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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

PUBLIC MEETING:  
2004 PRODUCE SAFETY ACTION PLAN

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P R O C E E D I N G S

DR. BERU: Good afternoon. Welcome to this public meeting and FDA's draft action plan to minimize foodborne illness associated with fresh produce consumption to the greatest extent possible.

My name is Nega Beru and I am the Director of the Division of Plant Product Safety in CFSAN's Office of Plant and Dairy Foods. I will serve as moderator for this meeting.

Before I introduce the panelists for our meeting and we go into the public comments on the action plan, I would like to invite Dr. Bob Brackett, Director of our Center for Food Safety and Applied Nutrition to make his opening remarks.

**Opening Remarks**

DR. BRACKETT: Good afternoon and welcome to the public meeting on FDA's new produce safety action plan. It is a pleasure to be here today to discuss this important issue with you.

Produce is recognized as an important component of a healthy diet and can play an

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important role in weight management. However, most produce is grown in a natural environment and, as such, is vulnerable to contamination with pathogens.

CDC estimates that, in the 1990s, at least 12 percent of foodborne-outbreak-associated illnesses were linked to fresh produce items. Over the past decade, we have focused significant resources on reducing foodborne illness for all sources. However, despite our efforts, foodborne illness associated with fresh produce continues.

The good news is we believe foodborne illness associated with fresh produce is a problem that can be solved. We are committed to minimizing foodborne illness associated with the consumption of fresh produce and are developing an action plan that will achieve these goals.

It may be interesting to document outbreaks and the organisms that were responsible for the outbreak. However, better questions to ask are why outbreaks are happening, what is the source of the organisms and what we can do about it.

We believe that each entity involved in producing, packing, processing, distributing or preparing fresh product has a responsibility to conduct its activities so as to reduce, control or eliminate microbial contamination of produce. Therefore, we are proposing that the action plan extend to all parts of the food chain, from farm through retail or consumer consumption or preparation.

We believe that the most effective strategy for reducing foodborne illness from fresh produce is likely to be one that approaches the problem from several different angles. It is important that we consider the reviews and ideas of all our food-safety partners, both public and private. By working together, we can achieve our goal.

We look forward to hearing your views and comments.

#### **Introduction of Invited Speakers**

DR. BERU: Thank you, Bob.

As you will note from the agenda you

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picked up on your way in, we have a pretty full afternoon.

We will have a panel of speakers to provide context to our discussions. First, Dr. Michelle Smith, Interdisciplinary Scientist in the Division of Plant Product Safety will present the draft action plan.

Then Dr. Michael Lynch, Epidemic Intelligence Service Officer from the Foodborne and Diarrheal Diseases Branch in the CDC will present on outbreaks associated with fresh produce.

Because Dr. Stenzel has to leave for the airport, there will be a slight change in the order. Mr. Stenzel, President of the United Fresh Fruits and Vegetables Association will go next and present the first part of the iud perspective.

Ms. Laurie Girard, Produce Programs Manager of Safe Tables Our Priority will then give a consumer perspective. Finally, Mr. Bryan Silbermann, President of Produce Marketing Association, will give the second part of the industry perspective.

We have an FDA panel of listeners. They are Dr. Terry Troxell, Director of the Office of Plant and Dairy Foods; Mr. Jack Guzewich, CFSAN's Director of Emergency Coordination and Response; Ms. Mary Ayling, Inspections and Compliance Team Leader in the Food Safety and Security Staff; and Ms. Shirley Bohm, Consumer Safety Officer, Retail Food Protection Team in the Office of Compliance's Division of Cooperative Programs.

The role of the listening panel will be to listen but to also ask clarification questions of the invited speakers as well as those attendees who will be making oral presentations. After the presentations and the Question and Answer Period, we will take a brief break and reconvene for the second half of the meeting which will be devoted to public comments.

The entire proceedings will be transcribed. Therefore, when speaking, be sure to state your name as well as your affiliation. We intend to make the transcript available on our web site in approximately thirty days.

With that, I would like to invite Dr. Smith to present the draft action plan.

**Invited Speakers**

DR. SMITH: Good afternoon. I am Michelle Smith from the Office of Plant and Dairy Foods at the Center for Safety and Applied Nutrition.

I am here to talk the proposed produce safety action plan, a proposed action plan to minimize foodborne illness associated with the consumption of fresh produce.

A few points about the proposed action plan; it is a priority for CFSAN and Dr. Brackett. It builds upon existing programs. We have had some experience, now, working in the area of produce food safety as have most of the folks in the audience here, so we want to take things to the next level. It covers fresh fruits and vegetables from farm to table.

The goal of this plan is to minimize foodborne illness associated with fresh produce consumption.

Some of the items in the scope of this

plan will look familiar to people, particularly people that have been involved in produce-initiative issues since '97. Some of these points will be new points, points that are specific to this action plan as we go forward. Everything here is on the table so we are open for comment.

The scope, as it stands now, is that it would cover fresh fruits and vegetables in their unpeeled natural form, the traditional raw agricultural commodities. It would also cover raw minimally processed products such as precut or fresh-cut fruits and vegetables.

It targets fresh produce consumed in the U.S. whether the produce is produced domestically or abroad. A new item is that it covers the entire food chain. This is something whose time has come. We focused originally on farm and packing-house operations with our 1998 Guidance because that was an area that needed emphasis, that needed awareness to go up. It is time for everything now to be pulled together in more of a continuum.

The proposed action plan does not cover

processed products such as juice or frozen fruits and vegetables or other agricultural products other than fruits and vegetables; for example, tree nuts that traditionally have not been considered as fresh produce. Again, everything is on the table.

Why are we looking at produce? Why all this attention now with a new produce food-safety plan. Produce has always been recognized as an important component of a healthy diet. The more we know about a healthy diet, the more important the role of produce becomes. At the same time, as Dr. Brackett mentioned, fresh produce is produced in a natural environment.

Because it is produced in that type of environment, there are opportunities for contamination that may not be significant for other types of food groups. In addition, although it is not unique to fresh produce, there are opportunities for contamination throughout the distribution chain and at the point of safety if preparation practices are not such as they should be.

With fresh produce, however, you are talking about a food that is most often consumed raw without interventions to control or eliminate the pathogens prior to consumption. So, if contamination does happen to this product, foodborne illness is likely to become an issue.

The potential for outbreaks associated with fresh produce is more than just theoretical. Outbreaks have occurred and continue. Given the importance of fresh produce in a healthy diet, it is imperative that we lower the number of foodborne illnesses associated with fresh produce.

This is something that can be done. In our experiment with foodborne-illness investigations and other investigations since we have begun to implement the good agricultural practices and other manufacturing practices for fresh produce, we are not always able to find a smoking gun. But we have seen enough things in these investigations that indicate that the most likely causes of contamination in many of the foodborne-illness outbreaks are things that are

preventable, whether it is improving handwashing practices and the availability of toilet facilities for workers in the field and packing house or whether it is food preparation practices, and, again, handwashing at point-of-service, these are things that can be addressed.

How do we address those things? How do we solve the problem? Well, FDA believes the most effective strategy for reducing foodborne-illness outbreaks from fresh produce is likely to be one that approaches the problem from many different angles. There is no single solution.

The proposed action plan has four general objectives. The objectives are listed here. It is a framework to build upon and we are seeking input at this public meeting and in the comments that come afterwards to help us best accomplish these objectives.

The Federal Register notice announcing this public meeting contained a series of questions to help focus the public comment. I don't want to read every question, but some of the things that we

are asking for input on at this meeting are things like comment on the concepts and underlying principles of the proposed action plan. Have we identified appropriate objectives? Have we identified appropriate actions to accomplish those objectives? What about the scope and the coverage? Are these the products that would make the most difference to be the focus of this action plan?

A particularly important area is do we measure progress of these objectives as we move forward and also how can we all work together. Now, working together will be key to the success of this action plan. Some of this may be working in collaboration. Some of it may be working independently. There is plenty of work to go around.

For this to be effective and long-lasting change in those areas that our experience, your experience, FDA's experience, the experience of other food-safety partners have identified as areas that need additional work, we really do need to work together.

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In summary, the foodborne illnesses associated with fresh produce are real. This action plan is only one of many steps to achieve the goal of produce safety. To be fully effective, it needs to be more than a paper plan on a shelf. It needs to be implemented.

However, working in collaboration with other federal, state, local and foreign agencies, academia, consumer groups and the private sector, the problem can be solved.

DR. BERU: Thank you, Michelle. We will hold questions to the end until all presentations have been made. I would like next to invite Dr. Michael Lynch from the CDC.

DR. LYNCH: Good afternoon. It is a pleasure to be here in support of this effort to reduce foodborne illness. I am going to begin with a brief background on the burden of foodborne illness in the United States and some background on CDC's foodborne outbreak surveillance system, as CDC's role in this effort, I think, is going to be mainly keeping track of what is causing foodborne

outbreaks and also helping the state and local departments investigate foodborne outbreaks.

