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**MICROBIAL SAFETY OF PRODUCE
INTERNATIONAL MEETING**

DECEMBER 8, 1997

**HUMPHREY BUILDING AUDITORIUM
200 INDEPENDENCE AVENUE, S.W.
WASHINGTON, D.C.**

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SPEAKERS:

**Catherine Carnevale, VMD, Director, Office
of Constituent Operations, CFSAN, FDA**

**Tom Gardine, Food Safety Initiative Staff, CFSAN,
FDA**

Linda Horton, Director, International Policy, FDA

**Mary Ann Keeffe, Deputy Administrator,
International Cooperation and Development,
FAS, USDA**

**L. Robert Lake, Director, Office of Policy, Planning
and Strategic Initiatives, CFSAN, FDA**

**James O'Hara, Deputy Assistant Secretary for
Health, DHHS**

**Dr. Catherine Woteki, Under Secretary for Food
Safety, USDA**

Verbatim Transcript of Meeting

Janice Oliver:

Good morning we have with us Jim O'Hara, the Deputy Assistant Secretary for Health from the Department, Health and Human Services and Dr. Catherine Woteki, Under Secretary for Food Safety from the US Department of Agriculture to welcome you to this meeting on Microbial Safety of Produce in the International Sector. And with that I will this over to Jim O'Hara.

Jim O'Hara:

Thank you Janice. Good morning. On behalf of the Secretary, Secretary Shalala, and Secretary Glickman, the Department of Health and Human Services, the Food and Drug Administration, and the US Department of Agriculture, I would like to welcome you to this International Town Meeting to discuss and explain the President's initiative to ensure the safety of fresh fruits and vegetables offered to US consumers.

We're here sollicitating your comments, suggestions and recommendations for developing good agricultural and good manufacturing practices for fresh produce. The President, as you know, announced this initiative on October 2, 1997. In addition to this meeting we have been holding six grassroots meetings around the country to sollicitate views and comments from producers, farmers, consumers, universities, and agricultural schools as primary interested parties on our working draft guidance which has the bureaucratic title, I'm afraid, Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. Not quite a tongue twister as HASPA. But as HASPA

very, very important. A significant portion of produce consumed in the United States is supplied today from abroad by our Trading Partners. No initiative to maintain but perhaps improve the safety of our produce supply in this country can be effective without the full support of international growers. That does not simply the safety for our consumers but the safety for consumers around the world, because we know that all of our Trading Partners have concerns that their population be protected as well.

In this regard I would like to emphasize a few points about the President's initiative. First off, and perhaps most importantly it is an inclusive and collaborative. We understand that we cannot do this important job alone. That is why several Agencies and Departments of the Federal Government are very involved in this initiative. The US Department of Agriculture, the Department of Health and Human Services, and its constituency operating divisions such as the Centers for Disease Control and Health Prevention, the Food and Drug Administration. Other Federal Agencies, such as the Environment Protection Agency and the Department of Labor. States and Local Departments of Agriculture and Public Health. Most importantly today, it includes all of you in this audience. Today I encourage you to listen carefully, but speak frankly and candidly on this topic. We need to hear what you are saying. We need to know your concerns. So that we may fashion but truly practical and useful guides.

Second. We are developing guidance, not regulations. Our working draft does not impose new regulations on growers. Whether they be domestic or foreign.

Third. In developing the guidance we and our partners at the US Department of Agriculture are well aware of our international trade commitments. We intend while

implementing the President's initiative to ensure that all of these commitments are maintained and met.

The draft guidance that you will receive and discuss today, is just that, a working draft. We understand we don't have all of the answers. That is why we are holding these meetings such as the one today.

Today, it is your turn. We need the input from our Trading Partners to determine if the guidance contained in this draft document is useful and practical. Not only in the United States, but also in growing areas around the world that supplies produce to this country. Please review the working draft guidance critically and provide us your best comments. I want to emphasize that this meeting and its discussion are integral to openly developing sales and practical guides to protect the safety of fresh produce. And your participation cannot just be today, it has to be on going. Please we need to have your participation throughout our process.

Transcripts from this meeting and other meetings we are holding, will be compiled and assessed for consideration and incorporation in the final draft. The final draft will be published early in 1998 in the Federal Register. At that point, you will have another opportunity to provide comments from the draft guidance.

Again, let me welcome you today, and thank you very much for being involved in this. We need for you to be frank and candid in your comments. And we again, hope that this will provide practical and useful guidance to do what we are all committed to doing, protecting all of our people. Thank you.

Dr. Catherine Woteki:

Thank you very much Mr. O'Hara for the invitation to participate in these meetings today. I am very pleased to be part of this and also welcome all of you who are here to learn more about this initiative on Microbial Safety of Fresh Produce.

The Departments of Health and Human Services, and Agriculture here in the United States have had many opportunities over the years to work very closely together on a number of initiative designed to improve the safety and nutritional quality of our food supply. Examples are for example, nutrition labeling, the whole foreign food safety strategy that we are now implementing. And most recently because of the President's food safety initiative in which view this fruit and vegetables initiative being a very prominent part.

We look forward to working very close with the Food and Drug Administration on this new Presidential Initiative to ensure the safety of both imported as well as domestically produced fruits and vegetables. Although the reported incident that food-borne disease form fresh produce is relatively low, it's increasing we believe. And at the same time we encouraging the increased consumption of fruits and vegetables. Eating at least five (5) a day. Five (5) fruits and vegetables a day is the cornerstone of nutritional policy the recommendation that is in our dietary guidelines and other nutrition guidance that we provide to the public. And that guidance is issued by those of the Department of Health and Human Services directly with the Department of Agriculture. And we believe that we it is a very important dietary practice to follow to reduce the long term risks of several different chronic diseases. If our consumers to have proof to us, that they have available to them of fresh safe food supply particularly

produce, the government has a responsibility as the industry in providing that fresh safe produce. We certainly believe that industry has primary responsibility to produce safe food. The government also has a role to play. And that is to set standards and improvise guidance on food safety where it is appropriate. A one size fits all approach just isn't going to work these days. And it's not certainly going to work for all foods. The full range of options from education to regulation has to be explored through various commodities. For produce though we believe it's appropriate for government following a broad consultation of which this meetings a working part to provide guidelines for good agricultural and good manufacturing practices.

Regardless however of what approach is taken, standards and guidance has to be based on science. And that's one of the cornerstones of the approach we are taking. Guidance also should be established through the process providing all interested parties the opportunity to provide advise and comment. And that's why we are here today. And it's also why we will be holding more meetings on this topic around the country. As we know the Food and Drug Administration does have the lead responsibility on this initiative. But the US Department of Agriculture also has important roles to play as well. The President directed Secretary Glickman and Secretary Shalala to work closely together as well as in close cooperation with the agriculture community. The issues good agricultural and good manufacturing practices of produce. Secretary Glickman has asked me to the leadership responsibility within the USDA to coordinate in the activities of at least ten different Agencies that have got a role to play in this directive. I am also responsible for helping to provide

the Food and Drug Administration whatever technical support they need and I very pleased

to help with these responsibilities. I believe that USDA has got a lot to offer in helping to implement this initiative. We certainly have a strong food safety research program and we can provide expertise on related to produce safety. In fact USDA is going to be stepping up its commitment to research in this area this Spring with a major research initiative addressing fresh fruits and vegetables. The research will help us to answer some important questions regarding, for example, the use of manure in the cultivation of fruits and vegetables. We want to know the food safety implications of new post harvest processing techniques such as , modified atmosphere packaging. Once guidance is ultimately developed, USDA has the role to play through our extensive domestic education network to help get the word out. Through our cooperative extension system all producers in every county in the United States would have the opportunity to learn about proper growing techniques to minimize risk. We will have six or seven thousand educators across the U.S. to help producers to look at there own practices and determine what changes they need to make from a food safety prospective.

Later today you going to be hearing from Mary Ann Keeffe of the Foreign Agriculture Service regarding her Agency's educational-technical assistance program. FAS, the Foreign Agriculture Service, works with our Trading Partners involved in education and technical assistance areas including good safety.

In closing over the past several years we have learned a lot about what it takes to make our food system safer. We know for example, that we must base our decisions

on sound science and we have to have data to back up our decisions. We also each of us whether we represent government, industry, producers or the public have to take our fair share of the responsibilities to be taken. We know how important it is to form partnerships to get the work done, and done more quickly and more effectively. And we also know that the public has to be involved in the decision making process to gain wide support in accepting. So I think that for this initiative there are certainly many challenges ahead, but I think that we got a good framework in place for making some significant improvements in the safety of produce. I am optimistic that we can working together make all food safer for the public.

I certainly appreciate your willingness in participating in today's meeting and to share your views in the directions that this initiative is taking. I encourage you to contribute to today's discussions and to write to us if you have further thoughts in follow-up to today's meeting. I also would like to give you my apologies that I am not going to be able stay for the meeting today. In fact I'm going to have leave pretty much immediately. I have unfortunately a pressing meeting directly after this. But there are many people here from the Department of Agriculture and as well as the Food and Drug Administration who are playing very prominent roles in this activity and will be listening very closely to your comments .

Thank you very much again for the opportunity to greet everyone who is here today. And also to talk about what I feel are some of the goals for the Department of Agriculture..

Janice Oliver:

Thank you very much James and Cathy for your opening remarks and for setting the stage. And for taking the time out of your busy schedules. I know that you both have pressing needs to get to and I really appreciate it. Thank you.

Right now, I would like to introduce Marilyn Veek. Marilyn was in-charge of the arrangements for this meeting and I would like to thank her for that. And she has a few logistics to go over with you.

Marilyn Veek:

(Spoke about logistical matters regarding facilities and location of luncheon area.)

Janice Oliver:

Thanks Marilyn. Next we like to, we may have a change in the schedule. What we would like to try to do is go according to the schedule and have Tom Gardine who is currently on detail for the Center of Food Safety and Applied Nutrition on Food Safety Initiative Staff heading up the produce initiative and to talk about the fresh produce food safety initiative. What we'll have to do is to check the slides because we had a little logistical problem this morning. So let's see how that works out and if not we'll move him to the afternoon.

Tom Gardine:

Good morning as you heard we may or may not do this right now. Depending on whether the slides are readable. I don't know if any of you have been in a situation like

this, it's relatively unprecedented but I'm sure I will get through it.

Technology is a wonderful thing when it works. I'm sure that you all realize that. But it looks like we're going to be ready to go if you will just bare with us a moment longer.

First, of all for those of you in the back of the room where the type might be a bit small for me, I will read the slides but suggest that if it's really bad there are a few chairs up in the front.

We are here now to give you a brief overview of what we are calling, the President is calling the Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables. We all realize that Mr. O'Hara said that if we are going to do anything about the safety of fresh produce in this country we cannot simply look at our domestically produced products, we need the cooperation of our Trading Partners because fresh fruits and vegetables from multiple countries are becoming more and more significant part of our produce supply in this country.

The President announced his initiative on October 2, 1997. He directed the involved Federal Agencies, and Dr. Woteki and Mr. O'Hara mentioned who they are but essentially it is helping Human Services with FDA and CDC, USDA with there various components, the Extension Service, Foreign Agriculture and AFAC plus other Agencies with interest in this area such as OSHA and EPA. To take steps to approve the safety of fruits and vegetables both domestic and overseas partners from foreign countries.

We are in the process now under the President's directive for preparing guidance to industry focus on microbial hazards in fresh produce. There are many things that we

are all concerned about with food in general, produce in particular. But our guidance is focusing essentially on one problem, microbiological hazards associated with fresh produce and why the cause of recent illness outbreaks in the United States that have been associated with fresh produce and some processed foods. What is important to note, as Mr. O'Hara stated in his opening remarks, what we are preparing is guidance to industry. These are not new laws. They are not new regulations. They are guidance and will require a cooperative approach on the part of our domestic industry, our foreign suppliers, the US Government, and hopefully industry organizations within the United States and overseas as well as appropriate agencies in foreign countries that ship produce to this country. The guide is to minimize the risk of microbial hazards in produce. We realize in preparing this document that we are not living in a sterilized world, but we can all do much to minimize the microbial load of pathogenic organisms on fresh produce. We must all think about what we are doing and work carefully with the goal to control what we can control.

The objects of the initiative are legislative and if you look at your agenda you see that after me there's going to be a rather long discussion on the legislative components of this initiative. So I am going to skip over it and leave it for the next round of speakers. There is also an administrative component which is the guidance to the industry that we are preparing to minimize the microbial risks associated with fresh produce. There is also a budget request going forward from both USDA and FDA to help us effect the President's initiative. Obviously since we are in a budget cycle for FY1999 we are at this moment can't talk about how much resources we will be able to devote to this project. The President also required the involved Agencies to report to him in 90 days about our

plans to effect his initiative and to make it as effective as we possible can.

The administrative component as inferred states that _____ in cooperation with _____ components at USDA, and other involved Federal Agencies is to issue within one year guidance for good agricultural practices (GAP) and guidance for good manufacturing practices (GMP) for processed produce, i.e. fresh cut or atmosphere package, modified atmosphere package as Dr. Woteki mentioned. FDA and USDA because we realize that this is not deregulation, it is guidance. We want to coordinate a system that is educational activities to train and educate both the domestic and foreign industries in the guidance contained in the draft document, hopefully from _____, the document containing the _____ final document and to work with them to help our growers and our overseas suppliers effect change that may improve the quality of produce being sold to US consumers.

You will hear us frequently today, and I'm going to say again, the GAP's and GNP's are intended and will be guidance not regulation - not law. Our goal, and the goal of our partners in this exercise are to help foreign growers and producers identify appropriate practices to minimize microbial hazards. Key words up there, Guidance - Appropriate Practices - and Minimize. Until we have mechanisms to control the organisms in the product, the only thing that Agriculture can do is take appropriate steps within their control that are doable and practical to minimize the risk of microbial hazards on produce.

