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FOOD AND DRUG ADMINISTRATION

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MINIMIZING MICROBIAL FOOD SAFETY RISKS

FOR FRESH PRODUCE

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Dr. Terry Troxell
Dr. Catherine Woteki

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P R O C E E D I N G S

Welcome

DR. SHANK: Good morning. I would like to introduce a few people. At the in-between table will be seated the Subcommittee for Produce from the National Advisory Committee for Microbiological Criteria for Foods. Today is a public meeting on the President's Initiative to Minimize the Microbial Food Safety Risk from Fresh Produce. Tomorrow, the National Advisory Committee for Microbiological Criteria for Foods will be meeting. This will be an important topic on their agenda as well. For those of you who are wondering who I am, my name is Fred Shank. I am the Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. I think that we will move right on in to our program with introductory remarks. As we get further into the program this afternoon and really start discussing the guidance, or later this morning, at least, I will have some more comments to say at that time. But let me take this opportunity to welcome Dr. Michael Friedman who is the Lead Deputy

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Commissioner of the Food and Drug Administration. We will call on Dr. Friedman to present some opening remarks.

Introductory Remarks

Dr. Michael Friedman

DR. FRIEDMAN: Thank you.

Ladies and gentlemen, when President Clinton announced the Initiative to ensure the safety of imported and domestic fruits and vegetables last month, he assigned the Secretaries of Health and Human Services and the Department of Agriculture a very important task. He instructed them to work together with industry and all other relevant parties to design sensible, effective, scientifically-based guidances that will safeguard the wholesomeness of fruits and vegetables that we consume.

Today, we take the next step in the search for appropriate measures that will minimize the risk of microbial contamination of fresh fruits and vegetables, those grown both domestically and imported.

I certainly welcome all of you here and I especially welcome USDA's Under Secretary Cathy Woteki and her staff. They are

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our valued partners in this effort. We also appreciate the hard work of our sister agencies and especially I want to note EPA and CDC. Our is a collaborative effort amongst government agencies, as well as parties in the private sector.

I also particularly want to welcome the panel members of the Fresh Produce Subcommittee of the National Advisory Committee on Microbiological Criteria for Foods. Your role will certainly be an important one in helping FDA along with USDA and EPA as we develop these new guidances.

We are not, however, limiting this process to just the relevant parties in government and industry. This must be a very public discussion. No one agency or industry has all the wisdom necessary to guarantee the safety of our food. We are soliciting everyone's best ideas.

As the agency leading this effort, it is FDA's job to make sure that we capture and incorporate these best ideas. To achieve this, we will hold a number of grass-roots meetings nationwide to deal with the general issues that I have described and one in Washington to focus more specifically

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on international implications of these concerns. That will occur in the beginning of December.

These meetings will provide an opportunity for the public and for industry to comment on proposed guidance. This is a work very much in progress and today we will present our current thinking on the guidance for really the first time. The discussion will cover a number of important areas essential we think to Good Agricultural Practices, and these will include water, sanitation and hygiene, manure and municipal waste, sewage sludge, transportation, and traceback. Although the issues and discussions may be technical, their resolution can have a huge and direct impact on the public health.

Because of the very preliminary nature of these guidances, a complete, albeit an initial draft of the material will not be available until the public meetings beginning on December 1st. We want to be clear that we have ideas about what the guidances should include, but we also very much want to listen carefully to what you have to say before we assemble the first draft.

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We expect to publish the proposed guidance in the Federal Register sometime in early 1998 and allow adequate time for everyone to comment before the guidances are finalized.

I want to reassure you that the goal of our guidance is not to raise economic or administrative obstacles for food producers. The goal is to develop prudent, practical steps that enhance the safety of our food supply. These will be guidelines, not regulations, nonetheless, we take them very seriously.

Let me add a personal note, if I may. I apologize that I won't be able to stay throughout the entirety of this meeting, which is a polite way of saying I must make an exit immediately after my remarks. I apologize for that. My schedule is a conflicted one and I must be at another meeting. I would very much like to listen and participate in the meeting today, but I am very confident that the group assembled here will make a very productive start in our discussions.

We will work very hard to include everyone. Protecting the nation's food supply is a very serious business, it is a

very important job, and we all have very high expectations for doing it very well.

Again, I appreciate your attendance, I thank you for your participation, and wish you luck in this endeavor.

Thank you all very much.

[Applause.]

DR. SHANK: Thanks, Mike.

Our next presenter is Dr. Cathy Woteki. She is the first confirmed Under Secretary for Food Safety at the U.S. Department of Agriculture.

Cathy, would you come forward and give some introductory remarks.

Introductory Remarks

Dr. Catherine Woteki

DR. WOTEKI: Thank you, Dr. Shank, and good morning to all of you, as well.

It is a pleasure to join Dr. Friedman in welcoming you to this Public Meeting on Microbial Safety of Fresh Produce. The Food and Drug Administration and the Department of Agriculture have had many opportunities to work closely

together over the last several years on a variety of food and nutrition related topics. Nutrition labeling is a good example, the development of the Farm to Table strategy, the approach that we are using towards food safety is another, and most recently, this President's Safety Initiative.

We look forward to working with the Food and Drug Administration on this new aspect of the President's Food Safety Initiative to ensure the safety of imported and domestic fruits and vegetables.

Although the reported incidence of foodborne disease from fresh produce is relatively low, we believe that it is increasing, and at the same time, for the nutritional value and for the long-term health promotion value of the consumption of fruits and vegetables, we are recommending that people eat at least five fruits and vegetables a day. That is the cornerstone of the dietary guidance that the Department of Agriculture and the Department of Health and Human Services issued jointly.

Therefore, the consuming public has to have confidence that the produce that is available to them is consistently safe.

We certainly believe that industry has the primary responsibility to produce safe food, but government also has a responsibility, and that is to set standards and to provide guidance, as appropriate, on issues of food safety. A "one size fits all" approach won't work, however, for all foods. The full range of options from education to regulation has to be explored for each of the various commodities.

For produce, we believe it is appropriate for government to provide the industry with guidelines for guidance for Good Agricultural and Good Manufacturing Practices, but regardless of the approach that we take, standards and guidance should be science based and that is the direction that this initiative is taking.

They also should be established through a public process providing all interested parties the opportunity to provide input and therefore we are having this and the other meetings that Dr. Friedman described, so that is why we are here today and why FDA will be holding more public meetings around the country.

As you know, FDA will be taking the lead on this initiative, but the Department of Agriculture has an important role, as well. The President directed the Secretaries to work together and in close cooperation with the agricultural community to issue guidance on Good Agricultural and Good Manufacturing Practices for produce.

Secretary Glickman has asked that I coordinate the activities within the Department of Agriculture in implementing this directive and providing FDA with the support that it needs, and I am pleased actually to have been asked to take on this responsibility.

I believe that USDA has got a lot to offer to implement this initiative. We certainly have got a very strong food safety research program and can provide expertise on current knowledge related to produce safety. In fact, the Department is going to begin this spring a major research initiative addressing fresh fruits and vegetables in direct support of this initiative, and the research will help us to answer some important questions regarding the use of manure in the cultivation of fruits and vegetables. We also need

to know the food safety implications of some of the new processing techniques, such as fresh cut and modified atmosphere packaging.

Once guidance is developed, USDA has an extensive education network that can help to get the word out. Through the Cooperative Extension System, all producers in every county in the United States will have the opportunity to learn about proper growing techniques to minimize food safety hazards.

We have got thousands of educators across the United States who can help producers look at their own practices and determine what changes they need to make their produce safer.

So, in closing, over the past several years we have learned a lot about what it takes to make a good food safety strategy. We know, for example, that we have to base our decisions on sound science and we have to have the data to actually back up those decisions.

We also know that each of us, whether we represent government, industry, or the public, have to take on our own

fair share of the responsibility for food safety and we know how important it is to form partnerships to get the job done more quickly and more effectively.

Lastly, we know that the public has to be involved in every aspect of this decisionmaking process. There are many challenges ahead, but I believe we have got a good framework in place for making significant food safety improvements. I am by nature an optimist and I am optimistic that we can work together to make produce safer for the public.

Like Dr. Friedman, I also have to give you my regrets. I can't stay for the entirety of this meeting, but as I look out over the audience, we are well represented here from the Department of Agriculture. Maureen Kelly from my staff has a major role in coordinating activities and will be here through the meeting. I notice Jane Robbins is sitting in the back. She has had a major responsibility for the research aspects, and you are going to be hearing from Dr. Dye later on in this opening program.

So we, as I said, are well represented here and have an enormous interest in seeing that this initiative moves

forward on the soundest scientific base as possible with as much public input as possible, as well.

Thank you very much.

[Applause.]

DR. SHANK: Thank you, Cathy.

Our next speaker will actually address the Presidential Produce Initiative. This is Tom Gardine, who is Director of the Division of Import Operations and Policy at FDA.

Tom, are you ready to do it and do we have our slides ready to go?

Presidential Produce Initiative

MR. GARDINE: Good morning, everyone. It is a pleasure to be here today.

[Slide.]

I am here today to provide you with an overview of the President's new initiative to ensure the safety of fresh fruits and vegetables, both produced in the U.S. and imported produce, and how FDA, in conjunction with USDA and other involved federal agencies, are planning to implement the President's commitment to this important public health

project.

[Slide.]

President Clinton announced the new initiative on October 2, 1997. Although produce is generally considered a safe commodity, some problem areas have been noticed in recent years. The President stated in his announcement about the new initiative that, "We can and must do better especially at a time when Americans are eating more fruits and vegetables from all over the world."

This new initiative provides the mandate to improve the safety of fruits and vegetables. It is important to note that this initiative will not involve new regulations or legal requirements on U.S. industry or foreign industry. Rather, it will involve an effort by the government to provide guidance and assistance to industry, so that they can become more aware of the ways that they can best help ensure the safety of the foods they produce.

The initiative will also involve new efforts to ensure that foreign producers who ship foods to the U.S are meeting the same standards as U.S. producers and are not shipping unsafe

produce to the United States.

[Slide.]

Why now? Why is this initiative necessary at this time? As you may be aware, FDA is in the midst of a major food safety initiative since early 1997. Why is a special emphasis and a special initiative needed now for produce?

Thirty years ago, most produce sections in grocery stores had only about a dozen items year-round, increasing to about 50 in the summer months when more local fruits and vegetables were available. Only a few fruits and vegetables were imported and reaching American consumers.

Today, on the other hand, in most metropolitan areas across the country, there may be 100 items in the produce aisle to choose from, many of these available to consumers on a year-round basis. Americans in the nineties are more health conscious and are focused on living longer, healthier lives, and in eating a better diet.

As you have heard, the Federal Government is encouraging, through programs such as the National Cancer Institute's Five a Day Program, the increased consumption of fruits and

vegetables in this country, and data shows that the American public is indeed increasing its consumption of fruits and vegetables.

At the same time, our environment is changing. New and exotic microbes are emerging faster than scientists can develop effective detection methods and identify ways to kill the new microbes. We have seen a number of high-profile outbreaks in the past year, two of which are up there, Cyclospora in raspberries, hepatitis A in strawberries, E. coli 0157:H7 in apple cider.

[Slide.]

Why now? Why produce now? Imports of produce have increased considerably and are expected to continue to increase. This is the reality that we are all living with. Current data is not complete enough to tell us whether more foodborne illnesses are due to imported fruits and vegetables than domestic produce.

That is in no way sure. However, we do know that some safety problems exist in imports because a number of the recent foodborne illness outbreaks have been traced to

imported produce, the most well known being Cyclospora, which was epidemiologically linked to Guatemalan raspberries in 1996 and 1997.

Furthermore, the reality is we do not know as much about the conditions and regulatory systems under which many foreign fruits and vegetables are produced. While we do conduct some border sampling of incoming produce for microbiological hazards, our resource constraints have kept that sampling to fairly low levels.

Furthermore, we have simply not had enough resources, personnel, nor specific statutory authority in the past to send inspectors abroad to adequately evaluate conditions in exporting countries.

[Slide.]

What are the elements of the President's initiative? There is, first, a legislative component of it, an administrative component of it which has two parts, the industry guidance that both USDA and FDA and other agencies are developing which you will hear a great deal about today, a budget request, and a requirement for the involved agencies to

submit a 90-day report to the President.

[Slide.]

First, a little about the legislative proposal. The President is proposing that Congress enact new legislation that would allow FDA to halt food imports from any foreign country whose food safety systems do not achieve the level of protection required by U.S. law.

Under current law, FDA can halt imports at the border if they appear to be adulterated. The burden of proof, however, is one FDA. We have to sample the product, analyze it, and find it bad.

This is an inefficient system from the resource point of view and from a food safety point of view. We believe the best way to ensure the safety of imported foods is by having systems in place that minimize microbial contamination at each point along the production chain, not only to rely on endproduct testing.

Therefore, the new legislation would allow FDA to take action should it be determined that a country's food safety system for fruits and vegetables, and other foods, are not

comparable to ours. This is the type of system already being used by USDA's Food Safety and Inspection Service to regulate imports of meat and poultry.

USDA first examines the foreign country's food safety system to see if it is equivalent to the U.S. system before allowing meat or poultry imports from that country to be imported into the United States. USDA monitors these countries to be sure that their systems remain acceptable.

So, what President Clinton is proposing that Congress approve for the FDA is not a new idea, it is something that USDA has been working with for some time, and it is a system that has been proved effective.

The proposed legislation would also allow FDA to consider refusals of inspection as one criteria in determining if it is necessary to halt imports from specific firms or areas of the world.

It is important to note that the new legislative proposal would be consistent with free trade principles and the Unites States' obligation under trade agreements with other countries.

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[Slide.]

The second major elements in the President's new produce safety initiative is administrative. FDA, in cooperation with USDA, is to issue within one year guidance for Good Agricultural Practices, which I will probably refer to as GAPs hereon out, and guidance for Good Manufacturing Practices, which I would refer to when they come up as GMPs. Furthermore, and very importantly, to build on what you have heard already, FDA and USDA are to coordinate assistance and educational activities to both domestic and foreign industry to educate them in the Good Agricultural Practices being designed to minimize microbial hazard. We can't eliminate it, the goal is to minimize microbial hazards in fresh produce.

[Slide.]

The status report to the President, due in 90 days, will have to involve a plan to improve monitoring of agricultural and manufacturing practices both domestically and with countries exporting produce to the United States, a plan to increase border surveillance and surveillance in exporting

countries to minimize the importation of unsafe produce, and once again very importantly, our plan to assist both domestic growers and foreign countries to improve agricultural practices when possible problems or routes of contamination of microbes are noted.

[Slide.]

As you will hear many, many, many times today, the GAPs and GMPs being developed are guidance based on the available science, the good science, not regulations, not binding requirements on the agricultural sector. Our goal is to help firms identify appropriate practices to minimize microbial hazards, to educate them in these GAPs and GMPs, and to work with them to correct any problems that might be noted.

[Slide.]

I will go over this very quickly, but you will be hearing today that our broad-scope, Good Agricultural Practice document being developed jointly by FDA, USDA, and other involved agencies, will focus essentially on four major areas of possible microbial contamination - water quality,

manure management, sanitation, both worker sanitation and facility, and transportation and handling of the produce.

[Slide.]

The real question becomes what impact will these documents have once they are completed, how will they affect the farmer in practical terms. The President has instructed the involved federal agencies to develop outreach in educational activities, and we have already taken steps to begin this work.

FDA and USDA are developing plans to work with farmers and answer their questions about the new Good Agricultural Practices and Good Manufacturing Practices. Domestically, the bulk of the outreach in educational work will probably be carried out by the network of USDA agricultural extension service agents, who already have strong ties with farmers and practical knowledge of local farming practices.

These agents are knowledgeable in non-farm assessments and can provide advice to individual farmers on potential problem areas in their operations and how to improve their practices. We also hope to work with trade associations in

this process, and states, as well.

[Slide.]

You will be hearing a great deal today about the Good Agricultural broad-scoped document being developed. I would like to talk a bit about my area of expertise, and that is dealing with imports.

Let's talk a bit about the steps we plan to take in getting ready for Fiscal Year 1999. We hope to select countries and products to be evaluated overseas based on criteria of those that are likely to exhibit the most risk to the American consumer.

We have to plan on how to best use both FDA and USDA resources. This is a joint effort. FDA has a role and certainly USDA, through APHIS and the Foreign Agricultural Service, will play a very, very big role in planning these assessment visits and doing the assessments.

We have to plan for sampling in FY '99, both domestically and imported, to try and develop baselines for the amount of microbes of potential hazard that might be associated with fresh produce.

We have to prepare our protocol for foreign country evaluations, what exactly are we going to look at when we do these foreign country assessments, and working with the Foreign Agricultural Service and APHIS, develop profiles of some of the countries shipping produce to the United States.

[Slide.]

Once again, a large goal of this initiative is technical assistance, not only to the domestic grower, but we will be required to provide technical assistance to foreign countries. We will in the coming year be developing training modules to work with foreign countries, and we will be coordinating development of non-FDA training networks, working with international organizations, the foreign country governments, and non-governmental organizations to do a lot of this training.

