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HEARING TO REVIEW CURRENT FOOD SAFETY SYSTEMS

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

APRIL 2, 2009

Serial No. 111–8

Printed for the use of the Committee on Agriculture
agriculture.house.gov

U.S. GOVERNMENT PRINTING OFFICE

52–483 PDF WASHINGTON : 2009

For sale by the Superintendent of Documents, U.S. Government Printing Office
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HEARING TO REVIEW CURRENT FOOD SAFETY SYSTEMS

THURSDAY, APRIL 2, 2009

HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The Committee met, pursuant to call, at 12:07 p.m., in Room 1300 of the Longworth House Office Building, Hon. Collin C. Peterson [Chairman of the Committee] presiding.

Members present: Representatives Peterson, Boswell, Baca, Scott, Costa, Kagen, Schrader, Dahlkemper, Massa, Bright, Markey, Kissell, Boccieri, Pomeroy, Childers, Minnick, Lucas, Goodlatte, Moran, Smith, and Lummis.

Staff present: Nathan Fretz, Alejandra Gonzalez-Arias, Chandler Goule, Keith Jones, John Konya, Robert L. Larew, April Slayton, Rebekah Solem, Kristin Sosanie, Patricia Barr, John Goldberg, Pam Miller, Nicole Scott, Pete Thomson, and Jamie Mitchell.

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

The CHAIRMAN. We will call the Committee to order. We apologize for the late delay or the late start here. We have had some other difficulties and rearranged things, so we appreciate everybody being patient with us. But we welcome everyone to today's hearing of the House Agriculture Committee.

Food safety has been on the minds of many Americans with these recent recalls and foodborne illness outbreaks. At the beginning of this Congress our Committee adopted an aggressive oversight plan that makes food safety a priority. It is our responsibility to ensure that we have the most modern and effective food safety system possible, so you can expect rigorous oversight and action from us.

While it is true that our current food safety system, and those entrusted to produce wholesome and safe food products, do a good job most of the time, it is clear that there are gaping holes in some points of the process. Modernization and reform are needed. During the farm bill I worked hard to ensure an open and transparent process that allowed for many different points of view, and I will use a similar process with food safety.

Today's hearing, the first in a series of hearings that we will hold on this topic in this Congress, is just the opening round. The next hearing will be a joint event in April with the Subcommittee on Livestock, Dairy and Poultry and the Subcommittee on Horticulture and Organic Agriculture. Now, future hearings are being

planned, and throughout this process, I expect this Committee to do its homework, to listen to all stakeholders, to understand the issues and consider possible improvements. We will use the knowledge and insight gained through these hearings to consider all of the alternatives that could be included in a food safety modernization bill developed by the House Committee on Agriculture.

This is an important task, and we will work with everyone who shares the responsibility for safe food from the farmers and ranchers to the processors and handlers; the handlers to the retailers, and also to the consumers. As we start on this work, I look forward to learning from the experience of today's witnesses. I believe this will be a good, educational hearing for all of our Members, and we have a lot of work to do so let us get started.

[The prepared statement of Mr. Peterson follows:]

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

Good morning and welcome to today's hearing of the House Agriculture Committee. Food safety has been on the minds of many Americans with the recent recalls and foodborne illness outbreaks. At the beginning of this Congress, our Committee adopted an aggressive oversight plan that makes food safety a priority. It's our responsibility to ensure that we have the most modern and effective food safety system possible, so you can expect rigorous oversight and action from us.

While it's true that our current food safety system and those entrusted to produce wholesome and safe products do a good job most of the time, it's clear that there are gaping holes at some points of the process. Modernization and reform are needed.

During the farm bill, I worked hard to ensure an open and transparent process that allowed for many different points of view. I will use a similar process with food safety. Today's hearing is the first in a series of hearings that we will hold on this topic this Congress. The next hearing will be a joint event in April with the Subcommittee on Livestock, Dairy, and Poultry and the Subcommittee on Horticulture and Organic Agriculture. Future hearings are being planned. Throughout this process, I expect this Committee to do its homework—to listen to all stakeholders, understand the issues, and consider possible improvements.

We will use the knowledge and insight gained through these hearings to consider all of the alternatives that could be included in a food safety modernization bill developed by the House Committee on Agriculture. This is an important task, and we will work with everyone who shares the responsibility for safe food—from the farmers and ranchers to the processors and handlers to the retailers and consumers.

As we get started on this work, I look forward to learning from the experience of today's witnesses. I believe this will be a good educational hearing for all of our Members. We have a lot of work to do. Let's get started.

The CHAIRMAN. And with that, I will recognize the gentleman from Oklahoma, the Ranking Member, Mr. Lucas.

OPENING STATEMENT OF HON. FRANK D. LUCAS, A REPRESENTATIVE IN CONGRESS FROM OKLAHOMA

Mr. LUCAS. Thank you, Mr. Chairman, for calling this hearing which is intended to be the first in a series of Agriculture Committee food safety hearings this session. The theme of this first hearing was presented to us as educational, intended to lay a foundation to refresh the minds of our colleagues regarding the current state of the Federal food safety system.

While we have many fine witnesses today, I believe it would have been helpful to have begun with the current representatives from our regulatory agencies and the many producers and processors who actually are subject to Federal food safety regulation.

I am hopeful that we will hear from these interests fully in later hearings.

Consumers, producers, processors and retailers I talked to have questions about where our food safety system is going. A series of foodborne illness incidents, most recently *Salmonella* illnesses and deaths associated with peanut better and peanut paste from a commercial supplier, have focused criticism on the Food and Drug Administration. It is therefore not surprising that most of the legislative proposals under current discussion have implications for FDA and the producers and processors of foods under their jurisdiction. It would be easy to simply adopt those legislative proposals, declare victory, issue our press releases and get on with our business. Agency reorganization, farm-to-table traceback, mandatory recall, hazard analysis plans and performance in standards, inspection frequency, import inspection, civil and criminal penalties, third-party certification and regulation of on-farm production practices, to name just a few of the proposals, all have implications for the future of our Federal food safety system.

However, as we consider these ideas both in hearings and through the legislative activities, we must consider the merits of each proposal according to a very simple standard. We must judge each of these as to whether they contribute to or reduce the ability of our farmers and ranchers to provide our consumers with the safest, most affordable, the most abundant food supply in the history of the world.

Again, Mr. Chairman, thank you. I look forward to the testimony of our witnesses and the response to our questions.

The CHAIRMAN. I thank the gentleman for his statement, and I thank the other Members for their attendance. I would ask the other Members if they have opening statements that they will be made part of the record so that we can move forward. We are already a little over an hour behind.

We welcome our first panel to the Committee. Mr. Chandler Keys, the Head of the Government Relations for JBS, LLC; Mr. David Dever, the CEO and President of Pandol Brothers Incorporated of Delano, California; and Mr. Tony DiMare, Vice President of DiMare Homestead, Inc., and DiMare Ruskin, Inc., of Ruskin, Florida.

This was rearranged as I said from an earlier deal, but one of the things I wanted to do was something that has not been focused on enough, and that is look at the situation of agriculture products that are coming in from other countries. I want to get a better understanding of how that system works and find out if there are equivalent systems there as it affects our domestic producers.

So we welcome the panel to the Committee. You have 5 minutes to summarize your testimony. Your testimony will be made part of the record in full, and we will probably have some questions for you when we get done with your testimony. So welcome to the Committee.

Mr. Keys, you can begin.

STATEMENT OF CHANDLER KEYS III, HEAD OF GOVERNMENT AFFAIRS AND INDUSTRY RELATIONS, JBS USA LLC, WASHINGTON, D.C.

Mr. KEYS. Thank you. Chairman Peterson, Ranking Member Lucas, and Members of the House Agriculture Committee, my name is Chandler Keys, and I am Head of Government Affairs for JBS in Washington, D.C.

JBS is currently the world's largest beef processor with operations in Brazil, Argentina, Australia, Italy and the United States. Currently, our U.S. operations are one of the top three U.S. processors in both beef and pork. We also process lamb in Australia and the United States. Our U.S. operations are headquartered in Greeley, Colorado, in the Congressional District of the Committee's Representative Betsy Markey.

Food safety is the number one priority for JBS. From the moment livestock enters our facilities to the time the meat is boxed for shipment to further processors and retailers, we are focused on mitigating risk and ensuring that we provide a safe product. We stand ready to assist Congress and the Administration as you look for ways to enhance meat inspection systems and food safety through strong science-based and risk-based principles.

At the request of the Chairman, I will focus my testimony on our Australian operations and how this division of the company works with Australian and U.S. regulatory officials to ship frozen beef trimmings into the United States.

JBS is very familiar with the USDA regulatory regime and its hallmarks of continuous inspection at slaughter facilities, domestic plant certification, and hazard requirements. We are also well-versed in the system of equivalency and the requirement that our foreign plants must meet the same food safety and regulatory requirements as their U.S. counterparts in order to ship product into the United States. We have a strong professional working relationship with both Australian and American inspectors and regulatory bodies, and the import/export process. It is handled by consummate professionals who work every day to ensure that the process runs smoothly, efficiently and effectively without sacrificing the tenets of food safety for the swift movement of product.

As an importer, JBS' Australia division is required to submit all imported meat products from Australia for inspection by Federal agencies, including U.S. Customs, which looks for things requiring a duty and contraband, and the other divisions of the USDA that acts to stop dangerous insects and diseases from entering the country. USDA's Food Safety and Inspection Service further inspects imported meat products upon arrival into the U.S., determining their fitness for consumption and verifying that no unacceptable or illegal residues are present. This inspection at the port of entry is often called re-inspection since all JBS Australian meat processing plants are already under an in-plant USDA inspection guidelines under the auspices of the Australian Quarantine and Inspection Service, AQIS.

The majority of imported meat from Australia is shipped in containers on sea freight to points of entry in the United States. JBS operations are consolidated into the major ports across the country,

Philadelphia, Long Beach, Houston, and these three ports are the busiest for bringing in product.

To explain the process of importing beef into the United States, we must first understand the regulatory requirements of both the Australian and United States that an establishment must follow in order to ship to the United States.

One, the Australian regulatory regime, AQIS, a regulatory body equivalent to the USDA, requires an establishment be engaged in the preparation of meat and meat products for export has an approved arrangement. The approved arrangement describes companies like JBS Australia will meet legislative requirements, including compliance with good hygienic practices and HACCP systems; product integrity including product identification, segregation, traceability; importing country requirements and animal welfare requirements.

AQIS further requires the establishment to be listed to export to the United States and that all meat, meat products and edible offal must be slaughtered, processed and stored in U.S. listed establishments at all times.

USDA regulatory requirements: in order for Australian product to be eligible for export, U.S. listed establishments must also comply with U.S. requirements. These requirements constitute the hallmark of USDA's regulation of foreign plants, equivalency.

First, the Federal Meat Inspection Act requires foreign countries that export meat and poultry into the United States to establish and maintain an inspection system that is equivalent to that of the United States and to conform with HACCP systems. Exporting countries like Australia must undergo a rigorous review process before they can become eligible to export meat and poultry to the United States. Even after a country is granted eligibility, FSIS constantly reviews its inspection program to ensure it remains equivalent to the U.S. system.

The equivalency standard is a dynamic one. Foreign establishments are subject to additional regulatory measures applied to the U.S. plants by FSIS. For example, BSE now is part of the process that Australian meat has to go through to make sure that it is equivalent to the United States.

On an annual basis, a representative from FSIS will visit Australia and perform reviews, and often JBS operations are part of these reviews. In addition, AQIS performs verification activities to ensure JBS Australian establishments are compliant with U.S. country requirements at all times. These activities are performed through daily, weekly and monthly on-plant inspections by the AQIS veterinary officers and the AQIS technical team managers.

In order to comply with the U.S. requirements, U.S. listed establishments must have the following in place: an effective HACCP plan to prevent fecal, ingesta and milk contamination; standard operation procedures to cover all pre-operational and operational sanitation procedures; standard operating procedures for individual employee work instructions that describe hygiene operations establishment for each task performed; product monitoring records that are reviewed on at least a daily basis to confirm that the product has met the critical limits at each critical control point; and an ef-

fective means to segregate non-ambulatory and disabled animals not eligible for the U.S. market.

Mr. Chairman, I ask that the rest of my testimony be put in the record to move along on time, but we look forward to working with this Committee in explaining the rigor of the USDA system as it works with the Australian system to make sure that the product that comes into the United States is safe and is equivalent.

[The prepared statement of Mr. Keys follows:]

PREPARED STATEMENT OF CHANDLER KEYS III, HEAD OF GOVERNMENT AFFAIRS AND INDUSTRY RELATIONS, JBS USA LLC, WASHINGTON, D.C.

Chairman Peterson, Ranking Member Lucas, and Members of the House Agriculture Committee, I am Chandler Keys, Head of Government Affairs and Industry Relations for JBS USA in Washington D.C. As past Vice President of the National Cattlemen's Beef Association and in my more recent role as a government relations executive for Swift & Company and its successor, JBS, I have had the pleasure of working alongside many of you over the years. I look forward to working with this Committee again in the future as we strive to collaboratively address issues impacting the livestock sector and enhancing the safety of the U.S. food supply.

JBS is currently the world's largest beef processor—with beef operations in Brazil, Argentina, Australia, Italy and the United States. Currently, our U.S. operations are one of the top three U.S. processors in both beef and pork. We also process lamb in both Australia and the United States. Our U.S. operations are headquartered in Greeley, Colorado, in the Congressional District of the Committee's own, Representative Betsy Markey.

Food safety is the number one priority at JBS. From the moment livestock enter our facilities to the time meat is boxed for shipment to further processors and retailers, we are focused on mitigating risk and ensuring that we provide a safe product. We stand ready to assist Congress and the Administration as you look to enhance meat inspection and food safety through strong science-based and risk-based principles.

Importing Frozen Beef Trimmings From Australia Into the U.S.

At the request of the Chairman, I will focus my testimony on our Australian operations and how this division of the company works with Australian and U.S. regulatory officials to ship "fresh and frozen" beef trimmings into the United States. I hope the Committee will find this information instructive to its deliberations on how we can enhance the safety of products regulated by the U.S. Department of Agriculture.

JBS is very familiar with the USDA regulatory regime and its hallmarks of continuous inspection at slaughtering facilities, domestic plant certification, and Hazard Analysis and Critical Control Point (HACCP) requirements. We are also well-versed in the system of equivalency and the requirement that our foreign plants must meet the same food safety and regulatory standards as their U.S. counterparts in order to ship product into the U.S. We have a strong professional relationship with both Australian and American inspectors and regulatory bodies, and the import/export process is handled by consummate professionals who work every day to ensure that the process runs smoothly, efficiently, and effectively without sacrificing the tenets of food safety for the swift movement of product.

Overview

As an importer, JBS' Australia division is required to submit all imported meat products from Australia for inspection by Federal agencies, including U.S. Customs and Border Protection, which looks for items requiring a duty and contraband, and the USDA, which acts to stop dangerous insects and diseases from entering the country. USDA's Food Safety and Inspection Service (FSIS) further inspects imported meat products upon arrival into the U.S., determining their fitness for consumption and verifying that no unacceptable or illegal residues are present. This inspection at the port of entry is often considered a "re-inspection" since all JBS Australian meat processing plants are already under in-plant USDA inspection guidelines under the auspices of the Australian Quarantine and Inspection Service (AQIS).

The majority of imported meat from Australia is shipped in containerized sea freight to ports of entry across the United States. JBS operations are consolidated into the major ports across the country; however the majority of our business goes

through the ports of Philadelphia, PA, Long Beach, CA and Houston, TX. These three ports are the busiest and most adequately equipped for the importing of fresh and frozen meat products.

Regulatory Requirements

To explain the process of importing beef into the U.S., we must first understand the regulatory requirements—both Australian and U.S.—that an establishment must follow in order to ship to the U.S.

Australian Quarantine and Inspection Service (AQIS)

The Australian Quarantine and Inspection Service, a regulatory body equivalent to the U.S. Department of Agriculture, requires, through Australian Export Control (meat and meat products) Orders, that the occupier of an establishment engaged in the preparation of meat and meat products for export has an "Approved Arrangement."

The purpose of the approved arrangement is to clearly describe those processes and practices which underpin AQIS certification of meat and meat products for export.

The approved arrangement describes how companies like JBS Australia will meet legislative requirements, including compliance with:

- Good hygienic practices (GHP) to ensure that food is wholesome;
- The application of HACCP systems for food safety;
- Product integrity through the application of product identification, segregation and traceability practices ensuring the product is accurately described and maintains relevant importing country identification;
- Importing country requirements necessary to maintain market eligibility; and
- Animal welfare requirements.

In addition, Australian producing establishments must be registered by AQIS and "listed" as eligible to export to the U.S. and its territories. All meat, meat products and edible offal must be slaughtered, processed and stored in U.S. listed establishments at all times.

United States Department of Agriculture

In order for Australian product to be eligible for export, U.S. listed establishments must also comply with U.S. requirements. These requirements constitute the hallmark of USDA's regulation of foreign plants: equivalency.

The Federal Meat Inspection Act requires foreign countries that export meat and poultry into the United States to establish and maintain inspection systems that are *equivalent* to those of the United States and conform with HACCP systems. Exporting countries like Australia must undergo a rigorous review process before they can become eligible to export meat and poultry to the United States. Even after a country is granted eligibility, FSIS continually reviews its inspection program to ensure it remains equivalent to the U.S. system.

The equivalency standard is a dynamic one. Foreign establishments are subject to the same additional regulatory measures applied to U.S. plants by FSIS. For example, when additional requirements were imposed on U.S. plants to mitigate the risks of Bovine Spongiform Encephalopathy (BSE); our JBS Australia plants had to meet those same standards in order to maintain eligibility to ship to the U.S.

On an annual basis, a representative from FSIS will visit Australia to perform a country review to ensure the Australian systems in place are achieving the requirements or deliver an equivalent outcome as agreed upon by the two countries. JBS Australia regularly has plants involved in these FSIS reviews.

In addition, AQIS performs verification activities to ensure JBS Australia establishments are compliant with U.S. country requirements at all times. These activities are performed through daily, weekly and monthly on-plant inspections by the On-Plant AQIS Veterinary Officer and the AQIS Area Technical Manager.

Understanding Equivalency

JBS Australia establishments have systems in place that comply with the AQIS approved arrangement guidelines, which include importing country requirements such as those for the U.S.

In order to comply with U.S. requirements, U.S. listed establishments must have the following in place:

- **Hazard Analysis and Critical Control Points (HACCP)**—An effective HACCP plan that considers issues related to food safety hazards (*E. coli O157:H7*) and includes critical control points (CCPs) for all processes conducted

at the establishment with set critical limits that have been validated and monitored. The HACCP plan is required to be reviewed annually or whenever an alteration to the process has been made.

- FSIS requires zero tolerances for feces, ingesta, and milk on the slaughter floor on all U.S. listed establishments. U.S. listed establishments must also adopt effective controls for preventing contamination of carcasses with fecal, ingesta, and milk. These zero tolerances must be included in the company's HACCP plans.
- Raw ground beef products destined for export to the U.S. must be tested for *E. coli O157:H7,* utilizing a N=60 sampling plan for each 700 carton lot. In addition, an Association of Official Analytical Chemists (AOAC) accredited screening test method is required.
- U.S. listed establishments are also required to review product-monitoring records on at least a daily basis to confirm that the product has met the critical limits at each critical control point prior to being loaded for export to the U.S.

- **Sanitation Standard Operating Procedures** (SSOP) that relate to the process controls for producing the meat product, which covers procedures conducted both before (pre-operational) and during (operational) operations. All corrective and preventive actions undertaken to prevent product contamination need to be documented.
- **Standard Operating Procedures (SOP)** and **individual employee Work Instructions (WI)** that describe the hygiene operations of the establishment for each process task performed including corrective and preventive actions undertaken where there is failure in a SOP or WI procedure.
- **Non-ambulatory disabled animals** "that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions" are required to be segregated as they are not eligible for the U.S. market.

The Export/Import Process

- ***Product Transfer and Loadout Requirements***

Meat and meat products from JBS Australia establishments eligible to export to the U.S. must adhere to strict documentation requirements while being transferred and loaded for shipment.

- **Meat Transfer Certificates** must be used to cover the transfer of product from one establishment to another for further processing or storage. These certificates must be endorsed to prove the meat is eligible for export to the U.S.
- **Shipping marks**—Unique shipping marks are used for all shipments of edible meat to the U.S. These shipping marks must be clear and legible, and cannot be hand-written. Shipping marks must be unique over a thirteen-month period and not exceed 12 characters/digits. The first three characters are the alpha prefix registered in the Export Documentation (EXDOC) system for the purpose of monitoring shipping marks. Shipping marks may be either applied as a stencil or as an adhesive label. If adhesive labels are used they must be tamper evident with an adhesive that ensures they remain securely attached in adverse conditions such as excess moisture.
- Upon container loading, a traceable and accountable AQIS high security seal is applied to the container and recorded on the relevant documentation.
- Through the JBS Australia electronic export documentation system and the AQIS EXDOC system, the JBS Head Office and the shipping line are notified of the intention to export product.
- AQIS receives a Request for Permit (RFP) from JBS Australia from which a health certificate is generated for each shipping mark represented within the container.

- **Health Certification** for meat and edible offal is accomplished through an E7 health certificate. The E7 health certificate is granted when the following endorsements are made:
  - All production lots of manufacturing beef exported to the U.S. have been tested and cleared in accordance with the AQIS *E. coli O157:H7* protocol.
  - The product:

- was derived from animals that have never been in;
- did not originate in and was never stored, rendered or otherwise processed in;
- was not otherwise physically associated with a facility located in; and
- has not been otherwise physically associated with or exposed to, or commingled with ruminant material from:

○ Any region listed in Title 9, Code of Federal Regulations part 94.18(a), which governs the prohibition and or restriction of the importation of products from countries with rinderpest, foot and mouth disease, bovine spongiform encephalopathy and other foreign animal diseases of livestock and poultry.

○ All health certificates for all shipments of edible meat, meat products and offal must include a product description as defined on the label of the product.

○ The shipping line receives a pre-receivable advice (PRA) from which the container is added to the vessel manifest. The shipping line provides customs with the manifest, and Customs contacts AQIS EXDOC to ascertain if there is health certification for the container load of product.

○ AQIS provides the original health certificate to JBS Australia.

○ JBS Australia supplies the original health certificate, the bill of lading and the commercial invoice to the customer prior to the arrival of the container in the U.S. port.

○ A copy of all documentation for each consignment is kept on file at the JBS Australia Head Office documentation department.

- ***U.S. Customs Clearance***

When a shipment of imported meat arrives in the United States from Australia, JBS, via our customs broker (licensed by U.S. Customs and Border Protection), files entry documents with U.S. Customs.

U.S. Customs examine the goods to determine:

1. The value of the goods for any applicable duties, and if commercial invoices are accurate;
2. Any special markings from the country of origin that are required by Federal law; and
3. Whether the shipment contains prohibited items.

The container may not legally enter the U.S. until the shipment has arrived at the port and U.S. Customs has authorized the clearance of the container from the pier to a USDA inspection warehouse. Upon delivery of the container to the warehouse, the USDA inspection process begins.

- ***USDA Inspection—the "Re-Inspection Process"***

Once at the warehouse, each container is presented to FSIS. FSIS enters information about the shipment into a centralized computer system called the Automated Import Information System (AIIS). The AIIS scans its memory bank to determine if the country, plant, and product are eligible for export to the United States. When the shipment is ready to be re-inspected by FSIS, the AIIS will generate an inspection assignment, based on the plant and country's compliance history for that specific product. Inspection results are later entered into the AIIS, helping to establish the level of re-inspection for future shipments from JBS Australia and for shipments from Australia in general.

FSIS import inspectors first check the documents to assure the shipment is properly certified by the foreign country. Inspection may be delayed or refused if the documents contain irregularities or errors. If there are issues with documents, the importer is required to rectify the problem. Inspectors commence by examining each shipment for general condition and labeling.

A recurring problem that many importers face involves inaccurate shipping marks (unique ID numbers stamped on each box by the exporting establishment that link the shipment to the government health certificate). The shipping marks must correspond with the Australian health certificate, and if they don't, a guarantee must be issued by the Australian Embassy. Any boxes missing shipping marks must be stamped by a representative of the Australian government or destroyed. USDA will also hold any shipment when the physical inventory count does not match the Australian health certificate. Overages or shortages also require a guarantee issued by the Australian Embassy.

Once documentation and labeling are approved, the inspection continues with assignments directed by the AIIS. AIIS may designate the shipment as a "skip", and no further inspections are required. A plant with a good compliance history will not have as many inspections assigned.

There are three levels of inspection:

(a) "normal" level of inspection—all lots are re-inspected;

(b) "skip 1" (S1) level—one of every four lots is re-inspected; and

(c) "skip 2" (S2) level—one of every 12 lots is re-inspected.

JBS Australian plants have the highest performance record and we currently are on "skip 2" level for all beef plants.

If the container is marked for an intensive inspection, several types of inspection may be assigned by the AIIS, including net weight checks of retail packages; examination of the container's condition; physical examination for product defects; and laboratory analysis for product composition, microbiological contamination, residues, and species verification. In conducting these inspections, a certain amount of product is randomly selected and examined by FSIS import inspectors. Microbiological analysis includes tests for *Listeria monocytogenes, E. coli O157:H7,* and *Salmonella* among others. Residue analysis testing targets include sulfonamides, chlorinated hydrocarbons, arsenic, antibiotics, carbadox and ivermectin.

However, even with a good record, if a lot fails an intensive inspection, future shipments of product from the plant may be allocated a different inspection level. This allocation by AIIS is based on formulas that rate the type of defect; however, for a failed residue and microbiological analyses, the plant stays on "tightened and hold" until 15 consecutive lots pass within 180 days.

When product samples are sent to FSIS laboratories for analysis, the shipment is usually released before test results are received. However, if the plant had previous violations or a problem is suspected, the shipment is held until the laboratory results are known. Even though JBS plants in Australia have the lowest possible incidence of problems during inspection, our internal protocols require all product that undergoes an intensive inspection to be withheld from commerce until results have been returned.

When a shipment passes inspection, each shipping container is stamped with the official mark of inspection and released into U.S. commerce.

If a shipment does not meet U.S. requirements, the cartons are stamped "U.S. Refused Entry," and within 45 days must be exported, destroyed or converted to animal feed (with the approval of the Food and Drug Administration).

JBS typically will have some boxes rejected by USDA. This is generally due to carton damage. Due to container moment during the overseas voyage, cartons may tear. Any cartons with exposed meat (through poly plastic liner and cardboard) are rejected. USDA will also reject cartons that may contain leaking chilled vacuum packages.

Conclusion

In summary, the importation of meat and meat products from Australia into the U.S. is a very intensive and robust process with failsafe mechanisms at each step. Our products are not only subject to intense scrutiny and inspection in Australia; but to re-inspection at the U.S. port of entry. In addition, our plants must adhere to the same regulatory requirements and procedures as American-produced products—ensuring that American consumers enjoy a safe, quality product irrespective of its origin.

The CHAIRMAN. Thank you very much, Mr. Keys, and we appreciate your being with us.

Mr. Dever, you are recognized for 5 minutes.

STATEMENT OF DAVID D. DEVER, CEO AND PRESIDENT, PANDOL BROTHERS, INCORPORATED, DELANO, CA

Mr. DEVER. Thank you very much. Good morning, Chairman Peterson, Ranking Member Lucas and the Members of the Committee. My name is David Dever and I am CEO and President of Pandol Brothers, Inc. Our headquarters are located in Delano, California, which is in the San Joaquin Valley. Today we farm approximately 5,000 acres, primarily of California table grapes in addition to importing product from Latin America.

Pandol has led the industry with transparent forms of self-regulation for many years. These produce-based standards work to identify: risks, control points, control measures, and to provide for independent verification. This starts with land use through to the transportation of our products to market. Good agricultural products, good manufacturing practices, food security, hazard analysis, and critical control point programs have been developed and updated annually.

Pandol utilizes internal and external verification processes to provide verification of the effectiveness of these systems and to provide guidance for improvement. In addition, Pandol has introduced a Trace Recall Program and a Management Plan to ensure our ability to trace the product through the supply chain. We have complied with the U.S. Bioterrorism Act of 2002 which requires the ability to establish and maintain records, to document movement of our products both one step forward and one step back through the supply chain.

Pandol is a member of the Steering Committee of the Produce Traceability Initiative, created and led by three leading industry organizations, the United Fresh Produce Association, Produce Marketing Association and the Canadian Produce Marketing Association. Adoption of these standards is now in motion, and complete details on this initiative can be found on the industry website *www.producetraceability.org*.

However, with all of that that has been accomplished to ensure our products are safe, we acknowledge there are many challenges that continue to face us today in strengthening the safety of our food source. These include, first, the industry must work together at developing and improving systems and processes on a commodity-specific basis. Simultaneously, government regulation must be created to support the process, to provide the necessary enforcement policies to equalize the playing field, and to strengthen the consumer confidence in the overall process. We also believe these food safety standards must be consistent and applicable to the identified commodity, irrespective of its origin.

