

at

101

response needed to address the food-safety problems coming with fruits and vegetables.

Thank you.

DR. BERU: Thank you

MR. GUZEWICH: I have a question here, Nega. I ask you the same question I asked Dr. Lynch. It would be very helpful for us if you reported some 400 produce outbreaks in your database of outbreaks. It would be very helpful for us if you could break those down into how many of those were due to contamination at the field or packing shed as opposed to those that were involved with problems at the transportation level, how many of those were involved with contamination or problems at the retail or supermarket level, how many at the consumer level, so we can see the relative importance each of those steps plays in the overall issue of produce contamination.

By the way you say it, it implies that it is all due to contamination at the farm and I suspect that that isn't the case for all of them.

MS. EGBERT: No, no; we are not saying

that. We gather our information from a number of sources including state and local health departments, the CDC and other sources. To the extent we have that information, we can try to provide it. But we don't provide that data in our analysis.

DR. TROXELL: I have a question, too. You are advocating HCCAP on the farm. Do you have any idea of the practicality of executing that?

MS. EGBERT: We will provide a response to that in our written comments.

DR. TROXELL: Okay.

DR. BERU: Thank you. Next up is Jim Gorny, Vice President of Technology and Regulatory Affairs, International Fresh Cut Produce Association.

MR. GORNY: Good afternoon. My name is Jim Gorny. I am the V.P. of Technology and Regulatory Affairs for the International Fresh Cut Produce Association. We are a trade association who represents people who are fresh-cut processors, people who supply products like fresh-cut salads,

broccoli florets, sliced apples, products like that.

As a preface, I would really like to say that today we are here to discuss how to make a safe-food category even safer. It would really be a disservice to consumers to imply or infer that substantiated and well-documented long-term health benefits of consuming fresh fruits and vegetables is outweighed by risk.

First I would like to outline six key areas where we feel that we can make the biggest impact. I would like to hand these to Nega. They are copies so that the panel can follow along.

First, we really believe, as has been said earlier today, a supply-chain approach is really what is needed. To be effective, the supply-chain approach must be taken and include everyone that handles fresh produce including growers, packers, processors, distributors and retailers.

The reason is because no one industry segment in the produce continuum from field to fork has the resources or ability to identify all the

risks and mitigation measures across the entire supply chain. Therefore, it is really imperative that industry, government and consumers collaborate and take an active role working together and implement measurements that enhance produce food safety.

Second of all, we do believe that enhanced trace-back investigations are truly needed. Currently, it is unclear if recent outbreaks associated with the consumption of produce are due to lack of compliance with GAPs or if there are true deficiencies in how GAPs are currently formulated.

Therefore, there must be more efficient and effective trace-back investigations to more effectively identify and communicate where in the supply chain and what the most likely cause of contamination was. In our comments, we have listed three areas. One is for the FDA to review their 1992 trace-back guidance document. Two is to potentially involve produce-safety experts in their investigations.

The third point would be to--we really need to get on the same page with regard to terminology. In a number of the outbreaks when lettuce was identified, it was actually spinach or it was actually spring mix and not a lettuce product per se. So we need to harmonize our terminology so we can better communicate with each other back and forth.

The third point is really we do need enhanced research efforts. The FDA and industry must collaborate, facilitate and support produce food-safety research that provides a meaningful assessment of fresh-produce handling practices during the field, production, processing and preparation by retailers and consumers, because a better understanding of the interaction between produce and human pathogens will aid in the development of intervention strategies and increase the safety of our food supply.

Again, we agree with WGA's comments; microbial ecology, safe water use, soil amendment use. How close it too close with regard to

at

106

potential contamination sources and also we need this information to develop affective intervention strategies.

We certainly don't believe that increased surveillance--we can't sample our way to food safety, so increased surveillance is truly not the answer. We have addressed that in our written comments.

Fourthly, we would like enhanced education outreach. The entire supply chain must enhance educational outreach to the entire produce continuum from field to fork to facilitate the exchange of the most current and effective food-safety information and best practices.

