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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
U.S. FOOD AND DRUG ADMINISTRATION  
CENTER FOR APPLIED FOOD SAFETY AND APPLIED  
NUTRITION (CFSAN)

-----  ORIGINAL

SAFETY OF FRESH PRODUCE PUBLIC HEARING

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FRIDAY, APRIL 13, 2007  
9:00 A.M. to 4:30 P.M.

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FDA/CFSAN  
5100 PAINT BRANCH PARKWAY  
COLLEGE PARK, MARYLAND

1           A P P E A R A N C E S

2

3   PARTICIPANTS:

4

5   ROBERT BRACKETT, PH.D.

6   Director

7   Center for Food Safety and Applied

8    Nutrition (CFSAN)

9   Food and Drug Administration

10   ART LIANG, M.D.

11   Acting Director

12   Foodborne Disease

13   Centers for Disease Control and

14    Prevention

15   MICHELLE SMITH, PH.D.

16   Office of Food Safety

17   Center for Food Safety and Applied

18    Nutrition (CFSAN)

19   Food and Drug Administration

20   MARION ALLER, PH.D.

21   President

22   Association of Food and Drug Officials

1 PARTICIPANTS:  
2  
3 CPT. THOMAS HILL  
4 Office of Food Defense, Communications  
5 and Emergency Response  
6 Center for Food Safety and Applied  
7 Nutrition (CFSAN)  
8 Food and Drug Administration  
9 JIM RUSHING, PH.D.  
10 Director of the Coastal Research and  
11 Education Center  
12 Clemson University  
13 THOMAS E. STENZEL  
14 President  
15 United Fresh Produce Association  
16 BRYAN SILBERMANN  
17 President  
18 Produce Marketing Association  
19 CAROLINE SMITH DeWAAL  
20 Director of Food Safety  
21 Center for Science in the Public  
22 Interest

1 PARTICIPANTS:  
2  
3 MARTHA ROBERTS, PH.D.  
4 Special Assistant to the Director  
5 Florida Agricultural  
6 Experiment Station  
7 University of Florida  
8 AMY GREEN  
9 Office of Food Safety  
10 Center for Food Safety and Applied  
11 Nutrition (CFSAN)  
12 Food and Drug Administration  
13 MICHAEL M. LANDA, ESQ.  
14 Deputy Director for Regulatory  
15 Affairs  
16 Center for Food Safety and Applied  
17 Nutrition (CFSAN)  
18 Food and Drug Administration  
19  
20  
21  
22

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- 1 PUBLIC PARTICIPANTS:
- 2
- 3 THOMAS NASSIF
- 4 Western Growers Association
- 5 RICHARD ROSS
- 6 Path Tracer
- 7 MICHELLE MARCOTTE
- 8 International Irradiation
- 9 Association
- 10 REGINALD BROWN
- 11 Florida Tomato Exchange
- 12 ANTHONY CORBO
- 13 Food and Water Watch
- 14 RAYNE THOMPSON
- 15 California Farm Bureau Federation
- 16 JOE RAJKOVACZ
- 17 Owner-Operator Independent Drivers
- 18 Association
- 19 ALFRED MURRAY
- 20 New Jersey Department of Agriculture
- 21 GREG DROUILLARD
- 22 Sunkist Growers

(866)448-DEPO

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1 PUBLIC PARTICIPANTS:

2

3 CHARLES HALL

4 Georgia Fruit and Vegetable Growers

5 Association

6 SALLY GREENBERG

7 Consumers Union

8 ROBERT GRAVANI

9 Cornell University

10 JENNY SCOTT

11 Grocery Manufacturers/Food Products

12 Association

13 JILL HOLLINGSWORTH

14 Food Marketing Institute

15

16

17

18

19

20

21

22

1 FDA PANEL:

2

3 RAYNE THOMPSON

4 California Farm Bureau Federation

5 JOE BACA

6 Director

7 Office of Compliance

8 Center for Food Safety and Applied

9 Nutrition (CFSAN)

10 Food and Drug Administration

11 JACK GUZEWICH

12 Acting Director

13 Division of Public Health and

14 Biostatistics

15 Office of Food Defense, Communication

16 and Emergency Response

17 Center for Food Safety and Applied

18 Nutrition (CFSAN)

19 Food and Drug Administration

20

21

22

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Page 8

1 FDA PANEL:  
2  
3 STEVE SOLOMON, DVM, MPH  
4 Deputy Director  
5 Office of Regional Operations  
6 Office of Regulatory Affairs (ORA)  
7 Food and Drug Administration  
8 DON ZINK, PH.D.  
9 Senior Food Scientist  
10 Office of Food Safety  
11 Center for Food Safety and Applied  
12 Nutrition (CFSAN)  
13 Food and Drug Administration  
14 GLENDA LEWIS  
15 Supervisor  
16 Retail Food Protection Team  
17 Office of Food Safety  
18 Center for Food Safety and Applied  
19 Nutrition (CFSAN)  
20 Food and Drug Administration  
21  
22

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1 P-R-O-C-E-E-D-I-N-G-S

2 (9:00 A.M.)

3 WELCOME/OPENING REMARKS/OVERVIEW

4 DR. BRACKETT: Welcome to a public hearing  
5 with the Center for Food Safety and Applied Nutrition.  
6 For those of you who don't know me, I'm Bob Brackett.  
7 I'm the director of the Center here.

8 Today, I am going to be the presiding  
9 officer of today's hearing, which is called a Part 15  
10 hearing because the rules for it appear in Part 15 of  
11 Title 21 of the Code Federal Regulations.

12 A Part 15 hearing is informational. There  
13 is no direct or cross-examination or no redirect or  
14 recross examination, and the rules of evidence do not  
15 apply as in other types of hearings.

16 There is one hard-and-fast rule, which is  
17 that the only people may ask questions of the speakers  
18 are the members of the FDA Panel, sitting in front,  
19 and me.

20 In addition, I will insist that speakers  
21 keep to their allotted time for two reasons. First of  
22 all, because we have a lot of ground to cover today

1 and we want to make sure that everyone scheduled to  
2 speak gets his or her time to speak. Second, because  
3 it would be unfair to the speakers who do keep to  
4 their allotted time for others to take up more than  
5 their fair share. To help you with that, we have in  
6 the second row here a big, fluorescent, red stop.

7 (General laughter.)

8 DR. BRACKETT: I do have a book. There is  
9 no food allowed in this room, so we appreciate it if  
10 you remember that.

11 We do know that there are people from the  
12 press here, so we want to make sure that we facilitate  
13 things for you as well. For those of you who may have  
14 questions here today, we will provide some assistance  
15 for you in that we have some FDA CFSAN staff that will  
16 be wearing blue name tags. If you have questions, ask  
17 them, and they should be able to help you with that.  
18 We will keep to the schedule as I said.

19 We do have a sign language interpreter on  
20 hand today for those individuals needing information  
21 regarding the recent outbreaks that we have seen in  
22 the last year.

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1 More importantly, we are here to solicit  
2 your comments, data that you might have, or any other  
3 information that will help today. We will have a  
4 series of FDA speakers, some invited speakers, then  
5 questions from the FDA Panel, and towards the end of  
6 the day we will have public comments.

7 After the hearing, when we are finished, all  
8 of the presentations will be provided to Dockets. We  
9 will accept public comments onto the Dockets as well.  
10 Again, the date is June 15, 2007. We will have  
11 transcripts of the hearing available within about two  
12 or three weeks of this hearing.

13 Just to tell you who we have on our FDA  
14 Panel participants, as I mentioned, I am the presiding  
15 officer over this hearing. We have Mr. Joe Baca, who  
16 is director of Office of Compliance.

17 Joe, you can raise your hand.

18 (Mr. Baca complies.)

19 DR. BRACKETT: Jack Guzewich, acting  
20 director of the Division of Public Health and  
21 Biostatistics, Office of Food Defense, Communication  
22 and Emergency Response.

1 Dr. Steve Solomon, deputy director of the  
2 Office of Regional Operations. Dr. Don Zink, senior  
3 food scientist, Office of Food Safety. Finally,  
4 Glenda Lewis, supervisor of the Retail Food Protection  
5 Team with the Office of Food Safety.

6 Our first speaker this morning will be  
7 Dr. Art Liang, who is acting director of the Division  
8 of Public Health and Biostatistics and Zoonotic,  
9 Vectorborne and Enteric Diseases in Atlanta. He is  
10 also the acting associate director for the Science  
11 Center's Division of Foodborne Bacterial and Mycotic  
12 Diseases at the CDC.

13 From 1989 through 2006, he currently serves  
14 on a number of committees throughout the food safety  
15 area including the Executive Committee of the National  
16 Advisory Committee for Microbiological Criteria for  
17 Foods and the Preventative Residency Advisory  
18 Committee for the Walter Reed Army Institute of  
19 Research.

20 Dr. Liang is the chief of the Communicable  
21 Disease Division with the Hawaii Department of Health.  
22 Dr. Liang currently serves on a number of committees

1 throughout in the food safety area, including: the  
2 Executive Committee of the National Advisory Committee  
3 for Microbiological Criteria for Foods, and the  
4 Preventative Medicine Advisory Committee for the  
5 Walter Reed Army Institute of Research, as well as the  
6 Board of Directors of the American Association for  
7 Public Health Physicians.

8 With that, Dr. Liang.

9 FOODBORNE ILLNESS OUTBREAKS ASSOCIATED  
10 WITH PRODUCT CONSUMPTION  
11 (PowerPoint™ slide presentation in  
12 progress.)

13 DR. LIANG: Thank you.

14 Good morning. Hopefully, I only have ten  
15 minutes now. I know this is a very sophisticated  
16 audience, and a lot of you will be aware of a number  
17 of slides, the information that I show. To get  
18 started, we know that foodborne illnesses are common.

19 Luckily most of them are not serious, but  
20 unfortunately a share of them are. About one in a  
21 thousand Americans may end up being hospitalized for a  
22 foodborne illness, then of course we know that from

1 the economic research from the FDA that there is a  
2 considerable loss, economic loss due to direct and  
3 indirect costs of foodborne illness.

4 I think generally we, society, have agreed  
5 that foodborne diseases, the ecology of foodborne  
6 diseases, is complex and that efforts from farm to  
7 table need to be considered as we try to prevent  
8 foodborne illness.

9 Of course, today's talk is about produce.  
10 From CDC's perspective and from the public health  
11 departments' perspective, fresh produce is  
12 increasingly recognized as a problem.

13 Again, I know a lot of this is sort of  
14 foodborne disease 101, but of course foodborne  
15 illnesses are not one thing. They are a number of  
16 different chemicals as well as microbiologic agents.  
17 We are going to mainly talk about microbiology. We  
18 seem to be adding to that list on a daily basis.

19 Microorganisms all have different ecologies,  
20 some of them are what we would call in sort of a  
21 "human reservoir," meaning where does this organism  
22 normally hang out so that there are human,

1 person-to-person type illnesses like Shigella  
2 hepatitis or Norovirus are probably the more common  
3 ones that we deal with.

4           Some seem to make their home in animals of  
5 various sorts, again, Salmonella and Campylobacter. I  
6 think many of you are familiar with the list, the cast  
7 of characters here.

