although 71 percent of the small businesses in the United States have Internet access, only 3 percent of the population of China, the country that has the largest number of manufacturers that export to the United States, has access to the Internet (Ref. 7). To get an idea of how many facilities that export to the United States have access to the Internet, FDA looked at Internet access for the 26 countries that represent 80 percent of the manufacturers that export to the United States (OASIS) and the percent of the population that has access to the Internet worldwide for the remaining 20 percent. A weighted average of these 26 countries by the number of manufacturers suggests that 26 percent of the population that exports to the United States has Internet access. Because businesses are more likely to have Internet access than individuals, FDA adjusts the percent of the populations of other countries with Internet access upward by the percent difference in Internet access between individuals and small businesses in the United States. Seventy one percent of small businesses in the United States have Internet access versus 59 percent of the population, or the percent of businesses with Internet access represents a 20 percent increase over the population. Applying this adjustment to Internet access in foreign countries increases the percent of businesses with Internet access from 26 percent to 31 percent. FDA therefore assumes that 31 percent of foreign manufacturers would be able to research the new requirements electronically. Regardless of whether the cost of obtaining Internet access is borne by the facility, or by a third party, for ease of computation FDA estimates the cost per facility. FDA expects that, due to the overall lower level of Internet access in foreign countries, it will be more difficult for foreign facilities without Internet access at their place of business than it will be for domestic facilities to access the Internet elsewhere. FDA assumes it would take foreign facility operators that do not have access to the Internet 5 additional hours to search for the recordkeeping requirements. FDA requests comments on these assumptions.

In addition to search costs, there are costs for reading and comprehending the regulation requirements. Reading costs depend on the length of the document that describes the requirements and the reading speed of the user. Costs for comprehending the regulation requirements are linked to the reading speed of the user. For purposes of simplicity FDA assumes that, on average, the user comprehends the requirements described in the regulation after one reading. FDA requests comments on this assumption.

The online speed-reading training course, TurboRead Speed Reading (Ref. 10), estimates that the average reading speeds for the vast majority of the worlds' readers is between 200 and 250 words per minute. Dividing the approximate length of the current proposal (approximately 44,450 words) by an average speed of 225 words per minute yields an estimate of the time required to read the regulation of about 3 hours and 18 minutes. Because the length of the document may change and the approximate nature of the calculation, FDA rounds up to the nearest half-hour to 3 1/2 hours for the time required for reading and comprehending the requirements of this rule for all English reading users. FDA requests comments on this assumption.

Users who have limited ability to read English may take longer to read and comprehend the requirements. Comments suggest that many foreign manufacturers are limited in their ability to read and write English. Estimates of the number of people outside of countries where English is the primary language who are able to speak English fluently vary widely, ranging from 300 million to 750 million (Ref. 11). To estimate the number of English speakers outside of the United States, FDA adds the number of English speakers in countries where English is the primary language, excluding the United States (151 million), the number of English speakers in countries where English is a secondary language (300 million), and the midpoint (525 million) of the range of the estimate of the number of speakers of English as a foreign language. FDA then divides this total number of English speakers by 5.9 billion—the world population minus the U.S. population (Ref. 11) to tentatively conclude that 16 percent of foreign manufacturers read and write English well enough to research the recordkeeping requirement directly. FDA requests comments on this calculation. Facilities without the capacity to read and write English would have to hire a translator to aid them in comprehending the regulatory requirements. Alternatively, trade groups, distributors, or the government may provide translation services. Regardless of whether the translation is paid for directly by the registrant or a third party, for ease of computation we assume there is a cost for translation for 84 percent of foreign facilities. FDA assumes it would take foreign facility operators who do not understand English 5 additional hours to read and comprehend the recordkeeping requirements. FDA requests comments on these assumptions.

Table 3 summarizes these cost estimates, which do not differ across any of the options that do not grant exemptions. These include costs for searching, reading, and comprehending the requirements of the rule for English and non-English speaking users, and for users with and without Internet access.

TABLE 3.—LEARNING COSTS

	Firm Count	Cost (at labor rate of $25.10)	Average Learning Costs per Firm
Domestic			
Manufacturers	43,376	$5,215,000	$120
Wholesalers/Warehouses	95,745	$11,511,000	$120
Packaging[1]	73,813	$8,875,000	$120
Transporter/Packer	16,773	$2,017,000	$120
Retail Grocery and Specialty Food	207,657	$24,966,000	$120
Convenience Stores	128,985	$15,508,000	$120
Mixed-Type Facilities that Engage in Farming	30,497	$3,667,000	$120
Importer	5,036	$605,000	$120
Total Domestic	601,883	$72,364,000	$120
Foreign			
Final Holders	77,427	$23,613,000	$305
Manufacturers	125,450	$38,258,000	$305
Other Facility Types	457,836	$139,624,000	$305
Total Foreign	660,713	$201,495,000	$305

[1] Includes both outer packaging material and food contact substances.

New and closing facilities: In future years new businesses will open and existing businesses will close. Since the total number of firms in the food industry remains stable from year to year, we assume that the rate at which new firms enter the industry is the same as the rate at which existing firms leave the industry. The Small Business Administration estimates that in 2000 approximately 10 percent of all businesses were new businesses and 10 percent of all businesses closed (Ref. 31). FDA estimates that new businesses will also have to incur learning costs.

New information collection costs: These costs include the burden of redesigning records to accommodate new information specified in possible options, and the burden of collecting and maintaining that new information within the recordkeeping system.

Records redesign: In order to estimate the cost of adding additional information to a firm's records, we used the Label Cost Model developed for FDA by RTI International (Ref. 13). We modified this model to estimate the graphic design and printing cost for adding information onto existing records such as Bills of Lading, Invoices, and Purchase Orders. We also used the model to estimate the cost of designing an entirely new input-to-output ingredient record for part of option 13.

Based on a sample of bills of lading collected through FDA's early outreach efforts and through the Web sites of companies and trade associations, FDA assumes that firms already collect most

of the information necessary to comply with options 2–12. Bills of lading, purchase orders, or invoices typically have the full address of all parties, the transaction date, and descriptions of the relevant food articles. Based on the samples, FDA assumes that firms will have to add a limited amount of new information to their standard documents. This new information principally depends on how the precise definition of "description of the food article" developed in these regulations differs from that commonly used by industry under its current recordkeeping practices. In some of the sample bills of lading the description of the food article being transported did not have the precision required under these proposed regulations. In addition, some bills of lading did not have a design that would allow for the identification of other entities in custody, or control of the transported food articles, or an official spot to record the mode of transportation.

The FDA Labeling Cost Model was designed to estimate the costs of designing and printing new food labels, but many of the design issues should be similar when designing and printing a new food product record. For example, both a label and a document designer must make similar decisions regarding wording and spacing, and both activities should include administrative activity, graphic design, and printing. The model also includes cost categories, such as analytical testing and focus groups that we do not use, since they are not relevant for document redesign. FDA does acknowledge that these estimates are only approximations; we believe the values this model generates are reasonable, and request comments on all assumptions. For the purposes of the analysis of options 2–12, FDA assumes a limited information, one-color redesign of a paper document. For the purposes of option 13, FDA assumes an additional full design of a new paper document.

The model also includes an estimate of central tendency, and a low and a high estimate for each cost category included in the document redesign cost. For each component of cost in this model, FDA's contractor, RTI International, received a range of estimates from food companies. The lowest of these estimates is considered the limit of the low range, and the highest of the estimates is considered the limit of the high range. The low and high range of total cost is calculated by adding together all of the low and high range estimates of each component cost, so the low and high range estimates of this model are unlikely. The estimated cost of a limited information redesign in year 1 is $1,309, with an uncertainty range of between $897 and $2,299. The estimated cost of a full information redesign in year 1 is $6,193, with an uncertainty range of between $4,653 and $11,198. The label cost model estimates an approximately 10 percent efficiency savings in redesign costs incurred by very small firms in year 2.

The cost of redesigning product records will not be borne by all firms. For each step in the chain of custody, copies of the same bills of lading or invoices probably will be used for records of the immediate previous source, records of the immediate subsequent recipient, and transportation records. Consider the following example of a long chain of custody for a food product: (1) Farmer, (2) transporter, (3) bulk collection (e.g. grain silo), (4) transporter, (5) processor, (6) transporter, (7) warehouse, (8) transporter, and (9) retailer. The number of entities in this series is clearly limited by the total number of transporters in the country, so FDA assumes that all transporting firms have to redesign their records. This supply chain should generate four sets of bills of lading and four sets of invoices for all products. Similarly, a six-step supply chain should generate three separate sets of records. Since farmers are exempt under this proposed regulation, the number of records possibly containing new information is roughly equal to the number of facilities in the supply chain, but FDA assumes a substantial number of nontransporters will depend on storing only the redesigned bill of lading to comply with the regulation. Assuming an equal probability of a firm using the bill of lading or redesigning its own documents, FDA assumes that half of the nontransporting firms will incur redesign costs.

We modify this estimate for convenience stores. Individual convenience stores have a small sales volume and—according to a comment received during FDA's early outreach efforts—only 11.4 percent of their average total sales are for food products. In addition, the majority of convenience stores are locally owned franchises of large corporations, and these stores may have access to the parent corporation to assist in redesign. FDA therefore assumes that 90 percent of convenience stores will rely on other parties for records redesign. The total costs for other firm types may also be an overestimate; FDA expects that trade groups may assist in the needed redesign of existing records, further lowering the burden, but we do not estimate the cost savings for this activity.

In addition, we make a further adjustment for foreign facilities: According to comments received, firms exporting from the European Union (EU) are already subject to similar recordkeeping requirements under EU regulation 178/2002. Article 18: *Traceability* of the EU regulation states: * * *

(1) The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

(2) Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures, which allow for this information to be made available to the competent authorities on demand.

(3) Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand * * *. (Ref. 14).

Because of these regulations, FDA assumes that the firms from EU member states (31.9 percent of all foreign firms that export to the United States) will already be subject to recordkeeping requirements similar to the requirements of this proposed rule. Therefore these foreign firms would not have to redesign their records and would not incur a redesign burden.

Additional records maintenance: FDA expects that personnel at most facilities will incur a burden in order to collect and maintain a limited amount of additional information. However, as in the redesign section previously discussed in this document, FDA assumes that one set of records can serve as source, transportation, and recipient records, so the estimated burden of collecting and maintaining the additional information will be shared among more than one facility.

FDA does not have a direct estimate of this recordkeeping burden; we rely on a previous analysis of Juice Hazard Analysis and Critical Control Point (HACCP) recordkeeping (Ref. 15) because that analysis also dealt with the costs of additional recordkeeping. In that analysis an estimate of 3 minutes per hour is made of the burden that would be incurred by some food

processing facilities for the additional monitoring of critical control points and keeping HACCP system records that would be required. In this proposed rule the additional monitoring activities required would be negligible since records will likely only need to be modified. Furthermore, compared to the Juice HACCP requirements, there would be less additional information that would need to be maintained in this proposed rule. If the weekly burden for additional monitoring and recordkeeping required for Juice HACCP compliance is 120 minutes (assuming 3 minutes per hour of additional monitoring and recordkeeping for 8 hours a day and 5 days a week) a burden estimate of about 6 minutes per day or 30 minutes per week seems reasonable for this proposed rule. We request comments on this assumption. FDA treats foreign facilities already subject to a similar recordkeeping regulation as already in compliance, and assumes that the burden of additional records maintenance will be shared among an average of two covered entities, including transporters, for an average of 15 minutes per week per facility or 13 hours per year per facility.

Grocery stores, convenience stores, and packaging producers and distributors may have different additional records maintenance burdens. Since, under the proposed rule, grocery stores only have to maintain immediate previous source records, their additional burden may be lower but they also receive many shipment records they would need to maintain. In a comment FDA received during our early outreach efforts, a large retail grocery chain estimated that they received approximately 300 purchase orders per store per year, or approximately 6 purchase orders per week per store. A purchase order could contain many invoices and may be more of a burden to maintain, so FDA considers the estimated additional burden of 15 minutes per week reasonable for grocery stores. We request comments on the assumptions used to derive this estimate.

Convenience stores have a lower records maintenance burden than grocery stores. According to comments received during our early outreach efforts, approximately 50–70 percent of grocery store stock keeping units (SKUs) are food products, while only 11.4 percent of the sales of convenience stores are from food products. SKUs and sales are not equivalent measures of size, but this comparison is a reasonable basis to lower the estimated additional burden for convenience stores relative to grocery stores. Dividing the grocery store burden by the ratio of the percent of food sales for convenience stores and grocery stores (assumed to be 60 percent, or an average between 50 percent and 70 percent of SKU totals) yields an additional records maintenance burden of approximately 2.5 hours per year for convenience stores. We request comments on the assumptions used to derive this estimate.

Finally, the data sources do not distinguish between facilities that produce packaging for food and packaging for other products. Although we assume that all packaging facilities potentially could be producing or handling food packaging, not all of their output would be dedicated in this way. We assume that, for the average packaging facility, 50 percent of the output is for food packaging and that an information collection burden of 50 percent would be required of packaging facilities. We request comments on this assumption.

Storage costs: Although FDA does not believe the marginal burden of storing records to the specified times in any of the options is zero, evidence on record storage times suggests that the burden would be minimal. Since FDA was unable to gather any evidence suggesting the size of this extra burden, however small, and since the specified storage time requirement in these options is well within industry norms, we estimate the cost for extra storage time to be zero.

Many comments received in response to FDA's early outreach supported requirements of either 1 year for perishable products or 2 years for nonperishable products, stating that the maximum allowable 2-year requirement was both reasonable and necessary. In addition, a survey of dietary supplement manufacturing practices conducted by FDA's contractor, RTI International, asked a representative sample of dietary supplement manufacturers how long they kept records of shipped ingredients (Ref. 16). The facilities had a choice of two response types: Keeping records a certain amount of time past the date of expiration, and keeping records a certain amount of time past the manufacturing date. The survey did not distinguish between perishable and nonperishable ingredients. Because of nonresponse weighting, stratification, and deductive disclosure problems, FDA's contractor, RTI International, did not report confidence intervals for these estimates, but the mean number of years that firms kept data records was 2.31 years for facilities that reported retention from the date of the expiration of the ingredient, and 4.57 years for facilities that reported retention from the date of product manufacture. The lowest mean response from any facility category was 1.94 years from the expiration date of the ingredient, which is still probably more than 2 years from the delivery date.