Finally, we have to find ways within the limits of our resources to increase screening and evaluation of produce entries coming into the United States. A component of our program is, and always will be, border surveillance, focusing on high-risk produce to be the last check before

the product enters the United States to give us a hint of where problems may be developing.

[Slide.]

Finally, some guiding principles for the President's initiative. As you have heard already, it will be science and risk based. Our goal is to minimize the burden that the initiative places on farmers. We are not interested in setting up a lot of meaningless hoops for farmers to jump through.

Our goal is to come up with the best practices for handling produce on the farm that are practical, sensible, doable, and will contribute to food safety without overburdening the grower.

Third, we are committed to equal treatment of domestic and foreign firms. We have a commitment to domestic firms to ensure that there is an equal playing field between them and foreign firms, and we have an equal commitment to foreign firms not to discriminate against them in any way. Our goal is simply to ensure that both domestic and foreign firms meet the same standards and produce a safe product for the

American consumer.

Fourth, we are committed to acting in a way that is consistent with World Trade Organization rules, that is, the rules of our international trading obligations. We have no interest in setting up trade barriers. Our mission is to carry out a science-based process to ensure that the U.S. level of health protection is met and that the U.S. consumer is assured a safe supply of fresh fruits and vegetables.

With that, lights on, projector off, and thank you very much.

[Applause.]

DR. SHANK: We have got a couple of minutes if anyone has any questions for Tom.

MR. AGUIRRE: John Aguirre with United Fresh Fruit and Vegetable Association.

You indicated that one of the reasons for moving forward with this produce initiative was the occurrence of two high-profile outbreaks, one of which was hepatitis A in strawberries. Then, also, Tom, you mentioned E. coli 0157:H7 in unpasteurized juices.

MR. GARDINE: Correct.

MR. AGUIRRE: I am very disturbed by those references. The hepatitis A in strawberry outbreak was, in fact, with a frozen processed commodity. Likewise, unpasteurized juice again is a form of processing, and I would like to understand why the Food and Drug Administration chooses to use references to processed goods as indicating that there is a problem with whole produce commodities.

MR. GARDINE: John, I referenced those because they were very, very high profile cases. I think no one in this room is about to say that we know exactly where the hepatitis A entered the product, and I will grant you that. My purpose in mentioning those three instances was to show the high visibility this is getting and the fact that it is certainly reaching the antenna of the American consumer.

MR. AGUIRRE: Just one comment. Since we do have the benefit of having press here today, it is extremely important that we be very clear and precise about the examples that we use and that we not make mistakes as we have seen in the past in the press to confuse frozen

strawberries that have very distinct handling characteristics with the safety and quality of fresh whole strawberries, and I just want to make that point clear.

MR. GARDINE: And for the press, a point very well taken.

DR. SHANK: Any other questions? Yes.

MS. VOGT: I am Donna Vogt from the Congressional Research Service.

MR. GARDINE: Yes, Donna, good to see you again.

MS. VOGT: My question is simple. Do you have any time frame for this legislation that will be introduced?

MR. GARDINE: Well, the legislation, to the best of my knowledge, was submitted to both Vice President Gore and Speaker Gingrich by Secretary Shalala November 13. I believe we have two congressional sponsors to submit the legislation. I do not have a number for the bill yet, unfortunately. As of Friday, I couldn't find that out.

MS. VOGT: Thank you.

DR. SHANK: Thanks, Tom.

Our next presenter is from USDA, Dr. A.J. Dye, who is Assistant to the Administrator, Competitive State, Research,

Education and Extension Service.

Dr. Dye will address the FDA/USDA Partnership.

FDA/USDA Partnership

DR. DYE: Thank you, Dr. Shank. Good morning.

I came late, so I didn't get to hear everything that Dr. Friedman said, but it was shortly after this announcement came out many of us were together in a room that Dr. Woteki hosted a lot of different agencies to come to this thing and talk about how are we going to handle it from the federal perspective, and upfront, even though I am asked to talk about the USDA/FDA relationship, we had other agencies there - EPA was with us in force, as well as CDC and others.

To talk about this partnership, one quick sentence. When I spoke to Tom last week, he said, A.J., I would rather be giving your speech than the one he just finished, so it is truly a partnership.

Within the domestic side, within USDA, we have got several agencies that are actively working with us, the Agricultural Research Service, the Cooperative State, Research, Education and Extension Service, which I am part of, the Ag Marketing

Service, and APHIS, the Animal and Plant Health Inspection Service.

Those agencies are primarily working on the domestic side, then, APHIS helps, of course, as you well know, on the international side, as well as FAS, which Tom has already referred to, will be working with us to get the message put together.

Now, with Extension Service, we have got about 6,000 or so educators across the country working primarily in agriculture and natural resources. Those educators live in the community, they are part of the community, they are used to having a very open decisionmaking process. So, as far as the industry is concerned, I think accuracy and precision, as a question earlier referred to, we have got to be accurate, but it also allows an opportunity to let everyone at the table, and when we get groups together that may not agree on an issue, but that can discuss it and can witness the decisionmaking process, it has been our experience generally that the decisions are stronger, everyone may not leave the table happy, but at any rate they understand how

the decisions were reached, and I am hoping that that is what we can more forward with, with the FDA/USDA partnership and reaching the growers.

I think Dr. Gomez will be addressing some of the issues in a few minutes around what the states can do and what Cooperative Extension can do, and what tools are available, because it has to be a voluntary process to a large extent. We have got a system in place, we don't have to create another one, and we want to encourage your input to these town hall listening sessions.

Dr. Shank, were they mentioned earlier?

DR. SHANK: The concept has been introduced. We haven't go into any specifics.

DR. DYE: Okay. Let me just very quickly say to you, so that you are aware, of six listening sessions that are coming up the first two weeks in December. We will start in Michigan on December 1, Grand Rapids. Over on December 3 to Geneva, New York. On December 5 -- Dr. Gomez is shaking his head, because I think he is the lucky individual that gets to go to all of these -- on December 5, we are down at West

Palm Beach. December 8, San Antonio, Texas. December 10, Salinas, California. December 12, suburb of Portland, Oregon.

So, encourage your colleagues in the different regions of the U.S. to be there and to provide input and to ask questions, and be part of the process as we develop the guidelines.

I think, Tom, you have said just about everything else that we need to worry about saying on the USDA/FDA partnership.

MR. GARDINE: One advantage of going first.

DR. DYE: Thank you.

[Applause.]

DR. SHANK: Continuing with the concept or partnerships, the next presenter will address the State Perspective, Dr. Richard Kirchhoff, who is the Executive Vice President and Chief Executive Officer, National Association of State Departments of Agriculture.

I don't see him. Caroline, do you want to go early? Do you promise not to use a whole half-hour?

Ms. Caroline Smith DeWaal, who is the Director of the Food

Safety Program, Center for Science in the Public Interest will present a Consumer Perspective.

Consumer Perspective

MS. DeWAAL: Thank you, Fred.

It is good to see people from the National Advisory Committee on Micro Criteria for Foods here, as well.

My name is Caroline Smith DeWaal, Director of the Food Safety Program at the Center for Science in the Public Interest.

CSPI is the largest consumer advocacy organization which focuses almost entirely on food issues. We represent nearly 1 million consumers in the U.S. and 100,000 consumers in Canada. My job is to focus exclusively on food safety issues, and as you can imagine, this is keeping me pretty busy these days.

Since 1990, food poisoning outbreaks from fruits and vegetables have been common fare for American consumers. Salmonella on cantaloupes, tomatoes, alfalfa sprouts, and in orange juice, harmful E. coli in apple cider and on lettuce and in alfalfa sprouts, parasites like Cyclospora and

Cryptosporidium on raspberries, lettuce, and in apple cider, and hepatitis A on strawberries. We have had two outbreaks, not just the one last spring, but also one around 1990. CSPI has identified 26 outbreaks since 1990 involving over 5,000 cases of illness, and these outbreaks represent just the tip of the iceberg. Fruits and vegetables are rarely the first food suspected when people become ill from Salmonella or E. coli, so it takes a lot of detective work to track down a fruit or a vegetable culprit in a food poisoning outbreak. There are many outbreaks that go unrecognized and many, many consumers that remain uncounted.

Second, let me be clear. Food poisoning is not just a bellyache anymore. When we talk about the bacterium E. coli 0157:H7, for example, we are talking about a devastating human pathogen. It is the single largest cause of renal failure among American children.

Just a few bacteria can leave a child hanging between life and death for weeks on end, while the parents hope and pray. There is no treatment yet. Doctors support the children through blood transfusions and kidney dialysis, which can be

very tough treatment for a little child. Not all infected children die, thankfully, but the survivors often have life-long effects from the illness, and children aren't the only victims. It causes severe illnesses and deaths in adults and elderly, as well.

Cyclospora can cause a devastating illness if left untreated. It can cause weeks of extreme fatigue and result in consumers losing 20 or more pounds. While fruits and vegetables are, for the most part, safe and wholesome, these outbreaks signal a disturbing trend.

Because these products are frequently eaten without cooking, they must be safe when they reach consumers. There is no at-home treatment that I can tell consumers about that will guarantee that the products are safe. Safety has to be built in from the ground up, so to speak.

Eliminating the source of contamination, whatever is putting E. coli 0157:H7 or other pathogens onto these fresh products is the key to protecting the consumer from our standpoint.

The President announced that this administration would establish guidelines for agriculture to help identify and

implement a set of practices, both on farm and in commerce, that will maximize the safety of these products. While we strongly applaud President Clinton's recognition of this product, CSPI urges the Clinton administration to mandate HACCP systems for the produce industry rather than guidelines. It is not enough to set guidelines for industry to follow as they wish. Guidelines will not address the problems with the domestic industry and they will be unenforceable internationally.

HACCP was first developed as a safety control program for the food industry. Its history documents that where you have motivated companies with a commitment to safety and good scientific backing, HACCP provides an excellent framework for improving the safety of food.

HACCP is a highly useful tool for changing food production practices. HACCP is designed to meet the individual circumstances of each farm or food processor. HACCP plans would ensure that the water is checked and that the manure is composted or otherwise sanitized.

HACCP plans could cover employee handwashing before handling

food and temperature controls for storage of fruits and vegetables. HACCP systems cover many things that good producers and processors are already doing, but it requires them to monitor and record these steps. In the long run, HACCP will be widely used in the food industry and even on the farm.

The Clinton administration should embrace this movement and require that fruits and vegetables be covered quickly. While HACCP provides a good structure for these food safety reforms, it is not a magic bullet in producing safe products. To work effectively, HACCP should be married to the best science and the best technology. However, we are lacking a lot of the science that we need to create perfect systems for safe food production.

Luckily, HACCP is a system that is flexible enough to allow new scientific findings to be utilized as they become available without the burden of changing the regulatory framework. Under this system, the industry is not frozen in time to the science of the day, which makes it an excellent system to implement today for the fruit and vegetable

industry.

As the science and the technology improve, the HACCP systems in use can also improve, and we will have the opportunity to enforce these newer safeguards for foreign fruits and vegetable producers if we mandate HACCP, but not if we only mandate guidelines or develop guidelines.

HACCP also gives the industry the flexibility to use one pasteurization step, if it's available, or multiple contamination hurdles, so that you can maximize safety while retaining full control over the final product.

Voluntary guidelines are not the public health response needed to address the myriad food safety problems cropping up in fruits and vegetables. Instead, a mandatory HACCP system will provide the maximum protection for the public, together with the most flexibility to incorporate new science and technology as it becomes available.

It is important to remember that this is not a minimal public health problem, nor is it one linked solely to imported foods. Outbreaks linked to E. coli 0157:H7 on fruits and vegetables have increased from 5 to 15 percent in

just a few years, and these have mostly been linked to domestic products.

Ultimately, the goal must be to identify and eliminate the source of contamination for fruits and vegetables. This in the long run will have the greatest public health impacts, which I am sure we are all seeking.

Thank you.

[Applause.]

DR. SHANK: Thank you, Caroline.

Farm Perspective, Dr. Ricardo Gomez, who is the Principal Horticulturalist, Competitive State, Research, Education and Extension Service of the USDA.

Dr. Gomez will address the issue from a Farm Perspective.

Farm Perspective

DR. GOMEZ: Thank you, Dr. Shank, and good morning. It is a privilege to be here to describe, first of all, myself, my agency, and some of the farm needs for this type of program to go forward and be fulfilled.

First of all, my academic training in research and extension was at the University of Florida, in both soils, soil

fertility, and horticulture, and fruit production. From there I went to a land-grant institution, New Mexico State, where I had statewide responsibilities in horticulture, both in fruits and vegetables, so I have had ample experience in fruit and vegetable production, in being able to work with producers and with industry, processors.

Here, at USDA, I am, as was stated, the Principal Horticulturist, which means that I have both research and extension responsibilities.

What does that mean? Well, I need to describe my agency a little bit more, and we should have given Dr. Dye about two additional minutes, and he would have done so, but my agency is a merger of the Extension Service and the Cooperative State Research Service.

Bring those two together and you have what we are now, the Cooperative State Research, Education and Extension Service, and we have nationwide leadership responsibilities for programs through the Agricultural Experiment Station system and the Extension system.

We have Experiment Stations and Extension Services

throughout all states, territories, and possessions. As Dr. Dye mentioned, we have over 6,000 capable staff in the Extension system. We have fewer than that in the Research, and many individuals are both Research and Extension, so that there is a link, and this link, the Research and Extension link is what makes us, at the state level and at the local level, know of what the needs of the farmers are. Extension brings back to the researchers the knowledge and the feedback from the farmers, so that they can be addressed through research.

Our agency is a partner in both the experiment station and the extension systems. It does not run, it is not a direct line type agency group, it is a partnership. The Federal partner funds about 30 percent of the whole system, and the State and local, the rest, so it is a true partnership.

The agenda says that I am to address the farm perspective, and I just want to make it -- some of the words may sound familiar -- perfectly clear to you that I am not speaking for the industry itself. I am trying to give you some of my insights into how one works with the producers and the

agriculture industry as a whole.

To do that, I need to give you a couple of examples. I would like to give you a couple of examples of very successful programs and how they came about. One of them is the Integrated Pest Management Program, which has been adapted and adopted by a large percentage, and continuing to increase the percentage, of the farm community or the agricultural industry.

It is a program that is based on good science, carried out by three entities that are in the agricultural research arena. One is the Experiment Station System, the other one is, as Dr. Dye mentioned, the Agricultural Research Service, which is the intrahouse research arm of USDA, and private industry.

That is where the knowledge is generated, and it is extended through information and educational programs, through the Extension Service, from the State and local levels, as well as other groups, and one of them is the agricultural consultants, and we are very, very much aware that that is a growing facet of the agricultural production industry.

By the way, the agricultural consultants is a group that really is an offshoot of the Extension Service training for producers in the area of Integrated Pest Management. That group of consultants grew and is still backed up on recent research and education by the Extension system, so it is an industry that has been created to meet the needs of producers because Extension really does not have, at this point in time, the resources to meet all the needs of the producers.

One of the reasons that it is a very successful program is that it is a voluntary program. There are few, if any, regulations. As a matter of fact, there are no regulations in IPM other than those imposed on producers by EPA through their pesticide regulatory process, but it is a voluntary. It also is an environmentally sound process, and as we refine the program, we become more and more environmentally friendly. It is a program that has involved from the beginning the agricultural industry itself to tell both the researcher and the extension what their needs are, so there is involvement from the industry itself right in the

beginning.

It is a partnership. It is also economically sound in the majority of cases, so you have environmentally sound, economically sound, a volunteer type program that really works, and the acreage is increasing, has been increasing for a long time, and if you see the letters IPM, Integrated Pest Management, you know what it is.

Another not so well known program is our Pharmacist Program, which is based or developed through a partnership with the Natural Resources Conservation Service at USDA, EPA, and our agency. It is a program that presents to the producer a total farm management program. It is computerized, but it also can be in its simplest form a written-up program involving environmental regs, environmentally sound practices, soil and water conservation, as well as crop and crop sequencing and production.

This program has been developed for most crops and now Michigan and other institutions, not only Michigan, are putting into the program some food safety considerations, so it is a program that has been evolving, it is a living

program, if you wish, that will consider some of the food and safety aspects of fruit and vegetable production.

One of the questions that is always asked, and really never answered, is how do farmers get information. We, at the USDA, always say from USDA. Well, that is not quite right. Producers get their information mostly from their neighbors, other producers, from some of their input dealers, from consultants obviously, and from both researchers and extension staff in the states and research at USDA-ARS.

What I am trying to tell you is that as this food safety issue starts to get involved in programming for information and education to the producers, that we ought to involve all of those entities that I described, not only rely on the Extension Service at the state level, but we must educate and inform all of us involved in that education and information process.

If I have one thing that I would like for you to remember, is that we need to bring all the various groups together as soon as possible to help in the development of a guidance

document, and I want to emphasize that it ought to be a guidance document coupled with a complete education and information program. If there is no such educational component, it won't work, but the educational component needs to be targeted, not only to the farm producer, but to those that really have an impact on farm production.

I really would like to conclude saying that even though we have heard that there are some problems in fresh fruit and vegetable production, it is still a higher risk not to eat them than to eat potentially contaminated fruits and vegetables.

Thank you.

[Applause.]

DR. SHANK: Thank you, Dr. Gomez.