Imported products need to meet equivalent standards as that required of domestic produce. Although some countries have sophisticated food safety operations, we encourage U.S. food safety officials to work together with our foreign counterparts to ensure and verify that equivalent policies and standards are in place.

Third, the additional cost to develop and implement the systems along with the verification and audit process is costly. We must encourage, as part of this commodity-specific approach, that FDA develop a rule-making procedure that establishes risk and science-based regulations for the production, handling and distribution of those types of fruits and vegetables for which the Secretary determines such standards are necessary to minimize the risk of microbial illness.

Fourth, time is critical when an incident occurs. A standardized electronic web-based record-keeping throughout the supply chain will provide crisis managers with the ability to instantaneously trace the source product, thereby allowing them to identify the contaminating source, limiting the threat and strengthening the consumers' confidence.

Last, even with all of the proactive development of food safety systems, including verification processes, we continue to be dependent on those we do business with to apply the same standards to ensure the integrity of the supply chain. Therefore, we believe achieving consistent produce safety standards across the industry requires strong Federal Government oversight and responsibility in order to optimize our credibility to the consumer and to be equitable to all producers.

Let me conclude with these closing thoughts. Produce safety must be a process of continuous improvement, not a static achievement. As long as there is the potential of even one individual getting sick, as an industry we will do all we can to prevent that from happening. It can be discouraging when events such as the jalapeño pepper, peanut, and now the pistachio incidents occur, and as bad as those have been, as producers, regulators, policymakers and consumers, we need to understand that the produce industry has achieved an overwhelming success record in regards to food safety with the actual incidents of illness at an extremely low level. Please look at the numbers. Over one billion servings of fresh produce are eaten every day. More than five million bags of fresh salads are sold every day. Of the hundreds of fruits and vegetables offered in the produce section of the supermarket, only a handful have been implicated in illness outbreaks, and when they are, the incident is small in volume in comparison to their volume of consumption.

But, we also know that consumers today are very concerned about the safety of their food. They don't care about the statistics or industry's effort put forth to date. They want improved results, and it is both the industry and government's obligation to restore the consumers' confidence by working together to develop, implement, verify and ensure the most thorough, state-of-the art food safety systems possible. We must all be able to trust the overall system of government insight and industry responsibility working together to produce the safest possible supply of fresh, healthy and nutritious fruits and vegetables.

Thank you.

[The prepared statement of Mr. Dever follows:]

PREPARED STATEMENT OF DAVID D. DEVER, CEO AND PRESIDENT, PANDOL BROTHERS, INCORPORATED, DELANO, CA

Good morning Chairman Peterson, Ranking Member Lucas and the Members of the Committee. My name is David Dever and I am CEO and President of Pandol Bros., Inc. (Pandol). Our headquarters are located in Delano, California which is in the San Joaquin Valley between Fresno and Bakersfield. The Pandol Family has been farming and bringing to market fresh produce for more than half a century. In 1908 Steve Pandol immigrated from modern day Croatia to the United States. In the early 1940's he and his wife Margaret, also from the old country, purchased 160 acres in the San Joaquin Valley and began farming and raising a family. Their three sons joined the business and together, with each contributing their special set of skills, they expanded the business into a major grower, marketer and shipper of fresh quality produce, primarily table grapes. Today, with the third generation in the lead and as the fourth generation of the Pandol Family enters the organization, the company continues to focus on its core competency of growing, shipping, importing, exporting and marketing premium quality table grapes and other fresh produce items. The Pandol Family farms approximately 5,000 acres in California. Together with sources in Latin America, Pandol has a supply of table grapes to bring to the marketplace year round. From California in the summer and fall, Mexico in the

spring, and Chile, Peru and Brazil in late fall and winter, Pandol Bros, Inc. almost always has fresh table grapes available to the market. In addition to domestic markets Pandol has a long history of exporting products to the world marketplace including Canada, Europe, Latin American, the Middle East and especially the Pacific Rim.

As this business has evolved over the years, so have the challenges over the safety of our food supply. Meeting or exceeding these challenges and delivering safe, quality produce to the marketplace has always been a primary goal of the Pandol Company. From the start of our company to the present day the Pandol family has been advocates of developing and implementing procedures that give our customers and consumers' confidence in the products that we grow and deliver.

Pandol Bros. has led the industry with transparent forms of self-regulation for many years. These produce based standards work to identify risks, identify control points and control measures, and to provide for independent verification of compliance. In fulfilling these produce standards Pandol evaluates and reviews:

- Land history and use.
- Adjacent land use.
- Soil amendments.
- Pesticide usage.
- Irrigation water source and quality.
- Employee hygiene and sanitation practices, including training procedures.
- Employee habits and conditions, including training procedures.
- Harvest procedures.
- Transportation procedures.
- Packaging materials.
- Field packing sanitation procedures.

In each of these categories Pandol identifies any potential areas of hazard or exposure and develops a plan to monitor for, prevent and mitigate any undesirable conditions.

Pandol utilizes verification processes which include internal standard operating procedures, independent experts and governmental agencies. We periodically perform reviews and evaluations of the systems and develop corrective actions as needed. Additionally, we utilize third party audit companies to provide verification of the effectiveness of the systems and to provide guidance for improvement.

These tests or procedures are extensive but as a sample include:

- Conducting a pre-harvest pesticide residue testing program which establishes that the product tested meets or exceeds U.S. EPA established standards. This program is conducted and monitored by an independent, third-party laboratory which posts, to its website, United States tolerance levels whenever residues are detected.
- We monitor microbial or physical adulteration of product by participating in Good Agricultural Practices (GAP), field and harvest crew audits by independent third party auditors, and HACCP/GMP programs for our cold storage operation, also audited by an independent third party.
- In our fields Pandol conducts independent lab testing of soil and water sources, conducts fertilizer and chemical monitoring and reporting programs, and assessment of adjacent land uses, and other risks from surrounding activities.
- Harvest practices and employee hygiene/sanitation issues are also monitored and subject to periodic third party review and periodic unannounced inspection by state and Federal authorities.
- Mock product recalls are periodically implemented to test the traceability system.

Pandol requires its suppliers to certify they have food safety programs in place that include compliance with the following guidelines:

- Compliance with the FDA Guide to Minimizing Microbial Food Safety Hazards for Fresh Food and Vegetables.
- Good Agricultural Practices (GAP).
- Good Manufacturing Practices (GMP), if applicable.
- Third Party Audits (Field/Facility).
- Food Security Program (Field/Facility).
- Trace Recall Program.

- Multi-Residue screening of all supplied product.
- Meet all COOL regulatory requirements.

In addition, Pandol has long been committed to the ability to trace its product through the supply chain, and has complied with the U.S. Bioterrorism Act of 2002 which requires the ability to establish and maintain records to document movement of its products both one step forward and one step back through the supply chain.

Pandol has developed a Trace Recall Program in the event a product may be deemed to be potentially hazardous or defective. In addition we have developed a Crisis Management Plan in the unlikely event that a situation reaches the point of a "disaster" or "crisis" beyond the scope of what usual policies address. The availability of such a plan insures that management and employees have a clear, well thought out guide and plan of action if a disaster should ever arise.

Pandol is also a member of the Steering Committee of the Produce Traceability Initiative, an industry wide initiative created by the three leading industry organizations United Fresh Produce Association, Produce Marketing Association and the Canadian Produce Marketing Association. This initiative that began in late 2007 was designed to assist the industry maximize the effectiveness of current traceback procedures, while developing a standardized industry approach to enhance the speed and efficiency of traceability systems for the future. The Steering Committee representing every segment of the produce supply chain; from farm to store and restaurant, and actively involved nine U.S. and Canadian trade associations met numerous times and spent countless hours in collaborative discussions and sub-groups to develop unparalleled standardization policies for the industry as a whole. Pandol, who agrees with and supports this Initiative, is working diligently at developing systems and procedures to be able to adhere to the Milestones as established by this Committee. Adoption of these standards is now in motion, and complete details on this initiative can be found on the industry website *www.producetraceability.org.*

However, it is important to acknowledge and address the challenges that we face today in strengthening the safety of our food source:

1. Food safety is our industry's top priority. The men and women who grow, pack, prepare and deliver fresh produce are committed to providing consumers with safe and wholesome foods. The industry, as a whole, must work together at developing systems and processes on a commodity-specific basis to enhance our food safety policies. Industry needs to take the lead in assessing the risks and exposure depending on the commodity, location and processes involved in the production of our food. Government regulation must be created to support the process, to provide the necessary enforcement policies to equalize the playing field and to strengthen the consumer confidence in the overall process. Therefore we believe food safety standards must be consistent and applicable to the identified commodity or commodity sector, no matter where grown or packaged in the United States, or imported into the country. Consumers must have the confidence that safety standards are met no matter where the commodity is grown or processed.

2. We believe that product imported into the United States needs to meet equivalent standards as that required of domestic produce. U.S. food safety officials can work together with foreign food safety officials to ensure and verify that equivalent policies and standards are in place. Many foreign governments work closely with their industries to establish and enforce food safety guidance and traceability systems. We have found that some of the more sophisticated food safety operations are found outside of the United States. When foreign countries are working congruently with U.S. standards we should acknowledge their food safety programs accordingly. This approach of working with and recognizing foreign regulatory systems is necessary to save government and industry resources. If the U.S. industry is required to police the supply chain outside of the U.S., this will put U.S. companies at a competitive disadvantage in the global marketplace.

3. Within the food supply chain there are many people involved in the process and many procedures that need to be complied with in order to minimize risk of contaminated food. The additional cost to develop and implement the systems along with the verification and audit process is costly. We must encourage participation of governmental agencies in providing input into the ongoing development of commodity-specific science based standards. In particular, as part of this commodity specific approach, FDA must develop a rule-making procedure that establishes risk and science-based regulations for the production, handling and distribution of those types of fruits and vegetables for which the Secretary

determines such standards are necessary to minimize the risk of microbial illness.

4. Electronic record-keeping with web based search features is the next level. When an incident is reported electronic record-keeping will give the investigating process the ability to instantaneously trace the source product in order to expediently identify potential sources of the problem or to eliminate possible exposures.

5. Last, with all of the proactive development of systems in addition to the independent verification processes we employ to ensure that we are holding ourselves accountable for compliance, we continue to be dependent on those we do business with and the overall integrity of the people involved in the supply chain. We do not have the systems in place or the necessary personnel to monitor the compliance of non-Pandol affiliated suppliers and must rely upon the honesty and integrity of those we do business with. Therefore, we believe achieving consistent produce safety standards across the industry requires strong Federal Government oversight and responsibility in order to be most credible to consumers and equitable to producers.

Let me conclude with these closing thoughts. Produce food safety must be a process of continuous improvement, not a static achievement. We are on a continuum, constantly striving toward perfection, while understanding scientifically that perfection—or zero risk—is not possible. Because our products are enjoyed by consumers in their fresh and natural state without cooking, we have to be right every single time—not one in a million, or even one in a billion. But as long as there is the potential of even one individual getting sick, we will do all we can to prevent that from happening.

The good news is that this is happening now. For the produce industry we have an overwhelming success record in regards to food safety with actual incidence of illness extremely low. Just look at the numbers.

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

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

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

The CHAIRMAN. Thank you very much for your testimony. Mr. DiMare?

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

Mr. DIMARE. Good morning, Mr. Chairman, Ranking Member Lucas, Committee Members, my name is Tony DiMare, and I am Vice President of DiMare Homestead and DiMare Ruskin, Inc.

The DiMare Company is an 80 year old company and the largest vertically integrated tomato company in the United States. We are

growers, packers, re-packers, and distributors of all types of fresh tomatoes. Our company has been one of the industry leaders and instrumental in helping form food safety guidelines that are in place in our industry today. The DiMare Company started a Food Safety and HACCP Program as early as 1990 at our Tampa, Florida repack facility. Food safety is not new to the DiMare Company. We then expanded the Food Safety Program to the remainder of our growing and packing facilities in the mid-1990s.

I would like to give the Committee an overview and sense of what we do as a company to ensure that the products we produce, pack, and distribute are handled in the safest possible manner by our stringent Food Safety and Food Security Programs and our ability to positively identify and traceback our products.

Starting with our farms, we routinely test our irrigation water and the water we use for spraying our crops to ensure it is free from harmful pathogens. We have invested heavily in some areas, installing fences where animal intrusion had been a problem. Our field workers are trained prior to the start of each crop season on awareness of food safety procedures. They are also trained on proper personal hygiene. Proper hand-washing after restroom use is one example of this. Our key personnel have been trained to identify worker illnesses and health issues and report them immediately to management. Our key personnel have also been trained for food security with special attention to any unusual activities and awareness of any unauthorized people coming onto our farms and facilities. Everything we do relative to food safety is documented and reviewed annually by one or more third-party auditors. We also conduct self-audits during each crop season and document those results. Any deficiencies are noted, and corrective actions are immediately addressed.

At our packinghouses, we also have worker training sessions prior to the start of every season, educating workers on proper personal hygiene, including proper hand-washing, proper use of protective gloves, smocks, and hairnets. The workers are educated to not wear jewelry, have personal items, or food or drinks in the work area. There are designated eating and drinking areas for all employees. All of these procedures are in place to help minimize any possibility of contamination to our food products. Any machinery sprays and lubricants are of Food Grade quality, and MSDS records are kept for these and all other chemicals.

The water we use to wash and rinse our product in our packinghouses is required to be of potable quality and is tested seasonally to ensure it is of safe quality. Our product at the packinghouse level typically goes through a chlorine bath wash procedure followed by a fresh water rinse, and then one final sanitizing rinse before it is quality sorted and sized for packaging. We very closely monitor our bath wash water on an hourly basis, recording chlorine levels, pH, and the water temperature, which are critical for ensuring proper kills of any bacteria or pathogens and prevention of infiltration of these contaminants into the tomatoes.

The containers we harvest in are cleansed with a chlorine wash to rid them of any dirt and debris after they have been emptied of product and prior to returning to the farm for harvesting use again. The equipment used for all packing in all our operations is

sanitized before the start of each packing day. Swab tests are conducted on the equipment twice per season and sent off to an independent lab for presence of total coliforms, *E. coli O157:H7,* and *Salmonella*.

Pest control is another important area of our overall Food Safety Program. We contract with independent and licensed pest control companies to manage pest control in all of our packing operations. Traps and bait stations are placed around the perimeter of our properties, around the perimeter of our buildings, and around the inside of our packing facilities. In essence, we have three layers of pest control protections in place.

After our product has been packed and readied for shipment, independent trucks used for transportation are inspected for cleanliness and absence of any foul odors and documented. Temperatures are set according to customer requests and temperature recorders are placed on every truck to monitor temperature settings during transportation. Again, everything we do is documented, and third-party audits are conducted annually to ensure we are delivering the most wholesome and safest products possible.

The final process in our Food Safety Program is a Recall and Traceback Program. There is a Crisis Management Team in place at every level of our operation to act on a recall and quickly and timely trace our product back. I will share with the Committee a recent mock recall that was conducted on July 8, 2008, by one of our repacking operations in California during the *Salmonella saintpaul* outbreak in which tomatoes were incorrectly named as the source. Our facility in Sacramento, California, was chosen to conduct the mock recall to test the ability of industry to effectively conduct traceback, and more importantly, the timeliness of a recall from an individual quick-serve restaurant all the way back to the individual farm and specific field.

Present at the traceback were the Quality Assurance Director of the quick-serve restaurant, a DiMare Company official, industry representatives from the California Tomato Farmers and Western Growers Association, and four Congressional investigators. The recall was initiated by the QA Director of the quick-serve restaurant by randomly and literally selecting one of their individual restaurant stores from a Yellow Pages phone book in the Sacramento area. He proceeded to call the store and asked the employee to give him the identification numbers on the side of the DiMare Fresh tomato box. The information was then given to the general manager at our Sacramento location, who then began the traceback of the delivery. The individual box was tracked to an order number and accompanying PO number, which was tied to our internal repack number. From this information, we identified the packer/shipper, who in turn identified the individual farm and the field from which this individual box was harvested. This entire process took less than 1 hour to complete.

We strive and have achieved for tracebacks to be done in less than 4 hours each and every time we conduct a mock recall. We conduct these mock recalls twice a year in each of our repacking locations.

In conclusion, I want to share the "proactiveness" of the Florida and California tomato industries with the establishment of manda-

tory food safety programs encompassing farms and packing operations of all tomato types. The two states represent approximately 80 percent of the total fresh tomatoes produced in the United States. The programs are audited by USDA and enforced by their respective state agricultural agencies. In the case of Florida, the growers unanimously voted in support of the mandatory Food Safety Program back in 2006. This program became law this past July 1, 2008, and is in place today.

Mr. Chairman, I appreciate the opportunity to share with the Committee the rigorous steps and procedures we have implemented and practice every day at the DiMare Company. Thank you for your time today and the opportunity to discuss these issues. Thank you.

[The prepared statement of Mr. DiMare follows:]

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

Good Morning Chairman Peterson and Committee Members.

My name is Tony DiMare, and I am Vice President of DiMare Homestead and DiMare Ruskin, Inc. The DiMare Company is an 80 year old company and the largest vertically integrated tomato company in the United States. We are growers, packers, repackers, and distributors of all types of fresh tomatoes. Our company has been one of the industry leaders and instrumental in helping form Food Safety Guidelines that are in place in our industry today. The DiMare Company started a Food Safety and HACCP Program as early as 1990 at our Tampa, Florida repack facility. Food safety is not new to our company. We then expanded the Food Safety Program to the remainder of our growing and packing facilities in the mid-1990's.

I would like to give the Committee an overview and sense of what we do as a company to ensure that the products we produce, pack, and distribute are handled in the safest possible manner by our stringent Food Safety and Food Security Programs we have in place, and our ability to positively identify and traceback our products.

Starting with our farms, we routinely test our irrigation water and the water we use for spraying our crops to ensure it is free from harmful pathogens. We have invested heavily in some areas, installing fences where animal intrusion had been a problem. Our field workers are trained prior to the start of each crop season on awareness of food safety procedures. They are also educated on proper personal hygiene . . . proper hand-washing after restroom use is one example. Our key personnel have been educated to identify worker illnesses and health issues, such as tuberculosis, and report them immediately to management. Our key personnel have also been trained for Food Security with special attention to any unusual activities and awareness of any unauthorized people coming onto our farms. Everything we do relative to food safety is documented and reviewed annually by one or more third-party auditors. We also conduct self-audits during each crop season and document those results; any deficiencies are noted, and corrective actions are immediately addressed.

At our packinghouses, we have worker training sessions prior to the start of every season, educating workers on proper personal hygiene, including: proper hand-washing, proper use of gloves, smocks, and hairnets. The workers are educated to not wear jewelry, have personal items, or food or drinks in the work area. There are designated eating and drinking areas for all employees. All of these procedures are in place to help minimize any possibility of contamination to our food products. Any machinery sprays and lubricants are of Food Grade quality and MSDS records are kept for these and all other chemicals.

The water we use to wash and rinse our product in our packinghouses is required to be of potable quality and is tested seasonally to ensure it is of safe quality. Our product at the packinghouse level typically goes through a chlorine bath wash procedure followed by a water rinse, and then one final sanitizing rinse before it is quality sorted and sized for packaging. We very closely monitor our bath wash water on an hourly basis, recording chlorine levels, pH, and the water temperature, which

are critical for ensuring proper kills of any bacteria or pathogens, and prevention of infiltration of these contaminants into the tomatoes.

The containers we harvest in are cleansed with a chlorine wash to rid them of any dirt and debris after they have been emptied of product, and prior to returning to the farm for harvesting use again. The equipment used for packing in all our operations is sanitized before the start of each packing day. Swab tests are conducted on the equipment twice per season and sent off to an independent lab for presence of total coliforms, *E. coli, E. coli O157H7,* and *Salmonella*.

Pest control is another important part of our overall Food Safety Program. We have contracted an independent and licensed pest control company to manage pest control in all of our packing operations. Traps and bait stations are placed around the perimeter of our properties, around the perimeter of our buildings, and around the inside of our packing facilities. In essence, we have three layers of pest protections in place.

After our product has been packed and readied for shipment, independent trucks used for transportation are inspected for cleanliness and absence of any foul odors and documented. Temperatures are set according to customer requests and temperature recorders are placed on every truck to monitor temperature settings during transportation. Again, everything we do is documented, and third-party audits are conducted annually to ensure we are delivering the most wholesome and safest products possible.

The final process in our Food Safety Program is a Recall and Traceback Program. There is a Crisis Management Team in place at every level of our operation to act on a recall and quickly and timely traceback our product. I will share with the Committee a recent mock recall that was conducted July 8, 2008, by one of our repacking operations in California during the *Salmonella saintpaul* outbreak in which tomatoes were incorrectly named as the source. Our facility in Sacramento, California, was chosen to conduct the mock recall to test the ability of industry to effectively conduct traceback and more importantly, the timeliness of a recall from an individual quick-serve restaurant (QSR) all the way back to the individual farm and specific field. Present at the traceback were the Quality Assurance (QA) Director of the quick-serve restaurant, a DiMare Company official, industry representatives from the California Tomato Farmers and Western Growers Association, and several congressional investigators. The recall was initiated by the QA Director of the QSR by randomly and literally selecting one of their individual restaurant stores from a Yellow Pages phone book in the Sacramento area. He proceeded to call the store and asked the employee to give him the identification numbers on the side of the DiMare Fresh tomato box. The information was then given to the general manager at our Sacramento location, who then began the traceback of the delivery. The individual box was tracked to an order number and accompanying PO number, which was tied to our internal repack number. From this information, we identified the packer/shipper, who in turn identified the individual farm and field from which this individual box was harvested. This entire process took less than 1 hour to complete. We strive and have achieved for tracebacks to be done in less than 4 hours each and every time we conduct a mock recall. We conduct these mock recalls twice a year in each of our repacking locations.

I appreciate the opportunity to share with the Committee the rigorous steps and procedures we have implemented and practice every day at the DiMare Company.

Thank you for your time today and the opportunity to discuss these issues, Mr. Chairman and Committee Members.

- A Risk Management Program and Self-Audit System are in place to help reduce and eliminate potential exposures.
- Our facilities are registered with the FDA in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
- We have positive lot identification and can traceback our product from retail store or restaurant all the way back to our farms through our internal accounting programs.
- We begin by sourcing from only approved growers and packers, requiring they follow Good Agricultural Practices and that they are audited by third parties.
- All products are obtained by a Purchase Order, which begins the traceability—one step forward and one step back.
- Internal self-audits are conducted monthly at our repack operations and seasonally at our farming and packing operations to help maintain compliance.
- Customers routinely conduct unannounced audits at our repacking facilities to review our Food Safety Programs and verify compliance.

The CHAIRMAN. Thank you, Mr. DiMare. I want to thank again the panel for being with us.

Mr. Keys, how often are your facilities reevaluated for equivalency and when the FSIS visits your plants abroad, are they scheduled or can they come in any time? Can they just——

Mr. KEYS. Mr. Chairman, FSIS informs AQIS, which is their equivalent in Australia, that they are going to come for a review of the plants, and then AQIS will pick out of all the plants that are certified to export to the United States within Australia, they will pick a series of plants to go see. And we won't know at any given time when we will be inspected. It will be a short period of time. We will know, but we have AQIS officials that are in our plants every day. So they see that if we are doing something different to get prepared for the Americans, of course, they would be wise to that very quickly.

The CHAIRMAN. But before any of these plants can ship, they actually get a visit from FSIS before they are certified, right?

Mr. KEYS. Well, they have to be certified by the Australians to be equivalent——

The CHAIRMAN. Right.

Mr. KEYS.—so then we can ship. It is up to the Australians——

The CHAIRMAN. But FSIS doesn't actually come to every plant. In some cases they will just take the word of the Australians?

Mr. KEYS. Yes, it is the same way when we are exporting a United States product to Japan or Korea. They don't certify each individual plant.

The CHAIRMAN. Right.

Mr. KEYS. FSIS does that, and then you can ship.

The CHAIRMAN. They have an agreement. Mr. Dever, is it Dever?

Mr. DEVER. Dever.

The CHAIRMAN. I am sorry. In the case of the plants that are fruits and vegetable plants, does FDA have an equivalent system to FSIS in terms of going to each of these plants and inspecting them?

Mr. DEVER. No, they do not. We deal typically with the FDA who has grade inspections performed by FDA for a product being imported from outside the country.

The CHAIRMAN. So FDA goes to these plants?

Mr. DEVER. No, we have FDA actually at the ports of entry here in the United States.

The CHAIRMAN. And so in your case, as I understand it, you have some kind of agreement with your people that you are importing from that they meet some standards that you guys set?

Mr. DEVER. That is correct, yes. We expect equivalency from the standards within our organization. We require that of all of the——

The CHAIRMAN. And how do you check that?

Mr. DEVER. I am sorry?

The CHAIRMAN. How do you check that? Do you have third-party audits, do you send your own people down there?

Mr. DEVER. No, we do not require third-party audits. We do have people that do go on-site from time to time and check, but it is not on a normal basis. It is not something that we do typically unless we have a concern that is brought to our attention.

The CHAIRMAN. So nobody actually, necessarily, goes and visits that plant before they can important into the country?

Mr. DEVER. That is correct.

The CHAIRMAN. You are comfortable with that?

Mr. DEVER. We are comfortable with the Chilean operations that occur today, but what we are looking for is more equivalency as to the Chilean operations which is where our product, primarily, comes from, from South America. What we are looking for is from some equivalency of regulations down there to ensure the product comes in here that equals ours.

The CHAIRMAN. And they are not equivalent at this point in your opinion?

Mr. DEVER. In some cases they are even better than equivalent, but it is not as consistent. We are looking for consistency throughout——

The CHAIRMAN. So you are talking country by country?

Mr. DEVER. Yes, correct. As an example, in Mexico, we have substantially much more FDA inspections done on products coming into the United States out of Mexico than we do from South America.

The CHAIRMAN. Does FDA currently do anything to ensure that there are systems in place in these other countries?

Mr. DEVER. Not to my knowledge.

The CHAIRMAN. No? Are they talking about it?

Mr. DEVER. Not to my knowledge.

The CHAIRMAN. Mr. Keys, we understand that FSIS has a multilayered system for ensuring the safety of imported products that determines the equivalence. What are the benefits of approaching inspection with a system-based approach like the FSIS focusing on the potential importing country and evaluating each system as a whole?

Mr. KEYS. We think it is important for consistency, and it is two governments working with one another to figure out what those points of equivalency are. So we as a company, we of course give input and try to work with each one of our respective governments to figure out what that equivalency is or if we can sustain it in plants. But at the end of the day, it is a negotiation and a deal between two sovereign countries to decide what is equivalency and then working together.

They manage that over a continuum, and if you look how long Australian product has been coming into the United States, that history going back, two governments working together to figure out what equivalency means. You have that consistency and quality of government-to-government work that really helps trade flow and industry to work. And we struggle with that in the United States as we work with the Koreans and the Japanese on equivalency with their meat inspection systems, or the Chinese, back and forth. But it is a process that we believe that works well between two governments, not two industries or two companies.

The CHAIRMAN. I know I am a little bit over my time, but Mr. DiMare and Mr. Dever, why do you think FDA has never done this, or why can't they do the same kind of a system that USDA does with these other countries? I mean, they don't have the resources, or they don't care?

Mr. DEVER. I don't know enough to speculate on why they don't. Typically we deal a lot with FDA on grade standards, but not a lot with USDA, and why they may be focused on other things other than fresh fruit and vegetables.

The CHAIRMAN. Mr. DiMare?

Mr. DIMARE. Yes, Mr. Chairman, I would like to comment on that. You know, having gone through the *Salmonella saintpaul* outbreak last year and having FDA officials in both our packing operations and repacking operations around the country, in talking with some of those folks, they do wish they had more presence, particularly in Mexico, but a lack of resources is part of the issue. And I know they were a little bit frustrated because they don't have personnel down in Mexico to better monitor what was going on down there. And I know from speaking with some of these folks that when they did go down during this whole investigation and conducted inspections for tomatoes at the time, before peppers were named, comments were made back to me in the area they were investigating that this particular area was rich in *Salmonella*, although it wasn't the *Salmonella saintpaul* strain that they were trying to find.

I think they would love to have the ability to have more oversight and presence, particularly in Latin American countries and particularly in Mexico, but, again, the lack of resources, from what they have conveyed to me, is part of the problem.

The CHAIRMAN. Within the government, and I know I am—if it is all right, Mr. Lucas—is there any pressure from the people that want to have more trade to try to not get in the way of that? In other words, if we put too rigorous a test on things that they are going to see that as restraining trade and whatever. Is there pressure within the government itself not to do this because we are going to somehow or another restrict ability of Mexicans to send fruit and vegetables up here?