Each year, there are an estimated 76 million cases of foodborne illness in the United States. That translates in to 1 in 4 Americans getting a foodborne illness each year, 1 in 1,000 Americans hospitalized for a foodborne illness and \$6.5 billion in medical and other costs incurred.

The prevention of foodborne illness depends on efforts from farm to table to reduce the contamination of food. We have increasingly recognized a problem with produce which will require similar effort to prevent.

Foodborne illness represents infection with a variety of pathogens, or the bacteria, viruses and parasites that can cause illness. Each pathogen has a characteristic reservoir, its ecological niche or the place where it lives when it is not causing illness in people. Some of these are human reservoirs and some have animal reservoirs.

They can be transmitted or get from their

reservoir to the person who they make ill in several ways, through food, water or direct contact with the animal or infected human.

Foodborne illness can occur in identifiable groups of people which we call outbreaks. Most of these outbreaks are detected and investigated and controlled by local and state health departments. CDC collects reports in these investigations. The reporting is voluntary and, admittedly, incomplete, but it is still a rich source of information on foodborne illness.

The definition of an outbreak we use is two or more cases of a similar illness resulting from the ingestion of a common food. The data collected include the number of cases, the implicated food if it is known, and the etiology or the pathogen that is causing people to be ill.

This is a graph of the number of foodborne-illness outbreaks reported to CDC by year from 1990 to 2003. Before 1998--in fact, going back to 1973--we received approximately 500 reports per year. In 1998, CDC instituted enhanced surveillance

which meant that we called states on a regular basis to remind them to send in their reports and we also set up a web-based reporting system which is called EFORS, or Electronic Foodborne Outbreak Reporting System.

Consequently, the number of foodborne outbreaks reported to CDC increased to over 1,000 per year. We think this represents increased reporting and not an increase in the true number of outbreaks in the United States.

Because the number of outbreaks vary from year to year, we look not only at the total number of outbreaks but also the proportion of outbreaks associated with different pathogens and different foods.

This data from 1990 to 2001 is now available on the web. 2002 has been finalized and will soon be available on our website. Many people have worked very hard to make this information available.

One of my colleagues recently completed a review of foodborne outbreaks associated with

produce from 1973 to 1997. I will review some of the highlights with you. The full report is coming out soon in the Journal of Food Protection.

Fresh produce was defined as uncooked produce or salad without eggs, cheeses, seafood or meat. From 1973 to 1997, there were 198 outbreaks linked to fresh produce, over 16,000 illnesses, almost 600 hospitalizations and eight deaths. This represents 3 percent of outbreaks during this time period and 6 percent of the outbreak-associated illnesses or cases.

These could be considered conservative estimates b the denominator includes a large category of outbreaks where the food vehicle was uncategorizable, either unknown or a dish that included many ingredients or multiple food items were identified as possible sources of illness.

So a 25-year summary is interesting but a look at trends and what has been happening more recently would be more informative. This table compares outbreaks in the 1970s to outbreaks in the 1990s. As you can see, the percent of outbreaks

associated with produce increased from 0.7 percent to 6.0 percent and the percent of cases from produce-associated outbreaks increased from 0.6 percent to 12 percent.

If we look at the type of produce items implicated in the outbreaks from 1973 to 1997, the generic produce category accounts for more than half of the outbreaks. Among outbreaks where one specific produce item was implicated, the top seven items account for 88 percent of these and include lettuce, melon, sprouts, juices, berries, tomatoes and green onions.

A specific pathogen or the organism causing the infection was identified in about half of the outbreaks and include the bacteria, the viruses and parasites shown. The main point is that these pathogens have both animal and human reservoirs or animal and human sources.

A comprehensive analysis of the data since 1997 is underway. We looked, in a similar way, at data from 2001. This data is still preliminary but I don't think it should change much in our final

analysis. In 2001, there were 57 outbreaks linked to fresh produce, over 2,000 illness, 81 hospitalizations and three deaths. This represent 7 percent of outbreaks and 11 percent of outbreak-associated illnesses during 2001 which is similar to what we saw in the 1990s.

The range of produce items implicated in outbreaks in 2001 is similar to those implicated in 1973 to 1997. One interesting exception is that there were no outbreaks associated with juice reported in 2001. If this bears out for subsequent years, it would be a testament to the work done by the juice industry in government in response to the juice outbreaks in the mid-1990s.

The range of pathogens identified in these outbreaks in 2001 is also similar to that which was seen in 1973 to 1997. Of note, all the viral outbreaks here listed, for anyone who is quick at math, there are a higher proportion of viral outbreaks in 2001, and all of these are neurovirus. I think this is probably attributable to the fact that we are better and diagnosing neurovirus these

days.

So, in conclusion, the CDC surveillance data suggests that produce is associated with a greater proportion of foodborne outbreaks than in the past, going back over the last 30 years, approximately 11 to 12 percent of outbreak-associated cases. This represents both a larger number of outbreaks and the larger size of the outbreaks when they occur.

A variety of fruits and vegetables are involved and the spectrum of pathogens reflects contamination with human and animal reservoirs. Preventing contact with human and animal feces is key to preventing foodborne illness due to produce.

Implicated items are both imported and domestically produced and contamination and amplification can occur at any point from farm to table. We at CDC will work hard to continue to provide the information needed to help solve this problem.

Thank you.

DR. BERU: Thank you, Dr. Lynch. Mr.

Stenzel, President of the UFFVA is next.

MR. STENZEL: Thank you very much, Dr. Beru. I appreciate the opportunity to be here this afternoon to share perspective on behalf of the United Fresh Fruit and Vegetable Association. Our association recently celebrated its 100th anniversary and has worked with growers and marketers of fruits and vegetables since 1904 to deliver safe and wholesome produce to America and to the world.

As you might imagine, what was considered state-of-the-art farming, packing and distribution of fresh produce in 1904 is significantly different from the sophisticated practices and scientific bases for food safety in our industry today.

Is our produce supply today far safer than ever before? Absolutely. Are we satisfied? Absolutely not.

My point is that our industry is on a continuum. We are constantly striving toward perfection in food safety as our No. 1 priority. Food safety is not just a legal responsibility of

everyone throughout the distribution chain, it is our moral responsibility.

Now, science forces us to recognize that zero risk is not possible with a product grown in nature, that is often handled by food preparers and customers along the line, and that is enjoyed by consumers in its fresh and natural form without cooking.

But the potential of even one child getting sick forces us to do everything we possibly can to prevent that occurrence. Today our industry is proud to serve Americans over 1 billion servings of fruits and vegetables every day. When outbreaks of illness do occur, they are rare compared to that level of consumption. But we are committed to reducing rare occurrences to extremely rare occurrences and, as science and experience allow us, we hope to drive "extremely rare" to "obsolete."

In the mid-1990s, our industry and the FDA undertook a systematic and thorough look at best agricultural practices for growing and packing

fresh produce. Based on the very best science available, FDA's 1998 publication of Guidance to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables has been instrumental in driving ever-increasing attention and commitment to reducing these risks throughout our industry.

Since that time, our association has developed food safety auditing guidelines to help our industry measure compliance with these standards, work with numerous universities, state departments of agriculture and the U.S. Department of Agriculture to provide field education and enlisted buyers of fresh produce at retail and food service to specifically ask their suppliers about their food-safety practices.

But, as I said, we are on a continuum. FDA's attention here today is welcome to help us drive increased knowledge about ways we can all further reduce what is already very low risk. First, we must learn all of the lessons from the experience we have. When these unfortunate outbreaks occur, we must not be satisfied with

generalizations or hypothetical opinions.

We must use every scientific method possible to determine the specific cause of the problem and ways in which product handling and preparation may have exacerbated the problem.

In the case of fresh produce, usually the implicated food item is long gone from distribution. So we are not talking about immediate public-health consequences. But we still need FDA, CDC and the industry to leave no stone unturned in learning the lessons that science allows.

Unfortunately, most of the outbreak investigations have raised more questions than scientific proof. So it is also critical for FDA, USDA and others, to help us research those questions. How could a certain pathogen have found its way into the food supply? Where is the contamination most likely to have occurred? What steps or procedures could have been taken to prevent the contamination in the first place or reduce its impact along the food chain.

Today's meeting is a sign of FDA's commitment to answering those questions. We in the produce industry are equally committed to finding those answers so that we can continue to drive ever-reduce risk.

Of course, anyway responsible in the food industry would want to produce the safest possible product. But, for us, somehow, it seems even more important because of the healthfulness of fresh produce. The number one public-health recommendation for Americans when it comes to nutrition is to consume five to nine servings a day of fruits and vegetables.

FDA and CDC's own parent agency, the Department of Health and Human Services, promotes the critical importance of eating a wide variety of produce to prevent chronic diseases such as cancer, heart disease, stroke and more. Now our nation is faced with an obesity crisis that literally demands that we eat more fruits and vegetables to reduce the risk of obesity and diabetes.

We simply have no choice but to deliver

the safest possible produce supply to consumers every day. That is our industry's commitment and that is why we are working with the FDA and CDC here today.