The GAP, the good agricultural practices, as Mr. O'Hara mentioned, is in bureaucratese called The Guide to Minimizing Microbial Food Safety Risks for Fruits and

Vegetables. The development of this document is intended to be as public a process as we can make it. We are now in the process of developing what we call a broad scope GAP, good agricultural practices document for industry. We plan to publish in early in 1998 a draft of this document. Please bare this in mind, sometime in early 1998 we will be publishing a draft. It is very public process, We had the first public meeting on this on November 17th. We are now in the process of having seven grassroots meetings. We held three last week. There is one being held today in San Antonio, Texas. The domestic ones are viewed as regional agricultural meetings. This is the International Meeting. Once we get the input from these meetings and by the way, you read the Federal Register announcement that we are accepting written comments up until December 19th on what you hear today, because frequently if you have not had a chance to study the document it might be difficult to give your complete thoughts at the meeting such as this. After we review and incorporate all the comments we are planning sometime in late February or early March of 1998 to hopefully publish a draft document in the Federal Register. I must stress that this document is also simply a draft. It is the draft based on the input we receive from advisory committees. It is the input we receive from meeting such as this and written comments. And the draft will allow for a 45 day comment period. The draft document in the Federal Register will allow for written comments to docket for us to do further evaluation with any comment, further evaluation, study and changes of the document before a final is published hopefully sometime in middle of 1998.

The President in giving the charge to improve the already very, very good safety record for produce in this country, wanted the involved Agencies to account for

specific commodities and regional differences an options on how do that are being considered. Among the things we consider are perhaps preparing commodities or groups of commodities, specific types, perhaps working through agricultural research stations in the United States to work on documents that address regional difficulties. Perhaps it can be done through working with foreign governments and domestic industries to develop guidance that would address regional and commodity differences. I want you to think long and hard about this slid because one of the things we hope to solicit today and perhaps in your written comments. What are the best ways to address commodities specific growing requirements to minimize microbial risks? What are the best ways to put out guidance that will address regional differences? We want your thoughts on that as we determine how we are going to go forward in this matter.

Because the guidance documents are not regulation, a very, very important part of of this initiative is education and outreach. And one of the things we and our partners at USDA will be planning in the rest of this fiscal year, is how to--what is the best way to use FDA and USDA reports to provide assistance to the US grower on implementing our good agriculture practices (GAP). As you heard from Dr. Woteki, in the United States we already have a very extensive system for communicating with our growers. We have the USDA Extension Service. We have other arms of the US Department of Agriculture. We are aware and can communicate with numerous trade organizations to get the word out and work with the farmer to improve agricultural practices in this country where and if necessary to take steps to minimize the microbial risks on produce. But we are going to make effective, because more and more of the produce eaten in this

country is coming from overseas sources. It is a very significant collection of the produce that the American consumer has available to them. We have to find ways to provide similar but not perhaps exactly the same type of technical assistance to foreign countries. How can we do that? We have to find ways to evaluate what resources are available to FDA and USDA to do this. We have to develop training modules. And by training modules perhaps provide documents in necessary languages or to work with agriculture with our major trading countries to let me have the benefits of the guidance we are developing through this process. We need to work with the foreign countries agricultural sector and we need to work with their trade organizations to get the word out about what needs to be done. And we will coordinate development of non-FDA . Everything should be non-FDA, non-USDA, non-government training networks through international organizations, consultants perhaps, and certainly in country trade organizations.

As I believe you hear, produce is very, very important to the American diet. The government of this country is encouraging our people to eat more fresh produce. Why? Because it is good for them. It's a healthy dietary choice. If we want to keep the healthy dietary choice, government, industry, individual growers in the United States and our Trading Partners, in terms their government and our foreign suppliers, must work with us to keep the produce supply in this country safe as is now and hopefully we can even make some improvements if we all thinking about things that we can control that might be added to the microbial risks of fresh produce.

And that very quickly are some of the high points of the President's initiative. And at this point if there are any questions from the floor if you would just raise your hands. I will repeat the question to the audience and me or some other people from FDA and

USDA will try to answer them for you. Do we have any questions?

Barry Marshall with the New Zealand Embassy:

(Question repeated by Tom Gardine) Okay, the question was what percentage of produce consumed in this country comes from imported produce?

A. I'm going to look around and see if I get these numbers wrong. In his announcement I believe the President said some where between 10 to 15% of vegetables and almost 30% of fruits is from---38% of fruit is supplied by foreign sources. Barry, follow up and then we have another question. You can't dominate these questions.

Barry Marshall:

(Question repeated by Tom Gardine.) Okay. Barry asked what percentage of the illness outbreaks in this country are associated with imported produce as opposed to domestic produce?

A. We don't have a breakdown on that. However, there have been incidences associated both domestic produce and imported produce and while growing slightly they still very, very low. And we want to keep them that way.

Lynn Bradley (representative origination not audible)

(Question repeated by Tom Gardine)

A. Well very briefly, perhaps some of the other people who will be coming up to speak can do it better. Yes, there is a role for Codex. At this moment the President's initiative just came out October 2nd. We have not yet

clarified what the best way would be to work with the international organizations and is simply the truth. We have made a lot of progress but not that far yet.

Carolyn Smith-Dewalt with the Center for Science in the Public Interest:

(Question repeated by Tom Gardine) Why did you choose to make them guidance rather than regulations? It seems to me that regulations would be more protective of public health both the US consumers and their need to enforce those standards for foreign governments.

- A. Okay. We have people here work clearly on developing regulations. Let me give you my understanding of the process. The science is such that at this point we felt it was better to go out in guidance and more appropriate with guidance as necessary research is done. We do not believe that there is an absolute need to do this through a regulation. And we believe working with industry, working with the extension service and working with our Trading Partners we could get the significant effect through guidance. Terry (Dr. Terry C. Toxell) do you want to join. That's a question you may want to ask other people as the day goes on. But essentially, we believe guidance would be effective because this is something that is good for everybody to do and at this point the science is good, but we believe it would get better and we did not see the need to need to go out with a binding regulation.

Ed Scarborough (USDA - Codes Unit):

Just as a follow-up on the question from the floor. Codex is being fully integrated into the President's food safety initiative. Working very closely with Dr. Woteki with the Department of Agriculture, so that through these Committee on Hygiene and Committee Fresh Fruits and Vegetables has a considerable role to play and the US is very active leader in Codex through the years and intend to continue that to make sure this foreign (not audible).

Tom Gardine: Thank you very much for your attention.

Janice Oliver:

Tom thank you very much. I think Tom mentioned a couple of things that I would like to reiterate. And that is that the process of developing the guidance to reduce or to minimize the risks of microbial hazards on produce is a very open and public process. We want to get the input of all our state holders, whether they be the international community, the domestic community or consumer group academia. We need everybody's input on this to have the appropriate input and yet have the appropriate balance. Why are we going with guidance instead of regulations? And I think in the area of produce and in setting regulations there are many areas that in which research is still needed in which FDA and USDA as well as other Federal Agencies have committed to accelerating our research in the produce area, to minimize safety. And because of this research need, we believe that guidance and getting those out more rapidly were we have the information and where industries has already done a considerable amount of work is the way to go. Industry has done a lot of work in this area. A lot of the various trade associations and

specific commodities have done work and other things. And they want to work with what is already has been developed.

We're running a little ahead of schedule. And since we are running ahead of schedule what I would like to do is start the next session and go on back and then take a break and come back with Q and A's after that since we did get going a little bit late I think that might be the best way to utilize our time and your time. So thank you Tom and with that I would like to ask the Panel on the Imported Food Safety Act Overview to come up.

And by the way, I am Janice Oliver. I am Deputy Director for the Center for Food Safety and Applied Nutrition at FDA. I don't think that I introduced myself at the beginning. So for those who don't know me. I do know that I know many of you already.

Our next topic is one in which we know your very much interested because many of you have specifically asked a lot of questions or been at various meetings before and expressed your interest in the topics. So we're going have some discussion on the next subject and then open it to questions and answers after a brief break. And we'll try to take all of your questions and answers before lunch time. We've allotted the most time for here today.

Our speakers are Robert Lake who is Director for the Office of Policy, Planning and Strategic Initiatives at FDA Center for Food Safety and Applied Nutrition. Next to him is Dr. Catherine Carnevale, Director of the Office of Constituent Operations at FDA Center for Food Safety and Applied Nutrition. And Linda Horton, Director of International Policy at FDA. And with that I will turn it over to Bob.

L. Robert Lake:

Thank you Janice. Let me first add my welcome to all of you. Glad that you are here. The purpose of this next little discussion is to explain as best we can at this point the proposed legislation the President has sent Congress on the imports. Also, we would like as we get into the questions and solicitate your questions and comments on how we might implement the new legislation on the assumption that it does pass. And I also would like to emphasize before we get into all of that, that the purpose of all this is to enhance the safety in our food. As Tom pointed out the food supply is basically safe and includes both domestically produce and imports, but any avoidable should be avoided. And the reality is that we do have certain amount of foodborne illness and we believe it can be reduced. And so that is what we are about.

It occurred to me that in talking about the proposed legislation that it might be useful to sort of put it in context. So I am going to do that before I actually talk about the legislation.

Incidentally, it has been formerly submitted by the Administration to Congress and it has been introduced in the House of Representatives as H.R. 3052. Copies of the proposed legislation are on the desk out front, if you haven't already obtained a copy please feel free to do so.

Of course the legislation was introduce really right at the time Congress was adjourning for the rest of the year. It will not actually be taken up until after Congress returns in January. We do not know at this point what the priorities for this piece of legislation will be. But again before I get into the legislation its self, let me talk a little

bit the context.

I said the pertinent message, then I'll emphasize again the goal is to enhance food and safety. There are existing statutory commitments. We'll have to get into the first one, the Food, Drug and Cosmetic Act, maybe not. We've laid out certain basic safety standards that Congress has enacted and the President has signed into Law in past years. Basically, the Law requires that producers of food produced safe food. There are specific requirements enforced in the legislation for pre-market approval of food additives, of pesticides, animal drugs so that the residues of each of these --- the safety of all of these residues are to be determined in advance of their use in the food supply. And that's true whether the domestic producer say wanting use a food additive or a foreign producer wanting to use a food additive. The way the Food, Drug and Cosmetic Act is structured the matters that relate to public health are covered under what we call the adulteration provision and the new statutory provisions would amend the adulteration provisions.

In of the basic provisions of Law that are enacted by statutes by the Congress, we also, the FDA has over the many, many years issued a number of regulations for instance all of the regulations relate to all of these. Rules relative to what food additives are allowed are issued in form of regulations by FDA. The tolerance for pesticides are issued by EPA but under authority of the Food, Drug and Cosmetic Act. So it's a combination of statutory frame work followed by implementing regulations.

In terms of FDA's enforcement activities, of course we do inspections of domestic firms particularly in situations where we are following up either complaints of illness or other evidence that there could be a problem associated with food coming

from a particular manufacture. And if we find that a manufacture has been in violation of the Law, or the food is in violation of the Law, then we can and do pursue legal action against either the food or the producer depending on the situation. The most common I guess situation is where we take action against the food by seizing it. We also ask for recalls and for violators who we think are way out of line we can't prosecute. We also have authority to go into US District Court to get an injunction to prohibit activities that we believe are not in the interest to the public health.

For imports again, I'm talking about the existing frame work before getting into the new legislation. I think it is important to keep it in context. The same standards apply to imports that apply to domestic food. With imports the typical manner in which we enforce is to detain at the border food that appears to be adulterated. We also do presently conduct a small number of inspections abroad particularly in facilities that produce low acid canned food.

Now let me shift gears and talk a little bit about the President's proposed legislation. First, he is indeed backed by the Administration to develop with concentration among the food safety agencies as well as the trade agencies that is intended to strike an appropriate balance between ensuring public health while also maintaining our obligations in international trade. This, as I said, would amend the adulteration provision of the Act which relate to food safety. The legislation would apply to all food, not limited to fresh fruits and vegetables. It would apply to them, but would also apply to all other foods except for beef and poultry which are regulated by the Department of Agriculture.

The basic idea, or one of the basic ideas, is to include in the Food, Drug and Cosmetic Act the idea that is already in existence in the WTO (World Trade Organization) Agreement that allows each country to determine the level of the tax code that he thinks appropriate for citizens. The Trade recognize that but at the present time is nothing in the Food, Drug and Cosmetic Act that really picks up that notion. So one of the provisions or one of the punches of the new law is to build into the Food, Drug and Cosmetic Act the idea that if the level of protection of imported food does not measure up to US standards, then that would be a basis for not allowing that food into the United States.

The standards to be applied however, are not being changed and would in fact be the existing standards that already exist in the Law as well as the existing regulations that apply already to both foreign and domestic produced foods. Basically I think, you know when all is said and done, the bottom line question is, is the food safe for US consumers to eat? That's the question for domestic. It's for import as well.

So one purpose of the Law and one aspect of it, is to add a provision to the food safety provision of the Food, Drug and Cosmetic Act that would then allow us to prevent entry into the United States of a food that did not provide the level of tax that we have come to expect in the United States and that we believe is appropriate. Secondly, the proposed Law would add another provision providing an incentive for foreign producers to allow inspectors from the FDA to visit their facilities. We presently elect to do certain number of inspections abroad and what this provision is intended to do is to give us an additional ability to ascertain in advance whether, well not necessary in advance. Let me clarify that, it's not in advance, it to ascertain whether

food coming to this country is on a system that meets our level of protection. I think as a practical matter the way that would work, is that we would be working with governments of other countries and since we do not have a lot of resources for doing inspections, I think as a practical matter --- in fact we don't have any new money for the current fiscal year.. So this whole fiscal year is largely for gearing up for what happens thereafter. But even in the future, though we will probably or hopefully get additional resources, I think the reality we will not get a lot of resources for doing inspections abroad. So what I would envision is that we would in conjunction with our counterparts in other countries be looking at few facilities that appear to be representative of the types of producers in other countries to confirm the information that we already would have obtained in discussions and submissions of _____ from other governments. Again I would emphasize that what we envision is working with our counterparts in other countries on this. So the second piece, part of the legislation, is incentive for allowing or foreign producers allowing US inspectors on an as needed bases.

The third idea that is build into the legislation is that we are required --- we would be required to develop an implementation plan. And that is to be largely the inference that we would _____. In terms of implementation we would like your input. We haven't obviously, this is just _____ of legislation. We obviously are still at the early stages of figuring out how it would be implemented.

Part of the purpose for these meeting and particularly this one, is to obtain the input from effective parties--interested parties on what the best way of implementing this would be. And after break when we get into questions, I certainly want hear you

questions, but we would also like hear your suggestions on how this new Law would be implemented. How we would work with other governments in assuring that the level of protection that American consumers demand, is in fact the best.