Access costs: For purposes of evaluating the marginal cost of the record access time provision, FDA considered two possible requirements: The combination of 4 hours during normal business hours and 8 hours at other times, or 1-day regardless of when the request was made. Accessing records in a shorter time period than what industry is currently capable of will impose a burden on firms and facilities, and the shorter the required response time the larger the burden. The cost of records access response fall into two categories: Costs that would be incurred only in the event that FDA requests records under this authority, and costs that would be incurred to plan for records access and to change business practices to allow for a rapid response. The latter costs would be incurred regardless of whether or not FDA ever requested records under this authority.

For the first cost, FDA expects that in the event of a records request under this authority, any access requirements less than the current average access time of 2–3 days would impose a burden on businesses involved in providing those records. All other things equal, a 4-hour or 8-hour requirement would probably impose a greater burden than the 1-day requirement. However, we cannot quantify the probability of this burden for the same reason as the lack of quantification in the benefits section: It is impossible to predict when FDA will have to invoke this authority in response to an adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

For the second cost, FDA assumes that a 1-day records access time requirement is approximately the shortest possible response time that would not compel some firms to change their business practices. The costs for a 1-day records access requirement are considered in option 5. We assume that the 4-hour or 8-hour response time required in all options except option 5 is more likely to compel business practice changes and preemptive emergency planning than is the 1-day response requirement. A 1-day response time is possible with the types of recordkeeping systems currently in use, including automated recordkeeping technology, and offsite storage and paper retrieval. While the average access

time for FDA traceback investigations is 2–3 days, we believe the same information could be provided in one day with the types of recordkeeping systems currently in use. Therefore, the difference between the cost of a 2–3 day response time and a 1-day response time is assumed to be negligible. However, the shorter access time requirements of 4 hours or 8 hours would likely impose a new burden on a number of firms.

FDA assumes that regardless of whether or not the firms maintain records electronically, every firm would probably have to devise a predetermined compliance strategy to deal with the situation where FDA requested records under this authority. Furthermore, a comprehensive response plan may allow firms to maintain their current business practices, such as maintaining paper records or maintaining records offsite, and still comply with a request, so it may be the lowest cost solution. Therefore, as a first estimate of the potential impact of this proposed rule, FDA assumes a burden for each firm of devising a response plan that could accommodate a 4-hour or 8-hour access time for an FDA record request. Since European firms are required to supply their tracing records on demand to the appropriate authorities, FDA assumes that they already have in place a plan that would accommodate a 4-hour or 8-hours records required response time. (Ref. 14).

In the analysis of previous regulations, we estimated a related planning cost for food firms. In the juice HACCP rule, (Ref. 15), we estimated a 60-hour labor burden per firm of developing a HACCP plan. Developing a HACCP plan is very complicated and includes the establishment of: (1) Critical control points and critical limits for every hazard identified, (2) protocols on how to manage deviations from these limits, and (3) procedures for verifying and validating all aspects of the plan. By contrast, developing a records access plan requires: (1) Evaluating current recordkeeping practices including records maintenances and records storage practices, which we assume would take on average about 3 hours; and (2) identifying and planning for any changes in recordkeeping practices that would be required, which we assume would also take on average about 3 hours. FDA considers the planning needed to deal with a possible records request under this authority much less complicated than what would be needed in a HACCP plan. If developing a HACCP plan takes 60 hours, then 6 hours of administrative labor per firm (lowered to 3 hours per convenience store firm) is a reasonable estimate of the burden imposed from this planning requirement, which is far more simple than a HACCP plan. We request comments on this assumption. FDA estimates that new businesses will also have to incur records access costs.

FDA requests comments regarding how many firms may need to adopt a new records retention strategy under both the 4-hour or 8-hour, and 1-day records access time requirements, and the additional time and capital needed to comply with these requirements. We plan to conduct further research on all of these burden estimates before publishing the final rule, and expect that the estimates could change.

Option 2: Comprehensive foreign and domestic coverage with 4-hour and 8-hour records access times and 1 and 2 year records retention times.

FDA assumes that facilities currently collect and keep records with most of the information required by this option in their normal business activities. FDA assumes that learning and redesign costs will be incurred per firm, and that the additional records maintenance costs will be incurred per facility. For all options the learning costs are explained in the general cost section above.

Redesign Costs, option 2. Table 4 of this document presents the average redesign cost calculations. For the purposes of presentation, Table 4 only includes calculations for the mean number of exclusive importers affected. FDA assumes that large and small firms incur all redesign costs in the first year following the final rule, while very small firms will incur all redesign costs in the second year following the final rule. The label cost model estimated planning efficiencies of 10 percent for redesign processes further than 1 year in the future, and this savings is included in the categorical totals in table 4.

TABLE 4.—REDESIGN COSTS, OPTION 2

	Firm Count	Middle Estimate	Low Estimate	High Estimate	Average Middle Cost per Firm
Domestic					
Manufacturers	18,474	$22,488,000	$15,402,000	$39,497,000	$1,217
Wholesalers/Warehouses	38,476	$46,601,000	$31,916,000	$81,845,000	$1,211
Packaging[1]	34,633	$42,092,000	$28,827,000	$73,926,000	$1,215
Transporters/Packers	15,171	$18,243,000	$12,494,000	$32,040,000	$1,203
Retail Grocery and Specialty Food	76,639	$92,308,000	$63,220,000	$162,122,000	$1,204
Convenience Stores	6,887	$8,415,000	$5,763,000	$14,779,000	$1,222
Mixed-Type Facilities that Engage in Farming	12,199	$14,786,000	$10,127,000	$25,969,000	$1,212
Importers	7,561	$9,165,000	$6,277,000	$16,096,000	$1,212
Total Domestic	210,038	$254,098,000	$174,026,000	$446,274,000	$1,210
Foreign					
Final Holders	21,091	$25,565,000	$17,509,000	$44,900,000	$1,212
Manufacturers	36,385	$44,103,000	$30,205,000	$77,459,000	$1,212

TABLE 4.—REDESIGN COSTS, OPTION 2—Continued

	Firm Count	Middle Estimate	Low Estimate	High Estimate	Average Middle Cost per Firm
Other Facility Types	124,714	$151,170,000	$103,532,000	$265,500,000	$1,212
Total Foreign	182,191	$220,838,000	$151,246,000	$387,859,000	$1,212

[1] Includes both outer packaging and food contact substances.

Additional records maintenance: Table 5 of this document presents the calculations for additional records maintenance costs. Based on the previous discussion, the annual burden per facility that is assumed in the computation of the cost of additional records maintenance is: 13 hours for most facilities, 2.5 hours for convenience stores, and 6.5 hours for packaging facilities. A $25.10 hourly wage is also assumed in the computation. For example, the additional records maintenance costs for manufacturers reported in the top row of Table 5 is calculated by multiplying the number of facilities (43,376) by the number of hours required (13) and the hourly wage ($25.10).

In Table 5, variation in the number of importers reflects the range of uncertainty in the data on the number of these facilities. Additional records maintenance costs are assumed to be incurred by facility. The estimated average cost per firm for additional records maintenance is also reported in table 5 and is computed using the facilities-to-firm adjustment factor reported in table 1. FDA assumes that facilities will begin to incur the additional records maintenance burden in the second year following the enactment of the final rule. There is considerable nonquantified uncertainty surrounding these estimates; FDA requests comments.

TABLE 5.—ADDITIONAL RECORDS MAINTENANCE COSTS, OPTION 2

	Facility Count	Cost	Average Cost per Firm
Manufacturers	43,376	$14,154,000	$383
Wholesalers/Warehouses	95,745	$31,242,000	$406
Packaging[1]	73,813	$12,043,000	$174
Transporters/Packers	16,773	$5,473,000	$361
Retail Grocery and Specialty Food	207,657	$67,759,000	$442
Convenience Stores	128,985	$8,094,000	$118
Mixed-Type Facilities that Engage in Farming	30,497	$9,951,000	$408
Importers	5,036	$1,643,000	$408
Total Domestic	601,883	$150,359,000	$335
Foreign			
Final Holders	52,728	$17,205,000	$278
Manufacturers	85,431	$27,876,000	$261
Other Facility Types	311,786	$101,736,000	$278
Total Foreign	449,945	$146,817,000	$274

[1] Includes both outer packaging and food contact substances.

Access costs: For the purposes of this analysis, as mentioned above, FDA assumes that the 4-hour or 8-hour records access times in option 2 imply extra planning and may imply a change in record retention practices for many firms. FDA has little information on the possible impact of this requirement, and requests comments. As previously discussed, the computation of the access costs reported in Table 6 of this document assumes a 6-hour burden per firm for developing an access plan and a $25.10 hourly wage. FDA assumes that all access planning costs will be incurred in the first year following the final rule for large and small firms, and in the second year following the final rule for very small firms. Table 6 presents the calculations.

TABLE 6.—ACCESS COSTS OPTION 2

	Firm Count	Cost	Average Cost per Firm
Domestic			
Manufacturers	36,948	$5,564,000	$151
Wholesalers/Warehouses	76,952	$11,589,000	$151
Packaging[1]	69,266	$10,431,000	$151
Transporters/Packers	15,171	$2,285,000	$151
Retail Grocery and Specialty Food	153,277	$23,084,000	$151
Convenience Stores	68,866	$5,186,000	$75
Mixed-Type Facilities that Engage in Farming	24,397	$3,674,000	$151
Importers	4,029	$607,000	$151
Total Domestic	448,905	$62,420,000	$139
Foreign			
Final Holders	42,182	$6,353,000	$151
Manufacturers	72,770	$10,959,000	$151
Other Facility Types	249,429	$37,564,000	$151
Total Foreign	364,381	$54,876,000	$151

[1] Includes both outer packaging and food contact substances.

Total quantified costs for option 2. Table 7 of this document presents the total quantifiable startup and recurring costs for option 2, and a range of uncertainty based on the uncertain number of exclusive importers and the range of uncertainty in design costs. We calculated the range of uncertainty using the 5th and 95th percentiles of the range of costs, with a uniform distribution of importers and a separate triangular distribution of redesign costs for each facility category and size. Both distributions represent the most amount of information implied by the known characteristics of the uncertain ranges. This procedure allows each component of cost uncertainty to vary independently, but this range cannot be interpreted in probabilistic terms.

Table 7 of this document presents the range of undiscounted annual costs of future compliance for option 2. Costs incurred in year 1 are learning costs for all existing firms, redesign costs for large and small firms, and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. The cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate. Table 8 presents the discounted annual costs incurred in future years and the present value of total costs incurred for option 2. The computations are made using the mean costs, and assume no increase in real labor cost and a 7 percent real discount rate. Although the recurring costs reported for year 3 and later years are the same in nominal terms ($341,669,000 reported in Table 7), they are reported in discounted terms for each year in Table 8 to account for the fact that a dollar in 5 years, for example, is worth less than a dollar today. Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above. FDA acknowledges considerable nonquantifiable uncertainty in the estimates presented in Table 7 and requests comments.

TABLE 7.—TOTAL ANNUAL COSTS, OPTION 2

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$412,474,000	$389,256,000	$432,307,000	$415
Year 2	$737,595,000	$665,189,000	$816,183,000	$741
Year 3 and later years	$341,669,000	$327,575,000	$355,445,000	$343

TABLE 8.—DISCOUNTED ANNUAL COSTS, OPTION 2

Year 1	$412,474,000
Year 2	$689,341,000
Year 3	$298,427,000
Year 4	$278,904,000
Year 5	$260,658,000
Year 6	$243,605,000
:[1]	:
:	:
Year 15	$132,505,000
:	:
:	:
Year 30	$48,026,000
:	:
:	:
Present Value	$5,663,484,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 3: Require all elements of option 2 (comprehensive coverage, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except persons who manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging are excluded.

FDA identifies the option excluding outer packaging facilities separately because the fundamental risk to the public from contaminated packaging is probably different from the risk associated with contaminated food, including inner materials that are food contact substances.

FDA was unable to find any data that discriminated between outer packaging manufacturers and distributors and those that manufacture or distribute materials that FDA currently regulates as food contact substances, including plastic beverage bottles and inner cereal box liners. The possibility exists that some of these data describe manufacturers and distributors of outer packaging materials only, and the remainder describe manufacturers and distributors of both outer packaging materials and food contact substances. To distinguish between manufacturers and distributors of outer packaging materials and food contact substances, we assume that the data is distributed uniformly over the interval between 0 and 1, and each packaging facility has an equal probability (0.5) of being either one or both types of facilities. Based on this distributional assumption, the expected number of manufacturers and distributors of outer packaging materials exclusive of food contact substances is 36,906.5 (or 73,813 divided by 2). We request comments on this distributional assumption.

The range and discounted costs for option 3 are estimated to be the same as for option 4, as explained in the following paragraphs, and are reported in tables 9 and 10. The discount computations are made using mean costs. Although the recurring costs reported for year 3 and later years are the same in nominal terms (i.e., $334,682,000 reported in table 9), they are reported in discounted terms for each year in table 10. As previously discussed, costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

Option 4: Require all components of option 3 (no outer packagers, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) but do not require persons that are required to establish and maintain records on food to establish and maintain records on the food's outer packaging.

FDA is unable to distinguish between the costs incurred when these persons are required to keep records on the food's outer packaging and when they are not required to keep such records. Persons required to establish and maintain records on foods will also keep records on the food contact substances they use because these substances meet the definition of food. Moreover, we believe that a large portion of outer packaging materials used by persons required to establish records is shipped to that person along with food contact substances. Consequently, persons keeping records on food contact substances are also likely to keep records on the food's outer packaging under current recordkeeping practices. As a result, the cost savings from exempting recordkeeping on outer packaging are assumed to be negligible and the costs of this option are assumed to be the same as option 3. We request comments on this assumption.

Tables 9 and 10 present the range and discounted cost estimates for options 3 and 4.