Dr. Richard Kirchhoff is here, the Executive Vice President and Chief Executive Officer of the National Association of State Departments of Agriculture.

He will address the President's initiative from a state perspective.

State Perspective

MR. KIRCHHOFF: Thank you. I apologize for not being here earlier when you called me. I was just getting back into town actually.

I feel a little bit like I am here under false pretenses and now even more so when I see "Doctor" by my name. I am not a doctor, but I appreciate the courtesy of whoever put that on the schedule.

My name is Richard Krichhoff and I am the Executive Vice President of the National Association of the National Association of State Departments of Agriculture, and I was asked to be here this morning to share just a few thoughts, initial thoughts, with you about the perspective of the State Agriculture Departments. Our association represents the 50 State Agriculture Departments, as well as in the territories of Puerto Rico, Guam, Samoa, and the Virgin Islands, so we do have a network there that touches all 50 State Agriculture Departments.

We are keenly interested in this initiative. I have only recently learned of it through telephone calls and some briefing materials that I received. I think the

announcement came at a time when we were actually out having our annual meeting, so it didn't catch up with us for a little while, but we are very anxious to work collectively with the Federal Government to institute this initiative and to do our part in helping to ensure that the nation's fruit and vegetable supplies are safe.

I noted that part of the initiative talked about the need to look into the transportation area. This is one area where we have found that some contamination of fresh produce occurred simply because the vehicles were not cleaned out after a load was hauled or actually the way the produce was stored, where they had I think it was like lettuce on the bottom of the truck and some other material on top, and the way it was packaged or packed on the trucks for shipment caused some contamination of a product that was not contaminated when it was loaded in the vehicle at the beginning.

This is frankly going to be challenge for the States Agriculture Departments simply because this is not an area yet where we have been extensively involved in regulation,

so our committee that handles food safety and food regulatory matters is going to be looking into this.

We hope to have substantial input to give over the coming round of public outreach meetings that will be held with producer groups around the country to get their input. We would stress that this very much needs to be a voluntary effort, something that is inclusive of the produce producers, something that they have been in on from the beginning, something that they have been a part of drafting and defining.

I noted in the statement from United, and if it has not already been delivered, I apologize for stealing a few lines from it, but it does make the point that there is such a diversity of production throughout the country in terms of regions, in terms of crops, and in terms of cultural practices that this is going to be quite an undertaking to make sure that these diversities are accounted for and properly so in the drafting of this guidance document.

This is something that the farmers are going to have to feel that they can reasonably comply with without undue stress on

their financial situation and without undue burden on their operation just from a day-to-day basis. Otherwise, it is going to have some difficulty.

The State Agriculture Departments will certainly be there to do their part in terms of education. I think this is one area where we can greatly assist. We do have all manner of people in the fields every day. They may not necessarily be doing the regulatory job of the nature of any type of produce inspection, but they are there on the farm and they can certainly carry messages whether they are there as pesticide regulatory officials or whether they are there as extension people, whatever the case may be, there is an ability for them to deliver information.

In fact, one thing I would offer, that NASDA has a cooperative agreement with the Agricultural Statistic Service, and we employ 3- to 4,000 people on a part-time basis that actually go out and do farm visits, collecting data that actually gets used to do crop estimates and livestock reports, and a lot of the other types of things. This year we will also be involved in doing the agriculture

census. So, our people are visiting farms on a very routine basis, and there is no reason why those people can't deliver information while they are there doing that survey work. We have to make sure that their work is kept segregated, but certainly there is no reason why they cannot drop off information on their visits.

As I said earlier, we have a committee that deals with food regulation and food safety issues. We have been asked to assist in reviewing the guidance document, and we certainly want to do that. We are working to identify an individual or two that can give input into the initial draft and then certainly we would like to have input into the subsequent iterations of the document as it is worked on and completed. I would say that is probably all I can offer at the moment in terms of general remarks. I guess I would just simply again stress to this group that as you develop this initiative, I know it is on a fast timetable, and it is certainly something that needs to be taken a look at, and everything that can reasonably and prudently be done needs to be done, but again I would stress the voluntary nature of

this thing, understand the business that you are dealing with and understand the unique aspects of it, make sure that we have the grower cooperation in this.

Finally, I would stress that consumer education, I think needs again to be a large portion of this initiative, and I don't know exactly how this one meshes in, if it does, or if they are separate initiatives, but how it meshes in with the President's earlier initiative on food safety, but one thing that was a major part of that was actually a side memorandum of understanding with grower organizations, USDA, Food and Drug Administration, and EPA, on a public outreach campaign. I think it is called the Partnership for Food Safety Education.

If this initiative has not already been folded into the activities of that partnership, it certainly needs to be, and this is not really reaching farmer producer portion of it, this is reaching the consumer, which is where frankly a lot of the final word on safety has to be.

As government people, we can only do so much, and we owe it to the American public to do everything we reasonably can do

to ensure that the food supply that is delivered to them is safe, but once they take responsibility for it, once the consumers take responsibility for it in terms of the final preparation, they need to understand what it is that they can do to take that final measure of safety, and we need to make sure that the Partnership for Food Safety Education is included in this initiative.

Thank you.

[Applause.]

DR. SHANK: Thank you, Richard.

We are a little bit of ahead of time, so let's make sure everything is ready for the next session before we take a break, and I will ask the Subcommittee to introduce themselves. That way, you will know who to talk to at the break and we will find out whether or not the mikes are working.

Colonel Goolsby.

LTC GOOLSBY: Dave Goolsby from the Department of the Army, Office of the Surgeon General, and the DOD Veterinary Service Activity.

DR. GRAVANI: Bob Gravani from the Institute of Food Science at Cornell University.

MR. BERNARD: Dane Bernard with the National Food Processors Association.

DR. HEDBERG: Craig Hedberg with the Minnesota Department of Health.

DR. KILGEN: Marilyn Kilgen with the Department of Biological Sciences, Nicholls State University in Thibodaux, Louisiana.

DR. KOBAYASHI: John Kobayashi with the Washington State Department of Health.

DR. DOYLE: Mike Doyle with the Center for Food Safety and Quality Enhancement of the University of Georgia.

DR. BUCHANAN: Bob Buchanan with the Agricultural Research Service, Wyndmoor, Pennsylvania.

DR. SHANK: The next event that is scheduled is a break. Like I said, we are a little bit ahead of time, but let's try to keep it to approximately 15 minutes and be back about five after 10:00, please.

[Recess.]

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DR. SHANK: You met the Advisory Committee before we broke. If we could have your attention, please, we will get started.

I will introduce the head table for you at this point in time. Steve Schaub is on the far end. Steve represents EPA. Terry Troxell, you will be meeting him in a moment. You have met Tom Gardine. John Kvenberg is from FDA. Dr. Ricardo Gomez has joined us at the head table.

Let me make a few remarks about how we envision the program. I would remind you that Dr. Friedman talked about a draft guide by December 1. Today, we do not have the draft guidance document. We do have some substantive portions that are being presented for your consideration.

The Advisory Committee later this week will address what they are presented with here today, along with their own expertise, their knowledge, and we certainly look forward to their contribution that will help us to advance the material in the concept of draft guidance.

There will be a document that we will call a draft guidance by December 1. That will be used at the various meetings

that were mentioned to you. A draft document will be published in January, early next year, for public comment, and it is envisioned that it will be finalized come June. We do not have a draft today. We are going to be presenting slides. Hard copies of those slides will be available for you after the presentation, which should give you a fair amount of information and we look forward to you all's comments and the deliberations of the Subcommittee as we move forward this week.

Any questions?

[No response.]

DR. SHANK: Then, let's proceed with Dr. Terry Troxell, who is Director of the Division of Programs and Enforcement Policy within the Center. He is going to address guidance. Terry.

Guidance

DR. TROXELL: Good morning. I am going to try to do this. Two days ago, it would have been at a whisper.

[Slide.]

I would like to introduce the guidance that we are working

on, which we have entitled, "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables."

[Slide.]

Recent outbreaks have raised concerns about the safety of foods, including fresh fruits and vegetables, that are not processed to eliminate pathogens. As public health officials, we are concerned about the outbreaks in illnesses associated with fresh produce, but the federal agencies are also concerned about what has been described by some as a decrease in the public confidence in the safety of fresh produce.

Notwithstanding a certain past President's aversion to broccoli, fruits and vegetables are highly nutritious and always should be a major component of any good diet.

In addition to the negative nutritional impacts, the public safety concerns may result in loss of markets for growers. Thus, it is important that we, in industry and government, take steps to minimize any hazards by looking for the potential sources of the problems and controlling them to the extent practicable and, yes, the consumer and food

service establishments have a role in using proper practices for refrigerating and preparing produce.

[Slide.]

Of course, the major distinction of these foods from others is that fresh fruits and vegetables are not generally subject to many of the steps designed to reduce or eliminate microbial load that processed foods receive, whether that processing occurs in a food plant or on a homemaker's stove top.

Therefore, taking steps to reduce the risk of microbial contamination is especially important for raw produce. Since fresh produce is picked and shipped, or shipped after minimal washing, this means taking steps down on the farm. That means we are dealing with dirt, farm animals, and agricultural waters, and not state-of-the-art food processing facilities. We recognize this means that steps will not result in definitive complete solutions, thus, our use of the phrase "minimize hazards."

[Slide.]

We have divided potential vehicles into four broad areas and

have used these areas for drafting broad-scope guidance. These are water, manure/sewage sludge, worker and facility sanitation and hygiene, and transportation. We are also considering including in our guidance a section on tracebacks.

While the ability to traceback from an illness, outbreak, or microbial contamination is a follow-up action, it can limit the extent of an outbreak, lessen economic impact on the grower segment involved, and potentially help correct a practice when a grower is identified, thus, preventing future outbreaks and adverse market impacts.

[Slide.]

As I said, the immediate objective is development of a broad-scope guidance, sometimes referred to as a generic GAP. We will issue further guidance documents for specific fruits and vegetables addressing Good Agricultural Practices and Good Manufacturing Practices. These will take into account regional differences and many other variables.

[Slide.]

The Guide focuses on common elements in growing, production,

and distribution. As you will see from other presentations, the guidance we are working on related to packing houses, as well as the farm. This guidance is somewhat more than Good Agricultural Practices.

Ultimately, we envision the specific fresh produce guidance documents to cover both agricultural and manufacturing practices including operations that prepare fresh-cut packaged produce.

[Slide.]

It is intended as guidance only. Growers are urged to take a proactive role in minimizing food safety risks. Farmers are not alone in this, as the USDA Extension Service will provide advice to farmers on potential problem areas in their operations. Internationally, the U.S. Government will provide technical assistance as discussed earlier.

Our intention is to provide the best advice of FDA and USDA in consultation with industry and consumer groups. FDA is obviously not a farm organization. That is one reason why we have as a principal partner, USDA, but the partnering goes well beyond that and includes, for example, EPA for

water issues, and OSHA for employee practices.

We also intend to involve State Agriculture and food officials substantially in the process in order to provide the best advice we especially need the input of farmers, and I will tell you later how we intend to do that.

This is a good time to recognize and commend the efforts already underway by industry. A number of produce associations have already developed guidance. Two examples of these are the voluntary food safety guidelines for fresh produce by the International Fresh-Cut Produce Association and Western Growers Association, and the guidance to minimize microbiological food safety risk for produce by the United Fresh Fruit and Vegetable Association.

Industry has made significant progress, not only in articulating good practices, but also in raising the awareness among growers. These efforts certainly will make our efforts easier on this very complex problem.

[Slide.]

Since the Guide will provide guidance, it is not binding, nor do we intend that it becomes requirements through

contracts requirements of purchasers of fresh produce. Because of the expected qualitative nature of the guidance relating to many aspects of farm practices, it will not be easy to view the guidance as requirements.

The Guide is a primary effort designed to improve the safety of, and increase consumer confidence in, the safety of fresh fruits and vegetables. Our other major effort is to develop the juice HACCP proposal, which will be published early in 1998.

[Slide.]

It is intended to raise awareness of growers to food-safety related farming practices, but once awareness is raised, the logical question by a grower is what should I do, and without triggering action, the improvement in overall practices and lowering of potential risk will not occur.

[Slide.]

There are many gaps in the science that lead to uncertainties in the degree of risk associated with particular farming practices. Clearly, if a pathogen is on a piece of fruit going into a consumer's mouth, we have

definable problem, however, we are trying to deal with the potential hazard from, for example, manures, raw and processed to varying degrees, used in a wide number of ways at different times in the growing season.

For a consumer from consuming that piece of fruit, and because of the gaps in scientific data, some of the estimated risk would have very large associated uncertainty. Where there is substantial uncertainty, the guidance will be qualified, using terms like "minimize" and "avoid where feasible."

In these situations, we clearly would urge growers to do what is doable, but without the science, we would be hesitant in making the advice too strong where that advice would be costly for certain growers to follow, especially when they were practicing previously acceptable farming methods.

[Slide.]

In this way, we intend to provide practical advice, appropriately qualified, however, two principles besides an awareness are fundamental for growers to lower the risk:

One, assessing their particular farm and farming practices; and two, implementing the feasible changes. This will be facilitated by available guidances and the help with an Extension Service, State Agriculture, or other consultants as needed.

As I said, we recognize there are many gaps in our knowledge and we are accelerating research in an attempt to answer some of the major questions that have arisen.

[Slide.]

In some areas, guidance may properly be more specific, such as when practices are subject to federal, state, or local laws. Packing houses often qualify as food establishment that should be following the general Good Manufacturing Practices in FDA's Code of Federal Regulations.

[Slide.]

As anther example, facilities that have sufficient numbers of employees must also provide drinking water complying with EPA drinking water standards. Nevertheless, however we construct this guidance, any guidance issued does not preempt any of the applicable law.

[--- Unable To Translate Graphic ---] 6

[Slide.]

One of the questions we would like you to help us with today is how much practical advice can a broad scope GAP provide. There are common potential vectors for pathogens for all fresh produce, such as water and manure. Thus, on one hand, it would seem that a great deal could be accomplished by thoroughly addressing the four principal areas - water, manure, worker and facilities, sanitation and hygiene, and transportation in the broad scope document, and that this would serve as a common basis for the specific commodity documents to follow.

On the other hand, there is also an enormous range in farm size, available water sources, climatic and soil differences, fertilizer sources, employee availability, farm practices, et cetera.

[Slide.]

Further cultural practices vary widely between different types of produce and different varieties of a specific type of produce. These differences are as dramatic as strawberries that grow close to the ground are picked and

shipped without washing versus oranges, which of course grow far from the ground and have a thick, rugged skin which is peeled before consumption.

So, how can we best provide practical, concrete advice to growers that will move us toward safer produce without being unnecessarily costly to growers?

[Slide.]

Should some of this advice be in the broad scope GAP or should that be reserved for specific GAPS and GMPs and how should we do it there?

[Slide.]

I want to say a few words about process. I think most of this has been covered. Let's go over a couple of points. Obviously, we have planned a very public process. This meeting is the first step in that process. In the packet of information, that includes the slides from these presentations, you also find a Federal Register notice for this meeting. That notice includes the docket number and address for submitting comments.

Please send comments as soon as possible, so we may use them

in developing the next draft. The Federal Register notice also contains information on obtaining a transcript. We will be developing a working draft document based on input from this meeting and the Produce Subcommittee of the National Advisory Committee for Microbiological Criteria for Foods.

We will announce the December 1 availability of that working draft through a Federal Register notice that announces grass-roots meetings. Again, please submit comments as soon as possible.

As has been said, we have planned six grass-roots meetings in major fresh produce production regions and an international meeting to solicit input. These meetings are joint meetings between FDA and USDA's Extension Service, and are especially interested in obtaining input from the farming communities who would have to implement the advice in the Guide. Of course, as always, all constituencies are invited and are welcome to comment.

Dr. Dye already identified the sites. I will just also mention that the meeting for the international community

will be held in D.C. on December 8th, and the sites and dates are provided in a little more detail in the information packet.

We will use the comments received from these meetings and those submitted to the docket to develop a proposed Guide for public comment. We hope that the notice announcing its availability will be published probably closer to the end of February than in January, unless Dr. Shank shortens my date. We are planning a 45-day comment period. We will revise the Guide based on comments received with an anticipated publication of the final Guide by the end of June. If the comments indicate the need for another public meeting, we will certainly do that before finalizing it, and if there are major changes in the draft, we would put it out again for comment.

[Slide.]

We plan to begin developing GAPs and GMPs for four fresh fruit or vegetable products early in the new year. The plan is to complete the four in Fiscal '98, including a public meeting. We also intend to identify additional fresh fruit

or vegetable products for GAPs and GMPs on which we would start development work probably in the spring.

We will soon publish a notice requesting input on the priority of fresh fruits and vegetables for which GAPs and GMPs should be developed. By this notice, we will also solicit submission of available specific GAP or GMP guidance information on fresh produce.

That ends my comments.

DR. SHANK: Questions for Terry? You need to go to the mike. We have got one now in the middle of the room.

No questions for Terry? Yes, Mike.

DR. DOYLE: Am I entitled to a question?

DR. SHANK: Sure.

DR. DOYLE: Terry, how will you identify or focus on the four fruits and vegetables, the first four to address?