We really appreciate the opportunity to be here. I would like to extend my apologies for having to speak so quickly and rush out to catch an airplane, but I personally wanted to be here to deliver as strong a possible commitment to Bob and the rest of the staff and leadership here at FDA on our industry's part.

I would like to take this opportunity to introduce Dr. Donna Garren who is our Vice President of Science and Technology, a food-safety expert in her own right. So, if there are issues from our association's standpoint that you would like to address after I have had to step out, feel free to call on Dr. Garren.

Thank you.

DR. BERU: Next we have Ms. Laurie Girand, Safe Tables our Priority.

MS. GIRAND: Thank you very much. I would

like to open with a quote from Marc Isaacs of Sun Orchard. In the fall of 1998, the citrus-juice industry had just convinced FDA that it should give them more time to explore the science of citrus-juice safety. Their argument was that citrus fruit was uniquely different than apples and, therefore, its juice did not need to be pasteurized.

At the time of this quote, Mr. Isaacs' company, which sold unpasteurized citrus juices, was conducting research into how to improve the safety of citrus juice without actually pasteurizing the juice.

Within seven months, Sun Orchard became responsible for the single largest unpasteurized juice outbreak in the United States which sent over 400 people to doctors and hospitals, caused at least one known miscarriage and killed at least one person.

In November of 1998, one whole year after this quote, and three months after FDA allowed Sun Orchard to sell juice again, Sun Orchard was,

again, in the news with a massive recall of contaminated juice.

Today, I want to remind you that industry does not have the most to lose from delays and outbreaks. I would like to be sure that we are all clear about this. Consumers can lose their lives from contaminated foods. They can lose their livelihoods and they can also be left with life-long injuries.

Haylee was five when she and her sister came down with blood diarrhea. In three months of subsequent hospitalizations, she also suffered from inhaling her own vomit, shock, pneumonia, diabetes, seizures and, ultimately, brain bleeding.

She was subjected to extensive medical treatments, having multiple holes cut into her to perform dialysis and to drain fluids from her chests, going on to a ventilator and brain surgery. When she came home, she was blind and had to take 12 medications every day.

She is a survivor, having been poisoned in 1996 by lettuce contaminated with E. coli 0157:H7.

Tragically, in just the last year, seven years later, children and the elderly have, again, been poisoned by pathogens in multiple outbreaks of lettuce and spinach.

Like Haylee, Rustin was also five.

The latest lettuce outbreak was reported on CFSAN's What's New page and is dated May 21, 2004. Outbreaks from sprouts have been ongoing since 1996. The latest sprout recall was publicized on June 3rd of this year.

Everyone needs to understand that what we are talking about today is not just a little diarrhea. It is a very real poisoning of the body with foreign organisms known in laboratories as biohazards. To children, these organisms and their toxins can be lethal.

Most children under five are unable to contain the blood diarrhea that virtually explodes from their rectums. They scream in their agony. These organisms are also life-threatening to the elderly and people that are immunocompromised including pregnant women.

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Not surprisingly, these three at-risk groups often seek the health benefits purported to come from raw fruits and vegetables.

It is critical that we all work from facts and the facts are these. The single largest source of contamination of produce is animal feces. The simple, direct proximity of animals, cattle, deer and other mammals and birds, and the application of feces, whether intentionally or unintentionally to crops, has been implicated in countless produce outbreaks.

When this contact has not been direct, it has been indirect by proximity. Flies and birds have been proven to carry fecal germs to fruit. Windblown dust can harbor organisms. In many outbreaks, fecally contaminated water has been sprayed onto, irrigated around or run off onto produce or the well water used to irrigate produce.

Science conducted in the study of sprouts has indicated that once pathogens are present in the sprouts' water supply, pathogens are taken up by the root system and are then conducted

internally to the top of the sprout. Science has proven that pathogens exposed to lettuce are attracted to and absorbed at the broken edges of lettuce.

Science has also proven that produce such as tomato and apples floating in contaminated water can update pathogens through the stem or flower end. So, once pathogens are present, the fruit or vegetable can become internally contaminated. Science has also proven that once E. coli 0157:H7 forms a biofilm, it is protected to withstand rinsing and washing.

In a study conducted by FDA researchers in Illinois, the only effective way to remove E. coli from the exterior of contaminated apples was with both heat and chlorine, not just one or the other.

Science has demonstrated that E. coli can survive for months in soil and up to a year in sheep manure. So the intentional application of manure results in long-term contamination of the growing environment.

Science has also proven that the only

effective consumer method for preventing illness against fecally contaminated fruits and vegetables is heating to high temperatures. Indeed, current advice coming from government as to how consumers should rinse their produce under cold water reeks of superstition. Rinsing in hot water may reduce some organisms but when the dosage of germs required to kill a child is less than 10 or as little as one organism, cold water will not prevent illness.

With these facts in mind, Safe Tables believes that three key underlying principles should guide the 2004 Produce Safety Action Plan. These are; one, our inability to remove pathogens once they come into contact with produce demands that we focus on preventing contamination; two, all fruits and vegetables are not alike. The action plan must treat ground-grown crops which come into direct contact with soil differently from pole-grown crops, differently than orchard-grown crops, differently than sprouts and wheat grass.

Regulations must be developed that are

food-specific and address hazards, harvesting practices and post-harvesting processes specific to the type of fruit or vegetable grown. Crop-safety standards must be consistently applied across the country regardless of the size or location of the business; three, as ongoing outbreaks in lettuce and sprouts have proven, voluntary guidelines do nothing to improve the safety levels of outbreak-causing producers. Only regulations can ensure that the bottom-feeder producers and fly-by-night operations are required to comply.

In order to achieve safer produce, FDA must regulate manure and the application of human waste to crops. I hope that is not new news for a lot of people here. Owing to the extended survival of the E. coli 0147:H7 in soil, the practice of applying untreated feces to any soil or crops for human consumption should be ended.

B, all animal fecal products should be aged for a minimum of one year or composted to eliminate pathogens prior to application of unplanted soil or to crops. Time and temperatures

for composting must be scientifically determined to eliminate pathogens.

Next, the success of composing and aging should be verified by testing. No animal fecal products should be sold or distributed without proper treatment. In addition, any animal fecal fertilization must be applied prior to planting of the crop. The FDA must set soil-quality standards by level of biological contamination.

If a crop farm is adjacent to an animal farm or wildlife refuge or downhill from either, soil testing should be mandated. A positive identification of E. coli or Salmonella in crop soil should result in crop tissue testing.

Lastly, the application of human waste and undertreated human waste, which is still in practice in this country, and are given undertreated human waste water, should be strictly prohibited.

Two, restrict the proximity of livestock and animal farms to crop farms. Crops should not be grown close to animal farms and, in particular,

downhill from them, to reduce the risk of contamination by runoff, insect transmission and dust. Dust-management programs must be introduced to animal farms.

Three, mandate water quality. FDA must set water-quality standards. Only potable water should be allowed to be sprayed on crops. Ground-irrigation water must meet or exceed quality standards. Using potentially lower-quality water earlier in the growing process is unacceptable.

Four, on-farm inspections must insure that these basic water and feces hygiene and sanitation regulations are followed. As one farmer reminded me long ago, you get what you inspect, not what you expect.

Five require national registration of all participants in the food-growing and distribution chain, not just processors. FDA cannot communicate with businesses for which it has no records. It cannot inspect farms if it doesn't know whether they exist. Registering all food processors and ensuring that they must have either a fax or e-mail

address would enhance communication and accountability.

Six, require certification that proves that growers have read and are aware of FDA crop-safety regulations and guidelines and without which no one in the United States should sell food commercially.

Seven, mandate a real trace-back system in which the sellers, shippers, distributors and processors maintain records and can quickly identify the sources of batches of fruit, vegetables and other crops, and the vehicles in which they were transported.

Eight, mandate the farm-of-origin and country-of-origin labeling on produce at retail. U.S. food producers concerned about cheap imports should recognize that safer food is a feature for which consumers are willing to pay more.

Nine, maintain a list of nationally identified outbreaks, the organisms involved in the outbreaks, the ages of victims, often overlooked, and the foods involved. To truly own the issue of

food safety, FDA must document and maintain information about outbreaks. This is also the only way to measure relative harm caused by different types of produce.

Ten, penalize industries with producers that cause repeated outbreaks. Not only should a producer be held accountable, all similar producers should share the burden. Should a crop have more than three nationally identified outbreaks in a year, those foods should be required to bear red labels that indicate to consumers that the industry is unable to deliver safe products reliably to market.

With repeated outbreaks beyond these, FDA should require that the strictest growing conditions available to employed until the food-safety record is brought back to par. Safe Tables will make additional recommendations addressing processing, transportation and imports in its comments to the dockets.

In conclusion, I would like to remind you all of Mr. Isaacs. In 1998, nearly six years ago,

Mr. Isaacs and his company faced a choice; embrace and act on the current science of food safety or delay an experiment to see if other options existed. Every person in this room today faces the same choice. As we deliberate, people's lives, and particularly those of children, hang in the balance.