Fifthly, we would like a regulatory review. We believe that a comprehensive review of regulations is warranted to identify discordant municipal county, state and federal statutes which may actually increase food-safety risk and pursue their amendment, one example of which was APHIS and their hot-water treatment of mangos. I believe that the FDA has addressed that now but there are

at

other municipal, county, discordant statues which may actually increase food-safety risk such as reuse of tail water or irrigation water.

Sixth is enhanced communications. We really need to communicate better with each other. With that regard, I would like to say that it is imperative that the FDA improve communications with industry and consumers to best serve our public-health goals and, first and foremost, the produce industry is extraordinarily diverse and complex and really, the more directly the agency can communicate with persons actively involved in the industry, the more accurate the informational flow back to the agency.

I would like to also, just at this point--you are probably wondering why I brought this case here. The IFPA, we have taken this issue very diligently and deliberately we have addressed the area of food safety. We have produced a number of documents over the last four years and I would like to present those to the FDA.

In 2001, the IFPA put together food-safety

guidelines for the fresh-cut produce industry. It was first put together in 1992. This document is also available in Spanish. Also, the number-one cause of recalls in the United States of food products is food allergens or inappropriate labeling on the ingredient label.

This year, we just released our model food-allergen plan for the fresh-cut produce industry. It is in its first edition. Although fresh-cut fruits and vegetables are not a major allergen, some of things like croutons and other components may be.

We also have a packaging guide which addresses the issue of botulism in modified atmosphere packaging and also a whole chapter dedicated to the interaction of food packaging and human pathogens.

We don't stop there. The IFPA also has a three-day HACCP workshop for our industry in collaboration with the University of Georgia. Here is the HACCP notebook. This has been doing on--we have trained over 500 people so far. Also, the

University of California at Davis teams with the International Fresh Cut Produce Association. We have a course, a three-day course, on maintaining the quality and safety of fresh-cut products.

We also have collaborated with the FDA and the California Department of Health Services to produce a training video on safety fresh-cut processing for our industry.

We don't stop there. We also work up the chain and back. We also work with our customers and with grower members. In 1999, IFPA, with the Produce Marketing Association, put together produce handling guidelines for fresh-cut products with the Produce Marketing Association.

Also, the Association of Food and Drug Officials has put together fresh cut guidance documents for retail handling of fresh-cut products and Food Marketing Institute, retail handling of products. Again, both these were published in 2004.

In 1997, IFPA and WGA put together voluntary food safety guidelines for the produce

at

110

industry which essentially became the GAPs document. In 2002, we published a guidance document with regard to best practices for field-cleaned and corded lettuce. And we also have a basic training for our members twice a year.

We also have sponsored this year, in 2004, in three states, California, Texas and Florida a sanitation workshop for packinghouses, fresh-cut processors and people who handle produce. We have teamed with the University of Florida, University of California at Davis, Texas A&M, and our regional produce trade associations, Florida Fruit and Vegetable, United Fruit and Vegetable and Western Growers.

With that, I would like to conclude and I just wanted to say that we do take this issue very seriously and we have worked deliberately and diligently to address it and we look forward to working with you in the future.

Thank you.

DR. BERU: Thank you, Dr. Gorny. Any questions?

at

111

MS. AYLING: I have a question. This is Mary Ayling. That was a rather impressive bag full of stuff you brought. I was wondering if, in your comments, or now, you could comment on how you measure the success of the training programs and the various outreach materials that you have.

MR. GORNY: It is difficult for us to measure, but I think the proof is in the pudding with regard to foodborne illness. We have been working diligently on this issue and one of the issues that we address in our comments is how to measure success.

We very explicitly go into that. I think, first of all, we need standardized metrics, some type of baseline data to establish where we are. If we don't know where we are at, how do we know where we are going and if we are successful.

