

UNITED STATES
FOOD AND DRUG
ADMINISTRATION

UNITED STATES
DEPARTMENT OF
AGRICULTURE

The Microbial Safety of Fresh Produce

TOWN MEETING

Monarch Hotel
12566 S.E. 93rd Avenue
Clackamas, Oregon 97015

Friday, December 12, 1997
9:00 a.m.

PANEL MEMBERS

Donald J. Voeller, State Contract Specialist, FDA

Thomas D. Gardine, Food Safety Initiative Staff, FDA

Dr. Joyce Saltsman, Consumer Safety Officer, FDA

Roger Lowell, District Director, FDA

N.S. (Bill) Mansour, Ph.D., Extension Vegetable Crops
Specialist, Oregon State University

Ronald W. McKay, Field Operations Manager, Oregon
Department of Agriculture

Ricardo E. Gomez, Ph.D., Horticulturist,
Cooperative State Research, Education and Extension
Service (Invited)

PROCEEDINGS

MR. VOELLER: As the final people enter the room, I would like to say good morning to and welcome you all here to the Northwest area grassroots meeting on the Microbial Safety of Fresh Produce. My name is Don Voeller, and I will serve as your host and moderator today.

Let me begin by covering the essential questions of all meetings. Where is the coffee? Where is the food? And where are the restrooms? The coffee and tea is situated in the back. Restrooms are located outside the rear entrance. There are also additional restrooms upstairs to the right of the restaurant and bar.

There are plenty of people here to assist you, and I'm going to just briefly introduce them. Tom Gardine, Roger Lowell, Ron McKay, Bill Mansour, and Joyce Saltsman. And there are other individuals in the audience that you probably are already familiar with, and this is important for you to have an informal atmosphere to present your comments.

We have a simple agenda, and I have that agenda -- you do not have it in your packet -- and it is very flexible, and I'll just go through it very briefly. After my opening remarks, Roger Lowell will give an introduction and welcome. Ron McKay will follow with another welcome and comments. We'll have opportunity for clarifications of any questions you may have after each presenter.

After the welcomes, Tom Gardine will present the review of the President's Fresh Produce Food Safety Initiative with review of the good agricultural practices and good manufacturing practices. Chances are Tom will be completed well before noon, and we'll invite Dr. Gomez up from USDA to give a presentation for their agency.

After lunch, there will then be ample time for industry group presentations and comments from all interested parties. So any specific group that would like to make a formal presentation from the podium, I would like you to get in touch with me and provide your name and affiliation.

Following the final presentation, there will be a wrapup, I believe, by Tom Gardine. And we will best keep to our schedule by saving any general comments until that time. If we each keep our comments to the point, there will be time for everyone to have their opportunity to speak.

We are here today, for anybody that isn't aware by now, to discuss Microbial Safety of Fresh Produce as a result of President Clinton's announcement of October 2nd known as the Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables. As part of that initiative, federal agencies were directed to work together in close cooperation with the agricultural community in order to issue guidance on good agricultural practices and good manufacturing practices for fruits and vegetables.

As a result of the President's directive, FDA and USDA have developed a working draft to address the practices and safety hazards associated with water quality, sanitation, hygiene, transportation, and manure and municipal sewage sludge. These issues are common to the growing and harvesting to most fruits and vegetables which are sold to the consumers in an unprocessed or minimally processed form.

Please keep in mind that we are all here today to contribute to a working draft which needs input, development, and refinement. We can best accomplish our mutual goal by focusing on the positive aspects of the guide and suggesting ways in which it can be improved. Your participation is the critical ingredient in this meeting.

In addition to your opportunity to state your suggestions today, we welcome your written comments following the meeting. Detailed information regarding how to submit your comments can be found on the copy of the Federal Register announcement in your packet. And I want to make certain that everyone has signed in and received a packet of material. And in that material there is a Federal Register announcement which lists the address and the docket number for comments. And it's important that you do use -- include that docket number, 97N, as in Nancy, 0451.

And written comments in the announcement say it must be submitted by December 19th. However, that date has been flexed a little to allow comments in until the end of December. And the agencies will review those comments as quickly and thoroughly as possible. This meeting is being recorded by Yvonne Fred located in the front of the room. Please use the microphones and speak so your comments are accurately captured. Be sure to state your name and affiliation, or your comments will be tagged as "audience member" only.

Is there anything you need me to clarify? No questions. At this time I would like to introduce Roger Lowell, acting Regional Director for the Pacific region of the FDA. Roger.

MR. LOWELL: Thank you, and good morning. I do appreciate that you've all taken time out of your busy schedules to come to this meeting today and give us feedback on this Presidential Initiative. Just a few things that I'd like to emphasize that he said that maybe it's okay to be an anonymous member of the audience instead of giving your name, but Food and Drug is kinder and gentler now than we used to be in the past. So feel free to give your name; there will be no retaliation. I'll guarantee you that.

This is a cooperative effort, as Don indicated, between USDA and FDA. And I, of course, on the part of FDA thank USDA for the work they've done in organizing this conference through their Extension Service and having the people here. We definitely appreciate that.

A little bit about FDA in case you are not familiar

with FDA, but the Food and Drug Administration as the federal agency in charge of regulating, protecting, and promoting the public health of the American public through enforcement of the acts that Congress has made to us, and that's what this is all about, actually, is to look at a public health problem which is illnesses coming from cut produce and fresh produce industry and to find out if there isn't something that we and industry and USDA can do to assist in that process.

And I must emphasize -- and it will be emphasized over and over again -- that what we're working on is a draft product right now. It is a guideline. It is not intended to be a regulation or have the force and effect of law, but is it intended to be a guideline so that that is understood.

A little bit about FDA here locally in -- I'm also Acting Regional Director, as Don said, but I'm really -- my real life job is the director of Seattle district of Food and Drug, which is the five northwestern states of Alaska, Montana, Idaho, Washington, and Oregon.

And I know many of you out there, some of you I don't, and I'm anxious to hear from you about what is going on.

The other thing that I think is important that I emphasize the protect part of FDA's mission, but about two or three years ago the promote side came into our mission. I know when I started with FDA it was simply protect the public health, and we considered ourselves regulators, and we were sort of the cop on the beat.

The promote part that has come into our mission statement is to promote public health. And I see what we're doing here as a part of that role to try to promote a better way to get these products onto the market so that they are safer. We all understand that the agency has been promoting the consumption of fresh produce. USDA has been promoting that for the health of the American public.

So we want to make sure that that message gets out that these are good products. They are not harmful products. I know some people gave some stories about people stopping using these products because they're afraid of E. coli in the product, when the benefit of using the products far outweighs the risks that may be there.

So we've got to get all that under control, and that's what we're trying to do. This town meeting is a unique opportunity. We're looking for your feedback. We're not going to give you answers to most of your questions. What we're looking for are comments to go into the record to assist this process and to get a draft guideline out.

In some of the other sessions of this that we've had, there's a question -- and I know Tom will get into it, and you'll probably hear it over and over again -- about how this process works. This is a draft guideline at this point. It's very much in the molding stage.

The next step in the process is that all of the comments that come from the -- this is the sixth meeting like this. All these comments will be taken into account, will be addressed. Often they're similar comments, so they're grouped together. They will be answered in the next step of the process, which would be a Federal Register announcement, which would be a draft guideline that would come out, which, again, there will be an opportunity for comments when that draft guideline comes out.

The question is often asked, "Well, how do I find out what your response was to my comment?" There's usually a preamble as well. There will be a preamble in the guidelines when they come out. And in that preamble, every question that has been brought up will get addressed in that preamble. So that's the point that you will be able to get those answers back.

With that, I will turn it over to Ron McKay.

MR. MCKAY: Thank you. I'm Ron McKay. I'm from the Food Safety Division of the Oregon Department of Agriculture. We license and inspect food processors in the State of Oregon. Hence, we have an interest in what goes on here today. We work with federal agencies, USDA, FDA, National Marine Fisheries. We have contracts. We have partnerships. We do work share with these agencies.

The Code of Federal Regulations, many sections of it are adopted into Oregon law and regulation, so we have a keen interest in the development of these, and, obviously, your comments that go into them. So, again, I'd like to welcome you all here today, and at this point in time will listen to your comments.

MR. VOELLER: Next will be Bill Mansour with the Oregon State University Cooperative Extension Service.

MR. MANSOUR: Good morning everybody. I am here as -- my job is Vegetable Extension Specialist at Oregon State University. I work with commercial and vegetable growers, and I'm here representing the Extension Service, Dr. Lila Houglum, our director.

I've been asked to sort of explain to you folks our role as Extension people working with the university. Oregon State University Cooperative Extension Services, as always, it's been its role to provide unbiased, research-based information to -- on issues that are relevant to the public.

In the case of food safety and produce handling, and so on, our job is to get this information and provide it to the handlers. These people might be field production, fresh packing facilities, transportation, post harvest handling industries, and so on. The Extension Service serves as sort of the link between the private sector, the producers, the packers, the shippers, and the university research people. So our role is an educational role, and we -- and that's an important distinction that I'll emphasize.

The science of producing food has come a long ways. Producing wholesome food has come a long ways in recent years, but

the picture is continuously changing. It continuously offers challenges to producers. And newly discovered organisms come up so that we've got to continuously upgrade our knowledge on these issues and how they impact the public.

There's a lot of information on these organisms. But we know, for example, there have been documented cases of organisms, new organisms, that are resistant to antibiotics, and there's a fair amount of information on how that comes about, but it's still -- this is still an area that needs quite a bit of research.

What Extension's job is is to get this information from researchers through the examination of publications, and libraries, research reports, and so on. Extension has intimate links with the industry, and the industry itself develops its own guidelines on how to produce and handle food that results in a wholesome product to the consumer.

So Extension works with industry people, and industry people share this information with the university, with Extension people. So our job is to sort of glean all this information from all these different sources and even develop some of our own.

Extension agents and specialists do research -- applied research. So our job is to sort of look at all this information, run it through our filter, so to speak, and then provide this, as best as we can, good, accurate, timely, unbiased research-based information to the public through meetings like this, and through meetings -- through the mass media and publications, and so on.

The -- at the university, the people that work in the area of food safety work in a number of different departments. We have -- I'm from the Department of Horticulture -- people in crop science, people in ag. chemistry, folks in botany and plant pathology, biochemists, soil science people, people that work with plant fertility, people that work in most harvest handling, and the food science technology people that work with the industry that is involved in packaging and fresh processing these things and packaging them for the public. So the remarks that you make will go through us and be relayed back to the people in these various disciplines.

The Extension Service deals not just with producers, but also with the consumer and consumer education. So you've got -- I know this meeting is focused primarily on the producer and the handler, but we have folks in home economics that work with the consumer education side of things, food preparation issues, food sanitation issues.

I had intended to allow part of this time to be used by a colleague of mine, Dr. Raab, who is here in the audience, but I think I'll just leave that time slot open so that when we take your questions, maybe at that time she can address some of those questions. And I'll relay them to her, if that's

appropriate.

So I think my closing comment would be that we hope our participation in this meeting will allow us to learn some things from you folks and allow us to do our job more effectively. Thank you.

MR. VOELLER: Joyce, would you like to introduce yourself and explain your expertise?

MS. SALTSMAN: Sure. I have no formal comments to make, but I'm Joyce Saltsman. I'm with FDA in Washington. I was detailed to this produce initiative for food safety, and I've been working with another woman, too, on drafting the document, which is all that we've been living and breathing for the last three months.

Your comments are very welcomed, and we consider each and every one of them as they pertain to the details in the document, what is appropriate and what is not. So please do submit your comments, and we will consider them all very carefully. Thank you.

MR. VOELLER: Before we make the transition for Tom Gardine's presentation, are there any questions for clarification for the persons who have already spoken on the panel? Seeing none, we will have the panelists take chairs in the audience so we can see the slides, and turn it over to Tom Gardine for the next portion of the program. Thank you.

MR. GARDINE: Good morning. I hope this mike is set up properly so you can all hear me. In your package today you will have a copy of the draft Guidance Document that has been prepared by FDA/USDA with cooperation from other involved federal agencies, such as OSHA and EPA.

I do not know how many of you yet had an opportunity to read it, since it has been posted on the Internet, copies were available. Could I have a show of hands to give me an idea of those of you who have really had a chance to read the entire document yet? In general, it's been running at meetings at less than half, and this is no different.

My role today is to talk to you a little bit about the President's initiative, try to answer the question, "Why is this happening? Why are we doing this now?" And to go over very quickly some of the points in the Guidance Document that you received today.

I will say something that you probably are all smart enough to know, but I'll repeat it anyway. My presentation on the document runs 40 minutes to an hour, depending on questions. The devil is always in the details. We are not here to have you listen to us; we're here to get your comments. Please do not make a final determination, opinion, or feel whether comments are appropriate or not on the Guidance Document based on what I present today.

This is -- what I will be presenting today is a very broad overview. The details are in the document. As we all know the expression, "the devil is in the details," you have to

read the document to know exactly where it is leading, and how it may impact your operations, and what your concerns with it might be, and how you could advise us to make it a little bit better. So please do read the document, and if you feel comments are necessary, submit them in writing if you choice not to make comments today.

The President's initiative, as you've heard, is called the Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables. The President announced this initiative on October 2nd of this year. And he gave a directive to the FDA and the U.S. Department of Agriculture to work cooperatively with industry, with other involved federal agencies to improve the safety of fruits and vegetables, both domestic and those imported from foreign countries.

Obviously, for this to work, we cannot simply work with domestic industry. More and more of our fruits and vegetables in this country are imported. I believe the numbers are running about 15 percent of the vegetables, and over 30 percent of the fruit products that the American people are consuming are being imported into this country. We were told to prepare guidance to industry about what we believe industry, the grower, can do to minimize the risk of microbial contamination in fresh produce.

Please bear in mind what we're going to be talking about today is a document very limited in scope. It is designed not to address the myriad of problems that could occur with foods, any kind of foods, but strictly microbial pathogens on fresh produce. We're not going to talk about pesticides. We're not going to talk about product quality, or other items like that.

What we're talking about right now is a broad scope Guidance Document. As you've heard from Roger Lowell, this is not a regulation. It does not impose new requirements on industry. But, obviously, we're not doing this to pass time. We have plenty of other things to do to pass our time and keep ourselves busy in the office. We believe we want to get this guidance as good as it can be and we want industry, where applicable, to adopt this guidance.

And we will, as part of our outreach -- we will be, through our outreach programs, encouraging industry to adopt this guidance in those instances where they have not already done so. At this point, I would like to point out that in his initiative, the President did state that fresh produce in this country is, indeed, safe. It's probably the safest in the world, and we all believe that.

And we really want to encourage the consumption of fresh fruits and vegetables in this country, and the federal government is so doing.

I came across a brochure the other day when we were doing this road show in Salinas, California. It is put out by the California Strawberry Commission, and I would like to quote from it: "Leading health association research links increased consumption of fruits and vegetables to reduce risk of heart

disease and various cancers. To support these findings, the National Cancer Institute encourages Americans to consume at least five servings of fruits and vegetables every day."

That's the truth. The federal government, local government, health authorities are encouraging people to eat more fruits and vegetables. We have to keep the supply of fruits and vegetables as safe as possible.

They're encouraging people to eat fruits and vegetables because it's good for them. It is a sound life choice to make.

If that's the case, the President says keep it safe as possible. If the President says it's the safest food supply in the world, why aren't we doing this? And if we want people to eat fruits and vegetables, why aren't we doing this? Because of a number of well publicized outbreaks of microbial-induced illness associated with fresh produce.

We are talking about E. coli 017 -- 0157:H7, listeria, salmonella, cyclospora. They've been associated with both foreign produced product and domestically produced product. These are not benign bugs. Many of these illnesses are very, very serious life threatening, and some of them have debilitating long-term effects.

We want to do what we can to protect the American public from these diseases. You heard Roger Lowell say the purpose of the Food and Drug Administration is public health safety. That's why we're involved in this. We have to do what we can to protect the American people. We want to work with industry to do that.

And what we are talking about here is what we think growers can do to minimize microbial risk in fresh produce. We realize this is not a sterile world, that this is not a risk that can be eliminated completely without a great deal more research and control steps being developed, products that are grown in the earth and under the open sky. We are talking about minimizing risk to the extent that we can, and we realize that this is not something that growers can do alone.

I want to stress right now that the President's food safety is called Safety from Farm to Table. There is a component involved in it for retail food handling, food service, restaurants, the markets that self-produce. And for the consumer, a very large education program on the proper handling of fruits. I'm not going to go into that in depth today because the idea is not for you to listen to me for three to four hours, but for us to listen to you.

But I wanted, for the record, to stress that we are looking at a holistic approach, everything that can increase microbial risks on fresh produce through education and outreach we are planning to do. Okay.

The elements of the President's initiative are essentially two; there's a legislative element and an administrative element. The legislative element is really

addressing imported produce. It gives the Food and Drug Administration authority to prevent the importation of foods, not strictly produce, but any food that is produced under a system that does not meet the United States level of protection.

What we are looking at here is the system to monitor and regulate foods in a foreign country, either through the government or industry sources. It -- it states that if a determination is made that the level of protection is not comparable -- maybe not exact. They don't have to do it exactly the way we do -- not comparable to that in the United States. The Secretary of Health and Human Services can make such a determination, and the product could be prevented from entry into the United States.