DR. TROXELL: Well, there is a series of criteria we can look at - the level of consumption, outbreaks, and potential for hazards. You know, some are like oranges, are more rugged, and not as vulnerable as something like, for example, strawberries. So, we will try to rank them and we

would like to have input from the public on which ones we should be addressing.

MR. FRANKEL: My name is Lee Frankel. I am with the Fresh Produce Association of the Americas, and I have a general question on if you are planning even field visits to overseas farms, so you could better understand what the production practices are in terms of trying to draw up some guidelines or GMPs or GAPs, and if you have scheduled any overseas visits at this point in time?

DR. TROXELL: The planning for the international work has not been completed. Thank you for that comment. We will take that into consideration.

MR. RUCKERT: Ed Ruckert. With respect to separating out four commodities of raw foods, doesn't that provide some degree of concern that all of a sudden you are going to have four foods listed as sort of poster child for this initiative? In other words, there may be some adverse reactions rather than coming out with a guidance document applicable to the food industry, if that is the direction you are going.

DR. TROXELL: Well, our intention is to do this broad scope Good Agricultural Practice document, which would apply across the board, and to try to address the different cultural needs for specific produce in documents targeted to a specific produce.

MR. RUCKERT: I appreciate that, but why single out four I guess is the question.

DR. TROXELL: Well, that is what we believe we can handle as an initial program. We can't deal with them all at once.

MR. GARDINE: But, Terry, there is no plan to end at four, is there?

DR. TROXELL: No. We have just got to start somewhere.

DR. SHANK: Other questions?

[No response.]

DR. SHANK: Thanks, Terry.

Now, for those of you who have looked at your agenda, you can see we are going to start the Dr. Smith, Saltsman show. We were concerned about how some of these topics were going to be positioned, and we wanted to make sure that neither Michelle nor Joyce had to do all the presentations at one

time. There were some other considerations relative to time, but let's move on with water. Dr. Michelle Smith will present some of our current thinking relative to what might be appropriate for water.

Michelle.

Water

DR. SMITH: Good morning. It is a real pleasure to be here. It is not often that I get a chance to make three presentations in a single day in front of such a good group, but I hope we can all work through this together and get a lot done.

I am with FDA's Center for Food Safety and Applied Nutrition. The topics that I will be speaking with out of the four areas that Dr. Troxell identified as potential risk factors in agricultural processing of fresh fruits and vegetables will be water, manure, and then later in the afternoon, I will talk a little bit about traceback, which we are considering incorporating into this guide.

To repeat a couple of things that other people have said, but to help put my talk in context, this is the first public

viewing of this information. It is an initial draft. This is an opportunity for us to get input from all of you and we are looking forward to doing that.

Almost everyone that has been up here has stressed the point that this is guidance, it is not regulation, so I figured I would jump on that bandwagon. The guidance is general in nature. The types of things that we suggest here will still have to be modified for individual operations and it is not meant to replace any federal, state, or local law where it applies.

One of the things that we are considering doing with this guidance document is, where we can, to cite regulations or to cite guidance that other agencies have put together which may be appropriate, and if you have any suggestions on how we might do that most effectively, we are certainly open for it.

Late Friday afternoon, talking with Dr. Saltsman and some of the other people putting together today's meeting, she made the remark that we could give all of today's presentations or at least our part of the show in a single sentence, and

that sentence is anything that comes in contact with fresh produce, if it itself is contaminated, has the possibility of contaminating the fresh produce.

Just to, you know, make sure that we appear like we are doing a little more work than that, though, I will jump into my presentation.

[Slide.]

As I said, the first element that I am going to talk about today is water. Water is a concern in two aspects, first, as an inherent source of contamination, and secondly, as a vehicle for spreading pathogens whether in the field, harvest, or packing house environment.

[Slide.]

Water can be a carrier of certain microbial hazards including pathogenic strains of the following microorganisms and parasites. Much of the information on this slide is based on drinking water, outbreaks, outbreaks that have been epidemiologically linked to drinking water. For those of you that are taking notes, all of these slides, the material that is on these slides will be the package, so you don't

need to try to write as quickly as I am talking.

[Slide.]

Outbreaks linked to agricultural water use are a lot more difficult to traceback. It has been mentioned before that fresh produce is not one of the first things that consumers think about if they are suffering from a foodborne illness. Fresh produce has a relative short shelf life and may be gone by the time an outbreak is reported.

Other things that make traceback difficult involve the fact that it is difficult for some commodities to follow the path of the product from the consumer, retail, and backwards to identify any particular packing house or farm.

Finally, if a packing house or farm is linked to an outbreak, it may still not be possible to identify the source of contamination. For example, if an open water source had been used to irrigate the crop, and there was a transient source of contamination, such as cows swimming upstream, by the time the investigators get to the farm and take environmental samples, they are not going to be likely to be able to identify for sure where the contamination

originated.

[Slide.]

Two outbreaks, one in 1990, and another in 1993, were linked with the consumption of fresh tomatoes. Tomatoes from both of these outbreaks were traced back to a single packing house. A water-bath used by the packed appeared to be the likely source of contamination and the most practical point for control.

In 1995, an outbreak of E. coli 0157:H7 infections was linked to leaf lettuce. In this particular instance, it is not known where the lettuce became contaminated. Investigators noted that the lettuce in question had been irrigated with surface water which is more vulnerable to contamination, but that was never proven.

Another point noted by investigators is the source of contamination might have been poor lettuce handling practices at retail. So, in this instance, you have a combination of an agricultural situation where if, in fact, that was the source of the problem, Good Agricultural Practices might have helped minimize the risk, but there is

a need for everyone throughout the entire chain to coordinate efforts and work together.

[Slide.]

Water is an essential element in the production and handling of produce and is used in numerous operations, including: irrigation, crop protection sprays, cooling and washing operations, which we are focusing on in the current draft.

[Slide.]

Because of water's potential as a source of pathogenic microorganisms, growers should carefully analyze practices involving water, and seek to limit the possibility for waterborne contamination.

[Slide.]

Once recognizing the potential for water sources to contain pathogens -- and this will vary depending on the water source and a number of other factors -- for example, open water systems may be more vulnerable than properly constructed closed systems, the grower may need to look at their situation and make sure that the water quality is sufficient for its intended use.

[--- Unable To Translate Graphic ---] 8

[Slide.]

Now, what that water quality needs to be will vary depending on the use. Good Agricultural Practices should be tailored to meet the needs of a particular operation. Again, the guidance in this document does not preempt existing laws and regulations where they apply.

[Slide.]

In establishing Good Agricultural Practices, growers should also recognize the potential for water to reduce microbial hazards, for example, by cleaning produce, cleaning harvesting and transportation equipment, water containing sanitizers may also be used to reduce surface contamination of fresh produce.

[Slide.]

Some of the general Good Agricultural Practice recommendations that we have for water across the board. Again, identify and review the source of water. As the degree of water-to-produce contact increases, so does the need for good quality water.

[Slide.]

Other factors, such as the degree of exposure, frequency of application, presence of surfactants, powders, or debris in the water or spray, and the biological characteristics of any pathogens that may be present will all influence the level of risk associated with the possibility of contaminating fresh produce.

[Slide.]

Where water quality varies, for example, an open water source that may be subject to intermittent contamination from runoff or some other factor, growers should be aware of the conditions that make the water source more susceptible and follow control practices to ensure that water quality is sufficient for its intended use.

[Slide.]

Controls may include many options and these are things that individual growers and operators will need to work with. Such of these options are things like delaying water use until water quality improves. Water treatment is a possibility. Alternative application methods that avoid or minimize water-to-produce contact, and for some operations,

it may be feasible to maintain an alternative water supply.

[Slide.]

With respect to the more specific GAPs associated with particular water uses, irrigation water.

[Slide.]

The water delivery method, the physical characteristics of the crop and the topography of the field may all affect the potential for water to serve as a mechanism for spreading contaminants.

[Slide.]

Water-to-produce contact is obviously a lot greater for overhead irrigation than it is for systems, such as drip irrigation or flooding. Many factors influence a grower's choice of their water system, but depending on what the needs are of the individual operation, they want to consider instituting irrigation systems that minimize produce-to-water contact.

[Slide.]

Another water use is for crop protection sprays. Admittedly, the volume of water in crop protection sprays

may be significantly less than the amount of water used in irrigation, but again, anything that comes in contact with produce has the potential for contaminating the produce if, in fact, it itself contains contaminants.

[Slide.]

When mixing crop protection sprays, growers may need to use water of adequate quality and employ Good Agricultural Practices to protect the integrity of the water source. This point comes from anecdotal information that some people may be using a secondary water source because they don't want to contaminate their primary water source with pesticides.

[Slide.]

Rather than use water that may not be of sufficient quality, Good Agricultural Practices would suggest setting aside an area for mixing of the pesticide or taking other steps to protect the primary water supply.

[Slide.]

Another water use common to most, but not all, operations is washing fresh produce.

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[Slide.]

Washing produce in the field or packing house involves a high degree of water-to-produce contact. In addition, this water may be reused, which could result in the build-up of heavy microbial loads, including pathogens. While water may be a useful tool for reducing potential contamination, it may also serve as a source of cross- contamination. Washing should never make the situation worse than it was when you started.

[Slide.]

Safe and sanitary water is recommended for use in washing produce in the field and in the packing house environment.

[Slide.]

Good Manufacturing Practices for water supply used for food or food contact surfaces in processing facilities are set out in Title 21 CFR Part 110.

[Slide.]

Where appropriate, growers and handlers may want to consider applying the guidance in these GMPs to operations in the field and packing house.

[Slide.]

Wash water, even with sanitizers, may reduce but not eliminate, pathogens on the surface of produce. If pathogens are internalized, washing has even less effect.

[Slide.]

Some researchers have found that Salmonella in a water bath may be rapidly internalized by tomatoes when the water bath temperature is colder than the tomatoes. This has led to recommendations that wash water for tomatoes by hyperchlorinated and 10 degree Fahrenheit warmer than the tomatoes. This recommendation may have broad application to other products, such as apples.

[Slide.]

Further, if pathogens are not removed or inactivated, they can spread so that a significant proportion of the produce is contaminated instead of sporadic items.

[Slide.]

This header should read Wash Water. Chlorine is commonly used to help prevent cross-contamination and to increase the efficiency of washing. Chlorine dioxide, hypochlorite, and

trisodium phosphate have also been studied.

[Slide.]

Water used in cooling operations. As produce quality deteriorates, some researchers believe that the possibility of microbial contamination and growth increase. On the other hand, the benefits of chilling to remove field heat and the temperature requirements for optimum keeping quality will vary for different types of produce. Produce that does not undergo a cooling or chilling operation is not concerned with the risk factors in this section.

[Slide.]

Again, water and ice used in chilling should be considered a potential source of contamination. Outbreaks of Shigellosis and Shigella have potentially been associated with cooling operations.

Growers should be aware of the water source used to make the ice and follow practices to reduce the risk of contamination.

[Slide.]

Also, again, the guidance set out in the Good Manufacturing

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Practices in Part 110 may have application to cooling in field and packing house environments.

[Slide.]

Finally, water is a vehicle for spreading localized contamination primarily in the field, although Dr. Saltsman will talk about some of the aspects to be considered in the packing house in her talk.

[Slide.]

Growers should evaluate the area and the direction of runoff from excess irrigation or heavy rainfall. They may want to consider management practices to limit the spread of irrigation water or that limit the planting of fresh market crop downhill from a possible source of microbial contamination.

Possible sources might be animal manure storage facilities. Operators may need to consider providing physical barriers, such as ditches and mounds where necessary to prevent or redirect runoff of contaminants from adjacent fields.

This is where we are right now. If anyone has any comments or suggestions?

DR. SHANK: Questions or comments for Dr. Smith? Yes, ma'am.

DR. KILGEN: I have one question. I have not had to involve myself in irrigation in agriculture. In south Louisiana, we have to worry that it rains so much, it will flood the crops. But you talked about using what was called safe and sanitary water? Is there a definition for that, do you mean drinking water quality?

DR. SMITH: Drinking water quality is a different level of water quality from what may be used as agricultural water. It is not necessary that it be drinking level.

DR. KILGEN: So, safe and sanitary?

DR. SMITH: Have we defined safe and sanitary?

DR. KILGEN: Thank you.

DR. SMITH: Okay.

DR. BUCHANAN: With the potential increased use of chlorine in water systems, is there any concern about build-up of chlorinated organics resulting from this increased use?

DR. SMITH: One of the things that we will be keeping in mind as this draft guidance develops is the need to balance

water treatments to improved water quality with environmental effects and other factors that would also be undesirable.

DR. BUCHANAN: To follow up that line of thought, and I may have missed it in listening, is there any feedback process built into this initiative where you have made certain assumptions about what the Good Agricultural Practices that are most important are, is there going to be a feedback loop where we now evaluate the incidence of produce-related disease and see if we are having an impact, is that built into this initiative?

DR. SMITH: This initiative involves a high level of cooperation between the agencies. We are in the process and we have begun pulling in technical assistance from groups like USDA, EPA, OSHA, CDC. Some of the information that is out there, we are incorporating as we receive it. Separate from this guidance document there is another initiative to identify necessary research areas and put them on a fast track. So, in those instances where we do not have the science at this point in time to support definitive

GAP recommendations, we will be using terms like to the extent practical, as feasible, or minimize a certain condition.

We are also making a point of identifying those areas where we really do have knowledge GAPs and urging growers and operators to, as additional information becomes available, to modify their practices, and a lot of that, I am certain, we will be counting on the educational and outreach arms of this effort to spread that information as it becomes available.

DR. KVENBERG: Dr. Smith, this is related, is it not, to the Food Safety Initiative documents that were put out earlier, and there is a surveillance component which may go to your point or to your question, relative to anything that would be picked up under the surveillance thing could feed as an intelligence, could it not, to guidance on this document, feedback from that?

DR. SMITH: I would think so. We are open to any useful source of information.

DR. HEDBERG: You used the tomato outbreaks as an example of

risk associated with irrigation, but to my knowledge, irrigation actually wasn't identified as a contributing factor to the occurrence of those two outbreaks.

The other point that I wanted to raise is in regard to the use of water in cooling produce, since work with tomatoes, and you are suggesting with apples, has shown that putting a warm body of fruit into cool water can lead to the internalization, and if that is a generalized process, what are the implications for using water as a cooling substance?

DR. SMITH: To your first point, my intention with the tomato outbreaks was to identify those outbreaks as being traced back to a packing house, not irrigation water.

With respect to the second point, we have indications that pathogens can become internalized for some crops, such as tomato and apple. I don't know to what degree it goes beyond those crops. There is an article that is in press now, and as soon as it is publicly available, that would be incorporated into the advice that we give here.

Washing in general -- well, okay -- the real point or one factor to consider is that everything is linked together in

a very complex manner. Washing alone is not what you need to rely on, because of the possibility of internalization. Other Good Agricultural Practices to avoid the initial contamination, such as farm water that is used or manure handling practices, if you take steps to the extent possible to avoid that initial contamination, then, you have less of a concern about the contamination even being there to be spread in a washing situation.

DR. SHANK: Other questions, comments?

[No response.]

DR. SHANK: Thanks, Michelle.

DR. SMITH: Thank you.

[Applause.]

DR. SHANK: The next presenter is Dr. Joyce Saltsman. She will be talking on sanitation and hygiene. She, too, is with our Office of Food Labeling.

Joyce, come on up, please.

Sanitation and Hygiene

DR. SALTSMAN: Good morning. The GAPs that I am going to be covering this morning we have for workers and practices

within the field and the facilities, and will include the control of potential hazards, handling precautions, equipment, and pest controls.

[Slide.]

Illnesses associated with fresh fruits and vegetables are primarily transmitted by the fecal-oral route. Although raw produce can serve as a source of a variety of foodborne organisms, one of the greatest concerns of course is associated with the presence of any pathogenic organisms, such as the E. coli 0157 that we have mentioned several times this morning.

[Slide.]

The U.S. Code of Federal Regulations in Section 110.10 prescribes worker hygiene and sanitation practices within the context of Good Manufacturing Practices in the manufacturing, packing, and holding of human food.

The standards established in this section should always be considered when establishing hygiene and sanitation practices in the agricultural environment.

[Slide.]

Worker sanitation and hygiene play a critical role in the controls for minimizing microbial contamination of fresh produce. Proper cleaning and sanitizing slows the spread of pathogenic bacteria and other microbial hazards, limiting the potential for both pre- and post-harvest contamination due to human handling.

[Slide.]

Food handlers have been implicated as the source of several foodborne outbreaks of viral gastroenteritis. Without the proper sanitation and hygiene, dirty hands will continuously gather and spread germs to the surfaces that they contact.

[Slide.]

All personnel who are involved in the harvesting, packing, and distribution of fresh produce, whether they are full time, part time, seasonal, or you are a supervisor, should be trained in good sanitation and hygiene practices. Operators or growers may want to consider establishing a training program that would include a system to monitor and evaluate compliance with established sanitation practices. They should also consider follow-up training sessions as

needed just to encourage adherence to good sanitation and hygiene practices.

[Slide.]