Mr. DIMARE. In my opinion, I am sure there is some sentiment to that. Yes, I am sure there are some people that are sensitive to over-regulating and making regulations too stringent to obstruct trade. And there is no doubt having again gone through this investigation that as soon as Mexico was discussed as a possibility that this *Salmonella saintpaul* might have originated from there, the political pressure in Mexico to our government in Washington, particularly the State Department, was tremendous.

The CHAIRMAN. Yes.

Mr. DIMARE. They are extremely influential and very powerful in their lobby, and they put tremendous amount of pressure on our government to, in my opinion, to delay part of the process because you can't tell me an investigation could take 3 months like it did and all of a sudden the State of Minnesota Health Department, it was actually your state——

The CHAIRMAN. We are proud of them. They are——

Mr. DIMARE.—was the actual state agency that uncovered the *Salmonella* and indeed traced it back to a distributor in Texas who traced it back to two farms in Mexico, for 3 months to investigate and looking solely at tomatoes to come to find out it was Serrano and jalapeño peppers from Mexico. Something is wrong with the system.

The CHAIRMAN. No question about that. Thank you. The gentleman from Oklahoma.

Mr. LUCAS. Thank you, Mr. Chairman, and I am pursuing some of your thoughts there. Mr. Keys, your company has operations in many countries, sells products around the world. So your folks have experience in a wide range of food safety food regulatory systems.

Based on your company's experiences, how would you rate the United States in comparison to many of these other countries?

Mr. KEYS. On food as it relates to meat, meat inspection, which is I guess what we are talking about here. It is the standard. People have a lot of trust in FSIS. They look to it for answers on how to bring equivalency, and the gold standard is to be able to ship fresh meat and poultry into the United States, and to do that you have to satisfy the USDA and you have to work with the USDA. I think it is important to note that just in the last few years, three countries, I am not going to name them right here, but three countries voluntarily pulled their certification to export to the United States to work with FSIS to manage some equivalency problems. And that was done without fanfare. It was done very professionally between two governments, and I think that is important. It is really important to have the governments working, and the governments to have equivalency for food safety, so companies know where the bright lines are, not only companies that are in other countries but ourselves.

Mr. LUCAS. Mr. Dever, in your testimony you state that you found that some of the more sophisticated food safety operations are found outside of the United States. Would you take a moment to expand on that statement and perhaps give us a few examples?

Mr. DEVER. There are certain companies and/or countries that do have sanitation requirements that I do believe exceed what we have here in the United States, from a regulatory perspective. There are certain countries that we have done business with in the past and continue to do business with today that have very detailed, not only requirements related to sanitation, but also inspections that are done more so than what we do have here.

Mr. LUCAS. Could you give me an example or two of just how those systems are more sophisticated?

Mr. DEVER. The requirements are such that in certain areas, hair nets will be required in the production of grape packing. All of the product will come to one facility rather than packed out in the field. They will have lab coats so that everything is covered. People will ensure that everyone's hands are washed and sanitized at all times, and it will continue through the entire packing process in order to ensure that the product quality is not contaminated as it is going through the process.

Mr. LUCAS. Now, you have my curiosity. I have to ask without naming of all of these potential places, perhaps a couple examples of these countries?

Mr. DEVER. I would prefer not to mention them today.

Mr. LUCAS. Okay. You advocate that FDA commencing a rulemaking program to regulate on-farm production practices. Do you believe that FDA has the greater expertise and resources to regulate farming practices than USDA?

Mr. DEVER. No, sir.

Mr. LUCAS. I am not even going to ask then how you think farmers and ranchers would react to such a view. Enough said. Thank you, Mr. Chairman.

The CHAIRMAN. I thank the gentleman. Let me look at the list here. The gentleman from Georgia, Mr. Scott?

Mr. SCOTT. Mr. Chairman, I am going to forego questions on this panel in the interest of time, and I will reserve them for the next panel.

The CHAIRMAN. The gentleman from Wisconsin, Mr. Kagen.

Mr. KAGEN. Thank you for being here. I appreciate your testimony. I had the opportunity to read your prepared comments last evening. I don't have too many questions. I want to thank Mr. Keys for not renaming the Green Bay Packers after you brought the packing facility there in Green Bay. It has a lot to do with how we feel about ourselves.

Is there any way that consumers, when they go to the grocery store, can tell where that meat is coming from? Are you going to comply with the country of origin labeling?

Mr. KEYS. We are complying with the country of origin labeling. I could say right now that the vast majority of the beef that we are producing and labeling, we are talking close to 90 percent or more, is going to be labeled with an USA label. And that is what consumers will see in the stores, will be that. That is what we use primarily, what we would call label number one or label A.

Mr. KAGEN. And are you inspected in your rendering facilities every day?

Mr. KEYS. Do we inspect our rendering——

Mr. KAGEN. You have a rendering facility, and it is being inspected every day. Is that true?

Mr. KEYS. Well, the rendering is separate than red meat, the meat part of it, but it is run professionally every day by our professionals, and it is regulated of course as a feed or however the rendered product goes out.

Mr. KAGEN. Would you have any objection, either all three of you, of having reports that are made by any inspector at all made public on the Internet? Would you have any objection to that at all for full transparency?

Mr. KEYS. I think you can get most of the reports that come out of USDA now on when we have NR's in our plants and noncompliance.

Mr. KAGEN. Have you ever brought to the attention of any of the inspectors a problem that they may not have seen that you have corrected yourselves?

Mr. KEYS. I don't know that answer, but I could find out and get back to you.

Mr. KAGEN. I appreciate it. That is all I have for this group. Thank you.

The CHAIRMAN. I thank the gentleman. The gentleman from Kansas, Mr. Moran.

Mr. MORAN. Mr. Chairman, thank you very much. Mr. Keys, thank you all for your testimony today. My general inquiry is just about your recommendations as to what kind of the bottom line of what we need to do to improve food safety, and as you know, there

is a concerted effort on this topic. I am very interested in knowing what the industry's kind of best suggestion is. It seems to me that you have described a pretty robust system, Mr. Keys, but based upon your area, is there anything that you would do to recommend improvements?

Mr. KEYS. I am just a lobbyist, not a scientist. But I will say I think the elephant in the room here is that there is a difference. There is a difference, USDA inspects meat and poultry, and FDA inspects everything else. I don't think the American public really understands that. And the robustness of the inspection service at USDA, it is every carcass, every day. It is very robust, not only domestically but as we—you go around the world, people look at it as a gold standard if they can ship fresh meat or poultry into the United States, fresh, frozen or whatever you want to call it, noncooked. I think USDA has a long history here. I don't know enough about FDA. We are not regulated by FDA in our company, at any given site. But those are the big differences. I don't think we separate these things out and look at them in a way that it is meaningful to the public so they really understand. They just see it is inspected by the government. They don't know the difference between USDA and FDA and it never comes out, but that is something that maybe this hearing is trying to accomplish and good for you all.

We have a robust system. A lot of people say the law on meat inspection developed at the turn of the last century, but it is a very robust law with a lot of the power given to the Department of Agriculture to do a lot of different things in working with the industry on a daily basis, if not constant basis, to continue to work to make the products safer and safer for the public. And the industry has stepped up to that challenge. We certainly could always do more, and we should always think about doing more. But we are constantly looking for ways to improve our systems in working with USDA to make sure that we are doing a better and better job.

Mr. MORAN. Thank you, Mr. Keys. Mr. Dever, you advocate that FDA commence a rule-making process to regulate on-farm production practices. Why do you believe that FDA has greater expertise and resources to regulate farming practices than USDA?

Mr. DEVER. Well, from my perspective quite honestly, I am looking for a regulatory body. It is more up to Congress to decide which is the best regulatory body to do it. So I can correct my testimony accordingly, but I am looking for that particular fact and we are looking for that kind of regulation.

Second, is going back to your questions to Mr. Keys. From my perspective, the electronic record-keeping is one of the key things that we seriously need in this industry that is standardized throughout the entire supply chain. What Tony does in his company and what Mr. Keys is doing in their company is phenomenal, and I can tell you that for the most part, they can probably do anything within a matter of minutes and possibly an hour.

But the problem is that if we don't have it through the entire supply chain electronically, that is where the need is. And a lot of things are still done manually in this industry, so I would suggest that.

And last, the only thing I can say is I now, after listening to Mr. Keys, I am planning on having a filet mignon tonight for dinner.

Mr. MORAN. As a Kansan, we are delighted at your choice. Mr. DiMare, anything you would like to add for those specific suggestions?

Mr. DIMARE. I just want to clarify one thing. In the tomato industry, USDA's role in our industry, in our operation, is to inspect for quality, size, and grade. Now, as I mentioned in my testimony, Florida just adopted a mandatory food safety program this past July, and part of that program, USDA, under the auspices of the State Department of Agriculture in Florida, does the actual third-party audits which again is separate from quality or grade in the packing house. Same agency, two different roles at different times. And this is done now on an annual basis. It could be announced or unannounced, and that is for both farms and packing operations which is new, which is unprecedented in the produce industry. The tomato industry has been the leader to implement these programs which again, as I stated in my testimony, was unanimously supported by the growers. We, the growers, asked that to be mandated for food safety. As I said back in 2006, we actually took the vote in Florida, the Board of Directors, and it was unanimously passed to adopt this.

So I just wanted to clarify the USDA's role from our perspective in the packing houses *versus* third-party audits as far as quality of grade.

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

The CHAIRMAN. I thank the gentleman. The gentleman from Oregon, Mr. Schrader.

Mr. SCHRADER. Thank you, Mr. Chairman. I guess I would ask for the panel's comment, would enhanced regulation, as we are talking about here, really stop the absolute bad characters like we have seen in this most recent peanut butter fiasco? One person deliberately obstructs and has no intention of applying to any of the regulation. Any of the panelists? Just a real quick no, yes down the line.

Mr. KEYS. I would just tell you, the number one priority in our company, before anything, is food safety followed by worker safety. And our reputation is what we have to stand on. Regulations by and of themselves are not going to make us good players, so we constantly work on that. You know, we have built a culture in our company to work on these issues, and maybe some people don't have that culture, but I am not going to talk about them. I can only talk about us.

Mr. SCHRADER. Fair enough. Mr. Dever?

Mr. DEVER. Yes, if you look from Pandol's perspective, you look in our written testimony, it refers to how we still have to count on the integrity of the people we are doing business with. No matter how much regulation that we instill on the industry, at the end of the day, if somebody intentionally goes to harm another human being, I don't think regulation is going to avoid that.

Mr. SCHRADER. Thank you.

Mr. DIMARE. And I agree. You know, the liability factor, if you look at some of the companies that have been implicated in the meat industry, Cornett Foods about 6 or 7 years ago in West Virginia, had stores in Pennsylvania that had contaminated Roma tomatoes. It broke Cornett Foods. Do we as an individual company

or industry want to take that risk because in today's world, all that it takes is one incident with gross negligence. From what I can see on the surface knowing the food industry and watching the news media over the peanut butter situation, there is no doubt there was gross negligence going on. Just look at the physical facility.

Mr. SCHRADER. My time is running out, if I may. I appreciate that, and that is an important point.

Mr. DIMARE. Mr. Chairman, if I may, this is a commodity-specific *Food Safety Guidelines* that we developed in the tomato industry, and if the Chairman wishes, I would like to submit it.

The CHAIRMAN. Without objection, that will be made part of the record.

[The information is located on p. 87.]

Mr. DIMARE. Thank you. And we can get one to all Committee Members if so——

The CHAIRMAN. That would be good if you could make those available.

Mr. SCHRADER. Mr. Keys has talked several times about USDA's process being the gold standard by which much of the world tries to emulate the United States' inspection process. Mr. Dever and Mr. DiMare, would you say that FDA standards are the gold standard also with produce and inspection?

Mr. DEVER. Once again, from our perspective, we deal with FDA inspectors most of the time, so those are the people that we do a lot of business with. We don't with the other party. I can't answer the question from that perspective.

Mr. SCHRADER. All right.

Mr. DIMARE. And from our perspective, USDA does not have oversight of what we do on a daily basis, FDA does.

Mr. SCHRADER. That is fair enough. There has been a lot of talk from the panel as far as equivalency being the gold standard, also, that really helps any company deal with at least a consistent set of regulations. Does the panel have any opinion about FDA's equivalency *versus* the FDA's equivalency procedures?

Mr. KEYS. I would just say equivalency, if you really study it and you look at it, how you get governments to buy in with other governments and work things out, that is the beauty of equivalency, government-to-government equivalency because it makes them part of the process in getting it to an end goal. If you don't have that, then government is in, government is out, and you never know where the steady line is so you can produce for that marketplace, and that is the important thing about equivalency.

Mr. DEVER. I would agree with that. We export to 24 different countries, and we import from a number of different countries, and for us, if it was a global specification if you will, it would make it much better for the global industry from a food safety perspective.

So we are looking for countries to work together within the government regulatory bodies because we cannot as producers, we can't be expected nor can we afford to go and inspect every facility in every country that we do business with. It is impossible. So we have to count on countries developing the right equivalent standards so that we can count on that and have certifications if necessary. But that is the extent of it from my perspective.

Mr. SCHRADER. Last question. My time is actually running out. It has just come to my attention as a consumer and as a farmer, a person that spent some time in our state legislative situation that a lot of the problems that we are dealing with come from foreign countries where there is this inconsistency that the panel has talked about. That it is sometimes lost upon a great many Americans, that the fact that we catch a lot of the issues that we do catch in this country before they get out of hand is sometimes a testament to some of the inspection processes we already have in place that have stood the test of time, and in some cases are the gold standard. And while we can always improve them, and some of the improvements that have been suggested here today I am sure we will incorporate, I think Americans have to remember we have the safest food on the planet, we should feel lucky that way.

Thank you, Mr. Chairman. I yield back.

The CHAIRMAN. I thank the gentleman. The gentlelady from Wyoming, Mrs. Lummis?

Mrs. LUMMIS. Thank you, Mr. Chairman. My first question is for Mr. Dever. What regulations are required to equalize the playing field? You mentioned that term in your testimony.

Mr. DEVER. We are looking for regulations for the entire supply chain. So that starts at the farm, goes through the packing houses and the transportation for the product, and how it is both harvested, grown, and also transported.

Mrs. LUMMIS. Thank you. Mr. Keys, a question for you. Do you think the FSIS needs any additional funding or manpower, legislative authority, to make the process of importing, particularly Australian beef, any safer?

Mr. KEYS. Well, we think Australian beef is very safe because of the equivalency process that we have been going over. Look, I am not an FSIS employee. I am sure if I asked them in the back here they would certainly love more money. I am sure that probably wouldn't be a problem. But, more importantly, with the FSIS, is that the structure of their regulatory regime is very important, and to understand that and for them to work with industry to continue to modify it. I mean, *E. coli* took us from looking at every carcass every day to looking at the carcass basically through a microscope. And that whole transformation was done without new legislation. It was done within the guidelines of the current laws on the books.

So there is a lot of flexibility there in the law to get to the main point which is to provide a safe and wholesome product for the consumer, no matter if it comes from in the United States or it is imported from a foreign country. It has to meet that standard, the same way when we ship product, our beef, to Japan, Korea, and our main export markets, Mexico, Canada, is that we have to work with those countries to get their equivalencies down right.

So it is all a give and take, and if we try to do something a little sly or silly, we can bet that people in other countries that we are exporting beef to would do the same sly and silly thing. So what goes around comes around as my grandmother said.

Mrs. LUMMIS. Okay. Thank you for your answer. I have another question for you. Now I am going to ask you to put on a hat that you are not currently wearing. Obviously JBS is about as far as you could get from the very small cow/calf operator or rancher/

farmer in the United States, but could you talk about the perspective of a small rancher or processor? Do you think that they could continue to operate under the on-farm regulatory regime that has been contemplated by some of the proposed legislation?

Mr. KEYS. I grew up on one of those small operations, so I understand this. And what I think is always—to understand the beef industry, the cow/calf industry, is that it is 70 percent of our producers control 30 percent of our production in cow/calf. So you have a lot of small, part-time guys who do this. And if they feel at any given point in time that it is more trouble to raise that animal than it is worth, based on their time, effort, place in the food chain, they will just quit it. And I think you are seeing that right now. The cow herding in the United States is going down at the same time that globally, the demand for beef is going up. And a lot of it is land cost, it is demographics, but it could also become heavily regulatory burdens on small cow/calf producers that just say enough of that. I am not going to do that. I am going to grow wheat or whatever they want to do.

So I think that is an important balance to always watch.

Mrs. LUMMIS. The last number that I was aware of is that we have 1.2 million ranchers. There are now less than 900,000, and they are declining. And if you have a specific number that is more current than mine, I would love to see it.

Mr. KEYS. Well, I don't have it right now, but I will get that to you.

Mrs. LUMMIS. Thank you. Mr. DiMare, could you tell me, is there anything a Federal agency could do to help bolster your safety protocols that are already in place, or do you feel that they are adequate as is?

Mr. DIMARE. I don't believe there is because again, this document here was a creation from all stakeholders, from producers to users, to government regulators within FDA, scientists. The work has already been done in the tomato industry and put into this document from all these people, and we are currently revising and creating a new matrix for the tomato industry. It will be the first, again, commodity in produce that—I don't know when it is going to be done because we are right in the midst of it right now—that addresses every operation in the tomato chain from the farm all the way to the quick-serve restaurant, and the responsibilities at each one of those facets relative to food safety. We are doing it, we have been doing it.

Mrs. LUMMIS. Thank you, Mr. DiMare. My time is up, but I want to thank you all for being here today, and I am hopeful that the best practices that you are instituting in the tomato industry will be shared among other commodities. Thank you, Mr. Chairman.

The CHAIRMAN. I thank the gentlelady. The gentleman from New York, Mr. Massa.

Mr. MASSA. Thank you, Mr. Chairman, and thank you for the work you do in the private sector to secure the end product of what so many farmers try to get to the table. I have a lot of experience in supermarkets and not much on ranches. So I end up like most consumers seeing the end-product of their efforts. However, as we compare the oversight responsibilities of these two major government institutions, my concerns and focus are not necessarily about

what is happening here in the United States but rather the food safety and jurisdiction requirements of our overseas imports. We have members here on the panel who have significant overseas interests in grapes and beef, and I know that countries, specifically in Latin America, still use pesticides that are banned by regimes in this nation and we still import that food. And I know there are practices overseas in the beef industry that frankly are not conducted here.

And so my question to both of you today, if I might, could you please give us some insight as to how the United States, with its heavy, new importation of food, can move through these agencies to further secure our food safety? That really is one of the most critical issues we are going to be facing in the future. Mr. Keys?

Mr. KEYS. Thank you. The equivalency to ship fresh meat, fresh frozen meat, into the United States from foreign countries, there are only a few foreign countries that actually can ship here, that are certified to do so. The rigor that they have to go through to get that product in a container and get it to the United States is very robust, all the way to the point where USDA has a residue program to test for residues, chemical residues, drug residues, in all this product. And they do it not only for foreign product coming in but also domestic programs. FSIS runs a residue program. So the rigor that USDA has put into this system over the years on meat and poultry—and that is by the way the only thing they do regulate on the food side—we believe is very robust. And they are always looking for ways to make it better, and we just went through a big reclassification on how imported countries have to test for *E. coli*. And the Australians, New Zealanders, Uruguay, Nicaragua, all the countries, Mexico, Canada, they all came to Washington, worked with the USDA, came up with a regime for testing for *E. coli* in a better, more robust way.

And so you see those type of activities happening all the time at USDA because they are actively involved with their counterparts. That is the important link with equivalency with foreign countries when foreign meat and poultry comes into the United States.

Mr. MASSA. Thank you, sir. And with respect to grapes and agricultural products, this is something that we have a significant focus on in my district, and I would like your insight, specifically, for instance, Chile.

Mr. DEVER. We are looking at that all of the time because one of the problems that we do have in this industry is the equivalency portion, as we have talked about quite a bit throughout this hearing. Down in South America in numerous countries, including Chile, you have a lot of people that are implementing a lot of good safety regulations themselves, but that is by the industry, and the Chilean Fresh Fruit Association is doing a wonderful job, in particular, at spreading the word as to what is to go on down there in helping the people improve that aren't doing a good job. We have the same situation here in the United States, but from Chile's perspective, what we are looking for is we are trying to get as much assurance as possible and we want to deal with the Chilean Government to ensure that they understand what the requirements are here for safe product through the entire supply chain, and we are looking for that going down to the smallest grower. And whether

it be in the United States or Chile or Argentina, I can't say—if anybody asked me today, can we be sure 100 percent that everybody is complying with that, I can't say that today.

Mr. MASSA. But you would concur that the entire regime is built largely on one of trusting the foreign governments' certification of their systems?

Mr. DEVER. That is correct.

Mr. MASSA. With respect to beef, would you agree that we are relying heavily on the foreign governments' certification of their inspection regime?

Mr. KEYS. No, I would say it is sort of an equivalency. We sign off, FSIS signs off, so they can say yes, this is what we are going to do——

Mr. MASSA. But they are not——

Mr. KEYS.—and FSIS can say, well, no that is not good enough. You have to——

Mr. MASSA. But they are not American inspectors.

Mr. KEYS. But we go and audit every year. We send teams over there. It is a very rigorous program. There are only a few countries that qualify to ship beef and ship red meat to the United States and poultry.

Mr. MASSA. Thank you both very much. Mr. Chairman, I yield back. Thank you.

The CHAIRMAN. I thank the gentleman. The gentleman from Nebraska is recognized. Pass? The gentleman from California, Mr. Costa?

Mr. COSTA. Thank you very much, Mr. Chairman, for this very timely hearing and for your efforts in working with myself and others on food safety efforts. As many of you know, I represent the highly diversified area in the San Joaquin Valley in which agriculture is the number one industry, and food safety is always job number one. I am also pleased that Mr. Dever from the Pandol family, an immigrant family from Croatia that has farmed in the San Joaquin Valley for generations now and is part of this panel, and Mr. DiMare whose family I have known for years as well. Good witnesses, Mr. Keys as well.

I want to go through a quick list of questions because I have introduced legislation that I would invite all the Members to look at. Congressman Putnam and I, a bipartisan effort to truly try to develop, one, a gold standard and uniformity across the country as it relates to food safety, but first, when we talk about the overlapping myriad of regulations and issues it is important to know that—raise your hands when I ask you the following questions if you are doing it. Do you currently operate under food safety standards imposed by the USDA or the FDA? USDA?

Mr. KEYS. USDA.

Mr. COSTA. Okay.

Mr. DIMARE. Well, again, the Florida Tomato Industry developed their own food safety——

Mr. COSTA. No, I know that. I want to quickly—my time is limited. Yes or no.

Mr. DIMARE. No.

Mr. COSTA. No? Okay. Or is it a combination in any cases? Mr. Dever?

Mr. DEVER. It can be a combination, but primarily FDA.

Mr. COSTA. Okay. How many of you currently follow a hazardous analysis critical control plan, otherwise known as a HACCP? Okay. How many of you are currently following good agricultural practices, otherwise known as GAPs? You all follow which we like to refer to as a gold standard, right? How can you discuss differences between the HACCP and the GAPs and do you believe that safety on the field requires a different approach to those that are in the—where we do the value-added and the processing facilities? Yes, Mr. DiMare?

Mr. DIMARE. There are some variances between the two, between the farms and packaging.

Mr. COSTA. And we have to take those into account, correct?

Mr. DEVER. In most cases, we follow GAP in fields. We have internal GAP as well as regular, but over and above that you also follow good manufacturing practices when it comes to some of the processing of product.

Mr. COSTA. Which brings me to my next question. How many of you follow additional food safety requirements not required by law but are part of your marketing orders, part of agreements that you have with co-ops or farmer-collective operations? All of you do, which never gets taken into account when people are looking at the food safety issues, right?

Mr. DEVER. Correct.

Mr. COSTA. It is my understanding, and this is probably with Mr. Dever and Mr. DiMare—I don't know, Mr. Keys if it would apply to you—as we talk about our efforts to improve the GAPs—standards in food safety, do you support a mandatory commodity-specific, risk-based regulation effort and guidelines to fill in the holes and to create the greater confidence that we need among American consumers?

Mr. DEVER. Yes.

Mr. COSTA. Do you support the Safe FEAST Act? Yes?

Mr. DEVER. Yes.

Mr. COSTA. Thank you. Mr. DiMare, and I think this is really at the heart of the traceability program and we knew what happened with the tomato market last summer because of the scare that ended up being jalapeño peppers imported from Mexico. But, you mentioned your initiative in Florida and the guidelines of the programs that were developed in conjunction with the FDA, is that correct?

Mr. DIMARE. That is correct.

Mr. COSTA. And the enforcement or the audits were in conjunction with the FDA as well? Or the USDA? They were done by the USDA?

Mr. DIMARE. FDA.

Mr. COSTA. Okay. Do you think that system is effective?

Mr. DIMARE. Pardon?

Mr. COSTA. Do you think that system is effective?

Mr. DIMARE. I think it is very effective.

Mr. COSTA. Because I was wondering whether or not you can promulgate a system in which the FDA promulgates the regulations and then the USDA does the administration because a lot of the different food safety proposals that are out there want to know

whether or not or how you are going to be able to do this as we look at developing a new food safety program.

Mr. DIMARE. Well, I just want to comment in going back to the investigation. I will give you a little example what happened with us. In our Houston facility, we had folks come in from FDA that came in from the drug side that had no experience in the produce industry in conducting these actual investigation, with no knowledge of produce. I think that is just absolutely ludicrous that in today's society with a regulating agency that they send in people that have no experience investigating something that was so serious. I think that is a serious problem. That needs to be looked at.

Mr. COSTA. Well, my time has expired here, but Mr. Chairman, can I finish this? Thank you. So you think it is possible then for the FDA to work on the science and then the USDA to work with other efforts especially when we talk about imported foods to in effect be the foot boots on the ground to provide the enforcement?

Mr. DIMARE. I think it is possible as long as both agencies are willing to work together.

Mr. COSTA. Under the category of not wanting to reinvent the wheel, I would like, at least, Mr. DiMare and Mr. Dever to talk about the traceability program because we have witnessed it just in the random sampling right now with the pistachio issue here in the last few days. But in the tomato industry, we have taken people of the Energy and Commerce Committee out to California, and we had a random sample that I am aware of in which they tried to pick five different farms. And the earliest they could traceback the sampling was within a ½ an hour to the farm. The longest took 5⅕ hours, and that was because the farmer was a single operator. He was gone from the farm, and there was a message on his phone. When he got to his phone, he checked it and he called back. But the traceability factor is a critical part in terms of best management practices.

Mr. DEVER. I fully agree from Pandol's perspective. We are also on the Produce Traceability Initiative put together by the three industry associations that was mentioned in my testimony.

We are very much involved in traceability, and that is one reason why we do believe electronic record-keeping is important because we do mock recalls continuously. We fortunately have not had the experience to date of having to use it in real life like Tony has. You know, grapes so far have been off of the hit list, and we are very fortunate for that, and I suggest everybody go and buy a couple pounds this afternoon. But to your point, traceability is extremely key to minimizing the damage that is caused when an incident occurs. And if you have the right traceability in place, it solves many of the problems, rather than a shotgun approach that has been used in other commodities that I have seen recently. Once again, we have not experienced that ourselves. It is just what we see in the industry. But from our perspective, traceability is it. And for the most part, the people that are in this business, if they don't have a good traceability program, they won't be in the business for very long. I mean, it is crucial to our industry and it is crucial to the consumer to be able to trace the product.

Last, we are the ones that suffer the most if we can't do it because it puts us out of business. I don't know how much money

Tony lost in the last tomato recall, but a lot of companies wouldn't have survived that.

Mr. COSTA. To that point, and I know all the Members of this Committee understand that because of their own representation in their own districts, but I try to explain to people when we are talking about food safety, the farmers first of all consume the products they grow. So they don't want to have products that potentially may be contaminated and neither do their neighbors and their friends. Number two, they have an economic interest because if you have a contamination scare, I mean, the bottom drops out of the market. So it is in this industry's interest, and a lot has changed in 20 years in our ability in best sciences. But, frankly, the industry really, I think, wants to come together. That is why we have broad support for our legislation and others as we try to use best management practices based on risk assessment and risk management, and how we can assure the American consuming public that we grow the absolute best food in the world. That those same standards are required for food that is imported to the United States, that it is not two standards but it is the same standard, the gold standard, which is what we are trying to achieve.

Mr. DEVER. And we applaud you for that.

Mr. COSTA. I have gone way past my time, and the Chairman has been very generous. Thank you. But just for the——

The CHAIRMAN. I thank the gentleman. Pardon?

Mr. COSTA. I don't know if they want to comment. Both the other two gentlemen deal in other parts of the world, and if we are talking about how you establish a gold standard, at some point in time, I think it would be interesting for the Committee to know, based upon their experiences in South America and other places where they grow food, what lessons we can learn or what should be the very best standards.

The CHAIRMAN. I think we covered that a little bit when you were out, but you are right on. We appreciate your leadership and the work that you have done on this issue, Mr. Costa. I look forward to working with you. The gentleman from——

Mr. COSTA. I thank the Chairman for coauthoring my bill.

