

Louis J. Carson

Good morning. Welcome to the first of three public meetings that we will be holding that the Food and Drug Administration, the Department of Agriculture and the Centers for Disease Control as well as our state counterparts. And **hopefully** you picked up materials as you came in the door. I just want to mention what you should have in front of you as we go through the program today. Each one of you should have an agenda, as well as materials that we've provided, which is a summary of the guide, the guide itself and other information associated with the guide.

Louis J. Carson

Okay, my name is Lou Carson; I am the Deputy Director of the Food Safety Initiative Staff here at the Center for Food Safety and Applied Nutrition within FDA. And at the table, we have a number of speakers who are going to be welcoming you here to this first public meeting. Before I turn over the mic to **them**, I'd like to go through a few housekeeping chores. We will be meeting this morning until around **noon**, we will break then for lunch and then this **afternoon**, we will have a more in depth discussion of the guide. This morning, we would like to bring everybody up to speed as to where we are in the process and the development of the good agricultural practices. And then, this afternoon go into much more depth about those and to seek your input. These **public** meetings are for us to learn from the public, the best way to proceed and should be within the guide. And, we need for you to have a very **integral** role as we go forward with these three public meetings. Today, we are **meeting** here in Washington, DC; on Thursday, we will be in Miami, FL; and **next week**, we'll be in San Diego. All three meetings are to allow a broad **cross-section** of

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consumers, industry, state and local governments to participate in the development of the good agricultural practices. We also have a translated version of the guide. If you are interested, a Spanish version is at the table as you came in and you can ask for it. We hope to have a French version in a couple of weeks. We are also transcribing the public meetings and we ask that each person who wishes to ask a question or to offer comments, would go to the microphone and there's a microphone in the back of the room so that the transcription service can capture that information and so that would be part of our record. When you get up and ask a question or make a comment, if you would introduce yourself and your affiliation so we can have that as part of the record, we'd appreciate it.

Secondly, if anyone would like to make a public statement, as we have time hereon the agenda. Currently, we have one person who has asked to make a public statement. We ask that you approach Ms. Naomi Kawin here and she will make arrangements so that we can orderly ask people to come up to the microphone and make your public statement at the appropriate time on the agenda. We do have time for those statements and if you wish to make one, we'll be glad to hear from you. For those of you, again, on the housekeeping issues, just outside the door on the left are the restrooms. Beyond the elevators on the right-hand side is the cafeteria and that will be the most convenient place for the lunch time break. We want to make sure that these public meetings areas open and congenial and as informative as possible. And to make that happen, we would like these to be an informal session where we have good give and take and good open discussion. So, we would like to make these as informal as possible, but again with the number of people, we will try and see your hand for a question or ask you to go to a mic so that everyone may hear the question. We may also have to repeat questions just so the whole audience has an opportunity to hear what you have to say either as a question or a comment. Our first speaker is Mr. Joseph Levitt. He is the Director for the Center of Food Safety and Applied Nutrition here at the Food and Drug Administration. Mr. Levitt directs a staff devoted to the safety and nutrition of quality and labeling of foods and food

products. And, we also conduct research and develop regulations in association with those programs. To that end, the Center for Food Safety and FDA along with our colleagues at USDA, Centers for Disease Control is the lead administrative agency putting forward the good agricultural practices which we are here today to discuss. And, I'd like to introduce Mr. Levitt.

Joseph A. Levitt

Thank you very much. Let me extend my welcome to everybody here today. And for not only coming here today, but participating in this process. I think everybody here knows certainly by now that the issue of foodborne illness has really, you know, risen to the level of (inaudible) imported. The administration has made it a major priority. And we at the FDA are really making a significant shift much more towards prevention, preventing microbial hazards in the first place and less focus proportionately on reacting afterwards. We really feel that prevention is the key and we are looking at each step in the food processing chain. Literally from farm to table at ways we can take prevention steps and get prevention techniques put into place. I think everybody here also understands that the number and extent of foodborne outbreaks, illness outbreaks, over the last couple of years associated with fresh produce really galvanized us and put special focus on this area. And, last of Fall, we developed a process and started developing the guide that we're here talking about today. I want you to know, we at the FDA, we recognize that many in the fresh produce community are not historically used to working with the FDA. And so, we have tried to go to considerable lengths to reach out to the community and be sure that you're very much a part of this process. We put together an early discussion draft of this guide last Fall, held a series of grassroots meetings around the country. We tried to not just get feedback, but to listen to the feedback and put together internal working groups that included folks from the states as well as folks from the federal government, Department of Agriculture to really try and set what the issues are. We know that this

kind of guidance, this kind of steps, you know, will not be effectively implemented if they're not viewed as important and useful to the growing community as we try to get that in. We also, I think everybody understands that the ultimate goal here is to enhance consumer protection. And we need these steps to be meaningful as well as reliable and productive steps. I want to emphasize that this is a guidance document. It is not a regulation. We feel that it is an important step. We feel it will be **helpful**. And it mirrors the many respects for a lot of what is being done here in the industry itself But, it is not a regulation that carries with it that force of law that comes with a **regulation**, but it, we do think it's a significant step to something that can help consumers to a material degree. I also want to emphasize particularly at this meeting that this guide would have equal applicability regardless of the source of produce. Whether it's grown in this country or whether it's grown abroad. We are looking at produce from a consumer point of view. And a consumer wants safety, regardless of the source of its product. And so, we are looking at achieving the same level of protection around the globe for foods that are consumed in this country whether they're grown within this country, or in another country. That is what we're trying to achieve. We very much want your comments, want your continued input. **Our** impression so far, and you all correct us, or **reinforce** this, is that the level and type of comment that we're getting at this stage has showed that the early steps have been worth while. They were, I would say a much higher level of concern out in the grower community, were during last Fall, even last winter when I took this job. I think that the publication of this guide while I am sure that there are additional steps we need to take and things we need to hear. At least I have a feeling that we are closer to the same wavelength and kind of see the light at the end of the tunnel. We very much are committed to getting a final guide in place by the end of our fiscal year, the first of October. And, we'll be holding to the end of the comment period as it was identified in the document. So, please consider the period for public comment **info**, but we also need to draw a close to that and we need to then try and bring this process to a close. With

that, I think I will turn it back over. Again, thank you for coming. Most importantly, the American consumer, thank you for coming because I think collaborated, really, we can put in place together the kind of prevention steps that really will bring **meaningful** reduction to the microbial hazards in the fresh produce supply. **Again**, thank you very much. Lou, I'll turn it back to you.

Louis J. Carson

Thank you Joe. As I mentioned in my opening remarks, and as Joe's mentioned, this has been an interactive process with our colleagues at the federal level and at the state and local level. And next, I'd like to introduce Mary Ann Keeffe, the Deputy Administrator International Cooperation, Foreign Agriculture Service, US Department of Agriculture. International Cooperation at the Foreign Ag directs activities promoting and enhancing USDA's involvement in cooperation and development activities worldwide. For the benefit of the US and cooperating countries, Foreign Agriculture Service provides those linkages to world resources, new technologies and international organizations. Ms. Keeffe...

Mary Ann Keeffe

Thank you very much, Lou. I'm very pleased to have the opportunity to speak with you today. Indeed, USDA and FDA have had a very long and **successful** partnership and it's a pleasure to discuss with you USDA's commitment to President Clinton's initiative to ensure the safety of **fresh fruits** and vegetables. You may be wondering why Foreign Agricultural Service, so let me take just a couple minutes to tell you a little bit about our operation in terms of this issue. We, at 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 both by, helping US farmers export their food products, and by cooperating with foreign **farmers**, food businesses and governments to improve global

food production, processing and distribution. The Foreign Agricultural Service also serves as an important liaison to facilitate linkages with other US Department of Agriculture agencies on key international issues including food safety. Foreign Agricultural Services international liaison role spans the spectrum of USDA responsibilities, including regulatory issues with agencies such as: Food Safety and Inspection Service. The important research agenda, including: The Agricultural Research Service. And marketing with agencies such as: The Agricultural Marketing Service. Foreign Agricultural Service has developed an effective partnership with the agricultural private sector throughout the world. For example, since the mid 1980's, Foreign Agricultural Service has worked closely with the produce industries in the United States, Latin America, the Caribbean and Asia to promote concepts of quality grades and standards, post harvest treatment, improved packaging and distribution for traded fresh fruits and vegetables. That experience will be invaluable in working with those industries on food safety issues. Foreign Agricultural Service has a number of ongoing activities to address international aspects of overall food safety and food quality. In cooperation with other US agencies, FAS is implementing international food safety related programs under four general areas of cooperation. The first is training and technical assistance. Of which, a good example is the **Cochran** Fellowship Program. I am sure, known by many of you. This is funded by USDA appropriations and provides short-term training in the United States for international agriculturists. Over the past three years, the **Cochran** program has provided food safety, and sanitary and **phytosanitary** training to over a hundred and twenty international participants from thirty-five countries. The second area is data management. Where FAS is working cooperatively with our Animal Plant Health Inspection Service, **AFIS**; to develop a database to track international visitors, particularly those visitors who are interested in sanitary and **phytosanitary** issues, including food safety. Currently, a series of FDS training modules are being developed by AFIS and FAS staff for use with international visitors and for distance learning. The third area is

international cooperative research. Where FAS administers numerous cooperative research programs in the area of food safety, utilizing appropriated finding, foreign currency and funds provided by the State Department. These research projects are being carried out in over twenty countries worldwide. And finally, the fourth area of FAS involvement is with international organizations. Foreign Agricultural Service is facilitating harmonization of sanitary and **phytosanitary** standards by working with official multi-lateral standard setting bodies; such as the CODEX and the International Plant Protection Convention of FAO. These initiatives help to ensure that imported products are safe for US consumers, that our international trading partners understand the US 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** under agreements with other US agencies, such as the Agency for International Development and the State Department, or with international organizations such as the FAO. 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. 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 and the world will be better for safe food. Of course it is essential that all food safety regulations including those being developed for fruit and vegetables are based on scientific principals and consistent with our international obligations under the World Trade Organization and the North American Free Trade Agreement. We intend to continue to dialogue established at earlier briefings and public meetings since the President's initial directive on the Safety of Imported Foods in October of '97. Today's meetings is another occasion for insuring the input of our trading partners into the guidance on good agriculture and manufacturing practices for both domestic and imported produce. We look forward in particular to hearing your comments on the good

agricultural practices guidance document. 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. The key will be to continue to develop effective partnerships among all interested parties, to facilitate cooperation and bring sufficient resources to ensure the safety of domestic and imported food. Thank you very much for your participation, I look forward to spending the morning with you and I have several staff in attendance who are going to be part of the entire day. Thank you.

Louis J. Carson

Thank you, Mary Ann. Next, we have Dr. Michelle Smith who will bring us up to date on the development process of the guide. As it's already been mentioned, we have pursued, to what extent we can, a very **collegial** and collaborative process **with**, again, the federal and state governments, as well as holding a number of public meetings starting last Fall. And, Dr. Smith will bring us up to date on the guidance for industry, the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. Dr. Smith is a member of the Center for Food Safety and Applied Nutrition's food safety initiative staff. She is one of the authors of "The Guide" and she is very knowledgeable as a scientist in the hazards which microbes may cause to fresh produce. Dr. Smith...

Dr. Michelle A. Smith

Thank you Lou, and good morning ladies and gentlemen. It is a pleasure to be here on such a **beautiful** day and especially in that context. So, I thank you all for your participation in today's meeting. Wouldn't be a bad day to be out playing golf, if you're into that. Now, as most of you are aware, on April 13th, FDA released for public comment, a guidance document, entitled "Guide to **Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables**". I'll refer to this document as "The Guide" as a kind of shorthand. "The Guide" covers good agriculture and good manufacturing

practices most likely to reduce the risk of microbial contamination of **fresh** produce in the fields and packing house environment. Shortly, Lou Carson will look at the relevant aspects of the larger food safety initiatives, the produce and imported food safety initiatives and talk a bit about how all these pieces fit together. My job this morning is to introduce the proposed guidance document and explain a little bit about the process that we follow to arrive at this point and where we expect to go from here. One of the reasons that I personally think that it's important that everyone understand the process is just to help involve people **further**, to let them know that comments to us are valuable. And to give you more of a feel about ways that you can participate in this process as we proceed. I maybe a little bit biased, but I think that the guidance document has come quite a long way from the working drafts that we released in November of last year. Later this **afternoon**, in our section by section review of "The Guide", we're hoping to get the kinds of feedback that will help us start taking the next step towards the final document. Next slide please... One of the questions that I've heard when we've gone out for site visits and other meetings is, "why produce?, why now?". Clearly the incidents of foodborne illness linked with fresh produce is relatively low, however it's come to our attention that the incidents of foodborne illness linked to produce is increasing relative to other foods. Now this may be due in part to the fact that consumption of fresh produce is increasing. Public health agencies are encouraging the increased consumption of produce and consumers are listening. They're getting the message. There's nothing that we want any of our current actions to do to hamper that message getting across. Some of the other factors involved in this increase may be changing distribution patterns in a **global** supply that make **fresh** produce available on a nearly year-round basis. Other changes are consumer demands driving new technologies and new products, things like fresh cut. Finally, an additional challenge we face is a changing population. People, the number of people that are especially at risk, such as the aging and people with weakened immune systems is increasing. So these are all concerns that we have that are helping to drive this initiative.

Next slide.. .Now, a few points about the guidance document itself. The proposed guide is a broad-scope document addressing general practices common to the growing, harvesting and packing of most **fresh** produce in all regions of the US and abroad. For our purposes, fresh produce means raw, unprocessed, or minimally processed fruits and vegetables, including fresh cut. “The Guide” is voluntary as a number of people have said before and we expect to stress throughout the day. It does not impose any new requirements for domestic or imported produce. “The Guide” focuses on rich production, not elimination. How might “The Guide” best be used? “The Guide” is intended to increase awareness of the potential sources of microbial contamination in field and packinghouse environments. And to provide suggestions for practices that are likely to minimize these hazards. “The Guide” represents generally accepted recommendations based on current science. The current scientific knowledge of FDA and USDA with input from experts and a host of federal and state agencies. We believe that “The Guide” will be most effective when growers and packers apply the principles in this document to their individual operations and fit them with the needs that they have. The proposed guidance document sets out general principles, a list of general principles common to **successful** food safety programs. Two of these principles are listed on the slide. The first, very importantly, is that prevention of food safety hazards is preferred over correction once contamination has occurred. Another important principle is that there needs to be a system established for accountability. No matter how good your plan may be, if there aren’t steps in place to make sure that the plan is followed, then the value of the plan diminishes greatly. One of the first things that became clear to us in drafting the guidance document and in other aspects of this initiative was how much we did not know. For some people, that’s hard to admit. But, I think that it gets everybody off to the right start if you’re up front about that. For example, no one knows how much contamination of fresh produce occurs at the **farm**, or at the packing facility environment. On the other hand, there is sufficient, current, sound science and knowledge of the pathways by which

fresh produce might become contaminated. To set out recommendations which if followed, may help minimize the risk of microbial contamination. This slide lists the areas of potential hazards that we've covered in the guidance document. Including, water, manure and biosolids, worker health and hygiene, field and facility sanitation and transportation. Now, a little bit about the development process. When we began to draft the early drafts of the guidance document in October of last year; the place that we started and one of the first things we did was to review existing guidance documents. Guidance documents developed by industry associations, universities, state departments of health and agriculture. We relied very heavily on those guidance documents to develop science-safe guidelines that could be applied uniformly across commodities and across regions. The early drafts of the document were reviewed by a broad range of technical experts in a host of federal and state agencies. And then subsequently consistent with FDA's good guidance practices policy FDA and USDA sought public input at a series of public meetings. This slide shows some of the avenues for seeking public input. Our first meeting was in November of last year to discuss the concepts in "The Guide". Subsequently, we worked with the National Advisory Committee for Microbiological Criteria for Food, Produce Subcommittee to obtain additional feedback on this concept. November 25th, we released a working draft of the guidance document. We then took this guidance document out on the road for a series of six regional meetings and an international meeting that was held here in Washington. Comments at these meetings from consumer representatives and the agricultural community were captured in hundreds of pages of transcripts just as we're capturing the comments of today's meeting in a transcript. We also received fifty-five letters from growers, packers, industry associations, academia, state agencies, containing comments on the working draft. Comments at the public meetings help shape the next steps for developing the guide. For example, one of the things that came up repeatedly at the public meetings was the importance of the agricultural community and their relationships with other federal agencies and state and

local agencies. Based on those comments, FDA invited in a group of people from other federal agencies and state departments of agriculture and public health to roll up their sleeves and really jump into the transcripts and the letters, pulling out the issue areas and then participating in round table discussions of how the guidance document might best be revised. What did the comments have to say to us? Well most of the comments agreed with the goal of improving food safety and the general concepts that were expressed in the guidance document. Some comments did express concerns about specific GAP's and GMP's and I'll cover some of these concerns in a little more detail in a minute. Some comments offered specific suggestions for improving "The Guide". Right now, I'll say thanks for those comments, those are the most useful kind of comments. If anyone has an idea about how to take those the next step, we're certainly open to that. And we'll do everything in our power to listen to what you have to say. A number of comments did address issue areas that were outside the of scope of the guidance document. By outside the scope, I mean that the comments weren't dealing with specific recommended practices, they were dealing more with the process of developing the guidance document or some of the trade issues that might be involved. We did feel that these comments were very important and we wanted to indicate that they have been taken into consideration. At least in some of the more subtle changes that we made in "The Guide". But in addition to that, we tried to address the comments in a section, we've called an addendum. And that's attached to the proposed guidance document, just to help clarify issue areas where people did have questions. Based on comments and with the help of our extended review team, we have made a significant number of changes to "The Guide". The first type of change is pretty much tone and format, trying to be more responsive to people's concerns to make the guidance document more user friendly. And we're certainly open to any suggestions anyone has about taking them further. We've increased the emphasis on the health benefits of increased consumption of fresh produce. We've recognized the efforts of industries, states and universities to promote food safety programs. And the leadership