8           Then, the other issue to be made is that  
9 from CDC and the state and local health departments of  
10 tracking illnesses and outbreaks illnesses, many of  
11 these agents, though, can have multiple modes of  
12 transmission.

13           Even though some of them may commonly be  
14 transmitted by food, we know that they can find their  
15 way into people's mouths via water; maybe from direct  
16 contact hand-to-mouth; contact from animals; or from  
17 other human beings.

18           A little bit of background on the foodborne  
19 outbreak surveillance, which is the major way that we  
20 can make the association. How do we know whether this  
21 agent was caused by food or water or aerosol.

22           Our major way of making that inference is

1 from the foodborne outbreaks that are conducted by the  
2 state and local health departments, sometimes with CDC  
3 assistance, most often without.

4 When CDC does collect reports from the  
5 50 states -- but these reports I need to point out are  
6 done voluntarily, and even though we request certain  
7 kinds of data, and as many of you know, we like to  
8 collect more and more -- it's really up to the states  
9 how much information they can or will provide.

10 Although, we think what has been provided is quite  
11 good.

12 For the purposes of analyzing this database  
13 from the 50 states, our definition for a "foodborne  
14 outbreak" is two more cases of illnesses resulting  
15 from the ingestion of a common food.

16 Again, what we normally monitor are the  
17 illnesses through the investigation we conclude or  
18 don't conclude what the vehicle is and whether it is  
19 food-related.

20 What kind of data do we get from the states  
21 or do we request from states, clearly whether or not  
22 they think that an outbreak has happened and whether

1 it is foodborne in order to get into the database and  
2 how many cases. We ask them what food was implicated  
3 and what was the causative agent or the ideology.

4 For the period prior to 1998 and before, we  
5 received about a total of 500, plus or minus,  
6 outbreaks reported per year to CDC. This is just  
7 showing you a chunk of that data, not going all the  
8 way back to the fifties and sixties and seventies, but  
9 you can see that from '90 up until '98 you can see  
10 what the level of reporting was. That was fairly  
11 stable.

12 After '98, partly related to the Food Safety  
13 Initiative at that time, the CDC began stimulating  
14 more reporting, in the beginning it was paper,  
15 requesting states to report on a more regular basis

16 We provided more guidance on what we wanted  
17 them to report, and indeed the states complied and we  
18 had increased reporting. Later, after 2000, the  
19 system became automated, and now it's no longer just a  
20 paper-based system.

21 I show this to you now because you can take  
22 this into consideration when I show you some of the

1 data and when we try interpret some of the data.

2           Because of this change, this is why I'm  
3 presenting the data actually in two chunks. The  
4 chunks are related, but the analysis is not exactly  
5 the same. You need to keep that in mind.

6           From the period from 1973 to 1997, using the  
7 definition of "fresh produce" as being uncooked  
8 produce items or salad which did not have another  
9 ingredient -- just mainly eggs, cheese, seafood, or  
10 meat included -- that is the case definition for what  
11 we are going to be showing you in terms of a  
12 produce-associated outbreak.

13           During that period, there are a total of  
14 190 foodborne outbreaks linked to fresh produce. You  
15 can see there are over 16,000 illnesses, almost  
16 600 hospitalizations, and 8 deaths.

17           Again, for the entire reporting period, this  
18 represented about 3.2 percent of all outbreaks that  
19 were reported that had a determined source and agent  
20 identified.

21           Then, when you count up the number of cases  
22 that occurred amongst that 3.2 percent, it was a total

1 of 6.2 percent outbreak-associated cases. Okay, so  
2 that is how many outbreaks and how big they were, just  
3 how many people were involved as compared to all  
4 outbreaks that were reported -- oh, I'm sorry, all  
5 other outbreaks, not produce-associated.

6 This gives you some a little different.  
7 This gives you a comparison of in the seventies on the  
8 early end, there was 190 cases, and then what happened  
9 in the nineties up to and including 1997.

10 You can see that during the seventies part  
11 of this period there was an average of 2 outbreaks,  
12 produce-associated outbreaks, per year and then by the  
13 time we get to the seventies there are 16, then the  
14 average number of cases per outbreak in the seventies  
15 was 21 as compared to the nineties where there are an  
16 average of 43 cases per outbreak.

17 The percent of outbreaks of known vehicle,  
18 comparing produce-associated outbreaks with other  
19 outbreaks where we knew what the vehicle was, that  
20 turned out to be .7 percent. Produce-associated  
21 outbreaks were .7 percent of all outbreaks of known  
22 vehicle, with a known vehicle. In the seventies and

1 in the nineties, it's 6 percent.

2 Then, the same comparison this time of the  
3 outbreak-associated cases and how many people got ill,  
4 in the seventies we have .6 percent and then compared  
5 to 12 percent in the nineties.

6 Okay. Then, with the same period, '73 to  
7 '97, there is a peak. This is a summary of what were  
8 the vehicles, what types of vehicles were implicated.  
9 "Generic" and "multiple" are things like not a single  
10 item.

11 Salad is probably the simplest example.  
12 There may be a number of items in the salad but they  
13 are all produce, so that's when we say "generic" and  
14 "multiple." We can't say, we don't know whether it is  
15 one component of that salad or the whole salad. There  
16 are 105 of those outbreaks.

17 Then, the rest are outbreaks where a single,  
18 specific food could be could be implicated. There are  
19 85 of those outbreaks during this period. You can  
20 see, you can read the slide, you can see that those  
21 seven items sort of represent 88 percent of all the  
22 outbreaks where one item was able to be implicated.

1           Okay. Then, of course, this is how we see  
2 the world. We see the world in terms of infections,  
3 diseases at CDC. This gives you a breakdown of how  
4 many were bacterial, viral, parastic, and chemical.

5           We do get chemical outbreaks, but they are  
6 usually very small. Frankly, that's not our area of  
7 expertise, so we don't do a lot work in that area in  
8 the part of CDC where I work.

9           Then, there is a breakdown here of also,  
10 roughly, which have animal reservoirs versus human  
11 reservoirs. Don't try to add up the columns because  
12 there are some there that are in that other column  
13 that are thrown into that categorization.

14           The point is that, again, sort of in keeping  
15 with this farm-to-table theme, these represent a  
16 variety of foods, of produce items, with basically a  
17 variety of ecologies. You know better than I in terms  
18 of the farm-to-table continuum that that continuum can  
19 be quite different depending on the item and the  
20 animal, human, or otherwise.

21           Now I'm going to talk about this period from  
22 '98 up through 2004. A similar question looking at

1 produce-associated outbreaks, but because of the  
2 changes in the reporting it's not precisely comparable  
3 to the other years, although it is relatable. We can  
4 talk about that.

5 Again, in this case produce was defined  
6 somewhat differently. We tried to classify them as  
7 either they were fruit- or vegetable-associated  
8 outbreaks, okay.

9 Then, from '98 to 2004, the total number of  
10 outbreaks was 384, nearly 16,000 cases, over  
11 700 hospitalizations, and 15 deaths. Now, remember  
12 that this is a time where reporting, overall  
13 reporting, has increased.

14 Then, we see that overall 7 percent of all  
15 outbreaks that had a determined ideology were  
16 produce-associated. Then, 14 percent of outbreaks  
17 associated with produce, 14 percent of the cases, were  
18 aa part of these outbreaks. Again, these are compared  
19 to the denominator here. The percentage is the  
20 percentage of all outbreaks where we identified an  
21 agent and a vehicle.

22 Okay. I realize this is a little bit hard

1 to see, but the main reason for showing this is the  
2 type of categorization that we use. It is still  
3 produce focused, but it's not the same as what we  
4 defined earlier, in the earlier period.

5 I think the take-home message here is you  
6 see it's a polychrome slide, meaning, again that we  
7 are talking about a number of different types of food  
8 items throughout the years.

9 Okay. Then, the next slides are presented  
10 in a way similar to what you already have seen. You  
11 see the number of generic or mixed produce outbreaks,  
12 and then you see the items that were implicated when  
13 there was a single, specific food that was able to be  
14 implicated.

15 Okay. Then, again, bacterial, viral, and  
16 parasitic -- I think that as the slide tries to point  
17 out, again, we are talking about pathogens that have  
18 animal as well as human reservoirs, this is a very  
19 diverse problem and involves a diverse farm-to-table  
20 continuum.

21 To point out the increase in norovirus  
22 outbreaks, we don't think that means that there is

1 more norovirus-associated produce as much as we know  
2 during that period that there were now diagnostics  
3 available to the public health community where you  
4 could actually document and confirm that, yes, this  
5 was not just your suspicion that this was norovirus,  
6 but this in fact was norovirus.

7 We think that 70 percent, that apparent  
8 increase is not necessarily a real one. It is more  
9 associated with our ability to diagnose norovirus in  
10 the public health community.

11 Okay. Bottom line, we think there has been  
12 an increase, a real increase, in produce-associated  
13 outbreaks from the seventies to the nineties, and that  
14 from the nineties to 2004, it hasn't gone away.

15 I guess the current estimate, the current  
16 figure, is that 14 percent of all outbreak-associated  
17 cases, that's the current figure of the percent of all  
18 outbreak-associated cases that were associated with  
19 produce outbreaks.

20 There have been more outbreaks through the  
21 nineties, and even through the two thousands there  
22 seem to be larger outbreaks. As I said, there are a

1 variety of produce items implicated. There are a  
2 variety of different pathogens.

3 In terms of looking at where to intervene in  
4 terms of contamination amplification, it's  
5 complicated. You probably know more than I it's going  
6 to depend on the ecology of what is that  
7 farm-to-continuum pathway that we are looking or how  
8 are those items handled.

9 Thank you. I certainly welcome any  
10 questions. If anything is not clear, please ask, feel  
11 free to ask any clarifying questions.

12 (Applause.)

13 DR. BRACKETT: Thank you, Dr. Liang.

14 Next on the agenda is Dr. Michelle Smith.  
15 Michelle is a interdisciplinary scientists with FDA's  
16 Office of Food Safety, and she was the lead author on  
17 FDA's "Guide to the Minimized Microbial Food Safety  
18 Hazards for Fresh Fruits and Vegetables," or the  
19 so-called "GAPs and GMPs Guide."

20 Dr. Smith also led the development of FDA's  
21 2004 Produce Safety Action Plan. She has played an  
22 active role in implementing the guidance, the

1 educational and the outreach as well as regulatory  
2 oversight and research components of the Produce  
3 Safety Action Plan. Dr. Smith is currently leading a  
4 workgroup to identify options to enhance fresh produce  
5 safety.

6 GAPS/GMPs, PRODUCE SAFETY ACTION PLAN

7 OPPORTUNITIES AND CHALLENGES

8 (PowerPoint presentation in progress.)

9 DR. SMITH: Thank you for that wonderful  
10 introduction that I had the opportunity to write  
11 myself.

12 (General laughter.)

13 DR. SMITH: It's a pleasure to be here, and  
14 I'm really happy to see so many familiar faces in the  
15 audience including my past boss who is now retired,  
16 Terry Troxel.