The CHAIRMAN. The gentleman from California, Mr. Baca.

Mr. BACA. Thank you very much, Mr. Chairman. Just to follow up on what Mr. Costa has just said, and the question I guess would go for Tony DiMare. If you can elaborate a little bit more on how to ensure proper traceability when a crisis hits so that another industry does not have to go through what the tomato industry did, to receive false blame for the outbreak? Would you elaborate a little bit more on that?

Mr. DIMARE. I guess we are fortunate in the tomato industry we do have the ability to identify products that we ship out into the marketplace, which is really a tool to help, not only identify what your product is or where the origin is, but God forbid you have an issue you need to investigate and quickly traceback the product, you do have the ability, either through labeling or otherwise on the package or even the specific commodity to trace it back and identify where that product came from.

Mr. BACA. Because now we are getting a lot of tomatoes from Mexico, and a lot of people don't even know that we are getting a

lot of tomatoes. And the pesticides, the requirements, and the safeties are not there in comparison to those of you here in the United States, is that correct?

Mr. DIMARE. That is correct, and that is part of the challenge with country of origin labeling that has just been passed. You know, that is again a tool to help identify, for consumers, where products are coming from because there are a lot of products that come in from outside the United States.

Mr. BACA. Mr. Dever, could you please give us a little bit more details of the Trace Recall Program?

Mr. DEVER. Specifically to Pandol's Trace Recall Program?

Mr. BACA. Yes.

Mr. DEVER. What we do is we have a mock recall that is done every couple of weeks that comes through. We hire an independent third party facilitator to assist with that, and that comes into our corporate office with a phone call that says there is a problem. And then it goes through to the supply chain down to the grower that grew the product, as well as which ranch that product came from as well as the block that that product came from We typically can do that anywhere—the best we have been to date has been about 45 minutes, and the worst we have been has been about 6 hours.

Mr. BACA. How effective is it when needed and do you think this is something that we can apply to the Federal level?

Mr. DEVER. Well, it is effective and I think it is beneficial for us to do it, so in case we do have that one incident where there is a problem, we are able to trace it. I can tell you, to give you an example, there was recently this season a call in to our office that was real life, that there was a black widow spider found in a bag of grapes. We identified within approximately 45 minutes that that bag did not come from our company. If we didn't have the ability to know that, that could have been a huge problem for us.

So I think it is extremely beneficial for all corporations to have the ability to traceback that product, and also it helped the consumer know very quickly where that product came from and be able to deal with it.

Mr. BACA. Thank you. In your opinion, how critical is that electronic record-keeping and food safety procedures?

Mr. DEVER. I think it is very critical because if it is done on a manual basis, it takes too much time. Time is money in this industry, and time is health to the consumer. Every day that goes by that we haven't identified the contaminated product and the source of that contaminated product, another person can have a health issue and/or more of the industry gets hurt from the instance. So to me it is key.

Mr. BACA. Thank you. I yield back the balance of my time.

Mr. SCOTT [presiding.] The gentlelady from Pennsylvania, Mrs. Dahlkemper.

Mrs. DAHLKEMPER. Thank you, Mr. Chairman. Since I just came in and I haven't really heard all the questions, I am going to yield back.

Mr. SCOTT. All right. The gentlelady from Colorado.

Ms. MARKEY. Yes, thank you very much. I also knew I had a markup in another Committee, but Mr. Keys, as you mentioned in your testimony you are headquartered in Greeley, Colorado, which

is in my district. I can tell you I have had an extensive tour of JBS' facility in Greeley and met with several USDA inspectors there and can attest to the vigorous control standards that are in place at that facility. So I look forward to going on another tour, that was a couple of years ago, and working with you.

But I wanted to also ask the panel, how do you verify that your suppliers are also falling under compliance and have you ever dropped a supplier that you used because of noncompliance? And you may want to answer that Mr. Dever.

Mr. DEVER. It depends greatly on the source of the product, but in most cases all of our contracts with our growers—we don't have a lot of growers, first of all. So it is easier for us, but for the most part in our industry, we have contracts with growers that require this and also there is a lot of testing that is done at pre-harvest to understand the pesticide levels that are on the products prior to them being harvested.

We also have independent audits that will be done from time to time to give us the assurance, make sure that people are complying. To date we have not had a grower that had to be eliminated from our source because of noncompliance.

Ms. MARKEY. Thank you very much.

Mr. KEYS. USDA regulates right to the consumer, so if anybody takes our product and does something else with it, they have to answer to the government. We try to work with the people we sell our beef, pork, and lamb to, to make sure if they need expertise or they need help figuring out HACCP programs, we will work with them and we like to do that. But the USDA has that responsibility all the way to the consumer as it relates to red meat and poultry.

Ms. MARKEY. Thank you, Mr. Keys. Thank you, Mr. Chairman.

Mr. SCOTT. Thank you. The gentleman from North Carolina, Mr. Kissell.

Mr. KISSELL. Thank you, Mr. Chairman. Thank you, panel, for being here. I am going to pull back a little bit from some of the more specific questions, and I am looking for a general overview. And this is to each of the people on the panel if you could answer. In your opinions, what are the top two weakest points, the weakest links, in food safety? Is it the farmers, is it the processing, is it being able to follow the goods, is it imports, pesticides, regulations, lack of regulations? What are the top two biggest threats to food safety as you see them?

Mr. KEYS. That is 50,000 feet. I will give you what it is. I think it is the lack of willingness of governments around the world, using the WTO, the Codex, to come up with some kind of a standardization of sanitary, globally. I know it is tough, but a lot of countries, including our own, Europe, Japan, use non-tariff trade barriers for phyto-sanitary reasons. And they do it for protectionist reasons, and that is a big problem because it confuses the public in a general term on what is science and what is not science and how do you cut through it when you know the government is using a science issue to stop trade. I think that really slows us down in getting to true equivalency around the world on trade.

And then the number two issue would be making sure that we have the research dollars, infrastructure dollars going into critical research facilities at USDA or in the land-grant university to con-

tinue to look for ways to improve our food safety system, and then getting that technology out on the field and implementing it.

Mr. DEVER. Going back to the original testimony, I do think consistency throughout the globe is the critical thing for us. Food now is global. All of our sources come from around the world in order to be a year-round supplier of produce. As such, we would like to see the other countries that grow our products be held to the same equivalency and be consistent within the grower base, first of all. Second of all, I would like to see an electronic, as mentioned previously, traceability initiative that allows us to be able to trace that product to a grower, any country where they happen to be where that product was grown at any point in time. But that all costs money, and we are looking for support to have that happen.

Mr. DIMARE. If you again take the tomato industry as a model of what we have developed over years of collaboration between all stakeholders and the success that we have had, maybe it is something to consider across other commodity groups is to have a document such as this that addresses the whole food chain from farm to the end-user to make sure the best management practices, good agricultural practices, are adhered to and that there are third-party audits that are conducted to make sure.

None of this is a guarantee. There is always going to be risk in our food chain because there are many different factors that play into it. But what we can do as an industry is to continue to address any of the gaps, try to close those gaps within the operation or individual company and look to prevent them in the future by good management practices.

Mr. KISSELL. Thank you, Mr. Chairman.

Mr. SCOTT. The gentleman from Ohio, Mr. Boccieri.

Mr. BOCCIERI. Thank you, Mr. Chairman. One quick question I just have. How often or frequent are the containers that come into the country from overseas inspected? Is there any data out there that shows the frequency?

Mr. KEYS. I can get that for you, Congressman. A lot depends on your track record. I mean, if you have a plant that is not going well and FSIS gets onto it, every container. And they are pretty rough on it, rough on you when you have a residue or you have some paperwork, literally paperwork, that doesn't line up, they will inspect you very hard. So there is a huge incentive to be a good actor and have all your ducks in a row.

Mr. BOCCIERI. Those are the containers that are coming in from the ports, ships, and the like?

Mr. KEYS. Yes. Yes.

Mr. BOCCIERI. Okay. Thank you, Mr. Chairman. I will yield back.

Mr. SCOTT. Thank you very much. I believe we have relinquished all of our questions for this panel. I want to thank this panel. Thank you for your expert testimonies, it is very appreciated. We will now have the second panel.

Kind of ease your conversations out into the hallway so we can begin our second panel. Thank you very much. We will introduce our second panel, which was our third panel, but we will make it our second panel now. First we have Dr. Elsa A. Murano, President of Texas A&M University, College Station, Texas. Thank you very much for coming, Dr. Murano. Next we have Mr. Michael Taylor,

Research Professor, Department of Health Policy, George Washington University School of Public Health and Health Services, Washington, D.C. Thank you for being here with us. Then we have Ms. Carol Tucker-Foreman. Ms. Tucker-Foreman is Distinguished Fellow, The Food Policy Institute, Consumer Federation of America, Chevy Chase, Maryland.

Thank you all for coming. We are delighted to have you, and Dr. Murano, we will begin with you.

STATEMENT OF ELSA A. MURANO, PH.D., PRESIDENT, TEXAS A&M UNIVERSITY, COLLEGE STATION, TX

Dr. MURANO. Thank you, Mr. Chairman. My name is Elsa Murano, and I am currently the President of Texas A&M University, the best university in the country. From October of 2001 to December of 2004, I had the tremendous privilege, Mr. Chairman, of serving the American people as Under Secretary for Food Safety at the U.S. Department of Agriculture. I have had a long career as a food microbiologist, a teacher, and as a research scientist working on many of the issues in the laboratory that I then became familiar with as a regulator later on while I served as Under Secretary.

I served as the first food microbiologist to take the position of Under Secretary, so I felt had a special responsibility and certainly an opportunity to inject science into the policy of food safety.

But as I began my tenure as Under Secretary, I soon learned that what happens in the laboratory is very different than what happens in the real world. You have crises that happen that frankly don't like to wait for laboratory results to come in.

We had in 2002 what we later referred to as the perfect storm, Mr. Chairman. We had two very large outbreaks of foodborne illness, one involving *E. coli O157:H7* in ground beef which resulted in a very large recall of ground beef product, about 19 million pounds at the time, and then very soon after that, there was another incident of foodborne illness due to listeriosis, and that was involving deli meats and that totaled about 28 million pounds. It was a perfect storm because it showed that when things go bad, a lot of things can go bad at the same time, and it really indicated to me that we needed to roll up our sleeves in a very deliberate manner and get to work on addressing the underlying reasons why these outbreaks and recalls happened. And by the way, 2002 was not the only year. It had been happening for about a decade, almost on an annual basis.

So that situation really became an opportunity, to be honest with you, even though it was a trying time it was an opportunity to assess the case of these outbreaks and recalls. And what we came down to, really, is two issues, a human factor issue and a science issue, and let me explain. People can make a tremendous difference. At USDA, Food Safety and Inspection Service has about 8,000 inspectors at our at 6,500 meat and poultry processing plants every day, and as you can imagine, there is a lot of product that is under their jurisdiction, about 110 billion pounds, plus another 10 billion pounds of imported product every year.

So, it became evident to me that we needed to make sure these people, these 8,000 strong needed to be trained in a different way, needed to receive the kind of training that would help them know

the science behind food safety, behind the regulations that they were enforcing, behind their inspection practices, if you will. So, that they would know and be able to discern better what was going on in the plants, so that they could actually pick up on problems before they happened.

So what we did is we launched a Food Safety Regulatory Essentials program that trained our inspectors on how to verify that food safety systems were working based on science.

We also established an Office of Program Evaluation, Enforcement and Review, that would help supervise those inspectors because when you have people, you have to have supervision and accountability, and also we created a new class of inspector, the Enforcement Investigations and Analysis Officer. These would be super-experts, if you will, that would go into plants that had problems or that had a history, a track record of failures that we would be able to then identify the problems before they got to develop into an outbreak or a large recall.

But the human factor, of course, also involves the plant operators themselves. It is not just left to the inspectors. And the plants had been left, frankly, in my opinion, largely to their own devices to implement HACCP, which is really the food safety prevention program FSIS had been operating under for several years. They were left to implement that system basically up to their own judgment.

And what we found is that when we ordered reassessment of their HACCP plans, there was a lot of mistakes, frankly, in my opinion, that had been made, lack of assessing the risks properly. And if you think there is not a risk due to a certain pathogen, perhaps deeming it not likely to be present, then you are not going to do anything about it.

So the first step in assessing the risk, the likelihood of that pathogen being in the food, is the first step that has to be done right. That analysis has to be done correctly.

So to make a long story short, in ordering these reassessments of these plants in 2002, 62 percent of these operations changed their plans as a result, and 60 percent of them started to include *E. coli O157:H7* as a hazard reasonably likely to occur. So that was a dramatic change in the human factor that was operating those plants. And of course, the training that we undertook, the education I should say of consumers, because they certainly have a role to play as well in terms of good, safe food handling practices, cooking practices and so forth which culminated in the launching of——

Mr. SCOTT. Thank you, Dr. Murano. We are going to ask you to kind of wrap it up just a bit, please.

Dr. MURANO. Yes, sir.

Mr. SCOTT. Thank you.

Dr. MURANO. I will tell you very quickly that the second element, that of science, became very important as well, and the science of risk assessment is what really made a big difference for us to develop policies and regulations that would work. So as a result, Mr. Chairman, just to tell you in a nutshell, we saw a tremendous decrease in the incidents of foodborne pathogens in foods, we saw a tremendous decrease in the illnesses and we achieved the Healthy

People 2010 goals for reduction of *E. coli* illnesses in 2004, 6 years early.

So it can be done, but it requires vigilance and paying attention to the human factor as well as to the science that goes into the regulations, and results can be had. USDA has a tremendous cadre of very dedicated——

Mr. SCOTT. Dr. Murano, I am going to have to close you down.

Dr. MURANO. Yes, sir. I am done.

[The prepared statement of Dr. Murano follows:]

PREPARED STATEMENT OF ELSA A. MURANO, PH.D., PRESIDENT, TEXAS A&M UNIVERSITY, COLLEGE STATION, TX

My name is Elsa Murano, and I am currently the President of Texas A&M University. From October of 2001 to December of 2004, I had the tremendous privilege of serving the American people as Under Secretary for Food Safety at the U.S. Department of Agriculture. Prior to my appointment, I had been a successful researcher and educator in the field of food microbiology, working on the very pathogens that have been the thorn on the side of regulators, the food industry, and consumers for many years. When I first arrived in Washington, exactly 1 week before 9/11, I remember thinking that as the first food microbiologist to serve as Under Secretary for food safety, I had a special responsibility, as well as an opportunity, to inject science into the process of making our food supply as safe as possible. By this I meant I would use the scientific method to examine the causes and to arrive at solutions that would minimize food contamination and increase our ability to prevent foodborne illness.

I soon learned that the most significant difference between working on food safety at the laboratory *versus* the real world is that the real world doesn't like waiting for results, that crises can happen while you are in the middle of finding solutions to problems, and so one must learn to balance the need to act quickly with the need to provide solutions that will stand the test of time. Such was the case in the Summer and Fall of 2002. We had been working to identify where, in the production of ground beef, would contamination with the pathogen *E. coli O157:H7* be most likely to occur, as well as to determine what we could do to minimize it. As we were pondering this, we started to receive reports of several people becoming ill with this pathogen, resulting in one of the largest recalls of ground beef in our nation's history, totaling 19 million pounds. As we worked to control the outbreak, and to determine what went wrong so we could address the problem, we soon received news of several people becoming ill with listeriosis, resulting in one of the largest recalls of processed deli meats in our nation's history, totaling 28 million pounds. We referred to this period as "the perfect storm" because it showed how weaknesses in our system could line up in such a way as to produce the worst results, with multiple outbreaks by multiple pathogens in rapid succession.

I've always been a believer that the worst of times can also become the best of times, because they can be the best teacher. So, I was determined that we would learn from these situations and that those lessons would be the basis for our strategy in order to prevent this from happening again. In assessing the causes, I confirmed what I had known before I even took the position, which is that people can make a tremendous difference. FSIS has almost 8,000 inspectors at over 6,500 meat and poultry processing plants in the U.S., and these folks are responsible for inspecting 110 billion pounds of meat, poultry, and egg products, plus another 10 billion pounds of imported product each year. That translates to nine million inspection procedures being carried out every year, or a thousand procedures per inspector per year! So, it became evident to me that we needed to make sure that these hard-working men and women needed to be trained in a different way, in a way that ensured they knew the science behind what they were doing with regard to food safety, so they could do a better job of anticipating problems, and also, that they would be supervised adequately. The underlying idea was to address *the human factor* so that errors in inspection would be minimized. So, we went to work to design a training program that would help address this, and in April of 2003, we launched our Food Safety Regulatory Essentials program, or FSRE, to help inspectors know how to verify that food safety systems implemented by the companies were done correctly. We also created an Office of Program Evaluation, Enforcement and Review, to improve our inspector supervision activities, and created a new class of inspector, the Enforcement Investigations and Analysis Officer, charged with conducting com-

prehensive food safety assessments, which could be targeted to specific plants based on their track-record.

Speaking of the human factor, we also realized that over the previous years, meat and poultry processing plants had been left to their own devices to figure out how to implement food safety preventive programs with little oversight by FSIS. In the mid 1990s, the Hazard Analysis Critical Control Points system, known as HACCP, became a requirement of all meat and poultry processing plants, but how it would be implemented was left largely to each plant to determine. Let me explain what I mean. The very first step in implementing HACCP is to determine the types of hazards that are most likely to occur in a specific food. For ground beef, for example, plants are expected to determine whether in their operations, *E. coli O157:H7* should be considered a hazard likely to be found in their product. If a plant answers this question with a "no" then they don't need to worry about it anymore. We found that many ground beef processing plants had in fact answered "no" and therefore, they were not taking direct steps to deal with this hazard. So, in October of 2002, we ordered each plant to reassess their HACCP plans. As a result, 62% changed their operations, and 60% changed their plans to include *E. coli O157:H7* as a hazard reasonably likely to occur.

The human factor also included consumers, for they are the ones at the end of the food supply chain, and what they do, or fail to do, can also have an impact. So, we launched a comprehensive food safety education campaign, designed to address three elements: a mass media campaign, a cluster targeting to segmented audiences, and one-on-one activities utilizing our brand-new "food safety mobile" which would impart the message of safe food handling practices to various locations throughout the country. Turns out that our mobile was also very useful during the aftermath of Hurricane Katrina, helping New Orleans residents know what to do during the storm and afterwards, and helping distribute safe food and water to those affected.

Besides addressing the human factor, we also knew that we needed to use *science* to determine what else we could do to prevent contamination wherever possible, and how to control it, as our only other option. At the time of the listeriosis outbreak in the Fall of 2002, we came under a lot of pressure to implement regulations before our risk assessment on this pathogen was completed. Standing firm, we resisted the temptation to come up with a quick-fix solution before data was available, so we continued our risk assessment work. In October of 2003, our new *Listeria* rule was published, based on the results of our risk assessment. It offered a new approach in which we created incentives for the industry to do more microbial testing, and to implement post-processing intervention technologies that would reduce, if not eliminate this hazard. As a result, 87% of food plants changed their operations, 57% started testing more for the presence of *Listeria*, 27% introduced antimicrobial treatments in their operations, and 17% began using technologies that would eliminate the pathogen after cooking. We also launched a New Technologies Office so that we could streamline the approval process to introduce new pathogen-reduction methodologies as part of the arsenal available to food processors to control microbial contamination.

With these two approaches, concentrating on the *human factor* and on *science*, at the end of my time at USDA, we achieved results beyond our wildest dreams. By the end of 2004, we realized a 78% reduction in the prevalence of *E. coli O157:H7* in ground beef, and a 47% reduction in the prevalence of *Listeria monocytogenes* in deli meats compared with 2002, which you will remember was the year of the "perfect storm". Most rewarding is the fact that by 2004 we were able to achieve the Healthy People 2020 goals for reduction of illnesses due to *E. coli O157:H7* 6 years ahead of schedule! Of course, all this also translated into decreases in other foodborne illnesses, and in breaking the yearly cycle of large single-event recalls of meat and poultry products down to zero in 2003 and 2004.

There were two fundamental factors that contributed to our success. One is the *culture* that exists at FSIS, which has developed over many decades. It is a culture of commitment to prevention through continuous inspection and enforcement. History will attest to the fact that inspection is "in the DNA" of these incredible professionals. They know what to do, they know it is their responsibility to do it well, and they know that they are there to ensure public health. That is a culture of dedicated professionals which is not easy to duplicate. I would put FSIS inspectors against any other food inspectors in the world. I guarantee they are by far the best regarded among their colleagues, and this is due to a track record that is the envy of the world.

The second factor is that FSIS is guided by *legislation* that requires daily inspection of meat and poultry products, making it essential for the agency to have enough personnel to accomplish this task, and enough funding to operate it. The laws I'm referring to are the Federal Meat Inspection, Poultry Inspection, and Egg Products

Inspection Acts of 1906, 1957, and 1970. By comparison, the Food and Drug Administration, which is responsible for all other foods over which FSIS has no jurisdiction, is directed by the Food, Drug, and Cosmetics Act of 1938, which has no such requirements. As a result, most foods under FDA regulation are not inspected daily and are not subjected to the degree of scrutiny they should. Some don't see an inspector for years. This has certainly played a role in outbreaks of foodborne illness in foods inspected by FDA, such as tomatoes, spinach, and most recently, peanut butter.

The bottom line is that in order to ensure that we are doing all we can to improve food safety, we need to pay attention to the human factor and to utilizing science, but we need to do so within a culture that understands how inspection works, and which is armed with the regulations to carry out this mission. If I could offer advice to the Committee, it would be to allow FSIS and FDA to play to their strengths. The specialty at FSIS is food policy and food inspection, while FDA is primarily a drug and medical device regulatory agency. Perhaps now is the time to consider moving all food-related activities from FDA to FSIS, and allow FDA to concentrate on what it does best, and provide FSIS the regulatory authority and funding to inspect all foods, not just meat and poultry. An alternative that has often been discussed is the creation of a single food safety agency, as a stand-alone entity that would take over the functions of FSIS, FDA, and others like the National Marine Fisheries Service. Before this alternative is considered, I would ask the Committee to determine whether the formation of the Department of Homeland Security as a single agency right after 9/11 contributed to the problems encountered at FEMA in the handling of Hurricane Katrina, or whether transferring the import inspection from the Animal and Plant Health Inspection Agency at USDA to the Department of Homeland Security has reduced the number of illegal items introduced into commerce. My point is that forming a single food safety agency would disturb the operations at FSIS and would require the creation of a culture of inspection and enforcement that has taken decades to develop at a time when we need to enhance, not disrupt our food safety system.

I've now been gone from Washington longer than the time I served there. Unfortunately, in that time we have seen some setbacks in the gains we made at FSIS. We have also seen more outbreaks due to consumption of foods regulated by FDA. It is a reminder that we need to be ever vigilant about making sure that the human factor, and the science behind food safety, are paid attention to. This requires leadership and I urge the President to select people to the important positions overseeing FSIS and FDA very carefully. We need professionals with the scientific expertise to understand how to improve public health through risk reduction, and with the decision-making skills and character to do what is right. Thank you so much for this opportunity to give you my perspective. It has been a pleasure, Mr. Chairman. I would be happy to answer any questions you may have.

Mr. SCOTT. We have been long.

Dr. MURANO. Thank you, sir.

Mr. SCOTT. We certainly will follow up that with some questions.

Dr. MURANO. All right.

Mr. SCOTT. Five minutes is not nearly long enough——

Dr. MURANO. It is not.

Mr. SCOTT.—nearly to get everything, and we appreciate everyone kind of keeping remarks to 5 minutes. This is indeed a very, very growing and urgent issue facing our country, and we appreciate all of your information.

Mr. Michael Taylor.

STATEMENT OF MICHAEL R. TAYLOR, J.D., RESEARCH PROFESSOR, DEPARTMENT OF HEALTH POLICY, GEORGE WASHINGTON UNIVERSITY SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES, WASHINGTON, D.C.

Mr. TAYLOR. Thank you, Mr. Chairman, Ranking Member Lucas, Members of the Committee, I appreciate the chance to testify today.

The Committee's review of the government's food safety system is without question timely. The public is paying close attention,

and food safety reform is quite properly a front-runner issue for this Congress. Government, of course, doesn't make food and government cannot make it safe. But government has an absolutely central role on behalf of consumers in ensuring that food companies do their food safety job in keeping with what science and public expectations tell us is necessary, and what modern techniques show is possible.

Unfortunately, recent illness outbreaks and problems with imported food demonstrate that the government's food safety system has fallen far behind dramatic changes in the global food system, and is simply not equipped to deal with today's food safety challenges.

Mr. Chairman, we need a food safety system that takes a farm-to-table approach to preventing food safety problems, that uses the best available science to understand potential hazards and how to prevent them, and that establishes and enforces science-based food safety standards that hold companies accountable for meeting their prevention duty.

What we have on the other hand is a food safety system that focuses more on reaction than prevention, under-invests in the science and data analysis needed for prevention, and lacks both modern standards and strong enforcement. It is a system that the National Academy of Sciences and the Government Accountability Office have found in numerous studies to be plagued by obsolete laws, inadequate and often poor use of resources, and fragmented organizational structures.

I know from personal experience a lot of talented and committed people at USDA and FDA are working hard on food safety within the existing system, but today's food safety system is fundamentally flawed. Let me give you just a few examples of what I mean, first with respect to the FDA program.

Core elements of FDA's food safety law date back to 1906. It is thus not surprising that the law lacks a mandate for companies to implement modern preventive controls, and it establishes little or no accountability for prevention on the part of the companies or on the part of FDA. FDA's current law takes the same weak, reactive approach to imports that it takes to domestic food. To have any chance of success, the reaction paradigm in current law depends heavily on vigorous FDA inspection and enforcement, yet due to chronic under-funding of its food safety program, FDA is unable to inspect even high-risk domestic plants as much as once a year, or to examine more than about one percent of import shipments. FDA also lacks other basic elements of a modern enforcement toolkit such as traceback and mandatory recall authority.

Finally, FDA's management structure for food safety is fragmented internally, and FDA lacks the management connections and working relationships with the CDC, Centers for Disease Control, which are essential both to better manage major outbreaks and to assemble the data and analysis needed for prevention.

Mr. Chairman, FSIS and USDA have a quite different set of problems stemming primarily from the obsolete mandates in the meat and poultry inspection laws. The NAS and GAO have found, repeatedly, that the mandated carcass-by-carcass visual approach to slaughter inspection and the requirement for daily inspection of

all processing plants without regard to relative risk make poor use of scarce food safety resources. Moreover, FSIS has no authority to address food safety at the point of animal production where many pathogen problems originate. Even within slaughter and processing plants, the authority of FSIS to establish and enforce pathogen reduction standards is under a legal cloud because the inspection laws do not expressly authorize them. FSIS is even precluded from conducting food safety research.

Beyond FDA and FSIS, of course, there are other Federal agencies and literally thousands of state and local agencies working on food safety. They all need to be considered in crafting a comprehensive systems approach to food safety and food safety reform.

Mr. Chairman, I am convinced that unless Congress addresses the problems and gaps all across the nation's food safety system, we will continue to fall short in fulfilling the modern vision of a science and risk-based system that is effective in preventing foodborne illness.

So again, I commend the Committee for taking the time to consider these issues and look forward to your questions.

[The prepared statement of Mr. Taylor follows:]

PREPARED STATEMENT OF MICHAEL R. TAYLOR, J.D., RESEARCH PROFESSOR, DEPARTMENT OF HEALTH POLICY, GEORGE WASHINGTON UNIVERSITY SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES, WASHINGTON, D.C. [1]

Chairman Peterson, Ranking Member Lucas, Members of the Committee, thank you for the opportunity to testify at today's hearing to review the current food safety systems at the Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA).

Introduction

The Committee is right to be reviewing food safety systems at both HHS and USDA, which, primarily through the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS), carry out most of the Federal Government's food safety regulatory activity.

I would note, of course, that the Environmental Protection Agency (EPA) also plays an important role in food safety as the agency charged by Congress with setting tolerances for pesticide residues in food, and many other agencies within HHS and USDA and across the Federal Government perform food safety data collection, research and inspection activities. Moreover, literally thousands of state and local health and agriculture departments and laboratories play critical frontline roles in the nation's food safety system, with primary responsibility lodged at the state and local level for responding to illness outbreaks and regulating the food safety practices of the one million retail food outlets in this country.

My testimony today will focus primarily on FDA and FSIS, but one of my key messages is that we need to understand food safety as a system problem that needs an integrated system solution, and we need a comprehensive food safety reform strategy that takes account of the severe challenges faced by both FDA *and* FSIS, as well as the many other agencies in the system, in carrying out their food safety responsibilities.