Obviously, before we do something like that, there would be a great deal of work with the foreign government to see what corrections and improvements can be made. The legislation also has a provision whereby the Food and Drug Administration can prevent the entry of food, should we wish to do an investigation, perhaps an illness, outbreak follow-up in a foreign country, and we are denied permission to do that.

The legislation also says we will prepare a plan to implement this legislation. The plan has not yet been written because the legislation obviously has not been passed. The legislation has been submitted by the Secretary of Health and Human Services to Congress for consideration. It has a sponsor in the House and has been submitted to the House of Representatives. It does not yet have a sponsor in the Senate. That is probably because the legislation was submitted two or three days before Congress closed down for the year.

We strongly support the legislation. We believe it's necessary. But, quite frankly, at this point, because Congress hasn't considered it, we do not know if it will pass nor what final form it will pass in.

The second part of the President's initiative involved preparing the guidance to industry that we're going to be talking a great deal about today, and a budget request to allow the involved agencies, FDA and USDA, to do what is necessary to implement and educate and work within this guidance that we are preparing.

Can't say much about the budget requests we're preparing for the fiscal 1999 budget. Requests have been made for how much money we think we'll need to do this, and how much resources. We can't determine what we'll do till we see what they actually give us, and that's a bit down the line. We do not know how this will come out.

The President, because he wants this done, has required that the involved agencies submit a 90-day report to him due sometime in early January about what our plans are, what steps we intend to take to implement his initiative. A bit more about the initiative.

Specifically, the President stated that FDA, as lead agency in cooperation with the U.S. Department of Agriculture, is to issue within one year -- okay, this is the time line -- guidance for good agricultural practices, GAPs, and guidance for good manufacturing practices. GMPs involving the production of fresh and minimally processed, such as cut or -- or atmosphere controlled packaged fresh fruits and vegetables. And FDA and USDA are to coordinate assistance and educational activities to both domestic and foreign industry.

Once again, because of the increased importance of our foreign suppliers, whatever education effort we do, and outreach effort we do in the United States, something comparable must be planned to reach our foreign suppliers. Otherwise, this will be a somewhat hollow effort.

We keep stressing that what you have in front of you is guidance, not a regulation. It does not have the force of law. It does not impose requirements or burdens on either government or industry. It is guidance. It is advice. But, obviously, in our outreach program because, as I said, we have plenty of other things to do. We're not doing this just to pass time.

We are doing it though for our health, I think. We want industry to adopt this, but you must work with us to make the guidance as good as possible. For that reason, we have been asking people -- and I will do it now -- if you, as industry groups, have any documents that addressed this in turning guidance to your industry that might talk about things unique to the growing conditions for the product you produce, that you have developed and shared as the people most knowledgeable with the needs of your commodity, please share it with us.

You can give it to us a number of ways. One way to do it is entering it into the docket, which Don talked about. But if you do have anything, speak to me, we might be able to give you an address to ask you to get it to us a bit quicker. This is going to be as public a process as we could make it. What you have in front of you is a broad scope, good agricultural practice Guidance Document. We are hoping to publish a draft of this document early in 1998 in the Federal Register.

As I said, it is intended to be as public a process as we could make it. We had the first public meeting on this Guidance Document November 17 of this year. At that time we didn't have a document actually, we were just talking concepts. It was reviewed by the National Advisory Committee on microbiological criteria in foods, the produce sub-committee, who supplied comments to us on where we thought we were going. We then developed the draft document you have in front of you and went through the series of grassroots meetings.

This is the sixth and final regional grassroots meetings that we've had over the past two weeks. We've also had an international meeting in Washington in an attempt

to outreach and get comments from our foreign suppliers of fresh produce. This -- what we solicit from you at these meetings, and what you submit to us in writing will be critically evaluated -- as you heard Mr. Lowell say -- and your comments reviewed and evaluated during January and February of 1998.

We are aiming to have -- to publish as a draft in the Federal Register a document incorporating your comments, other work done by FDA and USDA staff, comments from state agencies, and publish it as a draft in the Federal Register late February or early March of 1998.

That is a draft. When you've published something in the Federal Register, it is published for comment when you publish a draft. It will be published with a 45-day comment period, at which point we may or may not do another series of grassroots meetings, depending on how significantly the document may have changed from what you have in front of you today. If the changes are not significant, we probably will not go through this exercise again, but rely on the Federal Register.

But we will tell you you have 45 days to submit comments. We will review those comments, incorporate and evaluate them, and try to publish a broad scope good agricultural practice document sometime -- we are aiming for July, 1998. Those are time lines. As some other speakers mentioned at earlier grassroots meetings, time lines are nice, but they sometimes slip.

It may seem like a relatively fast process, and to some extent it is. But if we meet the July date is questionable, and how fast it goes depends a lot on the feedback you give us. If we don't hear from you -- if we don't hear comments, we're going to think we pretty much got it right. We need thoughts and opinions from you.

The President's initiative and this slide was created to address what has been a very contentious point at many of our grassroots meetings. The President's directive requires that good agricultural practice and good manufacturing practices be developed to account for specific commodity and regional differences. Options on how to do that are being considered, and we want your comments on how to account for commodity and regional differences.

What we had originally thought, and which is not necessarily not going to happen -- and I must stress that -- was that in addition to this broad scope document, which we believe is addressing as close to universal roots of contamination to produce as we could determine, develop more specific guidance for specific crops with the idea that the advice we could give will be better, because it will be focusing on the unique cultural needs of specific crops.

We were initially hoping to do four of these -- or begin four of these -- in fiscal year 1998, which will end in October of 1998, but there was a great deal of concern on the part of industry in doing that. The concern being; one, does that

tarnish the reputation of whichever commodity is selected or whichever region is selected? And, therefore, might limit its marketability with the public.

You know, that -- that -- something like that may be able to be handled with the way you present it, with the publicity that follows it. But what are the other ways? We want to hear from you. Things we think about is contracting through some of the land grant colleges to do this research and development for us, working with the trade organizations to review what documents they have prepared, and see if we and they could work together to come to a meeting of the minds.

But we need to hear from you, but please remember, this is the directive from the President. We have to find a way to account for unique cultural practices with certain crops, and perhaps regional differences. Options are being considered, but this option is also still being considered. As part of the President's initiative, once you put out guidance, you will be attempting to encourage people to use that guidance. And in encouraging them, you must educate them in the guidance.

During the rest of this fiscal year, which will end in October of 1998, FDA and USDA will be planning and considering how best to do outreach to domestic growers. FDA and USDA, once again, because foreign agriculture -- foreign produce is becoming more and more a significant and important part of our diet, will be trying to figure out ways to do outreach to our foreign suppliers. How can we also educate them when we don't have the infrastructure perhaps to reach growers that we have in this country through Extension Service, the state agencies, and numerous ways that our government can talk to domestic agriculture.

Now, I want to point out -- before I open this part to comments -- that much of what we've done has been built on what industry has already done. I want to recognize the various trade organizations that have already taken steps to address this very issue, microbial safety of produce through developing industry-wide guidance. Industry recognizes the potential problem and was attempting to address it through their own guidance.

Those of you who are familiar with some of this guidance prepared by Western Growers, United Fresh Fruits and Vegetables, and numerous commodity specific organizations around the country will see -- I don't want to say we plagiarized -- but we certainly borrowed very heavily from guidance that is already out there. So what you will see in this Guidance Document is not going to be anything particularly new. It is building on issues and concerns that industry had already identified.

And kudos and thanks to industry for their willingness to address this very important public issue is certainly due from those of us in government who are now working on it. Okay. At this point, any -- I would like to open the floor to any questions of clarification overall on the President's initiative. And I would ask you if there are any, to please come

to the mikes and introduce yourself.

Sir, would you --

MR. TORRES: Antonio Torres; University of Oregon State University, Food Science. My question is how you can gather information from foreign countries and their production practices? So you're gathering information in the U.S., all the things you've talked about gathering information in the U.S.; how do you gather information from outside the U.S.?

MR. GARDINE: The same way -- the question was: All right. You're going out doing this series of meetings; how are you going to learn what advice we could give you, and what we could tell you about agriculture here in the U.S., but what are you doing in terms of our trading partners? Which is a very good question.

Number one, we did mention we had the international grassroots meeting this past Monday in Washington where we made the same request of the people who attended that, please tell us what guidance you have already existing in your industry, and give us your comments about how the guidance we're preparing would be applicable in your agriculture.

But more than that, while the infrastructure in foreign countries is not exactly the same as we have in the U.S., please remember we do know something about how agriculture is handled with most of our major trading partners. The Foreign Agricultural Service of the USDA has been out there looking into this, to some extent, for a number of years. FAS at USDA knows a great deal about some of the agricultural cultural practices among our major trading partners. This is the information that right now we are attempting to work together with USDA to find a way to incorporate it into our databases. Basically, we've been there.

And please, for the transcriber, you may want to stay at the mike.

MR. TORRES: Just a follow up. What has been the reaction from foreign countries? I mean Mexico, and all those.

MR. GARDINE: So far the reaction from the foreign countries has been to withhold judgment. Rather like the reaction from domestic growers, they are -- I believe they are less concerned, frankly, with the Good Agricultural Practice Guidance Document, which they see, and which we have been telling them, as we're telling you, as an -- to be an educational outreach program, and perhaps a way to solicit technical assistance from both international organizations and involved U.S. government agencies.

The reaction of our trading partners, most of their concern involved the legislative component, and its applicability and appropriateness in terms of some of our trade agreements, and its legality under the World Trade Organization. We took a great deal of care in working with the trade representative of the U.S., the appropriate organizations at USDA to craft that very carefully in a way that was consistent with our trade obligations and our treaty obligations. And I must state we have every intention of meeting these treaty obligations.

So at the moment, they are -- I guess I'd say, as I did already -- our trading partners are withholding judgment, but their concerns have less to do with the draft Guidance Document we prepared, than with the impact of legislation they have, and how we're going to do that. And, once again, it's very difficult to tell them exactly how we are going to find a way to implement the legislation, when the legislation has not passed, and we do not know its final form.

Are there any other questions at this point?

AUDIENCE MEMBER: Yeah. Have you looked into a way of maybe using as a marketing tool to increase exports rather than just trade -- you know, the importing of produce?

MR. GARDINE: That is one of the items being -- if I misinterpreted your question, please -- you know, please feel free to come back. The Food and Drug Administration, as you heard, we're a public health safety agency. We normally do not get involved in the marketing of foods or the promotion of U.S. foods or agricultural commodities. However, we have lately, as Mr. Roger Lowell said, become a much more user-friendly organization and are attempting, and I believe we are becoming much more aware of some of the concerns of industry.

And an example of that in our seafood HACCP regulation, we have indicated in the regulation itself that we are going to look for ways to see if we could develop a, perhaps, certificate that people could put on their packaging of their product. We are considering the same thing under this Good Agricultural Practice Guidance Document, but it's very, very difficult.

Because as we get into the exact guidance, you will see that much of it -- we admit, research isn't there, and research needs to be done. So it's very difficult for us to say that you will test this four times a year. You will -- or, you know, to suggest that you do this or suggest that a good thing to test for is this product and how often you should do it.

The guidance was described at one of our meetings -- and this is one of the favorable comments we got, by the way -- as almost a self-assessment guide for a grower as to the things a grower should be concerned with and aware of in their operation. And it's real difficult to find a way to give some sort of certificate or logo, when the guidance at this point is -- is -- lacks a great deal of precision, because, you know, what criteria would be necessary to determine if people are, indeed, meeting the guidance.

It is something we're considering, but it may be too early to get into such a program until perhaps more research is done and more specific guidance can be developed. That's the sort of thing that may be more possible as you get into more commodity specific type guidance.

Was that the intent of your question?

AUDIENCE MEMBER: Uh-huh.

MR. GARDINE: Okay. Any other questions? Please, and if you'd go to the mike, state your name and address -- or affiliation. I don't need to know where you live.

MR. ASHCOM: Scott Ashcom with the Oregon Fresh Market Growers Association. Simple question, you said that the legislation has a sponsor in the house. Who is that?

MR. GARDINE: Damn. It is a congresswoman from California.

AUDIENCE MEMBER: Eshu (phonetic).

MR. GARDINE: Congresswoman Eshu, and I believe it's cosponsored by Congresswoman Palom (phonetic) of New Jersey.

MR. CRAIG: I'm Chuck Craig with the Oregon Department of Agriculture. And the question that I have is that the State of Oregon and many other states currently are in the process of dealing with requirements of the Clean Water Act, and producers are being encouraged to adopt conservation plans that are protective of water quality.

Have you given thought to trying to integrate the agricultural practices aspect of this with those other planning concepts so that you have more of a single point of reference for the producer?

MR. GARDINE: Okay. I understand what you're saying, but we made the determination that since we are, you know, a public health agency, what we are looking at here is microbial contamination, things that might impact the safety of the produce. But I do want to add, once again, that we are working with EPA, OSHA, just to make sure there is nothing in our guidance that would contradict their requirements.

But in terms of making this a one document fits all concern for agriculture, no, we're not planning to do that.

MR. CRAIG: I'd just suggest that some consideration be given to that to get a better response overall, because farmers are being deluged with things that they're being expected to do.

MR. GARDINE: Yes. We've been hearing that. Any other questions right now? There will be plenty of opportunity, you know, for questions at the end of the presentation. Please, sir.

MR. CURRY: Gary Curry with Oregon Onions. I've got -- I don't know if it's a question or more of a comment -- my concern is with this outreach into other countries. If -- one, we're going to get into sovereignty issues is a question, and those of us that are involved in import and exports, if we're going to get into aspects of trade barriers and lead to something that might be more than what we're anticipating.

MR. GARDINE: Okay. Just stay at the mike just to make sure I answered your question. One, there is no way that FDA or USDA just appears at foreign farms whether they are manufacturing or agricultural. You know, if I went down to Peru,

went to a farmer and said, "Hi, I'm with the U.S. FDA. I'm here to evaluate and assess your facilities"; he will probably take me and throw he me the hell out, and rightly so.

Anything like this has to be done through cooperation with the involved governments, and/or trade organizations. Sometimes you could deal directly with the industry. We are -- we do have treaty obligations. We cannot do anything by treaty that would appear favorable to domestic agriculture, or different with our trading partners, than what we would expect of domestic agriculture.

And we're aware of that, and we're going to be very, very careful of it. Our plans are, in doing assessments, to determine what technical assistance or outreach is needed in foreign countries to work as close as possible with the foreign governments, all of whom we would hope would be willing to do that.

There is -- there has been another series of questions that I would like to address now. You know, if we're going to do this, and if part of the program is, you know, to determine where you need technical assistance and outreach internationally, you have to do some assessment.

We have not yet determined how we're going to do that assessment, but if it involves FDA folks going to some farms in conjunction with the appropriate regulatory agency in a foreign country, are they going to want to do that on U.S. farms? And are you going to see people from Mexico, Peru, you know, Thailand, coming to your farm? You know, they're doing that now.

There are a number of -- you know, with the European Union are doing domestic inspections basically with processed food. But, you know, quite frankly, if they do that and if it's in conformance with international treaty and it does not conflict with what they are doing with their domestic industry, it might happen. And I just believe we have to put that on the table for people.

MR. CRAIG: I think the issue, too, is we want to be very careful on what we're trying to accomplish so that it doesn't interfere with our whole international trade picture. I mean, which is for agriculture, it's the dominant thing as a trading force for us.

MR. GARDINE: Yes. And you have no disagreement from us or USDA. We have to be very careful about how we do this.

MR. CRAIG: Thank you.

MR. GARDINE: Okay.

MR. MANSOUR: Bill Mansour again; Oregon State University. Just a follow up on Mr. Curry's question. One of the first questions that came up in reviewing this guide, the guide is primarily directed at producers -- American producers. The safety of -- assuring the safety of food for the public takes two forms. One is the production of it. Another part of it is the monitoring

and the inspection of these products, both domestic and imported.

It has already been stated that -- what -- 38 percent, Paul Harvey said yesterday, fruit was imported, and 17 percent of the vegetables. What are there -- I would encourage that some guides will be developed or some publication and procedures of how these foods are going to be monitored for microbial contamination.

There are lots of procedures for monitoring for pesticides, and things like this, but the microbial monitoring, I'm not sure how that's going on. Maybe you'd care to comment on what form that will be in.

MR. GARDINE: You're probably going to be sorry you asked that question. It's something that I normally talk about during this part of the presentation, and it's something that in my rush to get through and hear your comments, I kind of forgot about.

One of the reasons -- another one of the reasons the President is doing this, in addition to the instances of microbial illnesses associated with fresh produce, is the nature of these organisms. They fall -- many of them, not salmonella, obviously -- but many of them into the area of emergent pathogens.

Pathogens for which our detection methodology either doesn't exist, or, frankly, is poor. The -- for example, E. coli 1057:H7 we believe to be a relatively new bug. We believe now for cyclospora that has been associated with raspberries from Guatemala. We are still working on a viable detection methodology. There is something in -- it is just -- we have never found cyclospora on Guatemalan raspberries, and we've tested lots and lots of them.

The issue of hepatitis A, there was recently -- and I want to make clear that the outbreak that made the news this year about the process, and I'm stressing it was processed strawberries -- fresh strawberries came from Mexico, were processed in California, and then went through food service operation, I believe, in Minnesota or Michigan.

So we don't know, you know -- we don't know what the hell occurred with the fresh strawberries in the processing plants, but there is an inhibitory, something that makes it damn difficult for our methodology to find hepatitis A in strawberries. We're working on the problem.