17 With that, my objectives for this morning  
18 are to share a little bit of the background on the  
19 GAPS guidance; the 2004 Produce Safety Action Plan;  
20 some of the opportunities and challenges that we've  
21 encountered in implementing both the GAPS guidance and  
22 the action plan; a little bit about where we are now;

1 and some speculation, probably mostly questions, about  
2 where we may go from here towards ensuring food safety  
3 of fresh produce.

4 Now, the first three points on this slide  
5 many of you have seen and heard quite a few times.  
6 Fresh produce is grown in a nonsterile environment.  
7 There are opportunities for contamination, and fresh  
8 produce by its very nature is likely to be consumed  
9 raw. There is not a cook or kill step if pathogens  
10 are present.

11 FDA does not expect fresh produce to be  
12 sterile. However, the presence of pathogens is not  
13 the natural state of fresh produce. There are  
14 practices that can and should be implemented to reduce  
15 or minimize the opportunities for contamination of  
16 fresh fruits and vegetables.

17 As Art Liang mentioned, there was a  
18 significant increase in foodborne illness outbreaks  
19 associated with fresh produce between 1973 and 1997.  
20 CDC brought this data to our attention in the late  
21 nineties, and that was the driving force behind  
22 development of the good agricultural practices.

1           Since the time of the good agricultural  
2 practices, there have been approximately 72 reported  
3 outbreaks associated with about 20 fresh produce  
4 commodities.

5           Now, FDA is concerned about fresh produce in  
6 general. Twenty commodities, as I mentioned, have  
7 been identified as the vehicle in these outbreaks  
8 during this time frame.

9           On this slide, I've listed leafy greens,  
10 tomatoes, and melons because these commodities  
11 together accounted for more than half of those  
12 outbreaks.

13           Now, I could have listed four commodities,  
14 five, or six instead of these three. The point is  
15 that there are trends that we're seeing, trends in  
16 burden associated with particular commodities. Part  
17 of what we will need to address is how or should we do  
18 things for individual commodities as opposed to fresh  
19 produce across the board.

20           The GAPs guidance document, very briefly,  
21 was broad-scope guidance. We needed to cover  
22 practices common to the growing and packing of most

1 fresh produce consumed in the United States,  
2 regardless of what region of the United States the  
3 produce was grown in or which other country. The  
4 objective of the guide is risk reduction, not  
5 elimination; and it's guidance, not a regulation.

6 A few comments about what we have seen in  
7 our experience over the last eight to ten years from  
8 foodborne illness investigations. One of the phrases  
9 that's showing up more and more often is that "There  
10 was no smoking gun," or "Investigators were not able  
11 to determine the source of contamination."

12 An investigation by it's very nature occurs  
13 after the contamination event has happened. Sometimes  
14 it may take a significant amount of time to identify  
15 where the produce came from and get investigators back  
16 to that location to try to figure out what has  
17 happened, what went wrong.

18 Even if the investigators find the outbreak  
19 strain of the pathogen at or near that location, they  
20 may not be able to say how it got from where it was  
21 found onto the produce. This is what is kind of meant  
22 by "We couldn't find the source of contamination."

1           We are a regulatory agency, and we need to  
2 state things very explicitly. Thomas Hill in his  
3 presentation will present in a lot more detail some of  
4 his observations.

5           As we gain more experience, we are relying  
6 very heavily on continued information coming in from  
7 our investigators, also information from researchers  
8 and other experts in areas such as wildlife and water  
9 quality management that we had not engaged in this  
10 kind of search some time ago.

11           Now, having said that there is a need for  
12 research and a need for more information, the other  
13 aspect of what we see in our investigations are  
14 instances where failure to implement appropriate good  
15 agricultural practices and good manufacturing  
16 practices in the field, packing facility very well  
17 could have led to contamination of fresh produce.

18           Examples of things like insanitary  
19 conditions, failure to have adequate sanitary  
20 facilities or hand washing facilities for workers,  
21 failure to have appropriate training for workers,  
22 these are things that we have seen and these are

1 causes of contamination that are preventable.

2 The 2004 Produce Safety Action Plan remains  
3 a priority for FDA and for the Center for Food Safety  
4 and Applied Nutrition. This action plan builds upon  
5 existing programs and expertise and it covers fresh  
6 fruits and vegetables from the farm to the table.

7 The overarching goal of the Produce Safety  
8 Action Plan is to minimize foodborne illness  
9 associated with the consumption of fresh produce.  
10 There are four general objectives in the action plan.

11 When we developed this action plan with  
12 input from stakeholders, we realized that the plan  
13 itself was just the first step, that implementation of  
14 the plan is critical, so we also built into the plan  
15 measurable outcomes, actions within the plans that  
16 could achieve these objectives and accomplishments  
17 that would count towards achieving the objectives.

18 For example, under the first objective,  
19 preventing microbial contamination, measurable  
20 outcomes would include: the release of guidance,  
21 regulations, or other tools to assist the industry in  
22 implementing appropriate best practices.

1 Under objective two, "Minimizing public  
2 health impact when contamination occurs," measurable  
3 outcomes would include things like guidance for  
4 investigators, farm investigation training, things  
5 like that that would help speed the traceback process  
6 and better ensure that the information that  
7 investigators are able to gather in the course of an  
8 investigation is the best possible information  
9 available.

10 Just a few of the things that we have  
11 accomplished in implementing the Action Plan, in March  
12 we released a draft final guidance for fresh-cut  
13 produce. This guidance complements existing GMP  
14 regulations in Part 110.

15 In August of last year, FDA in cooperation  
16 with the California Department of Health Services and  
17 the California Food and Agriculture initiated a  
18 multiyear, risk-based, ongoing Leafy-Greens Safety  
19 Initiative.

20 This initiative gave the three agencies an  
21 opportunity to work together in collaboration,  
22 strengthened that collaboration, and goes out to

1 various fields, cooling facilities, and fresh-cut  
2 operations in California to observe operations in  
3 advance of an outbreak.

4 This initiative also included an important  
5 communications component to build cooperation and to  
6 very rapidly initiate communication with consumers and  
7 others in the event of an outbreak, which in fact did  
8 occur shortly after the initiative started.

9 One of the other things that we did in 2006  
10 was update materials for training for farm  
11 investigations and hold training in the state of  
12 California for FDA, state investigators, and foreign  
13 counterparts.

14 We also finalized guidance for farm  
15 investigations to provide more detailed instructions  
16 to investigators on what to look for and how to do  
17 that.

18 Now, the 1998 GAPs guidance has been both a  
19 challenge and an opportunity. The opportunity  
20 includes a chance to raise awareness about potential  
21 sources of microbial contamination at the farm and  
22 packing facility and of the food supply chain.

1           This is an area that had not previously  
2 gotten much attention, so the guidance was very  
3 timely. It has given us a basis to work with many of  
4 our food safety partners.

5           The challenge is that it is guidance. It is  
6 voluntary, not a regulation. In implementing the GAPs  
7 Guide, we have taken the approach of making  
8 recommendations for practices and encouraging  
9 adoption.

10           In a compliance situation, we are not able  
11 to specifically enforce the recommendations in the  
12 guidance; however, we can and do reach back to our  
13 statutory authority to ensure that fresh produce is  
14 not adulterated.

15           In addition, the guidance was broad scope.  
16 In the guidance itself, we recommended that operators  
17 take these recommendations and tailor them to their  
18 individual operations. Doing this without more  
19 specific information can be a challenge.

20           We understand that one size does not fit  
21 all, that the risk of microbial contamination results  
22 from the interaction of several factors, including:

1 the characteristics of the commodity, the production  
2 environment where the commodity is grown, and the  
3 practices that are used by the individual operations.

4 Some of the opportunities that we have  
5 experienced in implementing the action plan are  
6 communication with research, academia, federal, state,  
7 and industry partners.

8 An example of this collaborative cooperation  
9 is the industry-led, commodity-specific supply chain  
10 guidance. Public and private partners are also  
11 forming coalitions to get research identified and  
12 funded to address some of the specific issues that we  
13 have identified as needing more science.

14 When we developed the 2004 Produce Safety  
15 Action Plan, that is an FDA guidance or that is an FDA  
16 action plan, we understood for it to be most effective  
17 it would require all food safety partners working  
18 independently and collaboratively to achieve the most  
19 effective results. Many of the food safety partners  
20 that we are working with are here today.

21 Just another few words about the  
22 commodity-specific guidance. Today, guidance is

1 available for melons, lettuce and leafy greens, and  
2 tomatoes.

3           One of the advantages of guidance is that  
4 guidance is a living document. As the science  
5 advances, the guidance can be reopened and updated.  
6 In fact, this is the case with the lettuce and  
7 leafy-greens guidance.

8           Additions to the production of this section  
9 have been drafted based on our experiences and things  
10 that have been learned since the outbreaks last fall.  
11 The tomato guidance is also being reopened and groups  
12 formed to see what they can take from those lessons  
13 and apply to tomatoes.

14           Some of the challenges that we face, clearly  
15 fresh produce outbreaks are continuing. The  
16 challenges include things like globalization,  
17 complexity of distribution, and the variety of  
18 products available.

19           There is a growing high-risk population in  
20 the United States. There are currently practical  
21 limitations to investigations and the information  
22 gained.

1           Traceback is certainly an area where we can  
2 all do better. This is also an area where there are  
3 significant opportunities for collaboration.

4           Lastly, probably most importantly, there is  
5 the challenge of identifying and promoting risk-based,  
6 preventive controls.

7           Our starting point, we believe that the  
8 measures outlined in the Produce Safety Action Plan  
9 and the GAPs Guide and other public and private  
10 guidelines have or can be effective when properly  
11 implemented.

12           However, the continuing outbreaks cause us  
13 to ask a number of questions, including: What is the  
14 extent of implementation of the current  
15 recommendations? What is the effectiveness of these  
16 recommendations when they are implemented properly?  
17 What additional or different interventions might be  
18 appropriate to reduce future outbreaks?

19           The purpose of this meeting is to gather  
20 information along those lines and help determine which  
21 path we should take from here. Should it be guidance,  
22 regulations or different or additional mechanisms?

1           In "The Federal Register Notice" for this  
2 public hearing, there is a section that talks about  
3 the regulatory approach that FDA has taken for a  
4 number of different food groups other than fresh  
5 produce. For purposes of this presentation, I've  
6 pulled out juice HACCP, which is 21 C.F.R., Part 120,  
7 as an example.

8           I want to say first and foremost that I  
9 recognize fresh produce is not juice. In juice, we  
10 have the advantage of having multiple treatments  
11 available to juice processors to deliver a five-log  
12 pathogen reduction or greater to the product. I don't  
13 think we are there with fresh produce at this point in  
14 time.

15           In addition, I don't think that HAACP itself  
16 is appropriate for the farm level, but there are many  
17 things in HAACP that might be applied to farms,  
18 packing facilities, and other aspects of produce  
19 production.

20           For example, the idea that you look at an  
21 operation and you identify potential risk factors, and  
22 based on this assessment you develop a safety plan

1 that may put in place appropriate preventive controls.