I think one of the things we would like to see is some type of--it is imperative that the agency work with the industry to accurately establish baseline information regarding compliance to GAPS. Future surveys would then be able to

at

112

determine the efficacy of the produce action plan. Thirdly, in detailing foodborne illnesses associated with produce consumption, we have got to index and standardize the data because the data that Michael showed, Dr. Lynch showed, from CDC, we see that aberration and they clearly say that it is aberration and an increase because they changed the reporting.

Also, as time goes on, we will have better and better detection methods. So we need to make sure that, if we are being effective, we are not seeing just aberrations or increases. So I think those are very important aspects.

DR. TROXELL: This is Terry. Do you have a program at all that goes out to determine the level of adherence of your members to all these good guidances?

MR. GORNY: No. As with PMA and United, we really let the market forces take care. It is truly coming from the buyers. We have third-party audits and we also have audits from our buyers. Our customers come and look at our operations,

at

113

also.

DR. BERU: Thank you. Next up is Marie Claude Thibault, Director of Health and Food Safety, Canadian Produce Marketing Association. She is not here? Okay. One less. Todd Wichmann, President, HealthPro Brands, Incident.

MR. WICHMANN: Thank you very much. My name is Todd Wichmann. I think I will probably be the only small company or small business in this entire room today. You are looking at half the company here in a company of two people. In fact, you are looking at the only executive in my entire company so any question you want to ask, I will be more than happy to answer anything today. There won't be any written comments following up.

I also don't have a big bag of materials here. As a small company, I am trying to bring common sense to the meeting so, hopefully, that will fly in this room.

Just a quick background of myself. I am entrepreneur. Like I said, it is a very small company that I have. We acquired a brand called

FIT Produce Wash from a former manufacturer a couple of years ago. The reason why I acquired this brand is the I feel very, very strongly that cleaning produce and improving the consumption of produce in this country is very, very important. There are some personal reasons why I feel so strongly about that. I won't go into it today.

But I felt so strongly with it that I actually bought this brand from this prior company. As the commercial goes, I believed in it so much, I bought the company. Well, this is really true for me and, as any small business owner and any small entrepreneur, you have to really believe passionately in something if you really want to go after it, which I do here, as well.

The common-sense gap I see in this plan, and I applaud everything that has been said today and I think all the steps are great, but the gap that I see, really, is in the home. As we have talked several, several times, it is very hard to pinpoint when any contamination would occur. Is it the field? Is it the processing? Is it at the

at

115

supermarket. I mean, how many times is something handled before it is purchased at a supermarket?

So, since it is almost impossible to identify, sometimes, exactly where the contamination occurred, we really need to give consumers their own tools and their own power to try to help control this problem.

Specifically, and I will follow up with a written statement to this effect, there needs to be a fifth objective to this plan, I really believe. That fifth objective would be to provide new recommendations for consumers to help clean their produce in their home. You can word it any way you want but the basic idea is to really get consumers to help take control of the situation themselves by improving cleaning produce within their home.

Therefore, wherever any contamination would occur, you are addressing it right before consumption which, then, alleviates every single issue in this entire debate of where it occurred.

I haven't heard anything today address this issue and I would really challenge the

at

116

assumption in the background statement, and it has been mentioned several times today, which is that produce is consumed raw without any type of intervention to control or eliminate pathogens prior to consumption.

I think that is a false assumption. Someone mentioned hot water as one way to solve this problem. That is, I think, another way to say, of cooking raw produce. So, for the consumers that won't wash their produce in hot water, there have to be other choices. And there are.

There are natural, completely safe, products that are made with vegetable-based sources, these produce-wash categories, that consumers can use to really help eliminate and clean their produce in their homes. Consumers are already doing this, so I think, for those consumers that want to choose to go beyond all the other safe agricultural practices and everything else that has been mentioned today, 25 percent of consumers--and this data comes from some prior consumer research that was done a couple a years ago--but 25 percent

at

117

of consumers are already using dish liquids, bleach, hand soaps, things that the FDA correctly points out, should not be used on produce because of the chemicals that are in there. They are not designed to be used on food.