We urge you to avoid repeating the mistakes of the past. Choose wisely.

DR. BERU: Thank you, Ms. Girand.

Our last speaker is Mr. Bryan Silbermann, President of Produce Marketing Association.

MR. SILBERMANN: Good afternoon and thank you very much, Nega. I appreciate the introduction and the opportunity to be here. I am Bryan Silbermann, President of the Produce Marketing Association and I am pleased to be here to address our industry's commitment to food safety as well as to continue what has been FMPA's long-standing and very productive relationship over the last several decades with FDA.

Given the short lead time since the

announcement of this meeting, I will focus here just on some broad themes and I will reserve our detailed responses for the written comments to follow.

For those of you who do not know, PMA is the largest worldwide trade association representing the produce industry and our members range from growers to the largest supermarket chains, from whole-foods stores to restaurant chains, a very varied and diverse group.

I want to say that we are here today across our industry because we want to continue to make a difference to the safety of the food supply. When we have a food-safety outbreak, it affects everyone. That is why food-safety practices from field to fork are some important to all of us.

We all have the same goals, to protect public health, to protect the food supply and to protect businesses. We are here today to build upon the substantial and successful food-safety efforts the produce industry has made so far. We will continue the industry's proactive efforts by

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addressing the single most important issue that is facing us and that is ensuring public health both through enhanced nutrition as well as through safe products.

The fresh produce industry at every level of distribution rates food safety as its top priority, no matter who you speak to. A strong food safety chain is as strong as its weakest link only and we, as an industry, work daily to strengthen those links against contamination by pathogens. Our member growers and shippers, some of who are here today, collaborate with their partners on the buying side, some of who are here today.

Our retail and restaurant members are equally committed to food safety and work very closely with these suppliers. We also rely constantly on the valuable insight and commitment of our regulatory partners represented here whose goal is surely to protect and enhance public health.

Including every link as FDA has told us it

wants to do is the only way we can build a strong chain that uses the foundation of what has already been done, supplements it where needed, and pulls it altogether into a cohesive approach. We want to see FDA's plan become part of the ongoing efforts to enhance food-safety programs for the entire produce supply chain including consumers and we are proud to be involved. We are committed to seeing it through.

For that to happen, we must focus on solutions and solutions that make a difference. Being proactive means addressing real risks and doing everything in our power to reduce those risks to the lowest levels possible.

Safety truly starts at the farm and packing house with good agricultural practices and good handling practices. It continues when we transport our products and move them through distribution centers. From there, we take them to the store shelf or restaurant tables, through good retail and food-service-handling practices. And it doesn't stop there. Consumers have a role as well.

For over two decades, PMA has served consumers, too, first by researching and developing the nutrition values of produce that FDA, a few years ago, in fact, accepted as part of the list of the top twenty and top twenty vegetables that retailers now provide to consumers.

We then helped launch the National 5 A Day Program in 1991 to bring industry and government together to fight against poor nutrition. As Tom mentioned earlier, that we have an obesity epidemic in our country today proves how much more remains to be done.

Six years ago, I joined with then-Vice President Al Gore to help launch the Partnership for Food Safety Education, a public-private campaign to teach consumers about safe food handling through its FightBAC message. This program involves all the major food-industry associations, the federal departments of health and human services, agriculture and education as well as consumer groups. This fall, we will release an initiative through the partnership and its FightBAC

Program specifically aimed to educate and empower consumers about safe produce handling, especially in the home.

I mention this consumer outreach, too, because if there is one message I can leave you with today, it is this. We have to, all of us in this room, put more focus on the word "and" and a little less focus on the word "or."

Let me explain. Produce safety efforts cannot be focused just on farms or wholesalers or retailers or restaurants or consumers. To focus on any one area is simply a recipe for disaster. We--and, by "we," I mean industry, government and the public--have to include them all in a systematic way that aims to remove as many real risks of contamination as are practically possible.

PMA wants to encourage positive steps to ensure food safety. We know that contamination can happen at any time from when the product leaves the field to when it gets to a restaurant or to your home. Every link in the food-safety chain, including consumers, needs to have the tools and

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the information to prevent contamination of fresh produce.

That brings me to a few key points I want to stress about FDA's draft action plan as we move forward. First, we must all work to ensure that we are focusing on areas of the greatest risk. We must also approach solutions with science as our guide. Common sense, as previous speakers have said, tells us that we do not live in a risk-free world.

Don't get me wrong; that does not relieve anybody of the responsibility to continually enhance their food-safety practices. But it does tell us that some efforts will have a greater impact on public health than others. To be truly meaningful, what comes out of FDA's action plan must make a difference to public health.

Second, we must guard against frightening consumers away from the very foods that enhance their health. I don't mean a policy of silence. However, the vast majority of fresh produce items have never been implicated in foodborne illness

outbreaks.

Characterizing the entire category of fresh produce as a culprit in anything is simply irresponsible. So it is critical for public-health authorities and the industry to identify problems should they occur as quickly as possible and ensure that accurate specific information is communicated to the public.

It is dangerous to offer broad generalizations using phrases such as "fresh produce," or "salad items," in the event of an outbreak. To do so does not tell the public how to protect itself. Using such broad-brush strokes only serves to perplex consumers.

In addition, this information must be accurate. It is dangerous to public health and the national effort to increase consumption if the wrong product is identified. And this has happened before.

Third, and I state this in the strongest terms to those in industry, there is simply no room anywhere in our industry for anyone not committed

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to the strongest food-safety practices. These practices protect not only public health but also our industry's health. Even in the most safety-conscious organizations, mistakes, though rare, can happen and, when they do, they must be analyzed and corrected immediately.

But I would say to anyone that seeks to cut corners or plead ignorance of good food safety practice, you just don't belong in this business.

Finally, the Produce Marketing Association welcomes the opportunity to work with FDA on this action plan. As I noted earlier, we will comment substantively on the plan and the questions outlined in the Federal Register announcement of this meeting.

Like FDA, we want to continue preventing contamination of our products. Like FDA, we also want to minimize public-health impacts should contamination occur. Improved responsible, accurate communication is another goal that we all share. And we look forward to working with FDA on the research priorities in this area.

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As I said at the beginning, we all have the same goals; to enhance and protect public health with delicious, nutritious and safe fresh produce. American consumers expect nothing less. People all across our industry stand committed to delivering on that expectation.

Thank you.

DR. BERU: Thank you, Mr. Silbermann, and thank you all invited speakers for wonderful presentations.

#### **Question and Answer Period**

I will now open it up to the Question and Answer Period which is of clarification. As I said at the outset, these questions will be primarily from our panel of FDA listeners. Time permitting, we will also open it up to others.

We are slightly ahead of schedule and this is good because it means we will have more time for the Public Comment Period after the break.

DR. TROXELL: This is Terry Troxell, if I could start off with Mike. You talked about 76 million illnesses and then you went to 3 percent

outbreak, 6 percent of illness associated with outbreaks. Do you expect the estimate--I mean, what is the fraction of the overall illness rate, would you estimate, is associated with produce out of that 76 million? How would you go about trying to get that estimate versus the outbreaks?

DR. LYNCH: That is a good question. I think that outbreaks, even though they get a lot of attention, represent only a small fraction of all the foodborne illness in country. We actually get our best information, and our only information, on the cause of the illness from outbreaks because, when people get individual cases of foodborne illness, it is very difficult to figure out what it was that made them ill.

Trying to extrapolate from the percentage of cases associated with outbreaks to the percentage of all the cases is difficult. You have to take into account not only what percentage of illness is due to outbreaks but also what percentage of the outbreaks are due to different pathogens that may be responsible for a certain

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percentage of all the illness in the country.

There are actually people in our department working on that. I think that--when I mentioned that the 12 percent of cases that we see in the '90s and the 11 percent we see in 2001, I call that conservative because I think it is going to be higher. I can't say--I don't want to hazard a guess as to how much higher that would be.

MS. AYLING: I have a question. I am Mary Ayling, one of the listeners. And I did listen. And I listened to all of you and I have one question that is basically for all of you. Bryan, one of your last statements was that if a person in the business who doesn't adhere to food safety doesn't belong in the business. This is for all of you. How do you get them out of the business?

That is a fair question. I think we looked at the plan, looked for enforcement. Laurie, you mentioned kind of around the edges of enforcement. But that statement; I was just wondering how do you get them out if they don't belong in?

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DR. BERU: Dr. Silbermann?

DR. SILBERMANN: I think there are a number of ways in which we can make sure that happens. First of all, I think you are seeing the greatest pressure in the marketplace is coming from the buying side of the business that is increasingly making very exacting demands on its suppliers.

I think it is up to the companies in our industry who buy product for sale to consumers, whether it is stores or in use in restaurants, to stand by the specifications that they dictate and not to cut corners. I think the market pressure, frankly, is the most powerful pressure to ensure that the bad actors, if they are in the industry, will not be in the industry for very long.