2           Some of the other requirements in the juice  
3 HAACP rule that may have a place in consideration for  
4 fresh produce include training and other requirements  
5 for specific job functions to ensure that the person  
6 who is performing that function either has the  
7 training or the experience to do that function well.

8           There are options for importers to choose  
9 between to be able to verify that the product that  
10 they are importing into this country was produced in a  
11 manner consistent with the rule, and there are records  
12 that would allow producers and investigators to be  
13 able to verify that the appropriate practices are  
14 being followed over time.

15           In addition, the juice HAACP rule is  
16 augmented by a number of other things including a  
17 hazards and controls guide to assist in implementation  
18 and a recognized training curriculum to ensure that  
19 the job functions that have training or experience  
20 requirements have guidelines to go by to make sure  
21 that the training or experience is adequate to do the  
22 job.

1           FDA's mission is to ensure the safety of all  
2 domestic and imported fresh and fresh-cut fruits and  
3 vegetables consumed in the United States. For as long  
4 as we have been pursuing this mission with fresh  
5 produce, our continuing themes have been increasing  
6 Americans' consumption of fruits and vegetables to  
7 achieve a healthier diet and improving the safety of  
8 fresh fruits and vegetables to the greatest extent  
9 possible. Common to both these themes is the need,  
10 the critical need, for consumer confidence in fresh  
11 produce.

12           Thank you.

13           (Applause.)

14           DR. BRACKETT: Thank you, Michelle.

15           Our next speaker is going to provide the  
16 AFDO's -- that is, "Association of Food and Drug  
17 Officials," for those of you who don't know --  
18 perspective.

19           Since 1998, Dr. Marion Aller has served as  
20 the director of the Division of Food Safety with the  
21 Florida Department of Agriculture and Consumer  
22 Services and her current responsibilities include

1 oversight of a comprehensive inspection and compliance  
2 program along with laboratories which analyze food  
3 samples for microbiological and chemical  
4 contamination.

5 She has held several offices and  
6 chairmanships in AFDO. She received her bachelor of  
7 arts in English from Stetson University and her  
8 doctorate of veterinary medicine from the University  
9 of Georgia.

10 AFDO PERSPECTIVE

11 (PowerPoint presentation in progress.)

12 DR. ALLER: Thank you.

13 As he said, or as Dr. Brackett just  
14 indicated, I am Marian Aller. I am with the  
15 Association of Food and Drug Officials, also called  
16 "AFDO."

17 I wanted to give you a little bit of  
18 background on AFDO, who we are and what brings us here  
19 and our perspective on this issue. We were  
20 established in 1896, and the mission of our  
21 organization is to foster uniformity in the adoption  
22 of food safety laws, rules, and regulations.

1           We are made up of predominantly regulatory  
2 officials from state, local, and federal authorities.  
3 We also have memberships in academia and associate  
4 memberships with industry.

5           The background in this issue comes  
6 specifically from a forum which was held in Florida in  
7 November of last year by the tomato industry, which is  
8 calling for regulations to address produce safety,  
9 particularly the safety of fresh tomatoes.

10           During that forum, a number of concerns were  
11 expressed, and some of the other speakers will address  
12 those. I want to focus on the regulatory aspect and  
13 the concerns spoken of there.

14           As I said, there was a general call for  
15 regulations, and at the same time a very real concern  
16 expressed about the potential in the absence of a  
17 federal regulation for states to adopt a patchwork of  
18 different regulations based on potentially different  
19 factors or perhaps even an understanding of what those  
20 specific causative agents may or may not be and how  
21 best to mitigate those or address those.

22           Also, as the background factor, there is a

1 general recognition I think by all of us here that the  
2 size and scope, as we heard from Dr. Liang, of  
3 foodborne illnesses associated with fresh produce are  
4 unacceptable and that we do need to move forward  
5 collaboratively to address this issue.

6 I want to talk a little bit about the  
7 existing guidances which we believe are a very strong  
8 first step, but the challenges that Michelle addressed  
9 are that the existing guidances lack specific criteria  
10 and metrics.

11 It is difficult for a producer or a grower  
12 to know both what specific criteria they need to meet  
13 and then more importantly what to do in response if  
14 their operation is outside of those guidance or  
15 criteria. It is identifying the criteria and  
16 identifying the appropriate response.

17 Also, as previously alluded to, those  
18 factors and criteria may be very different, depending  
19 on various production practices and the  
20 commodity-specific practices as well. We have  
21 regional, geographic, and commodity-specific issues to  
22 be addressing.

1           There is a very real need for research to  
2 address these causes. That again I'm not going to go  
3 into, and we will let other speakers address that. We  
4 do believe that FDA does have a very real role, and we  
5 turn to our federal partners to guide that.

6           I do think, however, that we do need and it  
7 is our association's belief that we do need to move  
8 forward, recognizing that science is not always there,  
9 and, that where science is lacking, we do need to move  
10 forward and exercise our best professional judgment.

11           In light of all of that, our association,  
12 and to respond to the request that was made of us, has  
13 appointed an ad hoc committee. They have asked me to  
14 chair this group.

15           The charge that we have been given in this  
16 group is to go beyond, however, just tomatoes,  
17 recognizing again that we are dealing with a very much  
18 broader concern about produce safety. Our charge is  
19 specifically to develop a model code, and by "model  
20 code" I do mean regulation, to address produce safety  
21 at the farm and packing house.

22           We have been asked to look, the group has

1 been asked to look at those specific areas in general  
2 because we believe FDA has and there are other  
3 mechanisms to address the contamination issues further  
4 along that supply chain, and that this is where the  
5 greatest lack has been.

6 Why AFDO and some of why we may have been  
7 approached with this? Well, I think, first of all,  
8 we've had a very long history of a strong partnership  
9 with FDA and USDA. We also have some experience in  
10 development of model codes going back more than  
11 20 years ago with a model food safety law.

12 I've listed a couple of more recent codes  
13 that have been developed. These codes are developed  
14 in partnership with academia; federal, state, and  
15 local regulatory officials; industry; and consumer  
16 input.

17 Why a model code as opposed to federal  
18 regulation? I don't want to suggest here that federal  
19 regulation should not be considered. However, we  
20 think that just given the encumbrances of federal  
21 rulemaking processes, that the development of a model  
22 code by our organization might be a little bit more

1 quick in bringing it about. It is also more readily  
2 modified going through a process of this nature.

3 It is a more open process. By that, I don't  
4 want to suggest that FDA does not seek input from all  
5 of the stakeholders. However, there is a point in the  
6 federal rulemaking process when the public comment  
7 period closes at which FDA or the federal agencies can  
8 no longer discuss where they are going with that.

9 The time of closure of public comment to  
10 publication of a rule can, as we all know, be somewhat  
11 lengthy. Again, this is just part of the process.  
12 With the process that we are envisioning through an  
13 AFDO Working Group, it is a more iterative and open  
14 process throughout.

15 I think, again, one of the advantages to a  
16 process of this nature in developing a model code like  
17 this is that it does provide for what I consider to be  
18 ground truthing, again, through the participation of a  
19 broad spectrum of people providing input into it and  
20 can undergo continual modification as necessary.

21 Also, as a model code, and I think to  
22 address industry concerns, the model code through the

1 addition of annexes or appendices provides for state  
2 and local authorities, regulatory authorities to  
3 tailor equivalences in production practices over  
4 geographic concerns may be not applicable across the  
5 board through the national regulations.

6 If I'm not being very clear, ask me  
7 questions what I mean about that. But I think that  
8 this is a process that provides for that, to address  
9 those concerns as well. Again, I want to stress  
10 equivalency there in levels of protection.

11 Again, to carry that theme, we believe that  
12 because of the process potentially involved here that  
13 it is a more collaborative work product and therefore  
14 can enjoy wider success and, most importantly, broader  
15 implementation.

16 Because states and locals have ongoing  
17 partnerships and certainly a perception, I won't say  
18 it's always the reality, but as we know what  
19 perception and reality are, we can work much more  
20 closely with the smaller- and medium-sized farms and  
21 businesses.

22 It is often those where our regulatory

1 options and regulatory compliance tends to break down.  
2 Again, we need for regulation to ensure that all  
3 producers are participating.

4 I mentioned a moment ago that we have, AFDO  
5 has, set up a committee. At this point in time the  
6 Committee has had one meeting, that's by conference  
7 call, at the moment.

8 At the moment members include state  
9 regulators from Florida, California, Virginia, Ohio,  
10 North Carolina, and members from FDA and USDA. It  
11 also includes a representative from the Association of  
12 Fruit and Vegetable Inspection Standardization  
13 Agencies, a bigger mouthful than AFDO, "AFVISA."

14 We have industry representation. We have  
15 several growers -- or at least, excuse me, one grower.  
16 We will probably be adding a couple of other growers  
17 to come and go as we are addressing specific  
18 commodities, again, for that ground truthing.

19 Academia is on this committee, and I say  
20 others. When I was first approached to put this  
21 together, I had a wonderful idea that this would be a  
22 small, very nimble group and quickly found out that

1 no, small doesn't quite cut it. You really need to  
2 have very broad membership. We hope we will keep that  
3 agility and ensure that we cover all of our bases in  
4 terms of membership.

5 Specifically, what are the next steps. Our  
6 goal is to pick up where existing guidance documents  
7 have left off. We want to incorporate the, I think,  
8 very good and excellent work, recent work, by both  
9 leafy greens efforts out in California and through the  
10 tomato industry out on the East Coast.

11 We want to extract from those documents  
12 those overarching principles and then, as I mentioned  
13 before, tailor to specific commodities and perhaps  
14 geographic-specific concerns as well or specific  
15 production practices.

16 I would love to think that AFDO had all the  
17 money in the world, and that we could do this through  
18 great meetings and have public input. We are a very  
19 small organization. We are made up of regulators. We  
20 don't have a lot of dollars, so we will be working  
21 predominantly through emails and conference calls. We  
22 do plan to meet at our annual educational conference

1 this June in San Antonio.

2 In summary, I want to stress our support for  
3 FDA's leadership and desire to move forward on this  
4 issue. We applaud those efforts. We do not believe  
5 we are trying to go divergently but collaboratively,  
6 maybe along parallel tracks.

7 Those tracks may merge at some point in  
8 time, if regulation is the path chosen; if not, we  
9 want to have something in place for states to have and  
10 for industry.

11 We also urge our federal partners to  
12 "leverage." I use that word. You hear it a lot more  
13 when money is tight. Money is certainly tight. We've  
14 all heard of the budgetary woes to leverage the very  
15 limited research dollars and ensure that we do get the  
16 biggest bang for our buck researchwise.

17 There are many, many, many questions that  
18 one can ask. We want to ensure that the funding is  
19 directed to those that have the greatest application  
20 for risk mitigation.

21 We think that we offer a slightly different  
22 approach than a federal regulatory approach, as I've

1 said, not necessarily in lieu of, but at least as a  
2 step forward in that process as FDA determines where  
3 it's going to go.

4 We welcome both FDA's comments and  
5 suggestion as well as any of you here. We will  
6 continue to work together. I also just want to  
7 mention we will be providing more specific comments on  
8 the issues raised in "The Federal Register Notice." I  
9 have listed my contact information here at the bottom.  
10 Denise Rooney is AFDO's executive director. That's  
11 her phone number.