A training program should focus on the importance of good hygiene. All personnel should understand the impact of poor personal cleanliness and unsanitary practices on food safety. Use of proper handling techniques and food protection principles helps to ensure safe foods.

[Slide.]

The training program should also focus the importance on hand washing. Washing hands before and after every absence from the work station, using the bathroom, before and after eating, and before coming to work is very important. Again dirty hands have the potential to gather and spread germs to the surfaces they contact. Washing hands with soap and warm water helps to stop the spread of germs.

[Slide.]

It is also important that you don't assume that workers know proper hand washing techniques. They should be taught how to do that. This would include hand washing with warm

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water, if it's available, proper use of soaps and sanitizers, and scrubbing, rinsing, and drying of hands. Use of sanitation facilities, such as on-site latrines, should be encouraged, and workers should be encouraged to avoid eliminating waste outside of these facilities.

[Slide.]

Training should also focus on the importance of personal health. Infectious diseases, open lesions, and other ailments are a source of microbial contamination that can contaminate food and raw produce.

Employees should report any such conditions to their supervisors.

[Slide.]

Likewise, supervisors should monitor the health of their employees. Disposable rubber or similar gloves, leak-proof band aids, or other corrective measures for minor cuts should be provided for all personnel who handle produce.

[Slide.]

Now, let's focus a little bit more on the field environment. Microbial contamination or produce can occur during

pre-harvest and harvest activities with contact with soil and fertilizers, water, labor, and equipment. Any of these has the potential for being a source of pathogenic microorganisms.

Operations with poor management of human and other waste in the field can significantly increase the risk of contaminating fresh produce.

[Slide.]

Pathogenic microorganisms may also be found in soil and water and on the surfaces of any equipment used to harvest produce in the field.

Good sanitation practices should be employed throughout the environment and handling processes.

[Slide.]

As a first step in the control of potential hazards, it is important for operators to become familiar with all applicable laws and regulations, whether local, state, regional, or national, that describe appropriate field sanitation practices.

Such laws generally outline appropriate number of restrooms

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to the number of workers, the maximum worker-to-restroom distance, and how often such facilities should be cleaned.

[Slide.]

Operators should also consider the importance of the proximity and accessibility of toilet facilities to harvest crews in all sectors of the fresh produce production. The more accessible the facilities, the greater the likelihood that they are going to be used. They should be within an easy walking distance to where the workers are actually involved in work.

Workers should always the opportunity use the facilities when they need to, not just on their breaks. This will help reduce the incidence of them relieving themselves elsewhere, such as in the fields, if they cannot go on their break.

[Slide.]

Growers need to assure that the location of where workers use a facility to relieve themselves, if it is in the field, is not near a water source used in irrigation or in a location that would subject it to potential runoff in the event of heavy rains.

Toilet facilities should be provided to all employees. Consider separate facilities, if possible, if you have larger crews, such as five of more.

[Slide.]

Portable toilet facilities need to provide adequate hand washing stations or hand dip stations, and with water that is suitable for hand washing or drinking. Ideally, they would also provide warm water for hand washing.

[Slide.]

Toilet facilities should also be well supplied . Adequate supplies of paper, sanitary hand drying equipment, and soap, preferably anti-bacterial soap, are desirable.

Toilet facilities should be maintained in a sanitary condition and in good repair at all times.

[Slide.]

In consideration with toilets, you have to also be concerned about the issue of sewage disposal. Improper disposal of human waste from portable toilets can lead to water, soil, animal, or crop contamination. Practices should be in place to insure safe management and disposal of waste from

portable toilets to prevent drainage into the field. Operators should practice and follow all applicable local regulations regarding the use of disposal of sewage.

[Slide.]

Now, some good practices to consider in this area. Clean or service portable toilets away from the field. Waste water from portable toilets or temporary toilet facilities that drain into fields can obviously contaminate produce. Drain waste water away from the field or collect the waste in a drainage tank to be correctly disposed of at a remote site.

[Slide.]

Septic trucks that service portable toilets should have direct access to the toilets if they are in the field area. Where possible, toilets should be located in areas, such as on a downhill slope or downhill from a field, to minimize the likelihood of contamination of produce in the event of a leakage or spill.

[Slide.]

Handling precautions for the field are those that help reduce product contamination during growing seasons and at

harvest time. Harvest crews should remove as much dirt and mud as possible from the produce before it leaves the field. Damaged or muddy cartons should be repaired, cleaned or discarded in an effort to reduce possible contamination of fresh produce.

[Slide.]

For those who harvest, cool, and package products right in the field, care should be taken to ensure that the produce is not contaminated in that process. Contact with manure, fertilizers, poor quality water in hydrocoolers, workers with poor hygiene, and unclean packaging boxes greatly increase the risk of contamination from pathogenic organisms.

[Slide.]

It is recommended that everyone handling produce wash their hands and wear clean disposable gloves. This could be even people coming to inspect produce for purposes of buying it, but anytime produce is handled, you have a potential source for contamination.

[Slide.]

Now some good practices for handling equipment in the field includes keeping harvesting and any processing equipment as clean and sanitary as practicable. Harvesting equipment includes, among others, harvesting machinery, cartons, tables, baskets, packaging materials, brushes, et cetera. Personnel should not use any harvesting equipment for carrying items such as personal items, perhaps lunches or tools, fuel, et cetera. Only the harvested product should be carried on harvesting equipment.

Proper equipment maintenance includes removing contaminants, such as mud, diesel, grease, oil, produce, and debris, from handling equipment daily.

[Slide.]

Good sanitation and hygiene practices in the field are also very applicable to facilities. Within facilities, anything that comes in contact with food has the potential for contaminating it. Operations with poor sanitation in the packing house can increase the risk of contaminating fresh produce. It is important again to be familiar with all laws and regulations that describe appropriate sanitation

practices within a facility.

21 CFR 110.20 to 100.93 is a good resource to guide the development of any mitigation programs.

[Slide.]

Toilet facilities within a packing house may be portable, they may be built into the facility, but again they should be provided for all employees. Consider separate toilet facilities, once again, for men and women and with larger crews.

All the guidance that we have gone over for the portable toilets within fields essentially applies here to the packing house. Toilet facilities should be located within an easy walking distance to the workers.

[Slide.]

Likewise, adequate hand washing stations or hand dip stations should be provided, and water suitable for hand washing and drinking should be provided. If possible, warm water is desirable for hand washing.

Toilet facilities should be well supplied again with the paper, hand drying equipment, and soaps.

[Slide.]

Sewage disposal again. Waste water for toilet facilities that drain into a field can contaminate it. It is important to try to collect waste water in a drainage tank to be correctly disposed of at a remote site.

[Slide.]

Some handling precautions. Damaged or muddy cartons should be repaired, cleaned, or discarded. You want to set aside, if possible an area in your receiving yard for treatment of pallets and containers.

Keep pallets and containers clean and sanitary as practical before using in contact with fresh produce.

Once again, it is recommended that anyone handling produce should wear gloves before handling produce.

[Slide.]

Equipment maintenance in the facility. Equipment and utensils should be of materials that are adequately cleanable.

Again, remove contaminants from handling equipment daily. Consider the repairing, cleaning, or discarding of any

damaged or muddy cartons to reduce microbial contamination.

[Slide.]

Again, keeping equipment clean as possible and equipment, such as knives, saws, blades, anything that is used in contact with fresh produce should be inspected on a regular basis and then, if necessary, repair it, replace it, or fix it, make sure that you are not interspersing some contamination into your packing house.

[Slide.]

The packing house and cooling facility should be kept clean and sanitary. With cooling systems, it is important that you inspect them daily, if possible. You want to look for any debris or dirt or any other contaminants that may have come into the cooling facility. Clean out any product storage and processing areas on a regular basis, clean and remove all debris, soil, dirt on an ongoing basis, and try to keep any airborne contaminants to a minimum, such as dust.

[Slide.]

For pest controls in a facility, all animals are considered

potential sources or vectors for carrying contaminants, and this would include mammals, birds, reptiles, and insects. Therefore, a pest control program is essential to reducing the risk of contamination by rodents and other animals. Packing house, processing facilities, and the grounds around such facilities should be kept in good enough condition as possible to reduce the opportunity for pests to get inside the facility and contaminate produce.

[Slide.]

Some suggestions for pest control within the facilities include proper storage of equipment. All facilities and grounds in the immediately vicinity should be kept clear of waste and litter, and all grasses should be cut in an effort to discourage the breeding and harboring of pests.

Maintain adequate surface drainage where needed to reduce the risk of contamination of produce and to further reduce breeding places for pests.

Clean daily to remove any excess remnants that might attract pests.

[Slide.]

Inspect all facilities on a regular basis to check for evidence of pest populations or animal contamination. Operators should ensure that all potential nesting or hiding places for pests have been eliminated. Try to exclude pests by blocking areas, such as holes that you may find in walls, doors, or flooring, and vents possibly by blocking them off to keep them from entering the facility. Consider the use of traps as needed.

[Slide.]

Lastly, maintain a pest control log to include perhaps dates of inspection, inspection report, and steps taken to eliminate problems.

The pest control program should also include re-inspection of any affected or treated areas to determine the effectiveness of treatment that has been applied.

That is all I have to say this morning.

Are there any questions?

DR. SHANK: At least on this subject.

DR. SALTSMAN: On this subject, yes.

DR. SHANK: Any comments or questions for Dr. Saltsman?

Yes.

LTC GOOLSBY: You have defined several very important areas. I just want to address a little more closely the personnel factor, if you will. Probably in the experience of you, certainly in mine, and maybe most of rest here in attendance, would agree that the personal hygiene factor is probably the most difficult to modify.

In particular, in the areas of unskilled labor, such as what we have on the farms, and complicating that at the point that there is probably a tremendous rate of turnover there, I am wondering if, in fact, that is the case, if that is the case, and secondly, how we encourage the owner-operators-producers to address that factor in a positive way, such that they can make advantage of the parts of the guide that you are promoting here.

DR. SALTSMAN: To be quite honest, we haven't gotten to that point of dealing with this specific issue of personnel and hygiene. That is a very important point. Obviously, there can be a lot of turnover with labor.

That is something that we need to get some comments on from

the public and more information on, and what you think would be important to include in a document like this, but specifically, I don't have any answer to that right now.

DR. BUCHANAN: A comment on your facilities management recommendations. While the Good Manufacturing Practices you indicated are appropriate for processing facilities, I think there is going to be a bit of a problem when you get down to the packing houses, particularly in warm weather areas. Many of them are partially or totally open to the environment, particularly some of the smaller facilities. So, many of the recommendations that you have given here, while appropriate for an enclosed facility, would be very difficult to implement when you basically have a roof and no sides.

DR. SALTSMAN: We realize there is a lot of packing going on out in the field, and that is a challenge for the operator to maintain good practices, but, you know, hopefully -- I have only briefly touched on it, but that is an area that you don't have the controls that you have when you have a closed-in facility and any more guidance and insight we can

get on that area would be very helpful, too.

MR. AGUIRRE: Dr. Saltsman, John Aguirre with United Fresh Fruit and Vegetable Association.

I noted the recommendation that anyone handling produce should wear disposable gloves. Would you elaborate a little bit on how expansive that recommendation is in the produce environment, and then secondly, what benefit is thought to be provided by the use of disposable gloves over hands that are properly kept clean and sanitary through good washing practices.

DR. SALTSMAN: Again, it is a recommendation to use gloves and if good sanitation practices or good hygiene practices are followed, I think that the gloves -- again, this is a recommendation -- would not be necessary, but just again, it is a recommendation, if you can, encourage people to wear gloves in handling. If it is not practical for the type of work being done, then, just ensure that you have got good hygiene, that the workers, or however is handling the equipment, have done good hand washing.

MR. AGUIRRE: My comment that, for example, with some

citrus, cloth gloves are used to provide for a good quality product to prevent bruising, and so that recommendation may need some necessary exceptions to that in the industry.

DR. SALTSMAN: Right. Again, this is a very broad-based document. You are right, there are situations where you have got other kinds of gloves perhaps even being used where you couldn't put rubber gloves on top of them or other types of gloves.

MS. ZAWEL: Stacey Zawel with the United Fresh Fruit and Vegetable Association.

I just wanted to address a question that was asked before, which deals with the turnover rate, and how do you maintain sanitation of your employees when the turnover is so great.

I think the food service industry is certainly representative of the difficulty of doing so, but nevertheless, I want to kind of convey to you that there is a widespread industry practice in major growers to actually have as a stipulation for employment the crew member must follow the company around from California to Arizona or whatever route they take, that is a stipulation for

employment.

So, it might, in fact, not be as difficult an issue as it is perceived to be.

DR. SALTSMAN: Thank you very much.

MR. GARDINE: Stacey, a question for you. One of the things we talk about in this guidance document is grower training of workers. Are there sufficient programs out there, not necessarily on the part of the grower, but perhaps state and local organizations giving such training and perhaps requiring it, that might also address this question?

MS. ZAWEL: You mean from an industry program, you are saying a state program?

MR. GARDINE: Industry, state, any program.

MS. ZAWEL: I can't give you a specific reference to any hardbound document that everybody in the industry follows. I think what we are seeing now is kind of a widespread implementation of a concept that sanitation practices must be followed, and my personal experience with some of our growers has been very enlightening in the implementation steps that they have done.

One thing I have encouraged them to do is document what it is that they are doing, and I would certainly, I think, in the grass-roots meetings, we will be able to get a good representation of what that is.

MR. GARDINE: Thank you.

DR. HEDBERG: I just wanted to follow up on John Aguirre's comments on the gloves. In Minnesota, we have not been big advocates of food handlers wearing gloves frequently because it becomes a substitute for good hygiene, and I think the other comments you made in addressing him sort of suggested that they were sort of an acceptable substitute for good hygiene and hand washing, and I think in addition to potentially being a very expensive item for production workers to have on hand, you know, may actually not get us at what we want to get at.

DR. SALTSMAN: Thank you.

MR. BERNARD: First of all, thanks for your presentation. I enjoyed it. There were a couple of things in reference to GMPs for packing houses, processing facilities. Earlier speakers have referenced 21 CFR 110, which is the umbrella

GMPs which already apply to a wide variety of facilities in the industry.

The things that you talked about specifically on rodent control, however, appeared to be a bit more in depth than what is in 110. I don't know that there is an answer or even a question. I just wonder whether we are creating a different document in relation to the overall sanitary requirements or are we getting a bit more specific here. Maybe somebody else on the panel would want to address that.

DR. SALTSMAN: My reference to 110 in a lot of those instances was to use it as guidance to establishing programs. That is a starting point, but it wasn't necessarily to be the only direction to go in. A lot of the recommendations I had, that may have seemed very specific, came out of a lot of the references that we had were from the practices that are in the field or are used out in agriculture now.

DR. KILGEN: I had a similar question I guess as Dane. I was sitting here listening, and I was wondering, because a lot of what of presented were those CFRs, and I can see them

in a processing plant, but I jumped all the way back to the field. I live in the middle of a sugar cane operation, and I know it is not exactly fresh produce, but it goes on as far as you can see.

It seems to me when you are out in the field with hundreds, thousands of acres, those GMPs, it would be very difficult to take them out a processing plant and put them there. I can't see -- I am not sure about mud, diesel, and grease coming off of huge farm equipment every single day. I know what sugar cane harvesters look like after a day in the field. Where would that be done and can be done? Those kinds of questions came to my mind. It didn't seem like a direct translation from processing to field, not even close maybe.

DR. SALTSMAN: Well, the field, again, we are using the GMPs as guidance to how to apply this to the field. The field is a unique situation and a unique environment, and it is going to be different for different produce situations, as you said, between sugar cane and growing strawberries. I mean, you know, we are not even talking the same language.

As a broad-based document, you know, we try to give what we consider to be the best guidance overall, and then the individual grower is going to have to apply it to their own situation. If one thing doesn't work for them, then, they have to accept the fact it just doesn't work.

DR. BUCHANAN: There is a series of we will call them good practices associated with minimizing quality-related microbiological concerns with fruits and vegetables. Do we have any feel for the overlap between the Food Safety Practices and the Good Quality Practices, are they similar or are they divergent?

For example, you have a whole series of practices that are used in fruits and vegetables to limit market diseases. Do they also have a positive impact on avoiding pathogens?

DR. TROXELL: We haven't looked at the quality practices. That would be very interesting to look at them to see what possible impact they might have on public health practices.

DR. BUCHANAN: This might be very important since a major component of this is education. The industry is already used to these practices.

DR. KVENBERG: Dr. Buchanan, could I ask you a question? Is there a research component here relative to pathogens and quality and disease that you would guess that we need to look at, too?

DR. BUCHANAN: There is some indication that there is a correlation between the incidence of market disease and the carriage of pathogens, however, there has also been cases where we have identified contaminated fruit that had high quality in terms of total bacterial numbers, but were still contaminated with pathogen, so I am not sure.

DR. GRAVANI: A quick question and comment on training programs. As we look at this whole area across the board, in all of these areas, I think that the document needs to reflect the diversities that you addressed earlier, but also there needs to be some uniformity of this training through the Cooperative Extension Service and Farm Advisers, et cetera, so as much guidance as could be provided, I would recommend that we look at that, because that is going to be critical to all of these different aspects of farm and field workers, packing house employees, et cetera, all through the

system.