FDA and FSIS both have a lot of good people working hard within the existing system, but today's food safety system is fundamentally flawed. As the National Academy of Sciences (NAS) and Government Accountability Office (GAO) have found in numerous studies, the Federal food safety system is plagued by obsolete laws and food safety strategies, inadequate and often poor use of resources, and fragmented organizational structures. Based on these problems, the GAO has placed the Federal Government's food safety program on the list of Federal programs at

[1] 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 and Acting Under Secretary for Food Safety (1994–1996) and as Deputy Commissioner for Policy of the Food and Drug Administration (1991–1994).

high risk of failure, and GAO included food safety among the 13 problems most in need of urgent attention by the new Administration and Congress.

It is thus important that President Obama has already made food safety a high priority for the Administration, as has Secretary Vilsack, and I'm sure food safety reform will be high on the agenda of Governor Sebelius and Dr. Hamburg upon their confirmations by the Senate as Secretary of HHS and Commissioner of FDA.

But, while there is much the food safety agencies can do on their own to improve their programs, transformative and sustainable food safety reform requires strong action by Congress, based on a 21st century vision of what a modern food safety system can and should do.

In my testimony today, I will briefly outline the elements of a modern vision for the nation's food safety system and then analyze the challenges FDA and FSIS face in fulfilling the vision.

Vision

The vision I outline here is rooted in the seminal 1998 NAS report *Ensuring Safe Food From Production to Consumption.* That report and a series of subsequent GAO reports have called for a science- and risk-based food safety system that focuses on preventing food safety problems and that makes efficient use of all available public resources for that purpose. The key functional elements of such a preventive system include:

1. Taking a farm-to-table approach to preventing food safety problems;
2. Using risk analysis to better understand potential hazards, design interventions, and prioritize prevention efforts;
3. Collecting necessary data to support risk analysis, through monitoring of the food supply, foodborne illness surveillance, and food safety research;
4. Harnessing the primary role of food producers, processors, retailers and consumers in preventing food safety problems;
5. Implementing preventive process control, such as HACCP, throughout the food industry;
6. Establishing science-based food safety performance standards;
7. Carrying out a modern inspection program to support the vigorous enforcement of food safety standards;
8. Integrating food safety efforts among Federal, state, and local food safety agencies;
9. Allocating government food safety efforts and resources in relation to risk and opportunities to reduce risk; and
10. Observing sound food safety practices at the final preparation and consumption stage through well-informed commercial food handlers and consumers.

This system-oriented vision for the food safety system is widely embraced. The question for Congress is: what reforms will it take to implement the modern vision of an effective food safety system? My view is that it will take a modern legislative mandate, adequate resources that are better used, and effective leadership and management structures. These are the key ingredients for any successful government program, and all are lacking in the case of food safety. FDA and FSIS simply do not have the tools to be successful.

Gaps in the Food Safety Tool Kit

Modern Legislative Mandate

FDA's basic food safety legislative tools date back to 1938, while the principles governing FSIS slaughter inspection under the meat and poultry inspection laws were adopted in 1906. Today's food safety laws were passed before foodborne pathogens emerged as a central public health concern and as a threat to the well-being of the food industry, and before globalization made the United States as dependent on food imports as it is today. As a result, neither FDA nor FSIS has the modern mandate and legal tools to deal with today's food safety challenges.

Food and Drug Administration

FDA's basic, 1938-vintage statutory tools for dealing with *Salmonella* and other foodborne pathogens and chemical contaminants consist of authority to enter and inspect food factories, warehouses and other establishments; a broad definition of when a contaminant renders food legally "adulterated;" and the ability to seek judicial intervention to remove adulterated food from commerce. With respect to imports, FDA's legal authority is limited to examining shipments at the port of entry and blocking them if FDA inspectors can detect a problem.

These limited tools give FDA some ability to react to problems after they occur, but very limited ability to ensure that food safety problems are prevented in the first place.

In particular, under current law, FDA lacks:

- A legislative mandate and accountability for reducing foodborne illness;
- Authority to hold the operators of all food facilities accountable for implementing modern preventive controls that reduce the risk of foodborne illness;
- An inspection mandate that ensures an adequate frequency of inspection;
- Authority to routinely examine company records to verify that proper food safety procedures have been followed;
- Authority to administratively detain products that have not been produced under proper conditions;
- Authority to require that companies be able to provide immediate traceback information so that major outbreaks can be more promptly contained;
- Authority to order a recall of unsafe products and enforce rigorous implementation of needed recalls;
- Authority to penalize violations of food safety standards other than through cumbersome and time-consuming court proceedings; and
- Authority to hold importers accountable for ensuring that imported food is produced using modern preventive controls and in a manner that meets U.S. standards.

Food Safety and Inspection Service

The core FSIS legislative mandate is to conduct inspection in slaughter houses and in plants that process meat and poultry products. The original 1906 mandate for carcass-by-carcass slaughter inspection was a response to *The Jungle* and Upton Sinclair's documentation of diseased animals, gross insanitary conditions and often intentional commingling of bad meat with good. The visual inspection Congress mandated was effective in addressing those problems, but, as found by the NAS and other expert bodies, this mode of inspection is ineffective in dealing with today's food safety concerns. Pathogenic bacteria are, of course, invisible.

Congress also mandates daily FSIS inspection of all plants that process meat and poultry products, without regard to the nature of the operation, which today may range from the relatively high-risk processing of raw ground meat products all the way to the pizza plant that applies pepperoni slices to a pizza that will be cooked to a very high temperature. In the case of the pepperoni pizza plant, FSIS will already have inspected the slaughter of the animals that provided the meat and the manufacture of the pepperoni at the processing plant.

Slaughter plants and many meat processing plants are among the most sensitive and risk-prone links in the farm-to-table food safety system and deserve substantial government inspection. It is very clear, however, that the current inspection mandate and the resulting mode of inspection at FSIS is obsolete and wastes government resources that could be used more effectively in those plants and elsewhere to prevent foodborne illness.

Despite its obsolete statutory mandate, important changes have occurred in the FSIS program in recent years. Prior to 1994, the official position of the Department of Agriculture was that slaughter houses and plants processing raw meat were not responsible or accountable for pathogen contamination, on the ground that consumers were expected to properly cook the product. We changed that when I was Administrator of FSIS by (1) declaring that *E. coli O157:H7* is an adulterant in raw ground beef, (2) mandating that all slaughter and processing plants implement a modern preventive control system called HACCP (Hazard Analysis and Critical Control Points), and (3) establishing for the first time microbial test requirements and pathogen reduction performance standards.

Since the reforms of the mid-1990s, FSIS and the industries it regulates have made progress in reducing pathogens, but progress has been constrained by the agency's obsolete statutes. On the positive side, minimizing pathogen contamination is now seen as a central part of the FSIS mission, and the professional staff at FSIS has been creative in using the tools they have to pursue pathogen reduction. Reductions in the incidence of contamination have been achieved for some pathogens, such as *Listeria* in deli meats and *Salmonella* in poultry, and many companies in the meat and poultry industry have substantially increased their own pathogen testing and pathogen reduction efforts in response to both FSIS initiatives and market incentives.

On the negative side, an industry legal challenge has put a cloud over the enforceability of the pathogen reduction standards FSIS established in the 1990s, and those

standards have not been updated in the way we originally intended. Thus, FSIS is forced to rely on obsolete benchmarks and indirect means in an attempt to drive pathogen contamination down to levels we know are achievable, when it should be setting and enforcing science-based performance standards to protect consumers. Moreover, because meeting the obsolete statutory inspection mandate consumes nearly all FSIS resources, it has limited capacity to invest in more modern approaches to enforcing every plant's duty to prevent food safety problems through HACCP and other means.

There is room for more food safety progress at FSIS within the current statutory framework, but FSIS is unable to fulfill the vision of a modern, science- and risk-based food safety system because it lacks a modern food safety law. Most importantly, FSIS lacks:

- A legislative mandate and accountability for reducing foodborne illness;
- A mandate and authority to deploy resources efficiently to prevent foodborne illness;
- Authority to address food safety problems at the point of animal production, where many pathogen problems originate;
- A mandate and clear authority to set and enforce science-based pathogen reduction performance standards;
- Authority to order a recall of unsafe products and enforce rigorous implementation of needed recalls; and
- Authority to conduct food safety research.

Adequate Resources That Are Used Efficiently

FDA regulates 80% of the food supply and the vast majority of food imports with a budget of about $650 million. FSIS regulates about 20% of the food supply with a budget of about $1 billion. The primary explanation for this dichotomy is that FDA has no food safety legislative mandate that requires a certain level of funding to fulfill, while FSIS has an inspection mandate that provides a strong anchor for FSIS resources. Slaughter plants cannot operate unless FSIS mans the slaughter lines, and issuance of the FSIS mark of inspection, which processing plants must have to ship food, depends on the daily inspection.

Fulfilling the vision of a modern, science- and risk-based food safety system requires not only an adequate level of resources but the targeting of government food safety efforts and allocation of resources based on risk and the best opportunities to reduce risk. The differences in the current resource situations at FDA and FSIS mean they have distinct resource challenges.

Food and Drug Administration

FDA currently has ample flexibility legally to allocate its resources based on risk. FDA's primary problem is that it has too few resources to allocate. FDA can inspect food facilities on average once every 10 years, and is unable to inspect all high-risk facilities even once per year. Moreover, as documented by the FDA Science Board, a group of independent experts from outside FDA, FDA's science base for food safety has eroded over the years; it has miniscule resources for applied food safety research; and it lacks the modern information systems that are essential to implementation of a science-based and preventive food safety program.

Fortunately, Congress has recognized this funding shortfall at FDA and begun to correct it with increases in the last two budgets, and the Obama Administration has signaled plans for further significant increases. This is good news.

It is essential to remember, however, that FDA will never have enough resources to be successful on food safety as long as it remains in a primarily reactive mode. That is why it is so important that Congress give FDA the mandate and authority to change the food safety paradigm to one that holds all food facilities accountable for implementing modern preventive controls and meeting science-based standards and gives FDA the tools to enforce that duty efficiently and effectively.

Food Safety and Inspection Service

The resource problem at FSIS is less the level of resources and more the inefficient use of those resources, which is driven by the obsolete nature of the inspection mandate. I believe that FSIS needs a strong inspection mandate and that FSIS needs every one of the billion dollars Congress gives it to do its food safety job. But, FSIS needs a modern inspection mandate that is aimed at addressing today's food safety challenges and preventing foodborne illness and that directs and empowers FSIS to better allocate its resources within slaughter and processing plants and outside those plants, in ways most likely to improve food safety.

Effective Leadership and Management Structures

One of the key findings of the 1998 NAS report *Ensuring Safe Food From Production to Consumption* was that the organizationally fragmented nature of the nation's food safety system is an obstacle to fulfilling the vision of a science- and risk-based program that is effective in preventing foodborne illness. With responsibilities spread across numerous Federal agencies and thousands of state and local agencies, it is often unclear which agency is responsible for what, and there is a fundamental lack of clearly lodged responsibility and accountability for mounting an integrated, systems approach to preventing foodborne illness. That is why the NAS recommended unifying all Federal food safety programs under a single, accountable leadership structure.

I believe the creation of a single food safety agency is a worthy long-term goal, but consideration of that possibility should take a back seat to the immediate need and opportunity we have to improve the food safety programs of FDA and FSIS, where they sit today within HHS and USDA. This includes improving the leadership and management structures through which they implement their food safety programs.

Food and Drug Administration

Last week, Trust for America's Health (TFAH) issued a report *Keeping America's Food Safe: A Blueprint for Fixing the Food Safety System at the Department of Health and Human Services.* This report noted the fragmentation of management responsibility for food safety within FDA. Two headquarters units and the FDA field force having major food safety responsibilities but are separately managed, with no official whose full-time job is food safety having management responsibility and accountability for the program's success. In order to implement a new paradigm of risk-based prevention of foodborne illness, FDA, HHS and Congress need to address this management problem.

In addition, as noted in the TFAH report, the Centers for Disease Control and Prevention (CDC) is also a separately managed unit within HHS but plays a central role in investigating and thus helping to contain foodborne illness outbreaks. CDC also must play an even larger role in implementing the new prevention-oriented, risk-based food safety paradigm, as the agency on which the nation relies to compile and analyze information on foodborne illness—information that FDA and the food industry need to design and implement preventive measures. New mechanisms are required to improve management of multi-state outbreaks involving both FDA- and FSIS-regulated products and to ensure that CDC has the resources and accountability to provide the data and analysis on human illness that FDA and FSIS need for prevention.

Food Safety and Inspection Service

FSIS, through the Administrator and Under Secretary for Food Safety has ample full-time leadership for food safety.

The primary structural issue at USDA is that FSIS and the Under Secretary for Food Safety are precluded from conducting food safety research and must rely solely on the Agricultural Research Service (ARS) for the applied intramural research that FSIS needs to do its job. ARS has many fine researchers, and its mission includes meeting the research needs of operating agencies within USDA, such as FSIS, but ARS also has competing priorities, and its food safety research priorities are influenced by factors other than the FSIS program needs. A science-based food safety regulatory program should have the authority to conduct its own applied food safety research, in addition to collaborating with researchers in other agencies and in academia.

Conclusion

In considering food safety reform at FDA and FSIS, it is critical that Congress keep its eye on the big picture and address the needs of these agencies comprehensively. We owe the people working on food safety at FDA and FSIS the legal tools, resource levels and flexibility, and management structures they need to meet today's challenges.

Thank you again, Mr. Chairman, for the opportunity to testify today. I look forward to the Committee's questions.

Mr. BOSWELL [presiding.] Thank you very much. Ms. Tucker-Foreman, please?

STATEMENT OF HON. CAROL L. TUCKER-FOREMAN, DISTINGUISHED FELLOW, THE FOOD POLICY INSTITUTE, CONSUMER FEDERATION OF AMERICA, WASHINGTON, D.C.

Ms. TUCKER-FOREMAN. Thank you. Mr. Chairman, Ranking Member Lucas, and Members of the Committee, thank you for having me here today.

I am Carol Tucker-Foreman. I was Assistant Secretary for Food and Consumer Services at USDA from 1977 to 1981, and in those days had responsibility for meat and poultry inspection, all the food and nutrition service programs, and the grading programs that are now in the agricultural marketing system. I was busy.

No hearing you hold this year will be more important to American consumers and to food processors and to farmers. The continuing series of foodborne illness outbreaks, both imported and domestic food products, doesn't just threaten our health, it threatens the confidence that Americans have in our government food safety system and in the industry.

The Government Accountability Office has warned that food safety programs are at a high risk of failure and urged President Obama to take steps to act quickly on them. In 2007, data from the Centers for Disease Control showed just how big the problem is. We are far from meeting the objectives of Healthy People 2010. There has been no reduction in *E. coli* poisoning since the agency began tracking food. *Salmonella* illnesses are double the national objective. *Listeria* was as high in 2007 as it was in 2004. The Food and Drug Administration, sapped of funds and leadership and saddled with a law that gives no mandate to prevent illness, has been unable to contain these illnesses that have hit people in your states and districts.

Just *Salmonella saintpaul* from imported peppers hit people in 43 states including 559 Texans, 120 people in Illinois, 42 in Georgia, and 59 in Arizona. The fresh sprout outbreak that occurred earlier this year, earlier last month, 27 Iowans, five Kansans, 84 Nebraskans, and five South Dakotans were among those people who got ill. So these are illnesses that hit all the way across the country.

The medical costs of foodborne illness are staggering. One study set the annual total cost of foodborne illness in 2006, including medical care and lost productivity and wages, at over $1 trillion, $1.4 trillion in 1 year.

Obviously, you could tell from the last panel these outbreaks hit businesses and they hit farmers as well. The ERS reported that spinach shipments dropped 17 percent and green onion shipments dropped ten percent after those products were implicated in *E. coli* outbreaks in 2006.

I urge you, and my organization urges you, to act quickly to direct the FDA to concentrate on preventing foodborne illness and give it the power and the funding to do so. We also believe that it would be useful to give food safety a separate organization within HHS.

I think that the Congress can take a look at FSIS to see how important that separate organizational structure can be. Since 1994, FSIS has come out of the dark ages. Unlike FDA, the FSIS system has focused on preventing illness. For imported products, there is

a strict equivalence system. Inspectors are in the plant every day examining product to ensure it is safe. Congress has acted to give FSIS an adequate leadership structure, including the position of the Under Secretary for Food Safety, the highest ranking food safety official in the government .

The agency, as Mike Taylor pointed out, is burdened by a seriously outmoded statute and by inadequate money to fulfill its obligation to have inspectors in the plant every day, and it doesn't have the staff of statisticians and scientists as it should have.

However, I have come to think of FSIS as the Rodney Dangerfield of food safety. It gets no respect despite the fact that it has made major strides in the last 15 years to improve its food safety efforts. Taking food safety and putting it in a separate public health agency in USDA so that it is separated from marketing, and separated from the conflict of interest that arises when it has to compete with production agriculture issues has been very, very important.

Now, if you would just modernize the Meat and Poultry Inspection Acts to let them follow through on the scientific basis that Mr. Taylor and Dr. Murano established, I think you would do the American people a great service. Thank you.

[The prepared statement of Ms. Tucker-Foreman follows:]

PREPARED STATEMENT OF HON. CAROL L. TUCKER-FOREMAN, DISTINGUISHED FELLOW, THE FOOD POLICY INSTITUTE, CONSUMER FEDERATION OF AMERICA, WASHINGTON, D.C.

Good morning Chairman Peterson, Ranking Member Lucas and Members of the Committee. My name is Carol Tucker-Foreman. I am Distinguished Fellow in the Food Policy Institute at Consumer Federation of America. CFA is a nonprofit association of over 300 local, state and national organizations, representing a combined membership of over 50 million American consumers. Since 1968 we have conducted research, provided educational materials and engaged in advocacy on behalf of consumers on a range of issues including banking and financial services, food and agriculture, and product safety. Our positions and priorities are set by vote of representatives of our member groups.

From 1977–1981 I served as Assistant Secretary of Agriculture. My responsibilities included oversight of the nation's meat, poultry and egg inspection and food assistance programs. In 1986 I founded the Safe Food Coalition which includes foodborne illness victims, consumer and public health organizations and a trade union to seek improvements in U.S. Government food safety programs, especially meat and poultry inspection. I am a member of the Food and Drug Administration Food Advisory Committee, the National Advisory Committee on Meat and Poultry Inspection and USDA's Advisory Committee on Agricultural Biotechnology.

No hearing you hold this year will be more important to American consumers, to the food industry, or to the people who produce our food. Americans are acutely aware of the crisis in our food safety system. We have experienced recurring outbreaks over the past few years, including a new one involving pistachio nuts this week.

Consumers are not the only ones who fear our food safety system is failing. In January 2007, the Government Accountability Office declared the Federal food safety programs at "high risk" of failure. In November 2008, the GAO named food safety as one of 13 topics most in need of urgent action by the new Administration and the new Congress.

Each spring the Centers of Disease Control and Prevention (CDC) reports on levels of foodborne illness. The April 2007 report was sobering. The agency announced that there has been almost no reduction in foodborne illness in recent years. In 2007, the *Salmonella* illness rate was more than double the national goal. There has been no real decline in the rate of *E. coli* illness since the FoodNet tracking began. There has been no decline in *Campylobacter* illnesses since 2002 and the *Listeria*

rate was as high in 2007 as it was in 2004.[1] Unless something changes quickly and radically, the nation will not meet the *Healthy People 2010* national objectives for reducing foodborne illness.

At a time when everyone is feeling the pinch of severe recession, the economic costs of foodborne illness continue to rise. Dr. Tanya Roberts, formerly of USDA's Economic Research Service, estimates that illnesses caused by all foodborne pathogens cost the nation $1.4 trillion each year in medical expenses, lost productivity and wages.[2]

Numbers as large as these have a certain unreality about them. They may seem unconnected to what goes on in our daily lives. It is important to remember the personal suffering and loss that are involved but not factored into the trillion dollar loss. There is no calculation for physical suffering or the pain when a family loses a young child or beloved grandparent to a foodborne disease.

I urge you to remember that we are talking about individual lives. Over the past 5 years, thousands of people have, literally, been poisoned by common, everyday foods that we serve at the family dinner table—spinach, lettuce, tomatoes, peppers and peanut products.

In addition, we have been threatened by high levels of drug residues and toxic chemicals in fish and dairy products imported from China.

The largest foodborne disease outbreak was the most recent. Almost 700 people got sick and nine deaths have been tied to consumption of a variety of foods that contained peanut products contaminated with *Salmonella typhimurium.* Starting early this year, 2,100 products from more than 200 companies were recalled.

This was the second major *Salmonella* contamination, outbreak and recall of peanut butter products in 2 years. Previously, FDA had viewed peanut butter and related products as "low-risk" foods, not particularly susceptible to contamination. That illusion should have ended with the outbreak of *Salmonella* illnesses traced to peanut products produced by Con-Agra at a plant a short distance away from the one involved in the most recent outbreak. However, FDA made no substantive changes in order to effectively prevent another peanut related outbreak.

That next outbreak wasn't long in coming. Between April and June 2008, more than 1,300 people in 43 states, the District of Columbia and Canada were infected by *Salmonella saintpaul,* an unusual strain of the bacterium. The outbreak, originally thought to have been caused by tomatoes, was ultimately traced to Serrano and jalapeño peppers imported from Mexico.

Foodborne illness is not something that happens just to other people. Citizens of 46 states were hit by the Peanut Corporation of America outbreak. The victims included 100 Ohioans; 76 Californians; 43 Minnesotans. The 2008 *Salmonella saintpaul* outbreak traced to contaminated Serrano and jalapeño peppers hit 559 Texans, 120 people in Illinois, 42 in Georgia, 59 in Arizona. This month 84 Nebraskans, 27 Iowans, and five Kansans and South Dakotans were among the victims of a *Salmonella saintpaul* outbreak traced to eating contaminated fresh sprouts.

These people are your friends, neighbors and constituents. They and all the rest of us need your help and your leadership to rewrite the archaic laws and organizational structure that govern our food safety system.

The outbreaks I've discussed were the result of poor sanitation or mishandling at some point in the food chain. None resulted from consumer mishandling, although a great deal of foodborne illness can be traced to consumers' failure to handle foods carefully.

Thankfully, Americans have not been subjected to illnesses caused by intentional efforts to poison our food. We cannot assume, however, that that will never happen. Former Secretary of HHS Tommy Thompson, as he left office, noted that we are unprepared to address attacks on our food supply and urged that the nation begin to address this.

The continuing series of foodborne illness outbreaks have seriously shaken consumer confidence in the safety of our food supply.

- After the Peanut Corporation of America outbreak, the University of Minnesota's Food Industry Center reported that only 22.5% of consumers were confident the food supply is safer today than it was a year ago.[3]

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[1] Centers for Disease Control and Prevention, "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food—10 States, 2007." MMWR 57(14): 366–370, April 11, 2008.

[2] Roberts T, "Estimates of the Societal Costs of U.S. Food-Borne Illness." *American Journal of Agricultural Economics,* Vol. 89, Issue 5, pp. 1183–1188, December 2007.

[3] *Consumer Confidence in Food Safety Plunges in Wake of Peanut Butter Contamination, University of MN Study Finds,* UMN NEWS, Feb. 23, 2009).

- A Consumers Union study conducted last November, found that 48 percent of those polled said their confidence in the food supply had declined.[4]
- Last spring, the United Fresh Produce Association conducted a survey of consumer attitudes toward produce safety. In April 46% of consumers were concerned about produce safety. Four months later, the tomato/pepper *Salmonella saintpaul* outbreak had occurred and the number of people concerned about produce safety had risen substantially. 54% were concerned about produce safety and 56% were concerned about salad mix.

That lack of confidence is bad for the food business and for food producers. The CEO of Kellogg's told the House Energy & Commerce Committee that the PCA recall cost the company $65–$70 million.[5] Although no major brands of peanut butter sold at retail were involved in the PCA outbreak, sales of those products plunged after the outbreak became known.

Foodborne illness outbreaks are also bad for farmers who grow the crops implicated. Florida tomato farmers were devastated by the connection of their product to the *Salmonella saintpaul* outbreak that came at the height of their growing season. Spinach and lettuce farmers experienced a drop in demand after their products were implicated in outbreaks. USDA recently announced that farmers will likely cut their production of peanuts by about 27 percent this year as a result of smaller contracts from buyers.[6] It is true that these markets often come back but the lost sales and lost income are not recoverable.

We can expect that outbreaks like these will continue, threatening the health of consumers and the businesses of food processors and farmers until Congress acts to address the archaic laws, confused organizational structure and under-funded food safety system.

The Source of the Problem

The U.S. food safety system is broken. The Government Accountability Office (GAO) has identified 15 agencies involved in administering 30 different Federal laws that touch on food safety.

The two agencies with primary responsibility for protecting our food are the Food Safety and Inspection Service (FSIS), located in the Department of Agriculture (USDA) and the Food and Drug Administration (FDA) located in the Department of Health and Human Services (HHS). The primary laws governing food safety were written over 100 years ago.[7] The most recent major food amendments to the Food Drug and Cosmetic Act were passed 70 years ago. The last rewrite of the Meat Inspection Act was over 50 years ago. The world we live in and the way we produce, process and consume food have all changed radically but the laws remain the same.

We Need A 21st Century Food Safety System

Consumer Federation of America and other consumer and public health organizations have called on Congress and the President for over 20 years to undertake a comprehensive revision and modernization of food safety laws and to combine all food safety activities in an independent food safety agency.

Both the GAO and a number of expert committees have examined the problems with the food safety system. The GAO has produced a number of studies, beginning in the mid-1990s, documenting the pressing need to modernize food safety laws and organization.[8]

In 1998, the National Academy of Sciences recommended that Congress modernize food safety laws and overhaul the Federal Government's food safety structure to meet current needs.[9] My colleague Mike Taylor served on that committee and has

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[4] Food-Labeling Poll 2008, *Consumer Reports* National Research Center, NRC #2008. 18, Nov. 11, 2008.

[5] Statement of David Mackay, President & CEO, Kellogg Company, before the House Committee on Oversight and Investigations, "The *Salmonella* Outbreak: The Role of Industry in Protecting the Nation's Food Supply." U.S. House of Representatives, March 19, 2009.

[6] Rampton R., "U.S. peanut plantings to drop 27 percent after peanut scare." *Reuters*, March 31, 2009.

[7] The primary legal authorities for the FDA are the Federal Food Drug and Cosmetic Act, as amended (21 U.S.C. 301 *et seq.*); the Public Health Service Act, as amended (42 U.S.C., *et seq.*) and the Egg Products Inspection Act, as amended (21 U.S.C., 1031 *et seq.*) Governing authorities for FSIS are the Federal Meat Inspection Act of 1906, as amended (21 U.S.C. 601 *et seq.*) the Poultry Products Inspection Act of 1957, as amended (21 U.S.C. 451 *et seq.* and the Egg Products Inspection Act, as amended (21 U.S.C. 1031 *et seq.*).

[8] Numerous reports available at U.S. Government Accountability Office website, *http://gao.gov/*.

[9] Institute of Medicine, National Research Council *Ensuring Safe Food from Production to Consumption,* 1998.

taken a lead role in updating some of its recommendations. In 2003 another NAS committee recommended that Congress give the agencies the authority to set and enforce microbiological criteria.[10]

Starting in the 1990s, Senator Richard Durbin and Representatives Rosa DeLauro, Frank Pallone and John Dingell introduced bills that gave FDA enhanced authority to prevent foodborne illness. Senator Durbin and Representative DeLauro also introduced legislation to create an independent single food safety agency.

In the 111th Congress, nearly a dozen bills have been introduced so far, including H.R. 1332, The Safe FEAST Act sponsored by Rep. Costa and several Members of this Committee. All the bills embrace at least some of the elements identified by the NAS and GAO as necessary for securing the safety of both domestic and imported foods.

Some key elements of what is required for an effective modern food safety system appear in the recommendations of almost all of the outside panels and most are reflected to some degree in all the bills introduced in Congress this year.

Frequently Noted Elements of An Adequate Food Safety System

1. Create a system that addresses risks of foodborne illness that may arise anywhere along the food chain, from farm to fork and into the consumer's mouth. Microbiological pathogens can enter food at any point.
2. Make prevention the focal point of the new system.
3. Require food companies to develop and implement controls to assure that the food they sell is safe.
4. Require food safety agencies to establish and enforce microbial performance standards that will reduce pathogens to a minimum and assure an acceptable level of public health protection.
5. Protect the integrity of the system and the food supply by providing for comprehensive enforcement. This should include: regular oversight (inspection) conducted by public officials and based on the risk presented by the product; require sampling and testing for pathogens and reporting; assure food safety officials have access to company food safety records; and authorize agencies to require recalls of contaminated food.
6. Ensure that the food we import is as safe as that produced and processed here.
7. Provide for research capacity to develop the best means to address current and emerging pathogens.
8. Assure adequate financial and staff resources in an institutional setting that provides the leadership, visibility, and status needed to support the program.