TABLE 9: TOTAL ANNUAL COSTS, OPTIONS 3 AND 4

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$400,491,000	$318,274,000	$404,529,000	$417
Year 2	$711,860,000	$566,254,000	$738,803,000	$741
Year 3 and later years	$334,682,000	$279,074,000	$334,079,000	$348

TABLE 10.—DISCOUNTED ANNUAL COSTS OF OPTIONS 3 AND 4

Year 1	$400,491,000
Year 2	$665,290,000
Year 3	$292,324,000
Year 4	$273,200,000
Year 5	$255,327,000
Year 6	$238,624,000
:[1]	:
:	:
Year 15	$129,795,000
:	:
:	:
Year 30	$47,044,000
:	:
:	:
Present Value as of Year 1	$5,534,165,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 5: Require all components of option 4, but change the required records access time to 24 hours.

All costs for this option will be identical to those for option 4 except for the access costs for records detailed in that section. As mentioned previously, FDA believes that 24 hours is the least amount of time allowable that would not cause any firms to need to plan for a rapid response or change their business practices. While the average access time for FDA traceback investigations is 2–3 days, we believe the same information could be provided in 1 day with the types of recordkeeping systems currently in use, including automated recordkeeping technology, and offsite storage and paper retrieval. Therefore, the difference between the cost of a 2–3 day response time and a 1-day response time is assumed to be negligible. However, the shorter response time requirements of 4 hours or 8 hours would likely impose a new burden on a number of firms. Therefore, we assume that the difference between 4 or 8 hours and 24 hours is the difference between having to preplan a response and being able to react with normal personnel in an emergency capacity. In order to estimate this cost difference, FDA assumes that no firm would incur extra planning costs detailed in option 2, and requests comments on this assumption. The marginal cost savings of extending the records access time requirement is approximately $715,355,000.

Table 11 of this document presents the range of undiscounted costs of future compliance and Table 12 of this document presents the discounted annual costs incurred in all future years and the present value of total costs incurred for option 5. In addition, Table 12 reports the marginal savings of option 5 with respect to option 4 as well as the discounted annual costs and the present value of total costs. The marginal savings of option 5 with respect to option 4 reflect the cost savings realized from relaxing the records access requirements from 4 and 8 hours in option 4 to 24 hours in option 5. As discussed earlier in this document, discounted computations are made using mean costs and assume no increase in real labor cost and a 7 percent real discount rate. Costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 11.—TOTAL ANNUAL COSTS, OPTION 5

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$338,594,000	$288,569,000	$387,887,000	$387
Year 2	$567,921,000	$481,993,000	$659,106,000	$649
Year 3 and later years	$295,813,000	$258,715,000	$326,509,000	$338

TABLE 12.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS OF OPTION 5

	Discounted Annual Costs of Option 5	Marginal Savings of Option 5 With Respect to Option 4
Year 1	$338,594,000	$61,897,000
Year 2	$530,767,000	$134,523,000
Year 3	$258,375,000	$33,949,000
Year 4	$241,472,000	$31,728,000
Year 5	$225,675,000	$29,652,000
Year 6	$210,911,000	$27,713,000
:[1]	:	:
:	:	:

TABLE 12.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS OF OPTION 5—Continued

	Discounted Annual Costs of Option 5	Marginal Savings of Option 5 With Respect to Option 4
Year 15	$114,722,000	$15,073,000
:	:	:
:	:	:
Year 30	$41,580,000	$5,464,000
:	:	:
:	:	:
Present Value	$4,818,810,000	$715,355,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 6: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except intrastate facilities are excluded.

In the datasets used for this analysis, it is difficult to distinguish between interstate and intrastate facilities. In order to be considered only engaged in intrastate commerce, a food or food packaging facility must obtain all its ingredients and sell its entire product within a single state. Since all food and food ingredients are regulated in a similar manner, even one ingredient in a food not obtained from within a particular state would make the food facility involved in interstate commerce. None of these datasets distinguishes facilities based on interstate or intrastate commerce. It is reasonable to assume, however, that intrastate facilities will be very small and are unlikely to be retailers or transporters.

The FACTS database of currently regulated facilities contains 71,781 facilities possibly engaged in manufacturing, warehousing, and wholesale marketing of foods. Since the FACTS database gives a count of facilities that FDA inspects, this would estimate the total number of manufacturing, warehousing, and wholesale marketing facilities that are engaged in interstate commerce. The count of covered facilities of these types obtained from the CBP and non-employer statistics and presented in table 1, is 139,121 and includes both intrastate and interstate facilities. We estimate the number of intrastate facilities engaged in manufacturing, warehousing, and wholesale marketing by subtracting the number of facilities in FACTS from the number of corresponding facilities reported in table 1. The FACTS database does not track food packaging producers and distributors, so we assume that the ratio of intrastate to total packaging facilities is the same as that of the facility types (48.3 percent) that are tracked by FACTS. This estimate may underestimate the intrastate facilities by the number of mixed-type facilities that engage in farming and other facility types engaged in only intrastate commerce. For the firm estimates, we assume one firm per facility for the facilities not counted in the FACTS data; intrastate firms are likely to be very small, and the average number of facilities to firms for small firms in the Census datasets is almost exactly 1.

Table 13 of this document presents the effects of excluding these intrastate firms on the number of facilities affected, and Tables 14 and 15 of this document present the range of undiscounted costs and the discounted annual costs, present value of total costs, and marginal savings of option 6 with respect to option 4.

TABLE 13.—NUMBER OF FACILITIES AND FIRMS AFFECTED, OPTION 6

Type	Facility Estimate	Firm Estimate
Manufacturers	34,437	28,009
Wholesalers/Warehouses	37,434	30,189
Packaging[1]	17,840	16,741
Transporters/Packers	16,773	15,171
Retail Grocery and Specialty Food	207,657	153,277
Convenience Stores	128,985	68,866
Mixed-Type Facilities that Engage in Farming	30,497	24,397
Importers	18,902	15,122
Total Domestic	492,525	351,772
Foreign		

TABLE 13.—NUMBER OF FACILITIES AND FIRMS AFFECTED, OPTION 6—Continued

Type	Facility Estimate	Firm Estimate
Final Holders	77,427	61,942
Manufacturers	125,450	107,222
Other Facility Types	423,348	338,678
Total Foreign	626,225	507,842

[1] Includes both outer packaging and food contact substances.

TABLE 14.—TOTAL ANNUAL COSTS, OPTION 6

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$376,263,000	$358,454,000	$397,619,000	$424
Year 2	$648,418,000	$583,071,000	$720,849,000	$731
Year 3 and later years	$307,485,000	$286,089,000	$317,845,000	$347

TABLE 15.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS OF OPTION 6

	Discounted Annual Costs of Option 6	Marginal Savings of Option 6 With Respect to Option 4
Year 1	$376,263,000	$24,228,000
Year 2	$605,998,000	$59,292,000
Year 3	$268,569,000	$23,755,000
Year 4	$250,999,000	$22,201,000
Year 5	$234,579,000	$20,748,000
Year 6	$219,233,000	$19,391,000
:[1]	:	:
:	:	:
Year 15	$119,248,000	$10,547,000
:	:	:
:	:	:
Year 30	$43,221,000	$3,823,000
:	:	:
:	:	:
Present Value as of Year 1	$5,087,535,000	$446,630,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 7: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except persons who operate mixed-type facilities that engage in farming are excluded.

This option would exempt from recordkeeping requirements all persons who operate mixed-type facilities that engage in farming. The total number of mixed-type facilities that would be exempt under this option is estimated to be 30,497, and the estimated numbers of such facilities by commodity type are reported in table 2. Tables 16 and 17 of this document summarize the estimated range and impact of this exemption on total costs and marginal savings into the future.

TABLE 16.—TOTAL ANNUAL COSTS, OPTION 7

	Mean	Low	High	Average Cost per Firm
Year 1	$379,977,000	$354,015,000	$406,264,000	$406
Year 2	$689,275,000	$619,484,000	$771,484,000	$736
Year 3 and later years	$322,701,000	$309,635,000	$337,022,000	$345

TABLE 17.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS OF OPTION 7

	Discounted Annual Costs of Option 7	Marginal Savings of Option 7 With Respect to Option 4
Year 1	$379,977,000	$20,514,000
Year 2	$644,182,000	$21,108,000
Year 3	$281,860,000	$10,464,000
Year 4	$263,420,000	$9,780,000
Year 5	$246,187,000	$9,140,000
Year 6	$230,081,000	$8,543,000
:[1]	:	:
:	:	:
Year 15	$125,149,000	$4,646,000
:	:	:
:	:	:
Year 30	$45,360,000	$1,684,000
:	:	:
:	:	:
Present Value	$5,332,584,000	$201,581,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

We believe that there is an even smaller number of mixed-type facilities that have restaurants. We have assumed that the costs and marginal savings for these facilities would be negligible. We invite comment and information relating to this assumption.

Options 8 and 9: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) but change required records-retention times for perishables and all other foods to 1 year (option 8), and 2 years (option 9).

FDA believes that the 1-year record retention requirement for perishable foods not intended for processing into nonperishable foods and the 2-year record retention requirement for all other food products is well within industry norms (see the discussion of evidence supporting provided in a previous section of this document). We do not have enough information to quantify any marginal change in the cost of record storage under a universal 1-year required storage time (option 8) or a universal 2-year required storage time (option 9). All other things equal, FDA assumes that option 8 would be less costly than option 4, which in turn would be less costly than option 9. Because evidence suggests that most firms keep records for 2 years or more, FDA also believes that the marginal difference in storage costs between all of these options is smaller than the marginal difference in cost between other options we consider in this analysis. Therefore, while there may be a benefit from simplifying requirements by requiring the same storage time for both perishable and nonperishable foods, because the increased benefit is negligible, we assume that the marginal cost is zero for both options 8 and 9. We explicitly specify these options principally to request comments, including specific examples where required record retention times may have a large impact on cost.

Option 10: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) but cover only those foreign facilities also covered by FDA's proposed registration regulation published at 68 FR 5378, February 3, 2003.

The proposed registration regulation (68 FR 5378, February 3, 2003) would require certain foreign facilities that manufacture, process, pack, and hold food for consumption in the United States to register. Therefore, a useful alternative to explore may be to cover the same facilities in both regulations. This exclusion implies that these

regulations would not cover most of the category "Other Facility Types" in the last row of Table 1 of this document. Only facilities that do de minimis processing or packaging of food, such as affixing a label, are included in this option from the category of "Other Facility Types". Because the minimal degree of processing that de minimis processing facilities perform, they are not included in the OASIS count of foreign manufacturers.

We assume that domestic packers and repackers are the domestic counterpart to foreign de minimis food processing facilities. This seems reasonable since the amount of processing performed by packers and repackers is minimal. To estimate the number of foreign packers and repackers, FDA takes the number of packers and repackers in the FACTS database, 6,204, and adjusts it by the ratio of foreign manufacturers in OASIS to the number of domestic manufacturers in FACTS. This adjustment of 3.64 (125,450 foreign facilities divided by 34,437 domestic facilities), estimates the total number of foreign packers and repackers (or foreign de minimis processing facilities) as 22,600. The facilities-to-firms adjustment factor of 1.25, used to compute the number of firms in the "Other Facility Types" category, indicated that 18,080 firms were included in the foreign de minimis category. Table 18 reports the numbers of facilities and firms that were used in the cost estimates. FDA requests comments on these estimates.

TABLE 18.—NUMBER OF FACILITIES AND FIRMS AFFECTED. OPTION 10

Type	Facility Estimate	Facility to Firm Adjust. Factor	Firm Estimate
Domestic			
Manufacturers	43,376	1.17	36,948
Wholesalers/Warehouses	95,745	1.24	76,952
Packaging[1]	36,907	1.07	34,633
Transporters/Packers	16,773	1.11	15,171
Retail Grocery and Specialty Food	207,657	1.35	153,277
Convenience Stores	128,985	1.87	68,866
Mixed-Type Facilities that Engage in Farming	30,497	1.25	24,397
Importers	18,902	1.25	15,122
Total Domestic	578,842		425,366
Foreign			
Final Holders	77,427	1.25	61,942
De minimus Processors/Packagers	22,600	1.25	18,080
Manufacturers	125,450	1.17	106,858
Other Facility Types	0	0	0
Total Foreign	225,477		186,879

[1] Includes both outer packaging and food contact substances.

Since "Other Facility Types" is such a large and uncertain category, the exclusion of most of the category has a significant impact on all cost estimates.

The estimated ranges of the costs for learning, records access planning, additional records maintenance, and records redesign, as well as the total for this option are reported in table 19. The costs reported in the table are identified by the applicable Code of Federal Regulations (CFR) section and are expressed in present value terms to account for the fact that some costs are one-time costs while others are recurring costs. The cost estimate that is greater than 95 percent of all other estimates generated by the model is reported as the high value. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low value.

TABLE 19.—COST DESCRIPTION IN PRESENT VALUE TERMS: OPTION 10

21 CFR Section	Mean	Low	High
1.337, 1.345, and 1.352, (Learning)	$138,357,000	$134,017,000	$142,346,000
1.337, 1.345, and 1.352, (Redesign)	$381,292,000	$326,799,000	$430,439,000
1.361 (Access Planning)	$78,834,000	$73,176,000	$84,179,000

TABLE 19.—COST DESCRIPTION IN PRESENT VALUE TERMS: OPTION 10—Continued

21 CFR Section	Mean	Low	High
1.337, 1.345, and 1.352 (Additional Records Maintenance)	$2,952,309,000	$2,817,570,000	$3,070,891,000
1.337, 1.345, and 1.352, (Learning for New Firms)	$13,836,000	$13,310,000	$14,328,000
1.361 (Access Preparation for New Firms)	$7,883,000	$7,318,000	$8,418,000
Total[1]	$3,660,808,000	$3,478,944,000	$3,833,452,000

[1] The totals reported at the bottom of each column differ slightly from the results that would be obtained by adding together all of the cells in the column. This is because the computation of the totals reported here is made assuming a joint distribution of the cost components, as described elsewhere in the analysis, rather then by adding together the individually computed component costs.