Finally, let me wrap up this part of the presentation by thanking you for your attention. The two ladies sitting at the table, Cathy Carnevale and Linda Horton will assist me in answering your questions. Also, we will recording any suggestions that have, so please feel free to give us those. They will be considered. And with that let me close and I guess the what we probably should do now is take a short break. Janice how much time should we or do you want to come up and talk about that and then we will take questions and suggestions following the break. Thanks.

Janice Oliver:

We will take a fifteen minute break. Come back at 10:30AM.

L. Robert Lake, Director for Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition

Mr. Lake is the moderator for this segment of the meeting's

topic: Imported Food Safety Act Overview

I have been asked to make another suggestion which we do have an overflow crowd when we get everybody back in the room. Those of you who have coats maybe you could put them on one of these chairs over here. We want to be sure that everyone has an opportunity to sit down if at all possible. Thank you.

We will begin in another minute or so.

This is the question and answer session (Imported Food Safety Act Overview).

I will sit over here with my colleagues, Cathy Carnevale and Linda Horton and take your questions. We will try to repeat the questions for the whole audience and then do the best we can to answer it. Also, an opportunity for any of you who have any suggestions about how we could implement the program, we would welcome those suggestions. Let me also remind you that because the legislation is still proposed legislation and has not yet passed Congress, we are still engaged in a preliminary thinking on how it might be implemented so we will not have answers to some of your questions but we will do the best we can. So with that we will take your questions.

Barry Marshall, New Zealand Embassy:

(Bob Lake repeated the question) Barry, in addition to comments in it obviously being in everyones interest to have safe food, asked about our inspection of imports versus our inspection of domestic and what are the percentage?

A. (Bob Lake) I guess that question has more to do with what we're doing now than what we might do in the future because we obviously have authorities to look at foods sold domestic and we can do so and we also look at foods imported. I don't know, but I don't think anyone here has precise numbers. We do certainly inspect in domestic facilities far more frequently than we do in foreign facilities. We do inspections as well as outside inspection process like analyze samples to determine whether there are any problems with food. That is done with both domestic and import. I think the legislation will not change any of that current practice, but will rather put more of a focus actually not so much on increasing our look at foods as they come to the boarder. But rather, interacting with governments of other countries in making a determination as to whether the system provides level of protection than is provided by the standard in the US. And I would further envision that one of the things that is brought out of that probably increased the desire for mutual recognition.

A. (Catherine Carnevale) I just want to build on what Bob Lake just said. I think countries around are getting away from doing boarder checks and relying on boarder checks for the food safety, because no country, no government has the resources to look at all products that cross their boarder. So there looking instead to how countries are producing food. And were not going to talk about fresh produce here, we're really talking about all foods. That's why countries are going toward

And in the area of fresh fruit we are going towards guidance on good agriculture practices (GAP) and good manufacturing practices (GAP). So I don't think our focus on the food safety initiative is going to be on the boarder. We recognize as those New Zealand and other other countries that is not the most efficient and certainly not the most successful way of protecting their food supply.

Elizabeth Dahl, Center for Science in the Public Interest.

FDA has had a problem in a couple of cases of recalls. And one of these involved a product smoked salmon where they distributed this and refused to cooperate with the recall even though didn't. And there was one involving salads and dip where FDA had to issue repeated recalls because they weren't complying. Do you anticipate that this legislation would create anyway for FDA to get better compliance on recalls for both domestic and imported products?

- A. (Linda Horton) The question from Elizabeth whether making the legislation would give us a better handle on recall problems. There were two incidents uncovered by Center for Science in the Public Interest in which distributors repeated to cooperate fully with FDA because the recall ---- one involved salmon and one involved humus. Situations for a formal recall (not audible) FDA does not have authority to order companies to give recalls for food. We do have recalls authority under (not audible) discussions

of whether FDA should have the authority to order recalls and
(not audible)

We can under existing law seize products failure to cooperate
with the Agency on recall. This is often inadequate and difficult because
the sort of records that are kept on the distribution of foods.

(portion not audible)

And that is why we keep having to rely on public warnings. The import
food legislation are trying to meet this because there are other initiatives
that . Now in the good guidance practice, in the good
agriculture practice (GAP) document that is sitting on the table. There
is a section in there that we encourage the use of record keeping, coding,
and other means to status. That is the closest things to have
to deal with . Cathy do you have anything to add?

A. (Bob Lake) I just have some other facts. The recall issue is an
important one. It is, let me point out, not a direct
Another piece of legislation that does relate to recall and also
was introduced in Congress as well. So that issue is on the table for
consideration by Congress and is separate from this piece of legislation.

A. (Linda Horton)

(not audible)

same way and we go to importers, just like we go to domestic distributors

cooperating with the inspection.

A. (Bob Lake) That is correct.

(name of individual not audible) with USDA.

You mentioned about food safety technical assistance. We had a very limited as we have now increasing the fund or replacing them (not audible) World Trade Organization.

A. (Catherine Carnevale) Technical assistance?

(unidentified USDA person)

Yes.

A. (Catherine Carnevale) The question has to do with is there any additional money that are contemplated under this initiative that would be given to USDA or other Agencies for carrying out the technical assistance under this program. And I think what I am going to do is put you off on this question because USDA is going to be speaking to this issue later on this afternoon. Other than say, that yes there are there is a budget that is being put together for this overall program related to fresh produce. And the budget would be money allocated in part in 1999. But beyond that I think perhaps we should wait until USDA to give its presentation.

As with regards to your second question, would you mind restating that so I can understand the question regarding the World Trade Organization.

(Unidentified USDA person) Well (not audible)

the WTO, but that means they have to meet the international standard. So were talking about food safety and international standards. So I am assuming, if there is what can be arranged and the obligations to meet those and how does the resources . We get the technical assistance but regards to the WTO in that regards.

A. (Catherine Carnevale) The question relates to the fact that there over 100 countries, a 124 countries that are currently members of the WTO and all of those countries are expected to meet their WTO obligations under the SPS Agreement. And so we would expect that those countries would be in the process of meeting their obligations with the regards to food safety. And I guess I am hearing in your question is more of a statement than a question, but the fact of the matter is yes, all countries that have signed the WTO Agreement that came out under the Uruguay Conference including the SPS are expected to meet their international obligations. Some of the countries however, do better at SPS through the agreement are in a category of developing countries where the expectation was that they were given a grace period of two years before they had to implement the terms of the agreement. Some of the countries are just now beginning to get up to speed. I think that this legislation is fully recognized and the countries expected to meet their obligations under the agreements with regards to food safety. There was one

comment that was made with regard to countries having to utilize international standards. And the fact of the matter is that the trade agreement does say that the countries are expected to base their measures on international standards, guidelines and recommendations. That is basically an obligation of the agreement. Nevertheless, countries can have more stringent requirements in effect if there is time to of if it's necessary to meet with their level protection. I suggest that we add that into our final remarks.

Ed Ruckert of McDermott, Will and Emery:

We talked about legislation that hadn't been enacted yet. As soon as the legislation has been , I've got to understand practically how this would work. You could pick a winter crop. If it's winter time you could talk about South America. Central America we get a lot of produce from Central South America. How would you see this working for a particular industry? What kind of procedures would be in place? Have you given any thought to that at all?

- A. (Bob Lake) I believe the question is one of practical implementation assuming that the statute has passed. I guess what I am reading into that question is what happens on day one after the statute is passed? And I think the answer to that questions is that nothing changes immediately after passage of the statute. Again the statute its self contemplates that there would be development of a plan and the Agency would be following

that plan. It seems to me that that is the notion that nothing would happen until such time as the Agency in the implementation of the plan work in determining in certain, you know, with regards to certain countries that the system of that country did not meet the level of protection required by the United States. It would be my understanding that unless and until such a determination is made that the produce would continue to come into the United States as it has in the past. Of course that is also with the caveat that obviously as we are going along in looking at imported products we would as we do now, if we see any problems that a particular imported product is violation of our Law then we would obviously detain it at the point of entry.

Ed Ruckert with McDermott, Will & Emery:

In follow up. I think I understand what happens when product comes today in the United States. And that the FDA inspectors make a or something in terms of processing these standards, there are certain things that happen to that product. Would you envision then some determine due process (not audible)

- A. (Bob Lake) The question is what is the processed for determining whether another system or particular segment of the industry in another country meeting US standards. And I guess I'll take a shot at that, and then my colleagues may wish to join in. Topically, as you know most legislation is implemented through regulation so there's a good chance

here that there will be some regulations in addition to a plan. Also as I mentioned earlier, we certainly envision that there will be interaction between FDA and its counterparts in other countries. You know, it seems to me that as a practical matter, the way that is going to work, is if the other countries will become aware of areas of concern before we have actually made a final judgment. And again, the details of how that is going to work out are at this point are unknown, but again I remind you that part of these of this section is to make comments on exactly what the procedures perhaps ought to be. What implementation plan ought to include? Things of that nature, so we much welcome suggestions along those lines.

- A. (Linda Horton) Under the existing Federal Food, Drug and Cosmetic Act -- Section 801 deals with the process of handling imports entering and it also has regulations and FDA has ones to supplement (not audible)

Jill Hollingworth, Food Marketing Institute:

Recently in a letter signed by , FDA notified Guatemalan officials that raspberries from that country would not be allowed into the United States. It appears so FDA has the authority to settle protection from consumers this country and enforce it, what authority is this legislation seeking that you do not already have, if you have if can in fact block a specific produce or product from entering the United States now.

A. (Bob Lake) Two points, one as I pointed out earlier part of what the President is intending with this legislation initiative that he has put forward, is to build into the Food, Drug and Cosmetic Act a notion that already exists under the World Trade Organization Agreement but is not specifically in the Food, Drug and Cosmetic Act. Now with regard to the particular situation in Guatemala, again the question related to the fact that we have a form the Government of Guatemala that we will not be accepting raspberries until the situation there is straightened out. Again that particular situation though is one in which we have had several outbreaks of illness in the United States both last year and again this year resulting from an organism know as chyco sporium on raspberries from Guatemala Again because the fact of human illness has now occurred two years in a row, we have actually in the case done something extraordinary. I think it is without precedent in that we have notified the Government of Guatemala that raspberries will not be accepted from that country until this is problem is solved.

Peggy Rochette, National Food Processors Associations:

We all know that national treatment works both ways. And my question has to do with the appropriateness of the legislation is obvious acceptability to foreign facilities of the FDA. What type of obligations does that put on US for foreign acceptance to have (not audible) ?

- A. (Bob Lake) Before she takes that question. Let me just note a clarification on the previous one. The problem is really with the Guatemalan raspberries does resolve, does occur during the Spring and Summer, so the notification becomes effective on May 15, 1998 and from then through August 15, 1998 just to be sure that everyone understands exactly what we have said to Guatemala.
- A. (Catherine Carnevale) Peggy Brochette's question had to do with the national treatment. And national treatment for those of you who are not familiar with the term, has to do with treating goods of one country more favorably than goods you produce yourself. An under the WTO Agreement that is prohibitive. So I think when we're talking about accessibility as far as FDA going to other countries and having access to facilities in order to conduct inspections or evaluate to see how products are produced, certainly that is something that when we have reasons and required to do that we would like that access to be facilitated. But I think it is important to understand under the SPS agreement under Article 4 that portion of the agreement that deals with equivalents, that subject is already addressed. And when Bob Lake was saying that the reason behind this legislation had to do with the notion of taking parts of the WTO SPS Agreement and them in our statute really the portion of SPS Agreement that we were referring to does have a section on equivalents. And under Article 4 for those of you who are not familiar with equivalents basically it is saying that all signatories to WTO

are required to accept SPS measures of other countries even though they may differ from those of the importing country. If those measures are meeting the importing countries level of protection and what it says under the SPS Agreement is for this purpose in evaluating equivalents reasonable access shall be given upon request to the importing member for inspection testing and other relevant procedures". So in answer to the question, I would again say that this is really something that concentrated in the SPS Agreement that reasonable access shall be provided .

- A. (Bob Lake) Let me just build on Cathy Carnevale's remarks. I think it is important to emphasize that in the development of this legislation that the White House, the FDA, the USDA, and the US Trade Representatives all were involved in developing it. So it clearly has a food safety focus -- that's the primary focus -- but it was very much the desire of the Administration obviously to adhere to the trade obligation and we believe, the Administration believes that proposal that has been introduced into Congress does indeed strike the appropriate balance. And I think they of it we will support that .
- At the same time, we do understand that a lot of people are apprehensive about it. And I suppose if I were in the audience I would be apprehensive as well. And that is why we again want very much not only respond to your questions, but also urge that you forward any suggestions that you have about how this can implemented in a way that is fair and reasonable.

Natalie Landreth with Manate, Phelps & Phillips:

What is the implications for domestic producers that other countries might be regulations? What does that do to US (not audible)

A. (Catherine Carnevale) Some countries already have such legislation already and that's something that they can use. We do not see this particular amendment as being something that will put trade barriers will end up causing trade barriers. It is a strengthening of our existing authority. It also is a WTO concept in our Law and I think that all countries who have the WTO are in the process of doing this very thing. So I don't think that we are looking upon this as a tremendous burden because other countries do the same thing.

A. (Bob Lake) Let me add to that a well. Again emphasizing that our purpose here is not to create trade barriers but promote safety of produce bought by the US consumers. We have no with other governments are going to do anything different or have a different intention than we have. But if it were to turn out that other governments try to misuse this concept which again, they too, I mean other governments have obviously the right to protect, have always had the right to protect, their own citizens But the whole purpose of WTO is try to ensure that is not in a way based on science that it's fair etc. And certainly if we had any reason for believing that other governments were misusing this type

of authority to impose inappropriate trade barriers, we would join with other Agencies in the US Government in opposing that in the strongest possible terms.

(unknown attendee -- unidentified)

I have a question about, considering limited resources for inspections abroad etc. Do you envision that this might (not audible) check list and here are our guidelines to explain your procedures as it might be (not audible)

A. (Bob Lake) I would take that as a suggestion.

(unknown attendee)

My question is about the legislation. When FDA is evaluating the conditions (not audible) produce particular food and caring out to the level of protection within the US, would you be taking into account from the entire package of similar protection that made this in the US. For example: If there is an OSHA regulation or even a state regulation that requires a certain number of portable toilets and hand washing facilities in a field, an agricultural field, where people are picking fruits or something, would you consider whether the other the country had something similar?