But invariably what happens as soon as we solve one analytical problem, another organism comes up that we have to deal with. And in developing detection methods, the food matrix, the analytical methodology that you have to use is frequently going to be unique to the food matrix to overcome some of the inhibitory characteristics that might exist in the food.

So, essentially, we believe the way to address this is not so much finished product testing, although the President did indicate in his announcement that he expects us to look for ways to increase monitoring. But, you know, there is a real feeling that

that may not be the way to go. The way to go is to solve the problem at the source, because with microbiological problems, even when you can detect them, even when you have a good methodology, it's not uniform throughout a production lot, and that holds true generally for processed foods, as well as produce.

While we'll probably do some more testing for microbiology, the answer is we've questioned whether that is the way to go, and we believe that the best way to go is through education outreach with the grower, with the food handler. From the grower to the consumer, and with the consumer to educate them as to what they could do to minimize the risk of adding microbial pathogens to the produce.

MR. MANSOUR: Can I follow up on that a little bit? That's true of locally produced food -- produce. U.S. I mean by local. But we don't have control over foreign agricultural practices, other than just good will kinds of things. And where these imports represents such a high percentage of our fresh fruit and produce, I think there's got to be some -- some effort to address that in any kind of guidelines that are published that would tend to make the consumer feel that -- you know, greater confidence in the product.

If we're saying that we control our American producers through education or we can help improve the situation, but we don't do anything on the other part of it, I think we're misleading the public.

MR. GARDINE: I think the education and outreach programs going with our produce suppliers from overseas and the legislation on the part of the President might be one way to address instances where we get no cooperation. And we believe that there are cultural practices of great concern in those countries.

But, once again, I think the bottom line is more and more in terms of food safety. Finished product testing is not the way to go. You've got to try and work with people to build it in from the beginning and have them aware of what they must do to minimize the risk of adding pathogens to their produce, because we do realize that there is no way to totally eliminate it.

One last question, then I do have to move on, and there will be more opportunity for questions.

MR. ISMOND: I'm Alan Ismond; Aqua-Terra Consultants. I've got a question for you concerning food and vegetable safety relative to another food problem we have, which is meat safety. That's been on the boards a lot longer, and we've gone down a road with meat safety where I believe there hasn't been much work done at the source. And now we're looking at irradiation -- or excuse me -- ionization/pasturization. So I'm just wondering what are you going to do differently with fruits and vegetables relative to what's been done with meats?

MR. GARDINE: I don't quite -- I'm not sure of the question, but when you talk about what has been done with meats, you really have to speak to USDA. The FDA does not regulate it,

and I'm probably not the person to answer that question for you. I'm sorry.

I would like to move on now. There will be more opportunity for questions after this part of the presentation. What you have in your package is the draft guidance -- the draft guide to minimize microbial food safety hazards for fresh fruits and vegetables. It's a Guidance Document, not a regulation.

We talked about minimizing microbial food safety hazards, because at the moment, until research is done to find control procedures, perhaps such as irradiation in those products that could handle it, eliminating microbial hazards in products grown in the ground and under the sky may not be totally possible. But we have to work toward minimizing it to the extent within our control, and we're talking about fresh fruits and vegetables and those that might be minimally processed, such as fresh cut or modified atmosphere packaged products.

As I stated, recent outbreaks have brought concerns about the safety of foods, including fruits and vegetables that are not processed to eliminate pathogens. What makes your product kind of unique, and why are we talking to you as growers? Because it's not going to the processing plant where it's going to be cooked.

It's not going to -- much of the produce that we're talking about here is not the produce that's going to be canned. We're talking about those products that the consumer will ingest as-is without cooking in the home. So there is nothing along the way at the moment, no safety steps that will destroy the organisms that might be present. Therefore, we have to try to minimize the microbial load to the extent currently feasible.

As I said, fresh fruits and vegetables are not generally cooked or subject to any additional safety factor after they leave the grower. Indeed, the increased handling in distribution and marketing might be adding to the microbial load. That's why there will be aspects of this effort dealing with retail and dealing with the consumer.

Therefore, the responsibility, we believe, of the grower is to take steps to reduce the risk of microbial contamination. The document in front of you, as a template, we talked about four, what we believe universally or as universal as any damn thing could be in this world. Vehicles for pathogenic contamination that the grower should consider in their operation and try to be aware of and think about ways to do it in a manner that will reduce microbial load.

They have water use in all its aspects, manure, municipal sewer sludge, hygiene, worker, field and facility sanitation and hygiene, and transportation; that part of the transportation of the produce that is in the grower's control. The guide, as we will repeat many times, is intended as guidance only, but that does not mean it's guidance that we're just going to put out there and walk away from. It's guidance that we will encourage, actively, people to use and adopt to their operation.

Growers must take a proactive role in minimizing the food safety risk. We expect a grower to take this guidance and see where it can be applied. It's broad scope. It's not one size fits all. A grower, depending on where you are, the crops you're growing, the cultural needs of your product are going to have to look at this and see what parts of it he can use, where he might be -- he or she might be able to amend their processes and operations to minimize risk -- the risk of adding pathogens to the food.

And it is the best advice of FDA in consultation with industry through much of the Guidance Documents already prepared there and consumer groups. Hopefully, it reflects some consumer concerns. It focuses on common elements. As I said, it's a broad scope document we think applicable to much of the produce industry, the growing production, and distribution. And we firmly believe that some of the guidance in here, if followed, will reduce the risk of microbial contamination in produce.

We do understand that there are many gaps in the science. That is why I gave the answer to the question before about any sort of logo that -- that I -- you know, I follow good agricultural practices. It's very difficult for us to do that, although we are considering how we can.

In the Guidance Document where there is uncertainty, we try to point out where research is needed and try to specify those sections in the Guidance Document. It's intended to provide practical advice appropriately qualified. It has to be doable. That's one of the things we need to hear from you today where we talk pie in the sky.

We beg you to get up, and say, "What world do you people live in? Do you know what that will cost us? Do you realize the consequences that if we do that now we have a problem with contamination of ground water if we follow some of the advice in this Guidance Document?" We need to hear that from you. Otherwise, it may stay there, or, otherwise -- you know, it might stay there anyway, quite frankly -- but we will never critically evaluate your concept, concerns, and thoughts.

As part of the -- research is a very big part of the President's initiative. We are working with USDA to determine where research is necessary to close some of the holes in the Guidance Document and some of the requests for research that we've heard from growers. We're in the process of working with USDA now to develop a research agenda. This is here to remind you that under no circumstances does this Guidance Document preempt any local, state, or existing federal rules and regulations.

You have to obey the laws as they are now. We are taking every effort to make sure there are no contradictions. If you know of any, you must tell us.

And as an example, we talk about a packing house. A packing house, even if on the farm, would fall under -- would be considered a processing facility by FDA. And in that case, it would fall under our existing good manufacturing practice regulation found in 21 CFR

110.10, and frequently in the guidance, especially when you talk about packing houses, we refer you to the already existing regulations covering the preparing, packing, and holding of foods.

How much goodwill, broad scope, good agricultural practice? That depends on how good we did our job. Did we identify potential factors common to fresh produce, and did we give guidance appropriate to industry that will suggest areas whereby you can minimize the risk of introducing unnecessary pathogens?

We do realize that a broad scope document has problems because of their enormous sizes and differences in farm size and resources, climatic and soil difference, fertilizers, employee availability, and general cultural practices necessary for the produce grown. That's why we're saying this is not a cookie-cutter document.

A grower is expected to look at this critically and see what they could possibly adopt. And the last bullet here before the break is the question we are asking today: How can we best provide practical and concrete advice to growers that will move us towards safer produce without being unnecessarily costly?

It has to be practical. It has to be doable. It has to be the real world. It has to have an affect, and it's something that growers must be able to do.

All right. Don, if you want to take a break now, it's a good spot.

MR. VOELLER: Okay. Do you want to give a preview of what's going to happen after the break?

MR. GARDINE: Just after the break. In order to give you grist for the mill -- grist for comments -- we are going to give a very broad scope review of each of the sections in the Guidance Document and what we think are some of the contentious sections in there, some of the things we specifically want comment on, and just give you some of the highlights of what we're saying in there.

Okay. How long?

MR. VOELLER: Ten-minute break, please.

MR. GARDINE: Okay.

(Whereupon a break was taken.)

MR. GARDINE: Okay. If you would settle down so that we could get to your comments, and a number of you have approached me during the break about that you will have comments.

Let's go over some of the specific sections in the Guidance Document and some of the specific advice-giving in the document to reduce, to the extent feasible, microbial load on fresh produce. First is water, and water is a concern in two aspects. First of all, if the water itself is contaminated with pathogens, it is an inherent source of contamination; and second, as a vehicle to spreading pathogens in the field, harvest, or packing house. We frequently think of water as what we use to clean our product. But if we don't use that properly, what we might be doing is taking a

localized contaminate and spreading it throughout the harvested product.

Here is just a list of microorganisms that have been associated with water and which are pathogens and have been associated with outbreaks. Not all of them involving fresh produce, but water pathogen illness in the U.S. Once again, not all of these have been associated with an illness in fresh produce.

Waters potential as a source of pathogenic microorganisms, growers should analyze their practices involving water and seek to limit the possibility of water-borne contamination. You've got to recognize, as you're looking at your operation, the potential for water simply to contain pathogens. And then the second bullet is real interesting. We say water should be of sufficient quality for its intended use, and we do not proceed to define what that quality is.

We would be interested in comments, thoughts, and opinions, but what we -- if asked what we would say is to look at the microbial criteria for potable water. We're not worried about heavy metals. We're not worried about other things that define potable water, but look at the microbial criteria for potable water as possible advice.

Your use of water and water source will vary and should be tailored to the needs of your particular operation. Remember that as a grower, the closer your product gets to the consumer, the closer it is to the consumer's table, the more care should be exercised in everything, including the quality of the water used.

And, once again, I must stress we're dealing with water quality. You're involved with state, local EPA requirements, nothing in this guidance preempts any applicable rule, state or local laws. One of the things in the document I suggest you consider doing is identifying and review the sources of water used on the growing operation. Bear in mind, that as the degree of water to produce contact increases, so does the need for better quality water.

For example, as you get into the washing house, the last wash should be using your best water because that's the one that is closest to the consumer. Your review may include determining your water source and whether it's from a well, and the quality of that well water, if it's from a canal, reservoir, reused irrigation water, and municipality of other sources. None of these are inherently bad water sources, but each of them impose different concerns and different things that a grower should think about in the use of water.

Well, people point out that, "Hey, we've got to get a crop to market. The crop may need to be irrigated now. Our crop is coming in. We're harvesting and the product needs to be washed now, and we only have one water source." We realize that. We're talking about things you should consider and control when you can to reduce the amount you can, microbial -- getting to the microbial

load of the product.

But, even if you have to, you know, bring your crop in and wash it and you only have one water source, and there may be a problem due to run-off at that time, what about a water treatment? It is possible when you're irrigating to consider alternative application methods that avoid water to produce contact? It's expensive to have two different irrigation methods in your field. We know that. It's just something you have to consider.

And if possible, do you have alternative water sources, and can you move from one to another as potential concerns develop? The feasibility of these or other controls will depend on the intended water use.

Once again, water becomes more important the more it contacts the produce and the needs and resources of a particular operation.

If your only water source is the river water, and you're downstream from that dairy farm -- well, you know, your options start becoming limited. Many factors, we realize, influence a grower's choice of irrigation water; economics, water availability, and cultural requirements for the crop.

Depending on the crop, growers may need to consider using water delivery systems, such as drip irrigation, if that is feasible, given the cultural requirements of your crop, that minimize direct water to produce contact for certain crops. One thing to bear in mind is water -- you know, water is used in many ways. One way to use water is mix crop protection sprays, fungicides pesticides.

The water used to mix and load pesticide sprays should be considered as serious a source of potential pathogens being added to produce, and be controlled as much as your other sources of water. The cause, for example, of cyclospora in Guatemalan raspberries has never really been resolved by any of the researchers that I'm aware of. But one of the theories many of these people have come back with is that some of the growers in Guatemala were using a very good well water to irrigate their crops, but because of a concern with back flow from chemical sprays contaminating their well water supply, their primary water supply, when they were getting ready to use pesticides, fungicides, whatever, they'd go to the local river and get that water to mix the pesticide spray. It's something they are now aware of, and we have to make other growers around the world and the U.S. aware of.

Wash water; wash water we usually think of as our friend, but if used improperly, we're going to be adding contaminants, pathogens to produce, or spreading localized contamination. Safe and sanitary water is recommended for use in washing produce in the field and packing environment in the guidance.

Wash water, even when sanitized, may reduce, but not eliminate pathogens on the surface of produce. We say that because we do not want anyone to think that we could do whatever we

-- you know, this is our safety step. This is what we'll rely on. You have to take a holistic approach. Use of sanitizers are wonderful, but they may not totally eliminate pathogens on your product. You have to use care throughout the growing cycle.

And for some produce, pathogens can be internalized. So if it's contaminated by then, and it's an internalized contamination, all the sanitizers in the world likely aren't going to help you. If pathogens are not removed or inactivated, they can spread so that a significant proportion of the produce is contaminated, instead of sporadic items. Once again, if we do our washing, which we think of as a safety step, cleaning step, what you're doing -- or without care what you're doing may be taking localized contamination and spreading it throughout the harvest.

We talk in the Guidance Document about chlorine as a potential water treatment to help with this issue. Cooling operations. Any time water or ice come into contact with the produce, you have to take care -- and that includes, as we said, the irrigation, crop protection sprays, washing and cooling. Water and ice used in cooling should be considered a potential source of contamination. Growers should be aware of the water source used to make ice, or, in general, in the cooling operations, and follow practices recommended throughout the Guidance Document to reduce the risk of contamination during the cooling operation.

Final point to stress again and again, you can't rely strictly on your wash water, even if sanitized water, if care is not exercised, can be a vehicle for spreading localized contamination. The next section of the regulation -- excuse me -- of the Guidance Document -- I have a habit of falling into that --

AUDIENCE MEMBER: Freudian slip.

MR. GARDINE: No. It's not a Freudian slip. I explained this a number of ways. And my cohorts who have been traveling with me during this session have threatened to throw things at me as I say that. It's really my contrarian nature. I've been advised so much not to make that mistake, I think I naturally do it. We are not talking about a regulation. If I slip again, please do not read anything into it, but an aging mind that is making errors, please.

Most of the illnesses we are talking about of concern, we discussed them, the cyclospora, the E. coli, salmonella, they are spread through the fecal-oral route. So health officials and scientists agree that animal manure and human fecal matter represent a significant source of pathogen contamination, whether it's through manure, or as we speak later about worker sanitation and hygiene. The use of manure or municipal sewage sludge in the production of produce must be closely managed to limit the potential of pathogen contamination of produce.

Growers must be alert that the presence of human or animal fecal matter that may be unwittingly introduced into the

produce growing and handling environment. Here we're talking about partly -- and one of the points of contention in the document -- control of animals and animal populations and bird populations in fields.

One of the growers in, I believe it was, Grand Rapids got up and asked me: "Do you know how high a deer can jump? And do you know how much it costs to put deer preventing fences up around my land?" And I said, "No, I don't, but I suspect it's a heck of a lot of money." And we're not asking that, but it's something that's in the document. We want your comments. And it is a source of fecal contamination of your produce, and something we do urge you to consider and control as you can.

Properly treated manure or municipal sewage sludge can be an effective and safe fertilizer. Untreated, or improperly, manure or sludge used as a fertilizer to improve soil structure for that entry surface water to run-off may contain pathogens that can contaminate produce. Bottom line, manure can contain pathogens; got to use it carefully. Well, we would just put this up to say that we know municipal sewage sludge is not widely used, but there have been some studies that it can have beneficial affects. That's why we talk about it to some extent in the document, but most of the conversation in the Guidance Document is about manure.

Just a listing of sources of fecal contamination, once again, we're concerned about the fecal-oral route disease transmission on produce. And some of the sources we believe are the use of untreated or improperly treated manure. That's why we'll talk a great deal about that.

Improperly controlled composting or treatment operation near the growing fields, nearby livestock or poultry operations that can cause you problems, municipal waste water storage in disposal areas and high concentrations, once again, of wild life in growing areas. Growers now, how do you control this?

You know what suggestions are in the Guidance Document. Growers may need to develop and follow good agricultural practices in handling manure to reduce the potential for introducing microbial hazards to produce. Practices may include processes such as composting to reduce possible levels of pathogens in manure, minimizing, to the extent feasible, direct or indirect manure to product contact, especially close to harvest.

Once again, as with water, the closer you get to the consumer's table, the more care we suggest that you use. And, of course, the need to assess adjacent or nearby land uses to determine risks from animals that may shed pathogens that can cause contamination. There's nothing you could do if the operation next to you is, indeed, a dairy farm. You can't do anything about the dairy farm, but you should consider that in your operations to see what -- is there anything you could do about the concern of rub off from that operation.

There are a number of treatments for manure that can reduce pathogens. They're discussed in the document. We put

them up there to show that we know that there are a number of ways to do it. But what we talked about essentially in the document is composting where we're talking about managed process in which organic materials are digested by microbial action, and where, hopefully, this microbial action is generating heat and other activities to destroy pathogens.

Properly composted manure can be an effective and safe fertilizer and/or soil amendment. Here is one of the areas where we admit research is necessary, and it is one of the areas where we are seeing now. We cannot, and we do not, in the document give time temperatures for manure, regardless of the type of manure you are using, because we don't think we really know yet. We have to work on that.