The annual range and discounted costs for option 10 as well as the marginal savings of option 10 with respect to option 4 are detailed in tables 20 and 21 of this document. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 20.—TOTAL ANNUAL COSTS, OPTION 10

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$234,425,000	$215,030,000	$252,196,000	$383
Year 2	$507,230,000	$459,345,000	$550,801,000	$828
Year 3 and later years	$221,130,000	$212,313,000	$229,680,000	$361

TABLE 21.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS: OPTION 10

	Discounted Annual Costs: Option 10	Marginal Savings of Option 10 With Respect to Option 4
Year 1	$234,425,000	$166,066,000
Year 2	$474,047,000	$191,243,000
Year 3	$193,144,000	$99,180,000
Year 4	$180,508,000	$92,692,000
Year 5	$168,699,000	$86,628,000
Year 6	$157,663,000	$80,961,000
:[1]	:	:
:	:	:
Year 15	$85,758,000	$44,037,000
:	:	:
:	:	:
Year 30	$31,083,000	$15,961,000
:	:	:
:	:	:
Present Value as of Year 1	$3,660,808,000	$1,873,357,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 11: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except foreign coverage includes only facilities that are the final holders of the product before export to the United States.

We estimate that there would be approximately 62,000 foreign facilities covered under this option. We assumed that the number of foreign final holding facilities is equivalent to the number of domestic importers. Since foreign manufacturing facilities and foreign de minimus processors/packagers would be excluded from recordkeeping requirements, the coverage under this option is more limited than the coverage under option 10. The rationale for specifying this option is that final holders may be the most accessible foreign facilities in the event of an FDA traceback investigation. In addition, foreign final holders may be particularly at risk at this level in the food chain if the food is clearly identified as destined for consumption in the United States.

Tables 22 and 23 of this document present the cost estimates for option 11. As previously discussed, discount computations are made using mean costs and assume no increase in real labor cost and a 7 percent real discount rate. Although the recurring costs reported for year 3 and later years are the same in nominal terms (i.e., $182,429,000 reported in Table 22 of this document), they are reported in discounted terms for each year in Table 23 of this document to account for the fact that a dollar in 5 years, for example, is worth less than a dollar today. Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above. Costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 22.—TOTAL ANNUAL COSTS, OPTION 11

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$172,973,000	$156,033,000	$190,831,000	$355
Year 2	$413,484,000	$369,335,000	$458,871,000	$849
Year 3 and later years	$182,429,000	$174,474,000	$190,610,000	$374

TABLE 23.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS: OPTION 11

	Discounted Annual Costs: Option 11	Marginal Savings of Option 11 With Respect to Option 4
Year 1	$172,973,000	$227,518,000
Year 2	$386,434,000	$278,856,000
Year 3	$159,341,000	$132,983,000
Year 4	$148,916,000	$124,284,000
Year 5	$139,174,000	$116,153,000
Year 6	$130,069,000	$108,555,000
:[1]	:	:
:	:	:
Year 15	$70,749,000	$59,046,000
:	:	:
:	:	:
Year 30	$25,643,000	$21,401,000
:	:	:
:	:	:
Present Value as of Year 1	$2,995,041,000	$2,539,124,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 12: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except all foreign food facilities are excluded.

This option excludes all foreign firms from recordkeeping requirements and has even less coverage than under option 11. Tables 24 and 25 of this document present the cost estimates. As previously discussed, discount computations are made using mean costs and assume no increase in real labor cost and a 7 percent real discount rate. Although the recurring costs reported for year 3 and later years are the same in nominal terms (i.e., $162,228,000 reported in Table 24), they are reported in discounted terms for each year in Table 25 of this document. Costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 24.—TOTAL ANNUAL COSTS, OPTION 12

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$139,947,000	$125,857,000	$152,775,000	$329
Year 2	$376,310,000	$334,230,000	$421,832,000	$885
Year 3 and later years	$162,228,000	$155,337,000	$169,446,000	$381

TABLE 25.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS: OPTION 12

	Discounted Annual Costs: Option 12	Marginal Savings of Option 12 With Respect to Option 4
Year 1	$139,947,000	$260,544,000
Year 2	$351,692,000	$313,598,000
Year 3	$141,696,000	$150,628,000
Year 4	$132,426,000	$140,774,000
Year 5	$123,763,000	$131,564,000
Year 6	$115,666,000	$122,958,000
:[1]	:	:
:	:	:
Year 15	$62,915,000	$66,880,000
:	:	:
:	:	:
Year 30	$22,803,000	$24,241,000
:	:	:
:	:	:
Present Value as of Year 1	$2,657,566,000	$2,876,599,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 13: Facilities must be able to tie specific input ingredients to specific products.

Most comments FDA received during its early outreach efforts for this proposed rule stated that tying specific raw input ingredients to specific finished products would significantly increase the burden on industry, which would translate into large social costs. Some comments suggested that some facilities have systems in place that can link each lot of raw ingredient to each lot of finished product, but such systems are rare for bulk agricultural commodities. For example, it is common practice in handling agricultural commodities to commingle raw ingredients from several suppliers in a large silo or storage tank. While this business practice would not be required to change under options 2–12, option 13 would add the significant new burden of requiring firms that traditionally commingle raw ingredients from several suppliers to redesign a production or storage strategy that would allow them

to identify more precisely the source of all the food products.

Most agricultural crops are traded as bulk commodities; bulk trading operates on the premise that crops produced by different farmers are sufficiently similar to be traded at a common price and with a common grading specification. For various reasons, some firms have put in place identity preservation systems, which they use to track individual lots of products throughout production and distribution. These identity preservations systems exist for organic products, kosher products, and some specialty versions of bulk products. FDA estimated the potential impact of this option by reviewing studies of current identity preservation systems. We assume that the identity preservation systems put in place for specialty versions of traditionally commingled products closely resembles what would be required to comply with the input-to-output requirement of this option. The study we rely on for our estimates (Ref. 17) is for corn and soybeans, the largest crops by value in the United States, but the issues should be similar for other types of bulk products.

The cost of identity preservation consists of: (1) The cost of segregating crops to prevent commingling, and (2) the cost of tracking ingredients. First, commodity suppliers should incur an increase in cost due to their inability to mix commodities in bulk. The Bender et al (Ref. 16) study estimates costs based on responses to a small survey of specialty elevators, grain firms, seed companies, and brokers. On average, 35 percent of the volume handled by these firms is specialty product, so they have ample experience in identifying cost differences, including storage, handling and segregation, risk management, transportation, analysis and testing, and marketing costs. Of the 84 survey responses, 55 estimated the cost of segregating and handling specialty crops. FDA used the overall average across facility types to estimate an average cost premium to be applied to each preprocessed commodity: $0.17 per bushel for corn and $0.48 per bushel for soybeans. The original estimate included a premium paid to farmers, but we subtracted this amount out of the total. Since option 13 would only require the identification of a particular immediate previous source, in this case a farm, we assume no new farming activity would have to take place. At an average price of $1.81 per bushel for corn and $4.60 per bushel for soybeans in 1999 (Ref. 18), the premium estimated for corn is 9.4 percent and for soybeans is 10.4 percent. Due to the small sample, standard errors were not reported in this study, but considerable nonquantified uncertainty exists around these estimates. These estimates may be an overestimate of premiums if economies of scale are possible in identity preservations systems. These estimates may be an underestimate if the reason these specialty product systems exist is that it is easier to preserve identities for corn and soybeans than for other products.

Table 26 of this document presents the calculations of the cost based on these segregation premiums. We apply the premium to the 1999 farm value of commodities, not to the retail values as retail prices include many other aspects of branding and bringing the product to market. These are also the latest data available, and since agricultural prices have been fairly stable, we do not adjust these dollar amounts to 2002. The estimated corn premium from the studies is used for all other bulk grain products, and the estimated soybean premium is also used for nuts, sugarcane and beets, sunflowers, and flaxseeds. Milk is assumed to have a lower cost increase; most milk production is local and already includes a tracking system to allow for the use of expiration dates for the final product. Vegetables destined for final consumption in an unaltered state, vegetables used for production, and eggs are also assumed to have a lower cost of tracking since current commingling practices for these products are limited. The table includes nuts, but we were unable to find a satisfactory price estimate. FDA requests comments on these assumptions.

TABLE 26.—COMMINGLING COSTS BASED ON SPECIALTY PREMIUMS, OPTION 13

Food Type	Count	Unit	$ Farm gate	Premium %	Premium $
Corn (for grain)	9,430,612,000	bushels	$17,103,991,000	9.4%	$1,603,204,000
Soybeans	2,653,758,000	bushels	$12,205,352,000	10.4%	$1,273,804,000
Milk	162,716,000,000	pounds	$23,400,050,000	5.0%	$1,170,003,000
Wheat	2,299,010,000	bushels	$5,593,989,000	9.4%	$524,340,000
Fruits	31,152,000	tons	$9,345,600,000	5.0%	$467,280,000
Fresh Vegetables	22,484,150	tons	$7,610,780,000	5.0%	$380,539,000
Eggs	82,715,000,000	eggs	$4,321,859,000	5.0%	$216,093,000
Sugar beets	33,420,000	tons	$1,242,898,000	10.4%	$129,714,000
Rice	20,602,700,000	pounds	$1,231,207,000	9.4%	$115,404,000
Peanuts	3,829,490,000	pounds	$971,608,000	10.4%	$101,401,000
Sugarcane	35,299,000	tons	$941,791,000	10.4%	$98,290,000
Sorghum	595,166,000	bushels	$937,406,000	9.4%	$87,866,000
Prod. Vegetables	15,476,230	tons	$1,660,051,000	5.0%	$83,003,000
Barley	280,292,000	bushels	$597,038,000	9.4%	$55,962,000
Sunflower	4,341,862,000	pounds	$339,993,000	10.4%	$35,483,000

TABLE 26.—COMMINGLING COSTS BASED ON SPECIALTY PREMIUMS, OPTION 13—Continued

Food Type	Count	Unit	$ Farm gate	Premium %	Premium $
Oats	146,193,000	bushels	$175,172,000	9.4%	$16,419,000
Honey	205,250,000	pounds	$126,075,000	5.0%	$6,304,000
Flaxseed	7,864,000	bushels	$30,098,000	10.4%	$3,141,000
Rye	11,038,000	bushels	$25,084,000	9.4%	$2,351,000
Nuts	1,295,700,000	pounds	$0	5.0%	$0
Total			$87,860,042,000		$6,370,601,000

As the second component of cost, FDA assumes that manufacturers using bulk production processes would have to adopt a new tracking system for their input ingredients. Having identity-preserved input ingredients delivered from their suppliers would help in this task, but the disruption to production practices could be substantial. FDA does not have an estimate of the percentage of producers that may be affected by this option, or the amount of change in production practices that would have to take place, but we assume that a useful lower bound of the increase in production cost would be the increase in information design and collection costs that manufacturers would face in this system.

For redesign costs, FDA used the Labeling Cost Model, assuming a full new document design as opposed to simple addition of information. FDA also assumed a doubling of information collection burden for manufacturers when compared to other options; they would have to track three sets of records (input sources, output sources, and input to output tracking) instead of two, but could not share the information collection burden with others in the production chain for these manufacturing records. As in the other options, we assumed the design costs would be incurred at the firm level and the additional records maintenance costs would be incurred at the facility level. FDA considers these design and records maintenance costs a probable underestimate of the total cost of disruption in manufacturing possible under this option, since it does not consider production process changes or additional tracking costs required in the post-production distribution chain. Table 26 of this document summarizes the redesign and additional records maintenance burden calculations unique to option 13.

TABLE 27.—ADDITIONAL REDESIGN AND RECORDS MAINTENANCE COSTS, OPTION 13.

	Count	Medium	Low	High
Redesign				
Domestic Manufacturing Firms	36,948	$228,816,000	$171,917,000	$413,738,000
Foreign Manufacturing Firms	72,770	$450,666,000	$338,600,000	$814,880,000
Total	109,718	$679,482,000	$510,517,000	$1,228,618,000
Additional Records Maintenance				
Domestic Manufacturing Facilities	43,376	$14,154,000		
Foreign Manufacturing Facilities	85,431	$27,876,000		
Total	128,807	$42,030,000		

Tables 28 and 29 of this document present the estimated range and impact of option 13 on total costs into the future. As the tables indicate, option 13 is much costlier than any of the other regulatory options. The numbers in parentheses in the right hand column of Table 29 reflect a negative marginal cost savings of option 13 with respect to option 4. As previously discussed, discount computations are made using mean costs and assume no increase in real labor cost and a 7 percent real discount rate. Although the recurring costs reported for year 3 and later years are the same in nominal terms (i.e., $6,743,086,000 reported in Table 28), they are reported in discounted terms for each year in Table 29 to account for the fact that a dollar in 5 years, for example, is worth less than a dollar today. Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above. Costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 28.—ANNUAL TOTAL COSTS, OPTION 13

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$442,970,000	$405,800,000	$484,402,000	$445
Year 2	$2,692,790,000	$2,504,068,000	$2,921,375,000	$2,706
Year 3 and later years	$6,743,086,000	$6,702,239,000	$6,726,422,000	$6,748

TABLE 29.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS: OPTION 13 (NUMBERS IN PARENTHESES ARE NEGATIVE)

	Discounted Annual Costs: Option 13	Marginal Savings of Option 13 With Respect to Option 4
Year 1	$442,970,000	($183,745,000)
Year 2	$2,516,626,000	($1,901,433,000)
Year 3	$5,889,672,000	($5,630,368,000)
Year 4	$5,504,367,000	($5,262,026,000)
Year 5	$5,144,268,000	($4,917,781,000)
Year 6	$4,807,727,000	($4,596,057,000)
:[1]	:	:
:	:	:
Year 15	$2,615,085,000	($2,499,951,000)
:	:	:
:	:	:
Year 30	$947,827,000	($906,097,000)
:	:	:
:	:	:
Present Value as of Year 1	$92,987,447,000	($88,149,370,000)

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Marginal analysis: As a way of comparing the options, Table 30 of this document presents the present values of total costs and the marginal savings of each option compared with option 4. Option 4 was chosen for comparison since it differs by only one provision from almost all the other options considered in the analysis. The marginal savings for all options, except options 2 and 13, are either zero or positive reflecting either a lower total cost or equivalent total cost compared with option 4.