12 Oh, my, my, there we go. I didn't know that  
13 was in there, my apologies, as it fades into  
14 existence, fades away, comes into existence.

15 Those are our contact information there.  
16 Thank you very much, and I'll be available obviously  
17 for questions.

18 (Applause.)

19 DR. BRACKETT: Thank you Dr. Aller.

20 The final speaker before our scheduled break  
21 is Thomas Hill. Thomas is an environmental health  
22 officer here at CFSAN with the U.S. Public Health

1 Service, and he is assigned to the Emergency  
2 Coordination Response Team here within the Center for  
3 Food Safety and Applied Nutrition.

4 Captain Hill has been involved in numerous  
5 farm and packing houses' investigations that are  
6 related to produce outbreaks, so he comes with some  
7 experience.

8 INVESTIGATION FINDINGS

9 CPT. HILL: Thank you. Can somebody help me  
10 find my slides?

11 (General laughter.)

12 (PowerPoint presentation in progress.)

13 CPT. HILL: Here is the question for today.  
14 Does anyone know the answer?

15 (No verbal response.)

16 CPT. HILL: No? There are only two things  
17 in life money can't buy. That is true love and  
18 homegrown tomatoes.

19 (General laughter.)

20 CPT. HILL: All right. Okay. You can start  
21 the clock now. All right, I'm Thomas Hill, and I'm  
22 going to talk a little bit today about some of the

1 environmental findings that we have seen at tomato  
2 farms and packing houses.

3 I have a lot of slides to get through, all  
4 right. In the next 15 minutes I'm going to try to  
5 cover all of this material, so bear with me. I'm  
6 going to talk really fast.

7 Okay. I need to give you a little  
8 background, the references that we use for farm  
9 investigations, and four sources of particular  
10 concern.

11 I'm going to focus really on two, and then  
12 I'm going to show you some of our farm and packing  
13 house findings and give you a summary. You have often  
14 heard it said, "Tell them what you're going to tell  
15 them, tell them, and then tell them what you told  
16 them."

17 (General laughter.)

18 CPT. HILL: Four points. After I finish  
19 this slide, I'm done. "We don't know exactly how the  
20 contamination occurs." You've heard that before this  
21 morning, but we have found salmonella species in the  
22 environment on the farm.

1           Growers and packers, unfortunately, don't  
2 always follow good agricultural practices or good  
3 manufacturing practices and research is needed.  
4 You've heard that before.

5           I'm basically done, but I'll go forward as  
6 quickly as I can. If Dr. Brackett doesn't bring out  
7 the hook, I'll go as quickly as I can.

8           Okay. Some background, these are just  
9 general characteristics and of course include  
10 tomatoes. These outbreaks are widely dispersed. We  
11 have individual patient cases in many states, low  
12 attach rates, the epidemiology is tedious. You know,  
13 what goes on a sandwich? Lettuce, tomatoes, and  
14 cheese. Often, it takes a long time to tease out  
15 exactly what is contaminated.

16           Tracebacks are extremely difficult because  
17 of the nature of the supply chain. You have the farm,  
18 you have the packer, you have wholesalers, and  
19 repackers. It's a very arduous task to do a  
20 traceback.

21           The contamination is intermittent; it is  
22 very low level; and the implicated produce is rarely

1 still available. We go to the farm, and it has  
2 planted in another crop.

3 The one very important characteristic, there  
4 seems to be some geography here. When we look at  
5 leafy greens, it's California. When we look at  
6 tomatoes, it's the East Coast. We have seen repeated  
7 outbreaks in two areas, in Florida and in Virginia.  
8 Keep that in mind.

9 These are stake tomatoes -- mature, green  
10 tomatoes. East Coast style, the plants are on  
11 plastic, a very, very neat, tidy operation as opposed  
12 to in California they have bush tomatoes that are just  
13 picked once. The stake tomatoes are picked one, two,  
14 three, or more times.

15 Shifting gears, we do have guidance that we  
16 use when we do a farm and packing house investigation.  
17 Here it is, and it's available on the Web. You can  
18 take a look at that.

19 Again, four areas of particular concern:  
20 soil, water, animals, and workers. I'm really going  
21 to talk and focus, I'll mention all of the them, but  
22 I'm really going to focus on water and domestic and

1 wild animals.

2 Okay. When you're talking about soil, you  
3 want to know what it's the soil, how does it drain,  
4 and what is its contact with the plant or the fruit.

5 These are just some photos that show you some  
6 well-drained soils and sandy soils, just to give you a  
7 little flavor of what we see out there.

8 Weather, weather is not soil but weather has  
9 an impact on the soil and these other variables that  
10 we are going to talk about. Outbreaks are often  
11 chased away by hurricanes like Hurricane Charley.

12 You can see evidence of weather, flooding or  
13 drought. In this case, in this slide, you can see  
14 where the plants, their roots have been saturated and  
15 the plants are dwarfed by excessive rain or flooding.

16 Places like Florida in particular where  
17 drainage is poor there are large ditches and  
18 dewatering operations. These ditches are very great  
19 environments for animals and plants and habitat, if  
20 you will. These are some pictures of dewatering  
21 equipment.

22 Also, on the other extreme is drought. When

1 there is a drought, animals are drawn to the areas of  
2 moisture and many times you will see animals or animal  
3 activity in these ditches around the field.

4 Here are some FDA investigators. Normally,  
5 the water would be up to their waist here, and they  
6 are taking samples. This particular sample did test  
7 positive for salmonella. You know, when there is a  
8 drought, you have the plant which has lots of moisture  
9 and can serve as an attractant to animals to the  
10 field.

11 Okay. Let's get into water. This is where  
12 I will spend most of my time. The microbial quality  
13 of water is very important here, and the water that's  
14 used must be suitable for the intended purpose.

15 Here you see pictures of wells; ponds;  
16 sprayers; and the actual dump tank, the washing of  
17 produce. Water is also used in irrigation, just to  
18 give you an idea of what's going on.

19 Wells, we go from deep agricultural wells to  
20 shallow wells, wells that are used that go directly to  
21 the field, and wells that recharge ponds.

22 This is a busy picture, but just to give you

1 an idea. A well, this well is very close to a pond.  
2 It's used to keep a pond filled. There may be several  
3 of these wells around the pond. Well water in this  
4 case is being used to also mix chemicals.

5 There are some current concerns and research  
6 needs to be done on what's happening between this well  
7 and the pond and what may be happening between the  
8 sprayer and the well. Cross connections are something  
9 that we are very concerned about in  
10 cross-contamination.

11 Here, you see a picture. The pipe on the  
12 right is coming from the well, and the overflow pipe  
13 or drain is above. That is a potential cross  
14 connection if you were to lose power. Or, if the  
15 ponds got high enough, you could see water go back and  
16 contaminate the well.

17 This is another example. This well is very  
18 close to the pond, and you can actually see the rust  
19 stain on the fill pipe from where the pond has gotten  
20 so high, and then again you have another connection to  
21 a sprayer and a potential cross connection. We see  
22 lots of this while we are out in the field.

1 All kinds of ponds are used, natural ponds  
2 and manmade ponds. We will talk about that. Now,  
3 this is a pond, source water to irrigate a field.  
4 Here are some investigators. Dr. Mark Walderhaug  
5 taking a sample.

6 That sample did test positive for  
7 salmonella, but they cleaned this water up. It's  
8 filtered, drip-tape cleanser is added; and fertilizer,  
9 the plant is fed under the plastic as you saw earlier.  
10 Here we have an FDA laboratory person collecting  
11 samples from sand filters, and we found salmonella  
12 there.

13 Moving on into other uses of water, crop  
14 sprays are very important. They are always using a  
15 spray on tomatoes after a rain event and at least  
16 weekly herbicides, pesticides, and fungicides. The  
17 stake tomatoes aren't just picked one time, so they  
18 may be spraying the day before picking. Some of these  
19 crop sprays can be applied the day before picking.

20 Where does this water come from? Again,  
21 ponds, wells, and something that is particularly  
22 concerning is using portable pumps to draw raw pond

1 water and mix that with chemicals. Some people seem  
2 to think those chemicals will kill bacteria that may  
3 be in the pond, but that isn't so.

4 Here is another connection here to a pipe  
5 that's going to irrigate a field. In this case,  
6 filtered pond water would be used to mix sprays. Here  
7 is the portable pump that we see sometimes that really  
8 shouldn't be used.

9 When you look up close at a tomato, in this  
10 case you can see the residue on the tomato either from  
11 splash or from spray, so these tomatoes are constantly  
12 wetted and dried and wetted and dried from all kinds  
13 of sources of water.

14 Let's talk a little bit about different  
15 potential sources of contamination. These are animals  
16 that we see in and around ponds: turtles, frogs,  
17 ducks, geese, waterfowl and their evidence, feathers  
18 and droppings.

19 Now, this is a drainage ditch teeming with  
20 fish and frogs and alligators and you name it. I  
21 mean, this is just the perfect environment. Here  
22 actually we have gators in the pond. We can swab

1 turtles, but we're not too good at gators yet.

2 (General laughter.)

3 CPT. HILL: Here is a investigator swabbing  
4 the rear end of a turtle. Again, the proximity of  
5 these nice environments to the tomatoes, we need to  
6 look at that and see what's going on. This is another  
7 ditch in close proximity to a field of tomatoes.

8 Also, bordering some of these farms are  
9 cattle operations. You can see here the potential for  
10 movement of cattle waste into a ditch in close  
11 proximity to a tomato field.

12 Drainage, again, here this picture is kind  
13 of busy but in the background you can see a ditch, and  
14 there is a swell there. In times of heavy rain or  
15 flooding, that swell is going to carry water away from  
16 the field or from the ditch towards the field.  
17 Equipment is crossing here. You have cattle on the  
18 other side. You have these situations that are  
19 something we need to look at.

20 Also, here we have a swell, a drainage ditch  
21 where wild pigs have broken the fence and are going  
22 between the cattle ranch and the tomato farm in this

1 ditch that is dry right now, which would be filled  
2 during heavy rain.

3           You can see the tomato field in the  
4 background and places where wild hogs have been  
5 looking for moisture, rooting in these ditches that  
6 may be dry.

7           This is just to illustrate some of the  
8 salmonella's that we are finding in the environment on  
9 animals, lizards, and turtles in animal droppings that  
10 we collect; ditch water media, sand media from  
11 filters.

12           I will just mention a little bit about  
13 harvesting. We really haven't seen evidence of  
14 problems with harvesting in the investigations that  
15 I've been on. Port-o-Potties are there. Workers are  
16 trained, and they are doing a good job. But it is an  
17 area that we need to look at closer.

18           Here we have some workers about to pick a  
19 field of tomatoes. Here FDA is collecting tomato  
20 samples and flowers in one of our investigations.

21           I will mention just briefly the packing  
22 house. This is a dump tank. Take note of the organic

1 debris in the tank. They use chlorine and hot water  
2 here, but it's something we need to look at closer.  
3 You can see the quantities of organic material that is  
4 being removed from the dump tank on the right there.