So I really think the FDA, if anything, as a way to help clarify what consumers should be using on their produce, because, right now, you say what you shouldn't be using. But I really think it would be a very helpful service to consumers if you could say, as an extra step for those that choose to want to do this, there are natural-based, vegetable-based, produce washes that are out there that will really help bring this issue to the home.

I guess I would just wrap up this perspective by saying we all have addressed here, today, and it is well-documented in any single report that you would look at, that washing your hands with soap is critical in any kind of food-handling process, whether it be at a restaurant, in a field, in a processor.

Before eating, everybody--your

at

118

mother--like I said, common sense here. Your mother told you, from when you were little, that you should wash your hands with soap before eating. And yet, for something that is consumed raw, the only guidance we tell consumers right now is to use water alone. If water, alone, isn't good enough to clean your hands, then why would water, alone, ever be good enough to clean your food before eating it?

I know it is not anything but common sense, but I think it is pretty powerful common sense. These produce washes provide the same kind of surfactant with some vegetable-based fatty acids to remove any kind of material that is on there the same way that soap works on your hands.

So, I would end with that. If there are any questions, I would be more than happy to answer them.

DR. BERU: Thank you, Mr. Wichmann. Any questions? Thank you.

Next up is Mr. Bob Sanderson of Sanderson Jonathan Sprouts.

MR. SANDERSON: I am very, very pleased to

at

119

be able to be here and offer the perspective of someone in a problematic industry which I am very happy to say a lot of people still like sprouts a lot and also I think there is hope.

I am President of a small company in Massachusetts. I am also Vice President of the International Sprout Growers Association but it wouldn't quite be right for me to say I am--I am certainly not presenting a perspective that the Association has worked on so I am speaking mostly as an individual grower.

It was requested that comments relate to the questions listed in the June 15 Federal Register and I would like to primarily address Question 1 which is, what concepts, or underlying principles, should guide the 2004 Safety Action Plan.

Since the two sprout guidance documents issued by the FDA in 1999 are mentioned under Objective 1 as a possible model for developing guidance for other produce, I would like to share my impressions of the pros and cons that these

recommendations have had on the sprout industry and what their impact has been.

I have heard a few people say that they don't think surveillance is the way to go and I can understand their position, but I should just tell you I think, right now, it is crucial with sprouts. So, sprouts are different.

The two guidances that were issued, one of them calls for strong chlorine seed soaks, 20,000 parts per million. I think that is roughly one-third the concentration of a bottle of Clorox. The other is for every batch production, spent irrigation-water testing.

An interesting thing about sprouts is that, although they are wonderful incubators of bad bugs, if bad bugs get in them, that makes them very testable through irrigation-water sampling, the theory being that water that is used to grow the sprouts comes in contact with every sprout in the production batch and will carry a profile of the organisms on the sprouts into a sample.

Now, to talk about the impact of these two

guidance recommendations, the 20,000 parts per million treatment recommendation divided the sprouting community between organic growers who felt that this treatment was inconsistent with organic standards, non-U.S. growers who, in many cases, are prohibited by law in their native countries from using anything approaching that kind of chlorine concentration and growers who rejoiced that the answer had been found and considered people who didn't buy into that to be jeopardizing the whole industry.

So the sprouting community was split and you might say that is the way it goes. But a split industry doesn't communicate well and is demoralized. So it if it possible to relate to industries in way where that doesn't happen and it may not be in all cases, I think it would be an advantage.

A second problem was that two guidance recommendations were made just about simultaneously and there was, at that time, and continues to be, no way to assess the relative value of each

recommendation in reducing the likelihood of contaminated sprouts getting sent out to the market.

One unfortunate result of that is that people can attribute improvements, if there have been slight improvements, or continued problems which there still are, to compliance or non-compliance with either guidance as they are predisposed. And so I think science gets lost in the shuffle.