Secondly, I think when FDA finds, as they have done, certain instances of contamination that concern them, they have the tools already to prevent product from those facilities entering the flow of commerce. That has already happened and, in fact, there has been an incidence reported just

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recently of that, again.

So I think that there are the requisite market forces in place and I think there are the requisite regulatory forces in place. But, once again, I would go back to my comment about focusing on what is truly the source and making sure that our facts are right before we pull the trigger in making announcements.

I am not pointing any fingers at FDA. I am pointing fingers, primarily, and I have to say I mention that, at some local and regional public-health authorities who, in the past, have sent people scurrying in the wrong direction with conflicting advice. I think it is very important for us to better identify the sources of outbreaks before we start making public pronouncements about them.

DR. BERU: Ms. Girand, would you like to address that?

MS. GIRAND: Sure. I think I mentioned, but I think this is really fundamental, that we have to have registration of people in the food

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business. I keep thinking, I get in my car and I drive and I have a driver's license and people check, every once in a while, at least, to see if I still live there and if I can still drive.

Without registration and the ability for FDA to immediately contact lettuce producers or sprout producers, they are legitimately out of the loop of communication because FDA can't get the information out there. With electronic systems today, we have the ability to communicate with people very effectively, very quickly, if, presumably, you don't overwhelm their mailbox. We should be using them, frankly.

We need regulations because what we find in a lot of these outbreaks is very few laws have actually been broken. We have lots of guidance and no rules and it is pretty fundamental that, without a rule in place, the worst producers won't rise to that particular occasion.

We need inspection because you can go out, or the organic industry can go out, anyone can go out to these farms and say oh, my good, look at

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these lousy conditions you are working under. You shouldn't be doing this. But if nobody ever goes out there to see it, then no one will ever be told they should stop doing it.

I would say that it would be very gratifying to see industry work on more self-policing in that way. But I am not convinced that industry knows who the latest, the last, lettuce grower was to sign up to become a lettuce grower. So it seems to me it is government's fundamental responsibility but, if industry could step in and at least tour some of the facilities of the new producers and get that information to them more quickly, we might do a little bit better.

DR. BERU: Mary asked a question of everyone. Dr. Lynch, would you like to address that as well?

DR. LYNCH: I think that we are in a similar position with FDA at times and we would always like better records because it would certainly make our job easier and I think it would ultimately be better for everyone because I think

the more information we get about why something went wrong and the faster we get it, the better off we are going to be because then we can prevent it from happening again.

DR. SMITH: First of all, I think prevention is key. So if you reach people and you keep them out of trouble in the first place, that would be optimum. Communication is key. We have heard that over and over again. People should know what the expectations are, the food safety partners, state, local, federal level, should be talking with each other.

I don't, myself, wear the compliance hat but I have been part of a lot of discussions where decisions are being made whether or not to take action if it is appropriate in a certain situation. Communication really is key.

Laurie mentioned that guidance isn't a requirement. That is something we deal with all the time. But, often, when you do have problems to the extent that someone should not be in the business, you don't even need to look at the

recommendations and the guidance. You can go straight to the act and you can say that these are insanitary conditions and someone is operating in a way that they shouldn't be operating.

If all that fails, I tell Jack Guzewich and his team goes out there and they do what they can.

DR. BERU: Thank you, Michelle

MR. GUZEWICH: This is Jack Guzewich. I have a question for Dr. Lynch. When we look at the epidemiology information, it is possible to interpret all those outbreaks as being associated with a farm or a packing shed when, in fact, I think a lot of the outbreaks are due to problems that occur downstream from there, possibly in transportation but more likely at the supermarket or restaurant level.

It gets counted as a produce outbreak but, in terms of where the focus for attention and improvements have to be made, it is, perhaps, not the farm in those cases. It is at the restaurant or supermarket level. Can you comment on the role

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that those places play in those numbers that you provided earlier?

DR. LYNCH: Sure. Actually, I think, in those numbers I provided, there isn't anything in those numbers that could tell you where contamination occurred. That is often very difficult to show. I mean, sometimes, there is suggestion that it at a certain point in the chain. We are seeing a lot of outbreaks that occur among people in multiple states. We know that they all didn't eat at the same restaurant or make their food in the same kitchen.

But we are also seeing a lot of the outbreaks that get reported are smaller outbreaks. Then tend to be localized. In those instance, I think the contamination most likely occurred further down the chain, at the preparation or at a restaurant or at the home.

I think that, in fact, the most common pathogen that we see, as far as foodborne outbreaks, is the noravirus. For those who don't know, it is a virus that is often associated with

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cruise ships--not to malign the cruise-ship industry but just to give you some context. It is transferrable from person to person but also easily transferrable when an infected person prepares food and someone eats that food.

So, again, it is hard to really come up with exact proportions but I think a large proportion of the outbreaks we see are noravirus outbreaks. A large proportion of noravirus outbreaks are related to contamination at the level of preparation.

DR. BERU: Mr. Silbermann, do you have a comment?

DR. SILBERMANN: Jack, I would say in response to that that it is not just the restaurant and supermarket industry that must look at its handling of the product. It is also consumers, as I said in my comments.

All too often, I think we say, gee, it is farmers and then it's distributors and then it is the restaurants and then it is the supermarket and we fail to also say, and it is also consumers who

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have a responsibility. I know you didn't mean it that way, but I want to just focus on that.

My comments about the partnership of food-safety education and this handling campaign, I will tell you that there are four simple messages that have been developed, and they have been developed with the input from FDA and CDC's own experts, you know, in terms of cleaning and separating and cooking and chilling properly for all foods could probably do more than any one other single action on the part of everybody in this room to reduce the amount of foodborne illness in the United States.

MS. GIRAND: May I make one comment about the noravirus thing? I want to be really careful about our ability to study and outbreak that starts from food that way and, thereby, decide that noravirus is the single biggest culprit because I have been on the Disney cruise. I have been on the Disney cruise while one of those noravirus outbreak things are going on.

It is really unclear exactly where it came

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in, but the people were falling all around you like--you know, you are walking through the halls and it is a spooky thing. It is not just, at that point, food anymore. The level of acceleration of that virus through a ship is incredible and represents the strength of that virus in its ability to move human-human, door handle to door handle, toilet seat to toilet seat and swimming pool to swimming pool.

DR. BERU: Jack?

MR. GUZEWICH: I was going to say one more thing. I don't want to get off too much on noravirus. But I would say that, and I think there are a lot of people in this room know, one issue when the contamination occurs further back in the chain as they tend to be larger outbreaks and they make a lot of people ill.

I think that this plan is--I think the focus is right to try to address each stage from farm to table. Each stage has its own specific issues and consequences.

DR. LYNCH: I have one point of

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clarification for Ms. Girand. A lot of people think that applying manure as a fertilizer has been a role in these outbreaks. We have been investigating outbreaks since 1998 and we have yet to go a farm and an outbreak investigation where they have been using manure as a fertilizer.

We have had animals as a source of contamination because individual animals have been in the field, or while they have been in the field. But the actual use of using manure or compost as a fertilizer, we have not found it being practiced in any of the farms we have gone to so far.

MS. GIRAND: There is a surveillance that just came out by Mukarjee in which she compared conventional produce to organic produce and found that farms that had used fertilizer that had been aged for less than a year had 19 times higher level of contamination. The produce ended up having 19 times higher levels of contamination than produce where manure was used--that had been aged.

I think you may not have detected them in specific outbreaks, but it is clear that when we

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talk about the distribution system, and clearly it is an important part of the overall contamination problem, we have to understand that generally birds don't fly into restaurants and drop feces into the food, that there is something else going on in which animal fecal matter is getting into food.

Yes, it can be cross-contamination between eggs, but then we are going to see Salmonella and lots of the other things we see. So, when we talk about manure, it is just not manure. It is also poultry feces that is used very frequently and so there are things that may play a role here that you may not see in the biggest outbreaks but are probably still playing a role in contamination.

DR. BERU: Shirley?

MS. BOHN: I am Shirley Bohn. I am a listener, too. I wanted to ask a question to Dr. Lynch and to Mr. Silbermann. When you reviewed the outbreak reports from '73 to 2001, were you able to identify contributing factors, not just the source of contamination but other contributing factors as well and, if you did, is there a way that that

information gets back to the producers. For Mr. Silbermann, certainly, as an insider, you would know in an investigation what some of the potential contributing factors were or actual ones and what happens then, when you have identified some of the contributing factors to the outbreak and illnesses?

DR. LYNCH: I don't have the data on the contributing factors off the top of my head. But I will say that I think there are two sources we look to for contributing factors. One is the outbreak reports we get where the local or state health department--they actually have places where they can list what their local investigators thought were contributing factors to the outbreak.

Again, those tend to be contributing factors at outbreaks that seem to be where the contamination seemed to be further down the chain. There has been--the data on those types of contributing factors are somewhat problematic. I mean, sometimes they are helpful. Sometimes, they are not.

But I think the data on contributing

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factors back further in the chain at the distribution or at the farm comes more from the in-depth trace-back investigations that are done by FDA. I am sure Jack and others could tell us how difficult those are.