role that these groups have placed in reducing microbial hazards for fresh produce. With the help of our team of technical experts, we've examined each of the recommendations in "The Guide" to ensure that the recommendations are based on generally accepted scientific knowledge. As I mentioned earlier, there were some comments on specific recommendations in "The Guide" and I'm going to cover a few just as an example of what comments had to say and how "The Guide" has been revised. With respect to the specific recommendations, this afternoon's working session is meant to get into this in a little bit more detail. Having said that, in the area of agricultural water, many comments questioned a recommendation for microbial testing of agricultural waters, such as water used for irrigation. When there are currently no established action levels, or corrective actions for irrigation water. In response to these comments, we've revised the proposed guide to recognize the difficulties and limitations of microbial testing for agricultural water and we've **shifted** our focus to good agricultural practices for maintaining water quality. We also refer growers to local water quality experts for additional **information** and advice more specific to their operation and region. In the working draft, we noted that submerging from produce and colder waters, may result in the internalization of water and if pathogens are present, pathogens (inaudible) also. This finding that pathogens maybe internalized in produce particularly in produce with airspace has lead to the recommendation that some produce items to be washed in water that's ten degrees warmer than the produce and possibly even that the water by hydrochlorinated. Many comments on the working draft were concerns about this recommendation primarily on the basis that they thought that it would conflict with an over-riding need to remove field heat from the produce. What we've done as a proposed guide is we've narrowed the recommendation to cover tomatoes, which are **known** to be susceptible to water uptake. As additional information on other crops becomes **available**, this recommendation may be updated. But right now, it's limited to tomatoes with **the caution** that more maybe known in the **future**. Recent site visits have shown that **tomato packinghouse** operations are

carefully monitoring water temperatures. So, we feel that this recommendation right now is consistent with current good manufacturing practices in industry and has a solid (inaudible). In the manure section, a number of comments question the recommendation for at least sixty to one hundred and twenty day interval between the application of manure and harvest of fresh produce. Some comments noted that the growing season in some regions of the country is less than one hundred and twenty days. The one hundred and twenty day recommendation was based on anecdotal evidence presented to the agency. The sixty day minimum is from the National Organic Standard Board recommendation for use of manure on organic crops. We have revised the proposed guide to continue to reference the sixty day minimum. We've deleted reference to one hundred and twenty days. And we state that no one knows for sure how long pathogens may survive in manure or in the field. Many comments on the working **draft** express concerns about the difficulty of wild animal control. A number of comments noted that animal control measures might **conflict** with local or state animal protection regulations. In response to these comments, we've revised "The Guide" to take into account the difficulties that are involved and the need for growers to comply with other recommendations. However, we continue to caution that wild animals maybe a significant source of human pathogens and we urge people to do what they can for their own particular situation. In the worker health **area**, a number of comments stated that monitoring employee health is impractical and **infringes** on employee rights. The proposed guide recommends that operators do be aware of symptoms of infectious disease with employees that handle fresh produce. And to help operators do this, we've cited the FDA food code, which contains a section to help people become **familiar** with the signs and symptoms of infectious diseases. Glove use was also an area that generated a lot of comments. Comments question the recommendation that workers and visitors wear gloves. And they noted a number of situations where specific crops have their own individual requirements either for or against the use of gloves. The proposed guidance

document now says that gloves may be an important practice in conjunction with proper hand washing techniques. But that in no case should gloves serve as a vehicle for spreading contamination. Finally, in the **traceback** section, a number of comments express concern about the cost and paperwork of **traceback** systems. Some of the comments also maintain that operators have little control over produce when it leaves the **farm** or packing operation. This section now contains an expanded discussion talking about both the economic and public health benefits of an effective **traceback** system. And, on recent site visits, many of the operations that we saw employed lot numbering or other systems that would be very **useful** in assisting traceback operations. While some of these systems may have been initiated for other reasons, such as keeping track of payment to a **farm** or a harvester, they do show a lot of promise as potentially being part of an improved **traceback**. Where do we expect to go from here? We're now in a seventy-five day comment period on the proposed guide. The comment period ends June 29th. While we're seeking input and comments, we're having a series of public meetings. This is the first of those public meetings. We also intend to continue site visits to **farms** and packinghouses. When I say we, a group of people **from** FDA and USDA are going out to a number of locations to observe current practices and seek additional feedback. We expect to begin comment review and revisions to the guide in July and August along with the expanded technical review team looking at the document. With the final guide publishing by October 1998. We expect a lot of the comment review and revision to follow a similar track as before with considerable input from other federal and state agencies. As additional information becomes available, that October 1998 final guide may be revised again. So in essence, we expect it to be a living document. And I am open now to any questions.

Louis J. Carson

At this point and time, I'd like to offer an opportunity for, from the audience to ask any questions of the three opening remarks, of the three people up front. Are there any questions at this point and time? We do plan to go into the guide in much greater detail later. Yes...

Carolyn Smith deWaal

Thank you. I'm Carolyn Smith deWaal, the Director of Food Safety for CSPI. And I unfortunately won't be able to be with you most of today. Elizabeth Dahl is here from my office. But I did have one question for clarification. The first sentence in the guidebook says, "American consumers enjoy one of the safest food supplies in the world". I notice there's no citation to that and I'm interested in the basis of that statement. I'd also like to recommend that given that this guidance document, is intended not only for domestic growers, but also for growers in foreign countries. It might, you might want to change that statement 'cause it's somewhat **put-offish**, I think for many of our foreign growers as well as not based on any studies that I'm aware of in terms of government studies or surveys of our food supply.

Louis J. Carson

Okay, thank you for the comment. The purpose of that statement is again, as it's been mentioned earlier, that we in drafting the guide in putting out the good agricultural practices, at the same time, want to recognize the importance of fresh produce in the diet. And we wanted to encourage people that we still believe in consumption of fresh fruits and vegetables are very nutritious, but at the same time that we must be wary. So we wanted to put some sense of that forward, but certainly we can improve the guide.

Carolyn Smith deWaal

Yes, and nobody questions that they're an important nutritional part of the diet and also that they're generally very safe. But that particular statement, does anyone have an actual citation or basis for that? Because I think if we want a document based on science that we should just put rhetoric in it.

Louis J. Carson

Thank you for that comment. Are there any other questions or comments? Yes sir?

David Holzworth

I'm David Holzworth and I'm hereon behalf of the Chilean Exporters Association and the Chilean Fresh Fruits Association. I would liie to thank the Center for Science and Public Interest for pointing out that there are other countries in the world that have an equally safe food supply. I'd highly endorse that comment. My question goes to the **flip** side of the question that was just asked. And that goes to the data that the FDA has cited. Not only the FDA, but the Food Safety Initiative groups generally have cited suggesting that there is an increasing risk of microbial pathogens in fresh fruit and vegetables, Again, I haven't seen any scientifically based data that would document an actual increase in instance or risks. Although that is also thrown out in these meetings as a basis for the whole food safety initiative. I'm just curious to know exactly what data the agencies are relying on for the detection ifthere's increased risk associated with fresh **fruits** and vegetables. The data I have seen have indicated that most of the risk of foodborne pathogens occurs in the meat/dairy/poultry products. And any increases in that category as opposed to fresh **fruits** and vegetables.

Dr. Michelle A. Smith

When we talk about the increase in risk for fresh produce, we're talking about the portion relative to other food. It's not an increase in total numbers, it's an increase in proportions. Now, the proportion is still relatively low. The proportion of illness associated with fresh fruits and vegetables has always been low, but it has in fact doubled. And CDC brought this to our attention recently. I don't have the reference at the top of my list, but we can try and incorporate that into our discussion.

Louis J. Carson

Again, I was, **I should've** repeated the question because as I understand the camera can only feed from this **mic**. And the question was from Mr. **Holtzworth**, "What data is there to show that there is an increased instance of foodborne illness associated with fresh produce?". His understanding was it was mostly associated with meat and poultry. And Dr. Smith was answering that we have received reports and there area number of reports in the literature associated with fresh produce and those incidents, or reported incidents have increased. But the proportion necessarily is not greater than any other commodity, but that it is increasing. And we can cite those reports in the literature to you later and we can also make reference to them in the document as we **further** refine it. But there have been a significant number associated with fresh produce and I think they've made quite a bit of notoriety in the news as well. So, we're referring to those reports both from CDC and others that we have received at the Food and Drug Administration and the Department of Agriculture.

David **Holtzworth**

As a follow up to that, I have in my hand right here the CDC surveillance summaries for the last several years. **Again**, I think it's important instead of using terms like double or increased to, if you're going to have a science-based document, say exactly what the

percentages are as well as the underlying numerical data. Because going from one incident in ten years to two incidents in ten years is as we know, a hundred percent increase, but it's hardly a magnitude to **justify** an overall target hack on an issue. And I think it's also important because we also hear in the various, not only in this agency, but also with Congress linkages or attempted linkages between this and imported groups point out that most of the recent incidents have not been with imported product but have been with domestic product. Or at least to give the qualifiable basis or the conclusions that are being drawn. And finally, I'd like to note that there has been no report of any foodborne pathogen linked to Chilean fruit in the United States.

Louis J. Carson

Thank you, any other questions or comments? Yes sir?

Chris Moore

Hi, Chris Moore with Shaw-Pif&nan. I noticed that the most recent iteration of the guidance no longer mentions commodities specific guidance. And I wonder if that's something you're still considering?

Louis J. Carson

I'll handle guidance. As had been pointed out by Dr. Smith in her notes, the commodities specific guidance and the comments made to the working **draft** have been fairly clear. What we see as producing the broad-scope guidance is that, come October when we have a final guide, we will need to work through the Department of Agriculture, the Cooperative Research and Extension Service through Foreign Agriculture Service, Trade Associations, Industry in applying "The Guide" to specific crop, regional crop production practices so that they can be applied in that way. What we're trying to do is engage the industry, so, and what we've heard from the industry is that they want to be at the ground

floor in making these good agricultural practices doable, practical and achievable. And so, our approach has been to come up with broad-scope guidance based on the best science. And then through old mechanisms available to us with our colleagues at The Department of Agriculture to make those apply in the best cases to whatever commodities and crops people want to apply them to. So our approach has been in a ***simplest*** fashion, I think, to come up with general principles and then to apply those with the cooperation of industry.

Melissa Keyes

Hello Mr. Levitt, I'm here on behalf of Sherman & Sterling. And it was mentioned by Ms. Smith that there will be an attempt made to make site visits to **farms** with packinghouses as you develop the final document due in October. And I was **kind** of wondering whether or not there have been in the past, or will be in the future, efforts to visit foreign **farms** with packinghouses in addition to US?

Dr. Michelle A. Smith

Our visits are starting out climactically. We have done a number of site visits in conjunction with people on the development team going out and giving presentations in other areas. We're currently involved in sending teams of people from FDA out to site visits that have been organized by industry groups and others in major growing regions where there is activity and things to see at this point and time. The people on the team that are making the arrangements for the site visits have made some contacts as **far** as arranging foreign visits. But I think all that is under negotiation at this point. And we are certainly open to invitations and will also be a **function** of logistics and resources and time. Coming out of the comment period, we need to start taking (inaudible) on the guidance.

Louis J. Carson

Let me just follow on with that. Certainly we want to appreciate the variety and diversity of agricultural practices worldwide. We at the Food and Drug Administration along with the Foreign Ag Service, AID, Department of State are working on means and mechanisms so that we can **fully** appreciate the agricultural practices abroad. Within this time period, as Dr. Smith has mentioned, we have made some in-roads and have done a few visits in Mexico associated with a number of meetings that we have made presentations on the food safety initiative in general and on the produce initiative in particular. We, likewise, are working through NAFTA with our colleagues in Canada and Mexico to try and broaden it. Next fiscal year when we actually receive **funds hopefully** for the produce initiative, we would hope to do much more in a broad-scope way and work with foreign governments, foreign country, foreign producers. This year, we are really focusing, as Dr. Smith said, around the country and trying to get that and then apply as best we can with our foreign country partners in this.

John W. Farquhar

I'm John **Farquhar**, Marketing Institute, Washington, DC. We are working, currently with the Embassy of Guatemala and implementing a program to bring around the level of expertise of their raspberry operations. The records for this work really goes to the CODEX Food Hygiene Committee on import-export inspection. And that particular section has to do with equivalency. For you students in **CODEX**, look at that section and you will see where you will have to dissect the entire operation of a product and begin as we did in Guatemala implementing the guidelines that we are talking about today. I might also add, in regard to inspection, that FDA as well as CDC has been in that country on numerous times and there is a game plan **again**, based on equivalency that is being carried out in conjunction with these two agencies. Thank you very much.

Chris Silva

Hi, I'm Chris **Silva** with Nutrition Weekly. I was just wondering in addition to broadening visits, if perhaps, there is recommendations in the guide to perhaps more expeditiously get inspectors onto sites once reports were made. I was t **hinking** in reference to, specifically, **Dionne Walluck**, is an incident comes to mind where fatally, one little girl died **from** drinking the juice. And I was wondering if there were going to be attempts or recommendations made to perhaps get inspectors maybe to expand the number of inspectors and then to get them onto these sites more expeditiously once reports are filed?

Joseph A. Levitt

That's a very important comment, but what **I** would say to that and to a number of others that are starting to creep up. The purpose of today is the topic of the content of the guide. And issues as fouled inspection or what's happening with particular countries right now is really beyond the scope of what we're here to talk about. **I** mean I think your question is **an** important one, but if we start fielding all questions on food safety today, we won't get to the issue of we have a **draft** out here today, we're trying to get comments on the contents or the scope of that **draft** as it is. We certainly understand that inspection coverage fouled and so **forth**, but that's really related to a different topic.

Louis J. Carson

Are there any other questions or comments? Then I want to thank the panel for their moving remarks and we will bring up the next panel and we might take a five minute standing break while we move onto the next panel.

Catherine Carnevale

— There are about ten countries in addition to the United States at this meeting. We have **Guatemala, Panama, Argentina, Thailand, New Zealand, Chili, Australia, Spain, Mexico**

and Canada represented at this meeting. I'd say that's a pretty good showing. And we have Uganda here as well. And Uruguay. And Taiwan. Also, I'd like to mention there are eight press organizations represented in the room today. I'm not going to name all of **them**, but there are eight **different** organizations that are represented here today.

Individuals, we have eleven people here from the Food and Drug Administration. Other government agencies, we have eleven people here. Industry, we have twenty people at the meeting, and there are seven people who have identified themselves as individuals. This is our second meeting that has been expressly designated as an international meeting, and it is held for the international community, but especially for our neighbors on Embassy Row in **Washington**, which is why we're holding it here, where as I also want to mention there will be two other meetings held, one in San Diego and one in Miami, and people from the international community, of course, are welcome at those meetings as well. At the first meeting that we held for the international community back in December, we presented the working draft of the guide and went over that for your consideration and input into it.

You just heard a bit about the process that we are going through in developing the guide. Later this **afternoon**, you will hear a description of the guide in **far** more detail, and so I expect all of you to show up **after** lunch. Right now, we are having a panel session, and the panel is entitled, Good Agricultural Practices in the Global Context. The purpose of this panel is to examine the importance of the guide in meeting the broad goal of improving food safety and reducing foodborne illness. We're going to explore examples of international cooperation and collaboration again to reduce foodborne illness and discuss models for information **dissemination**, technical assistance and educational GAPs. All of panelists are experts in their own areas, and I'd **like** to introduce them to you right now. The first person you have already met this morning, Lou **Carson**, who is our new Deputy Director for the Food Safety Initiative within the Center for Food Safety. He will be discussing promotion of food safety, how the produce initiative fits into the overall food safety initiative and the farm to table concept. Larry **Slutsker**, who is the next person in

our panel, is the Director of the Foodborne and **Diarrheal** Disease Branch at Centers for Disease Control and Prevention, and he will be concentrating on actual experience in disease surveillance and emerging pathogens. Lloyd **Harbert**, in the center, is from the Foreign Agriculture Service, US Department of Agriculture and he will be talking about technical cooperation activities the USDA has with other governments. John Becker, next **in line**, **is** from the Sustainable Development Office at the US Agency for International Development, USAID, who will give us a short review of US agencies involved in foreign **education**, technical assistance and training. And, last but certainly not least, is FDA's own Ellen **Morrison**, who is the Deputy Director for Emergency and Investigational Operations in our Office of Regulatory **Affairs**. She **is** going to discuss traceback and international **traceback**. The biographies of all panel members are contained in a one pager that you received at the registration desk so I'm not going to go into that **information** which you have. Each panel member, and I'm saying this for you attention panel members, has about 10 minutes to present your topic. What I'm asking of the audience is that you hold your questions until we're at the end of the entire panel presentation. I will mention that Naomi **Kawin** has index cards in her hands. If you need one or two or five, signal her. She's going to be roaming around as we're doing this so that we can give questions to the panel members. You still are welcome are go to the **mic** and do it that way, but if you do fill out a card, we would appreciate you putting your name and **organization**, country, whatever on it. I'm looking forward to a stimulating panel session and without **farther** ado, Lou Carson.