So, if you are doing research, you probably should minimize the number of variables you change at any one time. With sprouts, there were really just common-sense good manufacturing practices which weren't very good a lot of the time. Suddenly, there were two recommendations which were very drastic ones.

A third problem with the guidance recommendations is that they have become the primary definer of due diligence for safe sprout production. My own feeling is that more emphasis is being put on the less effective intervention,

the treatment, possibly because it is consistent with risk-reduction approaches which work well for other foods.

A fourth complication is that the National Organic Standards Board is understandably apprehensive about questioning and FDA safety recommendation. Obviously, if an organic producer isn't using chlorine and gets involved in an outbreak and actually, realistically, from any cause, it would be a huge crisis for the organics industry.

This is not a good situation in the sprout business. Maybe the sprout business is inherently so problematic that it can't be improved, but I think it can. A suggestion I would have, possibly, to move in that direction is, as a condition of issuing guidance recommendations to an industry, a quantitative risk analysis of the benefits of what is being recommended would be very clearly stated. I don't believe that has ever been done in the case of the two recommendations that were made for safe sprouting.

I think if it were done--well, I wish it were being done. I have lots of feelings about this but it hasn't been done. So some people think the chlorine does it. Other people think the testing does it. Chlorine treatment is cheaper than testing so growers prefer it because they can't get a price premium for testing because the people they are selling the product to don't understand these fine points.

In the absence of a quantitative analysis, the issuance of a guidance recommendation can seem arbitrary or even punitive with resulting confusion and sometimes ill will. I feel this has happened in the case of sprouts.

Thank you very much. I would be happy to answer any questions.

DR. BERU: Thank you, Mr. Sanderson. Any questions from the panel?

DR. TROXELL: Terry Troxell. You talked about surveillance being crucial. What about surveillance relating to the seeds used for sprouting?

MR. SANDERSON: I have been a proponent of seed sampling and have worked out a sampling protocol. Obviously, it is far from a guarantee, but I've tried to reads everything that has been publishd where seed sampling has been mentioned. I find, again and again and again, that it is written off not because it doesn't work but it wasn't done right. So I think it has a great potential and should be done as a matter of course. But, obviously, it can't be a guarantee.

Unfortunately, these bugs don't behave, as everybody who deals with microorganisms knows. They can pop up here and there. They are very rarely consistent but sometimes they are. I think a number of outbreaks would have been averted if seed had been tested beforehand. I can say that.

DR. BERU: Thank you.

MR. SANDERSON: Thank you very much.

DR. BERU: Next up is Bob Gravani, Professor of Food Science, Cornell University.

DR. GRAVANI: Thank you very much. It is, indeed, an honor and privilege to have a chance to

at

126

share some thoughts with the agency. My name is Bob Gravani. I am Professor of Food Science at Cornell University and also Director of the National GAPs Program housed at Cornell University. Along with Elizabeth Benn, who is our project coordinator, I would like to address some items in the action plan.

We represent about 25 state collaborators throughout the country in our Nation GAPs Program. Unlike many of the speakers who preceded me, I want to commend the agency on developing the action plan. It is certainly the next logical step as we approach continuing improvement efforts in the area of produce safety.

I think it is important to recognize, and most people in the audience do, that many of the items in this action plan are already being worked on by the produce industry, by many people in academia and certainly many people in local, state and federal regulatory agencies.

It is, indeed, a partnership. Certainly continuous improvement is warranted and needed.

One of recommendations that I would suggest the agency look at is to focus attention on the greatest areas of risk and prioritize the list of objectives in this action plan. I think that is very, very important.

In terms of Objective 1, I think that we need to continue to promote the application of good agricultural practices because, believe it or not, and this audience excepted, many people are still not aware of good agricultural practices.

In a survey done in New York State with our growers there, about 30 percent of the growers were unaware of good agricultural practices. Those that said they were aware of good agricultural practices and were beginning to think about implementation indicated several barriers to implementation of GAPs. Those barriers included things like lack of knowledge, lack of assistance and they just didn't know where to begin.