Jack and I were just talking before the meeting about how a lot of things have to come together for us to put together a story about how things likely happened and it doesn't happen that often.

But, again, I think with more focus and more resources and better information we can figure it out more often.

DR. SILBERMANN: I would echo that and certainly say that the gentleman in the tan suit sitting across from me knows more about tracing back to what the causes may have been than I would suggest that I know. I will also say, as Michael pointed out, that the vast majority of safety outbreaks that have been traced back to produce appear to have been downstream from production.

I think Jack is nodding his head, so we

are in agreement on that. They appear to be downstream from production. Is there any one specific criterion that links them all? I can't say that there is. Michael, would you say that there is only one handling practice or anything like that? It seems to be a wide variety of different things.

I will say that the need for there to be improved traceability practices in the produce industry is paramount and the industry is already addressing that. We already have a binational traceability pilot project going on between the United States and Canada working across the entire industry to develop best practices for tracing produce from farm all the way through to use.

That is not just from a technological standpoint but also from a business-operations standpoint. Later this year, that will really provide some best practices and guidelines to the industry that I think will help FDA and CDC tremendously in some of its monitoring. So that is another example in which I think government and the

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private sector really have a lot of work to do and we are already started on that path.

DR. TROXELL: This is Terry Troxell. Bryan, you made a rather broad statement, work on areas of greatest risk. Can you break that down a little for us, what, in your view, are some of the areas of greatest risk and, if you have any follow up on what industry is doing in those areas.

DR. SILBERMANN: I would be happy to address those areas of greatest risk and will do so in our written comments when we have had a bit more time to put it together, Terry.

MS. AYLING: This is Mary Ayling again. I have a question about communication, again, for any, or all of you, dealing with--Laurie made some comments about labeling, country-of-origin labeling and identification-of-grower labeling.

Number one, I would like to hear what that communicates to the consumer because you have talked about registration and I understand what that would communicate to FDA. But what does country of origin or grower communicate? I mean,

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what message does it send? Then I would also like to hear from PMA and Donna, if she would like to join into this, of what the trade organizations feel that does or doesn't communicate to the consumer.

MS. GIRAND: I would say that grown in the USA sort of says it all. I think there are two aspects to it and one is the preference consumers have for buying foods from certain places. Maybe it is their local grower. Maybe it is their grower in their state. Maybe it is the grower in the next state over.

I think the other thing it says is it sends a very strong message about accountability because when an outbreak occurs, we won't be hearing it came from Safeway or Trader Joe's or CostCo. What we will be hearing is that it occurred from Farm A. Farm A will then be penalized, I believe, by other growers who will believe that Farm A did a terrible thing and I think also the consumers will stop buying produce from Farm A to a large extent until FDA finally

gives them the go-ahead and says it is clear.

That will enable, as well, FDA to pull produce off the shelf more quickly. So I think it has massive benefits to consumers and the rest of the growers who want to not be identified as selling blueberries from Farm A if they were Farm A blueberries that were causing the problem.

So I think it has health benefits. It has accountability benefits and it has consumer preference benefits as well.

DR. BERU: Donna, since Mr. Stenzel had to leave early, if you want to answer that question.

DR. GARREN: I will let Bryan finish up because Bryan, PMA and I have been working closely on this issue. But, in regards to country-of-origin labeling, it is not about food safety. It is about consumer knowledge about product origin. It is not intended to be about food safety.

If you follow guidelines and you are doing everything responsibly along the supply chain, you can do it responsibly and safely anywhere in the

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world. If people have a preference about one place or another, then that is what country-of-origin labeling is about is about consumer knowledge.

I think you can't make the statement necessarily that it is U.S. versus imported. I don't think it should be about that debate. I think this should be more about food safety and doing it safely wherever, globally.

DR. SILBERMANN: Thanks, Donna. Let me add a couple of stakes in the ground. Number one, there should be absolutely no unsafe produce entering the chain of commerce in the United States. I don't care if it comes from Bulgaria, if it comes from Chile or if it comes from California. It makes absolutely no difference. It should not be entering the chain of supply.

For us to assume that consumers are going to be using country or origin or any kind of other labeling, are going to use that information to determine whether or not a product is safe I think is playing Russian roulette with the food supply.

So I would say, especially based on the

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regulatory studies that have been done over the last several years that have shown no statistical difference in the level of contamination between domestically produced and imported produce, that this is a non-issue.

Labeling by country of origin is a marketing issue. It is why PMA and United and many of our members support the Goodlet-Stanhope bill that has recently been introduced into the House of Representatives. We look forward to seeing that passed later this year and that will, then, provide the greatest incentive to our industry to have origin labeling at the point of sale.

But to say that this is a safety issue is simply a misstatement of fact and I think does the consumers a disservice.

DR. GARREN: I would say that when FDA, in the State of California, announced that Salmonella-contaminated melon keeps coming in from Mexico, it is very much a food-safety issue and if FDA refuses to stop Salmonella-contaminated melon coming into the country, that consumers are



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deserving of the information as to whether or not their melons are coming from Mexico if that country or other countries have been implicated in frequent outbreaks.

We recognize that, at some point, FDA has finally taken a statement and taken a stand on that. But consumers should be allowed to make that stand before FDA decides to make that stand.

DR. SMITH: I think we have taken plenty of action on that particular issue. One point that I would like to make, and this is just to reinforce. When you talk about country-of-origin labeling, outbreaks have traced back to both domestic and imported product and they are in roughly the same proportion as the proportion that each of those two sources contributes to our food supply.

You can't give consumers--well, first of all, how many consumers have particular opinions about all of the different trading partners that we have to be able to use that kind of information wisely from a food-safety standpoint. I don't know.

You can't characterize big blocks like that. You can have good practices worldwide. You can have bad practices anywhere. The benefit that you are urging, though, to be able to get back to the source of a product quickly can be addressed by improved traceability systems. That is what I would very much want to promote.

DR. BERU: I think we have addressed that issue, it looks like. We will take one or two more questions from the panel and then some questions from the audience as well.

DR. TROXELL: Terry Troxell, again. Mike, you talked about a greater proportion of the outbreaks being attributed to outbreaks than in the past. Do you have some list of factors that you think are contributing to that phenomenon?

DR. LYNCH: This question has come up very often. We can make a list. I think some of the things on the list are easier to agree with than others. I think, certainly, we recognize produce as a potential vehicle in foodborne outbreaks more. There are just specific items that we didn't even

know could cause outbreaks that we now know have caused many outbreaks.

I think also we are consuming more fruits and vegetables. I don't have the numbers on that but I think it is quite possible that that is part of the reason, too. I think the more centralized supply is also possible as I mentioned. When something goes wrong way back in the chain, and food gets contaminated, more people, a larger number of people get ill because that food item is distributed to more people.

But, even so, I think that there is--so there are some things where I think that we are detecting produce as a food vehicle more often but I think also part of that is a true increase.

MS. BOHN: Shirley Bohn. I wanted to ask all of the panelists if they felt that there was any value to third-party certification process independent of government inspections at any place along the food chain.

DR. BERU: Shirley, since you are asking that of all panelists, I would ask them to keep

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their responses short so we can get to the audience questions. Michelle, do you want to start?

DR. SMITH: Okay. I will start. Shirley, I don't know if you have any idea what a loaded question that is. I am very opinionated. I think there can be some value to third-party audits and that the value is largely dependent on the ability of the auditor and the criteria they use.

DR. BERU: Dr. Lynch?

DR. LYNCH: This us where I can say that I am not from a regulatory agency. I really don't feel like I have enough experience in these kinds of things to comment.

DR. BERU: Mr. Girand?

MS. GIRAND: I guess the question would be, if there were no one going out to inspect any fields at all, then I would be happy if the man down the street went down and took a look at something. But I would have a strong preference for government oversight as opposed to third parties.

DR. BERU: Finally, Mr. Silbermann?

DR. SILBERMANN: I wish that I could follow Mark Twain's advice on this and say that it is better to keep your mouth shut and appear stupid than to open it and to remove all doubt.

Unfortunately, you asked me the question knowing very well that I do know a fair amount about this and I also am very opinionated about it.

Let me be as politically correct as I possibly can, Shirley, in this environment. I remember a day back in the '80s, I think it was, when Former Commissioner Young published a paper that said that the roll of government in ensuring the safety of the produce supply should be reduced and that private industry should take a larger role. There was a huge outcry from everybody at the time.

There were consumer groups, others in government, the industry and so forth, about this is government's responsibility. Government and, specifically, the FDA, should be tasked with insuring the safety of the food supply. Since then, marketplace forces, especially major buyers,

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have used third-party certifications as a way of reducing their level of liability, putting more pressure on the production side of the industry to ensure that it was following good agricultural practices and, in those instances of manufacturing, HACCP principles, et cetera.

Has that led to a safer food supply? I don't know. Has it led to more inspections? Absolutely. Has it led to a tremendous amount of cost to the production side of the industry? No question whatsoever. Has it lead to an increased cost to consumers? Yes. That I know for a fact.