DR. SALTSMAN: Thank you.

DR. SHANK: Any other questions or comments?

[No response.]

DR. SHANK: Thanks, Joyce.

[Applause.]

DR. SHANK: It is Dr. Smith's turn again. At this point, Michelle is going to address manure and municipal sewage sludge.

Manure and Municipal Sewage Sludge

DR. SMITH: When we were working on the agenda a couple of days ago, we did originally have manure and sewage sludge before lunch, and we decided for a number of reasons, aesthetics not being the least of them, to shift it to after lunch, so I am a bit surprised to be called up here now, but we will just go with it, and here we go.

[Slide.]

Health officials and scientists agree that animal manure and human fecal matter represent a significant source of human pathogens.

[Slide.]

The use of manure or municipal sewage sludge in the production of produce must be closely managed to limit the potential for pathogen contamination of produce. Growers must also be alert to the presence of human or animal fecal matter that may be unwittingly introduced into the growing environment.

[Slide.]

Properly treated manure or municipal sewer sludge can be an effective and safe fertilizer. Untreated or improperly treated manure or sludge used as a fertilizer, to improve soil structure, or that enters surface waters through runoff, may contain pathogens that can contaminate produce.

[Slide.]

The initial draft guide that we are working on right now deal primarily with the use of manure. We understand that municipal sewage sludge is not widely used on fields growing fresh produce. However, we have included a discussion on sewage sludge for a number of reasons. In addition to the potential for untreated sludge to serve as a source of

contamination, properly treated municipal sewage sludge has been shown to have beneficial agricultural uses.

[Slide.]

Further, much research has been done on treatments to reduce levels of pathogens in sludge. Some of the recommendations from these studies may be applicable to manure.

[Slide.]

Growers may need to develop and follow Good Agricultural Practices for handling manure to reduce the potential of introducing microbial hazards to produce. Practices in terms of general principles may include things such as: processes to reduce the possible levels of pathogens in manure; minimizing, to the extent feasible, direct or indirect manure-to-produce contact, especially close to harvest; and assessing adjacent or nearby land uses to determine risks from animals that may shed pathogens that can cause contamination.

[Slide.]

In looking at nearby land uses, some of the examples of sources of fecal contamination are listed on this slide.

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organic materials are digested aerobically or anaerobically by microbial action.

Properly composted manure can be an effective and safe fertilizer and/or soil amendment.

[Slide.]

Historically, much of the research on the composting of manure and handling practices in the field have focused on the effects of different practices on soil fertility and crop quality.

Research on pathogen survival in untreated manure, treatments to reduce pathogen levels, and assessing the risk of cross-contamination of food crops from manure under varying conditions is largely just beginning.

On November 5th, I had the pleasure of visiting USDA Beltsville Agricultural Research Center for a stakeholder's meeting, at which they talked about a new, two-acre research facility that they are dedicating to the study of pathogen survival in composted materials and other factors, such as potential travel in a field environment. It looks like a very interesting and ambitious set of research, and it is

going to be very interesting to see what comes out of that.

[Slide.]

In addition to the fact that much of the research on pathogen reduction in treated manure is just beginning, the specific requirements of any particular treatment situation will vary based on many different factors.

To that extent, the guidance document right now does not list specific conditions that people should be following as part of our Good Agricultural Practices, however, we are receiving resources and references, contacts from a number of the different groups that we are working with, and when we have had a chance to review those materials, we intend to reference them and provide as much guidance as possible.

[Slide.]

As this information becomes available on the viability of microorganisms in manure, and on treatments that most effectively reduce those levels, growers may need to take note of these recommendations and this information and adjust practices accordingly.

[Slide.]

While we don't have sufficient data at this time to make specific time, temperature recommendations for the different potential treatments, we do have ideas of practices, GAPs, that growers may want to consider in their particular operation with the goal of reducing the risk of microbial cross-contamination from manure to fresh produce.

[Slide.]

These GAPs will differ for treated versus untreated manure.

[Slide.]

For untreated manure, growers may reduce the risk of contamination by maximizing the time between application and harvest of fresh produce. Recommended minimums generally range from 40 to 60 days before harvest. Some recommendations depending on the crop and the situation may be longer.

[Slide.]

Microbial survival is greater in warm, moist climates than in extremely arid or cold environments. Some researchers have found that E. coli 0157:H7 may survive in dairy cattle manure for at least 42 to 70 days.

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[Slide.]

Depending on the climate, the crop, and other factors, growers may want to consider choosing the longest possible interval rather than going towards the short intervals, and they take these same factors into consideration when they are deciding whether even to use treated as opposed to untreated manure.

[Slide.]

Ways to maximize the interval between application of untreated manure and harvest include incorporating manure into the soil prior to planting. Growers may also consider maximizing the interval by planting crop rotations where manure is applied to fields planted to crops that are to be cooked or heat processed prior to being delivered to consumers.

[Slide.]

Growers should avoid side-dressing of mature plants with untreated manure close to harvest.

[Slide.]

With respect to treated manures, natural fertilizers, such

as composted manure, may need to be produced in a manner to reduce the likelihood of introducing microbial hazards.

[Slide.]

While we are not giving specific recommendations at this time as to what those treatments should be, whatever parameters the grower selects, they may need to ensure that all materials receive an adequate treatment, such as by turning outside edges into the center of a compost pile or bin.

[Slide.]

Care should be taken to avoid cross-contamination of fresh produce from manure that is the process of being composted or otherwise treated. Likewise, improperly treated or incompletely treated manure may also be a source of contamination.

[Slide.]

Further, composting and other treatments may reduce but not eliminate potential pathogens in manure. Furthermore, it is unknown to what extent pathogens that survive treatment such as composting may regrow in the manure if it is stored

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before use.

[Slide.]

For these reasons, to the extent feasible, growers using treated manure may still want to consider some of the recommendations made for the use and handling of untreated manure, such as maximizing time between application and harvest.

[Slide.]

A few words about manure handling. Handling practices that minimize cross-contamination from manure in open fields, compost piles or storage areas onto nearby maturing crops will decrease the opportunities for contamination.

[Slide.]

GAPs for handling manure might include things like making sure manure or compost facilities and storage areas are secure to prevent cross-contamination from runoff, leaching or wind spread.

[Slide.]

The final area under the kind of manure, sewage sludge chapter is the uncontrolled exposure of the crop by animal

feces. Growers should assess the prevalence and likelihood of animal feces significantly coming into contact with crops.

[Slide.]

To the extent possible, growers should take a look at their wild animal populations. High concentrations of wildlife, such as deer or waterfowl in a field, may increase the potential for microbial contamination.

[Slide.]

Depending on the operation and the type of wildlife in question, growers may be able to establish good management practices or GAPs which effectively deter or redirect wildlife to crop areas that are not destined for the fresh produce market.

[Slide.]

Domestic animals, such as cows or sheep, should not be allowed to come into contact with fresh market crops. Depending on the operation, GAPs may include things like keeping livestock confined, keeping them in pens or in yards, or preventing their entry into the field.

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[--- Unable To Translate Graphic ---] 13

[Slide.]

Physical barriers, such as fences, to prevent movement of wild and domestic animals into the crop area are desirable when something like that is possible. It is certainly not practical in all situations, but where it can be done, it can be an effective control.

That concludes my presentation on this topic.

DR. SHANK: Comments or questions for Dr. Smith?

DR. BUCHANAN: In developing these recommendations for manure handling, is there any specific target pathogen that you have in mind around which these recommendations are going to be designed?

DR. SMITH: We haven't gone as far as coming up with a target pathogen. On the other hand, we may find that some of the enteric pathogens survive very poorly in the environment. E. coli 0157:H7 has a longer survival time and it is also one of significant concern. So, it is possible that that would be on our list of targets.

Any suggestions and recommendations that people have in that respect we are certainly open to.

DR. KILGEN: I had a question. I was just wondering if human sewage runoff was going to be considered with all of the potential enteric viruses.

DR. SMITH: It is certainly a potential source.

DR. SHANK: Everybody is not interested or else they are hungry. I think they are hungry.

Thank you, Michelle.

DR. SMITH: Thank you, everyone.

[Applause.]

DR. SHANK: It is ten minutes of 12:00. Let's reconvene at 1 o'clock.

[Whereupon, at 11:50 a.m., the proceedings were recessed, to be resumed at 1:00 p.m. the same day.]

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AFTERNOON PROCEEDINGS

[1:00 p.m.]

DR. SHANK: For those of you who were not here this morning, the next presentation is on Transportation.

Joyce.

Transportation

DR. SALTSMAN: Most of the practices mentioned this morning relative to sanitation and hygiene in the field and facilities are going to apply here as well in transportation.

[Slide.]

Contamination of produce may occur due to improper practices during handling, loading, unloading, and transportation operations.

Wherever produce is transported, the sanitation conditions should be evaluated, especially between links in the distribution chain.

[Slide.]

21 CFR 110.93 states that "storage and transportation of finished food shall be under conditions that will protect

food against physical, chemical, and microbial contamination."

[Slide.]

Cross-contamination from potentially hazardous foods and contaminated surfaces may occur during transportation and handling.

Fresh produce should be segregated from other food and nonfood sources of pathogens in order to prevent contamination.

[Slide.]

Now, some controls of potential hazards would include handling precautions where workers who are handling any kind of produce in the loading and unloading of the product should practice again good hygiene practices. That is just good common sense.

Product handling equipment, any forklifts or conveyors should be free of obvious contaminants, mud, oil, or debris.

Washing hands and wearing disposable gloves when handling produce. Again, this morning, maybe if you practice good hand washing techniques, the gloves may not necessarily be

necessary.

[Slide.]

Under trucking precautions, try to assure that the truck or other carrier sanitation requirements are met before loading to reduce the likelihood for microbial contamination.

Keep open communication along the transportation route regarding food safety risks and the need for adequate safety steps.

[Slide.]

Now there are some basics to consider in this area, and that is again clean and sanitation transportation vehicles are important. For example, trucks that were used perhaps to haul chickens and then are turned around and used to haul produce, would be a high potential for being a source of microbial hazards. Such trucks should be cleaned and sanitized.

The best advice here is that the truck should be inspected before loading, know what the truck has been used for, and take the necessary precautions as necessary.

[Slide.]

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Many fruits and vegetables are best maintained at refrigerated temperatures, which would be not over 40 degrees Fahrenheit to reduce the potential for microbial growth. If such is the case, then try to ensure that those temperatures are well kept.

For fresh produce that are not held at refrigerated temperatures, care should be taken to reduce the potential for microbial contamination of the product, such as injury to the outside of the product that could allow microbes to enter and to grow.

[Slide.]

To reduce the potential for microbial growth, produce that is stored at refrigerated temperatures should be transported from cold storage to a precooled trailer.

Consider precooling the trailer to proper loading temperatures prior to loading the produce.

Fresh produce should be carefully loaded in a manner designed to minimize physical damage to the produce to reduce the potential for contamination during transport.

[Slide.]

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Maintenance of appropriate temperatures for the produce after loading and during transport of the product is very important.

For refrigerated produce, the temperature of the product in transportation should be monitored as appropriate to ensure the proper functioning of refrigeration units.

Care is needed to maintain appropriate temperatures for the produce after unloading and transport to storage to reduce the potential for further growth.

[Slide.]

The last thing I want to mention is that some researchers believe that damage to diseased produce may be vulnerable to the outgrowth of microorganisms, especially pathogens.

Operators should maintain good sanitation practices to avoid the potential for localized contamination from becoming more widespread.

That is it for transportation.

DR. SHANK: Any comments or questions? Yes, Mike.

DR. BUCHANAN: How common is the practice of carrying chickens followed by produce?

DR. SALTSMAN: I don't know exactly how common it is, but in discussions among our group, for independent truckers, apparently, when they cross the country, they don't like to go with an empty load, so they attempt to book their truck for carrying something, so that was just used as an example primarily. For companies or larger operations that have their own trucks, that probably doesn't even apply, but for these independent truckers who don't want to drive around with an empty load, and want to carry something, and they don't care what so much, it is more important to be aware of what they haul and the condition of the truck before you start using it.

DR. SHANK: Mike, maybe not the best examples, but we all recognize that backhauling is a problem.

Other comments or questions?

[No response.]

DR. SHANK: Thanks, Joyce.

Dr. Michelle Smith is going to talk about tracebacks, and I would suggest that maybe we don't have the proper term here as far as tracebacks goes. Maybe it is product

identification, maybe it is source identification, so I would ask you to think in the broader sense of what is intended here.

Traceback

DR. SMITH: I will use the term traceback because that is what I have got written into my notes, but I think it is a good idea to think in as broad a term as possible.

[Slide.]

Now, this is an area that is not strictly the same kind of area as the four that we have just finished talking about. It is not a hazard to be minimized or avoided. Traceback is not going to prevent a hazard, but it can do a number of things that are very useful both to the industry and to health professionals.

First of all, an effective traceback system can limit the potential scope of an outbreak. It can limit the populations at risk. A traceback system that leads to a specific company source or growing field is the best of all possible situations.

Such a system would lessen the economic burden on operators

not responsible for a problem. As noted in the water section, there are a lot of difficulties with traceback.

[Slide.]

From a public health standpoint, traceback minimizes the unnecessary expenditure of health resources. It can help reduce consumer anxiety. Free consumers to enjoy fruits and vegetables not implicated in an outbreak.

Operators should examine the current system that they have in place to track product from the farm to the receiver, and vice versa, and where possible, develop procedures and technology to improve traceback from the receiver to the farm.

[Slide.]

Now, there are a number of things about traceback and about the way different commodities are handled that will make it more or less difficult for certain industry segments to institute a traceback system.

An effective traceback system should have as much detail as possible. For example, documenting the source of product including date of harvest, farm identification, and chain of

custody from farm to receiver.

There should also, to the extent possible, be a mechanism for identifying product that can follow from farm to consumer.

Now, these are the points that we are making in a situation that we are encouraging people to do the best that they can do. We understand that there are a lot of practices that make this difficult, such as commingling of certain fruits and vegetables, how a distributor may handle product that they have gotten from a number of different sources.

There is also the practice of recycling shipping containers, so you may have a container that is being reused over and over again, and the label on that container says tomatoes from the Salinas Valley, and the product in it has nothing to do with those tomatoes.

Even being able to traceback once a fresh fruit or vegetable is implicated, even being able to traceback to a region or a handful of farms is a big advantage over having the entire segment of that particular item be suspect.

This is our feeling towards traceback. We encourage it. If

anyone has a system or a practice that they have found to be effective, that may be useful as an example in this guidance document, we are open to those suggestions.

That concludes my section on traceback.

DR. GOMEZ: Are there any questions or comments? Yes, sir.

MR. BERNARD: A comment, if I may. In addition to the list that you provided of factors that make this difficult, there is something that those of us in industry have had to struggle with on occasion, and it is a practice called product diversion. That makes tracing through the system very, very difficult.

That is the practice of, for example, a producer may run a special in a certain area of the country because sales lag there, and to make that work, they offer the product at a reduced price through the distribution chain. Occasionally, those shipments end up in places where the product is selling at full price, a somewhat disturbing practice, but it is one that you may need to consider as you think about how to make tracebacks work.

DR. SMITH: Thank you.

DR. SHANK: Other comments or questions?

[No response.]

Public Comment

DR. SHANK: Then, moving forward with the agenda, the next item would be the public comment portion of our program. We have a number of individuals. Let me suggest that we go through the ones that have indicated that they would like to speak. We will do those first and then we will open it up to anyone else in attendance that would like to present something.

Let me start off with Stacey Zawel with the United Fresh Fruit and Vegetable Association.

Stacey.

MS. ZAWEL: Thank you, Fred, and thank you for the opportunity to speak on behalf of the industry today. The 1,100 member companies of the United Fresh Fruit and Vegetable Association take pride in delivering safe, high quality, and nutritious foods to consumers around the world. We certainly believe that through a partnership with the produce industry, the President's Food Safety Initiative can

provide important benefits to consumers and the industry alike, and in order to deliver these benefits, the initiative must achieve two equally important public health objectives.

First, the initiative should endeavor, through policy research and industry practice, to minimize the risks of foodborne disease associated with the consumption of fruits and vegetables, and second, the initiative must promote the consumption of fresh fruits and vegetables.

Unfortunately, the goal of promoting fresh fruit and vegetable consumption seems only to be an assumed part, if that, of the initiative. This could be a serious mistake. The United States is certainly a country that suffers disproportionately from many avoidable diet-related health problems including cancer, heart disease, diabetes, and obesity. In fact, several recent studies confirm the startling health benefits of consuming produce and preventing chronic disease.

I am very happy to see certainly more information in the press lately in regards to the benefits of consumption of

fresh fruits and vegetables, and I have one here that was in Tuesday, November 11th, Washington Post, which summarized a report by the National Heart, Lung, and Blood Institute, that in fact stated that one way to prevent high blood pressure was to consume eight to 10 servings per day of fruits and vegetables.

One of the most difficult tasks that we have, however, is changing poor dietary habits of these consumers and therefore in developing and implementing this initiative, we must maintain a steady focus on the need to increase consumption of fresh fruits and vegetables.