Since option 3 and options 5–12 involve a single modification of the requirements in option 4, the marginal savings expressed for each of those options reflects the cost savings from removing that requirement. Furthermore, while option 2 differs from option 4 by two provisions, rather than one provision (option 4 does not require persons that manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging to keep records and does not require persons that are required to keep records on foods to keep records on the food's outer packaging), the costs computed for both options are equivalent. As a result, there is no loss in meaning by comparing the costs of all options to option 4 in Table 30. Consequently, for option 10, the marginal savings in present value terms from relaxing the comprehensive foreign coverage requirement in option 4 to the reduced level of coverage specified by the registration rule is $1,873,357,000 as reported in the following table.

TABLE 30.—PRESENT VALUE AND MARGINAL SAVINGS WITH RESPECT TO OPTION 4

Option	Present Value of Total Cost	Marginal Savings With Respect to Option 4	Description of Option Requirements
2	$5,663,484,000	($129,319,000)[1]	Comprehensive coverage, 4 or 8 hour records-access requirement, 1 and 2-year records-retention requirement

TABLE 30.—PRESENT VALUE AND MARGINAL SAVINGS WITH RESPECT TO OPTION 4—Continued

Option	Present Value of Total Cost	Marginal Savings With Respect to Option 4	Description of Option Requirements
3	$5,534,165,000	$0	Exclude outer packagers
4	$5,534,165,000	$0	Exclude outer packagers and recordkeeping on outer packaging
5	$4,818,810,000	$715,355,000	Same as option 4 except records-access requirement is relaxed to 24 hours
6	$5,087,535,000	$446,630,000	Same as option 4 except intrastate facilities are excluded
7	$5,332,584,000	$201,581,000	Same as optioh 4 except mixed-type facilities that engage in farming are excluded
8	$5,534,165,000	$0	Same as option 4 except universal records retention of 1 year
9	$5,534,165,000	$0	Same as option 4 except universal records retention of 2 years
10	$3,660,808,000	$1,873,357,000	Proposed. Same as option 4 but limit foreign coverage to be the same as registration.
11	$2,995,041,000	$2,539,124,000	Same as option 4 but limit foreign coverage to the final holders prior to export.
12	$2,657,566,000	$2,876,599,000	Same as option 4 except all foreign facilities are excluded.
13	$93,137,167,000	($87,603,002,000)[1]	Comprehensive coverage. Precise input to output recordkeeping requirement.

[1] Numbers in parentheses are negative.

Sensitivity of cost estimates to assumptions: For all the options, FDA attempted to quantify the uncertainty associated with redesign costs and the number firms and facilities exclusively dedicated to imports, but we had no basis for assigning distributions to other uncertain components. By far the largest source of uncertainty is the premium on products that would be subject to new identity preservation under option 13. FDA also tested the sensitivity of other sources of uncertainty under option 10, in order for the reader to compare various sources of uncertainty and submit comments regarding our assumptions. Although the dollar sensitivities to the assumptions specified in Table 31 of this document should be similar across the options, many of the percentage sensitivities would—because of different base costs—differ under other options. FDA believes that the ranking of the costs of these options is not affected by any uncertainty in our estimates.

There is significant uncertainty in the estimate of the number of mixed-type facilities that engage in farming. Based on research described earlier, our estimate of the number of mixed-type facilities that engage in farming that would be covered by this proposed rule is 30,497. To determine the sensitivity of the cost estimates to changes in the numbers of mixed-type facilities that engage in farming, a sensitivity analysis was performed in which the number of these types of facilities was increased by 10 percent.

Table 31 of this document presents the results of the sensitivity analyses that we conducted. For option 13, Table 31 reports the effect of an increase in crop premium for identity preservation of 1 percent for all crops. For option 10, Table 31 reports the effect of a 10 percent increase in the estimate of the number of mixed-type facilities that engage in farming, and 10 percent cost increases for each component cost on the mean first-year total cost estimates. For redesign costs, we assumed a 10 percent increase in the medium cost estimate.

Finally, to be consistent with the analysis conducted for the Registration proposed rule, a sensitivity analysis was conducted that accounted for the possibility that a number of foreign firms would cease to export to the United States because of the burden imposed by these regulations. This is particularly relevant when considering the burden imposed on foreign firms by the Registration proposed rule. In the analysis of the registration proposed rule, it was estimated that approximately 16 percent of small manufacturers and processors (defined in that analysis as those exporting 10 or fewer line items to the United States) would cease exporting to the United States because of the increase in costs due to that proposed rule. Consistent with the analysis of the Registration proposed rule, we analyzed the cost sensitivity of a 16 percent reduction in the number of foreign firms. FDA requests comments on other desired sensitivity analyses.

TABLE 31.—SENSITIVITY ANALYSIS

Test	Option	Effect on Present Value Mean Cost ($)	Percent Effect
10% increase in records maintenance	10	$276,513,000	7.02%
10% increase mixed-type facilities that engage in farming	10	$17,061,000	0.46%
10% decrease in percent European	10	$33,529,000	0.91%
10% increase in redesign	10	$38,006,000	1.03%
10% increase in learning	10	$32,185,000	0.87%
10% increase in access	10	$18,873,000	0.51%
16% decrease in number of foreign firms	10	($138,484,000)[1]	(3.93%)[1]
1% increase in identity preservation premium	13	$490,117,000	0.52%

[1] Numbers in parentheses are negative.

Benefits: These options would improve FDA's ability to address adulterated food and food packaging that presents a threat of serious adverse health consequences or death to humans and animals. FDA is unable to quantify the benefits of these regulations, though we consider them substantial. While the probability of a deliberate contamination of the food supply may be low, the potential cost of a deliberate contamination of the food supply may be high. Below we present some examples to demonstrate what such a contamination may look like. Without having any hypothesis on the likelihood of a deliberate contamination, it is impossible to quantitatively measure the benefits of the reduced impact due to each of these regulatory options.

Further hindering any quantification of benefits is the interactive effect of other regulations that are being developed to implement Title III of the Bioterrorism Act of 2002. The registration (section 305 of the Bioterrorism Act) and recordkeeping regulations would work cooperatively to identify and track possible sources of an outbreak. The prior notice for imported shipments (section 307 of the Bioterrorism Act) would allow the agency time to identify possible sources of risk from adulterated food and its packaging that presents a threat of serious adverse health consequences or death to humans and animals, which could then be investigated with the aid of the new registration and recordkeeping regulations.

To understand possible costs of an intentional attack on the food supply, we examine five outbreaks resulting from accidental and deliberate contamination, and from both domestic and imported foods. It is possible that an intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens would be much larger. Also, intentional attacks may be fundamentally more difficult to trace than natural outbreaks due to deliberate obfuscation of the source and possible multiple contamination events of different food types and food facilities. We then examine mechanisms through which each regulatory option discussed in this analysis may act and analyze how each of the options affects the mechanisms.

TABLE 32.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and Year	Vehicle	Confirmed or Reported Cases	Estimated Number of Cases	Total Illness Cost (dollars)
Salmonella enteritidis	Minnesota 1994	Ice cream	150 cases; 30 hospitalized	29,100 in MN; 224,00 nationwide	3,187,744,000 to 5,629,792,000
Shigella sonnei	Michigan 1988	Tofu salad	3,175 cases	Not available	45,183,000 to 79,797,000
Outbreaks resulting from deliberate contamination					
Salmonella Typhimurium	Dalles, Oregon 1984	Salad bars	751 cases; 45 hospitalized	Not available	10,687,000 to 18,875,000
Shigella dysentreriae type 2	Texas 1996	Muffins and doughnuts	12 cases; 4 hospitalized	All cases identified	83,000
Outbreaks resulting from imported foods					
Cyclospora cayaetanensis	United States and Canada 1996	Raspberries (probably imported from Guatemala)	1465 cases identified, less than 20 hospitalized	Not available	3,941,000

Salmonella enteritidis in ice cream

In 1994, approximately 224,000 people were sickened by ice cream contaminated with *Salmonella enteritidis*. The source of the contamination appeared to be pasteurized premix that had been contaminated during transport in tanker trailers that carried nonpasteurized eggs. There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota. However, ice cream processed during the contamination period was distributed to 48 states. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000 (Ref. 19).

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause 1 to 3 days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as cases that require a trip to a physician, account for 8 percent of the cases. These cases typically have a duration of 2 to 12 days. Severe cases require hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over 1 percent of cases develop short-term reactive arthritis and 2 percent of cases develop chronic, reactive arthritis.

FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Table 32 of this document provides a summary of these estimates. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. FDA uses the value placed by consumers on the risks to life found in current economic literature (See Refs. 20, 21, 22, and 23). In addition, FDA presents two estimates of values of pain and suffering associated with arithritis, one based on physician estimates (Ref. 24) and another based on a regression analysis approach (Ref. 25). This gives a range of costs for the average case of salmonellosis between $14,231 and $25,133.

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between $3,187,744,000 and $5,629,792,000 from this accidental food disaster.

TABLE 33.—THE COST OF A TYPICAL CASE OF SALMONELLOSIS

Severity	Case Breakdown (percent)	Total QALDs Lost per Illness	Health Loss (dollars) per Case (Discounted)	Medical Costs (dollars) per Case (Discounted)	Weighted Dollar Loss per Case
Illness					
Mild	90.7	1.05	660	0	599
Moderate	8.1	3.68	2,310	283	209
Severe	1.2	9.99	6,266	9,250	188
Arthritis					
Regression approach					
Short-term	1.26	5.41	3,391	100	44
Long-term	2.40	2,613.12	452,554	7,322	11,048
Direct survey approach					
Short-term	1.26	10.81	6,778	100	87
Long-term	2.40	5,223.15	904,573	7,322	21,906
Death	0.04		5,000,000		2,143
Total expected loss per case					
Regression approach					14,231
Direct survey approach					25,133

Shigella sonnei in tofu salad

In 1988, a tofu salad at an outdoor music festival was contaminated with Shigella sonnei and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival (Ref. 26). Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short term and chronic reactive arthritis; thus FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of $45,183,000 to $79,797,000.

Salmonella typhimirium in salad bars

During September and October of 1984, two outbreaks of *Salmonella* typhimirium occurred in association with salad bars in restaurants in The Dalles, Oregon. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally caused the outbreak by spraying *Salmonella* typhimirium on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout. Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks (Ref. 27).

The 751 people affected primarily were identified through passive surveillance; thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak. We use the cost estimates for salmonellosis as ranging from $14,231 to $25,133. This gives an estimated cost

of known cases for the outbreak of $10,687,000 to $18,875,000.

Shigella dysenteriae type 2 among laboratory workers

Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All twelve affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 28).

To estimate the cost of this outbreak, FDA assumed that the eight cases requiring consultation with a doctor, but not requiring hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of $83,000 for illnesses associated with the event.

TABLE 34.—SUMMARY OF COSTS FOR CASES OF SHIGELLOSIS

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	0	0	0
Moderate	8	2,593	21,000
Severe	4	15,516	62,000
Grand total			83,000

Cyclospora cayatanensis in imported raspberries

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. 29). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 states, two Canadian provinces, and the District of Columbia (Ref. 30).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref. 30). We estimated the cost of a mild case of cyclosporiasis as two and a half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak (Ref. 29). No deaths were confirmed.

TABLE 35.—SUMMARY OF COSTS FOR CASES OF CYCLOSPORIASIS

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	879	1,650	1,450,000
Moderate	586	3,748	2,196,000
Severe	19	15,516	295,000
Grand total			$3,941,000

Mechanisms: The new recordkeeping provisions we describe in the options section would not only help FDA determine the cause of a particular outbreak by tracing the source, they would also reduce further adverse health effects by enabling FDA to trace forward to locate adulterated food and its packaging that presents a threat of serious adverse health consequences or death to humans and animals. We expect that, working in concert with other regulations, having complete records identifying all links in the chain of custody for a particular product will allow FDA to more efficiently deploy its compliance and regulatory resources in an event of an outbreak. Having complete records increases the probabilities of FDA being able to trace back to the source of an outbreak and of FDA being able to trace forward to locate adulterated food and its packaging. FDA conducts approximately 20 emergency traceback investigations per year. Although no investigation has been completely halted by a lack of adequate records in the past several years, inadequate records have hindered investigations. For example, FDA attempted to conduct approximately 38 tracebacks in a Cyclospora outbreak in 1997. Of those, we were able to complete 33, and the majority of failures were due to the lack of available records. More commonly, incomplete records severely impede the ability of FDA to conduct effective investigations.

Faster required record access times may allow FDA to more rapidly identify the source of an outbreak and limit its effects. Over the past several years of FDA traceback investigations, the normal response time between a request for data and the receipt of the records from the firm is 2–3 days. The response times in these options would greatly speed up the traceback process, which would be critical in limiting a deliberate or accidental major outbreak.

Comparison of benefits under each option: Because we cannot quantify these benefits, we cannot differentiate the benefits of each option in dollar terms. Instead, we explore how effectively each of the two mechanisms, trace back and response, would operate under each of the options. The extent of coverage by each option is one criterion that we use to evaluate the effectiveness of each mechanism since the extent of coverage may influence the effectiveness of both trace-back and response times. Tables 36 and 37 of this document present the numbers of firms covered under each option, and the reduction in the numbers of firms covered under each option when compared to those covered under option 4. As in the costs section, option 4 was chosen for comparison purposes for the sake of consistency. Foreign and domestic coverage are presented separately in Tables 36 and 37 of this document since there may be reason to weigh the benefits from the inclusion of each category differently. Table 38 of this document provides a summary of the expected effects.