DR. BERU: Before we break, any questions from the audience? I know this gentleman has been wanting to ask a question.

AUDIENCE: Thank you. My name is Todd Wichman. I am President and Founder of a company called HealthPro Brands. My question is to Dr. Lynch. In your slides, you showed, in two different cases, a chemical causing an outbreak. I am familiar with viruses, bacteria, pathogens, but this is the first time I ever have seen anything

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related to a non-living substance, a chemical, causing an outbreak.

Could you explain what that was, what was the nature of that outbreak and what does that mean?

DR. LYNCH: I don't remember exactly what the chemical was. I know there have been outbreaks where poisons or pesticides inadvertently got onto food. My recollection is they were small outbreaks so it was a local phenomenon, not a large outbreak. But I don't really remember much about the chemical outbreaks.

AUDIENCE: So it was poisoning then, not a--

DR. LYNCH: It is a foodborne illness in the sense that people become symptomatic and it is linked to ingestion of a common food.

DR. BERU: Any other questions? Way in the back?

AUDIENCE: Jim Still with Traceability Partners, a question for Mike. The fresh produce supply in the U.S. contrasted with the rest of the

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world, Japan, the U.K., Holland, how do we measure up? Are we truly the safest in the world?

DR. LYNCH: Actually, I don't know enough about the distribution of food items causing outbreaks in other countries to really make an accurate comments. I know that other countries see fresh-produce-related outbreaks and oftentimes share them. I think we have had instances where we have seen a certain type of illness and it has also been seen on other continents, too.

I think that just speaks to the global nature of the food supply these days.

MS. GIRAND: I live in The Netherlands. Currently, one of the things that you need to be really aware of when you look at that type of cross-data is there are countries that literally repress medical information. They discourage people from going to the doctor. They attempt to imply that, if they have diarrhea, it is their own fault.

They can be living within 100 feet of a massive pig farm and just keep ignoring it. So, in

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fact, outbreak data is very specific to the ability of the country to actually survey and pick up that type of data. The countries you mentioned, the U.K., Canada, U.S. and Japan tend to be better at that data, but there are other countries that just wilfully will kind of push it aside and an outbreak is only an outbreak when hundreds and hundreds and hundreds of people fall sick.

DR. BERU: We will take one last question, if there is one.

DR. SILBERMANN: Nega, could I just comment on that?

DR. BERU: Please.

DR. SILBERMANN: I would just like to note that Laurie and I are in absolutely 100 percent agreement on this issue. As somebody who was born outside of this country, obviously, from my accent and have lived all over the world, no question that the U.S., Canada, Japan, the U.K., do have far better practices of reporting this which is why we tend to see, perhaps, although I don't know that it has ever been compiled in one place, higher

incidences of foodborne outbreaks traced back to produce just because we know more about the sources of the product.

But the other thing is that our level of consumption is also significantly higher than in most parts of the world with the possible exception of the Southern Europe and Mediterranean Belt. So it would be very, very difficult to jump to simple conclusions about, oh, well, we aren't as good as other countries because we may have a higher statistical figure. That is because the statisticians here are better than they are elsewhere.

DR. BERU: Thank you. We are now midway through this public meeting. We will take a short break. But, before we break, I would like to make a couple of points. Those of you who have signed up to give oral presentations after the break, I would appreciate it if you would sit in the first couple of rows so it will make it easier for you to get to the podium to make your oral presentation.

In addition, we have some nine or ten

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people who have registered so far. If there are some of you who want to make oral presentations but didn't preregister, you can still do so. Please see me or Amy Green, who is the lady in the green here, during the break and we will add you to the list.

Let's get back together here at 2:45.

Thank you.

(Break.)

#### **Open Public Comment**

DR. BERU: Welcome back. We will now hear from those who have asked for time to provide comments. We believe that a good first step in moving the process of the action plan forward is to engage and solicit the views of other government agencies at the federal, state and local levels, industry groups and from the public, generally.

We ask that your comments focus, as much as possible, on the questions set out in the Federal Register that announced this meeting.

We have about nine people who have registered to give comments. Since we anticipate

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that there might be some questions from our FDA listeners, we are going to limit the time allotted for each speaker to five minutes. Keep in mind, though, that written comments on the draft action plan can be submitted until July 24. We will consider comments we receive at this meeting as well as written comments submitted by July 24 in finalizing the draft action plan.

I will now call upon those who have requested time to make oral comments. As I call your name, please step up to the podium. Amy Green will be our timekeeper.

Our first speaker will be Jessica Wasserman, Fresh Produce Association of the Americas.

MS. WASSERMAN: Good afternoon. My name is Jessica Wasserman. I am here on behalf of the Fresh Produce Association of the Americas which represents more than 125 member companies involved in the growing, harvesting, marketing and importing the Mexican produce.

Fresh produce shares, along with the

private and public sectors both domestically and abroad the common goal of improving food supply and reducing foodborne illness. We appreciate the work that FDA has done in setting out the objectives of the proposed action plan and would like to state a few areas of emphasis and enhancement.

Under Objective 1, we would like to suggest that there is need for the development of meaningful process guides for the specific steps of the production and handling chain, not just commodity-specific guides. For instance, it would be useful to create similar guidance documents for packing-house wash water similar to the guidance on microbial testing of spent irrigation water during sprout-production guidance issued by FDA in the past.

Under Objective 2, FDA and others on epidemiology teams must visit with industry to better understand what records are kept and how they are kept. Record-keeping requirements in bioterrorism legislation may have limited legal applicability. Therefore, direct knowledge or

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records already kept of Department of Homeland Security and USDA should be part of training for FDA and CDC at a minimum.

FDA must learn to leverage other existing legal authorities such as the Perishable Agricultural Commodities Act and the Customs Modernization Act to help ensure the accuracy of records being used during trace-back investigations.

We would suggest that PulseNet and FoodNet should focus on better defining circumstances and sources of their findings as a basic first step before expanding the number of sites. For instance, one population group in the PulseNet system is defined as U.S./Mexico border region and travelers returning from Mexico.

This definition includes nearly half of the U.S. and Mexican fruits and vegetable production zones and the majority of employees in the production, packing and preparation of fresh fruits and vegetables. More precise definitions may help the effectiveness of the databases moving

into the future.

We would also suggest that FDA work with organizations such as the U.S./Mexico Binational Health Commission to better understand the health implications of current U.S. immigration policy as it affects food-production workers in the U.S.

Under Objective 3, we have one suggestion which is that assistance to better education food-service and consumers regarding preparation practices for fresh produce must be part of the action plan. For example, beef and poultry handling instructions included with the product at retail was likely more effective than producer and slaughterhouse changes at reducing total foodborne illness related to consumption of meats.

Under Objective 4, FDA must not only support in theory but also fund practical projects to secure the safety and integrity of the supply of fresh produce. For example, the proposed FPAA study to reduce risks by narrowing the windows of opportunity for biological attacks of fresh produce should be taken under serious consideration and

funded. This study would test existing technologies to determine the best approach for industry to guard against biological attacks.

Finally, given that microbial testing will be a tool used by the agency and the industry, FDA should accelerate the process of developing faster and more reliable methods. FDA should also accelerate the implementation of existing methods not yet adopted by FDA.

Thank you for the opportunity to make these suggestions.

DR. BERU: Thank you, Ms. Wasserman. Any questions? After you make your presentations, if you could hold for just a minute in case there are questions of clarification that the panel wants to ask. Are there any questions?

Our next speaker is Mr. Carter Brown speaking for Western Growers Association.

MR. BROWN: Good afternoon. My name is Carter Brown and I am here this afternoon to present a statement on behalf of Western Growers. Western Growers is a California-based nonprofit

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agricultural trade association representing growers, packers and shippers of fresh fruits, nuts and vegetables in California and Arizona.

Western Growers' 3,000 members account for approximately 50 percent of the over \$30 billion of fruit, nut and vegetable production in the U.S. These member companies place a high priority on the quality and safety of their products and are firmly committed to the continual advancement and implementation of systems and practices that will improve them.

As such, Western Growers is extremely interested in FDA's recently announced proposed action plan. We are supportive of FDA's overarching goal and are committed to working closely with FDA on its key objectives. Western Growers concurs with FDA that this action plan requires the active participation of all partners in the academic, public and private sectors and that it will require the cooperation and collaboration of all sectors of the produce industry.

Each one of these discrete entities is a critical link in the chain of custody of a product from the field to the fork. While the percentage of foodborne illness attributable to fresh produce is small, as low as 12 percent of all foodborne illness, the vast majority of these outbreaks are not associated with the grower, packer or shipper.

In fact, in a recent survey of CDC data, the Alliance of Food and Farming concluded that only 17 percent of the outbreaks associated with fresh produce are potentially attributable to growers. So that is less than 20 percent of all foodborne illness.

This is evidence of the innovations the production industry has employed to help prevent the introduction of pathogens in fresh fruit, nut and vegetable systems. However, we still believe improvements are possible.