A. (Linda Horton) Yes. The question was whether to consider what another country has the level of protection similar to that in the United States, that we took into account requirements or guidance in areas

that not directly imposed by FDA, would they be imposed by other Federal Agencies, such as the US Occupational Safety Health Administration (OSHA) or states? The answer is, yes. It would be systemic. You would be looking at the combination of requirements or guidance and public sector and private sector relationship in the other country as well as here because the situation were no single institution in a country is capable of assuring the food that is produced in that country. I makes the situation rather complex. And I think the failure to consider requirement for guidance on institutions other than the FDA or the FDA counterparts in the other country, you would not be looking at the whole picture of when it comes to safety of produce and other food.

Also I want to take this time just to supplement an earlier statement.

I have a little more information here about the Codex effort. Ed Scarbrough the US Codex Manager mentioned earlier, the new initiative doesn't Committee. That Committee happens to meet here whether you can get over to the State Department. There are two initiatives actually. One is the

(not audible)

and this will be lead Canada with assistance from several countries who want to get involved the meeting. They are Argentina, Chile, Denmark, Guatemala, Honduras, Japan, India, Mexico, United

Kingdom, and the United States. The there is a second

(not audible) for Pre-cut Fruits and Vegetables.

It is recognized for being essential for (not audible) The
work here will be lead by France, with assistance from Mexico, the
Netherlands, United Kingdom, and Guatemala and the United States.

(not audible)

(Name not audible - Guatemala Embassy)

(This statement was not audible)

A. (Bob Lake) Thank you for that clarification.

Francisco Gurria, Agriculture Department of Mexico:

I was wondering what goal of private organizations certification
organizations would be and how would those blend with complying
with the regulation? It seems like Mexico a lot of producers groups
are shifting toward having certification organizations for quality purposes
a sieve for SPS issues complying with those. But then going to quality
oriented certification, who would those blend or be part of or inserted
proposal complying with the regulation than allowing those other come
above the border?

A. (Linda Horton) As I mentioned earlier, I think private
organizations have a very important role to play under this
initiative and (not audible) I think that it is

very important for the government to explain ultimate responsibility and certainly do audits of the work of private sector bodies. However, what could probably be done and I think this is true in the United States or in other countries, to make sure that (not audible) that they be looking for compliance of food safety requirements destination of open market that the Mexican requirements, the US markets, the US requirements. Certainly in this country the better private sector auditor are looking not only cooperative other guidance. They are also working for compliance, regulatory compliance. I think its only logical. (not audible)

Peggy Rochette, National Food Processors Association:

Do I assume, in reading this I assume that this is the good agricultural practice that you're going to add to good manufacturing practice and that these will be the documents that are the basis of the international inspection? Is that right?

A. (Catherine Carnevale) We up here to talk about the legislation and I think this is a linking comment as to how the GAP that Tom Gardine had discussed this morning how that guide relates to what we are talking about in the international in this legislation. The

decide

legislation is contemplating the notion of equivalents. And as Linda has said a few minutes ago, when she was addressing the session on would you take OSHA requirements into account. We are looking at equivalents in a very systematic way. When we talk about our level of protection we're looking at our level of protection as something that has as it is contemplated under the WTO. It is something that is a sovereign right of a country to how it's going to protect its citizens. And so therefore, it can decide that level of protection it deems appropriate. Whether you take into account when you look at the level of protection. Well the measures that a country puts in place of what they are to achieve the level of protection they have chosen. So if the US decides that they want the product safe we further define that in our regulation to make it clear what they . When it comes to fresh produce we are not going out with regulations perse. And as Tom stated this morning, the science is not considered to be quite far enough along to become regulation. So we're starting with guidance. And the GAP and the GMP that we'll come up with in 90 days, will give us a place to start. This is going to be a very interactive process, our domestic producers with international producers. It is going to be hopefully when we have GAPs and GMPs, these are going to the end

product of many meetings of this kind that will have us, have an end result product that foreign growers should be able to live with or at least guidance. And the same goes with domestic growers. How we will use that in evaluating equivalents, well when we are evaluating equivalents with the guidance will be taken into account, because hopefully it would be a realistic product that will say this is what our expectations are for safety.

Barry Marshall, from the New Zealand Embassy:

I was just wondering if the panel (not audible) there is a proposed bill which which will (not audible)

- A. (Bob Lake) We need to separate two things. The statutory requirement or proposed legislation (not audible) applies to all food and it really I think that will pass separately from the produce initiative where you get into guideline issues. The guidelines for produce will be guidelines for the domestic as you point out. They will however, be guideline for foreign producers as well. So the guidelines we are talking about with regards to fresh fruits and vegetables will be the same on both domestic and foreign producers. There will be no difference.

Kathleen Melat, Montgomery County, Maryland Public Health:

I have a question relating talking about guidance. At this point because it is applying to levels, where is the research heading

right now? What are you looking at in the future?

- A. (Janice Oliver) Let me address that generally. We had a meeting several months ago that we invited the industry into talk to us and (not audible) USDA and FDA asking the produce industry what research they were doing that the addressed food safety in the area of produce and also what they were considering as their priority needs in research addressing food safety. We have also been reviewing our own research agenda in FDA and in USDA and met with other government agencies. There have been a number of government agencies that have been meeting and looking at our research agenda in the areas of food safety and produce to actively accelerate what we are doing in the produce area. We are in the process of doing that. We had several meetings. The results of that will become early next year. But we're looking at number of the areas that were brought to us by industry. We are looking at prevention. We are looking at methodology. We are looking at kill-steps in various things. The irradiation was an issue that came up when we had the chycosporium meeting looking at what research was need for various chycosporium produce last summer. And some research was being done irradiation. But it's a broad scope research plan. And looking at what's

being afterward by industry and academia as well as ourselves.

I can't give you the specifics now but we will be able to give you more on that every in the year.

A. (Bob Lake) Thank you Jancie.

Lynn Bradely, ASTPHLD:

Safe Public Health Class Directors support a program for pathogenic, like on food products. Now, I want to ask if you considered developing such a monitoring program for especially fresh fruits and veggies apart of this initiative?

A. (Bob Lake) I guess we would say we would invite your specific suggestion about that. I think it's got consideration.

I don't think a decision has been made, but certainly it can figure ideas about that results.

Bob Lake, FDA:

Maybe while you are thinking of questions, maybe I'll ask one of a panel member.

Let me ask Linda (Horton) when do we think the legislation might actually become Law?

A. (Linda Horton) Bob that's a hard question to answer because it really has not had Congressional Action. And as many of you know the Congress recently enacted FDA Modernization Act and this will probably . Why it wasn't put on the table

soon enough for consideration . We are very hopeful that soon. Early in the year. The President was quoted in yesterday's (Dec. 7, 1997) New York Times as naming food safety generally one of his top priorities. I think that signals a desire by the President for FDA and everyone including for the legislation on Capital Hill. And I think that there will be groups that are interested in improving the insurance of public that food is safe. The increasing food safety and also increasing the protection of food safety. So I think these people will be talking to their contacts in Congress about action on the bill. Now one thing we all know the but there steps needed. You said that Tom Gardine said he would need , so if we got into a situation where and (not audible) perfectible acceptable. We know that a lot of tests .

Bob Lake, FDA:

Let me ask Cathy (Carnevale) a question too.

When will this legislation be notified to WTO?

A. (Cathy Carneval) That's interesting point. As everyone here probably knows when a country is putting a in requirement in that they do need to notify the WTO and preferably do it at a time when other countries can comment on any new requirement they are

going to put in place. At this point in time, we are dealing with proposed legislation. So we do not have legislation that is enacted. We normally do notify our legislation however, as you know in the United States normally or legislation is giving you a legal framework and it's rather general in its construct. Usually the more important notification of WTO. And certainly most legislations do not go into effect until implementing regulations are written. We normally notify WTO when we come out with proposed regulations. And that is a point where countries as well as US public can make comment on the legislation. And so we would contemplate that since this amendment has in it, as it's currently drafted, an implementation plan we will probably at that point decide what regulations are necessary and any other things that (not audible).

- A. (Bob Lake) The Administration forwarded this proposal to the Congress just before Congress adjourned. I was introduced in the House. It has not been introduced in Senate at this point.

Peggy Rochette, National Food Processors Association:

Does it have a sponsor?

- A. (Bob Lake) I don't know the answer.

Donna Haseley, FDA Week:

If the legislation passes, would you envision (not audible)

A. (Catherine Carnevale) We just not there yet. We are considering all the possibilities. Part of the reason for this meeting, and I want to emphasize this again, as Jim O'Hara said when he addressed this meeting today, we looking for your comments on this legislation as far as how it would be implemented. The suggestions we've heard today will be recorded and we can take them into account, but I am sure as a result of this meeting that those wheels are turning, and as you think of ideas please get them into us. As Bob has said it is not our intention to be barriers, our intention is safety. We are interested in how you think we should implement it.

A. (Bob Lake) Let me build on that because in addition we would like have your written submissions and that includes suggestions you made earlier.

Francisco Gurria, representative from the Department of Agriculture of Mexico:

Along the lines of the last question, is FDA prepared to comply.

Application for exploring countries to be evaluate. (not audible)

How is FDA prepared to comply or to attempt those applications

because if we started with the alphabet Mexico for example, we'd

have to wait quite a while and the same with the other countries.

It seems like this take effect. And how fast will the evaluation

be done?

A. (Catherine Carnevale) First of all let me assure you we're not going to do it in alphabetical order. Let me just go back to what we said earlier, and that is that when and if this legislation is enacted, we are not contemplating that (attendee coughing made this section not audible) This legislation is similar to legislation that we currently have in this country for meat and poultry. But its implementation will and must be different than

. In that case (not audible)

I think that everyone recognizes that when we were dealing with numbers of countries that export fruits and vegetables to the United States, the number of farms and the number of facilities and industries that are involved with fresh produce. And recognize that this legislation is covering really all foods not just fresh produce.

There is certainly no way to deal with legislation .

So we are going to have to sit down for many hours and many meetings like this, to figure out exactly how we are going to do this, the implementation of this legislation. We have reviewed your comments. But if we do find ourselves evaluating equivalents on a number of countries to facilitate trade, not to allow trade to continue to (not audible) Application take a long time.

A. (Bob Lake) Let me just emphasize a point that Cathy made.

about the difference in the implementation between this piece of legislation and what is currently done by the Food Safety Inspection Service (FSIS) relative to meat and poultry. With that it is contemplated that you the clearance before the food is shipped. Let me emphasize that this legislation does not require and we do not envision a system in which you have to apply to the FDA in order to get your food into the country. That's not what we envision at all. Again let me emphasize that is certainly not what the intent. An earlier point, what happens on the first day. Will get lots of applications and we will have to deal with those in some fashion. But in the mean time the food continues to come in as it always comes in, unless we find something in particular wrong with specific shipment of food. Unless and until FDA decides that the system for food in another country to level the protection required in the US. Again (not audible)

A.. (Linda Horton) No, only that I think the issue is (not audible) the good agricultural practice factor on certain kinds of produce on high risk than others. We are focusing on the high risk situation for others and think (not audible) The science issues will also be (not audible)

?? Al Yamada, Fresh Produce Associates:

You keep talking about the level of protection, but you haven't really describe the level of protection. Except to say that this is guidance and the GAPs and GMPs. The problem those are volunteer guidance , so what happens in an international conference -- international trade -- helping to do something that's volunteer. So eventually going to have to turn those into regulations so that we WTO .

- A. (Bob Lake) Let me respond in part that, my colleagues may want to answer that. Let me start with the same point which I think is important -- although all the fruits and vegetable initiative and it's provisions were spoken on at the same time. I think it is best to look at them differently. Let me elaborate a little more on that and perhaps better answer your question. The legislation relates to requirements and level of protection. The requirements are spelled out in the regulations. Now the level of protection does encompass I think a broader notion which I think really is not a . Different foods safe . That's what the legislation is about. Now let's go over and talk about the fruit and vegetable initiative. Right now what we are envision not only because of the fact that we are still developing the science. That quite frankly we don't have a experience in implementing any kind of system involving good agricultural practices and we would like

very to have that experience as well as your scientific knowledge. So what we really envisioning there -- both for domestic producers and foreign producers -- is guidance that we believe we hope will be basically common sense guidance. And at the end of the day it will result in improved safety both domestic and imported fresh fruits and vegetables. I think it's best to keep those -- legislate these and the good guidance for fruits and vegetables it's different things. Now to answer the questions about whether we might ultimately issue regulations and that is certainly a possibility down the road. As we gain experience and we get more scientific knowledge and are better able to decide with a scientific basis what really should be going on, then there is certainly the possibility of regulations down the road. But it seems to me that is quite sometime away if it happens and let me also emphasize that no decision has been made at this point to move the regulation. What we're struggling with now is developing the guidance. It is our belief, that structure the guidance in some way that it will be usable by both domestic and foreign producers and that it will be used and that will result in improved safety of fruits and vegetables for US consumers and hopefully, as incidental factor, maybe others consumers as well.

Tom Gardine:

Just to point out and concur what Robert has just said. This is a question that comes up at the domestic grassroots meetings that we've been having also. How will this play with imports, but more domestic growers are looking at it from a slightly different angle than here. We point out, under unequivocally that with this guidance for domestic industry, is guidance for our foreign growers, and that more than likely if we do work with foreign government to assistance and evaluate their industry, we may use this guidance document as something to help us in that evaluation to determine if technical assistance and some sort outreach effort is necessary to foreign growers. But this document is not a regulation. It is not a Law. It will not be the standards implied in terms of legislation.

Q. (Linda Horton) And by this document, you mean the good agricultural practice?

A. (Tom Gardine) Exactly.

Q (Cathy Carnevale) I think that was a good answer. If you have requirements in the Law (not audible)

Natalie Landreth from Manate, Phelps & Phillips:

What are the standards which you refer?

A. (Bob Lake) The standards would be various provisions of Food, Drug and Cosmetic Act and the implementing regulations. The ones that already exist and in fact are being applied. Clearly

the domestic and to the extent it can apply food import as well.