Lou Carson

Thank you Cathy. I want to put into context the produce initiative within the overall President's Food Safety Initiative. Last year the President announced on January 25 his initiative towards the Food Safety Initiative and a request for this fiscal year's of \$43.2 million. What was contained within that document, and as a matter of fact, many industry

our panel, is the Director of the Foodborne and **Diarrheal** Disease Branch at Centers for Disease Control and **Prevention**, and he will be concentrating on actual experience in disease surveillance and emerging pathogens. Lloyd Harbert, in the center, is from the Foreign Agriculture Service, US Department of Agriculture and he will be talking about technical cooperation activities the USDA has with other governments. John Becker, next in line, is from the Sustainable Development Office at the US Agency for International Development, USAID, who will give us a short review of US agencies involved in foreign **education**, technical assistance and training. And, last but certainly not least, is FDA's own Ellen **Morrison**, who is the Deputy Director for Emergency and Investigational Operations in our **Office** of Regulatory **Affairs**. She is going to discuss **traceback** and international **traceback**. The biographies of all panel members are contained in a one pager that you received at the registration desk so I'm not going to go into that information which you have. Each panel member, and I'm saying this for you attention panel members, has about 10 minutes to present your topic. What I'm asking of the audience is that you hold your questions until we're at the end of the entire panel presentation. I will mention that Naomi **Kawin** has index cards in her hands. If you need one or two or five, signal her. She's going to be roaming around as we're doing this so that we can give questions to the panel members. You still are welcome are go to the mic and do it that way, but if you do fill out a card, we would appreciate you putting your name and **organization**, country, whatever on it. I'm looking forward to a stimulating panel session and without farther ado, Lou Carson.

Lou Carson

Thank you Cathy. I want to put into context the produce initiative within the overall President's Food Safety Initiative. Last year the President announced on January 25 his initiative towards the Food Safety Initiative and a request for this fiscal year's of \$43.2 million. What was contained within that document, and as a matter of fact, many industry

and consumer groups worked with the federal agencies in putting together the reports the President that was dated May 1997, included a nationwide early warning **system**, increased seafood inspections, expanded **research**, education and training. So at this point in time, the produce initiative was not even a twinkle in the eye. On October 2, just at the start of our fiscal year, when we have **hopefully** all of our plans in place and what we are going to do for that fiscal year, the President announced a new directive to both the FDA and USDA, and the goal was to improve the safety of **fruits** and vegetables, both domestic and imported from foreign countries. **Again**, within the Food Safety Initiative, within the report to the President, we had always included produce as one of those commodities in which we needed to devote both research, **education**, and risk assessment resources to so that we could better understand microbial contamination of those food commodities. US consumers again enjoy one of the safest food supplies. I know we had an earlier comment, but again we wanted to promote, and we still want to promote the consumption of fresh **fruits** and vegetables. But at the same time, **again**, from the best **information** we have to date, from the best data that we have, we can only estimate that there are 6.5 million to 33 million illnesses and up to 9,000 deaths annually associated with contaminated foods. Estimated costs of foodborne illnesses again estimated are around \$5.5 billion. However, we can relate to a specific number where food product recalls from life threatening bacteria have increased from 79 reports in 1988 to nearly 400 in 1995. So what is the goal of the produce initiative? The goal of the Produce Initiative and the Food Safety Initiative are two-fold, and I have one hereon the slide. To reduce to the greatest extent possible the incidence of foodborne illness and secondly, to form a better, more effective food safety network at the federal, state and local level. I would like to spend the most time on this slide here and try and describe what the context is for the produce initiative. Within the food safety initiative, we have been charged with improving the effectiveness response of the federal and state food safety network. Based on the increased numbers of foodborne illnesses, based on the

diverse reactions to those foodborne illnesses, we see our role in working with our federal counterparts in better coordination of response, better identification of those diseases, linking those diseases to a particular product. The slide here identifies the six major areas within the Food Safety Initiative. Surveillance, which the next speaker **will** speak on more, is the effort with USDA, FDA working with CDC. CDC has its Food Net central sites that for us to work with CDC in evaluating the data that they receive through those active **surveillance** sites. Inspections, within the inspections is the area for the Produce Initiative. We have within the inspection arm all of the good agriculture guidance, regulations that we would put forward to improve the overall food safety **system**, including good agriculture practices. Risk assessment and Research: As has been pointed out earlier, there is much we do not know. There is much about microbial contaminants when it applies to the food system as opposed to clinical situations that scientists today do not know. We do not know why certain microorganisms become pathogenic, why certain microorganisms are more pathogenic with certain populations. We do not know microecology, and we do not know how best to target our resources yet based on those vectors. We need to invest in the risk assessment and research so that we can have the supporting documentation to apply better practices, to give better intervention strategies, and to understand why traditional preservation techniques such as heating or high acid are not working with certain microorganisms. I think, as Dr. Smith pointed out earlier, the microbes are evolving. They're able to overcome certain obstacles that have been traditionally put there so that we can have a safer food supply. Education: Education cuts through each one of the activities. As we develop new regulations or new practices or learn more about the science, we need to inform and educate, make people aware of **all** segments, from **farm** to table. Today we are focusing on the **farm** load. We are applying good agricultural practices and trying to use that vehicle to educate **farm** workers, **farm** owners and producers of what those hazards are, but within the Food Safety Initiative, we are making those efforts at each stage both at the production processing, transportation

retail and at the consumer level. We need to coordinate this effort better than we have in the past. With the more than ten federal agencies, the hundreds of state and local food safety agencies, we need to have a better coordinated effort so that we're duplicating efforts, but we're adding to each one's efforts to make a better food supply. That's why I say the second goal of the President's Food Safety Initiative is for us at the federal and state level to work smarter and better together. Much of the effort in FY '98, this year, has been devoted to establishing those linkages and to creating good formal partnerships with our federal and state counterparts so that we can have mechanisms in place as we develop new regulations or new guidance's as we learn more about the sciences that we can then use those mechanisms to distribute that information and get it to where it needs to be. We **further** need, in the next years, to enhance our abilities to work with the state and local governments and with foreign community. Our efforts this year are starting small. We are working with Codex in working on a similar guide, as we have developed here. Canada is the lead on the **Codex** document so we're trying to be transparent. Whatever we're doing domestically, we're trying likewise to do world wide, and we're using a consistent approach. As has been mentioned already, the good agricultural practices are voluntary. These are voluntary guidelines. What we believe we need to do is to promote these good agriculture practices because we believe that in the end as they are applied that we will improve the overall food supply. My purpose here was to simply tell you that we are not only devoting attention to the farm part of the **farm** to table **continuum**, but that we have many activities under way devoted to the retail and consumer levels, at transportation and at processing, and that we see that each one of those areas are important to sustaining a safe and quaky food supply. We are here today though to lower our attention to good agricultural practices and the proposed guide that's under **discussion**, but we wanted to make sure that you understood that within the context of the Food Safety Initiative it is one part, and we don't believe that we're undeservedly bringing attention to this area because we need to make sure that at every level we are applying

affirmative steps to improving the food supply through awareness, education and the best that science has to offer.

Larry **Slutsker**

I want to thank the organizers of the meeting for inviting me here today to share a little bit of **information** with you. Basically, I want to do three things today very briefly. First, I just want to share with you some of the data on the **draft** of what we learned from some of the most recent foodborne outbreak investigations relating to fresh produce and how some of those findings that contributed to the document that you are hereto discuss today. I want to **highlight** some of the surveillance methodologies that we're using to try to better understand and detect these outbreaks, The third thing I want to do is note that I'm not the director of the Foodborne and **Diarrheal** Diseases Branch seeming my real boss Rob Totes could be a little bit shocked to find that I came to Washington to do a coupe while he was back in Atlanta. I'm the staff epidemiologist and Dr. Rob Totes is the director at the branch. First slide please. We're really faced with changing scenarios for foodborne outbreaks, as many of you may know. The old scenario outbreaks that are certainly classically taught in textbooks involve sort of a church picnic scenario where there's an obvious contamination event. It usually occurs at a local level involving just a few people, and there is some sort of gross mishandling, usually the time or temperature abuse or a food handler. Produce related outbreaks are really more the prototypical event for the new scenario where we have widely dispersed outbreaks occurring over many states, perhaps even here nationally. There's often a very low attack rate because the contamination rate may be low and, of course, there's a long complex chain of **production**, processing and distribution at any point along which the contamination can occur so it makes investigation these outbreaks a real challenge. We think we've done a little bit better both with recognition and response to these kinds of outbreaks because of improved surveillance, some laboratory methods and some better collaboration among agencies,

both at the federal and state levels. Next slide please. I think you're all pretty **familiar** with this, the Complex Farm to Table Chain for Produce, but basically this is just to emphasize the point that produce like a lot of other foods goes through a complex history before it winds up on the consumer's table and that there are plenty of handling events and environmental **factors** in each step along the way, which could potentially result in a contaminated product at the level of the consumer. Next slide. These are some of the data that we have alluded to a little bit in the first session. These show a report of foodborne outbreaks related to **fruits** and vegetables in the United States **from** 1973 to 1991. They are showing a two-year period here beginning back herein 1973-74 and basically we've had about five to ten produce-related outbreaks per two year period until this point here when the number of outbreaks doubled to an average of about 15 to 20 per two year period. This still represents a small proportion of reported foodborne outbreaks. Basically, back here was around 2 %. Here, it's around 5 % of reported outbreaks and perhaps 8 % of patients. Each year there are about 500 outbreaks reported in the United States. This is not a Cadillac surveillance system. This is a passive surveillance. The state health departments send reports into CDC. Sometimes it takes years for the reports to come into us, and it's a pay for pay system so there's no rapid turnaround, but nothing has changed in the system during this time, so we think that represents the real increase. Next slide. This is just sort of a laundry list of some of the selected produce associated outbreaks since the beginning of the decade. The point here is not to memorize the details but to make a couple of points. First, a number of pathogens have been involved. We've had bacterial pathogens, **salmonella**, **E. coli** 0157, and **shigella** here. We've had parasites, **cyclospora**, of course, and we've had viral pathogens, hepatitis A couple of times. A number of kinds of different produce vehicles have been involved. Very **often** these are outbreaks which are fairly large involving dozens, sometimes hundreds of cases, sometimes several, even dozens of states and occasionally other countries, and again to make the point, the source of the produce sometimes comes **from** a foreign source and

often it comes from a domestic source, and I don't really want to emphasize the source here so much as the **fact** that it can occur with produce from either source. Next slide. I just want to highlight a couple of recent outbreak investigations just to show you some of the tools that we're hoping will help us do a little **bit** better job on these. These are data from a salmonella outbreak detection **ulger** that we run our surveillance data every week. State health departments stereotype so that there are isolations of salmonella. Stereotyping is just a typing method and they send them electronically to **CDC** on a weekly basis. Sometimes it doesn't come in quite so timely, but they usually send it in at least twice a month and we are able to compare their reports to a historical base line, based on the previous five years of **data**, so we can do some statistical calculations and see if there are deviations **from** the expected, and this just shows a salmonella base line. Here, these are the actual number of case reports in 1995, and every time there's a little star here, it means that there is a statistically significant deviation from what would be expected from a historical base line. In fact, this was flagging all over the United States in 23 different states and we thought it deserved **further** investigation so we began an investigation there. Next slide. And, in fact, we went to Arizona where one of those flags was occurring and an alfalfa sprouts **epidemiological** investigation implicated alfalfa sprouts pretty convincingly. There were no other food exposures that were found associated with illness. A separate independent study in Michigan also implicated the same food vehicle. Next slide. With our colleagues at the state health departments and the FDA, we began a rather elaborate **traceback**. We **tracedback** the source of sprouts for 50 cases in six states. There were nine different growers involved, so there clearly was not a common grower that explained the cases. All cases did track back to one US seed supplier, who supplies 60 to 70 % of the market. Next slide. The seed supplier had gotten his seeds **from** a shipper in the Netherlands. All of the seeds that caused cases in the United States had come over on one shipment, a 40,000 pound shipment, and at the same time the outbreak was occurring in the United States, a part of that same shipment

had gone to Finland and also caused an outbreak in Finland, same salmonella **stanley**. So we know that the contaminations did not occur in the United States but occurred somewhere before that. The source of the seeds was not the Netherlands. We were never able to **traceback** the source of the seeds. Some of the difficulties of **tracebacks** are what you get really far down the line. We learned a lot from this outbreak. We learned that alfalfa seeds are a (raw) agriculture product, lots of opportunity for contamination by salmonella. During their growing and distribution, they sometimes go for years without actually making it to the market and may reside in interesting places along the way. Salmonella do survive pretty well in dry conditions so they can survive on the outside of the seed, and the sprouting process is red flag application step. You can take one cell and multiply it up to an infectious dose just during the sprouting process so it's really a potentially risky situation. This was kind of a central event for us, and then we've had five additional sprout-related outbreaks involving nearly a thousand culture-confirmed cases so we think that these outbreaks are quite real and deserve some attention. Next slide. With this outbreak I think it was demonstrated the utility of some of our surveillance tools, salmonella stereotyping by state laboratories that we should have done for years, but now report electronically through the Public Health Laboratory Information System we call **PHLIS**, and that rapid reporting really helps us to at least be able to better detect these clusters that are spread out over many states. And implementing this **ulger** also helps us quite a bit. And this was a really collaborative effort among public health agencies. The industry was extremely involved in this and helped to pay to support studies looking at ways to decontaminate seed, and they paid academia to do these decontamination experiments, so we thought it was good melding of public and private activity. Next slide. Let me just mention one more outbreak. This was an *E. coli* O 157:H7 outbreak due to leaf lettuce in 1996. Next slide. This shows what we call epidemic curves occurring in two states simultaneously in the summer of 1996. On top you see Illinois, and on the bottom you see Connecticut. Each one of these boxes represents one case of infection

with E. coli O 157:H7, and this is approximately four times the number of cases either of these states would expect to see during this time period. Next slide. We were wondering if the outbreaks were related although the states are several hundred miles apart. The patients had similar demographics. These were mostly middle-aged women living in affluent areas. In Illinois, epidemiological study implicated red leaf lettuce and in Connecticut an epidemiologic study independently implicated mescaline mix, which is a mix of baby lettuces that does not include red leaf lettuce usually. We wondered if they were related, but we weren't really sure and so the laboratory really performed a critical element here, the molecular sub-typing by this method basically doing molecular fingerprinting of the bacterial strains from patients in Illinois and patients in Connecticut, and we found there were indistinguishable. Next slide. As you can see here, this just shows the fingerprints basically. It's just a DNA from the bacteria from the patients in Connecticut and the patients in Illinois right next to each other. These are the outbreak-related strains. They're exactly the same, and these are unrelated strains from both Connecticut and Illinois, and they are very different. So we thought that this is good evidence that the bacteria came from a common source. Next slide. The investigators in Illinois then went back and did another epidemiological study and indeed, mescaline mix had been eaten by the majority of the Illinois patients. It wasn't asked about in the original questionnaire because none of the investigators had ever heard of it. The traceback implicated one grower in California, and you see here the results of the follow-up investigations at the growing site, and some of these are some of the kinds of things that are addressed in the guidance document. Next slide. This outbreak really demonstrated for us the value of this kind of molecular sub-typing to link these kinds of widely dispersed outbreaks and also emphasized the importance of the ongoing collective research with state health departments, which led us to industry practices, which is still ongoing. That's still a fruitful collaboration that's occurring to help to identify critical control points in that industry, That outbreak was really one of early models or progenitors of what we now

call Pulse Net. Pulse Net is one of the surveillance networks that we've developed along with the FDA and the USDA over the last few years to link state health department laboratories electronically so they can compare those finger print patterns of bacteria and, therefore, a health department in Oregon that's investigating cluster can compare their pattern to a pattern on the East Coast almost instantaneously and see if they have identical patterns and perhaps identify a common link that would have been difficult, if not impossible, to come by just a few years ago. I don't have a slide that shows the Food Net sites. Food Net has been mentioned a couple of times. Food Net sites are collaborations between several state health departments, schools of public health, FDA, USDA and CDC. The current Food Net sites are in Oregon and Northern California, Minnesota, Georgia, Connecticut, Maryland and New York, and in each of these sites, investigators do very active surveillance. They identify all foodborne related infections by canvassing laboratories in the states. They conduct special surveys of the general population to find out about food consumption patterns, and they do extensive case interviews to find out histories of patients who have these foodborne illnesses. They are doing studies on patients who are not part of outbreaks to find out what their risk factors are for certain kinds of foodborne infections, such as salmonella or E. coli, and we hoping to gain some information about risk in terms of non-outbreak situations. Next slide. This is the last slide, and it is sort of a summary that we think to meet the challenge of produce-associated outbreaks, we need to, as we are doing with the public health laboratory information system and the salmonella outbreak detection ~~ulger~~ and enhancing our surveillance, making it more rapid, easier to detect clusters, implementing sub-typing, including salmonella stereotyping and the Pulse Net networks and the international networks that are linked electronically, conducting further applied research through cooperative efforts with industry and continuing to collaborate among all the elements that work together to help alleviate this problem. Thank you.

Catherine Carnevale

Now we're going to switch from Department of Health and Human Services over to the US Department of Agriculture.