Any consequences in the initiative, intended or not, that undermines that goal must be viewed as a very serious lapse in public health policy.

Estimates of foodborne disease in this country, as many of you are very well familiar with, are from 6 1/2 to 81 million cases every year with approximately 9,000 deaths annually.

Numbers like these, and our own industry's experience, have prompted the produce industry to act aggressively to

minimize foodborne disease risks because we understand very well the significance of foodborne disease, and we intend to do our part in addressing this complex and very serious public health issue.

The produce industry is unlike any other sector in the food economy, dairy, meat, poultry, seafood, or processed foods. The industry has over 600 produce grower and commodities specific organizations supported through dues and assessments.

Why is there so many? Because the needs and the conditions of the many different aspects of produce growing, harvesting, packing, shipping, handling, and marketing varies so greatly, so much so that industry operators certainly feel it is essential to support specific groups that reflect these very specific needs, and it illustrates the reason why United and other industry groups continue to insist that Food and Drug Administration guidance be drafted, so as to accommodate this enormous range of practices that define our industry.

Despite the variety of practices and the differences, many

compelling reasons exist for the produce industry to act proactively to prevent foodborne disease, and in fact, in October of this year, 20 produce organizations endorsed a document intended for broad application to the produce industry, and I believe many of you have seen that.

It is the industrywide guidance to prevent microbiological food safety risks for produce. This document identifies four key aspects of the produce environment that merit attention, not at all unlike what was shared today, and these include water, manure, worker field and facility sanitation, as well as transportation and handling.

I think it is evident that we can all agree that good common sense sanitation practices are extremely important to minimizing the risks of foodborne disease, but there is very little scientific evidence to tell us what other standard production handling practices employed by the industry merit change or what kinds of changes may be necessary to minimize risks.

For example, the industrywide guidance document acknowledges that animal manure could be a potential source of pathogens.

Therefore, the industry understands that careful handling of manure is an important consideration, however, we must demand that any federal policy which may dictate standards for manure handling be based upon sound information.

Similarly, we acknowledge that water, which comes into intimate contact with produce should also be of good quality, yet, what specific minimum quality standards are needed in the produce environment to protect public health, and I think we got to this earlier today, that we don't really know what we should define good quality standards to be in the produce environment.

But it is for these reasons that we place heavy emphasis on the need to conduct targeted research to provide the growers and handlers of produce practical, effective tools to prevent this problem.

We certainly want to recognize and acknowledge FDA for recognizing the lack of scientific information and to move forward in a direction that we have seen today, that stays within the confines of the science that we understand.

But in moving forward, then, with this initiative, we also

must acknowledge this lack of information and indicate clearly what gives rise to potential microbiological hazards in produce.

The President's initiative must cope with, and rather than discard, this very difficult, important challenge. For example, the industrywide guidance document focuses industry's attention on what we collectively believe to be the most significant microbiological health issues based on our best intuition, and such focus on these important issues is critically important. A lack of focus will squander resources and dilute the effectiveness of any of these efforts, and FDA, too, should heed this rationale.

FDA guidance must be limited to these key microbiological risk areas, which we have certainly seen today to have been taken into account, and consist of responses known to be necessary and effective in minimizing risks of illness.

As we have seen FDA lead this effort based on science, we would also like to see FDA lead public opinion rather than be led by it, and so in discussing specific instances of foodborne disease related to different fruits and vegetables

or even processed fruits and vegetables, the details of those incidences need to be confined and need to be discussed clearly and need to be presented to the press in a very, very detailed manner to make sure that we understand that hepatitis A in frozen strawberries was the issue, and that processed apple juice was the issue of E. coli 0157, which may or may not have anything to do with what happened to the raw produce handling.

Nevertheless, we certainly appreciate this opportunity today to share our thoughts regarding the general process of developing guidance, and we will definitely provide more detailed response to the specific proposals in the future. Thank you.

DR. SHANK: Our next presenter will be Sue Doneth, Hepatitis Foundation.

MS. DONETH: My name is Sue Doneth, and on March 11, 1997, my 10-year-old daughter Lindsey became one of the millions of victims of foodborne illness.

My daughter consumed contaminated strawberry shortcake as a part of her school lunch and contracted hepatitis A. What

the experts described to me as a mild flu-like illness was in reality a horrifying experience for Lindsey and our family.

Lindsey was hospitalized for several days and endured extreme physical pain and suffering. Eight months later, she continues to battle fatigue, unexplained back and joint pain, and uses an inhaler for ongoing respiratory problems. Lindsey has also endured hair loss, loss of appetite, and in July, she endured a 10-day bout of shingles. I am angered that Lindsey and the 300-plus hepatitis A victims in my community have been viewed as mildly ill.

There is a perception that hepatitis A is not a serious illness, and because nobody died, somehow the people who suffered are not important. I have talked to many victims in my community, and Lindsey is not the only victim still suffering physical effects from this virus.

As a result of Lindsey's illness, I have become actively involved in issues regarding food safety. I serve on the National Board of STOP, Safe Tables Our Priority, a grass-roots national organization devoted to demanding a

safe food supply.

I formed a Michigan chapter of STOP and serve as president of that chapter. Our national president, Nancy Donnely, was standing next to the President of the United States when he publicly announced the initiative to ensure the safety of imported and domestic fruits and vegetables.

My daughter Lindsey and I were present at the White House in May when Vice President Gore announced the original Food Safety Initiative.

The number one priority of the FDA and every other agency charged with overseeing the food supply should be prevention. As a society and as especially as government agencies, we tend to be reactive rather than proactive.

It is outrageous to me that the saying "an ounce of caution is worth a pound of cure," continually escapes government and industry. The increased incidence of foodborne illness and death have prompted the President to aggressively address issues of food safety, yet, industry uses all of its resources and lobbying power to fight reform.

There are over 30 foodborne pathogens invading our food

supply and we are only beginning to acknowledge their existence and the threat they pose to consumers. Viruses like hepatitis A pose unique challenges when determining how to fight them. For example, hepatitis A is difficult, if not impossible, to detect in food.

Industry practices of chlorine washing are ineffective in cleansing fruits and vegetables because it does not kill the virus. The recent popularity of implementing irradiation for fruits and vegetables is also ineffective in killing hepatitis A, as well as some other pathogens like Cyclospora.

As consumers, we have no way to ensure the safety of our fresh fruits and vegetables other than simply washing them, which does little to protect us. The food industry continually attempts to shift the responsibility for safe food to the consumer, yet, the government can't even tell us how to protect ourselves when dealing with fresh fruits and vegetables.

There is no way for consumers to protect themselves if they receive hepatitis A contaminated fruit. Therefore,

prevention is the key when examining how to prevent viruses like hepatitis A from invading our food supply.

It is absolutely essential that we spend the time, the money, and the energy to research use of the hepatitis A vaccine for use in high risk populations and/or certain food industry areas. Hepatitis A appears to be the one foodborne illness that is preventable through vaccination.

Extensive research needs to be conducted to determine the feasibility of using the Hepatitis A vaccine as a preventive measure, therefore eliminating the possibility of future hepatitis A outbreaks like the one experienced by those in my community.

Hepatitis A outbreaks are not uncommon, and I believe that we will see the incidence of hepatitis A increase unless we do something to prevent it. Certain foods require unique methods to prepare them for mass production and distribution.

For instance, strawberries that are to be processed for freezing must have the stems completely removed during the picking phase. This means that workers in the field are

physically manipulating the fruit, often with their fingernails, to completely remove the stem. This provides a very high risk probability for contamination to occur, particularly when hand washing facilities are either not available or not used in the fields.

As a consumer, I am tired of hearing about cost-benefit analysis whenever changes to current industry practices are discussed. Industry would be far better off to stop worrying about their pennies and pay more attention to their dollars.

When a company is responsible for a foodborne illness outbreak and distributing contaminated food, the economical costs to the company can be astronomical. Society as a whole also carries the burden of these costs through economic losses of the victims, insurance costs, and costs incurred by health departments and federal agencies when responding to a foodborne illness outbreak.

The food industry needs to realize that it is cheaper in the long run to do things the right way rather than the least expensive way. After all, how do you tell the parent of a

child who dies from foodborne illness that preventing their child's death isn't worth the cost.

Mandatory standards and guidelines are needed. Voluntary compliance simply doesn't work in the for-profit industry arena.

I urge the FDA to closely examine the need for rapid microbial testing and research in preventive measures to avoid pathogenic contamination in our food supply. The faith and trust in the system of ensuring a safe food supply is being destroyed and consumers deserve to have that trust restored.

Strong labeling laws are needed to inform consumers about what they are purchasing and feeding their families. Consumers have the right to make informed decisions about their food choices and should be warned of potential hazards, such as drinking unpasteurized or unsterilized juices. Consumers also have a right to know when a product is linked to foodborne illness.

We have a right to be informed of any recalls and the company distributing the product should be named. Recalls

must be classified much like they are in the meat and poultry industry, and it is essential that press releases are issued as a matter of practice.

As a federal agency, it is the FDA's responsibility and obligation to protect and inform the people. The food industry has the distinct advantage of having tremendous resources and power to protect themselves, and their actions have demonstrated time and time again that often their first priority is to protect their profits.

As consumers, we don't have the money, the time, or the power to lobby Congress and to appear at meetings like the one being held today, but I can assure you, as the number of victims of foodborne illness increases, our power increases and our voices demand to be heard.

Thank you.

DR. SHANK: Thanks, Sue.

Our next presenter will be Mr. Lee Frankel, President of the Fresh Produce Association of the Americas.

MR. FRANKEL: My name is Lee Frankel and I am the President of the Fresh Produce Association of the Americas, which is

based in Nogales, Arizona.

The association represents the interests of American businesses involved in the marketing of fresh fruits and vegetables grown mostly on the West Coast of Mexico.

During the last shipping season, association members were responsible for two-way trade exceeding $1.2 million. The primary shipping season is between November and June.

The association and its members are fully supportive of efforts to ensure a safe food supply for American consumers. Our safety record is excellent. Nevertheless, the association has adopted the five points Food Safety Assurance Standards which addresses such key points as water treatment, hygiene for workers, proactive pesticide practices, minimum handling practices, and protective packing house systems.

One factor I would like to point out is that Mexican producers have long been aware of pathogens, the need for clean water, tracebacks, and other precautions because all of them affect the condition in which the produce will arrive at the final destination.

Practical forms of GMP and GAP already exist for produce imports from Mexico, otherwise, there would not have been the growth in the industry that we have seen to this point. President Clinton's Food Safety Initiative and the proposed guidance must be science based. There is little evidence showing that foodborne illnesses are increasing at a rate greater than the expansion of the food service and manufacturing industries, nor is there much evidence showing that the foodborne illnesses are constituting a major public health crisis, although it is quite clear that public awareness and media interest have increased.

In addition, there has been no presentation of evidence showing that imported fruits and vegetables are more likely to be contaminated than domestic produce. In fact, information and data given by U.S. officials to foreign government representatives in Washington seem to show a higher rate of domestic fruits and vegetables being involved in outbreaks of foodborne illnesses and imports.

There should be increased and approved training for public health officials, as well, to better track sources of

foodborne illnesses. Since contamination can occur through many ways for many reasons, public health personnel must be trained to determine the real cause, not simply the most convenient one because of prejudice or lack of understanding of the seed to table process.

This prejudice and complete lack of understanding is often displayed by certain public health officials when they say they cannot eat vegetables in certain overseas countries, so why should they assume that fruits and vegetables from those countries to be safe to eat when they are imported into the United States.

They show their lack of knowledge and understanding of the farming, harvesting, and packing and shipping processes.

Simply put, the contamination point is generally involved with the handling, not in the cultivation and production in these foreign countries.

Therefore, if one were traveling in those countries normally associated with contaminated fresh produce, one would not eat raw U.S. grown produce either.

Another general point is that the guidance must be WTO

legal, and not curtail any international obligations of the Unites States. It must also assure national treatment. Domestic produce, as was mentioned earlier, should face the same level of regulatory scrutiny and testing as required for any imported product, and likewise, for imported produce being held to the same standard as domestic produce.

I have a general concern on the issue of national treatment based on the history of the pesticide monitoring programs. Currently imported produce is five times more likely to be inspected by the FDA than domestic produce in spite of very similar rates of violations.

In addition, just because imported produce tends to go through check points, rather than being on farms spread out around the country, that that should not be used as a justification to focus sampling and collection on imported produce.

A sort of an additional example is at present, domestic farmers can seek Section 18 special use exemptions for pesticides which if found on imported fruit or vegetables, would require that import to be destroyed. Section 18

exemptions therefore create a dual standard.

Our association is concerned that a similar double standard might be written into the proposed guidances especially in regard to how and when foods are considered to be adulterated.

If the administration is truly interested in improving public health, it must not repeat and perpetuate the double standards that guide existing FDA produce programs.

We are also concerned about the idea or the thought that these guidelines will just be a voluntary item. In general, we believe that the industry or the retailers and the wholesalers will look to these FDA guidelines as being a de facto standard in which all their suppliers should certify that they meet. We are already seeing this in terms of much of the produce exporters whose product that we handle are already working with third party certification systems, and many retailers are already demanding that of the products that we handle.

Therefore, I would like the FDA to focus, and the team to focus, on making sure, at least on the core guidance

documents, that they focus on items that do have a measurable scientific benefit as opposed to, well, this just seems like good practice, and theoretically, it could help prevent something in the future.

Therefore, maybe there can be like a second portion of the guidance where there isn't the scientific background, but at least there is the information as to what seems like it might make sense even if we can't measure anything to this date.

Lastly, the FPA, the Fresh Produce Association of the Americas, urges that the produce team drafting the guidelines to come out and hold field hearings and hold visits on some of these foreign production areas just to get an idea of yes, we already have things in place and maybe there are certain areas that are so commonplace in the U.S. that they are being overlooked overseas, and they are items that should be included in the guidance, but, you know, whether we are above or below what we think U.S. producers are doing, we think it would be best if the team kind of came out and saw for itself what is going on and what needs

to be addressed.

DR. SHANK: Thanks, Lee.

The next presenter is Nancy Snider with the International Sprout Growers.

MS. SNIDER: I am Nancy Snider, President of the International Sprout Growers Association. I want to thank this panel for letting me speak in front of you, I appreciate it.

Probably you are wondering who we are and what we do. Well, we are an international organization which is headquartered in Lynn, Massachusetts. Our membership includes the full spectrum from the very large to the very small grower. Our members produce the majority of the sprouts which are consumed in the United States.

Most of our members, in fact, I would say all of our members have the interest of their industry and their consumers at heart, and are pledged to the highest standards of hygiene and quality control to provide nutritious and healthy sprout products and to show our customers how to enjoy those sprouts in a wide variety of food dishes.

ISGA is extremely -- extremely concerned about the outbreaks of E. coli and Salmonella infection which have been traced to alfalfa and radish sprouts.

What our industry had done to date. We are currently supporting three research projects with U.S. Department of Agriculture, one with the University of Georgia, and one with the University of Massachusetts.

On the 3rd of September, we were notified by Dr. Hicks of the USDA that our research project at Philadelphia was being given a top priority for which we are very appreciative.

We are also appreciative to Beltsville Research, Dr. Moline and Dr. Nicky O'Neill there, who have done a great deal of work on sprouts and have given us some very interesting strategies for combatting microbiological hazards.

ISGA members recognize the importance of research and the need to collect money for future research. USDA research has shown the use of calcium hypochlorite at 2 percent will kill Salmonella a E. coli on seed and not damage the germ. However, before we can recommend that to our members, we need confirming research, and Larry Beuchat at the

University of Georgia is conducting that research.

We also need research to develop alternative methods of sanitizing seed which are sensitive to chlorine. We need to know if the nutritional value of sprouts are reduced by sanitizing seed. We need to know if sanitizing affects the natural ability of the sprout to combat microbial infections and shorten shelf life.

We need to know what seeds can tolerate a high chlorine treatment and what seeds cannot. Finally, we are investigating what preventative measures can realistically be imposed at the farm level to prevent the contamination from occurring in the first place.

All of this much needed research costs money. Our research is being supported by our grower members, industry members and other interested non-members by the way of contributions to a special fund at ISGA which was established to support research and research only.

Caudill Seed Company, one of our members, is also sponsoring research into sanitizing seed. They are using a mixture of irradiation and gassing prior. The results of the

laboratory work of this particular research is very promising and now they are experimenting on larger lots of seed.

ISGA has developed and published detailed sanitary guidelines for our members to follow in the growing and packaging of sprouts. These guidelines concentrate on facility cleanliness, employee hygiene, growing and processing procedures, microbial testing procedures, and seed treatment prior to sprouting, but more on that from Barbara.

ISGA, the California Department of Health Services and the FDA are actively supporting the California Sprout Working Group in the development of voluntary guidelines to insure that sprouts remain a healthy choice for California consumers.

The Canadian Government has adopted California's sanitary guidelines for their sprouting industry, but our California sprouters are unhappy because there the inspection program is lagging due to lack of funding and inspectors. The California sprouters have adopted a really good inspection

program, but it has yet to be implemented, and we hope that funds will be available to implement this program in the near future.