A. (Linda Horton) We were just looking to see where standards are actually mentioned, and I don't believe that the legislation calls for the --

A. (Bob Lake) I just think it is just requirements.

Natalie Landreth, Manate, Phelps & Phillips:

The Law already sets the requirements and standards. Why then do
(not audible)

A. (Bob Lake) That's a good point. The question is -- A number of requirements in the statute and regulations, what is the need of guidance are on GAP and the answer to that is just kind factual one. The fact of the matter we don't have regulations today on good guidance practice type thing. Nor are we prepared to write regulations at least at this time. And so, when we don't have a requirement but think something more should be done then response is to try to develop some guidance that we believe will be helpful to producing a safe product.

Marsha Echoles, National Association for the Speciality Foods Trade:

You have in the bill two things. One, issue of whether food is safe or whether there's a risk? And then there's, how you respond to that risk?
(not audible) in terms of response, not the determination of whether there's a risk. And the response is already in the statute. The

requirement is already in the statute. I don't understand what you adding with the reference to the level of protection because our Law says the level of protection ?

A. (Linda Horton) Marsha's question is, what does the bill add to the existing Law? The Law already says has to be adulteration. (Not audible)

What this bill does is concept that already are (not audible)

It is true that you cannot market food in the US if it's adulterated. It also says that it cannot be shipped domestic commerce or imported into the US if the food is produced under conditions . What this bill adds is a notion that we should look at, the system of the country that is offering food to the US to see whether the requirements are met or as stated in the SPS Agreement, or will protect us . And so I think it's adding the concept. I think it's very true that the

(not audible --- several persons coughing during this response made it difficult to hear the panel member)

new concepts that are consistent with the international principles that are apparent in the SPS Agreement and the WTO generally. I think that's -- really if anything probably giving people more

and how to reach the goal. Going back to the question from the woman in the back of the room about why . I think it has not been enough to have the Law because doesn't give enough information to producers on how avoid food safety problems. I think what we are trying to get and Terry has to look at the legislation under one hand, the present law and new law, and good agricultural practice --- together they will clear picture of what is presently needed to have

(unknown gentleman from the Columbian Embassy:

Are you going to assess countries or assessing like sectors within produce industry?

A. (Catherine Carneval) An excellent question. And the question was, are we going to be assessing or are we going to be assessing sectors? At this point in time, I'm not sure if we know exactly what we are going to assess or even if we are going have the need for and be able to conduct assessments. I think that is what we are looking for from you as far as input on how we might implement this. What we are dealing with today, and what this panel is about, is looking at the legislation that we we and expressing what our intentions are with regard to that legislation. Recognizing that legislation talks about an plan. And I know that most of the sessions have been

related to how they may implement this and we are considering this implementation right now. But I will mention that and Linda reminded me that we have a regulation on seafood that is going into effect on December 18th. We are in the process right now of looking at for seafood. And we are going evaluation on countries but just for seafood. And we are looking at the evaluations more or less in terms (not audible) guidance.

Peggy Rochette, National Food Processors Association:

You have gathered which is typically for the record of your (not audible) Would that give you enough information to or resources, could you use that as a source for you to say that we need to look at another countries?

A. (Catherine Carnevale) I think Tom Gardine probably can give a very specific response. Our input has been, let's put it this way, we do not have the resources to do the level of import management that we would like. We're doing probably and if you're looking at pesticides, then you looking at microbial pathogens. But if you're looking at any other specific We are probably looking at ,sometimes less sometimes more around two million entries per year. So for us to do adequate monitoring of food, it's simply not a problem. Now

how does that relate to your question about the data base? I'm not sure that we really have statical to give you a good however, we do use the data and we do analyze the data to look and see areas (not audible)

So we do utilize our data the best that we can. But how we would utilize the I don't know. Certainly it would be (not audible)

- A. (Tom Gardine) Yes we do use research data to focus our limited resource for border sampling. But I think what were at in terms of the President's initiative, and what we have to remember is we are dealing with emerging pathogens that frequently we don't have methodology or only have only poor methodology to test fresh produce. So therefore, border examinations is frequently a least appealing option to us because it is least effective. Methodology may not be there or if it is there is a . What we are trying to do with the guidance document is develop procedures that will minimize the risks of any microbial pathogens being on produce. That is why we are trying and have not yet developed a mechanism for outreach and evaluation in foreign countries. That deals with produce. In terms of other problems, low acid canned foods, of pesticides that is a prim example, we have and do use our border sampling one year to focus on resources in the following year, because it helps identify where the problems are.

A. (Catherine Carnevale) That's right, and Tom is basically saying in answering that question, the reason why the world is moving in the direction it is moving is for prevention.

(not audible) Department of Agriculture of Mexico:

What about produce say that are not produced in the United States, but are produce in other countries and how would guidelines relate to that?

A. (Tom Gardine) The guidelines that are being developed --- could I defer that question until the afternoon when we are talking about the guidelines and will see. I think that's intended to be very broad in scope and should have some universal applicability to most produce production.

Bill Hewitt, Canadian Embassy:

You mention the bill requests also that the (not audible -- coughing in audience caused difficulty in hearing what was being said) a little bit about what the other issues address there products for example you had in mind or have had in mind when developing the legislation on fresh produce.

A. (Bob Lake) I think the answer to that is there is nothing in particular in mind. The legislation will be generic for any final

Suzanne Bont, the Royal Netherlands Embassy:

(Attendee was at the far back of the auditorium and her question could not be picked up by the recorder.)

- A. (Linda Horton) Question is: Whether we would consider the concept of regionalization? And this is a concept that is more currently discussed in animal health circles, in-house health circle?
- A. Regionalization is a concept that is again in the Trade Agreement and it is one that we have recently implemented again plant and animal health areas in the United States. It is not one that we are contemplating for the type issues that we deal with for food safety or human health, I guess, in the United States. It's not one that we have really contemplated at all. If you can again see an avenue for utilizing that kind concept, we would be interested in hearing it. But it's not one that we have considered.

Kathleen Milet, Montgomery County, Maryland Public Health:

For comment, we have had great success with what we've termed, certification of food handlers. You might want to consider long-term It's not certification of processes, it's certification of people, that is having them go through a formal education test to become raise them up to a level of knowledge so they can properly handle their food products.

A. (Bob Lake) Thank you for your suggestion.

LUNCH BREAK

AFTERNOON SESSION

Catherine Carnevale, VMD, Director of Office of Constituent Operations, Center
for Food Safety and Applied Nutrition at the
Food and Drug Administration

Good afternoon. I am Cathy Carnevale and I am the Director of the Office of Constituent Operations, Food and Drug Administration Center for Food Safety and Applied Nutrition. And I welcome all of you who came back after lunch. I know that we gave you a little bit shortened period of time for lunch.

This morning I think we had an extremely interesting session. And this afternoon promises to be every bit as interesting. I want to emphasize as USDA and FDA did this morning when they opened up the session that this meeting which is one of seven meeting that are going on around the country to discuss his fresh produce food safety initiative is intended to present our thinking thus far on what is really a workable process and solicitate your participation in this process so that good agricultural practices and eventually our good manufacturing practices, and this overall program can be as realistic, workable and as valuable. This afternoon we have Marry Ann Keeffe who is the Deputy Administrator of the International cooperation and Development in the Foreign Agricultural Service at USDA here to talk about Foreign Agricultural Services Role in technical Assistance and Education.

Mary Ann Keeffe:

Thank you very much, Catherine. And thank you all very much. I'm pleased to be with you this afternoon. This is actually my maiden voyage, if you will, in my current

position in the Foreign Agricultural Service where I have been now for all of three weeks. However, I am not here for agriculture, I've been in the Deputy Under Secretary in Food and Nutrition area for the past several years and had worked in the Food and Nutrition Agency well before that. I am very excited about the new role that I have taken on and obviously part of my former life I am hoping is going to be a benefit in my current role.

As President Clinton said in his October 2nd Memorandum to the Secretaries of Agriculture and of Health and Human Services, "American consumers today enjoy the safest food supply in the world". The President and indeed all members of his Administration take great pride in this record.

The Department of Agriculture and the Food and Drug Administration have been partners and will remain so in assuring the continued safety of our food. Success in this objective requires our continued good working relationship. And I have to say that I have first hand experience with this. Indeed I the occasion to work very closely with FDA over a situation last Spring that involved frozen strawberries in school lunch. And although we were dealing with a crises situation we were able not only work through that but work through the larger picture that effected that whole situation. We worked very hard in it. We had daily phone conversations and CDC was also an important part of that. It was very positive working relationship.

Since October 2nd, when the President announced his new initiative to enhance the safety of imported fresh produce, USDA, in cooperation with FDA, has organized several briefing to address our trading partners' concerns about this initiative and ensure them that they will have input into the development of the new US regulation. The Foreign

Agricultural Service in cooperation with FSIS, which is the Food Safety Inspection Service and FDA held a briefing for all foreign attaches on the Food Safety Initiative on October 16th here in Washington, DC. Very quickly after that announcement on the 2nd. In addition, as has been referenced this morning, you know about the grassroots meetings that are being conducted around the country.

We are working to provide guidance on good agricultural and manufacturing practices for both domestic and imported produce. We have been making every effort to keep our trading partners informed and see their comments as we develop this guidance.

We believe that all food safety regulations, including those being developed for fruits and vegetables, should be based on scientific principles, and will be consistent with our international obligations under the World Trade Organization and the North American Free Trade Agreement.

We in the Foreign Agricultural Service play an important role in promoting world food security by helping supply the world with safe, nutritious food products. We do this in two ways: First, by helping US farmers export their food; and secondly, by cooperating with foreign farmers, food businesses and governments to improve global food production, processing and distribution.

Since the mid-1980s, the Foreign Agricultural Service has worked closely with the produce industries in the US and Latin America and the Caribbean to promote concepts of quality grades and standards, post harvest treatment, improved packaging and distribution for traded fresh fruits and vegetables. This experience will be invaluable in our future working with those industries on safety issues.

The Foreign Agricultural Service has a number of ongoing activities to address international aspects of overall food safety and food quality. These initiatives help to ensure that imported products are safe for US consumers, that our international trading partners understand the United States' regulatory and policy framework relating to food safety, and that US scientists and technical experts gain access to the most current technologies being developed internationally. Some of these initiatives are funded with USDA appropriations. Others are funded with agreements with other US agencies such as the Agency for International Development (AID) and the State Department or with international organizations such as the UN Food and Agriculture Organization (FAO).

The Foreign Agricultural Service is implementing international food safety related programs under four general areas of cooperation: The first is, training and technical assistance; secondly, data management; third, international cooperative research; and fourth, cooperation with international organizations. I would like to look at each of these areas and give you some examples of the kind of initiatives that have been undertaken.

The first is Training and Technical Assistance.

The Cochran Fellowship Program which is funded by USDA appropriations, provides short term training in the United States for international agriculturalists. Over the past three years, the Cochran Fellowship Program has provided food safety and sanitary and phytosanitary (SPS) training to over 120 international participants from 35 countries.

These training programs have helped other USDA agencies (such as APJIS, FSIS, GIPSA

Grain Inspection, AMS which is our Agricultural Management Service) educate their international counterparts on the US food safety system. The Cochran Program has also provided training for international food safety journalism teams who return to publish articles in their local media explaining food safety concerns and issues. The Cochran Fellowship Program intends to fund approximately fifty food safety training participants over the next two fiscal years.

The Technical Issues Resolution Fund, which is funded by Foreign Agricultural Services Emerging Markets Office, competitively funds activities which support the resolution of technical barriers to trade. These activities may focus on short term, high priority barriers to trade, or longer term, more strategic efforts of training and technical assistance. Foreign Agricultural Service and the Food Safety Inspection Service are currently collaborating to develop a Technical Issue Resolution Fund (TIRF) proposal to provide regional HACCP training to Central European participants in the Spring of 1998.

In the area of Technical Assistance, the Foreign Agricultural Service has implemented and designed a number of food safety related efforts.

In 1996 a team of three USDA scientists from the Agricultural Marketing Service conducted a two-week training program on microbiological and chemical procedures used in the food industries to prevent the spread of foodborne illness and to acquaint them with US laboratory standards. Thirty health and food safety technicians from El Salvador, Guatemala and Honduras attended this course which was held in Honduras. This was funded by the Foreign Agricultural Service Emerging Markets Office which also funded a *Russian Food Safety Initiative*, which has provided policy guidance and technical

training to Russian officials responsible for food safety and regulatory reform. An example of technical assistance funded outside of the Foreign Agricultural Service is the *Indonesian Food Code Initiative*. Financed by AID, the Foreign Agricultural Service heads a multi-agency effort to provide assistance to the Government of Indonesia in drafting its Food Code and reviewing related legislation.

The second area of cooperation I mentioned was Data Management.

Foreign Agricultural Service is working cooperatively with APHIS to develop a database to track international visitors, who are interested in sanitary and phytosanitary issues (SPS), including food safety. Currently, a series of SPS training modules are being developed by APHIS and Foreign Agricultural Service staff for use with international visitors and for distance learning. Additionally, Foreign Agricultural Service has received funds from AID to provide information and materials to US overseas staff and international colleagues who are interested in US agriculture, including food safety and food quality.

The third area is International Cooperative Research.

Foreign Agricultural Service administers numerous cooperative research programs in the area of food safety utilizing appropriate funding, foreign currency and funds provided by the State Department. These research projects are being carried out in over twenty countries worldwide. For example, US scientists are working with scientists from Japan to develop low cost indicators of viral and protozoan parasites on food; with scientists from Indonesia to improve commercial fermentation processes with scientists

from Mexico to detect clostridium contamination in food with scientists from Poland to monitor antibiotic residues in food and with scientist from Hungary to extend the shelf life of fresh foods. USDA appropriations have funded approximately \$125,000 in food safety and nutritional research over the past three years, while State Department funding has supported an additional \$285,000 in related research during the same period of time.

The last general area I mentioned was, Cooperation with International Organizations.

Foreign Agricultural Service is facilitating harmonization of sanitary and phytosanitary standards by working with official multilateral standards setting bodies, such as the Codex Alimentarius and the International Plant Protection Convention of FAO. The US Associate Professional Officer (APO) Program is managed by the Foreign Agricultural Service. Foreign Agricultural Service is currently hiring an APIIS funded APO to serve in the International Plant Protection Convention Secretariat at UNFAO.