Lloyd Harbert

I must admit I really enjoyed Dr. Slutsker's presentation because, in fact, that was one of the key messages that we at the Department of Agriculture wanted to get out to the international audience, and that's our Food Net and this Pulse Net net work out there that is creating all this information about new foodborne illness outbreaks, and each time we have an outbreak reported in the popular press, it immediately calls into question the safety of our domestic food supply, and we get a lot of questions over the Foreign Ag Service from exactly a 101 of the people sitting in this audience about what's going on. So I just wanted to thank Dr. Slutsker for that presentation. That was excellent. Today, I have been charged with giving a brief breakdown on our foreign technical cooperation within the Department of Agriculture. I thought that was covered fairly well earlier on by our Deputy Administrator for International Cooperation and Development, Mary Ann Keefe. I would like to touch on a few points. I think, as you well know, the Department of Agriculture has a long history of working with the Food and Drug Administration and other agencies within the United States Government to design and implement technical cooperation agreements, cooperative research programs, and technical assistance and training programs with foreign governments. The area of food safety is no exception. The Department of Agriculture directly through international programs undertaken by the Food Safety and Inspection Service were in cooperation with the Department of Health and Human Services, Food and Drug Administration has initiated a number of activities to facilitate food safety internationally. As Mary Ann pointed out, the department has sponsored a host of foreign visitors, and as she mentioned in her remarks, over 120 international participants from over 35 countries have visited us in the last 35 years. And I

can tell you from recent experience it's increasing daily because of the popular press reports we've had around food safety, and foodborne illness outbreaks. We inundated. In fact, in the next two weeks, I think we have delegations coming in from Europe, press writers, all that are interested in learning more about what's happening in the United States in the area of food safety. In addition to this, the Department of Agriculture is also undertaking specific food safety related technical assistance efforts, such as working with 30 health and food safety technicians from El Salvador, Guatemala, Honduras to develop methods for conducting tests for microbial hazards. We have similar programs ongoing with Morocco, Egypt, Indonesia and Russia. The Department Foreign Ag Service also administers numerous cooperative research programs in the area of food safety utilizing appropriated funds, foreign currency and funds provided by the Department of State and also the US Agency for International Development, which will be touched on by the next speaker. I think one of the things that has come out of the President's Food Safety Initiative from my perspective are the efforts in the international area of food safety are becoming much better focused and better coordinated. I want to draw attention to that because now we have an international meeting which is chaired by the Food and Drug Administration that meets once every two weeks. And that is now providing us an opportunity to discuss, not only visitors who are coming into town, but also what kind of technical assistance outreach efforts do we want to target because we are dealing with limited resources. In addition to that, this cooperative spirit has expanded to our efforts to develop international food safety standards and make sure they're based on sound science. The USA Codex, for example, office, which is housed in the Food Safety Inspection Service, now operates under the guidance of a policy level and a technical level group that includes representatives from the Environmental Protection Agency, the Food and Drug Administration, the Department of Agriculture, the Department of State and several other agencies. And those policy and technical groups are meeting on a frequent basis. When we look at foreign governments are ways we can strengthen institutional linkages,

between our public health authorities are hoping better understanding of how regulatory decisions are made, build trust and retain public confidence in the safety of our respective food supplies. In designing the future technical cooperation agreements with foreign governments, I think we're going to be focusing on four key areas. The first is increasing international awareness of how our Food Net system works, and that was one of the key reasons we had Dr. Slutsker here today, so he could give some insight into that, and that is a message that we're going to be building more and more technical assistance and outreach programs in the future. The second area is improving risk assessment methods for microbial contamination. Our knowledge base is expanding rapidly particularly in regard to a broad range of foods, particularly seafood, meat and poultry. However, an understanding of the factors that determine the risks associated with microbial contamination on produce has evolved. A third area, and the one that particularly has an interest for my office, is improved risk communication. A central concern is how is a government to raise public awareness of an emerging public health concern without unnecessarily eroding confidence in the food supply. As you've heard, the United States is significantly expanding our surveillance system. It is certain when we look harder we will find more foodborne illnesses. At the same time, it will be imperative to communicate to our domestic and international consumers the comparable risks. And finally, the fourth area that we're going to be focusing more attention on is the development of international guidelines, recommendations and standards in this microbial area. Efforts are already under way within the Codex, particularly within the Food Hygiene Committee. I think the success of our international effort will in large part be determined by commitment of our consumers, producers, and academic community to work together and support this initiative. It is not simply a question of budgetary resource. It is also a question of will, and how we perceive the problem. As our ability to identify the source of foodborne illness outbreaks improve, and this information finds its way onto the internet, consumers' perceptions of the safety of the specific food, the reliability of an individual supplier and

the integrity of the public health authorities can change overnight. That's the challenge before us, and I think all of us involved in promoting the President's Food Safety Initiative welcome all you here today to become involved in this effort. That's why we made a specific attempt with this panel to show a broad range of the departments and agencies interested in promoting this initiative. The challenge facing each country represented here today is how we proceed. As we uncover more knowledge relative to microbial contamination on produce, will it be presented as a threat? Will it be viewed as a reason to halt trade? Or will it be seen as an opportunity to improve international food safety and cooperation? Thank you.

Catherine Carnevale

Just as a reminder, if you do have questions for panelists, please pass them to Naomi Kawin as she cruises up and down the aisle. We're now going to here from John Becker from USAID, Before we get to John, I was reminded, when Lloyd was mentioning the web materials that the Food Safety Initiative does have its own web site under FDA's web site, so you can get to that by fda.gov or you can go to the _____ page, but if you just go to fda.gov, you will see icons, and there will be one for food, so you go to that and get to the Food Safety Initiative.

John Becker

I can attest to the fact that it's on the web site. Over the weekend, in preparation for this meeting, I think I spent about five hours on the Internet going over the good agricultural practices and material. Let me very quickly cover two broad points regarding USAID's interest in microbial safety of fresh produce and secondly what USAID is doing to help developing countries come to grips with this issue of microbial safety in fresh produce. First, the agency objective in economic growth is to strengthen agriculture and food security systems in developing countries. That's one of our objectives globally. With

respect to fresh produce and the Latin region, and I am with the Latin-American Bureau, rather than representing the entire agency, although I can comment on some of the other programs. We have been long supporting expanded fruit and vegetable production in the Latin-American region. It is a key element of our nontraditional ag export strategy that was implemented in the 80's and into the early 90's, and then we were backing off on some other things, and agriculture has gone down, but we are coming back, and we're looking at agriculture again. In that context, I understand about a third of the imported foodstuffs in the United States are fruits and vegetables, and approximately 80% of those emanate from the Latin-America region. So quite clearly, this issue, microbial safety of fresh produce, is a Latin-American agriculture issue that we're interested in. We're also interested in it from a hemispheric, economic integration markets perspective, if you would, Last month at the Santiago Summit of the Americas, we reiterated that it's US policy to advance economic integration and free trade. In that context, our discussions with developing countries and our partners in the region, agricultural trade is very important to these countries, as they're all trying to adjust to globalization, not just market access to the United States, but in the European union. It's the growth within their own domestic economics down there and some of the sub-regionalism that's going on. Then, obviously, microbial contamination of foodstuff is a serious problem that needs to be addressed as soon as possible so that this integration process can continue unimpeded. In this context, USAID is interested in the issue from two other perspectives. First, USAID is interested in verbalizing both public and private sector investments to improve food systems. And secondly, in particular, we are concerned about the equity of the integration process, the sustainability of it, which means the participation rates of the small growers, small packers, etc., by making certain that they can continue to participate in the food systems that are evolving. Often times it involves a great deal more certification. The second broad point I would like to make is regarding what are we doing. I want to point out that we really are just getting started, Our agricultural programs were going down in

the early 90's. They are coming back as we look at the importance of the agricultural sector and the development proposition. Over this past year, we have been working with the USDA to assist particularly the Caribbean countries to improve their sanitary and phytosanitary systems to ensure market access. We working with the Caricom member states. There's probably going to be an expansion of that agreement this year working more closely with the FDA as well as the USDA. The second thing that we're doing is we're working with the USDA on a market survey that's going out to the trade associations, some 700 of them, and we're going to try to find out a little bit more about their interests in the rest of the world. What parts of the world that they're interested in, etc. As you move away from broad guidelines, you're going to be looking at commodities in specific regions, and we certainly want to be finding out a little bit more about the trade associations in the United States and how they see their goal in perhaps standard setting in terms of investment and these sorts of things. Our second area that we are just getting started with is the US AID partnership with the Inter-American Development Bank. There's a great deal of interest on the part of the bank looking at their current portfolio of investment programs in the region to address some of the lower quality issues. Some of the larger public center investments that are being made, and there is currently a diagnostic that's being introduced, I think they expect by July, that diagnostic to be completed. Carol, who is working with us, and is with the USDA FAS, is the counter of the main point of those discussions to date. But we are working with IADB on the diagnostic, and that should probably lead to some technical assistance to complement their loan programs. Again, we've viewed quite a bit of investment in sanitation investment in lower quality issues, and we're trying to appease those things out at this juncture. And then thirdly, we are examining the impact of the certification schemes and the systems that are evolving on small growers with non-governmental organizations. Specifically, we want to make certain that small growers remain in the system and recognize we take a special effort to assure their continued role. This may be some research that we're looking at, their

particular role in competitiveness and then essentially there **will** be some targeted educational programs. At that point, we'll probably have some more ideas. I think that one thing that is quite interesting is some of the surveillance stuff **that's** going on and event monitoring. We've been working with a number of institutions about event monitoring and conflict resolution in the region. But certainly that monitoring of the news media as it relates to these outbreaks and this sort of thing, it's important and of interest to the trade associations. Thank you,

Catherine Carnevale

Thank you John. That was very informative, I wanted to mention, we started this panel about a half hour late, and as you can see from the presentations so far, there's a tremendous amount of information that this group has to convey, and so we will be running over, and we will allow time for questions, And with **that**, we go back to FDA,

Ellen Morrison

When we get to an outbreak stage, we've had a failure of system that all this leads up to, and one of the challenges for outbreak management for the FDA or the USDA and everybody else involved, is trying to figure out where that product has come from. We call this **traceback**, and the document addresses it in some specifics that I would like to talk about the challenges and what we do in **traceback** today and the difficulties in doing it. First, we call **traceback** the ability to track food items, including fresh produce, back to their source, growers or packers, even to the farms in some cases. It's a system to identify the source of a fresh product, and it can't prevent the occurrence of the microbiological hazard, but it may lead us to clues on what caused the outbreak so that we will be prepared to look at that issue at the level of the farm in fact. The ability to identify the source of a product **traceback** can serve, we believe, as an important complement to good management practices, good agricultural practices, intended to prevent the occurrence of

food safety problems. And the information gained from **traceback**, as we have seen in our work in the last few years, will assist in identifying and eliminating a hazardous pathway and will help avoid effecting unassociated produce for farms for that matter. We can define it, as I say, as an investigation to determine where the product originated and document the distribution in commerce. We know that the criteria we have been using for **traceback** in the FDA, we've worked extensively with the CDC developing the process for our own staff to do **traceback** when there's a multi-state outbreak, interstate outbreak for that matter, and it's very difficult, we can tell you this from our own experience. The criteria that we were using, and we still believe we continue to use, is that **epidemiological evidence** implicate the specific product in that the hazard analysis done in that FDA investigation show that other contributing factors were not to blame, such as cross contamination or food handlers, So we don't want to be necessarily doing **traceback** when the cause of the illness is something other than a contamination that occurred someplace else. If it's occurring in a restaurant or occurring in distribution, we need to know that. It needs to be factored into the **epi**. We depend, therefore, on the states, the counties, the CDC to provide us this information. Now, what are **tracebacks** likely to do in the real world? Well, they're rarely clean and straight forward we can tell you. They're complex and involved multiple distributors at each level. The ones Larry was showing you had only a couple of distributors, maybe even one. The ones we have seen in **Cyclospora** involve nine, ten different arms, four different distributors, and five different states. In many cases, they're a nightmare to do. It involves multiple FDA regions, districts. The length of time has to be factored in from the date of the event until the reporting of the outbreak. There are variations in the strength in FDA investigations that we get from across the country. And we're working on that and another arena on the Foodborne Outbreak Response Coordination Group to try to standardize what the federal agencies want in the case of a multi-state outbreak, by the way. But there are often multiple jurisdictions, multiple states, multiple distribution involving FDA districts all over the

country and the lack of specific information as to the date of purchase of the suspect part that the consumer buys. However, the challenges facing the produce industry, as we say in the document, that fresh produce with a relatively short shelf life, is often gone by the time an outbreak is reported making it extremely difficult to identify the item causing the foodborne illness. That's particularly true in the parasitic diseases as we've seen in Cyclospora. If fresh produce is linked to an outbreak, current practices in the fresh produce marketing and distribution systems, such as using recycled shipping crates and co-mingling during distribution, make a direct identification of the source of the product very difficult. Now if an implicated source, a field or packing house, is identified, the source of contamination may no longer be present when the investigators arrive on the scene. Another great challenge. As we've seen in Cyclospora, the economic burden is especially troublesome for those industry segments for those industry segments that may later prove to not have been related to the outbreak. And certainly in Cyclospora in 1996, when strawberries were wrongly implicated, it cost domestic strawberry producers over \$40 billion in lost sales. In terms of the complexity of the tracebacks in our view, the most important factor causing difficulty is the fact that there's no federal requirement for records being maintained for processing and distribution of food products. The exceptions, there are a few, low acid canned foods, acidified foods and infant formula. But there's no question where we are today, that the lack of record requirements prevent tracebacks from being done much more rapidly, and the source of the suspect product being identified more quickly, which would be an advantage to both the industry and public health. What are the advantages of an effective traceback system? As we've seen in the document, despite the best efforts of food industry operators, food may never completely be free of microbial hazards. We know this. However, in an effective traceback system, even if only some items carry identification, can give investigators clues that may lead to a specific region, packing house, even field, rather than an entire commodity. From a public health perspective, improving the speed and accuracy of

tracing implicated food items back to their source may help limit the population at risk during an outbreak. And rapid and effective traceback can also minimize the unnecessary expenditure of valuable public health resources and reduce consumer anxiety. As soon as we can identify the source, the better. Limiting the potential scope of an outbreak, lessens the economic burden on those industry operators not responsible for the problem. So improving the speed and accuracy of tracing implicated food items back to their source may also improve the ability of public health officials to determine the potential causes of contamination thereby providing data for growers, operators and others for identifying and minimizing risk factors. It's the FDA's view that it's critical for farmers and packers to work with their partners in transportation, distribution and retail to develop technologies that allow grower-packinghouse information in identification to follow produce from the farm to the table. We know some industry groups are developing technology, such as Bar Code stamps, stickers, etc. to identify the source of produce and software to assist retailers in providing more accurate traceback to the grower path or level. It would be our view that continued efforts along those lines would be advantageous to all. Thank you.

Catherine Carnevale

Thank you Ellen. Now we're going to allow some time for questions. We already have a number of questions that have been sent up that are in writing and we'll let anyone that wants to come to the mic also do that.

Catherine Carnevale

A couple of questions for Larry, and this comes from David Holzworth with the Chilean Exporters Association. And the first question is,,,

—
David Holzworth

To what extent is the increase in reported outbreaks in 1996-98 attributable to better reporting and surveillance techniques?

Catherine Carnevale

And these mics here should both be alive, so...

Laurence Slutsker

Yes, those are good questions. The slide that I showed that showed that increase in produce related outbreaks actually went through 1991. The current foodborne operating system as I mentioned, is an extremely slow database system and it's not a high priority for the state health departments to send those reports, although we plead with them on a regular basis to do so. So, the increase that you saw was really before a lot of the attention that has been focused on produce had even come to light. So, data from '96 to '98 are not available, we do have some data from '92 through '95 that are still being cleaned, but should potentially be available in the next six months or so. So, if I understand the question correctly, I guess that we don't have data from '96 to '98, I think that it's, but I would say that better reporting and better detection will change the number of outbreaks that we can detect, And I think that it'll be a challenge to evaluate, you know, a new set of data obtained by, you know, different better methods. It will be challenging and we'll have to be real careful to compare it to the old baseline. 'Cause I hope that we do get better at detecting outbreaks. As an example, we did not, you know we did a study of E.coli O 157:H7 infections in 1990, trying to ascertain the risks associated with sporadic infections, not outbreaks. And we didn't even have on the questionnaire or anything about alfalfa sprouts nobody had even really thought about alfalfa sprouts as a food control that would be important at that time. So you know as we learn more things, you change your tools and you get better at detecting them.

Catherine Carnevale

Thank you, Larry. There's a second one for you also from David Holzworth.

David Holzworth

Why doesn't the guide contain an evaluation of relative risk based on the actual number of reported outbreaks from fresh fruits and vegetables compared to actual outbreaks for all foodborne illnesses?

Laurence Slutsker

I'm not sure I'm the proper person to answer that but I guess the relative risk would be if the proportion of produce related outbreaks had changed over time, and I think that it has based on the data that we have now. The relative risk is, kind of a tricky term, is the outbreak data as I say are not the kind of data that you would want to compute a relative risk on. I don't think anyone has done that. It's again, it's not, it's just passive surveillance data and the denominator as I said, has stayed the same, about the same from year to year. We haven't seen an overall increase in the number of foodborne outbreaks reported suggesting that overall reporting hasn't changed all that much. So, I guess that's the best I can do in answering the question. Relative risk is usually something you try to get at with a population based study where you're really determining all the illnesses, which you don't do with a foodborne outbreak reporting system.

Louis J. Carson

Let me try and address the point made about the guide. I think roughly for the same reasons as have already been mentioned the food net system and the active surveillance is just now starting to generate what in several years may be at base line prime which we may be able to do some prioritization or categorization of relative risks. Currently we've developed that the science was not sufficient or the database efficient to make those calls.

Hence we didn't, we refrained from doing such at this point and time. But I think as we learn more we wanted to approach the vector standpoint and that's why as the presentation earlier, we wanted to show water and manure as the science-based roots of contamination that we know of. But we do not have information on the relative incidence for particular microorganisms or a particular commodity, nor do we have the propensity of one commodity to have more microorganisms than another. But it's a very complex and complicated question and we just don't believe that science is there to make those kinds of determinations at this point.

Catherine Carnevale

Okay, thank you both. I have a question here from Uganda from Nimisha Madhvani or close to that, It says...

Nimisha Madhvani

This effort is excellent however, for greater or broader effectiveness than embracing awareness it is essential that USAID and other NGO'S practice or provide practical sessions in rural areas in Uganda and the region. I'm not sure whether this should be for Lloyd or for John. There's more to it in talking specifically about Uganda and the fact that they emphasize production of products for exports of avocados, fish, etc. But I think, maybe it would be interesting to talk a little bit about how we are going to do (inaudible).