TABLE 36.—NUMBER OF FIRMS COVERED BY OPTION

Option	Domestic	Foreign	Total
2	459,998	535,432	995,431
3	425,365	449,676	875,041
4	425,365	449,676	875,041
5	425,365	449,676	875,041
6	351,772	449,676	801,448
7	400,968	449,676	850,644
8	425,365	449,676	875,041
9	425,365	449,676	875,041
10	425,365	186,879	612,245
11	425,365	61,942	487,307
12	425,365	0	425,365
13	459,998	535,432	995,431

TABLE 37.—MARGINAL REDUCTION IN THE NUMBERS OF FIRMS COVERED WITH RESPECT TO OPTION 4

Option	Domestic	Foreign	Total
2	(34,633)[1]	(85,756)[1]	(120,389)[1]
3	0	0	0
4	0	0	0
5	0	0	0
6	73,594	0	73,594
7	24,397	0	24,397
8	0	0	0
9	0	0	0
10	0	262,797	262,797
11	0	387,735	387,735
12	0	449,676	449,676
13	(34,633)[1]	(85,756)[1]	(120,389)[1]

[1] Numbers in parentheses are negative.

Evaluating the benefits by option using two mechanisms: (1) Complete records (which increase the probability of a thorough trace-back investigation), and (2) faster records access times (which may allow for more rapid identification of the source of an outbreak and limit its effects).

Option 1, no action: No impact.

Option 2, comprehensive coverage, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products: This option contains no exemptions, so it has the largest coverage of any of the options we consider and ranks high with regard to improving the ability to perform a thorough trace-back investigation. However, option 13 requires even greater additional record information collection, which would aid in trace-back investigations. So, based on mechanism 1, this option has the second highest benefits. With regard to the speed criterion—this option also has the quickest response time specified in any of the options. It is ranked second in overall benefits behind option 13.

Option 3, same as option 2 except outer-packaging manufacturers and distributors are excluded: The exclusion of outer food packagers from recordkeeping requirements reduces the coverage and the potential to perform a thorough trace-back investigation compared with option 2. It is also unclear what the relative risk of outer food packaging is compared with the risk of the food itself (including food contact substances), but FDA assumes that the potential harm through packaging adulteration, although serious, is lower than the potential harm through adulteration of food. This would tend to mitigate the consequences on potential trace-back capability from excluding these facilities. This option also scores relatively well if rated by the speed criterion since the records-access time is the same as in option 2. The exclusion of outer packaging manufacturers and distributors will not reduce benefits by much compared with option 2—especially because the risk of contamination through outer packaging is likely to be small.

Option 4, same as option 3 except recordkeeping on outer-packaging is excluded: The reduction in benefits from not requiring recordkeeping on outer food packaging is assumed to be negligible compared with option 3. Therefore, the benefits from this option are about the same as option 3 using both the complete records criterion and the speed criterion.

Option 5, same as option 4 except records access requirement is relaxed to 24 hours: This option does not differ much from option 4 by this ranking criterion, since it has the same domestic and foreign coverage and record scope requirements. However, this option scores relatively low by the speed criterion, since all other options would require a much faster response time for records access.

Option 6, same as option 4 except intrastate facilities are excluded: This option has lower benefits than many other options since it exempts the largest number of domestic facilities of any option. The relative ranking of options that offer exemptions will be affected by the total number of facilities exempted and the breadth of the supply chain these facilities cross. This intrastate exclusion would affect many different facility types throughout the supply chain, including approximately 91,383 domestic manufacturers, wholesalers, and warehouses. In addition, many facilities involved only in intrastate commerce handle food products that eventually will be introduced into interstate commerce farther along the supply chain. While intrastate facilities are likely to be small, if they are participants in the chain of custody of the food that causes a major outbreak, their exclusion could disrupt FDA's ability to identify the source of an outbreak and limit its effects. The overall ranking of this option is behind option 10.

Option 7, same as option 4 except mixed-type facilities that engage in farming are excluded: There are fewer exempted facilities in this option, owned by approximately 24,397 domestic firms, than in option 6. Furthermore, these exempt firms are mixed-type facilities that engage in farming and would be closer to the beginning of the chain of custody for food products. FDA considers this option to have lower benefits than option 5, since fewer facilities would be required to keep records that may be needed for a traceback investigation, but higher benefits than options 6 and 10–12, since fewer facilities would be exempt and especially since these facilities are closer to the beginning of the supply chain.

Option 8, same as option 4 except there is a universal records-retention requirement of 1 year for perishables and all other products: All other things being equal, the shorter the retention time for records, the more likely that those records would be missing when needed for a trace-back investigation. Most nonperishable products and perishable products that are processed into finished food products may be in the supply chain for longer than a year, but it is very likely that the effects of a contamination of nonperishable goods would be seen within a year of being introduced in the market. FDA considers this option to have higher benefits than options 6 and 7, and higher benefits than the other exemptions offered in options 10–12. Option 8 is ranked lower than option 9 because of the nonzero probability that a nonperishable food is adulterated and that adulteration is not discovered until more than a year after the event.

Option 9, same as option 4 except there is a universal records-retention requirement of 2 years for perishables and all other products: Once again, all other things being equal, the longer the record retention the better, so this option probably has more benefits than option 2. While option 9 has the benefit of simplicity in that there is only one retention requirement for all records, in practical terms the danger from a perishable good will be known soon after that good is consumed. Consequently, keeping records longer than one year for perishable goods that are consumed in an unaltered state would most likely exceed the time period of many tracing investigations. Therefore, based on the ability to conduct a thorough investigation, FDA ranks the benefits of this option as roughly equal to option 4, especially since the longer records-retention requirement should not affect the speed of an investigation.

Option 10, same as option 4 except that foreign coverage is the same as for the registration proposed rule: The proposed option would generate more benefits than other options that exempt foreign facilities. Since the foreign coverage is progressively lower for options 10, 11, and 12, the benefits also decrease for those options accordingly. However, the benefit from improved recordkeeping practices by a given set of facilities also depends on the amount of food produced by those facilities. Because imported food accounts for a small percentage of total domestic food consumption, the average amount of domestically consumed food from foreign facilities is smaller than that from domestic facilities. Under this option, the reduction in the number of foreign facilities that are covered is proportionally greater than the reduction in the amount of food covered. As a result, the incremental reduction in potential costs caused by the exemption of foreign facilities should be larger than the incremental reduction in benefits. The exemption of foreign facilities under this option

would likely hamper trace-back capability by less than an exemption of the same number of domestic facilities.

Moreover, option 10 has the added benefit of simplicity in that the foreign coverage would be the same as that covered under the registration rule. This parallel coverage to the registration rule would make monitoring both recordkeeping and registration practices less costly.

Option 11, same as option 4 except that foreign coverage includes only the final holders before export: In addition to the exemptions in option 10, this option exempts an additional single category in the middle of the foreign supply chain and with a large number of facilities. Consequently, the benefits under this option are lower than under option 10 by both the speed criterion and the thorough investigation criterion. However, as we explained in the discussion of option 10, the proportionally smaller importance of imported foods in the domestic food supply implies that the exemption should have relatively little effect on benefits.

Option 12, same as option 4 except that all foreign facilities are excluded: This option exempts all foreign suppliers from record-keeping requirements. When compared to options 10 and 11, the number of foreign firms covered under this option is the lowest. As such, the benefits of this option, when compared to the other two, are the lowest as well using both the speed criterion and the ability to conduct a thorough investigation.

Option 13, comprehensive coverage that requires facilities to be able to tie specific input ingredients to specific products: This option generates the highest benefits. A complete list of the specific source of all ingredients would be available for all processed and raw foods, greatly aiding traceback and trace forward investigations. In addtion, of all the options, this would allow investigators to most quickly identify candidate traceback facilities, since it would allow FDA to effectively narrow our search to specific entities.

Table 38 of this document presents the overall ranking of each option based on the previous summary. Option 13, requiring input ingredients to be connected to output ingredients through records, has the highest absolute benefits, followed by option 2. The lowest ranked option in terms of absolute benefits is the baseline, option 1, and the lowest benefits of the possible interventions would be the proposed rule with a complete foreign facility exemption, due to the large number of foreign facilities where adulteration might occur. FDA requests comments on this ranking.

TABLE 38.—RANKING OF EFFECTIVENESS OF EACH MECHANISM UNDER EACH OPTION

Option:	Benefit 1	Benefit 2	Overall Ranking
1) No action	13	13	13
2) 4 or 8 hour records access	2	2	2
3) Outer packaging exemption	3	3	3
4) Exclude recordkeeping on outer packaging	3	3	3
5) 24-hour records access	7	9	8
6) Intrastate exemption	10	10	10
7) Mixed-type facilities that engage in farming	5	5	5
8) 1-year record retention	7	7	7
9) 2-year record retention	6	6	6
10) Proposed. Same foreign coverage as Registration	8	8	8
11) Cover only final foreign holders	11	11	11
12) Exempt all foreign suppliers	12	12	12
13) Input to output requirement	1	1	1

B. Initial Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this proposed rule would have a significant economic impact on a substantial number of small entities.

Impact per firm: We define small as employing fewer than 500 full-time-equivalent workers. The SBA uses several criteria for identifying a small firm based on its NAICS code, but having less than 500 employees is the most common SBA small definition in the food industry (Ref. 31). We also consider two definitions of very small: Less than 20 employees and less than 10 employees. The great majority of firms are considered small when classified by any of these definitions. Table 39 presents the percent of firms in each of these categories. Not included in this table are farm numbers. We calculated farm percentages using the Agricultural census through the NASS, but the Agricultural census only classifies farm size by sales and acreage, not by the number of employees (Ref. 19). Fifty percent of farms have less than $10,000 in annual sales. Neither SBA definitions nor employee data exist for exclusive food importers; we assume that the percentage of small firms in this category is similar to the percentage in other food categories. We do not include foreign firms in this analysis because the Regulatory Flexibility Act does not

apply to foreign entities. It is clear from Table 39 of this document that any provision in this regulation that takes the size of the facility into account would cover a significant percent of food businesses.

TABLE 39.—PERCENTAGE OF SMALL AND VERY SMALL FIRMS

Type	< 500 Employees	< 20 Employees	< 10 Employees
Manufacturers	98.0%	85.3%	77.0%
Wholesalers/Warehouses	99.3%	89.4%	82.2%
Packaging[1]	98.6%	87.0%	78.7%
Transporter/Packers	99.5%	94.8%	89.5%
Grocery and other Retail	99.7%	93.9%	87.8%
Convenience Stores	99.6%	88.9%	73.1%
Mixed-Type Facilities that Have Farms	—	—	—
Importers	—	—	—

[1] Includes both outer packaging and food contact substances.

In Tables 40 and 41 of this document, FDA presents the average and maximum possible burden placed on each small and very small firm following the adoption of the final rule. We explain these costs in detail in the preliminary regulatory impact analysis. Costs fall into four categories: learning about the regulation, redesigning records to accommodate new information, collecting and maintaining new information, and planning for a rapid response in the event of a records request from FDA under this authority. The average mean startup costs reported in the table are approximately $888, and the average mean recurring costs reported in the table are approximately $222. Based on our assumptions, average maximum startup costs are approximately $2569 and the average maximum recurring costs reported in the table are $521. We also acknowledge considerable nonquantifiable uncertainty in these estimates, so the true burden of the regulation on small businesses could be higher or lower.

The estimated burden on convenience stores is lower since: (1) We assume that most convenience stores will depend on either a corporate parent or other facility in the supply chain for document redesign, and (2) only a small percentage of convenience stores sales (11.4 percent according to a comment received through FDA's early outreach) is for food products, so the volume of food products for which they would have to collect information and prepare access is relatively small. Transporters and Packing firm costs are larger since we assume that transporting firms would not be able to share records redesign costs with firms up or down the supply chain. We also assumed that packaging producers and distributors would have to maintain relatively less additional information since not all of their products will be used to pack food. In subsequent years, all firms will only incur the additional records maintenance burden.

TABLE 40.—AVERAGE STARTUP AND RECURRING COSTS PER FIRM

Cost	Transporter/ Packer	Convenience Store	Packaging[1]	Other
Startup				
Learning	$120	$120	$120	$120
Redesign	$1,211	$121	$606	$606
Access Preparation	$151	$75	$151	$151
Total Startup	$1,482	$317	$876	$876
Recurring				
Additional Records Maintenance	$326	$63	$163	$326

[1] Includes both outer packaging and food contact substances.

The maximum first year costs per firm are calculated using the following assumptions: First, a firm may not have Internet access, so it may have a 5 1/2 hour learning burden. Next, a firm may incur the largest value in the distribution of redesign costs, and may not be able to share the redesign burden with other facilities. Finally, the firm may not receive records with any additional information previously collected that is required in this proposed rule. Thus they may incur the entire burden of additional records maintenance. We assume access preparation costs do not vary.

TABLE 41.—MAXIMUM STARTUP AND RECURRING COSTS PER FIRM

Cost	Transporter/ Packer	Convenience Store	Packaging[1]	Other
Startup				
Learning	$138	$138	$138	$138
Redesign	$2,299	$2,299	$2,299	$2,299
Access Preparation	$151	$75	$151	$151
Total Startup	$2,588	$2,512	$2,588	$2,588
Recurring				
Additional Records Maintenance	$653	$126	$653	$653

[1] Includes both outer packaging and food contact substances.

In order to get a rough estimate of the impact of higher recordkeeping costs on small businesses, we ran the small business simulation model that was developed by FDA's contractor, RTI International (Ref. 31), for the candy and ready-to-eat food sectors. In the simulation, we used the high annual costs of the second year per-firm recordkeeping costs (about $850) to see the impact on revenues and cash flow. The results from the simulation indicate that when firm size (by number of employees) is assumed to be normally distributed, the recordkeeping costs in the second year would result in pre-tax costs being greater than cash flow for 0.1 percent of firms with fewer than 20 employees in the candy industry. For the ready-to-eat sector, the results indicate that the high second year per-firm recordkeeping costs would not result in pre-tax costs being greater than cash flow for any firms.

Additional flexibility considered: Agencies can consider three basic small business regulatory options: First, if the implementing statute allows, an agency could exempt small businesses from all regulatory requirements. In addition, an agency could modify the regulatory requirements for small businesses, including offering an exemption from part of the regulation. Finally, an agency could specify a longer effective compliance date for small businesses. In this proposed rule, FDA considers each of these possibilities. We designed several provisions to lower the impact on small firms, some of which apply to small firms exclusively, and some of which apply to all firms.