Now, obviously, New York may not be indicative of the entire country, but three other states will be using our instrument to survey their

at

128

growers, in California, Texas and Florida, so stay tuned to see what information ensues from there.

Also, I think improving awareness of the importance of GAPs through more effective educational outreach efforts is clearly warranted and everybody in the room is charged with that responsibility as well.

In terms of Objective 3, we need to improve and enhance communication between and among all parties in the food system. An interactive inter-web resource that has been recently been funded that will certainly improve and enhance this communication effort. It will be designed for growers, people in the industry, in academia, and the agencies to interact and learn about current recommendations, et cetera.

I think we also need to increase practical GAPs research. I stress, here, practical. There is a lot of research out there but it needs to be practical and it needs to be dedicated to updating scientific knowledge and practical recommendations and intervention strategies to farmers and growers.

at

129

We have lots of very interesting laboratory research but we need field research that is going to generate some new recommendations.

As all of you in this audience know, we are dealing with a number of recommendations that are based on antiquated science. So, clearly, we need that to happen. We also need the financial support to be able to conduct that effective practical research, and I want to make that point very clear and strong for the committee. We can't do these things without assistance from the agencies, from Congress, to appropriate funds to help us do this.

I want to make you aware that there will be GAPS research conference in January in Orlando, Florida and I invite you to be present for that as well. We certainly will provide additional comments on the plan but I thank you very much for your attention and for the opportunity to make this presentation today.

DR. BERU: Thank you, Dr. Gravani.

MR. GUZEWICH: I have a question here,

Bob.

DR. BERU: Jack?

MR. GUZEWICH: Your recommendation that the action plan assign things or prioritize things by risk, have you got examples of what you mean by the risk priorities? What would be your risk priorities, Bob?

DR. GRAVANI: Like, certainly, most other people in this room, I will provide those in written comments. However, clearly, some of the issues that have already been addressed--worker health and hygiene, manure and s**oil amendments, animal intervention, those kinds of things would be among my top priorities.

Again, we need to look at where we get the biggest bang for our increasingly small buck. Clearly, it is a great action plan with wonderful objectives, but it is going to be hard to address all of those all at once by everything. It is going to take time, money and a lot of effort. While I applaud the agency, I think we need to clearly look at where we are going to get the

at

131

biggest bang for our buck to continuously improve, to reduce the risks and to clearly improve the safety of produce.

Terry, you look like you have a question.

DR. TROXELL: Yes. Terry Troxell. You said 30 percent of the producers in New York State were unaware. Have you tried to analyze what is missing and why they are falling through the cracks? We are talking about five years or so down the road with our good ag practices.

DR. GRAVANI: We were certainly embarrassed by that result. We have been to every grower meeting. We have conducted numerous good agricultural practices training programs with every sector of the produce industry in New York State, so we were flabbergasted by those results.

We said, we think we are getting good coverage and we are still missing about 30 percent, what is the problem? We are now analyzing that and trying to tease out some of that information so we can, again, go back in and do a better job of reaching some of these people we want to reach.

at

132

DR. TROXELL: We certainly would like help from you and your effort to understand what we can do to reach the 100 percent.

DR. GRAVANI: Absolutely. I think that is why our collaborators in Florida, Texas and California were very interested in our survey instrument because they wanted to get a handle on some of the same questions with their growers. I think, as we look at some of the larger fruit-and-vegetable-producing states, that data will be immensely helpful in getting us closer to the answer that you are looking for and I think, "Stay tuned."

We are going to be presenting that paper at the International Association for Food Protection this August so certainly more information, more data, will be forthcoming then. But when our collaborators in these other states also conduct a survey, I think we are going to have some very good information to share with you all.

DR. BERU: Thank you.

DR. GRAVANI: Oh; Mary has got a question.

at

133

MS. AYLING: Did you say that there was an interactive website on GAPS that is already being developed or has been developed or will be?