Unknown person speaking from the audience

(Inaudible - not speaking at a microphone and very mumbled)

Lloyd Harbert

Yes, I think, as I mentioned in my remarks we've set up this international activities group that meets bi-weekly and part of that is so we can start getting a sense of what, how's the best way to do the outreach. In part, I think the reason there's been a focus, I think on the Latin American countries to an extent is because they're such a major supplier to the US market of produce so it was an obvious first step. What we like to look at in our international activities group from a broader context is the overall presence food safety initiative that applies across the board to seafood or, all food products; not just limited strictly to produce. And I think there, we'll start looking at how we might also be able to use CODEX and some of the international organizations to design programs. As John said, he's primarily with the Latin Bureau and I, we are just in fact now getting in a systematic way, AID involved in getting the activity. In the past, most of our food safety efforts were somewhat, I don't want to say disjointed, but they aren't particularly focused. They tended to be on, as somebody would come in and say I'd like to get some specific training or something, we would try to direct them where there was some **funding** resource available. We're trying to be much more focused in our approach now in terms of starting to look at our foreign visitors who are coming in. Making sure rather than just having these foreign visitors go to five or six **different** sites around the city here in **Washington**, or around the country, that we can start having them come into a central point and get a much more comprehensive briefing somewhat similar, we might have here. As opposed to going to one individual agency and maybe not talking to the right person at the end of the day. And I think that the fact that you've drawn our attention to Uganda's interest, I think that's something we will drum up for discussion in our next public meeting.

—
Catherine **Carnevale**

Okay, we have a problem in that, we need to speak into microphones. Is there any possibility that you can...

Mary Ann **Keefe**

Oh, I've never needed a microphone my children will tell ya...

Catherine **Carnevale**

Well, we're having all kinds of, yes...

Mary Ann **Keefe**

Well, I'll just be very quick and say, I happened to be in Uganda a couple of months ago and it was another area of AID that was involved in meetings there, and the African Bureau. And there was quite a bit of discussion related to food safety. And as well, I had been meeting with officials of the Ugandan Agricultural Department. And so, this is definitely on the radar screen there and I think what you're talking about is something that everyone's concerned with and realizes obviously if we can do this sort of thing up front, it'll save everybody a lot of trouble.

Catherine **Carnevale**

And, you don't need a microphone. Yes, John.

John **Becker**

I just wanted to add, actually I sort of focus the issue here on fresh produce and microbial safety issue. We, AID, has been very much involved in passive training around the world. The **African** Trade and Investment Program is certainly **examining** these issues. But, I think, in 1991 there was a major effort with an agri business program that was looking at

the competitiveness of the export dimension. So, AID, I think has always been very much involved in some of these issues relating to food safety. Just getting started here and focusing on the microbial safety issue is what I was counting on in terms of just getting started.

Catherine Carnevale

Thank you. One question that I think is probably on a lot of people's minds is whether we can possibly share some of the speakers presentations with the group. And I don't know whether there has, particularly the slides. Is that something that can be done for speakers, no problem? Okay. So, if people do want to get copies of the slides that were shown today, you need to contact one of the staff people that are standing around the room and we can make arrangements to get those to you. I have a question here and it is from Lynn Bradley with the Association of State and Territorial Public Health Laboratory Directors and it says...

Lynn Bradley

Please discuss the value of monitoring produce for microbial contamination as prevention/quality assurance.

Catherine Carnevale

And I guess that could potentially be for Ellen or for Lou. Let's see what he does.

Louis J. Carson

The question about just simply testing produce for the level or incidents for microorganisms, by in large, **from** our point of view, we believe the simple survey of that nature is not very helpful, nor **informative**. I think we need to better target a survey to look for a specific microorganism and/or it's **pathogenicity** at its vector into the food

supply, into the human population. Simply **identifying** the load or number of microorganisms on a product doesn't really say whether that product is safe or unsafe because bacteria, not all bacteria are bad. We, I think we need to know better what we're looking for and to design a program that will give us some valuable information that we could use; in either providing better guidance to those people who are producing that product or in helping the food safety network of state and local people to test for a particular microorganism. But, to simply do a general load test, I don't think is very beneficial, at least from our standpoint. It doesn't really give us much information. We know bacteria is the ubiquitous, we know it's there, but not all bacteria is bad. So, you have to **differentiate** and you have to know what it is you're looking for before you can apply a test. Just doing total plague count I don't think really does much benefit to anyone.

Al Yarnada

There's a question about whether there is a danger that gaps will be treated as requirements for foreign firms, but it's voluntary guidance for domestic firms. And I guess that's the summary.

Louis J. Carson

Yes, let me try and pick up and answer that again. I think Dr. Smith tried to do that this morning in her opening remarks. From the Food and Drug Administration standpoint, and certainly **from** the Department of Agriculture's, we look on these guidelines as voluntary. We hope that they are applied, but **again**, we want to promote their application. But in no way shape or form are we putting these out as regulations. These are simply voluntary guidelines, applied practices which we believe they will be a greater likelihood of safer food supply. But again, not all of the points in the guide apply to all commodities. And this afternoon as we go through the individual sections of the guide, I believe that point will be

brought home. We recognize there is a great diversity in the agricultural practices, the regional differences, the **differences** in commodities, the manner which certain commodities may be produced in a safe manner. And so these broad-scope guidelines need to be applied and need to be applied at the local level that makes sense. As I mentioned earlier in my remarks, we hope to use the Department of Agriculture's Cooperative Research and Extension Service, Foreign Agriculture Service, State Department AID, WHO, FAO, all these different mechanisms who have much more direct involvement with the producer level to make sure that we are applying these in a proper way. We also want the guide to be a living document. So as we put forward our recommendations within the guide, we need feedback through these applications of what worked and what didn't work. We really see the publication of the guide in October as a starting point, it is not a final document. It is something that needs to be applied and as it's applied, we'll learn better what needs to be changed or what we can refine within the guidance. So again, we want to reemphasize that based on the manner in which it's **written**, we wanted to allow great flexibility in its application. But we do on the other hand, want to promote its application.

Catherine **Carnevale**

Okay, and there is, we'll get to remaining questions from the floor, after, in just a moment.

Was this related to this...

Sue **Doneth**

Oh, I wanted to ask...

Catherine **Carnevale**

Okay, do you mind going to a microphone? You can come up here if you'd like,

Sue Doneth

This will follow the questions asked. My name is Sue **Doneth**, I'm from STOP, **Safe** Tables Our Priority. If I could just have some clarification I guess on the voluntary guidance for industry and in reading the GAO report that came out and some of the problems with imported food. If we're going to be using this as a voluntary guideline domestically and we're saying that we're going to be using this as a voluntary guideline for imported food as well? Am I understanding that correctly?

Louis J. Carson

That's correct.

Sue Doneth

How is that going to improve the safety of imported food, when essentially what we're using now for imports is a voluntary system which doesn't appear to be working?

Louis J. Carson

I guess what I would say is that we see is that there is a material improvement and by putting out the good agricultural practices over what the status quo is already. I think **from** what we've learned over the last six months, the amount of interaction we've had with industry governments and alike, we have made great progress in making people aware of when they produce a commodity, it's a food. **Often** times at the producer level, they've always thought of their products as commodities and not food and that there is some accountability as to going down the food chain to the consumer that they need to be aware of. We do not believe within the good agricultural practices, we have sufficient science for a particular commodity base right now to go any **further**. As we develop that information we may then establish rules and regulations that are **far** more specific based on the science that we have. Beyond the good agricultural practices and beyond fresh

produce, the Food and Drug Administration and the Department of Agriculture certainly have established passive and other regulations where they can apply and truly do improve the food safety system. So, I would disagree with your point of view that since the status quo of the President's food safety initiative let's say in '97, I think we've seen a great number of changes both from FDA and USDA and others in implementing measures that we believe will have a better impact on improving food supply. In particular, these are voluntary because we believe that the broad scope cannot be applied simply to each and every commodity. It has to be done in a manner in which we can get the industry and the **farmers** to actually understand what is there and then to develop programs that will make that happen. We have tried to make this a positive step. We're fearful that if we take a **different** tactic, we'll be very negative and we will not get compliance. It's a very, I think very important for us to make that first step about awareness. And we would then have subsequent steps after that as we learn from the science. So, I don't think I would agree with you that these are simply status quo, I think there is a change.

Sue Doneth

I guess I just have one comment in response to that. I don't see the difficulty if we're implementing mandatory (inaudible) since USDA (remaining portion inaudible).

Catherine **Carnevale**

And I think. I'm going to cut you off just because I have some more questions here. But I think we're going to be talking about that in the months to come as GAO's recent report on imported foods is going to be discussed **further**.

Catherine **Carnevale**

I wanted to ask Ellen a question. And that is, what do you think are the most effective, excuse me, important and effective characteristics of the **traceback** system?

Ellen Morrison

Certainly, from prior experience, if there was some way we could identify a food product that ends up in a retail shelf going to a consumer who becomes ill back to the grower, that's one thing. This is extremely **difficult**. We understand that and with industry growth we continue to seek solutions that are voluntary with the industry. But the key is knowing where that product came **from**, as we would with packaged food. Now, understanding where the contamination occurs is a difficult process as well. And that does depend on the epidemiology and it also depends on our work with **CDC** and the states and counties. Where is the distribution of cases? If the distribution of cases is more than one place, as Larry had said in one of the outbreaks he looked at, you know that the contamination didn't occur at this place, when the cases are all over the place and they didn't go through the same distributor. It's not a science, traceback is right now, not a science. We're trying to make it more standardized and a better process, but it's very, very **difficult**. But the key to be able to go back to a particular producer/farm would be the best thing we could get.

Catherine Carnevale

Okay. Could I have some idea, is there going to be, if there's some questions from the floor that are remaining, just a show of hands of people who have additional questions. Let me just finish the questions that I have on the cards then. And this one is from John **Farquhar** with the Food Marketing Institute. And basically, it says that...

John Farquhar

Recognizing that *cyclospora cayentensis* has not been detected in raspberries to date. And there appears to be little knowledge about this emerging pathogens and **information** to that would lead to the source of the contamination. What was the FDA ban based on? Larry?

Laurence Slutsker

Well, maybe I can make a few comments and then someone from FDA would also comment. It's obviously a sensitive issue and I can appreciate that. I think a couple of points. First, it is, as the question directly points out, it is an emerging pathogen and sometimes these pathogens emerge before **all** the diagnostic assays are available to **fully** characterize them in all the kinds of situations that you would like to do that. We're pretty good at identifying it in patient's stool specimens, but the technology for **identifying** it in foods wasn't there, certainly during the time of the 1996 outbreak. And **I** believe there is a fair amount of work going on and that now maybe somebody else can comment on that on the panel here. Second point is that when in the epidemiology in that particular situation was I think overwhelming. There were at least I don't remember the exact number, but there were at least **fifty** outbreaks. And the particular vehicle was overwhelmingly implicated time and time again. And **I** think that it's certainly reasonable to act on the epidemiologic evidence alone without microbiologic confirmation. If there's a need to, public health need to do so, and if the quality of the evidence is good enough and I do believe it was in this investigation. And the precedent was also there for the Guatemala outbreak when the company was notified and the decision was made to act on the epidemiologic evidence alone before the organism was recovered from the juice. So, you know, I think that those were some of the thoughts that went into the decision. And if somebody from the FDA wants to come and...

Louis J. Carson

I'm going to be brief because I think the right people to answer the question are not really here. But we certainly have worked, as you have already pointed out, in your earlier comment, Mr. Farquhar, about the **CDC/FDA** efforts with the **Guatemalan** Berry Commission and the **Guatemalan** Government. We in FDA are a public health agency and

we have been working with the **Guatemalan** Berry Commission in trying to resolve this matter. You currently point out that the science is still not there for us to properly target which commodities are most likely to have **cycrospora** nor have we been successful in recovering it when we target it. We are accelerating our research on cycrospora within the President's food safety initiative. It is one of our highest priorities. We may have methods of detection that are more suitable today. However we still do not have an appropriate sampling regime that will give us any better identification of cycrosporan in a product back in '96. So, we're still struggling with it from a scientific standpoint. And I would again defer on the compliance activity that FDA and the Guatemala Berry Commission have undertaken, I don't think we have the right people here to talk about that.

Catherine Carnevale

Okay, I will allow time for one more question if there is one more from the floor. **All** right, well then I will thank our panelists, they did a wonderful job. Before you leave, take out your pens, I'm going to give you a phone number. For those of you who want a hard copy of the slide, call Joyce Fesker at, this is (202) 260-8920. That's 260-8920. And I also have been asked to remind you that there will be a **full** transcript of today's meeting that will be available on the web in some period of time. And I'm looking at the time, I think that we **can**, you're supposed to be back here, I believe the program's going to resume at 1:30. Is that something we can probably do? That's forty minutes for lunch. I think I'm just going to keep it at 1:30 for the session to resume. And with that, I thank you for your attention.

Louis J. Carson

During this afternoon we will go through the individual sections of the guide and to engage the audience in how we might improve the guide and to **clarify** the guide if you have questions of certification. So we do want to make this **informal** by recognizing that we are trying to have a transcript made of this session. We

will ask you to use the microphone so that our transcriber can capture that comment or that question. Secondly, I invited people if they would like to make a public comment at the end of the **session**, again to let us know. Currently we have two people who have asked to make a public comment and there will be ample time if you wish to do so. Please let us know. Again we have allotted the rest of the afternoon, except for the public comments, for the **full** discussion on the guide and full interaction with you in the audience. So Dr. Smith and Dr. **Saltzman** will be taking you through the **different** segments of the guide and then seeking any and all comments and questions based on those sections. So, Michelle.

Dr. Michelle A. Smith

What we have in mind for this afternoon was to go through the guidance document section by section. Both myself and Dr. **Saltzman** who is the other co-author of this document will present basically one section at a time and then at the end of that presentation trying to get a dialog going about some of the recommendations and some of things we might do. I am going to start with water now and in the proposed guide we have noted that the source and quality dictated the potential for pathogen contamination. Water is the concern in two regards. First, as a direct source of contamination if pathogens are present in the water itself that was used. And then secondly, as a vehicle for spreading localized contamination either in the field or the packinghouse. One of the overlying factors is not just the exposure of produce to pathogens in water or in other vehicle, but whether or not those pathogens survive until harvest and through the post-harvest handling operation to the point of the consumers. There are many variables involved here that impact on the types of guidance that we are able to provide. We will get into them as we go along. Next slide please. Now just very briefly this slide shows some of the pathogens

that may be carried by water. Next please. It is important to remember that even same numbers of pathogens can cause foodborne illness. No one knows what proportion of contamination of fresh **fruits** and vegetables occurs on the farm or in the packinghouse. That was stated this morning, I will repeat it right now. Other compounding factors are things like many neighbors sharing a watershed. Operators may have limited control over the activity outside of the boundaries of their own property. However, this guidance is urging growers and packers to be pro-active in minimizing those hazards in areas which they have some control. Next please. Water quality needs will vary depending on a number of interrelated factors such as when and how the water is used. Just in very general terms, as the degree of water to produce contact increases so does the need for higher quality water. For **example**, for some crops overhead irrigation may cause a greater risk than drip irrigation. This is a very general statement. **I** comes with a multitude of caveats. For example, on recent site visits we saw a field where the only overhead irrigation that was applied, was applied at the time of planting because that is so **far** removed from harvest and there wasn't even at that point a crop growing for the overhead irrigation water to contact the edible portion of a crop. Obviously, any potential hazard there is a lot less compared to other situations where we saw crops that were being irrigated up until about the day of harvest. So these many interrelated factors that need to be taken into consideration. In **addition**, crop characteristics that foster attachment or entrapment may enhance risk especially close to harvest. For example, if you have crop with surface characteristics or that would help trap water as opposed to a smooth surface crop where the water runs off or if you have **leafy** vegetables that may trap water, you would have a potentially riskier situation there. The previous statement were water in general. For agricultural water uses again, water quality should be adequate for its intended

use. What is adequate? That varies depending on so many interrelated factors it's difficult to say. As I mentioned this morning there are no current action levels for microbial contaminants in agricultural water. Having said that, what can growers do. There are a number of things they can do to help minimize risks. First of all to **identify** the water sources that they use. Farms that divert water for its use in an agricultural environment are listed on the slid. For some growers they may have options, they may have access to more than one source of water. For other growers they may not have choices it maybe just a single water source. In general ground water such as deep wells or municipal water supplies would have less potential for exposure to heavy loads of pathogens compared to surface water. And important thing to kept in mind, if you operation has those options. So **far** as maintaining water quality, we are recommending that growers be aware of current and historical land use. Make sure potential sources of microbial contamination **on-farm** sources of contamination include sources such as leaking or overflowing manure storage lagoons, or livestock access to surface waters or pump areas. Growers should follow good agricultural practices to eliminate obvious sources of contamination. Soil conservation practices such as sod waterways and diversion berms may also help protect water sources form contamination in runoff situations. We could take questions right now on agricultural water before getting into water use and the processing or packinghouse operation. Does anybody have any questions on agricultural water?

Sue Doneth, STOP (Safe Table Our Priority)

Some of the terminology that is used in this document, you know, we're talking about using water of better quality and water quality should be adequate for it's intended purposes. Those are pretty subjective terms to be interpreted

a number of ways. I am also looking under reviewing existing practices and conditions to **identify** potential sources of contamination. These or other potential sources of water contamination should be assessed and controlled to the extent feasible to minimize microbial food safety hazards. How is an independent grower suppose to interpret what the potential sources of a contamination are? How do they assess them? And how do they control them? And what is the feasible extent?