We have to work with industry and other agencies to develop this. But good agricultural practices can help you prevent cross contamination of manure to fresh produce and for composting, can work with local agricultural agencies, the Extension Service for the best advice, the best science, which is pretty good science currently available.

For untreated manure, for those of you using untreated manure, we give some specific recommendations in the Guidance Document. It's untreated. It's -- no attempt was made to -- no controlled step was made to try and reduce the pathogen load. How can you use it? We recommend you reduce the risk of contamination from untreated manure by maximizing the time between application and harvest. Recommended minimal use generally range from 40 to 60 days before harvesting. Some recommendations are for as much as 120 days or longer.

And here's where we get into the matter of cultural and regional differences. In upstate New York we had one of these grassroots in Geneva -- Geneva, New York -- excuse me. And one of the growers there who was running a joint operation, part dairy/part produce, and he says too much -- he doesn't compost. He can't compost. It's just too much that he doesn't do it. He says it's a nice recommendation. Do you have any idea what the growing season is in upstate New York? And those are the kind of problems that we have to try and face, and might best be faced by specific crop and regional type Guidance Documents, however it is determined to develop them.

And he went on to point out -- he obviously had researched the matter as part of his operation and done this for years -- you can't -- you don't want to put this down in the fall because the soil is frozen. You're going to get run off. Now you're dealing with contaminating water supplies. And even if that doesn't happen, you don't get the affect you want in the soil. So these are problems we've got to try to work together to face.

The treated manure, the composted manure, or treated however, natural fertilizers such as compost manure may need to be produced in a manner to reduce the likelihood in cross-contamination microbial hazards. What do we mean by that?

Care should be taken to avoid cross-contamination of fresh produce from manure that is in the process of being composted, or otherwise treated. You, obviously, have to try to control and secure these piles and probably not have them uphill from the fields. Improperly treated or incompletely treated manure may be a source of contamination, not only your composted pile, but, obviously, your produce.

Compost or other treatments may reduce -- and we say here "may" because we don't really know; once again, research is needed -- may reduce, but might not eliminate pathogens in the manure. Furthermore, it is unknown to what extent pathogens that survive treatment may regrow in compost manure that is stored before use. Obviously, a research need.

Therefore, we recommend in the Guidance Document that to the extent feasible, growers using treated manure may want to consider some of the recommendations. Because of the research that needs to be done, some of the recommendations made for untreated manure, such as maximizing time between application and harvest.

Some good agricultural practices recommended in the Guidance Document for handling manure might include security of manure or compost to prevent cross-contamination from run-off, to prevent cross-contamination from leaching into the soil and then spread.

The next section of the Guidance Document involves sanitation and hygiene. Once again, very important, we're talking about diseases spread through a fecal-oral route most of the time. Worker health and hygiene play a critical role in the controls to minimize microbial contamination of produce. Fecal-oral disease are the primary microbial concern here.

Good hygienic practices by all workers are essential in the control of microbial hazards. Infectious diseases -- workers, we should say, with infectious diseases, ill health with diarrhea, open lesions, et cetera, on the hands that are going to come in contact with the product are a source of microbial contamination that can be transmitted to produce. And it's something that a grower needs to be concerned about, just as it needs to be a concern in the retail setting, in the marketing setting, and in the home setting.

But once again, just as in a restaurant, this is a concern in dealing with fresh produce, it's something that frequently is going from the market to the table, perhaps especially in a farm type market setting.

Employees -- now here is -- once again, let's just go through this and talk about it a moment first, control of potential hazards, control of personal health of your employees. Employees should report to a person in charge any information about their health or activities as they relate to diseases transmissible through food. There should be a person in charge to monitor the health of employees. And individuals with diarrheal disease should

not work with fresh produce.

This is hard in a farm setting -- in a grower setting. But, nonetheless, it is also a universally accepted proposal that food workers with these sort of illnesses should not be working with the food. We've had a retail food code for restaurants, and other food service establishments for years that say essentially this: Someone should be monitoring the health of workers and someone should be concerned with it. And, if possible, you know, minimize -- or I shouldn't say that -- I should say eliminate people with these sort of problems from contact with the food.

Growers say, "Well, you know what's going to happen the first time I send someone home after they report a diarrheal illness, it will be the last time anyone does." Might be so, but you should be aware of it. It's very difficult -- it's going to be very difficult for public health officials to ignore this very important route of disease transmission. We understand the problems associated with it, but they are the same problems that are associated with attempting to control this in a retail setting.

All employees who are involved in the harvesting, packing, and distribution of fresh produce should be trained in good hygienic practices. The Guidance Document suggests that you consider establishing either your own, a county or regional training program for agricultural workers, and develop a system to monitor and evaluate compliance with personal hygiene requirements.

Employees should be taught proper hand washing techniques -- you can't assume they know it -- and use of sanitation facilities, such as on-site latrines, and avoiding the elimination of waste outside of these facilities should be encouraged, and I think -- not should be encouraged -- should be required might be a better statement there.

Field sanitation. Once again, we're talking about toilets and field workers and proximity, Proximity and accessibility of facilities to harvest food in all sections of fresh produce production is important. They should be available. They should be relatively close. Workers should have the opportunity to use some of these when needed. This will help reduce the instance of workers relieving themselves elsewhere.

The Guidance Document reminds you, as you well know, to assure that location of portable toilet facilities -- we're talking about field as we are -- is not near a water source used for irrigation or in a location that is subjected to potential run-off in the event of rains. Facilities should be available, once again, for all employees. A toilet facility should be adequately maintained and sanitary, and maintained in a sanitary condition.

Some examples of good practices that the Guidance Documents advise be followed, as you saw, the portable toilets, clean them, service them away from the field, if possible. Dispose of waste through -- in a manner such as the sub-surface septic

tank. That will avoid contamination of the product. You have to drain away from the field or collect in a drainage tank to be correctly disposed of at a remote site. Once again, fecal-oral route, we want to keep this off the produce, and care should be exercised, as I'm sure it is, in handling this waste.

For harvesting precautions, once again, you don't want to bring filth or any potential routes of microbial contamination into a packing house. So the document, very common sense wise, recommends removing as much dirt and mud as possible from produce while it is in the field. Things that you can control, such as the use of damaged or muddy cartons should be controlled. They should be repaired, cleaned, or discarded in an effort to reduce the microbial load -- the unnecessary microbial load on fresh produce.

Care is needed to ensure produce that's packaged in the field is not contaminated in the process. Suggestions on how to do that are given, and it recommends that inspectors, buyers, visitors, wash their hands and will wear cleaning, disposable gloves before inspecting produce.

Equipment maintenance. We're talking now about equipment maintenance in the field. We do not expect field equipment to be maintained as sterile. We understand that, but remember what we're asking you to do, limit the unnecessary microbial load. What we suggest, as we do in many of our other documents, that a person should be in charge of maintaining equipment sanitation.

Keep the equipment as clean as possible in the field and harvesting condition. Items such as lunches, tools, fuels, et cetera, should not be carried on harvesting equipment. Remove contaminants -- visible contaminants, mud, diesel, grease from equipment daily. The person in charge should be aware of the use various pieces of equipment are being put through, and make sure that the same piece of equipment that is harvesting manure the day before is not used to transport the harvested crop the next day without appropriate cleaning and steps being taken.

Now we're talking about the facility. We're in the packaging house. One of the things the Guidance Document reminds you is that anything in the process from harvest to processing that makes contact with produce has the potential to contaminate it. Your work tables, the lines moving, the produce not becoming a matter of concern. Poor sanitation in the packaging house can increase the risk of contamination of produce and water supplies used with the produce, used in cleaning the produce.

Once again, we remind you that you're in a packaging house, existing laws and regulations cover the preparing, and packing, and holding of food. We remind you that there is probably some very good guidance available to you both locally, state, and under FDA regulations in this case, Item 21 of the Code of Federal Regulations, part 110 in the section involving general good manufacturing practices with foods.

Equipment should be clean and sanitary, repaired as needed in a packing house. Workers shouldn't use equipment for inappropriate purposes, and you should keep it as clean and sanitary as possible.

Pest control; fecal-oral route. All animals are potential sources of contamination of adding unnecessary microbial pathogen load to produce. In an enclosed facility and enclosed packing house a pest control program is needed, and packing house processing facilities and grounds around them should be kept in good condition protected from pest contamination.

These are very bland and common sense statements. Once again, you have to go to the document for details, and how doable the details are. The final item that can -- that we believe is one of these universal components that must be considered in all produce transportation. We're talking about transportation from the field to the packing house, and then from the packing house to the ultimate -- to the purchaser. We know that some of that is not in your control as a grower.

Once again, I must remind you that we're asking you to control here what you can control. There are other aspects of the President's program to address the other steps in the process. Contamination of produce may occur due to improper packing during handling, loading, unloading. And transportation operations. Wherever produce is transported, sanitation conditions should be evaluated, especially between links in the distribution chain. You should probably be talking to the people moving your produce and see how they're handling it to do their best.

Cross-contamination from other foods and non-food sources and contaminated surfaces may occur during transport. It suggests fresh produce should be segregated from other food or non-food sources of pathogens in order to prevent contamination of the produce. Try to assure that the trucks or other carrier sanitation requirements are met before loading your produce.

Once again, produce is not a sterile food. We don't expect the trucks moving it to be sterilized, but my God, they should be clean. Residue should be removed, and depending on what they did move before you, maybe they deserve some sort of -- if they were holding garbage maybe before you put your produce on it, you should consider or the carrier should consider sanitizing it. That's why the communication is very important, and keep open communication, of course, along transportation routes regarding food safety risks and the need for adequate safety steps.

Those are the four things in the document that are discussed as things that should be considered and controlled involving the potential addition of unnecessary microbial pathogen load on fresh produce.

We then drafted onto this document a section on what we are now calling -- and I don't happen to have the slide prepared to fix this yet -- positive lot identification, but I think you know what we mean when we talk about trace back. The

ability, if there is an illness to the extent possible, to trace the contaminated product to a specific field.

There are many advantages in doing this. Fresh produce will never be free of contaminants. It's not a sterile world. We've been saying that the whole purpose here is to minimize to the extent feasible. You know, we're not sloughing off here. We say to the extent feasible to control as much as you can, what you can, the microbial risks, but you are growing this product in a field under the sky.

Trace backs don't prevent a hazard, but it can limit the scope of an outbreak, limit populations that may be at risk. Because there's a trace back mechanism, we can respond very quickly to identifying the problem, finding out where it went, it will help us identify a specific source or growing field that might be the source of the problem, and prevent it from reoccurring in the future, thus lessening the economic burden on operators not responsible for the problem.

And we do realize, depending on how the produce is traditionally marketed, this is more easily to do for certain product than others. You know, if it's a product that is traditionally displayed in bulk in a supermarket, a grower could only go so far. You might identify your process. They leave your farm. They go to a distributor, and perhaps he may or may not keep a record of what was sent to who, but we are asking you for your part of the chain, and we will be asking distribution for their part of the chain to think positively about the benefits of positive lot identification.

As a federal worker responsible for public health safety who has spent much of the past year hearing about -- although my unit was not necessarily responsible for dealing with them -- outbreaks of illnesses associated with produce fresh, or in other cases, processed produce where we don't know where the contamination occurred, the advantages of trace back are such that, you know, they will minimize the unnecessary expenditure of public health resources. With this trace back mechanism, we can focus on the problem real quickly and don't have to spend time trying to figure out what came from where and was sold to who.

It will reduce consumer anxiety if they know that the problem has been identified and is being controlled, and they don't have to worry about the entire strawberry crop for the year. They know it's this product, or the entire raspberry product; they know it's that product. As we said, we want consumers to have confidence in fresh fruits and vegetables to eat them because it's a wise dietary source.

We ask you to look at your ability to do trace back. We know you cannot do that job completely yourself, but we ask you to consider doing what you can as a grower to make sure that it is your control; it's adequately identified. And the document does talk about what should be the components of a good positive lot identification tracking system.

Once again, you can do what you can. Product, you know, it might all fall apart when it leaves you. You have to work with other parts of the processing of the distribution chain, and as part of the initiative we will be.

I think now we have time for any questions of clarification, or any sort of questions for anything that I've spoken about this morning. I apologize for going through this quickly. We go through it very quickly at each meeting of this -- of this type because while we want to give you some highlights and things to think about, you're not here -- we're here to listen to you, and we want to have as much time for that as possible. So if there are any questions, we will be delighted to take them now and get them on the record.

Please come -- and do come to the mike, please.

MR. TRUMBALL: My name is Rick Trumball, and I work for Broetje Orchard, which is a large apple grower in the State of Washington. Some of the concerns that this raises, you know, for us, we have a lot of people. We're, you know, growing this year about 200,000 bins of apples. And looking at a deal like you've adopted chlorine in a solution on a drench for a microbial, you know, control, what about the regulations as far as what would you do with the solution as far as disposing of it? And the recontamination of -- like if they're bringing trucks in, and you're, you know, recontaminating the fruit as you -- throughout the day, you're bringing it into the packing facility, and you're doing a drench to try to knock down the microbial count of recontaminating everything in the deal behind you.

MR. GARDINE: Well, to clarify your concern is, my God, we get in a lot of apples. We have a wash step where a sanitizer is included. If the sanitizer for chlorine is -- for example, chlorine as the load increases, the chlorine decreases. You obviously have to keep adjusting that. And if you don't do it properly, you may be putting your apples into water to wash them, but coming out with dirt removed, but microbes added to it because there may have been a spotty contamination?

MR. TRUMBALL: Right. Well, what we do now is we do like a post harvest drench with a solution, and we run it on concentration and --

MR. GARDINE: Is this on a belt or --

MR. TRUMBALL: No. It's in a big tank.

MR. GARDINE: All right.

MR. TRUMBALL: Where you drive trucks through a big overhead drench system where it's sprayed through the bins and run down, recaptured. It's monitored and maintained at a certain part per --

MR. GARDINE: Okay.

MR. TRUMBALL: The one thing is I don't believe chlorine would be a label deal on fruit.

MR. GARDINE: If you use it in accordance with good manufacturing practices, I do not believe it will be.

MR. TRUMBALL: Okay.

MR. GARDINE: I'm trying to think -- off the top of my head I cannot remember the recommendations for GMP use. But, no, you wouldn't have to label -- you know, put apples with chlorine on your label.

MR. TRUMBALL: It's just the deal -- we're looking at a deal here and talking to a very, very deep subject here when we start talking microorganisms. I mean, and we all know that we don't know a lot about it, and it's scary from the standpoint of thinking of regulatory.

And what the gentleman with the onion marketing deal referred to as far as if it could ever, you know, come back to haunt us in a deal where it would almost be a detriment rather than a benefit. You know, there's just some concerns.

MR. GARDINE: Okay. But I just want to say that, you know, you appear, from what you're saying, to be taking steps that this Guidance Document -- and this is not at all surprising, because as I said, American agriculture appeared to be responding to and addressing these needs, because you are consumers. You are concerned with your customers, and it's just damn good business to do what you can to avoid problems like this.

You appear to be -- what you are doing is the sort of guidance that is suggested by the document, I think, once you start reading it.

Any other questions comments at this appointment?

MS. PAUL: I'm Peggy Paul. I'm a dietitian for the Oregon Dairy Council. But my question is what sort of alliances or cooperative efforts are you looking towards the media in this campaign? Because consumers get their information from the media, and it seems like in recent years, the media comes out with a story without all the information. And consumers make their decisions with that initial blitz, and they fail to follow up two, three weeks later when you hear, "Well, it was just this one lot in a state." And they've lost the need to follow up because they've already made their decision; they're not going to eat strawberries this summer.

MR. GARDINE: It is a real problem. We cannot -- and more than that -- even when a story hits the press and is reported that the facts are there and it's reported properly, frequently a consumer will make the decision that, "I don't care what they say, I'm not sure. I'm not buying this for myself or my family."

I don't quite know the intent of your comment, but I do know that at a number of these other meetings, FDA and USDA were complimented in the instance, just as strawberries, as you mentioned, in that our press was pretty good.

We kept telling people, "We don't know what the problem is right now. We don't know what caused it." You know, a prime example is the instance with cyclospora about two years ago when, based on some very early epidemiological studies,

strawberries was implicated as the source -- domestically produced strawberries, and they weren't. But, boy, did the strawberry industry take a hit based on that press getting reported.

We could only do what we can to get a better feedback loop with local agencies, and to get the right story out in the press, and we tried to do that.

And one of the components, by the way, of the President's initiative is to work and find ways for better communication with local and state agencies. We're going to start with the state, because there's -- hopefully, the multiply effect will go from them to local health departments so that we get the word out right before we get any word out. And that is a concern and an understanding concern.

Any other -- I guess it's you.

MR. TRUMBALL: Well, I've been in the tree fruit industry my whole life, and what she's referring to, I believe, would be like the thing that happened in the apple industry that cost us over 100 million dollars.

MR. GARDINE: Go ahead.

MR. TRUMBALL: And it only represented about five percent of the annual sales that went on apples. And we're still reporting crops today that are treated with this, and sometimes in the rates of ten times what we've ever used on apples. So what she's saying -- that is an enormous fear, you know, as we sit out here as an industry.

MR. GARDINE: The only thing I'll say is thank you for the comment. And, yes, it is a fear and a concern. We understand. Could you -- or actually we have a hand mike that maybe we could just pass forward. This is sort of like the Thursday Time talk show.