Comparison of How Existing Food Safety Authorities and Organizations Address the Elements of a Modern Food Safety Program

As a starting point for thinking about what kind of statutory changes may be necessary to build the kind of system envisioned in these elements, it is useful to examine the basic legal mandates of the two agencies and compare how they address the elements under current law.

The Food and Drug Administration has responsibility for ensuring that all domestic and imported foods except meat, poultry, processed eggs and, since passage of the 2008 Farm Bill, farm-raised catfish, are safe, nutritious, wholesome and accurately labeled. Domestically, FDA has responsibility for some 44,000 food processors, 114,000 food retailers and 935,000 restaurants.

The Food Safety and Inspection Service is responsible for the safety, wholesomeness and proper labeling of most domestic and imported meat and poultry and their products sold for human consumption. It regulates over 6,000 domestic meat, poultry plants and egg plants.

1. System Authority Should Extend From Farm to Fork

FDA—has some ability to regulate on-farm activities. However, this ability is limited and according to the Congressional Research Service, FDA's general approach has been not to impose mandatory on-farm safety standards or inspections of agricultural facilities but to rely on farmers' adoption of good agricultural practices to

[10] Institute of Medicine, National Research Council *Scientific Criteria to Ensure Safe Food,* 2003.

reduce hazards prior to harvest. FDA issues good agricultural practices as guidance, not regulations; they are advisory and not legally enforceable.[11]

FSIS—authority begins at the door of the slaughterhouse. Has no on-farm authority.

2. System Designed to Prevent Contamination and Foodborne Illness

Prevention is a core public health value. It is always better to prevent a problem than try to resolve it. The language in the FFDCA and the FMIA and PPIA is quite similar but the results are quite different.

FDA—system is reactive. The FFDCA contains no specific direction to the agency to prevent food contamination or foodborne illness. FDA's primary food safety authority is the power to seize adulterated or misbranded food. The burden is on FDA to prove a product is adulterated or mislabeled before it can act. To justify a product seizure FDA must have laboratory tests to show that the product is adulterated or misbranded before it acts. As a result, FDA often doesn't act at all until there are confirmed reports of illness or death.

FSIS—system is preventive. Meat and poultry processors must, in effect, prove to a USDA inspector that the plant's product is safe and accurately labeled. Products can't be entered into commerce until a USDA inspector applies the "mark of inspection." This means that trained Federal inspectors paid by public funds must take an affirmative action before food products can leave the plant.

3. System Requires Companies to Take Responsibility for Safety of Their Products

FDA—The FFDCA does not give FDA specific authority to require companies to establish or follow preventive controls. FDA's primary method of operation is to rely on each company's self-interest in producing safe products, and to work with the industry to encourage improved production practices.[12] FDA has required HACCP systems in seafood and fresh juices. A HACCP plan for shell eggs has been in process for several years.

Virtually all large processors have some form of process control, many with higher standards than the government would require. Majority of other facilities do not have formal process controls. Very few farms have adopted formal systems for avoiding food safety problems.

FDA's failure to require food companies to institute preventive process controls was partially responsible for the Peanut Corporation of America's ability to hide their activity. Since PCA wasn't required to show the FDA or Georgia State inspectors their plans, inspection was just a quick visual review of what the plant looked like at a given moment.

FSIS—Since 2000, FSIS has required all meat and poultry companies to adopt HACCP systems and sanitary operating plans. A dozen years into HACCP, many companies still have not identified any critical control points or adopted meaningful HACCP programs. Lack of specific statutory authorization for HACCP and sanitation procedures prevents full benefits of HACCP. The agency cannot permanently withdraw inspection from a plant that fails to follow its HACCP and sanitation plans.

One of the most glaring weaknesses of the FSIS system is that, unable to withdraw inspection from plants that fail to adopt effective HACCP plans, FSIS then tries to "help" them comply, contrary to the notion that this is the "company's" plan. This requires additional agency resources to assist a company that is unable or unwilling to develop an effective HACCP plan. It also means that FSIS is caught between the old inspection system in which it often was the only quality control in the plant, and the new system where companies are supposed to take ownership of their food safety plans.

4. System Requires Agencies to Establish and Enforce Pathogen Reduction Performance Standards

FDA—has no specific mandate or authority to establish pathogen reduction performance standards that companies must meet. FDA has adopted some performance criteria and standards. Government needs to establish a minimum acceptable level of public health protection. If food companies know what the standard is most will immediately set their own systems to meet or exceed the standard.

FSIS—has no specific authority to establish or apply performance standards, nor to withdraw inspection from companies that fail to meet them. But agency has instituted standards for generic *E. coli* and *Salmonella* on animal and poultry carcasses.

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[11] Congressional Research Service, RS22600, *The Federal Food Safety System: A Primer,* Geoffrey S. Becker, March 3, 2009.

[12] *Ibid.*

Lack of specific authority to set and enforce these standards limits effectiveness. Enforcement of performance standards is a key public health element but courts have limited FSIS's enforcement. The agency does have authority to set a zero tolerance standard for *E. coli O157:H7* in ground beef and trim, and zero tolerance for *Listeria* and *Salmonella* in ready-to-eat products.

5. System Provides for Adequate Enforcement, applied according to the risk presented by the product. Must include regular oversight (inspection) by public officials to assure companies are complying with standards; microbial testing and reporting; access to records; mandatory recall. Food safety system integrity depends upon adequate enforcement authority.

FDA—

Inspection—Consistent with its reactive approach to food safety, FDA makes little investment in preventive inspections to assure a company is complying with the law. FDA contracts with state governments to conduct inspection of some facilities and works with states to set safety standards for food establishments.[13] Common practice is to rely on non-FDA sources for information that a particular facility may be in need of additional inspection or to act after having cause to believe a facility is connected to an outbreak of foodborne illness.[14]

Risk-Based Inspection—Current effort to devise mechanism to assign inspector based on risk. Work plan and budget say FDA inspects "high-risk" facilities more often. Many plants are inspected only once in a decade. FDA has no organized system for determining level of risk and applying resources accordingly but has begun analysis of relative risk, working with outside groups, including the Institute of Food Technologists.

Government Access to Company Records—FDA does not have authority to require access to plant records; does not require companies to keep records and provide FDA information on source of material or destination of products.

Traceback—no authority or capacity to track products back to source.

Recall—no authority to require recall. Recalls are voluntary but FDA, with a court order, can seize a product that is adulterated.

FSIS—

Inspection—law requires continuous inspection in slaughter and processing of animals and birds. For animals, FSIS must inspect before slaughter; individual postmortem carcass inspection for red meat animals and poultry. At least daily visit to every processing plant.

Risk-Based Inspection—Inspection resources not applied according to risk. Agency has been trying to devise a risk-ranking system but has been unable to produce one that meets scientific criteria. Statutory requirement to inspect every poultry carcass is not risk-based, but FSIS has no alternative given law and lack of data to support another system.

Consumer groups oppose attempts to alter system without rewriting underlying law to include better enforcement tools and more science. Requirement to visit every processing plant daily is also not risk-based but agency has failed to offer a valid alternative or to persuade Congress to change the law. FSIS has trouble meeting responsibility to visit every processing plant at least daily. In addition, many high risk meat grinding operations are visited only once daily when a more intensive regime would offer more protection for consumers. Plants that are not high risk often have same level of inspection.

Government Access to Company Records—most records must be made available on request of inspector.

Traceback—each inspected plant is identified by a plant number which follows product making it easier to identify products and recall them. Products packaged for final sale in a USDA inspected plant will have the plant number on the final package so that consumers can identify a recalled product. FSIS has no authority to track product back to the farm of origin. No way to determine if some ranches and feed lots have cattle that consistently turns up with high levels of *E. coli* contamination.

Recall—no authority to require plant to recall products. Recalls are voluntary on part of plant.

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[13] Much of the information on the basic information about FDA and FSIS authorities, jurisdiction and funding is from Congressional Research Service paper, 7–5700. *The Federal Food Safety System: A Primer,* by Geoffrey S. Becker, March 3, 2009.

[14] Food Safety Primer.

6. System Ensures Safety of Imported Foods

FDA—countries wishing to export to the U.S. may do so after filing registration forms with the agency as required by the Bioterrorism Act.

As of Jan. 2009, 367,600 facilities in 180 foreign countries were registered to export to the U.S.[15] The exporting country is not required to demonstrate its food safety system is equivalent to the U.S. system.

FDA inspects less than one percent of all the food that enters the country. Imported foods are responsible for a large proportion of foodborne illnesses that arise from FDA-regulated products. In 2006 the FDA stated, "to the best of our knowledge, approximately half of the foods that have been associated with foodborne illness have been imported."[16]

In June 2007, FDA detained imports of farm-raised seafood from China because of the possibility they were contaminated with unapproved drug residues. In late 2008, FDA held up further imports of dairy products from China until importers could prove they were not contaminated with melamine, a toxic chemical intentionally added to milk to increased measured protein levels. The same chemical was implicated in the recall of large amounts of pet food and in infant formula in China.

FSIS—no country can export meat or poultry to the U.S. until FSIS has certified that the exporting country has an inspection system that is equivalent to the U.S. In addition, each foreign plant that wants to export to the U.S. must be found to be operating in a manner that is equivalent to that required of U.S. plants.

FSIS inspectors are present at all points of import into the country to carry out statistical sampling and testing to assure the safety of imported products. The agency inspects approximately 10% of all meat and poultry imports at port.

7. System Provides for Research Capacity

FDA—little research capacity.

FSIS—USDA does most of the government's food safety research but it is done at ARS and FSIS has virtually no influence over focus of efforts.

8. System Has Appropriate Organizational Structure and Accountability

FDA—new paper from George Washington University's School of Public Health reports that no single official at FDA has a full time job directing food safety as well as budget and line authority over all the food elements of the FDA.[17] Within FDA, food safety is dispersed among three organizational units, the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine and the Office of Regulatory Affairs. Directors of each unit report to the Commissioner but coordination responsibility rests with Associate Commissioner for Foods who is housed in the Office of FDA's Deputy Commissioner for Operations. The Associate Commissioner for Foods, sometimes called the FDA's food "czar" has no line authority and no control over the food safety budget. The FDA Commissioner reports directly to the Secretary of HHS but historically the Commissioner has given little time to oversight of food safety functions.

FSIS—The USDA Reorganization Act of 1994 removed food safety activities from USDA marketing and animal health activities and created a separate entity to protect public health program from undue influence.

The Act also created the Under Secretary for Food Safety, the highest ranking food safety official in government and gave this Level III official direct and specific responsibility for oversight and administration of the USDA's meat, poultry and egg inspection programs. Act requires that Under Secretary be someone qualified by training or experience to address food safety issues. Under Secretary is under direction of the USDA Secretary and therefore not entirely free from influence driven by agricultural interests. However, both Democratic and Republican Administrations have, since 1994, sought to appoint individuals with food safety or public health credentials. Industry continues to apply pressure to appoint someone with ties to the industry.

System Has Adequate Budget and Staff Resources

FDA—the FDA's food budget for FY 2009 is $648.7 million ($210 million for the Center for Food Safety and $438.2 million for food related activities of the Office of Regulatory Affairs). In FY 2008, there were 2,800 food related staff, 1,900 in the

[15] *http://www.cfsan.fda.gov/~furls/ffregsum.html,* Accessed March 30, 2009.

[16] FDA Office of Regulatory Affairs. "FY 2007 ORA Field Workplan," October 1, 2006, p. 03–20.

[17] Taylor, Michael R. & David, Stephanie, 2009 *Unifying and Elevating Food Safety Leadership at HHS,* George Washington University Medical Center, School of Public and Health Services.

field and 900 headquarters staff. FDA inspection (compliance) staff have science education and training.

For most of the last 25 years, until recently, the FDA budget has been either reduced or flat. The food portion of the FDA budget suffered during part of that period because money was directed to the drug program in order to assure that appropriated funds were sufficient to keep drug user fees in place.

FSIS—2008 budget of $930 million in appropriated funds in FY 2008, and $140 million in fees paid by companies that want to operate additional shifts beyond those covered by Federal inspection. FSIS has 9,400 staff. Approximately 8,000 of the staff are present in meat and poultry plants on a daily basis. The FSIS staff includes 1,000 doctors of veterinary medicine. Since HACCP, FSIS has created a compliance staff with 300 Enforcement, Investigations and Analysis Officers (EIAO) and program investigators in addition to the inspection staff. A risk-based system will require FSIS to upgrade GS level and training of inspectors to handle new tasks.

Conclusion

There has been extensive discussion of reorganizing inspection functions. CFA supports creation of a single independent food safety agency that would combine all Federal food safety functions.

As an interim step we support the approach Representative DeLauro has taken in H.R. 875 to divide FDA into a Federal Drug Administration and a Food Safety Administration within HHS, providing separate budget authority and leadership for food.

CFA does not support moving meat and poultry inspection to the Department of HHS. Addressing the very serious problems that now plague FDA's food safety programs and possibly creating a new Food Safety Administration within HHS will be a major undertaking, not leaving resources for integrating a much larger program.

In addition, as the FDA has slipped into dysfunction, the food safety functions of the USDA have made some progress toward a more modern and science-based program. Little more can be done without rewriting the authorizing statutes. We urge this Committee, in cooperation with the Obama Administration, to take the lead in developing new authority embracing the elements discussed here.

Occasionally, it is proposed that FDA's food safety functions be moved to a new Department of Food and Agriculture. I'm not sure how Consumer Federation of America would feel about that. However, with or without food safety functions, creating a Department of Food and Agriculture that acknowledges and embraces all the people of the U.S. as its constituency is an idea whose time I hope will come.

The CHAIRMAN [presiding.] Thank you very much. I want to thank all of the witnesses for being here and putting up with us with all this stuff going on. We didn't know the budget was going to be up today when we set this up.

Dr. Murano and Mr. Taylor, the industry values the USDA mark of inspection. Can you tell me what the USDA mark of inspection means and does FDA provide an equivalent to the USDA mark, and if so, what level of inspection backs up the inspection mark?

Dr. MURANO. Let me address that a little bit, and Mr. Taylor can follow up as well, obviously. Mr. Chairman, the mark of inspection at its most basic level means that there has been an inspector who has actually been at the plant who has looked at that carcass. But it is not only that, it is also backed up by an entire system that was developed and implemented in the early 1990s as a result of some foodborne illness outbreaks. It is called HACCP, Hazard Analysis Critical Control Points, which the USDA requires every meat and poultry plant to have. And that program, that system, involves microbial testing, involves monitoring every step that is critical to control the hazards that may be present in that product. So it is a whole array of different things that are involved in ensuring to the greatest extent that one can that that product has been inspected, by not only an actual inspector being there, but an inspector that is looking at the entire process; not only at the carcasses what you can see with the naked eye, which is insufficient clearly

because microorganisms are not seen with the naked eye. And this comes out of these laws that are pretty old, hearkening back to 1906, and so forth, that require that there be carcass-by-carcass inspection. And that is why there has to be an inspector in every plant every day from the USDA perspective.

FDA is under no such laws, and therefore plants sometimes don't see an FDA inspector for a year or longer. And so it is a huge difference. You do not see a mark of inspection by FDA that is in the same vein, and I don't know that the public realizes that, the robustness and the rigor with which meat and poultry is inspected in this country. It is not perfect because, obviously, we continue to have outbreaks of meat and poultry products, but I would agree with Ms. Tucker-Foreman that there has been tremendous improvements at USDA. It is the Rodney Dangerfield. I will tell you that when I was at USDA as Under Secretary, one of the things that bothered me a lot is that there was not the same expectation of product that was inspected by FDA in terms of if there was an outbreak, FDA would put out the Food Safety Alerts and things like that. And I always said, boy, if something happened at USDA with a USDA product, if all we did was put out a Food Safety Alert it would be chaotic. We were expected to stop the outbreak. We were expected, rightfully so, to find out the source of the outbreak, to get at who and what caused the outbreak. And that fundamental difference between the two agencies is really rooted in regulations, the lack of robustness in the regulations that FDA operates under, but also, frankly, a culture, a culture of inspection that exists at USDA borne out of decades, and that culture is really not at FDA from my point of view.

The CHAIRMAN. Mr. Taylor?

Mr. TAYLOR. Since your having served at both USDA and FDA, I may turn out to be the designated FDA defender at the hearing here today, but I do want to answer your question about the mark of inspection and Dr. Murano's reference to the history of it is germane. The concept of carcass-by-carcass inspection and the issuance of a mark came about in the aftermath, as you know, of *The Jungle*, 1906, when gross sanitation conditions, diseased animals were common in the food supply. And the judgment, correctly, at the time was that a carcass-by-carcass visual inspection could solve that problem, could eliminate those animals from the food supply. And the mark of inspection and the inspection program that is in place stems from the fact that you have done a good job of dealing with those visible problems.

The reason why the National Academy of Sciences and GAO have criticized that approach to inspection and said that it is not really contributing significantly to today's food safety problems is because today we are concerned about invisible, microbial pathogens, and the visual inspection program simply doesn't address those. I referred to the lack of standards in my testimony. One of the limitations in terms of what that mark stands for is that because there are not enforceable standards for microbial pathogens that make people sick, there is very wide variability across slaughter plants with respect to control of pathogens. Many have made enormous progress, and they are doing a terrific job, others less so.

But the mark of inspection doesn't reflect in any way directly the degree of control over the pathogens that make people sick.

The CHAIRMAN. Thank you. Carol, you want to comment on this, too? And my time is out, but we appreciate you being with us and the work that we did together during the farm bill, we very much appreciated that.

Ms. TUCKER-FOREMAN. Thank you. I thought it came out very well. Now, if we can just get the regulations out.

I am going to agree just a little bit with both of the other panelists. The mark of inspection doesn't represent today what it did in the beginning, but it is still important. It does say to the American people a government official who has pledged to protect public health has been present and looked at this product. And it is not just looking anymore. Under HACCP, we have developed and Mr. Taylor started it, an intensive system of microbial testing to determine that meat and poultry are not adulterated. There were performance standards that were established when he was at USDA, and it is an important point to make that USDA continues to have a number of recalls every year. I just took a quick look at the recalls for 2008 which was a pretty good year for USDA; over half of the recalls that occurred at USDA occurred because USDA inspectors tested the product, found that it had *E. coli* or in the case of ready-to-eat products, *Salmonella* or *Campylobacter* or *Listeria* and recalled the products before they got into retail commerce. This is prevention, and FDA because it is not oriented to prevention, the product is out there and it has been eaten and people get sick and then someone says, uh-oh, I guess we better call the FDA. That is too late in the system.

Now, Consumer Federation and other consumer groups and the National Academy of Sciences have urged that Congress give USDA and FDA specific authority to enforce those microbial standards. Right now if a plant does not comply, the only thing USDA can do is go in and say, Hey guys, you didn't comply. And if they still don't comply, ultimately they send in an assessment team, and the assessment team sits there until the company finally does it right. That is not a very good use of public resources. There ought to be the ability to say you failed the test, there is the penalty, fix the problem and we will go on. Thank you.

The CHAIRMAN. Thank you, and all of the panel. I just want to make the point which has kind of been made but to make it clear that you know, one of the problems here is that USDA actually has a law, and FDA doesn't, basically. I mean, that is what it boils down to. I mean, they don't have to do this stuff. And, like in the case of the previous panel, they don't have to go in and have an equivalency on the plants and so forth.

You know, I still don't quite understand why they don't, you know. If it is pressure from the industry, that they don't want this stuff inspected overseas or exactly what is going on there, but, we are again part of the problem, the Congress. We haven't given these agencies the tools to do what they should be doing. And hopefully out of this process that we are starting here, we can be helpful along with the other committees to get these people the tools and the resources to do what has to be done. That is what we intend to do.

So I recognize the gentleman from Oklahoma, the Ranking Member, for his questions.

Mr. LUCAS. Thank you, Mr. Chairman. Dr. Murano, some advocates have proposed the creation of a single food safety agency. Let us discuss for a moment the nature of risk profiles for different food products. Do they lend themselves to a one-size-fits-all model of food inspection?

Dr. MURANO. Well, the simple answer is no, and it is because it is tied to risk. Some products are very highly processed, meaning that they have steps in the preparation of those products that kills microbial contaminants, for example. So those products are relatively safe. You know, nothing is absolutely safe unless it is sterilized completely which a canned food product is.

So there is a degree of risk. The fresher products, the products that are not processed are more likely to be contaminated, the highly processed products, less likely to be contaminated after processing. And so there is a whole family of products that fall into many of these categories. One of the things that needs to happen is for there to be a recognition that the products that are more risky need to be subjected to more inspection, more monitoring, more testing. The products that are less risky, there can be less of that oversight.

I will say that from my perspective on the issue of single food safety agency or what should we do, if we just kind of take all those words out of the discussion and just look at what makes sense, what does common sense dictate. When I worked at USDA and now of course I have been away for even longer than I served as Under Secretary, I certainly got an opportunity to see what USDA does, got an opportunity to see what my colleagues at FDA were doing and the differences in the laws and so forth, as the Chairman just mentioned. And it is clear to me that at FSIS, because of the laws, there has been as I said earlier a culture of inspection, an expectation that things would be done a certain way which I don't believe is as prevalent at FDA. Plus FDA, frankly, has jurisdiction over medical devices and drugs and other kinds of products. So they are spread pretty thin at FDA.

So I would offer the suggestion that maybe what we need to do is play to these agencies' strengths. In other words, if FSIS as I believe is where the strength is in terms of food inspection, as one of the gentlemen from the last panel talked about, he even uses USDA personnel as third-party auditors of his fruit and vegetable operation. Perhaps all food inspection, not just meat and poultry, needs to reside at FSIS because these people have that culture over decades of being able to do that, and then FDA has some other activities related to food.

One thing the Chairman mentioned or maybe somebody else did, I guess it was Mike Taylor, that FSIS does not have the ability to conduct research, and that is something that frankly, as a scientist, troubled me when I was at USDA. There are research agencies within USDA, and we tried to work as well as we could with them and we did. But a more direct line for FSIS to participate in research funding would have been helpful, when I was there.

So I will just finish by telling you, sir, that to me, putting everything under one umbrella, even though it may sound good, we need

to study that very carefully. What makes most sense to me is look at the agencies we have now, play to their strengths, and frankly the laws need to be changed. But FSIS is more adept to conduct inspections, I believe, at this point than any other agency in the government .

Mr. LUCAS. Thank you, Doctor. Ms. Tucker-Foreman, do you think FDA authority should be extended to regulate on-farm production practices?

Ms. TUCKER-FOREMAN. Yes, sir, in some cases I do. We have supported that legislation.

Mr. LUCAS. I guess one of the concerns I have always had, from my understanding they have something like 1,900 field personnel, and they are already charged with the responsibility with 44,000 food processors to look at and 114,000 retail establishments, 900,000+ restaurants. I just have always been concerned about how we then expand that out to cover probably two million-plus farms across the country. Tell me with the time remaining that I have how you envision how we would be able to do that.

Ms. TUCKER-FOREMAN. Let me answer you very quickly since your time is up, and I can talk to you about it in more detail later.

Mr. LUCAS. Of course.

Ms. TUCKER-FOREMAN. First of all, under Congresswoman DeLauro's bill, H.R. 875, there are categories of risk established so that some plants, those with the highest risk, would be inspected most frequently, and those with lower risk would be inspected less frequently. In addition, there is a provision that you have the assistance of state governments and even some third-party certifiers for on-farm work. There is no way you are ever going to give FDA enough inspectors to do that job, so you are absolutely right.

Mr. LUCAS. Mr. Chairman, would you indulge me with one more question? If FDA issues regulations regarding on-farm production practices in the United States, do you believe that these identical regulations should be enforced on foreign farms producing products that are then imported into the United States?

Ms. TUCKER-FOREMAN. Oh, I can certainly agree with you on that because again, to my mind, the greatest strength of the Meat and Poultry Inspection Program is the equivalence. Now, the trade folks just don't like that equivalence. They say, we are only getting meat and poultry from 34 countries. All you have to do to export FDA-regulated products to the United States of America is register under the Bioterrorism Act.

Mr. LUCAS. To flesh up in the way that would be necessary for FDA to be able to do this, you know how challenging appropriations are in this place. So from your perspective, would you envision a user-fee system that would generate the revenue to provide the enforcement?

Ms. TUCKER-FOREMAN. No, registration fee yes, and we have urged the adoption of registration fee on food processing companies. I really think that the on-farm program, the place that it is needed most, is with regard to produce, fresh produce, that is being shipped as fresh produce. And we think that Senator Durbin and Congresswoman DeLauro have developed mechanisms that would ease the demands on FDA for inspection resources to do that.

Mr. LUCAS. Mr. Chairman, I appreciate the Committee's indulgence on extra time.

The CHAIRMAN. I thank the gentleman. The gentleman from Georgia, Mr. Scott.

Mr. SCOTT. Thank you very much, Mr. Chairman. As you may know, I am Chairman of our Subcommittee on Livestock, Dairy, Poultry, Seafood, and Food Safety and Inspection for those areas come under us. I am very concerned about the fact we are not moving even fast enough. But let me first start with you, Mr. Taylor. In your testimony, you mentioned that FDA lacks the resources to adequately inspect food facilities. Would you please clarify for us exactly what constitutes an inspection by the FDA? My understanding is that such inspections are actually just audits of food establishments, and the agency never actually inspects the food itself. Does the FDA notify food establishments in advance that they will be coming to inspect?

Mr. TAYLOR. First of all, there is no one type of FDA inspection. There are different kinds of inspections based on the facility and based on the reason for the inspection. And those inspections are unannounced, and they do include more than just auditing. In fact, FDA, one of the problems it has got with its statute, it does not have routine access to the records that relate to a company's food safety system. They need that access. In fact, the typical inspection includes visually observing and taking samples from the production line of the food itself, samples from the equipment to see if it is contaminated. So it is a direct inspection, hands-on inspection, of the facilities and the food there.

Mr. SCOTT. But I mean, are you adamant on your point that the FDA lacks the resources to adequately inspect food facilities?

Mr. TAYLOR. The inspection frequency that they are able to achieve, if you average out the number of inspections they are able to do annually, and the number of plants, averages out to about one every 10 years. I consider that inadequate resources. There is a critical point here though which comes up, and it is a comparison between USDA and FDA. The gap in inspection intensity is obviously enormous, and that reflects a lot of the history of why we do what we do on meat and poultry, why we do carcass-by-carcass. And you can debate whether that makes sense. You don't want to aspire, I would argue, to a system at FDA for all the rest of the food supply and all of its diversity that emulates the USDA approach, which is all about inspection in a very constant way.

FDA inspection will be sufficient and effective when it is with respect to enforcing a company's duty to have modern, preventive controls. If the company is not obligated to have modern, preventive controls, then FDA is in the position of looking around for the problem as opposed to being able to yes, audit the company's system but also take the verification samples, do the microbial testing and so forth to really, in an efficient way, determine whether that company is operating an effective system.

Mr. SCOTT. Dr. Murano, let me ask you as a follow-up on that, how does what Mr. Taylor is saying compare to how FSIS conducts its inspections?

Dr. MURANO. Well, sir, as I alluded to, because FSIS is in the plants every day, they have access to the records that are the food

safety records that the plant has. If they have an operation where they are processing, say, hot dogs, they look at the records that the plant is keeping of the temperature controls, for example, for the oven, their sanitation operating procedures and records of the percent chlorine in a solution that sanitizes equipment, things of that nature, all the time. They are able to look at that as well as take samples, and that is the essence of the difference. I agree with Mr. Taylor that not every product requires that kind of oversight, but certainly on a regular basis, on a frequent basis being able to look at the complete process is extremely important. And it is the basis for why USDA has done so well. Again, not perfect because we are dealing with human beings, and human beings make mistakes, but it is a fundamental difference that has enabled USDA to be much more proactive, much more preventive.

Mr. SCOTT. Let me ask you one other thing as my time is running out, I listened intently to your testimony, and it seems to me that I picked up that you were saying that the weak link is in plant operators. Is that an accurate assessment?

Dr. MURANO. Well, let me put it to you this way. There are several links in this food safety chain, and just like inspectors are an important link, another important link, if not the most important link, are the plant operators themselves. They are the ones that are making the food, that are producing the products. So just as we went about training our inspection personnel, we knew that if they had been making mistakes based on lack of adequate scientific training and so forth, that the plant personnel maybe needed some looking into. And so we, as a regulatory agency, what we could do is mandate reassessments to make sure that those operators looked at their process, explained and justified why they did what they did based on science, and that had not happened very well before. That made a difference.

Mr. SCOTT. By plant operator, you are distinguishing a plant operator from regular plant worker, food processor, somewhere down the line. Is that plant operator a supervisory designation?

Dr. MURANO. Yes, sir, that is what I mean. A supervisor that would be accountable for monitoring the various steps in the process and for supervising their own line people.

Mr. SCOTT. Okay. Thank you very much, Mr. Chairman.

The CHAIRMAN. I thank the gentleman. I think we are going to recess. We have one vote. If the panel would stay if you have time to do that, I know the Members have some more questions. Mr. Boswell will be recognized as soon as we get back, and we appreciate your patience and being with us. It is very helpful, and it is just how things go around here. You guys know about that.