First, FDA proposes a staggered effective compliance date for this regulation. The compliance dates are the following: 6 months for large firms, 12 months for small firms, defined as having less than 500 but more than 10 full-time equivalent employees, and 18 months for very small firms, defined as having 10 or fewer full-time equivalent employees. Only one of the cost estimates we explained in detail in the preliminary regulatory impact analysis directly depends on the compliance date; records redesign cost. We estimated using the FDA Label Cost Model that very small firms would save an average of 10 percent in their redesign costs by having longer than a year to comply. The medium 1-year redesign cost estimate is $1,309 per redesign. We assume this cost is shared between two firms, since a single set of records can serve as source, recipient, and transport records. The average redesign cost per firm is $655 for firm types other than transporters and convenience stores. The median 18-month redesign cost estimate is $1,190 per redesign, for an average cost of $595 per firm. The estimated medium redesign burden would drop by $60 per firm, or 8 percent of the estimated average first startup burden of the regulation. Also, present value considerations will result in reduced future cost estimates. Thus, the later compliance dates specified in the proposed rule will reduce the total cost for all small firms. FDA requests comments regarding these assumptions.

In addition, FDA is proposing to describe the specific information a covered entity must keep, but not specify the form or type of system in which those records must be maintained, which will allow firms to comply with the regulation in a manner that is cost effective. Mandated structural changes to records or required retention technology probably would not be the most cost effective solution for every firm, so not specifying the form or type of system in which the records must be maintained almost certainly would impose a smaller burden on industry, including small businesses. Comments to FDA's preliminary outreach generally agreed with this position. FDA believes that describing the specific information a covered entity must keep, but not specifying the form or type of system in which those records must be maintained is the most flexible means of proposing this regulation for all businesses. However, FDA also believes that each provision in this proposed rule is necessary to tracing investigations, so we do not propose any additional flexibility for small or very small businesses.

Finally, FDA is proposing several exemptions based on facility type. Since the majority of facilities of each type are small businesses, these exemptions will reduce the small business burden of this regulation. In the proposed rule, FDA exempts retail facilities from having to maintain records of final consumers who purchase retail food products. Requiring firms to collect and maintain consumer information would increase the burden on retail facilities by at least the amount of the current redesign burden and current additional records maintenance burden summarized in Table 40 of this document. Without this exemption, retail firms (including small retail firms) would have to design and maintain an entirely new recordkeeping system.

Most other small business exemptions are infeasible for this regulation because we believe records held by these businesses are an important link in the chain of custody for the food products. As shown in Table 39 of this document, a large percentage of the food industry would be exempt under any blanket small business exemption. Even nonemployee businesses (who have no paid employees, the smallest exemption possible) still constitute a substantial proportion of the food industry. Any type of exemption in the middle of the

supply chain very likely would make records unavailable and therefore would break the chain of custody of many products during tracing investigations.

The Bioterrorism Act exempts farms and restaurants. Because most farms and restaurants are small businesses, this exemption provides regulatory relief to small entities. In addition, in this proposed rule the term "farm" includes facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; "farm" also includes facilities that manufacture or process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. Most of these facilities are small entities. The statutory exemptions provide considerable relief to small entities without compromising the purpose of the recordkeeping regulation. FDA will continue to conduct research regarding possible further exemptions, and requests comments regarding possible exemptions that would provide additional relief for small businesses while still accomplishing the goals of the Bioterrorism Act.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is $112,300,000. FDA has determined that this proposed rule does constitute a significant rule under the Unfunded Mandates Reform Act.

Most of the requirements of the Unfunded Mandates are fulfilled in the Executive Order 12866 analysis, above. The requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on future costs; productivity; particular regions, communities, or industrial sectors; economic growth; full employment; job creation; and exports.

Future costs: The future costs from the recordkeeping rule include the recurring costs, which reach their long-term value in the third year after the proposed rule would become final. These costs would be incurred by domestic facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food, and the foreign facilities that are subject to this proposed rule (foreign manufacturers, processors, packers, and holders of food that would be required to register).

Recurring costs from collecting new information would be incurred in each future year. The estimates of these costs were modeled using the previous analysis of the juice HAACP regulation as a frame of reference. An hourly burden of 30 minutes a week was used for the additional monitoring and recordkeeping that would be required from this proposed rule. This hourly burden estimate was modified for foreign facilities and convenience stores to allow for structural differences assumed in their operations. For a fuller illustration of the future costs of the proposed rule, see Table 20 of this document.

TABLE 42.—FUTURE COSTS

	Mean	Low	High
Year 3 and later years	$221,130,000	$212,313,000	$229,680,000

Particular regions, communities, or industrial sectors: The costs of the recordkeeping requirement will be shared among domestic manufacturers, processors, packers, transporters, receivers, holders, and importers of food, and the foreign facilities that would be subject to this proposed rule (foreign holders, packers, manufacturers, and processors that would be required to register) as well as domestic consumers. The higher costs incurred by domestic and foreign suppliers as a result of these regulations will mostly be passed on to consumers in the form of higher food prices. Since consumer demand for food is highly inelastic almost all of the higher costs incurred by food suppliers will be passed on to consumers. Consequently, higher food prices will reduce real incomes for all consumers. However, we believe that the benefits from these regulations will justify the reduction in real incomes. These benefits are measured as an improved ability by the FDA to respond to and contain threats of serious adverse health consequences from accidental or deliberate contamination of food.

National productivity, economic growth, job creation, and full employment: Although this proposed regulation is costly, we do not expect it to substantially affect national productivity, growth, jobs, or full employment. The total costs will be small relative to the economy, and will be offset by benefits. The improved ability to respond to, and contain, serious adverse health consequences means less illness and fewer sick days taken by employees, and lower adjustment costs by firms that would otherwise need to hire replacement employees.

Exports: This proposed rule would require additional records to be kept throughout the production and distribution chain for food. The additional recordkeeping costs would increase the total costs of production and distribution for all of the regulated products, including products sold within the United States and across national borders. These increased costs will be largely passed on to consumers in the form of higher prices, which will tend to reduce the quantity demanded of the regulated products. The increased prices of U.S. exports could reduce the quantity of U.S. exports demanded, particularly in comparison with exports from countries that do not implement similar recordkeeping regulations. We expect this effect to be insignificant, because under the proposed rule (option 10, described above), the increases in the price of U.S. exports (and resulting decreases in quantity demanded) would be quite small.

D. SBREFA Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that

this proposed rule, when final, will be a major rule for the purpose of congressional review.

IV. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information would have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Recordkeeping and Records Access Requirements for Food Facilities

Description: The Bioterrorism Act contains a provision authorizing the Secretary to develop regulations requiring food facilities that manufacture, process, pack, hold, receive, distribute, transport, or import food to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food, animal food, or food ingredients. Records for nontransporters must include the name and full contact information of sources, recipients, and transporters, an adequate description of the food including the quantity and the way that it is packaged, and the receipt and shipping dates. Records for transporters must include similar information about the food or food packaging, sources, and recipients, identification of all modes of transportation, and responsible individuals, while the food or food packaging is in the custody of the transporter.

Description of Respondents: Facilities that manufacture, process, pack, hold, receive, distribute, transport, or import food are required to establish and maintain records, including facilities in both interstate and intrastate commerce. Foreign manufacturers, processors, packers, and holders of food that would be required to register are required to maintain records if they ship food to the United States.

Burden: FDA estimates that the paperwork burden of this rule will be incurred by the number and types of firms and facilities listed in Table 43 of this document. FDA assumes that, approximately 841,000 facilities owned by approximately 646,000 firms would be covered. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food, and the foreign facilities that manufacture, process, package, or hold food destined for consumption or use in the United States that would be required to register. Some of the recordkeeping burden will be incurred at the firm level and some of the burden will be incurred at the facility level.

TABLE 43.—AFFECTED FACILITY AND FIRM DETAILS

Type	Facility Estimate	Firm Estimate
Manufacturers	43,376	36,948
Wholesalers/Warehouses	95,745	76,952
Packaging[1]	36,907	34,633
Transporters/Packers	16,773	15,171
Retail Grocery and Specialty Food	207,657	153,277
Convenience Stores	128,985	68,866
Mixed-Type Facilities That Have Farms	30,497	24,397
Importers	18,902	15,122
Total Domestic	578,842	425,366
Final Holders	77,427	61,942
De minimus Processors/Packagers	22,600	18,080
Manufacturers	125,450	106,858
Other Facility Types		
Total Foreign	225,477	186,879

[1] Including outer packaging and food contact substances.

The recordkeeping burden for §§ 1.337, 1.345, and 1.352 includes learning about the regulation requirements, the redesign of records, and records maintenance including information collection for these records. The burden for § 1.361 is associated with planning for and executing an FDA request for records. Because it is difficult to estimate with any degree of precision the burden incurred from executing a records access request, we only compute the burden for firms to prepare for a potential records access request from FDA.

The burden for learning the regulatory requirements of this proposed recordkeeping rule may be shared by firms that also need to learn the regulatory requirements of the proposed rule entitled "Registration of Food Facilities" (68 FR 5378, February 3, 2003). The learning burden presented in Table 44 of this document includes the total number of hours needed to learn and understand the records required for compliance. This is a one-time burden that covered firms will incur in the first year following enactment of the final rule.

The records redesign burden presented in Table 44 of this document reflects the burden that some firms will incur by adding a limited amount of new information to their records. Some firms will not already be keeping the required information in a readily accessible form. The records redesign burden includes labor and capital costs associated with modifying existing forms so that they are better suited to meet the recordkeeping requirements. This is assumed to be a one-time burden incurred by each covered firm in the first and second years following implementation of the final rule.

The records access preparation burden presented in Table 44 of this document reflects the burden of preparing a plan for modifying current business practices in order to be able to respond to an FDA records request in the 4-hour or 8-hour required timeframe. The estimate of the records access planning burden is a one-time burden that would be incurred in the first and second years following enactment of the final rule. We assume that this burden will be incurred by each facility.

FDA expects that personnel at most facilities will incur a records maintenance burden due to collecting, recording, and checking for accuracy the limited amount of additional information required by the proposed rule. The burden from this activity is reported in table 45 of this document and is assumed to be incurred by all facilities in each subsequent year following enactment of the final rule. Finally, new firms are assumed to incur burdens from learning and records access preparation in each subsequent year following enactment of the final rule. These burdens for new firms are reported in table 44 of this document.

TABLE 44.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—ONE-TIME BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Capital Costs	Total Hours
1.337, 1.345, and 1.352, (Learning)	804,319	1	804,319	6.853		5,512,000
1.337, 1.345, and 1.352, (Redesign)	278,858	1	278,858	29.607	$130,582,000	8,256,000
1.361 (Access Preparation)	552,630	1	552,630	5.626		3,109,000
Total						16,877,000

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 45.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—SUBSEQUENT YEARS[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (Additional Records Maintenance)	772,410	1	772,410	10.625	8,207,000
1.337, 1.345, and 1.352, (Learning for New Firms)	80,432	1	80,432	6.853	551,000
1.361 (Access Preparation for New Firms)	55,263	1	55,263	5.626	311,000
Total					9,069,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to OMB (see **ADDRESSES**).

V. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the

heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical or SPS measure of general application necessary to address an urgent problem related to the protection of human, plant, or animal health. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." In order to meet these objectives, section 306 of the act requires FDA to propose and issue final regulations requiring the establishment and maintenance of records within 18 months of the Bioterrorism Act's enactment, which is by December 12, 2003. This expedited timeframe reflects the urgency of the U.S. Government's need to prepare to respond to bioterrorism and other food-related emergencies. Accordingly, FDA has concluded that the urgency of this matter is sufficient justification for shortening the public comment period for this proposal to 60 days, consistent with Executive Order 12889.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's December 12, 2003, deadline.

VIII. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses in this document, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1 and 11 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart J is added to part 1 to read as follows:

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

Sec.
1.326 Who is subject to this subpart?
1.327 Who is excluded from all or part of the regulations in this subpart?
1.328 What definitions apply to this subpart?
1.329 Do other statutory provisions and regulations apply?
1.330 Can existing records satisfy the requirements of this subpart?

Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Source of All Food

1.337 What information is required in the records you must establish and maintain to identify the nontransporter and transporter immediate previous source?

Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipient of All Food

1.345 What information is required in the records you must establish and maintain to identify the nontransporter and transporter immediate subsequent recipient?

Requirements to Establish and Maintain Records to Trace the Transportation of All Food

1.351 Who is required to establish and maintain records for tracing the transportation of all food?
1.352 What information is required in the transportation records?

General Requirements

1.360 What are the record retention requirements?
1.361 What are the record availability requirements?
1.362 What records are excluded from this subpart?
1.363 What are the consequences of failing to establish or maintain records or make them available to FDA?

Effective Dates

1.368 What are the compliance dates for this subpart?

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

§ 1.326 Who is subject to this subpart?

(a) Domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for consumption in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in § 1.327. In addition, foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are subject to these regulations, unless you qualify for one of the exclusions in § 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in § 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food enters interstate commerce.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the regulations in this subpart;

(b) Restaurants are excluded from all of the regulations in this subpart;

(c) Fishing vessels including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel are excluded from all of the regulations in this subpart, except § 1.361 and § 1.363. However, those fishing vessels otherwise engaged in processing fish, which for purposes of this subsection means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding, are subject to all of the regulations in this subpart;

(d)(1) All retail facilities are excluded from § 1.345 of this subpart;

(2) Retail facilities that employ 10 or fewer full-time equivalent employees that:

(i) Are located in the same general physical location as a farm; and

(ii) Sell unprocessed food grown or raised on that farm or on another farm located in the same general physical location are excluded from all of the regulations in this subpart, except § 1.361 and § 1.363, with respect to that unprocessed food.

(e) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food that is within the exclusive jurisdiction of the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are excluded from all of the regulations in this subpart with respect to that food.

(f) Foreign facilities are excluded from all the regulations in this subpart, if food from such facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States. This exclusion does not apply to a foreign facility if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import pet food who are not subject to the recordkeeping provisions of the animal proteins prohibited in ruminant feed regulation (§ 589.2000 of this chapter) are, with respect to pet food records, excluded from all the regulations in this subpart except for § 1.361 and § 1.363.

§ 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart.