MR. CURRY: Gary Curry, Oregon Onions. Is this the right interpretation, that you are trying to take this document as guidance here and make it more commodity specific?

MR. GARDINE: One of -- the President has asked us, as part of his initiative, to make sure that commodity and regional differences are accounted for.

What we are asking people to work with us on is saying, "Tell us how to do that." We had initially -- and that's why I put up that second slide, and maybe it's worth showing again -- because this is something, from past experience, I know we will talk about a great deal before this day is done.

The President's directive requires that good agricultural practices and good manufacturing practices account for specific commodity and regional differences. How do you do that? How do you account for growing tree crops, you know, like apples or berries that grow close to the ground, or row crops, because initially -- well, you know, we would think that as you develop these more specific Guidance Documents as a group -- you know, grouping citrus together or berries together, there are more common elements where you could give better specific guidance that might

be more helpful for industry.

What we had thought -- initially thought to do was that we would start by picking individual commodities, and work with those growers and see what we could come up with. There is a great deal of concern, as you could well imagine, of how are you going to pick these people? Is it going to appear that what we have here is an at-risk list of fruits and vegetables? Right?

So people, you know, there's a great deal of concern. We were initially hoping -- our initial thoughts were to pick these crops sometime this month and start working, but now that's been postponed. We're asking people to tell us how we could work -- what's a better way to do this.

So the answer is: We are considering trying to develop more specific guidance either by grouping categories of crops together or going on certain commodity specific guidance.

MR. CURRY: I think to offer an opinion here, too. I think in my mind to try and be commodity specific is going to be terribly difficult, and you might not get to where you want to go. So, one, I'd recommend that you try and approach it on more of a generic basis.

MR. GARDINE: Are you saying something like citrus crops, and just put them all together, and then perhaps berries or bush type --

MR. CURRY: It could become a life long project if you try to.

MR. GARDINE: No, and no one intends to do every one. But one of the things we are thinking of is what you are saying now, are there ways to group crops?

MR. CURRY: And another comment, just as you were going through your presentation and looking through the more specifics is that, in my opinion, what you're laying out in terms of good practices and what you're setting down in your guidance is that most good businesses in our world of agriculture really follow these practices. And you're -- it's kind of like a good housekeeping process that you're going through, and so take that for what it's worth.

I mean there's always in every industry going to be those that are better than others. But the guidelines that you put down -- I think if we sat back as a company and looked at it, and we would say we do all of these already. And so you've got to get the most bang for your dollar is -- is -- and I don't know how many dollars are going to go into this project.

MR. GARDINE: Nor do we.

MR. CURRY: So I'll just give you that side line is that this industry is well on top of a lot of the issues that are here.

MR. GARDINE: Thank you for that comment. We realize that. One of the things that always bothers us is those folks who are prepared to come to these meetings, not the ones that are going to give you -- that are not following this -- that the

people come to the meetings are concerned, and that falls for the vast majority, I think, of domestic industry, for the reasons I gave before.

The vast majority of domestic industry as a consumer, the vast majority of the vast industry is taking prudent steps to protect their customer, and the vast majority of domestic industry and foreign industry. I don't mean to sleight our suppliers, because many of our foreign suppliers are also our domestic industry with operations overseas. It's just simply good businessmen, and they're following good business practices, which is protecting their product. We realize that.

We don't think that these guidance documents -- this broad scope Guidance Document -- we do believe it probably is something that is being followed by the majority of industry supplying produce in the United States. And I agree with your comment that most of the people here and in this industry are probably doing this to the extent feasible.

MS. ZAWEL: My name is Stacey Zawel. I'm with the United Fresh Fruit and Vegetable Association. I'd like to actually discuss the impact that was raised a couple of questions ago regarding media -- the role the media plays in all of this. And I think that it's been, on large part, my job as all of these outbreaks have unfolded, to fight and to make sure that the information -- the correct information gets across.

And so, well, the onus is on the industry to make sure their public health officials get these things right. Every single time we see an article in the Post or we see a public health official make a statement that is incorrect, I call that person specifically, or I write to the Post and United writes to the Post on behalf of our industry. But what I would like to see is not only that, but that the government also uses or takes the responsibility to convey the appropriate information.

For instance, in a recent meeting that an industry coalition has that belongs to United, one of our members asked the FDA what was driving this initiative.

The answer was, "The media calls every day." And so I think that what we have to do, rather than let that -- that debate proliferate throughout the media is be responsible, every single one of us, and make sure that we communicate, "Listen, this outbreak has occurred, but, as a matter of fact, we don't know where the source of contamination is"; whether it's somebody as the FDA that's talking to the New York Times or their public health official in Florida or a public health official Texas. What ever level you're on, whether you're a state official or local official or county official, every single person needs to communicate the appropriate information to the media so we can offer information out to consumers, because that's where they're getting their information.

As a matter of fact, the National Restaurant Association just published a study that they did asking their -- they pulled a number of consumers and said, "Where do you get all

your information?" They said the media was the number one source. So I think we need to be very careful.

MR. GARDINE: Stacey, just stay up there. There are a couple of things I do have to respond to there. Number one, yes, we've got to get -- first of all, I agree with your basic statement, we've got to get the message out. I would hope while FDA and USDA might occasionally make mistakes, that you would think you would be able to say that most of the times when they're brought to our attention, we change them. And most of the instances that have caused concern to agriculture, and not -- recently, you know, the result of the rush to judgment on the part of the federal government, but that's where I agree with you.

Where I disagree is -- we will speak later about who this FDA official was that made the statement that you said -- and I will repeat for the record that we are doing this as a public health initiative. It is not a respond to media because they call every day initiative. Our fresh fruits and vegetables in this country is the safest in the world. We think there are.

But there are problems now that we've never had to face before with the merging pathogens, with produce coming from, as folks have mentioned here, different countries with agricultural conditions, with environmental conditions that might bring new concerns to the produce with pathogens. As I said, getting associated with new pathogens, getting associated with domestic produce, and with the difficulty, and we believe, the inappropriateness of a vast -- and the impossibility of funding a vast testing program. We want to work with industry to find the best way to address this real concern in as cooperative up front, let's, you know, try and deal with it as the source of and/or as we can. I just didn't want to let it slide, but I think it's nothing but a PR reaction.

MS. ZAWEL: I have just two comments. From the federal versus local public health official standpoint, I think you're right, Tom, in that it's the basically local, state health officials and other personnel who perhaps are less used to dealing with, I think, the specifics of an outbreak there, and that we need to deal with on an overall basis, and that I focus my energy on.

From a federal standpoint, I don't imagine -- I can't recall of any one instance where I've had to do that. And I think that there's very good reason for that. You guys are very careful about the way you go about things. What I encourage from a federal level is that rather than having the media walk all over this and walk all over you, that you guys say, listen, you know, you have to provide some responsibility to the media and encourage them, like the industry does, to portray the correct industry.

That's what I'm suggesting from a federal level, that you provide leadership in that area. The second point I want to make in all of my statements that I will make eventually are based on the fact that the industry wants safe food, too, and they do not want their name associated with this.

So it's not to say that if done properly, if we increase the awareness of food safety issues across the industry, that makes good sense, that makes good business, like Gary was saying. But, however, I think we have to be very careful, because consumer advocate groups portray, and they're pushing their agenda very, very hard, and that's playing a very large role in this initiative, and it doesn't discount that in the end it may be a useful initiative depending on how it comes out, but they do play a very large role. The other thing that I would do and I encourage other officials within FDA to include the industry in the process -- in the outbreak investigations. I believe it's called Force G. A group that's pulled together multi-agency.

MR. GARDINE: It sounds like a movie, doesn't it?

MS. ZAWEL: It does.

MR. GARDINE: We have a swat team Force G.

MS. ZAWEL: Anyway, I've encouraged FDA and CDC officials to somehow develop a relationship and the relationships are there, but I think it warrants a more formal relationship so that you guys have a mechanism during outbreak investigations to help you through that process.

It's a very good thing to trace back product, but industry oftentimes knows that, in fact, produce is not -- or a specific commodity is not coming from that region at this time of year. And we can help in the process by providing some industry intelligence to that, and aid in trace back investigations so that we can, instead of implicating the source, which consumers are likely to do, let's find where the contamination is occurring and prevent these outbreaks from happening.

MR. VOELLER: Somebody over here has a question.

MR. TORRES: Are you talking about --

MR. VOELLER: Could you please introduce yourself?

MR. TORRES: Antonio Torres; Oregon State University, Food Science. We're talking about some way of proving to get specific recommendations out of this process, and I'm thinking that the alternative would be to focus on the microbial pathogens that we are talking about and try to learn more about ecology, that industry would have a piece of their production pathogens, take that knowledge to develop better practices.

So rather than trying to create a condition for the industry who knows much more than you will ever know about the specific commodity, what they don't know is what are the pathogens, how to deal with them, how can they be eliminated, so that would be much more useful purpose than trying to recommend for commodity group or a specific commodity itself. And then they have a better position to present a better science or technology or information base, than trying to come out with better recommendations than their use.

MR. GARDINE: Thank you. If there are no further questions, Don, do you want to break for lunch?

MR. VOELLER: Yes. We'll return at 1:00 p.m. to hear Dr. Rick Gomez represent the USDA.

(Whereupon a lunch break was taken.)

MR. VOELLER: I'm going to quickly introduce Dr. Rick Gomez. He's the chief horticulturist for the USDA Cooperative State Research Education and Extension Service.

DR. GOMEZ: Thank you, and welcome back. I hope you didn't have too much problem with that CSREES title. The role of USDA, it's very simple. It's very simple, and so it will only take a few minutes. The role of USDA is to bring agriculture to the table; simple, very simple.

The mechanism by which we can bring agriculture to the table here in this initiative is very complex though. And let me give you a brief description of some of the agencies involved in the USDA that will have a role here in this initiative. Although I'm not going to list all of them, most agencies within the department will play a role. This initiative is divided or separated into two parts, foreign and domestic. And USDA has foreign and domestic operations as well.

Through the Foreign Agricultural Service, through the Animal and Plant Health Inspection Service we touch foreign countries. The FAS not only is a promoter of U.S. product -- agricultural products, but it's also involved through its international cooperation and development activities in providing technology transfer to other countries. And if you've been to other countries in which -- from which we import materials, most of the technology used there is American technology.

USDA, in corporation with FAS, utilized many of the land grant university staff in providing some of the knowledge for these foreign operations. So we are involved in the foreign affairs, and we can take and develop some outreach and educational programs to fit those. And I think those are going to be definitely a part of this initiative. They must be a part of this initiative.

Domestically the Agricultural Marketing Service through its marketing orders and other activities also touches producers and producer groups. I'll explain again, that will be part of the outreach programs. Within my agency area -- mission area and that's how we are divided in the department, our mission area or the one that my agency belongs to is a research, education, and economics arena.

And we have several agencies, some of which are very well-known to you, such as the Agricultural Research Service, which is the intra-bureau research of the Department of Agriculture. The ARS has already started to redirect some of its activities and efforts into the area that we are dealing with in these guidelines. They have, I know, redirected into the composting and utilization of manures from their other activities.

So there is -- has been already some redirection. The President's budget for fiscal year '98 will include some

additional funds for research and education activities to cope with this initiative. So we're dealing with that. The Economic Research Service, which is the arm of the USDA that deals with the economic aspects of production -- agricultural production will be involved and is involved already.

And we can see through the ERS some of the changes that may come about because of this initiative. But let me tell you a little bit more about my agency since I know most about that one. It's a Cooperative State Research Education and Extension Service. And that agency is a brand new one as of three years ago. It's a merger of the Cooperative State Research and the Extension Service, which is a very, very logical union. It ties in research and extension activities. And the bodies that are included in that are the experimentation system and the extension system throughout the land grant universities.

Our idea in the department to merge those two agencies into the one now existing had occurred at the land grant system many, many, many years ago. As a matter of fact, you've heard Bill Mansour tell today that some of the staff are both experimentation and extension staff. We are now, in our agency, both extension and research staff. We are the federal part of the whole extra mural and extension service throughout the nation and territories.

There are over 100 institutions that are land grant institutions in the U.S. And we are responsible in the development of research and research priorities to help the agricultural producer in the U.S. The Agriculture Research Service that I mentioned before has a mission to do basic research, as well as apply. And so that's the experimentation system, although we tend in the experimentation to do it a little bit more towards the applied side of the research.

Priorities. This is where we start getting very interested in this initiative. Priorities for research and for extension programs occur or are determined at the local and state level. Very few of them are determined at the federal level. As a matter of fact, this initiative, even though it may seem to come from the federal level, it really comes from the producer level. And so, with the educational programs associated with it.

The whole complex of the federal and land grant system, the partnership that exists is a partnership that we at USDA will bring to this table here. But we're missing one element, and you'll hear from that element a little bit later on. The element that we're missing is the producer himself -- himself or herself.

As you will hear, there are some producer groups involved in this initiative, and the three groups, the producers, FDA, and USDA must, and I repeat, must become partners. We must agree on what type of programs, what type of guidelines we want out there and to be practiced. Otherwise, it will not get anywhere. We know that.

Extension system and the experimentation system have been working at this for many, many years, and we have within that system itself a method of feedback -- a mechanism for feedback that brings the needs of the producers through extension to the research. And once that research is done, through extension back to the producer. So there is a whole cycle, and that's what we must do with these things.

There was one question asked that was very interesting during the morning session on how does this initiative and the programs that may be generated, how can they -- how are we going to integrate them with other programs, such as a program on education for the Clean Water Act? Well, that is probably one of the roles of extension, but it's also a role of the producer. He is the ultimate -- he or she is the ultimate integrator of programs.

Those are the things that we at USDA and the land grant system bring to this table. And to give you an example, there is one program that's called -- it's a small program, it's a computer generated program called Farm Assist, which has, at this point in time, some of the economics and some of the environmental practices associated with farm production, and it goes on to determine what the economics of the operations are.

Michigan State University and other land grant institutions are already working on the Farm Assist program to bring in some of these guidelines or good agricultural practices into that model so it can be used. The beautiful thing about that model is that it does not, and I repeat, does not take anything away from the producer. It lets him or her still be the decision maker. It is a voluntary program. It serves as a guidance. And that's what this document, these hearings are all about, to generate a guidance document, but not to take away the right of the producer. Thank you.

MR. VOELLER: Any questions from the floor for clarification for Rick? Hearing none, we'll move onto the next portion of the program, which will be industry group presentations. And I have seven individuals that have already contacted me for this presentation. And the first will be representing the United Fresh Fruit and Vegetable Association, Stacey Zawel.

And if you do choose to use the podium, I want to warn you that there is no back on the platform, so be very careful.

MS. ZAWEL: Thank you very much. I am the director of Scientific and Regulatory Affairs for the United Fresh Fruit and Vegetable Association. United represents growers, packers, shippers, wholesalers, brokers of whole produce domestically, as well as abroad, and also work with processors and industry suppliers.

A number of different issues; this one obviously being one of them. What we've done is, throughout all these meetings, capitalized on this opportunity to gather together a

number of industry experts representing a number of commodities in the specific regions to convey some of why their practices are followed, to demonstrate the diversity and the complexity of the industry, to convey what is practical and what is reasonable, as well as demonstrate that the industry does, in fact, take the issues of food safety very, very seriously.

And I have -- actually what I would call both had the opportunity and the challenge to attend every single one of these meetings, so I must tell you I'm very happy that this is the last one. And I have also, in all of these meetings, taken an opportunity to make a number of recommendations on behalf of the industry, and I seem to never run out of ideas.

But I would just like to actually touch on three areas today, qualifying my statements both in the beginning and the end. The beginning qualification is that the industry does take food safety very seriously. We demonstrate that through a number of initiatives that are already underway. An industry wide Guidance Document, 20 organizations have developed, as well as regional, documents such as Western Growers Association, such as California Strawberry. There are initiatives all over the country that are developing this to -- initiatives to address food safety. So it's evident that the industry is moving very, very fast to address these issues and ensure consumer confidence in the food supply.

The first area I would like to touch on that certainly deserves emphasis, and as Tom said earlier, he would hear a lot about this, and he's right, one of those is the commodity specific guidance. United certainly opposes moving down that road, and we do so because there's no reason -- the commodity specific guidance cannot be developed for the same reason that it's very difficult to develop broad industry guidance. And that's because the diversity within one commodity is the same diversity that exists across the commodities, across regions because practices are so different.

So what we need to do instead is -- is develop this broad industry guidance. And if, in fact, it is done appropriately -- say it's done considering what's reasonable, and it's done considering what's practical, then what those limited resources should be focused on is something that will actually have an impact. And that is that these limited resources should be devoted to supporting research, to help guide future recommendations. It should be also devoted to developing education and outreach programs.

And we certainly, as one mechanism, to facilitate education and outreach programs, we encourage that the resources be used to marry together the efforts of land right universities and the knowledge of those universities, the efforts and the knowledge of the industry to develop educational programs and reach out to their specific regions and their respective commodities to address these issues on a more specific operator-by-operator basis. That

is what's going to be effective.

The second area that I wanted to talk a little bit about was the application to harvest delay use of manure, and any recommendations that are made in this guidance. As it stands now, there's a reference to a couple of different recommendations. And those are that perhaps a 40- to 60-day application to harvest the land manure is appropriate, or perhaps 120 days, because somebody uses it in that manner.

These are not based on science. These are based on, one, the organic standards that are out there, and the other 120-day recommendation is based on a casual comment that was made that it happens to be one operator's practices. Those are not appropriate references to be included in guidance, because they are not based on science.