DR. GRAVANI: We have been very fortunate. CSREES just notified us that we received a grant to develop this interactive website. The idea here is that we will put all of our GAPS training materials, our resource manual and a number of other items up on the website and make it interactive so that industry, academia, regulatory agencies, everyone, can participate.

We haven't gotten the check yet, but, as they say, it may be in the mail. I am hoping so. As soon as we get that, we are ready to go. We got our designers ready, so I think it will be a useful tool in promoting good communication, more effective communication, between and among. I don't think this is a one-way communication activity. I think we need to all share some thoughts, debate some issues and talk about some of the recommendations that are out there that may be, again, not exactly what we would all like to see

at

134

out there but base it on better science, that the research that lots of folks are doing will bear fruit.

Thank you.

DR. BERU: Thank you. Mr. Jim Cranney, U.S. Apple Association.

MR. CRANNY: Good afternoon. My name is Jim Cranny and I am here representing apple growers and companies that market fresh apples and process apple products.

I just had a couple of very fundamental points that I wanted to make today. We will be following up with some written comments but, just on the fundamental level, we just wanted to point out that FDA's efforts to minimize foodborne illness is a worthy goal and, perhaps, there are some measures that can be taken to try to further that goal.

But, when we do approach that in the action plan, we just felt that it was important to make sure that whatever is done in the action plan, that is it going to be science based and based on

risk.

So the first point that we really wanted to highlight today is that we just wanted to make sure that any action really addresses a real problem. Within that context, I just wanted to point out that there really has never been a reported microbiological food-safety outbreak involving fresh apple consumption.

We have heard about apple juice and cider but, in terms of fresh consumption, there have not been any microbiological problems associated with consumption of fresh apples.

The other point that I wanted to make was that FDA may or may not be aware that already quite a lot is being done in the apple industry to address issues of food safety on a preventative basis and there have been some comments here earlier by Bryan and others pointing to the market forces that are at work and the industries having to respond to those market forces to comply with regulations that are put out there by food retailers.

So I just wanted to comment that there is probably a lot more being done than FDA may be aware of and we will have some comments to make about that in our written comments to further inform the agency.

But, having said that, I just wanted to thank you for the opportunity to make those comments and we will be making further comments in writing.

DR. BERU: Thank you. Mr. Jim Still of the Freshability Partners.

MR. STILL: Hi. I am Jim Still with Traceability Partners and Global Logic. I hadn't planned on speaking today and I hate the spotlight so I promise to be brief. I have spent most of my life as a consultant and a builder of refrigeration systems for fresh produce, primarily pre-coolers, ripening and then cold storers.

For personal reasons, about six months ago, I decided to take my company into traceability. I wanted to just bring up two things. One is that produce is truly global, as

at

137

everyone, I think, knows but I haven't heard anybody say. You have got Europe GAP and E.U. regulations that exist. If you look at strawberries or apples, I would hate to see our industry, our growers overburdened by packing the same product but having to meet three different sets of standards for reporting, passing information forward, and I would propose that maybe we, at least, think about rather than Europe Gap or USA Gap, World Gap, if that is possible.

Secondly, I would just like to touch upon Europe GAP, which I haven't heard anybody mention. I was just in Belgium and was trained in Europe GAP two weeks ago. It is a consortium of 95 percent of the retailers in the E.U. as well as South Africa, believe it or not. What they have done is they have resolved by a combination of government and private. All growers need to be certified. The auditors do not certify but they audit only, pass forward the audit report to the certification body in Cologne. So there is as separation which makes sense. If you fail your audit, you are out of the

at

138

market.

So, talk about getting rid of the bad apples in the business, it is wonderful. But that is really industry-driven and, hopefully, the retailers will do as they promise and not buy from noncompliant farms.

Secondly, there was a law passed, and this is the teeth, EU Regulation 178 requiring traceability. If you have a problem and you don't furnish traceability, your company is dead.