5 We found little critters like this in the  
6 dump tank. Birds are a concern. In one packing  
7 house, they had evidence of birds, and they quickly  
8 resolved that.

9 When you look a little further down the  
10 line, fresh-cut operations, they may take nice, ripe  
11 tomatos right out of the ripening room and put those  
12 in ice-cold water. We know that tomatoes will suck  
13 water in, in those situations, so that's something we  
14 need to look at as well.

15 Again, here is our summary. Just two more  
16 bullets, the last two bullets. The FDA is committed  
17 to improving produce safety, and it's going to take  
18 collaboration between federal, state, local, academia,  
19 industry, trade associations, and consumers.

20 Thank you.

21 (Applause.)

22 DR. BRACKETT: Thank you, Thoms.

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1 Well, we do have a scheduled break now. We  
2 are just a few minutes behind here. It is now 10:25.  
3 We will reassemble back here at 10:40. Again, the  
4 restrooms, if you need them, if go out the door, back  
5 down to your left, they are on your right side.

6 Thank you.

7 (Recess is taken.)

8 DR. BRACKETT: Well, we do want to get  
9 started so we can keep on time, but I do have one  
10 reminder for all of you and those in the hallway who  
11 can't hear me, which is, we would like to ask you to  
12 make sure that you actually sit in the chairs in here.

13 There are plenty of chairs for the people  
14 that we have here, although you may have to shift  
15 around a bit, but what we cannot have are people  
16 sitting on the stairs. That is a violation of the  
17 fire code. Also, it makes it dangerous that are  
18 coming in after you. So if you would, please take  
19 your seats.

20 The final speaker of the first panel that we  
21 are having is Dr. Jim Rushing. Dr. Rushing is a  
22 professor of horticulture with Clemson University. He

1 is also the director of the Coastal Research and  
2 Education Center in Charleston, South Carolina.

3 He first began to work in fresh produce  
4 safety in 1990 when South Carolina tomatoes were  
5 implicated in outbreaks of illness. Since that time,  
6 he has collaborated both with national and regional  
7 programs in food safety and is an instructor for an  
8 internationally led course by JIFSN, the "Joint  
9 Institute for Food Safety Nutrition." He spent one  
10 year here at FDA CFSAN as a visiting scientist on  
11 sabbatical, so we are glad to have him back, too.

12 Jim.

13 STATE PERSPECTIVE

14 DR. RUSHING: Thank you. Good morning  
15 everyone.

16 I'm just going to talk for a few minutes  
17 with you. I'm not going to use photographs and things  
18 like that. I should be able to give a couple of  
19 minutes back to the organization here this morning.

20 It certainly is a pleasure to be here and  
21 see a few old friends. I've never seen Jack so  
22 well-dressed. He looks more like an attorney. I wore

1 my tweedy professor clothes so I couldn't be confused  
2 with the attorney-looking folks here.

3 My name is Jim Rushing, and I have worked  
4 with Clemson University for over 20 years. We have  
5 had our share of problems very early on with food  
6 safety, with outbreaks of illness associated with our  
7 fresh produce. Because of that, I got involved in  
8 1990 and have continued to try to stay with the things  
9 that are going on.

10 My purpose here this morning was to give a  
11 perspective of the states or from the states on the  
12 current status of fresh-produce food safety. First of  
13 all, there is no one person who can speak for all the  
14 states. I'm not sure even one person could speak for  
15 their own state because of the disagreement within.

16 That's going to be tough, but I see that  
17 there's a number of others on the program after me who  
18 will clarify any confusion that I create in the few  
19 minutes that I'm here.

20 I have had an opportunity to have a lot of  
21 collaboration with other states with the national GAPs  
22 program. Dr. Gravani from Cornell is here. It's been

1 a pleasure to work with him and 25 states or so.

2 We had a fourteen-state southern regent  
3 teaching program that I was involved in for seven or  
4 eight years that also gave me some opportunity to get  
5 a little insight and then I've been blessed with the  
6 opportunity to work in over 30 countries and always  
7 arrived home safely. Hopefully, some of that  
8 experience would be useful for this short discussion.

9 I also in that collaboration am not only  
10 with land-grant universities, there are state  
11 departments of agriculture and state health  
12 authorities who participate in those and provide some  
13 insight as well.

14 I studied the issues and the questions in  
15 "The Federal Register Notice." I've tried to limit my  
16 comments to those issues and questions, although I'm  
17 not going to go in exactly the order that they are  
18 stated in the "Notice." I believe the issues  
19 surrounding fresh-produce food safety are much broader  
20 than the points as they are described in that Notice,  
21 and so it will be necessary to stray just a little bit  
22 out of the box at times but not too much.

1           The first two issues there deal almost  
2 entirely with the guide that Michelle mentioned that  
3 was first published in 1998. I'm just going to refer  
4 to that as "the guide."

5           For those of us who teach, for those of us  
6 in the university system and who have collaborative  
7 programs, the guide has been an invaluable tool. It  
8 has provided the template for us to expand upon and  
9 develop the training programs.

10           But since the guide was released nine years  
11 ago, there has been a tremendous amount of research, a  
12 lot of industry experience, and I think we need to  
13 update that document with some really specific things.

14           I believe one of the highest priorities of  
15 FDA and other FDA authorities, USDA and perhaps  
16 others, would be update that with more specific  
17 information. There must be uniformity across state  
18 boundaries in the implementation of safe practices.  
19 There has to be uniformity.

20           The states are looking to the FDA and the  
21 USDA for leadership in establishing that uniformity.  
22 Only the federal folks really have the capacity to do

1 that in a way that can be broadly implemented.

2 I will give some examples about the things  
3 I'm talking about, but this would give all of us at  
4 the state level a uniform basis upon which to build  
5 our own programs.

6 While there are commodity-specific needs and  
7 commodity groups have developed their own documents,  
8 all of those commodity-specific documents need to go  
9 back to, in my opinion, one template -- one, uniform  
10 document that is well grounded in science that we can  
11 all refer to.

12 If I could give just a couple of the  
13 specific examples about that. In recent meeting with  
14 Dr. Gravani's group and those twenty or so states that  
15 were represented, this topic of agricultural water was  
16 one thing that we discussed in great detail.

17 While common sense tells us that we should  
18 test, I don't think anyone argues that it's wrong to  
19 test. Producers will counter that recommendation with  
20 a whole series of questions.

21 What do we test for? How often do we test?  
22 What's the critical level at which we should not use

1 water? And, the inevitable question, if it's dirty,  
2 how do we clean it up?

3 If we as public servants of the state or the  
4 Federal Government are unable to answer those  
5 questions, then I believe we cannot reasonably expect  
6 industry to make broad implementation of  
7 recommendations that are really quite vague and  
8 incomplete.

9 We have a responsibility in public service  
10 to do a better job with that. We need specific  
11 answers to those questions based upon science. The  
12 same questions that we ask about water could be asked  
13 about soil and organic fertilizers, exactly the same  
14 questions.

15 In the Eastern U.S., I believe that in terms  
16 of numbers not many numbers of fruit and vegetable  
17 growers have a formal testing program for irrigation  
18 water, not many I know, not many of our South Carolina  
19 folks do and many of the smaller operations do not.

20 If there is no regulation that requires  
21 testing and there are no specific guidelines that we  
22 can pass to a grower, then I would not anticipate that

1 many growers would begin to test water in the near  
2 future, unless they get in trouble of some kind.

3 Another critical issue that has been at the  
4 forefront is the proximity of animals to production  
5 areas. Again, common sense tells us that two types of  
6 farming, plants and animals, present risks to  
7 consumers of fresh produce, but once again those of us  
8 in public service are unable to answer the specific  
9 questions from producers.

10 How far away should animals be? How serious  
11 is the risk of airborne contamination? What is the  
12 proper way to design a buffer zone? What about  
13 waterborne contamination? The only thing I believe we  
14 are really certain of is that water runs down hill,  
15 and that can bring contamination with it.

16 There is not enough information there to  
17 convince producers to bring about change because they  
18 have not. We still have those kinds of practices  
19 going on. We cannot simply say, "There is an animal.  
20 You can't grow here." We have to do better than that  
21 to bring about change in the industry.

22 It is not my intent to criticize the FDA or

1 the USDA or anyone in state service. My only intent  
2 is to try to point out some of the areas where, in my  
3 opinion, we should dedicate resources for scientific  
4 study.

5 In addition to that research effort, we  
6 should continue to strive to improve our communication  
7 between researchers and those of us who need that  
8 information to develop guidelines and to extend that  
9 to the industries we serve.

10 This leads logically to the topic of  
11 regulation. I believe that most state agencies do not  
12 seek or desire more regulation. Certainly, I believe  
13 the industry in general would prefer not to be  
14 burdened with more regulation, but regulation seems to  
15 be the only recourse, unless there is some voluntary  
16 compliance with the things that we now believe to be  
17 true, safe, practices based upon common sense and some  
18 science.

19 Do we use that threat of regulation when we  
20 are training? When we are doing educational programs,  
21 do we use that threat of regulation to try to bring  
22 about change? I don't believe that is really going to

1 be a very effective way to get folks to change the way  
2 they do their business.

3 As an educator, education is critical to our  
4 effort. Food safety programs have been developed and  
5 taught, and they have been largely grounded in the  
6 land-grant university system. They have been  
7 delivered to broad audiences.

8 We have trained practically every extension  
9 county agent, I know we have in 14 Southern states, to  
10 go out and train others in safe-handling practices.  
11 Federal funding has generally been adequate for those  
12 programs. Anyone working in any discipline would like  
13 to have money, but we have had enough money to develop  
14 materials and travel and train those people.

15 What is the next step for educators like  
16 myself? Do we simply do more of the same? I believe  
17 in order for us to do our job better, we must have  
18 that more specific guidance with more specific  
19 science-based information that we can use in our  
20 teaching program.

21 If we go back just a minute to the topic of  
22 regulation, there is some human behavior involved here

1 in bringing about change, certainly some sociological  
2 aspects as well.

3 We know that many companies have implemented  
4 GAP and GMP. We also know that some have not. It  
5 might useful just to think for a moment about the  
6 challenges or the obstacles in getting people to bring  
7 about that change.

8 Many people in the fresh-produce industry  
9 still do not believe there is a problem. They don't  
10 perceive any problem. They say, "We've been doing  
11 this for decades, and no one has ever gotten sick from  
12 our produce."

13 Secondly, the cost of implementing a food  
14 safety program is large, and much of that cost is due  
15 to requirements or third-party audits, which I will  
16 mention briefly in a moment.

17 Then, third, we don't give those specific  
18 recommendations that we need to give. When we go in  
19 and talk about the management of processing water or  
20 irrigation water, we need to really know what we're  
21 talking about.

22 Then, companies that have never been

1 impacted by an outbreak of course say, "Well, we don't  
2 have a problem, so we don't worry." Money is a big  
3 motivator. When people lose money, they are more  
4 likely to do something. We have seen this in specific  
5 industries like melons and tomatoes and the leafy  
6 greens and so on.

7 But let's assume for a moment that all of  
8 our educational effort, all of the monetary  
9 considerations do not bring about industrywide  
10 compliance. Regulation becomes a necessity.