In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Domestic person means any person located in any State or Territory of the

United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Farm means a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. The term "farm" includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). Examples of food include, but are not limited to: Fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

Foreign facility means a facility other than a domestic person that manufactures/processes, packs, or holds food for consumption in the United States.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples include, but are not limited to: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

Nontransporter means a person who owns food or who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Nontransporter immediate previous source means a person that last had an article of food before transferring it to another nontransporter.

Nontransporter immediate subsequent recipient means a nontransporter that acquires an article of food from another nontransporter.

Perishable food means food that is not heat-treated, not frozen, and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions.

Pet food means food for nonfood-producing animals.

Recipe means the quantitative formula used in the manufacturing of the food product, but not the identity of the individual ingredients of the food.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. Restaurants include, but are not limited to, cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens. Facilities that provide food to interstate conveyances, rather than directly to consumers, are not restaurants.

Retail facility means a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries.

Transporter means a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food. A person who owns food or who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation is not a transporter.

Transporter's immediate previous source means a person from whom a transporter received an article of food. This source can be either another transporter or a nontransporter.

Transporter's immediate subsequent recipient means a person to whom a transporter delivered an article of food. This recipient can be either another transporter or a nontransporter.

You means a person or facility subject to this subpart under § 1.326.

§ 1.329 Do other statutory provisions and regulations apply?

(a) In addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods except as described in paragraph (b) of this section. For example, the regulations in this subpart are in addition to existing recordkeeping regulations for low acid canned foods, juice, seafood, infant formula, color additives, bottled water, animal feed, and medicated animal feed.

(b) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

§ 1.330 Can existing records satisfy the requirements of this subpart?

The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart in order to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements.

Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Source of All Food

§ 1.337 What information is required in the records you must establish and maintain to identify the nontransporter and transporter immediate previous source?

(a) If you are a nontransporter, you must establish and maintain the following records for all food you receive. Your records must include information reasonably available to you to identify the specific source of each ingredient that was used to make every lot of finished product.

(1) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;

(2) An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you received the food;

(4) The lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle); and

(6) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the transporters who transported the food to you.

Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipient of All Food

§ 1.345 What information is required in the records you must establish and maintain to identify the nontransporter and transporter immediate subsequent recipient?

(a) If you are a nontransporter, you must establish and maintain the

following records for all food you release:

(1) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;

(2) An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date the food was released;

(4) The lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle); and

(6) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the transporters who transported the food from you.

(b) [Reserved]

Requirements to Establish and Maintain Records to Trace the Transportation of All Food

§ 1.351 Who is required to establish and maintain records for tracing the transportation of all food?

If you are a domestic person and you are a transporter of food, you are required to establish and maintain records containing information not only about your transportation activities but also about the person from whom you received the food (the transporter's immediate previous source) and the person to whom you delivered it (the transporter's immediate subsequent recipient), as specified in § 1.352.

§ 1.352 What information is required in the transportation records?

(a) You must establish and maintain the following records for each food you transport:

(1) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the person who had the food immediately before you, and the date you received it from that person;

(2) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the person who had the food immediately after you, and the date you delivered it to that person;

(3) An adequate description of the type of food, including brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(4) The lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle);

(6) Identification of each and every mode of transportation (e.g., company truck, private carrier, rail, air, etc.), and the individual responsible, from the time you first received the food until the time you delivered it.

(b) [Reserved]

General Requirements

§ 1.360 What are the record retention requirements?

(a) You must create the required records at the time the activity occurs.

(b) You must retain for 1 year after the date the records were created all required records for perishable foods not intended for processing into nonperishable foods.

(c) You must retain for 2 years after the date the records were created all required records for all other foods, except animal foods.

(d) You must retain for 1 year after the date the records were created all required records for animal food, including pet food.

(e) You must retain all records required by these regulations at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(f) The maintenance of electronic records is acceptable.

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the act must be readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available within 4 hours of a request if the request is made between 8 a.m. and 6 p.m., Monday through Friday, or within 8 hours of a request if made at any other time, by an officer or employee duly designated by the Secretary who presents appropriate credentials and a written notice. If records and other information are stored offsite, the records must be retrieved and provided onsite within the specified time period. Electronic records are considered to be onsite if they are accessible from an onsite location.

§ 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA?

(a) The failure to establish or maintain records as required by section 414(b) of the act or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act (21 U.S.C. 331).

(b) The failure to make records or other information available to FDA as required by section 414 or 704(a) of the act is a prohibited act under section 301 of the act.

Effective Dates

§ 1.368 What are the compliance dates for this subpart?

(a) The regulations in this subpart shall be effective 6 months after the date of publication of the final rule in the **Federal Register**. However, this subpart is not binding on small and very small businesses until the dates listed in paragraphs (a)(1) and (a)(2) of this section.

(1) The regulations in this subpart are binding 12 months after the date of publication of the final rule in the **Federal Register**, for small businesses employing fewer than 500 but more than 10 full-time equivalent employees.

(2) The regulations are binding 18 months after the date of publication of the final rule in the **Federal Register**, for very small businesses that employ 10 or fewer full-time equivalent employees.

(b) [Reserved]

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

4. Section 11.1 is amended to add paragraph (f) to read as follows:

§ 11.1 Scope.

* * * * *

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of Part 1, Subpart J of this chapter but that are also required under other applicable statutory provisions or regulations remain subject to this part.

Dated: May 1, 2003.

Mark B. McClellan,

Commissioner of Food and Drugs.

Dated: May 2, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

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USDA United States Department of Agriculture
Economic Research Service
The Economics of Food, Farming, Natural Resources, and Rural America

Briefing Rooms

Vegetables and Melons: Tomatoes

The United States is one of the world's leading producers of tomatoes, second only to China. Fresh and processed tomatoes account for more than $2 billion in annual farm cash receipts.

The U.S. fresh- and processing-tomato industries target different markets, which is not true in many other tomato-producing countries. Characteristics of the two industries in the United States are:

- Tomato varieties are bred specifically to serve the requirements of either the fresh or the processing markets. Processing requires varieties that contain a higher percentage of soluble solids (averaging 5 percent to 9 percent) to efficiently make tomato paste, for example.
- Most tomatoes grown for processing are produced under contract between growers and processing firms. Fresh tomatoes are largely produced and sold on the open market.
- Processing tomatoes are machine-harvested while fresh-market tomatoes are hand-picked.
- Fresh-market tomato prices are higher and more variable than processing due to larger production costs and greater market uncertainty.

Fresh Tomato Industry

Commercial Acreage. Fresh-market tomatoes are produced in every State in the Nation, with commercial-scale production in about 20 States. National fresh-market tomato acreage has been trending lower over the past several decades. California and Florida each have around 40,000 acres used for growing fresh-market tomatoes. That is almost two-thirds of total U.S. fresh-tomato acreage, a number that has not changed much since the 1960s. Ohio, Georgia, Virginia, and Tennessee round out the top six in terms of area planted.

Production. U.S. fresh field-grown tomato production has trended higher over the past several decades with the most substantial growth occurring during the 1980s. As they have for decades, Florida and California annually account for two-thirds to three-fourths of all commercially produced fresh-market tomatoes in the United States. Including processing, Florida is the second-largest tomato-producing State, but it is tops in producing fresh-market tomatoes. Florida's season, October to June, has the greatest production in April and May and again in November to January.

California is the leading producer of all tomatoes in the United States, accounting for 95 percent of U.S. processing tomato output and just under one-third of the fresh crop. Fresh-market tomatoes are produced across the State in each season except winter. California's share of national fresh-market output has remained between 25 and 34 percent since the 1980s. Other major fresh-market tomato-producing States (in order of importance) include Georgia, Virginia, Ohio, Tennessee, North Carolina, Pennsylvania, and New Jersey.

Seasonality of Supply. Commercial fresh-market tomato shipments peak in the spring when Florida's volume is highest and California and various southeastern States begin to ship tomatoes. Commercial volume is smallest and prices are lowest in August to September due to the availability of local tomatoes. Fresh-

market tomatoes are available year-round in the United States because imports supplement tomatoes grown in Florida and in scattered greenhouses in the winter. Florida's winter crop is largely shipped to markets in the East, while the bulk of Mexico's crop is shipped to western States.

Market Structure. Supermarkets carry many varieties of fresh tomatoes. In addition to displays of the standard field-grown round tomatoes, shoppers find plum (Roma) tomatoes, grape and cherry tomatoes, and an array of greenhouse and hydroponic tomatoes in most areas of the country. Some greenhouse/hydroponic tomatoes (which were initially imported from places like the Netherlands) are marketed "on vine" (in clusters) to convey the appearance of freshness to consumers.

Domestic producers have recognized opportunity in this market niche. As a result, new or expanded greenhouse/hydroponic operations in several States have begun production over the last several years. (Domestic hothouse vegetables, however, are not included in official USDA annual production estimates but allowances are made for them in ERS consumption statistics.)

Some estimates suggest that the U.S. fresh-tomato market is about evenly divided between foodservice and retail consumer sales. However, in terms of total consumption from all sources, about 70 percent is consumed at home with 30 percent consumed away from home, according to a mid-1990s USDA food intake survey (the most recent survey with this breakout).

Prices. Statistical analysis suggests that the retail price of field-grown tomatoes is linked directly to the shipping-point price. Changes in the U.S. shipping-point price for tomatoes change retail prices for that month and the next month. Retail tomato prices include marketing costs such as wages, transportation, containers, advertising, fuel and power, and rent.

On average, the shipping-point price for fresh field-grown tomatoes averages about one-fourth of the retail value. This share has declined during the past three decades, averaging 37 percent in the 1980s, 31 percent in the 1990s, and 28 percent during the 2000s. Shipping-point prices for field-grown tomatoes have frequently been under pressure since the mid-1990s, largely due to increased imports and competition with hothouse products.

Trade. International trade is an important component of the U.S. fresh-market tomato industry. Imports account for about one-third of U.S. tomato consumption, up from one-fifth in the early 1990s. The percentage of U.S. fresh-tomato supply that is exported has slipped to about 6 percent this decade after having been a relatively constant 7 percent since the 1980s. Over the past decade, greenhouse/hydroponic products have made significant inroads into the U.S. fresh-tomato retail market, with Canada's burgeoning hothouse tomato industry taking advantage and wresting market share from Mexico.

Florida and Mexico historically compete for the U.S. winter and early spring market. Imports from Mexico tend to peak in the winter when southern Florida is the predominant U.S. producer. Florida tomatoes then dominate the market during the spring as Mexican production seasonally declines. Although its market share has declined somewhat over the past decade, Mexico remains the primary source of U.S. tomato imports. However, an increasing volume of greenhouse/hydroponic products, primarily supplied by Canada, has cut into Mexico's market share. Greenhouse tomatoes, in fact, have taken a greater share of the U.S. fresh-market tomato industry. The vast majority of U.S. fresh tomato exports are shipped to Canada, with exports to Mexico a distant second. A small volume is also exported to Japan—a market that was closed to U.S. shippers by phytosanitary restrictions (tobacco blue mold) from 1951 until 1997.

The U.S. Department of Commerce suspended an antidumping investigation involving fresh-market tomatoes from Mexico, by negotiated agreement, on

November 1, 1996. The agreement set a minimum price (called the reference price) that covers the majority of fresh-market tomatoes imported from Mexico. The intent of the agreement is to ensure there is no undercutting or suppressing of fresh-market tomato prices in the United States. Fresh-market tomatoes cannot enter the United States at less than the established reference price. Subsequent amendments clarified and expanded original provisions. The tomato season is now split into two periods—each with a separate reference price. California and Baja, Mexico are covered from July 1 to October 22 ($4.30 per 25-pound box), while Florida and Sinaloa, Mexico are covered from October 23 to June 30 with a higher floor price ($5.42 per 25-pound box). The latter floor price was put into effect upon review/renewal of the suspension agreement on January 22, 2008.

Per Capita Use. In terms of consumption, the tomato is the Nation's fourth most popular fresh-market vegetable behind potatoes, lettuce, and onions. Fresh-market tomato consumption has been on the rise due to the enduring popularity of salads, salad bars, and bacon-lettuce-tomato (BLT) and submarine (sub) sandwiches. Perhaps of greater importance has been the introduction of improved tomato varieties, heightened consumer interest in a wider range of tomatoes (such as hothouse tomatoes, grape tomatoes, and specialty/heirloom varieties), a surge of new immigrants who eat vegetable-intensive diets, and expanding national emphasis on health and nutrition.

Processing Tomato Industry

Commercial Acreage. Over the past several decades, the processing-tomato industry has been moving westward. California accounts for about 95 percent of the area harvested for processing tomatoes in the United States—up from 87 percent in 1990 and 79 percent in 1980. Texas, Utah, Illinois, Virginia, and Delaware once harvested thousands of acres, but today they have little or none.

Production. California has long been the primary source of processed-tomato products in the United States. By itself, California leads the world in the production of processing tomatoes. Harvest of the California processing-tomato crop is most active August to September. About 95 percent of U.S. processing tomatoes are grown and processed in California, with Indiana, Ohio, and Michigan accounting for most of the remaining production.

Market Structure. Growers contract with processors to process red-ripe tomatoes. Although many firms manufacture pulp-based products, such as stewed and diced tomatoes, most initial processing is by firms that manufacture tomato paste, a raw ingredient. Paste is manufactured and packed in bulk containers—large bags set into boxes and barrels—and stored for use up to 18 months later. This raw ingredient is distributed under contract or sold to remanufacturing firms that add water, spices, etc. to make retail and foodservice packs of soups, sauces, catsup, and paste.

In the past, many firms made paste and also remanufactured this paste into other products. The industry appears to be polarizing, with several firms specializing in the manufacture of bulk industrial paste and others specializing in the remanufacture of industrial paste into consumer products. Several California firms are also producing various dried and dehydrated tomato products, such as whole dried tomatoes and tomato powder.

Trade. Exports are becoming an important component of the U.S. processing-tomato industry. During the early 1990s, the United States became a net exporter of processed tomato products and has remained so. About 7 percent of processed tomato product supply has been exported during the 2000s, up from 5 percent during the 1990s and 1 percent during the 1980s. Top U.S. export