So that is all I really wanted to add. One last thing is that produce-to-farm traceability systems do exist. They have been in use in the EU for up to three years now. It is not that difficult.

Thank you.

DR. BERU: Thank you, Mr. Still. Mr. Still was the last of our commenters unless someone has registered and we have somehow overlooked. Donna?

DR. GARREN: Nega knows he is in trouble now for getting me. Donna Garren with the United

at

139

Fresh Fruit and Vegetable Association. United Fresh Fruit and Vegetable Association is 100 percent committed to food safety. Earlier, you heard that commitment from our President, Tom Stenzel.

It is my personal responsibility, as Vice President of Scientific and Technical Affairs, to provide expertise, leadership and resources to our members to fulfill on that commitment.

Upon completion of my doctorate in Food Microbiology at the University of Georgia, I went to work for a California grower, shipper and processor of fresh fruits and vegetables heading up their quality assurance department.

I learned first-hand the importance of food-safety practices at the field level with a management commitment that drove over all company actions from packing to sales. I joined the United Fresh Fruit and Vegetable Association in 1999 with a mandate to bring this commitment to our entire industry.

Today, I am pleased to say that good

food-safety practices permeate our industry. Can we do better? Of course. I am a scientist and I know risk reduction is a process that never ends. But it is a process that fully engages our industry and me, both personally and professionally.

As FDA embarked upon its new produce safety action plan, we intend to work with you as an agency every step of the way and we will be providing extensive comments in this process. To that, we need to better understand why these rare outbreaks that we have discussed have occurred. What went wrong in the process from field to table? Only with that detailed knowledge can we apply the tools at hand to prevent these cases.

We need more scientific evidence of how contamination is mostly likely to occur and less speculation on theories that take our attention away from more likely risks. We need to better communicate the critical importance of safe production and handling practices at every level in the chain including with consumers to reduce risk at all.

Food safety is everybody's responsibility. It starts at the farm but it does not end until the consumers enjoy a healthy, nutritious and safe produce item. And we need to look at public health in a macro sense, weighing the huge benefits to health from eating five to nine servings a day of fresh fruits and vegetables with the rare risk of foodborne disease.

Everything we do in this room and related to this issue must be tempered with the overwhelming and urgent public-health need for consumers to eat more fresh produce, not less. We cannot, as scientists and public-health officials, afford to scare people away from produce just because we are working hard to reduce what is already extraordinarily low risk.

I am my staff look forward to working with FDA, CDC and other stakeholders in crafting the strongest possible scientific review of these issues and continue to work hard to provide Americans with the safest possible supply of healthy and nutritious fresh produce. That must be

at

142

our common goal.

DR. BERU: Thank you, Donna. Sorry for that oversight. I think you just wanted to have the last word.

Summary of Meeting

DR. BERU: Thank you all for your comments. This has been a very useful meeting. We have heard from a good cross-section of our stakeholders, different segments of industry, academia, consumers, on what the action plan ought to be.

As we work to finalize the action plan, we will take all these comments to heart as well as written comments we hope to receive in the coming weeks. As you know, the comment period is open until July 24.

Of course, developing the action plan is only the first step. Its implementation is what is going to be critical to reduction in foodborne outbreaks related to fresh-produce consumption. We truly believe this is a collaborative effort and should be done in partnership with all parties

at

143

involved.

I would like to close by reminding you that the comment period on this draft action plan is open until July 24. I urge you to submit your comments for our consideration as we finalize the action plan.

Finally, I would like to thank all involved in making this important meeting happen. A special thanks to our panelists and thank you all very much for taking the time from your busy schedules to participate in this meeting.

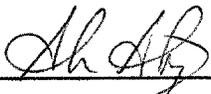
With that, I am declaring this public meeting closed. Thank you.

(Whereupon, at 3:55 p.m., the meeting was adjourned.)

- - -

C E R T I F I C A T E

I, **SHARON SHAPIRO**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.



SHARON SHAPIRO