Dr. MURANO. I understand.

The CHAIRMAN. The Committee will be in recess until the call of the chair.

[Recess]

The CHAIRMAN. The Committee will come back to order. Is Mr. Taylor in the vicinity? All right. We appreciate the panel sticking around. I now recognize the gentleman from Iowa, a Subcommittee Chairman for such time as he may consume.

Mr. BOSWELL. You got by Mr. Taylor. Is he, Chandler——

The CHAIRMAN. You want to ask Mr. Taylor?

Mr. BOSWELL. Well, I kind of want to go with him in a minute anyway.

The CHAIRMAN. We will find him.

Ms. TUCKER-FOREMAN. They sent out a party.

Mr. BOSWELL. Okay. Before we get started, I will just say this. First off, it is a great panel, Mr. Chairman, and they bring the expertise that we have been looking for. So we are certainly glad to have you here, and what you have done in the past that certainly makes you eminently qualified to be with us and help us out. I want to talk about some of the things we are importing here. We will give Chandler just a second here and we will go on without Mr. Taylor.

The CHAIRMAN. Here he comes.

Mr. BOSWELL. Mr. Taylor has arrived. What I want to do, to include you in, Mr. Taylor, and of course the whole panel, is with a recent CODEL we went to Japan and Vietnam and Korea and so on, and some concerns were brought back from that visit, particularly Vietnam. I want to ask some questions to you, but can you tell me, Mr. Taylor and the rest of you jump in, can you tell me how our fish and seafood are categorized with respect to risk? And we are all hearing very troubling things about the fish and seafood that is currently being imported into the United States. In the recent past FDA has issued import alerts of imported farm-raised fish and seafood, particularly from China. However, I was surprised to learn that domestic fish are only inspected by the Department of Commerce on a voluntary basis, and I wonder if that should be mandatory. And I would like for you to comment on this. There are about two or three items in there and I got more to follow.

Mr. TAYLOR. Thank you. If I may, let me just correct the facts on the domestic inspection. There is as voluntary Department of Commerce National Marine Fisheries Seafood Inspection Program, but it is a voluntary fee-for-service thing that is done by Commerce to support the trade, essentially. That is not the regulatory inspection program. FDA has a regulatory seafood HACCP inspection program, and they do inspect domestic seafood facilities. And in fact, they are typically considered, particularly ones processing raw seafood, high-risk facilities in terms of the frequency of inspection they get by FDA. So, FDA strives, I would have to check to be sure, but currently strives for at least annual inspection of high-risk domestic seafood establishments.

Mr. BOSWELL. So to put it in the right categorization, to categorize this, how is that done?

Mr. TAYLOR. Again, it has been a while since I have been at the agency.

Mr. BOSWELL. Okay.

Mr. TAYLOR. I haven't looked at this. I can certainly provide that for the record. Seafood is inherently a higher, particularly when it is being processed for sale in raw form, an inherently high-risk food. It promotes microbial growth. There are a lot of hazards that can come in. That is the one area in which FDA uses current authority to mandate modern preventative controls as HACCP systems mandated by FDA for seafood. The issue of the Chinese imports and those import alerts had to do with animal drug residues

and chemical residues from just the practices that go on in fish farming in some situations in China and even elsewhere in Asia. And so this is based on testing of the product, detecting illegal residues that don't meet our U.S. standards for such residues in food.

Mr. BOSWELL. That is a concern. To continue, where does Commerce's authority end and FDA begin and how do they work together?

Mr. TAYLOR. Again, FDA is the food safety regulatory agency with respect to seafood, other than catfish if I may note.

Mr. BOSWELL. I was going to get to that in just a minute.

Mr. TAYLOR. Yes, sir. Department of Commerce has no food safety regulatory authority. Again, they are conducting a voluntary service, basically, for the industry. They look to FDA standards as the template for their inspection, so they are borrowing FDA standards. They are providing a level of inspection that, frankly, FDA is unable to provide and that some companies want to have for their business purposes.

Mr. BOSWELL. So if we are not mandating domestic inspection at face, how can we guarantee the imports are safe? And you have just answered that, even if the importers meet the equivalent standards.

Now that we are giving FSIS the authority to inspect catfish, what exactly will change when the authority is transferred from FDA to FSIS?

Mr. TAYLOR. I think, Congressman, that remains to be seen based on how USDA chooses to implement that, and the nature of the program that they design. I hope that it will be a HACCP-based approach, and I hope they will find a way to make efficient use of inspection resources. There are a lot of catfish out there.

Mr. BOSWELL. Well, I hope you are right as well. What specifically will change, with regard to inspection presence at catfish farms and slaughter and processing facilities, and how will importers be affected? You may want to note that I would like for Dr. Murano to jump in, too, but would you like to finish up on anything you want to say, Mr. Taylor?

Mr. TAYLOR. No, I hope I have answered your question.

Mr. BOSWELL. Well, you might want to pursue it a little more.

Dr. MURANO. Sir, I would agree, and certainly based on my experience at USDA, I would expect that USDA would apply the same principles as they do to meat and poultry to the catfish. It is muscle food, after all. So the same kinds of things happen, in the harvesting would be akin to the slaughter part of things, the processing in terms of cleaning and packaging and all of that, all of those things would apply, and therefore, the same system, the HACCP preventive system I would expect is what would be implemented with inspection that is, I believe, not required for it to be carcass-by-carcass with catfish. I don't think that is the case. So I am sure it will be a modification. But I would expect that they would do it with more rigor than has been done in the past.

Mr. BOSWELL. This is my last question, Mr. Chairman, but would you feel, any comment from anybody, that as you check this out and food safety being the concern, we have certainly got to look at the processing and the packaging all that. I would like to know your thoughts about going out for catfish, for example, the spawn-

ing, the environment they are raised in, how concerned would you be about that?

Dr. MURANO. Certainly. I think that is very important. In fact, when it comes to cattle, there is a lot of contamination that happens when the animal is still alive. So some oversight over the production side of things of the live animal is required and is something that, frankly, needs to be applied to cattle as well. It is more difficult because you have an open environment that is a lot more difficult to control what goes on, but there are certain practices, best practices, sir, that can be identified that producers can adhere to that would minimize, never eliminate, but minimize contamination.

Mr. BOSWELL. I appreciate that. It seems to me like I have always heard that, for example, fish or catfish in particular pick up about everything in the environment. And if they are spawned and raised in unsanitary conditions, I won't quite go to farm language here, and there would be some concern. Would that be correct?

Dr. MURANO. That is correct. I am no fish expert, but I understand that certainly when you decontaminate fish by a process called purification where you put the fish in a tank with water that is clean and you process that for a while. So you can remove the contamination. But you are right, the place where it is raised certainly can have an impact on the colonization of microorganisms in that product.

Ms. TUCKER-FOREMAN. If I could add one thing about a the law that was passed last year, it applies only to farm-raised catfish, and the inspection is of processing plants. It applies only to domestic, farm-raised catfish and the inspection is of processing plants. And it is required to be continuous, which means that somebody will have to be in the plant once a day. It remains to be seen whether the Department will require that HACCP principles be attached, since it is required, as Dr. Murano said, for all the other products regulated by FSIS. I assume that that will be the case, but we haven't seen the regulations yet.

As for wild catfish, I grew up on them. They ate everything. That is what made them taste good.

Mr. BOSWELL. Okay. But would you share the concern that Dr. Murano said about the environment where they are spawned and raised in, though, in the fish farm operations?

Ms. TUCKER-FOREMAN. I think it is an interesting question, who will have that jurisdiction now because I am sorry, I can't remember exactly the legislation addressed, the ponds. These are all farm raised, so they have a very controlled environment.

In terms of on-farm food safety, we have advocated at Consumer Federation for years that on-farm food safety regulations of some sort be applied in order to use process controls, have people set standards, have the government set the standards. And then have companies have process controls that will assure that animals are not unduly contaminated all the way from birth to the point where they are slaughtered, because meat inspection now starts at the slaughterhouse, just a little late.

Mr. BOSWELL. I appreciate that very much, particularly since the trip. And I guess equivalency is the word I may have left out. We are talking about catfish. We understand that, but they are fish

that are very similar as you well know. There is some debate whether they are or they aren't. I guess I am also concerned about that as I am about a fish farm you just described. I think about a plot if you will, a tank if you will, earthen tank or whatever, but also some of them are put in rivers and considered fish farms, and there is not too much care about what goes into the river. That is a concern. So thank you very much, Mr. Chairman. Thank you, panel.

The CHAIRMAN. Mr. Kissell?

Mr. KISSELL. Thank you, Mr. Chairman. Thank you, panel. I had asked the first panel this question, and I want to ask you all the same thing. Of all the concerns about food safety, whether it be in the fields, processing, imports, pesticides, regulation, lack of regulation, whatever, what are your top two concerns about food safety and why?

Dr. MURANO. I can start. I will mention one, for example, that bothered me when I was at USDA as Under Secretary. What happens when you consider meat and poultry, once it is in the retail store and a butcher can grind product, co-mingle it, there are certain jurisdictions that end right there at the retail level, and you have the local health department that takes over. And I will tell you just from the experience that we had that there would be times that there would be outbreaks for example, foodborne illness, that it would have been a lot better to have prevented than if we had had some control, some way to control things at the retail level. Things can kind of get out of control at that point in terms of co-mingling of products. When we tried to identify, for example, from where was the outbreak originating, what product, we would find many times that a product was ground at the retail store from many different suppliers. That is what made the recalls as large as they were because we could never pinpoint it necessarily to one plant, in some cases. So that is one area that I think it would be nice to have more oversight, whether it is FDA or somebody else, have a little bit more oversight.

And I will just end by saying the fruit and vegetable arena is one that is always a challenge because you have products that are grown outside, out of doors, with birds flying overhead and contaminating product that is so closely tied to the soil. Anything that we can do to try to put interventions that will decontaminate those products before they get to the consumer, we can go a long way because so many people want to have fresh produce, salads, and healthy foods like that. Without the processing that can eliminate those microorganisms, the risk is always going to be there, be it tomatoes, peppers, whatever it may be.

Mr. TAYLOR. From my standpoint by far the highest priority food safety reform issue is FDA, and it is shifting FDA's paradigm from a reaction paradigm to prevention paradigm. That means very specifically a statutory mandate for FDA to require that all companies producing food for the commercial marketplace use modern preventive controls suitable to their operations, and that FDA have the mandated authority to set and enforce standards to ensure the adequacy of those controls. It sort of boils down to that.

If you look at the various bills pending, most of them embody those and have a lot of the provisions that are necessary to make

that happen, whether it is enforcement tools or inspection mandates or whatever. But that is the core as it shifts from a reactive paradigm to a preventive one and the ability to set standards and hold companies accountable for prevention.

Ms. TUCKER-FOREMAN. I agree with Mike Taylor on that, and second to that would be to modernize the Meat and Poultry Inspection Acts to have the same kind of authority to have enforceable standards as recommended by the National Academy of Sciences in 2003.

Mr. KISSELL. Thank you, panel. Thank you, Mr. Chairman.

The CHAIRMAN. I thank the gentleman. The gentleman from California.

Mr. COSTA. Thank you very much, Mr. Chairman. Ms. Tucker-Foreman, you have, I believe, made the statement and others that additional information is needed under the FSIS effort to fully implement what I refer to as a risk-based, risk assessment effort that uses FSIS. In your view, what data do we need to continue to pull through, especially as we are looking at the area of fresh fruits and vegetables?

Ms. TUCKER-FOREMAN. Congressman, you have asked me about FSIS. I think you meant to ask me about FDA. FSIS doesn't regulate——

Mr. COSTA. Yes, but under the FDA, what data would they require? I am sorry, I misspoke.

Ms. TUCKER-FOREMAN. I am not sure I have said it about FDA. At FSIS, we are very concerned that there is not adequate data to move ahead with a public health-based poultry slaughter system which they have proposed. With regard to fresh fruits and vegetables, what we think is appropriate is to require operations to set up process controls similar to HACCP. They can be HACCP. Those process controls can be as simple as the product and the operation underway at a particular location, or as complicated as those are to show that there is a mechanism for assuring food safety. Then, those need to be based on Federal health standards, public health standards. Does that answer your question? I am not sure that I——

Mr. COSTA. The pay-for would be the same methodology that you spoke in a response to my colleague who asked whether it would be a fee, I think. I am trying to remember the response you gave to him in terms of how you pay for this additional inspection program.

Ms. TUCKER-FOREMAN. And I am glad Mr. Lucas is here because in responding to his question, I did not factor in the most important element I believe which is that if each company is required to establish a process control system, then you can allocate your resources according to the adequacy of process control. I am assuming that nobody would be inspected on a daily basis under such a system.

Mr. COSTA. What are best science practices? And we had the analogy earlier going back to the book, *The Jungle,* and the inspection under USDA of each carcass on beef. But don't you think the scientific progress that has been made over almost now a century, in terms of best management practices, best science, that a random

methodology can really reduce the—so you can ensure the detection effort?

Ms. TUCKER-FOREMAN. I believe we are talking here about what I am calling process controls, but companies establish HACCP plans to identify all the places in their operation where something might go wrong, and then identify the steps that they need to take to prevent that from happening. But——

Mr. COSTA. Go ahead. I just want to get my time.

Ms. TUCKER-FOREMAN.—that has to be in our view calibrated to what Federal public health standards are. Otherwise, every company would set up their——

Mr. COSTA. Yes, I understand a national standard, a uniform standard.

Ms. TUCKER-FOREMAN. Yes, sir.

Mr. COSTA. My bill has that.

Ms. TUCKER-FOREMAN. Yes, it does.

Mr. COSTA. That is not the discussion. That is not my question anyway.

Ms. TUCKER-FOREMAN. Okay.

Mr. COSTA. The point I am trying to raise is at some point, I mean, the standards for clean water, for example, what is detectable. And it was every part per million, and that is what was detectable. Now every parts per billion and that is what is detectable. Now, we are able to determine every parts per trillion, and when you have the limited dollars for health safety and health protection to get your best bang for your buck, I don't think because the threshold because of the amazing ability of science to continue to improve our ability, in this case for detection. That when you are doing risk assessment *versus* risk management that we ought to be going out trying to trace very trillionth level of element that might be a carcinogen, for example.

Ms. TUCKER-FOREMAN. I think there is a difference between pathogens and chemical contamination.

Mr. COSTA. No, I know there is.

Ms. TUCKER-FOREMAN. They don't grow those chemicals.

Mr. COSTA. Correct, but the concept is the same in terms of trying to get the best bang for your dollar in terms of risk assessment *versus* risk management.

Ms. TUCKER-FOREMAN. We call that a risk-based system where you allocate your resources where there is the greatest risk, yes, sir.

Mr. COSTA. And you support that?

Ms. TUCKER-FOREMAN. I do.

Mr. COSTA. Mr. Taylor, you are anxious to—my time is out. I don't know how you want to——

Mr. TAYLOR. Just real briefly. In thinking about produce safety standards and what science is needed, we do need to get very specifically to the level of, for example, what is the appropriate microbial quality of the water that you use for irrigation in a tomato-growing operation.

Mr. COSTA. Right.

Mr. TAYLOR. And you are right. I mean, you have to look at that from the standpoint of its contribution to a system, all the controls that are in place, and what the finished result is. It is not a matter

of chasing zero in terms of microbial content of the water, it is looking at it in a system way.

The point I want to make though is that one of the weaknesses in our system is that FDA, which is the agency responsible for developing those standards, has never been given among the mandates they have, they are not precluded from research but they have no mandate to do research and provide leadership to get that practical applied research. So again, this whole shift to a risk-based system does require equipping our regulatory agencies with the scientific tools to get this right from a public health standpoint.

Mr. COSTA. Dr. Murano, did you want to comment?

Dr. MURANO. Just very briefly, sir. As a microbiologist, I will tell you that the best way to control contaminates, hopefully even eliminate them, is to first know what the risk is. What are the contaminants likely to be found, where are they introduced along the line, and then you can start to intervene and put steps in the process to intervene. So risk assessment, you are absolutely right. That is exactly at the crux of the matter but not to have a zero risk because I think we all——

Mr. COSTA. That is impossible.

Dr. MURANO. That is impossible.

Mr. COSTA. You will never achieve it.

Dr. MURANO. And risk assessment ties, not only the likelihood of the presence but the likelihood of someone getting ill and with all of the——

Mr. COSTA. It is the difference of preventive health maintenance *versus* the FDA which I would liken to the emergency room physician.

Dr. MURANO. Exactly.

Mr. COSTA. I mean, the way the FDA works today——

Dr. MURANO. It is a little late.

Mr. COSTA.—I mean, the car wreck has happened already——

Dr. MURANO. Yes, sir.

Mr. COSTA.—or the person is already very sick and they may be in ICU and they are there. They are in the emergency room.

Dr. MURANO. Correct. I agree.

Mr. COSTA. There is a whole lot of stuff you could have done before they ever got there.

Dr. MURANO. This is correct, and they do have good agricultural practices, GAPs, as guidelines for farmers to use, but they are really not enforced to be honest with you. It is up to each producer as we saw with the panelists who testified before us.

Mr. COSTA. Well, if there is a second round there are a couple other questions I would like in this line, but thank you very much, Mr. Chairman.

The CHAIRMAN. I thank the gentleman. I recognize the gentleman from Iowa.

Mr. BOSWELL. Just a comment, Mr. Chairman. I want to compliment you for assembling this panel of expertise today. The trip we went on, Pete was there, Mr. Lucas, from your staff and made a great contribution, Chandler. I see Mr. Goule in the back of the room. I won't call him out because he was on FSIS, and we know some things that we probably ought to talk about. And with the expertise of these folks to work for this, we may want to huddle and

talk some. And if everything is okay, we will leave it alone. If it is not, maybe we ought to do something about it. Thank you.

The CHAIRMAN. I agree with you and we need to get some of these trade people in here and straighten them out. That is part of the problem with all this stuff in my opinion. I just wanted to, if I could, ask a question.

You know, it seems to me that these companies that are in this business that have developed brand names, they have put a lot of money into developing brands and so forth—and I may be getting off field here—they seem to me to be more focused or concerned on this than people that don't have that situation because if they have a problem, it really hurts them. So they have a very good motivating influence to make sure that whatever they are doing is not a problem. And it seems like with a lot of these things that crop up, it is some little company that doesn't have a brand name that is in the middle of all of this that nobody ever heard of. Is that something that is taken into consideration when you are looking at risk in terms of—not scientific, but it does have a big influence or at least in my mind—and I would like to know what you think about that.

Dr. MURANO. If I may, Mr. Chairman, very quickly I will give you a very good example of that being so true. The companies, the small companies, that don't have a recognizable brand that supply to bigger meat and poultry companies, sometimes, were the cause of the problems in meat contamination. And so when we order the reassessments of HACCP plans, one of the things that we required is that these plants would have to verify from their suppliers that things were done right. So, when you start to put the burden on the companies that want to protect their brand, it is in their best interest for many reasons, public health reasons, their bottom line as well, to do the right thing. It kind of goes downstream and they start requiring it of their suppliers that may not be as accountable as those big companies are.

The CHAIRMAN. But we as a government, do you think we should inspect those people more?

Dr. MURANO. And we do, and that is exactly right. At FSIS, that is what we started to discover is that we needed to go to those companies that maybe were falling through the cracks, if you will, that were not being monitored as robustly as they should have been, that they themselves maybe didn't have the expertise. We found that out with *Listeria*. That was a big problem because a lot of mom and pop operations producing deli meats were the cause of outbreaks. And so we started to target those companies more through our new cadre of inspectors that were doing the more thorough analysis.

The CHAIRMAN. Mr. Taylor, it looks like you wanted to——

Mr. TAYLOR. Yes, I guess I hesitate to make it a big company/small company issue. I think the fact is that there are different business incentives for companies to put extra effort into food safety, and brands are very much one of those factors. A lot of small businesses do fantastic job on food safety as well. I think there is a much bigger point here, though, suggested by your question is that innovation on food safety has typically come from the private sector, from leaders in the industry who have incentives to do

more. Certainly when we were trying to put the HACCP system in place following the Jack in the Box outbreak in the early 1990s, McDonald's was driving progress, Jack in the Box was driving progress through their systems way faster than we were able to do it. And there are big retailers today who have specifications, supply chain management techniques, traceability systems that really represent best practices, and government needs to learn from those. To figure out how you set—create a level playing field that is workable across an industry that elevates all of the players to a level that meets public expectations with those industry best practices leadership really providing a lot of input into where standards should go.

Ms. TUCKER-FOREMAN. If I could add just one thing to that, I absolutely agree that the brand name is desperately important and people protect it, but they have to have some help. The Chief Executive Officer at Kellogg testified that it cost his company $65 to $70 million to recall the peanut products that were contaminated by peanuts from Peanut Corporation of America. And they had supply chain management. They paid a certifier to go in and certify that plant, but the certifier kind of went in and looked around, didn't check it very well, and the company was able to hide records because there was no food/drug law that said you can't do that and you have to provide them to inspectors from Georgia and FDA.

So there is always going to be somebody who tries to get around the best system, but systems get set up assuming, just like the cop on the beat, that somebody will not play by the rules and you want to reduce their window for not playing by the rules to the smallest one that is possible. Thank you.

The CHAIRMAN. Thank you. I don't know, we have one more panel. Everybody is not completed. I guess we will dismiss this panel. Dr. Murano, Mr. Ralph Hall is waiting back there for you. He has been patient. Welcome to the Committee, Ralph.

So thank you very much to this panel, and thank you for being with us and being so patient. It was very helpful.

We will call the next panel, which we apologize to for making you sit through this whole ordeal here today, but I would encourage the Members that are here to stay and listen to this. They have done some good thinking, and they have some ideas that should be considered by the Committee. And from my home State of Minnesota, which has been one of the leaders in ferreting out a lot of these issues, we are very proud of our people there that have done some outstanding work in some of these food safety issues. So we welcome to the Committee from the SUPERVALU Corporation in Minnesota, Dr. Hanlin who is their food safety person. I don't know exactly what your title is, he has been at a number of other companies and he is accompanied by Mike Erlandson who a lot of you may know used to be Mr. Sabo's Chief of Staff. So welcome to the Committee, and thank you for your patience and sitting through all of this until we got here. You are recognized, Dr. Hanlin.

STATEMENT OF JOHN H. HANLIN, PH.D., VICE PRESIDENT FOOD SAFETY, SUPERVALU INC., EDEN PRAIRIE, MN; ACCOMPANIED BY MICHAEL S. ERLANDSON, VICE PRESIDENT GOVERNMENT AFFAIRS, SUPERVALU INC.

Dr. HANLIN. Good afternoon, Chairman Peterson, Ranking Member Lucas, Committee Members, ladies and gentlemen. My name is John Hanlin, I am the Vice President of Food Safety at SUPERVALU. We are one of the largest grocery chains in the United States, and I refer you to *figure 1* of the packet that I hope you have in front of you that will tell you a little bit more about who we are.

We are based in Minnesota. We operate over 2,500 retail stores, 35 distribution centers and employ over 190,000 people. Many of you may know us better by the banners under which we operate, and these include ACME and Shaw's in the Northeast, Jewel/Osco, Cub Foods, Albertson's on the West Coast, and others.

I am joined this afternoon by Mike Erlandson. Mike is SUPERVALU's Vice President for Government Affairs, and we bring a unique perspective to the national discussion on improving the safety of our nation's food supply. I have almost 25 years' experience working in the food safety area on both the manufacturing and the retail aspects of the business. And prior to joining SUPERVALU, I worked for companies that included Campbell Soup, The Pillsbury Company and General Mills. Mr. Erlandson spent 20 years working here in the nation's Capitol as Chief of Staff to former U.S. Congressman Martin Sabo from Minnesota.

As one of the largest grocery store chains, we find ourselves removing products from our shelves and our DCs almost daily due to food safety issues reported to us by the USDA, FDA and food manufacturers. Consumers are losing confidence in the food supply. Equally important is the fact we have entered a new age of food safety. The same bacteria that were traditionally associated with beef, poultry, eggs and pork are contaminating raw agricultural commodities, and people are getting sick.

Several of the largest outbreaks of *E. coli O157:H7* and *Salmonella* in recent memory have been associated with fruits and vegetables. For example, the spinach out break of 2006, last summer's *Salmonella* outbreak due to jalapeño peppers and possibly tomatoes and most recently peanut butter.

If you refer to *figure 2* in your handouts, as you well know, both USDA, on the right hand of the slide, and FDA lead our food safety inspections systems. USDA has primary responsibility for meat, poultry and eggs products, while FDA has jurisdictional responsibility over everything else.

In the past, this made sense given the historical association of foodborne illness with animals and poultry, a diet different than today's and a simpler supply chain. But currently inspection of meat and poultry and its products is not always clear-cut. On *figure 2* about halfway down you will notice several arrows going from right to left. Under some circumstances, meat, poultry and egg products move from USDA inspection to FDA jurisdiction depending upon how the item is manipulated further down the manufacturing or the supply chain.

For example, in *figure 3* we show a frozen breakfast entrée comprising a sandwich with two side items. This product is under inspection of the USDA, and you will see that mark of inspection on left-hand side. However, a breakfast sandwich-only product, as shown in *figure 4,* is not under the inspection of the USDA. Similarly, in *figure 5* you see a steak Panini-style product. This product is fully enrobed by bread and is under USDA inspection; however in *figure 6* a similar steak Panini-style sandwich that looks more like a sandwich is not under USDA inspection. And finally, in *figure 7,* these cheeseburger sandwiches are not required to be inspected by the USDA nor do they bear the USDA mark of inspection.

We show these slides to highlight the fact that all of these products generally carry the same relatively low food safety risk, yet the inspection requirements vary differently. I will come back to this notion of risk-based inspections in a moment as we offer some ideas on new approaches to risk-based inspections and a re-deployment of resources that we have today.

We need to modernize our food safety inspection and enforcement system. Consumers are changing their dietary habits. They are listening to the messages about the importance of increased consumption of fruit and produce. And as I said, organisms traditionally associated with animals and birds can contaminate fruit and produce and make people sick.

Our supply chain grows in complexity. A few lots of a raw agricultural commodities when used as an ingredient in other products can contaminate hundreds of products representing millions of pounds of food. Given all of these converging factors, we propose a refocus and re-alignment of the current Federal food safety inspection systems. Specifically we propose taking the successful risk-based USDA surveillance, inspection and enforcement model that has helped reduce the incidence of *Salmonella* in poultry, and has highlighted the challenges with reducing *E. coli* in ground beef, and expanding that risk-based inspection model to other agricultural commodities like spinach and other leafy greens, tomatoes, fresh fruits, peanuts, grains and other raw agricultural commodities. This is shown in *figure 8.* In other words expand USDA's risk-based inspection system to include commodities that today receive minimal inspection due to budget challenges at FDA.

What we propose in *figure 8* is to focus USDA risk-based efforts against improving the safety of all commodities, particularly those commodities that are consumed in the raw state, or those that are cooked or pasteurized and eaten without a further microbial step. We believe an approach like this—pushing food safety upstream in the supply chain, that will help all of us. It will do three things. It will reduce overall public exposure to pathogens, thereby improving food safety; it will provide greatest synergies in the implementation of good agricultural practices; and we believe it will strengthen international competitiveness of U.S. agriculture.

As I close here, I would like to go back for a minute and talk about redeployment of resources. This type of model would enable the agency to deploy resources against the greatest food safety risks. Imagine for a moment being able to redeploy the FTE resource currently inspecting a facility making frozen sandwiches as

an entrée and re-training that inspector to inspect and be in a peanut facility every day, or perhaps inspecting and surveilling and sampling a spinach farm just prior to harvest. We believe the proposed model would work if we, as a nation, create a single food agency or whether we maintain dual jurisdictional responsibilities within USDA and FDA.

In a dual role we would envision FDA providing the food safety leadership further down the supply chain, for example, in the manufacture of frozen pizza, entrées, canned soup, broths, sauces, snacks, and other packaged products.

In closing we understand where our food safety risks are. We must look beyond the current meat and poultry divide and focus on food safety systems across all categories of commodities using a risk-based approach. There is nothing more important than safe food to those of us in the food business and all of us as consumers.

Mr. Erlandson and I look forward to further discussions, and all of us at SUPERVALU look forward to working with you to ensure that we prevent foodborne illness. Thank you.

[The prepared statement of Dr. Hanlin follows:]

PREPARED STATEMENT OF JOHN H. HANLIN, PH.D., VICE PRESIDENT FOOD SAFETY, SUPERVALU INC., EDEN PRAIRIE, MN

JOHN H. HANLIN, PH.D.—*Vice President Food Safety,* SUPERVALU INC.

MICHAEL S. ERLANDSON—*Vice President Government Affairs,* SUPERVALU INC.