The second area under the application to harvest delay issue is the two research studies which are referenced inappropriately. In my mind, they should not -- they need to also be deleted from the guidance. And they need to be deleted from the guidance because they don't provide a basis for any recommendation. And they should, in fact, not be used in that manner.

And this is because one of them -- one of the references suggest that E. coli can survive in manure -- cow manure -- for 70 days. But if you look at the fine print and you really dig into that study, what you'll find is that that study was done in a test tube. And I find it very difficult to understand why we need to extrapolate an experiment that was done in a test tube to demonstrate that we need to have a specific recommendation governed by that. I appreciate basic research. I've done a lot of basic research.

However, basic research provides a tool and a basis to do the applied research, and that's what we need to do. We need to move into applied research. There's going to be a number of initiatives undertaken in the area. They need to be funded, and then we'll provide some answers that will have potentially a public health impact. So when the science fact is available and is used to form the basis of a recommendation, then it warrants an inclusion, but not until then.

The third area that I wanted to cover is something that is a very, very, very fine point, but it's very important. And that is stating that this guidance is going to include good agricultural practices and good manufacturing practices, but that it's guidance. Right now good manufacturing practices -- everybody knows who deals with good manufacturing practices are codified. You have to follow those in certain circumstances.

It's going to be very difficult and provide a tremendous amount of confusion that something that's codified is law, and yet in another instance, it's guidance. And so what we recommend instead of calling it good manufacturing practices, call it good handling practices. There won't be confusion amongst the industry. There won't be confusion amongst the regulating bodies

who are going to be following this and make sure -- and interpreting it for themselves. There's enough confusion about what guidance means to introduce another confusion point in there. So I encourage you to change that acronym.

And the last thing that has been said over and over by FDA and USDA and a number of industry groups is that we must continue to clearly state the importance of increasing consumption of fresh fruits and vegetables. At a time when incidents of chronic diseases, such as cancer and heart disease are increasing, and, in fact, an overwhelming number of studies indicate the consumption of fresh fruit and vegetables up to ten servings a day can, in fact, decrease one's risk of many of these diseases.

And we cannot jeopardize the public's health by inappropriately steering them away from fresh fruits and vegetables. But instead, we must all encourage increased consumption. Thank you.

MR. VOELLER: Thank you. The next individual is from -- representing California Grape and Tree Fruit League; Brian Haddix.

MR. HADDIX: Good afternoon. My name is Brian Haddix. I am here on behalf of the California Grape and Tree Fruit League, which is a voluntary industry trade association representing approximately 80 percent of the deciduous tree fruit and packer/shippers in the state of California. I'd like to start by saying that it's unfortunate that this panel was unable to meet in Selma a few days ago, considering the incredible volume production of California's San Joaquin Valley, and cannot collect the views of those growers as they wrapup this meeting session only half done.

As I have shared with some on this panel earlier, our San Joaquin Valley where the Selma site is located, and we were to have had a meeting there, alone includes approximately six of the top ten ag. producing counties in the United States. Its farm gained revenues of over ten billion dollars exceeds that of Iowa and Nebraska, and was only 200 million dollars shy of the total production of the state of Texas. Many of the growers and packers in the San Joaquin Valley are already ahead of this issue by having incorporated food safety plans into their operations.

I also commend this panel on what has already been achieved. You are the catalyst of change. You may see it that you're only here to collect the views of the public on how to minimize microbiological risk, yet your very attention to this issue is driving the industry to continue a process already started by retailers to see that the agricultural industry develop guidance plans.

When I started some years back with the California Grape and Tree Fruit League, the big concern with the packers was pesticides. Recent polling data among the public now shows that concern over food safety exceeds that of pesticides. These same packers are now scrutinizing their plants for avenues of contact

with food-borne pathogens.

But if you are the catalyst of change, the reacting agents of change here are the retailer and the packer. After the initial incidents of food contamination by Guatemalan raspberries and Mexican strawberries, retailers began to demand of the packers that they certify -- that they have a program for controlling food-borne pathogens. It is not uncommon for a retailer to require a packer to sign a hold harmless letter certifying that the packer has in place a plan to address this problem.

Likewise, an increasing number of packers are taking advantage of web sites like Primuslabs.com (phonetic) that indicates on their site which packers have in place a program to control food-borne pathogens. It's a marketing tool by packers to be able to show retailers that we have a plan in place and it's up on the Web. You can see it. In fact, when you launch on one of those -- a particular packer's Web site -- actually Primuslabs.com's Web site where they have the packer's name listed, it will actually bring up that packer's plan.

To that end, the marketplace has begun correcting this dilemma. No retailer wants to be sued by a customer, or to have its reputation damaged. In the competitive marketplace of fruit sales, having a program in place can give one packer an edge over his competitor.

Let me take a moment now to address some of the proposals in the draft that we saw put on the screen this morning. Beginning with the concept of commodity specific plans, I know Stacey -- I'll just reference these, but I come from a county that produces over 250 different agricultural products. Among stone fruits -- among stone fruit growers, which is defined as peaches, plums, nectarines, apricots from the California Grape and Tree Fruit League represents, is not uncommon for one packing line to run all four commodities in the course of a day. And many times these packing houses will also have in their -- within their structure a separate apple line, because apples have to be treated with a certain amount of care, and they may also have a grape line for table grapes coming through. And then some plants will even have a section for vegetables they may bring off the west side of the San Joaquin Valley; all this under the one roof.

To have a separate plan for each commodity would be unwieldy. We can reach the same end product with the program currently used by many of the League's packers. That is to have a program for the packing house which identifies avenues for contamination, such as workers, water, the fruit itself, et cetera, and ways to control this contamination.

On the issue of manure, stone fruit and table grape growers have been putting manure into their soil for decades. It's a way of enhancing your soil in a cheaper, softer manner. And over these many decades, there's yet to be seen a problem originating out of this. And I'm also kind of curious how we define manure. I believe it's a whole range from cattle to chickens to deer.

But we have not seen a problem originate out of the use of manure over these many decades. So if a problem does exist, we need to see the science to back it up so that we can address it.

Next we saw on the draft proposal here water. Now, in the San Joaquin Valley this is a major economic input, because basically the Valley is a desert. We import our water via irrigation districts from our reservoir, which is predominantly fed by snow melt off the Sierra Nevada Mountains. We also pump our water from the underground.

Let me take a moment to talk about our irrigation districts for just a moment. Our irrigation districts are fairly sophisticated operations. And, in fact, the California State Legislature recently gave irrigation districts a special tax advantage in the electric power deregulation law that becomes effective in California January 1, with the expectation that they would become the energy provider for agriculture.

So the state legislature recognizes the irrigation districts are sophisticated operations to manage not only an input called water, but an input called power. My point is that irrigation districts are in a far better position to manage the quality of irrigation water in California than a grower.

Also on the issue of water, the idea of keeping the water at ten degrees in a packing house -- keeping the waters at ten degrees warmer than the incoming fruit is impractical. Still fruit is picked during the summer season in the San Joaquin Valley. This means it arrives at a typical daytime temperature of 105 or lower. It is critical to hydro-cool that fruit as soon as possible to avoid decay, to bathe the fruit. 105 plus 10, being 115-degree water would cause spoilage very rapidly. A better route, the one currently practiced by many packers is to treat the water.

Now, I'd like to venture off of what I got up early this morning and typed up here, is to talk briefly about trade. And I heard some discussion here about practices for our international trading partners, as well as practices for our domestic partners. The California Grape and Tree Fruit League has a program in place for exporting stone fruits to Mexico. We call it our Fumigation Free Program.

And in order to do this, we bring up inspectors from Mexico. It's required. The Mexican government requires that we house -- we pay for, house, provide cars, the whole bit, to these inspectors for the course of the summer to travel around to our packing houses and to make sure that the protocol that we've established is correctly followed.

Yet, still even after this is signed off, many a time a truck will arrive at the border of Mexico and be stopped there because a larvae was found in the fruit. Now this larvae may have been signed off by the inspectors up in the San Joaquin Valley as being a -- not warranting stopping at the border because it's not a pest that would be introduced into Mexico.

But because of various trade reasons, this truck

may stay there on the border for two weeks while this larvae is taken down to Mexico City and keyed out and possibly grown to adulthood, and then later to say, "All right. It wasn't a problem." Well, it was a problem for the fruit because the fruit is now junk.

And we have seen in the last few years our trade with Mexico drop from 1.3 million cartons to 300,000 cartons, for a variety of reasons. And the incentives for growers is to start thinking -- and packers -- do I really want to trade? Well, Mexico -- you do want to trade with Mexico. They're our biggest trading partner.

And so we have to be very cognizant that if we impose programs on Mexican growers, that they not turn around and retaliate against us because they're feeling that we're running a very onerous program to keep their products out of the United States.

In conclusion, the retailers in the produce industry are already driving the grower, packer, shippers to document that they have plans in place. The industry urges the FDA and the USDA to work with us in a cooperative venture so that together we can put at ease the final judge of good food quality, and that is the consumer. Thank you very much.

MR. GARDINE: Just one thing. First of all, thank you, Brian, for your comments. And at other places I remembered to mention that your concern with the temperature of cooling water is shared with your colleagues in many parts around the country. That recommendation was one that was commented on in many places.

MR. HADDIX: Nobody likes to be in hot water.

MR. GARDINE: Yes.

MR. VOELLER: The next individual represents -- or is the executive director of Oregon Fresh Market Growers Association; Scott Ashcom. Scott has a prepared statement to be entered into the record and also has a verbal presentation.

MR. ASHCOM: Thank you, especially for pronouncing my name correctly. I ask right now that two copies -- three copies of our written comments be entered into the record. Since I've prepared written testimony, I'll just summarize the comments and make it very brief. And my comments will track the outline of the guidelines.

With respect to water, we, in the State of Oregon, have something better than guidelines with regard to protecting a consumer from microbial disease coming from water-borne sources. We have state laws. I brought a complete copy of Oregon's water quality laws with us, and I will ask that they be entered into the record as Item A.

(Whereupon Item A was received into the record.)

These are -- in Oregon we have a Department of Environmental Quality, who, under a memorandum of agreement with the Federal Environment Protection Agency, administering the Clean Water Act in the State of Oregon. There are federal EPA standards

for all of the pathogens which you have listed here today in the guidelines.

There are standards in the federal EPA clean water regulations and rules for those pathogens. And the State of Oregon, under the memorandum of agreement, enforces the Clean Water Act with our DEQ. These are the administrative rules which are laws in the State of Oregon that contain all of those microbial standards.

The farmers in the State of Oregon are all, to this day, complying with these rigorous laws, not guidelines. These laws are rigorous enough that violation of these water quality standards for these pathogens can trigger up to \$100,000 a day fine. So that's teeth. That's a law. That's not a guideline. We ask that these be entered into the record.

To move onto the issue of new manure and municipal sewer sludge, I'll just talk a little bit about what we call chemigation, or the pumping of manure onto fields for fertilization purposes. We do that in the State of Oregon under DEQ rules or Confined Animal Feeding or Holding Operations, which are administered by the Oregon Department of Agriculture. I have a copy of the DEQ rules on Confined Animal Feed Lot Operations right here.

Once again, extremely rigorous standards that farmers must comply with in order to utilize manure for purposes of fertilization, very rigorous standards. Violations, once again, can trigger significant fines. These are laws complying, not guidelines. Departments are complying with these right now.

I'd like to enter these into the record as Item B.
(Whereupon Item B was received into the record.)

MR. ASHCOM: With respect to sanitation and hygiene, the State of Oregon has regulations through Oregon OSHA, which implement under memorandum of agreement with federal OSHA the field sanitation and health standards that are in the federal OSHA laws. Here's those rules right here. They're rigorous. Violations of those frequently trigger serious fines for farmers if they are not in compliance with them. They're detailed laws, and they, I believe, are -- as with all of these laws -- they're even more stringent than the federal standards.

This has to do with workers washing their hands, with the temperature of water that has to be in the toilet facilities in the fields, the location of toilet facilities in the fields, clean toilet paper requirements. Literally, our Oregon OSHA has regulated farming right down to the most minuet details of the health of the workers. And farmers complying with these rules, there should be no opportunity or extremely limited opportunity for microbial contamination.

I'd like these rules entered into the record as Item C.

(Whereupon Item C was received for the record.)
MR. ASHCOM: In conclusion, I'd just like to make

two final points. Education is the key here. The growers and the workers that produce this food, and the handlers and the retailers that sell it to the consumer, and the consumer themselves needs to be educated into -- as to the proper ways of handling and treating fresh vegetables and fruits to minimize the chance of infection.

With regard to your goal that these guidelines represent regional differences, I submit that there is no better way to ensure that your guidelines recognize the vast and numerous regional differences in agricultural practices, that the guidelines rely on the rigorous state laws for field sanitation, water quality, and other environmental protections that already exist. They are laws that have teeth and sanctions against people that violate them.

If the FDA guidelines rely on the existing state laws of each state, the state governments have gone through the process of adapting those OSHA regulations and adapting the Clean Water Act laws to their individual state environments. So you already have regional differences taken into account by the existing state laws. We recommend that the guidelines find that compliance with the state laws for clean water and field sanitation constitute compliance with the guidelines. Thank you.

MR. GARDINE: Thank you.

MR. VOELLER: The next presentation will be the President of Oregon Fresh Market Growers Association; Joe Casale.

MR. CASALE: Good afternoon, and thank you. I'm Joe Casale. We represent more of the small -- Brian talked to the large industry of California -- and we're more of the small size family farms, smaller operations. The guidelines, as we saw on the slides this morning, we follow those, as Scott attested to there. And we don't need more regulations like those, which these would duplicate state and federal laws now.

And these guidelines could grow into regulations in the future. And we would say that education is the key for this proposal as opposed to more guidelines and regulations. Thank you.

MR. GARDINE: Thank you.

MR. VOELLER: Thank you, Joe. Representing Hood River Grower/Shippers, chairman of the board for Diamond Fruit Growers; Gene Euwer.

MR. EUWER: Good afternoon. I'm Eugene Euwer, and today I have the privilege to speak on behalf of the some four hundred growers who are members of the Hood River Grower/Shippers Association. Most of us are family farmers, as am I. My family and I produce seven varieties of pears, four varieties of apples on a little over 200 acres of Hood River, which is 60 miles east of here.

We farm at four different locations. We farm at elevations from 1,000 to over 2,000 feet; that's our family. We receive water from three different water districts. We employ over 40 people at peak periods, and we house most of them on site. Almost one-third of our production is exported.

We all live in homes in the middle of our orchards. And we and our workers are proud of our jobs and we're proud of the contribution to the good nutrition of the United States and the world. And we and our families eat our own products. We take it seriously.

We appreciate the fact that Food and Drug Administration wants to follow good agricultural practices and minimize microbial hazards, so do we. We appreciate the fact that the FDA prefers guidelines to regulation, so do we.

Fruit and vegetable production is an extremely complex business. Many people have pointed that out today, and I'm sure all week. This is the first one I've been to. And guidelines cannot hope to address that complexity without allowing flexibility to producers.

An increase in consumption of fresh fruits and vegetables is the goal of the FDA and of the produce industry, and is in the best interest of the nation's health. And incidentally will probably help to keep us in business.

Consumers need confidence in food safety. We've heard a lot about the media, but I believe -- maybe I'm an optimist; I think I am -- that in the long run, results, and not words, will give them that confidence. Most of my comments today will deal with water.

Mr. Ashcom -- did I pronounce your name correctly -- he said a lot of the things that I think needed to be said about the role of OSHA in this state and the cooperation of other state governments have with the federal OSHA guidelines. And I think that's probably all that needs to be said about that, in my opinion. I think he did an excellent job -- Mr. Ashcom.

I want to talk principally about irrigation, about water actually, which involves, of course, as the guidelines point out, both irrigation and processing water. The life blood of the produce industry is irrigation. Those of you who do this, know that. Without irrigation, we don't have an industry.

It's dry out here in the West. It's even dry in the Northwest in the summertime. And methods of water application vary widely, and they're dictated by soil characteristics, ground slope, cover crop, frost protection, drainage, row width, crop height, implement traffic, and method cost, among other things.

I strongly urge that the guidelines avoid method recommendations. I think that's been said before also. We do not have the scientific evidence to take these decisions out of grower's hands. Water safety standards are emphasized in the draft, but we do not have good information for making a recommendation either as to those indicators, such as E. coli, or as to the critical levels of those indicators if we did have them.

Water quality testing is expensive and burdensome. And I urge you to follow science, rather than to attempt to lead it through the imposition of arbitrary standards which lack basis. In our area, as in most of the Northwest, most of the water used in

agriculture comes from public sources. I urge FDA to work with local water districts, county and/or state governments, rather than growers, directly on water safety.

Our role, I feel, should be one of cooperation. Most of us serve or know people who serve or are intimately involved with the administration of these water districts. We have a role, but because this is public water and because we are individuals, I think this is a role that we should stay on farms, work within our districts and their government agencies that can handle these problems. It doesn't mean that we don't take them seriously, but I think that's the way to go about it.

In the draft there is mention of alternative water sources, or delaying water application until the contamination disappears. Growers have very little or no room at all to maneuver when a crop needs water. And I know of no alternative sources in our area in either the quantity or the quality necessary. In order to gain credibility, these guidelines have to be practical. That's been said enough times.