11 How will those regulations be developed?  
12 Who will develop them? How will you take the guide  
13 now, which is a very general document, and create  
14 regulations which must by definition be very specific?  
15 Once they are developed, how will they be enforced?  
16 At which level will enforcement reside? Do we do that  
17 as states, or will the federal folks do that?

18 I believe many states are in the same  
19 situation as we are in South Carolina. Our state  
20 Department of Ag, our Department of Health and  
21 Environmental Control, and Clemson University are the  
22 three agencies who would do that.

1           None of us really have the people or the  
2 funding or the training really across the board to go  
3 out and do inspections and enforce regulations.  
4 Development of fair and reasonable regulations  
5 followed by fair and reasonable inspection and  
6 enforcement are only two steps.

7           What will be the fair and reasonable  
8 punishment for people who do not comply? There are a  
9 lot of questions there with really no answers, and I  
10 think all of us together have to strive to fill in the  
11 blanks there.

12           I need to talk just a minute about auditors.  
13 I realize that auditing is not a responsibility of the  
14 FDA. But if we are going to move into the area of  
15 regulation, we need to consider that industry which  
16 has grown dramatically.

17           There may be auditors in the audience.  
18 Certainly, it is not my intention to criticize your  
19 work, but there is very little uniformity in the  
20 auditing process. Growers and handlers often are  
21 asked to have multiple audits, and different auditors  
22 have different expectations.

1           There is not an official, uniform auditing  
2 instrument. We need some consistency in that  
3 industry. Perhaps, USDA can handle this best, since  
4 they have developed an auditing tool. Qualifications  
5 of the auditors themselves are not understood, and, to  
6 my knowledge, they are not standardized.

7           If regulation is developed for this  
8 industry, I believe that regulation somehow has to  
9 consider the auditing industry as well. The audit, we  
10 all recognize, is merely a snapshot. It's just a  
11 picture of a moment that the company is doing  
12 business, and food safety has to be a lifestyle and  
13 not just passing an audit.

14           The last thing I would mention is the  
15 subject of risk. In my opinion, we could never  
16 eliminate all risk of consuming fresh produce or any  
17 other food.

18           We do not yet have compelling evidence that  
19 I know of that GAP has reduced our risk. I don't know  
20 of any study comparing GAP and non-GAP companies, and  
21 such a study would not be easy to conduct and perhaps  
22 would be impossible.

1 I think that we have not come to grips with  
2 the idea that small risk will always be present in  
3 almost anything we do. In closing, I believe at the  
4 state level we have reached a point where we need  
5 guidance about how to proceed.

6 I think, again, we in the states are looking  
7 to federal authorities to help us find that direction.  
8 I believe that in most states most of us are eager to  
9 collaborate and make a contribution where we can. My  
10 hope is that meetings like this will point us in the  
11 right direction. Thank you for your attention.

12 (Applause.)

13 DR. BRACKETT: Thank you, Dr. Rushing.

14 At this time we have provided time for the  
15 FDA panel to ask our speakers panel some questions,  
16 and I will go through starting from Dr. Solomon and  
17 then move down the line and provide each of them a  
18 question and then go back again, so we need to get  
19 microphones down to them.

20 Our first questioner is Dr. Steve Solomon.

21 QUESTIONS FROM THE FDA PANEL

22 DR. SOLOMON: Thank you. I guess my

1 question is, Dr. Smith, we heard that the GAPs/GMPs  
2 document was created in 1998, and that has not been  
3 updated. Yet, we have a lot of the specific guidances  
4 and we are looking to update those guidances. Do you  
5 feel there is a need to update the original 1998  
6 guidance?

7 DR. SMITH: That's a good question. We  
8 asked the same question in 2004 when we were working  
9 on the Produce Safety Action Plan, should we update  
10 the '98 GAPs guidance. Comments at that time were all  
11 over the board.

12 There was some leaning in the direction of  
13 keeping the 1998 GAPs guidance as it was based on the  
14 value of the principles set out in that guidance and  
15 putting resources towards supplementary, more specific  
16 guidance.

17 In fact, the industry-led, commodity-  
18 specific guidance fills part of that need, but it's  
19 not just commodity-specific guidance that we need. We  
20 also need practice-specific guidance, issue-area  
21 specific guidance such as Jim Rushing mentioned, more  
22 details on water quality management, water quality.

1 We need the standards before we can develop that  
2 guidance.

3 That doesn't mean that we are not going to  
4 revise the GAPs guidance. It's just a matter of  
5 deciding where is the best place to put our resources  
6 at this point and time. Some of our decision making  
7 for what to do next may ask that question again.

8 DR. BARRETT: Okay. Next, Dr. Zink.

9 DR. ZINK: (No microphone.) I have a  
10 question for Dr. Rushing. I appreciated your comments  
11 about the lack of specificity really with how close  
12 should animals be and about water contamination.

13 I'm wondering if you could elaborate on it a  
14 little bit more. I am intrigued by the recent  
15 publication of some new tests for fecal contamination  
16 of water based on mitochondrial DNA, looking at  
17 specific animal species, which I think that might be  
18 interesting, since I think our problem is fecal  
19 contamination of water.

20 You didn't mention feral animals. Do you  
21 have any thoughts about feral animals? Can you  
22 elaborate just a little bit more, maybe give us some

1 more specific direction?

2 DR. RUSHING: Well, probably I can't because  
3 I'm not a microbiologist or a genetic molecular  
4 biologist either, but I have been present in a number  
5 of discussions about testing for water.

6 It's so an incredibly complex. I'll stick  
7 my neck out a little bit. In the last discussion that  
8 I had, if I were a farmer in that room, I probably  
9 would as a farmer have chosen not to test.

10 Because, as the discussions went on, we just  
11 found more and more weaknesses in almost any plan we  
12 could come up with. We're dealing with bacteria, with  
13 waterborne parasites, with virus.

14 I don't know of tests -- well, perhaps this  
15 test that you mentioned is one that would allow us to  
16 do a broad test for all of those different forms of  
17 contamination.

18 I don't know that, but I see that as a real  
19 limitation in water testing is how to do a broad,  
20 comprehensive test that actually has utility that can  
21 be done fairly quickly and that can really tell us  
22 something about what is in the water.

1 DR. BARRETT: Jack Guzewich.

2 MR. GUZEWICH: I have a question for  
3 Dr. Aller, kind of a two-part question for her. She  
4 was talking about this concept of AFDO developing this  
5 model regulation or code. I want to see what you  
6 think the relationship is between that kind of a  
7 document and the commodity-specific documents that  
8 have been put together industry in recent times,  
9 that's Part A. The "B" part is what is your timeline  
10 for developing your guidance?

11 DR. ALLER: I knew you were going to ask  
12 that second part. The relationship between the  
13 commodity-specific guidances and where we are with  
14 what we are thinking of doing with AFDO, I think that  
15 we definitely need to draw from those. They are not  
16 out there in isolation.

17 We see those as a major contribution to  
18 this. We also see that that is guidance versus a  
19 code, which is regulatory and which will provide for  
20 those.

21 There is a very real call for regulation and  
22 that's our interest is to have something that states

1 can adopt for regulatory input. I understand there is  
2 a lot of complexity to that and what not, but those  
3 guidance documents would be drawn upon to develop,  
4 rate that code.

5           Timeline? Boy, if I had a crystal ball, if  
6 I could devote all of my time to this, and if all of  
7 the people on the Committee could devote all of their  
8 time to this, to the rest of you who are on the  
9 Committee that are sitting in the audience, I would  
10 love to try to put something out there.

11           It is very difficult because it is a fairly  
12 broad charge. To be quite honest, I'm not sure if the  
13 charge which is to cover all produce is in fact  
14 doable. I can't give you a timeline.

15           I would hope that it will be more rapid than  
16 it might take to do this through a federal rulemaking  
17 process, but I would like to say within a year or so.

18           DR. BARRETT: Mr. Baca.

19           MR. BACA: I have a question for Dr. Liang.  
20 I guess my question is we appear to be having an  
21 increase in the incidence in illnesses and operations  
22 associated with produce. My question is, is there a

1 correlation? Have you superimposed the increased  
2 consumption of fresh produce on the apparent increased  
3 illnesses?

4 DR. LIANG: The quick answer is no, only in  
5 the broadest sense of the way epidemiologist think,  
6 these medical epidemiologists see an increase in  
7 illness and then they start running through their  
8 minds, "What are the hypotheses? Well, you know, what  
9 could it be?" That's one of the hypotheses that we  
10 have run through our minds. Have we done a study to  
11 actually try to get more precisional? The answer  
12 would be no.

13 DR. BARRETT: Ms. Lewis.

14 MS. LEWIS: My question is for Dr. Aller.  
15 You mentioned that in your workgroup you would explore  
16 the options of states tailoring their equivalency  
17 levels in protection, and I'm wondering how much  
18 leeway would be involved in that? How would they  
19 determine equivalencies? How would maintain  
20 uniformity across a broad spectrum in doing that?

21 DR. ALLER: Yes. I probably need to clarify  
22 what I meant by that statement was that a model code

1 would provide for those practices, would actually set  
2 those that a state would choose to adopt those  
3 portions of a model code applicable to the commodities  
4 and/or geographical production practices. That is  
5 what I meant by that, that the model code would  
6 address that.

7 DR. BARRETT: Okay. We have time for  
8 another round.

9 Dr. Solmon.

10 DR. SOLOMON: (No microphone.) Thank you.  
11 I'll just open it up to anyone. I think theoretically  
12 when you look at the GAPs/GMPs document, I mean, you  
13 heard from Dr. Rushing that there is no editing right  
14 now to demonstrate how they work. How would you  
15 approach demonstrating that GAPs and GMPs works?

16 DR. SMITH: Okay. I'm going to defend the  
17 GAPs/GMPs Guide.

18 (General laughter.)

19 DR. SMITH: I've got to admit that I'm  
20 somewhat prejudice. CDC is the keeper of the data and  
21 so I'm not the final word, but I do know that there  
22 was this significant increase going on when we got

1 involved in the development of the guide. Things  
2 appear to have been leveling off since then.

3 I have a lot of anecdotal experience, things  
4 that I've seen where in foreign training efforts even  
5 where packing facilities have instituted hand washing  
6 and sanitary facilities. They have instituted worker  
7 training.

8 They have improved not just probably, in my  
9 opinion, the safety of their product and the health of  
10 their workers, but even the health and literacy of the  
11 community that the workers are coming from.

12 I think there are many substantive benefits  
13 from the GAPs/GMPs Guide. I have a friend who is in  
14 charge of the Integrated Pest Management Program in  
15 the state of Maryland. At a picnic a number of years  
16 ago he came up and he said, "There is something that  
17 I've noticed that I really don't understand. All of a  
18 sudden the farms I go to have these contraptions,  
19 Port-o-Potties connected with a hand-washing device in  
20 between." It's something that he was seeing with such  
21 an increased frequency that it was worth mentioning at  
22 a picnic.

1 I think that is not scientific data, but I  
2 think that it does point to positive changes and  
3 positive impact, as Jim mentioned, a study to actually  
4 gather data on the effect of good agricultural  
5 practices we've missed ground zero. We could just  
6 study what things are like now.