Our present and future plans. ISGA is presently constructing an Internet web site. It will inform the public what sprouts are, where to find them, who produces them, nutritional information, and most importantly, sanitation tips, if there is a problem in sprouts, recall, what to recall, the latest research results, and any other information, recipes, and any other information that might be of interest to consumers.

ISGA is educating its members and will continue to educate its members on microbiological problems. At our next meeting, we are planning to spend an entire day on these issues.

A long term goal of ISGA is to bring all sprout facilities up to the requirements of our sanitary guidelines. As a first step, ISGA will issue a seal of approval to all growers meeting the ISGA guidelines. All growers who meet the ISGA guidelines will be listed on the web site and will

be allowed to display the seal of approval on their products.

We are currently investigating various programs and organizations as certifying groups. Those approved by ISGA will conduct investigations and provide certifications for interested growers, possibly a "quality through verification program."

What do we wish for? The Department of Agriculture Research Lab in Philadelphia has made sprouts a priority project. I wish that USDA would provide additional funding to this project so that the Research Lab could hire a postdoctoral assistant until the project is finished. This would expedite the project and provide answers to the sprout industry much quicker.

Hydrogen peroxide is a GRAS product approved for many uses. However, it is not approved for sanitizing seeds or sprouts prior to shipment. I would like to see FDA approve hydrogen peroxide for sanitizing seeds which are too sensitive to chlorinate. At this time we are gathering data to support a request for that certification.

Although our research shows that sanitizing seeds with chlorine is an effective strategy against E. coli and Salmonella, the USDA is developing better and possibly more effective methods of seed sanitation. I would like to see regulations which allow flexibility in seed sanitation to take advantage of future research.

The inspection program around the country is a very mixed bag. The Washington metropolitan area is currently supplied by sprout growers from three states. Virginia classifies them as farmers with absolutely no inspection. Maryland and Pennsylvania classes them as food processors and inspects them as such. Sitting side by side on the supermarket shelf will be the uninspected and uncontrolled Virginia grown sprouts and the Maryland and Pennsylvania inspected sprouts. The consumer is completely unaware of the difference. She may get super clean, doubly inspected sprouts or she may get sprouts grown in an unsanitary facility that has never seen an inspector.

The sprouting industry is a unique subset of agriculture in that the grower, a farmer, is required to pack the product

in small containers for display in the supermarkets and direct consumption by the public, a food processor. Sprouts growers are a combination farmer and food processor. I would like to see consistent regulations for sprout growers in the U.S.

For example, consider my current operation. I am a small sprout grower in Maryland. I am inspected by the Maryland Department of Health and the Department of Army as a food processor. I am also inspected by the Maryland Department of Agriculture as an organic farmer. My sprouts are organic. The county considers me a farm for zoning purposes and my facility is considered a farm building. I start with a seed and I end up with a product that is in a little plastic bag. I am a combination organic farmer and food processor whose product goes directly from the "field" to the consumer's table.

Thank you.

DR. SHANK: Thank you.

There was one other person that identified themselves as desiring to speak at this time. Of course, we are one hour

ahead of what we thought we were going to be, and that individual is not here.

Is there anyone in the audience who would like to speak at this time? Would you come up and identify yourself, please.

MS. SANDERSON: Good afternoon. My name is Barbara Sanderson. I am from the International Sprout Growers Association. I am the chair of the Sanitation Committee. Nancy Snider, our president, asked me to speak briefly on our sanitation guidelines.

The International Sprout Growers well recognize the value of, and need for, the President's initiative to ensure the safety of imported and domestic fruits and vegetables and other foods.

This program is about raising the awareness of all people producing food for human consumption as to the potential hazards to consumers from microbial and other possible contamination of the food.

The International Sprout Growers Association has taken a strong role in educating all sprout growers, not just our members, in the particular hazards that we must address.

The Sanitation Committee has gathered information on Good Manufacturing Practices from the U.S., sprouting and seed guidelines from Australia, New Zealand, and the U.K., and guidelines from International Fresh-Cut Produce Association, the IFPA.

These are compiled along with reports on results of research sponsored by the ISGA members and other data collected by ISGA members. Experts from Silica Labs and the Universities of Massachusetts and legal counsel familiar with FDA regulations have reviewed and edited our document.

This information is now available to members of the sprouting industry in four papers known as the Sanitary Guidelines for the Growing and Packing for Sale of Fresh Sprouts.

I have brought two of these papers, the Procedural Guidelines and the HACCP to these meetings, so that they may be a part of the information that the FDA brings to the table when the guidance on Good Agricultural Practices and Good Manufacturing Practices for fruits and vegetables document is being drafted.

The other two papers that I didn't bring have to do with building of facilities and information about sanitizers, and so on.

These are the ones that I would like to submit.

These guidelines are not complete. There are at least two areas where research on human pathogens in sprouts is needed.

First, if there is a safe and effective way to sterilize the seed and eliminate all pathogenic bacteria without hurting the quality of the sprout, that would be important information for the industry. Members of the ISGA are funding several experiments which Nancy mentioned with chemical sterilization.

Second, we need to also be looking at ways to eliminate human pathogens more organically. We sell a product that people eat in order to be healthy, and we need to ensure that it is healthy in all ways.

Very interesting work is being done on investigating such things as antimicrobial compounds in foods and bacteria that make their own repellant against pathogens, such as E. coli

0157.

To quote Lester M. Crawford, Director of the Center for Food and Nutritional Quality at Georgetown University in Washington, "We have concentrated on the end product of food so long when we should be looking at how to stop it from being contaminated in the first place."

I submit an article from a local newspaper along with this paper with his quote in it. Also, some research on feeding bacteria to cows, which the bacteria, which is a normal bacteria in the cows' intestine, managed to kill off the E. coli in the cows. This is the kind of research we hope to see more of in this country.

Meanwhile, the guidelines have suggestions for minimizing the risk of initial contamination of seed. Also, there is a recommended procedure for testing seed upon arrival at the sprouting facility by sprouting a compilation of small samples from every bag of seed.

This procedure will enrich any possible contamination to detectable levels before testing the seed for pathogens. There are also recommendations for regular testing of the

finished crop, the irrigation water, and the environment, as well as the HACCP to minimize the risk of contamination at the grower level.

New methods for overnight testing of crops in-house will also minimize the risk of shipping contaminated product.

We sprout growers hope that our government will spend the necessary money to fund the research that will teach growers and other people in the many agricultural-related businesses how to ensure the safety of imported and domestic fruits and vegetables and other foods.

Researchers at Georgetown University, the University of Georgia, and other laboratories are involved in important research on behalf of the food industry. We need additional funds to keep this research going and to step up the pace of the research to address the critical present-time problems.

Thank you very much.

DR. SHANK: Does anyone else desire to take the floor at this time?

Our one remaining speaker has not been found yet.

The other issue that is on the agenda is questions and

answers.

Questions and Answers

DR. SHANK: Does anyone have any questions?

[No response.]

DR. SHANK: What you have heard today is some materials that are pooled together for purposes of a draft guidance document generically for fresh produce. Tomorrow, this information or Wednesday, whenever we get to it, on the agenda, this information will go to the Subcommittee of the National Advisory Committee.

We will ask them for their counsel, review, advice, and guidance. Another document then will be prepared, made available December 1, used as the basis for the town meetings that will be held during the first two parts of December.

Terry and I are going to negotiate when the thing is going to be published in January, we hope in January. Then, that will be for public comment, and moving towards a final document in June.

Yes, Dane.

MR. BERNARD: Thank you, Dr. Shank.

The meetings, as I remember, six in December, billed as town hall listening sessions, have you through about the format of those, what you intend to do there? There was also mention of an international meeting. Has the been roughly scheduled yet?

DR. SHANK: Ricardo, do you want to start on that one?

DR. GOMEZ: Not really.

DR. SHANK: Tom?

MR. GARDINE: Dane, I don't quite understand the question. The format of the six grass-roots, and I believe the dates were given already, will be to go to six regional agricultural areas. These are envisioned as regional meetings.

At that time, the draft document that Dr. Shank mentioned will be available. There will be an initial draft of this document. Of course, some people, especially at the first meeting in Grand Rapids, will be coming in and would not have had a chance to read that yet.

We are going to try to walk them through with a series of

slides to help them review the document, understand what is in it. We will speak. Local Extension people from USDA will speak. We hope to have a representative from the State Department of Agriculture for each state we are visiting, and basically, it is a listening session.

We will respond to people to the extent of trying to draw out their concern and questions, but we will not be attempting, nor will we have necessarily at each of these meetings appropriate staff to respond to technical questions should they be raised.

The international meeting is going to be focused pretty much the same way with the exception that because of the interest that that community might have with the legislative proposal, we are going to tack on a somewhat longer, more extended discussion of that there.

Did that in any way get to your question?

MR. BERNARD: That is exactly it. The date of the international meeting?

MR. GARDINE: December 8th, and it is going to be at the Hubert Humphrey Building here in D.C., a small auditorium, I

am told.

MR. BERNARD: That is at the same time as you have got a public listening meeting in San Antonio.

MR. GARDINE: That is correct. Time frames are tight.

DR. SHANK: Before going to another question, Dr. Shaw has joined us.

Public Comment (Continued)

DR. SHANK: Dr. Shaw, we appreciate your getting here a little bit earlier than what we had originally planned. This is Dr. Frederick Shaw, and he will be speaking as a physician.

DR. SHAW: Thank you. I am sorry I was a little late. Thank you for the opportunity to make comments as you are closing.

My name is Frederick Shaw. I am a physician and consultant in epidemiology and disease control. I have spent 10 years or so doing research in viral hepatitis control at the CDC and elsewhere.

I am a frequent consultant with Smith-Kline-Beecham Pharmaceuticals, one of the makers of hepatitis A vaccine,

but the remarks I am making today are my own and do not reflect the position of Smith-Kline-Beecham.

I am also editor of the Hepatitis Control Report that many of you may get. It is a newsletter devoted to the control of viral hepatitis, and last summer we put out a special issue on the infamous frozen strawberry outbreak earlier this year. We hope we will have copies here in the back of the room, but, Mr. Chairman, may I ask that that report be made part of the record?

DR. SHANK: Sure.

DR. SHAW: Thank you.

Hepatitis A is an important food pathogen and my topic today is that. In terms of pure numbers, people don't realize it actually occurs probably more in the average year than E. coli. If you take CDC's most recent data published recently for the 1988 to 1992 time period, there were 11 outbreaks of E. coli. There were 43 outbreaks of hepatitis A. There were 244 cases of E. coli part of those outbreaks. There were 2,109 cases of hepatitis A. There were not deaths associated with the E. coli outbreaks in that publication.

There were six deaths associated with the hepatitis A outbreaks. So, it is not an innocuous disease.

People who become ill, as you all know, lose time from work, up to 12 to 27 days. It has been published by CDC. It is not a nice disease to have. It is not very much a lethal disease, 1 to 3 per 1,000 is the death rate.

It is a very sturdy virus, too. It is resistant to inactivation by low levels of chlorination, and I know you have been talking about using chlorine washes for fruits and vegetables. Well, that won't work for hepatitis A virus.

It is also resistant to the kinds of levels or irradiation that we have been talking about for food. Irradiation is not a practical way to inactivate this virus. In fact, the only way to really inactivate it practically is to kill it by heating, but we know that a lot of people eat fruits and vegetables raw, they don't cook them prior to eating, and that is precisely why the virus has its risk.

Now, of course, a majority of these cases of hepatitis A caused by food are at the retail food level, at the restaurant level or church suppers, picnics, and so on, like

that. Contamination at the picker level or the producer or the packer level is quite rare. We only know of three instances in the United States, an outbreak in 1990 due to lettuce at the distributor level.

Another outbreak in 1990 due to frozen strawberries. That one went multi-state. And, of course, the infamous outbreak in earlier this year due to frozen strawberries. Both of those frozen strawberry outbreaks went multi-state.

I just learned this afternoon that the strawberry outbreak we thought was only in the State of Michigan, was probably also in Louisiana and Tennessee, and perhaps two other states. DNA fingerprinting has now confirmed that through CDC.

So, they are uncommon, but they are very costly, and the outbreak this year, the medical costs in lost wages of the 300 people who became cases, is an issue, but you also have to add the cost of immune globulin, which was administered to over 38,000 schoolchildren earlier this year. Surely, this outbreak will run into the 2- to 3 million dollar range.

Now, how do we prevent these from recurring? The USDA has tightened up their rules on Buy-American for the school lunch program, but nobody really believes that that is going to offer much protection against another outbreak of hepatitis A.

Keep in mind that the first frozen strawberry outbreak, the one I mentioned, those strawberries were processed in the United States and picked in the United States. Also, keep in mind that our children, every day, eat vegetables, strawberries from Mexico at home and in school. So, although it is a very good step, the USDA step, it is certainly not going to offer much protection.

I have already mentioned chlorinated washes won't work, irradiation won't work probably because the amount of rads is too high to disrupt the virus without damaging the fruit.

As I close, let me tell you what Dr. Minette Neu wrote -- the 1990 multi-state frozen strawberry outbreak -- let me tell you what she wrote in the Journal of Infectious Diseases. "The mainstay of prevention of hepatitis A is strict attention to hygiene and sanitation at all levels of

food preparation. For fruits and produce that are served raw, this requires a high level of sanitation during picking, processing, packing and food preparation. Workers harvesting fruit and produce must have the same access to handwashing and bathroom facilities as food handlers who process, package, and prepare these items.

"Hepatitis A immunization of certain high risk groups, including food handlers, may be beneficial in preventing similar outbreaks."

She wrote that in 1990 when there was no vaccine against hepatitis A available. We now have two vaccines in the United States that are licensed. Many of these vaccines are also licensed in countries where we import food.

The question is, is it now reasonable to examine whether or not vaccination could be one modality to use against the prevention of future hepatitis A outbreaks, whether it has merit.

I would submit that now is a good time, if we are ever going to examine that question, now would be the time to do that.

With that, I will close. Thank you.

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DR. SHANK: Thank you, Dr. Shaw.

Questions and Answers (Continued)

DR. SHANK: We were on questions and answers. I think we had one up here.

DR. BUCHANAN: I would like to commend the sprout growers for the aggressive action that they have taken in addressing the issue of E. coli and other pathogens that have recently been associated with sprouts, but I would like to ask, as a rhetorical question, what the large produce industry is doing to provide the leadership and the private support of research that is needed to identify the solutions to the key microbiological concerns that are associated with produce. We have identified lots of GAPs that are present in developing HACCP plans and HACCP procedures for controlling harmful bacteria in foods, in produce specifically, but we have a lot of research that needs to be done to come up with those solutions, and what is the industry doing to take the leadership role and provide, not only government support, but their own support to address these issues?

DR. SHANK: Interesting question. Do those of you who may

respond want to think a moment? Yes, Stacey.

MS. ZAWEL: It is not the easiest question to answer, but it is a good question to ask, and I think that one of easiest things for the industry to do is determine where the GAPs are and certainly the easiest thing for you guys to do is determine where the GAPs are.

You have seen some industry response. Certainly those groups who have been in the most trouble, in a sense, they are put in the most difficult spot, have gone forward to support specific research in the Cyclospora area, and certainly one of the things that we are trying to focus on right now is a means or a mechanism, developing a mechanism to increase appropriations on Capitol Hill for these issues, as well as trying to coordinate an industry response and develop a consolidated vehicle to fund some of this work from an industry perspective.

DR. SHANK: The other point that I would add to that is as a part of these initiatives. I don't want you to get too excited because there is not an unlimited budget, but as a part of these initiatives, the Food Safety Initiative, or

more specifically, the Produce Initiative, research is an important component.

There are some monies that are being made available in support of that research. We in the government right now, USDA, FDA, and others, are doing an in-depth review of where our research programs are and see how we can help address some of these needs.

DR. BUCHANAN: A question more for my information than anything. Since this is an international initiative or international scope, has either WHO or FAO or Codex, for that matter, provided any advisories in this area?

DR. SHANK: Codex is -- does someone want to take a shot at that or do you want me to? Go ahead, John.

DR. KVENBERG: In the area of Food Hygiene Committee, which is the committee that would be most interested in this, there has been the proposal that started to look at fresh produce and good hygiene practices associated with it. Canada volunteered to be the chair of this with many member nations, particularly the Americas, desiring to be a part of this working group.

So, yes, the question on developing international document is afoot, that was a result of the last meeting here in Washington in early October.

I am sorry, Dane Bernard is prompting me. In addition to the general overriding document, there is also a specific recommendation to move ahead with a fresh-cut salad type recommendation, which is going to be addressed, as well. Thank you.

DR. SHANK: Other questions or comments? Yes, Dane.

MR. BERNARD: Thank you, Dr. Shank.

During Dr. Woteki's talk this morning, she mentioned the topic of research. Due to this cooperative effort you are putting together, is there an inventory of the federal research that is going on in produce that is available to use yet or not?

DR. SHANK: Nothing that I am aware of is available at this time, but we are working on such a plan relative to research. The details of that have not been completed, but you can rest assured that it will be a public process either through the Advisory Committee or some other type of

organization.

Other questions or comments?

If there are none, let's close this meeting and thank all of you for being here, your attention. We appreciate the contributions and look forward to continuing dialogue on this most important topic.

Thank you very much.

[Meeting adjourned at 2:30 p.m.]

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