Dr. Michelle Smith

That's an **awful** of questions. I will try and start at one end and work my way through to the other. As I had mentioned there are a lot of soft words in there as such as to the extend feasible, and that's tied in with a lot of **different** factors some of which relate to the fact that the freer/packer do not have the control over our situation. For example, one potential sources of contamination might be if your **farm** is located across the street from a dairy operation or from a feedlot. The dairy operation or feedlot there is a potential from runoff onto your **farm**, one of the things that you might want to consider doing is putting in soil conservation practices as erosion control measures. So you may have the ability to protect your fields from possible contamination from that source. On the other hand if there is feedlot across the street and you have problems with possible dust or wind blown contamination, I'm not sure what kind of control measure anybody could put in place. Now they might be able to work with local people, and they might be able to work cooperatively with their neighbors and do something. What we are trying to do in this guidance document which is voluntary is raise peoples awareness about potential sources of contamination. To have them look at their own operation. Look around **them**, see what things

may impact on their operation and do what they can do. First of all to eliminate obvious sources of contamination. There's a lot that we don't know. Much of the research is just starting now on how pathogens can survive in the field. A recent workshop that USDA/ARL held in Kansas City on (inaudible) management, one of the people that I spoke with said that **preliminary** research that they are involved in is not isolating pathogens from dust particles they are collecting across the street from a feedlot. So part of the problem is that we don't know how much hazards **difference** imposed. Does that answer most of your questions? What does (inaudible)? And I think it has to be accepted as that. In my bias opinion a good beginning. But I don't think this is where we are going to stop. It will be combined with education outreach and any other effective tool that we can come up with. Any other questions on agricultural water? Again with processing water, just as with agricultural water, water quality should be sufficient for it's intended use. In a packinghouse environment we starting to be able to have more control over the environment compared to a field environment. We are able to say a little bit more about what quality criteria should be. But even here you have a lot of variables that come into place. **Again**, as the degree of water to produce contact increases, water quality needs also increase. Treatment towards the end of processing where the product is getting closer to the consumer such as the final rinse may require a higher water quality compared to earlier operations. An example of an earlier operation would be dump tanks or swimming type operation. Produce coming in from the field may contain a significant amount of field debris and so having the cost and effort of super clean water and then you dump a truck load carrots and dirt into that super clean water, it maybe possible to reuse water from earlier operation for that receiving operation. Now we said in the guidance document that water used for processing has to be "safe and sanitary" for its intended use. And although the quality requirements do vary with intended use, we would consider water that meets the microbial standards for drinking water to be "safe and sanitary".

If water is recycled within different unit operations, the reusable water should be counter current to the movement of product through this operation. For example, water that is used in a final rinse might be reused for an earlier process such as the dump tank operation. Although water quality needs may vary for these different unit operations the water should never contribute to a food safety hazard. In other words, the produce should never be in worse shape for contact with that water. Some of the water quality GMPs that we mention in the guide include periodic microbial testing; monitoring pH and the levels of antimicrobial present if they are used; and changing water for adding overflow as necessary. In **addition**, packers should routinely clean all water contact surfaces and equipment including removing debris and plant material from the equipment. Packers should also routinely inspect and maintain all equipment that has a **function** in insuring water quality, such as filters, backflow devices, chlorine, some other monitors. Now one of the first food safety principles that we mentioned in the guidance document is that prevention of contamination is preferred over correction of contamination once it has occurred. We can not expect at this time to be able to completely prevent all contamination from occurring So it maybe useful to have additional controls that may be built in for fresh produce. And especially for fresh produce which is not going to receive a lethal treatment, such as a cooking treatment to kill any pathogens that may be present. We suggest that antimicrobial treatments may have value for some crops. Now the value comes in two forms, one is reducing the pathogen level on the surface of the produce and the other is, reducing the potential for cross contamination or pathogen spread in the wash water. Chlorine is a commonly used antimicrobial. The guidance document also sets out information on a number of other antimicrobial that are being researched and may prove to be effective for use on fresh **fruits** and vegetables. When using antimicrobial in processing water we suggest that **all** applicable FDA and EPA requirements be followed. That

the operator follow the manufactures directions for the use of that antimicrobial chemical. When we had the folks in from the state departments of public health and agriculture, one of our visitors helping with comment review told us of an operation that he had visited that used maybe 500,000 gallons of water in its wash tanks and the operator would add one bottle of clorox and fell like he was doing something good. Now that is an extreme situation. I think that everything that I have seen people have really been making good strides to do the right thing, but is important to get the **information** to make sure that you are using the chemical appropriately, so they are both effective and don't pose a hazard to anyone else. In **addition**, the antimicrobial washes or dips should be followed with clean water rinse. It's important to know that antimicrobial washes maybe reduce but not eliminate pathogens, so back again to the prevention is preferred over correction principle. Typical reductions are 10- to 100 fold. Furthermore as organic materials builds up in wash water things like plant cells, juices, dirt and debris that will tie up the antimicrobial and decrease their efficacy. Good manufacturing practices that we recommend to maintain the efficacy of wash treatments includes things like removing as much field soil from the produce as you can before entering the packinghouse and if that is not possible then operators may want to consider something like a pre-wash before they get into any antimicrobial wash to get the organic matter off so the wash itself is more effective. That is the wrap up of the summary the agricultural and processing water **section**, does anyone have any questions or comments?

Sue Doneth, STOP

I'm looking back on page 16 "follow good management practices to minimize microbial contamination **from** processing water", if we are talking about, I guess I am interested in what the basis is for the statement in the document "water

quality used for a dump tanks or anything that comes from the field may not be as great as for water used later washing and rinsing treatments. If we are talking about **prevention**, you know, the grower might not be aware of the product is in worse shape. If the grower is not aware what mayor what may not be contamination the soil in his field. Not all pathogens can washed off and most of them can't. Is there a basis for -- I mean that's pretty open-ended. I mean can a dump tank be used for entire fields of crops? Should it be changed every so **often**, I guess my thought is if you have contaminated soil and you use this dump tank water you can essentially contaminate the entire dump tank and then every product that you put in it will be contaminated.

Dr. Michelle Smith

Point taken. That particular section there again is in reference to the fact that a dump tank is likely going to be receiving produce straight from the field and contains field soil, and so water that had been used earlier or actually later in the process for the clean water rinse is going to be **fairly** clean water when it gets into the dump tank but is potential for cross-contamination. It is still something that we need to consider, so we will take care of your comments -- into account.

Elizabeth Dahl, CSPI

I have a question that goes actually to both the irrigation water and the composting water, so I want to ask it at the same time if we are talking about both of them. The guidelines said that the water should be adequate for its intended use or compatible for its intended use, but if this water is going to go either to spray type irrigation system on ready-to-eat food that we eat after it is harvested or in processing water, what is the rationale for using any other type of water other than (inaudible) water or sterilized water. I guess what I am asking is

why doesn't the guide just come right out and require sane and sanitary i.e. safer drinking water for both of those type of uses?

Dr. Michelle Smith

First of all because this is a guidance document there are no requirements in it other than the **fact** that we did site existing regulations where relevant. And there are some regulations in place and the guidance is not meant to superseded any other requirements. There are no standards for water quality used in the agricultural environments for irrigation. We don't have data right now on pathogen survival in the field or the other **information** that we would need to establish water quality criteria if we wanted to. And that maybe EPA's job anyway. Furthermore, because of there are some many different factors, for example, your risk maybe greater for overhead irrigation than from the drip irrigation system for those crops. If your crop is carrots it probably does not matter how your water gets there. Some spray irrigation systems in an orchard for example, maybe above ground water delivery but below the level of the produce that is there. Some crops require irrigation only at certain limited times in there growing **season**, other crops may require irrigation right up to the point of harvest. It is really **difficult** to say that any one quality of water is necessary for all of those **different** water situations. The situations that I saw recently in Florida, the irrigation water sources were either generally most **often** deep water wells which we would expect to pose minimal hazards or in some case there were surface waters that were used for irrigation. There would be a very large expense involved in expecting and requiring (inaudible) wash be used for all agricultural water uses. And in some areas they have water districts which is not my area of expertise since there are additional requirements that are imposed on growers. Some of the requirements are financial, some of them are legal. It just goes beyond what we are able to do in a broad-scope document

like this.

Dr. Michelle Smith

Now the second section that I will go over -- Manure and Municipal **Biosolids** -- is kind of my favorite section. I mentioned that I went to a **USDA/ARL** manure workshop in Kansas City a couple of weeks ago and it was really something else to be in a room **full** of about 500 people that made manure their Me's work. And I have never heard so many manure jokes in my life. But it is really an important topic as **far** food safety in fresh produce goes. We recognize that animal manure and **biosolids** can be a significant source of nutrients for soil and a soil amendment at the meeting in Kansas City there was talk about billions of pounds of manure being generated annually and it really has to go somewhere -- land application makes a lot of sense in some areas particularly where there really big animal populations. So, our concerns here are two-fold. Let me back up a little bit. The animal manure and **biosolids** and feces from wild and domestic animals maybe a significant source of human pathogens. And some of those pathogens are shown on this slide. Next slide. As **far** as use of **biosolids** go, this an area that's largely regulated by EPA. In Title 40, **CFR** part 503 the EPA requirement for the use **biosolids** on non-public land are contained. Now for **biosolids** there's an EPA requirement that the pathogens in this material either be eliminated or **significantly** reduced, and there are additional restrictions on use such as limited access to the site and specified time intervals between application and harvest of the crop that is grown on those fields. For manure the research on pathogens survival in manure is just beginning. So once again we in a situation where we are providing good agricultural practice recommendations based on the state of current science and our best recommendations for minimizing hazards. The GAPs that we recommend when the norm is used intentionally on a field, the grower because of the potential

hazards needs to follow good agricultural practices to minimize that hazard. The GAPs that we recommend include things like treating the manure to reduce the levels of pathogens that maybe present, and maximizing the time between the application of manure to a field that will be used to grow fresh produce and the harvest of that fresh produce. In addition growers must be alert to the presence of fecal matter that may be unwittingly introduced into the growing environment. Potential sources of contamination includes untreated or improperly manure; nearby manure storage or treatment area; livestock or poultry operations; and high concentrations of wildlife. Treatments to reduce pathogens in manure maybe divided into two basic categories: first there is passive treatment which relies primarily on the pathogen time in conjunction with environmental factors such as natural temperature and moisture fluctuations and UV irradiation to reduce pathogens. To minimize microbial hazards growers relying on passive treatment should make sure that the manure is well aged and decomposed before applying to the fields. At this point and time we do not have a firmer definition of “well aged and decomposed” that we can provide. If anyone has one, feel free to share it. This language in here now is to raise awareness for those folks that may be storing manure for a very short term consider that as effective passive treatment and then be using it on the **farms**. Active treatments for pathogen reduction includes things like pasteurization, heat drying, anaerobic digestion, alkali stabilization, or combinations of these. It is important to remember that composting is an actively controlled and monitored process. It is a process that is commonly used to reduce pathogens in manure. The high temperature generated during composting can kill most pathogens in a number of days. However, some pathogens may have higher thermal resistance than others. In addition the time temperature combinations required for effective pathogen reduction may vary depending on a number of factors such as the material being decomposed, environmental factors of the **region**, how actively managed the

compost pile or structure is, how often it is turned and regulated, and how thoroughly it maybe turned. We discussed a number of good agricultural practices for the handling and application of manure including the fact that storage or treatment sites near fresh produce fields increase the risk. We suggest that growers look at their operation and where there is a concern put in place structures or whatever mechanisms are necessary to secure that compost lagoon or other treatment area. And growers may consider covering manure storage areas such as making sure they are under roof or under some appropriate covering. Next, untreated raw manure carries a higher risk compared to manure that has been treated to reduce pathogen levels. Applying raw manure to produce fields during the growing season is NOT recommended. Growers may reduce the risk of contamination **from** manure by maximizing the time between application of manure to a field and harvest. As I mentioned this morning for those of you who were here, the working **draft** of the guide cited a 60-to 120-day minimum between applications of manure and harvest. We've removed reference to the 120-days because we did not have a scientific basis for that. That was based on **antidotal** information provided to the Agency. The 60-day is sighted in the National Organic Standards Board. Under the Organic Food Production Act of 1990 guided the National Organic Standards Board to state raw manure should not be applied within 60-days of harvest of organic crops intended for human consumption. At this point and time no one knows how long pathogens may survive in manure or the field so we have a 60-day minimum. We don't have another number at this point and time, There is research going on at **USDA/ARL Beltsville** Agricultural Research Center and a number of other places are looking into this right now. But this is based on our current information. And finally because treatments to reduce pathogens in manure may reduce but not eliminate those pathogens, the guidance document is suggesting that the extent feasible growers may want to consider the recommendation

that we have made for use of raw manure when they are using treated manure.
Recommendations such as maximizing the time between application and harvest.
I am open for questions or comments.

Elizabeth Dahl

I really need to take issue with this 60-day time period between application and harvest. The Organic Food Production Act as you pointed out was passed in 1990. And we have learned a lot since then. And secondly the Organic Food Production Act was not a safety piece of legislation it was more for quality for organics. But there is a study that shows the *E. coli* 0157:H7 could live in cattle manure for up to 70-day. There is another study that shows it could live in sheep manure for over a year, and there is another study shows it could live in soil for 130-days. So I think we definitely have a basis for going beyond the 60-days. And then if you look at the EPA's sewage sludge biosolids regulation for untreated sewage they require -- it's a complex set of regulations -- but anywhere from 14 to 48 months between application and harvest for sewage sludge. And they don't have any special waiver for areas with short growing season, so people just can't use that form of fertilizer if they don't have a growing season that is long enough. If they aren't willing to leave it on there for that period of time. So I really don't think, I really am concerned that 60-days is not protective enough for the public's health and would urge that you look at the science on that.

Sue Doneth

We were talking about, it just appears to me that the report sort of contradicts itself and if this in fact is a voluntary guideline document I guess my feeling is that we should probably ask for the moon and be happy if we get one of the stars. I guess I take some exception to either recommending a passive approach to treatment to reduce

pathogen levels. Why are we not just coming out and recommending the active approach?

Dr. Michelle Smith

There is every likelihood that the passive approach if it is applied for a long enough period of time won't be effective, but we just don't know what that period of time will be. And that is being researched. The passive approach is very likely to be employed in a lot of operations just because of limited equipment, personnel etc. We also don't have any evidence to be prejudice against that kind of treatment if the manure is well aged enough.

Sue Doneth

If you don't have any clear cut guidelines on what "well aged" means, what you are saying a passive approach will be as effective if it is done correctly, but we can't tell growers what done correctly means.

Dr. Michelle Smith

And we can't even tell growers what done correctly means for all of the active treatments at this point and time either because there are just too many variables. The research on manure has focused largely on soil fertility issues. Research on Food Safety is largely just beginning. As a matter of fact there were two of us speaking in the Food Safety area specifically at the workshop. There have been a lot of other factors that kind of taken precedence in peoples minds. And that is one more reason for the guidance document at this point and time is to try and raise peoples awareness in an area that may not have been concerned about. I'll just relate one comment that came in on the working draft which you may appreciate. One comment said that people have been using irrigation water

and manure for thousands of years and we're still here. And so they thought that we had gone to far in the recommendations that we were making. But just to put a **different** prospective on things.

Chris **Silva**, Nutrition Weekly

On page 25, the handling and application -- I was just thinking perhaps if there could be a little bit more specification as to perhaps maybe the length of distance that could be suggested **from** the manure sites to or there holding pens in relation to the water tanks or other areas on the **farm** that are at risk for contamination. There just seems to kind of gloss over rather quickly. I know that this is suggested but can't really make requirements about, but perhaps it could suggest an appropriate length of distance that they can used as a guide. Also, if the FDA does think that a storage site would work then maybe they could go into a little bit more of what a good storage site would be, i.e. whether it would need a **roof**; what material it should be made out **of**; and some things a little more like that. And then backtrack then perhaps with the water that they could also suggest that the area that the water tanks are going to be **in**, that they be looked **after** a little bit more meticulously perhaps to bare animals **from** sheltering up in the area and causing concern of insects falling in or etc.

Dr. Michelle Smith

Thank for the comments. In reference to providing more explicated recommendations, again this is a very broad-scope document but if anybody can help us with **information** to make more explicated recommendations that would have broad application or even any kind of tool to provide information on what might be most appropriate in **different** situations, we are certainly open to that. There is some really neat research going on at **Beltsville** where they have land that has specifically been sloped to **different** degrees and they are measuring water travel and pathogen travel. It's on a kind of

fake roof almost with dirt on top and you climb underneath and collect **leachy** with **different** soil types. So, in some regards we are not there yet. In other regards we are looking to get as close to it as we can, based on any kind of help we can get between now and October. The other option is to work with USDA (inaudible) and others to develop more region specific guides where it maybe possible to get into some of the finer details. At this point and time, I would like to introduce the co-author of the guidance document, Dr. Joyce **Saltzman**. She is a Consumer Safety Officer with the Food and Drug Administration, the Center for Food Safety and Applied Nutrition. And in a previous **lifetime** she worked on health claims.