When the draft moves from irrigation to processing water sources, there's a reference made to maintaining a temperature differential -- and we've heard about that -- between the dump tank water and the temperature of the produce. In this case it was tomatoes and apples. I'm not going to spend a lot of time on this, but in order to avoid pathogen entry, the suggestion was made that we heat the water. As most of us know, industry uses cold water to take field heat out of produce harvested on hot days. In the Northwest this is a very common practice, and absolutely mandatory on cherries and sometimes on pears.

If this has utility, perhaps we still ought to stay away from it. And I think we need to concentrate on keeping the pathogens out of the water. A lot of the suggestions about back flow, some of the other suggestions, I think they're good. I don't want this to sound like all I can find is something wrong, because there are a lot of good things in this draft, but I don't think the temperature differential is one of them.

I'd urge the draft then to concentrate on pathogen free processing water and stay away from temperature differentials. They may cause more quality deterioration than enhancement.

In summary, I'd like to thank those responsible for grassroots opportunities for dialog. I've spent my entire life working to maintain one family's family farm on the ground that my father started to clear from forest and brush over 80 years ago. I belong to a cooperative that tries to help maintain ours and other family farms for its 140 grower member.

And as everybody in this room knows, farms continue to grow fewer and fewer, and larger and larger. The burden of record keeping goes exponentially. The acres grow slightly, and the margins diminish. The draft states that FDA wishes to be a guide, rather than a regulator. I accept that, but guidance has a way of becoming de facto regulation.

I urge you as drafters of guidance to ground your recommendations in good science and to keep those recommendations as simple as possible. Put yourselves, as you do this, in the shoes of those of us who have to implement these recommendations with our own money, at our own cost, and still try to make a profit. It seems to me that this draft has been put together rapidly. I urge all of you to slow down a bit, to do some more homework on site. And we'd be glad to have you come to Hood River and visit our plants and our orchards -- I think that needs to be done -- other growing districts as well.

To the extent that recommendations are founded in good science, the industry will follow. What we are doing now is working now. What we're doing now is grounded in science, for the most part. We guess sometimes, but it's also grounded in experience. If we're going to make changes, we need realistic cost analyses and cost benefit ratios that make significant improvements to public health.

I think "physician do no harm" is a phrase we all recognize, and I think that should be our precept as we fine tune our model. Again, I thank you for the opportunity to express some concerns.

MR. GARDINE: Thank you very much for those very pertinent comments. Right on line.

MR. VOELLER: We have two more individuals on the prepared list for industry representation. Then we'll have a short break for sodas in the back of the room water and refreshments. The next individual represents Diamond Fruit Growers as president and general manager; Ron Girardelli.

MR. GIRARDELLI: Thank you. Diamond is a cooperative in Hood River which packages and markets fresh pears and fresh cherries for approximately 140 family owned orchardists. On the average, each of our members farms about 65 acres, which is fairly typical in the pear and apple industries. Today I represent those growers, as well as the other pear producers in the Hood River valley where approximately 30 percent of the United States production of pears is grown.

We are very concerned and interested in food safety issues. And we want to thank the FDA and the USDA representatives for coming to the Northwest for this grassroots meeting with regard to good agricultural and manufacturing practices. We think it is important to also note that there have never in the past been public health problems related to whole fresh pears or whole fresh apples.

As it's been noted earlier today, the time line which has been proposed to conclude this study is very ambitious, and we urge you to take additional time to complete your research before publishing practices -- or guidelines for good practices. When published, it's essential that the guidelines be based upon sound science and reasonable information, because once published, our customers are likely to make these voluntary guidelines into de

facto standards by requiring us, as a supplier, to certify that we are complying with those guidelines.

The additional record keeping required to document compliance will add to the cost for the industry. For this reason, we must carefully balance the actual risks against the economic costs. Also, again, as has been noted earlier today with regard to worker health issues, we consider the Oregon OSHA code that's already in place to very adequately cover those concerns and would encourage that that be adopted, rather than duplicate or add additional or new provisions in the guidelines.

Finally, I'd also like to speak to the complex issue of product lot identification. The issue is being addressed in the produce industry. At Diamond it is possible to trace the producer, farm source through our operation and into the distribution system. The complexity arises in redistribution from the wholesale market to actual consumers, smaller retailers, and/or food service operators.

What may have left our operation as a single or several truckloads of around 1,000 boxes per truckload may consist of several different producers on each truck load. By the time the wholesaler redistributes this load or loads to many customers, it's virtually impossible to know which producer may have been on any particular redistribution quantity, unless we know the specific box and can read the code from the box.

While it is known that the majority of the contamination resulting in health problems actually occurs in the home or in the food service operation after the product leaves the shipper's premises, the burden of trace back falls on the shipper. Further, since the consumer may not even consume the product for several days after it is purchased, there is good probability that the time -- by the time the health problem is revealed and then traced back to the retailer or the food service operator, the box identifying the produce will, in all likelihood, have already been destroyed.

Because of these complexities, we believe that there must be some reasonable limits to how far reaching positive lot identification can be carried. While we support continued improvements in the positive lot identification, we view it more as an ongoing industry challenge, and not as a regulatory issue. Thank you.

MR. GARDINE: Thank you.

MR. VOELLER: In case I didn't make it clear, after the break everyone else that's interested in making any comments, please be prepared at that time. And if you prefer to give me your name and title to introduce you, that would be fine. Otherwise, it will be an open forum. Correct, Tom?

MR. GARDINE: And they'll introduce themselves.

MR. VOELLER: Correct. Okay. So representing Northwest Horticultural Council; Wally Ewart.

MR. EWART: Thank you for the opportunity to be

here today representing the Northwest Horticultural Council. Our council is an organization representing nine organizations in the Northwest that are the tree fruit growers, the packers and shippers, and marketers of tree fruit. For those who don't know, tree fruit is a very important crop in the Northwest. In fact, we have over 60 percent of the apples in the United States, over 50 percent of the pears in the United States, and over 55 percent of the sweet cherries.

Our organization works on federal and international issues, and we spend a lot of time on regulations administered by the Food and Drug Administration, the EPA, and the USDA, as well as working with many others in government for trade access for international markets. In the Northwest, international markets have been the only growth that we have, and, therefore, they've become very important, and they'll be a focus of our concern.

The proposed guidelines, as we've all heard, are on a very fast track. I'd say that that is probably the number one concern that we have. The concern is that the guidelines would move forward, and they would be implemented in the field, and they would become de facto regulation, as has been stated. And they would be put on such a track that much of what the content is would not be based on sound science.

There's a lot of research to be done. There's a lot of information that we don't have. As Stacy Zawel pointed out, we have some things from test tubes, but we really don't have practices to relate to what happens in the field, and that's what we really need.

The trade implications from this are enormous. Our industry, for example, with apple production, currently supports inspectors coming from two of our markets. Those inspections have become increasingly expensive. If we were faced with the growth to all the markets of that kind of imposition, I'm afraid that our exports would fall, and we would be unable to support those costs that we are bearing right now in only specific instances.

Food safety is a very important aspect of our growing and producing our tree fruit. We have, from the beginning, been challenged to get into markets around the world. And so we have to grow a product that is stable and has high quality all the way around the world, and it might even be stored for up to six to nine months before it makes that trip around the world. Therefore, the quality is extremely high. And as you know, the safety record of tree fruit has been exceptionally good.

We look forward to intentionally following this issue, continuing to put input through both our organization and also through the United Fresh Fruits and Vegetables, whom we are members of and actively participate in the committee. We believe that this issue and this proposal could have a very large impact on the growers, on the farms in this area, and also the economy of the area.

We believe, also, that the Food and Drug

Administration must realize that what they are putting into place right now will not only impact the growers here, it will not only impact the consumers in this country, but it will also impact the global markets and the health of people around the world. For that reason, we are asking that this proposal be looked at very carefully, be scrutinized, be based on sound science, and that all due process be taken to make sure that we have a safe food supply -- a continuing safe food supply. Thank you.

MR. GARDINE: Thank you.

MR. VOELLER: Very succinct comments by all those so far. We'll take a ten-minute break. At 2:20 we'll take other comments from interested parties.

MR. GARDINE: And questions.

MR. VOELLER: And questions for the panel, or whatever is needed.

(Whereupon a break was taken.)

MR. VOELLER: The next presentation will be Connie Kirby representing Northwest Food Processors.

MS. KIRBY: I'm Connie Kirby with the Northwest Food Processors Association. Is this on? Scientific Director with Northwest Food Processors Association, and we are a trade association representing food processors in Oregon, Washington, and Idaho, about 75 members, and well-known to many of the regulatory folks in this room for our work on food safety issues.

You perhaps wonder why food processors would be interested in regulatory -- excuse me, Freudian slip -- guidelines on fresh product, but one of the concerns that we have is that in many cases these crops are not segregated between what goes to fresh market and what goes on to the process market. So many of the comments that were expressed by my colleagues on the fresh side came as, you know, quite a relief to me because it's -- there are a lot of concerns with these guidelines.

And, in particular, the concerns that we have get down to the impact that these -- that these guidelines will have on the costs that the growers incur to undertake them. And on the process side, those costs will be passed on to processors and passed on to consumers as well. But the down side of that is that if -- there will be virtually no food safety gain, because in almost every case in the process industry there is a step that would take care of any kind of food safety concerns, so these simply become costs that are passed on to consumers.

So I really urge the agency to bear that in mind, and its consequent negative impact then on the consumption of fruits and vegetables, whether fresh or processed. With that in mind, I'd like to ask the agency to -- in these guidelines, to narrow their focus on known hazards with public health significance. I think that the guidelines that we have, as many other commentators have said, we have really gotten kind of outside of the guidelines or -- I mean outside of the purview of public health significance, and we need to focus on that.

We need to have specific guidelines to address those known public health hazards. We need to design a fluid document that's responsive to new food safety information. And, lastly, we need to prioritize our research to answer these questions about fresh fruit and vegetable safety so that we can develop this document in a more fluid, rather than a static, one size fits all sort of approach that we have here.

Just to reiterate the comments that we've heard over and over here, slow down the process, and base it on good science. Thank you.

MR. GARDINE: Thank you.

MR. VOELLER: Thank you. Another individual that would like to make a formal presentation is Rick Trumball with Broetje Orchards.

MR. TRUMBALL: I don't know how formal it's going to be. I came -- I had a real disadvantage this morning. I got here -- was told to be at this meeting. I didn't have any idea what the agenda was going to be, and when I started reading that microbial deal and thinking of, as from a producer standpoint, the catastrophic impact that that would have, it absolutely blew me away.

During lunch I was able to meet with some people that told me what has gone on, where we're at on the deal, the concerns, and I felt a lot better about it. I think that I would urge the directors in the USDA/FDA, the regulatory entities of the government that I think that there's something else that we have to look at in this industry, and that is the producer's confidence that would enable them to continue long term to produce and provide fruit, and jobs, and stuff for this, you know, country. Because without them, we really don't have anything. So that's all I've got to say. Thanks.

MR. VOELLER: Well said. Would anyone else like to step forward either to a microphone or wherever you feel comfortable, and identify yourself, give your association. And if you have a tricky name to spell, go ahead and spell it for the record.

MR. BOGART: Yeah. Bogart, like Humphrey. I'm Dennis Bogart. I'm the director of Technical Services for Great Western Chemical Company located in Portland. I would like to thank the agencies and USDA for their efforts in trying to control food poisoning and the public health, and everything. I know it's a tough job, and you guys don't really get your dues sometimes, so thank you very much for all the efforts that you're going through.

No one likes to get food poisoning. I've had a few times when I've been praying to that great white throne and praying to die at the same time, and it really is no fun. We've heard a lot today, all day long, about water. We've heard about people. We've heard about portapotties. We've heard about washing our hands, and everything.

And I'd like to speak a little more specifically

about a couple of the sections in the proposed guidelines that speak toward cleaning and sanitation -- the cleaning and sanitization portions of the guidelines. There's a few basic fundamental principals that have been around for years and years and years that have been either overlooked or misunderstood by the people who drafted some of the sections of the guidelines. And I'd like to try to clarify -- or to see if we can have some of these, at least, modified to a certain extent.

Now, I'll try to be a little specific. In one of the very first sections under the definitions -- you know, definitions are really kind of nice, because one of the guidelines that you've got is that the word clean -- what does the word "clean" mean? It means simply the removal of soil, and that term is not in the definition at all -- the word clean, and it's a critical term, because the word sanitize is in the definitions.

In the very first sentence it says "Sanitize means to adequately treat produce or food contact surfaces by a process"; et cetera, et cetera. There's one critical word that's missing, and there's one word that is ultimately important, and that is the word "clean." Because sanitizing is a treatment of a clean surface, you cannot sanitize a dirty surface. It's absolutely physically, chemically impossible to sanitize a surface that is not clean. And that has some real critical information or critical things to do with the following sections.

If you go to the section -- it's on page 14 under "Wash Water." There's a couple of other things that are misunderstood, because terms are intermittently floated around and interchanged throughout the entire section. There's one thing where you treat the water or flume water in a processing plant, or in a processing situation. This is done with chlorine, chlorine dioxide or peroxy-acidic acid. You mix in one to two parts per million of chlorine, a tenth or part per million of chlorine dioxide, 10 to 15 parts per million of proxy-acidic acid. These are not sanitizing solutions. They are not meant to sanitize anything. They are meant to control the microbial population in the water, not to control microbial populations on the food itself. It will not sanitize any kind of food, but it will help cut down cross-contamination between one piece of food or one apple or cherry to another cherry.

It also helps to cut down the biofilms that form on the inside of the surfaces of these water handling systems. Again, cutting down cross-contamination. This is not sanitizing in any way, shape, or form. If you look at another item in the second paragraph, it says, "Growers may need to add effective sanitizers or microbials to wash water to help prevent cross-contamination, and to increase the -- you know, here they're confusing the treatment of water again versus washing.

Now, when you wash fruits and vegetables you use one of two types of products; you use either a highly alkaline

detergent, or you use a highly acid detergent. Now, let's add chlorine to these and see what happens. If we add chlorine to a highly alkaline detergent at a PH of ten and a half to eleven and a half, that chlorine will, in fact, in some cases, boost the cleaning of that detergent. But due to the chemistry of chlorine -- and that's about a 45-minute lecture. If you'd like to hear it, I'll do it later. Due to the chemistry of chlorine, chlorine at that PH will not kill bacteria period. It won't happen.

So adding chlorine to an alkaline detergent will not help control anything. The other fundamental thing in cleaning and sanitizing, again, is that you cannot sanitize a dirty surface. Therefore, you must clean it first, and then sanitize it. It's a two-step operation. This principal has only been around a hundred years, give or take a few hundred.

The other thing, let's add chlorine now to the other type of wash solution, which is -- this solution is based on phosphoric acid, has a PH of around two and a half. So add a couple hundred parts per million of chlorine to it; we won't have to worry about food poisoning. All the people that deal with it will be dead, or run out of the place, because that generates chlorine gas. This is the way the Germans did it during World War I and developed chlorine gas.

So there's a number of confusing misstatements here. Another sentence in the second paragraph, it talks about adding trisodium phosphate, and other things, chlorine dioxide, trisodium phosphate. Again, we're talking about treating water, not sanitizing the fruits and vegetables. Totally, two different things, completely confusing in here in how it's been stated.

Then, if you look at the last paragraph on page 14, again, "Wash Water, even with sanitizers, may reduce but not eliminate, pathogens on the surface of produce." No big -- no big thing, because sanitizers in the wash water won't kill bugs anyway, so they won't be eliminating pathogens in the wash water. They go along again and again and again throughout the entire section and make the exact same error, washing versus sanitizing, confusing the two, confusing the treatment of water versus the washing and sanitizing of fruits and vegetables.

On page 28 it talks about equipment, very last sentence, "Keeping equipment or machinery that comes in contact with fresh produce as clean as practicable." We're talking about equipment in the plants. What happened to sanitize? It's a two-step operation. Do not confuse the terms. Cleaning is not sanitizing; sanitizing is not cleaning. And in several other places -- I guess the fundamental thing here is that where it talks about cleaning and sanitation and use of chemicals and the use of treatments is that it appears -- again, and a number of people have said the same thing -- that you've got a good draft here that was put together. It's a good working draft, a good document to work from, but it needs a lot of looking at, and a lot of looking at from people who are experienced in these fields and know what

they're talking about and can help keep some of these items separate.

Because if you, in fact, follow some of the recommendations that are in this guideline, that's exactly how some of the people that have hit the newspapers lately have gotten into trouble, because they actually tried to follow the guidelines that you've written here, and they're wrong. Thank you very much.

MR. GARDINE: Thank you. I just want to point out, if you want to make the effort to put these detailed comments in writing, we would love it.

MR. BOGART: I'll be happy to talk to you later.

MR. VOELLER: Here we have somebody that's ready. That's fine.

DR. RAAB: I'm Carolyn Raab from the OSHA Extension Service, and I've been very pleased to hear the comments that are acknowledging consumer concerns about food safety. Indeed, food microbiologists are identifying fruits and vegetables as an emerging food safety area. And we, indeed, are trying to teach consumers how to take that into account as they handle their fruits and vegetables. I also was very pleased that everyone has been acknowledging the importance of maintaining consumer confidence. That is very important.

But I think I'm leaving this meeting with some concerns imported produce. I'm glad you have the update on the various actions that growers in this country are taking, and that's very reassuring, but having kind of an out control feeling in regard to the imported products.

I thought the comment that was made earlier about the meat industry was kind of an interesting one.