We know that USDA and FDA alone will not be able to do the job of educating and training the world's produce industries about improved food safety practices. We must also seek cooperation from multilateral technical food organizations such as the United Nations FAO, and the Inter-American Institute for Cooperation on Agriculture (IICA). These are appropriate vehicles for sharing the technical and managerial knowledge necessary to produce the safe, high quality products the world's consumers deserve. I am planning on attending the meetings in mid January in Costa Rica, at IICA to discuss areas of food safety cooperative projects with them at that time.

USDA is committed to the continued expansion of world trade in food products and freer markets. If we all exploit our comparative economic advantages, the whole world benefits, including consumers the world over who all want safe foods.

I hope that these examples provide you with the flavor of the wide range of activities which we have undertaken on international food safety issues. Foreign Agricultural Service has many years of experience in working with people to help them solve problems. And we believe that through continuing cooperative, educational and technical initiatives we will solve food safety problems and provide a win-win situation for us all.

Thank you very, very much for allowing me to join you this afternoon. I am going to have to leave fairly shortly to get back for a two o'clock meeting. I will attempt to in my very new life to answer some questions if indeed you have any.

Q. (technical assistance)

A. Well you know the way these programs through my area operate are several fold. We are fortunate that we have various sources of funding for the types of projects. Unlike a lot of parts of government that is always at the whim of appropriations, if you will, and has to budget accordingly, we are able to take projects to AID or to other parts of the State Department or some of the international organizations. And we seek funding in that way. Sometimes it is jointly done where you have several sources of funding coming in for projects. Sometimes it's just from one particular stream or the other, but I think we're

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somewhat unique in that we do have a variety of areas that we will go to. So we are certainly hoping, I think that it's fair to say this is an area that we are all going to be looking for expansion. I think that on the part of it. They are certainly looking with varied interest with interest in our looking forward to these things. So from a budget standpoint we're rather hopeful that there will be additional funds from a variety of sources.

Q. (Agriculture Department of Mexico) Have you designed at this moment a new program to provide technical assistance for foreign countries for fruits and vegetable. (not audible)

A. Well generally a request would come into us through a variety of vehicles to provide this. Because we work very closely with so many of the international organizations, a lot of times we receive from them the word that a particular project has been requested or is necessary to look into. Obviously we don't go around and . . . You know it would come through a cooperative relationship, a request to us or if we determine that was a particular need we would certainly request or put forward that perhaps they would like a exchange program of some kind. Through the Cochran Program which is a very well received, well thought of program. People come from foreign countries here to, it's a very short term kind of a thing. It's usually a matter of just several weeks. But they would perhaps to a food industry here in this country or observe a particular problem. And that they work here and see what was being done here and then go back and implement. That's a

very positive program. It only works the one way. We don't send people there although there are vehicles through other programs that can provide that sort of follow up if it were requested to go into the country as well.

Thank you all very, very much.

Catherine Carnevale: Thank you Mary Ann, that was very interesting. This morning Tom Gardine gave us an overview of the produce food safety initiative. And this afternoon he is going to go into some details in reviewing the working grounds that what we are calling the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. And I guess you are going to stand up here.

Tom Gardine:

Well hello again and good afternoon. Let us begin by reminding all of you why we are here. The purpose of the grassroots meetings, of this grassroots meeting, is to get comments, opinions, suggestions, criticism, rage, outrage concerning the guidance we are trying to develop. We realize that many of you would probably not have had a great of time to look at the document in depth. So we have designed an approximate hour presentation to go over some of the highlights of the good agricultural practice guidance document.

May I have a show of hand from those of you so I could judge how quickly to go through these slides, from those of you who had a chance to read the document already. Once again it's left to the majority.

I put the slide up this morning, but I wanted to discuss it again this afternoon to remind you of what the President is trying to do with his initiative.

Before we discuss fruits and vegetables I wanted to talk about why.

I mentioned this morning that there have been a number of recent outbreaks of food illness associated with either fresh produce or where ever the contamination got into the processed produce. I want to stress as I did this morning the nature of some of the microbiological contaminations we've been seeing.

These are, the United States at least, (not audible)

one for which analytical methodology is another, quite frankly. To

apply analytical methodology for things like chycosporium, Hepatitis A, E. coli in the various food matrix that we have to deal is not as easy as some people may think. Frequently, the fruit or vegetable that we want to test for microorganisms some time inhibit our ability to detect it. You almost have to tailor analytical procedures for specific fruits and vegetables in some cases.

to develop the necessary methodology and as new pathogens are emerge we will be defining the methodology. That is why President Clinton in his directive wanted us

and the growers to prime the US consumer to take a proactive steps in address the problem of microbiological safety on fresh produce. And let's remember that the guidance document that we are talking about today is indeed limited in scope. There are many problems that could occur with fresh produce. As there are many problems that could occur with any part of the food supply.

But what we are talking about in the guidance document are microbial hazards.

There is the name of the guidance document. I will not repeat it again. We've heard recent outbreaks have raised concerns with the safety of produce. We believe produce marketed in the US is as safe as any food in the world. We agree we have a very safe supply. The important thing is to keep it that way. To have our growers do what they can in conjunction with government and academia and their trade organizations to minimize microbial risk for produce so that the American consumer can continue to enjoy a safe and very nutritious source for food which their government is telling them for their own health they should eat more of.

One of the problems with fresh fruits and vegetables are they are eaten fresh. Unlike processed food there's normally not a step between the grower and the consumer that will eliminate, kill by cooking, killed by other procedures any microorganisms that could be ingested with the food. This is what makes them a source of problems. Therefore taking steps to reduce the risks of microbial contamination is especially important for fresh raw produce. We have to try to limit the microbial load of pathogens on the produce. Then the other links in the chain, the retail stores and the consumer must also be educated to do what they can do to minimize the risk of food illness associated with fresh produce.

This is a very broad scope document. It is trying to bring out universal concerns that might be applicable to the growing and cultivation of produce worldwide that may be room for adding microbial contamination to produce if thought, concern and care is not taken for their use. They are use of water,

use of manure, sludge, worker, field and facility sanitation and hygiene and finally transportation.

If you have not heard your , you just came in this afternoon, we are not talking about a regulation to enforce the Law. We are talking about guidance with the intention of working with industries both domestic and foreign to explain to them the meaning for these good agricultural practices, what they are intended to do, encourage their adoption, and also work to improve the guidance. We want growers to be very proactive -- take proactive steps in this. What you have there is the best advise of FDA and USDA in consultation with our national advisory committee for microbiological criteria in food, in consultation with academia and in consultation with industry and consumer groups.

The document focus on common elements. Once again, very broad scope intended to be as, nothing is totally new first of all, so this is intended to be as universally applicable as we could get it in terms of growing, production and distribution. And its intent if followed is to reduce the risk of microbial contamination. Once again, until control mechanisms that can be applied to all produce in a cost efficient manner are developed, we cannot eliminate microbial risks on produce but we can all take proactive steps, especially our growers to reduce the microbial load on the produce being marketed in this country and around the world.

We recognize that there are gaps in the science as I indicated this morning. There much research to be done. And I believe Janice Oliver indicated that part

of the President's initiative is to fund the necessary research to close these gaps in our knowledge. We recognize the gaps, and in the guidance document you have in front of you, we will point out where the gaps exist. And we will use terms like _____ and minimize where the science is perhaps not where we would ultimately like it to be.

The guidance is intended provide practical advise appropriately followed by, please look at the word, facts. We are here to get comments from industry and industry includes our international trading partners when we talking about fresh produce. We want you whether you hear what I have to say or whether you read the guide, come back to us and say "my God do you live in the real world", we can't do that or come back and say certain parts of it are good, certain parts of it is bad. here's what I think. We need this to be practical and doable. It cannot be, what we refer to as pie in sky theorizing it must be something that will be workable in the growing for the growers where ever they are producing produce intended for the US markets.

We want to point out here, it was pointed out to me on some of sideline discussions this morning. In some area there is better guidance out there. There is in the United States good manufacturing practice regulations already on the book that aren't part of our code of Federal Regulations, that may be very implacable to some of the things we say about packing houses for produce. Nothing in this guidance eliminates the need to comply with already existing local laws and regulations for our foreign trading partners the good manufacturing

practice regulations or the laws of the United States. What we would be referring to here would be item 21 of the Code of Federal Regulations, I believe it is Part 110 for the general good manufacturing practices.

The guidance is based on the belief that there are common potential factors of pathogen on all fresh produce, and as before I mentioned before, water, manure, sanitation and handling, workers sanitation included there as well as transportation. But we do realize that there are enormous variations. Not only in the United States or foreign type global conditions and startling differences, employee availability and practices. And that's just in the United States were we bring this out to the world, to all the peoples supplying produce. These variations become even greater and that is why President Clinton wants us to find a way to address these regional differences. And once again, as I said this morning, that is another question that we like for you to comment on either today or in writing.

Our cultural practices we also realize vary a great deal between types of produce and different varieties of specific types of produce.

Here is the basic question we're trying to get at at all of our grassroots meetings. How can we best provide practical concrete advise to growers that will move us toward safer produce without being unnecessarily costly to growers? It has to be practical. It has to be doable. It has to be something within the cost range of the growers. But it has to move up toward continuing record of safety of produce marketed in the US and hopefully around the world.

Here are some of the basic guidance seen in the document. I must stress those of you who have not read the document, do not walk out of this meeting

basing your opinion on what I say. In the short time we only discuss hi-lites, basic concepts. There is a saying in the United States, that the devil is in the detail. The detail will make or break this document as to its practicability, its doability, and whether or not it's doing any good. It has to get up for guidance that if followed will result in safer produce.

First of all let's talk about some of the guidance concerning water. Water is a concern in two aspects. If the water itself contaminated and you use it and it comes in contact with the produce, it is an inherent source of contamination itself. But also, this is something that perhaps we don't think about, but we use water clean produce. If we do not use that carefully, water even if clean could be the vehicle for spreading pathogens in fields, in the harvest, or the packing house. So we even have to be careful about how we use clean microbial sound water.

Water can carry many types of pathogenic organisms. You are all concerned with this. You all know the illnesses. You all know the concern water.

Among the things we talk about in the guidance document for control of control of potential hazards, we say because of water's potential as a source of pathogenic microorganisms, growers should carefully analyze practices involving water and seek to limit the possibility for waterborne contamination. Very simple statement "the devil is indeed in the detail". But I think this shows the intent of this document to an extent. This document is not a one side fits all

document. It is intended for the grower to use as a template to evaluate the practices on his farm and to see where he could adopt this guidance. Everything in this guidance may not work or may not be practical for every grower, but certainly the grower should be thinking about each of these factors that are being discussed today.

Growers should recognize potential for water sources to contain pathogens. And water should be of a sufficient quality for its intended use. The document is a very wide side step, does not define sufficient quality. But if folks want to give us some comments as to what sufficient quality should be, that would be very appropriate for this process of town hall meetings such as this one, grass-roots meeting, and soliciting comments.

We should identify the source of water used. It will be different in operations. Water use should be tailored to needs of a particular operation. There are different uses for water throughout a growers operation. And the type of water you use can vary. I have stated already, guidance in this guidance document does not preempt any currently applicable federal, state local regulations.

Among the things we would expect, and hope where we should consider on their operation. You should identify and review the source of water used on the farm. Be aware that as the degree of water-to-produce contact increases so does the need for good quality water. As the water is becoming more and more in contact with the produce, the quality of the water we would hope would be better and better in terms of its microbiological safety.

This review by growers may include determining whether the source of the water is from a well, open canal, a reservoir, reused irrigation water, from the municipality or other sources. Each of those sources of water pose different concerns for the safety, appropriate use of the water and how to control the suitability of the water for the use that it is going to go to. Control options available to a grower may include such things as delaying water use until water quality improves. If you have a problem, that may be an option, but my God if crops are dying in the fields and you need to irrigate them, we realize the grower will have to irrigate their crops. But perhaps they consider water treatment if it's available as an option. Perhaps there are alternative application methods that would diminish the amount of water produce contacts. And where possible perhaps a grower could explore these meaningful alternatives supply of water. In the US if your whole source of water is from a river and you are down stream from a dairy herd or a beef cattle herd, you can't do that. You have to work with the water you have. The feasibility of all of these possibilities will depend on the intended water use and the resources of a particular operation. Once again, not one size fits all. Some growers can do some things, other should consider doing to control the quality of the water. A lot depends on your enviromental conditions, and the resources available to the farmer.

A little bit more about irrigation water. Many factors influence the growers choice of irrigation systems. The economics of it. The water available. The characteristics and cultural requirements for a particular crop. Sometimes

certain types of irrigation are necessary for the crop you growing. Depending on the crop growers may need to consider using deliveries systems, such as drip irrigation that minimize the direct water-to-produce contact to certain produce. It's an option available. What irrigation system are you using and if your water quality is not the best can you reconsider? If it the constraints of your financial resources and the needs of the crop, go into a system that would result in less produce-to-water contact.

Another item that growers should be aware of is water used to mix crop protection sprays. They should also be considered as a potential source of pathogens. It does not a great deal of good if you have a very well water source to irrigate you crops. But then to avoid potential contamination with crop protecting chemicals you don't used your well to mix these chemicals to mix these chemicals, you go down to the polluted water or the polluted pond to mix your chemicals and then spray it on your crops. You've don the same thing that poor irrigation source would do. You have added an unnecessary microbial load, potential pathogen, to the produce. You should be aware of this and think of alternate methods to protect the sounder more suitable water source for crop protection.

Wash water is some thing that growers should always consider also. Once again, you can only say the washing is some thing is going to solve the problems for us. That not always the case. You can take an isolated problem and spread it throughout more and more of you harvest. Safe and sanitary water is recommended to use in washing produce in the field and the

packing environment. The closer the produce gets to the consumer, the better the quality of the water used in contacting it should be. So for example, if you have several washes, you would want the last wash to be the one with the soundest quality of water available to you. You have to remember wash water even with sanitizers may reduce but not eliminate pathogens on the surface of the produce. If pathogens are internalized in the fruit of vegetable which happens occasionally washing has very little effect. And if washing is localized, a localized contamination in a certain part of the crop, washing may spread that contamination.

In wash water the guidance document seriously asks you to consider chlorination of the water to prevent it as a source microbial contamination or as a vehicle for spreading microbial contamination.

Cooling Operations, any operation where water comes in contact with the produce is a potential problem and water or ice used in cooling is no different than the water used in irrigation or the water used washing and the water used in crop protection sprays. Care should be taken to ensure that the water is of appropriate quality in this part of your operation.