Beginning the early 1990s, Western Growers worked with the International Fresh Cut Produce Association to develop the first good agricultural practice guidance which later became the model for

other industry groups and the FDA. Since the implementation of these gaps in 1997, produce-related illnesses attributable to the grower category have dropped by 131 percent.

Western Growers and other organizations continue to stress the importance of these voluntary guidelines and have conducted countless seminars and forums to educate and encourage industry members to adopt and employ GAPs. Buyers routinely look for not only the implementation of GAPs but, also, their independent and certification.

Western Growers continues to work to identify any potential weak points in the generic GAPs that could use further definition or refinement by commodity or pathogen. The current draft product safety action plan's strategy of expanded surveillance of fresh produce for the presence of human pathogens as a means of minimizing public-health impacts must be examined.

While we agree that the speed and accuracy of trace-backs, the preparation and training of

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inspectors and the further coordination of existing systems employed by FDA, state and local agencies are all part of an integrated approach to minimizing the impact on public health when outbreaks occur, we remain unconvinced that increased sampling and monitoring are the most effective use of limited resources when attempting to respond to outbreaks.

Enhanced sampling and better detection methods may not best advance the stated goal of reducing foodborne illnesses associated with produce. Western Growers is concerned that there is misplaced emphasis on the premise that we can sample our way to safer food supply and that this strategy may take valuable and limited resources away from prevention, research, education and communication objectives that may prove more effective in reducing the number of outbreaks of foodborne illnesses associated with fresh produce.

In order to best serve the overarching public-health goals of the FDA, it is imperative that FDA improve communications with all the

partners in the fresh-produce industry. This is an extreme challenge because the fresh-produce industry is characterized by an immense diversity of products, producers and regions

FDA must make an effort to have more direct contact with the regional produce associations, commodity boards or special produce trade associations. These organizations are most capable of actively reflecting current industry practices and can facilitate the most direct communication between growers, packers, shippers and the agency.

In addition, the agency must also develop communication protocols that inform consumers quickly of potential foodborne-illness outbreaks without necessarily scaring them from the consumption of commodities known to be safe.

FDA must again collaborate with commodity organizations to ensure the information is timely and that it effectively warns the public without endangering the industry. This is a delicate balance and Western Growers agrees that is it

prudent to err on the side of public caution.

In these instances, we strongly encourage FDA to continue to develop follow-up information that can be shared with the public when the concern has been mitigated. Western Growers strongly encourages FDA to release its proposal for communications protocols and to work with all parties to develop a sound communication policy.

Western Growers is supportive of research in a number of areas related to fresh-produce production and handling in an effort to gain better understanding of how human pathogens and produce interact.

There are five key areas of needed research. First, microbial ecology of human pathogens in the agricultural production environment; second, agricultural water--and, with agricultural water, we need to identify indicator organisms which highly correlate with the presence of absence of viable human pathogens.

Third, soil amendments; again, we need to identify indicator organisms which correlate with

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the presence or absence of viable human pathogens. And we need to determine time-temperature coefficients and strategies for incorporation and application.

Four, proximity to potential containment sources. And, five, intervention strategies to reduce the risk of human pathogens contaminating fresh produce such as water-based and non-water-based disinfectants.

Thank you for your time.

DR. BERU: Thank you, Mr. Brown.

MS. BOHN: I had a question. This is Shirley Bohm. Could you repeat your comment about enhanced sampling and expand on it a little bit?

MR. BROWN: Western Growers has asked me that we will expand on these comments in writing and that they would prefer to do it that way. I apologize for that ducking.

DR. BERU: Thank you, Mr. Brown. Karen Egbert, Center for Science in the Public Interest.

MS. EGBERT: Good afternoon. My name is Karen Egbert. I am here on behalf of Center of

Science in the Public Interest. CSPI is a non-profit health-advocacy and education organization focused on food safety and nutrition and alcohol issues.

In the last month, the FDA has reported illness outbreaks related to Salmonella in raw alfalfa sprouts and Cyclospora in raw basic and mesculin/spring mix salad. The alfalfa outbreak is particularly troubling since it is caused by a form of Salmonella rarely seen in the United States but capable of causing serious and sometimes fatal infections in young children, the elderly and those with weakened immune systems.

Contamination of romaine lettuce with E. coli 0157:H7 has been blamed for three foodborne-illness outbreaks reported between July 2002 and October 2003. According to the database of foodborne-illness outbreaks maintained by CSPI, there have been 428 outbreaks with 23,857 cases linked to produce and produce dishes between 1990 and 2003, the most cases of any other type of food.

These outbreaks signal that FDA's current

approach, which is a program of voluntary compliance with guidelines, education and awareness, is not effective in preventing foodborne-illness from fresh produce. In fact, just this year, the FDA had to send a letter to firms that grow, pack or ship fresh lettuce and/or fresh tomatoes reminding them of their obligation to review their current operations in light of the agency's guidance for minimizing microbial food-safety hazards in fresh produce.

The best way to prevent or minimize contamination is through implementation of on-farm safety programs based on HACCP principles and systems. HACCP is flexible and designed to meet the individual circumstances of each farm or food processor. It covers many things that good producers and processors are already doing. Implementation of on-farm HACCP is the only way to ensure that all processors and producers, not just the best one, are working to ensure the safety of their products.

Following outbreaks of infections with

Salmonella and E. coli 0157:H7 linked to orange juice and apple juice consumption, the FDA required the fresh juice industry to implement a HACCP plan. The FDA should not wait until there are further produce-related outbreaks to implement HACCP for the produce industry.

In the absence of mandatory HACCP for fresh produce, the current GAPS and GMPs must be revised and strengthened. The current ones generally lack specific recommendations on how to identify and address the risks inherent in produce production and are written in language that does little to assure compliance.

In fact, as many of the speakers have pointed out today, on many major grocery chains, produce distributors and restaurant chains use the GAPS and the GMPs for the basis for independent third-party audits. The stronger the GAPS and the GMPs, the more meaningful these audits will be.

We feel that the GAPS and the GMPs should be revised and strengthened in the following ways. First, the guidance should be commodity-specific.

The survival and/or growth of pathogens in fresh produce is influenced by the organism, the produce item and the environmental conditions in the field. Therefore, FDA should develop a series of GAPS or GMPs that focus on specific hazards in specific produce and how to control those hazards.

The agency should apply the most up-to-date knowledge and make specific recommendations for specific crops or where they can be grouped into classes to classes of crops. For example, all fruits grown on or harvested from trees could be grouped into a class.

There should be recommendations along the food chain from harvest to final distribution. In addition to good agricultural practices and sanitation, the guidance should indicate effective temperature controls for the product during storage and distribution as well as state the shelf-life expectancy with the used-by date that does not allow sufficient time for pathogens to grow to elevated levels.

The commodity-specific guidance should

focus on the highest-risk products first, those that have been linked to repeated outbreaks such as lettuce, tomatoes, cantaloupes, green onions and herbs.

Another recommendation we have is that the language of the GAPs and GMPs should be less passive and more direct. One of the greatest weaknesses is the language used. Growers should not be asked, to "consider" irrigation, water quality or use, or, to "consider" the temperature of wash water for certain produce. Rather they should be told with specificity which interventions and measures will best control hazards relating to the safety of their particular product.

If FDA does not have this specific information, then growers and processors should be advised that they should conduct a facility-specific review to identify the potential hazards in their operations and have written plans that identify hazard controls and interventions.

Another weakness of the current GAPs and the GMPs is that they offer only minimal guidance

in certain areas such as transportation of fresh produce. A 2000 survey of 71 California fruits and vegetable shippers who sell products to all regions of the country demonstrates the transportation sanitation is a continuing problem.

14 percent of the shippers reported that the physical condition of the trailer was not sufficiently clean and the same survey reported concerns about maintaining appropriate temperatures in mixed loads. This portion of the guidance should be revised to give specific advice on proper sanitation including the use of dedicated vehicles, ways to prevent potential cross-contamination, and appropriate temperature control during transportation.

A potential model are the guidelines for the transportation and distribution of meat, poultry and egg products developed by USDA's Food Safety and Inspection Service.

The guidance also needs to identify the documentation needed for speedy and accurate trace-backs. One of the goals of the draft-action

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plan is to minimize the public-health impact when contamination does occur. One way FDA hopes to achieve is to increase the speed and accuracy of trace-backs requiring adequate records and documentations at all stages from harvest through device is essential to speedy trace-backs.

The problems associated with the lack of adequate documentation were demonstrated during the 2002-2003 romaine lettuce outbreak where the lettuce was sold under different brand names. The FDA did not have a complete list of those brands and was unsure which states had actually received shipments.

DR. BERU: Ms. Egbert, if you could sum up. We need to leave time for the other commenters.

MS. EGBERT: Okay. Finally, I would just like to say that foodborne-illness outbreaks related to fresh produce are not a minor public-health problem. Risk prevention, detection and control measures must be in place at every step and voluntary guidelines are not the public-health