I'm in a field where I look at all food products. And I guess it is true that we kind of are approaching that one from the half way point, that if we can't approach it at the rural level. We're thinking ionization and pasteurization and radiation, but that, I guess, is another possible technique, and is that being taken into account thinking about foreign products which we may have less control?

MR. GARDINE: I believe there's a question there, and that is the role of ionizing, radiation, is it something that is likely to be required for imports? First of all, I must stress under our treaty obligations we can require nothing for imports that we are not prepared to require for domestic product, unless we can show a distinctive difference, and immediate public health need.

The other thing that I want to stress is that we must question whether irradiation is, indeed, going to be the silver bullet. It is a good step. Some fruits and vegetables may not be able to withstand it and maintain product quality. And certainly some microorganisms of concern, I believe hepatitis A would probably survive irradiation at the levels it is now approved. And I don't know if that gets to answering your

question, but I think those are the points I'd want to make on that.

MR. CRAIG: I'm Dick Craig with Rochester Midland Corporation, and I represent myself. And my question to the FDA is: How long will it be before we have your approval, authorization to use chlorine dioxide on cut fruit and vegetables?

I believe there is already an approval on uncut and unpeeled, but -- and also there is an approval for -- it's a letter that says there's no objection to use chlorine dioxide on cut and peel potatoes.

MR. LOWELL: We can't answer your question here, but I'll ask Sue or Alan to make a note, and, you know, if you could get a business card or something, and we'll get back to you with an answer, because that's something out of our center, and I don't think any of us here have got the answer for you.

MR. CRAIG: Well, it's -- as we're focusing here to help identify appropriate practices to minimize microbial hazards, I believe chlorine dioxide has a place. It may not be for everyone, but it does have a place on cut and peeled fruits and vegetables.

It is used by the EPA in drinking water and approved for municipal drinking water. It's approved for on-board airplanes up to five parts per million in drinking water. It's being used in water to feed poultry in South Africa, and they're reducing their problems and increasing the grow-out period. Chlorine dioxide is used with cucumbers here in western Washington; again, killing bacteria.

The FDA -- well, I mentioned that they were using it now at the five parts per million or up to five parts per million on your cut and peel potatoes, but I do believe we have a need to take a look at that. There has been a petition by the National Food Processors Association, I think about three, maybe four years ago, on their part asking the FDA to take a look at it and authorize it. And not only that, to also withdraw the claim to use a fresh water rinse after you use chlorine dioxide.

But I understand that there is some turf battles within the organization. Who is to control this? Who is to make the decision? And I also -- and even within the EPA where they have undergone some -- a lot of studies with the drinking water using chlorine dioxide, if we could talk -- if you could talk with the EPA and those divisions, and link into them with their knowledge, I think that would be helpful.

And a comment about some scientific study. There is a report to be published, and I believe it's already gone through the Review Board process, that it takes 600 parts per million of chlorine sodium hydrochloride to do the same job as what does three parts per million of chlorine dioxide. And the study was using E. coli 0157:H7. And the study is -- was trying to document how much chlorine dioxide and how much chlorine it takes in order to give you a reduction in 60 seconds.

And I guess my point here is that you're authorizing the use of sodium hydrochloride or chlorine as a sanitizer to kill emerging pathogens, but only at 200 parts per million we're allowed to use; is that correct?

AUDIENCE MEMBER: No. It's not correct. Up to 2,000 parts per million.

MR. CRAIG: Up to 2,000?

AUDIENCE MEMBER: Yes, sir, based on circumstances.

MR. GARDINE: Just for the record, I'm just going to ask that the record show that that was a comment from the audience, because I personally do not know what the regulation states.

MR. CRAIG: Well, the point of the study here is that I do, again, believe that chlorine dioxide has a place within helping to keep the emerging pathogens under control. Thanks.

MR. LOWELL: Sue or Alan, would you sort of wave your hands and get a business card.

MR. CURRY: I'm Gary Curry; Oregon Onions. Just a couple general comments and observations. It's -- maybe a little that's going to be repetition -- but, one, I think we should recognize that we do have probably the safest food system in the world, or if not one of; and two is I think everyone believes in food safety. And so -- but I think that -- that we ought not lower the level of consumer confidence of our food system by some unnecessary things that are concerns that we're raising here.

I do believe the issue of food pathogens is something that's not clearly defined in terms of research, and we're trying to react in a program or series of programs to compensate for that. And so I think that we ought to -- again, reiterate -- take our time, work our way through this system understanding that we do have in place a very solid food system providing a lot of health to the U.S. public and to the world.

And, again, to reemphasize that foreign trade is very important on this issue and that we ought to be very careful on how we position ourselves with food safety as it relates to other countries. So I appreciate you coming out and listening to us. Thank you.

MR. VOELLER: Thank you.

MR. ISMOND: Alan Ismond; Aqua-Terra Consultants. I just wanted to make a couple of comments based on everything I've heard today. The first one is I think it's better to grow quality in than to try and fix a harmful or defective product down the line. And the reason I make that statement is I took the time to check CDC records on the classification of pathogens, and I found that most of the ones we're talking about are classified as bio-safety level II. And I urge everyone here to look at the precautions required for a BSL2 pathogen in a lab.

You'll find that consumers can't follow those guidelines. Processors can't follow those guidelines. The distribution system can't follow those guidelines. Handling and

harvesting procedures would never follow those guidelines, nor can the producer or the farmer.

So given the fact that either CDC is overreacting with their biohazard classifications, as one option, or we're underestimating what it takes to handle these pathogens. I would suggest we look further upstream, ladies and gentlemen, rather than looking further downstream. We find out why it is we have them in the first place. Once you have pathogens on your farm, I think it's a slippery slope downhill from that point onwards; once you have them in your plant, once you have them in your home. Why don't we look at the source?

Let me digress for one second. We talked about risk benefit analysis, cost benefit analysis. If I believe the statistics in the documents that we've been given, we're looking at 9,000 fatalities a year, granted they're not all from fruits and vegetables, but they're supposedly from food safety related issues.

As we make our assessment of risk and benefit, let's remember 9,000 lives. What's an acceptable number? Cut it in half? Cut it by 80 percent? And it's kind of easy to be cavalier about lives when we're talking about somebody else's kids, somebody else's grandparents. I think we might be a little more in tune with risk benefit if it was our own children.

Another comment I'd like to make is it appears in the document that we're saying that most of the pathogens appear to be from fecal origins, human or animal.

And I'm wondering if research supports that most of it is animal, rather than human in terms of percentages of outbreak. And if it's animal, if it's mainly domesticated, not wild. And if it ends up domesticated animals, perhaps there's the source of our problem.

And if we talk about contaminated water sources from pathogens, we'll probably find that maybe from domesticated animals in run-off fecal material, and we'll probably find that some of the contamination on the farm is contamination from fecal material either brought on intentionally or unintentionally onto the farm.

So I'm wondering if we -- maybe we should focus our attention on eliminating our problem at the source, which is looking at domesticated animals, and in what way do we so change our way of rearing our domesticated animals? Because if I was a fruit and vegetable farmer, I'd be a little upset if I found out that pathogens were coming onto my farm from another source. I would want to worry about that source more than I'd want to worry -- and to handle the pathogens from that point onwards. Thanks.

MR. VOELLER: Thank you. Any other comments?

MS. ZAWEL: Stacey Zawel with the United Fresh Fruit and Vegetable Association. I just want to comment on the chlorine dioxide question, as well as the irradiation question in terms of should these be promoted by FDA, what is the status of the regulatory -- or with the regulations that govern tools like this. And the National Advisory Committee on microbial criteria for foods

two, three weeks ago, or something like that, made a recommendation in their list of recommendations to the FDA after an analysis of this issue, and stated that, in fact, something that the industry believes greatly in is the need to -- and no pun intended -- put this approval on a fast track and figure out who has jurisdiction over some of these, and those things need to be done quickly, so we can get the approval of some of these through the system.

The other thing I want to address, which I think is a very touchy area, but it needs clarification, but that is risk benefit, cost benefit analysis. When you talk about risk benefit, I think we all agree -- I'm going to speak on behalf of the entire industry -- that risk does not mean risk of death. And one death is certainly one too many, and no matter what product it's from, we cannot stand for that. And I think that's the basis for the President's Food Safety Initiative.

In these discussions when we talk about cost benefit, it really has to do with making sure the recommendations that are included in guidance are based on science that we're actually getting a public health impact as you go through and develop food safety systems. If, in fact -- and this is the basis of one food safety program by the agencies which is good -- but the basis is that you have to identify the key areas that will result in problems. If you don't identify the key areas, you have a plethora of items to deal with, and you never get to the specifics of ones you really need to be paying attention to.

For a multitude of reasons, what we need to do is make sure that any -- that the energy that the industry is going to put forth has a public health impact and is based on science, that we are focusing on the right areas, and we will be able to maximize -- further maximize the safety of our food supply.

MR. VOELLER: Thank you. Any other commentors?

MS. SANBURN: Hi, Mary Sanburn. We are a fresh cut processor here in Portland, Oregon. I am very concerned with the quality of the produce that arrives at our facility, of domestic as well as imported sources.

We are selling a fresh product that is packaged in a bag. So subsequently I am not comfortable with having a very clean product going into that bag. When I say clean, microbiologically clean to the point that there is not a competitive microflora left in the bag, where if there is a pathogen present, that the pathogen could take hold.

So from the viewpoint of packaged on through the consumer, I am concerned with consumer education of the proper handling of this product, as well as a designated shelf life for this product and starting product is critical. Thank you.

MR. VOELLER: Thank you very much. Any other commentors? Fair warning. I'm about to turn back to the panel for some final comments. This is your opportunity to contribute to the record. And if you decide later you come up with some, there are ways to submit those in writing. Yes, sir.

MR. TORRES: One last comment. We've been saying we need to encourage our consumers to eat fruits and vegetables. There's a reason. There's a nutritional value in doing that. I think in the research in Oregon State on cancer prevention, if we know more about those, maybe one direction we should do is encourage the consumption of processed food that has been processed in such a way that we prevent the destruction of those factors.

So let's not focus on eating the fresh product is the only one to provide the health benefit, but also making sure that we process our food in the best way possible, looking for alternative technology so we don't have only irrigation as a source, but maybe some other technology for their food processing industry. Those are also based on science.

I mean the best example that I teach in my class is I talk about the cold center in a convection heated product. So I have a liquid product and I'm saying I'm going to measure the temperature of the center -- at the cold center of the product. Well, if that product is moving around in a processing facility, there's no bug that will stay in the cold center. The bug will move around.

When I'm doing that, I'm only fooling myself, because I'm killing much more than I'm actually doing because all those regulations based on cold centers, they're meaningless. So we have a lot of science that's needed to be added to regulation, and this is just one example.

MR. VOELLER: Your name again for the record?

MR. TORRES: Antonio Torres; Food Science, Oregon State.

MR. VOELLER: If you have written comments there is a copy of the Federal Register announcement, which identifies these grassroots meetings, and you can submit those between now and the end of December.

Joyce, did you have any comment?

MS. SALTSMAN: Actually, I would like to ask a question of those growers in industry where you've already got guidelines in place to enhance the food safety of your own products, and our feedback from these meetings here, you're afraid that our guidance will be used as regulations by your buyers.

To what extent are your own guidelines being used in the same way by your buyers, and have created the same kind of -- you know, same kind of level of regulations on you when you've got guidance for your own members, but is being used otherwise?

MR. GIRARDELLI: Ron Girardelli with Fruit Growers. With our experience, unless it's a published guideline by some agency, we have never been asked to certify that we're complying with that, and we're seldom asked what our own internal provisions are.

MS. SALTSMAN: Thank you.

MR. GARDINE: Obviously, a follow up question. If you're doing it, and somehow documenting for yourself that you are

following internal industry trade association guidelines, what would be your objection to certifying to a buyer that you are?

MR. GIRARDELLI: I think the primary objection is that you then must document much more diligently than we're doing at this time what the -- what provisions are being taken internally.

MR. GARDINE: Okay. The level of documentation?

MR. GIRARDELLI: Yes.

MR. GARDINE: As opposed to your internal quality assurance, something to convince someone else about what you're doing?

MR. GIRARDELLI: Yes.

AUDIENCE MEMBER: One of the things that, depending on who -- what group of people develop these guidelines, whether it's an industry-wide guidance that has 20 organizations on it, or whether it's one sector of the industry representing one commodity, they are the ones who developed that guidance. And by endorsing contents of that, they would not be opposed to having a buyer say, "Do you follow your own guidance?" They developed it.

So it's more a fact that the guidance that you guys have has some mention in it that may be frequently interpreted by a buyer and misconstrued to mean something that it doesn't mean, and, therefore, impose regulation or certainly de facto regulations on a supplier unnecessarily. And if the industry is developing it, when they develop it, they consider that, and there are a lot of -- it becomes practical.

It's developed by the industry for the industry, which is much different. And it doesn't include things like X-days is appropriate for application harvest delay, because there's no science on which to base it, the industry doesn't write things like that. And so -- and if, in fact, they do include something more prescriptive for that group of people that it applies to, I don't have any doubt at all that they would not be in favor of complying with their own recommendations.

MR. VOELLER: Bill, do you have anything?

MR. MANSOUR: All I have to say, as part of the Extension group, is that I've got copies of the draft. I'll make them available to colleagues I think would be interested. A number of these colleagues are here in the room today, so they've had an opportunity to look at it, but we stand, I guess, open to comments, suggestions.

I'll comment a little bit about the fact that the Oregon Industry, Scott Ashcom was mentioning, is bound by laws restricting uses of manure and sewage sludge, and various other practices dealing with hygiene, and so on, you know. And those things are published and can be disseminated to our local industry, how that impacts your guidelines, is it preparing for national consumption, I think, is important.

So I think those -- you know, those have already been mentioned. But that's all I have to say.

MR. VOELLER: Thank you, Bill. Roger Lowell.

MR. LOWELL: I just want to share with you that we absolutely saved the best for the last. This is the sixth, and the questioning of the people that have been to all six, there was more feedback, and I would say of a higher quality at this meeting than we've had at any other meeting. And the other meetings have been about this size, except the one in California, which was well over 100 people. But the quality and the quantity of feedback here was outstanding, and I thank you for coming and doing that. It just simply makes me proud to be associated with the Northwest industry, which I have been for quite some time.

The other thing that I would like to share with you, I was listening to some of your comments about the difficulties of doing many of these things, and, you know, slow down, don't go fast. Your worst nightmare is my phone call on Friday night saying that there's something wrong with your product, and, you know, we've got an illness someplace, and there's going to be some people coming to your plant -- state people coming to your plant to look into your records and your distribution, and so on, and so forth that goes along with that.

I know two years ago I was sitting having a discussion of priority of issues that FDA should address and approve, and apple cider was not on our radar screen. It was not considered a high risk product. And today apple cider -- raw apple cider is considered a high risk product because of the episode that we had.

So whatever -- whatever we can do in this kind of format to prevent that Friday night call is to both our benefits, and that's why I would ask that we keep struggling with the issues that we're struggling with, you know, as difficult as they all are for all of us to get into, because it simply is not pleasant for any of us to be engaged in Friday night episodes that can ruin people's businesses and lives, which is not what we want at all.

I'd also definitely like to thank Joyce and Tom -- or Stacey out there -- I'm sorry, I was looking at Joyce and thinking of Stacey -- three people that have made all six of these.

MR. GARDINE: I think only Stacey made all six.

MR. LOWELL: The USDA folks, of course. It's been quite a grind for them and I certainly appreciate what they've done. And, again, thanks to Don for doing an excellent job for being a moderator today, and especially thank you all for taking time out of your schedules and traveling to come over here. I certainly appreciate that.

MR. GARDINE: Okay. First of all, I would like to once again thank you for coming, and reiterate Roger's thanks for quality of comments we received here today. It has been outstanding. Roger brought up a good point about the Friday night call that both he and I, as regulators, have had to make to industry. We don't like to make them. We don't like to receive them. Anything we can do together to make this guidance a doable

document that is also effective, we must find ways to work together to do that, and we will over time.

And one other thanks -- Roger was thanking people who put up with the grind, folks at USDA, Tom Willis and Rick Gomez who have been to all of these. A special thanks -- Stacey Zawel has been to all of these sessions. And Stacey and the FDA people have occasionally locked horns, as she very actively protected what she believes to be the concerns of industry.

But I just want to point out that the idea and concept of having a special time set aside for industry group presentations where industry regionally would come and speak to us about their unique concerns and unique challenges was Stacey's. She had to do a little convincing, but we were convinced, and she pulled the people together to do this. And it was one, I think, of the better parts of these grassroots. And Stacey, thank you for the idea, and thank you all for coming.

MR. VOELLER: Stand adjourned.

(Whereupon, the hearing was adjourned.)

STATE OF OREGON)
) ss.
COUNTY OF WASHINGTON)

I, YVONNE FRED, Certified Shorthand Reporter, CA CSR,
and Notary Public in and for the State of Oregon, certify;

That the foregoing hearing was held before me at the
time and place therein set forth;

That the testimony of the witnesses and all
proceedings held were recorded stenographically by me and
were thereafter transcribed;

That the foregoing transcript comprises a true record
of the testimony and of all proceedings held at the time of
the hearing;

That I am in no way related to the parties in this
action, nor interested in the outcome thereof.

IN WITNESS WHEREOF, I have hereunto set my hand on
this 18th day of December, 1997.

YVONNE FRED, CA CSR
Notary Public for the
State of Oregon