Dr. Joyce J. **Saltzman**

I think it is important that when we start looking at sanitation and hygiene with respect to our agricultural commodities in our environment that we have to recognize, that we have a very diverse agricultural work force in this country. And it is made up of individuals with many **different** backgrounds and coming from many **different** cultures. It can not be assumed that the work force knows about or even practices good hygiene while working with fresh produce. The guide therefore recommends that all operators establish good hygienic practices that should be followed by everyone that handles or works with **fresh** produce. Perhaps the first step in doing this is for operators to be aware of existing regulations that are out there now that deal with worker health and hygiene. For example, the Occupational Safety and Health Act has set standards for protecting worker health in the field and in packing facilities. Even though this approach is from OSHA it comes from the prospective of the worker, coming from the perspective of the produce we must realize that infected employees increase the risk of contaminating fresh produce when they handle fresh produce. So all personnel should be trained in good hygienic practices before working with fresh produce. What can an

employer due or an operator? First of all we recommend that they establish a training program. Each program should be geared toward the level of understanding for their employees. A formalized training program along with periodic evaluation and follow-up with training sessions has proven to be effective in other segments of our food industry. Operators or the person in-charge of employees should also become familiar with typical signs and symptoms of **infectious** diseases. This was briefly mentioned this morning that we did receive a number of comments on this questioning whether we are asking **farmers** now to become physicians, which we are not. We are simply asking that they become **familiar** with signs and symptoms. Workers with diarrhea disease and other signs of **infectious** diseases should not work with fresh produce or produce handling equipment. Lesions containing pus that are located on parts of the body that may have potential contact with fresh produce, has the potential of contaminating it. Operators should provide protection for any employees or workers that do have such lesions. It will easier to adequately cover it so it will not contact fresh produce, that worker should perhaps be reassigned to job where they won't have contact with **fresh** produce. I just mentioned the training **program**, this simply give some elements that we recommend for a training **program**, it is not limited to this. We want the training programs to be individually geared toward the different employees that an operator may hire. As we said all personnel should comply with established hygienic practices. To do so, you should teach them the importance of good hygiene and help them to understand what happens in the absence of good hygiene. They should be taught the importance of good handwashing, when to wash, and handwashing techniques that should be used. Don't assume that every one knows the correct way to wash their hands. This is a simple task but it is an important one, and it is certainly a measure that it can be done very easily and it should be done correctly. With some of our other public meetings

we had comments from a farmer that said well I never thought that I should teach my employee how to wash their hands but now I am going to reevaluate that. He just had the assumption that everybody knows their hands. This is what we want the operators off- to come away **with**, to reassess their own operation and take steps that they can do -- some of them maybe very simple to help reduce the potential hazards of microbial contamination of the **farms**. With respect to toilet facilities. The guide recommends that workers be encouraged to use available facilities to reduce the potential for crop contaminating fields, produce and other workers and water supply. Be sure that workers are given the opportunity to use the toilet facilities and not just have to wait until they go on breaks. The obvious reason for this is to try to discourage the elimination of waste in the field. Provision of toilet facilities is required for workers under OSHA. What is shown here is OSHA Regulation. **CFR** 1928.110 which addresses the field worker and OSHA Regulation 1910.141. subpart J, gets into the actual establishment which does include packing facilities. Any kind of an enclosed or partial enclosed establishment. Some general practices to apply to sanitary facilities including both toilets and handwashing equipment includes that they should be accessible to **all** employees. They should be properly located so not be near a water source used in irrigation or in an area that is subject to potential runoff in the event of a heavy rains. They also so should be well supplied with toilet paper, a water **basin**, water, soap, sanitary hand drying **facilities** or devices and a waste container. All facilities should be kept clean and sanitary. Containers that are used to store water for handwashing should be cleaned and sanitized on a routine basis and refilled with potable water. Now in discussing sanitary facilities we have to also address sewage disposal. In this situation we have to refer to our friends with EPA who have a number of regulations that are in place under

40 CFR Part 503. All operators should be following these regulations which have been in place for some time. What we recommend in the guidance document is that tank trucks should have direct access to toilets for servicing them. For all toilets it is important to have a plan for containment of effluent in the event of a spillage or leakage. We have seen in one operation where toilet facilities were moved along the field on the flatbed behind the tractor. This is while the workers were in the field harvesting produce. This situation maximized accessibility of the facilities to the worker, but care must be taken to ensure that the facilities in the field do not contaminate produce. In this particular operation the toilet facilities were moving behind the workers and were not actually rolling over produce. They were only going over land that was already harvested. Before I go on into the field sanitation, I would like to entertain any questions you might have on worker health and hygiene. On field sanitation. Some good manufacturing practices that we recommend in the guide: that when working in the field you want to have any storage facilities that are located in the field to be clean so they don't contaminate or cross-contaminate produce. If you are using cartons that are in need of repair or damaged they should be assessed. If they can't be repaired they ought to be thrown out and replaced. For muddy containers or cartons, they should be cleaned before being used. The produce that is being removed from the field for further packing or processing, remove as much mud and dirt from the product as practicable in the field. In other words, leave the contamination in the field as best as you can. And lastly, insure that produce that is packaged in the field is not contaminated during the process. Because we know there are a number of operations where there is just a little packing shed right in the field and produce just sits and then is processed for packaging right there in the field. So that has its own set of concerns that need to be addressed in order to maintain good field sanitation. Field equipment must be used properly whether it is planting, growing, or harvesting season. Field equipment

includes a number of different articles, not just large machinery but it also includes cartons and baskets, tables, packing materials, brushes, buckets etc. Many **different** things. But any equipment, particularly the large equipment that has been used to haul or carry items such a garbage, manure or any such material that could possible contaminate **fresh** produce should not be used unless it has been cleaned previously. And cleaned and disinfected depending on what has been hauled in it. The guide recommends that operators assign someone to be in-charge of equipment and be responsible for insuring that it is maintained, working properly, and kept as clean as practicable. Now looking a packing facilities. Just a general recommendation in the guide is that for all packing facilities or packinghouses in the ground around them that they may be maintained in good condition to reduce the potential for microbial contamination of fresh produce. With respect to the grounds around **them**, the packing facilities, it includes things of simply keeping the grasses cut; keeping trash hauled away -- you don't want to be attracting pests, rodents or animals that could possible get into the facility and then contaminate produce.

Sue Doneth, STOP

In the field portion of the guidelines there is no reference made at all to actually handling food products. Most of it talks about equipment; it talks about removing dirt from product. I guess specifically I'm think in terms of strawberries for instance that are picked for processing to be frozen. The **calyx** is a lot of times manually dug out of the **fruit** from a worker using a fingernail. Is there going to be anything added in here in terms of using tool or something else on certain kinds of produce where you actually have to manipulate the fruit?

Dr. Joyce **Saltzman**

We didn't attempt to get into specifics because of the broad-scope of this.

Initially as you hear early on in the produce safety initiative we were considering (inaudible) these specific documents which would have gotten into that direct issue, all of the issues related to specific harvesting of produce. At this point we have not considered it Try to address the handling in the sessions of training workers and ideally teaching them proper handling techniques for produce.

Sue Doneth

Well you can word it in a way (inaudible -- attendee was **speaking** from her seat)

Dr. Joyce **Saltzman**

Well that is a good suggestion. We'll take your comment on that. **Thank** you.

Are there anymore questions on that section?

Within the packing facility, recommendations not to unlike what we saw for the field. Before you bring produce into a packing facility try to remove as much dirt and mud as practicable from the product outside the facility or packing area.

Again for cartons, repair them or discard the darnaged carton that you cannot keep clean properly because they can harbor organisms that can contaminate the food. Clean muddy pallets, container -- all general practical knowledge that is very applicable to the packing facility and to the field. In one of our site visits we saw a carrot packing where trucks seemed to unloading at least as much as field soil as carrots, and this is just viewed that this extra field soil placed a huge burden on the cleaning operations for the produce. So any thing that can be done ahead of time away from the packing facility we think will maximize reduction of microbial contamination. The packaging equipment like field equipment it all needs to be kept in good working condition, as clean

as practicable, and used appropriately to prevent microbial contamination of fresh produce. If you have packing equipment be sure it does what it is suppose to do. Make sure it works. All packing areas should be cleaned at the end of each day or more frequently depending on the specific operation. Be sure that when you start a new operation that the equipment is specific for that, it has been cleaned, sanitized if necessary or disinfected if necessary. Operators should ensure that cooling systems are maintained in proper working order and be kept clean. I am not addressing the water quality here. That was addressed in Michelle's session. Here we **are** just talking the equipment itself. Be sure that it works. Be sure that it does what it is suppose to do. And keep it clean. It is also important to clean all product storage areas on a regular basis. Removing dirt, debris, and produce waste. Finally all packing facilities should have a pest control system in place. The guide recommends that operators establish a pest control system which would include maintaining the grounds in good **condition**; monitor and maintain facilities **regularly**; blocking access of pests into the enclosed facilities as best possible; and use a pest control log to help monitor what has been done, areas that might have been infested that have been treated, do spot rechecks to make sure that your pest control approaches are working and are effective. Now before I move onto the last section of my area, are there any comments on the packing facility. New to this guide that we didn't have in the working guide is in response to comments. Operators who permit customers to pick there own produce or who sell produce directly to customers should use the opportunity to teach customers about good handling practices for fresh produce, and to promote good hygienic practices. Customers should follow established hygienic practices just as if you would require an employee. The guide recommends that all customers who pick produce be provided with properly

equipped handwashing stations in the field, and that there be clean, well supplied, and convenient restrooms for their use. Encourage operators to educate customers about washing fresh produce that is going to be eaten raw.

With regard to transportation this general statement, that produce may become contaminated with the loading or unloading storage transport operations. Obviously anyone who is working in the transport area whether they are loading or unloading should follow good hygienic practices. So again an operator, if they are not the transporter whoever it is should have their own good hygienic practices established and apply the same kind of requirements that we would for workers in the field.

Anybody who is going to handling or transferring produce should follow. Operators should ensure that some is responsible for inspecting trucks that transport cartons before loading inspect for cleanliness, odors, any signs of **contamination**, and find out what prior loads were carried in the vehicle before loading the produce. It maybe prudent to clean and disinfect it before any loading is done. We had some farmers at our other public meeting who said that they automatically just clean the trucks. They don't even try to **find** out the answers to some of those questions. They just take it on themselves to ensure that those vehicles are ready for transporting their produce. It is important to keep in mind that transport vehicles to keep them clean in order to reduce microbial contamination or cross-contamination. Once **again**, focus on prevention of problems, and not be chasing **after** problems and to reduce them later. During transport it is recommended that proper storage temperatures be maintained to ensure both the quality and safety of fresh produce. If when trucks are loaded they the produce should be loaded so as to minimize damage to the products. Now the last section of our document is on **traceback**. Are there any question on transportation I will be glad to take them.

Catherine Carneval

Traceback was covered very well this morning by Ellen and she pretty much gave everything that we have in our guidance document so we can go over this fairly quickly. Traceback is the ability to trace, to track food items, from the consumer to the source of the products. An objective traceback program can serve as an important compliment to any good agricultural manufacturing practices intended to prevent the occurrence of food safety problems. In the guide, we give an overview of the traceback process. It begins with identifying the suspect food item and the point of service where the food that caused the outbreak was served or sold. Next, pertinent information is gathered such as identifying product type, packaging, labeling, lot numbers, expected shelf life, and so forth. Identification and documentation of the source of suspect shipments of the product can be obtained up to the point of service of one of two ways. One by tracing lot numbers or by reviewing delivery records for information about the timeperiod when the product was salable and usable combined with employee interviews in all points in the distribution chain. This option does require a lot of time and effort and the information gained may be less than perfect. Now Ellen also went through information about the challenges for the fresh

produce industry. We repeat those in the document. I am not going to go over them now. And advantages of an effective traceback system. As she pointed out, traceback is very difficult and very complicated, but we certainly do encourage operators to consider ways that they might be able to try to keep track of their own produce as far as possible along the food chain. In conclusion, that once your good practices, your good agriculture and manufacturing practices are in place, insure that the process is working correctly. Regularly monitor operations to insure all practices are being followed. Without accountability, the best attempts to minimize risk of contaminating fresh produce are going to be subject to failure. And that's all I have to say. Do you have any questions?

Sue Doneth

Just one comment on page 46 the sentence that reads, "assistants who identify the source of fresh product cannot prevent the occurrence of a microbiological hazard that may lead to an outbreak of foodborne disease." I would just suggest that may be reworded to just include the word "an initial" outbreak of foodborne disease. Because I think traceback capability will allow the reduction of an outbreak because it may prevent further distribution of a product, number one. And number two, if an outbreak occurs and you are able

to trace it back to find the origin, you may be able to clean up practices there and prevent a future outbreak.

Catherine Carneval

Thank you very much. Any other comments?

Louis J. Carson

I would like to emphasize that each one of the sections of the guide, while some people may think certain recommendations or actions are trivial such as hand washing, we do not. I'll share with you an antidotal story. There was a report in the paper about hospitals and what was leading to the increase of infections at hospitals. NIH did a study and found that physicians who should know what they are doing were not properly washing their hands which led to a significant increase in those infections. So, even in the section where we talk about taking some time to educate workers on how to wash, while it may seem trivial, can really pay off dividends where it can pose severe problems to that product. So, we believe that each one of the sections does have a value added to the overall quality and safety of the product. So we would like to emphasize that. I think some of these can be looked on as common sense, everyone does it, but you'll find if you look at the systems, not everyone really does that. So I would just like to offer that as encouragement that, while

these are voluntary, I think a lot of what we are trying to do and has been emphasized is raise the awareness on the food producers to make sure they are taking affirmative steps. And affirmative steps are what we're about. Many are, as we have said, we've based many of these recommendations on industry practices or industry documents, but more can be done. If there are no other comments or questions concerning the guide, then I am going to open it up for public comments and there were two people that have indicated so far that they would like to make a public comment. So let me first call on those two people and then, if anyone else would like to make a public comment, you may. I was reminded that I had forgotten to make one other statement about the good agricultural practices. One of the things that we've been struggling with is how are we going to assess progress. We have been grappling with this both from a domestic and an international standpoint. We are working with a national agricultural statistic service within the Department of Agriculture. We will collectively be developing a survey questionnaire which we will be using with farmers through the National Association of State Departments of Agriculture will directly conduct the survey for us. It will be to assess Ag practices as they are today and then, after a few years, to assess if there are changes in those practices. So this

survey, which we hope to do in a pilot form next fiscal year, will then, once we've learned how well the pilot has worked, we will then expand it. Those survey questions will then also be used to assess international agricultural practices. We need to first get a baseline. What we are struggling with currently is the fact that agricultural practices within the United States are widely diverse based on the commodity region and available systems. Likewise, it's even more diverse as you go beyond our boundaries. So we are trying to come up with a survey mechanism that will give us a general sense of those agricultural practices and then to assess what impact the voluntary guidelines have had on those practices. We are not going to be using the survey to say what practices are good and bad. We're going to be there to assess what the practices are and to what extent people have incorporated the guidance that we have put forward in changing those practices and what practicalities have been developed in using those guidelines. So I just wanted to let you know that we are working with the Department of Agriculture in trying to get an assessment tool. OK, let me next turn it over to Elizabeth Dahl who would like to make a public statement.

Elizabeth Dahl

Thank you very much. I would like first to just respond briefly to the comment that was referred to earlier about someone saying that we have been using irrigation and manure for thousands of years and we're still here. But we have also been getting sick and dying from infectious diseases for thousands of years and that doesn't mean that we should still be doing it. I mean, that's why I think that these guidelines are a good first step and that they include many, many excellent ideas. But the real question for my organization is what does this really mean for consumers? Are they going to be adopted? Are we going to see a decrease in foodborne illness from produce? That would be the real measure of success from our viewpoint. I would like to just point out that fruits and vegetables that are contaminated with pathogens are adulterated under the Federal Food, Drug and Cosmetic Act and the FDA therefore has the authority to require some kind of steps that producers take to reduce this contamination just as they did for seafood (inaudible). So we would like to strongly recommend that the FDA consider taking such a step particularly if producers don't immediately start complying with the voluntary guidelines. I understand that there was a statement made that we don't have the science to require maybe everything that needs to be required at this point. But we do have

science on some points and regulations could go into place in those areas. FDA should look for commonalties. For example, wherever in the process water is touching a product that's going to be eaten that's not going to be cooked first, I mean that could be a control step. That could be a point where intervention is made without having to analyze every step and agricultural process in the country. In talking about this particular guideline, as I said, a voluntary recommendation, I noticed a big difference in wording between the water in the manure sections and the sections after that. In that, the water in the manure sections are very vague and they contain language like, producers should be aware of risks or they may want to consider doing x, y or z. That really isn't enough. Action steps should be included. Just because it's a voluntary document doesn't mean that it shouldn't include a tough, clearly enunciated standard so that it really has some value to the growers, to the people it is trying to assist. Thanks very much for the opportunity to comment.

Louis J. Carson

Next is Jaime Almonte who would like to make a public comment.

Dr. Jaime Almonte-Alvarez

Thank you very much for the opportunity to make these comments. On behalf of the Department of Agriculture in Mexico, I would like to make some important comments. On behalf of Dr. Francisco Gurria-Trevino, Undersecretary, Secretariat de Agricultural in Mexico, I am pleased to provide these general comments on the draft guidance: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. Mexico has watched with interest the development of President Clinton's Food Safety Initiative. As a major source of the imported fresh fruits and vegetables consumed in the United States, Mexico is especially interested in the President's initiative to ensure the safety of imported fresh produce and is committed to working with the United States to develop appropriate guidance for the growing, harvesting, packing and transportation of its agricultural products. On behalf of the many relevant agencies in Mexico responsible for food safety, SAGAR is seeking to finalize a formal, comprehensive partnership agreement with the United States to ensure cooperation on research, technical assistance, training and education, surveillance, monitoring, technology and information-sharing and other aspects of the FSI. Mexico believes its food safety standards and enforcement will meet U.S. food safety standards and is committed to working with the

United States, Canada and other countries around the world to secure and sustain the confidence of the U.S. and global consumers in the safety and wholesomeness of the international food supply. Like the United States, Mexico is committed to science-based food safety standards. Food safety is an important international public health issue, and the protection of public health remains one of the most cherished responsibilities of every nation. Like the United States, Mexico also strongly believes that food safety should not become a trade issue. Valid public health issues should not be abused by competitors to disrupt the flow of trade. SAGAR urges the Food and Drug Administration, the U.S. Department of Agriculture, and the other relevant agencies of the U.S. Government to take care to ensure that any and all food safety regulations and procedures be based on verifiable science and that their enforcement be carried out in an objective, non-biased, and structured manner. Food safety rules should not be available as tools to confer a competitive advantage. SAGAR'S producer, processor and exporter constituents are confident that their systems and standards meet the requirements of the guidance, many of which are common practice in Mexico. But the nature of the guidance is that compliance with its requirements envisions additional supervision and/or surveillance. Whether or not the guidance

remains "voluntary, " Mexico's customers may seek some form of certification or assurance of compliance. And these certification procedures and protocols are likely to require substantial additional time, investment and training. Like our U.S. counterparts, we believe these requirements could be more effectively implemented with additional time. Our constituents are also concerned that the United States may lack sufficient information to provide appropriate guidance for products not grown in the United States. As you may know, Mexico has offered to work with the United States to develop appropriate guidance for the production, harvesting, packing, etc. of its products. We will provide additional, detailed comments to the Food and Drug Administration prior to the June 29 deadlines. I thank you for your attention.