Remember that water is a vehicle not only for contaminating produce but it is a vehicle for spreading localized contamination if you do not adequately consider, think about and tailor your water uses

The next major portion of the guidance document concerns manure and sewage sludge. Health officials and scientist agree that animal manure and human

fecal matter represent a significant source of human pathogens. Most of the illnesses that we are concerned about the association with produce, are associated with the fecal oral route. Fecal matter is another thing that should be considered and its contact, inappropriate contact with produce should be avoided wherever possible. The use of manure or municipal sewage sludge in the production of produce must be closely managed to limit the potential for pathogen contamination of produce. Growers must also be alerted to the presence of human or animal fecal matter that may unwittingly introduced into the produce growing and handling environments. Here we are talking essentially about uncontrolled animal, improper control of the storage of manure. These are the sort of things want comments on. How practical is it to ask the grower to be aware of and try to control wild animal sources of fecal matter coming in contact with the product? One thing we would be grateful for comments on.

Proper treated manure or municipal sewage sludge can be an effective and safe fertilizer. Un treated or improperly manure or sludge used as fertilizer to improve soil structure or that enters surface waters through run-off may contain pathogens and can contaminate produce. Once again, it's just like water. It's not a matter of don't use it because in the case of water you've got to. In the case of some kinds of manure, depending on the crop and how much is growing, we may have to also. Have to be careful of about what we do. And we have to think about it. That's the intent of the guidance document.

Municipal sewage sludge is not widely used in growing fresh produce in the . We do recognize that, and I personally do not know it

to be used by any of our trading partners. However in addition to the potential for untreated sludge has served as a source of contamination. Some studies have shown that properly treated municipal sewage sludge has been, can have benefits for agricultural uses. We talked about it in document on guidance, but it is some thing put out there as research is being done in this area and they want to consider its use.

One of the sources of fecal contamination on produce. The use of untreated or improperly manure which the guidance document will go into a great deal with discussing it more.

Some sources may include: Nearby composting or treating operations. If they are not controlled properly you may be producing an unnecessary problem. Nearby livestock or poultry operation. Nearby municipal waste. Water storage or disposal areas and high concentrations of wildlife in growing areas.

For the control of this. Growers may need to develop and follow good agricultural practices of handling the manure to reduce the potential of introducing microbial hazards to produce. Practices may include process such as composting. We will talk a great deal about 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 the produce gets closer to the consumer, more and more care should very appropriately be exercised in growing the produce. And also, the section adjacent or nearby land you should determine to risks of animals that shed pathogen effect causing

contamination. As I said, dairy operations next to your produce farm -- there is nothing that you can do, unless you buy up your neighbors land, but you should be aware and think about it and try and control the hazards associated with this as you are growing your products.

There are many ways to reduce pathogens in manure. These are mentioned in the document. You can read about them there, but the one we will talk most about is composting.

Composting refers to a managed process in which organic material are digested by microbial action. Properly composted manure can be an effective safe fertilizer and/or soil amendment.

This is one of the areas where more research is needed and it's referenced as such in the document.

The Agencies, neither FDA nor USDA are prepared at this time to make specific time and temperature recommendations that would apply to all composting or other manure treatment operations. But the use of the best guidance available through the USDA Extension Service, in foreign countries through whatever operations you have to . can they reduce the risk of microbial contamination for manures on fresh foods.

Some of the good agricultural practices of treated and untreated manure will vary. So untreated manure --- it's real simple --- Growers may reduce the risk of contamination form manure by maximizing the time between application and harvest.

Recommended minimum generally range from forty to sixty days before harvest but there are some recommendation out there for 120 days or longer for untreated, uncomposted manure because that is where you are likely to have largest pathogen load.

I have done two of the other domestic roots last week and they were in Grand Rapids, MI and Geneva, NY and I put this on the board "recommendations for 120 days" and I don't want to say the audience started laughing, but there was some snickering. And the snickering involved their agricultural conditions. The growing season in some of these area don't reach 120 days. These are some of the things that we need comments on. How a recommendation like this play in the reality of the growing season in Canada, for example. And some other countries where the growing season might be significantly limited. This is why we are doing this outreach meeting this grassroots meeting and the others around the country to help identify these local climatic problems. Please, many of you comment now but get something to us in writing about your concerns with local conditions, or conditions in your country that the growers there must deal with and how this reflects the reality of what growers marketing to the United States and your country must take considering their climatic conditions, growing seasons, soil needs.

Treated Manure. Natural fertilizers such as composted manure may need to be produced in a manner to reduce the likelihood of introducing microbial hazards. Care should be taken to avoid cross-contamination of fresh

produce from manure that is in the process of being composted or otherwise treated. Don't put your composted heap unsecured on top of a hill where run off will bring it right down to where you are growing your produce. It's to some extent common sense. Likewise improperly treated or uncompleted treated manure may also be a source of contamination of produce.

Composting and other treatments may reduce but may not reduce pathogens in manure. Another place where more research is necessary. Furthermore, it is unknown to what extent pathogens that survive treatment may regrow in composted manure that is stored before use. Another area where additional research is needed. To the extent feasible, grower using treated manure may want to consider some of the recommendations we made for untreated manure, such as those time line -- 40 to 60 days minimum and in some cases it may be 120 days between application and harvesting of the produce for marketing.

Good agricultural practices for handling manure might include securing the manure compost to prevent cross-contamination from run off. As I said those type of unsecured up-slop from the fields growing produce, reaching into the soil and wind spread if it is unsecured.

Another component of the regulation is sanitation and hygiene. We're talking about the fecal-oral route of contamination. Worker health and hygiene plays a critical role in the controls for minimizing microbial contamination of fresh produce. Fecal-oral diseases are the primary microbiological concern here.

Personal Health. Good hygienic practices by all workers are essential in the control of microbial hazards. Infectious disease, ill health with diarrhea and open lesions are a source of microbial contamination and can be transmitted to the produce. Just as we do not want ill workers working in retail foods, restaurants, care should be taken as to their appropriate use in a farm, packing house environment.

The document urges that employees should report to a person in charge any information about their health or activities as they relate to diseases that are transmissible through food. A person in charge should monitor the health of their employees. Individuals with diarrheal disease should not work with produce.

I want to point this out, domestic meeting. This got a great deal concern. Growers in this country feel very reluctant to put in charge of their workers health. We point out that in our retail code and anyone handling food, we make the same recommendations. But perhaps thoughts to be put together to re-craft the document so that it's made clear perhaps, they could do other jobs on certain days. Run the truck where they do not have to lift and come in contact with foods. A lot of the agricultural people are paid by piece work. The workers say, look lot of people a lot of the agricultural people are paid piece work and first that is sent home because they reported illness would be the last day because they need that

paycheck. That is true, but once again people with diarrhea illness should not be touching food. What's the way out of this? Please your comments and thoughts.

All employees involved in harvest and packing and distribution of fresh produce should trained in good hygienic practices. The documents talks about establishing a a training program and the program should include a system to monitor and evaluate compliance with what you trained the workers that they should be doing. The employees should be taught proper hand washing techniques. You can't assume that. The use of sanitation facilities such as on-site latrines and to avoid eliminating wastes outside of these facilities should be encouraged.

Field Sanitation. The proximity and accessibility of facilities to harvest crews we are talking about in all sectors of fresh produce production is important. They must have facilities available, not only in the packing house, but in the field where they are harvesting. Workers should have the opportunity to use facilities when they need to, not only on break. Growers need to ensure that the location of the facilities is not near water source use in irrigation. Don't let what you are trying to do correct a problem in one area lead to contamination of the water source. Facilities should be provided to all employees. Provide adequate hand washing if possible. Toilet facilities should be well supplied and maintained in a sanitary manner.

In cleaning the portable toilets, if possible, it should be done away from the field. You don't want to spill. You don't want something that will result in contaminating your field. Dispose waste through sub-surface septic tanks, if that is available. Drain waste away from the field or collect it in a drainage tank to be correctly disposed of at a remote site.

In harvesting you don't want bring dirt into the packing house. So the document that is guidance encourages that as much dirt and mud be removed from the produce while its still in the field.

Damaged or muddy cartons should be repaired, cleaned or discarded in an effort to reduce possible microbial contamination of fresh produce.

What we are simply trying to say here is control

One thing that you can control is authority for sanitation of the cartons for example that we are harvesting the fresh produce into.

Care should be taken to ensure that produce that is harvested in the field is not contaminated in the process. We recognize that inspectors, buyers, and visitors wash their hands just as we would expect the workers to wash their hands or wear clean disposable gloves before inspecting produce.

Equipment. Both in the field and in the packing house can also contaminate produce. Once again, let's control what we can. We cannot control the soil, we control the fact that we're blowing this in the open air in an open environment. But we can control the sanitary quality of the equipment used in harvesting. A person should be in charged maintaining

the equipment sanitation and making sure that the same truck that hauled manure the day before is not used to bring in the harvest the next day without adequate cleaning. The equipment should be kept as clean as possible. Items such as mud, fuel, tools and so forth should not be carried on harvesting equipment. And where possible remove contaminants daily. We're not asking you to sanitize your equipment, but it should be kept clean to minimize likely additions to microbial loads.

Facility sanitations pretty much the same thing. Here we are talking about packing houses. Out of the fields, you got the harvesting to the packing house. Anything in the process from harvest to processing that makes contact with produce has the potential to contaminate it. Poor sanitation in a packing house can increase the risk of contamination of produce and water supply. And here is where the document recommends that there is already dockets out there. There is already FDA's general good manufacturing practices regulations. And these are regulations for the processing of food. And these went to a very large extent applicable and apply in these, enforced by FDA in a packing house environment.

Once again, equipment such as knives, saws, blades should be inspected for defects on a regular basis and replaced as needed. This is something that you can control. Personnel should use equipment that has contact with produce for caring other materials that might result in contaminating produce. And keep the packing house and cooling facilities clean and sanitary.

Pest Control. Once you are in an enclosed packing house we would expect the same concern for pest control to apply there as it would in any other food processing operation. And it I believe is the only place in regulations where a recommendation is made for increase record keeping and that is a pest control log. You should be maintaining these in a matter free of pests that can result in contamination and we are talking about enclosed facilities.

Final area where we believe in this very broad view universal applicability. Final component that could result in contamination of produce is transportation. Contamination of produce may occur with improper practices or during the handling while unloading and transportation operations. Where ever produce is transported, the sanitation conditions should be evaluated, inspect for any breaks in the chain -- what does that mean? You brought in your crop, you cleaned it, you packed it, you've done the best you can --- don't load it on filthy truck! Don't load it a truck that the day before was chickens and had not been adequately cleaned and sanitized. In most case we do not say -- the document does not generally say sanitized and transported -- but its sort of foolish to unsanitary, unsanitized product into a sanitized container. But the should be clean and appropriate for the use. We must examine the transport facilities.

Cross-contamination from other foods and non-food sources and contaminated surfaces may incur in transport or segregating fresh produce from other food of non-specific sources and pathogens in order to prevent contamination of the produce.

Try to be sure that the truck or other carrier sanitation requirements are met before loading the produce. And talk to the people that transport your product not only when gets picked up at the farm, but throughout the distribution chain so that they are aware of their responsibilities to make sure that your product is as safe as possible when it gets to the growers.

Finally, is a section that really will not result in safer produce but is a section that as public health officials and as industry is likely to be helpful to them. And that is a Positive Lot Identification which is referred to as *Traceback*. Fresh produce as I said before is not a it will never be free of contamination until we find and control mechanisms to subjected it to after harvesting. The Traceback or Positive Lot Identification won't prevent that hazards but it can limit the potential scope of an outbreak, limit the population to risks, lead to possible specific source of growing field at the focal point for an outbreak as opposed to the necessity of perhaps implicating an entire industry. It could lessen the economic burden on operators not responsible for the problem, if it is properly coded and could be identified through to the actual grower associated with the illness outbreak. But we realize this will be more easily implementing for some types of commodities than others. Some types of commodities are marketed in supermarkets in open bins, others are packaged. So something like this might be applicable to those that are packaged in an open bin. A lot of times we lose lot identity but that doesn't mean that a grower shouldn't think about it with in the grower and distribution chain --- here we are talking about the retail market --- shouldn't think about some sort of positive lot identification within the constraints

of their ability. Make sure that the carton going off the farmer's truck is properly identified as best as possible. And the retail distribution thought should be given to keep track of which store is getting what.

Traceback from a public health point of view --- from the point of view of FDA and USDA and CDC and state agencies and foreign governments that are responding to illness outbreak, positive lot identification minimizes the unnecessary expenditure of public health resources. It could very quickly focus in important problems. It will reduce consumer anxiety. It frees the consumer to enjoy fresh fruits and vegetables, not implication of the outbreak. And as we said part of the reason for this initiative is because we, the Federal Government of the United States are encouraging our people to eat and enjoy fresh produce for their health, because it's good for them. It is something they should do as a right choice. So we need you where possible for risk commodities where the distribution channel will allow it, to get a positive -- to think about -- a positive lot identification system and even if it cannot go as far as the consumer unit to think about implementing something along these lines to be the extent possible for you.

The effective traceback with as much detail as possible should be capable to document the source of a product through it. Can find the date of harvest. Can identify the farm or field that it was grown. And chain of custody from farm to receiver.

As we talk about traceback I want to give just story that -- those of you who have been following me around to the grassroots meetings will have to hear this one more time.

You heard a little bit today about the incident of *Hepatitis A* in processed strawberries. These were processed frozen strawberries. And here at FDA and CDC never positively identified where the problem occurred. Did it occur in growing fields in Mexico? Did it occur in the US plant that processed the strawberries? Did it occur from the contamination that resulted in illness at

result food service? We were never able to identify it to our satisfaction and made that quite clear in our press releases. But what got out in the press was strawberries from Mexico processed at this plant in California. The week that story was breaking, my normal job as Director of the Division of Import Operations at FDA, one thing that we, I guess solely wanted and wasn't able to respond to the call until later in the day because of other matters on my desk, and I how a job "please excuse me I've been having a bad day and could we get to your call now". It initially started as silence on the other end of the line and then a man starts laughing. And he says, "Tom I am probably the biggest importer of strawberries from Mexico in the United States and you think right now you're having bad day." What that tells you, that the American consumer in instances like this don't fear we don't know where the problem is coming from. All they fear are strawberries. They don't even hear strawberries from Mexico. This effected the domestic strawberry industry tremendously. That's why the traceback system should be or positive lot identification

systems to the extent that it is feasible with product you are marketing to the US something that is not only is of benefit to the American consumer and public health officials it is a distinct benefit to the industry because it may help us focus, identify and determine the source of the problem quicker and get it off the news a lot quicker, also.