Good morning Chairman Peterson, Committee Members, ladies and gentlemen,

My name is John Hanlin, I am the Vice President of Food Safety at SUPERVALU. We are one of the largest grocery chains in the United States. I refer you to *figure 1* of your packet. We are headquartered in Minnesota and operate over 2,500 retail stores, 35 distributions centers and employ over 190,000 people. Many of you may know us better by the banners under which we operate. These include ACME and Shaw's in the Northeast, Jewel/Osco in the Chicago area, Cub Foods in Minnesota, Albertson on the West Coast, Save-A-Lot nationally and several others.

I am joined this morning by Mike Erlandson, SUPERVALU's Vice President for Government Affairs. We bring a unique perspective to the national discussion on improving the safety of our nation's food supply. I have almost 25 years experience working in the food safety area on both the manufacturing and retail aspects of the business. Prior to joining SUPERVALU, I worked for companies that included, Campbell Soup Company, The Pillsbury Company and General Mills. Mr. Erlandson spent 20 years working here in the nation's Capitol as Chief of Staff to former U.S. Congressman Martin Sabo from Minnesota.

As one of the largest grocery store chains, we must remove products from our shelves and our DC's almost daily due to food safety issues reported to us by USDA, FDA and food manufacturers. Consumers are losing confidence in our food supply and this has been highlighted in several public opinion surveys of recent.

We have entered a new age of food safety. Scientific advances in the fields of epidemiology, DNA fingerprinting of pathogens and good laboratory practices, are showing that the same bacteria that were traditionally associated with beef, poultry, eggs and pork are contaminating raw agricultural commodities. Several of the largest outbreaks of *E. coli O157:H7* and salmonellosis in recent memory have been associated with fruits and vegetables, *e.g.,* spinach, last summer's outbreak due to jalapeño peppers and possibly tomatoes and most recently peanut butter.

If you refer to *figure 2,* as you well know, both USDA (right hand side) and FDA (left hand side) lead our food safety inspections systems. USDA has primary responsibility for meat, poultry and eggs products, while FDA has jurisdictional responsibility over everything else we eat.

In the past, this made sense given the historical association of foodborne illness with animals and poultry, a diet different than today's and a simpler supply chain. Currently inspection of meat and poultry is not always clear cut and sometimes a meat and poultry containing product is under FDA jurisdiction, not USDA inspection.

On *figure 2,* you'll notice several arrows going from right to left. Under some circumstances, meat, poultry and egg products move from USDA inspection to FDA jurisdiction depending on how the item is manipulated further down the manufacturing chain.

Figure 3 shows a frozen breakfast entrée comprising a sandwich with two side items. This product is under inspection of the USDA (mark of inspection on left hand side). However, a breakfast sandwich-only product (*figure 4*) is not under the inspection of the USDA. In *figure 5* you see a steak Panini-style product. This product is fully enrobed by bread and is under USDA inspection; however in *Figure 6* a similar steak Panini-style product more in line with a sandwich is not under USDA inspection.

Similarly in *Figure 7,* these cheeseburger sandwiches are not required to be inspected by the USDA nor bear the USDA mark of inspection. We show these slides to highlight the fact that all of these products generally carry the same (relatively low) food safety risk yet the inspection requirements vary differently. I'll come back to this notion of risk-based inspections in a moment as we offer some ideas on new approaches to risk-based inspection and a re-deployment of resources.

We need to modernize our food safety inspection and enforcement system. Consumers are changing their dietary habits—they're listening to the messages about the importance of increased consumption of fresh fruit and produce. Our scientists in government, at Universities, in industry and those working for consumer groups understand how organisms traditionally associated with animals and birds can contaminate fruit and produce and make people sick.

Our supply chain grows in complexity—a few lots of a raw agricultural commodity when used as an ingredient in other products can contaminate hundreds of products representing millions of pounds of food.

Given all of these converging factors, we propose a refocus and re-alignment of our current food safety inspection systems. Specifically we propose taking the successful risk-based USDA surveillance, inspection and enforcement model that has helped reduce the incidence salmonella in poultry and has highlighted the challenges associated with reducing *E. coli O157:H7* in ground beef and expanding to other agricultural commodities like spinach, and other leafy greens, tomatoes, fresh fruits, peanuts, pistachios, grains and other raw agricultural commodities. This is shown in *figure 8.* In other words expand USDA's risk-based inspection system to include commodities that today receive minimal inspection due to budget challenges at FDA.

What we propose in *Figure 8* is to focus USDA risk-based efforts against improving the safety of all food commodities, particularly those commodities that are consumed in the raw state or those that are cooked or pasteurized and eaten without a further microbial inactivation step, *e.g.,* peanuts, almonds, cooked chicken. We believe an approach like this—pushing food safety upstream in the supply chain will:

1. reduce overall public exposure to pathogens and thereby improve food safety.
2. provide greatest synergies in the implementation of good agricultural practices.
3. strengthen international competitiveness of U.S. agriculture.

I'd like to go back for a minute and talk about redeployment of resources. This type of model would enable the agency to deploy resource against the greatest food safety risks. Imagine for a moment being able to redeploy the FTE resource currently inspecting a facility making a frozen, fully cooked, cheeseburger sandwich (*figure 8*) and re-training the Inspector to inspect a peanut facility or a spinach farm just prior to the harvest.

We believe this proposed model would work if we, as a nation, create a single food agency or maintain dual jurisdictional responsibilities within USDA and FDA. In a dual role we would envision FDA providing the food safety leadership further down the supply chain, *e.g.,* the manufacture of frozen pizza, entrées, canned soup, broths, sauces, snacks, seasonings, *etc.*

In closing we understand where our food safety risks are. We must look beyond the meat and poultry divide and focus on food safety systems across all categories of commodities using a risk-based approach. There is nothing more important than safe food to those of us in the food business and all of us as consumers.

Mr. Erlandson and I look forward to further discussions and all of us at SUPERVALU look forward to working with you to ensure that we prevent foodborne illness.

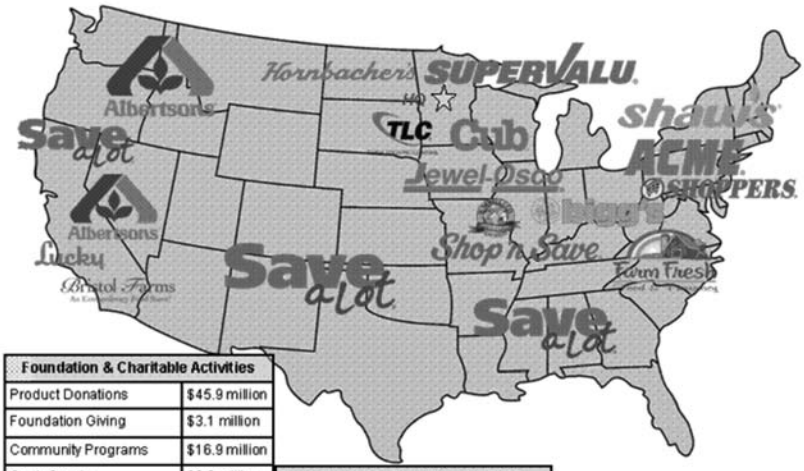
Thank you.

ATTACHMENT

Figure 1

SUPERVALU.

SUPERVALU INC. is the nation's third largest retail grocer with revenues of $44 billion. Headquartered in Minnesota, SUPERVALU operates over 2,500 stores, 923 in-store pharmacies, 124 fuel centers, and 35 distribution centers. SUPERVALU supplies over 5,000 grocery retail endpoints, it operates in 48 states employing over 190,000 people including 120,000 union members. Jeff Noddle is the Chairman and CEO.



Foundation & Charitable Activities	
Product Donations	$45.9 million
Foundation Giving	$3.1 million
Community Programs	$16.9 million
Cash Grants	$8.0 million
Other	$4.6 million

Total Charitable Donations for FY08
$78,673,308

Intermountain West Banners

Banner	No. of Stores
Albertsons	521
Bristol Farms	16
Lucky	7
Save-a-Lot	400*

*(1200 Save-a-Lot stores coast to coast)

Midwest Division Banners

Banner	No. of Stores
Cub	83
Hornbachers	6
Jewel-Osco	184
Biggs	11
Shop-n-Save	41
Save-a-lot	400*

Eastern Division Banners

Banner	No. of Stores
ACME	130
Shaw's	201
Shoppers	65
Farm Fresh	46
Save-a-Lot	400*

Military Commissaries Served
More than 90

National Industry Statistics

Number of Supermarkets = **34,967**

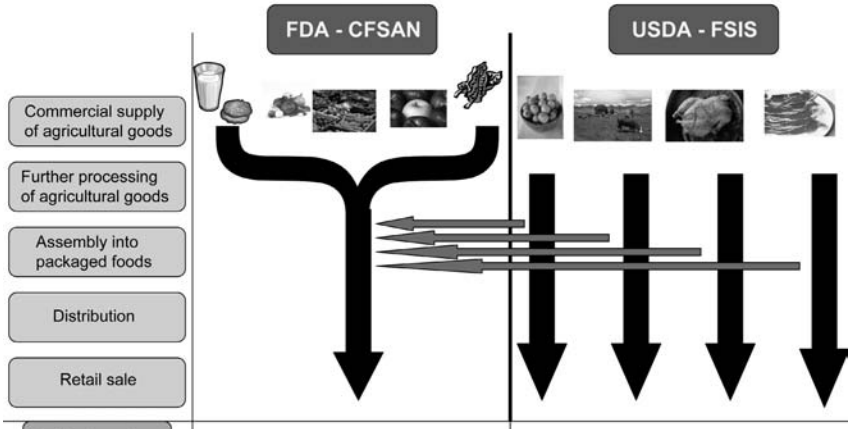
Total number of employees (2002) = **3.4 million**

Supermarket Sales (2007) = **$535.4 billion**

Net Profit after taxes 2007/2008 = **1.84%**

Mike Erlandson, Vice President, Government Affairs
mike.erlandson@supervalu.com ○ 952.828.4524 ○ Eden Prairie, MN

Figure 2 Current Food Safety Oversight



	FDA - CFSAN	USDA - FSIS
% of food regulated	80%	20%
% of food safety $	20%	80%
# of food facilities under jurisdiction	50,000+	6,000

Figure 3

Figure 4

Figure 5

HOT POCKETS
brand stuffed sandwiches
New! PANINI
STEAK & CHEDDAR
SEASONED COOKED BEEF STEAK, CHEESE & ROASTED ONIONS WITH SAUCE IN AN ONION FOCACCIA BREAD
0g Trans Fat per serving
Excellent Source of Calcium
NET WT 7.5 OZ (212g)
2 SERVINGS
KEEP FROZEN
COOK THOROUGHLY
SERVING SUGGESTION

Figure 6

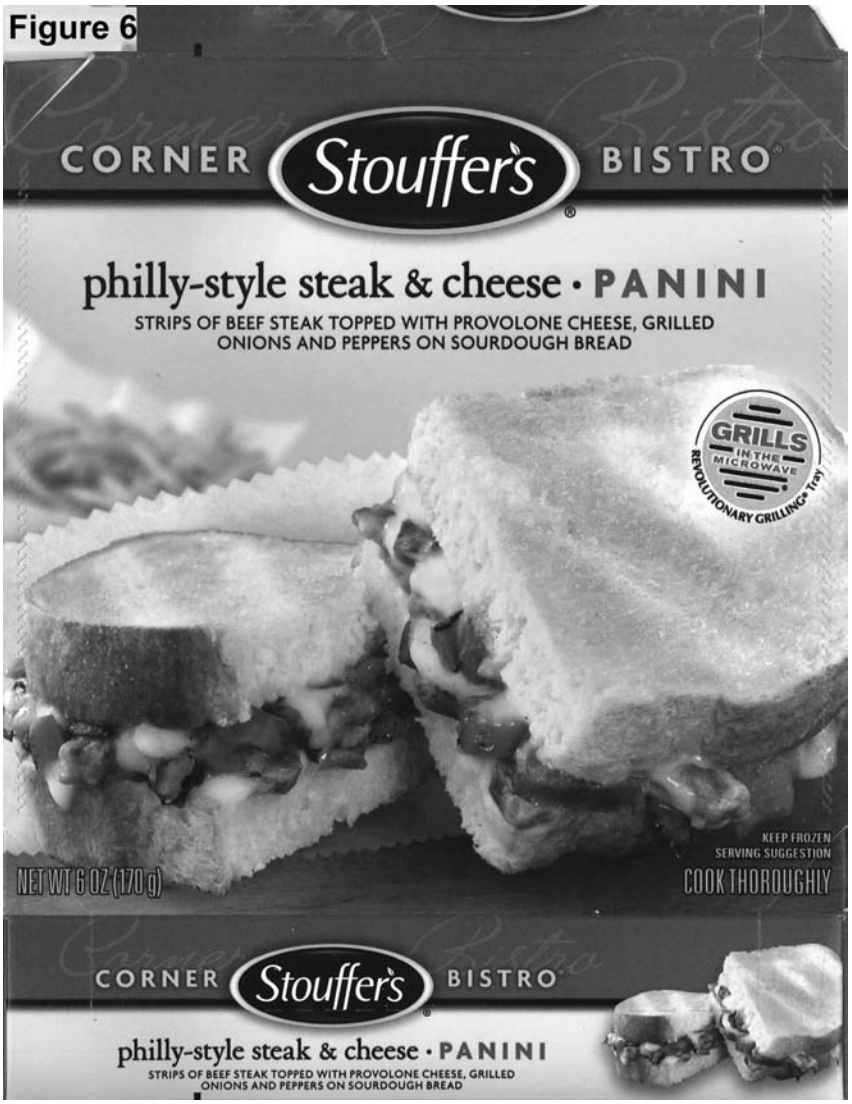
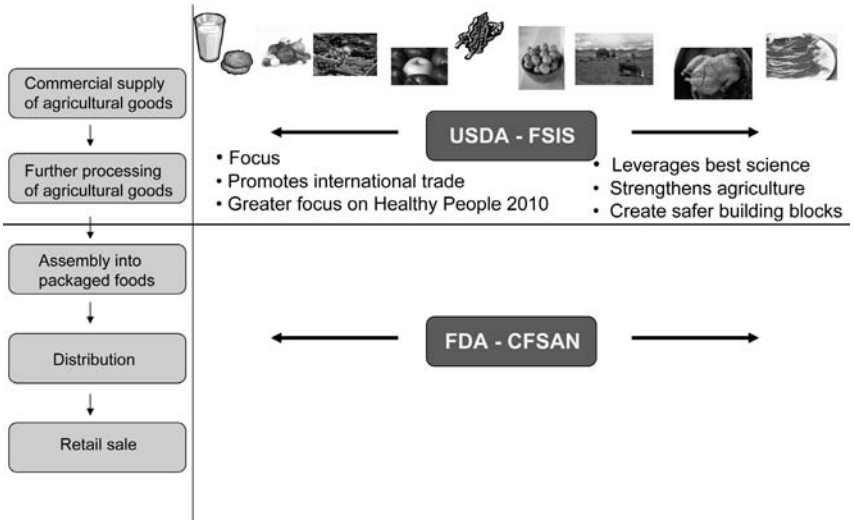

CORNER
Stouffer's
BISTRO
philly-style steak & cheese · PANINI
STRIPS OF BEEF STEAK TOPPED WITH PROVOLONE CHEESE, GRILLED ONIONS AND PEPPERS ON SOURDOUGH BREAD
GRILLS IN THE MICROWAVE
REVOLUTIONARY GRILLING® TRAY
NET WT 6 OZ (170 g)
KEEP FROZEN
SERVING SUGGESTION
COOK THOROUGHLY
CORNER
Stouffer's
BISTRO
philly-style steak & cheese · PANINI
STRIPS OF BEEF STEAK TOPPED WITH PROVOLONE CHEESE, GRILLED ONIONS AND PEPPERS ON SOURDOUGH BREAD

Figure 7

KEEP FROZEN NET WT. 11 OZ. (312g) SERVING SUGGESTION

Figure 8 Proposed Food Safety Oversight



The CHAIRMAN. Thank you very much for your testimony. I have tried to explain this to a couple other Members, and I found out that I didn't know as much about this as I needed to. So what you are proposing is that we would extend what FSIS does across all the commodities at the farm level, and then through the processing plant. So that would be like a slaughter plant or in the case of produce where they wash the lettuce and put them into bags and so forth, is that where the cutoff would be with USDA? I guess I am not as familiar with fruits and vegetables.

Dr. HANLIN. Yes, Chairman Peterson, that is fundamentally the concept that we are bringing to the Committee today as to where the bright light or the dividing line is. We believe that experts in government and academia and industry could really help flesh that out for different commodity groups. For example, perhaps USDA might have inspectional jurisdiction to the point where milk is pasteurized but then as milk goes to manufacturers who are making sour cream, cottage cheese, yogurt and other, more complex diary products, one could imagine perhaps that being a convenient split.

With respect to bagged salad, we would suggest that if the product is being field cored and immediately packaged that that would stay with USDA. However, if the spinach or the lettuce or the leafy greens are being brought into a facility, they are being sliced, diced, chopped, shredded, and put into bags where the raw commodities are being significantly transformed, we feel that would be again another breakpoint.

So it is really, where does that commodity substantially change its form?

The CHAIRMAN. Then in the case of that, why would FDA be better at regulating that plant that cuts this lettuce up or whatever as opposed to USDA? What is the logic behind that?

Dr. HANLIN. Well, sir, what we are trying to do is really try to provide a food safety framework that would work regardless of whether we, as a nation, go to a single agency or whether we feel that there is a role for both FSIS which really is the single agency within USDA or SFAN, if you will, the single food agency within FDA. So we wanted to try to provide a model that would work regardless of whether it is going to be a single agency or perhaps dual jurisdictions.

The CHAIRMAN. Well, I have been in a couple of these, I guess you would call, processing plants for lettuce, and I would compare that kind of to a slaughter plant. I mean, they come in and they wash them and they run them through these lines, and it is kind of like what we do in a slaughter facility. So I don't know why you wouldn't have USDA. You know, there probably should be inspectors on the line there like they are on a meat inspection. I don't know.

But anyway, what you are saying to us is that you are not locked into this, you are just making some suggestions about how to——

Dr. HANLIN. Correct. We are not locking in to say this must be the bright light for fruit, this must be the bright light or the line if you will for produce. What we are offering up today, sir, is just the concept of taking the very successful programs that have occurred within USDA, FSIS, and rather than cutting the pie this way with the dividing line being meat and poultry, can we cut it

another way and use the risk-based inspection, enforcement and surveillance programs that have worked for meat and poultry, and try to bring them over to other commodities that today are not inspected by the USDA for food safety.

Mr. ERLANDSON. In the case of your example, Chairman Peterson, I think that processing plant for fruits and vegetables or lettuce would probably fall under FSIS or the single food agency that would be housed under the USDA. Again, you are expanding both the USDA and the FDA in food safety, and you have a logical dividing line where products are clearly closer to the farm and closer to that process *versus* packaged goods, so to speak, which falls into a different area. And, that you also get USDA focused on what it does best, and you add I would think a new level of educating the farmers in this country as our world becomes more complicated with foodborne illnesses, things growing up from the ground, *et cetera*. Do this with more of a focus on addressing all of the commodities at that level instead of having only some of the commodities as it is today.

The CHAIRMAN. Thank you. The gentleman from Oklahoma.

Mr. LUCAS. Thank you, Mr. Chairman. Gentlemen, would you, for a little background reinforcement educational process because of the magnitude of your operation, remind me of when FDA or USDA requests a recall? Take me quickly through the steps that are involved for you at the retail level.

Dr. HANLIN. We would be happy to. We are only as good in terms of our recall function as the quality of the information that we receive through USDA, through FDA, and from the food manufacturers. We monitor all of the websites, we monitor all of the blogs, we have a good idea of what is happening out there, but once we get a formal communication from USDA, FDA or the manufacturer directly, they are calling us to say there is an issue, we then active our recall team.

Our recall team then works directly with the supplier to understand what DCs or distribution centers did that product go into. So we need to know which DCs was the product shipped to and what is or are the UPC codes, the barcode numbers, for that product. And then once we have that information, which typically we can gather in a matter of minutes, 30, 40 minutes, we are then able to electronically execute a recall. And for a health hazard recall, we require that the product be removed from the shelves within a 3 hour window. For a non-health hazard recall, we let it go longer But our focus is to get the product off of our shelves, out of our back rooms, out of our DCs quickly. What we also do is we also make sure that we are auditing our own shelves to determine that we have indeed removed the product from the shelves.

Mr. LUCAS. In your experiences in dealing with recalls, I know there is no such thing as typical, but could you tell me, based on your experiences, how much product usually comes back from the customers? Because more often than not a certain amount of whatever it is has made its way out the door.

Dr. HANLIN. Yes, sir. I can provide good information on what we are destroying at store level and at DC level. We would be very happy to follow up with you to try to understand how much prod-

uct is actually being returned by our shoppers. I don't have that information in front of me, but we can follow up with you on that.

Mr. ERLANDSON. And Congressman, I would add, on the recalls, in the case of just the pistachio situation, the retailers are pulling the product that is being targeted off the shelves as fast as they can because as many people have said today, there is nothing more important than food safety to those of us in the food business. And what becomes so important there is that as the investigation goes forward, that the people investigating the product, whether that be the manufacturers or the government do so efficiently and quickly so that you don't have products like in the case of tomatoes rotting on the shelves in the back or being destroyed when they certainly didn't need to be destroyed.

Mr. LUCAS. Exactly. Thank you for those insights. Thank you, Mr. Chairman.

The CHAIRMAN. The gentleman, from North Carolina, Mr. Kissell.

Mr. KISSELL. Thank you, Mr. Chairman. I apologize. I was enjoying some of these peanuts.

In the model that you are proposing, and the cutoff between FSIS and FDA, you talked about the bright light of where the divide should be, is any consideration given in your experiences to which side of those two agencies does a better job in terms of food safety?

Dr. HANLIN. Well, the previous panel articulated the fundamental differences between the jurisdictional powers that USDA and FDA have. Our concept here is that with respect to the USDA regulations, that we have a model that is working. We have a model whereby the USDA, their programs, have really helped drive down the *Salmonella* rate in poultry. We respect that there are huge challenges, and they haven't achieved the same quality of results with respect to *E. coli O157:H7* in ground beef, but the methodology, the inspection, the surveillance, the enforcement, the training that USDA provides, the risk-based approach, which really has helped improve the safety of the meat and poultry products. And so our concept here is how do we take the ideas, the concepts, the risk-based method and try to apply it to categories that currently don't see the same level of inspection.

It is not a one-size-fits-all, and clearly the type of inspection for spinach and leafy greens, the way that they are processed and handled may be different for tomatoes, it may be different for apples. But again, that concept of reducing, eliminating, and preventing hazards using a risk-based approach we think is very powerful.

Mr. KISSELL. You were also talking about when there is an alert that goes out, and the inspections that have to take place with what you have in the stores or in the supply chain or what is brought back to you. Is it consistent that the product is checked quickly or you might have insinuated, or maybe I just understood that perhaps there is a length of time there that we just don't get the inspections done as quickly as we should.

Dr. HANLIN. Could you describe what you mean by——

Mr. KISSELL. Well, once something has been defined as——

Mr. ERLANDSON. A recall?

Mr. KISSELL. A recall, yes. And you halt the product, whatever it is in the supply chain stores, warehouses, and it comes back in maybe from customers, is that inspected quickly? I just got the insinuation perhaps that you thought that perhaps it didn't get inspected as quickly as it should, and perhaps we didn't get on top of it as quickly as we could. I mean, it may have just been something I picked up.

Dr. HANLIN. At SUPERVALU, we execute recalls as quickly as we can with the best available information. It is all about protecting the consumer. And so we will execute recalls and pull product perhaps before we have all the information that we need. Sometimes we know if it is just going to be a couple more minutes while the supplier gives us the UPC, we will wait a couple more minutes. But again, we are ready to hit that recall button, but we want to make sure that we have accurate information. But it is very time-sensitive. As soon as we execute that recall for products that are frozen or refrigerated, we will dump and destroy. We want to get them out of our system as quickly as possible and make sure they are unavailable to anyone in our shops or DCs.

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

The CHAIRMAN. I thank the gentleman. Well, we have been called to vote, and the Members, like everybody else, have had about enough. But, you have brought some very interesting perspective to this debate, and it is a new way of thinking about how to approach this that has some merit. And I want to not only the Committee Members but others to be exposed to this as we go. I don't know how many Members you have had a chance to talk to yet of the other Members but——

Mr. ERLANDSON. We have been working our way around, and it is quite well-received. It just takes a little while for people to wrap their arms around. So we appreciate that.

The CHAIRMAN. Yes, I had a meeting yesterday with Ms. DeLauro for some time. Apparently you haven't got to her yet, I guess.

Mr. ERLANDSON. We have talked to her staff, but apparently they haven't gotten to her yet.

The CHAIRMAN. Okay. She wants to, if you get a chance, she would like to talk to you guys directly, too. So the more we can get all the different players that are involved in this, get as much information as we can, I think the better chance we have in coming up with the right solution. Clearly there is improvement that can be made in food safety, and that is what our Committee is about here. We are trying to do our part to make sure we get a safer food system and protect people as much as possible. And we appreciate very much your involvement and your addition to this process. Thank you for being with us, being so patient, and we will probably as we get down the line here, we will probably have you involved again in whatever we end up doing.

Mr. ERLANDSON. We appreciate it.

The CHAIRMAN. And the Committee stands adjourned.

[Whereupon, at 3:40 p.m., the Committee was adjourned.]

[Material submitted for inclusion in the record follows:]

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Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain

2ND EDITION

NAFTWG

United Fresh
PRODUCE ASSOCIATION

JULY 2008

Special thanks to all of the companies, agencies, trade associations and individuals who helped in developing the 2nd edition of this guidance.

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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.

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.

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.

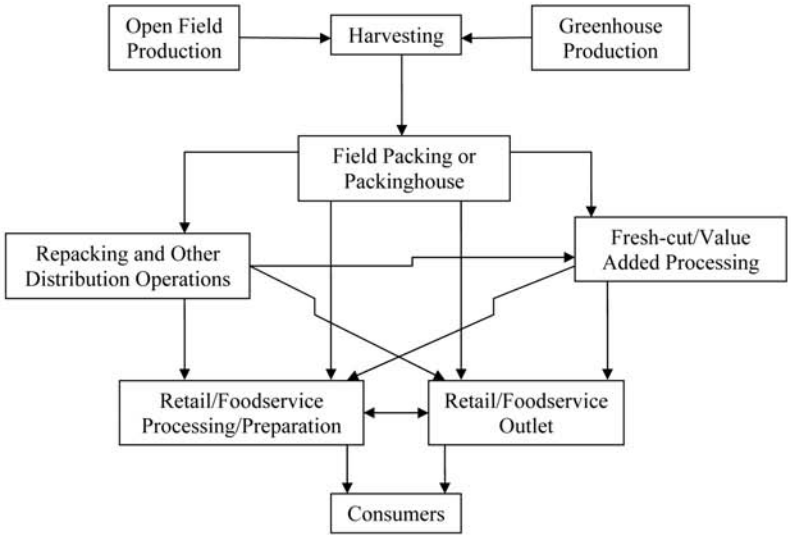
In 2004, the FDA published a food safety action plan that specifically requested produce industry leadership in developing the next generation of food safety guidance for fresh fruits and vegetables. These new commodity-specific guidelines focus on providing guidance that enhances the safe growing, processing, 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 (≥140ºF) 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 not in use should be stored appropriately.
   vi. 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 7 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.
i. If tomatoes are harvested at multiple times, fields should be assessed sufficiently to assure that new risk factors have not emerged.

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 (≥140ºF) 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.

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 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 (≥140ºF) 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 (≥140ºF) 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 with sanitizer, in accordance with label instructions, to reduce microbial levels.
   i. Consumer-ready containers shall be labeled to identify when the product has been field packed without washing.
b. A written procedure for washing and sanitization as well as records of implementation of the procedure shall be maintained.
c. 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.
d. 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.
e. 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.

f. Cold water immersion as a cooling technique shall not be done.
g. Water temperature shall be maintained at least 10ºF warmer than the pulp temperature of the tomato. Water temperature shall be monitored at least hourly.

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 recall program, 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 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 (≥140ºF) 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 (≥140ºF) 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 10ºF 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 recall program, 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.
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 10ºF 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 (≥140ºF) 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 recall program, 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.
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 (≥140ºF) 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 (≥140ºF) 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 10ºF 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 (≤41ºF).

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 41ºF.
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 41ºF.
b. Finished products shall be transported in pre-cooled vehicles equipped with a calibrated temperature monitoring 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 recall program, 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.

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$41ºF, and requires continuous temperature control during transport.
e. Cut tomatoes >41ºF 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$41ºF, 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. Do not allow food, drink or tobacco products in the food preparation, cleaning or storage areas except as permitted by the Food Code or state/local requirements.
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 authorized for hand contact of ready-to-eat tomatoes at foodservice/retail operations. When gloves are utilized, only single-use, disposable gloves should be worn.

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 (1.326-1.368). 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 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.

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

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