7 Also, Investigator Thomas' comment, the  
8 picture of the birds in the packing house, the  
9 investigators had cause to go to that packing house.  
10 They saw the bird problem. He also mentioned that  
11 they quickly remedied it. Those are anecdotal  
12 evidence of improvement resulting from the GAPs.

13 DR. BARRETT: Mr. Guzewich.

14 MR. GUZEWICH: This is Jack Guzewich for the  
15 recorder.

16 I want to follow up on Dr. Solomon's  
17 question with Dr. Rushing. I want this done before  
18 Dr. Solomon asks his question, by the way. I want to  
19 see from your perspective as a teacher and as an  
20 instructor, do the farmers, the growers, understand  
21 the GAPs? In your opinion, are they implementing the  
22 GAPs or trying to implement the GAPs?

1 DR. RUSHING: I think that GAPs are working,  
2 and I agree with Michelle's comment. I believe there  
3 is no study to show they are, but I believe they are.  
4 As an educator, I believe it is extremely important  
5 that we continue on the track that we are on.

6 To answer your question, some industries  
7 have done an excellent job. I had a talk with the  
8 peach industry in our state about eight or nine years  
9 ago, and I thought it was the least interested  
10 audience I had ever spoken with.

11 Since that time, every one of our growers  
12 and packers to the very last one have largely  
13 implemented GAP as they were taught to do so. We have  
14 actually had one significant grower, who because he  
15 farmed cattle and he was reaching retirement age, he  
16 felt like the best thing for him to do was just stop  
17 farming and so he did. We see industries like that  
18 where we have broad implementation.

19 I believe the tomato industry is another  
20 good example of broad implementation. But because of  
21 the environmental issues, I've heard Thomas,  
22 Captain Hill, say that salmonella can be found in

1 almost any stream or pond anywhere around the tomato.

2 With that kind of challenge, it doesn't mean  
3 we should not implement GAP at all. I'm just not  
4 sure, I'm at a complete loss for an idea about how to  
5 overcome that kind of environmental challenge. That  
6 was part of the basis for the concluding remark about  
7 risk. Every time we take a shower, drive our car, or  
8 ride our bicycle we are taking a risk.

9 In the balance I believe the produce  
10 industry has done an outstanding job. I think if you  
11 look at the thousand and thousands of tons of produce  
12 that we eat and the relatively small numbers of people  
13 who become ill, I think we are doing a good job, but  
14 we have to continue doing better. There are a lot of  
15 patient who have not implemented as they should.

16 DR. BARRETT: Mr. Baca.

17 MR. BACA: Joe Baca. A quick question for  
18 Captain Hill, and that is, would you comment on  
19 agricultural wells? I know there is a lot of concern  
20 about water and we talked about the ponds and the  
21 ditches. What have you seen buy way of wells?

22 CPT. HILL: Well, no pun intended there.

1 (General laughter.)

2 CPT. HILL: There are all kinds of wells out  
3 there. Agricultural wells are very different from  
4 residential or private wells. If we take the state of  
5 Virginia, for example, the requirements for  
6 agricultural wells are much less than the residential  
7 wells.

8 The issues with the use of ponds for  
9 irrigation water on the Eastern Shore, many wells are  
10 very close to those ponds. With Virginia's current  
11 regulations, they don't consider ponds sources of  
12 pollution.

13 But at least in those two counties on the  
14 Eastern Shore as an interim precaution, any new wells  
15 that are put in, any new agricultural wells, are going  
16 to be required to stand off 200 feet from any pond.

17 That is something that we need more research  
18 on, but good common sense. They are going to try and  
19 stand off from those wells for any new wells that are  
20 put in.

21 DR. BARRETT: Okay. Well, that is the end  
22 of time for the questioning period. What we're going

1 to do is take a minute here and switch out the panels.  
2 Next, we will have both private-industry perspectives,  
3 consumer perspectives, and research.

4 (Pause in the proceedings.)

5 INDUSTRY PERSPECTIVE

6 DR. BARRETT: Okay. Our first two speakers  
7 for this panel will represent the industry position.  
8 The first of them is Mr. Tom Stenzel, who is the  
9 president and CEO of United Fresh Produce Association.

10 He served as CEO for the United Fruit and  
11 Vegetable Association, its prior iteration, and  
12 continued this position after United Fresh had its  
13 merger with the International Fresh-Cut Association in  
14 2006.

15 Mr. Stenzel was a founding president of the  
16 International Food Information Council or "IFIC" in  
17 1986 where he built a very credible and sound  
18 scientific program in food safety, risk  
19 communications, and crisis management. He is a 1977  
20 magna cum laude graduate of the University of Richmond  
21 and achieved a certified association executive, a  
22 "CAE," designation in 1990.

1 I will introduce his partner in this today,  
2 which is Mr. Brian Silbermann. Brian Silbermann is  
3 the president of the Produce Marketing Association.  
4 It is the largest worldwide, not-for-profit trade  
5 association, representing companies that market fresh  
6 fruits, vegetables, and related products.

7 PMA's membership of 2,100 companies and  
8 nearly 50 countries ranges from supermarket retailers,  
9 farmers, foreign exporters, to restaurant chains.

10 The association's programs promote the  
11 efficient distribution and increased consumption of  
12 its members' products worldwide: through industry  
13 events, consumer research, training, standardized  
14 coding, information technology, global outreach,  
15 government relations, public affairs, and food safety  
16 efforts.

17 First, Mr. Stenzel.

18 MR. STENZEL: Thank you very much,  
19 Dr. Brackett.

20 Let me begin by thanking FDA and you  
21 personally for holding this hearing and your ongoing  
22 commitment to enhancing the safety of fresh produce.

1 Let me also thank two members of our staff for their  
2 support, Dr. David Gombas, who is here today, and also  
3 Dr. Jim Gorny, who lead our food safety efforts.

4 We in the industry look to FDA as our most  
5 important and credible partner in assuring the  
6 American public that the produce industry and  
7 government alike are taking all needed measures to  
8 assure a safe supply of fresh fruits and vegetables.

9 After all FDA's mandate to protect public  
10 health requires an equal commitment to promote public  
11 health through increase consumption of fresh fruits  
12 and vegetables to meet the U.S. dietary guidelines.

13 Public fear of consuming fresh, healthy, and  
14 safe produce, even with the inevitability of a small  
15 level of risk, cannot be an acceptable outcome to the  
16 public health mandate of the Department of Health and  
17 Human Services.

18 Let me quote from "The Federal Register  
19 Notice" announcing today's hearing:

20 FDA is responsible for ensuring the safety  
21 of all domestic and imported fresh and fresh-cut  
22 fruits and vegetables consumed in the United States.

1 We believe that responsibility is at the very core of  
2 our discussion today.

3 Our industry must and will do all that we  
4 can to grow, pack, and process the safest possible  
5 products. But no matter what steps we take as an  
6 industry, the law requires and the public expects that  
7 FDA as an independent public health agency be the  
8 final arbiter of what is safe enough.

9 The spinach outbreak last fall was a tragic  
10 occurrence, and we can never forget the real human  
11 impact when something goes wrong in our food safety  
12 systems.

13 That is what drives food safety to be a  
14 process of continuous improvement, not a static  
15 achievement. We are on a continuum constantly  
16 striving toward perfection while understanding that  
17 scientifically there is no such thing as zero risk.

18 When the spinach outbreak occurred, our  
19 entire industry immediately pulled all spinach from  
20 shelves nationwide and cooperated fully with FDA in  
21 tracking this problem back to its source.

22 That total industrywide shutdown was an

1 unprecedented action and one from which I hope we have  
2 all learned many lessons. In fact, we now know that  
3 the only contaminated product in the marketplace came  
4 from one 50-acre farm packaged in one processing plant  
5 and only on one production shift one day.

6 That's out of more than 300,000 acres of  
7 lettuce, spinach, and leafy greens grown in the  
8 nation's most productive growing region that was  
9 unnecessarily impugned last fall.

10 But, when faced with an immediate public  
11 health question, we readily accepted FDA's advice to  
12 err on the side of caution and literally destroyed  
13 truckloads of healthy foods and plowed under acres of  
14 safe production.

15 Our commitment to public confidence in all  
16 of our foods demanded nothing less, but it is also  
17 clear that neither government nor consumers are well  
18 served by generating such broad fear about wide swaths  
19 of a safe food supply.

20 Consumers know that when there is a peanut  
21 butter outbreak associated with one brand they have  
22 confidence in choosing another brand to feed their

1 children.

2           FDA must be committed to the same standard  
3 for fresh produce, aggressively addressing specific  
4 threats if they occur without implicating other  
5 sources of safe product.

6           But, while the source of this outbreak  
7 proved to be very narrow, our entire industry  
8 immediately began a comprehensive evaluation of all  
9 spinach production, handling and process to make sure  
10 that we were doing everything on an industrywide basis  
11 to assure safety.

12           This effort has led to an important  
13 initiative spearheaded by the leafy greens industry in  
14 California to adopt stringent food safety measurement  
15 criteria which can be implemented and verified.

16           The California Department of Food and  
17 Agriculture has recently certified a leafy greens  
18 marketing agreements which will serve as a means of  
19 setting rigorous measurements of safe production of  
20 leafy greens. These science-based standards include  
21 careful attention to all of the risk factors that we  
22 have talked about already today.

1           Taking a step like this towards  
2 self-regulation in a private-industry sector is not an  
3 easy task, but we believe it is a critical step in  
4 continuing to assure the public that our industry is  
5 doing everything we can to make our product safe.

6           It is within the context of these industry  
7 efforts that I now want to turn my attention to the  
8 appropriate regulatory framework that we believe is  
9 best suited for the fresh-produce industry.

10           While there is much our industry can and  
11 must do, we also recognize the important role of the  
12 Federal Government in setting the overall regulatory  
13 framework.

14           Our industry has but one goal when it comes  
15 to food safety, and it starts with the consumer. We  
16 believe consumers must be able to shop in any grocery  
17 store or order fresh produce in any restaurant with  
18 complete confidence that their produce selection is a  
19 safe and healthy choice.

20           Whatever low risk that might be present must  
21 be viewed as an acceptable risk based on strong  
22 government assurance that proper food safety systems

1 are in place and the benefits of consumption far  
2 outweigh the low risk.

3 Let me review, briefly, three key principles  
4 we believe are important in the food-safety regulatory  
5 framework. First, we believe produce-safety standards  
6 must be consistent for an individual produce commodity  
7 grown or packaged anywhere in the United States or  
8 imported into this country. Consumers must have  
9 confidence that safety standards are met no matter  
10 where the commodity is produced.

11 Second, we believe achieving those  
12 consistent produce safety standards across our entire  
13 industry requires strong Federal Government oversight  
14 and responsibility in order to be most credible to  
15 consumers and equitable to producers.

16 FDA has the legal mandate to determine  
17 appropriate nationwide safety standards in an open and  
18 transparent process with full input from the states,  
19 industry, academia, consumers, and all stakeholders.

20 We are strong advocates for food safety  
21 standards based on sound science and a clear consensus  
22 of expert stakeholders. In a situation where science