Louis J. Carson

Thank you. Previously, Ms. Edith Garrett from International Fresh Cut had also asked to make a public statement. Is she here? OK, I would then...

Dr. W. T. Jolly

I'm Dr. Jolly from the New Zealand Embassy. The statement that the Embassy would like to make is that throughout the guide there are references to basic legislation in the United States and although that

legislation is particularly relevant and the principles on which that legislation is based is very relevant, the Embassy and New Zealand would like to see an equivalent statement so that the guide does not only reference domestic legislation but recognizes the equivalence of overseas legislation with respect to hygienic requirements etc. etc. so the principles are carried through but we don't have producers just replicating the domestic legislation but the principles it contained and met with, where overseas legislation is more stringent than importers from the United States expect that their legislation is actually applied. The only other comment we'd like to make was made a little bit earlier this morning. The term "relative risk" is not really incorporated and that's been explained that the science is not quite there to actually give a ranking, but we'd like to see as the guide is progressed that if the principles had been considered and if it was directed to Ag, had the issues most significant so that we do get some stance improvement and we don't get over (inaudible) but it's some degree of relative risk and principles incorporated in the guidance. Thank you very much.

 Louis J. Carson

Thank you for those comments. Next, Ms. Nancy Snider from the Sprouts Association would like to make a comment.

Nancy Snider

Hello. I'm Nancy Snider, President of the International Sprout Growers Association. I want to say that I have really learned a great deal from listening to all these presentations this morning. It's surprising how much of this is quite appropriate to our sprout problems. Basically, I am going to talk just a minute about sprouts. I won't take long. I wanted to comment more on the microbiological safety evaluation and recommendation. To introduce my subject, I would like to give you just a few statistics that may surprise you. Worldwide sprout sales are approximately one billion dollars with the U.S. market being about 250 million dollars. There are approximately 5,000 sprout growers worldwide and this excludes China which is a huge sprout growing nation, but we don't have much statistics. There are about 475 growers in the U.S. and Canada. The sprouting industry in the U.S. and Canada is about an exact parallel to the farming industry which varies in size from very small growers about fifty thousand dollar a year type people to five million dollars to the larger growers. There are many

benefits from eating fresh sprouts. Not only are they rich in proteins, vitamins and minerals, but government and independent nutritional studies have shown that Americans should indeed increase their consumption of fruits and vegetables to at least that famous five a day. These same studies show that generous servings of fresh fruits and vegetables in our diet are protective against many cancers and lessen the risk of coronary heart disease. Researchers at Johns Hopkins University show that broccoli sprouts contain 20 to 50 times the amount of the compound, I'm sure you've all heard about, sulphoraphane as mature broccoli. Sulphoraphane is a very potent chemical which appears to protect human cells against cancer-causing chemicals. According to Dr. Talalay, a Hopkins molecular pharmacologist, "our prediction is that sulphoraphane will block tumor formation in animals and presumably in man... But because it will take many years to complete human trials on such chemoprotectors, the best we can do for now is to modify our diets in a way that has a scientific basis." For now, Dr. Talalay recommends that we simply eat more cruciferous vegetables. Based on the Johns Hopkins work, the consumption of broccoli, cauliflower and cabbage sprouts can be associated with lowering your risk of contracting cancer. Researchers at the University of Kentucky indicate that there may be compounds in alfalfa sprouts which will also benefit

in the fight against cancer. However, that research is just beginning. With all the good reasons we should include fresh sprouts in our diets, there are some risks associated with eating sprouts. These risks are about the same in fresh sprouts as for fresh cut produce, as the microbial loading for both is identical. Most sprout companies have never been associated with a foodborne illness and many of us have been growing and selling sprouts for more than twenty years. In the past five years, less than one percent of the growers in the United States have been involved in any sprout associated illness. Sprouts are generally locally grown and distributed in small geographic areas with most sprouting seed shipped through only a few distributors. As a result, outbreaks are easy to recognize, trace and contain. Sprouts are a unique product and consumers can easily remember if they have or have not eaten sprouts before they became ill making the traceback much easier in sprouts than in most fresh produce. Because all but one of the foodborne illnesses associated with sprouts have been attributed to contaminated seeds, we in the sprouting industry are vigorously pursuing all possible research avenues to find methods of sanitizing our seeds. We are exploring various chemical treatments which will sanitize the outside of the seed hull. Among those that we have tried are potassium sorbate, calcium propionate, sodium

hypochlorite, peroxide and ozone. The best results that thus far we've been able to obtain is by using 2% calcium hypochlorite for nearly twenty minutes, thoroughly rinsing and re-soaking the seed and then rinsing again in potable water. Various surfactants were tried but most inhibited germination while not increasing the efficacy of the treatment. The above treatments are very effective for seed contamination when the seed hull has not be penetrated by a pathogen. Several researchers out at ARS are experimenting with irradiation or gassing of seed which will penetrate the seed hull. Meanwhile, what are we doing? Before we can find a lethal treatment which will either kill or find the pathogens or something that we can introduce into sprouting seed that will crowd out all possible pathogens, we at the sprouting industries are viewing all sprout workers as food handlers and not agricultural workers and are following good manufacturing practices for food handling. We view all sprout seed as food and we insist that good agricultural and manufacturing practices be employed in seed production in the processing and storing of seeds that are designated for sprouting. We are updating our sanitary guidelines for our industry as more information is available. We have developed and are continuously upgrading a HACCP plan for the sprout industry. This plan includes a critical control point

for the chlorination of seed or, in the alternative, some method of seed sampling that will determine if the seed has been contaminated. ISGA is establishing a seal of approval for the sprout industry. This seal will only be awarded to sprout facilities that employ good sprouting practices which have been verified by a private inspector. We intend to advertise this program to all supermarkets and let them know what this seal means and to encourage them to buy only products which contain this seal. We are educating our members as well as non-members in safe sprouting processes. ISGA also recognize that we have not yet found a magic bullet that will kill all pathogens that might be on sprouting seed; however, by chlorinating our seeds at high levels and employing good farm practices and good manufacturing practices, we have greatly reduced or eliminated much of the risks associated with eating fresh sprouts. Thank you.

Louis J. Carson

Thank you for your comments. Next we have Ms. Sue Doneth who would like to make a comment from STOP.

Sue Doneth

I don't have a statement prepared, but I thought it necessary after sitting through the meeting to comment somewhat at the end of this. I'll be brief. I think

Elizabeth covered very adequately a lot of the concerns that consumers have. I will tell you again who I am. My name is Sue Doneth and I'm from STOP, Safe Tables Our Priority which is a national grass roots consumer organization of foodborne illness victims and their families. It was started during the Jack-in-the-Box Ecoli outbreak and has since grown to include a number of foodborne illness victims. I became involved in this issue when my own daughter became a victim of foodborne illness a year ago. Since then, I've become very involved in the issue involving the safety, or lack thereof, of produce both domestically and imported. One of the things that I want to stress, talking as a mother, talking as a consumer, and talking from a consumer group, I don't care where my food comes from, I want it to be safe. Period. I don't want it to be safe at the lowest cost. I want it to be safe. I don't think there is a consumer shopping or a mother feeding her family who is not going to pay a few pennies more to be relatively assured that the product that they are buying is safe for consumption and safe to feed to her children. Another thing that I want to stress and one of the reasons that I come to these meetings, I don't do this for a living. I'm not a paid professional speaker. I'm not a lobbyist. I have a full-time job. I use all of my vacation time to do this on a volunteer basis because I think it's important that industry and

government hear from consumers. I think it's important at these meetings for everyone in here to remember when we are talking about statistics and reports and guidelines and all of these other terms that, when we talk about the 80 million people who get sick every year from foodborne illness and the over nine thousand that die, all of the people have a face. They all have a name and they all have families. They all come from a community. My eleven-year-old daughter, a full year later, is still suffering medical difficulties as a result of getting ill from food. So I think it is important that everybody remember that. We're talking about people and a lot of times we are talking about children. The cost to the victims of foodborne illness is astronomical and it can't always be quantified. I can't put a cost on many of the things that have happened to my daughter in the last year. I can't tell you how much it costs a ten-year-old not to be able to participate in soccer or be able to participate in a dance class because she's not physically able to do so. There is no cost that I can be put on that and I hope that industry keeps that in mind when they are looking at the cost of improving their systems to assure a safer food supply. One of the other concerns I have as a consumer, and I think all consumers have, is red flags go up when we hear the word "voluntary." I know this is a start and I know that we have to start

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somewhere, but put quite simply, consumers do not trust voluntary actions all the time by industry. There have been a lot of mandatory standards in place that have not been followed. There have been rules that have been broken and laws that have been broken across the board that have happened. So there is a lot of consumer skepticism when we talk about voluntary which is why I think it is very, very important that when we are looking at a document like this, because we are calling it voluntary, because we're calling it a guideline, I think that we need to stay away from the soft words. I think we need to stay away from the passive approach and I think we need to be very, very specific because, I think we do know what works in some cases and what doesn't. I think, rather than dancing around the issues, sometimes we need to just spell it out and stress to industry that these are things that they should implement. Thank you.

Louis J. Carson

Thank you for your comments. We have two more speakers. One from the Embassy of Chile. Do you want to come up now? Will you please give your name when you come up and any other affiliations?

Eduardo Santos

My name is Eduardo Santos. I'm with the Agricultural Counsel for the Embassy of Chile responsible for all the agricultural issues and trade matters between Chile and the United States. As you are aware, we are an exporting country but basically depends to a very large extent on agricultural and agricultural exports. We like and we want to reassure our customers, our consumers, that we are producing to the best standards, the best international standards, and we would like to keep it that way. We will continue to cooperate with the United States and other countries to keep that matter. We have worked pretty closely with the Food and Drug Administration and the Chile Department of Agriculture and actually we have today the largest contingent of U.S. inspectors outside of the United States. Every single food package you get in this country has been inspected by U.S. officials in Chile and here on arrival at the U.S. ports. We want to assure consumers, we want to assure the United States, that we will continue to cooperate and work together closely with the United States on these matters and these issues. We would also like to work with international communities. We are cooperating very closely with the colleagues and Secretaries. A couple of weeks ago, we held in Chile a meeting of colleagues, Dr. Saltzman was present there representing the United

States. We will remain closely associated with the work that the international community is doing in these matters because it is most important to us. Having said all of that, we are getting a little bit concerned with some of the developments that have taken place in this country. We hear different information. I'm not going to claim that I am an expert on food safety or food issues, but since this discussion began to take place about a year ago in this country, I think that I have been attending every single meeting that has taken place. We get different information. We get different data. We get different recommendations. And some of them very (inaudible) recommendations. Those of you that were present at the hearing last week in Congress probably heard the Food and Drug Administration was being criticized very harshly on some type inspection on foreign food. Those are worrisome matters for us and I am particularly interested in them. We like to cooperate and will continue to cooperate with the United States and the international communities in this matter. They are of the most high importance to us. But we want all of these decisions being made on some science with respect to international rules, respect for international agreements. We wouldn't like to see these as a trade issue. We wouldn't like to see these interfere with normal trade relations between our countries. Thank you very much.

Louis J. Carson

Thank you for your comments. Next, from the Embassy of Guatemala, again if you would give your name and your affiliation.

Roberto Rosenberg

Thank you very much and my name is Roberto Rosenberg and I work in the Embassy of Guatemala here in Washington. I also would like to take this time to inform the audience that Guatemala has been taking the food safety issue very seriously. Guatemala has been cooperating with CDC and FDA in all investigations since last year and the government has taken this so seriously that we have created a high level commission for food safety with the minister of our country, minister of public health, minister of economy. We have created working groups for research for both harvest treatment and for the certification and inspection of farms. Cyclospora is our number one priority right now. In these working groups we have included FDA officials, CDC officials, scientists from Guatemala and from the U.S., from different universities, Cornell University, to help us out in this investigation. Because as we still don't know any thing about cyclospora. It's a big hypothesis what, you know, the science is not there. So we are trying to do everything we can to cooperate with

CDC and FDA. But the government and the Berry Commission has gone even further and we have implemented a quality assurance program with supervision from the FDA and the CDC in the farms in Guatemala. This quality assurance program has taken into account the guidance that have been discussed today. It's even more conservative than that and we presented to the FDA good support for the food safety initiative (inaudible) to be able to export throughout the year the raspberries. It's even much more conservative than the quality assurance or the guidance that we have discussed today. We have received a positive response from the FDA a couple of weeks ago for the export of some of these farms that we have selected a low risk. We are still waiting from the FDA for a letter which is going to specify exactly which are those farms that we will be able to export and what is the conditions that they have to meet to export to the U.S. the whole year. So that is the statement that I wanted to say and I thank you much for the opportunity.

Louis J. Carson

Thank you for your comments. Are there any further comments? Yes, Mr. Holzworth.

David Holzworth

I'm David Holzworth and I'm a Director of Government Relations for the Chilean Fresh Fruit Association and Chilean Exporters Association. I like to think of my group as a consumer group also. A consumer group because it has a product that is intended for consumption and our constituents consist of all those people in the United States who buy over sixty million cases of Chilean fruit every year. It is very important to our companies within the Chilean Exporters Association, that products to you continue to be popular and accepted by the consumer and meet the highest standard of food safety. Like everyone else in this room, the Chilean Exporters Association and the Chilean Fresh Fruit Association is in favor of food safety and is in favor of increasing standards for food safety as we find more and more effective means of getting a high quality product to the consumers. I have only a few comments to make generally. Our technical comments will follow in written form. First comment is that we believe that the data and all discussions of data including statistics about foodborne illness and the number of deaths that result from it must be very carefully made and very precisely communicated to the media so as to not create any confusion as to what we are talking about. Earlier in the day, we heard general sets of statistics about food safety applying to all

illnesses related to products including seafood, meat, poultry and dairy. We later heard some more precise statistics from the Center for Disease Control that quantified the amount of the problem that is directly attributable to fruits and vegetables. There has been no precise discussion of the data in terms of what the issue is and how it should be framed with respect to importing fruits and vegetables. One piece of data that I'm absolutely sure of is that there are zero instances of foodborne pathogens related to products imported from Chile and that's a very important point that if anybody in the media doesn't get right we'll be sure to remind them. Now, we have been very blessed in Chile by certain natural barriers to pests and also a very favorable climate often compared to California only in the southern hemisphere. That has allowed Chile to take advantages of its natural environment to develop its industry to the point where it is today. No one can guarantee with absolute certainty that there isn't going to be a food safety problem related to a product from a particular farm or from a particular country, but all of us here in this room want to work toward minimizing that possibility to the smallest degree possible. For that reason, we are glad to join with FDA, USDA, consumer groups, consumer representatives, or should I say the other consumer representatives, to work toward that goal. That's what we want to do. In

addition to participating in these proceedings and, as Eduardo Santos has mentioned, the Chilean Government has cooperated with agencies at the U.S. Government and that's also involved a trilateral arrangement with the Chilean Exporters Association to basically have a very large contention in the USDA inspectors down in Chile to look at the fruit. But, beyond that, what hasn't been mentioned much here are the efforts that take place in an ordinary course of commerce in a marketplace to increase food safety standards. There are a number of voluntary contractual agreements between exporters and growers and companies that ship the product to the United States that absolutely require a certain level of inspection, quality assurance, and meeting of standards to try and get that level of quality product up to the point where we all want it. Put all of those programs together, the voluntary programs that are entirely within the private sector as well as those programs that involve the USDA, FDA, Chilean Government, and Chilean Exporters Association are sited throughout the literature of the industries and by government officials in private industry as well as a model of cooperative effort aimed at the common goal of getting the best quality product to the consumer. We commend the agencies on their efforts here with the guidelines to get a discussion going from all the groups that are affected. We think

that's a very important discussion. We fully support it. We applaud the effort and we will continue to participate in it. At the present time, from the government side, in most cases, we think that voluntary guidelines and voluntary has to have quotation marks around it here because once the guidelines are out there and, as was pointed out, FDA does have certain authorities, those guidelines become a standard that is not exactly technically required but is still more than voluntary because it becomes a standard that the industry must meet to remain competitive in the market place and get their product to the consumer. We appreciate the opportunity to participate and make these comments and we look forward to meetings in the future.

Louis J. Carson

Thank you for your comments. Are there further comments people would like to make? That is the end of the program from our side. If you have any specific issues, we will still be here and you can ask us directly. Also, let me reiterate the phone number if you wanted slides from the speaker, the phone number is 260-8920 area code 202 and we will make copies of the slides that we presented this morning by the opening panel. We will be accepting comments to the docket as has been mentioned up until June 29. We encourage you to attend our other two public meetings. One

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will be in Miami this Thursday and on the 27th in San Diego.

Thank you for coming.