That's it and I think it's just questions.

FINAL QUESTION & ANSWER SESSION

Catherine Carnevale:

I think all of you today for Tom's presentation and see that, as we say in FDA, it is not rocket science. All of this comes down to as what is feasible. I think we can see all of these slides that Tom was putting up here and what will as guides regarding a check list. As he ended up the program for improvement in the food safety area.

Since we do not have any persons who are desiring to have presentations what we will do now is simply allow the remainder of the time for questions based on what Tom has just said and any remaining questions that you may have on some of the topics that were presented this morning based on Tom's and my ability to respond to those questions because not all of the presenters are here. And then we will have just a couple of closing remarks and that will be the end.

Tom Gardine:

I think to remind people that even if it is just a concern or comment, here is your opportunity to get it on the record. If you are a consumer group maybe you are dissatisfied with the extent the document goes. If you are representing a foreign government whose country ship to the US, you may have concerns regarding this as actually a non-tariff trade barrier. If you

are with domestic industry, perhaps there are additional comments to give then. But, please just as the guidance document is, we think very much a common sense approach to minimize microbial risk in fresh produce, and as Cathy said it is not brain science by any means, your questions and comments do not have to be brain science but they can adequately reflect what is making you uncomfortable for us to consider in revising the document.

Elizabeth Dahl, CSPI:

Q. I am being urged to be dissatisfied, and I guess I better chance again. The comment that I have to make involves question, isn't direct criticism of the document, but the concern that we have with the increasing number E. coli 157.H7 outbreaks from produce including domestic, this ongoing discussion about what exactly is the percentage of outbreaks, say to fruits and vegetables. Well when you see such a deadly pathogen that specifically has been linked and suddenly showing up in fruits and vegetables and we see a steady increase of deaths (not audible) pathogens, I think it is time to get concern. So I really hope that will be addressed by this document.

And specifically, I would like to give you thoughts on how the traceback position would help to facilitate identify the course of those outbreaks and some other pathogens, not specifically those. And will it turn up more that we haven't yet been identifying?

A. (Tom Gardine) Traceback mechanisms are very, very valuable in terms of our ability, depending on the detail that the lot identification gets down to -- to get to an actual field or grower associated with the problem, in terms of trying to identify the cause of an outbreak of E. coli 0157.H7 that might be associated with produce, fresh produce, it does us very little good if we could only trace the source back to the state of Michigan. But if we can get to a grower and analyze that operations specific practices we could learn perhaps what caused the outbreak and through education and outreach to other growers not associated with that outbreak avoid that problem in the future. It is an ability to go back to the actual source and be able to investigate the conditions that resulted in the problem. That is how traceback/positive lot identification may avoid problems in the future but as you all know a coding traceback system in the midst of a food illness outbreak makes it much easier for industry and government to rapidly remove that product from commerce. We agree there is a concern since we cannot identify the actual product causing the outbreak in terms of a specific shipment or area of growth. You spend a lot of time tracing backdown before you can give adequate information to local companies which leads to the consumer and get cooperation of the distributor to remove the products from the market. So not only would positive lot identification help in response to an immediate illness outbreak but it would help us in our investigation to see what caused it and how growers can prevent in the future.

(unidentified attendee)

Q. Thing that bothered me just from the recent discussion was that you earlier that there not tracebacks to anything from the Michigan incident. You couldn't tell whether it was the food handlers, the processing plant or the grower. And then it sounds like you are tracing back to the grower. I think it needs to be reiterated that was no proof found at any level.

A. (Tom Gardine) Yes, but none the less having the traceback mechanism once an illness broke out we would know where to focus our attention, and our analysis, and we would be able perhaps to learn quicker that we cannot identify what cause the outbreak. Rather than have all strawberries and then all from Mexico implicated in the consumers mind.

Tom Gardine:

I again repeat, that the devil is indeed in the detail. Read the document very, very closely. We did not try to skim over what we thought might be controversial, but what we recognize as potentially controversial may not always include all of your concerns. I would urge you to read the document carefully and make a determination as whether you want to submit formal written comments. Those of you who came while we still had a supply, should have received the Federal Register for Friday, November 28, 1997, page 63349. In that document it points out that written comments should be submitted by December 19, 1997. Those

of you who do not have the document may want to write down the following docket number and address. It is Docket No. 97N-0451 and you are to submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12430 Parklawn Drive, Room 1-23, Rockville, MD 20857.

Dr. Terry Troxell, Director of the Division of Programs and Enforcement Policy, FDA:

While the deadline is December 19th there should be plenty of time even if you get the comments by the end of December and even into the beginning of January. We encourage to give us as many comments can early in the process here and it will as previously stated a notice later with putting this out for comment later on, but don't worry about the December 19th deadline it should be fine to get them later. We will use as many in the process as we can.

Catherine Carnevale:

What is the plan as to actually publishing the Guidelines?

Tom Gardine:

- A. Guidelines currently are publication of the draft guidance for further comment is planned for the earliest, late February or more likely early March 1998. It will be a publication in the Federal Register of a draft document and there will be a 45-day comment period after which we would review and evaluate the second set of

comments. And frankly then, make a determination whether more public meetings may be necessary.

Larry Waterfield, Packer Newspaper:

Q. I suppose I have to deal in a hypothetical at this point. Suppose a country "A" doesn't meet the standards of the United States, but a group of its growers say that we follow these guidelines and we do meet the standards. What happens then?

A. (Tom Gardine) The question is, what if country "A" doesn't meet the guidance but there is a group of growers in the country that do. Number one, let me repeat what said from kibitzing from the side and this morning panel, this is guidance. It is guidance equally for domestic growers as it is for foreign suppliers so it is unlikely that this guidance will be used as a mechanism to determine not meeting US standards. What it is likely to be used as is a mechanism for reviewing evaluations of country systems to determine where technical assistance and outreach would be most appropriate. But your question goes beyond that. If this legislation passes, what happens if for whatever reason the Food and Drug Administration, I don't know if the legislation says the Secretary of the Department of Health and Human Services or whether the Food and Drug Administration makes, the Secretary

makes the determination that country "A" product does not meet the standards of the US, but there are some shippers in that country or manufactures who do. Currently in my real job as Director of Division of Import Operations, we publish what we call

these are guidance for field offices. We have entire countries under a program that we call About Physical Examination, requiring their product to be held up at the border pending submission of evidence from them that the product is not violating for the reason concern. This is not forever and even if we put entire country under this system, individual firms who develop a good record can and are being exempted. And I would expect that this new statute would work in a very similar manner.

Peggy Rochette, NFPA:

Q. I am somewhat confused about the outlook for what I --- the second half of this document for good manufacturing practices, refers to it in an appendix here.

Tom Gardine:

A. I believe we are simply referring you to the already published CFR 110.10.

Bill Hewitt, Canadian Embassy:

Q. (not audible) early in the new year that you will have to publish a draft guide for further comments. This is going to be

a guide and not regulations, is this going to be something that you can then even once published continue to discuss openly with the public or is it going (attendees close to recording site coughing -- not audible)

A. (Tom Gardine) I like to open this up perhaps to the floor and Dr. Troxell, but my personal opinion, and this is an opinion, because we have not gotten the first out -- we're not yet ready to talk about how we are going to deal with the second or third iteration. But this is a document as research comes along closing some of the holes. I fully expect we are going to have to revisit this in 2 or 3 years. And I fully do expect we can have an going open dialog with consumers, industry groups, academia, and the states about how this document can be implemented. Terry, get up and disagree.

A. (Terry Troxell) Under our new guidance practices we would put out something as significant as this for comments before finalize it. Even under the comment and procedure, we always are available to listen to people, although in this case I would imagine we would probably open to more discussion in the process to come up with final document which would be somewhere in the middle of the year. I think the whole point here is to have open discussion and find out what will work.

Catherine Carnevale:

I wasn't sure that you concerned about the confidentiality of the process because I don't it would be applicable here. Just like we have done, we're currently operating under a draft guidance when it comes to equivalents. There was virtually no secrets here. And we don't have the requirements to keep these type of things confidential, but we do have requirements to solicit comments. So we are doing that. We've come out with draft guidance and then final guidance. The final guidance again, if there is something significant that hasn't that would cause us to a final guidance we can go ahead and (not audible).

Tom Gardine:

There was a question this morning from a gentleman from Mexico, has that been answered to your satisfaction or would you care to repeat it?

Francisco Gurria, from the Department of Agriculture for Mexico:

Q. How are you going to deal with guidance for good agricultural practices and good manufacturing practices of produce that you the consumer do not produce in this country?

A. (Tom Gardine) I think that was already answered where we indicated that we believe that this broad scope document in attempting to address as close to universal sectors for microbial contamination of produce, we think it would apply to something that indeed, that the concerns we raised

here would also be concerns for produce that we don't grow in this country. And many of the things that we say here would be very applicable.

Jill Hollingsworth, Food Marketing Institute:

Q. One of the things that these guidelines (not audible) something along the FDA Food Code, and I would your thoughts on what would be the possibilities of even assuming the published and made available throughout the nation for producers and state organizations to look at would you some how --- could it someday become (not audible) I think the distribute guidelines and (not audible) at the same time you have this international legislation going, I think you made a very difficult situation in trying to into two. That the guidelines in fact are not going to be the end of thing (not audible)

A. (Tom Gardine) First of all about my use of the work "regulation" I think I have a mental block on that. The draft that has been traveling around -- I just been told, be careful about that so often, I just being contrary by nature I subconsciously slip in. Please do not read anything into my inappropriate use of that word. Can this become regulation in the future? None of us can predict the future but I can tell you unequivocally that at the moment there is planning for time line

concepts of doing that on the part of FDA. But no one every says never. One of the other things by the way that perhaps people would want to comment, it's very interesting that this question came from the Food Marketing Institute, and that is well Federal Government publishes it as a guideline but our producers in an attempt to avoid liability then contractual requirement so in effect it is not a guideline. So, that is one concern that has been raised recently at the two domestic grassroots that I have attended. It is something perhaps may want to comment on here as a concern, or comment on in writing later. And as for whether this is something that state agencies would adopt as their regulation, it is good guidance we believe and we believe there will be better guidance when the final document is published. I do not know how or if, you know that certainly is not the game plan being considered, turn this is to something like the Food Codes. But I must admit I do not know if we could prevent an individual state from adopting it.

Terry Troxell:

- A. I say the reason this is guidance because there so many research gaps it's not ready to become regulation. And I say that is going to be case for the foreseeable future. There is so much work to be done. To pin point the exact (not audible due to area noise) so on, to link the practices that are clearly associated with outbreaks.

Tom Gardine:

- A. And Terry, I think what, from our feed back from the states have indicated they are aware of these gaps also. So we doubt very much there will be a rush on the part of state agencies to turn these into regulations, their regulations..

Terry Troxell:

- A. Also the Food Code specific provisions in there for recommendations to the state to incorporate in their state statute on details and research. And again we are not, the guidance here is not of the type where you could incorporate many of these provisions specifically into state law. It would be unlikely for that to happen.

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Clearly our states do have a variety of laws on water criteria within there own states. And I don't know if this was emphasized before then, that this guidance is not intended to clean up any state or local laws. So there are things already in effect and safe.

Tom Gardine:

- A. I would like to just build on something that Terry said, the nature of this document is one that I think would make it unlikely or viable for a state to immediately adopt as a law or regulation. One of the good comments we received at the grassroots meetings held earlier last week that I attended, was the way the document was formatted. People in the

audience, and I do not disagree with them, viewed it and described it very favorably as a self assessment document for a grower who would then take appropriate steps depending on his agricultural needs and resources to address those defects as a grower identifies in his operation. That is not the way regulation is normally written.

Catherine Carnevale:

- A. And Jill with regards to your comment. You actually asked a lot of questions. You are talking separating this legislation from the guidance, and maybe that was kind of artificial separation (not audible) prevail in the end. My feeling is that the legislation, the amendment is intended to apply to all foods and it is something that basically giving another way to regulate foods that are imported based on the way those foods are produced. As far as assessing how products are meeting the US level of attention, that is not an easy thing and I don't want to say to anybody here that equivalent with any particular country, level of protection is an easy process is not. Even defining level of protection is not going to be an easy process across the board. But certainly guidance comes into play when you are describing a country's level of protection. And use guidance throughout the FDA in most areas. Guidance for food manufacturing approval. Guidance for many different things. This is another example of our using guidance. So, I'm not looking at this as something that other countries may take as being mandatory for them but may not be mandatory

but only guidance for the people within the US. We are looking at this to be guidance for the produce industry whatever the origin is.

Terry Troxell:

A. Let me make one comment on that angle. To me, a large extent of what they are saying here is a shift from end product trying to detect the problem to moving that to prevention. Let's go back to the source of where our problems come from rather than at the end, food establishments, such as the meat and poultry has some rules. In these case, we are talking about guidance and how to prevent the problems working with the industry to create the best kinds of guidance to do was is doable to prevent the problems. And the legislation also move , so that it's not only testing product that comes in to see if can detect one of those needles in a haystack -- of problem. And let see if the practices are appropriate to that so not produced under unsanitary conditions that could cause problems.

Patrick Atey, United Fresh Fruits and Vegetables Association:

Q. I've got a general question. What do you see as your outlook on how to legislation? Looking at H.R. 3052 (not audible)

Catherine Carnevale:

A. To be honest with you, I don't think we have the people here that can answer that question. So, I am just going to have say that we normally

support this. I mean this something learning about. We put together in conjunction with a number of other agencies including us and trade agencies. We mention this morning. It has strong support from all of the agencies behind it. And so we are planning to go through . And I can't say comments further than that.

Any thing else?

Okay, I guess with that I would like to thank everyone here especially those who have been here since the early morning for sticking it out for the entire day. And we appreciate all of the input we have received today. And please, if you have further comments we want them. We want this to be practical and workable. Thank you again for coming.